Washington State Health Care Authority

Health Technology Assessment

Facet Neurotomy

Final Evidence Report

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Facet Neurotomy

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The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

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Introduction

Condition/disease

A large proportion of the adult population suffers from back or neck pain at some point in life. One of the possible sources of chronic back pain is degeneration of the facet joints.[1] Typically, facet arthropathy (joint disease) develops progressively and the typical patient is over 50 years of age. Whiplash injuries can also result in cervical facet joint pain.[2] It has been estimated that the point prevalence of facet joint pain are 10-15% in the low back and 45-55% in the neck.[3] However, it is worth noting that the estimated prevalence of facet joint pain varies widely with diagnostic methodology employed, with reported estimates of the prevalence of facet joint pain ranging from less than 5% to greater than 90%.[4-7]

Diagnosis

The primary symptom suggestive of facet joint pain is paraspinal tenderness at the affected facet joints[3, 8] and other symptoms (e.g., radiating pain, pain that is exacerbated with certain movements) may also be present and suggestive of facet joint pain.[9] There is no "gold standard" diagnostic tool for facet joint pain. Diagnosis of facet joint pain cannot be accurately made by physical exam[10] or imaging studies[11] alone and diagnostic nerve blocks may be the most accurate assessment method. Diagnostic blocks involve injection of local anesthetic over/around the medial branch nerves (MBBs) or into the facet joint(s) (intra-articular injections) that are believed to be the source of the pain.[12-15] A positive block occurs when the patient experiences pain relief that lasts as long as the duration of action of the anesthetic used.

Intervention: Facet Neurotomy

Once the facet joint is determined to be the source of pain as indicated by a positive diagnostic block, then prolonged pain relief may be achieved with destruction of the nerves to the affected joint in a procedure called facet neurotomy. Neurotomy does not cure the source of pain, but instead cuts off the pain signal from the brain by damaging the nerve. Different types of facet neurotomy are available, but the most common type employs radiofrequency needles to destroy the nerve tissue with heat generated by an electric current.[16] During this procedure, the skin is anesthetized with a local anesthetic and the radiofrequency needles are advanced using guidance to confirm that the needles are properly positioned at the affected nerves. Then a radiofrequency current is applied to disrupt the ability of the nerves to transmit pain signals to the brain.[17, 18]

There are two types of radiofrequency neurotomy: thermal (or non-pulsed), and cooled (or pulsed). Pulsed radiofrequency neurotomy delivers short bursts of radiofrequency current rather than the continuous flow utilized in thermal or non-pulsed radiofrequency neurotomy.[19] Pulsed neurotomy allows the nerve tissue to cool between bursts, and is reported to reduce the destruction of neighboring tissue.[20] Some other names used for this procedure include percutaneous radiofrequency denervation,

nerve ablation, neurolysis, medial branch neurotomy, medial branch rhizotomy, and articular rhizolysis. Other types of facet neurotomy involve chemical ablation (application of ethyl alcohol, phenol, or sodium morrhuate; cryoablation (application of extreme cold); or laser ablation (application laser beams) of the medial branch nerves to destroy the nerves and reduce or eliminate pain.

Comparators: other treatment options and comparators

Comparators include sham neurotomy and therapeutic intra-articular injection or medial branch block. In the sham surgery, a radiofrequency needle is inserted to the same location as in radiofrequency neurotomy but the electric current is not turned on. Facet injections and medial branch blocks include injecting a corticosteroid plus local anesthetic into the facet joint and around the medial branch nerves, respectively.

Policy context provided by HTAP

Facet neurotomy aims to treat pain resulting from facet joint disease, but it does not cure the condition. There are significant questions related to the diagnosis of facet joint pain, and treatment of facet joint pain with facet neurotomy. The Washington State Health Care Authority has selected facet neurotomy for review based on medium concern around efficacy, high concern around safety, and medium concern around cost.

To that end, the objective of the report is to systematically review, critically appraise, analyze and synthesize research evidence comparing the efficacy, effectiveness, and safety of facet neurotomy procedures for patients with chronic facet joint pain.

Key Questions

In patients with facet arthropathy or facetogenic pain:

1. What is the evidence that the use of diagnostic blocks (i.e., medial branch blocks or intra-articular injections with local anesthetic) to select patients for facet neurotomy improves clinical outcomes following facet neurotomy? Consider each of the following:
    a. diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)
    b. type of diagnostic block (i.e., medial branch block versus intra-articular injection) for patient selection
    c. use of a single diagnostic block versus two or more controlled diagnostic blocks (i.e., use of a short- versus a long-acting local anesthetic, or use of a local anesthetic versus saline)
    d. Degree of pain reduction from diagnostic block (i.e., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%)
    e. unilateral versus bilateral diagnostic block
    f. single versus multiple level diagnostic block

2. What is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy (FN) compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?
    a. What is the evidence of the short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)
    b. What is the evidence of the short- and long-term comparative efficacy of repeat neurotomy procedures at the same level and the same side as the initial procedure?
    c. Is there evidence of differential effectiveness when conducting unilateral versus bilateral facet neurotomy?
    d. Is there evidence of differential effectiveness when conducting facet neurotomy on single versus multiple spinal levels?

3. What is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term for facet neurotomy?

4. Is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

5. What is the evidence of cost effectiveness of facet neurotomy compared with other treatment options?

Inclusion and exclusion criteria are summarized as follows:

- *Population.* Studies of adult patients being considered for facet neurotomy due to suspected facet joint pain.
- *Intervention.* Studies on facet neurotomy using FDA approved devices or other ablation techniques (e.g., chemical denervation)
- *Comparators.* Including but not limited to: alternative treatments, including sham neurotomy, therapeutic intra-articular injections or medial branch blocks, medical therapy, physical therapy, chiropractic therapy, natural history. Different types of neurotomy will also be compared.
- *Outcomes.* The primary outcomes of interest are clinically meaningful pain relief and functional improvement. Secondary outcomes include health-related quality of life (including psychological status), return to work, patient satisfaction, and opioid use. Outcomes may include composite outcome measures. Additionally, safety and complications will be reported.
- *Study design.* Eligible studies evaluated facet neurotomy utilizing a randomized or cohort study design. Case series were considered for Key Question 2b (effectiveness of repeat neurotomy) and Key Question 3 (safety). Formal economic analyses published in peer-reviewed journals were sought to address Key Question 5.

Methods for evaluating comparative effectiveness

The scope of this report and final key questions were refined based on input from clinical experts from a variety of disciplines and public comments received on draft key questions. Clinical expert input was sought to confirm primary outcomes on which to focus.

A formal, structured systematic search of the peer-reviewed literature across a number of databases including PubMed to identify relevant peer reviewed literature as well as of other sources (National Guideline Clearinghouse, Center for Reviews and Dissemination Database) to identify pertinent clinical guidelines and previously performed assessments.
Studies were selected for inclusion based on pre-specified criteria detailed in the full report. All records were screened by two independent reviewers. Selection criteria included a focus on studies with the least potential for bias that were written in English and published in the peer-reviewed literature.

Pertinent studies were critically appraised independently by two reviewers based on Spectrum's Class of Evidence (CoE) system which evaluates the methodological quality and potential for bias based on study design as well as factors which may bias studies. An overall Quality of Evidence combines the appraisal of study limitations with consideration of the number of studies and the consistency across them, directness and precision of the findings to describe an overall confidence regarding the stability of estimates as further research is available. Included economic studies were also formally appraised based on criteria for quality of economic studies and pertinent epidemiological precepts.

Results: Summary of the highest quality evidence on primary outcomes

The following summaries of evidence for primary findings have been based on the highest quality of studies available. Additional information on lower quality studies is available in the report.

A summary of the primary results for each key question are provided in the tables that follow the text summaries below with a focus on the primary outcomes described above. Details of these and other outcomes are available in the full report. RCTs and comparative nonrandomized controlled trials are the focus for this summary.

Key Question 1:
What is the evidence that the use of diagnostic blocks (i.e., medial branch blocks or intra-articular injections with local anesthetic) to select patients for facet neurotomy improves clinical outcomes following facet neurotomy? Consider each of the following:

KQ1a: *Diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)*

Lumbar spine: diagnostic block versus physical examination: One RCT (Cohen 2010)[21] (CoE II) met our inclusion criteria. Patients were selected for facet neurotomy based on clinical exam alone (n = 51) or one diagnostic medial branch block (n = 19). Those who underwent medial branch block were required to have ≥50% pain relief following the block in order to proceed to neurotomy. At both one and three months following RF neurotomy, there was no difference between diagnostic groups in the percentage of patients who achieved the composite outcome of "success", which was defined as ≥50% pain relief and a positive global perceived effect (i.e., improvement of pain and satisfaction with treatment). The overall quality of this evidence is "Low".

***No evidence for any of the following*:**

- Diagnostic block versus physical examination in the thoracic or cervical spine
- Diagnostic block versus radiological examination in the lumbar, thoracic, or cervical spine

KQ1b: *Type of diagnostic block (i.e., medial branch block versus intra-articular injection) for patient selection*

Lumbar spine: diagnostic medial branch block versus pericapsular block: One RCT (Birkenmaier 2007)[12] (CoE II) met our inclusion criteria. Patients were selected for cryodenervation based on a positive response (≥50% pain relief) to either a diagnostic medial branch block (n = 13) or pericapsular block (n = 13). As measured up to six months following cryodenervation, there was no difference between diagnostic groups in the mean improvement in back pain (VAS scores) or function (modified MacNab score). In both instances, the overall quality of this evidence is "Low".

***No evidence for any of the following*:**

- Other diagnostic block comparators in the lumbar spine
- Thoracic or cervical spine

KQ1c: *Use of a single diagnostic block versus two or more controlled diagnostic blocks (i.e., use of a short- versus a long-acting local anesthetic, or use of a local anesthetic versus saline)*

Lumbar spine: diagnostic block versus physical examination One RCT (Cohen 2010)[21] (CoE II) met our inclusion criteria. Patients were selected for facet neurotomy on the basis of a positive response (≥50% pain relief) to either a single diagnostic medial branch block (n = 19) or two comparative diagnostic medial branch blocks (n = 14). At both one and three months following RF neurotomy, there was no difference between diagnostic groups in the percentage of patients who achieved the composite outcome of "success", which was defined as ≥50% pain relief and a positive global perceived effect (i.e., improvement of pain and satisfaction with treatment). The overall quality of this evidence is "Low".

***No evidence for any of the following*:**

- Single versus controlled diagnostic blocks in the lumbar spine
- Thoracic or cervical spine

KQ1d: *Degree of pain reduction from diagnostic block (i.e., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%)*

Lumbar spine: threshold of pain relief following diagnostic block: Four cohort studies (Cohen 2008, Cohen 2013, Derby 2012, Derby 2013)[22-25] met our inclusion criteria, all of which compared facet neurotomy outcomes in patients with varying degrees of pain relief (see below) following their diagnostic medial branch block. The patients who met

the diagnostic selection criteria received RF neurotomy. We separated results out into two diagnostic groups based on the pain relief thresholds reported across studies:

- 50-79% pain relief required following diagnostic medial branch block to proceed to RF neurotomy (for Cohen 2013, the cutoff is 50-83%)
- ≥80% pain relief required following diagnostic medial branch block to proceed to RF neurotomy (for Cohen 2013, the cutoff is ≥84%)

Taken together, the suggested that outcomes *may* be better following RF neurotomy in those patients who achieved a minimum of 80% pain relief following diagnostic medial branch block though this was not consistently shown across all studies. Results are summarized below:

- ***Pain relief "success" following RF neurotomy*** (≥50% pain relief)
  6 months (2 retrospective cohort studies):
  - One study (Cohen 2008, N = 262)[22] found no difference between the diagnostic pain threshold groups
  - One study(Derby 2012, N = 51)[24] found that patients required to achieve[23] 80% pain relief following the diagnostic block had significantly better results following RF neurotomy compared with those required to achieve 50% pain relief following the block (risk difference, 30% (95% CI, 6% to 54%) (*P* = .0216)).
  - The overall quality of this evidence is "Insufficient".

- **"Success" composite** (≥50% pain relief from baseline and "positive GPE" (improvement of pain and satisfaction with treatment)):
  1 month (1 prospective cohort study)
  - One study found no difference between diagnostic groups (Cohen 2013, N = 61)

  3 months (2 cohort studies):
  - One prospective cohort study found no difference between diagnostic groups (Cohen 2013, N = 61)
  - One retrospective cohort study found that patients who were required to achieve a higher pain threshold (≥80%) following diagnostic block were significantly more likely to have "success" following RF neurotomy than those who had lower levels of pain relief (50-79%) following the diagnostic block (risk difference, 41% (95% CI, 16% to 67%) (*P* = .044)) (Derby 2013, N = 52)[25]

  The overall quality of this evidence is "Insufficient".

- **Function** (≥50% improvement in activity level, which was not clearly defined):
  6 months (1 retrospective cohort study):
  - One study found that those required to achieve ≥80% pain relief following diagnostic block group had significantly better functional results than those who had lower levels of pain relief (50-79%) following the diagnostic block (risk difference, 43% (95% CI, 17% to 68%) (*P* = .0030)) (Derby 2012, N = 51)[24]

- The overall quality of this evidence is "Insufficient".

***No evidence for any of the following*:**

- Thoracic or cervical spine

KQ1e: Unilateral versus bilateral diagnostic block

No studies were identified which met our inclusion criteria.

KQ1f: Single- versus multi-level diagnostic block

No studies were identified which met our inclusion criteria.

Key Question 2: What is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy (FN) compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?

RF Neurotomy versus Sham Neurotomy: Efficacy in the lumbar spine

Six RCTs (Gallagher 1994, Leclaire 2001, Nath 2008, Tekin 2007, van Kleef 1999, van Wijk 2005)[26-31] (all CoE II) met our inclusion criteria. Three studies selected patients with diagnostic medial branch block(s) and required ≥50% (Tekin 2007, van Kleef 1999) or ≥80% (Nath 2008) pain relief following the block(s) in order for patients to proceed to neurotomy; the three remaining studies (Gallagher 1994, Leclaire 2001, van Wijk 2005) employed one or two intra-articular block(s) for patient selection but only one of these (van Wijk 2005) specified the percentage of pain relief required for patients to proceed to neurotomy. Taken together, the results suggest that outcomes *may* be better following RF neurotomy compared with sham neurotomy, though in many instances there were no differences between treatment groups. Results are summarized below:

Pain outcomes:

Back pain (see Section 4.2.1.2)

- **Back pain relief** (improvement in VAS scores)
  - Short-term (1- 6 months) (6 RCTs)
    - Overall, the difference in the mean improvement in back pain VAS scores between groups ranged from 5.0 to 19.4 more points (scale, 0-100) following RF neurotomy versus sham neurotomy.
    - Four RCTs[26, 27, 29, 31] found no difference between groups (Gallagher 1994, Leclaire 2001, van Wijk 2005, Tekin 2007, total N = 221).
    - One RCT[30] favored RF neurotomy, with results reported at two months (mean change difference in scores between groups, 19.4 points) ($P < .05$) (van Kleef 1999, N = 31).
    - One RCT[28] marginally favored RF neurotomy, with results reported at six months. While the p-value suggested near statistical significance, the mean improvement from baseline was clinically significant in the RFN group (35%) but not the sham neurotomy group (16%) (Nath 2008, N = 40).
    - The overall quality of this evidence is "Low".

  - Long-term (12 months) (1 RCT)
    - One RCT[29] found significantly better results following RF neurotomy (mean change difference in scores, 12.0 ± 5.9 points) (*P* = .0002) (Tekin 2007, N = 40).
    - The overall quality of this evidence is "Low".

- **Back pain relief "success"** (≥50% pain relief from baseline): One RCT reported no difference between groups at three months (van Wijk 2005, N = 81)[31]. The overall quality of this evidence is "Low".
- **Global perceived effect (GPE) of back pain relief "success"** (≥50% improvement in GPE of back pain): One RCT found that results favored RF neurotomy at three months (risk difference, 23% (95% CI, 12% to 44%) (van Wijk 2005, N = 81)[31] . The overall quality of this evidence is "Low".
- **Improvement in back pain** (McGill scores): One RCT found no difference between groups at six months (Gallagher 1994, N = 30)[26].

Leg pain (see Section 4.2.1.3)

- **Leg pain relief** (improvement in VAS scores):
  - Short-term (3 & 6 months) (2 RCTs)
    - Overall, the difference in the mean improvement in leg pain VAS scores between groups ranged from 5.0 to 14.7 more points (scale, 0-100) following RF neurotomy versus sham neurotomy.
    - One RCT[31] found no difference between groups at three months (van Wijk 2005, N = 81).
    - One RCT[28] favored RF neurotomy, with results reported at six months (mean change difference in scores between groups, 14.7 points) (*P* = 0.046) (Nath 2008, N = 40).
    - The overall quality of this evidence is "Low".
- **Leg pain relief "success"** (≥50% pain relief from baseline): One RCT[31] reported no difference between groups at three months (van Wijk 2005, N = 81). The overall quality of this evidence is "Low".

Generalized pain (see Section 4.2.1.4)

- **Generalized pain relief** (improvement in VAS scores):
  - Short-term (6 months) (RCT)
    - One RCT[28] favored RF neurotomy, with results reported at six months (mean change difference in scores between groups, 15.6 points) (*P* = 0.02) (Nath 2008, N = 40).
    - The overall quality of this evidence is "Low".

Function (see Section 4.2.1.5)

- **Function** (improvement in ODI scores):
  - Short-term (2- 6 months) (3 RCTs)
    - Overall, the difference in the mean improvement in ODI scores between groups ranged from 2.0 to 12.8 more points (scale, 0-100) following RF neurotomy versus sham neurotomy.

        - Two RCTs[29, 30] favored RF neurotomy, with outcomes measured at two and six months) (Tekin 2007, van Kleef 1999, total N = 71)
        - One RCT[27] found no difference between groups as measured at three months (Leclaire 2001, N = 70)
        - The overall quality of this evidence is "Low".
    - Long-term (12 months) (1 RCT)
        - One RCT[29] favored RF neurotomy (mean change difference in scores between groups, 4.7 points, scale 0-100) (*P* = 0.0015) (Tekin 2007, N = 40).
        - The overall quality of this evidence is "Low".
- **Function:** Three other outcome measures were used to evaluate function; no differences were found between treatment groups:
    - Improvement in Waddell scores: One RCT[30] found no difference between groups at two months (van Kleef 1999, N = 31). The overall quality of this evidence is "Low".
    - Improvement in Roland Morris scores: One RCT[27] found no difference between groups at three months (Leclaire 2001, N = 70). The overall quality of this evidence is "Low".
    - Improvement in physical activity scores: One RCT[31] found no difference between groups at three months (van Wijk 2005, N = 81). The overall quality of this evidence is "Low".

Composite outcomes (see Section 4.2.1.6)

Two difference composite outcome measures were used to evaluate "success"; no differences were found between treatment groups:

- "Success" (minimum of a 2-point reduction on the VAS scale (0-10) and a 50% or more reduction in pain on global perceived effect): One RCT[30] found no difference between groups at two months (van Kleef 1999, N = 31).
- "Success" (either of the following: (a) ≥50% reduction in VAS-back pain without a decrease in daily activities or an increase in analgesic use, or (b) ≥25% reduction in VAS-back pain, an increase in daily activities by ≥25%, and a decrease in analgesic use by ≥25%): One RCT[31] found no difference between groups at three months (van Wijk 2005, N = 81).
- The overall quality of this evidence is "Low".

***No evidence for the following*:**

- Effectiveness of neurotomy versus sham neurotomy in the lumbar spine
- Efficacy or effectiveness of other types of neurotomy compared with sham neurotomy in the lumbar spine

RF Neurotomy versus Sham Neurotomy: Efficacy in the cervical spine

One small RCT (Lord 1996)[32] (CoE II) met our inclusion criteria. Patients were selected for neurotomy via three medial branch blocks and were required to have 100% pain relief following blocks in which anesthetic was injected and 0% pain relief when saline was injected.

Back pain (see Section 4.2.3.2)

- At six months, significantly more patients in the RF neurotomy group had achieved freedom from "accustomed pain" compared with those in the sham neurotomy group (risk difference, 50% (95% CI, 18% to 82%) (*P* = 0.0110) (Lord 1996, N = 24)[32]. The overall quality of this evidence is "Insufficient".

***No evidence for the following*:**

- Effectiveness of neurotomy versus sham neurotomy in the cervical spine
- Efficacy or effectiveness of other types of neurotomy compared with sham neurotomy in the cervical spine

RF Neurotomy versus Sham Neurotomy: thoracic spine

***No evidence for the following*:**

- Efficacy or effectiveness of neurotomy compared with sham neurotomy in the thoracic spine

RF Neurotomy versus Spinal Injections: Efficacy in the lumbar spine

Two RCTs (Civelek 2012, Lakemeier 2013)[33, 34] (CoE II) met our inclusion criteria. Civelek did not provide any details regarding whether or not a diagnostic block was used for patient selection; Lakemeier selected patients for RFN based on ≥50% pain relief following a diagnostic medial branch block. While Civelek and colleagues compared neurotomy to therapeutic medial branch block, Lakemeier and colleagues compared neurotomy to therapeutic intra-articular injections. Taken together, the results suggest that outcomes are similar following RF neurotomy and spinal injections, though one RCT found that patients were more likely to have back pain relief "success" following RF neurotomy compared with spinal injections. Results are summarized below:

Pain outcomes:

Back pain (see Section 4.2.5.2)

- **Back pain relief** (improvement in VAS scores):
  - Short-term: There was no difference between treatment groups based on evidence from two RCTs[33, 34] (Civelek 2012, Lakemeier 2013; total N = 156). The overall quality of this evidence is "Low".
  - Long-term: One RCT[33] found no difference between groups as measured at 12 months (Civelek 2012, N = 100). The overall quality of this evidence is "Low".
- **Back pain relief "success"** (≥50% pain relief from baseline): One RCT[33] reported that significantly more RFN patients had back pain "success" at both 6 and 12 months compared with those in the spinal injection group (Civelek 2012, N = 100). In both cases, the overall quality of this evidence is "Low".
  - Short-term: One RCT[33] found that results favored RF neurotomy as measured at six months (risk difference, 22% (95% CI, 7% to 37%) (Civelek 2012, N = 100).
  - Long-term: One RCT[33] found that results favored RF neurotomy at 12 months (risk difference, 26% (95% CI, 10% to 42%) (Civelek 2012, N = 100).

Function outcomes:

- **Function:** Two outcome measures were used to evaluate function in one RCT; no differences were reported between treatment groups:
    - Improvement in ODI scores: One RCT[34] found no difference between groups at six months (Lakemeier 2013, N = 56).
    - Improvement in Roland-Morris scores: The same RCT[34] found no difference between groups at six months (Lakemeier 2013, N = 56).
    - In both cases, the overall quality of this evidence is "Low".

RF Neurotomy versus Spinal Injections: Effectiveness in the lumbar spine

One retrospective audit study (Chakraverty 2004)[35] (CoE III) met our inclusion criteria. This study reported on patients who received radiofrequency facet neurotomy or intra-articular injections in a secondary care setting. No difference was found in the percentage of patients who achieved back pain relief "success" (≥50% pain relief from baseline) as measured at six months. The overall quality of this evidence is "Low".

***No evidence for the following*:**

- Efficacy or effectiveness of other types of neurotomy compared with spinal injections in the lumbar spine

RF Neurotomy versus Spinal Injections: Efficacy in the cervical spine

One RCT (Haspeslagh 2006)[36] (CoE II) met our inclusion criteria and compared radiofrequency facet neurotomy to anesthetic injection of the major occipital nerve in patients with cervicogenic headache. No diagnostic blocks were used for patient selection. Taken together, the results suggest that outcomes are similar following RF neurotomy and injection of the major occipital nerve. Results are summarized below:

Pain outcomes:

- **Headache relief** (improvement in VAS scores): One RCT[36] found no difference between groups at two months (Haspeslagh 2006, N = 30). The overall quality of this evidence is "Low".

Composite outcomes:

- **"Success" composite** (20% reduction in pain (as measured on the VAS scale) or a global perceived effect (GPE) score of +2 or +3 ("much better" or "complete relief") (total GPE scores ranged from -3 to +3)): One RCT[36] found no difference between groups at two months (Haspeslagh 2006, N = 30).). The overall quality of this evidence is "Low".

***No evidence for the following*:**

- Effectiveness of neurotomy versus spinal injections in the cervical spine
- Efficacy or effectiveness of other types of neurotomy compared with spinal injections in the cervical spine

RF Neurotomy versus Spinal Injections: Thoracic spine

***No evidence for the following*:**

- Efficacy or effectiveness of neurotomy compared with spinal injections in the thoracic spine

KQ2a: What is the evidence of the short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)

Conventional versus Pulsed RF Neurotomy: Efficacy in the Lumbar spine

Two RCTs (Kroll 2008, Tekin 2007)[29, 37] (CoE II) met our inclusion criteria. Both studies selected patients for facet neurotomy on the basis of ≥50% pain relief following diagnostic medial branch block. Taken together, the results suggest that outcomes are similar following conventional and pulsed RF neurotomy. Results are summarized below:

Pain outcomes:

- **Back pain relief** (improvement in VAS scores):
  - Short-term: Two RCTs[29, 37] found no difference between groups as measured at three and six months (Kroll 2008, Tekin 2007; total N = 66).
  - Long-term: One RCT[29] reported that results favored conventional RF neurotomy as measured at 12 months (mean change difference in scores between groups of 10 points (scale, 0-100) (Tekin 2007, N = 40).
  - In both cases, the overall quality of evidence is "Low".

Function outcomes:

- **Function** (improvement in ODI scores):
  - Short-term: Two RCTs[29, 37] found no difference between groups as measured at three and six months (Kroll 2008, Tekin 2007; total N = 66).
  - Long-term: One RCT[29] found no difference between groups as measured at 12 months (Tekin 2007, N = 40).
  - In both cases, the overall quality of evidence is "Low".

***No evidence for the following*:**

- Effectiveness of conventional versus pulsed RF neurotomy in the lumbar spine
- Efficacy or effectiveness of conventional versus pulsed RF neurotomy in the cervical or thoracic spine

RF Neurotomy versus Alcohol Ablation: Efficacy in the Lumbar spine

One RCT (Joo 2013)[38] (CoE II) met our inclusion criteria. All patient had previously had a successful neurotomy. Two blocks were used for patient selection, but neither the type of block nor the percentage of pain relief required were specified. Taken together, the results suggest that in the long-term, outcomes may favor alcohol ablation, though there was no difference between treatment groups in the short-term results. Results are summarized below:

Composite outcomes:

- **"Success"** (VAS score less than 7 and a revised ODI score < 22%):
  - Short-term: One RCT[38] found no difference between groups as measured up to nine months (Joo 2013, N = 40).
  - Long-term: One RCT[38] reported that results favored alcohol ablation as measured between 12 and 24 months (risk differences ranged from 5% to 15%) (Joo 2013, N = 40).
  - The overall quality of this evidence is "Low".

***No evidence for the following*:**

- Effectiveness of RF neurotomy versus alcohol ablation in the lumbar spine
- Efficacy or effectiveness of RF neurotomy versus alcohol ablation in the cervical or thoracic spine

KQ2b: What is the evidence of the short- and long-term comparative efficacy of repeat neurotomy procedures at the same level and the same side as the initial procedure?

Repeat neurotomy following successful first neurotomy: Lumbar spine

Six studies providing case series evidence (Joo 2013, Rambaransingh 2010, Son 2010, Schofferman 2004, Speldewinde 2011, Zotti 2010)[38-43] (all CoE IV) met our inclusion criteria. Taken together, the results suggest that following a successful first neurotomy, patients with recurrent pain who undergo a second or even a third neurotomy procedure may have similar results as those achieved after the first procedure. The overall quality of this evidence is "Insufficient".

Repeat neurotomy following successful first neurotomy: Cervical spine

Two studies providing case series evidence (Husted 2008, Rambaransingh 2010, Speldewinde 2011)[39, 42, 44] (all CoE IV) met our inclusion criteria. Taken together, the results suggest that following a successful first neurotomy, patients with recurrent pain who undergo a second or even a third neurotomy procedure may have similar results as those achieved after the first procedure. The overall quality of this evidence is "Insufficient".

Repeat neurotomy following successful first neurotomy: Thoracic spine

No studies met our inclusion criteria.

KQ2c: Is there evidence of differential effectiveness when conducting unilateral versus bilateral facet neurotomy?

Unilateral versus bilateral RF Neurotomy: Effectiveness in the Lumbar spine

One retrospective cohort study (Tzaan 2000)[45] (CoE III) met our inclusion criteria. The number of patients was not reported. Based on data from 69 procedures, no difference was found between treatment groups in terms of the percentage of procedures that resulted in back pain "success" (≥50% pain relief or complete elimination of pain) as measured at a mean of 5.6 months. The overall quality of this evidence is "Low".

KQ2d: Is there evidence of differential effectiveness when conducting facet neurotomy on single versus multiple spinal levels?

No studies were identified which met our inclusion criteria.

Key Question 3: What is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term for facet neurotomy?

RF Neurotomy versus Sham Neurotomy: Safety in the lumbar spine

We evaluated safety data from all comparative studies included in Key Question 2 that compared RF neurotomy to sham neurotomy. Of the six RCTs available, only one[31] (Van Wijk) reported on specific adverse events or complications (treatment-related pain, change of sensibility, and loss of motor function): no differences were found between treatment groups. Four RCTs[26, 27, 29, 30] (Gallagher, Leclaire, Tekin, van Kleef) only gave a vague statement indicating that no adverse events or complications occurred in either treatment group; one RCT[28] (Nath) made no mention of adverse events at all. No nonrandomized comparative studies or case series met our inclusion criteria.

For each outcome reported, the overall quality of the evidence is "Low".

RF Neurotomy versus Sham Neurotomy: Safety in the cervical spine

We evaluated safety data from the sole RCT included in Key Question 2. This RCT[32] (Lord) compared RF neurotomy with sham neurotomy and reported on safety outcomes, specifically psoriatic rash, pain associated with the procedure, and numbness in the area of the treated nerves. Aside from procedure-related numbness, which was significantly higher following RF neurotomy, there were no differences between treatment groups.

No nonrandomized comparative studies or case series met our inclusion criteria.

RF Neurotomy versus Sham Neurotomy: Safety in the thoracic spine

No studies met our inclusion criteria.

RF Neurotomy versus Spinal Injections: Safety in the lumbar spine

We evaluated safety data from all comparative studies included in Key Question 2. Of the three comparative studies available, one RCT[33] (Civelek) comparing RF neurotomy to medial branch block (MBB) and another RCT[34] (Lakemeier) comparing RF neurotomy to intra-articular steroid injections plus sham neurotomy reported data on harms. One retrospective cohort study[35] (Chakraverty) did not provide any harms data. Civelek and colleagues[33] found no difference between treatment groups in any of the following adverse events: infection, new motor deficit, new sensory deficit, superficial burns, and increase in lower back pain. Lakemeier and colleagues[34] reported vaguely on adverse events but did not define which specific outcomes they examined. No case series met our inclusion criteria.

For each outcome reported, the overall quality of the evidence is "Low".

RF Neurotomy versus Spinal Injections: Safety in the cervical spine

We evaluated safety data from the only RCT included in Key Question 2 that evaluated RF neurotomy and spinal injections in the cervical spine. This RCT[36] (Haspeslagh) made no mention of adverse events. No nonrandomized comparative studies or case series met our inclusion criteria.

RF Neurotomy versus Spinal Injections: Safety in the thoracic spine

No studies met our inclusion criteria.

Key Question 4: Is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

For this key question, we first evaluated differential efficacy, effectiveness, and safety of facet neurotomy compared with other treatment options by looking for subgroup analyses in comparative studies. Secondly, we conducted an analysis on a subgroup of studies included in Key Question 2 to determine the efficacy of facet neurotomy in patients selected on the basis of ≥50% pain relief following medial branch block.

Heterogeneity of treatment effect:

We evaluated differential efficacy, effectiveness, and safety of facet neurotomy compared with other treatment options by looking for subgroup analyses in comparative studies. One RCT (van Wijk)[31] met our inclusion criteria and reported on patients who underwent RF neurotomy (n = 40) or sham neurotomy (n = 41) in the lumbar spine following selection by either diagnostic medial branch block or clinical exam alone. Results suggested that none of the following subgroups had differential treatment effect in terms of the composite outcome "success" or GPE pain relief "success" following RF neurotomy versus sham neurotomy: sex, age (18-40 versus >40), duration of pain (≤5 versus > 5 years), employment status (unemployed versus employed), and previous low back surgery. For each subgroup reported, the overall quality of the evidence is "Low".

No studies were identified which evaluated differential efficacy, effectiveness, or safety of facet neurotomy compared with other treatment options in the cervical spine.

Comparative efficacy of RF Neurotomy: patients selected on the basis of ≥50% pain relief following medial branch block

In Key Question 1, no direct evidence was identified that type of diagnostic block (i.e., medial branch block versus intra-articular block) affected patient outcomes following facet neurotomy. As a result, no restrictions were placed on type of diagnostic block used for patient selection for studies included in Key Question 2. However, during the public comment period, a peer reviewer (Paul Dreyfuss, MD) indicated that the methods by which patients are selected for facet neurotomy affects the efficacy of the procedure. Specifically, he suggested that patients should be selected on the basis of ≥50% pain relief following one or more diagnostic medial branch block(s) (see also section 1.4.1).

In order to address this concern, we provided the results from on a subgroup studies included in Key Question 2 that selected patients on the basis of ≥50% pain relief following medial branch block.

RF Neurotomy versus Sham Neurotomy: Efficacy following MBB in the lumbar spine

Of the studies that compared RF neurotomy to sham neurotomy in the lumbar spine, three RCTs (Nath 2008, Tekin 2007, van Kleef 1999)[28-30] (all CoE II) selected patients on the basis of ≥50% (or ≥80%) pain relief following diagnostic medial branch block.

Taken together, the results suggested that outcomes favored RF neurotomy over sham neurotomy.

Pain outcomes:

Back pain

- **Back pain relief** (improvement in VAS scores)
  - Short-term (2- 6 months) (3 RCTs)
    - Overall, the difference in the mean improvement in back pain VAS scores between groups ranged from 5.0 to 19.4 more points (scale, 0-100) following RF neurotomy versus sham neurotomy.
    - One RCT[30] favored RF neurotomy, with results reported at two months (mean change difference in scores between groups, 19.4 points) ($P < .05$) (van Kleef 1999, N = 31).
    - One RCT[28] marginally favored RF neurotomy, with results reported at six months. While the p-value suggested near statistical significance, the mean improvement from baseline was clinically significant in the RFN group (35%) but not the sham neurotomy group (16%) (Nath 2008, N = 40).
    - One RCT[29] found no difference between groups (Tekin 2007, N = 40).
    - The overall quality of this evidence is "Low".
  - Long-term (12 months) (1 RCT)
    - One RCT[29] found significantly better results following RF neurotomy (mean change difference in scores, 12.0 ± 5.9 points) ($P = .0002$) (Tekin 2007, N = 40).
    - The overall quality of this evidence is "Low".

Leg pain (see Section 4.2.1.3)

- **Leg pain relief** (improvement in VAS scores):
  - Short-term (6 months) (1 RCT)
    - One RCT[28] favored RF neurotomy, with results reported at six months (mean change difference in scores between groups, 14.7 points) ($P = 0.046$) (Nath 2008, N = 40).
    - The overall quality of this evidence is "Low".

Generalized pain (see Section 4.2.1.4)

- **Generalized pain relief** (improvement in VAS scores):
  - Short-term (6 months) (RCT)
    - One RCT[28] favored RF neurotomy, with results reported at six months (mean change difference in scores between groups, 15.6 points) (*P* = 0.02) (Nath 2008, N = 40).
    - The overall quality of this evidence is "Low".

Function (see Section 4.2.1.5)

- **Function** (improvement in ODI scores):
  - Short-term (2- 6 months) (2 RCTs)
    - Overall, the difference in the mean improvement in ODI scores between groups ranged from 2.9 to 12.8 more points (scale, 0-100) following RF neurotomy versus sham neurotomy.
    - Two RCTs[29, 30] favored RF neurotomy, with outcomes measured at two and six months) (Tekin 2007, van Kleef 1999, total N = 71)
    - The overall quality of this evidence is "Low".
  - Long-term (12 months) (1 RCT)
    - One RCT[29] favored RF neurotomy (mean change difference in scores between groups, 4.7 points, scale 0-100) (*P* = 0.0015) (Tekin 2007, N = 40).
    - The overall quality of this evidence is "Low".
- **Function** (improvement in Waddell scores):
  - One RCT[30] found no difference between groups at two months (van Kleef 1999, N = 31). The overall quality of this evidence is "Low".

RF Neurotomy versus Sham Neurotomy: Efficacy following MBB in the lumbar spine

One small RCT (Lord 1996)[32] (CoE II) met our inclusion criteria. Patients were selected for neurotomy via three medial branch blocks and were required to have 100% pain relief following blocks in which anesthetic was injected and 0% pain relief when saline was injected. At approximately six months (27 weeks), significantly more patients were free from their "accustomed" pain in the RF neurotomy group compared with those in the sham neurotomy group. A larger trial is needed to confirm this result.

Back pain

- At six months, significantly more patients in the RF neurotomy group had achieved freedom from "accustomed pain" compared with those in the sham neurotomy group (risk difference, 50% (95% CI, 18% to 82%) (*P* = 0.0110) (Lord 1996, N = 24)[32]. The overall quality of this evidence is "Insufficient".

RF Neurotomy versus Sham Neurotomy: Efficacy following MBB in the lumbar spine

One RCT (Lakemeier 2013) (CoE II) forms the evidence base, and compared facet neurotomy to therapeutic intra-articular injection.[34] There were no statistically meaningful differences between treatment groups in terms of short-term pain or function.

Pain outcomes:

<u>Back pain</u>

- **Back pain relief** (improvement in VAS scores):
  - <u>Short-term:</u> There was no difference between treatment groups based on evidence from one RCT[33, 34] (Lakemeier 2013; N = 56). The overall quality of this evidence is "Low".

Function outcomes:

- **Function:** Two outcome measures were used to evaluate function in one RCT; no differences were reported between treatment groups:
  - Improvement in ODI scores: One RCT[34] found no difference between groups at six months (Lakemeier 2013, N = 56).
  - Improvement in Roland-Morris scores: The same RCT[34] found no difference between groups at six months (Lakemeier 2013, N = 56).
  - In both cases, the overall quality of this evidence is "Low".

<u>Key Question 5:</u> What is the evidence of cost effectiveness of facet neurotomy compared with other treatment options?

No studies met our inclusion criteria.

Key Question 1: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence that the use of diagnostic blocks to select patients for facet neurotomy improves clinical outcomes following facet neurotomy? Consider each of the following:

Key Question 1a: Diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)					RF Neurotomy		Effect size	
Outcome following RF neurotomy	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	MBB	Clinical exam	RR (95% CI) RD (95% CI)	Favors
					% patients			
Lumbar spine: Diagnostic block versus physical examination Evidence base: 1 RCT[21] (see footnotes for details)								
Short-term "Success" composite: ≥50% pain relief and positive GPE	**1 RCT[21] N = 70 1, 3 mos.**	**MBB (vs. clinical exam)**	**MBB group: ≥50% pain relief** **Clinical exam group: none**	**Low*†**	**39-63% (range)**	**33-59% (range)**	**RR: 1.07-1.17** **RD: 0.04-0.06** See below for 95% CIs	**neither**
	1 mos.				63% (12/19)	59% (30/51)	1.07 (0.71, 1.62) 0.04 (-0.21, 0.30)	neither
	3 mos.				39% (7/18)	33% (17/51)	1.17 (0.58, 2.34) 0.06 (-0.20, 0.32)	neither
No evidence for any of the following: • Diagnostic block versus physical examination in the thoracic or cervical spine • Diagnostic block versus radiological examination in the lumbar, thoracic, or cervical spine Evidence base: 1 RCT (N = 70) (Cohen 2010[21])								

GPE: global perceived effect; MBB: medial branch block; NS: differences between groups are not statistically significant; RF: radiofrequency

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size

Key Question 1b: Type of diagnostic block					Cryodenervation		Effect size	
Outcome following cryo-denervation	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	MBB	Peri-capsular block	Mean Δ difference (95% CI)	Favors
					Δ from baseline (mean (%))			
Lumbar spine: Medial branch block versus pericapsular block Evidence base: 1 RCT[12] (see footnotes for details)								
Short-term Back pain (VAS scores) (Scale: 0-100)	**1 RCT[12] N = 26 1.5 – 6 mos.**	**MBB vs. pericapsular block**	**≥50% pain relief**	**Low*†**	**47-52 points (range)**	**40 points (range)**	**7-12 points (range)**	**neither**
	1.5 mos.				52 (72%)	40 (49%)	12	neither
	3 mos.				51 (69%)	40 (49%)	11	neither
	6 mos.				47 (64%)	40 (57%)	7	neither
Short-term Function: MacNab (Scale: 0-3)	**1 RCT[12] N = 26 1.5 – 6 mos.**	**MBB vs. pericapsular block**	**≥50% pain relief**	**Low*†**	**1.1-1.2**	**1.0**	**0.1-0.2 points (range)**	**NC/NR**
	1.5 mos.				1.1	1.0	0.1	NC/NR
	3 mos.				1.2	1.0	0.2	NC/NR
	6 mos.				1.2	1.0	0.2	NC/NR
No evidence for any of the following: • Other diagnostic block comparators in the lumbar spine • Thoracic or cervical spine Evidence base: 1 RCT (N = 26) (Birkenmaier[12])								

MBB: medial branch block; NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size

Key Question 1c: Use of single versus two or more controlled or comparative diagnostic blocks					RF Neurotomy		Effect size	
Outcome following RF neurotomy	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	1 MBB	2 comp. MBBs	RR (95% CI) RD (95% CI)	Favors
					% patients			
Lumbar spine: Medial branch block versus pericapsular block Evidence base: 1 RCT[21] (see footnotes for details)								
Short-term "Success" composite: ≥50% pain relief and positive GPE	**1 RCT[21] N = 33 1, 3 mos.**	**MBB**	**≥50% pain relief**	**Low*†**	**39-63% (range)**	**64% (range)**	**RR: 0.60-0.98 RD: -0.25 to -0.01** See below for 95% CIs	**neither**
	1 mos.				63% (12/19)	64% (9/14)	0.98 (0.58, 1.65) -0.01 (-0.34, 0.32)	neither
	3 mos.				39% (7/18)	64% (9/14)	0.60 (0.30, 1.22) -0.25 (-0.59, 0.08)	neither
No evidence for any of the following: • Thoracic or cervical spine Evidence base: 1 RCT (N = 33) (Cohen 2010[21])								

MBB: medial branch block; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

†relatively small sample size

Key Question 1d: Degree and duration of pain reduction from diagnostic block				RF Neurotomy		Effect size	
Outcome following RF neurotomy	Studies N Follow-up	Diagnostic block	Overall quality of evidence	50-79% pain relief from MBB(s)	≥80% pain relief from MBB(s)	RR (95% CI) RD (95% CI)	Favors
				% patients			
Lumbar spine: 50-79% versus ≥80% pain relief from diagnostic block							
Evidence base: 1 prospective[23] and 3 retrospective[22, 24, 25] cohort studies (see footnotes for details)							
Short-term Back pain "Success": ≥50% pain relief	**2 retro. cohorts[22, 24] total N = 313 6 mos.**	**MBB**	**Insufficient*†**	**52-54% (range)**	**56-84% (range)**	**RR: 0.64-0.93 RD: -0.30 to -0.04** See below for 95% CIs	**See below**
	N = 262[22] 6 mos.	MBB		52% (76/145)	56% (66/117)	0.93 (0.74, 1.16) -0.04 (-0.16, 0.08)	neither
	N = 51[24] 6 mos.	MBB		54% (14/26)	84% (21/25)	0.64 (0.43, 0.95) -0.30 (-0.54, -0.06)	≥80% pain relief from block
Short-term "Success" composite: ≥50% pain relief and positive GPE	**2 cohort studies[23, 25] N = 113 total 1, 3 mos.**	**MBB**	**Insufficient*†**	**35-67% (range)**	**56-76% (range)**	**RR: 0.46-1.05 RD: -0.41 to 0.03** See below for 95% CIs	**See below**
	1 mos. 1 pro. cohort[23] N = 61	MBB		67% (26/39)†	69% (11/16)†	0.97 (0.65, 1.44) -0.02 (-0.29, 0.25)	neither
	3 mos. 1 pro. cohort[23] N = 61	MBB		59% (23/39)†	56% (9/16)†	1.05 (0.63, 1.74) 0.03 (-0.26, 0.32)	neither
	1 retro. cohort[25] N = 52	MBB		35% (8/23)	76% (19/25)	0.46 (0.25, 0.84) -0.41 (-0.67, -0.16)	≥80% pain relief from block

Key Question 1d: Degree and duration of pain reduction from diagnostic block				RF Neurotomy		Effect size	
Outcome following RF neurotomy	**Studies N**	**Diagnostic block**	**Overall quality of evidence**	**50-79% pain relief from MBB(s)**	**≥80% pain relief from MBB(s)**	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Function: ≥50% improvement in activity levels (not defined)	1 retro. cohort[24] N = 51 6 mos.	**MBB**	**Insufficient*†**	**33% (8/24)**	**76% (19/25)**	**0.44 (0.24, 0.80) -0.43 (-0.68, -0.17)**	**≥80% pain relief from block**
No evidence for any of the following: • Duration of pain relief following diagnostic block in the lumbar spine • Thoracic or cervical spine							

Evidence base:

- 1 prospective cohort study: (Cohen 2013[23], N = 61)
- 3 retrospective cohort studies: (Cohen 2008[22], N = 262), (Derby 2012[24], N = 51), (Derby 2013[25], N = 52)

MBB: medial branch block; NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; pro: prospective; retro.: retrospective; RFN: radiofrequency neurotomy

* the studies did not meet two or more important criteria of a good quality cohort studies (see Appendix C for details)

† relatively small sample size

‡ pain relief following diagnostic block divided as follows: 50-83% versus ≥84% (Cohen 2013)

Key Question 2: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, What is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy (FN) compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?

NOTE. See Key Question 4 for tables that limit evidence to studies that employed diagnostic MBB.

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine					Treatment groups		Effect size	
Efficacy Evidence base: 6 RCTs[26-31] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Sham** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**6 RCTs[26-31] N = 292 total 2-6 mos.**	**Varied**	**Varied**	**Low*†**	**-0.4 to 42.0 points (range)**	**2.0 to 37.0 points (range)**	**5.0 to 19.4 points (range)**	**neither**
	1 RCT[30] N = 31 2 mos.	1 MBB	≥50% pain relief		23.7 (46%)	4.3 (8%)	19.4	RFN
	1 RCT[27] N = 70 3 mos.	1 IAB	"Significant" response		-0.4 ± 25.0 (-1%)	7.1 ± 27.3 (14%)	7.5 ± 16.0	neither
	1 RCT[31] N = 81 3 mos.	2 IABs	≥50% pain relief		21.0 (36%)	16.0 (25%)	5.0	NR/NC
	1 RCT[26] N = 30 6 mos.	1 IAB	"Good" response		14.0 (24%)	2.0 (3%)	12.0	NR/NC
	1 RCT[28] N = 40 6 mos.	2 MBBs	≥80% pain relief		21.0 (35%)	7.0 (16%)	14.0	RFN (marginally)
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	5.0 ± 6.5	neither
Long-term Back pain (VAS scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**41.0 ± 9.1 (63%)**	**29.0 ± 9.6 (43%)**	**12.0 ± 5.9**	**RFN**

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine					Treatment groups		Effect size	
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN % patients	Sham % patients	RR (95% CI) RD (95% CI)	Favors
Short-term Back pain "success" (≥50% improvement in VAS scores)	**1 RCT[31] N = 81 3 mos.**	**2 IABs**	**≥50% pain relief**	**Low*‡**	**33% (13/40) patients**	**34% (14/41) patients**	**0.95 (0.51, 1.76) -0.02 (-0.22, 0.19)**	**neither**
Short-term GPE Back pain "success" (≥50% improvement in GPE of back pain)	**1 RCT[31] N = 81 3 mos.**	**2 IABs**	**≥50% pain relief**	**Low*‡**	**62% (24/39) patients**	**39% (16/41) patients**	**1.58 (0.9994, 2.49) 0.23 (0.12, 0.44)**	**RFN** (marginally)
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN Δ from baseline (mean (%))	Sham Δ from baseline (mean (%))	Mean Δ difference (95% CI)	Favors
Short-term Pain (McGill scores) (0-50)	**1 RCT[26] N = 30 1, 6 mos.**	**1 IAB**	**"Good" response**	**Low*‡**	**3 to 6 points (range)**	**2 to 3 points (range)**	**1 to 3 points (range)**	**neither**
	1 mos.				6 ± 1.5	3 ± 1.7	3	RFN
	6 mos.				3 ± 5.5	2 ± 1.9	1	neither
Short-term Leg Pain (VAS scores) (0-100)	**2 RCTs[28, 31] N = 121 total 3, 6 mos.**			**Low*‡**	**16 to 21 points (range)**	**1.3 to 16 points (range**	**5 to 14.7 points (range)**	**RFN**
	1 RCT[31] N = 81 3 mos.	1 IAB	"Good" response		21.0 (50%)	16.0 (25%)	5.0	NC
	1 RCT[28] N = 40 6 mos.	2 MBBs	≥80% pain relief		16.0 (37%)	1.3 (5%)	14.7	RFN

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine					Treatment groups		Effect size	
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN % patients	Sham % patients	RR (95% CI) RD (95% CI)	Favors
Short-term Leg pain "success" (≥50% improvement in VAS scores)	**1 RCT[31] N = 81 3 mos.**	**1 IAB**	**"Good" response**	**Low*†**	**50% (19/38) patients**	**37% (15/41) patients**	**1.37 (0.82, 2.28) 0.13 (-0.08, 0.35)**	**neither**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN Δ from baseline (mean (%))**	**Sham Δ from baseline (mean (%))**	**Mean Δ difference (95% CI)**	**Favors**
Short-term Generalized pain (VAS scores) (0-100)	1 RCT[28] N = 40 6 mos.	2 MBBs	≥80% pain relief	**Low*‡**	19.3	3.7	15.6	**RFN**
Short-term Function (ODI scores) (0-100)	**3 RCTs[27, 29, 30] N = 141 total 2-6 mos.**	**Varied**	**Varied**	**Low*†**	**4.7 to 14.1 points (range)**	**-1.7 to 11.2 points (range)**	**2.0 to 12.8 points (range)**	**RFN**
	1 RCT[30] N = 31 2 mos.	1 MBB	≥50% pain relief		11.1 (36%)	-1.7 (-4%)	12.8	RFN
	1 RCT[27] N = 70 3 mos.	1 IAB	"Significant" response		4.7 ± 12.0 (12%)	2.7 ± 9.1 (7%)	2.0	neither
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		14.1 ± 4.2 (36%)	11.2 ± 3.9 (28%)	2.9	RFN
Long-term Function (ODI scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**11.2 ± 4.8 (29%)**	**6.5 ± 3.9 (16%)**	**4.7**	**RFN**
Short-term Function (Roland-Morris scores) (converted to 0-100)	**1 RCT[27] N = 70 3 mos.**	**1 IAB**	**"Significant" response**	**Low*‡**	**9.8 ± 19.5 (19%)**	**7.2 ± 17.0 (14%)**	**2.6**	**neither**
Short-term Function (Waddell scores) (0-24)	**1 RCT[30] N = 31 2 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**0.33**	**0.07**	**0.26**	**neither**

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine					Treatment groups		Effect size	
Short-term Function (physical activity scores) (0-30)	**1 RCT[31] N = 81 3 mos.**	**1 IAB**	**"Good" response**	**Low*‡**	**1.5**	**0.9**	**0.6**	**NR/NC**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN**	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
					% patients			
Short-term "Success" composite (≥2-point improvement in VAS (0-10) and ≥50% improvement in GPE (1-4))	**1 RCT[30] N = 31 2 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**67% (10/15) patients**	**38% (6/16) patients**	**1.77(0.86, 3.68) 0.29 (-0.05, 0.63)**	**neither**
Short-term "Success" composite Either of the following: • ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or • ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%	**1 RCT[31] N = 81 3 mos.**	**1 IAB**	**"Good" response**	**Low*‡**	**28% (11/40)**	**29% (12/41)**	**0.94 (0.47, 1.88) -0.02 (-0.21, 0.18)**	**neither**

No evidence for any of the following:

- Effectiveness of neurotomy versus sham neurotomy in the lumbar spine
- Efficacy or effectiveness of other types of neurotomy versus sham neurotomy in the lumbar spine

Evidence base for efficacy in the lumbar spine: 6 RCTs

- Gallagher (1994)[26]: N = 30 (CoE II)
- Leclaire (2001)[27]: N = 70 (CoE II)
- Nath (2008)[28]: N = 31 (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)
- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Cervical Spine					Treatment groups		Effect size	
Evidence base: 1 RCT[32] (see footnotes for details)								
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN % patients	Sham % patients	RR (95% CI) RD (95% CI)	Favors
Short-term Freedom from "accustomed" pain	1 RCT[32] N = 81 6 mos.	3 MBBs	100% with anesthetics, 0% with saline	Insufficient*†	58% (7/12)	8% (1/12)	7.00 (1.01, 48.54) 0.50 (0.18, 0.82)	RFN
No evidence for any of the following: • Effectiveness of neurotomy versus sham neurotomy in the cervical spine • Efficacy or effectiveness of other types of neurotomy versus sham neurotomy in the cervical spine								

Evidence base for efficacy in the cervical spine: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size and wide confidence intervals

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine					Treatment groups		Effect size	
Efficacy Evidence base: 2 RCTs[33, 34] (see footnotes for details) **Injections:** Therapeutic medial branch block (1 RCT[33]); therapeutic intra-articular injections (1 RCT[34])								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Injection** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**2 RCTs[33, 34] N = 156 total 6 mos.**			**Low*†**	**19 to 57 points (range)**	**16 to 41 points (range)**	**3 to 16 points (range)**	**neither**
	1 RCT[33] N = 100 6 mos.	NR	NR		57 (70%)	41 (48%)	16	NR/NC
	1 RCT[34] N = 56 6 mos.	1 MBB	≥50% pain relief		19 ± 14.5 (29%)	16 ± 12.6 (23%)	3	neither
Long-**term Back pain** (VAS scores) (0-100)	1 RCT[33] N = 100 12 mos.	NR	NR	**Low*‡**	56 (68%)	36 (42%)	20	NR/NC
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Back pain "success" (≥50% improvement in VAS scores)	**1 RCT[33] N = 100 6 mos.**	**NR**	**NR**	**Low*‡**	**90% (45/50)**	**68% (34/50)**	**1.32 (1.11, 1.58) 0.22 (0.07, 0.37)**	**RFN**
Long-term Back pain "success" (≥50% improvement in VAS scores)	**1 RCT[33] N = 100 12 mos.**	**NR**	**NR**	**Low*‡**	**88% (44/50)**	**62% (31/50)**	**1.42 (1.12, 1.80) 0.26 (0.10, 0.42)**	**RFN**

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine					Treatment groups		Effect size	
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN Δ from baseline (mean (%))	Injection Δ from baseline (mean (%))	Mean Δ difference (95% CI)	Favors
Short-term Function (ODI scores) (0-100)	**1 RCT[34] N = 56 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**12.8 ± 12.0 (31%)**	**5.7 ± 11.4 (15%)**	**7.1 points**	**neither**
Short-term Function (Roland-Morris scores) (0-24, lower is better)	**1 RCT[34] N = 56 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**3.7 ± 3.7 (19%)**	**4.2 ± 3.9 (14%)**	**-0.5 points**	**neither**
Effectiveness Evidence base: 1 retrospective audit[35] (see footnotes for details) **Injections:** Therapeutic intra-articular injections								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN % patients**	**Injection % patients**	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Back pain "success" (≥50% global subjective improvement)	**1 retro. cohort[35] N = 66 6 mos.**	**IAI (# NR)**	**NR**	**Low*‡**	**50% (16/32)**	**29% (10/34)**	**1.70 (0.91, 3.18) 0.21 (-0.03, 0.44)**	**neither**
No evidence for any of the following: • Efficacy or effectiveness of other types of neurotomy versus spinal injections in the lumbar spine								

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Civelek (2012)[33]: N = 100 (CoE II)
- Lakemeier (2013)[34]: N = 56 (CoE II)

Evidence base for effectiveness in the lumbar spine: 1 retrospective audit study

- Chakraverty (2004)[35]: N = 66 (CoE III)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 2: RF Neurotomy versus Spinal Injections in the Cervical Spine					Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[36] (see footnotes for details) **Injections:** Anesthetic injection of the major occipital nerve (for cervicogenic headache)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN**	**Injection of GON**	**Mean Δ difference (95% CI)**	**Favors**
					Δ from baseline (mean (%))			
Short-term Headache pain (VAS scores) (0-100)	**1 RCT[36] N = 30 2 mos.**	**None**	**-**	**Low*†**	**30.5 ± 17.3 (45%)**	**32.4 ± 24.7 (42%)**	**1.9**	**neither**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN**	**Injection of GON**	**RR (95% CI) RD (95% CI)**	**Favors**
					% patients			
Short-term "Success" composite (GPE score +2 or +3 and/or ≥ 20-point improvement VAS)	**1 RCT[36] N = 30 2 mos.**	**None**	**-**	**Low*†**	**80% (12/15)**	**71% (10/14)**	**1.12 (0.79, 1.59) 0.09 (-0.23, 0.40)**	**neither**
No evidence for any of the following: • Effectiveness of neurotomy versus spinal injections in the cervical spine • Efficacy or effectiveness of other types of neurotomy versus spinal injections in the cervical spine								

Evidence base for efficacy in the cervical spine: 1 RCT

- Haspeslagh (2006)[36]: N = 100 (CoE II)

GON: greater occipital nerve; NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2a: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)?

Key Question 2a: Conventional versus pulsed RF neurotomy in the lumbar spine					**Treatment groups**		**Effect size**	
Efficacy Evidence base: 2 RCTs[29, 37] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**Conventional RFN**	**Pulsed RFN**	**Mean Δ difference (95% CI)**	**Favors**
					Δ from baseline (mean (%))			
Short-term Back pain (VAS scores) (0-100)	**2 RCTs[29, 37] N = 66 total 3, 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**24.3 to 42 points (range)**	**12.3 to 37 points (range)**	**5 to 12 points (range)**	**neither**
	1 RCT[37] N = 26 3 mos.	1 MBB	≥50% pain relief		24.3 ± 17.5 (32%)	12.3 ± 13.0 (19%)	12.0	**neither**
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		42 ± 9 (65%)	37 ± 10 (56%)	5	**neither**
Long-term Back pain (VAS scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**41 ± 9 (63%)**	**31 ± 10 (47%)**	**10**	**Conv. RFN**
Short-term Function (ODI scores) (0-100)	**2 RCTs[29, 37] N = 66 total 3, 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**10.3 to 14.1 points (range)**	**2.7 to 14.1 points (range)**	**0 to 7.6 points (range)**	**neither**
	1 RCT[37] N = 26 3 mos.	1 MBB	≥50% pain relief		10.3 ± 10.8	2.7 ± 12.4	7.6	**neither**
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		14.1 ± 4.2	14.1 ± 4.2	0	**neither**
Long-term Function (ODI scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**11.2 ± 4.8**	**10.9 ± 3.7**	**0.3**	**neither**

Key Question 2a: Conventional versus pulsed RF neurotomy in the lumbar spine	Treatment groups	Effect size
No evidence for any of the following: • Effectiveness of conventional versus pulsed neurotomy in the lumbar spine • Efficacy or effectiveness of conventional versus pulsed neurotomy in the cervical spine		

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Kroll (2007)[37]: N = 50 (study on 26 patients) (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2a: RF neurotomy versus Alcohol ablation in the lumbar spine					Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[38] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN**	**Alcohol Ablation**	**RR (95% CI) RD (95% CI)**	**Favors**
					% patients			
Short-term "Success" composite (VAS < 7 (0-10 scale) and ODI < 22%)	**1 RCT[38] N = 40 3-9 mos.**	**2 blocks (type NR) All pts had previously successful RFN**	**NR**	**Low*†**	**85-100% (range)**	**100% (range)**	**RR: 0.85-0.95 RD: -0.15 to -0.05 See below for 95% CIs**	**neither**
	3 mos.				100% (20/20)	100% (20/20)	NC	**neither**
	6 mos.				95% (19/20)	100% (20/20)	0.95 (0.86, 1.05) -0.05 (-0.15, 0.05)	**neither**
	9 mos.				85%	100% (20/20)	0.85 (0.71, 1.02)	**neither**

Key Question 2a: RF neurotomy versus Alcohol ablation in the lumbar spine					Treatment groups		Effect size	
					(17/20)		-0.15 (-0.31, 0.01)	
Long-term "Success" composite (VAS < 7 (0-10 scale) and ODI < 22%)	**1 RCT[38] N = 40 12-24 mos.**	**2 blocks (type NR) All pts had previously successful RFN**	**NR**	**Low*†**	**5-25% (range)**	**85-100% (range)**	**RR: 0.85-0.95 RD: -0.15 to -0.05** See below for 95% CIs	**Alcohol ablation**
	12 mos.				25% (5/20)	100% (20/20)	0.25 (0.12, 0.53) -0.75 (-0.94, -0.56)	Alcohol ablation
	18 mos.				5% (1/20)	90% (18/20)	0.06 (0.01, 0.38) -0.85 (-1.01, -0.69)	Alcohol ablation
	24 mos.				5% (1/20)	85% (17/20)	0.06 (0.01, 0.40) -0.80 (-0.98, -0.62)	Alcohol ablation

No evidence for any of the following:

- Effectiveness of RFN versus alcohol ablation in the lumbar spine
- Efficacy or effectiveness of RFN versus alcohol ablation in the cervical spine
- Efficacy or effectiveness of different types of neurotomy in the lumbar or cervical spine

Evidence base for efficacy in the lumbar spine: 1 RCT

- Joo (2013)[38]: N = 40 (CoE II)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2b: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of repeat neurotomy procedures at the same level and the same side as the initial procedure?

Key Question 2b: Repeat neurotomy in the lumbar spine					**Treatment groups**		
Evidence base: 6 case series[38-43] (see footnotes for details)							
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
					% patients		
"Success" composite (Definitions varied by and within each study)	**4 case series**[38-41] **N = 157 total f/u NR**	**Varied**	**Varied**	**Insufficient*†**	**55% to 100% (range) (4 studies**[38-41]**, N = 157)**	**5% to 85% (range) (4 studies**[38-41]**, N = 157)**	**52-94% (range) (2 studies**[39, 40]**, N = 45)**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
					Mean		
Duration of pain relief	**3 case series**[38, 40, 41] **N = 100 total f/u NR**	**Varied**	**Varied**	**Insufficient*†**	**10.4-10.9 mos. (range of means) (3 studies**[38, 40, 41]**, N = 100)**	**10.2-11.6 mos. (range of means) (2 studies**[38, 40, 41]**, N = 95)**	**11.2 mos. (1 study**[40]**, N = 16)**

Evidence base for efficacy in the lumbar spine: 6 case series

- Joo (2013): N = 20 (CoE IV)
- Rambaransingh (2010)[39]: N = 84 (CoE IV)
- Schofferman (2004)[40]: N = 20 (CoE IV)
- Son (2010)[41]: N = 60 (CoE IV)
- Speldewinde (2011)[42]: N = NR (39 repeat procedures) (CoE IV)
- Zotti (2010)[43]: N = 65 (CoE IV)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* Case series (see Appendix C for details)

† relatively small sample size

Key Question 2b: Repeat neurotomy in the cervical spine					Treatment groups		
Evidence base: 3 case series[39, 42, 44] (see footnotes for details)							
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
					% patients		
"Success" composite (Definitions varied by and within each study)	**2 case series**[39, 44] **N = 36 total f/u NR**	**Varied**	**Varied**	**Insufficient*†**	**43% to 100% (range) (2 studies**[39, 44]**, N = 36**	**64% to 95% (range) (2 studies**[39, 44]**, N = 35**	**91% (1 study**[44]**, N = 11)**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
					Mean		
Duration of pain relief	**1 case series N = 22**[44] **f/u NR**	**Varied**	**Varied**	**Insufficient*†**	**12.5 mos. n = 22**	**12.7 mos. n = 21**	**9.5 mos. n = 11**

Evidence base for efficacy in the lumbar spine: 6 case series

- Husted (2008)[44]: N = 22 (CoE IV)
- Rambaransingh (2010)[39]: N = 14 (CoE IV)
- Speldewinde (2011)[42]: N = NR (40 repeat procedures) (CoE IV)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* Case series (see Appendix C for details)

† relatively small sample size

Key Question 2c: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of unilateral versus bilateral neurotomy?

Key Question 2c: Unilateral versus bilateral neurotomy in the lumbar spine					Treatment groups		Effect size	
Efficacy base: 1 cohort study[45] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**Unilateral RFN**	**Bilateral RFN**	**RR (95% CI) RD (95% CI)**	**Favors**
					% patients			
Short-term Back pain "Success" (≥50% pain relief or complete elimination of pain)	**1 retro. cohort[45] N = NR (69 procedures) Mean 5.6 mos.**	**1 block (type NR)**	**≥50% pain relief**	**Low*†**	**33% (6/18) procedures**	**45% (23/51) procedures**	**0.74 (0.36, 1.52) -0.12 (-0.37, 0.14)**	**neither**
No evidence for any of the following: • Efficacy of unilateral versus bilateral neurotomy in the lumbar spine • Efficacy or effectiveness of unilateral versus bilateral neurotomy in the cervical or thoracic spine								

Evidence base for the lumbar spine: 1 retrospective cohort study

- Tzaan (2000)[45]: N = NR (69 procedures) (CoE III)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality cohort study (see Appendix C for details)

† relatively small sample size

Key Question 3: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term for facet neurotomy?

Key Question 3: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine			Treatment groups		Effect size	
Efficacy Evidence base: 6 RCTs[26-31] (see footnotes for details)						
Outcome	**Studies N**	**Overall quality of evidence**	**RFN** % patients	**Sham** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Treatment-related pain (moderate or severe)	**1 RCT[31] N = 81**	**Low*†**	**59% (23/39)**	**36% (14/39)**	**1.40 (0.95, 2.04) 0.09 (-0.01, 0.20)**	**neither**
Treatment-related sensibility changes (irritating or evident dysaesthesia or allodynia)	**1 RCT[31] N = 81**	**Low*†**	**5% (2/39)**	**0% (0/39)**	**1.31 (0.74, 2.31) 0.41 (-0.04, 0.13)**	**neither**
Treatment-related motor changes (irritating or evident motor loss)	**1 RCT[31] N = 81**	**Low*†**	**0% (2/38)**	**2% (1/41)**	**0.00 (NC) -0.02 (-0.07, 0.02)**	**neither**
Treatment- related adverse events (undefined)	**4 RCTs[26, 27, 29, 30] N = 191 total**	**Low*†**	**0% (0/109)**	**0% (0/81)**	**NC**	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with sham neurotomy based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria)						

Evidence base for efficacy in the lumbar spine: 6 RCTs

- Gallagher (1994)[26]: N = 30 (CoE II)
- Leclaire (2001)[27]: N = 70 (CoE II)
- Nath (2008)[28]: N = 31 (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)
- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 3: RF Neurotomy versus Sham Neurotomy in the Cervical Spine			Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[32] (see footnotes for details)						
Outcome	**Studies N**	**Overall quality of evidence**	**RFN**	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
			% patients			
Psoriatic rash (postoperation)	**1 RCT[32] N = 24**	**Low*†**	**8% (1/12)**	**0% (0/12)**	**NC 0.08 (NC)**	**neither**
Procedure-related numbness	**1 RCT[32] N = 24**	**Low*†**	**38% (5/12)**	**0% (0/12)**	**NC 0.42 (NC)**	**Sham**
Outcome	**Studies N**	**Overall quality of evidence**	**RFN**	**Sham**	**Mean Δ difference (95% CI)**	**Favors**
			Median (interquartile range)			
Duration of procedure-related pain	**1 RCT[32] N = 24**	**Low*†**	**13.5 (6, 15) days**	**3.5 (1, 15) days**	**10 days**	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with sham neurotomy based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria)						

Evidence base for efficacy in the cervical spine: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT s (see Appendix C for details)

† relatively small sample size

Key Question 3: RF Neurotomy versus Spinal Injections in the Lumbar Spine			Treatment groups		Effect size	
Efficacy Evidence base: 2 RCTs[33, 34] (see footnotes for details)						
Outcome	**Studies N Follow-up**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Infection	**1 RCT[33] N = 100 6 mos.**	**Low*†**	**0% (0/50)**	**0% (0/50)**	**NC**	**neither**
New motor or sensory deficit	**1 RCT[33] N = 100 6 mos.**	**Low*†**	**0% (0/50)**	**0% (0/50)**	**NC**	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with spinal injections based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria) • Safety data for neurotomy compared with spinal injections in the cervical spine						

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Civelek (2012)[33]: N = 100 (CoE II)
- Lakemeier (2013)[34]: N = 56 (CoE II)

Evidence base for effectiveness in the lumbar spine: 1 retrospective audit study

- Chakraverty (2004)[35]: N = 66 (CoE III)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 4: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

> **NOTE**. For this key question, we first evaluated differential efficacy, effectiveness, and safety of facet neurotomy compared with other treatment options by looking for subgroup analyses in comparative studies. Secondly, we conducted an analysis on a subgroup of studies included in Key Question 2 to determine the efficacy of facet neurotomy in patients selected on the basis of ≥50% pain relief following medial branch block.

Heterogeneity of treatment effect:

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine						**Treatment groups**		**Effect**
Efficacy Evidence base: 1 RCT[31] (see footnotes for details)								
Subgroup	**Studies N**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**Subgroup**	**RFN** % patients	**Sham** % patients	**Favors**
Outcome: "Success" composite (either of the following: • ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or • ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%)								
Sex	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	Male	(2/10)	(6/13)	**neither**
					Female	(9/30)	(6/28)	
Age	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	18-40 years	(4/13)	(4/12)	**neither**
					> 41 years	(7/27)	(8/29)	
Duration of pain	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	2-5 years	(6/19)	(7/21)	**neither**
					> 5 years	(5/21)	(5/20)	
Employment status	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	Employed	(7/23)	(7/20)	**neither**
					Unemployed	(4/17)	(5/21)	
Previous low back	1 RCT[31]	2 IABs	≥50% pain	**Low*†**	None	(8/25)	(6/25)	**neither**

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine						Treatment groups		Effect
surgery	N = 81		relief		≥ 1 surgery	(3/15)	(6/16)	
Outcome: Pain relief "Success" composite (as measured by the 4-point GPE scale)								
Sex	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	Male Female	56% (5/9) 63% (19/30)	54% (7/13) 32% (9/28)	**neither**
Age	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	18-40 years > 41 years	(7/13) (17/26)	(6/12) (10/29)	**neither**
Duration of pain	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	2-5 years > 5 years	(10/18) (14/21)	(10/21) (6/20)	**neither**
Employment status	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	Employed Unemployed	(11/22) (13/17)	(9/20) (7/21)	**neither**
Previous low back surgery	1 RCT[31] N = 81	2 IABs	≥50% pain relief	**Low*†**	None ≥ 1 surgery	(16/24) (8/15)	(9/25) (7/16)	**neither**
No evidence for any of the following: • Differential effectiveness or safety for neurotomy compared with sham neurotomy in the lumbar spine • Differential efficacy, effectiveness, or safety for neurotomy compared with sham neurotomy in the cervical or thoracic spine • Differential efficacy, effectiveness, or safety for neurotomy compared with spinal injections in the lumbar, cervical or thoracic spine								

Evidence base for differential efficacy in the lumbar spine: 1 RCT

- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

‡ Based on the Breslow Day test for interaction.

Comparative efficacy of RF Neurotomy: patients selected on basis of ≥50% pain relief following diagnostic MBB

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB					Treatment groups		Effect size	
Efficacy Evidence base: 3 RCTs[28-30] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Sham** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**3 RCTs[26-31] N = 111 total 2-6 mos.**	**1-2 MBBs**	**≥50 - 80% pain relief**	**Low*†**	**21.0 to 42.0 points (range)**	**4.3 to 37.0 points (range)**	**5.0 to 19.4 points (range)**	**RFN**
	1 RCT[30] N = 31 2 mos.	1 MBB	≥50% pain relief		23.7 (46%)	4.3 (8%)	19.4	RFN
	1 RCT[28] N = 40 6 mos.	2 MBBs	≥80% pain relief		21.0 (35%)	7.0 (16%)	14.0	RFN (marginally)
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	5.0 ± 6.5	neither
Long-term Back pain (VAS scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**41.0 ± 9.1 (63%)**	**29.0 ± 9.6 (43%)**	**12.0 ± 5.9**	**RFN**
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Sham** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Leg Pain (VAS scores) (0-100)	**1 RCT[28] N = 40 6 mos.**	**2 MBBs**	**≥80% pain relief**	**Low*‡**	**16.0 (37%)**	**1.3 (5%)**	**14.7**	**RFN**

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB					Treatment groups		Effect size	
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN Δ from baseline (mean (%))	Sham	Mean Δ difference (95% CI)	Favors
Short-term Generalized pain (VAS scores) (0-100)	1 RCT[28] N = 40 6 mos.	2 MBBs	≥80% pain relief	**Low*‡**	19.3	3.7	15.6	**RFN**
Short-term Function (ODI scores) (0-100)	**2 RCTs[29, 30] N = 71 total 2-6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**11.1 to 14.1 points (range)**	**-1.7 to 11.2 points (range)**	**2.9 to 12.8 points (range)**	**RFN**
	1 RCT[30] N = 31 2 mos.	1 MBB	≥50% pain relief		11.1 (36%)	-1.7 (-4%)	12.8	RFN
	1 RCT[29] N = 40 6 mos.	1 MBB	≥50% pain relief		14.1 ± 4.2 (36%)	11.2 ± 3.9 (28%)	2.9	RFN
Long-term Function (ODI scores) (0-100)	**1 RCT[29] N = 40 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**11.2 ± 4.8 (29%)**	**6.5 ± 3.9 (16%)**	**4.7**	**RFN**
Short-term Function (Waddell scores) (0-24)	**1 RCT[30] N = 31 2 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**0.33**	**0.07**	**0.26**	**neither**
Outcome	Studies N Follow-up	Diagnostic block	% pain relief required for FN	Overall quality of evidence	RFN % patients	Sham	RR (95% CI) RD (95% CI)	Favors
Short-term "Success" composite (≥2-point improvement in VAS (0-10) and ≥50% improvement in GPE (1-4))	**1 RCT[30] N = 31 2 mos.**	**1 MBB**	**≥50% pain relief**	**Low*‡**	**67% (10/15) patients**	**38% (6/16) patients**	**1.77(0.86, 3.68) 0.29 (-0.05, 0.63)**	**neither**

Evidence base: 3 RCTs

- Nath (2008)[28]: N = 31 (CoE II)

- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Cervical Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB					**Treatment groups**		**Effect size**	
Evidence base: 1 RCT[32] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN**	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
					% patients			
Short-term Freedom from "accustomed" pain	**1 RCT[32] N = 81 6 mos.**	**3 MBBs**	**100% with anesthetics 0% with saline**	**Insufficient*†**	**58% (7/12)**	**8% (1/12)**	**7.00 (1.01, 48.54) 0.50 (0.18, 0.82)**	**RFN**

Evidence base: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size and wide confidence intervals

Key Question 4: RF Neurotomy versus Spinal Injections in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB					Treatment groups		Effect size	
Efficacy Evidence base: 1 RCTs[34] (see footnotes for details)								
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Therapeutic intra-articular injection** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**1 RCT**[34] **N = 56 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**19 ± 14.5 (29%)**	**16 ± 12.6 (23%)**	**3**	**neither**
Short-term Function (ODI scores) (0-100)	**1 RCT**[34] **N = 56 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**12.8 ± 12.0 (31%)**	**5.7 ± 11.4 (15%)**	**7.1 points**	**neither**
Short-term Function (Roland-Morris scores) (0-24, lower is better)	**1 RCT**[34] **N = 56 6 mos.**	**1 MBB**	**≥50% pain relief**	**Low*†**	**3.7 ± 3.7 (19%)**	**4.2 ± 3.9 (14%)**	**-0.5 points**	**neither**

Evidence base: 1 RCT

- Lakemeier (2013)[34]: N = 56 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 5: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of cost-effectiveness of facet neurotomy compared with other treatment options?

No studies were identified which met our inclusion criteria.

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1. Appraisal

1.1. Rationale

Facet neurotomy aims to treat pain resulting from facet joint disease, but it does not cure the condition. There are significant questions related to the diagnosis of facet joint pain, and treatment of facet joint pain with facet neurotomy. The Washington State Health Care Authority has selected facet neurotomy for review based on medium concern around efficacy, high concern around safety, and medium concern around cost.

The objective of the report is to systematically review, critically appraise, analyze and synthesize research evidence comparing the efficacy, effectiveness, and safety of facet neurotomy procedures for patients with chronic facet joint pain. Use of diagnostic blocks to identify patients with facet arthropathy, as well as the differential effectiveness, safety and cost-effectiveness of facet neurotomy will all be evaluated. The review will be limited to FDA-approved devices.

1.2. Key Questions

In patients with facet arthropathy or facetogenic pain, and with different regions of the spine (lumbar, thoracic, cervical facet) considered separately,

1. What is the evidence that the use of diagnostic blocks (i.e., medial branch blocks or intra-articular injections with local anesthetic) to select patients for facet neurotomy improves clinical outcomes following facet neurotomy? Consider each of the following:
    a. Diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)
    b. Type of diagnostic block (i.e., medial branch block versus intra-articular injection) for patient selection
    c. Use of a single diagnostic block versus two or more controlled diagnostic blocks (i.e., use of a short- versus a long-acting local anesthetic, or use of a local anesthetic versus saline)
    d. Degree and duration of pain reduction from diagnostic block (e.g., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%)
    e. Unilateral versus bilateral diagnostic block
    f. Diagnostic block of single versus multiple levels

2. With different regions of the spine (lumbar, thoracic, and cervical) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy (FN) compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?

a. What is the evidence of the short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)
b. What is the evidence of the short- and long-term comparative efficacy of repeat neurotomy procedures at the same level and the same side as the initial successful procedure?
c. Is there evidence of differential effectiveness when conducting unilateral versus bilateral facet neurotomy?
d. Is there evidence of differential effectiveness when conducting facet neurotomy on single versus multiple spinal levels?

3. With different regions of the spine (lumbar, thoracic, and cervical) considered separately, what is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term for facet neurotomy?

4. With different regions of the spine (lumbar, thoracic, and cervical) considered separately, is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

5. What is the evidence of cost effectiveness of facet neurotomy compared with other treatment options?

1.3. Outcomes Assessed

1.3.1. Efficacy and effectiveness measures

Studies reported functional and activity scores from generic quality of life, disease specific clinician-based or patient-reported outcomes, and pain, Table 1.

- Eight quality of life measures were used: the Dartmouth COOP/WONCA, EQ-5D, MPI-DLV, Physical Activities scale, SF-36, SF-MPQ, VAS and Zung-DV outcomes measures. The Dartmouth COOP Functional Health Assessment Charts/WHO of Primary Care Physicians (WONCA): COOP/WONCA measures 6 items of physical fitness, feelings, daily activities, social activities, change in health, and overall health, with an optional pain aspect.[46] Domains assessed by the EQ-5D (European Quality of Life) include patient mobility, self-care, usual activity, pain and anxiety/depression.[47] The MPI-DLV (Multidimensional Pain Inventory) has three parts assessing perceived pain intensity, perceptions of the responses of significant others to communications of pain, and frequency of common activities.[48] The Physical Activities scale has ten items about activities of daily living are scored on the ability of the patient to perform them on a scale of "without difficulty" (3 points) to "not possible" (0 points), with the best possible score being 30 points total.[31] The SF-36 (Short Form 36 health survey questionnaire) includes 8 subscales that assess physical function, role limitations due to physical health problems, pain, general health, vitality, limitations due to emotional problems, and mental health.[49] The SF-MPQ (Short-form McGill pain questionnaire) has two components, pain descriptors (PRI) (2 dimensions, 15 items) ranging in score from 0-45 and present pain intensity (PPI), 1 item that ranges in score from 1-5[50]. The VAS (Visual Analogue Scale) measures pain on a scale of 0 – 10.[51] The Zung Self Rating

Depression Scale includes 20 questions that are either positively or negatively worded to assess patient reported depression levels.[52]

- Four patient-reported disease specific outcomes measures were used: the NASS Patient Satisfaction questionnaire, the ODI, the Roland-Morris, and Waddell criteria. The NASS Patient Satisfaction questionnaire measures a patient's satisfaction with their procedure on a scale of 1 – 4.[33] The ODI includes ten items on pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling.[53] The Roland-Morris measure of disability has twelve categories on pain intensity, self-care, social life, walking, sitting, standing, sleeping, bending, stairs, appetite, general activity, and household chores.[54] The Waddell assessment measures severity of low-back disorders with nine items including bending, heavy lifting, sitting, traveling, standing, walking, sleeping, social life, and sex life.[55]
- One clinician based outcome was used, the McGill Pain Score, which measures pain location, how pain is described, pain change over time, and present pain intensity.[56]

Table 1. Outcome measures

Outcome measure	Instrument type	Components	Score range	Interpretation
PATIENT REPORTED OUTCOMES				
Dartmouth COOP Functional Health Assessment Charts/WHO of Primary Care Physicians (WONCA): COOP/WONCA[46]	Generic	6(7) items Physical fitness Feelings Daily activities Social activities Change in health Overall health Pain (optional aspect)	6 – 35*	Each item is rated a five point scale from 1 ('no limitation at all') to 5 ('severely limited'). For 'change in health' score 1 means 'much better' and score 5 'much worse'. The reference period is two weeks. Lower scores are better.
EQ-5D (European Quality of Life)[47]	Generic	Mobility (1–3) Self-care (1–3) Usual activity (1–3) Pain (1–3) Anxiety/depression (1–3)	0–1†	Optimal health: 1 Death: 0
MacNab rating (modified)[12, 57]	Spine	Ability to perform everyday activities in the presence of low back pain: 3: excellent 2: good 1: moderate 0: poor	0-3	Higher scores indicate better function
Multidimensional Pain Inventory (MPI-DLV)[48]	Generic	52 items in 3 parts (# items) *Part I:* Perceived pain intensity (20) *Part II:* Patients' perceptions of the responses of significant others to communications of pain (14) *Part III:* Frequency of common activities (18)	0 – 312*	*Part I:* 6 scales of pain perception recorded on a 6 - point scale (range varies by question) *Part II*: Frequency of responses from significant others rated on a 6-point scale ranging from 'never' to 'very frequently' *Part III:* 6-point scale from "never" to "very often" of how often 30 common activities are performed
NASS Patient Satisfaction Questionnaire	Spine Specific	NR	1 – 4	1 = patient's expectations fully

Outcome measure	Instrument type	Components	Score range	Interpretation
(North American Spine Society)[33]				met 2 = less improvement than the hoped, but the patient would undergo the same procedure again 3 = the procedure helped but the patient would not undergo again 4 = the same or worse status with respect to pre-operative status
Oswestry Disability Index (ODI)[53]	Low back pain	10 items Pain intensity Personal care Lifting Walking Sitting Standing Sleeping Sex life Social life Travelling	0-100 total; 0-5 each subscale	Total score is doubled and expressed as a percentage. The higher the score, the greater the disability.
(Van Wijk) Physical Activities Scale[31]	Generic	10 items Sitting down/standing up from a chair Getting in/out of bed Dressing/putting on shoes/undressing Sitting down during longer period Walking outside Talking a long walk Washing oneself Bending over/lifting Work/housekeeping/strenuous hobbies Fixing minor things at home	0-30 points total	Each item scored from 0-3: 3 = ‘‘without difficulty” 2 = ‘‘with difficulty’’ 1 = ‘‘with help from others’’ 0 = ‘‘not possible”
Roland-Morris[54]	Low back pain	12 categories (24 items) Pain intensity Self-care Social life Walking Sitting Standing Sleeping Bending Stairs Appetite	0-24	The higher the score the greater the disability. Each item is a “yes” (1 point) or “no” (0 points) statement that includes the phrase “because of my back.”

Outcome measure	Instrument type	Components	Score range	Interpretation
		General activity Household chores		
SF-36 (Short Form 36 health survey questionnaire)[49]	Generic	8 subscales (# items) Physical functioning (10) Role limitations due to physical health problems (4) Bodily pain (2) General health (5) Vitality (4) Social functioning (2) Role limitations due to emotional problems (3) Mental health (5)	0–100 for each subscale (total score not used)	Lower score = greater disability
SF-MPQ (Short Form McGill Pain Score)[50]	Generic	2 sections Pain descriptors (PRI) (2 dimensions, 15 items) Sensory Affective Present pain intensity (PPI) (1 item)	Total : not calculated Pain rating index (PRI): 0-45 PPI index: 1-5	The higher the score, the greater the pain disability.
VAS pain (Visual Analogue Scale)[51]	Generic	Pain	0–10	No pain: 0 Worst pain imaginable: 10
Waddell criteria for physical impairment[58]	Low back pain	9 items Bending Heavy lifting Sitting Traveling Standing Walking Sleeping Social life Sex life	0—9	Each item scored on a 0 to 1 point scale. The higher the score, the greater the disability.
Zung Self Rating Depression Scale (Zung-DV)[52]	Generic	20 items 10 positively worded questions 10 negatively worded questions	25-100*	Each question is scored 1-4 (‘a little of the time’ – ‘most of the time’) Higher scores indicate more severe depression.
CLINICIAN BASED OUTCOMES				
McGill Pain Score[56]	Generic	4 sections Pain location Pain descriptors (PRI) (4 dimensions, 20 items) Sensory	Total: not calculated Pain rating index (PRI):	The higher the score, the greater the pain disability.

Outcome measure	Instrument type	Components	Score range	Interpretation
		Affective Evaluative Miscellaneous Pain change over time Present pain intensity (PPI) (1 item)	0-78 PPI index: 1-5	

*These scores were calculated by adding up the possible scores for each item, to come to a total score.
†EQ-5D: final score is a 5-digit descriptor that corresponds to the level of disability in each subcomponent and ranges from 11111–33333; each score is assigned a preferential weight (e.g., 21111 = 0.85) to obtain a final score of 0 to 1.

1.3.2. Minimum Clinically Important Difference (MCID) & Minimum Detectable Change (MDC)

In order to more accurately observe the changes in patient outcome following facet neurotomy, parameters need to be defined that indicate what changes in patient reported or clinician based outcomes are clinically important. When results were reported as statistically significant between facet neurotomy and control treatment groups, we sought to use MCID/MDC to establish clinical importance.

First, a search was conducted to find reports that determined the minimum clinically important difference (MCID) or the minimum detectable change (MDC) in outcomes used in a facet joint pain population, however no reports were found. However, a number of studies included in this report evaluated the percentage of patents that achieved certain thresholds of improvement (often defined as "success"). These thresholds/definitions of "success" are summarized in Table 2. The most commonly used definition of "success" relates to pain relief, and the most commonly used definition of "success" was a 50% or more improvement in VAS back pain scores from baseline.

Table 2. Definitions of "success" used by comparative studies included in this report.

	Outcome Measure	"Success" definition	Included comparative studies
Lumbar spine			
"Success" Back pain	VAS	≥50% decrease in pain score from baseline	1. Chakraverty (2004) (cohort, KQ2) 2. Civelek (2012) (RCT, KQ2)) 3. Van Wijk (2005) (RCT, KQ2)) 4. Tzaan (2000) (cohort, KQ2c/d)
	VAS	≥25% decrease in pain score from baseline	1. Van Wijk (2005) (RCT, KQ2))
	VAS	≥2 point decrease in pain score (range, 0-10) from baseline	1. Van Wijk (2005) (RCT, KQ2))

	Outcome Measure	"Success" definition	Included comparative studies
	GPE	≥50% decrease in pain score from baseline	1. Van Wijk (2005) (RCT, KQ2))
	LBOS	Good: LBOS 50-64 Excellent: LBOS ≥ 65	1. Zotti (2010) (cohort, KQ2b)
"Success" Leg pain	GPE	≥50% decrease in pain score from baseline	1. Van Wijk (2005) (RCT, KQ2))
Composite definition of "success"	VAS & GPE	• ≥2 point decrease in pain score (range, 0-10) from baseline and • ≥50% pain reduction on GPE	1. Van Kleef (1999) (RCT, KQ2)
	VAS & ODI	• VAS < 7 (scale, 0-10) and • ODI ≥22%	1. Joo (2013) (RCT, KQ2a/b)
"Success" Function	EQ-5D	EQ-5D score < 9	1. Civelek (2012) (RCT, KQ2)
"Success" Patient satisfaction	NASS	EQ-5D score 1 or 2	1. Civelek (2012) (RCT, KQ2)
Cervical spine			
Composite definition of "success"	VAS, GPE	• ≥20% decrease in pain score from baseline VAS and/or • GPE score of 2 or 3 (scale, -3, 3)	1. Haspeslagh (2006) (RCT, KQ2)
	VAS, MPQ, ADL, and patient opinion	• Patient-reported complete relief of pain, and • VAS ≤ 5 (scale, 0-100) • MPQ word count ≤ 3 • Restoration of 4/4 ADL listed pre-operatively (not required if untreated pain (non-neck pain) also interfered with ADL) • Negative answer to "Is your usual pain present?" and "Do you require further treatment?"	1. Lord (1996) (RCT, KQ2)

ADL: activities of daily living; EQ-5D: (Euro-Qol in 5 dimensions); LBOS: Low Back Outcome Score; MPQ: McGill Pain Questionnaire; NASS: North American Spine Society patient satisfaction questionnaire; ODI: Oswestry Disability Index; RFN: Radiofrequency denervation; VAS: visual analog scale

Next, we searched for reports that determined the MCID or MDC in outcomes used in a back pain population. The following outcome measures with MCID/MDC were found in patients with low back pain:

- VAS Pain scale, IMMPACT Recommendations[59]:
  - According to the 2008 report on the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMPACCT)[59], the following benchmarks can be used to interpret changes in trials of chronic pain treatments:
    - Minimally important improvement: 10-20% improvement
    - Moderately important improvement: 30-49% improvement
    - Substantial improvement: ≥50% improvement

None of the other outcome measures reported in this HTA were included in the IMMPACT recommendations.

- The following outcome measures with MCID/MDC were found in patients with low back or neck pain:
  - EQ-5D (scale, 0-1): MCID in lumbar spinal fusion[60-62] or lumbar disc surgery[63] population: range, ≥0.30-0.54 minimum point improvement
  - ODI (scale, 0-100): MCID in low back pain[64-73], lumbar spinal fusion[60, 61, 63, 74, 75], lumbar surgery[76-78], or lumbar spinal stenosis[64] populations: range, ≥4.5-20 minimum point improvement (or minimum 50% improvement reported in one study). Of note, the FDA required an ODI change of 15 points in a study comparing lumbar fusion with total disc arthroplasty[79].
  - Roland-Morris (scale, 0-24): MCID in low back pain population[71-73, 80-83]: range, ≥2-14 minimum point improvement (or minimum 36% improvement reported in one study)
  - SF-36 (PCS subscale) (scale, 0-100): MCID in lumbar spinal surgery[76, 77] or lumbar fusion[62] population: range, ≥2.5-12.1 minimum point improvement
  - SF-36 (MCS subscale) (scale, 0-100): MCID in lumbar fusion[62] population: range, ≥7.0-15.9 minimum point improvement
  - Zung-DV (scale, 25-100): MCID in lumbar spinal fusion[62] or low back pain[84] populations: range, ≥3.0-18.6 minimum point improvement

1.4. Key considerations highlighted by clinical experts:

1.4.1. Key Concepts

The ability of cervical and lumbar medial branch RF neurotomy to result in clinically significant pain relief and functional improvement is dependent on two major considerations;

1. Appropriate selection of patients with the suspect clinical condition
2. The technical effectiveness or precision of the procedure.[85]

The literature, including randomized controlled trials, is replete with examples of both poor patient selection and invalid technical execution of the procedure.

1.4.2. Patient Selection

Dr. Shealy discovered medial branch radiofrequency neurotomy of the zygapophyseal (i.e. facet) joints in 1974. Since that time, there has been a critical evolution in our understanding of how to best diagnose facet joint pain via highly specific medial branch blocks, and how to best perform the procedure of medial branch radiofrequency neurotomy. Historically, patients have been selected on the results of pain reduction following intra-articular (inside the joint) facet injections. These injections, however, have been shown to have poor target specificity and incur a higher rate of false positive results than medial branch blocks. Low volume local anesthetic placed under fluoroscopy to block the medial branches of the dorsal rami specifically target only the sensory nerves innervating the facet joints, thus interrupting pain transmission from the facet joints. It has been shown that medial branch blocks (including L5 dorsal ramus and third occipital blocks) have excellent target

specificity and excellent physiological effectiveness.[15, 86, 87] Additionally, the medial branch nerves are the targets of the facet joint denervation procedure, and blockade of these nerves is a more appropriate simulation of what pain relief might occur from a subsequent neurotomy. For these reasons medial branch blocks, and not intra-articular or peri-capsular/peri-articular (near the joint) blocks, are the appropriate selection tool for medial branch radiofrequency neurotomy.

Medial branch anesthetic injections, i.e. blocks, are used to select patients for radiofrequency neurotomy based upon pain relief following the procedure. Patients typically report hourly any degree of index pain relief on a pain diary for 6 hours post procedure . The data obtained from the pain diary is used by the treating physician to determine whether or not the patient has facet mediated pain. Some clinicians and trials have accepted ≥50% relief of pain as a positive block while others accept ≥75 or 80% relief of pain and some only 100% relief of pain. The higher the degree of pain relief obtained from the medial branch blocks the more likely the patient has the target condition and the less likely the response was a false positive response.

Single medial branch blocks have an unacceptable false positive rate, which is especially apparent in the lumbar spine with a 29-45% false positive rate.[88-93] For this reason, controlled (dual) medial branch blocks, which involve blockade of these target nerves on two different visits, have been used to reduce the false positive rate. The false positive rate of controlled medial branch blocks in the cervical spine is an acceptable 12% as judged against placebo injections[88] but such a study has not been replicated in the lumbar spine. The ideal method to reduce false positive responses is to additionally use placebo blocks, but ethical considerations have limited their routine clinical use. With the use of controlled blocks, false positive responses are reduced when the use of two different anesthetic agents is employed for each block and the duration of relief is consistent with the agent used. For example, if the patient has a longer duration of relief with a longer acting local anesthetic, such as bupivacaine, than with the shorter acting lidocaine.

In summary, ideal candidates for medial branch radiofrequency are selected with the use of medial branch blocks, not with the use of intra-articular or peri-capsular blocks.. Furthermore, patient selection is improved by using controlled (dual) medial branch blocks and by requiring higher percentages of pain relief to establish the diagnosis. Selecting patients with less than ideal methods will predictably increase the number of neurotomy procedures consistent with a higher false positive rate, and decrease the percentage of patients with a positive outcome.

1.4.3. Technical Aspects of the Procedure

RF neurotomy involves heating tissue around the tip of a radiofrequency needle using radiofrequency energy. This heated area is called an isotherm and the shape of this isotherm is oblate spheroid in nature, and runs parallel to the long axis of the needle tip.

There has also been an evolution in the understanding of how to best perform medial branch radiofrequency neurotomy. This is due to an improved understanding of both fluoroscopic (x-ray) anatomy as it relates to location of the target nerves, the electrothermal physics of the radiofrequency lesion created with different RF needles, trajectory angles to maximize incorporating the target nerve within the oblate spheroid isotherm, and parameters used to generate the heat lesion.[35].

More recent anatomic studies have shown there is a greater variation in the position of the target medial branches in relation to known osseous landmarks than previously appreciated.[17, 94, 95] Appropriate radiofrequency lesioning techniques accommodate for these variations by lesioning a larger target area or volume and using a parallel needle placement to the target nerve. Methods used to appropriately obtain a larger target lesion volume include the use of larger electrodes (16 or 18 g needles vs. 20 or 22 g needles), higher lesion temperatures (80-90 degrees C) and longer lesion times (90 seconds vs. 30-60 seconds).
Additionally, as the goal of RFN is to coagulated as much of the target medial branch as possible, the goal of the physician performing RFN is to place the needle tip as parallel to and as close to the target medial branch as possible thus incorporating it within the largest isothermal area. This creates a larger and more effective lesion of the medial branch nerve. To place the needle perpendicular – as opposed to the parallel – to the medial branch nerve understandably creates a very small lesion, which leads to an increased likelihood that the nerve will be missed altogether, or that the small lesioned segment will rapidly regenerate and with return of pain. Indeed, studies showing poor outcomes invariably have used poor patient selection, poor RFN technique, or both.

1.4.4. Evaluation of the Literature

It should be apparent that not all medial branch radiofrequency studies are created equal and there is substantial variability in both patient selection and the technical aspects of the procedure. One should not pool the data of all these studies or risk diluting or not adequately representing the true value, efficacy and/or effectiveness of the procedure when patients are appropriately selected and the procedure appropriately performed.

The results of studies that used valid methods should be pooled separately from those that used invalid methods. Invalid methods include the use of:

1. intra-articular or peri-articular/peri-capsular blocks blocks to select patients for radiofrequency neurotomy
2. clinical assessment alone (without blocks) to select patients for radiofrequency neurotomy
3. improper technique, including improper needle placement, improper needle size, and an inadequate lesion volume.

The RFN technique used in some RCTs is so poor that the study amounts to little more than a sham vs. sham trial, as little to no actual lesioning of the medial branches was possible with the selected technique.

If one wishes to understand the true value and effectiveness of medial branch radiofrequency neurotomy then the data from more rigorous studies should be pooled and reported. Only these valid randomized controlled trials and prospective trials underscore the true nature of expected outcomes from medial branch radiofrequency neurotomy.[30, 32, 94, 96-101]

A key consensus paper "Interpreting the Clinical Importance of Treatment Outcomes in Chronic Pain Clinical Trials: IMMPACT Recommendations" produced provisional benchmarks for identifying

clinically important changes in specific outcome measures in chronic pain outcome studies. It was emphasized that moderate clinically important reductions in pain intensity in individuals following a pain intervention is at least 30%, which correlates to a VAS reduction of 2-2.7/10. A reduction in chronic pain intensity of at least 50% reflects a substantial improvement. It was recommended that percentages of patients responding with this degree of improvement be reported. It was also recommended that all chronic pain clinical trials report a cumulative proportion of responder analysis. In this approach, the entire distribution of treatment response is depicted in a graph of the proportion of responders for all percentages of pain reduction from 0% through 100%."[59]

Accordingly, in evaluating the RF neurotomy literature, the percentage of patients obtaining a minimum of 30% reduction in pain (or a VAS decrement of >2.0) should be considered clinically significant. Ideally, to more closely approximate the true treatment effect, the percentage of patients obtaining at least 50% improvement in pain should also be assessed. And, if available, the cumulative proportion of responders (including those with the highest bar of success, 100% relief of pain) should be noted.[59]

IMMPACT recommended that mean data reporting not be used as a sole or primary indicator of success.[59] When only a subgroup of patients benefits from a treatment, its effectiveness may be camouflaged when group data are used to assess or report effectiveness. Statistically, the good responses of those patients who benefit can be balanced by the responses of patients who do not benefit and those who deteriorate, such that the mean or median score of the group shows little or no change. Using categorical outcomes to determine success rates overcomes this problem of statistical camouflage and remains the recommended benchmark indicator of treatment success by the IMMPACT consensus group.

1.4.5. Repeat Neurotomy

The ability to reinstate relief after a previously successful radiofrequency neurotomy is largely dependent on optimizing the technical performance of the procedure and assuring the clinical presentation remains consistent with the original diagnosis of facet pain. Repeat neurotomy is not usually considered appropriate unless the prior RF proved effective for at least 6 months.

1.4.6. Special Considerations

A more recent development in radiofrequency methods is the use of pulsed radiofrequency. However, using this methodology heat is not created at a temperature known to coagulate neural tissue or result in an effective lesion. This method of energy delivery is not the conventional method of thermal medial branch radiofrequency neurotomy under primary assessment.

In regards to cervical radiofrequency neurotomy, there are unique anatomical and procedural considerations in regards to radiofrequency neurotomy targeting the C2-3 facet joint versus other cervical levels. Accordingly, studies that have largely or only assessed C2-3 facet neurotomy (third occipital nerve neurotomy)[94, 96, 99] should be evaluated separately from those studies in which C3-4 to C6-7 facet neurotomy was performed.

1.5. Washington State utilization and cost data

Figure 1. Facet Neurotomy Summary of Amount Paid by Agency

Agency/Year	2009	2010	2011	2012†	4 Yr Overall Total**	Avg Annual % Change	
Public Employee Benefits , Uniform Medical Plan							
PEB/UMP Average Annual Members	210,501	213,487	212,596	212,684		0.3%	
Facet Neurotomy Patients	216	226	237	63	583	-20.7%	*
Facet Neurotomy Procedures (encounters)	267	277	312	69	925	-20.8%	*
Average Encounters per Patient	1.2	1.2	1.3	1.1	1.6	-3.4%	
Total Paid* **	**$415,491**	**$393,527**	**$434,276**	**$98,999**	**$1,342,293**	**-25.5%**	*
Average Paid per Procedure	$1,556	$1,421	$1,392	$1,435	$1,451	-2.6%	
Average Paid/Proc, PEB/UMP Primary	$2,938	$2,488	$2,525	$1,928	$2,799	-12.5%	
Maximum Paid (outliers)	$18,231	$15,212	$11,382	$7,664	$18,231		
95% Upper Limit (2 standard deviations above mean)	$7,897	$7,539	$6,369	$5,525	$8,211		
Neurotomy Facet Counts (uni- vs bilateral, levels)	665	731	955	182	2533	-5.0%	*
Average/Patient	3.1	3.2	4.0	2.9	4.3	0.4%	
Average/Procedure (encounter)	2.5	2.6	3.1	2.6	2.7	2.7%	
Labor & Industries							
L&I Annual Claims	125,611	122,712	121,043	121,660		-1.1%	
Facet Neurotomy Patients	208	173	180	123	648	-13.8%	*
Facet Neurotomy Procedures (encounters)	254	222	240	146	862	-13.5%	*
Average Encounters per Patient	1.2	1.3	1.3	1.2	1.3	-.7%	
Total Paid* **	**$720,139**	**$574,616**	**$554,144**	**$349,420**	**$2,198,318**	**-19.3%**	*
Average Paid per Procedure	$2,422	$2,094	$2,006	$2,260	$2,507	-1.7%	
Maximum Paid (outliers)	$7,376	$7,544	$6,753	$5,574	$7,544		
95% Upper Limit (2 standard deviations above mean)	$5,179	$4,787	$4,118	$4,415	$4,873		
Neurotomy Facet Counts (uni- vs bilateral, levels)	629	536	567	381	2113	-12.9%	*
Average/Patient	3.0	3.1	3.2	3.1	3.3	.8%	
Average/Procedure (encounter)	2.5	2.4	2.4	2.6	2.5	1.9%	

Agency/Year	2009	2010	2011	2012	4 Yr Overall Total**	Avg Annual % Change	
Medicaid Fee For Service							
Medicaid FFS Population	463,966	474,676	473,356	477,727		1.0%	
Facet Neurotomy Patients	187	203	189	50	554	-24.8%	*
Facet Neurotomy Procedures (encounters)	248	274	262	59	843	-24.6%	*
Average Encounters per Patient	1.3	1.3	1.4	1.2	1.5	-3.5%	
Total Paid* **	**$197,365**	**$186,080**	**$245,082**	**$40,877**	**$669,404**	**-19.7%**	*
Average Paid per Procedure	$778	$641	$905	$649	$771	-1.6%	
Average Paid/Proc, Non-medicare	$789	$711	$1,078	$660	$844	0.9%	
Maximum Paid (outliers)	$2,458	$2,486	$3,335	$3,261	$3,335		
95% Upper Limit (2 standard deviations above mean)	$1,896	$1,560	$2,310	$2,154	$1,995		
Neurotomy Facet Counts (uni- vs bilateral, levels)	581	677	648	143	2049	-22.8%	*
Average/Patient	3.1	3.3	3.4	2.9	3.7	-2.1%	
Average/Procedure (encounter)	2.3	2.5	2.5	2.4	2.4	1.2%	

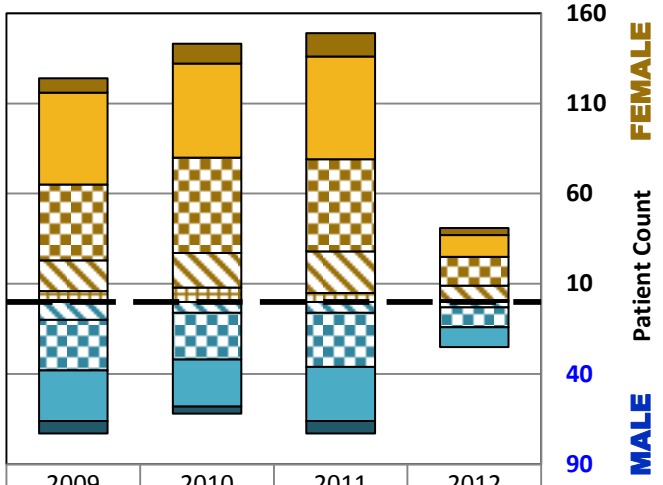
*Average % change adjusted for population

**Unique patients are counted over the 4 year period

*** Includes diagnostic injections 90 days ahead of procedure and related charges on day of procedure. PEB/UMP patients who had pre-neurotomy injections averaged 4.3 injections in 1.8 encounters, incurring an average of $450 per neurotomy (paid $). L&I patients who had pre-neurotomy diagnostic injections averaged 7.3 injections in 1.8 encounters incurring an average of $700 per neurotomy. Medicaid patients who had pre-neurotomy diagnostic injections averaged 3.5 injections in 1.2 encounters incurring an average of $260 per neurotomy. Patients with no reported pre-neurotomy diagnostic injections are not considered in these averages.

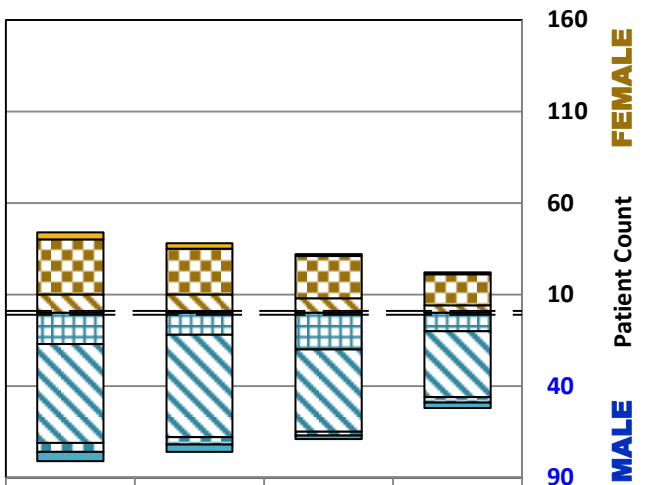
Figure 2a PEBB Facet Neurotomy Patients by Age and Gender, 2009-2012
Figure 2b L&I Facet Neurotomy Patients by Age and Gender, 2009-2012

PEB/UMP Facet Neurotomy Patients by Gender/Age Group, 2009-2012*



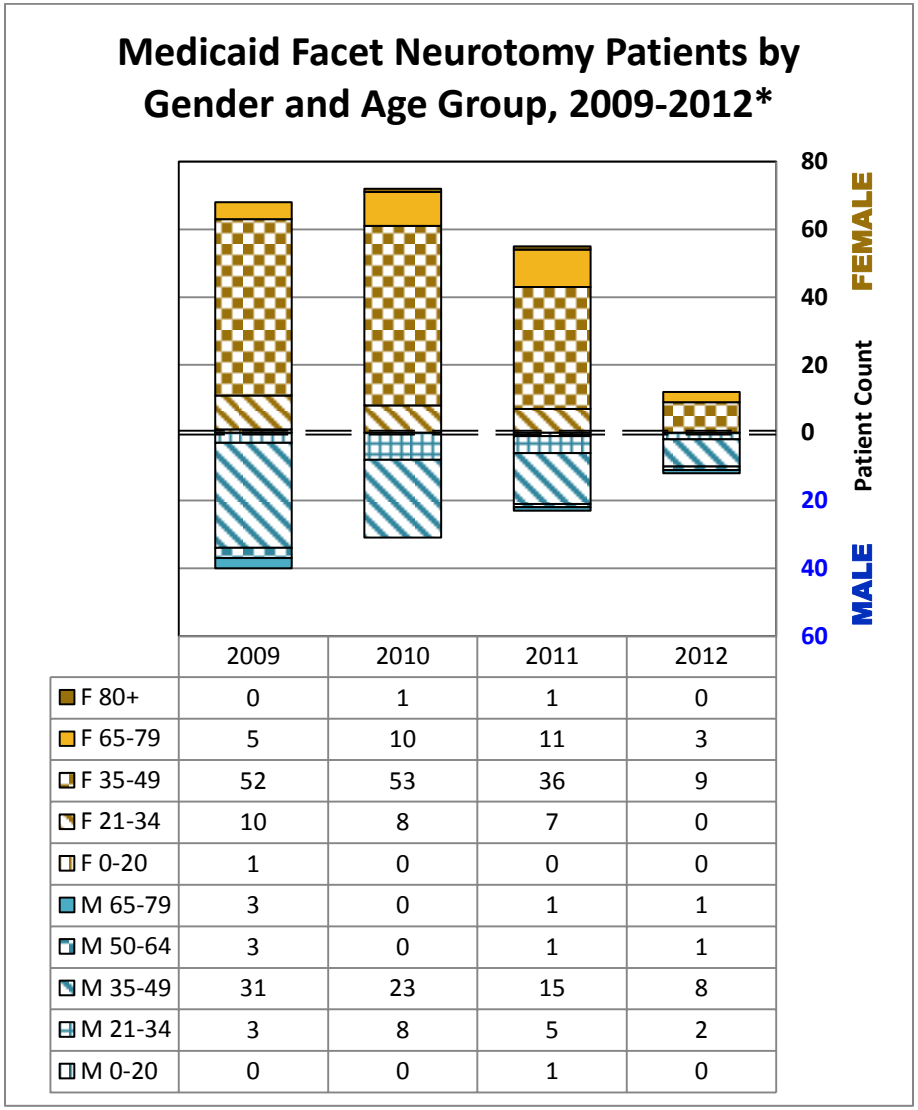
	2009	2010	2011	2012
F 80+	8	11	13	4
F 65-79	51	52	57	12
F 50-64	42	53	51	16
F 35-49	17	19	23	8
F 21-34	5	8	5	1
F 0-20	1	0	0	0
M 80+	7	4	7	0
M 65-79	28	26	30	11
M 50-64	28	26	30	11
M 35-49	10	6	6	3
M 21-34	0	0	0	0

L&I Facet Neurotomy Patients by Gender and Age Group, 2009-2012



	2009	2010	2011	2012
F 65-79	4	3	1	1
F 35-49	30	25	23	17
F 21-34	10	9	8	4
F 0-20	0	1	0	0
M 65-79	5	4	2	3
M 50-64	5	4	2	3
M 35-49	54	56	45	36
M 21-34	17	12	20	10

Figure 2c Medicaid Facet Neurotomy Patients by Age and Gender, 2009-2012



	2009	2010	2011	2012
F 80+	0	1	1	0
F 65-79	5	10	11	3
F 35-49	52	53	36	9
F 21-34	10	8	7	0
F 0-20	1	0	0	0
M 65-79	3	0	1	1
M 50-64	3	0	1	1
M 35-49	31	23	15	8
M 21-34	3	8	5	2
M 0-20	0	0	1	0

Figure 3. Average Allowed Amount Breakdown by Procedure, 2009-2012

Per Procedure Avg Allowed Charges by Agency, Setting & Payer	PEB/UMP Primary (n=435*)	PEB/UMP Medicare (n=441*)	L&I (n=815*)	Medicaid Non-Medicare (n=718*)	Medicaid Medicare (n=82*)
Breakdown 1					
Professional Services	$649	$356	$1,307	$224	$105
Facility/Other	$1,246	$464	$1,090	$689	$40
Breakdown 2					
Neurotomy	$1,739	$723	$1,494	$838	$126
Imaging/Guidance	$71	$39	$61	$3	$1
Diagnostic Injections*	$62	$25	$778	$56	$11
Other	$22	$34	$64	$16	$7
Avg Allowed/Procedure	**$1,895**	**$820**	**$2,397**	**$913**	**$145**

*Outliers with total allowed amounts more the 95% Upper Limit (2 standard deviations above the mean allowed amount) were excluded from the analysis

Figure 4a. PEB/UMP Top 10 Diagnosis codes for Neurotomy by Allowed Amount Desc

PEB/UMP Diagnosis Description for Neurotomy Procedures, 2009-2012	Allowed Amount	% of Overall Allowed
Overall Allowed Total:	**$1,214,721**	100.0%
Lumbosacral Spondylosis	$456,063	37.5%
Lumbago	$157,157	12.9%
Cervical Spondylosis	$154,892	12.8%
Other Back Symptoms	$85,669	7.1%
Lumb/Lumbosac Disc Degen	$71,566	5.9%
Sacroiliitis Nec	$44,200	3.6%
Chronic Pain Nec	$38,185	3.1%
Cervicalgia	$36,452	3.0%
Thoracic Spondylosis	$27,191	2.2%
Cervical Disc Degen	$15,545	1.3%

Figure 4b. L & I Top 10 Diagnosis codes for Neurotomy by Allowed Amount Desc.

L&I Diagnosis Description for Neurotomy Procedures, 2009-2012	Allowed Amount	% of Overall Allowed
Overall Allowed Total:	**$1,333,133**	**100.0%**
Lumbosacral Spondylosis Without Myelopat	$241,941	18.1%
Lumbar Sprain And Strain	$247,025	18.5%
Other Symptoms Referable To Back	$136,023	10.2%
Lumbago	$118,548	8.9%
Degen Lumbar/Lumbosacral Intervertebral	$79,169	5.9%
Cervical Spondylosis Without Myelopathy	$55,465	4.2%
Neck Sprain And Strain	$62,226	4.7%
Sprain And Strain Of Lumbosacral	$36,585	2.7%
Cervicalgia	$30,981	2.3%
Displcmt Lumbar Intervert Disc W/O Myelo	$22,611	1.7%

Figure 4c. Medicaid Top 10 Diagnosis codes for Neurotomy by Allowed Amount Desc

Medicaid Diagnosis Description for Neurotomy Procedures, 2009-2012	Allowed Amount	% of Overall Allowed
Overall Allowed Total:	**$731,903**	**100.0%**
Lumbosacral spondylosis	$312,280	42.7%
Lumbago	$96,163	13.1%
Chronic pain NEC	$81,529	11.1%
Cervical spondylosis	$57,982	7.9%
Lumb/lumbosac disc degen	$44,373	6.1%
Other back symptoms	$30,757	4.2%
Cervicalgia	$16,751	2.3%
Sacroiliitis NEC	$16,526	2.3%
Disorders of sacrum	$7,432	1.0%
Cervical disc degen	$7,183	1.0%

Figure 5a. PEB/UMP Neurotomy Encounters and Facets per Neurotomy Encounter by Provider, 2009-2012

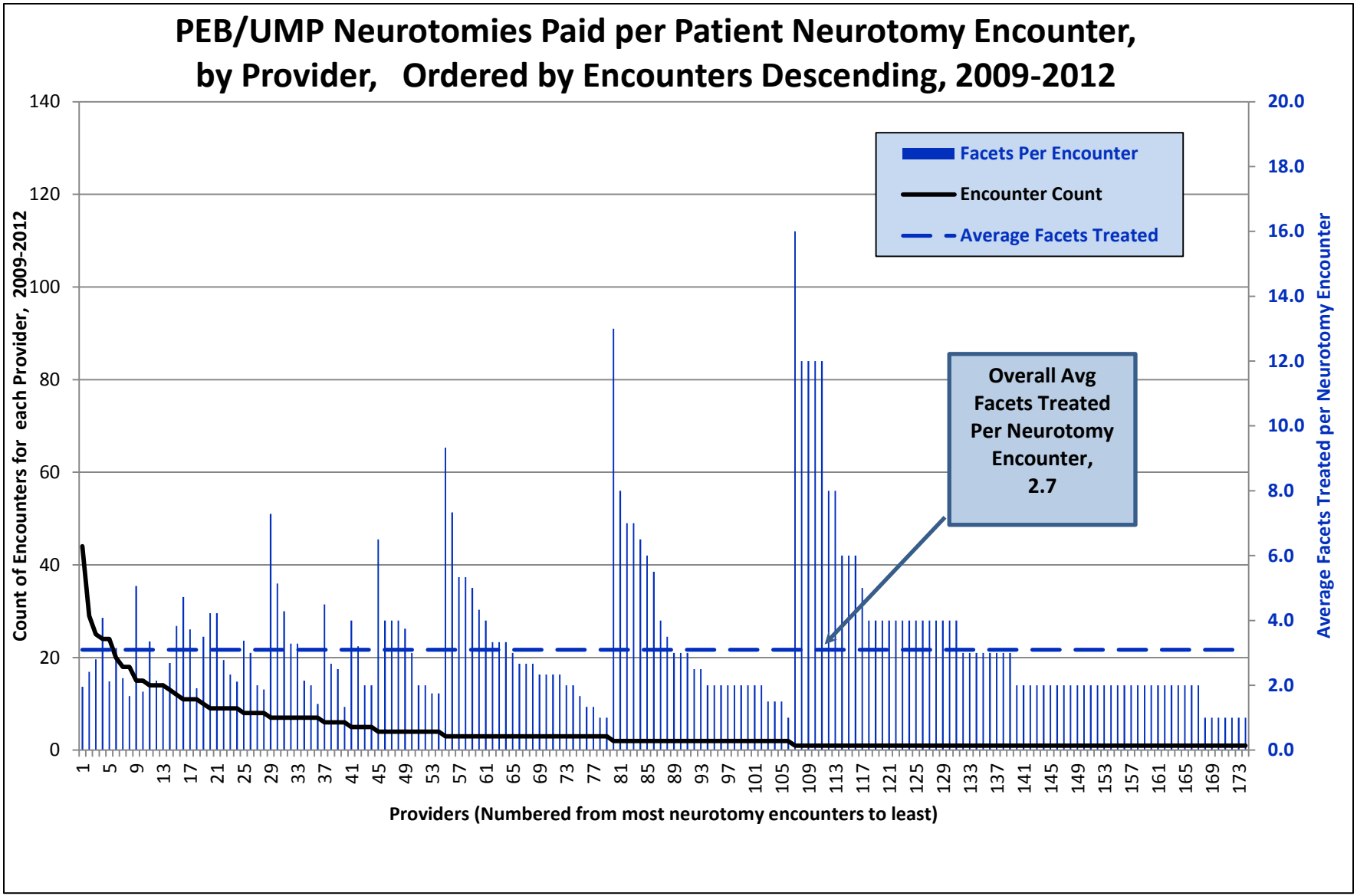


Figure 5b. L&I Neurotomy Encounters and Facets per Neurotomy Encounter by Provider, 2009-2012

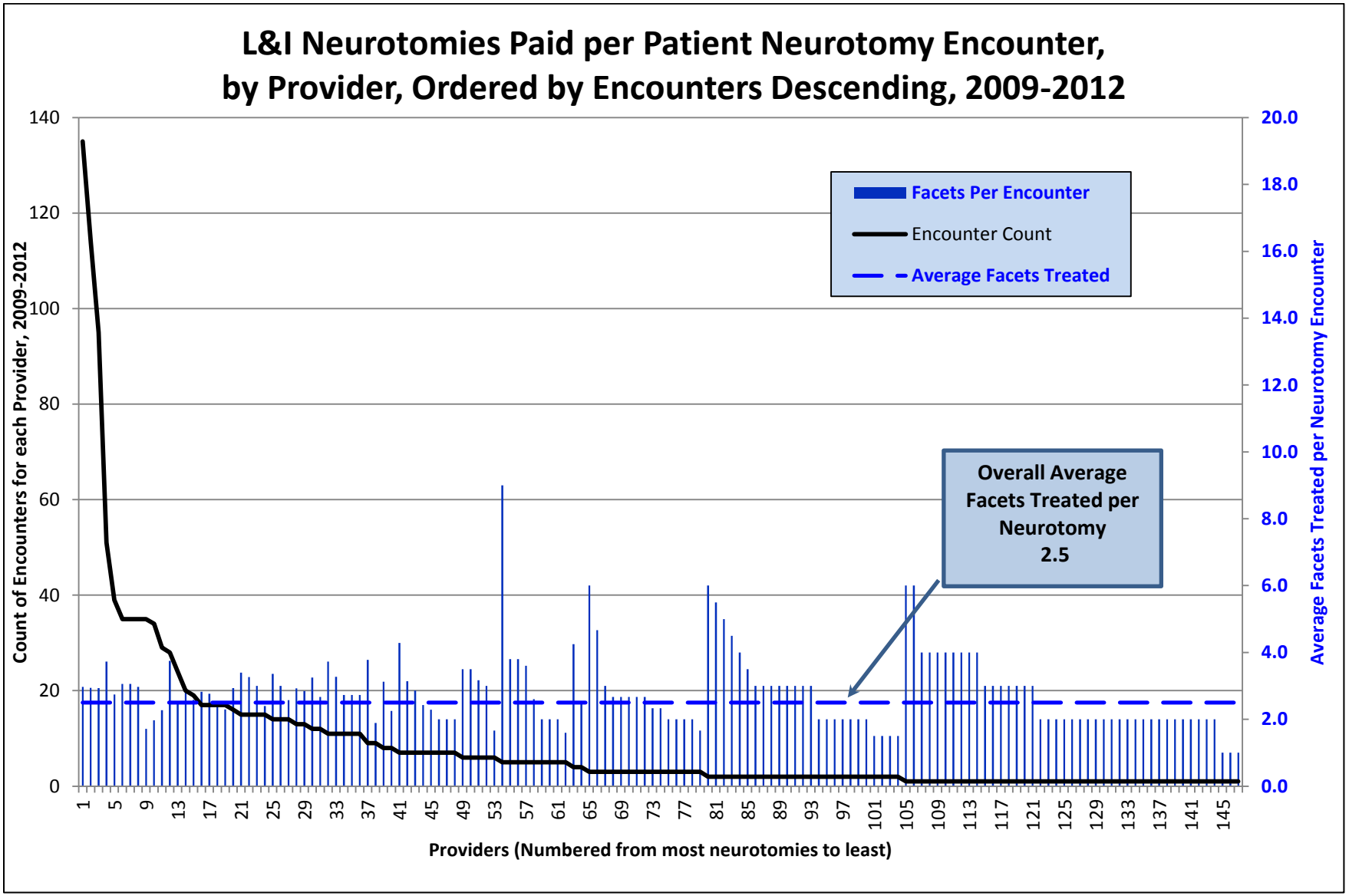


Figure 5c. Neurotomy Encounters and Facets per Neurotomy Encounter by Provider, 2009-2012

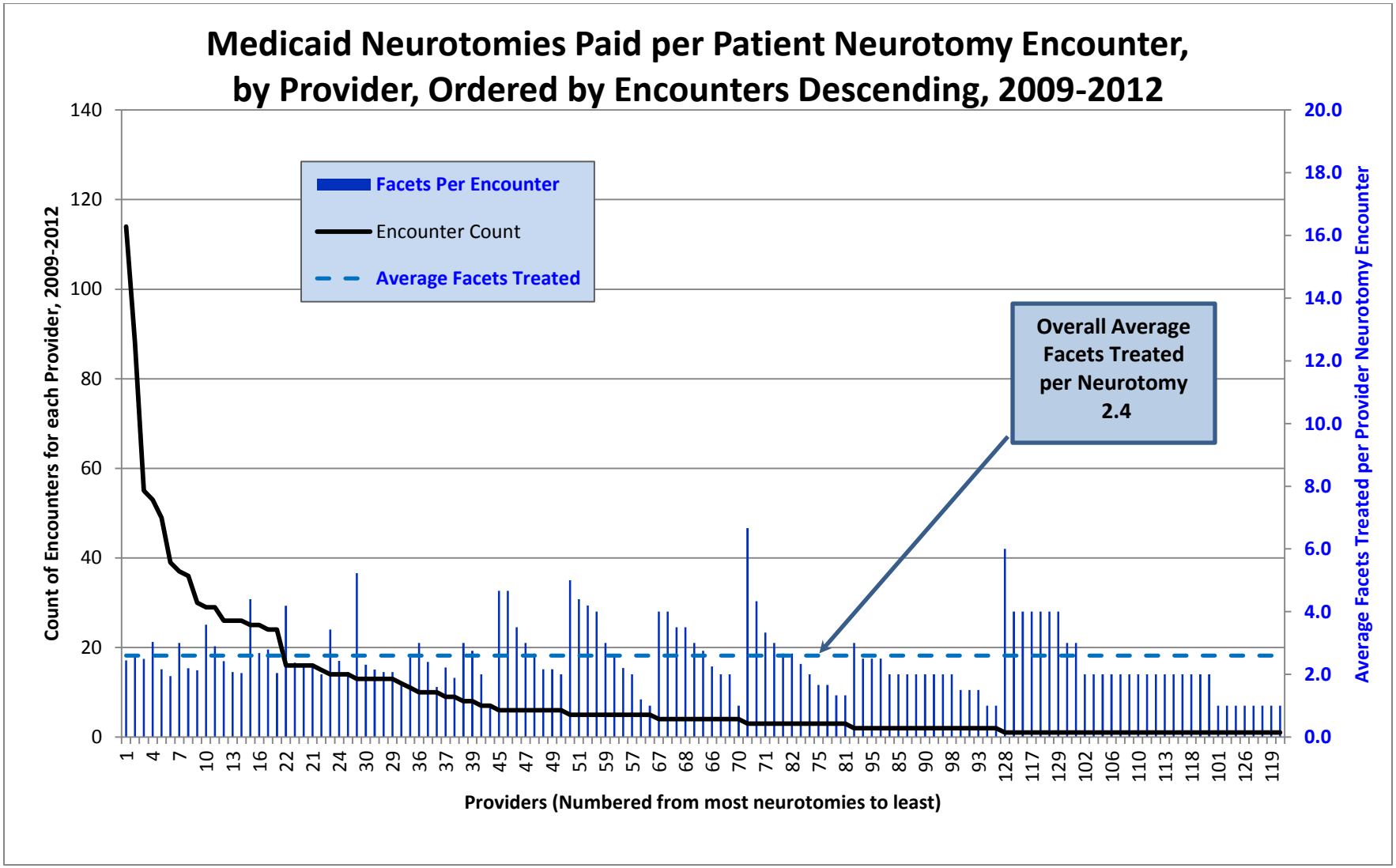


Figure 6a. PEB/UMP Repeated Neurotomies, 2009-2012

Neurotomy Encounters	Patient Count	% Total Patients
10	1	0.2%
6	5	0.8%
5	10	1.5%
4	16	2.5%
3	39	6.0%
2	156	23.9%
1	425	65.2%

Figure 6b. L&I Repeated Neurotomies, 2009-2012

Neurotomy Encounters	Patient Count	% Total Patients
5	1	0.2%
4	4	0.6%
3	8	1.2%
2	182	28.1%
1	452	69.9%

Figure 6c. Medicaid Repeated Neurotomies, 2009-2012

Neurotomy Encounters	Patient Count	% Total Patients
13	1	0.2%
6	7	1.3%
4	9	1.6%
3	27	4.9%
2	129	23.2%
1	380	68.5%

Related Medical Codes

Code Type	Codes	Short Description	Add'l Info	HTA	Code Changes
Facet Neurotomy	64622	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level	Primary		Del 2012
	64623	Lumbar or sacral, each additional level	Add'l		Del 2012
	64626	Cervical or thoracic, single level	Primary		Del 2012
	64627	Cervical or thoracic, each additional level	Add'l		Del 2012
	64633	Destruction by neurolytic agent, paravertebral facet joint nerves with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint	Primary		Add 2012
	64634	Cervical or thoracic, each additional facet joint	Add'l		Add 2012
	64635	Lumbar or sacral, single facet joint	Primary		Add 2012
	64636	Lumbar or sacral, each additional facet joint	Add'l		Add 2012

2. Background

2.1. Epidemiology and Burden of disease

The lifetime prevalence of spinal pain has been reported to be between 54% to 80%.[92] Over a quarter of adults in the U.S. have reported back pain lasting an entire day in the past three months,[102] and non-specific back pain is one of the top five reasons for physician visits in the U.S.[103] Fortunately, most people who develop back pain will recover within three months,[104] however some people suffer from back pain that does not resolve, affecting about 10% of the U.S population.[105]

For many, degeneration of the facet joints is the cause of chronic spinal pain.[1] A facet joint (also called zygapophysial, apophysial, or Z-joint) connects the adjacent vertebrae of the spine together. This joint is a type of synovial joint located between the inferior articular process of one vertebra and the superior articular process of the vertebra directly below it.[106] There are two facet joints in each level of the spine, providing stability while allowing motion.

Typically, facet arthropathy, or joint disease, develops progressively and more commonly affects older adults.[107] The facet joints in young individuals are usually strong, while the facet joints of elderly individuals tend to be weaker and more biplanar.[107] Other risk factors for facet joint pain are recurrent rotational strains to the back, excessive muscle weakness and heredity.[107-109] The primary physical sign suggestive of facet joint pain is paraspinal tenderness at the affected facet joints, and the dominant symptom is axial spinal pain. Other symptoms that may be suggestive of facet joint pain are pain or tenderness in the back, pain that radiates down to the buttocks or down the back of the leg, pain that increases with twisting at the waist or bending backward and extending the lower back, and stiffness or difficulty with certain movements.[110]

Whiplash injuries and cervical facet arthropathy can also result in facet joint pain in the cervical spine, with symptoms including difficulty rotating the head, neck and or shoulder pain, and headaches.[111, 112] Thoracic facet arthropathy is reportedly rare,[113] but when it does occur it is usually characterized by pain and tenderness above the thoracic facet joints and mid-back pain. Other symptoms of thoracic facet joint pain may include pain upon bending or rotating sideways, pain along the shoulder blade, and pain with overhead lifting.[114]

It is estimated that the prevalence of facet joint pain is 10-15% in the low back and 45-55% in the neck.[3] However, these estimates vary widely with the diagnostic methodology employed. Despite this wide variation of prevalence estimates, facet interventions represent the second most common type of procedure performed in pain management centers throughout the United States.[107]

2.2. Diagnosis of Facet Joint Pain

When a diagnosis of facet joint pain is suspected, a physical examination is often performed to rule out other pathologies as well as to identify any paraspinal tenderness, which is the only symptom

present on physical exam that is known to correlate with facet arthropathy.[3, 8, 115] Facet joint pain is not commonly associated with abnormalities on an MRI or on radiologic images, and therefore imaging studies are not typically considered to be useful in the diagnosis of facet arthropathy.[3, 11]

Because facet joint pain is often not accurately diagnosed by clinical exam[10] or with imaging,[11] isolating pain to the facet joints requires diagnostic blocks to identify localized pain. Facet joints are well innervated by the medial branches of the dorsal rami,[116] with each facet joint innervated by two medial branch nerves which function to carry pain signals from the joint to the brain.[13, 87] Facet joint pain may be diagnosed either by anesthetizing the medial branch nerves that innervate the symptomatic joint (called a medial branch block) or with intra-articular injections of local anesthetic (usually lidocaine or bupivacaine) into the entire joint cavity.[12-15] If the injection results in pain relief lasting at least as long as the duration of action of the anesthetic, then the facet joint is likely the source of the pain. Intra-articular injections are considered to be more technically challenging to perform than medial branch blocks[3] and are also thought to have potentially lower predictive value for success of radiofrequency denervation of the facet joints (see also section 1.4.1).[13, 117] While medial branch blocks may have higher predictive value for success following facet neurotomy, some individuals have atypical innervation to their facet joints and the medial branches innervate other pain-generating areas, which has created some suspicion into the ability of the medial branch block to isolate the facet joint as the source of pain. Despite much research, there is currently no consensus regarding which type of block (medial branch block or intra-articular block) is superior for the diagnosis of facet joint pain or if one block is a better predictor of outcome following a RF neurotomy procedure than the other.[3] Although no studies have been published in which the outcomes following facet neurotomy in patients selected by medial branch versus intra-articular block have been compared[3] (see also Key Question 1b), one such trial is reportedly underway at Johns Hopkins University.[118]

There are several factors that can lead to inaccurate (both false positive and false negative) diagnostic blocks for facet joint pain. False positive blocks can be caused by a placebo response, an excess amount of the superficial local anesthetic, effects from sedation, inadvertent infiltration of the local anesthetic, and false-negative blocks may be caused by an inadequate anesthetic dose, pain caused by the procedure, or vascular uptake of the anesthetic.[3] Because of the high false positive rate with uncontrolled single blocks,[97, 108, 119] controlled or comparative diagnostic blocks are considered more reliable.[13, 93] With a placebo-controlled block, the painful joint is first injected with an anesthetic and then later injected with saline in a second block. The rationale is that the anesthetic blockade of a painful joint will relieve pain whereas the saline block will not affect the pain report.[88, 107] In a comparative block, a series of two local anesthetic blocks with different durations of action is performed. The probability that the blocked joint is the true source of pain is greater if repeating the block with an anesthetic agent that has a different duration of action reproduces a concordant analgesic response.[13]

There are different requirements used for pain relief (most commonly ≥50% and ≥80% relief) in determining if a patient has a positive response to a diagnostic block. Different studies and clinical practice guidelines employ different cut-off values for efficacy of the block, and this can also be assessed with different measurements (e.g. extent and duration of pain relief, increase in range of motion); therefore the criteria for whether a patient is a candidate for facet neurotomy is variable.[120, 121] There is great controversy surrounding the optimum threshold for a positive medial branch block as it has been argued that using a high cut-off value such as ≥80% could result in the denial of effective treatment to suitable candidates, and it has been documented in the literature

that higher thresholds do not result in greater success rates following radiofrequency denervation procedures.[3] On the other hand, it has been shown that a low threshold such as ≥50% pain relief may be too low and could lead to over-diagnosis of facet joint pain as well as result in inferior outcomes following the denervation procedure.[121]

2.3. Technology: Facet Neurotomy

Once the facet joint is determined to be the source of pain as indicated by a positive diagnostic nerve block, then prolonged pain relief may be achieved with destruction of the nerves to the affected joint in a procedure called facet neurotomy. Facet neurotomy does not cure the source of pain, but instead destroys the pain signal to the brain by damaging the nerve, which can result in pain relief lasting from 6 months to, occasionally, greater than 12 months.[3] Different types of facet neurotomy are available, but the most common type employs radiofrequency needles to destroy the nerve tissue with heat generated by an electric current.[16] Other names used for the facet neurotomy procedure include percutaneous radiofrequency denervation, nerve ablation, neurolysis, medial branch neurotomy, medial branch rhizotomy, and articular rhizolysis.

During this outpatient procedure, the patient is positioned face down and the skin is anesthetized with a local anesthetic such as lidocaine. The radiofrequency needles are advanced using guidance (usually fluoroscopic) to confirm that the needles are properly positioned at the presumed location of the nerves from the affected joint. Often an initial electric pulse is applied to stimulate the target nerves and confirm that the needles are in an optimal position,[122] and then heat from a radiofrequency current is applied to the medial branch nerves above and below the target joint in order to disrupt the ability of the nerves to transmit pain signals to the brain.[17, 18] The heated area is oblate spheroid in shape and should run parallel to the long axis of the lesion tip.[3]

It is known that individual variation exists with regard to the anatomical position of the medial branch nerves and as a result the RF neurotomy technique has evolved so that a larger target area is lesioned. The goal of the operating surgeon is to place the needle tip parallel to and as close to the medial branch nerve as possible in order to create a larger lesion and hence a more effective disruption of the pain signal. Further, this may help minimize the likelihood that the procedure will miss the nerve altogether or that the nerve will very quickly regenerate (as it might from a small lesion). To obtain a larger lesion volume, larger electrodes (20-22 g needles), higher temperatures (80 – 90°C) or longer lesion times (90 seconds) may be used (see also section 1.4.1).[3]

One or more lesions may be made in the target nerves depending on the preference of the operating surgeon, however the evidence for performing multiple lesions is limited.[28] Some procedures also involve an intraoperative injection of a local anesthetic and/or corticosteroid agent into the target nerves to decrease pain and neural inflammation thought to be caused by the trauma of the needle insertion and subsequent lesioning of the nerves, however this approach remains controversial.[91, 107, 122, 123]

There are two types of radiofrequency neurotomy: thermal or non-pulsed, and pulsed. In thermal radiofrequency neurotomy, after determining that the probe is properly positioned, the radiofrequency current is turned on for 40 to 90 seconds at temperatures of 60° to 90° C. Alternatively, pulsed radiofrequency neurotomy delivers short bursts of the radiofrequency current at a slightly lower temperature (60° - 75° C) rather than the continuous flow utilized in thermal or non-pulsed radiofrequency neurotomy.[19] Pulsed neurotomy allows the nerve tissue to cool between

bursts, which is reported to reduce the destruction of neighboring tissue.[20] When pain recurs after an initial successful facet neurotomy procedure, the denervation procedure may be repeated one or more times to achieve continued pain relief.

There is evidence that facet neurotomy in the cervical spine is superior to that in the thoracic or lumbar spine due to the fact that facetogenic pain accounts for a larger proportion of pain in the cervical region and that denervation is easier to achieve in the cervical spine.[3] Research on the success of facet neurotomy procedures in the thoracic and lumbar spine regions is mixed and may be due to anatomical variability of the medial branch nerves in the thoracic region, use of improper patient selection criteria, and the technical skill of the operating surgeon.[3]

Other types of facet neurotomy involve applying ethyl alcohol, phenol, or sodium morrhuate (chemical or alcohol ablation), extreme cold (cryoablation), or laser beams (laser ablation) to the medial branch nerves to destroy the nerves and reduce or eliminate pain.

2.4. Comparators: Therapeutic medial branch block, therapeutic intra-articular injections

Therapeutic medial branch blocks and therapeutic intra-articular injections are two alternative procedures for the treatment of pain suspected to arise from the facet joint.

In a therapeutic medial branch block, the patient is lying face down and the skin above the target nerves is anesthetized with a local anesthetic. The needle is advanced using fluoroscopic guidance toward the medial branch nerves of the dorsal ramus where the anesthetic (often lignocaine or bupivacaine) is injected, either alone or in combination with a corticosteroid agent which is believed to provide longer term pain relief.[13]

The procedure for a therapeutic intra-articular injection is similar to the procedure for a therapeutic medial branch block, the primary difference being the placement of the needle. In a therapeutic intra-articular injection, rather than the needle being guided to the medial branch nerves that innervate the symptomatic joint, it is instead advanced directly into the cavity of the joint where the same or similar therapeutic agent is injected (again, often lignocaine or bupivacaine, alone or in combination with a steroid agent).[110] When a therapeutic intra-articular block is performed, contrast medium may be injected to confirm proper placement of the needle in the joint cavity.[110]

Other alternative treatment options for facet joint pain include pharmacotherapy (such as non-steroidal anti-inflammatory drugs, anti-depressants, opiates and muscle relaxants) physical therapy, rest, trigger-point injection, acupuncture, yoga, and other exercise regimens.

2.5. Indications and Contraindications for Facet Neurotomy

No information on indications and contraindications was identified in the FDA Summary of Safety and Effectiveness Data (SSED), so the indications and contraindications reported below were taken from the most common inclusion and exclusion criteria used in the RCTs included in this report.[27-34, 36, 124]

Indications for facet neurotomy include the following:

- Adults with continuous back or neck pain of at least 3 months duration and who have not responded to conservative therapy, such as bed rest, medication, physical therapy, trigger point injection, and epidural block
- A positive response to a diagnostic medial branch block (the definition of a positive response varies, however the majority of RCTs require at least 50% reduction in pain[3])
- Tenderness over the facet joints on palpation
- Pain on hyperextension, rotation of spine and/or referred pain
- Pain exacerbated by exercise and relieved by rest; pain exacerbated by sitting or standing
- Pain not exacerbated by coughing or sneezing

Contraindications for facet neurotomy include the following:

- Patients with a known specific cause of spinal pain (e.g. signs of herniation, spondylolisthesis, spinal stenosis, malignancy, infection, or trauma (other than whiplash trauma in the cervical spine)
- Patients with major mental illness or psychiatric disorder
- Malignancy, diabetes, pregnancy, coagulopathy, allergy to contrast media and/or local anesthetics

2.6. Potential Complications/Harms of Facet Neurotomy

Pain related to treatment is common after most facet neurotomy procedures. Pain is often reported as a "burning" pain in the deep soft tissue of the injection sites ***as well as in*** the hip, lower back and leg when neurotomy ***was performed betwe***en L5 and S1; however, deep pain tends to subside with 24 hours of treatment.[31, 32, 38, 125] Rarely, localized pain may last for more than two weeks.[125] Patients have also described head and neck pain following a procedure performed at the level of the cervical spine. Some head and neck pain was reported to persist for up to one year.[107, 126, 127]

Numbness or dysaesthesia in the cutaneous territory of the coagulated nerves has also been reported after a facet neurotomy procedure.[31, 32] Another potential complication is damage to the adjacent paraspinal musculature which is also innervated by the medial branch nerves, resulting in muscle weakness, decreased range of motion, and kyphosis.[128] Inflammation of one or more nerves (neuritis) has also been reported as a complication of facet neurotomy,[122, 123] in addition to superficial burns that are usually the result of electrical faults, insulation breaks in the electrodes and grounding pad adhesion sites.[33, 125]

Other complications include dizziness, blurred vision, tinnitus, widespread headaches and in some instances there have been accounts of psoriatic rashes at the site of the skin incision.[32, 38, 127] Loss of motor function and change of sensibility have also been reported, however the occurrences are rare.[31, 129-131] Bowel and bladder incontinence have also rarely occurred following radiofrequency neurotomy, and are usually the result of inadvertent lesioning of the S2-4 spinal nerves.[132] Furthermore, because most facet neurotomy procedures use fluoroscopy to assist with correct placement of the needles, certain risks are associated with radiation exposure, including injury to the skin, radiation-induced burns, radiodermatitis, genetic effects, and radiation-induced malignancy.[133-137]

2.7. FDA-Approved Facet Neurotomy Devices

There are currently eight lesion probe devices approved by the FDA (seven radiofrequency lesion probe devices and one cryo-lesion probe device). No FDA approved devices were identified for alcohol/chemical lesion probes or laser lesion probes. The seven radiofrequency lesion probe devices were approved between 2000 and 2007 and five of the devices have since been recalled for improper labeling and/or packaging, or faulty temperature control. The single cryo-lesion probe device was approved by the FDA in 2005 and has had no recalls. A table listing FDA approved devices can be found in Appendix G.

2.8. Cost

2.9. Clinical Guidelines

Sources, including the National Guideline Clearinghouse (NGC), major bibliographic databases, professional societies, and Medline were searched for guidelines related to facet neurotomy for the treatment of lumbar and cervical pain. Key word searches were performed: "facet OR facet rhizotomy OR medial branch neurotomy OR radiofrequency neurotomy OR radiofrequency denervation OR cryoablation neurotomy OR radiofrequency neurolysis OR zygapophysial OR laser facet denervation OR chemical facet neurolysis OR articular rhizolysis OR non-pulsed radiofrequency ablation OR cooled radiofrequency ablation OR phenol ablation OR pulsed radiofrequency ablation." Twelve documents were recovered that contained specific recommendations regarding this topic.

Guidelines from the following source are summarized:

1. American Pain Society (APS): 14 potential current guidelines were retrieved, 1 of which provided relevant guidance.

2. National Guideline Clearinghouse (NCG): 23 potential current guidelines were retrieved, 11 of which provided relevant guidance.

3. National Institute of Health and Clinical Excellence (NICE): 20 potential current guidelines were retrieved, 1 of which provided relevant guidance, but was a duplicate study retrieved from the American Pain Society.

A brief synopsis of each guideline is included below. Details of each included recommendation for facet neurotomy can be found in Table 3 that follows.

Guidelines by Diagnosis (Table 3)

Facet Neurotomy

- ***American Pain Society Clinical, 2009:***[138] *Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain An Evidence-Based Clinical Practice Guideline From the American Pain Society.* There is insufficient evidence to evaluate

validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy.

- ***National Institute for Health and Clinical Excellence, 2009:***[139] *Low back pain: early management of persistent non-specific low back pain Full Guideline.* Do not refer people for radiofrequency facet joint denervation.
- ***American College of Occupational and Environmental Medicine, 1997/2011:***[140] *Low back disorders Evaluation and management of common health problems and functional recovery in workers.* Does not recommend radiofrequency neurotomy, neurotomy and facet rhizotomy in most cases, based on limited intermediate evidence. There is insufficient evidence to recommend radiofrequency neurotomy, neurotomy, or facet rhizotomy for treatment in patients with chronic low back pain (without radiculopathy) who have failed more conservative options.
- ***American Society of Interventional Pain Physicians, 2003/2009:***[141] *Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain.* Diagnostic facet joint blocks are recommended in patients suffering from somatic or nonradicular low back, neck and thoracic pain. Therapeutic cervical and lumbar radiofrequency neurotomy is strongly recommended.
- ***Colorado Division of Workers' Compensation, 2011:***[142] *Chronic pain disorder medical treatment guidelines.* Radiofrequency medial branch neurotomy is recommended over alcohol, phenol, or cryoablation for patients with facetogenic pain and a minority of patients with low back pain. Not recommended for patients with multiple pain generators.
- ***American College of Occupational and Environmental Medicine, 2008:***[143] *Chronic pain.* Radiofrequency neurotomy, neurotomy, or facet rhizotomy is not recommended for lumbar spinal conditions. There is insufficient evidence to recommend radiofrequency neurotomy, neurotomy, or facet rhizotomy for cervicogenic spinal conditions.
- ***American College of Occupational and Environmental Medicine, 2011:***[144] *Cervical and thoracic spine disorders.* There is insufficient evidence to recommend radiofrequency neurotomy, neurotomy, and facet rhizotomy for chronic cervicothoracic pain. Radiofrequency neurotomy is moderately not recommended for patients with cervicogenic headaches.
- ***Institute of Health Economics, 2009/2011:***[145] *Guideline for the evidence-informed primary care management of low back pain.* Medial branch neurotomy is recommended for chronic low back pain.
- ***Work Loss Data Institute, 2003/2011:***[146] *Neck and upper back (acute & chronic).* Diagnostic facet blocks are recommended for most patients with disorders of the neck and upper back. Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.
- ***Institute for Clinical Systems Improvement (ICSI), 2011:***[147] *Assessment and management of chronic pain.* Percutaneous radiofrequency neurotomy is recommended as a commonly used Level I therapeutic procedure for patients with neck and back pain generated by facet joints.

- ***Work Loss Data Institute, 2003/2011:***[148] *Low Back-lumbar & thoracic (acute & chronic).* Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.
- ***American Society of Regional Anesthesia and Pain Medicine, 1997/2010:***[149] *Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine.* Chemical denervation is not recommended for routine care of patients with chronic non-cancer pain. Conventional or radiofrequency ablation to the facet joint is recommended for low back pain for most patients. Conventional radiofrequency ablation may be performed for neck pain.

Table 3. Clinical Guidelines

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
American Pain Society Clinical (2009) *Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain An Evidence-Based Clinical Practice Guideline From the American Pain Society.*	NR	Facet neurotomy, radiofrequency denervation	RCTs	Criteria and grading system adapted from methods developed by the US Preventative Services Task Force*	I	Poor
				Diagnostic: There is insufficient evidence to evaluate validity or utility of diagnostic selective nerve root block, intra-articular facet joint block, medial branch block, or sacroiliac joint block as diagnostic procedures for low back pain with or without radiculopathy. • No reliable data exist on the diagnostic accuracy or clinical utility of diagnostic facet joint, medial branch, or selective nerve root blocks. Correlation with imaging findings is variable and difficult to interpret in the absence of reliable reference standards for identifying "true" facet joint pain. Although positive responses are less frequent with controlled rather than uncontrolled facet joint blocks, it is not possible to determine whether this finding is due to fewer true- or false-positive cases. Some studies have evaluated the association between findings on invasive diagnostic tests and surgical outcomes, but no studies have investigated the effects of using facet joint, medial branch, or selective nerve root block to guide choice of therapy or how use of these tests affects subsequent patient outcomes,	I	Poor

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
				compared with selective therapy without using the invasive diagnostic test. **Therapeutic:** In patients with persistent nonradicular low back pain, there is insufficient evidence to adequately evaluate benefits of radiofrequency denervation. • Trials of radiofrequency denervation reported inconsistent results between small numbers of higher quality trials and (in the case of radiofrequency denervation) technical or methodologic shortcomings making it difficult to reach conclusions about benefits.		
National Institute for Health and Clinical Excellence/ National Collaborating Centre for Primary Care (2009) *Low back pain: early management of persistent non-specific low back pain Full Guideline.*		Radiofrequency facet joint denervation	NR	Evidence levels are based on the guidelines manual developed by the National Institute for Health and Clinical Excellence[†] <u>Do not refer people for any of the following procedures</u> • The role of specific therapeutic interventions remains unclear: Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomized controlled trials give conflicting evidence.	NR	1+, 1–
American College of Occupational and Environmental Medicine	1966 – 2010	Radiofrequency neurotomy, neurotomy, and facet rhizotomy	NR	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§]		

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
(2007/2011) *Low back disorders Evaluation and management of common health problems and functional recovery in workers.*				<u>Acute Low Back Pain, Subacute Low Back Pain, Radicular Pain Syndromes and Spinal Stenosis:</u> Radiofrequency neurotomy, neurotomy, and facet rhizotomy are not recommended. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence. <u>Chronic Low Back Pain:</u> Radiofrequency neurotomy, neurotomy, or facet rhizotomy for patients with chronic LBP confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment – no recommendation. The evidence is insufficient to recommend for or against routinely providing the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.	Not recommended No recommendation	C I
American Society of Interventional Pain Physicians (2003/2009)	1966 – Dec 2008	Facet or zygapophysial joint blocks, medial joint blocks, radiofrequency neurotomy	NR	Grading recommendations adapted from Guyatt et al. (2006)[††] Quality of Evidence modified from the grading system developed by the U.S. Preventive Services Task Force[**]		

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain.				**Diagnostic:** Low Back Pain: Diagnostic lumbar facet joint nerve blocks are recommended in patients suffering from somatic or non-radicular low back and lower extremity pain (avg. > 6 on scale of 0 – 10), with duration of pain of at least 3 months. Neck Pain: Diagnostic cervical facet joint nerve blocks are recommended in patients suffering from somatic or non-radicular neck pain or headache and upper extremity pain, with duration of pain (avg. > 6 on scale of 0 – 10) of at least 3 months. Thoracic Pain: Facet or zygapophysial joint blocks are recommended in patients suffering from somatic or nonradicular upper back or mid back pain (avg. > 6 on scale of 0 – 10) of at least 3 months. **Therapeutic:** Based on Guyatt et al.'s, (2006) criteria for cervical radiofrequency neurotomy and lumbar radiofrequency neurotomy, the recommendation is strong.	NR NR NR 1C	I or II-I I or II-I II-I II-1 to II-3

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
Colorado Division of Workers' Compensation (2011) *Chronic pain disorder medical treatment guidelines.*	2001 – 2010	Radiofrequency medial branch neurotomy/facet rhizotomy	NR	RF medial branch neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. This treatment is indicated for patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.	NR	NR
American College of Occupational and Environmental Medicine (2008) *Chronic pain.*	1966 – 2008	Radiofrequency neurotomy, neurotomy, or facet rhizotomy	RCTs	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§] <u>Chronic Low Back Pain:</u> There is no recommendation for radiofrequency neurotomy, neurotomy, or facet rhizotomy for cervicogenic spinal conditions. The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. Radiofrequency neurotomy, neurotomy, or facet rhizotomy for lumbar spinal conditions is not recommended. The EBPP found at least moderate evidence that harms and costs exceed benefits based on limited evidence.	No recommendation Not recommended	I C

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
American College of Occupational and Environmental Medicine (2011) *Cervical and thoracic spine disorders.*	NR	Use of radiofrequency neurotomy, neurotomy, and facet rhizotomy	NR	Criteria and grading system are drafted by the EBPP of the Guideline Methodology Committee for the American College of Occupational and Environmental Medicine[§] <u>Chronic Cervicothoracic Pain:</u> There is no recommendation for the use of radiofrequency neurotomy, neurotomy, and facet rhizotomy for chronic cervicothoracic pain confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment. The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. <u>Cervicogenic Headache:</u> Radiofrequency neurotomy is moderately not recommended. Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or costs outweigh benefits.	No recommendation	I
					Not recommended	B
Institute of Health Economics (2009/2011) *Guideline for the evidence-informed*	Jan 1996 – Dec 2010	Medial branch neurotomy	Systematic review (IHE) presenting consistent evidence to support the	Recommendation rating developed by the GDG[§§] <u>Chronic Low Back Pain:</u> Medial branch neurotomy is recommended for chronic low back pain.	Do	NR

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
primary care management of low back pain.			action.			
Work Loss Data Institute (2003/2008/2011) *Neck and upper back (acute & chronic).*	2003 – 2011	Facet joint radiofrequency neurotomy/facet rhizotomy	NR	Diagnostic facet blocks are recommended for patients with disorders of the neck and upper back, except those whom a surgical procedure is anticipated and in those who have had a previous fusion procedure at the planned injection level. Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.	NR NR	NR NR
Institute for Clinical Systems Improvement (ICSI) (2009/2011) *Assessment and management of chronic pain.*	Aug 2008 – Aug 2011	Percutaneous radiofrequency neurotomy	NR	Evidence grades determined by the ICSI[***] Percutaneous radiofrequency neurotomy is recommended as a commonly used Level I therapeutic procedure for patients with neck and back pain generated by facet joints.	NR	I
Work Loss Data Institute (2003/2008/2011) *Low Back-lumbar & thoracic (acute & chronic).*	NR	Facet joint radiofrequency neurotomy/facet rhizotomy	NR	Facet joint radiofrequency neurotomy/facet rhizotomy are currently under study and not specifically recommended.	NR	NR
American Society of Regional Anesthesia and Pain Medicine	1944 – 2009	Chemical denervation, Radiofrequency ablation, radiofrequency ablation	NR	Chemical denervation (e.g., alcohol, phenol, or high concentration local anesthetics) is not recommended for routine care of patients with chronic non-cancer pain.	NR	NR

Assessment (year)	Search dates	Procedure(s) evaluated	Evidence base available	Recommendations	Class/Grade of Recommendation	Level of Evidence
(1997/2010) *Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine.*		(facet joint)		<u>Radiofrequency ablation:</u> Conventional (e.g., 80°C) or thermal (e.g., 67°C) radiofrequency ablation of the medial branch nerves to the facet joint is recommended for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. Conventional radiofrequency ablation may be performed for neck pain. Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain.	NR	NR

EBPP: Evidence-based Practice Panel; GDG: Guideline Development Group; ICSI: Institute for Clinical Systems Improvement

* US Preventative Services Task Force Grading System:

Recommendation		Strength of Evidence	
A	The panel strongly recommends that clinicians consider offering the intervention to eligible patients. The panel found good evidence that the intervention improves health outcomes and concludes that benefits substantially outweigh harms.	Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality trials).
B	The panel recommends that clinicians consider offering the intervention to eligible patients. The panel found at least fair evidence that the intervention improves health outcomes and concludes that benefits moderately outweigh harms, or that benefits are small but there are no significant harms, costs, or burdens associated with the intervention.	Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the No. quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least 1 higher-quality trial of sufficient sample size; 2 or more higher-quality trials with some inconsistency; at least 2 consistent, lower-quality trials, or multiple consistent observational studies with no significant methodologic flaws).
C	The panel makes no recommendation for or against the intervention. The panel found at least fair evidence that the intervention can improve health outcomes, but concludes that benefits only slightly outweigh harms, or the balance of benefits and harms is too close to justify a general recommendation.		
D	The panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweighs benefits.	Poor	Evidence is insufficient to assess effects on health outcomes because of limited no. or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.
I	The panel found insufficient evidence to recommend for or against the intervention. Evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.		

*Adapted from methods developed by the US Preventive Services Task Force.[16]

† National Institute for Health and Clinical Excellence
Evidence level guidelines: 1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias; 1–: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.

§ Guideline Methodology Committee: Evidence Rating C: Limited evidence base, at least one study of moderate quality; I: Insufficient evidence, evidence is insufficient or irreconcilable.
Recommendation Definition, Not recommended: Recommendation against routinely providing the intervention. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence;

No recommendation – insufficient evidence: The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms and costs cannot be determined.

** Modified US Preventative Services Task Force Grading System, Quality of Evidence:
I: Evidence obtained from at least one properly randomized controlled trial or multiple properly conducted diagnostic accuracy studies.
II-1: Evidence obtained from one well-designed controlled trial without randomization or at least one properly conducted diagnostic accuracy study of adequate size.
II-2: Evidence obtained from at least one properly designed small diagnostic accuracy study.
II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

†† Guyatt et al. (2006) Grading Recommendations: 1C: Strong recommendation based on low or very-low quality evidence (observational studies or case series). Benefits clearly outweigh risk and burdens, but recommendation may change when higher quality evidence becomes available.

§§ GDG, Recommendation rating:
Do: GDG accepted the original recommendation, which provided a prescriptive direction to perform the action or used the term “effective” to describe it.

*** ICSI Evidence grades:
Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

2.10. Previous Systematic Reviews/Technology Assessments

Previously conducted reviews and assessments have not reached definitive conclusions regarding the safety and efficacy of facet denervation procedures or the accuracy of the diagnostic methods. Table 4 summarizes the previous technology assessments, rapid reviews, and systematic reviews.

Previous Health Technology Assessments

One prior Health Technology Assessment (HTA) from the Institute for Clinical Systems Improvement (ICSI)[150] has evaluated the safety and efficacy of facet neurotomy for treatment of facet joint pain of the lumbar or cervical spine. The results from this HTA suggest that radiofrequency neurotomy is safe for patients who are correctly diagnosed with facet joint pain. However, this HTA concluded that there is weak evidence for use of radiofrequency neurotomy for cervical facet joint pain after conservative therapy has failed and that there is insufficient evidence regarding the efficacy of radiofrequency neurotomy for pain arising in the lumbar facet joints. Table 4 provides more detailed information from this HTA.

Previous Rapid Reviews

Two rapid reviews (not full HTAs) by the Canadian Agency for Drugs and Technologies in Health (CADTH)[151, 152] have evaluated the clinical effectiveness and safety of radiofrequency neurotomy for treatment of facet joint pain. The 2012 rapid review included both systematic reviews and comparative studies in its evidence base, whereas the 2006 rapid review included only previous systematic reviews. The2012 review concluded that radiofrequency neurotomy is an effective treatment for back pain for varying periods of time and that there are no major safety issues of concern. The four systematic reviews summarized in the other rapid review had disparate conclusions: One systematic review found moderate evidence that placebo is most effective while another found strong evidence that radiofrequency neurotomy offers both short- and long-term pain relief. A third systematic review, however, found that the evidence was conflicting regarding the short-term effect of radiofrequency neurotomy. The fourth systematic review included in this rapid review found moderate to strong evidence that radiofrequency neurotomy is an effective procedure for facet joint pain. Table 4 provides more detailed information on these rapid reviews.

Previous Systematic Reviews

Fifteen systematic reviews have examined the effectiveness and/or safety of therapeutic facet neurotomy, diagnostic blocks, or both. Seven previous systematic reviews[9, 129, 131, 153-156] have evaluated the effectiveness and/or safety of radiofrequency neurotomy alone, and of these reviews, two[9, 131] looked at the evidence evaluating pulsed versus conventional radiofrequency neurotomy. Three previous systematic reviews[108, 157, 158] have examined the accuracy of diagnostic blocks alone and three others[114, 159, 160] evaluated both therapeutic injections and radiofrequency neurotomy. Two previous systematic reviews[117, 161] examined both the accuracy of diagnostic blocks and the effectiveness of therapeutic radiofrequency denervation. These 15 systematic reviews evaluated the literature across the cervical, thoracic and lumbar regions of the spine.

Table 4. Previous Health Technology Assessments and Systematic Reviews

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
Health Technology Assessments						
ICSI (2005)	NR	Percutaneous RF ablation of the medial branch of the dorsal rami Therapeutic	Investigating the efficacy of ablation of the medial branch of the dorsal rami for facet-mediated cervical or lumbar pain that has failed to respond to conservative therapy.	• 4 RCTs • 1 case-series	• ***Critical appraisal of individual studies***: Studies were graded based on their design and their evidence base, as outlined in the report* • The RCTs were all given a score of Class A, "-" quality • The case-series was given a score of Class D and "Ø" quality	• Percutaneous RF ablation is safe for patients who are correctly diagnosed with facet joint pain • There is weak evidence that percutaneous RF ablation may be an alternative to failed conservative treatment for cervical facet joint pain • Insufficient evidence about the efficacy of percutaneous RF ablation for lumbar facet joint pain
Rapid Reviews (not full HTAs)						
CADTH-Thermal Radiofrequency Neurotomy (2012)	January 1, 2007 – November 18, 2012	Thermal RF Neurotomy Therapeutic	1. What is the clinical effectiveness of thermal RF neurotomy for the treatment of back pain? 2. What is the clinical safety of thermal RF neurotomy for the treatment of back pain?	• 2 SRs • 2 RCTs • 3 non-randomized studies	• NR	• RF neurotomy is effective for the management of back pain for differing periods of time • No major safety issues were identified

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
CADTH-Radiofrequency Neurotomy (2006)	NR	Medial branch RF neurotomy Therapeutic	NR	• 4 SRs • Two of these SRs include only RCTs (Geurts and Niemesto) while Manchikanti and Boswell also include observational studies	• ***Critical appraisal of individual studies:*** Most of the studies included in the SRs used relied on single diagnostic blocks rather than controlled diagnostic blocks which could lead to invalid results	• 4 SRs offer disparate conclusions • One small well designed observational study has shown positive results but no RCT has been conducted • Systematic review findings: • Geurts found moderate evidence that placebo is most effective • Manchikanti found strong evidence that the procedure offers short and long term pain relief • Niemesto found conflicting evidence on the short term effect • Boswell found moderate to strong evidence in favor or efficacy
Systematic Reviews/Meta-analyses						

Cochrane (2003 (with 2010 update))	From beginning of MEDLINE, PsycLIT, and EMBASE up until February 2002	RF lesion
		
		Intra-articular facet injection
		
		Therapeutic
			Objective: To assess the effectiveness of radiofrequency denervation for the treatment of musculoskeletal pain disorders.	• Lumbar zygapophyseal joint pain:
				• 3 RCTs
				  • Van Kleef 1999, n = 31
				  • Gallagher 1994, n = 41
				  • Leclaire 2001, n = 70
				• Cervical
					• ***Critical appraisal of individual studies:*** methodological quality categorized using Cochrane guidelines.
					
					Van Kleef and Leclaire were of
						• RF denervation can offer short-term relief of pain in chronic neck pain of zygapophyseal joint origin
						• Limited evidence that high-temperature RF lesioning of the cervical dorsal root ganglion and low-temperature procedures for

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
				zygapophyseal joint pain • 1 RCT in two publications • Lord 1996/Wallis 1997, n = 24	high quality, but Gallagher was of low quality with respect to methodology.	cervicobrachial pain have differing effects • Conflicting evidence on short-term effects of RF lesioning for low-back zygapophyseal joint pain
Chou (2009)[162] American Pain Society Evidence Review	Through July 2008 of Ovid MEDLINE, Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials	RF denervation Diagnostic intra-articular facet joint block Therapeutic & Diagnostic	Objective: To systematically assess benefits and harms of nonsurgical interventional therapies for low back and radicular pain. KQ: What is the diagnostic accuracy and what are the potential harms associated with invasive tests for identifying patients who may benefit from invasive procedures?	Facet Joint Injection and Therapeutic Medial Branch Block • 9 RCTs Diagnostic intra-articular facet joint block • 2 SRs	• ***Critical appraisal of individual studies***: methodological quality categorized using 11 criteria developed by the Cochrane Back Review Group • ***Overall critical appraisal:*** Poor; 1 higher-quality trial used an inadequate technique, another had large baseline differences in pain scores	• There is good or fair evidence that prolotherapy, facet joint injection, intradiscal steroid injection, and percutaneous intradiscal radiofrequency thermocoagulation are not effective. • Insufficient evidence exists to reliably evaluate other interventional therapies. • One lower-quality trial found no clear differences in pain relief between patients selected for percutaneous facet joint cryodenervation based on a positive uncontrolled medial branch block, vs those selected based on a positive uncontrolled pericapsular block

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
Falco (2012) Update: Cervical Diagnostic Facet Joint Nerve Blocks (Pain Physician Series of SRs)	PubMed from 1966 and EMBASE from 1980 through June 2012	Cervical facet joint blocks Diagnostic	Objective: To evaluate and update the accuracy of diagnostic facet joint nerve blocks in the diagnosis of facet joint pain.	• Studies of diagnostic accuracy • 3 RCTs2 non-randomized studies	• ***Critical appraisal of individual studies:*** A methodological quality assessment of diagnostic accuracy studies meeting inclusion criteria was carried out utilizing QAREL criteria. Studies achieving 50% or higher scores were included. Scores of 67% or higher were considered to be high quality, 50% were considered to be moderate quality, and studies scoring less than 50% were considered to be of poor quality and excluded • ***Overall critical appraisal:*** The level of evidence was classified as	• Diagnostic cervical facet joint nerve blocks are safe, valid, and reliable. The strength of evidence for diagnostic facet joint nerve blocks is good with the utilization of controlled diagnostic blocks with at least 75% pain relief as the criterion standard based on multiple high quality studies • Evidence is limited for single blocks for pain relief of 50% to 74% based on 1 study (RCT) and single blocks with at least 75% pain relief based on 2 studies by the same author (non-randomized) • No studies were available for pain relief of 50%-74% for dual blocks • Evidence for controlled diagnostic blocks with 75%-100% relief is based on 9 high quality non-randomized studies

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					good, fair, and limited or poor based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF)† • There were 9 studies using controlled diagnostic blocks with a criterion standard ranging between 75% and 100% relief • 4 studies utilized ≥ 90% pain relief whereas 5 studies utilized 75% or greater relief as criterion standard	
Falco, Manchikanti et al. (2012) Update: Cervical Therapeutic Facet Joint Interventions	PubMed from 1966 and EMBASE from 1980 through June 2012	Cervical facet joint interventions Therapeutic	Objective: To determine and update the clinical utility of therapeutic cervical facet joint interventions in the management of chronic neck pain.	• 1 RCT evaluating radiofrequency neurotomy • 5 observational studies evaluating radiofrequency neurotomy • Note that studies that documented	• ***Critical appraisal of individual studies:*** The quality of each individual article used in this analysis was assessed by Cochrane review	• The indicated evidence for cervical radiofrequency neurotomy is limited, based on 2 moderate quality observational studies Evidence for medial branch blocks in managing chronic mid

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
(Pain Physician Series of SRs)				the existence of cervical spinal pain of facet joint origin using controlled diagnostic facet joint injections or medial branches were included	criteria for RCTs or the Newcastle-Ottawa Scale for observational studies† • ***Analysis of evidence:*** the analysis was conducted using 3 levels of evidence: good, fair, and limited or poor, based on USPSTF criteria‡ • For RCTs, a study was judged to be positive if the therapeutic cervical facet joint intervention was clinically relevant and effective, either with a placebo control or active control • For observational studies, a study was judged to be positive if the intervention was effective, with	back or upper back pain is fair based on 1 RCT (2 duplicate populations) and 1 observational report

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					outcomes reported at the reference point with positive or negative results at one month, 3 months, 6 months, and one year	
Atluri (2012) Update: Thoracic Diagnostic Facet Joint Nerve Blocks (Pain Physician Series of SRs)	PubMed from 1966 and EMBASE from 1980 through March 2012	Thoracic facet joint nerve blocks Diagnostic	Objective: To determine the diagnostic accuracy of thoracic facet joint nerve blocks in the assessment of chronic upper back and mid back pain.	• 3 observational studies evaluating diagnostic facet joint nerve blocks • Note that only the studies utilizing controlled diagnostic blocks under fluoroscopy were included • The criterion standard for diagnosis of thoracic facet joint pain was at least greater than 50% pain relief for the duration of local anesthetic and ability to perform previously painful movements	• ***Critical appraisal of individual studies:*** The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF)‡ • All three studies were of high quality, the evidence is good Diagnostic accuracy of diagnostic facet joint nerve blocks: • Accuracy was established in 3	Based on this systematic review, the evidence for the diagnostic accuracy of thoracic facet joint injections is good • Based on 3 studies with 80% or greater relief, all 3 studies being of high quality

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					observational studies based on a false-positive rate of 42%-58%, confidence intervals (95% CI) ranged from 26% to 78% • For a dual block 3 observational studies showed prevalence of 40% (95% CI of 33% to 48%) with dual blocks and a false positive rate of 42% (95% CI of 33% to 51%) • For a single block 3 observational studies showed the prevalence was illustrated to be 34% to 48%, confidence intervals (95% CI) ranged from 22% to 62% • The combination of results of all 3 observational studies yielded a prevalence rate of 40% (with a 95%	

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					CI of 33% to 48%) and a false-positive rate of 42% (with a 95% CI of 33% to 51%).	
Manchikanti, Atluri et al. (2012) Update: Thoracic Therapeutic Facet Joint Interventions (Pain Physician Series of SRs)	PubMed from 1966 and EMBASE from 1980 through March 2012	Thoracic facet joint interventions Therapeutic	Objective: To determine the clinical utility of therapeutic thoracic facet joint interventions in the therapeutic management of chronic upper back and mid back pain.	• 1 RCT (with 2 duplicate publications) • 1 non-randomized study of medial branch blocks • 2 non=randomized studies of thoracic radiofrequency neurotomy	• ***Critical appraisal of individual studies:*** The quality of each individual article used in this analysis was assessed by Cochrane review criteria for RCTs or the Newcastle-Ottawa Scale for observational studies§	• There is fair evidence for therapeutic medial branch blocks • There is a lack of available evidence for intra-articular injections • There is limited evidence for radiofrequency neurotomy • Based on 1 RCT of high quality, and 3 moderate quality observational studies
Falco, Manchikanti et al. (2012) Update: Lumbar Diagnostic Facet Joint Nerve Blocks (Pain Physician Series of SRs)	PubMed from 1966 and EMBASE from 1980 through June 2012	Lumbar facet joint nerve blocks Diagnostic	Objective: To determine and update the diagnostic accuracy of lumbar facet joint nerve blocks in the assessment of chronic low back pain.	• 25 diagnostic accuracy studies	• ***Critical appraisal of individual studies:*** The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF)‡	• There is good evidence for diagnostic facet joint nerve blocks with 75% to 100% pain relief as the criterion standard with dual blocks • There is fair evidence with 50% to 74% criterion standard with controlled diagnostic blocks • Evidence is limited with single diagnostic blocks of either 50% to 74% or 75% to 100% pain relief as the criterion standard

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					Diagnostic accuracy of diagnostic facet joint nerve blocks: • Controlled blocks with 75%-100% pain relief required for positive block: "Good" evidence of diagnostic accuracy based on data from 12 studies (1 RCTs, 12 nonrandomized studies) with prevalence of facet joint pain (as defined by a positive block) from 25%-45%, the false-positive rate was 25%-49% in a heterogeneous population as reported by a single RCT. • Controlled blocks with 50%-74% pain relief: "Fair" evidence based on 6 studies (0 RCTs, 5 nonrandomized studies), with	

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					prevalence of facet joint pain (as defined by a positive block) from 15%-61%, the false positive rate was 17%-66% in a heterogeneous population • Evidence is "Poor" for single diagnostic blocks with 50%-74% or 75% based on 5 studies, with a prevalence of facet joint pain (as defined by a positive block) of 33%-61%	
Falco, Manchikanti et al. (2012) Update: Lumbar Therapeutic Facet Joint Interventions (Pain Physician Series of SRs)	PubMed from 1966 and EMBASE from 1980 through June 2012	Lumbar facet joint interventions Therapeutic	Objective: To evaluate and update the effect of therapeutic lumbar facet joint interventions in managing chronic low back pain.	• 9 RCTs (2 duplicate publications) • 8 observational studies	• ***Critical appraisal of individual studies:*** The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional	• The evidence for conventional radiofrequency neurotomy in managing chronic low back pain of facet joint origin in the lumbar spine is good for short- and long-term relief based 6 positive RCTs and 7 positive observational studies • Of the 7 RCTs evaluating radiofrequency

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					techniques for randomized trials and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the U.S. Preventative Services Task Force (USPSTF) ‡ • For cohort studies, studies scoring 67% or higher were considered high quality, studies scoring 50% or higher were considered moderate quality and studies scoring less than 50% were considered low quality and were excluded	neurotomy 1 used triple diagnostic blocks, 2 with dial diagnostic blocks, 4 with single diagnostic blocks, and 2 did not use diagnostic blocks • Of these 7 RCTs, 6 showed positive results • Of the 8 observational studies, 7 reported positive results (6 moderate quality, 1 low quality) and 1 reported undetermined results (moderate quality) • Fair to good evidence for lumbar facet joint nerve blocks for the treatment of chronic lumbar facet joint pain resulting in short-term and long-term pain relief and functional improvement
Carragee	Medline	Facet neurotomy	Objective: To	• 1 study (Lord et al)	• There were no	• Surgical treatment and

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
(2008) Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders Evidence Synthesis	searched from 1980 to 2006	Therapeutic	identify, critically appraise, and synthesize literature from 1980 through 2006 on surgical interventions for neck pain alone or with radicular pain in the absence of serious pathologic disease. Secondarily, to identify: • gaps in and problems with the surgical literature • areas where the resources associated with surgical interventions should be expended in an effort to reduce the individual and societal burden of neck pain and its associated disorders	was frequently cited but scientifically inadmissible	scientifically admissible studies regarding radiofrequency neurotomy for suspected facet (zygapophysial) pain • ***Critical appraisal of individual studies:*** modified from the review forms used by the Quebec Task Force on Whiplash-Associated Disorders and the WHO Collaborating Centre for Neurotrauma, Prevention, Management, and Rehabilitation Task Force on Mild Traumatic Brain Injury	limited injection procedures for cervical radicular symptoms may be reasonably considered in patients with severe impairments
Bogduk (2008)	NR	Radiofrequency neurotomy, medial branch blocks, medial branch neurotomy	Objective: To help understand and evaluate the various commonly used	• 2 SRs • 1 RCT	• Systematic reviews have concluded that that there is	• Denervation of the lumbar Z joints remains the only available treatment

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
		Diagnostic/Therapeutic	nonsurgical approaches to chronic low back pain		insufficient evidence of the efficacy of lumbar medial branch neurotomy, based on three controlled studies • The RCT showed that immediate responses to active treatment significantly and substantially exceeded those from sham treatment	
Manchikanti (2013) University of Kentucky Updated Systematic Review (Pt. 1)	NA	Conventional and pulsed RF neurotomy Therapeutic	Objective: To develop evidence-based clinical practice guidelines for interventional techniques in the diagnosis and treatment of chronic spinal pain.	• 7 RCTs • 11 observational studies	• ***Critical appraisal of individual studies***: the quality of each individual article used in this analysis was assessed by Cochrane review criteria for randomized trials, Newcastle-Ottawa Scale for observational studies Quality Appraisal of Reliability Studies (QAREL) checklist	• In the *lumbar* spine evidence for therapeutic facet joint interventions is good for conventional radiofrequency and limited for pulsed radiofrequency • In the *cervical* spine evidence is fair for conventional cervical radiofrequency neurotomy • In the *thoracic* spine evidence is limited for radiofrequency neurotomy • Of the 7 randomized trials, 6 of them were

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
					for diagnostic accuracy studies • Analysis of evidence was based on the United States Preventive Services Task Force (USPSTF) criteria • The analysis was conducted using 3 levels of evidence, ranging from good, fair, and limited or poor, in all systematic reviews	positive and only one showed definite negative results • Among the 11 observational studies, 10 reported positive results
Chua (2011) Pulsed RF treatment in interventional pain management	Medline and Embase searched through May 30, 2010	Pulsed RF neurotomy Therapeutic	Objective: to evaluate the efficacy of Pulsed Radiofrequency (PRF) treatment in chronic pain management in randomized clinical trials (RCTs) and well-designed observational studies.	• 4 RCTs	• ***Critical appraisal of individual studies***: The methodological quality of the presented reports was scored using the original criteria proposed by Jadad et al.** • Jadad scores of included studies for RF neurotomy ranged from 2-4	• The use of PRF in lumbar zygapophyseal joint pain and TN was found to be less effective than conventional RF thermocoagulation techniques • The included studies in the latter two conditions were unfortunately not powered to detect a difference in heat related complications
Henschke (2010)[103]	Cochrane Back	Radiofrequency or thermal denervation	Objective: To provide an	• 7RCTs	• ***Critical appraisal of individual***	• Overall, there is only low to very low quality

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
The George Institute for International Health Systematic Review	Review Group trial register was searched up to November 17, 2009	procedures Therapeutic	evaluation of the current evidence associated with the use of these procedures		***studies:*** the GRADE approach was used to determine the quality of evidence, Risk of Bias was assessed using the criteria list advised by the Cochrane Back Review Group	evidence to support the use of injection therapy and denervation procedures over placebo or other treatments for patients with chronic LBP • 5 RCTs provided sufficient data on pain VAS scores to allow for pooling over a short-, intermediate- or long-term follow-up • There is low quality evidence (2 RCTs; n = 90; indirectness, imprecision) that radiofrequency denervation of lumbar facet joints is more effective than placebo for pain relief over a short-term follow-up • There is low quality evidence (2 RCTs; n = 112; indirectness, imprecision) that radiofrequency denervation of lumbar facet joints is no more effective than placebo for pain relief in the intermediate term • There is low quality evidence (3 RCTs; n = 130; indirectness, imprecision) that

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
						radiofrequency denervation of lumbar facet joints is no more effective than placebo for pain relief in the long term • There is very low quality evidence (1 RCT; n = 83; inconsistency, indirectness, imprecision) that radiofrequency denervation of the dorsal root ganglion is no more effective than placebo for pain relief in the intermediate term • There is very low quality evidence (1 RCT; n = 60; inconsistency, indirectness, imprecision) that radiofrequency denervation of lumbar facet joints is more effective than placebo for improvement of function in the short term • There is very low quality evidence (1 RCT; n = 40; inconsistency, indirectness, imprecision) that conventional radiofrequency denervation is more effective than pulsed

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
						radiofrequency denervation of the facet joints for pain relief or improvement of function over the long term • It cannot be ruled out that in carefully selected patients, some injection therapy or denervation procedures may be of benefit
Levin (2009)	Through 2008 (based on article's publication date)	Percutaneous radiofrequency lumbar and cervical medial branch neurotomy Therapeutic	Objective: This article will critically evaluate the highest quality interventional spine literature with strict interpretation of the results of these trials	• 7 observational studies	***NR***	• The prospective, double-blind, randomized placebo-controlled trials in the interventional spine literature demonstrate efficacy from several different procedures when properly performed on appropriate patients • Other procedures have been shown to lack efficacy, while inconclusive evidence exists from multiple other interventional spine procedures <u>Radiofrequency using 80C for 60 seconds:</u> • It is more effective than placebo in the short term (8 wk.) and long term (3–12 mo.) in patients with

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
						greater than or equal to 50% improvement from one diagnostic medial branch block • When using a perpendicular approach to the target nerve, it is not more effective than placebo (other than Global Perceived Effect and cost) at 3 months in patients with greater than or equal to 50% improvement from one diagnostic intra-articular zygapophysial joint block <u>Radiofrequency using 80C for 90 seconds</u>: • When using a perpendicular approach to the target nerve, it is more effective than placebo at 1 and 6 months in patients with a good response to one diagnostic injection ‘‘in and around’’ the zygapophysial joint • When using a perpendicular approach to the target nerve, it shows some functional benefit over placebo at 4 weeks, but no benefit at

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
						12 weeks, in patients with ''significant relief'' for at least 24 hours during the week after one intra-articular zygapophysial joint corticosteroid/anesthetic injection • When placing the electrode parallel to the target nerve, it is more effective than placebo at 6 months and 1 year in patients with greater than 50% improvement from one diagnostic medial branch block <u>Pulsed radiofrequency at 2 Hz for 4 minutes at 42 degrees</u>: It is more effective than placebo in patient satisfaction and analgesic requirements at 1 year in • patients with greater than 50% improvement from one diagnostic medial branch block
Smuck 2012	Through 2012 (based on article's publication	RF neurotomy Therapeutic	Objective: To review the duration of pain relief after initial and repeated radiofrequency neurotomy (RFN) for	• 13 observational studies	***The quality of included studies was not high enough to do a meta-analysis***	• The results of this review indicate that pain relief after initial RFN generally ends after 7-9 months and that repeating RFN is likely to provide

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
	date)		cervical and lumbar zygapophysial joint pain			additional pain relief initial RFN was successful • Results are similar between cervical and lumbar spine studies • The lowest and most common threshold level of pain relief studied was 50% and, among the 11 studies, ranged from 50% to 100% • The cervical studies found a non-weighted average of 84% of patients who met the 50% threshold at 3 weeks, 64% at 3 months, 71% at 9 months, and 55% at 12 months • The lumbar studies found a non-weighted average of 79% of patients who met the 50% threshold at 1 week, 71% at 3 weeks, 75% at 1 month, 64% at 6 months, 87% at 12 months, and 50% at 24 months • Three cervical studies reported that patients maintained a duration of more than 50% pain relief, which ranged from 7.3-8.6 months

Assessment (year)	Lit search dates	Procedure(s) evaluated (diagnostic or therapeutic)	KQs	Evidence base	Critical Appraisal	Conclusion
						• Two cervical studies reported that duration of 100% pain relief was 3.0 and 8.0 months • One lumbar study reported a 9.0-month duration of 50% pain relief

NR: not reported; NA: not applicable; RF: radiofrequency; SR: systematic review; RCT: randomized controlled trial; USPSTF: US Preventative Services Task Force; PRF: Pulsed radiofrequency;

*For an explanation of how the critical appraisal was done in ICSI 2005, see the report.

† Falco, Manchikanti et al. (2012): For an explanation of how the critical appraisal was done, see the report.

‡ Falco et al. method for grading the overall strength of evidence for an intervention as adapted and modified from methods developed by USPSTF: *Good*: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy); *Fair:* Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws); *Limited or Poor*: Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.\

§Manchikanti, Atluri et al. (2012): For an explanation of how the critical appraisal was done, see the report (Tables 2-4).

** Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ (1996) Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 17(1):1–12

2.11. Medicare and Representative Private Insurer Coverage Policies

Coverage policies are consistent for facet neurotomy for selected bell-weather payers. The payers will provide coverage for facet neurotomy as long as an FDA-approved device is used and certain patient conditions are met. Table 5 provides an overview of policy decisions.

- **Centers for Medicare and Medicaid Services**
  No national coverage decisions were found for facet neurotomy.

- **Aetna**
  Aetna considers non-pulsed radiofrequency facet denervation as medically necessary treatment for members with intractable cervical or back pain with or without sciatica in the outpatient setting, who meet the following criteria:
    - Member has experienced severe pain limiting activities of daily living for at least 6 months; and
    - Member has had no prior spinal fusion surgery; and
    - Neuroradiologic studies are negative or fail to confirm disc herniation; and
    - Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and
    - Member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants); and
    - Trial of facet joint injections has been successful in relieving the pain

  Aetna considers the use of non-pulsed radiofrequency facet denervation as experimental and investigational for all other indications. Aetna considers facet chemodenervation / chemical facet neurolysis and laser facet denervation as experimental and investigational. Aetna considers pulsed radiofrequency experimental and investigational for all indications, because its effectiveness has not been established.

- **Cigna**
  Cigna covers initial radiofrequency denervation of paravertebral facet joint nerves for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:
    - Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
    - There is severe pain unresponsive to at least six months of conservative medical management (e.g., pharmacological therapy, physical therapy, exercise)
    - Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in elimination or marked decrease in intensity of pain
    - Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)

  Cigna covers repeat radiofrequency denervation of paravertebral facet joint nerves at the same level for the treatment of chronic back or neck pain as medically necessary when BOTH of the following criteria are met:

- At least six months have elapsed since the previous radiofrequency ablation/neurolysis of paravertebral facet joint nerves
- More than 50% relief is obtained, with associated functional improvement, for at least ten weeks following the previous treatment

Cigna does not cover long-term or maintenance denervation of paravertebral facet joint nerves for any indication because it is considered not medically necessary.
Cigna does not cover pulsed radiofrequency, cryoablation / cryoneurolysis / cryodenervation, chemical ablation, laser ablation or SI joint nerve ablation by any method for the treatment of back or neck pain because each is considered experimental, investigational or unproven.

- **Health Net, Inc.**
  Facet Joint Denervation by either injecting neurolytic substances (alcohol 50-100% or phenol) or utilizing radiofrequency thermoneurolysis (e.g. radiofrequency ablation, radiofrequency neurolysis, and/or radiofrequency thermoablation) or cryoneurolysis is medically necessary for treatment of patients with intractable chronic zygapophyseal cervical or lumbar joint pain with or without neurological compression symptoms when all of the following are met:
  - Trial of facet joint injections using local anesthetic has been successful in relieving the pain or, at least, a > 50% reduction of pain; and
  - Severe low back pain or cervical neck pain limiting activities of daily living has been present for at least 6 months; and
  - No prior spinal fusion surgery in the same area of the spine that is to undergo radiofrequency treatment; and
  - Neuroradiologic studies are negative or fail to confirm disc herniation; and
  - Patient has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and
  - Patient has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g. anti-inflammatory agents, analgesics and muscle relaxants

  Health Net, Inc. considers pulsed radiofrequency ablation to be investigational.

Table 5. Overview of payer technology assessments and policies for facet neurotomy

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
CMS	None	None	None	• There are currently no National Coverage Decisions (NCDs) published from the Centers for Medicare and Medicaid Services (CMS).
Aetna (2013) *Clinical Policy Bulletin: Back Pain - Invasive Procedures* POLICY #: 0016 Effective Date: 07/31/1995 Last Review Date: 03/19/2013 Next Review Date: 01/09/2014	NR	NR ("Various Studies")	<u>Non-pulsed radiofrequency facet denervation</u> (also known as facet neurotomy, facet rhizotomy, or articular rhizolysis) is considered medically necessary for treatment of members with intractable cervical or back pain with or without sciatica in the outpatient setting when *all* of the following are met: • Member has experienced severe pain limiting activities of daily living for at least 6 months; *and* • Member has had no prior spinal fusion surgery; *and* • Neuroradiologic studies are negative or fail to confirm disc herniation; *and* • Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; *and* • Member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants); *and* • Trial of facet joint injections has been successful in relieving the pain. <u>Non-pulsed radiofrequency facet denervation</u> is considered experimental and investigational for all other indications because its effectiveness for indications other	• Only 1 treatment procedure per level per side is considered medically necessary in a 6-month period. *Radiofrequency Facet Denervation* • Percutaneous radiofrequency facet denervation, also known as radiofrequency facet joint rhizotomy or facet neurotomy, involves selective denervation using radiofrequency under fluoroscopic guidance • *Facet Chemodenervation/Chemical Facet Neurolysis and Laser Facet Denervation* • The use of chemical facet injections such as alcohol, phenol and hypertonic saline has been proposed as an option for lumbar facet pain. However, there is a lack of published data to support the safety and effectiveness of this technique.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			than the ones listed above has not been established. Aetna considers *any* of the following injections or procedures experimental and investigational: • Facet chemodenervation/ chemical facet neurolysis • Laser facet denervation	
Aetna (2012) *Clinical Policy Bulletin: Pulsed Radiofrequency* POLICY #: 0735 Effective Date: 08/21/2007 Last Review Date: 12/07/2012 Next Review Date: 09/23/2013		This policy is based upon references including RCTs, systematic reviews, retrospective Cohort study, case series study	Aetna considers pulsed radiofrequency experimental and investigational for all indications, including those in the following list, because its effectiveness has not been established. • Facet joint arthropathy • Zygapophyseal joint pain.	• Radiofrequency procedures have been reported to be associated with high number of complications compared with other ablative neurosurgical techniques. Furthermore, conventional (continuous) RF treatment occasionally results in worsening and even new onset of pain. The use of pulsed radiofrequency (PRF, also known as cold RF), a non- or minimally-neurodestructive and thus less painful technique, serves as an alternative to conventional RF therapy. Pulsed radiofrequency treatment, performed under fluoroscopic guidance, entails the use of pulsed time cycle that delivers short bursts of RF energy to nervous tissue.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments

Cigna (2012)
 	
Minimally Invasive Treatment of Back and Neck Pain
 	
POLICY #: 0139
 	
Effective Date: 7/15/2012
 	
Next Review Date: 7/15/2013
	NR	This policy is based upon references including RCTs, systematic reviews, retrospective Cohort study, case series study, Meta-analysis and ASIPP practice guideline	• Cigna covers initial radiofrequency denervation of paravertebral facet joint nerves (also referred to as radiofrequency neurolysis, neurotomy, facet rhizotomy) (CPT codes 64633-64636) for the treatment of chronic back or neck pain as medically necessary when ALL of the following criteria are met:
			
			  • Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity
			  • There is severe pain unresponsive to at least six months of conservative medical management. (e.g., pharmacological therapy, physical therapy, exercise)
			  • Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in elimination or marked decrease in intensity of pain
			  • Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)
			
			• Cigna covers repeat radiofrequency denervation of paravertebral facet joint nerves at the same level for the treatment of chronic back or neck pain as medically necessary when BOTH of the following criteria are met:
			
			  • At least six months have elapsed since the previous radiofrequency ablation/neurolysis of paravertebral facet joint nerves
			  • More than 50% relief is obtained, with associated functional improvement, for at least ten weeks following the previous treatment
				• Radiofrequency denervation of facet joints has been used to treat spinal pain presumed to be of facet origin. RFA was also been explored for the treatment of SI joint pain.

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments

			• Cigna does not cover long-term or maintenance denervation of paravertebral facet joint nerves for any indication because it is considered not medically necessary.
			
			• Cigna does not cover ANY of the following ablative procedures for the treatment of back or neck pain because each is considered experimental, investigational or unproven (this list may not be all-inclusive);
			  • Pulsed radiofrequency (CPT code 64999)
			  • Cryoablation/cryoneurolysis/cryodenervation (CPT code 64999)
			  • Chemical ablation (e.g., alcohol, phenol, glycerol) (CPT codes 64622-64627)
			  • Laser ablation (CPT code 64999)
			  • Sacroiliac (SI) joint nerve ablation by any method (CPT code 64640)	

Health Net (2012) *Facet Joint Denervation* POLICY #: NMP43 Effective Date: 10/2003 Last Review Date: 1/2012	PRF- Updated 1/2012 PRF (facet neurolysis)- Updated 7/2009	This policy is based upon references including RCTs, systematic reviews, cohort and retrospective studies	Facet Joint Denervation (also referred to as neurolysis, lesioning, facet neurotomy, facet rhizotomy, or articular rhizolysis) by either injecting neurolytic substances (alcohol 50-100% or phenol) or utilizing radiofrequency thermoneurolysis (e.g. radiofrequency ablation, radiofrequency neurolysis, and/or radiofrequency thermoablation) or cryoneurolysis is medically necessary for treatment of patients with intractable chronic zygapophyseal cervical or lumbar joint pain with or without neurological compression symptoms when all of the following are met: • Trial of facet joint injections using local anesthetic has been successful in relieving the pain or, at least, a > 50% reduction of pain; and • Severe low back pain or cervical neck pain limiting	• Note - Caution is recommended for RFA treatment in patients with diabetes mellitus and in those who have undergone prior back surgery at the pain site. Scientific Rationale – Update April 2008 (2007) American Society of Interventional Pain Physicians states: • "Among the diagnostic interventions, the accuracy of facet joint nerve blocks is strong in the diagnosis of lumbar and cervical facet joint pain."

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			activities of daily living has been present for at least 6 months; and • No prior spinal fusion surgery in the same area of the spine that is to undergo radiofrequency treatment; and • Neuroradiologic studies are negative or fail to confirm disc herniation; and • Patient has no significant narrowing of the vertebral canal or spinal instability requiring surgery; and • Patient has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g. anti-inflammatory agents, analgesics and muscle relaxants. <u>Relative or Absolute Contraindications to Radiofrequency Ablation</u>: • Neurologic abnormalities; • Definitive clinical and/or imaging findings; • Proven specific causes of low back pain, including herniation, spondylolisthesis, spondylosis ankylopoetica, spinal stenosis, discogenic or stenotic compression, extensive multilevel spondylosis, clinical radiculopathy, multiple sclerosis, coagulation disorders, pregnancy, malignancy, infection, and trauma; • Allergy to radiopaque contrast or local anesthetic; • More than one pain syndrome; • Lack of response to diagnostic nerve blocks; • Psychiatric disorders. <u>Pulsed Radiofrequency Ablation</u> • Health Net, Inc. considers pulsed radiofrequency ablation investigational. The available evidence on the effectiveness of pulsed radiofrequency in the treatment	

Payer (year)	Lit search dates	Evidence base available*	Policy	Rationale/comments
			of patients with various chronic pain syndromes is largely based on retrospective, case series studies. Its clinical value needs to be examined in well-designed, randomized controlled trials with large sample size and long-term follow-up. Studies on pulsed radiofrequency ablation continue to be done.	

3. The Evidence

3.1. Methods of the Systematic Literature Review

3.1.1. Inclusion/exclusion

Inclusion and exclusion criteria are summarized in Table 6 (for Key Question 1) and Table 7 (for Key Questions 2-5).

- *Population.* Studies of adult patients being considered for facet neurotomy due to suspected facet joint pain.
- *Intervention.* Studies on facet neurotomy using FDA approved devices or other ablation techniques (e.g., chemical denervation)
- *Comparators.* Including but not limited to: alternative treatments, including sham neurotomy, therapeutic intra-articular injections or medial branch blocks, medical therapy, physical therapy, chiropractic therapy, natural history. Different types of neurotomy will also be compared.
- *Outcomes.* The primary outcomes of interest are clinically meaningful pain relief and functional improvement. Secondary outcomes include health-related quality of life (including psychological status), return to work, patient satisfaction, and opioid use. Outcomes may include composite outcome measures. Additionally, safety and complications will be reported.
- *Study design.* Eligible studies evaluated facet neurotomy utilizing a randomized or cohort study design. Case series were considered for Key Question 2b (effectiveness of repeat neurotomy) and Key Question 3 (safety). Formal economic analyses published in peer-reviewed journals were sought to address Key Question 5.

Table 6. Summary of inclusion and exclusion criteria for Key Question 1: evaluation of diagnostic blocks

Study Component	Inclusion	Exclusion
Population	Patients being considered for facet neurotomy due to suspected facet joint pain in the: • Cervical spine (includes facet joint pain from whiplash trauma) • Lumbar spine • Thoracic spine	• Cancer • Trauma (other than whiplash trauma in the cervical spine)
Intervention	Diagnostic blocks to select patients for facet neurotomy, including: • Medial branch blocks • Intra-articular injections	Therapeutic injections
Comparator	Diagnostic blocks to select patients for facet neurotomy including: KQ1a: • Alternative diagnostic test (e.g., physical examination, radiological examination) KQ1b: • Different type of diagnostic block (i.e., medial branch block or intra-articular injection) KQ1c: • Controlled diagnostic blocks (i.e., single versus two or more controlled diagnostic blocks) KQ1d: • Same type of diagnostic block with different definition of a "successful" block (i.e., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%) KQ1e: • Bilateral diagnostic block (i.e., unilateral vs. bilateral diagnostic block) KQ1f: • Diagnostic block of single versus multiple levels	
Outcomes	Clinical outcomes following therapeutic facet neurotomy, including: • Primary outcomes: Pain, physical function • Secondary outcomes: health-related quality of life (QoL) (including psychological status), return to work, patient satisfaction, opioid use	• Outcomes following diagnostic block. • Outcomes following therapeutic facet injections (including medial branch block or intra-articular injections) • Nonclinical outcomes
Study Design	• Studies that provide a direct comparison of patient selection methods of interest • Diagnostic test and therapeutic facet neurotomy performed within 3 months of each other	• Case series • Case reports • Studies in which outcomes following facet neurotomy are not evaluated • Indirect comparisons
Publication	• Studies published in English in peer reviewed journals or publically available FDA reports	• Abstracts, editorials, letters • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • White papers

Study Component	Inclusion	Exclusion
		• Narrative reviews • Articles identified as preliminary reports when results are published in later versions

Table 7. Summary of inclusion and exclusion criteria for Key Questions 2-5: evaluation of facet neurotomy

Study Component	Inclusion	Exclusion
Population	Patients being considered for facet neurotomy due to suspected facet joint pain in the: • Cervical spine (includes facet joint pain from whiplash trauma) • Lumbar spine • Thoracic spine	• Cancer • Trauma (other than whiplash trauma in the cervical spine)
Intervention	Facet neurotomy (denervation) including: • Radiofrequency neurotomy • Pulsed (cooled) radiofrequency neurotomy • Chemical (e.g., alcohol, phenol) neurotomy • Cryoablation • Laser neurotomy	Use of therapeutic injections of anesthetic and/or steroids, including: • Intra-articular injections • Medial branch blocks
Comparator	For KQ2: • Sham neurotomy • Placebo • Therapeutic intra-articular injections • Therapeutic medial branch block • Medical therapy The following subcomponents of KQ2 will only to be addressed if facet neurotomy shown to be effective in KQ2: KQ2a: • Radiofrequency neurotomy • Pulsed (cooled) radiofrequency neurotomy • Chemical (e.g., alcohol, phenol) neurotomy • Cryoablation • Laser neurotomy KQ2b: • Repeat neurotomy (at same site)following successful neurotomy KQ2c: • Bilateral facet neurotomy (i.e., unilateral vs. bilateral facet neurotomy) KQ2d: • Single- versus multi-level facet neurotomy	• Comparisons of different techniques used in neurotomy (i.e., imaging, types of tips, approach etc.) • For KQ2: different types of neurotomy
Outcomes	Efficacy and Effectiveness: • Primary outcome: pain, physical function • Secondary outcomes: health-related quality of life	• Non-clinical outcomes

	(QoL) (including psychological status), return to work, patient satisfaction, opioid use Safety: • Complications and adverse effects (e.g. procedural complications and technical failures).	
Study Design	• For all key questions, focus will be placed on studies with the least potential for bias. • Key Questions 1 & 2: RCTs and nonrandomized comparative studies • Key Question 3 (safety): RCTs and non-randomized studies from Key Question 1 will be included. Additional comparative studies and case series designed specifically to evaluate adverse events will also be considered. • Key Question 4 (differential efficacy): RCTs or high quality cohort studies with low risk of bias • Formal, full economic studies will be sought for Key Question 5	• Non-clinical studies, studies of technique, imaging. • Studies with < 10 patients per treatment group • Case series except for KQ3 as specified in inclusion criteria: For case series related to safety: prospective series with N < 50 patients and retrospective series with N < 100 patients will be excluded • Studies with less than 80% of patients being treated for facetogenic pain will be excluded
Publication	• Studies published in English in peer-reviewed journals, published HTAs or publically available FDA reports • Full, formal economic analyses (e.g. cost-utility studies) published in English in HTAs or in a peer-reviewed journals published after those represented in previous HTAs	• Studies reporting only on the technical aspects of neurotomy (e.g., imaging, approach, etc.) • Abstracts, editorials, letters • Unpublished studies • Duplicate publications of the same study which do not report on unique outcomes • Single reports from multicenter trials • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions • Incomplete economic evaluations such as costing studies

3.1.2. Study design

As noted in Table 7, the focus for all key questions will be placed on studies with the least potential for bias. For Key Question 2, RCTs and nonrandomized comparative studies were included. Because this key question asks about the comparative efficacy and effectiveness of facet neurotomy compared with alternative treatments, the focus was necessarily placed on randomized controlled trials to address efficacy and nonrandomized comparative cohort studies to address effectiveness. Case series, which report on a group of patients who have been treated in a similar manner and don't include a concurrent control group, were not included to address this key question. While there are advantages to using case series (including evaluating rare outcomes, safety data, and new treatments), the effect of the treatment of interest can't be compared to that of another

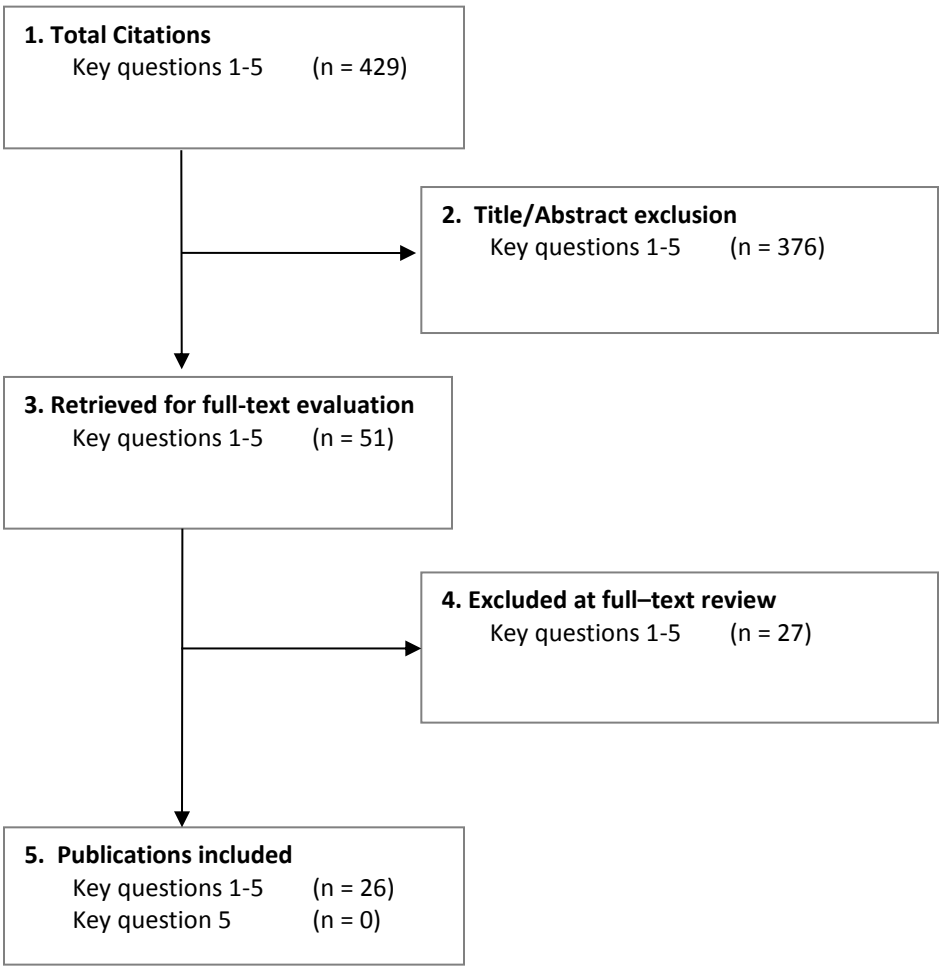
treatment.[163, 164] Without a comparator, a treatment can't be directly attributed to the treatment administered as the outcomes could be due to other factors, such as unaccounted for patient characteristics.[163] Although as noted by the Cochrane Handbook, there is a trade-off between using more restrictive study design criteria (in this case, including comparative studies, which have lower risk of bias) and more broad study design criteria (in this case, including case series, which would result in the inclusion of more studies that are at a higher risk of bias)[165]. In the case of this report, comparative studies were sought as they best answered the comparative questions being asked.

3.1.3. Data sources and search strategy

The clinical studies included in this report were identified using the algorithm shown in Appendix A. The search took place in four stages. The first stage of the study selection process consisted of a comprehensive literature search using electronic means and hand searching. We then screened all possible relevant articles using titles and abstracts in stage two. This was done by two individuals independently. Those articles that met a set of *a priori* retrieval criteria based on the criteria above were included. Any disagreement between screeners that were unresolved resulted in the article being included for the next stage. Stage three involved retrieval of the full text articles remaining. The final stage of the study selection algorithm consisted of the selection of those studies using a set of a priori inclusion criteria, again, by two independent investigators. Those articles selected form the evidence base for this report.

We searched electronic databases from their inception through October 4, 2013 to determine new publications since our original report. Electronic databases searched included PubMed, *The Cochrane Library*, FDA, and AHRQ for eligible studies, including health technology assessments (HTAs), systematic reviews, primary studies and FDA reports. The search strategies used for PubMed are shown in Appendix B. Figure 1 shows a flow chart of the results of all searches for included primary studies. Articles excluded at full-text review are listed in Appendix C.

Figure 1. Flow chart showing results of literature search



3.1.4. Data extraction

Reviewers extracted the following data from the included clinical studies: study design, study patient demographics (including population characteristics), intervention methods, diagnostic block and response required for patients to proceed to facet neurotomy, diagnostic evaluation (including clinical and radiological assessments and diagnostic block details), follow-up time, study outcomes (functional and clinical, motion, radiographic), inclusion/exclusion criteria, follow-up duration, and outcomes reported (including pain, function, patient satisfaction, medication use and return to work, and complications and adverse events (any reported) An attempt was made to reconcile conflicting information among multiple reports presenting the same data. For economic studies, data related to sources used, economic parameters and perspectives, results, and sensitivity analyses were abstracted.

3.1.5. Study quality assessment: Class of evidence (CoE) evaluation

The method used by Spectrum Research, Inc. (SRI) for assessing the quality of evidence of individual studies as well as the overall quality of evidence incorporates aspects of the rating scheme developed by the Oxford Centre for Evidence-based Medicine,[136] precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group,[6] and recommendations made by the Agency for Healthcare Research and Quality (AHRQ).[182]

Details of the Class of evidence (CoE) methodology are found in Appendix D. Each study chosen for inclusion was given a CoE rating based on the quality criteria listed in Appendix D. Standardized abstraction guidelines were used to determine the CoE for each study included in this assessment.

3.1.6. Analysis

While we attempted to pool functional outcomes when two or more randomized controlled studies presented identical outcomes over similar time periods, we did not pool the functional outcomes from observational studies due to heterogeneity between studies. Because of differences in methodology between trials, including differences in diagnostic block, comparator treatment, and/or length of follow-up, none of the outcomes were pooled. To compare the estimates of procedure effectiveness across studies using continuous outcomes, differences in means were computed. First, the pre- and post-procedure means were differenced within each treatment arm to arrive at a measure of change induced by each procedure. The mean change for each arm was then compared with the other. The difference between them was used as the effect size estimate. When necessary, standard deviations of the change within treatment groups were calculated assuming a correlation of 0.8. Standard deviations across groups were found using the formula below:

$$s_i = \sqrt{\frac{(n_{1i}-1)sd_{1i}^2 + (n_{2i}-1)sd_{2i}^2}{N_i - 2}}$$

where for study i: s_i is the pooled standard deviation, n_i is the sample size, N_i is the pooled sample size, and $sdj,_i$ is the standard deviation of treatment j.

When preoperative scores were not reported, the postoperative scores for each procedure were compared directly. We did not impute missing standard deviations from baseline or follow-up scores as suggested by the Cochrane handbook, as the majority of studies had missing standard deviations.[74]

P-values were calculated using the mean change score, the calculated (or reported) standard deviation for the mean change score, and patient numbers for each treatment group. The reported p-values were calculated using the unpaired t-test using GraphPad (http://graphpad.com/quickcalcs/ttest1/?Format=SD).

To compare proportions, we calculated the risk ratios and risk differences across treatments. Calculations were performed using the freely available Rothman Episheet (*www.k**rothman**.org/**Episheet**.xls*).

To explore the possibility of differential effectiveness (Key Question 4), we compared the difference in outcomes between RF neurotomy and sham neurotomy within each subgroup stratum. We tested the difference between subgroups by calculating the p-value according to the Breslow Day test for interaction.

3.2. Quality of Literature Available

3.2.1. Number and quality of studies retained

We identified 429 citations from our electronic search through October 4, 2013 using the search strategy in Appendix B.

Key Question 1a-d:

- ***Key Question 1a (diagnostic block versus alternative diagnostic test):***
  - Lumbar Spine: 1 RCT (Cohen 2011)[21] (CoE II) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria
  - 5 studies were excluded from this Key Question at full-text review (see Appendix C for details).
- ***Key Question 1b (type of diagnostic block):***
  - Lumbar Spine: 1 RCT (Birkenmaier 2007)[12] (CoE II) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria
  - No studies were excluded from this Key Question at full-text review.
- ***Key Question 1c (single versus controlled or comparative diagnostic blocks):***
  - Lumbar Spine: 1 RCT (Cohen 2011)[21] (CoE II) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria.
  - 6 studies were excluded from this Key Question at full-text review (see Appendix C for details).
- ***Key Question 1d (degree and duration of pain reduction from diagnostic block):***
  - Lumbar Spine: 4 cohort studies (Cohen 2008, Cohen 2013, Derby 2012, Derby 2013)[22-25] (all CoE II) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria

- 7 studies were excluded from this Key Question at full-text review (see Appendix C for details).

- ***Key Question 1e (unilateral versus bilateral diagnostic block):***
  - No studies met our inclusion criteria.
- ***Key Question 1f (single versus multilevel diagnostic block):***
  - No studies met our inclusion criteria.

Key Question 2: Comparative efficacy and effectiveness of facet neurotomy compared with alternatives:

A total of 4 studies were excluded from this Key Question at full-text review (see Appendix C for details).

- ***Efficacy, facet neurotomy versus sham neurotomy in the lumbar spine:***
  - 6 RCTs[26-31] (Gallagher 1994, Leclaire 2001, Nath 2008, Tekin 2007, van Kleef 1999, van Wijk 2005) met our inclusion criteria
- ***Effectiveness, facet neurotomy versus sham neurotomy in the lumbar spine:***
  - No studies met our inclusion criteria.
- ***Efficacy, facet neurotomy versus sham neurotomy in the cervical spine:***
  - 1 RCT[32] (Lord 1996) met our inclusion criteria.
- ***Effectiveness, facet neurotomy versus sham neurotomy in the cervical spine:***
  - No studies met our inclusion criteria.
- ***Efficacy, facet neurotomy versus therapeutic spinal injections in the lumbar spine:***
  - 2 RCTs[33, 34] (Civelek 2012, Lakemeier 2013) met our inclusion criteria.
- ***Effectiveness, facet neurotomy versus therapeutic spinal injections in the lumbar spine:***
  - 1 retrospective audit study[35] (Chakraverty 2004) met our inclusion criteria
- ***Efficacy, facet neurotomy versus therapeutic spinal injections in the cervical spine:***
  - 1 RCT[36] (Haspeslagh 2006) met our inclusion criteria.
- ***Effectiveness, facet neurotomy versus therapeutic spinal injections in the cervical spine:***
  - No studies met our inclusion criteria.
- No thoracic spine studies met our inclusion criteria.

Key Question 2a-d:

- ***Key Question 2a (comparison of different types of neurotomy):***
  - Lumbar Spine: 3 RCTs[29, 37, 38] (Kroll 2007, Tekin 2007, Joo 2013) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria
  - 2 studies were excluded from this Key Question at full-text review (see Appendix C for details).
- ***Key Question 2b (repeat neurotomy):***
  - Lumbar Spine: 6 studies[38-43] (Joo 2013, Rambaransingh 2010, Schofferman 2004, Speldewinde 2011, Son 2010, Zotti 2010) met our inclusion criteria.
  - Cervical Spine: 3 studies[39, 42, 44] (Husted 2009, Rambaransingh 2010, Speldewinde 2011) met our inclusion criteria.

- 6 studies were excluded from this Key Question at full-text review (see Appendix C for details).

- ***Key Question 2c (unilateral versus bilateral facet neurotomy):***
  - Lumbar Spine: 1 cohort study[45] (Tzaan) met our inclusion criteria.
  - Cervical, Thoracic Spine: no studies met our inclusion criteria
  - 4 studies were excluded from this Key Question at full-text review (see Appendix C for details).
- ***Key Question 2d (single versus multilevel facet neurotomy):***
  - No studies met our inclusion criteria.
  - 6 studies were excluded from this Key Question at full-text review (see Appendix C for details).

For Key Question 3: Comparative safety of facet neurotomy compared with other treatments

- Data on harms/complications as reported in the comparative studies included in Key Question 2 were included.
- No case series met our inclusion criteria.

For Key Question 4: Differential efficacy and safety of facet neurotomy compared with other treatments in subgroups

- Data on differential efficacy and safety as reported in the comparative studies included in Key Question 2 were included.
- In addition, results from studies included in KQ2 that selected patients for facet neurotomy on the basis of ≥50% pain relief following medial branch block were pooled.

For Key Question 5: Cost effectiveness of facet neurotomy

- No studies met our inclusion criteria.
- 6 studies were excluded from this Key Question at full-text review (see Appendix C for details).

3.2.2. Critical Appraisal

Studies included for each study are summarized below. Details on the Class of Evidence (CoE) grading are available in Appendix E, and detailed demographic information and results can be found in Appendix F.

Key Question 1a:

Cohen (2010)

Cohen et al. (2010)[21] conducted an RCT that evaluated different diagnostic paradigms to select patients to undergo RF neurotomy. For inclusion in the study, patients were required to have had predominantly axial low back pain for at least three months that has been unresponsive to conservative therapy, have paraspinal tenderness, and have an absence of focal neurologic signs or symptoms. Patients were randomized to undergo either no diagnostic block (i.e., clinical exam alone, as achieved by the inclusion criteria) or one diagnostic medial branch block with 0.5 ml 0.5% bupivacaine. All 51 patients randomized to receive no diagnostic block underwent RF neurotomy. In contrast, patients randomized to receive one diagnostic medial branch block were required to have 50% or more pain relief for at least three hours following the block: of the

50 patients who underwent the block, only 19 achieved sufficient pain relief to proceed to RF neurotomy. Facet neurotomy was performed within four weeks of the diagnostic block, details of which are available in Appendix F. Median patient age was 42 years, and 56% of patients were males. The median duration of symptoms was 3 years, and ranged from 0.5 to 14 years. The methods by which randomization and allocation concealment were achieved were not reported. Although there was no explicit statement that data were analyzed according to the intention to treat principle, they appear to have been handled this way. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. The objectives of this study were to assess which diagnostic and treatment paradigm was associated with the highest success rates following RF neurotomy. The complete follow-up rate was low, at 51%; outcomes were reported at three months follow-up. The study was funded by a Congressional Grant from the John P. Murtha Neuroscience and Pain Institute, the U.S. Army, and the Army Regional Anesthesia and Pain Medicine Initiative. This study received a class of evidence (CoE) grade of II.

Key Question 1b:

Birkenmaier (2007)

Birkenmaier et al. (2007)[12] conducted a small RCT in which patients with suspected lumbar facet joint pain were randomized to one of two different diagnostic blocks: medial branch blocks or pericapsular blocks. Patients with adequate response to these blocks proceeded to under cryodenervation of the facet joint. For inclusion in the study, patients were required to have had non-sciatic low back pain for at least three months that has been unresponsive to conservative therapy, have localized paraspinal tenderness and tenderness to pressure, and have a positive response to the diagnostic block. The diagnostic block was performed on the medial branch (medial branch block) or on the posterior surface of the facet joint (pericapsular block); both blocks used 1 ml 0.5% bupivacaine. In order to proceed to neurotomy, patients were required to have 50% or more pain relief for at least three hours following the block. Thirteen patients in each block group were treated with cryodenervation, details of which are available in Appendix F. Details on patient age, sex, and duration of pain were not reported. Patients were randomized to a computer-generated randomization list; details on how allocation concealment was achieved were not reported. Although there was no explicit statement that data were analyzed according to the intention to treat principle, they appear to have been handled this way. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. The objective of this study was to determine whether medial branch blocks are superior to simple pericapsular blocks when selecting patients to undergo lumbar facet joint cryodenervation. The percentage of patients with complete follow-up was not reported; outcomes were reported at up to six months follow-up. Study funding was not reported. This study received a class of evidence (CoE) grade of II.

Key Question 1c:

Cohen (2010)

Cohen et al. (2010)[21] conducted an RCT that evaluated different diagnostic paradigms to select patients to undergo RF neurotomy. For inclusion in the study, patients were required to have had predominantly axial low back pain for at least three months that has been unresponsive to conservative therapy, have paraspinal tenderness, and have an absence of focal neurologic signs or symptoms. Patients were randomized to undergo one either diagnostic medial branch block with 0.5 ml 0.5% bupivacaine or comparative diagnostic medial branch blocks (one with 0.5 ml 0.5% bupivacaine and another with 0.5 ml 2% lidocaine). Patients randomized to receive one

diagnostic medial branch block were required to have 50% or more pain relief for at least three hours following the block: of the 50 patients who underwent the block, only 19 achieved sufficient pain relief to proceed to RF neurotomy. Patients randomized to receive comparative blocks were required to have at least 50% concordant pain relief from both blocks. Facet neurotomy was performed within four weeks of the diagnostic block: of the 50 patients who underwent the block, only 14 achieved sufficient pain relief to proceed to RF neurotomy, details of which are available in Appendix F. Median patient age was 42 years, and 56% of patients were males. The median duration of symptoms was 3 years, and ranged from 0.5 to 14 years. The methods by which randomization and allocation concealment were achieved were not reported. Although there was no explicit statement that data were analyzed according to the intention to treat principle, they appear to have been handled this way. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. The objectives of this study were to assess which diagnostic and treatment paradigm was associated with the highest success rates following RF neurotomy. The complete follow-up rate was low, at 57%; outcomes were reported at three months follow-up. The study was funded by a Congressional Grant from the John P. Murtha Neuroscience and Pain Institute, the U.S. Army, and the Army Regional Anesthesia and Pain Medicine Initiative. This study received a class of evidence (CoE) grade of II.

Key Question 1d:

Cohen (2008)

Cohen et al. (2008)[22] conducted a retrospective cohort study in which different pain cutoff values following the diagnostic block were used for selecting patients to undergo RF neurotomy. For inclusion, patients were required to have had chronic lower back pain for more than three months with an absence of focal neurological signs or symptoms. Patients underwent diagnostic medial branch block with 0.5 ml bupivacaine or ropivacaine, and those who achieved at least 50% pain relief within the 6 to 8 hours after the block were selected for RF denervation. A total of 262 patients underwent neurotomy, details of which are available in Appendix F. The mean patient age was 54 years, and 47% of patients were males. The mean duration of symptoms was 5.7 years and ranged from 0.5 to 40 years. It was not possible for patients to be blinded to their diagnostic group, and the primary outcomes were patient-reported. The objective of this study was to compare RF denervation success rates between patients who achieved the "conventional" threshold of 50% pain relief with those who achieved a more stringent threshold of 80% pain relief following the diagnostic medial branch block. The complete follow-up rate was 90%; outcomes were reported at six months follow-up. The study was funded by the John P. Murtha Neuroscience and Pain Institute, and the Army Regional Anesthesia and Pain Medicine Initiative. This study received a class of evidence (CoE) grade of III.

Cohen (2013)

Cohen et al. (2013)[23] reported outcomes from a prospective cohort study in which different pain cutoff values following the diagnostic block were correlated with outcomes following RF neurotomy. For inclusion, patients were required to have predominantly axial lower back pain for at least three months that has been unresponsive to conservative therapy, have paraspinal tenderness, and an absence of focal neurological signs or symptoms. Patients were also required to be satisfied with the relief achieved from the diagnostic block, which employed 0.5 ml 0.5% bupivacaine. Pain relief following the diagnostic block was recorded every 30 minutes for 8 hours. RF denervation was performed within one month of diagnostic blocks on the 61 patients who met the inclusion criteria. Details on the procedure are available in Appendix F. The mean

patient age was 51 years, 59% of patients were males, and the mean duration of symptoms was 6.5 years. It was not possible for patients to be blinded to their diagnostic group, and the primary outcomes were patient-reported. The purpose of this study was to assess the ideal level of pain relief that should be obtained from diagnostic medial branch block in order to undergo RF denervation. Among patients who had a positive diagnostic block, the complete follow-up rate was not reported; outcomes were reported at three months follow-up. The study was funded by the John P. Murtha Neuroscience and Pain Institute, and the Army Regional Anesthesia and Pain Medicine Initiative. This study received a class of evidence (CoE) grade of III.

Derby (2012),

Derby et al. (2012)[24] conducted a retrospective cohort study in which the percentage of pain relief following the diagnostic block was incrementally correlated with outcomes following RF neurotomy. For inclusion, patients were required to have debilitating low back pain with or without proximal nonradicular extremity pain that has lasted for at least six months, was clinically suggestive of lumbar facet pain, and has been unresponsive to conservative treatment. Patients underwent one or two separate medial branch block procedures with 0.2-0.3 mL bupivacaine (0.5-0.75%); at least injections were performed per block along the target medial branch. Pain relief following the diagnostic block was recorded for several days and those who achieved at least 50% pain relief for two hours were offered RF neurotomy. A total of 51 patients underwent neurotomy; details on the procedure are available in Appendix F. The mean patient age was 58 years, 45% of patients were males, and the mean duration of symptoms was 10.1 years. It was not possible for patients to be blinded to their diagnostic group, and the primary outcomes were patient-reported. The purpose of this study was to determine the ideal cutoff value following medial branch block in order to optimize results following RF neurotomy. Among patients who had a positive diagnostic block, the complete follow-up rate was 61%; outcomes were reported at six months follow-up. Study funding was not reported, and the study received a class of evidence (CoE) grade of III. There were likely some patients reported in this study that overlap in the Derby 2013[25] study; here, patients were treated between August 2009 and September 2010 (versus August 2007 to February 2010 for the Derby 2013 study), however, different outcomes were reported for these studies.

Derby (2013)

Derby et al. (2013)[25] conducted a retrospective cohort study in which the percentage of pain relief following the diagnostic block was incrementally correlated with outcomes following RF neurotomy. Inclusion criteria and diagnostic block details were identical with those described above for Derby 2012[24]. Here, a total of 52 patients underwent neurotomy; details on the procedure are available in Appendix F. The mean patient age was 59 years, 50% of patients were males, and the mean duration of symptoms was 13 years. It was not possible for patients to be blinded to their diagnostic group, and the primary outcomes were patient-reported. One goal of this study was to correlate outcomes following RF neurotomy with the percentage of pain relief achieved with the diagnostic block. Among patients who had a positive diagnostic block, the complete follow-up rate was 57%; outcomes were reported at six months follow-up. Study funding was not reported, and the study received a class of evidence (CoE) grade of III. There were likely some patients reported in this study that overlap in the Derby 2012[24] study; here, patients were treated between August 2007 to February 2010 (versus August 2009 and September 2010 for the Derby 2012 study), however, different outcomes were reported for these studies.

Key Question 2:

RF neurotomy versus sham neurotomy (lumbar spine)

Gallagher (1994)

Gallagher et al.[26] conducted an RCT in which patients with back pain of greater than three months duration and was suggestive of originating in the facet joint (see Appendix F demographic table) underwent a diagnostic block with 0.5% bupivacaine into and around the affected joints. The 41 patients who had some pain relief from this block were then randomized to undergo either RF neurotomy (n = 24) or sham neurotomy (n = 17). The authors further subdivided the results into those who had a "good" response to the diagnostic block and those who had an "equivocal" response to a diagnostic block, though these terms were not specifically defined. For those who had "good" response to diagnostic block, 18 patients received RF neurotomy and 12 patients received sham neurotomy: although "good" response was not defined, these are the patients we have reported on in Key Question 2 to assess the efficacy of RF neurotomy since patients are typically required to have a positive response to diagnostic block in order to undergo facet neurotomy. The remaining 12 patients in the RF neurotomy group are used in our comparison of outcomes following facet neurotomy in patients with different levels of responses to diagnostic blocks (Key Question 1d). During the fluoroscopically-guided procedure, the electrode location was first confirmed using sensory stimulation, and the area was anesthetized. Patients then received either a RF lesion at 80°C for 90 seconds or received no lesion (sham). The number of levels treated was not reported. No statement was made regarding immediate or long-term post-treatment care. The authors reported very little demographic information: mean patient age was not reported, though were only eligible for inclusion if they were between the ages of 25 and 55 years. Patient sex and mean duration of pain were not reported. Patients who had undergone previous back operations or had pending compensation claims were excluded. The methods by which randomization and allocation concealment were achieved were not reported, nor was any information regarding whether data were analyzed according to the intention to treat principle. It was not clear whether patients were blinded to their treatment group, though the data collectors were blinded. The objectives of this study were to evaluate whether there were differences between the groups in pain outcomes (as measured by the patient-reported VAS and the clinician-reported McGill pain score) and complications. The complete follow-up rate was 100%; outcomes were reported at one and six months follow-up. No funding information was reported. This study received a class of evidence (CoE) grade of II.

Leclaire (2001)

Leclaire et al.[27] performed a double-blind RCT in which patients with low back pain of greater than three months duration and was suggestive of originating in the facet joint were considered for inclusion by undergoing an intra-articular diagnostic block. Those 70 patients who experienced "significant" (undefined) relief of their low back pain for at least 24 hours during the week after the block were randomized to undergo either RF neurotomy (n = 36) or sham neurotomy (n = 34). The procedures were performed using fluoroscopic guidance and local anesthetic. After confirmation of electrode location at each affected level, those randomized to receive RF neurotomy received two RF lesions at each affected nerve using a 5-mm tip electrode at 80°C for 90 seconds. Those randomized to receive sham neurotomy underwent the same procedure using an electrode maintained at 37°C. Patients were treated at a minimum of two levels, though the mean number of levels treated per patient was not reported. Participants were advised to limit concurrent inventions and medications, and noted any co-interventions

they used. For inclusion, patients were required to be between the ages of 18 and 65 years; the mean patient age was 46 ± 10 years. Males comprised 36% of the overall patient population, and the mean duration of pain was not reported. Patients who had undergone previous back surgery were excluded. The method by which randomization was performed were not reported, and allocation was concealed using opaque pre-numbered envelopes. Data were analyzed according to the intention to treat principle. The patients were blinded to their treatment group, as were the research assistant and the physicians responsible for post-neurotomy care. The objectives of this study were to evaluate whether there were differences between the groups in pain outcomes (as measured by the patient-reported VAS), function (as measured by the patient-reported Roland-Morris and ODI outcome measures), analgesic use, return to work, and complications. The complete follow-up rate was 94%; outcomes were reported at one and/or three months follow-up. The study was funded by a grant from the Institute de recherce en santé at sécurité du travail du Québec. This study received a class of evidence (CoE) grade of II.

Nath (2008)

Nath et al.[28] conducted a double-blind RCT in which patients who had been experiencing continuous low back pain for at least two years, had not responded to previous treatment, and whose pain was suspected of originating in the facet joint (i.e., paravertebral tenderness) were considered for inclusion by undergoing controlled diagnostic medial branch blocks. Those 40 patients who experienced at least 80% pain relief of their low back pain following both injections (lidocaine or bupivacaine) during the 24 hours following the block and who had longer lasting pain relief following injection of bupivacaine were randomized to undergo either RF neurotomy (n = 20) or sham neurotomy (n = 20). The procedures were performed using fluoroscopic guidance and local anesthetic. Aside from the temperature of the electrode, both procedures were identical. Patients in the RF neurotomy received between two and six RF lesions using a 5-mm tip electrode at 85°C for 60 seconds, while the electrode was maintained at 37°C for patients in the sham group. The number of levels treated was not reported. No statement was made regarding immediate or long-term post-treatment care. The mean patient age was 55 years, and patients were between 36 and 79 years of age. Males made up 38% of the overall patient population, and the mean duration of pain was not reported. Randomization was performed using a computer-generated randomization schedule, and the method by which allocation concealment was achieved was not reported. It was not clear that data were analyzed according to the intention to treat principle. Except for the person who controlled the RF machine, everyone in the study (including the patients) was blinded. The objectives of this study were to evaluate whether there were differences in outcomes between the patients with chronic facetogenic pain (and who had not responded to other treatments) after undergoing RF or sham neurotomy. Outcomes evaluated included pain (as measured by the patient-reported VAS), patient satisfaction (as measured by the patient-reported subjective global assessment of improvement), analgesic use, and work (as measured by patients on a six-point scale). The complete follow-up rate was 100%; outcomes were reported at six months follow-up. The authors received no funding or other benefits to support the study. This study received a class of evidence (CoE) grade of II.

Tekin (2007)

Tekin et al.[29] conducted a double-blind RCT in which patients who had been experiencing continuous low back pain for at least six months, had not responded to previous treatment, and whose pain was suspected of originating in the facet joint (i.e., paravertebral tenderness) were

considered for inclusion. Patients underwent a single diagnostic medial branch block with lidocaine, and patients who reported a minimum of 50% reduction in their VAS pain scores in a time frame that coincided with the expected duration of lidocaine were randomized to undergo either conventional (continuous) RF neurotomy (n = 20), pulsed RF neurotomy (n = 20), or sham neurotomy (n = 20). (Because all other studies included in Key Question 2 employed conventional continuous RF neurotomy, we included outcomes following this treatment to sham neurotomy in this key question. Outcomes following pulsed RF neurotomy were compared with those following conventional continuous RF neurotomy in Key Question 2a.) All procedures employed fluoroscopic guidance and local anesthetic and correct electrode placement was confirmed by both sensory and motor stimulation. Patients in the conventional continuous RF neurotomy group received a single lesion using a 10-mm tip electrode at 80°C for 90 seconds, while the electrode was not switched on for patients in the sham group. Pulsed neurotomy was achieved by applying 2 Hertz waves for four minutes (45 volts) using an electrode set at 42°C .The number of levels treated was not reported. No interventions beside nonsteroidal anti-inflammatory drugs were given during the follow-up group. Across all three groups, the mean patient age was 59 ± 9 years, and patients were greater than 17 years of age. Males comprised 43% of patients, and the mean duration of pain was not reported. Patients who had undergone previous RF neurotomy were excluded. Randomization was achieved by random number generation and was balanced after every eight patients, and the method by which allocation concealment was achieved was not reported. It was not clear that data were analyzed according to the intention to treat principle. Both the patients and the data collectors were blinded. The primary goal of this study was to compare outcomes following conventional versus pulsed RF neurotomy of medial branches of dorsal rami. Outcomes evaluated included pain (as measured by the patient-reported VAS), function (as measured by the patient-reported ODI outcome measure), patient satisfaction (patient-reported and measured on a four-point scale), analgesic use, and complications. The complete follow-up rate was 100%; outcomes were reported at six and/or twelve months follow-up. Study funding was not reported. This study received a class of evidence (CoE) grade of II.

van Kleef (1999)

Van Kleef et al.[30] performed a double-blind RCT that compared RF neurotomy to sham neurotomy. Patients considered for inclusion had chronic back pain of at least 12 months that was considered a mean of at least 4-points or reached a high of at least 7 points (on a 10-point VAS) and had failed conservative therapy treatment. Patients underwent diagnostic medial branch blocks of both levels for each affected joint, and those who reported a minimum of 50% reduction in their VAS pain scores 30 minutes after the injection of lidocaine were randomized to undergo either RF neurotomy (n = 15) or sham neurotomy (n = 16). All procedures were visualized using fluoroscopy and employed local anesthetic. After correct electrode placement was confirmed by both sensory and motor stimulation, those in the RF neurotomy group received a single lesion using a 5-mm tip electrode at 80°C for 60 seconds, while the electrode was not switched on for patients in the sham group. The number of levels treated was not reported. No statement was made regarding immediate or long-term post-treatment care, though patients were instructed to record analgesic use. For inclusion, patients had to be between 20 and 60 years of age; mean patient age was 44 ± 8 years. Males made up 36% of patients. Of note, patients in the RF group had considerably shorter median duration of pain (26 months, range 12 to 120 months) than did those in the sham group (median, 48 months, range of 12 to 192 months), and outcomes were adjusted for baseline differences between treatment groups . Patients who had undergone previous back surgery were excluded. Patients were

randomized in blocks of two using a computer program, and the method by which allocation concealment was achieved was not reported. It was not clear that data were analyzed according to the intention to treat principle. Both the patients and the data collectors were blinded. The primary goal of this study was to evaluate the efficacy of RF neurotomy of the lumbar facet joints in terms of pain (as measured by the patient-reported VAS), function (as measured by the patient-reported ODI outcome measure, and in change in physical impairment according to the Waddell scale), patient satisfaction (as measured by patient-reported global perceived effect, and the COOP/WONCA outcome measure), analgesic use, and complications. The complete follow-up rate was not reported; outcomes were reported at two months follow-up. The study was funded by a grant from the Nederlandse Organisatie voor Wetenschappe likj Onderzoek. This study received a class of evidence (CoE) grade of II.

van Wijk (2005)

Van Wijk et al.[31] conducted a double-blind RCT that compared RF neurotomy to sham neurotomy for the treatment of chronic back pain. Patients considered for inclusion had continuous back pain for more than six months with focal tenderness over the facet joints. Diagnostic intra-articular block was performed using lidocaine; patients who reported a minimum of 50% reduction in their VAS pain scores 30 minutes after the injection of lidocaine were randomized to undergo either RF neurotomy (n = 40) or sham neurotomy (n = 41). All procedures used fluoroscopic guidance and employed injection of local anesthetic. After correct electrode placement was confirmed by both sensory and motor stimulation, those in the RF neurotomy group received two lesions per level using a 5-mm tip electrode at 80°C for 60 seconds, while the electrode was not switched on for patients in the sham group. The number of levels treated was not reported. No statement was made regarding immediate or long-term post-treatment care. For inclusion, patients had to be greater than 17 years of age, and mean patient age was 48 ± 12 years. Males comprised 28% of included patients. Although the mean duration of symptoms was not reported, the authors reported that 21% of patients had pain of two years or less duration, 27% had pain of two to five years duration, and 49% had pain of greater than five years duration (two patients were not reported on). Patients who had undergone prior RF neurotomy or previous low back surgery were excluded. Randomization was performed by an independent organization, and patients were stratified according to sex; data appeared to be handled according to the intention to treat principle. Except for the person who controlled the RF machine, everyone in the study (including the patients) was blinded. The objective of this study was to assess the efficacy of RF facet joint neurotomy in terms of pain (as measured by the patient-reported VAS, as well as and global perceived effect), function (as measured by the patient-reported physical activities), a composite measure of success, quality of life (as measured by the patient-reported SF-36), analgesic use, and complications. The complete follow-up rate was 100% at three months but otherwise was not reported; outcomes were reported at three, six, nine, and twelve months follow-up. The study was funded by a grant from the Dutch Health Insurance Council and by a contribution from the Pain Expertise Center Nijmegen. This study received a class of evidence (CoE) grade of II.

RF neurotomy versus sham neurotomy (cervical spine)

Lord (1996)

Lord et al.[32] performed a double-blind RCT in which patients with cervical zygapophysial joint pain between C3-4 and C6-7, who had failed conservative treatment, and who had responded to medial branch block were randomized to receive RF neurotomy (n = 12) or sham neurotomy (n = 12). Prior to randomization, each patient had undergone controlled medial branch blocks with

lidocaine, bupivacaine, and saline on separate occasions. Only those patients who reported complete relief of pain when the anesthetic was injected and no pain relief when the saline was injected were included in the study. All procedures were performed using fluoroscopic guidance and regional anesthesia. No confirmation of electrode location was reported. Patients randomized to receive RF neurotomy received two to three RF lesions at each affected nerve using a 4-mm tip electrode at 80°C for 90 seconds. Those randomized to receive sham neurotomy underwent the same procedure using an electrode maintained at 37°C. The mean number of levels treated per patient was not reported. Most patients (17/24) had unilateral pain, while seven had pain stemming from more than one source. Mean patient age was 44 ± 12 years, and males comprised 38% of the overall patient population. The mean duration of pain was 44 months in the RF neurotomy group and 34 months in the sham neurotomy group, a difference which was not adjusted for. Randomization was performed using a computer-generated schedule of random numbers; the method by which allocation concealment was achieved as not reported. Although there was no statement regarding whether data were analyzed according to the intention to treat principle, data appear to have been handled this way through the eight week follow-up. Both the patients and the surgeon were blinded to treatment received. The objectives of this study were to evaluate whether there were differences between the groups in pain outcomes (as measured by patient's subjective report of improvement and time to relapse to 50% of pretreatment pain levels) and complications. The complete follow-up rate was 100%; the primary outcome of freedom from pain was reported at approximately six months. The study was funded by the Motor Accidents Authority of New South Wales. This study received a class of evidence (CoE) grade of II.

RF neurotomy versus spinal injections (lumbar spine)

Civelek (2012)

Civelek et al.[33] performed a randomized controlled trial (RCT) in which 100 patients with chronic debilitating back pain that was believed to originate in the facet joint and did not respond to conservative treatment. No information on diagnostic blocks was reported. Patients were randomized to undergo either RF neurotomy (n = 50) or therapeutic median branch block (n = 50). Both procedures were fluoroscopically-guided, and no patients received local anesthetic. Those in the RF neurotomy group were treated at a mean number of 1.6 levels per patient (range, one to four levels). Following confirmation of correct electrode placement using sensory and motor stimulation, patients received a single RF lesion at 80°C for 120 seconds using a 5-mm electrode tip. Those in the injection group were treated at a mean number of 1.7 levels per patient (range, one to four levels). An injection of steroid and anesthetic mixture was targeted at the medial branch of the dorsal spinal ramus. Patients were discharged approximately 24 hours post-treatment, and rested the treated region for several days. Pain medication was provided for one week. The mean patient age was 54 ± 17 years, and 30% of patients were male. Mean duration of pain was approximately 19 months in both treatment groups. Randomization was performed using random number generation, with patient numbers balanced after every ten patients. The method by which allocation concealment was achieved was not reported, nor was any information regarding whether data were analyzed according to the intention to treat principle. Patients were not blinded to their treatment group, and although the data collectors were blinded, most outcomes were patient-reported. The objectives of this study were to compare the efficacy of RF facet neurotomy to facet joint injections in patients with chronic low back pain. Outcomes reported included pain (as measured by the patient-reported VAS), patient satisfaction (as measured by the patient-reported NASS patient satisfaction outcome measure), quality of life (as measured by the

patient-reported EQ-5D outcome measure), a composite outcome of success, and complications. The complete follow-up rate was 100%; outcomes were reported at six and twelve months follow-up. No funding information was reported. This study received a class of evidence (CoE) grade of II.

Lakemeier (2013)

Lakemeier et al.[34] performed an RCT in which patients with facet-related chronic low back pain of at least 24 months and involving L3/L4 to L5/S1 were considered for inclusion. Patients received a diagnostic intra-articular block with bupivacaine into the affected joints; those who had at least 50% pain relief as well as MRI-confirmation of lumbar facet joint osteoarthritis and hypertrophy in the affected segments were included. Patients were randomized to undergo either RF neurotomy (n = 29) or therapeutic intra-articular facet joint injections plus sham neurotomy (n = 27). Both procedures were fluoroscopically-guided and correct electrode placement ensured (using sensory and motor stimulation for denervation patients and using contrast medium for injection patients). In the RF neurotomy group, patients received injection of 1 mL 0.5% bupivacaine followed by a single RF lesion at 80°C for 90 seconds. Those in the injection group were injected with a combination of bupivacaine (0.5 mL, 0.5%) and 3 mg betamethasone followed by sham denervation. Most patients received analgesics and were instructed to continue their previously directed exercise programs and work, though no specific physical exercise program was prescribed. The mean patient age was 57 ± 12 years, and 64% of patients were male. Mean duration of pain was not reported. Randomization was achieved using computer-generated random allocation sequence with permuted blocks of four and six; allocation concealment was achieved by performing randomization at an independent institution. Data were analyzed according to the intention to treat principle. Patients were blinded to their treatment group, and data collectors were blinded as well. The objectives of this study were to compare the efficacy of RF facet neurotomy to facet joint injections in patients with chronic low back pain. Outcomes reported included pain (as measured by the patient-reported VAS), function (as measured by the patient-reported ODI and Roland-Morris outcome measures), analgesic use, and complications. The complete follow-up rate was 93%; outcomes were reported at six months follow-up. No funding was received. This study received a class of evidence (CoE) grade of II.

Chakraverty (2004)

Chakraverty et al.[35] published the results of an audit of seven UK hospitals following facet joint procedures. The authors provided results for patients who had facet joint pain confirmed by intra-articular blocks though the details of pain relief required were not reported. For RF neurotomy, data from 38 patients treated between 2002 and 2004 were available. For therapeutic facet joint injection, data from 34 patients treated between 2000 and 2001 were available. Both procedures utilized fluoroscopic guidance. For RF neurotomy, correct electrode placement was confirmed by both sensory and motor stimulation and two lesions were applied to each medial branch of posterior primary rami at 80°C for 60 seconds. Patients treated with facet joint injection received intra-articular injection with less than 2.5 mL of 2% lignocaine and triamcinolone. The mean patient age was 61 years, and ranged from 30 to 90 years, and 38% of patients were male. The complete follow-up rate was not reported, and the follow-up was reported at 6 months. The source of funding was not reported. This study received a CoE grade of III and had numerous limitations, including lack of independent or blind assessment, not applying co-interventions equally, not reporting follow-up, inadequate sample size, and for not controlling for possible confounding.

RF neurotomy versus spinal injections (cervical spine)
Haspeslagh (2006)
Haspeslagh et al.[36] conducted an RCT in which patients with chronic cervicogenic headache of two or more years duration were randomized to receive RF facet joint denervation (n = 15) or anesthetic injection of the greater occipital nerve (n = 15). For inclusion, patients must have rated their pain to be at least 50 on a VAS scale (0-100) during a pain period, and have considerable pain at least two days per week. Diagnostic blocks were not performed prior to treatment. RF neurotomy was fluoroscopically-guided and correct electrode placement ensured using sensory and motor stimulation. Patients received injection of 1 mL 2% lidocaine at each affected level followed by a single RF lesion created by a 4-mm tip electrode set at 67°C for 60 seconds. Levels treated were C3 to C6; the neurotomy target was the medial branches of the posterior primary rami. Those in the injection group were injected with anesthetic only (2 mL 0.5% bupivacaine); the injection was aimed at the greater occipital nerve. The number of levels treated was not reported. No statement was made regarding immediate or long-term post-treatment care. Patients were evaluated at eight weeks, and those who did not respond were allowed to continue with additional treatment, including additional blocks and/or transcutaneous electrical nerve stimulation. Thus, we have reported results at eight weeks only in order to focus on the outcomes following RF facet neurotomy or injection. The mean patient age was 48 ± 12 years, and 27% of patients were male. Mean duration of pain was 10 years in the neurotomy group and 7 years in the injection group; this difference was not controlled for. Patients who had undergone previous cervical spine surgery or who had post-whiplash syndrome were excluded. The methods by which randomization and allocation concealment were achieved were not reported, although there was no statement regarding whether data were analyzed according to the intention to treat principle, data appear to have been handled this way through the eight week follow-up. It was not clear whether patients were blinded to their treatment group, though the data collectors were blinded. The objectives of this study were to evaluate a sequence of treatments for cervicogenic headache. Outcomes reported included pain (as measured by the patient-reported VAS and global perceived effect), quality of life (as measured by the patient-reported SF-36), and complications. The complete follow-up rate at eight weeks was 93%. No funding information was reported. This study received a class of evidence (CoE) grade of II.

Key Question 2a
RF neurotomy versus pulsed RF neurotomy (lumbar spine)
Kroll (2007):
Kroll and colleagues (2008)[37] conducted an RCT comparing conventional continuous RF neurotomy to pulsed RF neurotomy. For consideration, patients were required to have unilateral or bilateral lumbar back pain for at least one month and no symptoms radiating past the knee. Patients that obtained greater than 50% pain reduction for at least three hours after medial branch block (1.0 mL 0.5% bupivacaine) were included in the study. Twenty-five patients were randomized into each treatment group, but the study reported on only the thirteen patients in each group with complete follow-up data. Fluoroscopic guidance was used for both groups and electrode placement confirmed using sensory and motor stimulation. In the continuous RF neurotomy group, lesions were created using a 5-mm active tip needle set at 80°C for 75 seconds. In the pulsed RF neurotomy group, lesions were made using a 5-mm active tip needle at 42°C for 20 milliseconds at a pulse rate of 22 Hz for a total of 120 seconds. Following the procedure and initial VAS recording, patients in both groups were given 2 mg

midazolam and up to 100 µg of fentanyl. The average patient age was 58.3 years old, and 46% of patients were male. All patients had pain lasting greater than one month, but the actual mean duration of pain was not reported. Randomization was achieved by a random number generator, but the method by which allocation concealment was achieved was not reported. Data were not analyzed according to the intention to treat principle. Patients were blinded to the treatment received, and the outcomes were patient-reported. The primary goal of this study was to compare outcomes following conventional versus pulsed RF neurotomy . The authors reported VAS and ODI scores. The follow-up period was three months and complete follow-up was available for only 52% of patients. This study was funded by a grant from the Anesthesia Research Fund, Henry Ford Hospital and received a CoE grade of II.

Tekin (2007):

Tekin et al.[29] conducted a double-blind RCT in which patients who had been experiencing continuous low back pain for at least six months, had not responded to previous treatment, and whose pain was suspected of originating in the facet joint (i.e., paravertebral tenderness) were considered for inclusion. Patients underwent a single diagnostic medial branch block with lidocaine, and patients who reported a minimum of 50% reduction in their VAS pain scores in a time frame that coincided with the expected duration of lidocaine were randomized to undergo either conventional (continuous) RF neurotomy (n = 20), pulsed RF neurotomy (n = 20), or sham neurotomy (n = 20). For this key question, outcomes following pulsed RF neurotomy were compared with those following conventional continuous RF neurotomy. (Outcomes following sham neurotomy are included in key question 2.) All procedures employed fluoroscopic guidance and local anesthetic and correct electrode placement was confirmed by both sensory and motor stimulation. Patients in the conventional continuous RF neurotomy group received a single lesion using a 10-mm tip electrode at 80°C for 90 seconds, while the electrode was not switched on for patients in the sham group. Pulsed neurotomy was achieved by applying 2 Hertz waves for four minutes (45 volts) using an electrode set at 42°C .The number of levels treated was not reported. No interventions beside nonsteroidal anti-inflammatory drugs were given during the follow-up group. Across all three groups, the mean patient age was 59 ± 9 years, and patients were greater than 17 years of age. Males comprised 43% of patients, and the mean duration of pain was not reported. Patients who had undergone previous RF neurotomy were excluded. Randomization was achieved by random number generation and was balanced after every eight patients, and the method by which allocation concealment was achieved was not reported. It was not clear that data were analyzed according to the intention to treat principle. Both the patients and the data collectors were blinded. The primary goal of this study was to compare outcomes following conventional versus pulsed RF neurotomy of medial branches of dorsal rami. Outcomes evaluated included pain (as measured by the patient-reported VAS), function (as measured by the patient-reported ODI outcome measure), patient satisfaction (patient-reported and measured on a four-point scale), analgesic use, and complications. The complete follow-up rate was 100%; outcomes were reported at six and/or twelve months follow-up. Study funding was not reported. This study received a class of evidence (CoE) grade of II.

RF neurotomy versus alcohol ablation (lumbar spine)

Joo (2013):

Joo and colleagues (2013)[38] performed an RCT comparing alcohol ablation (AA) and thermal RF neurotomy in patients with recurrent thoracolumbar facet joint pain following a previous

successful RF neurotomy. That is, following their previous RF neurotomy, all patients had experienced at least 50% relief of the targeted pain that lasted for more than six months, and had sufficient patient satisfaction with the result of the neurotomy to have it performed again. Patients were considered to have recurrent thoracolumbar facet joint pain if they had a VAS score of at least 7 and an ODI score of at least 22%. Patients underwent controlled diagnostic blocks using lidocaine and bupivacaine; required pain relief following these blocks was not reported. Forty patients were randomized, with twenty patients per group. Both RF neurotomy and alcohol ablation were performed using fluoroscopic guidance. Iopamidol was injected to verify proper placement of the needle, and electrode placement confirmed using sensory and motor stimulation. In the RF neurotomy group, patients received a single lesion, which was created using a 10-mm active tip electrode at 80°C for 90 seconds. In the alcohol ablation group, contrast medium was injected into the facet joints to determine the amount of alcohol to inject. Once confirmed, 1% lidocaine was injected, followed by injection of dehydrated alcohol (the concentration of which was not reported) for 15 seconds. The average age of the patient population was 68 years old and 43% of all patients were male. In total, 28% (11/40) of the patients had undergone previous fusion surgery. The average duration of pain relief from the previous neurotomy was 11 months (ranging from 6 to 13 months). The methods by which randomization and allocation concealment were achieved were not reported. Although there was no explicit statement that data were analyzed according to the intention to treat principle, it appears that data were handled in this manner. There was no indication that patients were blinded to the treatment received, and the outcomes were patient-reported. The primary goal of this study was to compare outcomes following conventional RF neurotomy versus alcohol ablation in patients with recurrent pain following successful RF neurotomy. The study reported a composite outcome of "recurrence-free ratio", which was defined by a VAS score less than 7 and an ODI score greater than 22%. However, these outcomes were not reported individually. Patients were followed up to 24 months, though it wasn't clear what percentage of patients were followed to the end of the study. Study funding was not reported. This study received a CoE grade of II.

Key Question 2b
Lumbar spine:
Joo (2013):
Joo and colleagues (2013)[38] conducted a RCT (included in Key Question 2a) that evaluated RF neurotomy in patients with recurrent thoracolumbar facet joint pain following a previous successful RF neurotomy. For inclusion in the study, patients were required to have repeat pain (VAS ≥ 7 or ODI ≥ 22%) following a successful first neurotomy, from which they experienced at least 50% relief of the targeted pain that lasted for more than six months, and had sufficient patient satisfaction with the result of the neurotomy to have it performed again: 20 patients met these criteria. For this Key Question, outcomes following the initial RF neurotomy are compared to those following the second RF neurotomy.

Rambaransingh (2010)
Rambaransingh et al.[39] published a prospective series comparing outcomes following first, second, and third RF neurotomy procedures. For inclusion, patients must have achieved at least 30% pain relief following their initial RF neurotomy, be satisfied with the result, and have undergone at least one repeat procedure: 84 patients met these criteria.

Schofferman (2004)
Schofferman et al.[40] published a retrospective series comparing outcomes following first, second, and third RF neurotomy procedures. For inclusion, patients must have achieved ≥50% pain relief following their initial RF neurotomy, be satisfied with the result, and have undergone at least one repeat procedure: 20 patients met the inclusion criteria.

Son (2010)
Son et al.[41] performed a retrospective review comparing outcomes following first and second RF neurotomy procedures. For inclusion, patients must have achieved ≥50% pain relief following their initial RF neurotomy and have undergone at least one repeat procedure: 60 patients met the inclusion criteria.

Speldewinde (2011)
Speldewinde et al.[42] performed a prospective case series in which outcomes following first and repeat (range, 2 to 5) RF neurotomy procedures were compared. Not all patients in the series (N = 180) underwent repeat neurotomy. For patients to be eligible for a repeat procedure, they must have achieved ≥50% pain relief for at least two months following their initial RF neurotomy.

Zotti (2010)
Zotti et al.[43] performed a prospective case series comparing outcomes following first and repeat (range, 2 to 4) RF neurotomy procedures. For inclusion, patients must have achieved ≥50% pain relief following their initial RF neurotomy, be satisfied with the outcome from the initial procedure, and have undergone at least one repeat procedure: 65 patients met the inclusion criteria. Of the patients who completed follow-up, 47% (29/62) underwent 2 procedures, 32% (20/62) underwent 3 procedures, and 21% (13/62) underwent 4 procedures.

Cervical spine:
Husted (2009)
Husted et al.[44] performed a retrospective review outcomes following first, second, and third RF neurotomy procedures. For inclusion, patients must have achieved ≥50% pain relief following their initial RF neurotomy, be satisfied with the outcome from the initial procedure, and have undergone at least one repeat procedure: 22 patients met the inclusion criteria.

Rambaransingh (2010)
Rambaransingh et al.[39] published a prospective series comparing outcomes following first, second, and third RF neurotomy procedures. For inclusion, patients must have achieved at least 30% pain relief following their initial RF neurotomy, be satisfied with the result, and have undergone at least one repeat procedure: 14 patients met these criteria.

Speldewinde (2011)
Speldewinde et al.[42] performed a prospective case series in which outcomes following first and repeat (range, 2 to 5) RF neurotomy procedures were compared. Not all patients in the series (N = 151) underwent repeat neurotomy. For patients to be eligible for a repeat procedure, they must have achieved ≥50% pain relief for at least two months following their initial RF neurotomy.

Key Question 2c

Tzaan (2000)

Tzaan et al.[45] published a retrospective study in which unilateral RF neurotomy was compared to bilateral RF neurotomy. For inclusion, patients were required to have facetogenic pain for a minimum of six months that has been unresponsive to conservative treatment. In addition, patients must have experienced a 50% or greater reduction in pain following facet joint block. RF neurotomy was performed under fluoroscopic guidance and electrode placement confirmed using sensory and motor stimulation. Using a 5-mm active tip electrode, the neurotomy was performed for 90 seconds at a temperature of 80°C. Overall, 60% of the procedures were performed under general anesthesia (i.e., those done between 1991 and 1994), and 40% were conducted with the patient under local anesthesia (i.e., between 1983 and 1990). Patients with unilateral pain received unilateral neurotomy, while those with midline pain or pain on both sides of the trunk underwent bilateral neurotomy. The study followed 90 patients with a mean age of 43 years old: in these patients, a total of 118 procedures were performed (including lumbar, thoracic, and cervical procedures). Outcomes data on unilateral versus bilateral neurotomy was only available for lumbosacral procedures (69 procedures, the number of patients was not reported). The authors reported percent of successful procedures, defined as 50% reduction in pain. The study suffers from a number of methodological limitations. Patients were followed for a mean time of 5.6 months, and the follow-up rate was not reported. This study received a CoE grade of III. Authors did not report the source of their funding.

4. Results

4.1. Key question 1: What is the evidence that the use of diagnostic blocks to select patients for facet neurotomy improves clinical outcomes following facet neurotomy?

4.1.1. Key Question 1a: Diagnostic block versus alternative diagnostic test

We sought studies that performed facet neurotomy following patient selection using diagnostic block(s) compared with alternative diagnostic tests (e.g., clinical exam, discography, imaging). One small RCT (Cohen 2011)[21] met our inclusion criteria and reported on patients who underwent RF neurotomy in the lumbar spine following selection by either diagnostic medial branch block or clinical exam alone.

No studies were identified to answer this key question for the cervical spine. No studies were identified in which RF neurotomy was performed following patient selection by diagnostic block versus any other alternative diagnostic test.

4.1.1.1. Summary of study characteristics

One RCT met our inclusion criteria. Cohen et al. (2010)[21] conducted an RCT that evaluated different diagnostic paradigms to select patients to undergo RF neurotomy. For inclusion in the study, patients were required to have had predominantly axial low back pain for at least three months that has been unresponsive to conservative therapy, have paraspinal tenderness, and have an absence of focal neurologic signs or symptoms. Patients were randomized to undergo either no diagnostic block (i.e., clinical exam alone, as achieved by the inclusion criteria) or one diagnostic medial branch block with 0.5 ml 0.5% bupivacaine. All 51 patients randomized to receive no diagnostic block underwent RF neurotomy. In contrast, patients randomized to receive one diagnostic medial branch block were required to have 50% or more pain relief for at least three hours following the block: of the 50 patients who underwent the block, only 19 achieved sufficient pain relief to proceed to RF neurotomy. Facet neurotomy was performed within four weeks of the diagnostic block, details of which are available in Appendix F. Median patient age was 42 years, and 56% of patients were males. The median duration of symptoms was three years, and ranged from 0.5 to 14 years. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. This study received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.1.1.2. "Success" following RF neurotomy: Patient selection by diagnostic block versus clinical exam, Lumbar spine

Cohen et al. reported the percentage of patients who achieved "success" at one and three months follow-up. "Success" was defined as at least 50% pain relief from baseline (during activity or rest) and a positive global perceived effect (which was defined as improvement of pain and satisfaction with treatment). There was no difference in the percentage of patients that achieved success following neurotomy between diagnostic groups at one or three months follow-up (Table 8).[21]

Table 8. Composite measure of "success" at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by MBB or clinical exam

Back pain "success" following RF neurotomy: ≥50% pain relief from baseline and "positive GPE"	Patient selection by MBB (% patients (n/N))[21]	Patient selection by clinical exam (% patients (n/N))[21]	RR (95% CI)* RD (95% CI)*	Favors*
1 mos.	63% (12/19)	59% (30/51)	1.07 (0.71, 1.62) 0.04 (-0.21, 0.30)	NS
3 mos.	39% (7/18)	33% (17/51)	1.17 (0.58, 2.34) 0.06 (-0.20, 0.32)	NS

CI: confidence interval; GPE: global perceived effect; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RR: risk ratio
*Calculated

4.1.1.3. Pain relief and function following RF neurotomy: Patient selection by diagnostic block versus clinical exam, Lumbar spine

Although Cohen and colleagues (2010)[21] reported median pain scores and ODI scores at one and three months follow-up, it is difficult to arrive at any conclusions about these data for several reasons: only 60% of patients were available for follow-up, median and interquartile ranges were reported and thus p-values could not be calculated (nor were they reported), and improvement from follow-up could not be calculated due to missing baseline data. Data are available in Appendix F.

4.1.2. Key Question 1a: Diagnostic block versus alternative diagnostic test in the cervical spine

No studies were identified that met our inclusion criteria.

4.1.3. Key Question 1b: Type of diagnostic block

We sought studies that performed facet neurotomy following patient selection using different types of diagnostic block(s) (e.g., medial branch block versus intra-articular injection). One RCT (Birkenmaier 2007)[12] met our inclusion criteria and reported on patients who underwent cryodenervation of the lumbar facet joint following selection by either diagnostic medial branch block or pericapsular block.

4.1.3.1. Summary of study characteristics

Birkenmaier (2007)

One RCT met our inclusion criteria. Birkenmaier et al. (2007)[12] conducted a small RCT in which patients with suspected lumbar facet joint pain were randomized to one of two different diagnostic blocks: medial branch blocks or pericapsular blocks. Patients with adequate response to these blocks proceeded to undergo cryodenervation of the facet joint. For inclusion in the study, patients were required to have had non-sciatic low back pain for at least three months that has been unresponsive to conservative therapy, have localized paraspinal tenderness and tenderness to pressure, and have a positive response to the diagnostic block. The diagnostic block was performed on the medial branch (medial branch block) or on the posterior surface of the facet joint (pericapsular block); both blocks used 1 ml 0.5% bupivacaine. In order to proceed to neurotomy, patients were required to have 50% or more pain relief for at least three hours following the block. Thirteen patients in each block group were treated with cryodenervation, details of which are available in Appendix F. Details on patient age, sex, and duration of pain were not reported. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. This study received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.1.3.2. Back pain following RF neurotomy: Patient selection by medial branch block versus pericapsular block, Lumbar spine

- ***Back pain: VAS scores***

Short-term (< 12 months) (Table 9)

This RCT reported back pain up to six months following cryodenervation; back pain was measured by the patient-reported visual analogue scale (VAS). We have standardized the scores for all studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. Mean baseline, follow-up, and change from baseline scores are presented in Table 9.

Table 9. VAS back pain scores at baseline and short-term follow-up following cryodenervation in the lumbar facet joint: patients selected by MBB or pericapsular block

Range: 0-100, higher scores = greater pain

		Baseline score Mean (SD*)		**Follow-up score** Mean (SD*)		**Improvement from baseline** Mean (SD†) (%)		
		MBB	**Pericapsular block**	**MBB**	**Pericapsular block**	**MBB**	**Pericapsular block**	**p-value***
1.5 mos.	Birkenmaier 2007 (N = 26)	74	82	22	42	52 (72%)	40 (49%)	NR/NC (0.087*)
3 mos.	Birkenmaier 2007 (N = 26)	74	82	23	42	51 (69%)	40 (49%)	NR/NC (0.224*)
6	Birkenmaier	74	82	27	40	47	42	NR/NC

mos.	2007 (N = 26)					(64%)	(57%)	(0.523*)

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); NR: not reported; SD: standard deviation
*As reported by the study
†Calculated (unless otherwise indicated)

Regarding the mean change VAS back pain score from baseline:

- At 1.5, 3, and 6 months follow-up, the mean improvement was consistently higher in patients who had been selected for treatment with medial branch block versus pericapsular block. While we could not calculate the p-values for differences in mean improvement, the study reported that the differences between diagnostic groups in percent improvement from baseline were not significantly different (Table 9).[12]

Regarding the mean percent change from baseline in VAS back pain score:

- If the MCID is 30%:
  - There was not a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 1.5, 3, or 6 months follow-up.[12]
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful at any follow-up.[12]
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 1.5 and 3 months (but not at 6 months) follow-up.[12]
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful at any follow-up.[12]

4.1.3.3. Function following RF neurotomy: Patient selection by medial branch block versus pericapsular block, Lumbar spine

- ***Function: Everyday activities (Macnab rating)***

Short-term (< 12 months) (Table 10)

This RCT reported the ability of patients to perform everyday activities up to six months following cryodenervation. This outcome was evaluated using the Macnab rating, with a score of 3 indicating "excellent", 2 indicating "good", 1 indicating "moderate", and 0 indicating "poor". Mean baseline, follow-up, and change from baseline scores are presented in Table 10. Overall, there appeared to be no difference in the improvement from baseline between diagnostic groups following cryodenervation at 1.5, 3, and 6 months (Table 10), though p-values were not reported or calculable.[12]

Table 10. Macnab function scores at baseline and short-term follow-up following cryodenervation in the lumbar facet joint: patients selected by MBB or pericapsular block
Range: 0-3, higher scores = greater ability to perform everyday activities

		Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*)		
		MBB	Pericapsular block	MBB	Pericapsular block	MBB	Pericapsular block	p-value*
1.5 mos.	Birkenmaier 2007 (N = 26)	0.8	0.5	1.9	1.5	1.1	1.0	NR/NC
3 mos.	Birkenmaier 2007 (N = 26)	0.8	0.5	2.0	1.5	1.2	1.0	NR/NC
6 mos.	Birkenmaier 2007 (N = 26)	0.8	0.5	2.0	1.5	1.2	1.0	NR/NC

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); NR: not reported; SD: standard deviation
*As reported by the study

4.1.3.4. Patient satisfaction following RF neurotomy: Patient selection by medial branch block versus pericapsular block, Lumbar spine

- ***Patient satisfaction: Willingness to repeat procedure if pain returned***

Short-term (< 12 months) (Table 11)
The authors asked the patients the following question: "Given the same level of low back pain as before the procedure, would you choose to have it performed again?" There were no differences between diagnostic groups (Table 11) in terms of how the patients answered.[12]

Table 11. Patient satisfaction at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by MBB or pericapsular block

Would patient repeat procedure if needed?	Patient selection by MBB (% patients (n/N))	Patient selection by pericapsular block (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Yes	85% (11/13)	62% (8/13)	1.38 (0.84, 2.24) 0.23 (-0.10, 0.56)	NS
No	15% (2/13)	31% (4/13)	0.50 (0.11, 2.27) -0.15 (-0.47, 0.16)	NS
Undecided	0% (0/13)	8% (1/13)	0 (NC) -0.08 (-0.22, 0.07)	NS

CI: confidence interval; MBB: medial branch block; NS: difference between groups is not statistically significant; RD: risk difference; RR: risk ratio
*Calculated

4.1.4. Key Question 1c: Use of single versus controlled or comparative diagnostic blocks

We sought studies that performed facet neurotomy following patient selection using a single block compared with either controlled diagnostic blocks (i.e., one block with anesthetic and another block with saline) or comparative diagnostic blocks (i.e., one block with one type of anesthetic and another block with a different type of anesthetic). One small RCT (Cohen 2010)[21] met our inclusion criteria and reported on patients who underwent RF neurotomy following selection by a single diagnostic medial branch block or two comparative diagnostic medial branch blocks.

4.1.4.1. Summary of study characteristics

Cohen (2010)

One RCT met our inclusion criteria. Cohen et al. (2010)[21] conducted an RCT that evaluated different diagnostic paradigms to select patients to undergo RF neurotomy. For inclusion in the study, patients were required to have had predominantly axial low back pain for at least three months that has been unresponsive to conservative therapy, have paraspinal tenderness, and have an absence of focal neurologic signs or symptoms. Patients were randomized to undergo one either diagnostic medial branch block with 0.5 ml 0.5% bupivacaine or comparative diagnostic medial branch blocks (one with 0.5 ml 0.5% bupivacaine and another with 0.5 ml 2% lidocaine). Patients randomized to receive one diagnostic medial branch block were required to have 50% or more pain relief for at least three hours following the block: of the 50 patients who underwent the block, only 19 achieved sufficient pain relief to proceed to RF neurotomy. Patients randomized to receive comparative blocks were required to have at least 50% concordant pain relief from both blocks. Facet neurotomy was performed within four weeks of the diagnostic block: of the 50 patients who underwent the block, only 14 achieved sufficient pain relief to proceed to RF neurotomy, details of which are available in Appendix F. Median patient age was 42 years, and 56% of patients were males. The median duration of symptoms was three years, and ranged from 0.5 to 14 years. It was not possible for patients to be blinded to their diagnostic treatment, and the primary outcomes were patient-reported. The complete follow-up rate was low, at 57%; outcomes were reported at three months follow-up. This study received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.1.4.2. "Success" following RF neurotomy: Patient selection by single versus two comparative diagnostic blocks, Lumbar spine

Cohen et al. reported the percentage of patients who achieved "success" at one and three months follow-up. "Success" was defined as at least 50% pain relief from baseline (during activity or rest) and a positive global perceived effect (which was defined as improvement of pain and satisfaction with treatment). There was no difference in the percentage of patients that achieved success following neurotomy between diagnostic groups at one or three months follow-up (Table 12).[21]

Table 12. Composite measure of "success" at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by MBB or clinical exam

Back pain "success" following RF neurotomy: ≥50% pain relief from baseline and "positive GPE"	Patient selection by 1 MBB (% patients (n/N))[21]	Patient selection by 2 comparative MBBs (% patients (n/N))[21]	RR (95% CI)* RD (95% CI)*	Favors*
1 mos.	63% (12/19)	64% (9/14)	0.98 (0.58, 1.65) -0.01 (-0.34, 0.32)	NS
3 mos.	39% (7/18)	64% (9/14)	0.60 (0.30, 1.22) -0.25 (-0.59, 0.08)	NS

CI: confidence interval; GPE: global perceived effect; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RR: risk ratio
*Calculated

4.1.4.3. Pain relief and function following RF neurotomy: Patient selection by single versus two comparative diagnostic blocks, Lumbar spine

Although Cohen and colleagues (2010)[21] reported median pain scores and ODI scores at one and three months follow-up, it is difficult to arrive at any conclusions about these data for several reasons: only 57% of patients had complete follow-up available, median and interquartile ranges were reported and thus p-values could not be calculated (nor were they reported), and improvement from follow-up could not be calculated due to missing baseline data. Data are available in Appendix F.

4.1.5. Key Question 1d: Degree and duration of pain reduction from diagnostic block

We sought studies that were designed to assess outcomes following facet neurotomy in patients who had different levels (or duration) of pain relief following the diagnostic block. For example, a study might compare outcomes following facet neurotomy in patients who had 50-79% versus 80% or more pain relief following their diagnostic block. Four cohort studies (Cohen 2008, Cohen 2013, Derby 2012, Derby 2013)[22-25] met our inclusion criteria, all of which compared facet neurotomy outcomes in patients with varying degrees of pain relief following their diagnostic block. No studies were identified in which patients were selected for facet neurotomy based on different durations of pain relief following the diagnostic block.

4.1.5.1. Summary of study characteristics

One prospective (Cohen 2013)[23]and three retrospective (Cohen 2008, Derby 2012, Derby 2013)[22, 24, 25] cohort studies form the evidence base, all of which all of which compared facet neurotomy outcomes in patients with varying degrees of pain relief following their diagnostic block. For inclusion, patients were required to have had chronic lower back pain for more than three or six months with an absence of focal neurological signs or symptoms; three studies[23-25]

required that the pain failed to respond to conservative therapy. Patients underwent one or two diagnostic medial branch blocks, and those who achieved at least 50% pain relief[22, 24, 25] (or in Cohen 2013[23], were satisfied with the relief achieved) in the hours following the block were selected for RF denervation, details of which are available in Appendix F. The mean patient age was 51-59 years, and 45-59% of patients were males. The mean duration of symptoms was 5.7-13 years. It was not possible for patients to be blinded to their diagnostic group, and the primary outcomes were patient-reported. All studies received a class of evidence (CoE) grade of III. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.1.5.2. "Success" following RF neurotomy: Patient selection by thresholds of pain relief following diagnostic block, Lumbar spine

Two studies (Cohen 2008, Derby 2012) reported the percentage of patients who achieved at least 50% pain relief at six months follow-up. The results from the larger of the two studies (Cohen 2008)[22] suggested that there was no difference in outcome between the diagnostic groups (i.e., those who achieved 50-79% versus ≥ 80% pain relief from the diagnostic block). However, results from the smaller study (Derby 2012)[24] suggested that compared with patients who achieved 50% to 79% pain relief following diagnostic MBB, those who achieved a minimum of 80% pain relief following diagnostic MBB were significantly more likely to achieve 50% or more pain relief following neurotomy ($P = 0.0216$) (Table 13). Given the relatively small number of patients in this study, especially compared with the larger Cohen 2008 study, however, results should be interpreted with caution.

Table 13. Pain relief "success" at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by thresholds of pain relief achieved following diagnostic block

Back pain "success" following RF neurotomy: ≥ 50% pain relief		**50-79% pain relief following diagnostic block** (% patients (n/N))	**≥80% pain relief following diagnostic block** (% patients (n/N))	**RR (95% CI)*** **RD (95% CI)***	**Favors***
6 mos.	Cohen 2008 (N = 262)	52% (76/145)	56% (66/117)	0.93 (0.74, 1.16) -0.04 (-0.16, 0.08)	NS
	Derby 2012 (N = 51)	54% (14/26)	84% (21/25)	0.64 (0.43, 0.95) -0.30 (-0.54, -0.06)	≥ 80% pain relief threshold following block

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated

4.1.5.3. "Success" composite outcome following RF neurotomy: Patient selection by thresholds of pain relief following diagnostic block, Lumbar spine

Two studies (Cohen 2013, Derby 2013)[23, 25] reported a composite measure of "success", which was defined as at least 50% pain relief plus a positive global perceived effect (indicating that the treatment either met expectations or that it didn't help as much as they had hoped but that they would undergo the procedure again if they achieved the same outcome). Cohen et al. (2013)[23] reported one and three month outcomes, and found no difference in the percentage of patients who achieved this composite outcome between groups (i.e., those who achieved 50-83% versus ≥ 84% pain relief from the diagnostic block) at either timepoint. In contrast, Derby et al. (2013)[25] reported that patients who had at least 80% pain relief following their diagnostic block were significantly more likely to have a successful outcome compared with patients who achieved between 50% and 79% pain relief from the diagnostic block (*P* = 0.044) (Table 14). Given the different effects in the two studies coupled with the small number of patients in both studies, results should be interpreted with caution.

Table 14. Composite outcome of "success" at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by thresholds of pain relief achieved following diagnostic block

Back pain "success" following RF neurotomy: ≥ 50% pain relief and positive GPE		**50-79%† pain relief following diagnostic MBB** (% patients (n/N))	**≥80%† pain relief following diagnostic MBB** (% patients (n/N))	**RR (95% CI)*** **RD (95% CI)***	**Favors***
1 mos.	Cohen 2013 (N = 61)	67% (26/39)†	69% (11/16)†	0.97 (0.65, 1.44) -0.02 (-0.29, 0.25)	NS
3 mos.	Cohen 2013 (N = 61)	59% (23/39)†	56% (9/16)†	1.05 (0.63, 1.74) 0.03 (-0.26, 0.32)	NS
	Derby 2013 (N = 52)	35% (8/23)	76% (19/25)	0.46 (0.25, 0.84) -0.41 (-0.67, -0.16)	≥ 80% pain relief threshold following block

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated
† Cohen 2013: pain relief following diagnostic block divided as follows: 50-83% versus ≥84%

4.1.5.4. Function following RF neurotomy: Patient selection by thresholds of pain relief following diagnostic block, Lumbar spine

Derby et al. (2012)[24] found that those patients who achieved a minimum of 80% pain relief following diagnostic MBB were significantly more likely to have 50% or more improvement in their activity level than those who achieved between 50% and 79% pain relief following diagnostic block (*P* = .0030) (Table 15). Authors did not describe how patient activity was measured and defined.

Table 15. Patient activity at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by thresholds of pain relief achieved following diagnostic block

≥ 50% improvement in activity level (not defined)		50-79% pain relief following diagnostic block (% patients (n/N))	≥80% pain relief following diagnostic block (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
6 mos.	Derby 2012 (N = 51)	33% (8/24)	76% (19/25)	0.44 (0.24, 0.80) -0.43 (-0.68, -0.17)	≥ 80% pain relief threshold following block

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated

4.1.5.5. Patient satisfaction following RF neurotomy: Patient selection by thresholds of pain relief following diagnostic block, Lumbar spine

Two studies (Cohen 2013, Derby 2012)[23, 24] reported the percentage of patients who were satisfied with their treatment. In both studies, patient satisfaction was defined as patients indicating the treatment either met expectations or that it didn't help as much as they had hoped but that they would undergo the procedure again if they achieved the same outcome. Cohen et al. (2013)[23] reported one and three month outcomes, and found no difference in the percentage of patients who were satisfied with the treatment between diagnostic groups (i.e., those who achieved 50-83% versus ≥ 84% pain relief from the diagnostic block) at either timepoint. In contrast, Derby et al. (2012)[24] reported that patients who had at least 80% pain relief following their diagnostic block were significantly more likely to be satisfied with their treatment compared with patients who achieved between 50% and 79% pain relief from the diagnostic block (P = 0.0027) (Table 16). As discussed above, since there are different effects in the two studies and a small number of patients in both studies, caution should be used when interpreting the results.

Table 16. Patient satisfaction at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by thresholds of pain relief achieved following diagnostic block

Patient satisfaction "success" following RF neurotomy: Met expectations, would undergo again		**50-79%† pain relief following diagnostic MBB** (% patients (n/N))	**≥80%† pain relief following diagnostic MBB** (% patients (n/N))	**RR (95% CI)*** **RD (95% CI)***	**Favors***
1 mos.	Cohen 2013 (N = 61)	74% (29/39)†	75% (12/16)†	0.99 (0.71, 1.39) -0.01 (-0.26, 0.25)	NS
3 mos.	Cohen 2013 (N = 61)	71% (25/35)†	67% (10/15)†	1.06 (0.71, 1.62) 0.05 (-0.23, 0.33)	NS
6 mos.	Derby 2012 (N = 51)	45% (10/22)	88% (21/24)	0.52 (0.32, 0.84) -0.42 (-0.67, -0.17)	≥ 80% pain relief threshold following block (p= 0.0027)

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio

*Calculated

† Cohen 2013: pain relief following diagnostic block divided as follows: 50-83% versus ≥84%

4.1.5.6. Medication reduction following RF neurotomy: Patient selection by thresholds of pain relief following diagnostic block, Lumbar spine

Two studies (Cohen 2013, Derby 2012)[23, 24] reported the percentage of patients who were able to reduce their medication usage following RF neurotomy. Cohen defined medication reduction as a 20% or more decrease in opioid use or a complete cessation of usage of nonopioid analgesics; Derby did not define medication reduction. Comparing patients with different levels of pain relief following the diagnostic block, neither study reported a significant difference in the percentage of patients who achieved this outcome (Table 17).

Table 17. Medication reduction at short-term follow-up following RF neurotomy in the lumbar spine: patients selected by thresholds of pain relief achieved following diagnostic block

Medication reduction		50-79%† pain relief following diagnostic MBB (% patients (n/N))	≥80%† pain relief following diagnostic MBB (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
1 mos.	Cohen 2013 (N = 61)	49% (19/39)†	44% (7/16)†	1.11 (0.58, 2.12) 0.05 (-0.24, 0.34)	NS
3 mos.	Cohen 2013 (N = 61)	61% (14/23)†	60% (6/10)†	1.01 (0.56, 1.85) 0.01 (-0.35, 0.37)	NS
6 mos.	Derby 2012 (N = 51)	55% (11/20)	74% (17/23)	0.74 (0.47, 1.18) -0.19 (-0.47, 0.09)	NS

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated
† Cohen 2013: pain relief following diagnostic block divided as follows: 50-83% versus ≥84%

4.1.6. Key Question 1e: Unilateral versus bilateral diagnostic block

No studies were identified which met our inclusion criteria.

4.1.7. Key Question 1f: Diagnostic block of single versus multiple levels

No studies were identified which met our inclusion criteria.

4.2. Key question 2: What is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?

4.2.1. RF Neurotomy versus Sham Neurotomy: Efficacy in the Lumbar Spine

We report on six RCTs[26-31] that compared radiofrequency facet neurotomy to sham neurotomy.

4.2.1.1. Summary of study characteristics

Six RCTs form the evidence base, all of which all of which compared facet neurotomy with sham neurotomy in patients with low back pain. For inclusion, patients were required to have had suspected facet joint pain in the lumbar spine with an absence of cancer and trauma. All patients underwent diagnostic blocks: patients in three RCTs[26, 27, 31] underwent intra-articular injections, whereas one RCT[28] used a controlled medial branch block, and two RCTs[29, 30] used a

single medial branch block for diagnosis. Those patients who achieved at least 80%[28] or 50% pain relief[29-31], or experienced "a good response"[26] or "significant"[27] pain relief in the hours following the diagnostic block were included, details of which are available in Appendix F. Patients ranged in age from 18 to 79 years, and 28-43% of patients were males. The mean duration of pain was not reported in five of the RCTs, but one trial[30] reported that the neurotomy group had a shorter median duration of pain (26 months) compared with the sham group (48 months). Patients in all RCTs were blinded to their treatment group, with the exception of one trial (Gallagher)[26] in which blinding was unclear, and the primary outcomes were patient-reported in all studies. The length of follow-up ranged from one to twelve months. All studies received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Table 18. Diagnostic block overview for studies included in KQ2: RF or sham neurotomy in the lumbar spine (RCT data).

	Patients (n)		Diagnostic block	Response required from diagnostic block to proceed to treatment
	RFN	Sham		
Gallagher 1994 (N = 30)	18	12	1 intra-articular block (bupivacaine)	"Good" response (not defined)
Leclaire 2001 (N = 70)	36	34	1 intra-articular block (lidocaine)	"Significant" relief (undefined)
Nath 2008 (N = 40)	20	20	2 MBBs (lidocaine, bupivacaine)	≥80% pain relief
Tekin 2007 (N = 40)	20	20	1 MBB (lidocaine)	≥50% pain relief
van Kleef 1999 (N = 31)	15	16	1 MBB (lidocaine)	≥50% pain relief
van Wijk 2005 (N = 81)	40	41	2 intra-articular blocks (lidocaine)	≥50% pain relief

MBB: medial branch block; RF: radiofrequency

4.2.1.2. Back pain: RF neurotomy or Sham neurotomy, Lumbar spine

- ***Back pain: VAS scores***

Short-term (< 12 months) (Table 19)

All six RCTs[26-31] reported back pain up to six months follow-up; back pain was measured by the patient-reported visual analogue scale (VAS). We have standardized the scores for all studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. In all studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 19. P-values were calculated for mean change from baseline scores if standard deviations were reported or calculable: this was not the case in three[28, 30, 31] of the six RCTs.

Table 19. VAS back pain scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
1 mos.	Gallagher 1994 (N = 30)	1 IAB ("good" response")	58.0 ± 4.2 (SE)	72 ± 5.6 (SE)	34.0 ± 6.9 (SE)	60.0 ± 9.8 (SE)	24.0 (41%)	12.0 (17%)	NR/NC
	Leclaire 2001 (N = 70)	1 IAB ("significant" relief"	51.9 ± 26.7	51.5 ± 20.8	48.2	52.1	3.6 ± 24.0* (7%)	0.6 ± 23.6* (1%)	0.5999
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	52.0 ± 17.0	52.0 ± 16.0	28.3	47.7	23.7 (46%)	4.3 (8%)	<0.05* (adj & unadj)
3 mos.	Leclaire 2001 (N = 70)	1 IAB ("significant" relief"	51.9 ± 26.7	51.5 ± 20.8	52.3	44.4	-0.4 ± 25.0* (-1%)	7.1 ± 27.3* (14%)	0.2344
	van Wijk 2005 (N = 81)	2 IABs (≥50% pain relief)	58.0‡ ± 18.0	65‡ ± 18	NR/NC	NR/NC	21.0 (36%)	16.0 (25%)	NR/NC
6 mos.	Gallagher 1994 (N = 30)	1 IAB ("good" response"	58.0 ± 4.2 (SE)	72 ± 5.6 (SE)	44.0 ±7.2 (SE)	70.0 ± 8.5 (SE)	14.0 (24%)	2.0 (3%)	NR/NC
	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	59.8	43.8	38.8	36.8	21.0 (35%)	7.0 (16%)	0.08*
	Tekin 2007 (N = 40)	1MBB (≥50% pain relief)	65.0 ± 15.0	68.0 ±16.0	23.0 ±13.0	31.0 ± 8.0	42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	0.1196

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; SE: standard error; Sham: sham neurotomy; unadj: unadjusted for baseline differences; VAS: visual analog score

*As reported by the study

†Calculated (unless otherwise indicated)

‡Median

Regarding the mean change VAS back pain score from baseline:

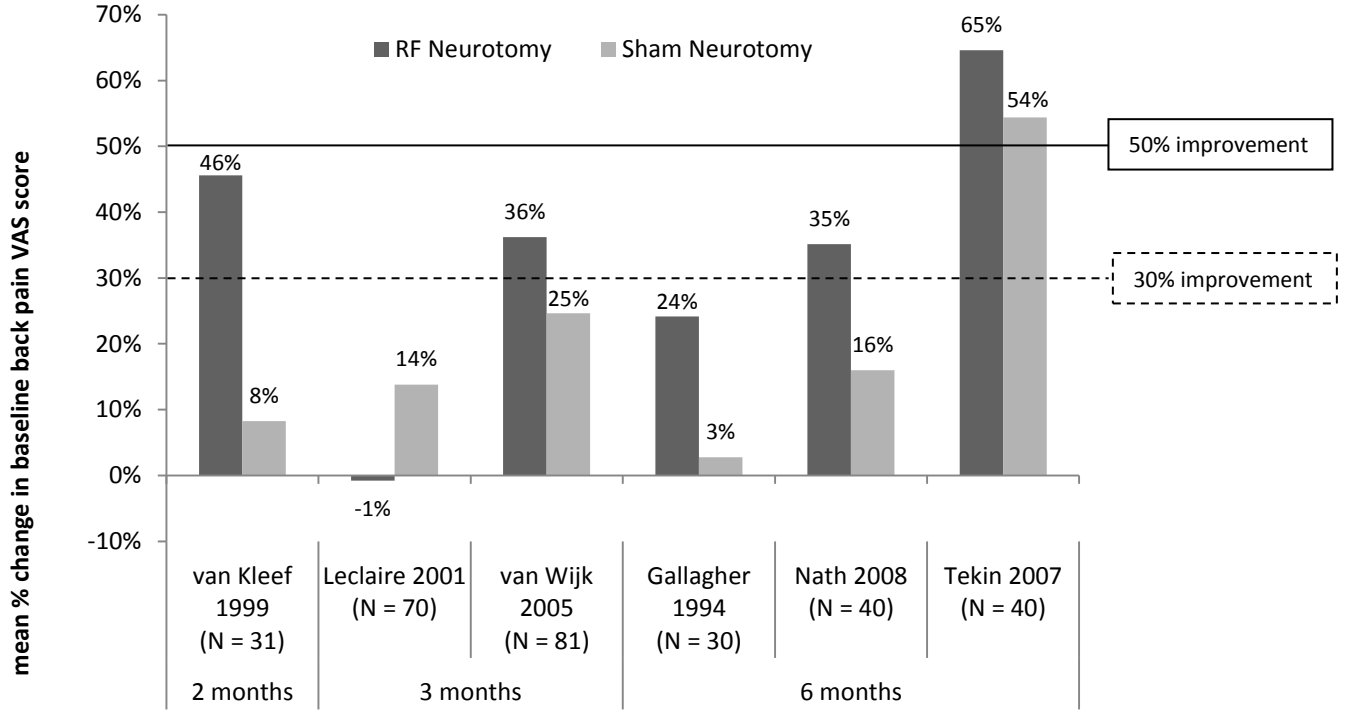
- Four of the six RCTs reported greater improvement in VAS scores following RF neurotomy compared with sham at 2, 3, or 6 months follow-up. Leclaire and colleagues [27] reported that RF neurotomy patients had worse VAS scores at 3 months follow-up; this was not the case in the sham neurotomy group.
- Of the four RCTs[27-30] for which p-values for mean change from baseline back pain VAS scores were either calculated or reported:

- There was a statistically significant difference between treatment groups in one RCT (van Kleef)[30] such that the results favored RF neurotomy.
- The difference between treatment groups was not statistically significant in three RCTs (Leclaire, Nath, Tekin).[27-29]

Regarding the mean percent change from baseline in VAS back pain score (Figure 2):

- If the MCID is 30%:
  - There was a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 2, 3, or 6 months follow-up in three[28, 30, 31] of the six RCTs.
  - The difference in the percent change in back pain VAS scores between treatment groups was clinically meaningful in only one (van Kleef)[30] of the six RCTs.
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 2, 3, or 6 months follow-up in none of the six RCTs.
  - The difference in the percent change in back pain VAS scores between treatment groups was clinically meaningful in none of the six RCTs.

Figure 2. Percent change in back pain VAS scores from baseline to 2, 3, or 6 months postoperative RF neurotomy or sham neurotomy: lumbar spine RCT data.



Long-term (≥ 12 months) (Table 20)

One RCT[29] reported long-term back pain as measured by the patient-reported visual analogue scale (VAS). We have standardized the scores so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. Patients were blinded to treatment received, thus the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 20. P-values were calculated for mean change from baseline scores.

Table 20. VAS back pain scores at baseline and long-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
12 mos.	Tekin 2007 (N = 40)	1 MBB (≥50% pain relief)	65.0 ± 15.0	68.0 ± 16.0	24.0 ± 11.0	39.0 ± 12.0	41.0 ± 9.1 (63%)	29.0 ± 9.6 (43%)	0.0002

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*Standard deviation included as reported.

†Calculated (unless otherwise indicated)

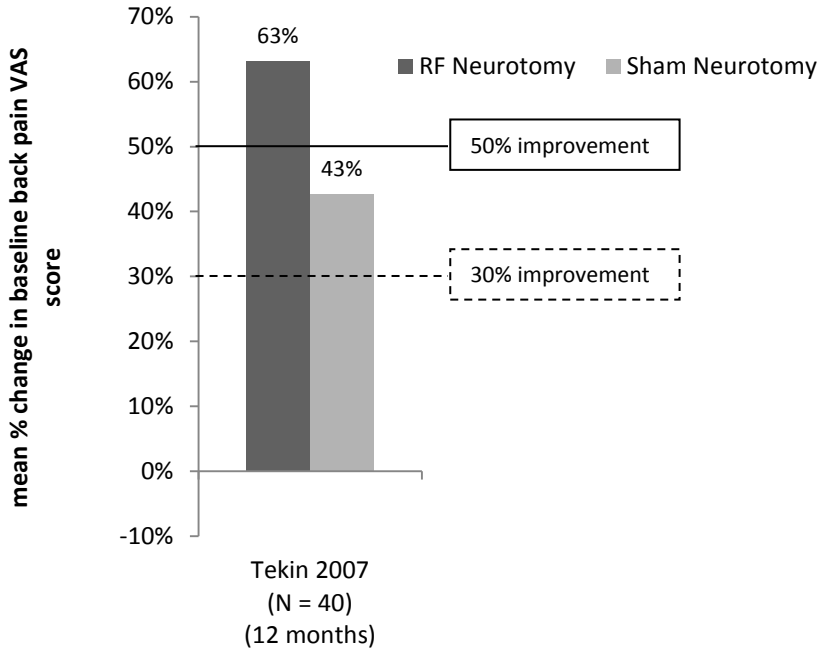
Regarding the mean change VAS back pain score from baseline:

- This RCT (Tekin)[29] reported significantly greater improvement in VAS scores following RF neurotomy compared with sham at 12 months follow-up.

Regarding the mean percent change from baseline in VAS back pain score (Figure 3):

- If the MCID is 30%:
  - There was not clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 12 months follow-up.[29]
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful.[29]
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at 12 months follow-up.[29]
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful.[29]

Figure 3. Percent change in back pain VAS scores from baseline to 12 months postoperative RF neurotomy or sham neurotomy: lumbar spine RCT data.



- ***Back pain: "Success" (Table 21)***

  Short-term (< 12 months) (Table 21)

  One RCT (Van Wijk et al.)[31] reported the percentage of patients who achieved a specific reduction in back pain from baseline. Specifically, the study reported the percentage of patients who achieved a reduction of at least 2 points, 25%, or 50% as measured by the patient-reported VAS (11-point scale). Patients were blinded to treatment received, thus the outcome was assessed in a blinded fashion. There was not a statistically significant difference between treatment groups in the percentage of patients who achieved any of these back pain improvement thresholds as reported at three months follow-up (Table 21). However, when the authors reported the percentage of patients who achieved a 50% or more improvement in back pain as measured by the patient-reported global perceived effect (GPE) outcome measure (4-point scale), the results suggested that there was a marginally significant difference between the groups in favor of RF neurotomy. According to relative risk calculations, patients in the RF neurotomy group were 1.58 times as likely to achieve 50% improvement in GPE (95% CI, 0.9994, 2.49); and the risk difference between the treatment groups was 23% (95% CI, 12%, 44%) (Table 21).

Table 21. Back pain measures of "success" at short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Diagnostic block(s) Pain relief required	Back pain: Change from baseline to 3 mos.	RF Neurotomy (% patients (n/N))[31]	Sham Neurotomy (% patients (n/N))[31]	RR (95% CI)* RD (95% CI)*	Favors*
2 IABs (≥50% pain relief)	≥ 2 point improvement in VAS (0-10)	48% (19/40)	49% (20/41)	0.97 (0.62, 1.53) -0.01 (-0.23, 0.20)	NS
	≥ 25% improvement in VAS (0-10)	63% (25/40)	49% (20/41)	1.28 (0.86, 1.90) 0.14 (-0.08, 0.35)	NS
	≥ 50% improvement in VAS (0-10)	33% (13/40)	34% (14/41)	0.95 (0.51, 1.76) -0.02 (-0.22, 0.19)	NS
	≥ 50% improvement in back pain as measured by GPE (1-4)	62% (24/39)	39% (16/41)	1.58 (0.9994, 2.49) 0.23 (0.12, 0.44)	RF neurotomy (marginally significant)

CI: confidence interval; GPE: global perceived effect; IAB: intra-articular block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio; VAS: visual analogue scale
*Calculated (unless otherwise indicated)

Long-term (≥ 12 months)
No data were reported.

- ***Pain: Short Form McGill Pain Questionnaire scores***

Short-term (< 12 months) (Table 22)
One RCT[26] reported pain at six months follow-up as measured by the shortened McGill Pain Questionnaire. The Short Form McGill Pain Questionnaire is a patient-reported outcome that scores the pain rating index (PRI) (score range, 0-45) as well as the present pain intensity (PPI) (score range, 1-5). Higher scores indicate greater pain disability. Because patients were blinded to treatment received, the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 22. P-values were calculated for mean change from baseline scores if standard deviations were reported or calculable: this was not the case in this RCT. Gallagher et al.[26] reported that results were significantly better following RF neurotomy compared with sham neurotomy at one month, but this difference was not sustained when measured at six months (Table 22).

Table 22. Short Form McGill Pain Questionnaire scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).
Range: unclear whether just PRI was reported (range, 0-45), or whether the PRI and PPI were both reported (range, 0-50), higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SE*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
1 mos.	Gallagher 1994 (N = 30)	1 IAB ("good" response)	15 ± 2.3	19 ± 2.4	9 ± 2.3	16 ± 2.8	6 ± 1.45	3 ± 1.69	< .0001
6 mos.	Gallagher 1994 (N = 30)	1 IAB ("good" response)	15 ± 2.3	19 ± 2.4	12 ± 7.2	17 ± 3.2	3 ± 5.53	2 ± 1.93	0.5536

IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable (due to missing standard deviations); PPI: present pain intensity; PRI: pain rating index; RFN: radiofrequency neurotomy; SD: standard deviation; SE: standard error; Sham: sham neurotomy
*As reported by the study
†Calculated (unless otherwise indicated)
‡Median

Long-term (≥ 12 months)
No data were reported.

- ***Patient global perceived effect (GPE) of improvement***

Short-term (< 12 months) (Table 23)
Mean global perceived effect scores were reported by two RCTs (van Kleef, Nath)[28, 30] using two slightly different scales. In both studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion.

Van Kleef et al.[30] reported global perceived effect (GPE) at two months follow-up. Patients were asked to rate GPE on a 7-point scale, with -3 indicating "much worse", 0 indicating "no change", and +3 indicating "total pain relief". While baseline values were not reported, the authors found that the mean score at two months was 1.33 in the RF neurotomy group and 0.37 in the sham neurotomy group. The authors reported that both the unadjusted difference (-0.96 (90% CI, -1.70, -0.22) ($P < .05$)) and the adjusted difference (-1.10 (90% CI, -1.89, -0.30) ($P < .05$) were statistically significant such that the overall score was better following RF neurotomy. (The adjusted difference took into account differences in gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks.) (Table 23)

Nath et al.[28] reported global improvement, which asked patients to assess their improvement on a 6-point scale. No details on scoring were provided. The authors reported that, when measured at six months, the mean improvement from baseline was significantly better in the RF

neurotomy group compared with the sham neurotomy group (1.1 versus 0.30, *P* = .004). (Table 23)

Mean baseline, follow-up, and change from baseline scores are presented in Table 23.

Table 23. GPE scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

		Diagnostic block(s) Pain relief required	GPE scale (range)	Baseline score Mean (SD*)		Follow-up score Mean (SD*)			Improvement from baseline Mean (SD†)		
				RFN	Sham	RFN	Sham	p-value*	RFN	Sham	p-value*
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	7 points (-3, 3)	NR	NR	1.33	0.37	<0.05* (adj & unadj)	NR	NR	-
6 mos.	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	6 points (NR)	3.85	3.35	2.75	3.05	NC/NR	1.1	0.30	.004*

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; GPE: global perceived effect; IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy; unadj: unadjusted for baseline differences
*As reported by the study
†Calculated (unless otherwise indicated)

Long-term (≥ 12 months)
No data were reported.

4.2.1.3. Leg Pain: RF neurotomy or Sham neurotomy, Lumbar spine

- ***Leg pain: VAS scores***

Short-term (< 12 months) (Table 24)
Two RCTs[28, 31] reported leg pain up to six months follow-up as measured by the patient-reported visual analogue scale (VAS). We have standardized the scores for all studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. In both studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 24. P-values could not be calculated for mean change from baseline scores because standard deviations were not reported for all relevant timepoints.

Table 24. VAS leg pain scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
3 mos.	van Wijk 2005 (N = 81)	2 IABs (≥50% pain relief)	42.0‡ ± 26.0	65.0‡ ± 18.0	NR/NC	NR/NC	21.0 (50%)	16.0 (25%)	NR/NC
6 mos.	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	43.3	26.8	27.3	25.5	16.0 (37%)	1.3 (5%)	0.046*

IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*As reported by the study

†Calculated (unless otherwise indicated)

‡ Median

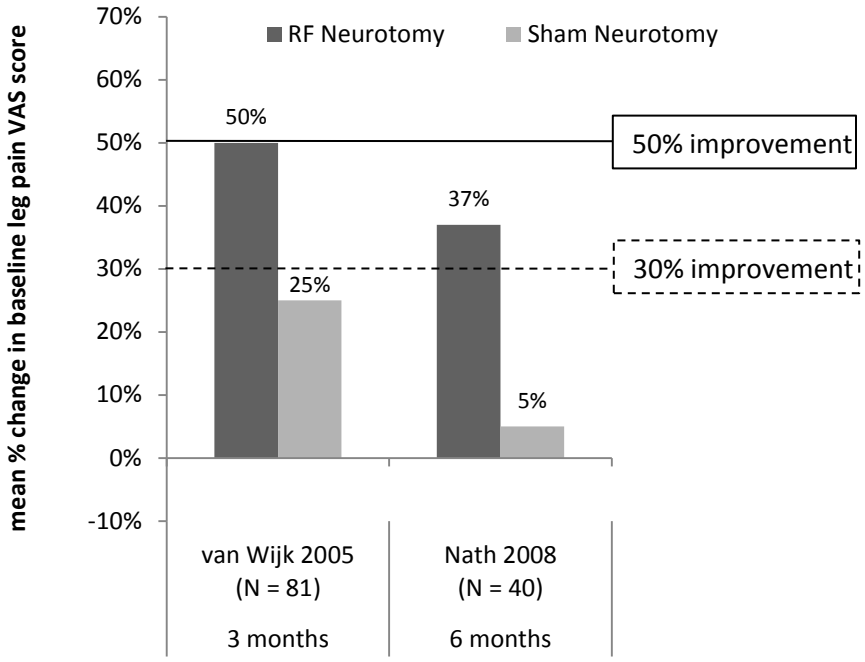
Regarding the mean change VAS leg pain score from baseline:

- Both RCTs reported greater improvement in VAS scores following RF neurotomy compared with sham at three or six months follow-up. However, the statistical significance of these results could not be calculated.
- In the one RCT[28] for which p-values for mean change from baseline back pain VAS scores were reported:
  - At six months, the difference in pain reduction from baseline between treatment groups was statistically significant (*P* = .046) in favor of RF neurotomy.

Regarding the mean percent change from baseline in VAS leg pain score (Figure 4):

- If the MCID is 30%:
  - There was a clinically important improvement in leg pain following RF neurotomy but not sham neurotomy at three or six months follow-up in both of the RCTs.[28, 31]
  - The difference in the percent change in back pain VAS scores between treatment groups was clinically meaningful in one (Nath)[28] of the two RCTs.
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not sham neurotomy at three or six month follow-ups in one[31] of the two RCTs.
  - The difference in the percent change in back pain VAS scores between treatment groups was clinically meaningful in none of the six RCTs.

Figure 4. Percent change in leg pain VAS scores from baseline to 3 or 6 months postoperative RF neurotomy or sham neurotomy: lumbar spine RCT data.



Long-term (≥ 12 months)
No data were reported.

- ***Leg pain: "Success"***

Short-term (< 12 months) (Table 25)
One RCT (Van Wijk et al.)[31] reported the percentage of patients who achieved a 50% or more reduction in leg pain from baseline as measured by the patient-reported outcome global perceived effect (scored on a modified 4-point Likert scale). Because patients were blinded to treatment received, the outcome was assessed in a blinded fashion. There was not a statistically significant difference between treatment groups in the percentage of patients who achieved this back pain improvement threshold as reported at three months follow-up (Table 25).

Table 25. Leg pain measures of "success" at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Diagnostic block(s) Pain relief required	Leg pain: Change from baseline to 3 mos.	RF Neurotomy (% patients (n/N))[31]	Sham Neurotomy (% patients (n/N))[31]	RR (95% CI)* RD (95% CI)*	Favors*
2 IABs (≥50% pain relief)	≥ 50% improvement in GPE (1-4)	50% (19/38)	37% (15/41)	1.37 (0.82, 2.28) 0.13 (-0.08, 0.35)	NS

CI: confidence interval; GPE: global perceived effect; IAB: intra-articular block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated (unless otherwise indicated)

Long-term (≥ 12 months)
No data were reported.

4.2.1.4. Generalized pain: RF neurotomy or Sham neurotomy, Lumbar spine

Short-term (< 12 months) (Table 25a)
One RCT[28] reported generalized pain at six months follow-up as measured by the visual analogue scale (VAS). We have standardized the scores for all studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. Patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. In all studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion.

While the results suggest that there was significantly greater improvement in VAS scores following RF neurotomy compared with sham at six months follow-up, there were significant differences in baseline scores between the groups which weren't controlled for (Table 25a).

Table 25a. VAS generalized pain scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).
Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
6 mos.	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	60.3	43.5	41.0	39.8	19.3	3.7	0.02

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy
*Standard deviation included as reported.
†As reported by the study

4.2.1.5. Function: RF neurotomy or Sham neurotomy, Lumbar spine

- ***Function: Oswestry Disability Index (ODI)***

Short-term (< 12 months) (Table 26)

Three RCTs[27, 29, 30] reported function up to six months follow-up as measured by the patient-reported Oswestry Disability Index (ODI). ODI scores are reported on a scale of 0 to 100, with higher scores indicating greater disability. In all studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 26. P-values not reported in the study were calculated for mean change from baseline scores if standard deviations were reported or calculable.

Table 26. ODI scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
1 mos.	Leclaire 2001 (N = 70)	1 IAB ("significant" relief)	38.3 ± 14.7	36.4 ± 14.6	35.6	34.4	2.7 ± 12.4* (7%)	2.1 ± 9.4* (6%)	0.82
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	31.0 ± 14.2	38.0 ± 13.1	19.9	39.7	11.1 (36%)	-1.7 (-4%)	<0.05* (adj & unadj)
3 mos.	Leclaire 2001 (N = 70)	1 IAB ("significant" relief)	38.3 ± 14.7	36.4 ± 14.6	33.6	33.7	4.7± 12.0* (12%)	2.7 ± 9.1* (7%)	0.44
6 mos.	Tekin 2007 (N = 40)	1 MBB (≥50% pain relief)	39.2 ± 3.5	40.1 ± 2.8	25.1 ± 6.4	28.9 ± 5.7	14.1 ± 4.2 (36%)	11.2 ± 3.9 (28%)	0.03

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; SD: standard deviation; SE: standard error; Sham: sham neurotomy; unadj: unadjusted for baseline differences

*As reported by the study

†Calculated (unless otherwise indicated)

Regarding the mean change ODI score from baseline and clinical relevance of this result:

- One study reported no difference in mean ODI improvement between treatment groups at one month follow-up.[27]
- All[27, 29, 30] of the three RCTs reported greater improvement in ODI scores following RF neurotomy compared with sham at two, three, or six months follow-up.

- P-values for mean change from baseline back pain VAS scores were either calculated or reported for all three studies:
  - There was a statistically significant difference between treatment groups in two RCTs (van Kleef, Tekin)[29, 30] such that the results favored RF neurotomy.
    - Depending on the interpretation of MCID used, which we found ranges from 4.5 to 20 points in low back pain and lumbar spinal fusion patients (see section 1.3.2):
      - Van Kleef[30]: There may be a clinically relevant improvement from baseline to two months in the RF neurotomy (11.1-point improvement) but not sham neurotomy (score worsened by 1.7 points) treatment group.
      - Tekin[29]: Both groups are likely to have clinically similar improvement from baseline to six months (RF neurotomy: 14.1 ± 4.2; sham neurotomy: 11.2 ± 3.9 point improvement).
  - The difference between treatment groups was not statistically significant in one RCT (Leclaire).[27]

Long-term (≥ 12 months) (Table 27)

One RCT[29] reported function at 12 months follow-up as measured by the patient-reported Oswestry Disability Index (ODI). ODI scores are reported on a scale of 0 to 100, with higher scores indicating greater disability. Because patients were blinded to treatment received, the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 27. P-values not reported in the study were calculated for mean change from baseline scores if standard deviations were reported or calculable.

Table 27. ODI scores at baseline and long-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
12 mos.	Tekin 2007 (N = 40)	1 MBB (≥50% pain relief)	39.2 ± 3.5	40.1 ± 2.8	28.0 ± 7.1	33.6 ± 5.7	11.2 ± 4.8 (29%)	6.5 ± 3.9 (16%)	0.0015

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*Standard deviation included as reported.

†Calculated (unless otherwise indicated)

Regarding the mean change ODI score from baseline and clinical relevance of this result:

- This RCT[29] reported greater improvement in ODI scores following RF neurotomy compared with sham at 12 months follow-up, a difference which was statistically significant.
  - Whether the results were clinically meaningful depends on the interpretation of clinically important change (which we found ranges from 4.5 to 20 points in low back pain or spinal fusion patients (see section 1.3.2)).

- ***Function: Roland-Morris***

Short-term (< 12 months) (Table 28)

One RCT (Leclaire)[27] reported function at one and three months follow-up as measured by the patient-reported Roland-Morris outcome measure. Roland-Morris scores are reported on a scale of 0 to 24, with higher scores indicating greater disability, however Leclaire et al. reported this outcome on a converted scale of 0 to 100. As patients were blinded to treatment received, the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 28. The difference in the mean change Roland-Morris scores between treatment groups from baseline to one or three months follow-up was not statistically significant.

Table 28. Roland-Morris scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Converted score range: 0-100, higher scores = greater disability (normal Roland-Morris range is 0-24).

		Diagnostic block(s) Pain relief required	Converted baseline score Mean (SD*)		Converted follow-up score Mean (SD*)		Improvement from baseline (converted scores) Mean (SD*) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
1 mos.	Leclaire 2001 (N = 70)	1 IAB ("significant" relief)	52.9 ± 18.2	51.6 ± 22.8	44.5	49.5	8.4 ± 17.4 (16%)	2.2 ± 14.7 (4%)	0.1130
3 mos.	Leclaire 2001 (N = 70)	1 IAB ("significant" relief)	52.9 ± 18.2	51.6 ± 22.8	9.8 ± 19.5	7.2 ± 17.0	9.8 ± 19.5 (19%)	7.2 ± 17.0 (14%)	0.67

Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*As reported by the study

†Calculated (unless otherwise indicated)

Long-term (≥ 12 months)

No data were reported.

- ***Function: Waddell criteria for physical impairment***

Short-term (< 12 months) (Table 29)

One RCT (van Kleef)[30] reported function at to three months follow-up as measured by the patient-reported Waddell criteria for physical impairment outcome measure. Waddell scores are reported on a scale of 0 to 24, with higher scores indicating greater disability. Because patients were blinded to treatment received, the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 29. Both the unadjusted and adjusted difference in the mean change Waddell scores between treatment groups from baseline to two months follow-up was not statistically significant. (The adjusted difference took into account differences in gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks.)

Table 29. Waddell scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-24, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	1.8 ± 1.5	2.8 ± 1.1	1.47	2.73	0.33	0.07	≥0.05* (adj & unadj)

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy; unadj: unadjusted for baseline differences

*As reported by the study

†Calculated (unless otherwise indicated)

Long-term (≥ 12 months)

No data were reported.

- ***Function: physical activities***

Short-term (< 12 months) (Table 30)

One RCT (van Wijk)[31] reported function at three months follow-up as measured by a patient-reported physical activities scale. The scale asks patients about their ability to perform basic activities, such as sitting down and standing up from a chair, taking a long walk, getting dressed, among others. Scores were reported on a scale of 0 to 30, with lower scores indicating greater disability. Patients were blinded to treatment received, thus the outcome was assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 30. While the p-values were not reported or calculable, there was little difference between treatment groups in mean change scores from baseline to follow-up (RF neurotomy: 1.5; Sham neurotomy: 0.9).

Table 30. Physical activity scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-30, lower scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Median (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
3 mos.	van Wijk 2005 (N = 81)	2 IABs (≥50% pain relief)	20.6‡ ± 4.2	18.4‡ ± 4.5	NR/NC	NR/NC	1.5	0.9	NR/NC

IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*As reported by the study

†Calculated (unless otherwise indicated)

‡Median

Long-term (≥ 12 months)
No data were reported.

4.2.1.6. Composite outcome measures of "Success": RF neurotomy or Sham neurotomy, Lumbar spine

- ***Composite measure of "success"***

Short-term (< 12 months) (Table 31)
Two RCTs[30, 31] reported a composite outcome measures of "success".

Van Kleef et al. (1999)[30] considered patients to have a "successful" outcome at two months if they achieved a minimum of a 2-point reduction on the VAS scale (0-10) and a 50% or more reduction in pain on global perceived effect (GPE). This measure was reported in a blinded manner, as patients were blinded to treatment received. In the RF neurotomy group, 67% (10/15) of patients achieved this measure of success compared with 38% (6/16) of those in the sham neurotomy group. The corresponding relative risk and risk differences were not significantly different between groups as determined by the 95% confidence intervals (Table 31). However, the study reported that while the corresponding unadjusted odds ratio was 3.3 (90% CI, 1.0, 11.5) was not statistically significant (*P* = .05), after adjusting for differences between treatment groups in sex, age, duration of pain, baseline pain intensity and Likert scores after diagnostic blocks, the adjusted odds ratio was 9.5 (90% CI, 1.5, 60.5), a difference which was statistically significant (*P* < .05). Caution should be used when interpreting these results, as there were only 31 patients total enrolled in the study.

Van Wijk and colleagues (2005)[31] defined "success" as either of the following: (a) ≥50% reduction in VAS-back pain without a decrease in daily activities or an increase in analgesic use, or (b) ≥25% reduction in VAS-back pain, an increase in daily activities by ≥25%, and a decrease in analgesic use by ≥25%. This measure was reported in a blinded manner, as patients were blinded to treatment received. In the RF neurotomy group, 28% (11/40) of patients achieved this composite outcome versus 29% (12/41) of those in the sham neurotomy group, differences which were not statistically significant (Table 31).

Table 31. Composite outcome measure of "success" at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

		Diagnostic block(s) Pain relief required	"Success" composite outcome Change from baseline	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
2 mos.	van Kleef 1999	1 MBB (≥50% pain relief)	≥ 2 point improvement in VAS (0-10) and ≥ 50% improvement in GPE (1-4)	67% (10/15)	38% (6/16)	1.77 (0.86, 3.68) 0.29 (-0.05, 0.63)	NS
3 mos.	van Wijk 2005	2 IABs (≥50% pain relief)	Either of the following: • ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or • ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%	28% (11/40)	29% (12/41)	0.94 (0.47, 1.88) -0.02 (-0.21, 0.18)`NS	NS

CI: confidence interval; GPE: global perceived effect; IAB: intra-articular block; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR; risk ratio; VAS: visual analogue scale
*Calculated (unless otherwise indicated)

Long-term (≥ 12 months)
No data were reported.

4.2.1.7. Quality of life: RF neurotomy or Sham neurotomy, Lumbar spine

- ***Quality of life: SF-36***

Short-term (< 12 months) (Table 32)
One RCT (van Wijk)[31] reported quality of life at three months follow-up using several subscales of the patient-reported SF-36 outcome measure. Scores for each subscale are reported on a range from 0 to 100, with lower scores indicating greater disability. Patients were blinded to treatment received, thus the outcome was assessed in a blinded fashion. Mean baseline and change from baseline scores are presented in Table 32 (follow-up scores were not reported).

Table 32. SF-36 subscale scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Range: 0-100, lower scores = greater disability

		Diagnostic block(s) Pain relief required		Baseline score Mean (SD*)		Improvement from baseline Mean (SD*)		
			SF-36 subscale	RFN	Sham	RFN (n = 40)	Sham (n = 41)	p-value†
3 mos.	van Wijk 2005 (N = 81)	2 IABs (≥50% pain relief)	Physical functioning	42.9 ± 19.3	33.8 ± 17.0	4.7 ± 16.9	7.8 ± 19.7	0.45
			Social functioning	59.7 ± 23.1	53.0 ± 24.7	5.3 ± 36.1	2.6 ± 29.6	0.71
			Mental health	62.9 ± 21.8	70.2 ± 16.8	2.7 ± 26.8	0.7 ± 23.9	0.72
			Vitality	43.5 ± 21.6	49.2 ± 19.6	5.3 ± 14.6	-2.4 ± 17.7	0.04
			Pain	37.3 ± 15.6	31.2 ± 15.3	11.8 ± 22.9	11.6 ± 20.6	0.97
			General health	56.8 ± 21.9	57.3 ± 19.8	1.8 ± 13.6	-1.3 ± 17.5	0.38

IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*As reported by the study

†Calculated (unless otherwise indicated)

Regarding the mean change SF-36 subscale scores from baseline to 3 months:

- The differences in improvement between treatment groups were not statistically significant for the following subscales[31]:
  - Physical functioning
  - Social functioning
  - Mental health
  - Pain
  - General health
- There was greater improvement in the SF-36 vitality subscale scores following RF neurotomy compared with sham neurotomy (5.3 ± 14.6 versus -2.4 ± 17.7, respectively), a difference that was statistically significant (P = .04)[31].
  - We did not find any definitions of MCID relevant to this population for this subscale, so are unable to make definitive interpretations regarding the clinical significance of these results.

Long-term (≥ 12 months)

No data were reported.

- ***Quality of life: COOP/WONCA***

Short-term (< 12 months) (Table 33)
One RCT (van Kleef)[30] reported quality of life at two months as measured by the patient-reported Dartmouth COOP Functional Health Assessment Charts/WHO of Primary Care Physicians (WONCA) (COOP/WONCA) outcome measure. Scores are reported on a scale from 6 to 35, with lower scores indicating better quality of life. As patients were blinded to treatment received, outcomes were assessed in a blinded manner. Mean baseline, follow-up, and change from baseline scores are presented in Table 33. Both the unadjusted and adjusted difference in the mean change Waddell scores between treatment groups from baseline to two months follow-up was not statistically significant. (The adjusted difference took into account differences in gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks.)

Table 33. COOP/WONCA scores at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).
Range: 6-35, lower scores = better quality of life

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*) (%)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	20.2 ± 3.8	21.6 ± 3.6	17.1	20.0	3.13	1.62	≥0.05* (adj & unadj)

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy; unadj: unadjusted for baseline differences
*As reported by the study
†Calculated (unless otherwise indicated)

Long-term (≥ 12 months)
No data were reported.

4.2.1.8. Patient satisfaction: RF neurotomy or Sham neurotomy, Lumbar spine

Short-term (< 12 months)
No data were reported.

Long-term (≥ 12 months) (Table 34)
One RCT (Tekin)[29] reported patient satisfaction at twelve months follow-up. Patients were asked about their satisfaction, scores were reported on a scale of 0 to 3, (3: excellent; 2: good; 1: moderate; 0: bad). As patients were unaware of which treatment they had received, outcomes were reported in a blinded manner. The percentage of patients with each score at 12 months is reported in Table 34. Significantly more patients in the RF neurotomy group had a patient

satisfaction of "excellent" compared with the sham neurotomy group (65% versus 20%, respectively) ((RR: 3.25 (95% CI, 1.48, 7.12)), (RD: 45% (95% CI, 18%, 72%)) (*P* = 0.0045 for both). However, the differences between treatment groups in the percentages of patients who had a patient satisfaction of "good", "moderate", or "bad" was not a statistically significant when scored separately (Table 34).

Table 34. Patient satisfaction scores at baseline and long-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

		Diagnostic block(s) Pain relief required	Patient satisfaction	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
12 mos.	Tekin 2007 (N = 40)	1 MBB (≥50% pain relief)	"Excellent" (3)	65% (13/20)	20% (4/20)	3.25 (1.48, 7.12) 0.45 (0.18, 0.72)	RF neurotomy
			"Good" (2)	30% (6/20)	50% (10/20)	0.60 (0.31, 1.17) -0.20 (-0.50, 0.10)	NS
			"Moderate" (1)	5% (1/20)	25% (5/20)	0.20 (0.03, 1.56) -0.20 (-0.41, 0.01)	NS
			"Bad" (0)	0% (0/20)	5% (1/20)	0.00 (NC) -0.05 (-0.15, 0.05)	NS

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR; risk ratio
*Calculated

4.2.1.9. Analgesic use: RF neurotomy or Sham neurotomy, Lumbar spine

Short-term (< 12 months) (Table 35)
Four[27, 28, 30, 31] of the six RCTs reported analgesic use up to six months follow-up. Each study reported analgesic use using different methodology, which is outlined in Table 35 and in the text below.

Table 35. Analgesic use at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

Various methods of reporting analgesic use were used.

		Diagnostic block(s) Pain relief required	Scoring method	Baseline score Mean (SD)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†)		
				RFN	Sham	RFN	Sham	RFN	Sham	p-value†
2 mos.	van Kleef 1999 (N = 31)	1 MBB (≥50% pain relief)	Median number of tablets (mostly NSAIDs) per 4 days	Median: 0 (range, 0-12)	Median: 0 (range, 0-12)	NR	NR	Median: 2.13 (fewer)	Median: -1.75 (more)	<0.05* (unadj) --- ≥0.05* (adj)
3 mos.	Leclaire 2001 (N = 70)	1 IAB ("signifi-cant" relief)	NSAIDs or acetamino phen usage	NR	NR	NR	NR	NR	NR	NS*
	van Wijk 2005 (N = 81)	2 IABs (≥50% pain relief)	Analgesic intake scale (0-8) (higher score indicates greater usage)	1.0‡ ± 1.0	1.5‡ ± 1.7	NR/ NC	NR/ NC	0.1	0.2	NR/ NC
6 mos.	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	Analgesic intake scale (6-points, range & details NR)	3.95	3.80	2.55	3.20	1.40	0.60	0.04*

adj: analysis adjusted for gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks; IAB: intra-articular block; Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy; unadj: unadjusted for baseline differences

*As reported by the study

†Calculated (unless otherwise indicated)

‡Median

Number of tablets taken (median number over 4 days)(van Kleef, 2 months):

- Van Kleef et al.[30] reported the median number of analgesic tablets (primarily nonsteroidal anti-inflammatory drugs (NSAIDs) that patients were taking over four days. There appeared to be no difference in these numbers at baseline between treatment groups. However, at two months, patients who had received RF neurotomy were taking 2.13 less analgesic tablets every 4 days, while those who had received sham neurotomy were taking 1.75 more analgesic tablets every 4 days. The authors reported that the unadjusted difference in the change between treatment groups from baseline to two months follow-up was statistically significant, but that the adjusted difference between groups was not statistically significant. (The adjusted difference

took into account differences in gender, age, duration of pain before treatment, pretreatment pain intensity, and Likert scores after diagnostic nerve blocks.)

Usage, scale of 0-8 (median of 4 scores over 2 weeks)(van Wijk, 3 months):

- Van Wijk et al.[31] had patients rate their acetaminophen/NSAID usage on a scale of 0-8, with higher scores indicating greater usage. At three months, the RF neurotomy group had a mean improvement of 0.1, and those in the sham neurotomy group had a mean improvement of 0.2 (when compared with baseline). The statistical significance of this outcome was not reported and could not be calculated, however, the difference between treatment groups is unlikely to be meaningful.

"Analgesic use" (details/data not reported) (Leclaire, 3 months):

- Leclaire et al.[27] reported that there was no statistical difference found between treatment groups in terms of acetaminophen or NSAIDs used at three months, however, no data were reported.

Usage, 6-point scale (Nath, 6 months):

- Nath et al.[28] had patients rate their analgesic consumption on a 6-point scale; the scoring range and details were not given. At six months, the RF neurotomy group had a mean improvement from baseline of 1.4, while those in the sham neurotomy group had a mean improvement of 0.6, a difference which the authors reported was statistically significant (difference: 0.8 (95% CI, 0.04, 1.56; P = .04).

Long-term (≥ 12 months) (Table 36)

One RCT[29] reported the percentage of patients using analgesics at 12 months follow-up; the types of analgesics being used was not reported. (Analgesic usage at baseline was not reported). Overall, significantly fewer patients in the RF neurotomy group were using analgesics at 12 months compared with patients in the sham neurotomy group (40% versus 95%), a difference that was statistically significant. Because we don't know the percentage of patients using analgesics at baseline, caution should be used when interpreting this result. Details are available in Table 36.

Table 36. Percentage of patients using analgesics at baseline and long-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

			Baseline		Follow-up			
		Diagnostic block(s) Pain relief required	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
12 mos.	Tekin 2007 (N = 40)	1 MBB (≥50% pain relief)	NR	NR	40% (8/20)	95% (19/20)	0.42 (0.24, 0.73) -0.55 (-0.79, -0.32)	RF neurotomy

CI: confidence interval; MBB: medial branch block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR; risk ratio
*Calculated

4.2.1.10. Return to work: RF neurotomy or Sham neurotomy, Lumbar spine

Short-term (< 12 months)

One RCT (Leclaire et al.)[27] reported the percentage of patients who had returned to work at three months. Of those patients who were not working at baseline, 44% (8/18) in the RF neurotomy group had returned to work, compared with 38% (8/21) in the sham neurotomy group. This difference was not statistically significant, with a relative risk of 1.17 (95% CI, 0.55, 2.47) and a risk difference of 6% (95% CI, -25%, 37%).

Another RCT (Nath et al.)[28] had patients rate "work" on a 6-point quality of life scale; the scoring range and details were not given. At six months, the RF neurotomy group had a mean improvement from baseline of 1.6, while those in the sham neurotomy group had a mean improvement of 0.15, a difference which the authors reported was statistically significant (difference: 1.45 (95% CI, 0.5, 2.4; P = .004)). However, there were differences in the baseline scores which were not controlled for.

Table 37. "Work" as measured at baseline and short-term follow-up following RF or sham neurotomy in the lumbar spine (RCT data).

"Work": patient-reported on a 6-point scale (range not reported)

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†)		
			RFN	Sham	RFN	Sham	RFN	Sham	p-value†
6 mos.	Nath 2008 (N = 40)	2 MBBs (≥80% pain relief)	4.75	3.70	3.15	3.55	1.60	0.15	0.004*

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy

*As reported by the study

†Calculated (unless otherwise indicated)

Long-term (≥ 12 months)

No data were reported.

4.2.2. RF Neurotomy versus Sham Neurotomy: Effectiveness in the Lumbar Spine

No studies were identified.

4.2.3. RF Neurotomy versus Sham Neurotomy: Efficacy in the Cervical Spine

We report on one RCT[32] that compared radiofrequency facet neurotomy to sham neurotomy.

4.2.3.1. Summary of study characteristics

Lord et al.[32] performed a double-blind RCT in which patients with cervical facet joint pain between C3-4 and C6-7, who had failed conservative treatment, and who had responded to medial branch block were randomized to receive RF neurotomy (n = 12) or sham neurotomy (n = 12). Prior to randomization, each patient had undergone controlled medial branch blocks with lidocaine, bupivacaine, and saline on separate occasions. An overview of diagnostic blocks used to select patients for treatment can be found in Table 38. Mean patient age was 44 ± 12 years, and males comprised 38% of the overall patient population. The mean duration of pain was 44 months in the RF neurotomy group and 34 months in the sham neurotomy group, a difference which was not adjusted for. Both the patients and the surgeon were blinded to treatment received. This study received a class of evidence (CoE) grade of II. Additional descriptions (including descriptions of the neurotomy procedures) can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Table 38. Diagnostic block overview for studies included in KQ2: RF or sham neurotomy in the cervical spine (RCT data).

	Patients (n)		Diagnostic block	Response required from diagnostic block to proceed to treatment
	RFN	Sham		
Lord (1996) (N = 24)	12	12	3 MBBs (lidocaine, bupivacaine, saline)	100% with anesthetics, 0% with saline

MBB: medial branch block; RFN: radiofrequency neurotomy; Sham: sham neurotomy

4.2.3.2. Neck pain: RF neurotomy or Sham neurotomy, Cervical spine

- ***Freedom from pain***

Short-term (< 12 months) (Table 39)

Lord et al.[32] reported that at approximately six months (27 weeks), significantly more patients were free from their "accustomed" pain in the RF neurotomy group (7/12) compared with those in the sham neurotomy group (1/12) (RR, 7.00 (95% CI, 1.01, 48.54); (RD, 50% (95% CI, 18%, 82%) (*P* = 0.0110)) (Table 39). A larger trial is needed to confirm this result.

Table 39. Freedom from pain at short-term follow-up following RF or sham neurotomy in the cervical spine (RCT data).

Diagnostic block(s) Pain relief required		RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
3 MBBs (100% with anesthetics, 0% with saline)	6 months	58% (7/12)	8% (1/12)	7.00 (1.01, 48.54) 0.50 (0.18, 0.82)	RF neurotomy

CI: confidence interval; MBB: medial branch block; mos.: months; RD: risk difference; RF: radiofrequency; RR; risk ratio
*Calculated
†27 weeks

Long-term (≥ 12 months)
No data were reported.

- ***Time to return of ≥50% of baseline pain***

Short-term (< 12 months)
Lord and colleagues[32] reported that the median time to a return of pain that was at least 50% of the baseline level of pain was significantly longer following RF neurotomy compared with sham neurotomy (median, 263 days versus 8 days) (*P* = 0.04). The mean time to return to pain was not reported.

Long-term (≥ 12 months)
No data were reported.

4.2.4. RF Neurotomy versus Sham Neurotomy: Effectiveness in the Cervical Spine

No studies were identified.

4.2.5. RF Neurotomy versus Spinal Injections: Efficacy in the Lumbar Spine

We report on two RCTs[33, 34] that compared radiofrequency facet neurotomy to spinal injections in the facet joint. While Civelek and colleagues compared neurotomy to therapeutic medial branch block, Lakemeier and colleagues compared neurotomy to therapeutic intra-articular injections. Results are presented together, but we did not pool results because different methods of spinal injections were used.

4.2.5.1. Summary of study characteristics

Two RCTs form the evidence base, one of which compared facet neurotomy to therapeutic medial branch block[33] and the other of which compared facet neurotomy to therapeutic intra-articular injections[34]. For inclusion, patients were required to have had suspected facet joint pain in the lumbar spine with an absence of cancer and trauma. Diagnostic block details are available in Table 40. The mean patient age was 54 ± 17 years in one study[33] and 57 ± 12 years in the other[34], and 30-64% of patients were male. The mean duration of pain was approximately 19 months in both groups in one trial[33] and was not reported in the other trial[34]. Patients were blinded in one study (Lakemeier) but not the other (Civelek); thus patient-reported outcomes from the latter study were not assessed in a blinded manner. Both studies had blinded data collectors. Both studies also had a length of follow-up of six months and Civelek also reported on outcomes at 12 months. Both studies received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Table 40. Diagnostic block overview for studies included in KQ2: RF neurotomy or spinal injections in the lumbar spine (RCT data).

	Patients (n)		Diagnostic block	Response required from diagnostic block to proceed to treatment
	RFN	Sham		
Civelek (2012) (N = 100)	50	50	NR	NR
Lakemeier (2013) (N = 56)	29	27	1 MBB (bupivacaine)	≥50% pain relief

MBB: medial branch block; NR: not reported; RFN: radiofrequency neurotomy; Sham: sham neurotomy

4.2.5.2. Back pain: RF neurotomy or Spinal injections, Lumbar spine

- ***Back pain: VAS scores***

Short-term (< 12 months) (Table 41)

Civelek reported outcomes at one month, and both RCTs reported back pain at six months follow-up[33, 34]; back pain was measured by the patient-reported visual analogue scale (VAS). We have standardized the scores for the studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. Mean baseline, follow-up, and change from baseline scores are presented in Table 41. P-values were calculated for mean change from baseline scores if standard deviations were reported or calculable.

Table 41. VAS back pain scores at baseline and short-term follow-up following RF or spinal injections in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Injection	RFN	Injection	RFN	Injection	p-value†
1 mos.	Civelek 2012 (N = 100)	NR (NR)	82	85	22	34	60 (73%)	51 (60%)	NR/NC
6 mos.	Civelek 2012 (N = 100)	NR (NR)	82	85	25	44	57 (70%)	41 (48%)	NR/NC
	Lakemeier 2013 (N = 56)	1 MBB (≥50% pain relief)	66 ± 18	70 ± 17	47 ± 24	54 ± 21	19 ± 14.5 (29%)	16 ± 12.6 (23%)	0.429

MBB: medial branch block; mos.: months; NC: not calculable; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation

*Reported by the study
†Calculated

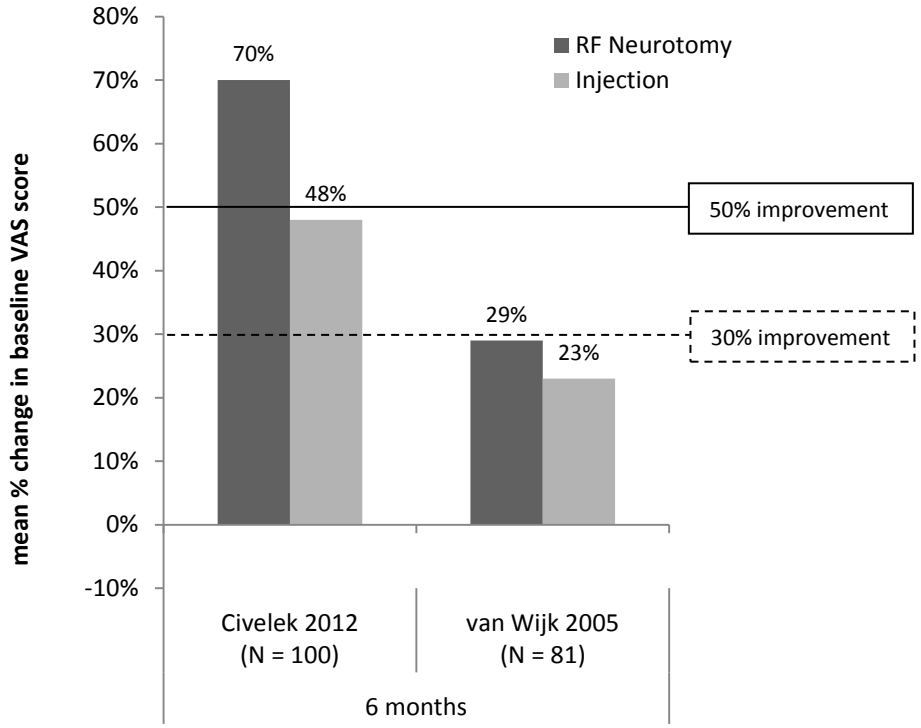
Regarding the mean change VAS back pain score from baseline:

- Both[33, 34] of the RCTs reported greater improvement in VAS scores following RF neurotomy compared with spinal injections (therapeutic MBB (Civelek) or intra-articular injection (Lakemeier)) at six months follow-up.
- P-values for mean change from baseline back pain VAS scores could be calculated for one RCT[34] (and were not calculable or reported for Civelek), and the difference between treatment groups was not statistically significant (Table 41).

Regarding the mean percent change from baseline in VAS back pain score (Figure 5):

- If the MCID is 30%:
  - There was not a clinically important improvement in back pain following RF neurotomy but not spinal injections at six months follow-up in either of the RCTs.
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful at six months follow-up in either RCT.
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not spinal injections at six months follow-up in one[33] of the two RCTs.
  - The difference in the percent change in back pain VAS scores between treatment groups was clinically meaningful at six months follow-up in neither of the RCTs.

Figure 5. Percent change in back pain VAS scores from baseline to 6 months postoperative RF neurotomy or spinal injections: lumbar spine RCT data.



Long-term (≥ 12 months) (Table 42)

One RCT (Civelek)[33] reported long-term back pain as measured by the patient-reported visual analogue scale (VAS). We have standardized the scores so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. Mean baseline, follow-up, and change from baseline scores are presented in Table 42. P-values were calculated for mean change from baseline scores.

Table 42. VAS back pain scores at baseline and long-term follow-up following RF or spinal injections in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*) RFN	Baseline score Mean (SD*) Injection	Follow-up score Mean (SD*) RFN	Follow-up score Mean (SD*) Injection	Improvement from baseline Mean (SD†) (%) RFN	Improvement from baseline Mean (SD†) (%) Injection	p-value†
12 mos.	Civelek 2012 (N = 100)	NR (NR)	82	85	26	49	56 (68%)	36 (42%)	NR/NC

Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable (due to missing standard deviations); NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

†Calculated (unless otherwise indicated)

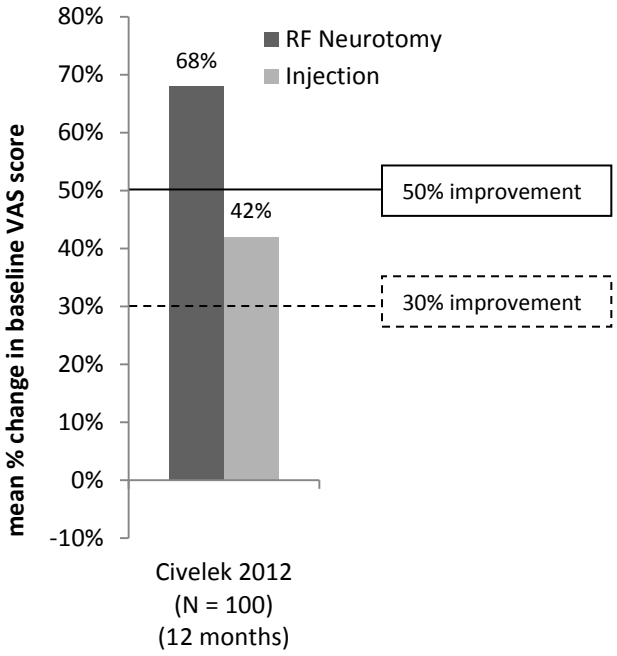
Regarding the mean change VAS back pain score from baseline:

- This RCT[33] reported greater improvement in VAS scores following RF neurotomy compared with therapeutic MBB at 12 months follow-up; however the statistical significance of this result could not be calculated.

Regarding the mean percent change from baseline in VAS back pain score (Figure 6):

- If the MCID is 30%:
  - There was not a clinically important improvement in back pain following RF neurotomy but not spinal injections at 12 months.
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful at 12 months follow-up.
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following RF neurotomy but not spinal injections at 12 months follow-up[33] of the two RCTs.
  - However, the difference in the percent change in back pain VAS scores between treatment groups at 12 months was not clinically meaningful.

Figure 6. Percent change in back pain VAS scores from baseline to 12 months postoperative RF neurotomy or spinal injection: lumbar spine RCT data.



- ***Back pain: "Success" (Table 43)***

  Short-term (< 12 months) and Long-term (≥ 12 months) (Table 43)
  One RCT (Civelek)[33] reported the percentage of patients who achieved 50% reduction or more in back pain from baseline as measured by the patient-reported VAS (0-10). The results suggested that there was a significant difference between the groups in favor of RF neurotomy at one, six, and twelve months (Table 43).

Table 43. Back pain measures of "success" at baseline and short- or long-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Diagnostic block(s) Pain relief required	Length follow-up	Back pain: Change from baseline	RF Neurotomy (% patients (n/N))[33]	Injection (% patients (n/N))[33]	RR (95% CI)* RD (95% CI)*	Favors*
NR (NR)	1 mos.	≥ 50% improvement in VAS (0-10)	100% (50/50)	80% (40/50)	1.25 (1.09, 1.44) 0.20 (0.00, 0.31)	RF neurotomy
	6 mos.	≥ 50% improvement in VAS (0-10)	90% (45/50)	68% (34/50)	1.32 (1.11, 1.58) 0.22 (0.07, 0.37)	RF neurotomy
	12 mos.	≥ 50% improvement in VAS (0-10)	88% (44/50)	62% (31/50)	1.42 (1.12, 1.80) 0.26 (0.10, 0.42)	RF neurotomy

CI: confidence interval; mos.: months; RD: risk difference; RF: radiofrequency; RR: risk ratio; VAS: visual analogue scale
*Calculated (unless otherwise indicated)

4.2.5.3. Function: RF neurotomy or Spinal injection, Lumbar spine

- ***Function: Oswestry Disability Index (ODI)***

Short-term (< 12 months) (Table 44)

One RCT (Lakemeier)[34] reported function at six months follow-up as measured by the patient-reported Oswestry Disability Index (ODI). ODI scores are reported on a scale of 0 to 100, with higher scores indicating greater disability. Mean baseline, follow-up, and change from baseline scores are presented in Table 44. P-values were calculated for mean change from baseline scores. Lakemeier and colleagues[34] reported the difference in the mean change Roland-Morris scores between treatment groups from baseline to six months follow-up was not statistically significant (*P* = .069).

Table 44. ODI scores at baseline and short-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD†) (%)		
			RFN	Injection	RFN	Injection	RFN	Injection	p-value*
6 mos.	Lakemeier 2013 (N = 56)	1 MBB (≥50% pain relief)	40.8 ± 16.4	38.7 ± 18.4	28.0 ± 20.0	33.0 ± 17.4	12.8 ± 12.0 (31%)	5.7 ± 11.4 (15%)	0.069

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

†Calculated

Long-term (≥ 12 months)

No data were reported.

- ***Function: Roland-Morris***

Short-term (< 12 months) (Table 45)

One RCT (Lakemeier)[34] reported function at six months follow-up as measured by the patient-reported Roland-Morris outcome measure. Roland-Morris scores are reported on a scale of 0 to 24, with higher scores indicating greater disability. Mean baseline, follow-up, and change from baseline scores are presented in Table 45. The difference in the mean change Roland-Morris scores between treatment groups from baseline to six months follow-up was not statistically significant.

Table 45. Roland-Morris scores at baseline and short-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Score range: 0-24, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*) (%)		
			RFN	Injection	RFN	Injection	RFN	Injection	p-value†
6 mos.	Lakemeier 2013 (N = 56)	1 MBB (≥50% pain relief)	12.8 ± 5.4	13.2 ± 5.9	9.1 ± 6.0	9.0 ± 6.4	3.7 ± 3.7 (19%)	4.2 ± 3.9 (14%)	0.64

Improvement from baseline: positive numbers indicate a better score at follow-up; MBB: medial branch block; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

†Calculated

Long-term (≥ 12 months)
No data were reported.

4.2.5.4. Patient satisfaction: RF neurotomy or Spinal injection, Lumbar spine

- ***Patient satisfaction: NASS Patient Satisfaction Questionnaire***

Short-term (< 12 months) and Long-term (≥ 12 months) (Tables 46-47)
One RCT (Civelek)[33] reported patient satisfaction at six and twelve months follow-up as measured by the patient-reported NASS (North American Spine Society) Patient Satisfaction Questionnaire. Scores are reported on a scale of 1-4, with higher scores indicating greater disability. Mean baseline, follow-up, and change from baseline scores are presented in Table 46. The authors also reported the percentage of patients who achieved "success" in terms of patient satisfaction, which was defined as a NASS score of 1 or 2 (i.e., procedure fully met the patient's expectation, or resulted in less improvement than the hoped-for result but patient would undergo procedure again); the results are presented in Table 47.

Table 46. NASS Patient Satisfaction scores at baseline and short- or long-term follow-up following RF or spinal injection in the lumbar spine (RCT data).
Score range: 1-4, higher scores = greater disability

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*)		Follow-up score Mean (SD*)		
			RFN	Injection	RFN	Injection	p-value*
1 mos.	Civelek 2012 (N = 100)	NR (NR)	NR	NR	1.3	1.3	1.00
6 mos.	Civelek 2012 (N = 100)	NR (NR)	NR	NR	1.4	1.7	0.13
12 mos.	Civelek 2012 (N = 100)	NR (NR)	NR	NR	1.5	2.0	0.04

mos.: months; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation
*As reported by the study

Table 47. Patient satisfaction "success" at baseline and short- or long-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Diagnostic block(s) Pain relief required	Length follow-up	Patient Satisfaction "Success"	RF Neurotomy (% patients (n/N))[33]	Injection (% patients (n/N))[33]	RR (95% CI)* RD (95% CI)*	Favors*
NR (NR)	1 mos.	NASS Patient Satisfaction score of 1-2	100% (50/50)	88% (44/50)	1.14 (1.03, 1.26) 0.12 (0.03, 0.21)	RF neurotomy
	6 mos.	NASS Patient Satisfaction score of 1-2	90% (45/50)	76% (38/50)	1.18 (0.99, 1.42) 0.14 (-0.005, 0.28)	NS

Diagnostic block(s) Pain relief required	Length follow-up	Patient Satisfaction "Success"	RF Neurotomy (% patients (n/N))[33]	Injection (% patients (n/N))[33]	RR (95% CI)* RD (95% CI)*	Favors*
	12 mos.	NASS Patient Satisfaction score of 1-2	88% (44/50)	68% (34/50)	1.29 (1.04,1.61) 0.20 (0.04, 0.36)	RF neurotomy

CI: confidence interval; mos.: months; NASS: North American Spine Society; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated

Short-term follow-up (1 and 6 months)

- Civelek and colleagues[33] reported that patients in the RF neurotomy group had similar NASS patient satisfaction scores at both one and six months follow-up compared with the therapeutic medial branch block group.
- At one month, significantly more patients in the RF neurotomy group achieved "success" compared with those in the medial branch block group, with a relative risk of 1.14 (95% CI, 1.03, 1.26) and a risk reduction of 12% (95% CI, 3%, 21%) (*P* = .0119).
- At six months, though, the percentage of patients who achieved "success" in terms of patient satisfaction was similar in both groups, with a relative risk of 1.18 (95% CI, 0.99, 1.42) and a risk reduction of 14% (95% CI, -0.5%, 28%) (*P* = .0637).

Long-term follow-up (12 months)

- In contrast, this RCT[33] found that RF neurotomy patients had significantly better NASS patient satisfaction scores at 12 months follow-up than did those in the therapeutic medial branch block group (1.5 versus 2.0, respectively; *P* = 0.04).
- Similarly, the percentage of patients who achieved "success" in terms of patient satisfaction was significantly higher in the RF neurotomy group (88%) compared with the injections group (68%). Patients in the neurotomy group were 1.29 times as likely to have a successful result than those in the injection group (95% CI, 1.04, 1.62), and the risk difference between groups was 20% (95% CI, 4%, 36%) (P = .0163).[33]

4.2.5.5. Quality of life: RF neurotomy or Spinal injection, Lumbar spine

- ***Quality of life: EQ-5D***

Short-term (< 12 months) and Long-term (≥ 12 months) (Tables 48-49)

One RCT (Civelek)[33] reported quality of life at one, six and twelve months follow-up as measured by the patient-reported EQ-5D. The authors reported EQ-5D scores on a scale of 5-15, with a score of 5 indicating no problems and a score of 15 indicating extreme problems. Mean baseline, follow-up, and change from baseline scores are presented in Table 48. The authors also reported the percentage of patients who achieved quality of life "success", which was defined as a EQ-5D score that was less than 9; the results are presented in Table 49.

Table 48. EQ-5D scores at baseline and short- or long-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Score range: 5-15, higher scores = greater problems

Diagnostic block(s) Pain relief required			Baseline score Mean (SD*)		Follow-up score Mean (SD*)		Improvement from baseline Mean (SD*)		
			RFN	Injection	RFN	Injection			p-value*
NR (NR)	1 mos.	Civelek 2012 (N = 100)	13.8	14.9	5.6	6.0	8.2	8.9	NR/NC
	6 mos.	Civelek 2012 (N = 100)	13.8	14.9	6.5	7.2	7.3	7.7	NR/NC
	12 mos.	Civelek 2012 (N = 100)	13.8	14.9	6.7	8.0	6.8	6.9	NR/NC

mos.: months; NC: not calculable; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

Table 49. EQ-5D "success" at baseline and short- or long-term follow-up following RF or spinal injection in the lumbar spine (RCT data).

Diagnostic block(s) Pain relief required	Length follow-up	Patient Satisfaction "Success"	RF Neurotomy (% patients (n/N))[33]	Injection (% patients (n/N))[33]	RR (95% CI)* RD (95% CI)*	Favors*
NR (NR)	1 mos.	EQ-5D score < 9	98% (49/50)	90% (45/50)	1.09 (0.98, 1.20) 0.08 (-0.01, 0.17)	NS
	6 mos.	EQ-5D score < 9	92% (46/50)	76% (38/50)	1.21 (1.02, 1.44) 0.16 (0.02, 0.30)	RF neurotomy
	12 mos.	EQ-5D score < 9	90% (45/50)	69% (35/50)	1.29 (1.05,1.58) 0.20 (0.05, 0.35)	RF neurotomy

CI: confidence interval; mos.: months; NASS: North American Spine Society; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR; risk ratio

*Calculated

Short-term follow-up (1 and 6 months)

- Civelek and colleagues[33] reported that the mean EQ-5D scores at one and six months follow-up were statistically similar; the mean difference from baseline to one and six months were also similar between groups, though we were unable to calculate p-values (Table 49).
- The percentage of patients who achieved "success" at one month in terms of the EQ-5D scores was statistically similar in both treatment groups (Table 49).[33]

- However, the percentage of patients who achieved "success" at six months in terms of the EQ-5D scores was significantly higher in the RF neurotomy group (92%) compared with the injections group (76%), with patients in the neurotomy group being 1.21 times as likely to have a successful result than those in the injection group (95% CI, 1.02, 1.44), and a risk difference between groups of 16% (95% CI, 2%, 30%) (P = .0299).[33]

Long-term follow-up (12 months)

- Similar results were found at 12 months.
- The mean EQ-5D scores at 12 months follow-up were reported by the authors to be statistically similar (*P* = 0.11); the mean difference from baseline to 12 months were also similar between groups (6.8 versus 6.9 points improvement following RF neurotomy versus injection, respectively).
- As at six months, the percentage of patients who achieved "successful" EQ-5D scores at 12 months was significantly higher in the RF neurotomy group (90%) compared with the injections group (69%), with patients in the neurotomy group 1.29 times as likely to have a successful result versus those in the injection group (95% CI, 1.05, 1.58). The risk difference between groups was 20% (95% CI, 5%, 35%) (*P* = .0129).[33]

Analgesic use: RF neurotomy or Spinal injection, Lumbar spine

Short-term (< 12 months)

Lakemeier and colleagues[34] reported that there were no "measurable differences" between treatment groups in analgesic use, though no data were reported.

Long-term (≥ 12 months)

No data were reported.

4.2.6. RF Neurotomy versus Spinal Injections: Effectiveness in the Lumbar Spine

We identified one retrospective cohort study[35] that reported results from an audit of patients who received radiofrequency facet neurotomy or intra-articular injections in a secondary care setting.

4.2.6.1. Summary of study characteristics

Chakraverty (2004)

Chakraverty et al.[35] published the results of an audit of seven United Kingdom hospitals following facet joint procedures. The authors provided results for patients who had facet joint pain confirmed by intra-articular blocks though the details of pain relief required were not reported. For RF neurotomy, data from 38 patients treated between 2002 and 2004 were available. For therapeutic facet joint injection, data from 34 patients treated between 2000 and 2001 were available. The mean patient age was 61 years, and ranged from 30 to 90 years, and 38% of patients were male. The complete follow-up rate was not reported, and the follow-up was reported at 6 months. This study received a CoE grade of III and had numerous limitations,

including lack of independent or blind assessment. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.2.6.2. Back pain: RF neurotomy or Spinal injections, Lumbar spine

- ***Back pain: "Success"***

Short-term (< 12 months) (Table 50)
The audit[35] reported the percentage of patients who achieved 50% or more subjective global improvement in pain severity from baseline. There was not a statistically significant difference between treatment groups in the percentage of patients who achieved this as reported at six months follow-up (*P* = .0896) (Table 50).

Table 50. Global improvement of pain "success" at baseline and short-term follow-up following RF or spinal injection in the lumbar spine (nonrandomized data).

Diagnostic block(s) Pain relief required	Length follow-up	Patient Satisfaction "Success"	RF Neurotomy (% patients (n/N))[35]	Injection (% patients (n/N))[35]	RR (95% CI)* RD (95% CI)*	Favors*
IAB (NR)	6 mos.	≥ 50% improvement in global subjective improvement	50% (16/32)	29% (10/34)	1.70 (0.91, 3.18) 0.21 (-0.03, 0.44)	NS

CI: confidence interval; IAB: intra-articular block; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR; risk ratio
*Calculated

Long-term (≥ 12 months)
No comparative data were reported.

4.2.7. RF Neurotomy versus Spinal Injections: Efficacy in the Cervical Spine

We report on one RCT[36] that compared radiofrequency facet neurotomy to anesthetic injection of the major occipital nerve in patients with cervicogenic headache. Study characteristics are described below. Detailed results can be found in Appendix F. An overview of diagnostic blocks used to select patients for treatment can be found in Table 51.

4.2.7.1. Study characteristics and critical appraisal

Haspeslagh (2006)

Haspeslagh et al.[36] conducted an RCT in which patients with chronic cervicogenic headache of two or more years duration were randomized to receive RF facet joint denervation (n = 15) at cervical levels C3 to C6 or anesthetic injection of the greater occipital nerve (n = 15). For inclusion, patients must have rated their pain to be at least 50 on a VAS scale (0-100) during a pain period, and have considerable pain at least two days per week. Diagnostic blocks were not performed prior to treatment. Patients were evaluated at eight weeks, and those who did not respond were allowed to continue with additional treatment, including additional blocks and/or transcutaneous electrical nerve stimulation. Thus, we have reported results at eight weeks only in order to focus on the outcomes following RF facet neurotomy or injection. The mean patient age was 48 ± 12 years, and 27% of patients were male. Mean duration of pain was 10 years in the neurotomy group and 7 years in the injection group; this difference was not controlled for. It was not clear whether patients were blinded to their treatment group, though the data collectors were blinded. This study received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Table 51. Diagnostic block overview for studies included in KQ2: RF neurotomy or spinal injections in the cervical spine (RCT data).

	Patients (n)		Diagnostic block	Response required from diagnostic block to proceed to treatment
	RFN	Sham		
Haspeslagh (2006) (N = 30)	15	15	None	-

RFN: radiofrequency neurotomy; Sham: sham neurotomy

4.2.7.2. Headache: RF neurotomy or Spinal injection, Cervical spine

- ***Headache: VAS scores***

Short-term (< 12 months) (Table 52)

Haspeslagh et al.[36] reported headache intensity at two months follow-up; pain was measured by the patient-reported visual analogue scale (VAS) and reported on a scale of 0 to 100, with higher scores indicating greater pain. Mean baseline, follow-up, and change from baseline scores are presented in Table 52. P-values were calculated for mean change from baseline scores.

Table 52. VAS headache pain scores at baseline and short-term follow-up following RF or spinal injection in the cervical spine (RCT data).

Range: 0-100, higher scores = greater pain

		Diagnostic block(s) Pain relief required	Baseline score Mean (SD*) RFN	Baseline score Mean (SD*) GON injection	Follow-up score Mean (SD†) RFN	Follow-up score Mean (SD†) GON injection	Improvement from baseline Mean (SD*) (%) RFN	Improvement from baseline Mean (SD*) (%) GON injection	p-value†
2 mos.	Haspeslagh 2006 (N = 30)	None	68.1 ± 12.7	76.5 ± 16.6	37.6	44.1	30.5 ± 17.3 (45%)	32.4 ± 24.7 (42%)	0.8155

GON: greater occipital nerve; Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; RFN: radiofrequency neurotomy; SD: standard deviation; Sham: sham neurotomy; VAS: visual analog scale

*As reported by the study

†Calculated

Regarding the mean change VAS back pain score from baseline:

- The difference between treatment groups was not statistically significant.[36]

Regarding the mean percent change from baseline in VAS back pain score:

- If the MCID is 30% or 50%:
  - There was not a clinically important improvement in back pain following RF neurotomy but not spinal injection at two months follow-up.[36]
  - The difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful.[36]

Long-term (≥ 12 months)

No data were reported.

- ***Number of days with headache per week***

Short-term (< 12 months) (Table 53)

The authors reported the mean number of days over a one week period of time at two months follow-up during which the patients experienced a headache. Mean baseline, follow-up, and change from baseline scores are presented in Table 53. P-values were calculated for mean change from baseline scores. There were no differences between treatment groups in terms of the improvement in number of days per week the patient experienced a headache ($P = 0.6336$) or an intense headache ($P = 0.4416$) (Table 53).[36]

Table 53. Days of headache over one week at baseline and short-term follow-up following RF or spinal injection in the cervical spine (RCT data).

Diagnostic block(s) Pain relief required		Baseline Mean (SD*)		Follow-up Mean (SD*)		Improvement from baseline Mean (SD*)		
		RFN	GON injection	RFN	GON injection	RFN	GON injection	p-value †
None	Mean days of headache/ week	NR	NR	NR	NR	4.2 ± 5.1	5.5 ± 8.7	0.6336
	Mean days of intense headache/ week	NR	NR	NR	NR	1.5 ± 4.0	-0.5 ± 8.7	0.4416

GON: greater occipital nerve; Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NR: not reported; RFN: radiofrequency neurotomy; SD: standard deviation;
*As reported by the study
†Calculated

4.2.7.3. "Success" composite outcome measure: RF neurotomy or Spinal injection, Cervical spine

- ***"Success": Composite outcome measure***

Short-term (< 12 months) (Table 54)

Haspeslagh et al.[36] reported the percentage of patients who achieved "success", which was defined as either a 20% reduction in pain (as measured on the VAS scale) or a global perceived effect (GPE) score of +2 or +3 ("much better" or "complete relief") (total GPE scores ranged from -3 to +3). The results, presented in Table 54, suggest that there was not a significant difference between the groups at two months, with a relative risk of 1.12 (95% CI, 0.79, 1.59); and a risk difference of 9% (95% CI, -23%, 40%) (P = 0.5964).[36]

Table 54. "Success" at baseline and short-term follow-up following RF or spinal injection in the cervical spine (RCT data).

Diagnostic block(s) Pain relief required	Length follow-up	"Success" composite outcome	RF Neurotomy (% patients (n/N))[35]	Injection (% patients (n/N))[35]	RR (95% CI)* RD (95% CI)*	Favors*
None	2 mos.	GPE score +2 or +3 and/or ≥ 20-point improvement VAS	80% (12/15)	71% (10/14)	1.12 (0.79, 1.59) 0.09 (-0.23, 0.40)	NS

CI: confidence interval; GON: greater occipital nerve; mos.: months; NS: difference between groups is not statistically significant; RD: risk difference; RF: radiofrequency; RR: risk ratio
*Calculated

4.2.7.4. Quality of life: RF neurotomy or Spinal injection, Cervical spine

- ***Quality of life: SF-36***

Short-term (< 12 months) (Table 54)
Haspeslagh et al.[36] reported that there was no difference between treatment groups in any of the SF-36 subscale scores as measured at two months follow-up, however actual scores were not reported. SF-36 subscales evaluated included Physical Function, Social Function, Role Physical Limitations, Role Emotional Limitations, Mental Health, Vitality, Bodily Pain, and General Health.

4.2.8. RF Neurotomy versus Spinal Injections: Effectiveness in the Cervical Spine

No studies were identified.

4.2.9. Key Question 2a: What is the evidence of short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy?

4.2.9.1. Conventional versus Pulsed RF Neurotomy

We identified two RCTs (Kroll, Tekin)[29, 37] that compared outcomes following conventional versus pulsed RF neurotomy in the lumbar facet joint.

4.2.9.1.1. Summary of study characteristics

Two RCTs (Kroll, Tekin)[29, 37] met our inclusion criteria. Tekin et al.[29] included patients who had been experiencing continuous low back pain for at least six months, had not responded to previous treatment, and whose pain was suspected of originating in the facet joint (i.e., paravertebral tenderness), while Kroll et al.[37] included patients to have unilateral or bilateral lumbar back pain for at least one month and no symptoms radiating past the knee. Both studies required patients to undergo a single diagnostic medial branch block, and patients who reported a minimum of 50% reduction in their VAS pain were randomized to undergo either RF neurotomy or sham neurotomy. Outcomes were reported in a blinded manner. The average patient age was 58-59 years old, and 43-46% of patients were male. Neither study reported the mean duration of pain prior to randomization. Both studies received a grade of CoE II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.2.9.1.2. Back pain: Conventional or pulsed RF neurotomy, Lumbar spine

- ***Back pain: VAS scores***

Two RCTs[29, 37] reported back pain as measured by the patient-reported visual analogue scale (VAS). We have standardized the scores for the studies so that outcomes are reported on a scale of 0 to 100, with higher scores indicating greater pain. In both studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 55. P-values were calculated for mean change from baseline scores.

Table 55. VAS back pain scores at baseline and short- and long-term follow-up following conventional or pulsed RF neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater pain

		Baseline score Mean (SD*)		**Follow-up score** Mean (SD*)		**Improvement from baseline** Mean (SD†) (%)		
		Conventional RFN	**Pulsed RFN**	**Conventional RFN**	**Pulsed RFN**	**Conventional RFN**	**Pulsed RFN**	**p-value†**
3 mos.	Kroll 2007 (N = 26)	76.2 ± 16.0	63.5 ± 18.3	51.9 ± 27.4	51.2 ± 21.5	24.3 ± 17.5 (32%)	12.3 ± 13.0 (19%)	0.0587
6 mos.	Tekin 2007 (N = 40)	65 ± 15	66 ± 16	23 ± 13	29 ± 16	42 ± 9 (65%)	37 ± 10 (56%)	0.1047
12 mos.	Tekin 2007 (N = 40)	65 ± 15	66 ± 16	24 ± 11	35 ± 13	41 ± 9 (63%)	31 ± 10 (47%)	0.0020

Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; NC: not calculable (due to missing standard deviations); RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

†Calculated (unless otherwise indicated)

Regarding the short-term results:

- Both RCTs[29, 37] reported greater improvement in VAS scores following conventional continuous RF neurotomy compared with pulsed RF neurotomy at three and six months, however, these results were not statistically significant (Table 55).

Regarding the long-term results:

- Tekin et al.[29] reported significantly greater improvement in VAS scores following conventional continuous RF neurotomy compared with pulsed RF neurotomy at 12 months (Table 55).

Regarding the mean percent change from baseline in long-term VAS back pain scores:

- If the MCID is 30%:
  - There was not clinically important improvement in back pain following conventional but not pulsed RF neurotomy at 12 months follow-up, nor was the difference in the percent change in back pain VAS scores between treatment groups clinically meaningful.[29]
- If the MCID is 50%:
  - There was a clinically important improvement in back pain following conventional but not pulsed RF neurotomy at 12 months follow-up in this RCT[29].
  - However, the difference in the percent change in back pain VAS scores between treatment groups was not clinically meaningful.
  -

4.2.9.1.3. Function: Conventional or pulsed RF neurotomy, Lumbar spine

- ***Function: ODI scores***

Two RCTs[29, 37] reported function as measured by the patient-reported Oswestry Disability Index (ODI). ODI scores are reported on a scale of 0 to 100, with higher scores indicating greater disability. In both studies, patients were blinded to treatment received, thus outcomes were assessed in a blinded fashion. Mean baseline, follow-up, and change from baseline scores are presented in Table 56. P-values were calculated for mean change from baseline scores. As shown in Table 56, there were not any statistically meaningful differences between treatment groups in terms of improvement from baseline at three months (Kroll)[37], six months (Tekin)[29], or twelve months (Tekin)[29].

Table 56. ODI scores at baseline and short- and long-term follow-up following conventional or pulsed RF neurotomy in the lumbar spine (RCT data).

Range: 0-100, higher scores = greater disability

		Baseline score Mean (SD*)		**Follow-up score** Mean (SD*)		**Improvement from baseline** Mean (SD†)		
		Conventional RFN	**Pulsed RFN**	**Conventional RFN**	**Pulsed RFN**	**Conventional RFN**	**Pulsed RFN**	**p-value†**
3 mos.	Kroll 2007 (N = 26)	52.0 ± 17.3	44.9 ± 10.4	41.7 ± 16.9	42.2 ± 19.0	10.3 ± 10.8	2.7 ± 12.4	0.1086
6 mos.	Tekin 2007 (N = 40)	39.2 ± 3.5	39.4 ± 5.0	25.1 ± 6.4	25.3 ± 6.9	14.1 ± 4.2	14.1 ± 4.2	1.000
12 mos.	Tekin 2007 (N = 40)	39.2 ± 3.5	39.4 ± 5.0	28.0 ± 7.1	28.5 ± 6.1	11.2 ± 4.8	10.9 ± 3.7	0.8260

Improvement from baseline: positive numbers indicate a better score at follow-up; mos.: months; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; SD: standard deviation

*As reported by the study

†Calculated (unless otherwise indicated)

4.2.9.1.4. Patient satisfaction: Conventional or pulsed RF neurotomy, Lumbar spine

One RCT (Tekin)[29] reported patient satisfaction at twelve months follow-up. Patients were asked about their satisfaction; scores were reported on a scale of 0 to 3, (3: excellent; 2: good; 1: moderate; 0: bad). As patients were unaware of which treatment they had received, outcomes were reported in a blinded manner. The percentage of patients with each score at 12 months is reported in Table 57. There was no difference between treatment groups in terms of the percentage of patients with a patient satisfaction response of "excellent", "good", or "bad".

Table 57. Patient satisfaction scores at baseline and long-term follow-up following conventional or pulsed RF neurotomy in the lumbar spine (RCT data).

		Patient satisfaction	Conventional RFN (% patients (n/N))	Pulsed RFN (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
12 mos.	Tekin 2007 (N = 40)	"Excellent" (3)	65% (13/20)	35% (7/20)	1.86 (0.94, 3.66) 0.30 (0.004, 0.60)	NS
		"Good" (2)	30% (6/20)	50% (10/20)	0.60 (0.27, 1.34) -0.20 (-0.50, 0.10)	NS
		"Moderate" (1)	5% (1/20)	15% (3/20)	0.33 (0.15, 0.74) -0.50 (-0.77, -0.23)	Pulsed RFN
		"Bad" (0)	0% (0/20)	0% (0/20)	NC	NC

CI: confidence interval; mos.: months; NC: not calculable; NS: difference between groups is not statistically significant; RD: risk difference; RFN: radiofrequency neurotomy; RR: risk ratio
*Calculated

4.2.9.1.5. Analgesic use: Conventional or pulsed RF neurotomy, Lumbar spine

Tekin and colleagues[29] reported the percentage of patients using analgesics at 12 months follow-up, though neither the types of analgesics being used nor analgesic use at baseline were reported. Overall, significantly fewer patients in the conventional RF neurotomy group were using analgesics at 12 months compared with patients in the pulsed RF neurotomy group (40% versus 75%), a difference that was statistically significant (*P* = .0271). (In comparison, 95% (19/20) of patients in the sham neurotomy group were using analgesics at 12 months.) Because percentage of patients using analgesics at baseline was not reported, caution should be used when interpreting this result. Details are available in Table 58.

Table 58. Percentage of patients using analgesics at baseline and long-term follow-up following conventional or pulsed RF neurotomy in the lumbar spine (RCT data).

	Baseline		Follow-up			
	Conventional RFN	Pulsed RFN	Conventional RFN	Pulsed RFN (% patients	RR (95% CI)* RD (95% CI)*	Favors*

		(% patients (n/N))	(% patients (n/N))	(% patients (n/N))	(n/N))		
12 mos.	Tekin 2007 (N = 40)	NR	NR	40% (8/20)	75% (15/20)	0.53 (0.29, 0.97) -0.35 (-0.64, -0.06)	Conventional RFN

CI: confidence interval; mos.: months; NR: not reported; RFN: radiofrequency neurotomy; RD: risk difference; RR; risk ratio
*Calculated

4.2.9.2. RF Neurotomy versus Alcohol Ablation

We identified one RCT (Joo)[38] that compared outcomes following RF neurotomy versus alcohol ablation in the lumbar facet joint.

4.2.9.2.1. Summary of study characteristics

Joo and colleagues (2013)[38] performed an RCT comparing alcohol ablation (AA) and thermal RF neurotomy in patients with recurrent thoracolumbar facet joint pain following a previous successful RF neurotomy. That is, following their previous RF neurotomy, all patients had experienced at least 50% relief of the targeted pain that lasted for more than six months, and had sufficient patient satisfaction with the result of the neurotomy to have it performed again. Patients were considered to have recurrent thoracolumbar facet joint pain if they had a VAS score of at least 7 and an ODI score of at least 22%. Patients underwent controlled diagnostic blocks using lidocaine and bupivacaine; required pain relief following these blocks was not reported. Forty patients were randomized, with twenty patients per group. The average age of the patient population was 68 years old and 43% of all patients were male. The average duration of pain relief from the previous neurotomy was 11 months. There was no indication that patients were blinded to the treatment received, and the outcomes were patient-reported. The primary goal of this study was to compare outcomes following conventional RF neurotomy versus alcohol ablation in patients with recurrent pain following successful RF neurotomy. The study reported a composite outcome of "recurrence-free ratio", which was defined by a VAS score less than 7 and an ODI score greater than 22%. However, these outcomes were not reported individually. Study funding was not reported. This study received a CoE grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.2.9.2.2. Composite outcome measures of "Success": RF neurotomy or Alcohol ablation

Joo and colleagues[38] reported the percentage of patients who were "without recurrence", meaning they had a VAS score less than 7 and a revised ODI score < 22% following RF neurotomy or alcohol ablation. There was no indication that patients were blinded to treatment received, so outcomes should not be considered to be reported in a blinded manner. There were no statistical differences between treatment groups up to nine months follow-up (Table

59). However, at each time point recorded between 12 and 24 months, patients who received alcohol ablation were significantly more likely to be "recurrence free" (or "successful") than those who received RF neurotomy. The authors reported that the median effective periods were 10.7 months in the RF neurotomy group (range, 5.4, 24 months) and 24 months in the alcohol ablation group (range, 16.8, 24 months) ($P < 0.000$)[38]. Caution should be used when interpreting these results, as there were only 40 patients enrolled in the study.

Table 59. "Success"/freedom from "recurrence" at short- and long-term follow-up following RF neurotomy or alcohol ablation in the lumbar spine (RCT data).

	"Success" composite outcome Change from baseline		RF Neurotomy (% patients (n/N))	Alcohol Ablation (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Joo (2013)	VAS < 7 (on scale 0-10) and ODI < 22%	**3 mos.**	100% (20/20)	100% (20/20)	NC	NS
		6 mos.	95% (19/20)	100% (20/20)	0.95 (0.86, 1.05) -0.05 (-0.15, 0.05)	NS
		9 mos.	85% (17/20)	100% (20/20)	0.85 (0.71, 1.02) -0.15 (-0.31, 0.01)	NS
		12 mos.	25% (5/20)	100% (20/20)	0.25 (0.12, 0.53) -0.75 (-0.94, -0.56)	Alcohol Ablation
		15 mos.	10% (2/20)	100% (20/20)	0.10 (0.03, 0.37) -0.90 (-1.03, -0.77)	Alcohol Ablation
		18 mos.	5% (1/20)	90% (18/20)	0.06 (0.01, 0.38) -0.85 (-1.01, -0.69)	Alcohol Ablation
		21 mos.	5% (1/20)	85% (17/20)	0.06 (0.01, 0.40) -0.80 (-0.98, -0.62)	Alcohol Ablation
		24 mos.	5% (1/20)	85% (17/20)	0.06 (0.01, 0.40) -0.80 (-0.98, -0.62)	Alcohol Ablation

CI: confidence interval; GPE: global perceived effect; mos.: months; NC: not calculable; NS: difference between groups is not statistically significant; ODI: Oswestry Disability Index; RD: risk difference; RF: radiofrequency; RR; risk ratio; VAS: visual analogue scale
*Calculated (unless otherwise indicated)

4.2.10. Key Question 2b: What is the evidence of short- and long-term comparative efficacy and effectiveness of repeat neurotomy procedures at the same level and the same side as the initial successful procedure?

4.2.10.1. Lumbar spine

A total of six studies[38-43] were identified to answer this key question as it applies to the lumbar spine. We sought studies that reported outcomes following repeat neurotomy at the same level and side as the primary neurotomy, which was considered successful in that it resulted in sufficient pain relief. Due to the nature of the question, all studies are considered case series (CoE IV). Drawing firm conclusions regarding the effectiveness of repeat RF neurotomy is challenging given the variable definitions of "success" and variety of outcomes measures used across studies. Most studies did not report diagnostic block use and follow-up times overall and between studies varied substantially and were often unclear. Study details may be found in Appendix F.

4.2.10.1.1. "Success"

Drawing firm conclusions regarding the effectiveness of repeat RF neurotomy is challenging given the variable definitions of "success" between and within studies. However, it appears that patients who elect to undergo second or even third procedures are likely to experience "success" as reported by five case series[38-42] (Table 60).

Table 60. "Success" following initial and repeat RF neurotomy in the lumbar spine (case series).

	"Success"	**RFN1** (% patients (n/N))	**RFN2** (% patients (n/N))	**RFN3** (% patients (n/N))	**RFN4** (% patients (n/N))
Rambaransingh (2010)	≥50% pain relief	55% (34/62)	55% (34/62)	52% (15/29)	-
Son (2010)	Varied	75% (45/60) ("Success": ≥50% pain relief)	85% (47/55) ("Success" compared with RFN1 (details NR))	n/a* (n = 5) ("Success" compared with RFN1 (details NR))	-
Joo (2013)	Varied	100% (20/20) ("Success": ≥50% pain relief and patient satisfaction)	95% (18/20) (6 mos.) 85% (17/20) (9 mos.) 25% (5/20) (12 mos.) 5% (1/20) (18-24 mos.) ("Success": VAS < 7 (scale 0-10) and ODI <22%)	-	-
Schofferman (2004)	Varied	100% (20/20) ("Success": ≥50% pain relief and patient satisfaction)	85% (17/20) ("Success": similar or greater pain relief than was achieved with RFN1)	94% (15/16) ("Success": similar or greater pain relief than was achieved with RFN1)	n/a* (n = 8)

Speldewinde (2011)	≥50 pain relief for 2 mos.	NR	91% (34/39) procedures (range, 2-5 procedures) (N = NR)		

mos.: months; n/a: not applicable; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; RFN1: first radiofrequency neurotomy; RFN2: second radiofrequency neurotomy (etc. for RFN3, RFN4); VAS: visual analogue scale

* Because there were less than 10 patients, outcomes for this procedure will not be analyzed in the results section. See Appendix F for outcome data.

4.2.10.1.2. Duration of pain relief

Overall, the duration of pain relief was similar following the first and second neurotomy procedures as reported by three case series[38, 40, 41], and between the first, second, and third neurotomy procedures as reported by one case series[40] (Table 61).

Table 61. Duration of pain relief following initial and repeat RF neurotomy in the lumbar spine (case series).

	RFN1 Mean duration (range) (n)	**RFN2** Mean duration (range) (n)	**RFN3** Mean duration (range) (n)	**RFN4** Mean duration (range) (n)
Joo (2013)	10.4 (6.3, 13.3) mos. (n = 20)	10.7 (median) (5.4, 20) mos. (n = 20)	-	-
Schofferman (2004)	10.5 (4, 19) mos. (n =20)	11.6 (6, 19) mos. (n = 20)	11.2 (5, 23) mos. (n = 16)	n/a* (n = 8)
Son (2010)	10.9 mos. (n = 60)	10.2 mos. (n = 55)	n/a* (n = 5)	-

mos.: months; n/a: not applicable RFN: radiofrequency neurotomy; RFN1: first radiofrequency neurotomy; RFN2: second radiofrequency neurotomy (etc. for RFN3, RFN4)

* Because there were fewer than 10 patients, outcomes for this procedure will not be analyzed in the results section. See Appendix F for outcome data.

4.2.10.1.3. Patient satisfaction

The percentage of patients with who were satisfied with their treatment outcome was lower in patients following two, three, or four repeat procedures than it was following the initial procedure (Zotti).[43]

- RFN1: 100% (62/62) of patients were satisfied with the outcome
- Repeat RFN (2, 3, or 4): 69% (43/62) of patients believed that the repeat procedure helped as much as the previous procedures

4.2.10.2. Cervical spine

We sought studies that reported outcomes following repeat neurotomy at the same level and side as the primary neurotomy, which was considered successful in that it resulted in sufficient pain relief. Three studies[39, 42, 44] were identified that address this key question as it applies to the cervical spine. Due to the nature of the question, all studies are considered case series (CoE IV). Again, drawing firm conclusions regarding the effectiveness of repeat RF neurotomy is

challenging given the variable definitions of "success" and variety of outcomes measures used across studies. Additional study details may be found in Appendix F.

4.2.10.2.1. "Success"

Again, it is difficult to arrive at firm conclusions regarding the effectiveness of repeat RF neurotomy due to the variable definitions of "success" between and within studies. However, it appears that patients who elect to undergo second or even third procedures are likely to experience "success" as reported by three case series[39, 42, 44].

Table 62. "Success" following initial and repeat RF neurotomy in the cervical spine (case series).

	"Success"	RFN1 (% patients (n/N))	RFN2 (% patients (n/N))	RFN3 (% patients (n/N))	RFN4 (% patients (n/N))
Rambaransingh (2010)	≥50% pain relief	43% (6/14)	64% (9/14)	n/a* (n = 7)	-
Husted (2008)	Varied	100% (22/22) ("Success": ≥50% pain relief and patient satisfaction)	95% (20/21) ("Success": similar or greater pain relief than was achieved with RFN1	91% (10/11) ("Success": similar or greater pain relief than was achieved with RFN1	n/a* (n = 4)
Speldewinde (2011)	≥50 pain relief for 2 mos.	NR	85% (34/40) procedures (range, 2-5 procedures) (N = NR)		

mos: months; n/a: not applicable; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; RFN1: first radiofrequency neurotomy; RFN2: second radiofrequency neurotomy (etc. for RFN3, RFN4); VAS: visual analogue scale

* Because there were less than 10 patients, outcomes for this procedure will not be analyzed in the results section. See Appendix F for outcome data.

4.2.10.2.2. Duration of pain relief

The average duration of pain relief was similar following the first, second, and third neurotomy procedures as reported by one case series[44] (Husted) (Table 63).

Table 63. Duration of pain relief following initial and repeat RF neurotomy in the cervical spine (case series).

	RFN1 Mean duration (range) (n)	RFN2 Mean duration (range) (n)	RFN3 Mean duration (range) (n)	RFN4 Mean duration (range) (n)
Husted (2008)	12.5 (3, 25) mos. (n = 22)	12.7 (3, 30) mos. (n = 21)	9.5 (3, 16 mos.) (n = 11)	n/a* (n = 4)

mos.: months; n/a: not applicable RFN: radiofrequency neurotomy; RFN1: first radiofrequency neurotomy; RFN2: second radiofrequency neurotomy (etc. for RFN3, RFN4)

* Because there were fewer than 10 patients, outcomes for this procedure will not be analyzed in the results section. See Appendix F for outcome data.

4.2.11. Key Question 2c: Is there evidence of differential effectiveness when conducting unilateral versus bilateral facet neurotomy?

We identified one retrospective cohort study (Tzaan)[45] that compared outcomes following unilateral versus bilateral neurotomy in the lumbar spine.

4.2.11.1.1. Study characteristics and critical appraisal

Tzaan et al.[45] published a retrospective study in which unilateral RF neurotomy was compared to bilateral RF neurotomy. For inclusion, patients were required to have facetogenic pain for a minimum of six months that has been unresponsive to conservative treatment. In addition, patients must have experienced a 50% or greater reduction in pain following facet joint block. The study followed 90 patients with a mean age of 43 years: in these patients, a total of 118 procedures were performed (including lumbar, thoracic, and cervical procedures). Outcomes data on unilateral versus bilateral neurotomy was only available for lumbosacral procedures (69 procedures; the number of patients was not reported). The study has a number of methodological limitations and received a CoE grade of III. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

4.2.11.1.2. "Success": Unilateral or Bilateral RF Neurotomy, Lumbar spine

Tzaan et al.[45] reported that a similar percentage of patients achieved "success", which was defined as complete elimination of back pain, or at least a 50% improvement in pain levels following unilateral versus bilateral neurotomy (Table 64).

Table 64. "Success" following unilateral versus bilateral RF neurotomy in the lumbar spine (retrospective cohort).

	"Success"		Unilateral RF Neurotomy (% procedures)	Bilateral RF Neurotomy (% procedures)	RR (95% CI)* RD (95% CI)*	Favors*
Tzaan (2000)	≥50% pain relief or complete elimination of pain	**Mean 5.6 (range, 1-33) mos.**	33% (6/18) procedures	45% (23/51) procedures	0.74 (0.36, 1.52) -0.12 (-0.37, 0.14)	NS

mos: months; NS: not significant; RF: radiofrequency

4.2.12. Key Question 2d: Is there evidence of differential effectiveness when conducting facet neurotomy on single versus multiple spinal levels?

No studies were identified that met our inclusion criteria.

4.3. Key Question 3:

4.3.1. RF Neurotomy versus Sham Neurotomy: Safety in the Lumbar Spine

4.3.1.1. Studies included

We evaluated safety data from all comparative studies included in Key Question 2 that compared RF neurotomy to sham neurotomy. Of the six RCTs available, only one[31] (Van Wijk) reported on specific adverse events or complications (treatment-related pain, change of sensibility, and loss of motor function), while four[26, 27, 29, 30] (Gallagher, Leclaire, Tekin, van Kleef) only gave a vague statement indicating that no adverse events or complications occurred in either treatment group; one RCT[28] (Nath) made no mention of adverse events at all. Critical appraisal of these studies is available in the section on Key Question 2; additional detailed information can be found in Appendix F.

4.3.1.2. Treatment-related pain

One RCT[31] (van Wijk) reported treatment-related pain event rates following RF neurotomy compared with sham neurotomy. Significantly fewer patients in the RF neurotomy group experienced no pain compared with those in the sham neurotomy group (31% versus 54%, respectively; *P* = 0.0404). There were no significant differences between groups in terms of the percentage of patients who experience "little", "moderate", or "severe" pain from the procedure. (Table 65)

Table 65. Treatment-related pain from RF neurotomy or sham neurotomy in the lumbar spine (RCT data).

	Treatment-related pain	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Van Wijk 2005 (N = 81)	"None"	30.8% (12/39)	53.8% (21/39)	0.57 (0.33, 0.99) -0.23 (-0.44, -0.02)	Sham Neurotomy
	"Little"	10.3% (4/39)	10.3% (4/39)	1.00 (0.27, 3.72) 0.00 (-0.13, 0.13)	NS
	"Moderate"	23.0% (9/39)	10.3% (4/39)	2.25 (0.76, 6.70) 0.13 (-0.03, 0.29)	NS
	"Severe"	35.9% (14/39)	25.6% (10/39)	1.40 (0.71, 2.76) 0.10 (-0.10, 0.31)	NS

CI: confidence interval; NS: difference between groups is not statistically significant; RF: radiofrequency; RD: risk difference; RR; risk ratio
*Calculated

4.3.1.3. Subjective sensory changes

One RCT[31] (van Wijk) reported no statistically significant differences in the percentage of patients describing *any* change in sensation following RF neurotomy compared with sham neurotomy, with a total of 5% (2/39) of RF neurotomy and 3% (1/40) of sham neurotomy patients experiencing any of the following changes in sensibility: "discrete", "irritating", or "evident dysaesthesia or allodynia" (*P* = 0.5437). Although patients were followed for 12 months, it was not clear at what time point this outcome was evaluated. Detailed outcomes for each descriptor are provided in Table 66.

Table 66. Sensibility changes as measured through 12 months follow-up following RF neurotomy or sham neurotomy in the lumbar spine (RCT data).

	Change of sensibility	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Van Wijk 2005 (N = 81)	"Unaltered"	95% (37/39)	98% (39/40)	0.97 (0.89, 1.06) -0.03 (-0.11, 0.06)	NS
	"Discrete"	0.0% (0/39)	3% (1/40)	0.00 (NC) -0.25 (-0.07, 0.02)	NS
	"Irritating"	3% (1/39)	0.0% (0/40)	NC 0.03 (NC)	NS
	"Evident dysaesthesia or allodynia"	3% (1/39)	0.0% (0/40)	NC 0.03 (NC)	NS

CI: confidence interval; NC: not calculable; NS: difference between groups is not statistically significant; RF: radiofrequency; RD: risk difference; RR; risk ratio
*Calculated

4.3.1.4. Subjective motor changes

One RCT[31] (van Wijk) reported no statistically significant differences in the percentage of patients describing *any* motor changes following RF neurotomy compared with sham neurotomy, with a total of 5% (2/38) of RF neurotomy and 5% (2/41) of sham neurotomy patients experiencing any of the following subjective motor changes: "discrete", "irritating", or "evident motor loss" (*P* = 0.9382). Although patients were followed for 12 months, it was not clear at what time point this outcome was evaluated. Detailed outcomes for each descriptor are provided in Table 67.

Table 67. Motor changes as measured through 12 months follow-up following RF neurotomy or sham neurotomy in the lumbar spine (RCT data).

	Change of sensibility	RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*

Van Wijk 2005 (N = 81)	"Unaltered"	94.7% (36/38)	95.2% (39/41)	1.00 (0.90, 1.10) -0.004 (-0.10, 0.09)	NS
	"Discrete"	5.3% (2/38)	2.4% (1/41)	2.16 (0.20, 22.84) 0.03 (-0.06, 0.11)	NS
	"Irritating"	0.0% (0/38)	2.4% (1/41)	0.00 (NC) -0.02 (-0.07, 0.02)	NS
	"Evident motor loss"	0.0% (0/38)	0% (0/41)	NC	NS

CI: confidence interval; NC: not calculable; NS: difference between groups is not statistically significant; RF: radiofrequency; RD: risk difference; RR; risk ratio
*Calculated

4.3.1.5. "Adverse events" (undefined)

Four RCTs[26, 27, 29, 30] (Gallagher, Leclaire, Tekin, van Kleef) reported that no patients experienced adverse events in either the RF neurotomy or the sham neurotomy groups, however, none of the studies defined what outcomes were included as adverse events. These four studies had follow-up timeframes that ranged from 3 months to 1 year.

Table 68. "Adverse events" (not defined) following RF neurotomy or sham neurotomy in the lumbar spine (RCT data).

		RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))
3 mos.	Leclaire 2001 (N = 70)	0% (0/36)	0% (0/34)
6 mos.	Gallagher 1994 (N = 30)	0% (0/18)	0% (0/12)
12 mos.	Tekin 2007 (N = 60)	PRF: 0% (0/20) CRF: 0% (0/20)	0% (0/20)
	van Kleef 1999 (N = 31)	0% (0/15)	0% (0/15)

NC: not calculable; NS: difference between groups is not statistically significant; CRF: conventional radiofrequency; PRF: pulsed radiofrequency; RF: radiofrequency; RD: risk difference; RR; risk ratio
*Calculated

4.3.2. RF Neurotomy versus Sham Neurotomy: Safety in the Cervical Spine

4.3.2.1. Studies included

We evaluated safety data from the sole RCT included in Key Question 2. This RCT[32] (Lord) compared RF neurotomy with sham neurotomy and reported on safety outcomes, specifically psoriatic rash, pain associated with the procedure, and numbness in the area of the treated

nerves. Critical appraisal of this study is available in the section on Key Question 2; additional detailed information can be found in Appendix F.

4.3.2.2. Psoriatic rash

One RCT[32] (Lord) reported one case of psoriatic rash (Köbner's phenomenon) at the site of the skin incision, which occurred one week following RF neurotomy, and no cases in those patients who underwent sham neurotomy (8% versus 0%, respectively; *P* = 0.1967).

Table 69. Psoriatic rash following RF neurotomy or sham neurotomy in the cervical spine (RCT data).

		RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Postoperation	Lord 1996 (N = 24)	8% (1/12)	0% (0/12)	NC 0.08 (NC)	NS

CI: confidence interval; NC: not calculable; NR: not reported; RF: radiofrequency; RD: risk difference; RR; risk ratio
*Calculated

4.3.2.3. Pain associated with the procedure

One RCT[32] (Lord) reported that patients in the RF neurotomy group had similar durations of postoperative pain associated with the procedure (*P* = 0.26) (Table 70).

Table 70. Duration of pain attributed to procedure following RF neurotomy or sham neurotomy in the cervical spine (RCT data).

		RF Neurotomy (Median (IQR))	Sham Neurotomy (Median (IQR))	P value*
Postoperation	Lord 1996 (N = 24)	13.5 (6, 15) days	3.5 (1, 15) days	0.26

IQR: interquartile range; RF: radiofrequency
*As reported by the study

4.3.2.4. Numbness in the area of the treated nerves

One RCT[32] (Lord) reported that five patients (38%) in the RF neurotomy group experienced numbness in the area of the coagulated nerves in the postoperative period, compared with no patients in the sham neurotomy group, a difference that was statistically significant (*P* = 0.0139). However, this numbness was not considered to be troubling to the RF neurotomy patients.

Table 71. Numbness in the territory of the treated nerves following RF neurotomy or sham neurotomy in the cervical spine (RCT data).

		RF Neurotomy (% patients (n/N))	Sham Neurotomy (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Postoperation	Lord 1996 (N = 24)	38% (5/12)	0% (0/12)	NC 0.42 (NC)	Sham Neurotomy

CI: confidence interval; NC: not calculable; NR: not reported; RF: radiofrequency; RD: risk difference; RR; risk ratio

*Calculated

4.3.3. RF Neurotomy versus Spinal Injections: Safety in the Lumbar Spine

4.3.3.1. Studies included

We evaluated safety data from all comparative studies included in Key Question 2. Of the three comparative studies available, one RCT[33] (Civelek) comparing RF neurotomy to medial branch block (MBB) and another RCT[34] (Lakemeier) comparing RF neurotomy to intra-articular steroid injections plus sham neurotomy reported data on harms. One retrospective cohort study[35] (Chakraverty) did not provide any harms data. Civelek and colleagues[33] reported on the following adverse events: infection, new motor deficit, new sensory deficit, superficial burns, and increase in lower back pain. Lakemeier and colleagues[34] reported vaguely on adverse events but did not define which specific outcomes they examined. Critical appraisal of each study is available in the section on Key Question 2; additional detailed information can be found in Appendix F.

4.3.3.2. Infection

One RCT[33] (Civelek) reported no cases of infection following RF neurotomy or therapeutic medial branch block at any time through the twelve month follow-up period.

Table 72. Infection following RF Neurotomy or Spinal Injection in the cervical spine (RCT data).

	RF Neurotomy (% patients (n/N))	Injection (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Civelek 2012 (N = 100)	0% (0/50)	0% (0/50)	NC	NS

CI: confidence interval; NC: not calculable; NS: difference between groups is not statistically significant; RD: risk difference; RR; risk ratio
*Calculated

4.3.3.3. New motor or sensory deficit

One RCT [33](Civelek) reported that at 6 months follow-up, no patients receiving either RF neurotomy or medial branch block experienced any new motor or sensory deficit following the intervention.

Table 73. New motor or sensory deficit following RF Neurotomy or Spinal Injection in the cervical spine (RCT data).

	RF Neurotomy (% patients (n/N))	Injection (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*

Civelek 2012 (N = 100)	0% (0/50)	0% (0/50)	NC	NS

CI: confidence interval; NC: not calculable; NS: difference between groups is not statistically significant; RD: risk difference; RR; risk ratio
*Calculated

4.3.3.4. Superficial burns and increase in lower back pain

One RCT[33] (Civelek) reported that 2 patients the RF neurotomy group (4%) experienced a "burning-like sensation" in the treatment area coupled with an increase in lower back pain in the period of time following the procedure, which resolved by 2 months following pharmacological treatment for neuropathy. Superficial burns are not possible in the injection group so no comparison can be made between these two treatment arms.

Table 74. Superficial burns and increase in lower back pain following RF Neurotomy or Spinal Injection in the cervical spine (RCT data).

	RF Neurotomy (% patients (n/N))	Injection (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Civelek 2012 (N = 100)	4% (2/50)	NA	NC	NS

CI: confidence interval; NA: not applicable; NC: not calculable; NS: difference between groups is not statistically significant; RD: risk difference; RR; risk ratio
*Calculated

4.3.3.5. Adverse events (undefined)

One RCT[34] (Lakemeier) reported that no patients experienced an adverse event in either the RF neurotomy or the medial branch block groups through the six month follow-up period, however the authors did not define what outcomes they included as adverse events.

Table 75. Adverse events (not defined) following RF Neurotomy or Spinal Injection in the cervical spine (RCT data).

	RF Neurotomy (% patients (n/N))	Injection (% patients (n/N))	RR (95% CI)* RD (95% CI)*	Favors*
Civelek 2012 (N = 100)	0% (0/50)	0% (0/50)	NC	NS

CI: confidence interval; NC: not calculable; NS: difference between groups is not statistically significant; RD: risk difference; RR; risk ratio
*Calculated

4.3.4. RF Neurotomy versus Spinal Injections: Safety in the Cervical Spine

4.3.4.1. Studies included

We evaluated safety data from the only RCT included in Key Question 2 that evaluated RF neurotomy and spinal injections in the cervical spine. This RCT[36] (Haspeslagh) made no mention of adverse events.

4.3.5. RF Neurotomy: Safety in the Lumbar Spine

4.3.5.1. Case series included

No case series were identified that met our inclusion criteria (i.e., case series designed specifically to evaluate adverse events and a minimum of 50 (prospective series) or 100 (retrospective series) patients.

4.3.6. RF Neurotomy: Safety in the Cervical Spine

4.3.6.1. Case series included

No case series were identified that met our inclusion criteria (i.e., case series designed specifically to evaluate adverse events and a minimum of 50 (prospective series) or 100 (retrospective series) patients.

4.4. Key Question 4: Is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

For this key question, we first evaluated differential efficacy, effectiveness, and safety of facet neurotomy compared with other treatment options by looking for subgroup analyses in comparative studies. Secondly, we conducted an analysis on a subgroup of studies included in Key Question 2 to determine the efficacy of facet neurotomy in patients selected on the basis of ≥50% pain relief following medial branch block.

4.4.1. Differential efficacy of RF Neurotomy versus Sham Neurotomy

One RCT (van Wijk)[31] met our inclusion criteria and reported on patients who underwent RF neurotomy (n = 40) or sham neurotomy (n = 41) in the lumbar spine following selection by either diagnostic medial branch block or clinical exam alone. Subgroups analyzed included sex, age (18-40 versus >40), duration of pain (≤5 versus > 5 years), employment status (unemployed versus employed), previous low back surgery, Zung Self Rating Depression Scale (Zung-DV) baseline rating, and Multidimensional Pain Inventory-Dutch Language versus (MPI-DLV) baseline

rating. Study characteristics are described in Key Question 2; detailed demographic information can be found in Appendix F.

No studies were identified which evaluated differential efficacy, effectiveness, or safety of facet neurotomy compared with other treatment options in the cervical spine.

4.4.1.1. "Success" composite outcome

Regarding the composite outcome of "success" (defined as either of the following: (a) ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or (b) ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%), van Wijk and colleagues[31] found that baseline MPI-DLV modified treatment effect such that patients who were scored as "dysfunctional" or "interpersonally distressed" favored sham neurotomy while those who were graded as "adaptive coper" or "normal" favored RF neurotomy (test for interaction: $P = 0.03551$) (Table 76). Caution should be exercised when interpreting this result due to a small sample size. No other subgroups were found to be modifiers of treatment effect in terms of this composite outcome of "success" (Table 76).[31]

Table 76. "Success" composite outcome following RF Neurotomy or Spinal Injection in the lumbar spine: differential efficacy (RCT data)

"Success" composite*	Subgroup	RF Neurotomy (% pts. (n/N)) (n = 40)	Sham Neurotomy (% pts. (n/N)) (n = 41)	RR (95% CI)	RD (95% CI)	Test for interaction *P*-value†
Van Wijk 2005 N = 81 3 mos. f/u	**Sex** • Male	(2/10)	(6/13)	0.43 (0.11, 1.71)	-0.26 (-0.63, 0.11)	0.1607
	• Female	(9/30)	(6/28)	1.40 (0.57, 3.42)	0.09 (-0.14, 0.31)	
	Age • 18-40 yrs.	(4/13)	(4/12)	0.92 (0.29, 2.89)	-0.03 (-0.39, 0.34)	0.9804
	• >40 yrs.	(7/27)	(8/29)	0.94 (0.39, 2.24)	-0.02 (-0.25, 0.22)	
	Duration of pain • ≤ 5 yrs.	(6/19)	(7/21)	0.95 (0.39, 2.32)	-0.02 (-0.26, 0.23)	0.9941
	• > 5 yrs.	(5/21)	(5/20)	0.95 (0.32, 2.80)	-0.01 (-0.28, 0.25)	
	Employment Status • Unemployed	(7/23)	(7/20)	0.87 (0.37, 2.05)	-0.05 (-0.33, 0.24)	0.8613
	• Employed	(4/17)	(5/21)	0.99 (0.31, 3.12)	0.00 (-0.27, 0.27)	
	Low Back Surgery • None	(8/25)	(6/25)	1.33 (0.54,3.29)	0.08 (-0.17, 0.33)	0.2305
	• ≥ 1	(3/15)	(6/16)	0.53 (0.16, 1.76)	-0.18 (-0.49,	

"Success" composite*	Subgroup	RF Neurotomy (% pts. (n/N)) (n = 40)	Sham Neurotomy (% pts. (n/N)) (n = 41)	RR (95% CI)	RD (95% CI)	Test for interaction *P*-value†
	operations				0.14)	
	Zung-DV • < 50	(9/30)	(11/32)	0.87 (0.42, 1.80)	-0.04 (-0.28, 0.19)	0.5444
	• ≥ 50	(2/10)	(1/9)	1.80 (0.19, 16.66)	0.09 (-0.23, 0.41)	
	MPI-DLV • DYS + ID	14% (3/22)	38% (8/21)	0.36 (0.11, 1.17)	-0.24 (-0.50, 0.01)	0.03551
	• AC + AV	44% (8/18)	24% (4/17)	1.89 (0.69, 5.14)	0.21 (-0.10, 0.51)	

CI: Confidence Interval; f/u: follow-up; mos.: months; RD: risk difference; RF: radiofrequency; RR: risk ratio; ZUNG-DV: Self rating Depression scale (Dutch Version),<50 = normal, ≥50 = min-moderate depression; MPI-DLV: Multidimensional Pain Inventory (Dutch Language Version; DYS: Dysfunctional; ID: interpersonally distressed; AC: adaptive coper; AV: average); yrs.: years

* "Success" defined by either of the following:
- ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or
- ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%

†Breslow Day test for interaction

4.4.1.2. Pain reduction "success" as measured by GPE

Regarding the outcome of "success" as measured by the 4-point Global Perceived Effect (GPE) scale (defined as ≥50% reduction in back pain), the authors found that none of the subgroups modified treatment effect (Table 77).[31]

Table 77. Global Perceived Effect (GPE) "Success" following RF Neurotomy or Spinal Injection in the lumbar spine: differential efficacy (RCT data)

"Success" in GPE outcome*	Subgroup	RF Neurotomy (% pts. (n/N)) (n = 40)	Sham Neurotomy (% pts. (n/N)) (n = 41)	RR (95% CI)	RD (95% CI)	Test for interaction *P*-value†
Van Wijk 2005 N = 81 3 mos. f/u	**Sex** • Male	56% (5/9)	54% (7/13)	1.03 (0.48, 2.23)	0.02 (-0.41, 0.44)	0.1955
	• Female	63% (19/30)	32% (9/28)	1.97 (1.08, 3.60)	0.31 (0.07, 0.56)	
	Age • 18-40 yrs.	(7/13)	(6/12)	1.08 (0.51, 2.30)	0.04 (-0.35, 0.43)	0.2441
	• >40 yrs.	(17/26)	(10/29)	1.90 (1.07, 3.37)	0.31 (0.06, 0.56)	
	Duration of pain • 2-5 yrs.	(10/18)	(10/21)	1.17 (0.63, 2.15)	0.08 (-0.23, 0.39)	0.1862

"Success" in GPE outcome*	Subgroup	RF Neurotomy (% pts. (n/N)) (n = 40)	Sham Neurotomy (% pts. (n/N)) (n = 41)	RR (95% CI)	RD (95% CI)	Test for interaction *P*-value†
	• > 5 yrs.	(14/21)	(6/20)	2.22 (1.07, 4.63)	0.37 (0.08, 0.65)	
	Employment Status • Unemployed	(11/22)	(9/20)	1.11 (0.59, 1.90)	0.05 (-0.25, 0.35)	0.1222
	• Employed	(13/17)	(7/21)	2.29 (1.19, 4.44)	0.43 (0.15, 0.72)	
	Low Back Surgery • None	(16/24)	(9/25)	1.85 (1.02, 3.36)	0.31 (0.04, 0.57)	0.384
	• ≥ 1 operations	(8/15)	(7/16)	1.22 (0.59, 2.53)	0.10 (-0.25, 0.45)	
	Zung-DV • < 50	(19/29)	(15/32)	1.40 (0.89, 2.20)	0.19 (-0.06, 0.43)	0.2529
	• ≥ 50	(5/10)	(1/9)	4.50 (0.64, 31.6)	0.39 (0.02, 0.76)	
	MPI-DLV • DYS + ID	(11/22)	(10/21)	1.05 (0.57, 1.94)	0.02 (-0.28, 0.32)	0.1257
	• AC + AV	(13/17)	(6/17)	2.17 (1.08, 4.34)	0.41 (0.11, 0.72)	

CI: Confidence Interval; f/u: follow-up; GPE: global perceived effect; mos.: months; RD: risk difference; RF: radiofrequency; RR: risk ratio; ZUNG-DV: Self rating Depression scale (Dutch Version), <50 = normal, ≥50 = min-moderate depression; MPI-DLV: Multidimensional Pain Inventory (Dutch Language Version; DYS: Dysfunctional; ID: interpersonally distressed; AC: adaptive coper; AV: average); yrs.: years

* "Success" defined by ≥50% reduction in pain relief as measured by the 4-point global perceived effect outcome measure.
†Breslow Day test for interaction

4.4.2. Comparative efficacy of RF Neurotomy: Patients selected on the basis of ≥50% pain relief following MBB

In Key Question 1, no direct evidence was identified that type of diagnostic block (i.e., medial branch block versus intra-articular block) affected patient outcomes following facet neurotomy. As a result, no restrictions were placed on type of diagnostic block used for patient selection for studies included in Key Question 2. However, during the public comment period, a peer reviewer (Paul Dreyfuss, MD) indicated that the methods by which patients are selected for facet neurotomy affects the efficacy of the procedure. Specifically, he suggested that patients should be selected on the basis of ≥50% pain relief following one or more diagnostic medial branch block(s) (see also section 1.4.1).

In order to address this concern, we provided the results from a subgroup of studies included in Key Question 2 that selected patients on the basis of ≥50% pain relief following medial branch block.

4.4.2.1. Efficacy of RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: Patient selection on the basis of ≥50% pain relief following MBB

Of the studies that compared RF neurotomy to sham neurotomy in the lumbar spine, three RCTs selected patients on the basis of ≥50% pain relief following diagnostic medial branch block. Diagnostic details for each study are available in Table 78. Due to missing standard deviations in the majority of studies, meta-analysis was not performed.

Mean patient age ranged from 44 to 59 years, and 36-43% of patients were males. For inclusion, patients were required to have chronic pain, and the minimum symptom duration was 1 year (van Kleef)[30], 2 years (Nath)[28], or 6 years (Tekin)[29]. One trial (van Kleef)[30] reported that the neurotomy group had a shorter median duration of pain (26 months) compared with the sham group (48 months). Patients in all RCTs were blinded to their treatment group, and the primary outcomes were patient-reported in all studies. The length of follow-up ranged from two to twelve months. All studies received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Results are summarized in Table 78. For the majority of the pain and function outcomes, results favored RF neurotomy over sham neurotomy.

Table 78. RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB

Outcome	RCTs N Follow-up	Diagnostic block	% pain relief required for FN	RFN	Sham	p-value
				Δ from baseline (mean (%))		
Short-term Back pain (VAS scores) (0-100)	van Kleef 1999 N = 31 2 mos.	1 MBB	≥50% pain relief	23.7 (46%)	4.3 (8%)	<0.05*
	Nath 2008 N = 40 6 mos.	2 MBBs	≥80% pain relief	21.0 (35%)	7.0 (16%)	0.08*
	Tekin 2007 N = 40 6 mos.	1 MBB	≥50% pain relief	42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	0.1196†
Long-term Back pain (VAS scores) (0-100)	Tekin 2007 N = 40 12 mos.	1 MBB	≥50% pain relief	41.0 ± 9.1 (63%)	29.0 ± 9.6 (43%)	0.0002†
Short-term Leg Pain (VAS scores) (0-100)	Nath 2008 N = 40 6 mos.	2 MBBs	≥80% pain relief	16.0 (37%)	1.3 (5%)	0.046*
Short-term Generalized pain (VAS scores) (0-100)	Nath 2008 N = 40 6 mos.	2 MBBs	≥80% pain relief	19.3	3.7	0.02*
Short-term Function (ODI scores) (0-100)	van Kleef 1999 N = 31 2 mos.	1 MBB	≥50% pain relief	11.1 (36%)	-1.7 (-4%)	<0.05*
	Tekin 2007 N = 40 6 mos.	1 MBB	≥50% pain relief	14.1 ± 4.2 (36%)	11.2 ± 3.9 (28%)	0.03†
Long-term Function (ODI scores) (0-100)	Tekin 2007 N = 40 12 mos.	1 MBB	≥50% pain relief	11.2 ± 4.8 (29%)	6.5 ± 3.9 (16%)	0.0015†
Short-term Function (Waddell scores) (0-24)	van Kleef 1999 N = 31 2 mos.	1 MBB	≥50% pain relief	0.33	0.07	≥0.05*
Outcome	**Studies N Follow-up**	**Diagnostic block**	**% pain relief required for FN**	**RFN**	**Sham**	**p-value**
				% patients		
Short-term "Success" composite (≥2-point improvement in VAS (0-10) and ≥50% improvement in GPE (1-4))	van Kleef 1999 N = 31 2 mos.	1 MBB	≥50% pain relief	67% (10/15) patients	38% (6/16) patients	≥0.05†

GPE: global perceived effect; MBB: medial branch block; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; VAS: visual analogue scale

*As reported by the study
†Calculated

4.4.2.2. Efficacy of RF Neurotomy versus Sham Neurotomy in the Cervical Spine: Patient selection on the basis of ≥50% pain relief following MBB

Lord et al.[32] performed a double-blind RCT in which patients with cervical facet joint pain between C3-4 and C6-7, who had failed conservative treatment, and who had responded to medial branch block were randomized to receive RF neurotomy (n = 12) or sham neurotomy (n = 12). Prior to randomization, each patient had undergone controlled medial branch blocks with lidocaine, bupivacaine, and saline on separate occasions. Mean patient age was 44 ± 12 years, and males comprised 38% of the overall patient population. The mean duration of pain was 44 months in the RF neurotomy group and 34 months in the sham neurotomy group, a difference which was not adjusted for. Both the patients and the surgeon were blinded to treatment received. This study received a class of evidence (CoE) grade of II. Additional descriptions (including descriptions of the neurotomy procedures) can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Results are summarized in Table 79. At approximately six months (27 weeks), significantly more patients were free from their "accustomed" pain in the RF neurotomy group compared with those in the sham neurotomy group. A larger trial is needed to confirm this result.

Table 79. RF Neurotomy versus Sham Neurotomy in the Cervical Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB

Outcome	RCTs N Follow-up	Diagnostic block	% pain relief required for FN	RFN	Sham	p-value
				% patients		
Short-term Freedom from "accustomed" pain	Lord 1999 N = 81 6 mos.	3 MBBs	100% with anesthetics 0% with saline	58% (7/12)	8% (1/12)	0.0110*

MBB: medial branch block; RFN: radiofrequency neurotomy

*Calculated

4.4.2.3. Efficacy of RF Neurotomy versus Spinal Injection in the Lumbar Spine: Patient selection on the basis of ≥50% pain relief following MBB

One RCT forms the evidence base, and compared facet neurotomy to therapeutic intra-articular injection[34]. For inclusion, patients were required to have had suspected facet joint pain in the lumbar spine with an absence of cancer and trauma. The mean patient age was 57 and 64% of patients were male. The mean duration of pain was not reported[34]. Both the patients and the surgeon were blinded to treatment received. Patients were followed for six months. This study

received a class of evidence (CoE) grade of II. Additional descriptions can be found in Section 3.2 of the Evidence Report; detailed demographic information and results can be found in Appendix F.

Results are summarized in Table 80. There were no statistically meaningful differences between treatment groups in terms of short-term pain or function.

Table 80. RF Neurotomy versus Therapeutic Intra-articular Injection in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB

Outcome	RCTs N Follow-up	Diagnostic block	% pain relief required for FN	RFN	Therapeutic intra-articular injection	p-value
				Δ from baseline (mean (%))		
Short-term Back pain (VAS scores) (0-100)	Lakemeier 2013 N = 56 6 mos.	1 MBB	≥50% pain relief	19 ± 14.5 (29%)	16 ± 12.6 (23%)	0.429*
Short-term Function (ODI scores) (0-100)	Lakemeier 2013 N = 56 6 mos.	1 MBB	≥50% pain relief	12.8 ± 12.0 (31%)	5.7 ± 11.4 (15%)	0.069*
Short-term Function (Roland-Morris scores) (0-24, lower is better)	Lakemeier 2013 N = 56 6 mos.	1 MBB	≥50% pain relief	3.7 ± 3.7 (19%)	4.2 ± 3.9 (14%)	0.64*

MBB: medial branch block; ODI: Oswestry Disability Index; RFN: radiofrequency neurotomy; VAS: visual analogue scale

*Calculated

4.5. Key Question 5: With different regions of the spine (lumbar, thoracic, and cervical) considered separately, what is the evidence of cost effectiveness of facet neurotomy compared with other treatment options?

No full economic studies evaluating the cost-effectiveness of various diagnostic block techniques for identifying suitable candidates for facet neurotomy were found nor were any full economic studies comparing facet neurotomy with other treatment options found. This precludes drawing conclusions regarding cost-effectiveness. Limited information from several poorly reported costing studies is summarized below.

As part of their randomized controlled trial in the Netherlands, van Wijk et. al determined direct (e.g. personnel, materials) and some indirect costs (overhead, cleaning) within the first three months of neurotomy from a provider perspective. Average estimated total costs for neurotomy

were €175 per one point VAS reduction after three months compared with €239 for sham/control treatment.[31] Burnham reported a decrease in patient direct costs for back-pain related treatment (including medication costs and costs for services such as massage, chiropractic and others) which lasted between 6 and 9 months post- neurotomy.[166] Most of the reduction (69%) of direct costs was related to reduced medication costs.

Two studies describe cost information related to diagnostic blocks.[21, 25] Results from these studies are somewhat conflicting, which may in part be due to different analytical methods and assumptions. Costs are influenced by the proportion of patients who go on to receive neurotomy following diagnostic block, which is determined at least in part, by the pain-relief cut-off threshold. None addressed the economic impact of successful versus failed neurotomy. Cohen, et.al looked at the costs per successful neurotomy (defined as ≥ 50% pain relief with a positive perceived effect persisting for 3 months) of doing no diagnostic block, one and two blocks to determine patient selection for neurotomy using a randomized design in 151 subjects. Those having no diagnostic block underwent neurotomy based on clinical findings alone. At three months, 33% (n=17) patients who received no diagnostic block had a successful outcome compared with 16% (n = 8) and 22% (n = 11) in the single and double block groups respectively. Authors report denervation success rates of 33%, 39% and 64% for the groups. The costs per successful treatment for each of these groups were $6282, $17,142 and $15, 214 respectively. They concluded that proceeding to neurotomy without a diagnostic block was most cost–effective. [21] Derby and colleagues reported on total facility costs and professional costs of medial branch neurotomy and diagnostic medial branch blocks using the same criterion for success as Cohen. They examined incremental cut-offs of 10% (50-100% pain relief) for diagnostic block success. The report that using progressively stringent cut-offs incrementally excluded those without posterior spine element pain. They noted cost savings when increasingly stringent cut off values were used and concluded that a threshold of ≥ 70% pain relief following diagnostic block resulted in cost savings in favor of performing diagnostic blocks based on their actual and theoretical cost modeling.

5. Summary by Key Question

Key Question 1: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence that the use of diagnostic blocks to select patients for facet neurotomy improves clinical outcomes following facet neurotomy? Consider each of the following:

Key Question 1a: Diagnostic block versus alternative diagnostic test (e.g., physical examination, radiological examination)								**RF Neurotomy**		**Effect size**	
Outcome following RF neurotomy	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**MBB**	**Clinical exam**	**RR (95% CI) RD (95% CI)**	**Favors**
								% patients			
Lumbar spine: Diagnostic block versus physical examination Evidence base: 1 RCT[21] (see footnotes for details)											
Short-term "Success" composite: ≥50% pain relief and positive GPE	**1 RCT[21] N = 70 1, 3 mos.**	**Serious risk of bias***	**No serious inconsistency**	**No serious indirectness**	**Serious risk of imprecision†**	**Undetected**	**Low**	**39-63% (range)**	**33-59% (range)**	**RR: 1.07-1.17 RD: 0.04-0.06** See below for 95% CIs	**neither**
	1 mos.							63% (12/19)	59% (30/51)	1.07 (0.71, 1.62) 0.04 (-0.21, 0.30)	neither
	3 mos.							39% (7/18)	33% (17/51)	1.17 (0.58, 2.34) 0.06 (-0.20, 0.32)	neither
No evidence for any of the following: • Diagnostic block versus physical examination in the thoracic or cervical spine • Diagnostic block versus radiological examination in the lumbar, thoracic, or cervical spine Evidence base: 1 RCT (N = 70) (Cohen 2010[21])											

GPE: global perceived effect; MBB: medial branch block; NS: differences between groups are not statistically significant; RF: radiofrequency

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size

Key Question 1b: Type of diagnostic block								Cryodenervation		Effect size	
Outcome following cryo-denervation	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	MBB Δ from baseline (mean (%))	Peri-capsular block Δ from baseline (mean (%))	Mean Δ difference (95% CI)	Favors
Lumbar spine: Medial branch block versus pericapsular block Evidence base: 1 RCT[12] (see footnotes for details)											
Short-term Back pain (VAS scores) (Scale: 0-100)	1 RCT[12] N = 26 1.5 – 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	47-52 points (range)	40 points (range)	7-12 points (range)	**neither**
	1.5 mos.							52 (72%)	40 (49%)	12	neither
	3 mos.							51 (69%)	40 (49%)	11	neither
	6 mos.							47 (64%)	40 (57%)	7	neither
Short-term Function: MacNab (Scale: 0-3)	1 RCT[12] N = 26 1.5 – 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	1.1-1.2	1.0	0.1-0.2 points (range)	**NC/NR**
	1.5 mos.							1.1	1.0	0.1	NC/NR
	3 mos.							1.2	1.0	0.2	NC/NR
	6 mos.							1.2	1.0	0.2	NC/NR
No evidence for any of the following: • Other diagnostic block comparators in the lumbar spine • Thoracic or cervical spine											

Evidence base: 1 RCT (N = 26) (Birkenmaier[12])

MBB: medial branch block; NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size

‡ as reported by the study

Key Question 1c: Use of single versus two or more controlled or comparative diagnostic blocks								RF Neurotomy		Effect size	
Outcome following RF neurotomy	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	1 MBB % patients	2 comp. MBBs % patients	RR (95% CI) RD (95% CI)	Favors
Lumbar spine: Medial branch block versus pericapsular block Evidence base: 1 RCT[21] (see footnotes for details)											
Short-term "Success" composite: ≥50% pain relief and positive GPE	1 RCT[21] N = 33 1, 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	39-63% (range)	64% (range)	RR: 0.60-0.98 RD: -0.25 to -0.01 See below for 95% CIs	**neither**
	1 mos.							63% (12/19)	64% (9/14)	0.98 (0.58, 1.65) -0.01 (-0.34, 0.32)	neither
	3 mos.							39% (7/18)	64% (9/14)	0.60 (0.30, 1.22) -0.25 (-0.59, 0.08)	neither
No evidence for any of the following: • Thoracic or cervical spine Evidence base: 1 RCT (N = 33) (Cohen 2010[21])											

MBB: medial branch block; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

†relatively small sample size

Key Question 1d: Degree and duration of pain reduction from diagnostic block								RF Neurotomy		Effect size	
Outcome following RF neurotomy	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	50-79% pain relief from MBB(s) % patients	≥80% pain relief from MBB(s) % patients	RR (95% CI) RD (95% CI)	Favors
Lumbar spine: 50-79% versus ≥80% pain relief from diagnostic block											
Evidence base: 1 prospective[23] and 3 retrospective[22, 24, 25] cohort studies (see footnotes for details)											
Short-term Back pain "Success": ≥50% pain relief	2 retro. cohorts[22, 24] total N = 313 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	52-54% (range)	56-84% (range)	RR: 0.64-0.93 RD: -0.30 to -0.04 See below for 95% CIs	**See below**
	N = 262[22] 6 mos.							52% (76/145)	56% (66/117)	0.93 (0.74, 1.16) -0.04 (-0.16, 0.08)	neither
	N = 51[24] 6 mos.							54% (14/26)	84% (21/25)	0.64 (0.43, 0.95) -0.30 (-0.54, -0.06)	≥80% pain relief from block
Short-term "Success" composite: ≥50% pain relief and positive GPE	2 cohort studies[23, 25] N = 113 total 1, 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	35-67% (range)	56-76% (range)	RR: 0.46-1.05 RD: -0.41 to 0.03 See below for 95% CIs	**See below**
	1 mos. 1 pro. cohort[23] N = 61							67% (26/39)†	69% (11/16)†	0.97 (0.65, 1.44) -0.02 (-0.29, 0.25)	neither
	3 mos. 1 pro. cohort[23] N = 61							59% (23/39)†	56% (9/16)†	1.05 (0.63, 1.74) 0.03 (-0.26, 0.32)	neither

Key Question 1d: Degree and duration of pain reduction from diagnostic block								RF Neurotomy		Effect size	
Outcome following RF neurotomy	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**50-79% pain relief from MBB(s)**	**≥80% pain relief from MBB(s)**	**RR (95% CI) RD (95% CI)**	**Favors**
	1 retro. cohort[25] N = 52							35% (8/23)	76% (19/25)	0.46 (0.25, 0.84) -0.41 (-0.67, -0.16)	≥ 80% pain relief threshold following MBB
Short-term Function: ≥50% improvement in activity levels (not defined)	1 retro. cohort[24] N = 51 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	33% (8/24)	76% (19/25)	0.44 (0.24, 0.80) -0.43 (-0.68, -0.17)	**≥ 80% pain relief threshold following block**
No evidence for any of the following: • Duration of pain relief following diagnostic block in the lumbar spine • Thoracic or cervical spine											

Evidence base:

- 1 prospective cohort study: (Cohen 2013[23], N = 61)
- 3 retrospective cohort studies: (Cohen 2008[22], N = 262), (Derby 2012[24], N = 51), (Derby 2013[25], N = 52)

MBB: medial branch block; NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; pro: prospective; retro.: retrospective; RFN: radiofrequency neurotomy

* the studies did not meet two or more important criteria of a good quality cohort studies (see Appendix C for details)

† relatively small sample size

‡ pain relief following diagnostic block divided as follows: 50-83% versus ≥84% (Cohen 2013)

Key Question 2: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, What is the evidence of short- and long-term comparative efficacy and effectiveness of facet neurotomy (FN) compared with alternatives (e.g., sham neurotomy, therapeutic intra-articular injections, etc.)?

NOTE. Tables stratified according to type of diagnostic block, with corresponding information regarding number of diagnostic blocks and percentage of pain relief following the blocks may be found in Appendix I.

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								**Treatment groups**		**Effect size**	
Efficacy Evidence base: 6 RCTs[26-31] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** **Δ from baseline (mean (%))**	**Sham** **Δ from baseline (mean (%))**	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	6 RCTs[26-31] N = 292 total 2-6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	-0.4 to 42.0 points (range)	2.0 to 37.0 points (range)	5.0 to 19.4 points (range)	**neither**
	1 RCT[30] N = 31 2 mos.							23.7 (46%)	4.3 (8%)	19.4	RFN
	1 RCT[27] N = 70 3 mos.							-0.4 ± 25.0 (-1%)	7.1 ± 27.3 (14%)	7.5 ± 16.0	neither
	1 RCT[31] N = 81 3 mos.							21.0 (36%)	16.0 (25%)	5.0	NR/NC
	1 RCT[26] N = 30 6 mos.							14.0 (24%)	2.0 (3%)	12.0	NR/NC
	1 RCT[28] N = 40 6 mos.							21.0 (35%)	7.0 (16%)	14.0	RFN (marginally)
	1 RCT[29] N = 40							42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	5.0 ± 6.5	neither

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								Treatment groups		Effect size	
	6 mos.										
Long-term Back pain (VAS scores) (0-100)	1 RCT[29] N = 40 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	41.0 ± 9.1 (63%)	29.0 ± 9.6 (43%)	12.0 ± 5.9	**RFN**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Back pain "success" (≥50% improvement in VAS scores)	1 RCT[31] N = 81 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	33% (13/40) patients	34% (14/41) patients	0.95 (0.51, 1.76) -0.02 (-0.22, 0.19)	**neither**
Short-term GPE Back pain "success" (≥50% improvement in GPE of back pain)	1 RCT[31] N = 81 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	62% (24/39) patients	39% (16/41) patients	1.58 (0.9994, 2.49) 0.23 (0.12, 0.44)	**RFN** (marginally)
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Sham**	**Mean Δ difference (95% CI)**	**Favors**
Short-term Pain (McGill scores) (0-50)	1 RCT[26] N = 30 1, 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	3 to 6 points (range)	2 to 3 points (range)	1 to 3 points (range)	**See below**
	1 mos.							6 ± 1.5	3 ± 1.7	3	RFN
	6 mos.							3 ± 5.5	2 ± 1.9	1	neither
Short-term	2 RCTs[28,	Serious	No serious	No serious	Serious risk of	Undetected	**Low**	16 to 21	1.3 to 16	5 to 14.7	**RFN**

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								Treatment groups		Effect size	
Leg Pain (VAS scores) (0-100)	[31] N = 121 total 3, 6 mos.	risk of bias*	inconsistency	indirectness	imprecision‡			points (range)	points (range	points (range)	
	1 RCT[31] N = 81 3 mos.							21.0 (50%)	16.0 (25%)	5.0	NC
	1 RCT[28] N = 40 6 mos.							16.0 (37%)	1.3 (5%)	14.7	RFN
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN**	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
								% patients			
Short-term Leg pain "success" (≥50% improvement in VAS scores)	1 RCT[31] N = 81 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	50% (19/38) patients	37% (15/41) patients	1.37 (0.82, 2.28) 0.13 (-0.08, 0.35)	**neither**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN**	**Sham**	**Mean Δ difference (95% CI)**	**Favors**
								Δ from baseline (mean (%))			
Short-term Generalized pain (VAS scores) (0-100)	1 RCT[28] N = 40 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	19.3	3.7	15.6	**RFN**
Short-term Function (ODI scores) (0-100)	3 RCTs[27, 29, 30] N = 141 total 2-6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	4.7 to 14.1 points (range)	-1.7 to 11.2 points (range)	2.0 to 12.8 points (range)	**RFN**
	1 RCT[30] N = 31							11.1 (36%)	-1.7 (-4%)	12.8	RFN

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								Treatment groups		Effect size	
	2 mos. 1 RCT[27] N = 70 3 mos. 1 RCT[29] N = 40 6 mos.							4.7 ± 12.0 (12%) 14.1 ± 4.2 (36%)	2.7 ± 9.1 (7%) 11.2 ± 3.9 (28%)	2.0 2.9	NS RFN
Long-term Function (ODI scores) (0-100)	1 RCT[29] N = 40 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	11.2 ± 4.8 (29%)	6.5 ± 3.9 (16%)	4.7	**RFN**
Short-term Function (Roland-Morris scores) (converted to 0-100)	1 RCT[27] N = 70 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	9.8 ± 19.5 (19%)	7.2 ± 17.0 (14%)	2.6	**neither**
Short-term Function (Waddell scores) (0-24)	1 RCT[30] N = 31 2 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	0.33	0.07	0.26	**neither**
Short-term Function (physical activity scores) (0-30)	1 RCT[31] N = 81 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	1.5	0.9	0.6	**NR/NC**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Sham**	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term "Success" composite (≥2-point	1 RCT[30] N = 31 2 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	67% (10/15) patients	38% (6/16) patients	1.77 (0.86, 3.68) 0.29	**neither**

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								Treatment groups		Effect size	
improvement in VAS (0-10) and ≥50% improvement in GPE (1-4))										(-0.05, 0.63)	
Short-term "Success" composite Either of the following: • ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or • ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%	1 RCT[31] N = 81 3 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	28% (11/40)	29% (12/41)	0.94 (0.47, 1.88) -0.02 (-0.21, 0.18)	**neither**
No evidence for any of the following:											

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine		Treatment groups	Effect size
• Effectiveness of neurotomy versus sham neurotomy in the lumbar spine • Efficacy or effectiveness of other types of neurotomy versus sham neurotomy in the lumbar spine			

Evidence base for efficacy in the lumbar spine: 6 RCTs

- Gallagher (1994)[26]: N = 30 (CoE II)
- Leclaire (2001)[27]: N = 70 (CoE II)
- Nath (2008)[28]: N = 31 (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)
- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 2: RF Neurotomy versus Sham Neurotomy in the Cervical Spine								Treatment groups		Effect size	
Evidence base: 1 RCT[32] (see footnotes for details)											
Outcome	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	RFN % patients	Sham % patients	RR (95% CI) RD (95% CI)	Favors
Short-term Freedom from "accustomed" pain	1 RCT[32] N = 81 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	58% (7/12)	8% (1/12)	7.00 (1.01, 48.54) 0.50 (0.18, 0.82)	**RFN**
No evidence for any of the following: • Effectiveness of neurotomy versus sham neurotomy in the cervical spine • Efficacy or effectiveness of other types of neurotomy versus sham neurotomy in the cervical spine											

Evidence base for efficacy in the cervical spine: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size and wide confidence intervals

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine								Treatment groups		Effect size	
Efficacy Evidence base: 2 RCTs[33, 34] (see footnotes for details) **Injections:** Therapeutic medial branch block (1 RCT[33]); therapeutic intra-articular injections (1 RCT[34])											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Injection** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	2 RCTs[33, 34] N = 156 total 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	19 to 57 points (range)	16 to 41 points (range)	3 to 16 points (range)	**neither**
	1 RCT[33] N = 100 6 mos.							57 (70%)	41 (48%)	16	NR/NC
	1 RCT[34] N = 56 6 mos.							19 ± 14.5 (29%)	16 ± 12.6 (23%)	3	neither
Long-term Back pain (VAS scores) (0-100)	1 RCT[33] N = 100 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	56 (68%)	36 (42%)	20	NR/NC
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Back pain "success" (≥50% improvement in VAS scores)	1 RCT[33] N = 100 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	90% (45/50)	68% (34/50)	1.32 (1.11, 1.58) 0.22 (0.07, 0.37)	**RFN**
Long-term Back pain "success" (≥50% improvement in VAS scores)	1 RCT[33] N = 100 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	88% (44/50)	62% (31/50)	1.42 (1.12, 1.80) 0.26 (0.10, 0.42)	**RFN**

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine								Treatment groups		Effect size	
Outcome	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	RFN	Injection	Mean Δ difference (95% CI)	Favors
								Δ from baseline (mean (%))			
Short-term Function (ODI scores) (0-100)	1 RCT[34] N = 56 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	12.8 ± 12.0 (31%)	5.7 ± 11.4 (15%)	7.1 points	**neither**
Short-term Function (Roland-Morris scores) (0-24, lower is better)	1 RCT[34] N = 56 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	3.7 ± 3.7 (19%)	4.2 ± 3.9 (14%)	-0.5 points	**neither**
Effectiveness Evidence base: 1 retrospective audit[35] (see footnotes for details) **Injections:** Therapeutic intra-articular injections											
Outcome	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	RFN	Injection	RR (95% CI) RD (95% CI)	Favors
								% patients			
Short-term Back pain "success" (≥50% global subjective improvement)	1 retro. cohort[35] N = 66 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	50% (16/32)	29% (10/34)	1.70 (0.91, 3.18) 0.21 (-0.03, 0.44)	**neither**
No evidence for any of the following: • Efficacy or effectiveness of other types of neurotomy versus spinal injections in the lumbar spine											

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Civelek (2012)[33]: N = 100 (CoE II)
- Lakemeier (2013)[34]: N = 56 (CoE II)

Evidence base for effectiveness in the lumbar spine: 1 retrospective audit study

- Chakraverty (2004)[35]: N = 66 (CoE III)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 2: RF Neurotomy versus Spinal Injections in the Cervical Spine								Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[36] (see footnotes for details) **Injections:** Anesthetic injection of the major occipital nerve (for cervicogenic headache)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Injection** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Headache pain (VAS scores) (0-100)	1 RCT[3b] N = 30 2 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	30.5 ± 17.3 (45%)	32.4 ± 24.7 (42%)	1.9	**neither**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term "Success" composite (GPE score +2 or +3 and/or ≥ 20-point improvement VAS)	1 RCT[3b] N = 30 2 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	80% (12/15)	71% (10/14)	1.12 (0.79, 1.59) 0.09 (-0.23, 0.40)	**neither**
No evidence for any of the following: • Effectiveness of neurotomy versus spinal injections in the cervical spine • Efficacy or effectiveness of other types of neurotomy versus spinal injections in the cervical spine											

Evidence base for efficacy in the cervical spine: 1 RCT

- Haspeslagh (2006)[36]: N = 100 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2a: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)?

Key Question 2a: Conventional versus pulsed RF neurotomy in the lumbar spine								**Treatment groups**		**Effect size**	
Efficacy Evidence base: 2 RCTs[29, 37] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**Conventional RFN** Δ from baseline (mean (%))	**Pulsed RFN** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	2 RCTs[29, 37] N = 66 total 3, 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	24.3 to 42 points (range)	12.3 to 37 points (range)	5 to 12 points (range)	**neither**
	1 RCT[37] N = 26 3 mos.							24.3 ± 17.5 (32%)	12.3 ± 13.0 (19%)	12.0	**neither**
	1 RCT[29] N = 40 6 mos.							42 ± 9 (65%)	37 ± 10 (56%)	5	**neither**
Long-term Back pain (VAS scores) (0-100)	1 RCT[29] N = 40 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	41 ± 9 (63%)	31 ± 10 (47%)	10	**Conv. RFN**
Short-term Function (ODI scores) (0-100)	2 RCTs[29, 37] N = 66 total 3, 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	10.3 to 14.1 points (range)	2.7 to 14.1 points (range)	0 to 7.6 points (range)	**neither**
	1 RCT[37] N = 26 3 mos.							10.3 ± 10.8	2.7 ± 12.4	7.6	**neither**
	1 RCT[29] N = 40 6 mos.							14.1 ± 4.2	14.1 ± 4.2	0	**neither**

Key Question 2a: Conventional versus pulsed RF neurotomy in the lumbar spine								Treatment groups		Effect size	
Long-term Function (ODI scores) (0-100)	1 RCT[29] N = 40 12 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	11.2 ± 4.8	10.9 ± 3.7	0.3	**neither**
No evidence for any of the following: • Effectiveness of conventional versus pulsed neurotomy in the lumbar spine • Efficacy or effectiveness of conventional versus pulsed neurotomy in the cervical spine											

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Kroll (2007)[37]: N = 50 (study on 26 patients) (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2a: RF neurotomy versus Alcohol ablation in the lumbar spine								Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[38] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Alcohol Ablation** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term "Success" composite (VAS < 7 (0-10 scale) and ODI < 22%)	1 RCT[38] N = 40 3-9 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	85-100% (range)	100% (range)	RR: 0.85-0.95 RD: -0.15 to -0.05 See below for 95% CIs	**neither**
	3 mos.							100% (20/20)	100% (20/20)	NC	**neither**
	6 mos.							95% (19/20)	100% (20/20)	0.95 (0.86, 1.05) -0.05 (-0.15, 0.05)	**neither**
	9 mos.							85% (17/20)	100% (20/20)	0.85 (0.71, 1.02) -0.15 (-0.31, 0.01)	**neither**
Long-term "Success" composite (VAS < 7 (0-10 scale) and ODI < 22%)	1 RCT[38] N = 40 12-24 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	5-25% (range)	85-100% (range)	RR: 0.85-0.95 RD: -0.15 to -0.05 See below for 95% CIs	**Alcohol ablation**
	12 mos.							25% (5/20)	100% (20/20)	0.25 (0.12, 0.53) -0.75	Alcohol ablation

Key Question 2a: RF neurotomy versus Alcohol ablation in the lumbar spine								Treatment groups		Effect size	
										(-0.94, -0.56)	
	18 mos.							5% (1/20)	90% (18/20)	0.06 (0.01, 0.38)	Alcohol ablation
										-0.85 (-1.01, -0.69)	
	24 mos.							5% (1/20)	85% (17/20)	0.06 (0.01, 0.40)	Alcohol ablation
										-0.80 (-0.98, -0.62)	

No evidence for any of the following:

- Effectiveness of RFN versus alcohol ablation in the lumbar spine
- Efficacy or effectiveness of RFN versus alcohol ablation in the cervical spine
- Efficacy or effectiveness of different types of neurotomy in the lumbar or cervical spine

Evidence base for efficacy in the lumbar spine: 1 RCT

- Joo (2013)[38]: N = 40 (CoE II)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 2b: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of repeat neurotomy procedures at the same level and the same side as the initial procedure?

Key Question 2b: Repeat neurotomy in the lumbar spine								**Treatment groups**		
Evidence base: 6 case series[38-43] (see footnotes for details)										
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
								% patients		
"Success" composite (Definitions varied by and within each study)	4 case series[38-41] N = 157 total f/u NR	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	55% to 100% (range) (4 studies[38-41], N = 157	5% to 85% (range) (4 studies[38-41], N = 157	52-94% (range) (2 studies[39, 40], N = 45)
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
								Mean		
Duration of pain relief	3 case series[38, 40, 41] N = 100 total f/u NR	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	10.4-10.9 mos. (range of means) (3 studies[38, 40, 41], N = 100	10.2-11.6 mos. (range of means) (2 studies[38, 40, 41], N = 95	11.2 mos. (1 study[40], N = 16)

Evidence base for efficacy in the lumbar spine: 6 case series

- Joo (2013): N = 20 (CoE IV)
- Rambaransingh (2010)[39]: N = 84 (CoE IV)
- Schofferman (2004)[40]: N = 20 (CoE IV)
- Son (2010)[41]: N = 60 (CoE IV)
- Speldewinde (2011)[42]: N = NR (39 repeat procedures) (CoE IV)

- Zotti (2010)[43]: N = 65 (CoE IV)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* Case series (see Appendix C for details)

† relatively small sample size

Key Question 2b: Repeat neurotomy in the cervical spine								Treatment groups		
Evidence base: 3 case series[39, 42, 44] (see footnotes for details)										
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
								% patients		
"Success" composite (Definitions varied by and within each study)	2 case series[39, 44] N = 36 total f/u NR	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	43% to 100% (range) (2 studies[39, 44], N = 36	64% to 95% (range) (2 studies[39, 44], N = 35	91% (1 study[44], N = 11)
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN1**	**RFN2**	**RFN3**
								Mean		
Duration of pain relief	1 case series N = 22[44] f/u NR	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Insufficient**	12.5 mos. n = 22	12.7 mos. n = 21	9.5 mos. n = 11

Evidence base for efficacy in the lumbar spine: 6 case series

- Husted (2008)[44]: N = 22 (CoE IV)
- Rambaransingh (2010)[39]: N = 14 (CoE IV)
- Speldewinde (2011)[42]: N = NR (40 repeat procedures) (CoE IV)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* Case series (see Appendix C for details)

† relatively small sample size

Key Question 2c: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of short- and long-term comparative efficacy and effectiveness of unilateral versus bilateral neurotomy?

Key Question 2c: Unilateral versus bilateral neurotomy in the lumbar spine								**Treatment groups**		**Effect size**	
Efficacy base: 1 cohort study[45](see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**Unilateral RFN** % patients	**Bilateral RFN** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Short-term Back pain "Success" (≥50% pain relief or complete elimination of pain)	1 retro. cohort[45] N = NR (69 procedures) Mean 5.6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	33% (6/18) procedures	45% (23/51) procedures	0.74 (0.36, 1.52) -0.12 (-0.37, 0.14)	**neither**
No evidence for any of the following: • Efficacy of unilateral versus bilateral neurotomy in the lumbar spine • Efficacy or effectiveness of unilateral versus bilateral neurotomy in the cervical or thoracic spine											

Evidence base for the lumbar spine: 1 retrospective cohort study

- Tzaan (2000)[45]: N = NR (69 procedures) (CoE III)

NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality cohort study (see Appendix C for details)

† relatively small sample size

Key Question 3: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the comparative evidence regarding adverse events and complications during the periprocedural period and longer term for facet neurotomy?

Key Question 3: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine								Treatment groups		Effect size	
Efficacy Evidence base: 6 RCTs[26-31] (see footnotes for details)											
Outcome	**Studies N**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Sham** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Treatment-related pain (moderate or severe)	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	59% (23/39)	36% (14/39)	1.40 (0.95, 2.04) 0.09 (-0.01, 0.20)	**neither**
Treatment-related sensibility changes (irritating or evident dysaesthesia or allodynia)	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	5% (2/39)	0% (0/39)	1.31 (0.74, 2.31) 0.41 (-0.04, 0.13)	**neither**
Treatment-related motor changes (irritating or evident motor loss)	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (2/38)	2% (1/41)	0.00 (NC) -0.02 (-0.07, 0.02)	**neither**
Treatment-related adverse events (undefined)	4 RCTs[26, 27, 29, 30] N = 191 total	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (0/109)	0% (0/81)	NC	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with sham neurotomy based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria)											

Evidence base for efficacy in the lumbar spine: 6 RCTs

- Gallagher (1994)[26]: N = 30 (CoE II)
- Leclaire (2001)[27]: N = 70 (CoE II)
- Nath (2008)[28]: N = 31 (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)
- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 3: RF Neurotomy versus Sham Neurotomy in the Cervical Spine								Treatment groups		Effect size	
Efficacy Evidence base: 1 RCT[32] (see footnotes for details)											
Outcome	**Studies N**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Sham** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Psoriatic rash (postoperation)	1 RCT[32] N = 24	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	8% (1/12)	0% (0/12)	NC 0.08 (NC)	**neither**
Procedure-related numbness	1 RCT[32] N = 24	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	38% (5/12)	0% (0/12)	NC 0.42 (NC)	**Sham**
Outcome	**Studies N**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** Median (interquartile range)	**Sham** Median (interquartile range)	**Mean Δ difference (95% CI)**	**Favors**
Duration of procedure-related pain	1 RCT[32] N = 24	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	13.5 (6, 15) days	3.5 (1, 15) days	10 days	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with sham neurotomy based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria)											

Evidence base for efficacy in the cervical spine: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT s (see Appendix C for details)

† relatively small sample size

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine								Treatment groups		Effect size	
Efficacy Evidence base: 2 RCTs[33, 34] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Infection	1 RCT[33] N = 100 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (0/50)	0% (0/50)	NC	**neither**
New motor or sensory deficit	1 RCT[33] N = 100 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (0/50)	0% (0/50)	NC	**neither**
No evidence for any of the following: • Safety data for neurotomy compared with spinal injections based on nonrandomized comparative studies • Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria) • Safety data for neurotomy compared with spinal injections in the cervical spine											

Evidence base for efficacy in the lumbar spine: 2 RCTs

- Civelek (2012)[33]: N = 100 (CoE II)
- Lakemeier (2013)[34]: N = 56 (CoE II)

Evidence base for effectiveness in the lumbar spine: 1 retrospective audit study

- Chakraverty (2004)[35]: N = 66 (CoE III)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 4: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, is there evidence of differential efficacy or safety compared with other treatment options in subpopulations? Include consideration of age, gender, race, ethnicity, disability, and workers compensation.

> **NOTE**. For this key question, we first evaluated differential efficacy, effectiveness, and safety of facet neurotomy compared with other treatment options by looking for subgroup analyses in comparative studies. Secondly, we conducted an analysis on a subgroup of studies included in Key Question 2 to determine the efficacy of facet neurotomy in patients selected on the basis of ≥50% pain relief following medial branch block.

Heterogeneity of treatment effect:

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine									**Treatment groups**		**Effect**
Efficacy Evidence base: 1 RCT[31] (see footnotes for details)											
Subgroup	**Studies N**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**Subgroup**	**RFN** % patients	**Sham**	**Favors**
Outcome: "Success" composite (either of the following: • ≥50% reduction in VAS-back pain without decrease in daily activities or increase in analgesic use, or • ≥25% reduction in VAS-back pain, increase in daily activities by ≥25%, decrease in analgesic use by ≥25%)											
Sex	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	Male Female	(2/10) (9/30)	(6/13) (6/28)	**neither**
Age	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	18-40 years > 41 years	(4/13) (7/27)	(4/12) (8/29)	**neither**
Duration of	1 RCT[31] N = 81	Serious risk of	No serious inconsistency	No serious indirectness	Serious risk of	Undetected	**Low**	2-5 years	(6/19)	(7/21)	**neither**

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine									Treatment groups		Effect
pain		bias*			imprecision†			> 5 years	(5/21)	(5/20)	
Employment status	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	Employed Unemployed	(7/23) (4/17)	(7/20) (5/21)	**neither**
Previous low back surgery	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	None ≥ 1 surgery	(8/25) (3/15)	(6/25) (6/16)	**neither**
Outcome: Pain relief "Success" composite (as measured by the 4-point GPE scale)											
Sex	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	Male Female	56% (5/9) 63% (19/30)	54% (7/13) 32% (9/28)	**neither**
Age	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	18-40 years > 41 years	(7/13) (17/26)	(6/12) (10/29)	**neither**
Duration of pain	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	2-5 years > 5 years	(10/18) (14/21)	(10/21) (6/20)	**neither**
Employment status	1 RCT[31] N = 81	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	Employed Unemployed	(11/22) (13/17)	(9/20) (7/21)	**neither**
Previous	1 RCT[31] N = 81	Serious risk of	No serious inconsistency	No serious indirectness	Serious risk of	Undetected	**Low**	None	(16/24)	(9/25)	**neither**

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine									Treatment groups		Effect
low back surgery		bias*			imprecision†			≥ 1 surgery	(8/15)	(7/16)	
No evidence for any of the following: • Differential effectiveness or safety for neurotomy compared with sham neurotomy in the lumbar spine • Differential efficacy, effectiveness, or safety for neurotomy compared with sham neurotomy in the cervical or thoracic spine • Differential efficacy, effectiveness, or safety for neurotomy compared with spinal injections in the lumbar, cervical or thoracic spine											

Evidence base for differential efficacy in the lumbar spine: 1 RCT

- Van Wijk (2005)[31]: N = 81 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

‡ Based on the Breslow Day test for interaction.

Key Question 2: RF Neurotomy versus Spinal Injections in the Lumbar Spine								Treatment groups		Effect size	
Efficacy Evidence base: 2 RCTs[33, 34] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** % patients	**Injection** % patients	**RR (95% CI) RD (95% CI)**	**Favors**
Infection	1 RCT[33] N = 100 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (0/50)	0% (0/50)	NC	**neither**
New motor or sensory deficit	1 RCT[33] N = 100 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	0% (0/50)	0% (0/50)	NC	**neither**

No evidence for any of the following:

- Safety data for neurotomy compared with spinal injections based on nonrandomized comparative studies
- Safety data for neurotomy in high-quality case series (see PICO table for inclusion criteria)
- Safety data for neurotomy compared with spinal injections in the cervical spine

Comparative efficacy of RF Neurotomy: patients selected on basis of ≥50% pain relief following diagnostic MBB

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB								Treatment groups		Effect size	
Efficacy Evidence base: 3 RCTs[28-30] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** **Δ from baseline (mean (%))**	**Sham**	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**3 RCTs[26-31] N = 111 total 2-6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	**21.0 to 42.0 points (range)**	**4.3 to 37.0 points (range)**	**5.0 to 19.4 points (range)**	**RFN**
	1 RCT[30] N = 31 2 mos.							23.7 (46%)	4.3 (8%)	19.4	RFN
	1 RCT[28] N = 40 6 mos.							21.0 (35%)	7.0 (16%)	14.0	RFN (marginally)
	1 RCT[29] N = 40 6 mos.							42.0 ± 9.1 (65%)	37.0 ± 10.7 (54%)	5.0 ± 6.5	neither
Long-term Back pain (VAS scores) (0-100)	**1 RCT[29] N = 40 12 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**41.0 ± 9.1 (63%)**	**29.0 ± 9.6 (43%)**	**12.0 ± 5.9**	**RFN**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** **Δ from baseline (mean (%))**	**Sham**	**Mean Δ difference (95% CI)**	**Favors**
Short-term Leg Pain (VAS scores) (0-100)	**1 RCT[28] N = 40 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**16.0 (37%)**	**1.3 (5%)**	**14.7**	**RFN**

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB								Treatment groups		Effect size	
Outcome	Studies N Follow-up						Overall quality of evidence	RFN	Sham	Mean Δ difference (95% CI)	Favors
								Δ from baseline (mean (%))			
Short-term Generalized pain (VAS scores) (0-100)	1 RCT[28] N = 40 6 mos.	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	19.3	3.7	15.6	**RFN**
Short-term Function (ODI scores) (0-100)	**2 RCTs[29, 30] N = 71 total 2-6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**11.1 to 14.1 points (range)**	**-1.7 to 11.2 points (range)**	**2.9 to 12.8 points (range)**	**RFN**
	1 RCT[30] N = 31 2 mos.							11.1 (36%)	-1.7 (-4%)	12.8	RFN
	1 RCT[29] N = 40 6 mos.							14.1 ± 4.2 (36%)	11.2 ± 3.9 (28%)	2.9	RFN
Long-term Function (ODI scores) (0-100)	**1 RCT[29] N = 40 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**11.2 ± 4.8 (29%)**	**6.5 ± 3.9 (16%)**	**4.7**	**RFN**
Short-term Function (Waddell scores) (0-24)	**1 RCT[30] N = 31 2 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**0.33**	**0.07**	**0.26**	**neither**
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN**	**Sham**	**RR (95% CI RD (95% CI)**	**Favors**
								% patients			

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB								Treatment groups		Effect size	
Short-term "Success" composite (≥2-point improvement in VAS (0-10) and ≥50% improvement in GPE (1-4))	**1 RCT[30] N = 31 2 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision‡	Undetected	**Low**	**67% (10/15) patients**	**38% (6/16) patients**	**1.77(0.86, 3.68) 0.29 (-0.05, 0.63)**	**neither**

Evidence base: 3 RCTs

- Nath (2008)[28]: N = 31 (CoE II)
- Tekin (2007)[29]: N = 40 (CoE II)
- Van Kleef (1999)[30]: N = 31 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† imprecise effect estimates (due to missing SDs)

‡ relatively small sample size

Key Question 4: RF Neurotomy versus Sham Neurotomy in the Cervical Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB								Treatment groups		Effect size	
Evidence base: 1 RCT[32] (see footnotes for details)											
Outcome	Studies N Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	RFN % patients	Sham % patients	RR (95% CI) RD (95% CI)	Favors
Short-term Freedom from "accustomed" pain	**1 RCT[32] N = 81 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	**58% (7/12)**	**8% (1/12)**	**7.00 (1.01, 48.54) 0.50 (0.18, 0.82)**	**RFN**

Evidence base: 1 RCT

- Lord (1996)[32]: N = 24

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details)

† relatively small sample size and wide confidence intervals

Key Question 4: RF Neurotomy versus Spinal Injections in the Lumbar Spine: patients selected on basis of ≥50% pain relief following diagnostic MBB								Treatment groups		Effect size	
Efficacy Evidence base: 1 RCTs[34] (see footnotes for details)											
Outcome	**Studies N Follow-up**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall quality of evidence**	**RFN** Δ from baseline (mean (%))	**Therapeutic intra-articular injection** Δ from baseline (mean (%))	**Mean Δ difference (95% CI)**	**Favors**
Short-term Back pain (VAS scores) (0-100)	**1 RCT[34] N = 56 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	**19 ± 14.5 (29%)**	**16 ± 12.6 (23%)**	**3**	**neither**
Short-term Function (ODI scores) (0-100)	**1 RCT[34] N = 56 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	**12.8 ± 12.0 (31%)**	**5.7 ± 11.4 (15%)**	**7.1 points**	**neither**
Short-term Function (Roland-Morris scores) (0-24, lower is better)	**1 RCT[34] N = 56 6 mos.**	Serious risk of bias*	No serious inconsistency	No serious indirectness	Serious risk of imprecision†	Undetected	**Low**	**3.7 ± 3.7 (19%)**	**4.2 ± 3.9 (14%)**	**-0.5 points**	**neither**

Evidence base: 1 RCT

- Lakemeier (2013)[34]: N = 56 (CoE II)

NC: not calculable; NR: not reported; NS: differences between groups are not statistically significant; RFN: radiofrequency neurotomy

* the studies (or the majority of the studies) did not meet two or more important criteria of a good quality RCT or cohort studies (see Appendix C for details)

† relatively small sample size

Key Question 5: With different regions of the spine (lumbar, thoracic, cervical facet) considered separately, what is the evidence of cost-effectiveness of facet neurotomy compared with other treatment options?

No studies were identified which met our inclusion criteria.

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