Washington State Health Care Authority

Health Technology Assessment

Facet Neurotomy

Responses to Draft Evidence Report

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Facet Neurotomy

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Responses To Comments Received For Draft Report

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This document responds to all peer reviews and public comments received for the draft report. Comments were received from the following parties:

- Paul Dreyfuss, MD, (Peer reviewer)
- Gary Franklin MD, MPH, (Medical Director WA State Department of Labor & Industries)
- David Hou, MD, (MultiCare)
- Jeffery Summers, MD, (President International Spine Intervention Society (ISIS))
- Lee Glass, MD (Associate Medical Director WA State Department of Labor & Industries)

Specific responses pertaining to each comment are included in Table 1.

For ease of reading, issues brought up more than once are discussed here; each point is referred to in the responses to comments received below.

1. **Patient selection: Type of diagnostic block (intraarticular block versus medial branch block (MBB))**

   The HTA evaluated whether the type of diagnostic block (i.e., medial branch block versus intra-articular injection) to select patients for facet neurotomy improves clinical outcomes following facet neurotomy (see Key Question 1b). (Because there is no reliable "gold standard" diagnostic tool for facet joint pain (see Executive Summary, Introduction for references), it is not possible to evaluate the diagnostic accuracy of these blocks.)

   To this end, inclusion was limited to studies in which outcomes following facet neurotomy were evaluated following patient selection by either block. This requirement was specified in both the draft and final key questions and in the inclusion criteria, all of which were finalized *a priori.* No studies were identified which compared outcomes following facet neurotomy in patients selected using intra-articular versus medial branch blocks, thus no conclusions could be drawn based on the literature available.

   As a result, in the studies included to evaluate the efficacy of facet neurotomy compared with alternative treatments (i.e., Key Question 2), the diagnostic method used to select patients for facet neurotomy is specified. However, studies were not excluded on the basis of the usage of certain types of diagnostic block.

   To further address the concerns brought up by the comments received, the following have been done:

   - Information as to the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block has been added to the data tables throughout KQ2 such that this information is readily available to readers.
   - Information regarding the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block in order for a patient to proceed to facet neurotomy has been added to the summary evidence tables in the Executive Summary.
   - Tables have been added to Key Question 4 in which the primary outcomes from comparative studies from KQ2 are reported from a subgroup of studies in which patients were selected on the basis of ≥50% pain relief following at least one MBB.
   - Additional information has been added to the background section.

2. **Patient selection: Percentage of pain relief achieved from diagnostic block**

   The evidence regarding the percentage of pain relief achieved following diagnostic block was evaluated in Key Question 1d, which asked whether the degree of pain reduction from diagnostic block (e.g., pain relief of ≥30% versus ≥50%, or ≥50% versus ≥80%)) to select patients

for facet neurotomy improves clinical outcomes following facet neurotomy. To this end, only those studies in which outcomes following facet neurotomy were evaluated in patients selected by the level of pain relief achieved following the diagnostic block were included. This requirement was specified in both the draft and final key questions and in the inclusion criteria, all of which were finalized *a priori.* This was done to determine the effect that patient selection has on the outcomes following facet neurotomy, which is the technology of interest for this report.

Overall, one prospective and three retrospective nonrandomized cohort studies met the inclusion criteria and were evaluated. While there were some data that suggested that significantly more patients that achieved "success" following RF neurotomy (definitions varied by study and included ≥50% pain relief; a composite of ≥50% pain relief and a positive global perceived effect score; or ≥50% improvement in activity levels) achieved ≥80% pain relief following diagnostic block (versus 50-79% pain relief following diagnostic block), the overall quality of this evidence as assessed using GRADE was determined to be "Insufficient" due to methodological concerns surrounding risks of study bias and study imprecision. (More details may be found in section 3.1.4 and section 5 of the report.)

As a result, in the studies included to evaluate the efficacy of facet neurotomy compared with alternative treatments (i.e., Key Question 2), the diagnostic method used to select patients for facet neurotomy is specified. However, studies were not excluded on the basis of percentage of pain relief required following diagnostic block.

To further address the concerns brought up by the comments received, the following have been done:

- Information as to the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block has been added to the data tables throughout KQ2 such that this information is readily available to readers.
- Information regarding the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block in order for a patient to proceed to facet neurotomy has been added to the summary evidence tables in the Executive Summary.
- Tables have been added to Key Question 4 in which the primary outcomes from comparative studies from KQ2 are reported from the subgroup of studies in which patients were selected on the basis of ≥50% pain relief following at least one MBB.

3. Patient selection: single versus two or more controlled diagnostic blocks

The evidence regarding the use of single versus two or more controlled diagnostic blocks affected outcomes following facet neurotomy was addressed in Key Question 1c. To this end,

only those studies in which outcomes following facet neurotomy were evaluated in patients selected by the level of pain relief achieved following the diagnostic block were included. This requirement was specified in both the draft and final key questions and in the inclusion criteria, all of which were finalized *a priori.* This was done to determine the effect that patient selection has on the outcomes following facet neurotomy, which is the technology of interest for this report.

Overall, one RCT of 33 patients met the inclusion criteria and was evaluated. The data suggested that there was no difference in the percentage of patients that achieved "success" following RF neurotomy (defined as a composite of ≥50% pain relief and a positive global perceived effect score). The overall quality of this evidence as assessed using GRADE was determined to be "Low" due to methodological concerns surrounding risks of study bias and study imprecision. (More details may be found in section 3.1.4 and section 5 of the report.)

As a result, in the studies included to evaluate the efficacy of facet neurotomy compared with alternative treatments (i.e., Key Question 2), the diagnostic method used to select patients for facet neurotomy is specified. However, studies were not excluded on the basis of the usage of one versus more than one diagnostic block.

To further address the concerns brought up by the comments received, the following have been done:

- Information as to the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block has been added to the data tables throughout KQ2 such that this information is readily available to readers.
- Information regarding the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block in order for a patient to proceed to facet neurotomy has been added to the summary evidence tables in the Executive Summary.

4. Patient selection: summary

For reasons stated above (points 1-3), the highest quality evidence available at the time of this report did not provide sufficient evidence to suggest a need for limiting studies to those that employed certain methods of patient selection for facet neurotomy. 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.

5. Technical aspects of the facet neurotomy procedure

This HTA was not designed to evaluate differences in neurotomy techniques. In addition, no guidelines were identified in which certain techniques were recommended over others. No

techniques of facet neurotomy were excluded after the scope of this report was refined based on input from clinical experts from a variety of disciplines and public comments received on draft key questions. Additional information has been added to the background section on this issue.

6. Pooling of data:

No outcomes data were pooled due to methodological differences between trials. As stated in the methods section of the draft report: "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."

7. Exclusion of case series to evaluate efficacy/effectiveness of facet neurotomy

Using case series to evaluate the efficacy and effectiveness of facet neurotomy is beyond the scope of the report. As such, this section has been omitted from the final report.
Because the key questions of interest were comparative in nature, evaluation of the efficacy and effectiveness of facet neurotomy was limited to comparative studies as noncomparative studies would not answer the questions that the report was designed to address.

Regarding the decision to exclude non-comparative studies to evaluate the efficacy and effectiveness of facet neurotomy:

- The key questions were comparative in nature; the inclusion and exclusion criteria were designed to answer these key questions. Both the key questions and the inclusion/exclusion criteria were decided on *a priori* and developed based on input from key stakeholders as well as from clinical experts and public opinion. As the draft report states (page 3), "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." All comments received were published here:
  http://www.hca.wa.gov/hta/documents/facet_responses_key_questions_082913.pdf

- Because the final key questions were comparative in nature, studies to address the efficacy and effectiveness of facet neurotomy were limited to comparative studies, as non-comparative studies would not answer the questions that the report was designed to address. For example, Key Question 2, which asks about the comparative efficacy and effectiveness of facet neurotomy, states: "With different regions of the spine considered separately, 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.)?"

Because a number of controlled studies (in this case, RCTs, as only one nonrandomized controlled study was identified) trials had been published, it was not necessary to review evidence from lower quality studies such as case series in order to address Key Question 2. Case series report on a group of patients who have been treated in a similar manner and don't include a concurrent control group. While there are advantages to using case series (including evaluating rare outcomes, safety data, and new treatments), case series lack a concurrent comparison or control group. As a result, the effect of the treatment of interest can't be compared to that of another treatment, and without a comparator, a treatment can't be directly attributed to the treatment administered as the outcomes could be due to some unaccounted for patient characteristic.[1]

A section on study design was added to the Methods section of the final report (3.1.2) in order to address the reasons for excluding case series to answer Key Question 2.

Paul Dreyfuss, MD

Report Section	Reviewer's Comments	SRI Response
		For ease of reading, the summary points listed by Dr. Dreyfuss appear before each relevant in-depth comment.
General	***Summary point:*** Spectrum did not use the peer expert considerations as a framework to evaluate the literature.	In order to ensure experts in the field have the opportunity to provide clinical insight into how the review should be framed, the key questions and scope were published in August, 2013: http://www.hca.wa.gov/hta/documents/facet_final_questions_082913.pdf Upon receiving public comments, each comment was responded to. Modifications to the key questions and scope were made as appropriate: http://www.hca.wa.gov/hta/documents/facet_responses_key_questions_082913.pdf Spectrum worked with clinicians in the field early on in the review process to ensure the review was evaluated appropriately. The background considerations submitted are included in the report and are further discussed below.
	Summary point: Appropriate selection of patients for RF is via medial branch blocks and RF should ideally be performed with higher volume lesions parallel to the target nerve.	Please see below in response to the considerations submitted.
	Summary point: Spectrum did not appreciate inappropriate (invalid) from appropriate selection methods for RF or anatomically sound from non-anatomically (invalid) sound RF	Please see below in response to the considerations submitted.

Report Section	Reviewer's Comments	SRI Response
	techniques.	
	Related comments from Dr. Dreyfuss' peer review Spectrum Research requested that I submit expert background considerations in preparation of their report. The goal was to provide a clinical framework to better understand appropriate selection of patients for radiofrequency (RF) neurotomy and technical considerations in the clinical performance of Radiofrequency (RF) neurotomy. Furthermore, insights into how to clinically interpret the literature and avoid common pitfalls were discussed. Several key references to illustrate these points were provided to Spectrum Research.	Invited peer review comments are included in the report.
	However, despite my comments being published in the draft report and despite statutory requirements, they were not read, acknowledged nor used in any capacity in preparation of the draft report.	All comments were read, considered, published in the draft report (section 1.4).
	In light of such, my initial background comments will be repeated and expanded upon to provide a framework to better understand the technology in question and to highlight important deficiencies in the report generated by Spectrum Research.	These comments are pasted below and used to update the original submitted comments in section 1.4 of the final report unless otherwise noted.
	Key Concept: The ability of cervical and lumbar medial branch radiofrequency 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. (6)	Each of these points is discussed in the proceeding sections.

Report Section	Reviewer's Comments	SRI Response
	The literature, including randomized controlled trials, is replete with examples of both poor patient selection and invalid technical execution of the procedure.	
	However, there are key prospective trials that have used validated selection criteria to identify those with the target condition and have used anatomically correct validated radiofrequency neurotomy methods to achieve technical effectiveness of the procedure. It is these later trials that depict the value of the procedure. The former trials are best interpreted as the outcomes expected when less rigorous selection and treatment methods are employed. Indeed, authors of these flawed studies have acknowledged this fact.	Thank you. As discussed above, this section has been omitted from the final report as using case series to evaluate the efficacy and effectiveness of facet neurotomy is beyond the scope of the report. See below for responses to comments regarding studies for which references were provided. Without supporting references, it is difficult to respond.

Report Section	Reviewer's Comments	SRI Response
	Patient Selection: Dr. Shealy discovered medial branch radiofrequency neurotomy of the zygapophyseal (aka 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 were selected on the results of pain reduction following intra-articular (inside the joint) facet injections. These injections, however, have been shown to have poor anatomic target specificity and incur a higher rate of false positive results than medial branch blocks. (51) 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. (2,19,28) 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	Thank you. The issue of type of diagnostic block used is discussed in point 1, above.

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	neurotomy. Medial branch anesthetic injections, aka 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. (34,39,40,41,42,51) 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 (34), 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	Thank you. The issue of percentage of pain relief as part of the patient selection process is discussed in point 2, above.

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	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 neurotomy 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.	Thank you. As stated in point 4, above: for reasons stated above, the highest quality evidence available at the time of this report did not support these claims to such a level that would suggest study inclusion should be limited based on type of diagnostic block.
	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 been an evolution in the understanding of how to best perform medial branch radiofrequency neurotomy. This is due to an improved understanding of fluoroscopic (x-ray) anatomy as it relates to location of the target nerves, the electrothermal physics of the radiofrequency lesion created with	Thank you . The issue of technical aspects of the neurotomy procedure is discussed in point 5, above.

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	different RF needles, trajectory angles to maximize incorporating the target nerve within the oblate spheroid isotherm, and parameters used to generate the heat lesion. (9) 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. (24,26,31) 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.	

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	Evaluation of the Literature: It should be apparent that not all medial branch radiofrequency neurotomy 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.	Thank you. Because of the methodological heterogeneity across included studies, no outcomes data were pooled. The methods section of the draft report states: "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." However, in order to address these concerns tables have been added to Key Question 4 in which the primary outcomes from comparative studies from KQ2 are reported from only those studies in which patients were selected on the basis of ≥50% pain relief following at least one MBB. Information as to the type of, number of, and pain relief following diagnostic block has also been added to the summary evidence tables in the Executive Summary as well as to the data tables throughout KQ2 such that this information is readily available to readers.
	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,	Thank you. These points have been addressed above.

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	improper needle size, and an inadequate lesion volume. The RFN technique used in some RCTs cited by Spectrum Research was 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.	
	Many trials, including randomized controlled trials, have used such improper methods largely as a means to determine the efficacy of community standards at the time. (22,25,32,54,57,60) As noted above, such studies only hold value to demonstrate what results are to be expected when patients are not appropriately selected and the radiofrequency technique is not appropriately performed.	The studies listed (i.e., Gallagher (ref. 22), Haspeslagh (ref. 25), Leclaire (ref. 32), and van Wijk (ref. 60) were re-reviewed. If the point is that trials were conducted with improper methods in order to determine the efficacy of the community standard at the time, no statements could be found in these trials to this effect. Rather, they sought to determine efficacy of the procedure itself. In the case of van Wijk, the authors did state that their methods reflected "common clinical practice as much as possible," and their objective was to "determine the efficacy of radiofrequency facet joint denervation as it is routinely performed."[2]
	It is widely accepted that evidence based medicine is not restricted to RCTs or comparison trials. As Dr. David Sackett, the father of evidence-based medicine, stated, "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." This definition has since been adopted by major organizations, including the Cochrane Collaboration and the Centre for Evidence Based Medicine. Sackett went on to state, "Evidence based medicine is not restricted to randomised trials and meta-analyses. It	Thank you. Using case series to evaluate the efficacy and effectiveness of facet neurotomy is beyond the scope of the report. This issue is discussed in detail in point 7 above. As such, this section has been omitted from the final report. Sackett also states (in the same article), "Because the randomised trial, and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the 'gold standard' for judging whether a treatment does more good than harm. However,

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	involves tracking down the best external evidence with which to answer our clinical questions." (49)	some questions about therapy do not require randomised trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomised trial has been carried out for our patient's predicament, we must follow the trail to the next best external evidence and work from there."
	As such, an evidence review of facet joint RF neurotomy should include valid prospective RF neurotomy trials in addition to RCTs or comparison trials, especially given the methodological flaws outlined above. Indeed, in the case of RF neurotomy, one could argue that the well performed prospective trials provide better external evidence than the poorly performed RCTs. (1,8,17,20,23,24,23,43,44,45,48,50) The inclusion of prospective trials, in addition to randomized controlled trials and comparison trials, has been accepted in other evidence reports used by the HTCC to make informed decisions.	Thank you. Using case series to evaluate the efficacy and effectiveness of facet neurotomy is beyond the scope of the report. This issue is discussed in detail in point 7 above. The key questions, which ask comparative questions, were published prior to initiating the report, and public input was sought and received regarding these key questions.

Report Section	Reviewer's Comments	SRI Response
	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%." (21) Accordingly, in evaluating the RF neurotomy literature, the percentage of patients obtaining a minimum of 30% reduction in pain (or a VAS decrement of $\geq$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. (21) IMMPACT recommended that mean data reporting not be used as a sole or primary indicator of success. (21) When	Note that the IMMPACT recommendations for interpreting categorical outcomes have been discussed in both the final and draft reports (Section 1.3.2). While it would be ideal if all studies reported outcomes in terms of the percentage of patients who achieved a benchmark indicator of treatment success, this was not the case in the majority of studies identified.

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	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.	
	Although secondary outcome measures are reported in various studies, there is inconsistency between trials as to which tools are reported. For ease of rapid comparison between studies and to prevent an even longer peer review response, in my comments on the referenced trials I will largely discuss only the primary indication of success of RF neurotomy, which is pain reduction.	The primary outcomes of interest, determined *a priori*, were clinically meaningful pain relief and functional improvement. Secondary outcomes included health-related quality of life (including psychological status), return to work, patient satisfaction, and opioid use.
	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.	Key Question 2b evaluates 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. See section 4.2.10.

Report Section	Reviewer's Comments	SRI Response
	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 a meaningful lesion. This method of energy delivery is not the conventional method of thermal medial branch radiofrequency neurotomy under primary assessment by the HCA. In regards to cervical radiofrequency neurotomy, there are unique anatomical and procedural considerations when targeting the C2-3 facet joint vs. other cervical levels. Accordingly, studies that have largely or only assessed C2-3 facet neurotomy (third occipital neurotomy) (1,24,44) should be evaluated separately from those studies in which C3-4 to C6-7 facet neurotomy was performed.	Key Question 2a evaluates the evidence of the short- and long-term comparative efficacy of conventional versus pulsed radiofrequency neurotomy. See section 4.2.9. Regarding studies that compared facet neurotomy to sham neurotomy, one RCT (Lord 1996) was identified 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). See section 4.2.3. Regarding studies that compared facet neurotomy to spinal injections, one RCT (Haspeslagh 2006) was identified in which patients with chronic cervicogenic headache of two or more years duration were randomized to receive RF facet joint denervation *at cervical levels C3 to C6* (n = 15) or anesthetic injection of the greater occipital nerve (n = 15). This study was not evaluated with any other studies. The italicized text has been added in the final report for clarity. See section 4.2.3.
Executive summary, introduction, page 1	In the draft report on page 15 it states, *"Diagnostic medial branch blocks or intra-articular injections involve injection of local anesthetic into the facet joint(s) that are believed to be the source of the pain."*	Thank you. This information has been corrected in the final version of the report.

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	Comment: This is not accurate. Intra-articular injections involve placing anesthetic into the facet joint itself, but medial branch blocks are performed over/around the medial branch nerves, not within the facet joints.	
Executive summary, background	On page 16 it states, *"In the sham surgery, a radiofrequency needle is inserted into the joint but the electric current is not turned on".* Comment: This is inaccurate. The radiofrequency needle is never inserted "into" the facet joint for any reason. For sham treatment, the needle is placed on/over the medial branch nerve, which lies outside the facet joint, but the current is not turned on. For active treatment, the needle is placed on/over the medial branch nerve, which lies outside the facet joint, and the current is turned on.	Thank you. This information has been corrected in the final version of the report.
Executive summary, background	On page 16 it states, *"Facet injections and medial branch blocks include injecting a corticosteroid plus local anesthetic into the facet joint and medial branch nerves, respectively."* Comment- this is inaccurate. No corticosteroid is injected for a diagnostic medial branch block procedure. Medial branch blocks are not performed via injection "into" the target nerves but rather around the target nerves.	Thank you. This information has been corrected in the final version of the report.

Report Section	Reviewer's Comments	SRI Response
Executive summary, background	Within the background information it is stated that: *"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* *• 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:* *• Prior radiofrequency treatment* *• Previous back surgeries"* Comment: It would be more appropriate to list indications for facet neurotomy as: • Adults with chronic back or neck pain of at least 3 months duration who have moderate to severe pain that limits function and for which the pain has not responded to alternate non-surgical care which may include, but is not limited to, physical or manual therapy, medications, rest and injections. • Positive response to diagnostic medial	Thank you. These indications from the draft report were pulled from the most common inclusion criteria across the comparative studies included in this HTA. In the final report, the indications list has been modified to note the definition of a positive block, while the contraindications list has been modified so that previous radiofrequency treatment and previous back surgeries are no longer listed.

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	branch blocks (≥ 80% relief of index pain). • Prior RF neurotomy and prior spinal surgery are not contraindications to RF neurotomy. ◦ It is important to understand that the medial branches regenerate after time, and the pain will typically return. At this point, repeat RFN is appropriate and efficacious ◦ Spinal surgery does not preclude the facet joints from becoming pain generators. Indeed, diagnostic blocks and medial branch neurotomy at levels not involved in a fusion have potential for positive response. Additionally, medial branch blocks and RF neurotomy can be performed at the levels of prior decompression surgery without fusion as well.	
Executive summary	In the results section of the executive summary the following is the summary statement regarding using quality evidence: *"The following summaries of evidence for primary findings have been based on the highest quality of studies available. RCTs and comparative nonrandomized controlled trials are the focus for this summary. Additional information on lower quality studies is available in the report."* Additionally it is stated, *"Eligible studies evaluated facet neurotomy utilizing a randomized or cohort study design." Case*	Thank you. This issue has been discussed in point 7, above.

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	series were only considered for Key Question 2b (effectiveness of repeat neurotomy) and Key Question 3 (safety)." Comment: RCT/comparative trials provide a higher level of evidence, but other types of prospective trials should not be excluded in the true practice of evidence based medicine and are of value. (49) The 'Lower quality studies' cited by Spectrum were not available in the report, however, they will be referenced/discussed below.	
	Excerpts from the report will continue to appear in italics with my comments to follow.	
Executive 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)* *No evidence for any of the following: Diagnostic blocks verses physical examination on the lumbar spine* Comments: There is only one study that made such a comparison. This prospective study compared physical examination to a single diagnostic medial	Thank you. Cohen et al. (2010)[3] is the only study that meets the inclusion criteria for this key question. While the report concluded that diagnosis via MBB versus clinical exam yielded similar results in terms of the percentage of patients who had "success" (defined as a composite of ≥50% pain relief and a positive global perceived effect) at one and three months, the overall quality of this evidence was determined to be "Low". An overall quality of evidence rating of "Low" indicates that there is "low confidence that the evidence reflects the true effect; further research is likely to change the confidence in the estimate of effect and likely to change the estimate."

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	branch block (mbb). (13) 51 pts were selected for RF on clinical grounds alone and 50 underwent single mbbs (≥50% relief) of which 19 underwent RF. Success was defined at ≥50% relief at 3 months post RF. In those without diagnostic blocks there was a 33% success and in those with a single medial branch block success was 39% with the difference not statistically significant. This singular study would suggest there is no added value to the use of a single medial branch blocks with ≥50% relief over selecting patients on clinical grounds only. However, realize the outcomes in this study are marginal as both selection techniques are limited by inclusion of a high percentage of patients without the index condition owing to the high false positive rate of physical examination only or single medial branch blocks vs. more specific and appropriate use of controlled (dual) medial branch blocks in which reported outcomes are substantially better as discussed below.	
Executive summary	*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* Comment: There are no trials that have compared physical examination to diagnostic blocks in the thoracic or cervical spine or diagnostic block versus radiological examination in the cervical, thoracic or lumbar spine.	Thank you.

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Executive summary	*KQ1b: Type of diagnostic block (i.e., medial branch block versus intra-articular injection) for patient selection:* *No evidence for any of the following: Other diagnostic block comparators in the lumbar spine or cervical or thoracic spine*. Comment: There is only one study that made such a comparison. (4) In the Birkenmaier study patients were selected for cryodenervation based on a positive response to either a diagnostic medial branch block or peri-capsular block. Cryodenervation is not radiofrequency neurotomy. Cryodenervation is a procedure in which compressed gas is circulated through a cannula, lowering the temperature of the cannula tip to near -90C. This very cold needle tip is placed on or near a target nerve and the nerve is frozen, destroying part but not all of the nerve. This procedure is expected to last 3-6 months. Post cryodenervation as measured at 6 weeks and three months the difference in mean improvement of pain between groups was significant favoring medial branch blocks, but this difference was lost at 6 months. At 6 months, the effects of cryodenervation would be expected to largely be lost based upon its mechanism of action. This study suggests there is value of a single medial branch block over pericapsular blocks in the selection of patients for cryodenervation only.	Thank you. Birkenmaier et al. (2007)[4] is the only study that meets the inclusion criteria for this key question. Cryodenervation is not radiofrequency neurotomy, but it is a form of "facet neurotomy", and meets the *a priori* inclusion criteria as an intervention of interest.
Executive summary	*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*	Thank you. With regards to Key Question 1c, one study met the inclusion criteria (Cohen

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	anesthetic versus saline: *No evidence for any of the following: Single versus controlled diagnostic blocks in the lumbar spine or the thoracic or cervical spine* *KQ1d: Degree of pain reduction from diagnostic block (i.e., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%): Note- as not stated otherwise assumes in relation to either single or controlled blocks/* *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.* Comment: KQ1c and KQ1d are best responded to together as there is cross over between studies in relation to these questions: Cohen performed a retrospective audit comparing the selection criteria of 50% vs. 80% relief criteria following single medial branch blocks vs. success post-RF defined as ≥50% relief at 6 months. The RF technique was reasonably anatomically sound. Of 145 patients selected using ≥50% relief (50-79%) (145 pts) 52% had success. Of 117 patients selected using ≥80% relief (80-100%) 56% had success. The difference was not significant. (11) Cohen performed a second prospective trial to address if there was a percentage of relief cut-off following single medial	2010)[3] (your reference 13), and evaluated different diagnostic paradigms to select patients to undergo RF neurotomy. 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. The conclusions may be found in the report. In particular, success was defined as ≥50% pain relief and a positive global perceived effect. While "those who actually received RF there was a 33% success rate on those without diagnostic blocks vs. 39% in those selected via a single medial branch block vs. 64% in those selected with controlled medial branch blocks", these differences were not statistically significant (see Section 4.1.4 of the report as well as the corresponding evidence table). With regards to Key Question 1d, one prospective[5] (your reference 12) and three retrospective cohort studies[6-8] met the inclusion criteria, all of which compared facet neurotomy outcomes in patients

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	branch blocks in which there is a greater success post RF neurotomy. 61 patients were selected for RF following single mbbs. The RF technique was reasonably anatomically sound. Successful RF outcome (≥50% reduction in pain) at 3 months was correlated with percentage of relief over 50% following single mbbs . There was no statistically significant difference between the percentage pain relief obtained from single diagnostic blocks among those patients who had a successful RF denervation, and those individuals who failed RF treatment. (12) In a retrospective analysis of 211 consecutive patients Derby evaluated cut-off values that corrected with improved RF outcomes in those following selection for RF with both single and dual medial branch blocks. (15) Those with at least 50% relief proceeded to RF with an anatomically sound lesioning technique. Success was defined at ≥50% relief of pain at 6 months with ≥50% improvement in activity level and no other physician visits required. In the single medial branch block (mbb) group, 80% cutoff predicted favorable outcome in two criteria: patient satisfaction and improvement in activity level. Using the 80% cutoff value, 58% (11/19) of patients reported 50% or greater pain relief for 6 months or longer with an average of 10.7 months. At the ≥70% cutoff value in a double-block group, 91% (10/11) of patients reported 50% or greater pain relief for ≥6 months of duration, with an average of 9.8 months. Of interest, no patient in the dual mbb group reporting less than 70% pain relief following mbbs reported satisfactory pain relief following RF	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[5, 7, 8] 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[6-8] (or in Cohen 2013[5], were satisfied with the relief achieved) in the hours following the block were selected for RF denervation. Results were separated into two diagnostic groups based on the pain relief thresholds reported across studies: • 50-79% pain relief required following diagnostic block to proceed to RF neurotomy (for Cohen 2013, the cutoff is 50-83%) • ≥80% pain relief required following diagnostic 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. More specific details on these conclusions may be found in the report.

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	neurotomy. Eighteen of 38 patients (47.4%) in the single-block group reported ≥6 month pain relief with a mean duration of relief of 9.9 months. In the double-block group, 10 of 13 patients (76.9%) reported ≥6 months pain relief with the mean duration of relief of 9.8 months. The difference was significant. Derby concluded dual (comparative) diagnostic medial branch blocks best predict medial branch neurotomy outcome compared with a single block due to the high false-positive rate of a single MBB. (15) In a second retrospective cohort study by Derby using anatomically sound RF lesioning techniques it was found that patients who were required to achieve a higher pain threshold (≥70%) following dual medial branch blocks were significantly more likely to have ≥50% relief following RF neurotomy than those who had lower levels of pain relief (50-79%) following dual medial branch blocks. (16) Additionally, in this study 11 of 12 patients (91.7%) in the double-block group reported ≥3 months of ≥50% pain relief which was a statistically higher percentage than the single-block group where 52.8% (19 out of 36 patients) had ≥50% pain relief. (16) Cohen performed a prospective study of 151 selected for RF on clinical grounds alone, single medial branch blocks with ≥50% relief and controlled mbbs with >50% relief. A reasonable anatomically sound RF technique was used. Success was defined at ≥50% relief assessed at 3 months post RF. In those who actually	

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	received RF there was a 33% success rate on those without diagnostic blocks vs. 39% in those selected via a single medial branch block vs. 64% in those selected with controlled medial branch blocks. (13) Summary The studies are conflicting regarding outcomes in those with >80% relief from single medial branch blocks vs. 50% relief. However, the evidence is consistent in these studies in that controlled medial branch blocks are the most predictive of future success from RF neurotomy over other selection methods. Collectively, these studies show that in those selected using controlled medial branch blocks a higher percentage of patients are expected to have a successful RF (≥50% relief occurred in 64-91% at 3 months, 77% at 6 months) vs. those selected with single medial branch blocks (≥50% relief in 39-52% at 3 months, 47% at 6 months) or those selected on clinical grounds only (≥50% relief in 33% at 3 months). If all prospective RF studies that report percentage of patients with at least 50% relief of pain are assessed in regards to selection criteria, success and duration of success an interesting trend is readily apparent. The worst results are seen in those selected on clinical grounds alone (>50% relief at 3 months in 33%). (13) Equally poor results are seen in those selected with single intraarticular blocks (0-33% with >50% relief). (32,60) In the trials in which patients were selected with single uncontrolled MBBs	

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	(>50% relief): 39% had ≥50% relief at 3 months (13) and 20-55% of patients had ≥50% relief at 12 months post RFN. (8,56,58) In the trials selecting patients with controlled medial branch blocks and reasonably sound or sound RF lesioning techniques, 57-60% were able to obtain ≥50% relief of pain at 6 months, 59% of pts had ≥75% relief of pain at 6 months, 42% had 100% relief of pain at 6 months, and 43% were able to obtain >50% relief of pain at 1 year. (20, 23, 53) In the trials selecting patients with controlled medial branch blocks (≥80% relief) and ideal RF lesioning techniques 53-60% of patients were able to obtain 80-100% relief of pain at 1 year. (18,45)	
Executive summary	*No evidence for any of the following: Thoracic or cervical spine* Comment: Although there were no studies that looked at the value of selecting patients for RF on clinical grounds vs. single medial branch blocks vs. dual medial branch blocks and at various cut-off values of pain relief from the diagnostic blocks there is information available across prospective studies that reported ≥50% or other categories of pain relief following RF in the cervical spine. In those selected on clinical grounds only for RF, results are no better than sham treatments. (25,54,57) Using 50-80% relief as the cut-off following dual medial branch blocks and	Thank you.

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	reasonably anatomically sound or anatomically sound RF lesioning techniques 62-68% obtain ≥75% pain relief at 6 months (52, 53) and 74% obtain ≥50% pain relief at 12 month follow-up. (50) When maximally specific selection of patients is undertaken (i.e. minimum of dual diagnostic blocks with 80-100% relief of pain) with ideal anatomically sound RF lesioning techniques, 54-86% of patients can be rendered pain free for a minimum of 10 months. (1,24,37,44)	
Executive summary	*KQ1e: Unilateral versus bilateral diagnostic block* *No studies were identified which met our inclusion criteria*. Comment: Agree, no studies exist. There is no justification for bilateral medial branch blocks or neurotomy when there is unilateral pain. Bilateral procedures are only appropriate in the context of bilateral pain.	Thank you.
Executive summary	*KQ1f: Single- versus multi-level diagnostic block* *No studies were identified which met our inclusion criteria.* Comment: Agree, no studies exist. Realize that each facet joint is innervated by two medial branch nerves. Thus by definition, although one joint/level may be targeted two nerves are targeted. Clinically, more than one level of facet pain can exist for which investigation and treatment would be indicated.	Thank you.
Executive	*Key Question 2:*	

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summary	*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. 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.* *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* Comment: The review by Spectrum has concluded that there is no efficacy or effectiveness of lumbar medial branch neurotomy. Their conclusion is invalid and erroneous because this publication lacked discrimination on two very important counts.	The effect of each outcome was evaluated separately, and in some cases the evidence suggested that the outcomes favored RF neurotomy over sham neurotomy, and in other cases the evidence suggested that the results did not differ between treatment groups. The summary evidence table provides

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		details and overall quality of evidence ratings for each conclusion (which were "Low" in all cases except one, which was "Moderate"). In the Executive Summary it was concluded that "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." There was no evidence regarding the effectiveness of facet neurotomy compared with sham neurotomy, as no non-randomized comparative studies were identified.
	First, they did not distinguish between studies that used flawed or invalid techniques and those that used correct technique. They admitted two RCTs that used the discredited Shealy RF technique (22) or a modification of it (17,32) and a third RCT (60) whose technique was ill-defined and as depicted in their paper would fail to reliably lesion the target nerves.	Thank you. The issue of neurotomy technique is addressed in point 5 above.
	A second factor confounding Spectrum's conclusions involves the indications used for RF neurotomy. A treatment is not likely to work if the patients treated do not have the condition for which the treatment was designed. If less than stringent criteria are used for diagnosis, patients with false-positive responses to diagnostic tests are unlikely to respond well, if at all, to treatment. Consequently, studies that selected their patients by less than optimal criteria (intra-articular or peri-articular blocks) will have less than impressive success rates, even if they used a correct RF	This report was designed to first evaluate whether any aspects of patient selection - including type of diagnostic block used, differentially affected outcomes following facet neurotomy- as part of Key Question 1. The comments regarding diagnostic blocks and neurotomy technique are discussed points 1-5 above. However, in order to address these concerns tables have been added to Key Question 4 in which the primary outcomes from comparative studies from KQ2 are reported from only those studies in which patients were selected on the basis of ≥50% pain relief following at least one

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	technique. The same three RCTs that were admitted by Spectrum despite the use of non-anatomically sound RF lesioning techniques also used invalid selection criteria (intra-articular blocks) to determine candidates for the procedure. The effects of poor indications and incorrect procedural technique on success rates are clear when individual studies are examined in detail but such were not appreciated by Spectrum. A more discriminating review found that, if only those studies (RCTS and prospective trials) are reviewed that used reasonable technique, no study has found evidence against the effectiveness of lumbar medial branch neurotomy, and all provided various grades of evidence in support of the procedure. (6) The details of such will be reviewed. <u>Invalid RCTs that were admitted as negative evidence for lumbar medial branch neurotomy:</u> LeClaire enrolled 70 pts with >3 mos LBP with "significant relief for at least 24 hrs during the week" after a single intra-articular facet joint injection. (32) 36 subjects were randomized to a modified "Shealy RF" without further technical details and 34 received placebo RF. Baseline, 4 weeks and 12 weeks post treatment VAS, Roland-Morris, Oswestry and were performed. At 12 weeks in the active group the VAS was 0.5% worse and 7% better in the placebo group. Leclaire stated in a subsequent editorial that "The present study's negative results exemplify the need for: 1) utilization of controlled medial branch	MBB. Information as to the type of, number of, and pain relief following diagnostic block has also been added to the summary evidence tables in the Executive Summary as well as to the data tables throughout KQ2 such that this information is readily available to readers.

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	blocks to select those that have pain emanating from the zygapophysial joints, and 2) utilization of meticulous technique to adequately coagulate the targeted nerves." (17) van Wijk selected subjects via a single 2 level intra-articuar facet injections if there was ≥50% relief 30 minutes post injection. (60) 81 subjects were enrolled for randomization. 40 received active RF and 41 sham RF in a double blind fashion. A non-anatomically sound RF lesioning technique was used. Follow-up was at 3, 6, 9, and 12 months. Outcome tools included VAS, Global perceived effect, analgesic intake, physical activities scale and SF-36. 33% of the active group had a ≥50% pain reduction vs. 34% in sham RF which the difference non-significant. van Wijk produced a subsequent editorial where it was noted "as stated in our article, we designed the study to evaluate if common practice in our community, at that time, had efficacy. In our study, less rigorous selection of patients was undertaken to more closely represent community practice." (59) By definition this study was not defined as an efficacy study under ideal conditions. Van wijk also stated "future research should be directed toward improvement of a more ideal selection of patients for RF using medial branch blocks, more robust RF lesion techniques, and use of psychological profiling of patients to select more ideal candidates for treatment and that "we need to be more particular as to when and how RF-facet denervation is performed, but not remove it as an option. (59)	

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	In the study by Gallagher patients were selected based upon a "good" anesthetic response to an intra and peri-articular facet joint injection. (22) Patients were randomized into active and sham RF groups. There were 18 subjects in the active group and 12 in the placebo group. RF was performed by the Shealy method. Patients were assessed at 1 and 6 months post treatment using the VAS and McGill pain questionnaire. Mean VAS in the active RF group was 58 pre-RF and 44 six months post-RF. Mean VAS was 68 pre-sham RF and 70 six months post-sham RF. The difference between groups was significant. Categorical pain relief data was not reported. The mean McGill outcomes also showed significant difference between groups at 6 months favoring the active group. Although the results were significant, the inclusion criteria and RF technique utilized were invalid. <u>Valid RCTs showing evidence for the efficacy of lumbar medial branch neurotomy:</u> VanKleef: VanKleef selected 31 subjects with chronic low back pain on the basis of <u>></u>50% relief from single medial branch blocks. (58) 15 were randomized to active RF and 16 to sham L3-5 medial branch RF neurotomy. Primary outcome measure were VAS and Oswestry. The mean baseline to 8 week f/u pain reduction was 46% in the active and 8% in the sham group which was statistically significant. Global perceived effect and Oswestry showed significant	

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	improvement in the active vs. sham group. 46% of the active and 12% of the sham pts obtained ≥50% pain reduction at 1 year which was also significant. (58) As single medial branch blocks were performed many would have been included on the basis of false-positive responses; and therefore, the success rate of treatment would have been compromised. The RF lesioning technique was fairly anatomically sound as the RF needles were placed more less than ideally parallel to the target nerves. Therefore, duration of relief would be expected to be compromised. All of these expectations emerged in the results as only a relatively small proportion of patients had successful and enduring relief. Nonetheless, the success rate in those patients who had active treatment was significantly greater statistically than the success rate in those who underwent sham treatment showing the effects of the treatment cannot be attributed to a placebo effect. (58) Nath: A later placebo-controlled trial carefully selected patients by using comparative diagnostic medial branch blocks with ≥80% relief of their index (not total body) pain as assessed by a 6 hour self reported pain diary. Patients had to have longer relief with the bupivicaine vs. lidocaine medial branch blocks . (47) 40 subjects were selected; 20 in the active arm and 20 in sham RF arm. Anatomically sound RF lesioning techniques were used. Outcome were assessed at 6 months. Primary outcome measures	

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	were global perception of improvement and visual analogue scale for generalized pain, back and leg pain. Secondary outcome tools include range of motion, analgesic use and quality of life variables. In terms of the patients' own global assessment, the active treatment group improved by 1.1 Units whereas the placebo group improved by only 0.3 Units. The difference in improvement between groups was 0.8 U and was statistically significant. Generalized pain was reduced in the active group by 1.9 U on an 11-point VAS scale, but by only 0.4 Units in the placebo group. The difference in reduction between groups was 1.55 and was statistically significant. Back pain was reduced in the active treatment group by 2.1 Units, and referred pain to the leg was reduced by 1.6. In the placebo group, the corresponding figures were 0.7 Units and 0.13. The differences in reduction between groups were statistically significant . Mean back pain improved from 5.98 to 3.88 (35% decrease) in the active group vs.4.38 to 3.68 (16%)in the sham group. Secondary measurements (movement, tenderness, analgesic use, quality of life) all showed statistically significant improvement in the active group. However, this study was conducted in patients who had other chronic pain problems, such as radicular pain. Therefore, a success rate for the elimination of pain could not be determined and the magnitude of effect	

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	from the RF was lessened in this challenging patient population. (47) Tekin: A comparison study sought to compare the efficacy of thermal radiofrequency neurotomy with that of pulsed radiofrequency. It included a control group receiving sham neurotomy in which no lesion was generated. (55) The study enrolled patients who obtained at least 50% relief of pain following single diagnostic medial branch blocks. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. There were 20 patients in the control group, 20 in the pulsed RF group and 20 in the continuous thermal RF group. Anatomically sound RF lesioning techniques were used. For the relief of pain, improvement in disability, and reduction in use of analgesics, thermal radiofrequency was significantly more effective than sham treatment immediately after treatment, at six months, and at one year. At 1 year f/u the continuous RF group had a statistically significant 65% mean VAS reduction (6.5 to 2.3) vs. the placebos group's 43% (6.8 to 4.3) VAS reduction. At 1 year f/u the mean Oswestry disability index improved 29% in the continuous group vs. 16% in the sham group. At 1 yr , 95% of the control vs. 40% of the thermal RF (active) groups were using analgesics. (55) Although showing superiority of active treatment over sham treatment, this	

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	study did not report data from which success rates for reduction of pain could be calculated. However, 65% of patients treated with active medial branch neurotomy reported excellent satisfaction with treatment, compared with 20% of those who underwent sham treatment. (55) Summary: Collectively, these three controlled studies provide sound evidence that medial branch thermal radiofrequency neurotomy has effects greater than those of placebo. Therefore, the outcomes of medial branch neurotomy cannot be dismissed as those of a placebo effect. Those controlled studies, however, were not designed to determine the long-term success rate of medial branch neurotomy, but other prospective studies were so designed.	
	<u>Prospective Non-Randomized Trials</u>: The effectiveness of lumbar medial branch radiofrequency neurotomy has been demonstrated by eight prospective non-randomized trials. All such trials were wrongfully excluded from the draft report by Spectrum. Such trials provide valuable insight into the effectiveness of lumbar RF. The original benchmarking prospective study used comparative local anesthetic blocks to select patients with chronic low back pain. To be eligible for treatment, patients had to report at least 80% relief of their back pain following controlled medial branch blocks. The study used ideal anatomically sound RF lesioning	All the studies cited are case series in which all participants received facet neurotomy. As discussed above (see point 7 for details), case series were excluded from Key Question 2.

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	techniques. 15 highly selected patients were enrolled. There was a 76% mean decrease in pain at 12 months. It found that 60% of patients maintained at least 80% relief of their pain at 12 months follow-up, and 80% of patients maintained at least 60% relief at 1 year. Relief of pain was associated with reduction of disability. There was a 90% technical success of the procedure as evidenced by normal pre-RF segmental multifidus EMG and a post RF segmental multifidus EMG showing denervation at the targeted RF levels. (17) Subsequent Prospective Trials Using Single Medial Branch Blocks: Burnham selected patients on the basis of at least 50% relief of pain following both an intra-articular block and a single medial branch block. Reasonably anatomically sound lesioning techniques were used. 39% (25 – 53%) of 44 patients achieved at least 50% relief of pain at six months after treatment, accompanied by significant improvements in disability, and reduced analgesic requirements. (8) Tome´-Bermejo, selected 86 patients by ≥50% relief of pain following a single medial branch block. A reasoably sound RF lesioning technique was used. 66% had ≥50% relief of pain at 6 months and 50% had ≥50% pain relief at 1 yr. (56) Subsequent Prospective Trials Using Controlled Medial Branch Blocks: Gofeld selected patients on the basis of at least 70% relief of pain following comparative medial branch blocks. (23) During a 10-year period, 209 patients	

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	were treated by lumbar medial branch neurotomy, and 174 were reviewed. Anatomically sound lesioning techniques were used. At six months after treatment, 35% (29 – 41%) of patients had at least 50% relief of pain, and a further 22% (16 – 28%) had 80% relief of pain for a total of 57% achieving significant relief. At one year follow-up 43% of patients had ≥50% relief. The proportions of patients with enduring relief decreased between six months and two years after treatment, but the median duration of relief was 12 months. (23) Macvicar enrolled patients only if they had complete relief of pain following controlled diagnostic blocks. (45) A total of 106 consecutive patients were recruited in two neighboring practices. Ideal anatomically sound lesioning techniques were used. Repeat treatment was allowed if pain recurred. The study reported the success rates achieved and the duration of success over a five-year period. Success was defined as complete relief of pain for at least six months, accompanied by restoration of all desired activities of daily living, and no further need for health care for the pain for which patients were treated. (45) The two practices achieved success rates of 58% (44-72%) and 53% (40-66%) respectively, i.e. complete relief of pain, restoration of activities, and elimination of other health care. Following the first radiofrequency neurotomy, the median (interquartile range) duration of relief was 15 (10 – 28) months in Practice A, and 15 (10 – 29) months in Practice B.	

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	When repeat treatments were assessed there was a median duration of relief of 13 months per treatment. (45) Roy selected 34 patients who had ≥80% reduction of pain following controlled blocks. A reasonably anatomically sound RF lesioning technique was used. Using the numeric pain rating scale, there was a mean reduction in pain of 62% at 6 months, and 60% at one 1 year. (48) Speldewinde selected 151 patients with controlled medial branch blocks with 80% relief of index pain. Anatomically sound RF lesioning techniques were used. At 6-36 months 59% of pts had ≥75% relief of pain and 42% had 100% relief of pain. (53) Dobrogowski selected 45 consecutive patients by "significant pain relief after two controlled diagnostic blocks". A fair anatomically sound RF lesioning technique was used. 60% of patients had ≥50% relief of pain at 6 months. Percentage of pts with >75% or 100% relief not reported. (20) Summary: In the trials selecting patients with controlled medial branch blocks and reasonably sound or sound RF lesioning techniques 57-60% were able to obtain ≥50% relief of pain at 6 months, 59% of pts had ≥75% relief of pain at 6 months, 42% had 100% relief of pain at 6 months, and 43% were able to obtain >50% relief of pain at 1 year. (20,23, 53) In the trials selecting patients with controlled medial branch blocks (80%	

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	relief) and ideal RF lesioning techniques 53-60% of patients were able to obtain 80-100% relief of pain at 1 year. (18,45) All studies using appropriate selection of patients (controlled medial branch blocks) and appropriate lesioning techniques have consistently shown positive benefits. Where the data differs is with respect to precise selection criteria, RF technique and definitions of success. No other non-surgical treatment in the lumbar spine can rival the degree and duration of relief obtained from lumbar medial branch radiofrequency neurotomy for the treatment of chronic lumbar facet pain.	
	RF Neurotomy versus Sham Neurotomy: Efficacy in the cervical spine *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* Comment: Efficacy: A randomized, double-blind, placebo-controlled trial was conducted on 24 patients, who had been diagnosed as having cervical zygapophysial joint pain on the basis of placebo-controlled diagnostic medial branch blocks. (38) The criterion for eligibility was complete relief of pain after active blocks with each of two different local anesthetic agents (lidocaine 2%, and bupivacaine	The conclusion for the efficacy of RF neurotomy versus sham neurotomy in the cervical spine was as follows (taken from page 8 in draft report and from the summary evidence table on page): One small RCT (Lord 1996)[9] (CoE II) met the inclusion criteria. 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) (N = 24). The overall quality of this evidence was "Insufficient" based on serious risk of bias (the study did not meet two or more important criteria of a good quality RCT (see Appendix C for details) and serious risk of imprecision (relatively small sample size, wide confidence intervals). No studies were identified which met the inclusion criteria to evaluate the effectiveness of neurotomy versus sham neurotomy in the cervical spine, or the

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	0.5%), and no relief when normal saline was used. Twelve patients were allocated to undergo genuine medial branch radiofrequency neurotomy. Anatomically sound lesioning techniques were used. Twelve were allocated to undergo exactly the same procedure, for exactly the same duration (three hours), except that no current was delivered to the electrode. The criteria for a successful outcome were complete relief of pain, associated with restoration of activities of daily living, and no need for continuing health care for neck pain. The results showed unequivocally that the therapeutic effect of radiofrequency neurotomy was not a placebo. In the control group, the median time for recurrence of pain was eight days. In the index group the median duration of relief was 263 days. At 6.5 months 8% of the controls and 58% of the active treatment patients had a successful outcome as defined above. These findings were significant. Although the sample sizes in this study were small and have been criticized as limiting the value of this study, the difference in outcome was so great that the study had 100% power to exclude a placebo effect. (38) There are no other RCTs for cervical facet pain except 3 invalid trials (due to both patient selection and RF technique) in those with cervicogenic headache. (25,54,57) These will be discussed under evidence for RF neurotomy for cervicogenic headache and specifically RF for C2-3 facet pain.	efficacy or effectiveness of other types of neurotomy compared with sham neurotomy in the cervical spine

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	Effectiveness: The effectiveness of cervical medial branch radiofrequency neurotomy has been demonstrated by seven prospective non-randomized trials. All trials were wrongly excluded from the draft report by Spectrum's. Such trials provide valuable insight into the effectiveness of cervical RF. The first was a long-term observational study of the patients enrolled in Lord's randomized controlled trial to which were added patients treated after the conclusion of the trial. Patients were selected by complete relief of pain via controlled or placebo controlled triple medial branch blocks at C3-4 to C6-7. Anatomically sound lesioning techniques were used. This study showed that of 28 patients treated, 71% obtained complete relief of pain that lasted for a median duration of 421.5 days. (43) Barnsley performed an observational study of 35 patients selected following complete relief of pain with dual medial branch blocks and no response to placebo medial branch injections. An anatomically sound lesioning technique was used. Of 35 patients treated, 21 (60%) obtained complete relief of pain for a median duration of 44 weeks. (1) In the study by Macvicar two practitioners reported the outcomes of all their consecutive patients over five years in their respective practices. (44) 104 patients were selected on the basis of complete relief of pain following controlled diagnostic, medial branch blocks and anatomically sound RF lesions	No studies were identified which met the inclusion criteria to evaluate the effectiveness of neurotomy versus sham neurotomy in the cervical spine. All of the studies cited are case series in which all participants received facet neurotomy. Case series were excluded from Key Question 2. This issue is discussed in more detail in point 7, above.

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	were performed. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work if applicable, and no need for any other health care for their previous neck pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted 17 – 20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 20 – 26 months, with some 60% still having relief at final follow-up (44) Shin performed a prospective audit of 28 patients who had ≥50% relief following comparative dual medial branch blocks. Anatomically sound RF lesions were created. Success was defined as ≥75% improvement in VAS at 6 month follow-up which was observed in 68%. (52) Speldewinde performed a prospective cohort of 109 patients. Patients were selected for RFN if dual medial branch blocks gave ≥80% relief of their index pain. RFN was performed in an anatomically sound fashion. 62% of patients had ≥75% relief of pain and 54% were pain free between 6 and 36 month follow-up. (53) Sapir performed a prospective cohort study on litigant and non-litigant patients. 50 patients were selected by ≥80% relief following controlled medial branch blocks. RF was performed with a reasonable, but not ideal anatomically sound RF technique. 74% of the non-litigants had >50% improvement in pain	

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	at 1 yr and 28% of the non-litigants had >80% reduction in pain at 1 yr. (50) Lee performed a prospective audit of 30 consecutive pts who had >50% relief from dual C3-4 medial branch blocks. RF was performed with a reasonable, but not ideal anatomically sound RF technique. There was >75% reduction in 83% at 6 months and 73% at 12 months. (33) Summary: Using 50-80% relief as the cut-off following dual medial branch blocks and reasonably anatomically sound RF lesioning techniques 62-68% obtain ≥75% pain relief at 6 months (52,53) and 74% obtain ≥50% pain relief at 12 month follow-up. (50) When maximally specific selection of patients is undertaken (i.e. minimum of dual diagnostic blocks with 80-100% relief of pain) with ideal anatomically sound RF lesioning techniques, 54-74% of patients can be rendered pain free for a minimum of 10 months. (1,38,44) No other non-surgical treatment in the cervical spine can rival this degree and duration of relief for the treatment of cervical facet pain.	
	<u>Treatment of C2-3 facet pain/cervicogenic headache via third occipital nerve (TON) RF neurotomy:</u> In patients with chronic neck pain, the representative prevalence of cervical zygapophysial joint pain is 55%. This	

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	makes it the single most common basis for chronic neck pain. (3,14,36,39,42,61) In patients who prove positive to controlled medial branch blocks, the segments most commonly positive are C2,3 and C5,6. (14) In 1994, a substantive study, using controlled diagnostic blocks of the third occipital nerve, (which is the innervation to the C2-3 zygapophysial joint) (5) reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint. (35) RF neurotomy of this joint is performed via third occipital nerve neurotomy. There has been a seminal RCT on cervical medial branch neurotomy that demonstrates the positive outcome of the procedure is clearly not due to placebo effects. (38) This study did not access the C2-3 level due to documented technical limitations of RF neurotomy of this level (at the time of the study) due to anatomic variation of the third occipital nerve. (37) More recently, subsequent to the Lord RCT, these RF technical limitations have been addressed. (24) There have been three RCTs on the treatment of cervicogenic headache by van Suijlekom, Stovner, and Haspelagh. (25, 54, 57)In these studies patients were selected on clinical criteria only and the anatomic source of pain was unknown. RF techniques were not anatomically sound and RF was performed at multiple levels indiscriminately. Active RF was compared to sham or control greater occipital nerve blocks (not third occipital nerve blocks). There was no differences between the active or sham arms. However, due to the above the studies	The study cited here (Lord et al., 1996) was included to evaluate the efficacy of RF neurotomy versus sham neurotomy in the cervical spine, as discussed above. Of the studies cited here: • The study by Van Suijlekom is a case series of 15 consecutive patients (not a RCT) • The study by Stovner was excluded at full-text review because the study includes less than 10 patients per treatment group (studies in which less than 10 patients per treatment group were excluded, as listed in the inclusion/exclusion criteria (which

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	used invalid methodology and no scientifically valid conclusion can drawn except that poorly selecting patients for RF and performing RF inappropriately will yield results that are no better than sham treatments, as expected.	was developed *a priori*). • The study by Haspeslagh was included to evaluate the efficacy of RF neurotomy versus spinal injections in the cervical spine and will be discussed in the corresponding section below.
	Although there are no RCTs on RF of established C2-3 facet pain there are three prospective trials that provide insight into the effectiveness of denervation of this joint via third occipital nerve neurotomy. One could argue a specific RCT to dispel the effects of the index procedure is not due to placebo effects is unnecessary when the RF procedure itself for the same condition (facet pain) has already been shown to be efficacious. (38) Since the TON RF technique has been appropriately modified following the Lord RCT there is one prospective trial that specifically evaluated the effect of TON neurotomy (24) and two additional trials using anatomically sound RF techniques at all cervical levels including C2-3. In these two trials, the C2-3 level was the predominant level treated (1) or one of the most predominant levels treated. (44) Govind selected patients with comparative blocks who had complete pain relief following each block. Anatomically sound RF lesions were performed. (24) Success was defined as complete pain relief (100%) for at least 90 days with full return of ADLs and no drug treatment for a headache. Govind	All of the studies cited here are case series in which all participants received facet neurotomy. Case series were excluded from Key Question 2. This issue is discussed in more detail in point 7, above.

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	found that 86% of 49 patients obtained complete relief of pain and had a successful outcome. At the time of publication, the median duration of relief was 297 days, with eight patients experiencing ongoing, complete relief. Fourteen patients underwent repeat neurotomy when their pain recurred. Twelve (86%) regained complete relief. (24) Barnsley performed an observational study of 35 patients selected following complete relief of pain with dual medial branch blocks and no response to placebo medial branch injections. An anatomically sound lesioning technique was used. Of 35 patients treated, 21 (60%) obtained complete relief of pain for a median duration of 44 weeks. (1) In the study by Macvicar two practitioners reported the outcomes of all their consecutive patients over five years in their respective practices. (44) 104 patients were selected on the basis of complete relief of pain following controlled diagnostic, medial branch blocks and anatomically sound RF lesions were performed. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work if applicable, and no need for any other health care for their previous neck pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted 17 – 20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration	

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	of 20 – 26 months, with some 60% still having relief at final follow-up (44) Summary: In these trials, when patients are selected with maximally specific diagnostic methods, i.e. dual diagnostic blocks with 100% relief of pain, and RF is appropriately performed then 60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a minimum duration of 10 months. No other non-surgical treatment in the cervical spine can rival this degree and duration of relief for the treatment of C2-3 facet pain or cervicogenic headache.	
	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.* Comment: Concur.	Thank you for your comment.
	RF Neurotomy versus Spinal Injections: Efficacy in the lumbar spine *Two RCTs (Civelek 2012, Lakemeier 2013)33, 34 (CoE II) met our inclusion criteria. 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.*	Thank you for your comment.

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	RF Neurotomy versus Spinal Injections: Effectiveness in the lumbar spine *One retrospective audit study (Chakraverty 2004)35 (CoE III) met our inclusion criteria. 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.* *No evidence for the following:* *Efficacy or effectiveness of other types of neurotomy compared with spinal injections in the* *lumbar spine* Comment: In the study by Civelek 100 pts selected on clinical grounds of having facet joint syndrome and yet no diagnostic blocks were performed. (10) Subjects were prospectively randomized 50 to MBBs and 50 to RF. MBBs performed with 2 cc of bupivicaine and 40 mg of methylprednisolone. A fair anatomically sound RF lesioning technique was used. At 6, and 12 months post treatment the VAS was significantly better in the RF vs. MBB group with 90% vs. 68% at 6 months and 88% vs. 62% having obtained ≥50% pain relief. However, there was no difference between groups for NASS satisfaction scale or EQ-5d. No categorical pain relief data was presented. (10) Lakemeier performed a prospective randomized trial of IA facet injections vs. RF Neurotomy for chronic LBP. (30) Patients were selected based on ≥50% relief following intra-articular (IA) L3-4-5-	

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	S1 anesthetic injections. IA injection was performed with 3 mg of betamethasone and a sham intraarticular RF lesion was also performed. RF was performed with a fair anatomically sound RF lesioning technique. Oswestry, Roland-Morris and VAS used at baseline and at 6 months. Mean VAS in the intra-articular group was 7 at baseline and 5.4 at 6 months. Mean VAS in the RF group was 6.6 at baseline and 4.7 at 6 months. There was no difference between groups nor was there for the Oswestry or Roland-Morris. There was no categorical pain relief data. (30) Chakraverty performed a retrospective audit on patients selected with the predominant use of single diagnostic intraarticular provided they had ≥50% relief of pain in the first hour post injection. (9) 34 subjects with a positive response to IA blocks underwent an IA injection of triamcinolone; 29% had subjective global improvement of >50% relief at 6 or more months. 38 pts were selected for RF neurotomy following single mbbs. At six months, 50% of the 32 patients available for review reported average subjective improvement of 70% (50-100). No statistics were performed, yet it was concluded RF is a better option than IA facet injections for longer term treatment of recalcitrant facet pain. (9) Summary: At face value it appears the results from these studies are inconsistent as to the value of RF vs. injection techniques. However, these studies produced no	

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	usable or valid comparison data for which any firm conclusions can be stated either positively or negatively. The source of pain in the study by Civelek (10) was unknown as no diagnostic blocks were used or invalid, non-specific single intra-articular blocks with a 50% cut-off were used. (9, 30) In all three studies the RF was not performed in an anatomically sound fashion.	
	RF Neurotomy versus Spinal Injections: *Efficacy in the cervical spine:* *One RCT (Haspeslagh 2006) (CoE II) met our inclusion criteria. The results suggest that outcomes are similar following RF neurotomy and spinal injections.* *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* Comment: In the study by Haspeslagh 30 patients were selected on clinical grounds only of having cervicogenic headache. (25) 15 were randomized to C3-6 RF neurotomy using non-anatomically sound lesioning techniques followed by dorsal root ganglion RF when necessary vs. greater occipital nerve blocks with anesthetic and steroid following by TENs when necessary. The primary end-point was at 8 weeks. VAS and Global Perceived Effect	Thank you for your comment.

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	(GPE) where the primary outcome tools. Treatment was scored as a success, if there was a reduction of the mean VAS of at least 2 points and/or a global perceived effect of +2 or +3. 20% of those receiving RF vs. 27% of those receiving GON blocks were considered a success at 8 weeks. The difference was not significant. (25) No conclusions, either positive or negative, can be drawn as to the effect of spine injections vs. RF in the cervical spine as this study used invalid diagnostic and treatment methods.. The source of pain in these patients is unknown as no diagnostic blocks were used and the RF technique was not anatomically sound. This study produced no usable data and the only conclusion that can be reached is to state that patients selected and treated by the methods used in this study are expected to do very poorly and likely represent placebo treatment effects.	
	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.* Comment-Concur	Thank you for your comment.
	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,*	Thank you for your comment.

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	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. Taken together, the results suggest that outcomes are similar following conventional and pulsed RF neurotomy.* *No evidence for the following: Effectiveness of conventional versus pulsed RF neurotomy in the lumbar spine.* Comment: It is important to note that pulsed radiofrequency treatment is not a neurodestructive procedure, rather it is proposed to be a non-destructive neuromodulatory procedure which affects the way nerves process pain. It is therefore erroneous to call it a type of "facet neurotomy." It is also erroneous to call pulsed radiofrequency treatment "cooled." as it is not cooled in any fashion. Rather temperatures are kept below 42 deg C at all times, purposely avoiding thermoablation of tissue which starts to occur around 45 deg C. Conventional thermal radiofrequency neurotomy is performed at temperatures typically around 80-90 deg C with the specific intent of destroying the target tissue. A comparison study sought to compare the efficacy of thermal radiofrequency neurotomy with that of pulsed radiofrequency treatment. (55) However, it included a controlled study, in which	

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	patients were randomized to receive active treatment with thermal neurotomy or sham neurotomy in which no lesion was generated. The study enrolled patients who obtained at least 50% relief of pain following single diagnostic medial branch blocks. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. There were 20 patients in the control group, 20 in the pulsed RF group and 20 in the continuous thermal RF group. Anatomically sound RF lesioning techniques were used. For the relief of pain, improvement in disability, and reduction in use of analgesics, thermal radiofrequency was significantly more effective than sham treatment immediately after treatment, at six months, and at one year. At 1 year f/u the continuous RF group had a statistically significant 65% mean VAS reduction (6.5 to 2.3) vs. the placebos group's 43% (6.8 to 4.3) VAS reduction vs. the pulsed group's 47% (6.6 to 3.5) VAS reduction. At 1 year f/u the mean Oswestry disability index improved 29% in the continuous group vs. 16% in the sham group and 26% in the pulsed RF group. At 1 yr , 95% of the control vs. 75% of pulsed RF group vs. 40% of the thermal RF group were using analgesics. Although showing superiority of active treatment over sham or pulsed treatment, this study did not report data from which success rates for percentage reduction of pain could be calculated.	

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	However, 65% (44% - 86%) of patients treated with active medial branch neurotomy reported excellent satisfaction with treatment, compared with 20% (2% - 38%) of those who underwent sham treatment vs. 35% of those receiving pulsed RF (55) Kroll performed a prospective, randomized, double-blinded study. (29) Patients were selected via high volume (1.0 cc) dual medial branch blocks with ≥50% relief of pain. Patients were randomized to pulsed RF treatment or thermal RF neurotomy. The thermal RF technique was performed in a fair, but not sound anatomical fashion. A total of 50 patients received either thermal or pulsed RF treatment equally divided between the two groups. 13 patients who received thermal RF and 13 patients who received pulsed RF completed their 3 month follow-up evaluation. Categorical data of percentages with various percentages of pain relief was not reported. With respect to mean VAS scores, the thermal group had a relative improvement over the three-month interval, on average, of 24.7% , and the pulsed RF group, by10.6% . In the thermal group, Oswestry scores improved by an average of 18.3% , and in the pulsed group by only 4.1%. There was no significant difference between the thermal RF and pulsed RF groups in relative improvements in either VAS or Oswestry scores. Within the thermal group, VAS and Oswestry scores showed significant improvement over the three-month interval. However, within the pulsed group, comparisons of the relative change over time for both VAS	

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	and Oswestry scores were not significant. (29) Summary: Consistent benefit of thermal RF vs. pulsed RF was not apparent at face value in these studies, although there was a clear trend in favor of thermal RF. However, in these two studies patients were not selected with ideal selection criteria (80-100% relief following low volume dual medial branch blocks, but ≥50% relief with single medial branch blocks or ≥50% relief with high volume dual medial branch blocks. Tekin, but not Kroll, used anatomically sound RF lesioning techniques. Due to such, as expected, he mean reduction in pain in the thermal RF groups within these studies were not consistent with known expected pain relief that occurs in patients that are selected with more specific dual medial branch blocks with high grade relief that subsequently undergo robust lesioning techniques. With these methodological limitations and literature perspective it would be inappropriate to make a firm conclusion that the results from pulsed RF treatment rivals relief following thermal RF neurotomy.	
	No evidence for the following: *Efficacy or effectiveness of conventional versus pulsed RF neurotomy in the cervical or* *thoracic spine* Comment: Agree as there are no relevant trials.	Thank you for your comment.

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	RF Neurotomy versus Alcohol Ablation: Efficacy in the Lumbar spine *One RCT (Joo 2013) (CoE II) met our inclusion criteria. 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*. Comment: In this prospective, randomized, controlled single center clinical study by Joo 40 patients with recurrent thoracolumbar facet joint pain after successful (>50% relief for 6 or more months) thermal RF ablation defined as numeric rating scale (NRS) score of ≥7. (27) Subjects were randomly allocated to two groups receiving either the same repeated RF ablation (n = 20) or alcohol ablation (n = 20). The recurrence rate was assessed with NRS and ODI during the next 24 months. In this thoracic spine the nerve was targeted along its "expected course of the nerve at the base of the transverse process". In the lumbar spine a perpendicular approach (ie poor technique) to the superior location of the target nerve was used. There was a significant difference in the recurrence ratios between the groups during the 24 months following the procedures (19 in the repeated thermal RF ablation and 3 in the AA group). The median effective periods in the RFA and AA groups were 10.7 (range 5.4–24) and 24 (range 16.8–24) months, respectively which was significant. In the patient cohort, initially equally	Thank you for your comment.

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	effective relief occurred between repeat RF and alcohol ablation, but alcohol ablation provided a longer period of pain relief than repeated radiofrequency medial branch neurotomy in the treatment of recurrent thoracolumbar facet joint pain syndrome after successful thermal RF. (27) Comment: This study cannot be used to assess the potential results of RF neurotomy vs. alcohol ablation in patients that have not had a prior neurotomy. Of note, although significant complications were not seen in this trial there is an increased potential risk of complications following alcohol chemoablation compared RF neurotomy that require additional procedural experience and precautions when being undertaken. Specifically, alcohol ablation near spinal nerve roots for benign chronic pain is incompatible with the American medico-legal mileau, as alcohol may "leak" onto spinal nerve roots or spinal cord, leading to palsy, paralysis or death. I agree with Spectrum's conclusions regarding all components of key question 2b, and 2c.	
	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.* Comment: Agree, no studies exist. In the absence of such studies, extrapolation of	Thank you for your comment.

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	the data from the other RF neurotomy studies in which multiple levels in addition to single levels were effectively treated would suggest it is unlikely there is a differential effectiveness.	
	I agree with Spectrum's conclusion regarding all components of Key Questions 3, 4 and 5.	Thank you for your comment.
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Gary Franklin, MD, Medical Director Washington State Labor and Industries

Report Section	Reviewer's Comments	SRI Response
Executive Summary-Introduction *Condition/disease* **(page 1)**	The Manchikanti reference is from a journal whose funding and quality of review has been questioned. I would delete this sentence unless it is based on a darn good epidemiological study with clear case criteria for presence/absence of facet pain, and just go with the next sentence, which is probably more accurate. Relevant text "It has been estimated that the point prevalence of facet joint pain are 10-15% in the low back, 40-50% in the mid-back, and 45-55% in the neck."	Thank you. The reference has been corrected; the data for the mid-back has been deleted as it is from the Manchikanti journal and is less relevant to the data in the HTA.
Executive Summary-Introduction *Diagnosis* **(page 1)**	But if you don't have a good idea from the physical exam about which facet joint might be the culprit, how do you even decide where to do the diagnostic injection?	Thank you. The primary symptom suggestive of facet joint pain is paraspinal tenderness at the affected facet joints and other symptoms (e.g., radiating pain, pain that is exacerbated with certain movements) may also be present and suggestive of facet joint pain. Patient selection is discussed in greater detail in the background section of the report.
Executive Summary-Introduction *Intervention: Facet Neurotomy* **(page 1)**	These 2 sentences do not make sense- these are local nerves to the facet joints- they are not part of spinal pathways. If there is not great scientific evidence to support these two sentences, I would delete them. Relevant text "Neurotomy does not cure the source of pain, but instead cuts off the pain signal from the brain by damaging the nerve." "Then a radiofrequency current is applied to disrupt the ability of the nerves to transmit pain signals to the brain."	Thank you. A recent review describes neurotomy/denervation as using "electrical current to generate a controlled lesion by which to safely interrupt nociceptive input." This description is consistent with descriptions found on the theory behind using neurotomy for facet pain. These pain signals travel from the local nerves and ultimately reach the brain.

Report Section	Reviewer's Comments	SRI Response
Executive Summary-Introduction *Policy context provided by HTAP* **(page 2)**	I would add to this point: Some papers described below count improvement in ANY ASPECT of back pain as counting towards improvement. This may be why this procedure is often not curative.	Thank you. The issue of clinically meaningful improvement and amount of back pain relief are addressed in this HTA.
Executive Summary-Introduction *Policy context provided by HTAP* **(page 2)**	Shouldn't this say, "…for patients with chronic back and neck pain when that pain is felt to be originating in the facet joint." Relevant text "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."	Thank you. The objective was finalized in conjunction with the Washington State HCA after the public comment period for the draft key questions.
Results: Summary of the highest quality evidence on primary outcomes *Function* **(page 6)**	Not sure why this refers to pain relief when the question at hand is function Relevant text "One study found that those required to achieve ≥80% pain relief following diagnostic block group had significantly better 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)"	Thank you. The text has been clarified; the "results" being described are for function (≥ 50% improvement in activity level) in patients who were selected for FN based on certain thresholds of pain relief required following the diagnostic block.
Results: Summary of the highest quality evidence on primary outcomes *RF Neurotomy versus Sham Neurotomy: Efficacy in the lumbar spine* **(page 7)**	As in the Tables below, most of the cited RCTs had serious risk of bias-this shoud be stated more clearly in the Executive summary, and the reasons briefly stated Relevant text "Six RCTs (Gallagher 1994, Leclaire 2001, Nath 2008, Tekin 2007, van Kleef 1999, van Wijk 2005)"	Thank you. The CoE of each study was included in the results summary. To provide additional information, the overall quality of evidence was added to each conclusion. (The overall quality of evidence takes into account all of the following: risk of bias, inconsistency, indirectness, imprecision, and publication bias. Further details can be found in the summary tables.)

Report Section	Reviewer's Comments	SRI Response
Results: Summary of the highest quality evidence on primary outcomes *Pain outcomes* **(page 7)**	Are you talking about leg pain or back pain here? Relevant text "Overall, the difference in the mean improvement in leg pain VAS scores between groups ranged from 5.0 to 19.4 more points (scale, 0-100) following RF neurotomy versus sham neurotomy"	Thank you. This has been corrected to "back pain".
Results: Summary of the highest quality evidence on primary outcomes *Function* **(page 8)**	Ref 29 doesn't look like neurotomy vs sham neurotomy Relevant text "Two RCTs29, 30 "	Thank you. This is the correct reference. The study is discussed in detail in section 3.2.2. Briefly, 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).
Results: Summary of the highest quality evidence on primary outcomes *RF Neurotomy versus Spinal Injections: Efficacy in the lumbar spine* **(page 9)**	RF Neurotomy versus Spinal Injections: Efficacy in the lumbar spine If these spinal injections were facet injections, that should be specified here	Thank you. The studies included used therapeutic medial branch block and therapeutic to therapeutic intra-articular injections. This detail has been added here and to the summary tables for clarification.

David Hou, MD

Report Section	Reviewer's Comments	SRI Response
General	I believe that facet neurotomy is a safe, cost effective procedure to treat facet mediated pain. I hope that insurance continues to cover the treatment for injured worker.	Thank you for your comment.

International Spine Intervention Society (ISIS)

Report Section	Reviewer's Comments	SRI Response
General	Relative to the practice of radiofrequency medial branch neurotomy, the International Spine Intervention Society (ISIS) encourages Washington State Health Care Authority to: 1. Recognize as valid only those procedures performed in accordance with techniques that have been validated. Optimal results have been achieved only when those techniques have been used. Results from the techniques described in the ISIS guidelines include complete relief of neck pain, back pain, or headache, accompanied by restoration of function, return to work, and no need for further health care. 2. Adopt the ISIS guidelines[1] as the standard for the performance of medial branch blocks, third occipital nerve blocks, and thermal radiofrequency neurotomy. Furthermore, the International Spine Intervention Society recommends that Washington State Health Care Authority regard as investigational any other techniques for radiofrequency medial branch neurotomy, or any other basis for the selection of patients for treatment by medial branch neurotomy. By adopting such measures Washington State Health Care Authority can make available to suffering patients the best standard of care currently available, and avoid continuing to	Thank you for your comments.

Report Section	Reviewer's Comments	SRI Response
	subsidize practices of lesser standard with substantially poorer outcomes. 1-2. Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.	
General	The draft evidence report, produced by Spectrum, poorly serves the needs of the Health Care Authority of Washington State. While the report adheres to the common requirements of a systematic review, its depiction of the evidence is flawed due to lack of insight into the details – not of the data published – but of the practices inherent in the procedures being assessed. In formal terms, the report suffers from lack of content expertise. The report includes a section on "Key considerations highlighted by clinical experts", but ironically, the report heeds none of the warnings and insights provided by these experts. It is important for the Committee to understand the seriousness of this oversight. Imagine that the topic was "the effectiveness of antibiotics for cough". Cough, similar to low back pain, is merely a symptom representing a variety of diseases. In the case of cough this could include: viral pneumonia, asthma, gastroesophageal reflux disease, heart failure, and even bacterial pneumonia. Without	Thank you. The issues brought up in the "Key considerations highlighted by clinical experts" are discussed in turn as part of the response to the peer review by Dr. Dreyfuss, above. Because it was recognized before conducting the review that patient selection was likely to be an important component of evaluating the efficacy and effectiveness of facet neurotomy, Key Question 1 sought to evaluate the highest quality literature available as to whether various aspects of patient selection (type of diagnostic block, percentage of pain relief achieved following diagnostic block, and single versus controlled diagnostic blocks) for facet neurotomy affects clinical outcomes following facet neurotomy. To this end, only studies in which outcomes following facet neurotomy were evaluated in patients selected by either block were included. In short, the highest quality evidence available at the time of this report did not support these claims to such a level that would prompt us to evaluate studies that only employed these methods of patient selection. Each of these patient selection considerations are discussed in detail in points 1-4, above.

Report Section	Reviewer's Comments	SRI Response
	proper patient selection and stratification one may be tempted to say antibiotics are not effective for all patients suffering from a cough. This would clearly be a disservice to those with bacterial pneumonia. In addition to the lack of specificity in the diagnosis, this analogy is also similar in that like spine interventions not all antibiotics are the same. There are a variety of antibiotic types with differing efficacies and routes of administration. The combination of these different treatments targeted at different diseases leads to the unfortunate misinterpretation of an effective treatment for a select group of patients as ineffective. Armed with such information, a review would not pool all data and diseases indiscriminately, while simultaneously not distinguishing the effectiveness of oral antibiotics and intravenous antibiotics, full---strength antibiotics, or even diluted antibiotics. Yet, in the case of facet neurotomy this is what has been done, in the past, and yet again in the report from Spectrum. The unnamed clinical experts warned • "The literature…is replete with examples of both poor patient selection and poor technical execution of the procedure."	However, in order to address these concerns tables have been added to Key Question 4 in which the primary outcomes from comparative studies from KQ2 are reported from only those studies in which patients were selected on the basis of ≥50% pain relief following at least one MBB. Information as to the type of diagnostic block, number of diagnostic blocks, and pain relief required following diagnostic block has been added to the summary tables in the Executive Summary as well as in data tables throughout KQ2 such that this information is readily available to readers. The report was not designed to evaluate technical aspects of facet neurotomy (see point 5, above) However, stratifying between acceptable and "poor technical execution" as suggested by Dr. Dreyfuss (see above) yields the same stratification of studies as stratification by type of diagnostic block.

Report Section	Reviewer's Comments	SRI Response
	• "…there are key trials which have used validated selection criteria…and validated radiofrequency neurotomy methods…It is these…trials that depict the value of the procedure." • "Selecting patients with less than ideal methods will only yield a greater percentage of patients for subsequent medial branch radiofrequency neurotomy who do not have the target condition, which will not translate into positive clinical outcomes following the RF neurotomy." • "Use of smaller needles, less than ideal parallel trajectories and lesser lesion temperatures/time than those recommended may not result in obtaining an effective lesion of the target nerve…would reduce the likelihood of obtaining a positive clinical outcome." • "Using invalid studies as a measure of the value of medial branch radiofrequency neurotomy would misrepresent its true effectiveness. Such studies only hold value to demonstrate what results are to be expected when patients are not appropriately selected and the radiofrequency technique is not appropriately performed." • "If one wishes to understand the true value and effectiveness of medial branch radiofrequency neurotomy then the data from more rigorous studies should be	

Report Section	Reviewer's Comments	SRI Response
	pooled and reported. Only these…underscore the true nature of expected outcomes…" In methodological terms, advice such as this requires that the literature on facet neurotomy be meticulously stratified. That stratification can be applied in each of three domains: selection, technique, and outcome (See Appendix: Figure 1).	
General	For a variety of reasons, practitioners – whether those in clinical practice or those who publish – use different techniques, yet call their procedure by the same name. The reasons include: • continuing to use older techniques that are not only out of date, but which have been disproven [1,2,3] • preferring techniques according to their inventor or country of origin, such as the Dutch technique or the Australian technique [1,2,3] • using personal adaptations or shortcuts in order to save time, because the published technique is labor---intensive and time---consuming, and not proportionately reimbursed; • using smaller electrodes because ostensibly these are what are marketed locally, and because larger electrodes are said to be not available. Correct technique is not	Thank you for your comments.

Report Section	Reviewer's Comments	SRI Response
	defined by arbitrary, personal choice; nor is it defined by randomized controlled trials. Correct technique is defined by studies in basic science. The Spectrum report is aware of this literature, for it cites it [4], but does not heed its message. For medial branch neurotomy to have face validity the electrode must be accurately placed such that the lesion that it produces optimally captures the target nerve. If the electrode is not placed near the nerve, the validity of the technique lapses. Somewhat contentious is whether electrodes can be placed perpendicular to the course of the target nerve or parallel to it. In both instances, the electrode may be sufficiently close to the nerve in order to capture it, but basic science studies indicate that perpendicular placements may fail to capture the entire diameter of the nerve, and that parallel placements are more likely both to capture a full thickness of the nerve and a substantial length of the nerve[4,5,6]. Therefore, the orientation of the electrode is likely to be pivotal to clinical outcome. Perpendicular placements could be successful, but are likely to have lower success rates and shorter durations of effect, whereas parallel placements are more likely to have greater success rates for longer periods. This, indeed, is borne out in the literature (see:	

Report Section	Reviewer's Comments	SRI Response
	OUTCOMES). In the light of these technical precepts, the literature can be stratified according to face validity of the technique used (Table 1). Specific considerations differ for lumbar and cervical procedures.	
RF Neurotomy versus Sham Neurotomy: Efficacy in the Lumbar Spine	The original technique for "facet denervation" described by Shealy was seriously flawed[5,7]. Electrodes were placed nowhere within reach of the target nerve. Therefore the procedure was tantamount to a sham procedure. Studies that used this disproven technique are, therefore, not representative of a correct technique. The clinical data that they provide might be of use to show what meager outcomes are obtained when flawed techniques are used, but they are inadmissible as evidence of the effectiveness or efficacy of facet neurotomy when correctly performed. Inadmissible for this reason is the study of Gallagher, which explicitly stated that it used the Shealy technique[8]. Similarly, the study of Leclaire et al [9] used a technique that was a modified version of the Shealy technique. Therefore, that study also lapses as providing valid data on the efficacy of facet neurotomy if correctly performed. Indeed, Leclaire et al acknowledged this flaw in surgical anatomy, and effectively retracted their results[10.]	Thank you. The report was not designed to evaluate technical aspects of facet neurotomy.

Report Section	Reviewer's Comments	SRI Response
	The study of Wijk et al [11] illustrated the technique used. It is patently inaccurate as pointed out by a letter to the editor.[12] Not only were electrodes placed perpendicular to the target nerve, but many placements were too far away from the nerve for the lesion made by the small electrodes used to be able to capture the nerve reliably and adequately. That controlled trial, therefore, pitted one sham procedure against another, thus it is not surprising that no statistically significant difference in outcome was found. (See Appendix: Table 1). The other studies that used perpendicular placements [13-18] either illustrated their procedure or described their technique in sufficient detail to credit that their electrodes were placed within range of the target nerve. However, the perpendicular placement, as well as the use of small---gauge electrodes, constitutes a risk of bias against good outcomes, because the target nerves may have been incompletely coagulated – resulting in a lower than optimal success rate – or insufficiently coagulated – resulting in duration of relief less than the duration achievable by other techniques. Therefore, the clinical outcomes of these studies need to be interpreted carefully and with insight. In the case of the one study that used perpendicular placement and which was also a controlled	

Report Section	Reviewer's Comments	SRI Response
	trial, the technical limitation may affect the success rate and durability of outcome, but it does not affect testing the technique against placebo, because the same placement was used in each arm. Nine studies used what appears to be correct technique: placement of the electrode parallel to the target nerve[19-28]. Of these, some provide evidence of outcomes[19-23]; others provide data on repeat treatment[20,23,24,25;] two are controlled trials[26,27;] and one was a comparison study[28]. In light of this stratification of studies by face validity of technique used, certain corrections apply to the conclusions of the report. The studies of Gallagher 1994, Leclaire 2001, and van Wijk 2005 do not qualify as providing evidence of efficacy because the techniques used for the active arm lacked face validity. Censoring these studies leaves only those of Nath 2008, Tekin 2007, and van Kleef 1999 eligible to provide evidence. The study of Nath 2008 showed a difference in favor of RF neurotomy that was not significant for the relief of back pain at six months, but which was significant for relief of leg pain, global perceived effect, and consumption of analgesics. For the relief of back pain, the group data of Van Kleef 1999 showed	

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	a difference in favor of RF neurotomy that was not significant statistically, but survival analysis showed a statistically significant greater success rate from three months to one year after RF neurotomy. Tekin 2007 showed statistically significant differences in favor of active RF neurotomy at six months and at one year, for group scores for back pain, and for disability, with a significantly greater proportion of patients reporting an excellent outcome. No study provided data that contradicted the superiority of active treatment over sham treatment.	
RF Neurotomy versus Sham Neurotomy: Efficacy in the Cervical Spine	The literature on cervical radiofrequency neurotomy is less contaminated by errors in technique than the literature on lumbar radiofrequency neurotomy. Although there is earlier literature[1-7], when this was reviewed in 1995 it was found that the techniques used lacked any formal anatomical basis, validated diagnostic tests were not used to select patients, and outcomes were less than impressive, both in terms of success rates, degree of relief, and duration of relief[8]. Fortunately, these errors have not been reiterated in the more recent literature. To no small extent, the errors committed in the past practice of lumbar medial branch neurotomy were avoided in the evolution of cervical medial branch neurotomy.	Thank you for your comments.

Report Section	Reviewer's Comments	SRI Response
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Report Section	Reviewer's Comments	SRI Response
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	The majority of the studies on cervical medial branch neurotomy have used valid techniques, in which electrodes are carefully placed parallel to the target nerves[9-14], in accordance	Thank you. The Tzaan study referred to was not included to evaluate cervical facet neurotomy versus sham neurotomy, as it was a case series. It was, however, included to evaluate KQ2c, which evaluated unilateral versus bilateral facet neurotomy.

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	with the guidelines of the International Spine Intervention Society[15]. The one exception is the study of Tzaan and Tasker[16] which reports outcomes for cervical medial branch neurotomy but does not describe the technique used. From the little information that is provided in the publication, it appears that the authors placed electrodes perpendicular to the target nerve. They did not recognize that poor outcomes from such placements were the reason that parallel placements were developed[17]. Consequently, the data of Tzaan and Tasker[16] serve to indicate what outcomes might be achieved if a less effective technique is used, but they do not indicate what can be achieved when optimal technique is used.	From KQ2c, it was concluded: "One retrospective cohort study (Tzaan 2000)[10] (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"."
	Of the studies that have used correct technique for cervical medial branch neurotomy, one has been a placebo---controlled trial[9]; the others have been long---term outcome studies[9-14]. The controlled trial showed conclusively that the outcomes of cervical medial branch neurotomy cannot be attributed to placebo effects[9]. The long---term outcome studies[10-13] corroborate the results of the controlled trial[9], showing that complete relief can be achieved in over 60% of patients, associated with restoration of function, and no need for further health care; and relief can be reinstated by repeat treatment[10,13,14].	Thank you.

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	There is no literature that refutes any of these conclusions. Nor does the Spectrum report provide any evidence to cast doubt upon either the efficacy or effectiveness of cervical medial branch thermal radiofrequency neurotomy, if performed correctly as recommended[15], for the treatment of chronic neck pain shown to be relieved by controlled blocks of the cervical medial branches. 1. Schaerer JP: Radiofrequency facet rhizotomy in the treatment of chronic neck and low back pain. Int Surg 1978; 63:53---59. 2. Sluijter ME, Koetsveld---Baart CC: Interruption of pain pathways in the treatment of the cervical syndrome. Anaesthesia 1980; 35:302---307. 3. Schaerer JP. Radiofrequency facet denervation in the treatment of persistent headache associated with chronic neck pain. J Neurol Orthop Surg 1980; 1:127---130. 4. Sluijter M E, Mehta M: Treatment of chronic back and neck pain by percutaneous thermal lesions. In: Lipton S, Miles J (eds) Persistent pain. Modern methods of treatment, Vol. 3. Academic Press, London, 1981, pp 141---179. 5. Hildebrandt J. Argyrakis A. Percutaneous nerve block of the cervical facets – a relatively new method in the treatment of chronic headache and neck pain.	

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RF Neurotomy versus Spinal Injections:	A particular application of cervical radiofrequency neurotomy is for the treatment of headache known as cervicogenic headache, which is a form of	Thank you. Of the references provided, only reference #2 met the inclusion criteria (Haspeslagh). The Stovner study was excluded at full-text review as they did not meet the *a priori* inclusion criteria (less than

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Efficacy in the Cervical Spine	referred pain from the upper cervical spine. Three studies purport to show that radiofrequency neurotomy is not effective[1,2,3]. In all studies patients were selected on clinical criteria. Diagnostic blocks were performed in one study 1, but the results were not used as an indication for treatment. In all studies, neurotomy was performed indiscriminately at all levels from C3 to C6. In the first study, only one of 15 patients achieved complete relief of pain[3]. In the second study, outcomes were no different in patients who received active lesions from those who received sham lesions[1]. In the third, outcomes from neurotomy were no different from those of an injection of local anesthetic onto the greater occipital nerve[2]. Three fatal, technical flaws apply to these studies. First, at no stage was the source of pain established. Second, the neurotomy technique used has never been validated. Third, neurotomy was performed at segmental levels (C3---C6) that have never been incriminated as a source of headache. Collectively, these flaws offend the principle of radiofrequency neurotomy.	10 patients per treatment group). The van Suijlekom study is a case series, and thus did not meet the *a priori* inclusion criteria.
	Totally opposite results are obtained if a diagnosis is carefully established using controlled diagnostic blocks, and meticulous technique is	

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	used. For patients in whom diagnostic blocks indicate that the C2---3 zygapophysial joint is the source of pain, it is possible to denervate that joint percutaneously by radiofrequency neurotomy of the third occipital nerve. The procedure involves placing an electrode parallel to the nerve where it crosses the joint, and using it to coagulate the nerve. An early study found that radiofrequency neurotomy of the third occipital nerve did not reliably achieve relief of pain[4]. The authors warned that radiofrequency neurotomy should not be adopted until technical deficiencies of the procedure had been overcome. That has now been achieved. A subsequent study reported improvements in the technique of percutaneous radiofrequency neurotomy of the third occipital nerve[5], which improved its success rate. The revisions included holding the electrode in place during coagulation, and ensuring that multiple lesions are made in order to encompass all possible locations of the nerve. Using the revised technique, complete relief of pain could be achieved in 88% of patients. The median duration of relief was 297 days with some patients still having continuing relief at the time of review[5]. These results have been corroborated by two independent	These studies (references 4, 5, 6, and 7) are all case series, and thus do not meet the inclusion criteria, which were developed *a priori.* This is discussed in point 7 above.

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	studies[6,7]. For patients in whom headache recurs, relief can be reinstated by repeating the neurotomy. By repeating neurotomy as required, some patients have been able to maintain relief of their headache for longer than two years[5,7]. It is not logistically possible to conduct a double---blind controlled trial of third occipital neurotomy. An unavoidable side---effect of the treatment is numbness in the territory of the third occipital nerve. Therefore patients cannot be blinded as to the treatment to which they have been randomized. For validity, third occipital neurotomy relies on inductive logic. Since it has been shown that cervical radiofrequency neurotomy at other segmental levels is not a placebo[8], it is reasonable to assume that it is not a placebo when the C3 medial branch is the target. 1. Stovner LJ, Kolstad F, Helde G. Radiofrequency denervation of facet joints C2---C6 in cervicogenic headache: a randomised, double---blind, sham---controlled study. Cephalalgia 2004; 24:821---830. 2. Haspeslagh SR, van Suijlekom HA, Lame IE, Kessels AG, van Kleef M, Weber WE. Randomised controlled trial of cervical radiofrequency lesions as a treatment for cervicogenic headache. BMC Anesthesiol 2006;	

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General	The outcomes of radiofrequency neurotomy can be quantified in several domains: • success rate: the proportion of patients who achieve a successful outcome; • the degree of relief that constitutes a success; • the duration of that relief; • the corroboration of relief by improvements in critical domains such as restoration of function, return to work, and use of other health care. To various extents, these criteria have been satisfied in various studies. Reviewers can choose which outcomes they consider to be worthwhile, or satisfactory.	Thank you.
General	The paradigm of lumbar medial branch neurotomy is that if patients obtain at least 80% relief of their index pain following controlled diagnostic blocks of one or more medial branches, then similar relief should be obtained if those nerves are successfully coagulated. Two studies have provided benchmarks for the optimal outcomes of lumbar medial branch radiofrequency neurotomy. Each used optimal technique, as discussed above. The first reported, in essence, that 80% of patients could expect at least 60% relief of their back pain at 12 months, and that 60% could expect at least 80% relief[1]. The second study reported the outcomes from	Thank you. This issue has been discussed above. The studies cited (references 1,2) are case series and thus did not meet the inclusion criteria, which were developed *a priori.* This has been discussed above (point 7).

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	two neighboring practices, in which 58% (44---72%) or 53% (40---66%) of patients respectively achieved complete relief of pain, accompanied by restoration of activities of daily living, return to work if applicable, and no need for further health care for their back pain[2]. The results of these two studies are statistically compatible with one another, and indicate what can be achieved by lumbar medial branch neurotomy if performed correctly, and in appropriately selected patients. In both instances the technique used for radiofrequency neurotomy was that recommended by the International Spine Intervention Society [3], and patients were selected using comparative local anesthetic blocks[4]. A success rate of 55% may not seem impressive, but is compensated by the definition of success: complete relief of pain, restoration of function, and no other health care. The modest success rate, however, is mathematically consistent with the vicissitudes of diagnostic blocks (see: **DIAGNOSIS**). Because the prevalence of lumbar zygapophysial joint pain is low, the rate of false---positive diagnoses is high, even if controlled blocks are used. Other studies that have used correct technique have reported lesser outcomes, such as 39% [5] or 35% [6] of patients achieving at least 50% relief of pain at six months.	

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	In each case, however, patients were selected for treatment using diagnostic blocks in a manner less rigorous than in the benchmark studies. 1. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine 2000; 25:1270---1277. 2. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. Pain Med 2013; 14:639-645. 3. International Spine Intervention Society. Lumbar medial branch thermal radiofrequency neurotomy. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013:601-641. 4. International Spine Intervention Society. Lumbar medial branch blocks. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013: 559---599. 5. Burnham RS, Hollistski S, Dimnu I. A prospective outcome study on the effects of facet joint radiofrequency denervation on pain, analgesic intake, disability, satisfaction, cost,	

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	and employment. Arch Phys Med Rehabil 2009; 90:201-205. 6. Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints: 10---year prospective audit. Pain Physician 2007; 10:291-300	
General	The literature on cervical medial branch radiofrequency neurotomy is less contaminated by variations in outcome than is the literature on lumbar medial branch neurotomy. In all modern studies, complete relief of pain has been the benchmark outcome [1-6]. Lesser degrees of relief have neither been reported nor entertained. Furthermore, complete relief of pain has been shown to be accompanied by restoration of activities of daily[1,2,4,5], return to work[1,2,5], and no need for other health care[1,2,5,6.] These outcomes are statistically not significantly affected by a compensation claim or ongoing litigation[1,3,6]. 1. Lord SM, Barnsley L, Wallis B, McDonald GM, Bogduk N. Percutaneous radio---frequency neurotomy for chronic cervical zygapophyseal joint pain. N Eng J Med 1996; 335:1721--1726. 2. McDonald GJ, Lord SM, Bogduk N. Long term follow---up of patients treated with cervical radiofrequency neurotomy for chronic neck pain. Neurosurgery 1999; 45:61---68.	Thank you for your comments.

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	3. Barnsley L. Percutaneous radiofrequency neurotomy for chronic neck pain: outcomes in a series of consecutive patients. Pain Medicine 2005; 6:282---286. 4. Speldewinde GC. Outcomes of percutaneous zygapophysial and sacroiliac joint neurotomy in a community setting. Pain Med 2011; 12:209---218. 5. MacVicar J, Borowczyk J, MacVicar AM, Loughnan BM, Bogduk N. Cervical medial branch radiofrequency neurotomy in New Zealand. Pain Med 2012; 13:647---654. 6. Govind J, King W, Bailey B, Bogduk N. Radiofrequency neurotomy for the treatment of third occipital headache. J Neurol Neurosurg Psychiat 2003; 74:88-93.	
General	The Spectrum report correctly recognizes that it is not possible to diagnose zygapophysial joint pain by physical examination or by medical imaging. Diagnostic blocks are the only means of establishing a diagnosis, and providing an indication for treatment by medial branch neurotomy. The acme of diagnostic blocks are placebo---controlled triple blocks [1,2,3]. These involve first administering an active agent, in order to find prima facie if anesthetizing the target nerves relieves the patient's pain. In order to test the response, the patient subsequently undergoes repeat	Thank you. Thank you. The issue of diagnostic blocks has been discussed above.

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	blocks, under double---blind conditions, in which a placebo and an active agent are randomly administered. A positive response is one in which pain is not relieved when the placebo is used, but is relieved each time that the active agent is used, and for a duration concordant with the expected duration of action of the agent used. Although placebo---controlled, triple blocks have been used in research studies [4], they are regarded by many as too consuming of resources to be practical in conventional practice. Meanwhile, insurers appear to be averse to funding triple blocks on the grounds that they are expensive. Interestingly, however, triple blocks are cost---effective in jurisdictions such as those in Australia and New Zealand, where the reimbursement for medial branch neurotomy substantially exceeds that of a diagnostic block[5]. A suitable alternative to placebo---controlled, triple blocks is comparative local anesthetic blocks. These involve administering, on a double---blind basis in random order, either a long--- acting or a short---acting local anesthetic agent. A positive response is one in which the patient obtains at least 80% relief of the index pain on each occasion. A concordant positive response is one in which the duration of relief is concordant with the expected duration of action of	

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	each of the agents used. A discordant response is one in which one of the agents, usually lidocaine, has a longer than expected duration of effect[1,2,3,6]. When compared with placebo---controlled blocks, comparative local anesthetic blocks are a reasonably expedient clinical tool. Concordant responses have a sensitivity of 54% and a specificity of 88%, generating a positive likelihood ratio of 4.5[1,7]. Discordant responses have a sensitivity of 100% but their specificity lapses to 65%, generating a positive likelihood ratio of 2.9. Although numerically different, likelihood ratios of 2.9 and 4.5 make little appreciable difference to clinical practice. Discordant responses and concordant responses provide effectively the same diagnostic confidence (post---test likelihood). However, diagnostic confidence is critically dependent on the prevalence of the condition being diagnosed (Figure 2). For a condition with a high prevalence, e.g. 60%, the diagnostic confidence for a discordant response is 81% and that for a concordant response is 87%. However, for conditions with a prevalence below 30%, diagnostic confidence plummets[1,3] (Figure 2). Comparative local anesthetic blocks are, therefore, applicable for the diagnosis of cervical zygapophysial	

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	joint pain, which has a prevalence between 50% and 60% [8]. They become less suitable for the diagnosis of lumbar zygapophysial joint pain, depending on what is accepted as the prevalence of this condition. Estimates have ranged from 40% to less than 10% or 5%[3,9,10]. Single diagnostic blocks, even if they provide complete relief, are not a dependable diagnostic tool, for they have an unacceptably high false---positive rate. Variously, the false--- positive rate has been measured as between 25% and 45%[6,7,11-16]. Such high values generate uncertainty as to whether a positive response is true or not. The practical utility of comparative local anesthetic blocks, and their limitations, can be illustrated in the following figures. Figure 3 shows the diagnostic confidence after single blocks, comparative blocks, and placebo--- controlled blocks, for conditions of different prevalence. After a single positive block, the diagnostic confidence is barely greater than the prevalence of the condition. Diagnostic confidence increases markedly if comparative blocks are positive, with little difference between the confidence generated by discordant or concordant responses. However, throughout, diagnostic confidence is affected by	

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	prevalence. Only for common conditions is diagnostic confidence high. Figure 4 shows the numbers of patients who would undergo radiofrequency neurotomy depending on if the indication was response to no blocks, a single block, comparative blocks, or placebo---controlled blocks. The graph shows that if no blocks are used, all patients undergo treatment. Those numbers reduce little if single blocks are the sole indication for treatment. Substantial reductions occur in the number of patients being treated if comparative blocks are applied, with those reductions being greater the less prevalent the condition being diagnosed. This figure underscores the utility of making a diagnosis using comparative blocks. It protects substantial numbers of patients from undergoing unnecessary and futile treatment. Figure 5 completes the sequence. It shows that the success rates of treatment increase substantially if comparative blocks (or placebo---controlled blocks) are used. Those success rates are greater in proportion to the prevalence of the condition diagnosed and treated. Conversely, success rates are adversely low if the prevalence is low. These principles have significant implications for the use of comparative local anesthetic	

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	blocks for selecting patients for treatment by radiofrequency neurotomy. The implications differ for cervical medial branch neurotomy and for lumbar medial branch neurotomy. 1. Bogduk N. On the rational use of diagnostic blocks for spinal pain. Neurosurgery Quarterly 2009; 19:88---100. 2. Curatolo M, Bogduk N. Diagnostic blocks for chronic pain. Scandinav J Pain 2010; 1:186---192. 3. Curatolo M, Bogduk N. Diagnostic and therapeutic nerve blocks. In: Fishman SM, Ballantyne JC, Rathmell JP (eds). Bonica's Management of Pain, 4th edn. Wolters Kluwer, Philadelphia, 2010. pp 1401---1423. 4. Lord SM, Barnsley L, Wallis B, McDonald GM, Bogduk N. Percutaneous radio---frequency neurotomy for chronic cervical zygapophyseal joint pain. N Eng J Med 1996; 335:1721---1726. 5. Bogduk N, Holmes S. Controlled zygapophysial joint blocks: the travesty of cost---effectiveness. Pain Med 2000, 1:25---34. 6. Barnsley L, Lord S, Bogduk N. Comparative local anaesthetic blocks in the diagnosis of cervical zygapophysial joint pain. Pain 1993; 55:99---106.	

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	7. Lord SM, Barnsley L, Bogduk N. The utility of comparative local anaesthetic blocks versus placebo---controlled blocks for the diagnosis of cervical zygapophysial joint pain. Clin J Pain 1995; 11:208---213. 8. Barnsley L, Lord SM, Wallis BJ, Bogduk N. The prevalence of chronic cervical zygapophysial joint pain after whiplash. Spine 1995; 20:20---26. 9. Bogduk N. Evidence---informed management of chronic back pain with facet injections and radiofrequency neurotomy. The Spine J 2008; 8:56-64. 10. Bogduk N. Lumbar medial branch neurotomy. In: Dagenais S, Haldeman S (eds). Evidence---Based Management of Low Back Pain. Elsevier, St Louis, 2012. pp 351---363. 11. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The false---positive rate of uncontrolled diagnostic blocks of the lumbar zygapophysial joints. Pain 1994; 58:195---200. 12. Manchikanti L, Pampati V, Fellows B, Bakhit CE. Prevalence of lumbar facet joint pain in chronic low back pain. Pain Physician 1999; 2:59---64. 13. Manchikanti L, Pampati V, Fellows B, Bakhit CE. The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or	

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	without adjuvant agents. Curr Rev Pain 2000; 4:337---44. 14. Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. BMC Musculoskeletal Disorders 2004; 5:15. 15. Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: an evaluation of prevalence and false---positive rate of diagnostic blocks. J Spinal Disord Tech 2007; 20:539---545. 16. Barnsley L, Lord S, Wallis B, Bogduk N. False---positive rates of cervical zygapophysial joint blocks. Clin J Pain 1993; 9:124---130.	
General	All of the studies on the efficacy of cervical radiofrequency neurotomy[1] and its effectiveness in clinical practice[2,3,4,5,6] have universally used positive responses to comparative local anesthetic blocks as the singular indication for cervical radiofrequency neurotomy. In all studies, the success rates for achieving complete relief of pain were not significantly different statistically from the indicative rate of 65%. In those studies that measured secondary outcomes, complete relief was consistently associated with restoration of function, and no need for further health care for neck pain[1,2,4,5].	Thank you for your comments.

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	Because the prevalence of cervical zygapophysial joint is high (50---60%), the diagnostic confidence provided by comparative local anesthetic blocks is high (ca 80%) (Figure 3); and about 65% of patients will be selected for treatment (Figure 4). The success rate encountered in practice (65%) is not significantly lower than that predicted by the models of comparative blocks (ca 75%) (Figure 4). There is no other literature that attests to any other diagnostic test, or response to test, being associated with complete relief of pain, or any other purported successful outcome. Therefore, there is no evidence upon which to base an indication for cervical radiofrequency neurotomy other than at least 80% relief of index pain from double---blind, comparative local anesthetic blocks. 1. Lord SM, Barnsley L, Wallis B, McDonald GM, Bogduk N. Percutaneous radio---frequency neurotomy for chronic cervical zygapophyseal joint pain. N Eng J Med 1996; 335:1721-1726. 2. McDonald GJ, Lord SM, Bogduk N. Long term follow---up of patients treated with cervical radiofrequency neurotomy for chronic neck pain. Neurosurgery 1999; 45:61-68. 3. Barnsley L. Percutaneous radiofrequency neurotomy for chronic neck pain: outcomes in a series of	

Report Section	Reviewer's Comments	SRI Response
	consecutive patients. Pain Medicine 2005; 6:282---286. 4. Speldewinde GC. Outcomes of percutaneous zygapophysial and sacroiliac joint neurotomy in a community setting. Pain Med 2011; 12:209---218. 5. MacVicar J, Borowczyk J, MacVicar AM, Loughnan BM, Bogduk N. Cervical medial branch radiofrequency neurotomy in New Zealand. Pain Med 2012; 13:647---654. 6. Govind J, King W, Bailey B, Bogduk N. Radiofrequency neurotomy for the treatment of third occipital headache. J Neurol Neurosurg Psychiat 2003; 74:88---93.	
General	In both of the benchmark studies of lumbar medial branch neurotomy[1,2] the singular indication was a positive response to comparative local anesthetic blocks. The earlier study used a relaxed criterion of 80% relief[1], whereas the later study required complete relief[2]. Both studies achieved the best results heretofore reported in the literature. The earlier study reported 60% of patients maintaining at least 80% relief for 12 months[1]. The later study reported complete relief of pain in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 13 months per treatment[2]. In isolation, a success rate of 55% or	Thank you. The studies cited are case series and did not meet the inclusion criteria. This issue has been discussed above (point 7).

Report Section	Reviewer's Comments	SRI Response
	60% may not seem impressive. However, this figure arises in two contexts. The first is that it applies to complete relief of pain. The second is that no other intervention of any kind, for any form of back pain, provides either such success or such a success rate. The reason for the modest success rate lies in the vicissitudes of comparative blocks for conditions of low prevalence (Figure 3). The prevalence of lumbar zygapophysial joint pain, based on complete relief of pain, is not known, but it appears to be low[3,4]. For a prevalence of 30%, Figure 3 indicates that the diagnostic confidence of comparative blocks is only about 65%, and Figure 5 indicates that the success rate of lumbar medial branch neurotomy should be of the order of 60%. Greater diagnostic confidence and greater success rates cannot be achieved unless the prevalence of lumbar zygapophysial joint pain is much greater than currently estimated, or unless placebo---controlled blocks are used to make the diagnosis[5]. Under those conditions, comparative local anesthetic blocks are the best available, most practical means of establishing an indication for lumbar medial branch neurotomy, if complete relief of pain is the desired outcome No other study has shown that complete relief of pain can be achieved using any	

Report Section	Reviewer's Comments	SRI Response
	indication other than complete, or near complete (at least 80%), relief of the index pain from comparative local anesthetic blocks. 1. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine 2000; 25:1270---1277. 2. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. Pain Med 2013; 14:639---645. 3. Bogduk N. Evidence---informed management of chronic back pain with facet injections and radiofrequency neurotomy. The Spine J 2008; 8:56--64. 4. Bogduk N. Lumbar medial branch neurotomy. In: Dagenais S, Haldeman S (eds). Evidence---Based Management of Low Back Pain. Elsevier, St Louis, 2012. pp 351-363. 5. Bogduk N. On the rational use of diagnostic blocks for spinal pain. Neurosurgery Quarterly 2009; 19:88-100.	
Conclusion (Page 24)	The International Spine Intervention Society has produced practice guidelines for the conduct of lumbar, thermal radiofrequency neurotomy [1] and cervical thermal	Thank you for your comments.

Report Section	Reviewer's Comments	SRI Response
	radiofrequency neurotomy [2], as well as guidelines for the conduct of lumbar medial branch blocks [3], third occipital nerve blocks [4], and cervical medial branch blocks[5], by which patients are selected for treatment by radiofrequency neurotomy. Based on the most rigorous studies using valid diagnostic techniques to select patients and using optimal techniques of radiofrequency neurotomy (RFN), • Over 50% of patients treated with lumbar RFN can expect to achieve complete relief of pain, accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their back pain, for a median duration of 15 months, with an interquartile range of 10-28 months[6]. • Some 70% of patients treated with cervical RFN can expect to achieve complete relief of pain, accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their neck pain, for a median duration of 17 months, with an interquartile range of 12-29 months[7]. • In the event of recurrence of pain, complete relief can be reinstated by repeating the treatment [6-7]. Such outcomes are unrivalled by	

Report Section	Reviewer's Comments	SRI Response
	any other intervention for back pain or neck pain. No other intervention has been shown to be capable of achieving complete relief of pain, accompanied by restoration to normal life, and cessation of health care for the condition treated. The available literature shows that these outcomes can be achieved. It also shows how they can be achieved. Surely the Washington State Health Care Authority would support practices that achieve such outcomes and would ensure that they are available to patients. 1. International Spine Intervention Society. Lumbar medial branch thermal radiofrequency neurotomy. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013:601---641. 2. International Spine Intervention Society. Cervical medial branch thermal radiofrequency neurotomy. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013:165---217. 3. International Spine Intervention Society. Lumbar medial branch blocks. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment	

Report Section	Reviewer's Comments	SRI Response
	Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013: 559---599. 4. International Spine Intervention Society. Third occipital nerve blocks. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013:141---163. 5. International Spine Intervention Society. Cervical medial branch blocks. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013:101---139. 6. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. Pain Med 2013; 14:639---645. 7. MacVicar J, Borowczyk J, MacVicar AM, Loughnan BM, Bogduk N. Cervical medial branch radiofrequency neurotomy in New Zealand. Pain Med 2012; 13:647---654.	

Lee Glass, MD, Associate Medical Director Washington State Labor and Industries

Report Section	Reviewer's Comments	SRI Response
General	It is stated on page 54 of the Draft Evidence Report that "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." The two considerations are asserted to be: a) the appropriate selection of patients, and b) the technical effectiveness or precision of the procedure. It would seem that there is actually a third major consideration – whether the pain that is the subject of the assessment and treatment has become centralized. Pain that is perceived to arise from a facet joint, but that has become centralized will not be successfully treated by the interruption of afferent nerve fibers from the facet joint, just as the pain of a diabetic foot condition may not be remedied by amputation of the involved foot. Presumably, centralization of pain is at least partially dependent upon the passage of time: one would not expect facet-mediated pain to become centralized in a single day, though it might, over a longer period.	Thank you for your comment.
KQ2, KQ4	The question that these observations prompt is whether in the assessment of the effectiveness of facet neurotomy to relieve pain, any of the studies controlled for the duration of time that the patients involved in the study had reported having the pain that was the subject of inquiry. If any studies controlled for the duration of pain, did the length of time that pain was present influence the outcome from the facet neurotomy?	One RCT (van Wijk) provided low quality evidence that duration of pain (2-5 years versus >5 years) did not modify the effect of RF neurotomy versus sham neurotomy (lumbar spine) in terms of two different "success" outcomes (KQ4; see also Tables 76 and 77). Of the remaining studies included in KQ2 to determine the comparative efficacy and effectiveness of facet neurotomy versus other treatments,

Report Section	Reviewer's Comments	SRI Response
		only one controlled for duration of pain. Van Kleef controlled for duration of pain (together with gender, age, pretreatment pain intensity, and Likert scores after diagnostic block). Controlling for these variables did not affect the results: pain (VAS) and function (ODI) outcomes were significantly better following neurotomy versus sham according to both the adjusted and unadjusted analyses. No difference between treatment groups was found for disability (Waddell) according to both analyses.
General	I anticipate that one response to my concern from the physicians who perform these procedures is that were pain centralized, the medial branch blocks should have no effect. However, it is not as clear to me as it appears to many others that one can be certain that a positive response to a medial branch block means that a facet problem has been proven. The medial branch nerve carries afferents not only from the facet joint, but from tendons, ligaments and the multifidus muscles. It is at least possible that pain from some structures innervate by the medial branch nerves may be centralized, while pain from other structures innervated by the same nerve has not become centralized. In any event, I think that centralization is an issue that should at least be considered.	Thank you for your comment.

References cited in responses to comments received

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INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate? Yes
- Topic of assessment is important to address? Yes
- Public policy and clinical relevance are well defined? Yes

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient? No. See attached comments.

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue? Yes
- Key questions clearly defined and adequate for achieving aims? Yes.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate? Yes
- Criteria for the inclusion and exclusion of studies is appropriate? No. See attached comments.
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained? Yes.
- Data abstraction and analysis/review are adequate? No. See attached comments.

RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate? No. Key clinical information within cited studies not included. See attached comments.
- Key questions are answered? Yes.
- Figures, tables and appendices clear and easy to read? Yes.
- Implications of the major findings clearly stated? Yes.
- Have gaps in the literature been dealt with adequately? No. See attached comments.
- Recommendations address limitations of literature? No, as full relevant literature analysis was not performed. See attached comments.

CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid? In part yes, in part no. See attached comments for detailed review of each key question in which conclusions were not valid and an alternate synopsis of the literature is presented with alternate conclusions provided.

OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized? Yes.
- Are the main points clearly presented? Yes.
- Is it relevant to clinical medicine? In part, but there are significant gaps in the clinical understanding of the technology and relevant literature. See attached comments for detail.
- Is it important for public policy or public health? Yes.

QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Fair to Good

See the following expanded comments-

Radiofrequency Neurotomy of Facet Joint Pain:

Key Expert Considerations and Review of Draft Report

Prepared by Paul Dreyfuss, MD

Draft Review Summary:

- Spectrum did not use the peer expert considerations as a framework to evaluate the literature.

- Appropriate selection of patients for RF is via medial branch blocks and RF should ideally be performed with higher volume lesions parallel to the target nerve.

- Spectrum did not appreciate inappropriate (invalid) from appropriate selection methods for RF or anatomically sound from non-anatomically (invalid) sound RF techniques.

- Spectrum pooled invalid and valid RCTs to make inappropriate negative conclusions regarding the efficacy of RF neurotomy.

- Spectrum ignored all prospective trials from the evidence report that have used valid selection techniques for RF and valid RF techniques.

- The valid RCTs underscore that the effects of RF are not attributable to placebo, but do not depict the true effectiveness of the procedure due to their methodological limitations.

- The available valid prospective trials depict the true effectiveness of RF neurotomy.

- When valid selection of patients occurs with controlled medial branch blocks with ≥80% relief and anatomically sound lesioning techniques are used, as in the highest quality valid prospective trials, then:

  60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a minimum duration of 10 months

  54-74% of patients with C3-4 to C6-7 facet pain can be pain free for a minimum of 10 months and

  53-60% of patients with lumbar facet pain are able to obtain 80-100% relief of pain for up to 1 year.

- No other non-surgical treatment options in the cervical or lumbar spine can rival the results of RF neurotomy for axial cervical or lumbar spine pain.

- The procedure is safe and if pain returns repeat RF neurotomy can reinstate provide pain relief in the vast majority.

Spectrum Research requested that I submit expert background considerations in preparation of their report. The goal was to provide a clinical framework to better understand appropriate selection of patients for radiofrequency (RF) neurotomy and technical considerations in the clinical performance of Radiofrequency (RF) neurotomy. Furthermore, insights into how to clinically interpret the literature and avoid common pitfalls were discussed. Several key references to illustrate these points were provided to Spectrum Research. However, despite my comments being published in the draft report and despite statutory requirements, they were not read, acknowledged nor used in any capacity in preparation of the draft report. In light of such, my initial background comments will be repeated and expanded upon to provide a framework to better understand the technology in question and to highlight important deficiencies in the report generated by Spectrum Research.

Key Concept:

The ability of cervical and lumbar medial branch radiofrequency 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. (6)

The literature, including randomized controlled trials, is replete with examples of both poor patient selection and invalid technical execution of the procedure. However, there are key prospective trials that have used validated selection criteria to identify those with the target condition and have used anatomically correct validated radiofrequency neurotomy methods to achieve technical effectiveness of the procedure. It is these later trials that depict the value of the procedure. The former trials are best interpreted as the outcomes expected when less rigorous selection and treatment methods are employed. Indeed, authors of these flawed studies have acknowledged this fact.

Patient Selection:

Dr. Shealy discovered medial branch radiofrequency neurotomy of the zygapophyseal (aka 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 were selected on the results of pain reduction following intra-articular (inside the joint) facet injections. These injections, however, have been shown to have poor anatomic target specificity and incur a higher rate of false positive results than medial branch blocks. (51) 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. (2,19,28) 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, aka 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. (34,39,40,41,42,51) 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 (34), 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 neurotomy 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.

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 been an evolution in the understanding of how to best perform medial branch radiofrequency neurotomy. This is due to an improved understanding of 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. (9) 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. (24,26,31) 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.

Evaluation of the Literature:

It should be apparent that not all medial branch radiofrequency neurotomy 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 cited by Spectrum Research was 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.

Many trials, including randomized controlled trials, have used such improper methods largely as a means to determine the efficacy of community standards at the time. (22,25,32,54,57,60) As noted above, such studies only hold value to demonstrate what results are to be expected when patients are not appropriately selected and the radiofrequency technique is not appropriately performed.

It is widely accepted that evidence based medicine is not restricted to RCTs or comparison trials. As Dr. David Sackett, the father of evidence-based medicine, stated, "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." This definition has since been adopted by major organizations, including the Cochrane Collaboration and the Centre for Evidence Based Medicine. Sackett went on to state, "Evidence based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions." (49) As such, an evidence review of facet joint RF neurotomy should include valid prospective RF neurotomy trials in addition to RCTs or comparison trials, especially given the methodological flaws outlined above. Indeed, in the case of RF neurotomy, one could argue that the well performed prospective trials provide better external evidence than the poorly performed RCTs. (1,8,17,20,23,24,23,43,44,45,48,50) The inclusion of prospective trials, in addition to randomized controlled trials and comparison trials, has been accepted in other evidence reports used by the HTCC to make informed decisions.

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%." (21)

Accordingly, in evaluating the RF neurotomy literature, the percentage of patients obtaining a minimum of 30% reduction in pain (or a VAS decrement of $\geq$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. (21)

IMMPACT recommended that mean data reporting not be used as a sole or primary indicator of success. (21) 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.

Although secondary outcome measures are reported in various studies, there is inconsistency between trials as to which tools are reported. For ease of rapid comparison between studies and to prevent an even longer peer review response, in my comments on the referenced trials I will largely discuss only the primary indication of success of RF neurotomy, which is pain reduction.

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.

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 a meaningful lesion. This method of energy delivery is not the conventional method of thermal medial branch radiofrequency neurotomy under primary assessment by the HCA.

In regards to cervical radiofrequency neurotomy, there are unique anatomical and procedural considerations when targeting the C2-3 facet joint vs. other cervical levels. Accordingly, studies that have largely or only assessed C2-3 facet neurotomy (third occipital neurotomy) (1,24,44) should be evaluated separately from those studies in which C3-4 to C6-7 facet neurotomy was performed.

Comments Regarding Spectrum's Draft Report:

The goal of my subsequent comments will be to provide a pragmatic, clinically oriented, and informative narrative with key data that is highly relevant to the clinician rather than provide additional data tables/figures or lengthy article reviews that are available in the draft report and can distract from the key message.

I will try to highlight errors of clinical interpretation of the current literature, amend the cited literature that provides additional value in understanding the true effects of RF neurotomy and illuminate key considerations in regards to optimal selection of patients for RF neurotomy and optimal technical performance of RF neurotomy where appropriate. I will provide summary statements when multiple studies are discussed in each section to further consolidate the data and provide and provide easy to understand conclusions.

I will comment on the draft report by first addressing errors in the background information then address the executive summary of the key questions.

In the draft report on page 15 it states, *"Diagnostic medial branch blocks or intra-articular injections involve injection of local anesthetic into the facet joint(s) that are believed to be the source of the pain."*

Comment: This is not accurate. Intra-articular injections involve placing anesthetic into the facet joint itself, but medial branch blocks are performed over/around the medial branch nerves, not within the facet joints.

On page 16 it states, *"In the sham surgery, a radiofrequency needle is inserted into the joint but the electric current is not turned on".*

Comment: This is inaccurate. The radiofrequency needle is never inserted “into” the facet joint for any reason. For sham treatment, the needle is placed on/over the medial branch nerve, which lies outside the facet joint, but the current is not turned on. For active treatment, the needle is placed on/over the medial branch nerve, which lies outside the facet joint, and the current is turned on.

On page 16 it states, *"Facet injections and medial branch blocks include injecting a corticosteroid plus local anesthetic into the facet joint and medial branch nerves, respectively."*

Comment- this is inaccurate. No corticosteroid is injected for a diagnostic medial branch block procedure. Medial branch blocks are not performed via injection “into” the target nerves but rather around the target nerves.

Within the background information it is stated that:

"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*

- *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:
- *Prior radiofrequency treatment*
- *Previous back surgeries"*

Comment: It would be more appropriate to list indications for facet neurotomy as:

- Adults with chronic back or neck pain of at least 3 months duration who have moderate to severe pain that limits function and for which the pain has not responded to alternate non-surgical care which may include, but is not limited to, physical or manual therapy, medications, rest and injections.

- Positive response to diagnostic medial branch blocks (≥ 80% relief of index pain).

- Prior RF neurotomy and prior spinal surgery are not contraindications to RF neurotomy.

    - It is important to understand that the medial branches regenerate after time, and the pain will typically return. At this point, repeat RFN is appropriate and efficacious

    - Spinal surgery does not preclude the facet joints from becoming pain generators. Indeed, diagnostic blocks and medial branch neurotomy at levels not involved in a fusion have potential for positive response. Additionally, medial branch blocks and RF neurotomy can be performed at the levels of prior decompression surgery without fusion as well.

In the results section of the executive summary the following is the summary statement regarding using quality evidence: *"The following summaries of evidence for primary findings have been based on the highest quality of studies available. RCTs and comparative nonrandomized controlled trials are the focus for this summary. Additional information on lower quality studies is available in the report."*

Additionally it is stated, *"Eligible studies evaluated facet neurotomy utilizing a randomized or cohort study design." Case series were only considered for Key Question 2b (effectiveness of repeat neurotomy) and Key Question 3 (safety)."*

Comment:

RCT/comparative trials provide a higher level of evidence, but other types of prospective trials should not be excluded in the true practice of evidence based medicine and are of value. (49) The 'Lower quality studies' cited by Spectrum were not available in the report, however, they will be referenced/discussed below.

Key questions/executive summary:

Excerpts from the report will continue to appear in italics with my comments to follow.

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)

No evidence for any of the following:
Diagnostic blocks verses physical examination on the lumbar spine

Comments: There is only one study that made such a comparison. This prospective study compared physical examination to a single diagnostic medial branch block (mbb). (13) 51 pts were selected for RF on clinical grounds alone and 50 underwent single mbbs (≥50% relief) of which 19 underwent RF. Success was defined at ≥50% relief at 3 months post RF. In those without diagnostic blocks there was a 33% success and in those with a single medial branch block success was 39% with the difference not statistically significant.

This singular study would suggest there is no added value to the use of a single medial branch blocks with ≥50% relief over selecting patients on clinical grounds only. However, realize the outcomes in this study are marginal as both selection techniques are limited by inclusion of a high percentage of patients without the index condition owing to the high false positive rate of physical examination only or single medial branch blocks vs. more specific and appropriate use of controlled (dual) medial branch blocks in which reported outcomes are substantially better as discussed below.

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

Comment: There are no trials that have compared physical examination to diagnostic blocks in the thoracic or cervical spine or diagnostic block versus radiological examination in the cervical, thoracic or lumbar spine.

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

No evidence for any of the following:
Other diagnostic block comparators in the lumbar spine or cervical or thoracic spine.

Comment:

There is only one study that made such a comparison. (4) In the Birkenmaier study patients were selected for cryodenervation based on a positive response to either a diagnostic medial branch block or peri-capsular block. Cryodenervation is not radiofrequency neurotomy. Cryodenervation is a procedure in which compressed gas is circulated through a cannula, lowering the temperature of the cannula tip to near -90C. This very cold needle tip is placed on or near a target nerve and the nerve is

frozen, destroying part but not all of the nerve. This procedure is expected to last 3-6 months. Post cryodenervation as measured at 6 weeks and three months the difference in mean improvement of pain between groups was significant favoring medial branch blocks, but this difference was lost at 6 months. At 6 months, the effects of cryodenervation would be expected to largely be lost based upon its mechanism of action. This study suggests there is value of a single medial branch block over pericapsular blocks in the selection of patients for cryodenervation only.

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:

No evidence for any of the following:
Single versus controlled diagnostic blocks in the lumbar spine or the thoracic or cervical spine

KQ1d: Degree of pain reduction from diagnostic block (i.e., pain relief of ≥ 30% versus ≥ 50%, or ≥ 50% versus ≥80%): Note- as not stated otherwise assumes in relation to either single or controlled blocks/

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.

Comment:

KQ1c and KQ1d are best responded to together as there is cross over between studies in relation to these questions:

Cohen performed a retrospective audit comparing the selection criteria of 50% vs. 80% relief criteria following single medial branch blocks vs. success post-RF defined as ≥50% relief at 6 months. The RF technique was reasonably anatomically sound. Of 145 patients selected using ≥50% relief (50-79%) (145 pts) 52% had success. Of 117 patients selected using ≥80% relief (80-100%) 56% had success. The difference was not significant. (11)

Cohen performed a second prospective trial to address if there was a percentage of relief cut-off following single medial branch blocks in which there is a greater success post RF neurotomy. 61 patients were selected for RF following single mbbs. The RF technique was reasonably anatomically sound. Successful RF outcome (≥50% reduction in pain) at 3 months was correlated with percentage of relief over 50% following single mbbs . There was no statistically significant difference between the percentage pain relief obtained from single diagnostic blocks among those patients who had a successful RF denervation, and those individuals who failed RF treatment. (12)

In a retrospective analysis of 211 consecutive patients Derby evaluated cut-off values that corrected with improved RF outcomes in those following selection for RF with both single and dual medial branch blocks. (15) Those with at least 50% relief proceeded to RF with an anatomically sound lesioning technique. Success was defined at ≥50% relief of pain at 6 months with ≥50% improvement in activity level and no other physician visits required. In the single medial branch block (mbb) group, 80% cutoff predicted favorable outcome in two criteria: patient satisfaction and improvement in activity level. Using the 80% cutoff value, 58% (11/19) of patients reported 50% or greater pain relief for 6 months or longer with an average of 10.7 months.

At the ≥70% cutoff value in a double-block group, 91% (10/11) of patients reported 50% or greater pain relief for ≥6 months of duration, with an average of 9.8 months. Of interest, no patient in the dual mbb group reporting less than 70% pain relief following mbbs reported satisfactory pain relief following RF neurotomy.

Eighteen of 38 patients (47.4%) in the single-block group reported ≥6 month pain relief with a mean duration of relief of 9.9 months. In the double-block group, 10 of 13 patients (76.9%) reported ≥6 months pain relief with the mean duration of relief of 9.8 months. The difference was significant. Derby concluded dual (comparative) diagnostic medial branch blocks best predict medial branch neurotomy outcome compared with a single block due to the high false-positive rate of a single MBB. (15)

In a second retrospective cohort study by Derby using anatomically sound RF lesioning techniques it was found that patients who were required to achieve a higher pain threshold (≥70%) following dual medial branch blocks were significantly more likely to have ≥50% relief following RF neurotomy than those who had lower levels of pain relief (50-79%) following dual medial branch blocks. (16)

Additionally, in this study 11 of 12 patients (91.7%) in the double-block group reported ≥3 months of ≥50% pain relief which was a statistically higher percentage than the single-block group where 52.8% (19 out of 36 patients) had ≥50% pain relief. (16)

Cohen performed a prospective study of 151 selected for RF on clinical grounds alone, single medial branch blocks with ≥50% relief and controlled mbbs with >50% relief. A reasonable anatomically sound RF technique was used. Success was defined at ≥50% relief assessed at 3 months post RF. In those who actually received RF there was a 33% success rate on those without diagnostic blocks vs. 39% in those selected via a single medial branch block vs. 64% in those selected with controlled medial branch blocks. (13)

Summary:

The studies are conflicting regarding outcomes in those with >80% relief from single medial branch blocks vs. 50% relief. However, the evidence is consistent in these studies in that controlled medial branch blocks are the most predictive of future success from RF neurotomy over other selection methods.

Collectively, these studies show that in those selected using controlled medial branch blocks a higher percentage of patients are expected to have a successful RF (≥50% relief occurred in 64-91% at 3 months, 77% at 6 months) vs. those selected with single medial branch blocks (≥50% relief in 39-52% at 3 months, 47% at 6 months) or those selected on clinical grounds only (≥50% relief in 33% at 3 months).

If all prospective RF studies that report percentage of patients with at least 50% relief of pain are assessed in regards to selection criteria, success and duration of success an interesting trend is readily apparent. The worst results are seen in those selected on clinical grounds alone (>50% relief at 3 months in 33%). (13) Equally poor results are seen in those selected with single intraarticular blocks (0-33% with >50% relief). (32,60)

In the trials in which patients were selected with single uncontrolled MBBs (>50% relief): 39% had ≥50% relief at 3 months (13) and 20-55% of patients had ≥50% relief at 12 months post RFN. (8,56,58)

In the trials selecting patients with controlled medial branch blocks and reasonably sound or sound RF lesioning techniques, 57-60% were able to obtain ≥50% relief of pain at 6 months, 59% of pts had ≥75% relief of pain at 6 months, 42% had 100% relief of pain at 6 months, and 43% were able to obtain >50% relief of pain at 1 year. (20, 23, 53)

In the trials selecting patients with controlled medial branch blocks (≥80% relief) and ideal RF lesioning techniques 53-60% of patients were able to obtain 80-100% relief of pain at 1 year. (18,45)

No evidence for any of the following:
Thoracic or cervical spine

Comment: Although there were no studies that looked at the value of selecting patients for RF on clinical grounds vs. single medial branch blocks vs. dual medial branch blocks and at various cut-off values of pain relief from the diagnostic blocks there is information available across prospective studies that reported ≥50% or other categories of pain relief following RF in the cervical spine.

In those selected on clinical grounds only for RF, results are no better than sham treatments. (25,54,57)

Using 50-80% relief as the cut-off following dual medial branch blocks and reasonably anatomically sound or anatomically sound RF lesioning techniques 62-68% obtain ≥75% pain relief at 6 months (52, 53) and 74% obtain ≥50% pain relief at 12 month follow-up. (50)

When maximally specific selection of patients is undertaken (i.e. minimum of dual diagnostic blocks with 80-100% relief of pain) with ideal anatomically sound RF lesioning techniques, 54-86% of patients can be rendered pain free for a minimum of 10 months. (1,24,37,44)

KQ1e: Unilateral versus bilateral diagnostic block
No studies were identified which met our inclusion criteria.

Comment: Agree, no studies exist. There is no justification for bilateral medial branch blocks or neurotomy when there is unilateral pain. Bilateral procedures are only appropriate in the context of bilateral pain.

KQ1f: Single- versus multi-level diagnostic block
No studies were identified which met our inclusion criteria.

Comment: Agree, no studies exist. Realize that each facet joint is innervated by two medial branch nerves. Thus by definition, although one joint/level may be targeted two nerves are targeted. Clinically, more than one level of facet pain can exist for which investigation and treatment would be indicated.

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. 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.

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

Comment:

The review by Spectrum has concluded that there is no efficacy or effectiveness of lumbar medial branch neurotomy. Their conclusion is invalid and erroneous because this publication lacked discrimination on two very important counts.

First, they did not distinguish between studies that used flawed or invalid techniques and those that used correct technique. They admitted two RCTs that used the discredited Shealy RF technique (22) or a modification of it (17,32) and a third RCT (60) whose technique was ill-defined and as depicted in their paper would fail to reliably lesion the target nerves.

A second factor confounding Spectrum's conclusions involves the indications used for RF neurotomy. A treatment is not likely to work if the patients treated do not have the condition for which the treatment was designed. If less than stringent criteria are used for diagnosis, patients with false-positive responses to diagnostic tests are unlikely to respond well, if at all, to treatment. Consequently, studies that selected their patients by less than optimal criteria (intra-articular or peri-articular blocks) will have less than impressive success rates, even if they used a correct RF technique. The same three RCTs that were admitted by Spectrum despite the use of non-anatomically sound RF lesioning techniques also used invalid selection criteria (intra-articular blocks) to determine candidates for the procedure.

The effects of poor indications and incorrect procedural technique on success rates are clear when individual studies are examined in detail but such were not appreciated by Spectrum. A more discriminating review found that, if only those studies (RCTS and prospective trials) are reviewed that used reasonable technique, no study has found evidence against the effectiveness of lumbar medial branch neurotomy, and all provided various grades of evidence in support of the procedure. (6) The details of such will be reviewed.

<u>Invalid RCTs that were admitted as negative evidence for lumbar medial branch neurotomy:</u>

LeClaire enrolled 70 pts with >3 mos LBP with “significant relief for at least 24 hrs during the week” after a single intra-articular facet joint injection. (32) 36 subjects were randomized to a modified “Shealy RF” without further technical details and 34 received placebo RF. Baseline, 4 weeks and 12 weeks post treatment VAS, Roland-Morris, Oswestry and were performed. At 12 weeks in the active group the VAS was 0.5% worse and 7% better in the placebo group. Leclaire stated in a subsequent editorial that "The present study’s negative results exemplify the need for: 1) utilization of controlled medial branch blocks to select those that have pain emanating from the zygapophysial joints, and 2) utilization of meticulous technique to adequately coagulate the targeted nerves." (17)

van Wijk selected subjects via a single 2 level intra-articuar facet injections if there was ≥50% relief 30 minutes post injection. (60) 81 subjects were enrolled for randomization. 40 received active RF and 41 sham RF in a double blind fashion. A non-anatomically sound RF lesioning technique was used. Follow-up was at 3, 6, 9, and 12 months. Outcome tools included VAS, Global perceived effect, analgesic intake, physical activities scale and SF-36. 33% of the active group had a ≥50% pain reduction vs. 34% in sham RF which the difference non-significant.

van Wijk produced a subsequent editorial where it was noted "as stated in our article, we designed the study to evaluate if common practice in our community, at that time, had efficacy. In our study, less rigorous selection of patients was undertaken to more closely represent community practice." (59) By definition this study was not defined as an efficacy study under ideal conditions. Van wijk also stated "future research should be directed toward improvement of a more ideal selection of patients for RF using medial branch blocks, more robust RF lesion techniques, and use of psychological profiling of patients to select more ideal candidates for treatment and that "we need to be more particular as to when and how RF-facet denervation is performed, but not remove it as an option. (59)

In the study by Gallagher patients were selected based upon a "good" anesthetic response to an intra and peri-articular facet joint injection. (22) Patients were randomized into active and sham RF groups. There were 18 subjects in the active group and 12 in the placebo group. RF was performed by the Shealy method. Patients were assessed at 1 and 6 months post treatment using the VAS and McGill pain questionnaire. Mean VAS in the active RF group was 58 pre-RF and 44 six months post-RF. Mean VAS was 68 pre-sham RF and 70 six months post-sham RF. The difference between groups was significant. Categorical pain relief data was not reported. The mean McGill outcomes also showed significant difference between groups at 6 months favoring the active group. Although the results were significant, the inclusion criteria and RF technique utilized were invalid.

Valid RCTs showing evidence for the efficacy of lumbar medial branch neurotomy:

VanKleef:

VanKleef selected 31 subjects with chronic low back pain on the basis of ≥50% relief from single medial branch blocks. (58) 15 were randomized to active RF and 16 to sham L3-5 medial branch RF neurotomy. Primary outcome measure were VAS and Oswestry. The mean baseline to 8 week f/u pain reduction was 46% in the active and 8% in the sham group which was statistically significant. Global perceived effect and Oswestry showed significant improvement in the active vs. sham group. 46% of the active and 12% of the sham pts obtained ≥50% pain reduction at 1 year which was also significant. (58)

As single medial branch blocks were performed many would have been included on the basis of false-positive responses; and therefore, the success rate of treatment would have been compromised. The RF lesioning technique was fairly anatomically sound as the RF needles were placed more less than ideally parallel to the target nerves. Therefore, duration of relief would be expected to be compromised. All of these expectations emerged in the results as only a relatively small proportion of patients had successful and enduring relief. Nonetheless, the success rate in those patients who had active treatment was significantly greater statistically than the success rate in those who underwent sham treatment showing the effects of the treatment cannot be attributed to a placebo effect. (58)

Nath:

A later placebo-controlled trial carefully selected patients by using comparative diagnostic medial branch blocks with $\geq$80% relief of their index (not total body) pain as assessed by a 6 hour self reported pain diary. Patients had to have longer relief with the bupivicaine vs. lidocaine medial branch blocks . (47) 40 subjects were selected; 20 in the active arm and 20 in sham RF arm. Anatomically sound RF lesioning techniques were used. Outcome were assessed at 6 months. Primary outcome measures were global perception of improvement and visual analogue scale for generalized pain, back and leg pain. Secondary outcome tools include range of motion, analgesic use and quality of life variables.

In terms of the patients' own global assessment, the active treatment group improved by 1.1 Units whereas the placebo group improved by only 0.3 Units. The difference in improvement between groups was 0.8 U and was statistically significant.

Generalized pain was reduced in the active group by 1.9 U on an 11-point VAS scale, but by only 0.4 Units in the placebo group. The difference in reduction between groups was 1.55 and was statistically significant.

Back pain was reduced in the active treatment group by 2.1 Units, and referred pain to the leg was reduced by 1.6. In the placebo group, the corresponding figures were 0.7 Units and 0.13. The differences in reduction between groups were statistically significant . Mean back pain improved from 5.98 to 3.88 (35% decrease) in the active group vs.4.38 to 3.68 (16%)in the sham group.

Secondary measurements (movement, tenderness, analgesic use, quality of life) all showed statistically significant improvement in the active group. However, this study was conducted in patients who had other chronic pain problems, such as radicular pain. Therefore, a success rate for the elimination of pain could not be determined and the magnitude of effect from the RF was lessened in this challenging patient population. (47)

Tekin:

A comparison study sought to compare the efficacy of thermal radiofrequency neurotomy with that of pulsed radiofrequency. It included a control group receiving sham neurotomy in which no lesion was generated. (55)

The study enrolled patients who obtained at least 50% relief of pain following single diagnostic medial branch blocks. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. There were 20 patients in the control group, 20 in the pulsed RF

group and 20 in the continuous thermal RF group. Anatomically sound RF lesioning techniques were used.

For the relief of pain, improvement in disability, and reduction in use of analgesics, thermal radiofrequency was significantly more effective than sham treatment immediately after treatment, at six months, and at one year. At 1 year f/u the continuous RF group had a statistically significant 65% mean VAS reduction (6.5 to 2.3) vs. the placebos group's 43% (6.8 to 4.3) VAS reduction. At 1 year f/u the mean Oswestry disability index improved 29% in the continuous group vs. 16% in the sham group. At 1 yr , 95% of the control vs. 40% of the thermal RF (active) groups were using analgesics. (55)

Although showing superiority of active treatment over sham treatment, this study did not report data from which success rates for reduction of pain could be calculated. However, 65% of patients treated with active medial branch neurotomy reported excellent satisfaction with treatment, compared with 20% of those who underwent sham treatment. (55)

Summary:

Collectively, these three controlled studies provide sound evidence that medial branch thermal radiofrequency neurotomy has effects greater than those of placebo. Therefore, the outcomes of medial branch neurotomy cannot be dismissed as those of a placebo effect. Those controlled studies, however, were not designed to determine the long-term success rate of medial branch neurotomy, but other prospective studies were so designed.

Prospective Non-Randomized Trials:

The effectiveness of lumbar medial branch radiofrequency neurotomy has been demonstrated by eight prospective non-randomized trials. All such trials were wrongfully excluded from the draft report by Spectrum. Such trials provide valuable insight into the effectiveness of lumbar RF.

The original benchmarking prospective study used comparative local anesthetic blocks to select patients with chronic low back pain. To be eligible for treatment, patients had to report at least 80% relief of their back pain following controlled medial branch blocks. The study used ideal anatomically sound RF lesioning techniques. 15 highly selected patients were enrolled. There was a 76% mean decrease in pain at 12 months. It found that 60% of patients maintained at least 80% relief of their pain at 12 months follow-up, and 80% of patients maintained at least 60% relief at 1 year. Relief of pain was associated with reduction of disability. There was a 90% technical success of the procedure as evidenced by normal pre-RF segmental multifidus EMG and a post RF segmental multifidus EMG showing denervation at the targeted RF levels. (17)

Subsequent Prospective Trials Using Single Medial Branch Blocks:

Burnham selected patients on the basis of at least 50% relief of pain following both an intra-articular block and a single medial branch block. Reasonably anatomically sound lesioning techniques were used. 39% (25 – 53%) of 44 patients achieved at least 50% relief of pain at six months after treatment, accompanied by significant improvements in disability, and reduced analgesic requirements. (8)

Tome´-Bermejo, selected 86 patients by ≥50% relief of pain following a single medial branch block. A reasoably sound RF lesioning technique was used. 66% had ≥50% relief of pain at 6 months and 50% had ≥50% pain relief at 1 yr. (56)

Subsequent Prospective Trials Using Controlled Medial Branch Blocks:

Gofeld selected patients on the basis of at least 70% relief of pain following comparative medial branch blocks. (23) During a 10-year period, 209 patients were treated by lumbar medial branch neurotomy, and 174 were reviewed. Anatomically sound lesioning techniques were used At six months after treatment, 35% (29 – 41%) of patients had at least 50% relief of pain, and a further 22% (16 – 28%) had 80% relief of pain for a total of 57% achieving significant relief. At one year follow-up 43% of patients had ≥50% relief. The proportions of patients with enduring relief decreased between six months and two years after treatment, but the median duration of relief was 12 months. (23)

Macvicar enrolled patients only if they had complete relief of pain following controlled diagnostic blocks. (45) A total of 106 consecutive patients were recruited in two neighboring practices. Ideal anatomically sound lesioning techniques were used. Repeat treatment was allowed if pain recurred. The study reported the success rates achieved and the duration of success over a five-year period. Success was defined as complete relief of pain for at least six months, accompanied by restoration of all desired activities of daily living, and no further need for health care for the pain for which patients were treated. (45)

The two practices achieved success rates of 58% (44-72%) and 53% (40-66%) respectively, i.e. complete relief of pain, restoration of activities, and elimination of other health care. Following the first radiofrequency neurotomy, the median (interquartile range) duration of relief was 15 (10 – 28) months in Practice A, and 15 (10 – 29) months in Practice B. When repeat treatments were assessed there was a median duration of relief of 13 months per treatment. (45)

Roy selected 34 patients who had ≥80% reduction of pain following controlled blocks. A reasonably anatomically sound RF lesioning technique was used. Using the numeric pain rating scale, there was a mean reduction in pain of 62% at 6 months, and 60% at one 1 year. (48)

Speldewinde selected 151 patients with controlled medial branch blocks with 80% relief of index pain. Anatomically sound RF lesioning techniques were used. At 6-36 months 59% of pts had ≥75% relief of pain and 42% had 100% relief of pain. (53)

Dobrogowski selected 45 consecutive patients by “significant pain relief after two controlled diagnostic blocks”. A fair anatomically sound RF lesioning technique was used. 60% of patients had ≥50% relief of pain at 6 months. Percentage of pts with >75% or 100% relief not reported. (20)

Summary:

In the trials selecting patients with controlled medial branch blocks and reasonably sound or sound RF lesioning techniques 57-60% were able to obtain ≥50% relief of pain at 6 months, 59% of pts had ≥75% relief of pain at 6 months, 42% had 100% relief of pain at 6 months, and 43% were able to obtain >50% relief of pain at 1 year. (20,23, 53)

In the trials selecting patients with controlled medial branch blocks (≥80% relief) and ideal RF lesioning techniques 53-60% of patients were able to obtain 80-100% relief of pain at 1 year. (18,45)

All studies using appropriate selection of patients (controlled medial branch blocks) and appropriate lesioning techniques have consistently shown positive benefits. Where the data differs is with respect to precise selection criteria, RF technique and definitions of success. No other non-surgical treatment in the lumbar spine can rival the degree and duration of relief obtained from lumbar medial branch radiofrequency neurotomy for the treatment of chronic lumbar facet pain.

RF Neurotomy versus Sham Neurotomy: Efficacy in the cervical spine

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

Comment:

Efficacy:

A randomized, double-blind, placebo-controlled trial was conducted on 24 patients, who had been diagnosed as having cervical zygapophysial joint pain on the basis of placebo-controlled diagnostic medial branch blocks. (38) The criterion for eligibility was complete relief of pain after active blocks with each of two different local anesthetic agents (lidocaine 2%, and bupivacaine 0.5%), and no relief when normal saline was used. Twelve patients were allocated to undergo genuine medial branch radiofrequency neurotomy. Anatomically sound lesioning techniques were used. Twelve were allocated to undergo exactly the same procedure, for exactly the same duration (three hours), except that no current was delivered to the electrode. The criteria for a successful outcome were complete relief of pain, associated with restoration of activities of daily living, and no need for continuing health care for neck pain.

The results showed unequivocally that the therapeutic effect of radiofrequency neurotomy was not a placebo. In the control group, the median time for recurrence of pain was eight days. In the index group the median duration of relief was 263 days. At 6.5 months 8% of the controls and 58% of the active treatment patients had a successful outcome as defined above. These findings were significant.

Although the sample sizes in this study were small and have been criticized as limiting the value of this study, the difference in outcome was so great that the study had 100% power to exclude a placebo effect. (38)

There are no other RCTs for cervical facet pain except 3 invalid trials (due to both patient selection and RF technique) in those with cervicogenic headache. (25,54,57) These will be discussed under evidence for RF neurotomy for cervicogenic headache and specifically RF for C2-3 facet pain.

Effectiveness:

The effectiveness of cervical medial branch radiofrequency neurotomy has been demonstrated by seven prospective non-randomized trials. All trials were wrongly excluded from the draft report by Spectrum's. Such trials provide valuable insight into the effectiveness of cervical RF.

The first was a long-term observational study of the patients enrolled in Lord's randomized controlled trial to which were added patients treated after the conclusion of the trial. Patients were selected by complete relief of pain via controlled or placebo controlled triple medial branch blocks at C3-4 to C6-7. Anatomically sound lesioning techniques were used. This study showed that of 28 patients treated, 71% obtained complete relief of pain that lasted for a median duration of 421.5 days. (43)

Barnsley performed an observational study of 35 patients selected following complete relief of pain with dual medial branch blocks and no response to placebo medial branch injections. An anatomically sound lesioning technique was used. Of 35 patients treated, 21 (60%) obtained complete relief of pain for a median duration of 44 weeks. (1)

In the study by Macvicar two practitioners reported the outcomes of all their consecutive patients over five years in their respective practices. (44) 104 patients were selected on the basis of complete relief of pain following controlled diagnostic, medial branch blocks and anatomically sound RF lesions were performed. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work if applicable, and no need for any other health care for their previous neck pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted 17 – 20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 20 – 26 months, with some 60% still having relief at final follow-up (44)

Shin performed a prospective audit of 28 patients who had $\geq$50% relief following comparative dual medial branch blocks. Anatomically sound RF lesions were created. Success was defined as $\geq$75% improvement in VAS at 6 month follow-up which was observed in 68%. (52)

Speldewinde performed a prospective cohort of 109 patients. Patients were selected for RFN if dual medial branch blocks gave $\geq$80% relief of their index pain. RFN was performed in an anatomically sound fashion. 62% of patients had $\geq$75% relief of pain and 54% were pain free between 6 and 36 month follow-up. (53)

Sapir performed a prospective cohort study on litigant and non-litigant patients. 50 patients were selected by $\geq$80% relief following controlled medial branch blocks. RF was performed with a reasonable, but not ideal anatomically sound RF technique. 74% of the non-litigants had >50% improvement in pain at 1 yr and 28% of the non-litigants had >80% reduction in pain at 1 yr. (50)

Lee performed a prospective audit of 30 consecutive pts who had >50% relief from dual C3-4 medial branch blocks. RF was performed with a reasonable, but not ideal anatomically sound RF technique. There was >75% reduction in 83% at 6 months and 73% at 12 months. (33)

Summary:

Using 50-80% relief as the cut-off following dual medial branch blocks and reasonably anatomically sound RF lesioning techniques 62-68% obtain ≥75% pain relief at 6 months (52,53) and 74% obtain ≥50% pain relief at 12 month follow-up. (50)

When maximally specific selection of patients is undertaken (i.e. minimum of dual diagnostic blocks with 80-100% relief of pain) with ideal anatomically sound RF lesioning techniques, 54-74% of patients can be rendered pain free for a minimum of 10 months. (1,38,44)

No other non-surgical treatment in the cervical spine can rival this degree and duration of relief for the treatment of cervical facet pain.

Treatment of C2-3 facet pain/cervicogenic headache via third occiptal nerve (TON) RF neurotomy:

In patients with chronic neck pain, the representative prevalence of cervical zygapophysial joint pain is 55%. This makes it the single most common basis for chronic neck pain. (3,14,36,39,42,61) In patients who prove positive to controlled medial branch blocks, the segments most commonly positive are C2,3 and C5,6. (14) In 1994, a substantive study, using controlled diagnostic blocks of the third occipital nerve, (which is the innervation to the C2-3 zygapophysial joint) (5) reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint. (35) RF neurotomy of this joint is performed via third occipital nerve neurotomy.

There has been a seminal RCT on cervical medial branch neurotomy that demonstrates the positive outcome of the procedure is clearly not due to placebo effects. (38) This study did not access the C2-3 level due to documented technical limitations of RF neurotomy of this level (at the time of the study) due to anatomic variation of the third occipital nerve. (37) More recently, subsequent to the Lord RCT, these RF technical limitations have been addressed. (24)

There have been three RCTs on the treatment of cervicogenic headache by van Suijlekom, Stovner, and Haspelagh. (25, 54, 57)In these studies patients were selected on clinical criteria only and the anatomic source of pain was unknown. RF techniques were not anatomically sound and RF was performed at multiple levels indiscriminately. Active RF was compared to sham or control greater occipital nerve blocks (not third occipital nerve blocks). There was no differences between the active or sham arms. However, due to the above the studies used invalid methodology and no scientifically valid conclusion can drawn except that poorly selecting patients for RF and performing RF inappropriately will yield results that are no better than sham treatments, as expected.

Although there are no RCTs on RF of established C2-3 facet pain there are three prospective trials that provide insight into the effectiveness of denervation of this joint via third occipital nerve neurotomy. One could argue a specific RCT to dispel the effects of the index procedure is not due to placebo effects is unnecessary when the RF procedure itself for the same condition (facet pain) has already been shown to be efficacious. (38)

Since the TON RF technique has been appropriately modified following the Lord RCT there is one prospective trial that specifically evaluated the effect of TON neurotomy (24) and two additional trials using anatomically sound RF techniques at all cervical levels including C2-3. In these two trials, the C2-3 level was the predominant level treated (1) or one of the most predominant levels treated. (44)

Govind selected patients with comparative blocks who had complete pain relief following each block. Anatomically sound RF lesions were performed. (24) Success was defined as complete pain relief (100%) for at least 90 days with full return of ADLs and no drug treatment for a headache. Govind found that 86% of 49 patients obtained complete relief of pain and had a successful outcome. At the time of publication, the median duration of relief was 297 days, with eight patients experiencing ongoing, complete relief. Fourteen patients underwent repeat neurotomy when their pain recurred. Twelve (86%) regained complete relief. (24)

Barnsley performed an observational study of 35 patients selected following complete relief of pain with dual medial branch blocks and no response to placebo medial branch injections. An anatomically sound lesioning technique was used. Of 35 patients treated, 21 (60%) obtained complete relief of pain for a median duration of 44 weeks. (1)

In the study by Macvicar two practitioners reported the outcomes of all their consecutive patients over five years in their respective practices. (44) 104 patients were selected on the basis of complete relief of pain following controlled diagnostic, medial branch blocks and anatomically sound RF lesions were performed. The criteria for a successful outcome were complete relief of pain for at least six months, accompanied by restoration of activities of daily living, return to work if applicable, and no need for any other health care for their previous neck pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted 17 – 20 months from the first radiofrequency neurotomy, and 15 months after repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 20 – 26 months, with some 60% still having relief at final follow-up (44)

Summary:

In these trials, when patients are selected with maximally specific diagnostic methods, i.e. dual diagnostic blocks with 100% relief of pain, and RF is appropriately performed then 60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a minimum duration of 10 months. No other non-surgical treatment in the cervical spine can rival this degree and duration of relief for the treatment of C2-3 facet pain or cervicogenic headache.

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.

Comment: Concur.

RF Neurotomy versus Spinal Injections: Efficacy in the lumbar spine

Two RCTs (Civelek 2012, Lakemeier 2013)33, 34 (CoE II) met our inclusion criteria. 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.

RF Neurotomy versus Spinal Injections: Effectiveness in the lumbar spine

One retrospective audit study (Chakraverty 2004)35 (CoE III) met our inclusion criteria. 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.

No evidence for the following:
Efficacy or effectiveness of other types of neurotomy compared with spinal injections in the lumbar spine

Comment:

In the study by Civelek 100 pts selected on clinical grounds of having facet joint syndrome and yet no diagnostic blocks were performed. (10) Subjects were prospectively randomized 50 to MBBs and 50 to RF. MBBs performed with 2 cc of bupivicaine and 40 mg of methylprednisolone. A fair anatomically sound RF lesioning technique was used. At 6, and 12 months post treatment the VAS was significantly better in the RF vs. MBB group with 90% vs. 68% at 6 months and 88% vs. 62% having obtained ≥50% pain relief. However, there was no difference between groups for NASS satisfaction scale or EQ-5d. No categorical pain relief data was presented. (10)

Lakemeier performed a prospective randomized trial of IA facet injections vs. RF Neurotomy for chronic LBP. (30) Patients were selected based on ≥50% relief following intra-articular (IA) L3-4-5-S1 anesthetic injections. IA injection was performed with 3 mg of betamethasone and a sham intraarticular RF lesion was also performed.

RF was performed with a fair anatomically sound RF lesioning technique. Oswestry, Roland-Morris and VAS used at baseline and at 6 months. Mean VAS in the intra-articular group was 7 at baseline and 5.4 at 6 months. Mean VAS in the RF group was 6.6 at baseline and 4.7 at 6 months. There was no difference between groups nor was there for the Oswestry or Roland-Morris. There was no categorical pain relief data. (30)

Chakraverty performed a retrospective audit on patients selected with the predominant use of single diagnostic intraarticular provided they had ≥50% relief of pain in the first hour post injection. (9) 34 subjects with a positive response to IA blocks underwent an IA injection of triamcinolone; 29% had subjective global improvement of >50% relief at 6 or more months. 38 pts were selected for RF neurotomy following single mbbs. At six months, 50% of the 32 patients available for review reported average subjective improvement of 70% (50-100). No statistics were performed, yet it was concluded RF is a better option than IA facet injections for longer term treatment of recalcitrant facet pain. (9)

Summary:

At face value it appears the results from these studies are inconsistent as to the value of RF vs. injection techniques. However, these studies produced no usable or valid comparison data for which any firm conclusions can be stated either positively or negatively.

The source of pain in the study by Civelek (10) was unknown as no diagnostic blocks were used or invalid, non-specific single intra-articular blocks with a 50% cut-off were used. (9, 30) In all three studies the RF was not performed in an anatomically sound fashion.

RF Neurotomy versus Spinal Injections:

Efficacy in the cervical spine:

One RCT (Haspeslagh 2006) (CoE II) met our inclusion criteria. The results suggest that outcomes are similar following RF neurotomy and spinal injections.

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

Comment:

In the study by Haspeslagh 30 patients were selected on clinical grounds only of having cervicogenic headache. (25) 15 were randomized to C3-6 RF neurotomy using non-anatomically sound lesioning techniques followed by dorsal root ganglion RF when necessary vs. greater occipital nerve blocks with anesthetic and steroid following by TENs when necessary. The primary end-point was at 8 weeks. VAS and Global Perceived Effect (GPE) where the primary outcome tools. Treatment was scored as a success, if there was a reduction of the mean VAS of at least 2 points and/or a global perceived effect of +2 or +3. 20% of those receiving RF vs. 27% of those receiving GON blocks were considered a success at 8 weeks. The difference was not significant. (25)

No conclusions, either positive or negative, can be drawn as to the effect of spine injections vs. RF in the cervical spine as this study used invalid diagnostic and treatment methods.. The source of pain in these patients is unknown as no diagnostic blocks were used and the RF technique was not anatomically sound. This study produced no usable data and the only conclusion that can be reached is to state that patients selected and treated by the methods used in this study are expected to do very poorly and likely represent placebo treatment effects.

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.

Comment-Concur

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. Taken together, the results suggest that outcomes are similar following conventional and pulsed RF neurotomy.

No evidence for the following:
Effectiveness of conventional versus pulsed RF neurotomy in the lumbar spine.

Comment:

It is important to note that pulsed radiofrequency treatment is not a neurodestructive procedure, rather it is proposed to be a non-destructive neuromodulatory procedure which affects the way nerves process pain. It is therefore erroneous to call it a type of “facet neurotomy.” It is also erroneous to call pulsed radiofrequency treatment “cooled.” as it is not cooled in any fashion. Rather temperatures are kept below 42 deg C at all times, purposely avoiding thermoablation of tissue which starts to occur around 45 deg C. Conventional thermal radiofrequency neurotomy is performed at temperatures typically around 80-90 deg C with the specific intent of destroying the target tissue.

A comparison study sought to compare the efficacy of thermal radiofrequency neurotomy with that of pulsed radiofrequency treatment. (55) However, it included a controlled study, in which patients were randomized to receive active treatment with thermal neurotomy or sham neurotomy in which no lesion was generated.

The study enrolled patients who obtained at least 50% relief of pain following single diagnostic medial branch blocks. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. There were 20 patients in the control group, 20 in the pulsed RF group and 20 in the continuous thermal RF group. Anatomically sound RF lesioning techniques were used.

For the relief of pain, improvement in disability, and reduction in use of analgesics, thermal radiofrequency was significantly more effective than sham treatment immediately after treatment, at six months, and at one year. At 1 year f/u the continuous RF group had a statistically significant 65% mean VAS reduction (6.5 to 2.3) vs. the placebos group’s 43% (6.8 to 4.3) VAS reduction vs. the pulsed group's 47% (6.6 to 3.5) VAS reduction.

At 1 year f/u the mean Oswestry disability index improved 29% in the continuous group vs. 16% in the sham group and 26% in the pulsed RF group. At 1 yr , 95% of the control vs. 75% of pulsed RF group vs. 40% of the thermal RF group were using analgesics.

Although showing superiority of active treatment over sham or pulsed treatment, this study did not report data from which success rates for percentage reduction of pain could be calculated. However, 65% (44% - 86%) of patients treated with active medial branch neurotomy reported excellent satisfaction with treatment, compared with 20% (2% - 38%) of those who underwent sham treatment vs. 35% of those receiving pulsed RF (55)

Kroll performed a prospective, randomized, double-blinded study. (29) Patients were selected via high volume (1.0 cc) dual medial branch blocks with $\geq$50% relief of pain. Patients were randomized to pulsed RF treatment or thermal RF neurotomy. The thermal RF technique was performed in a fair, but not sound anatomical fashion. A total of 50 patients received either thermal or pulsed RF treatment equally divided between the two groups. 13 patients who received thermal RF and 13 patients who received pulsed RF completed their 3 month follow-up evaluation.

Categorical data of percentages with various percentages of pain relief was not reported. With respect to mean VAS scores, the thermal group had a relative improvement over the three-month interval, on average, of 24.7% , and the pulsed RF group, by10.6% . In the thermal group, Oswestry scores

improved by an average of 18.3% , and in the pulsed group by only 4.1%. There was no significant difference between the thermal RF and pulsed RF groups in relative improvements in either VAS or Oswestry scores. Within the thermal group, VAS and Oswestry scores showed significant improvement over the three-month interval. However, within the pulsed group, comparisons of the relative change over time for both VAS and Oswestry scores were not significant. (29)

Summary:

Consistent benefit of thermal RF vs. pulsed RF was not apparent at face value in these studies, although there was a clear trend in favor of thermal RF.

However, in these two studies patients were not selected with ideal selection criteria (80-100% relief following low volume dual medial branch blocks, but ≥50% relief with single medial branch blocks or ≥50% relief with high volume dual medial branch blocks. Tekin, but not Kroll, used anatomically sound RF lesioning techniques. Due to such, as expected, he mean reduction in pain in the thermal RF groups within these studies were not consistent with known expected pain relief that occurs in patients that are selected with more specific dual medial branch blocks with high grade relief that subsequently undergo robust lesioning techniques. With these methodological limitations and literature perspective it would be inappropriate to make a firm conclusion that the results from pulsed RF treatment rivals relief following thermal RF neurotomy.

No evidence for the following:
Efficacy or effectiveness of conventional versus pulsed RF neurotomy in the cervical or thoracic spine

Comment: Agree as there are no relevant trials.

RF Neurotomy versus Alcohol Ablation: Efficacy in the Lumbar spine

One RCT (Joo 2013) (CoE II) met our inclusion criteria. 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.

Comment:

In this prospective, randomized, controlled single center clinical study by Joo 40 patients with recurrent thoracolumbar facet joint pain after successful (>50% relief for 6 or more months) thermal RF ablation defined as numeric rating scale (NRS) score of ≥7. (27) Subjects were randomly allocated to two groups receiving either the same repeated RF ablation (n = 20) or alcohol ablation (n = 20). The recurrence rate was assessed with NRS and ODI during the next 24 months. In this thoracic spine the nerve was targeted along its "expected course of the nerve at the base of the transverse process". In the lumbar spine a perpendicular approach (ie poor technique) to the superior location of the target nerve was used.

There was a significant difference in the recurrence ratios between the groups during the 24 months following the procedures (19 in the repeated thermal RF ablation and 3 in the AA group). The median effective periods in the RFA and AA groups were 10.7 (range 5.4–24) and 24 (range 16.8–24) months, respectively which was significant.

In the patient cohort, initially equally effective relief occurred between repeat RF and alcohol ablation, but alcohol ablation provided a longer period of pain relief than repeated radiofrequency medial branch neurotomy in the treatment of recurrent thoracolumbar facet joint pain syndrome after successful thermal RF. (27)

Comment: This study cannot be used to assess the potential results of RF neurotomy vs. alcohol ablation in patients that have not had a prior neurotomy.

Of note, although significant complications were not seen in this trial there is an increased potential risk of complications following alcohol chemoablation compared RF neurotomy that require additional procedural experience and precautions when being undertaken. Specifically, alcohol ablation near spinal nerve roots for benign chronic pain is incompatible with the American medico-legal mileau, as alcohol may "leak" onto spinal nerve roots or spinal cord, leading to palsy, paralysis or death.

I agree with Spectrum's conclusions regarding all components of key question 2b, and 2c.

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.

Comment: Agree, no studies exist. In the absence of such studies, extrapolation of the data from the other RF neurotomy studies in which multiple levels in addition to single levels were effectively treated would suggest it is unlikely there is a differential effectiveness.

I agree with Spectrum's conclusion regarding all components of Key Questions 3, 4 and 5.

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From: David Hou david.Hou@multicare.org

To: HCA ST Health Tech Assessment Prog Sent: Sun 1/5/2014 1:02 PM

Cc:

Subject:: Facet Neurotomy

I believe that facet neurotomy is a safe, cost effective procedure to treat facet mediated pain. I hope that insurance continues to cover the treatment for injured worker.
Thanks!
David Hou, MD

January 17, 2014

C. Craig Blackmore, MD, MPH **via Email**
Chair
Washington State Health Technology Committee
P.O. Box 42712
Olympia, WA 98504-2712

Dear Dr. Blackmore:

The International Spine Intervention Society (ISIS), a multi-specialty association of 3,000 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the draft evidence report on facet neurotomy.

Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer, or undergo more invasive surgical procedures, unnecessarily.

We extend to the committee an offer to provide national and international expert input as a resource in this process.

Washington State Health Care Authority appears to be concerned about the increasing cost of medial branch neurotomy and its associated diagnostic medial branch blocks; and justifiably so. In seeking to limit costs, however, it is important to identify the root of the problem. The root of the problem lies not in the procedures, but rather in their inappropriate application. Literature assessing medial branch blocks and medial branch neurotomy shows how these procedures can be performed in a disciplined, responsible manner, in order to achieve desirable outcomes that are clinically, socially, and economically worthwhile [1,2].

Surely **complete relief of pain, with restoration of function, return to work, and no need for further health care** is an outcome that Washington State does not want to deny their patients. Those outcomes can be achieved by the responsible application of the procedures in question. In order to address the true problem of the inappropriate application of these procedures, the following requirements should be applied:

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- At least 80% relief of index pain from medial branch blocks should be recognized as a pretext for further investigation.

- Less than 80% relief should be regarded as non-positive; and further medial branch blocks should not be pursued.

- At least 80% relief of index pain following comparative or placebo-controlled blocks should become the only indication for medial branch neurotomy.

By adopting such measures Washington State Health Care Authority will greatly reduce its burden of cost by eliminating unproductive procedures from its portfolio, while preserving, respecting, and supporting conscientious practice for those patients who can benefit from these procedures.

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SUMMARY OF RECOMMENDATIONS

Relative to the practice of radiofrequency medial branch neurotomy, the International Spine Intervention Society (ISIS) encourages Washington State Health Care Authority to:

1. Recognize as valid only those procedures performed in accordance with techniques that have been validated. Optimal results have been achieved only when those techniques have been used. Results from the techniques described in the ISIS guidelines include complete relief of neck pain, back pain, or headache, accompanied by restoration of function, return to work, and no need for further health care.

2. Adopt the ISIS guidelines [1] as the standard for the performance of medial branch blocks, third occipital nerve blocks, and thermal radiofrequency neurotomy.

Furthermore, the International Spine Intervention Society recommends that Washington State Health Care Authority regard as investigational any other techniques for radiofrequency medial branch neurotomy, or any other basis for the selection of patients for treatment by medial branch neurotomy.

By such measures Washington State Health Care Authority can make available to suffering patients the best standard of care currently available, and avoid continuing to subsidize practices of lesser standard with substantially poorer outcomes.

Reference

1. Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2nd edn. International Spine Intervention Society, San Francisco, 2013.

DISCUSSION

The draft evidence report, produced by Spectrum, poorly serves the needs of the Health Care Authority of Washington State. While the report adheres to the common requirements of a systematic review, its depiction of the evidence is flawed due to lack of insight into the details – not of the data published – but of the practices inherent in the procedures being assessed. In formal terms, the report suffers from lack of content expertise.

The report includes a section on "Key considerations highlighted by clinical experts", but ironically, the report heeds none of the warnings and insights provided by these experts. It is important for the Committee to understand the seriousness of this oversight. Imagine that the topic was "the effectiveness of antibiotics for cough". Cough, similar to low back pain, is merely a symptom representing a variety of diseases. In the case of cough this could include: viral pneumonia, asthma, gastroesophageal reflux disease, heart failure, and even bacterial pneumonia. Without proper patient selection and stratification one may be tempted to say antibiotics are not effective for all patients suffering from a cough. This would clearly be a disservice to those with bacterial pneumonia. In addition to the lack of specificity in the diagnosis, this analogy is also similar in that like spine interventions not all antibiotics are the same. There are a variety of antibiotic types with differing efficacies and routes of administration. The combination of these different treatments targeted at different diseases leads to the unfortunate misinterpretation of an effective treatment for a select group of patients as ineffective.

Armed with such information, a review would not pool all data and diseases indiscriminately, while simultaneously not distinguishing the effectiveness of oral antibiotics and intravenous antibiotics, full-strength antibiotics, or even diluted antibiotics. Yet, in the case of facet neurotomy this is what has been done, in the past, and yet again in the report from Spectrum.

The unnamed clinical experts warned

- "The literature…is replete with examples of both poor patient selection and poor technical execution of the procedure."
- "…there are key trials which have used validated selection criteria…and validated radiofrequency neurotomy methods…It is these…trials that depict the value of the procedure."
- "Selecting patients with less than ideal methods will only yield a greater percentage of patients for subsequent medial branch radiofrequency neurotomy who do not have the target condition, which will not translate into positive clinical outcomes following the RF neurotomy."
- "Use of smaller needles, less than ideal parallel trajectories and lesser lesion temperatures/time than those recommended may not result in obtaining an effective lesion of the target nerve…would reduce the likelihood of obtaining a positive clinical outcome."

- "Using invalid studies as a measure of the value of medial branch radiofrequency neurotomy would misrepresent its true effectiveness. Such studies only hold value to demonstrate what results are to be expected when patients are not appropriately selected and the radiofrequency technique is not appropriately performed."
- "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…underscore the true nature of expected outcomes…"

In methodological terms, advice such as this **requires** that the literature on facet neurotomy be meticulously stratified. That stratification can be applied in each of three domains: selection, technique, and outcome (Figure 1).

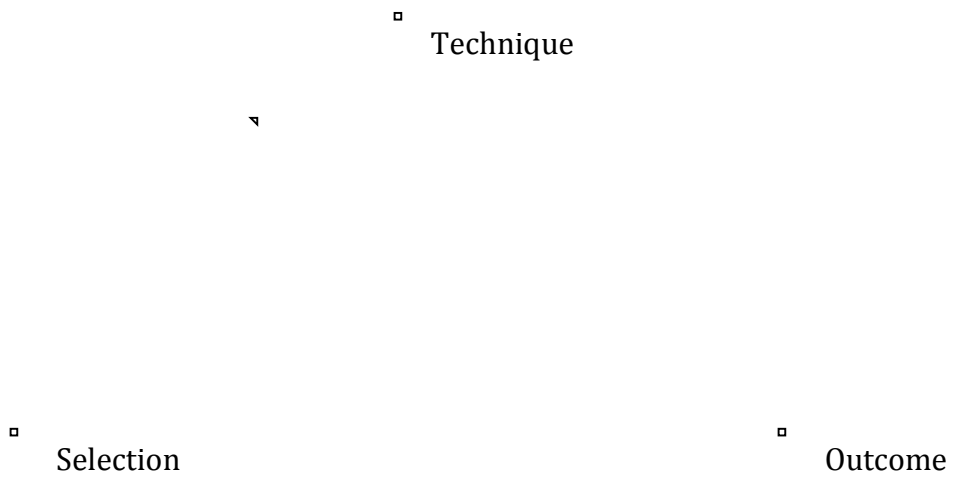

Figure 1. A graphic representation of a structure for the stratification of literature on medial branch neurotomy.

TECHNIQUE

For a variety of reasons, practitioners – whether those in clinical practice or those who publish – use different techniques, yet call their procedure by the same name. The reasons include:

- continuing to use older techniques that are not only out of date, but which have been disproven [1,2,3];
- preferring techniques according to their inventor or country of origin, such as the Dutch technique or the Australian technique [1,2,3];

- using personal adaptations or shortcuts in order to save time, because the published technique is labor-intensive and time-consuming, and not proportionately reimbursed;
- using smaller electrodes because ostensibly these are what are marketed locally, and because larger electrodes are said to be not available.

Correct technique is not defined by arbitrary, personal choice; nor is it defined by randomized controlled trials. Correct technique is defined by studies in basic science. The Spectrum report is aware of this literature, for it cites it [4], but does not heed its message.

For medial branch neurotomy to have face validity the electrode must be accurately placed such that the lesion that it produces optimally captures the target nerve. If the electrode is not placed near the nerve, the validity of the technique lapses.

Somewhat contentious is whether electrodes can be placed perpendicular to the course of the target nerve or parallel to it. In both instances, the electrode may be sufficiently close to the nerve in order to capture it, but basic science studies indicate that perpendicular placements may fail to capture the entire diameter of the nerve, and that parallel placements are more likely both to capture a full thickness of the nerve and a substantial length of the nerve [4,5,6]. Therefore, the orientation of the electrode is likely to be pivotal to clinical outcome. Perpendicular placements could be successful, but are likely to have lower success rates and shorter durations of effect, whereas parallel placements are more likely to have greater success rates for longer periods. This, indeed, is borne out in the literature (see: **OUTCOMES**).

In the light of these technical precepts, the literature can be stratified according to face validity of the technique used (Table 1). Specific considerations differ for lumbar and cervical procedures.

Lumbar

The original technique for "facet denervation" described by Shealy was seriously flawed [5,7]. Electrodes were placed nowhere within reach of the target nerve. Therefore the procedure was tantamount to a sham procedure. Studies that used this disproven technique are, therefore, not representative of a correct technique. The clinical data that they provide might be of use to show what meager outcomes are obtained when flawed techniques are used, but they are inadmissible as evidence of the effectiveness or efficacy of facet neurotomy when correctly performed.

Inadmissible for this reason is the study of Gallagher, which explicitly stated that it used the Shealy technique [8]. Similarly, the study of Leclaire *et al* [9] used a technique that was a modified version of the Shealy technique. Therefore, that study also lapses as providing valid data on the efficacy of facet neurotomy if correctly performed. Indeed, Leclaire *et al* acknowledged this flaw in surgical anatomy, and effectively retracted their results [10].

The study of Wijk *et al* [11] illustrated the technique used. It is patently inaccurate as pointed out by a letter to the editor.[12] Not only were electrodes placed perpendicular to the target nerve, but many placements were too far away from the nerve for the lesion made by the small electrodes used to be able to capture the nerve reliably and adequately. That controlled trial, therefore, pitted one sham procedure against another, thus it is not surprising that no statistically significant difference in outcome was found.

Orientation of Electrode	**Placement of Electrode in Relation to Target Nerve**	
	Within Reach	**Out of Reach**
Parallel	Valid Dreyfuss [19] MacVicar [20] Gofeld [21] Burnham [22] Speldewinde [23] Schofferman [24] Rambaransingh [25] Nath [26] Tekin [27] Lakemeier [28]	
Perpendicular	Questionable Tzaan [13] Civelek [14] Son [15] Chakraverty [16] Kroll [17] Van Kleef [18]	Inadmissible Gallagher [8] Leclaire [9] Wijk [11]

Table 1. The stratification of studies of lumbar medial branch neurotomy according to whether the technique used placed the electrode within reach of the target nerve, and whether the electrode was placed perpendicular or parallel to the nerve.

The other studies that used perpendicular placements [13-18] either illustrated their procedure or described their technique in sufficient detail to credit that their electrodes were placed within range of the target nerve. However, the perpendicular placement, as well as the use of small-gauge electrodes, constitutes a risk of bias against good outcomes, because the target nerves may have been incompletely coagulated – resulting in a lower than optimal success rate – or insufficiently coagulated – resulting in duration of relief less

than the duration achievable by other techniques. Therefore, the clinical outcomes of these studies need to be interpreted carefully and with insight.

In the case of the one study that used perpendicular placement and which was also a controlled trial, the technical limitation may affect the success rate and durability of outcome, but it does not affect testing the technique against placebo, because the same placement was used in each arm.

Nine studies used what appears to be correct technique: placement of the electrode parallel to the target nerve [19-28]. Of these, some provide evidence of outcomes [19-23]; others provide data on repeat treatment [20,23,24,25]; two are controlled trials [26,27]; and one was a comparison study [28].

In light of this stratification of studies by face validity of technique used, certain corrections apply to the conclusions of the report.

RF Neurotomy versus Sham Neurotomy: Efficacy in the Lumbar Spine

The studies of Gallagher 1994, Leclaire 2001, and van Wijk 2005 do not qualify as providing evidence of efficacy because the techniques used for the active arm lacked face validity. Censoring these studies leaves only those of Nath 2008, Tekin 2007, and van Kleef 1999 eligible to provide evidence.

The study of Nath 2008 showed a difference in favor of RF neurotomy that was not significant for the relief of back pain at six months, but which was significant for relief of leg pain, global perceived effect, and consumption of analgesics. For the relief of back pain, the group data of Van Kleef 1999 showed a difference in favor of RF neurotomy that was not significant statistically, but survival analysis showed a statistically significant greater success rate from three months to one year after RF neurotomy. Tekin 2007 showed statistically significant differences in favor of active RF neurotomy at six months and at one year, for group scores for back pain, and for disability, with a significantly greater proportion of patients reporting an excellent outcome.

No study provided data that contradicted the superiority of active treatment over sham treatment.

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Cervical

The literature on cervical radiofrequency neurotomy is less contaminated by errors in technique than the literature on lumbar radiofrequency neurotomy. Although there is earlier literature [1-7], when this was reviewed in 1995 it was found that the techniques used lacked any formal anatomical basis, validated diagnostic tests were not used to select patients, and outcomes were less than impressive, both in terms of success rates, degree of relief, and duration of relief [8]. Fortunately, these errors have not been reiterated in the more recent literature. To no small extent, the errors committed in the past practice of lumbar medial branch neurotomy were avoided in the evolution of cervical medial branch neurotomy.

The majority of the studies on cervical medial branch neurotomy have used valid techniques, in which electrodes are carefully placed parallel to the target nerves [9-14], in accordance with the guidelines of the International Spine Intervention Society [15]. The one exception is the study of Tzaan and Tasker [16] which reports outcomes for cervical medial branch neurotomy but does not describe the technique used. From the little information that is provided in the publication, it appears that the authors placed electrodes perpendicular to the target nerve. They did not recognize that poor outcomes from such placements were the reason that parallel placements were developed [17]. Consequently, the data of Tzaan and Tasker [16] serve to indicate what outcomes might be achieved if a less

effective technique is used, but they do not indicate what can be achieved when optimal technique is used.

Of the studies that have used correct technique for cervical medial branch neurotomy, one has been a placebo-controlled trial [9]; the others have been long-term outcome studies [9-14]. The controlled trial showed conclusively that the outcomes of cervical medial branch neurotomy cannot be attributed to placebo effects [9]. The long-term outcome studies [10-13] corroborate the results of the controlled trial [9], showing that complete relief can be achieved in over 60% of patients, associated with restoration of function, and no need for further health care; and relief can be reinstated by repeat treatment [10,13,14].

There is no literature that refutes any of these conclusions. Nor does the Spectrum report provide any evidence to cast doubt upon either the efficacy or effectiveness of cervical medial branch thermal radiofrequency neurotomy, if performed correctly as recommended [15], for the treatment of chronic neck pain shown to be relieved by controlled blocks of the cervical medial branches.

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Headache

A particular application of cervical radiofrequency neurotomy is for the treatment of headache known as cervicogenic headache, which is a form of referred pain from the upper cervical spine. Three studies purport to show that radiofrequency neurotomy is not effective [1,2,3]. In all studies patients were selected on clinical criteria. Diagnostic blocks were performed in one study [1], but the results were not used as an indication for treatment. In all studies, neurotomy was performed indiscriminately at all levels from C3 to C6.

In the first study, only one of 15 patients achieved complete relief of pain [3]. In the second study, outcomes were no different in patients who received active lesions from those who received sham lesions [1]. In the third, outcomes from neurotomy were no different from those of an injection of local anesthetic onto the greater occipital nerve [2].

Three fatal, technical flaws apply to these studies. First, at no stage was the source of pain established. Second, the neurotomy technique used has never been validated. Third, neurotomy was performed at segmental levels (C3-C6) that have never been incriminated as a source of headache. Collectively, these flaws offend the principle of radiofrequency neurotomy.

Totally opposite results are obtained if a diagnosis is carefully established using controlled diagnostic blocks, and meticulous technique is used. For patients in whom diagnostic blocks indicate that the C2-3 zygapophysial joint is the source of pain, it is possible to denervate that joint percutaneously by radiofrequency neurotomy of the third occipital nerve. The procedure involves placing an electrode parallel to the nerve where it crosses the joint, and using it to coagulate the nerve.

An early study found that radiofrequency neurotomy of the third occipital nerve did not reliably achieve relief of pain [4]. The authors warned that radiofrequency neurotomy should not be adopted until technical deficiencies of the procedure had been overcome. That has now been achieved.

A subsequent study reported improvements in the technique of percutaneous radiofrequency neurotomy of the third occipital nerve [5], which improved its success rate. The revisions included holding the electrode in place during coagulation, and ensuring that multiple lesions are made in order to encompass all possible locations of the nerve.

Using the revised technique, complete relief of pain could be achieved in 88% of patients. The median duration of relief was 297 days with some patients still having continuing relief at the time of review [5]. These results have been corroborated by two independent studies [6,7].

For patients in whom headache recurs, relief can be reinstated by repeating the neurotomy. By repeating neurotomy as required, some patients have been able to maintain relief of their headache for longer than two years [5,7].

It is not logistically possible to conduct a double-blind controlled trial of third occipital neurotomy. An unavoidable side-effect of the treatment is numbness in the territory of the third occipital nerve. Therefore patients cannot be blinded as to the treatment to which they have been randomized. For validity, third occipital neurotomy relies on inductive logic. Since it has been shown that cervical radiofrequency neurotomy at other segmental levels is not a placebo [8], it is reasonable to assume that it is not a placebo when the C3 medial branch is the target.

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OUTCOMES

The outcomes of radiofrequency neurotomy can be quantified in several domains:

- success rate: the proportion of patients who achieve a successful outcome;
- the degree of relief that constitutes a success;
- the duration of that relief;
- the corroboration of relief by improvements in critical domains such as restoration of function, return to work, and use of other health care.

To various extents, these criteria have been satisfied in various studies. Reviewers can choose which outcomes they consider to be worthwhile, or satisfactory.

Lumbar

The paradigm of lumbar medial branch neurotomy is that if patients obtain at least 80% relief of their index pain following controlled diagnostic blocks of one or more medial branches, then similar relief should be obtained if those nerves are successfully coagulated.

Two studies have provided benchmarks for the optimal outcomes of lumbar medial branch radiofrequency neurotomy. Each used optimal technique, as discussed above. The first reported, in essence, that 80% of patients could expect at least 60% relief of their back pain at 12 months, and that 60% could expect at least 80% relief [1]. The second study reported the outcomes from two neighboring practices, in which 58% (44-72%) or 53% (40-66%) of patients respectively achieved complete relief of pain, accompanied by restoration of activities of daily living, return to work if applicable, and no need for further health care for their back pain [2].

The results of these two studies are statistically compatible with one another, and indicate what can be achieved by lumbar medial branch neurotomy if performed correctly, and in appropriately selected patients. In both instances the technique used for radiofrequency neurotomy was that recommended by the International Spine Intervention Society [3], and patients were selected using comparative local anesthetic blocks [4].

A success rate of 55% may not seem impressive, but is compensated by the definition of success: complete relief of pain, restoration of function, and no other health care. The modest success rate, however, is mathematically consistent with the vicissitudes of diagnostic blocks (see: **DIAGNOSIS**). Because the prevalence of lumbar zygapophysial joint pain is low, the rate of false-positive diagnoses is high, even if controlled blocks are used.

Other studies that have used correct technique have reported lesser outcomes, such as 39% [5] or 35% [6] of patients achieving at least 50% relief of pain at six months. In each case, however, patients were selected for treatment using diagnostic blocks in a manner less rigorous than in the benchmark studies.

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Cervical

The literature on cervical medial branch radiofrequency neurotomy is less contaminated by variations in outcome than is the literature on lumbar medial branch neurotomy. In all modern studies, complete relief of pain has been the benchmark outcome [1-6]. Lesser degrees of relief have neither been reported nor entertained. Furthermore, complete relief of pain has been shown to be accompanied by restoration of activities of daily [1,2,4,5], return to work [1,2,5], and no need for other health care [1,2,5,6]. These outcomes are statistically not significantly affected by a compensation claim or ongoing litigation [1,3,6].

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DIAGNOSIS

The Spectrum report correctly recognizes that it is not possible to diagnose zygapophysial joint pain by physical examination or by medical imaging. Diagnostic blocks are the only means of establishing a diagnosis, and providing an indication for treatment by medial branch neurotomy.

The acme of diagnostic blocks are placebo-controlled triple blocks [1,2,3]. These involve first administering an active agent, in order to find *prima facie* if anesthetizing the target nerves relieves the patient's pain. In order to test the response, the patient subsequently undergoes repeat blocks, under double-blind conditions, in which a placebo and an active agent are randomly administered. A positive response is one in which pain is not relieved when the placebo is used, but is relieved each time that the active agent is used, and for a duration concordant with the expected duration of action of the agent used.

Although placebo-controlled, triple blocks have been used in research studies [4], they are regarded by many as too consuming of resources to be practical in conventional practice. Meanwhile, insurers appear to be averse to funding triple blocks on the grounds that they are expensive. Interestingly, however, triple blocks are cost-effective in jurisdictions such as those in Australia and New Zealand, where the reimbursement for medial branch neurotomy substantially exceeds that of a diagnostic block [5].

A suitable alternative to placebo-controlled, triple blocks is comparative local anesthetic blocks. These involve administering, on a double-blind basis in random order, either a long-acting or a short-acting local anesthetic agent. A positive response is one in which the patient obtains at least 80% relief of the index pain on each occasion. A concordant positive response is one in which the duration of relief is concordant with the expected duration of action of each of the agents used. A discordant response is one in which one of the agents, usually lidocaine, has a longer than expected duration of effect [1,2,3,6].

When compared with placebo-controlled blocks, comparative local anesthetic blocks are a reasonably expedient clinical tool. Concordant responses have a sensitivity of 54% and a specificity of 88%, generating a positive likelihood ratio of 4.5 [1,7]. Discordant responses have a sensitivity of 100% but their specificity lapses to 65%, generating a positive likelihood ratio of 2.9.

Although numerically different, likelihood ratios of 2.9 and 4.5 make little appreciable difference to clinical practice. Discordant responses and concordant responses provide effectively the same diagnostic confidence (post-test likelihood). However, diagnostic confidence is critically dependent on the prevalence of the condition being diagnosed (Figure 2). For a condition with a high prevalence, *e.g.* 60%, the diagnostic confidence for a discordant response is 81% and that for a concordant response is 87%. However, for conditions with a prevalence below 30%, diagnostic confidence plummets [1,3] (Figure 2).

Comparative local anesthetic blocks are, therefore, applicable for the diagnosis of cervical zygapophysial joint pain, which has a prevalence between 50% and 60% [8]. They become

less suitable for the diagnosis of lumbar zygapophysial joint pain, depending on what is accepted as the prevalence of this condition. Estimates have ranged from 40% to less than 10% or 5% [3,9,10].

Single diagnostic blocks, even if they provide complete relief, are not a dependable diagnostic tool, for they have an unacceptably high false-positive rate. Variously, the false-positive rate has been measured as between 25% and 45% [6,7,11-16]. Such high values generate uncertainty as to whether a positive response is true or not.

The practical utility of comparative local anesthetic blocks, and their limitations, can be illustrated in the following figures.

Figure 3 shows the diagnostic confidence after single blocks, comparative blocks, and placebo-controlled blocks, for conditions of different prevalence. After a single positive block, the diagnostic confidence is barely greater than the prevalence of the condition. Diagnostic confidence increases markedly if comparative blocks are positive, with little difference between the confidence generated by discordant or concordant responses. However, throughout, diagnostic confidence is affected by prevalence. Only for common conditions is diagnostic confidence high.

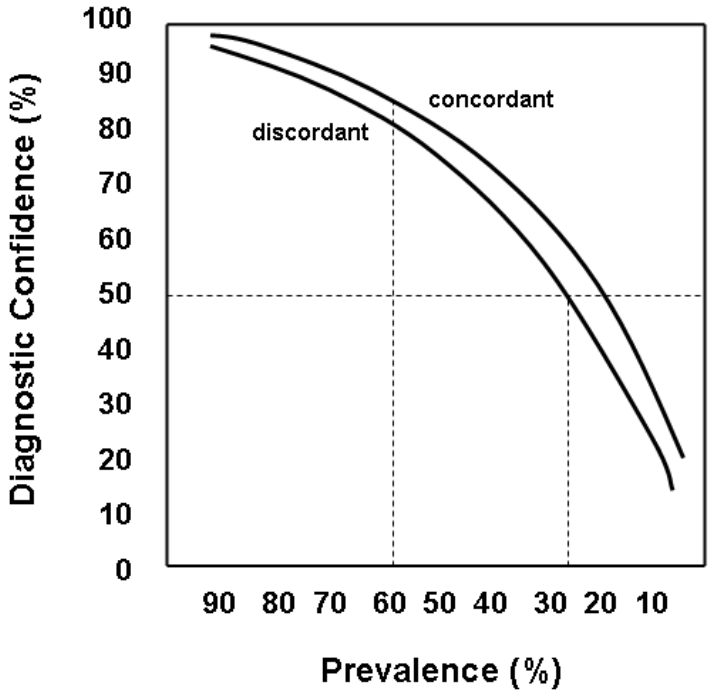

Figure 2. A graph of the relationship between diagnostic confidence, *i.e.* post-test probability, and the prevalence of the condition being diagnosed, for either discordant or concordant positive responses to comparative local anesthetic blocks.

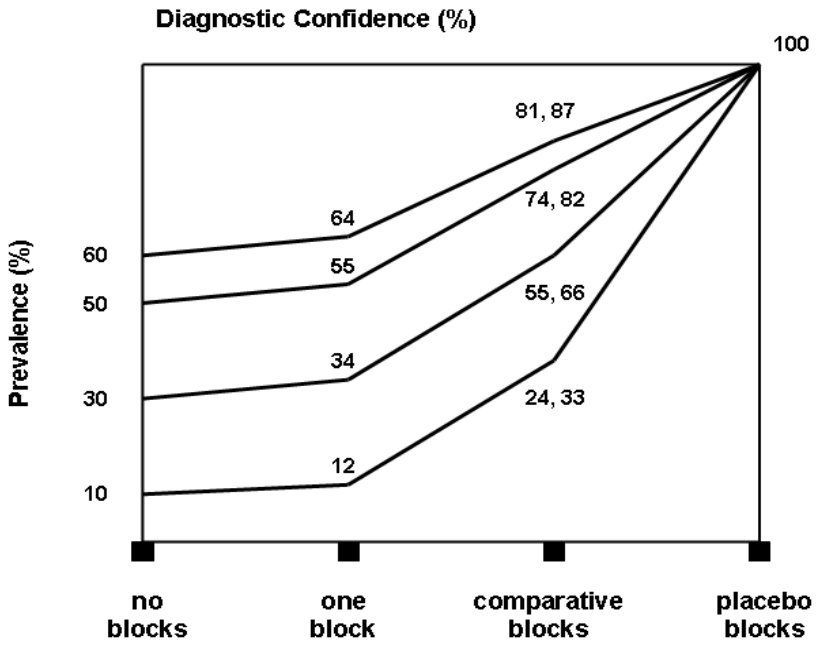

Figure 3. A graph of the relationships between diagnostic confidence and prevalence after positive responses to no blocks, one diagnostic block, comparative blocks, and placebo-controlled blocks. The pairs of figures above comparative blocks are the confidence after discordant and concordant responses, respectively.

Figure 4 shows the numbers of patients who would undergo radiofrequency neurotomy depending on if the indication was response to no blocks, a single block, comparative blocks, or placebo-controlled blocks. The graph shows that if no blocks are used, all patients undergo treatment. Those numbers reduce little if single blocks are the sole indication for treatment. Substantial reductions occur in the number of patients being treated if comparative blocks are applied, with those reductions being greater the less prevalent the condition being diagnosed. This figure underscores the utility of making a diagnosis using comparative blocks. It protects substantial numbers of patients from undergoing unnecessary and futile treatment.

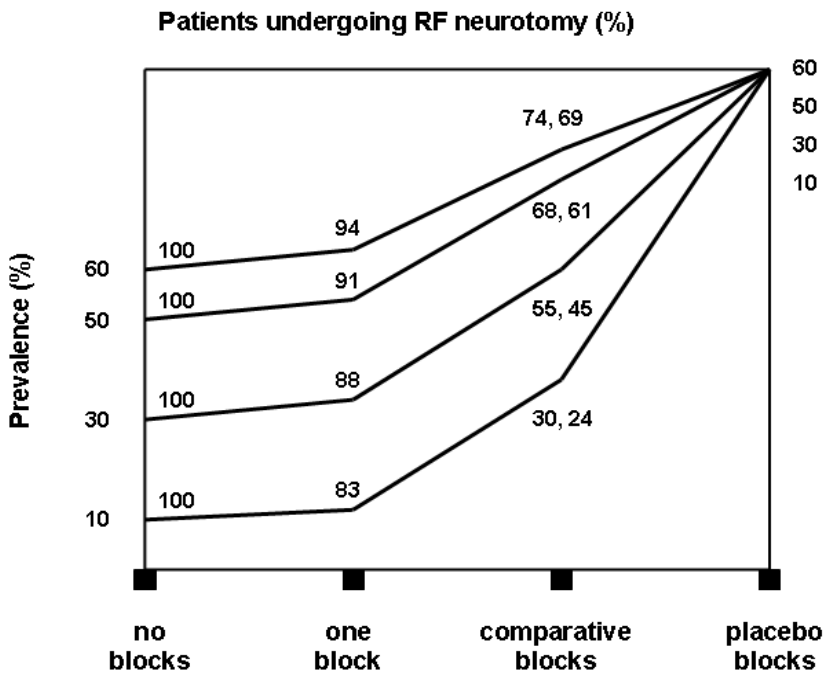

Figure 4. A graph showing the numbers of patients who would undergo radiofrequency (RF) neurotomy if the indication was a positive response to no blocks, one diagnostic block, comparative blocks, or placebo-controlled blocks. The pairs of figures above comparative blocks are the numbers of patients for whom discordant and concordant responses, respectively, would be the indication for treatment.

Figure 5 completes the sequence. It shows that the success rates of treatment increase substantially if comparative blocks (or placebo-controlled blocks) are used. Those success rates are greater in proportion to the prevalence of the condition diagnosed and treated. Conversely, success rates are adversely low if the prevalence is low.

These principles have significant implications for the use of comparative local anesthetic blocks for selecting patients for treatment by radiofrequency neurotomy. The implications differ for cervical medial branch neurotomy and for lumbar medial branch neurotomy.

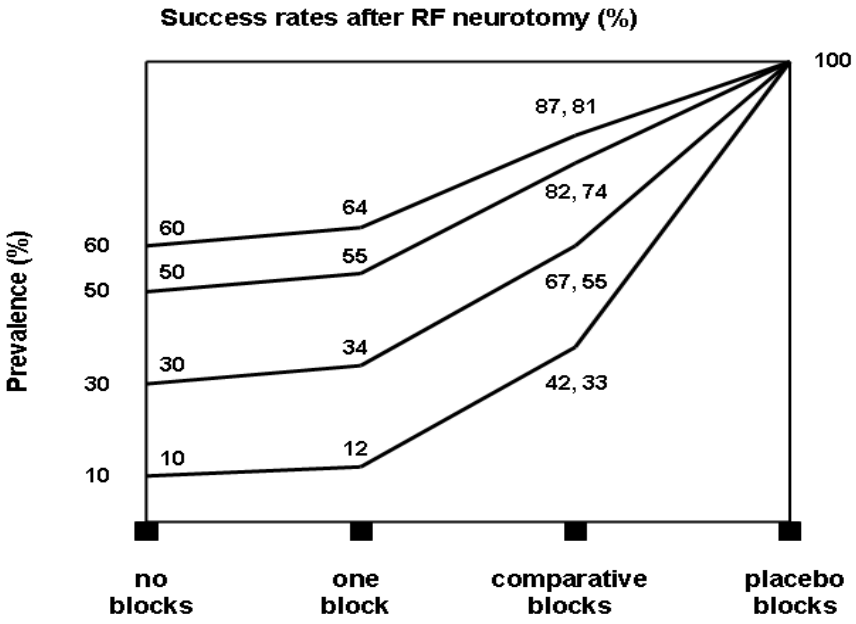

Figure 5. A graph of the relationships between prevalence and the expected success rates of radiofrequency neurotomy if the indication for treatment is a positive responses to no blocks, one diagnostic block, comparative blocks, or placebo-controlled blocks. The pairs of figures above comparative blocks are the success rates after discordant and concordant responses, respectively.

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Cervical

All of the studies on the efficacy of cervical radiofrequency neurotomy [1] and its effectiveness in clinical practice [2,3,4,5,6] have universally used positive responses to comparative local anesthetic blocks as the singular indication for cervical radiofrequency neurotomy. In all studies, the success rates for achieving complete relief of pain were not significantly different statistically from the indicative rate of 65%. In those studies that measured secondary outcomes, complete relief was consistently associated with restoration of function, and no need for further health care for neck pain [1,2,4,5].

Because the prevalence of cervical zygapophysial joint is high (50-60%), the diagnostic confidence provided by comparative local anesthetic blocks is high (*ca* 80%) (Figure 3); and about 65% of patients will be selected for treatment (Figure 4). The success rate encountered in practice (65%) is not significantly lower than that predicted by the models of comparative blocks (*ca* 75%) (Figure 4).

There is no other literature that attests to any other diagnostic test, or response to test, being associated with complete relief of pain, or any other purported successful outcome. Therefore, there is no evidence upon which to base an indication for cervical radiofrequency neurotomy other than at least 80% relief of index pain from double-blind, comparative local anesthetic blocks.

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Lumbar

In both of the benchmark studies of lumbar medial branch neurotomy [1,2] the singular indication was a positive response to comparative local anesthetic blocks. The earlier study used a relaxed criterion of 80% relief [1], whereas the later study required complete relief [2]. Both studies achieved the best results heretofore reported in the literature. The earlier study reported 60% of patients maintaining at least 80% relief for 12 months [1]. The later study reported complete relief of pain in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 13 months per treatment [2].

In isolation, a success rate of 55% or 60% may not seem impressive. However, this figure arises in two contexts. The first is that it applies to complete relief of pain. The second is that no other intervention of any kind, for any form of back pain, provides either such success or such a success rate.

The reason for the modest success rate lies in the vicissitudes of comparative blocks for conditions of low prevalence (Figure 3). The prevalence of lumbar zygapophysial joint pain, based on complete relief of pain, is not known, but it appears to be low [3,4].

For a prevalence of 30%, Figure 3 indicates that the diagnostic confidence of comparative blocks is only about 65%, and Figure 5 indicates that the success rate of lumbar medial branch neurotomy should be of the order of 60%. Greater diagnostic confidence and greater success rates cannot be achieved unless the prevalence of lumbar zygapophysial joint pain is much greater than currently estimated, or unless placebo-controlled blocks are used to make the diagnosis [5]. Under those conditions, comparative local anesthetic blocks are the best available, most practical means of establishing an indication for lumbar medial branch neurotomy, if complete relief of pain is the desired outcome.

No other study has shown that complete relief of pain can be achieved using any indication other than complete, or near complete (at least 80%), relief of the index pain from comparative local anesthetic blocks.

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CONCLUSION

The International Spine Intervention Society has produced practice guidelines for the conduct of lumbar, thermal radiofrequency neurotomy [1] and cervical thermal radiofrequency neurotomy [2], as well as guidelines for the conduct of lumbar medial branch blocks [3], third occipital nerve blocks [4], and cervical medial branch blocks [5], by which patients are selected for treatment by radiofrequency neurotomy.

Based on the most rigorous studies using valid diagnostic techniques to select patients and using optimal techniques of radiofrequency neurotomy (RFN),

- Over 50% of patients treated with lumbar RFN can expect to achieve complete relief of pain, accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their back pain, for a median duration of 15 months, with an interquartile range of 10-28 months [6].

- Some 70% of patients treated with cervical RFN can expect to achieve complete relief of pain, accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their neck pain, for a median duration of 17 months, with an interquartile range of 12-29 months [7].

- In the event of recurrence of pain, complete relief can be reinstated by repeating the treatment [6,7].

Such outcomes are unrivalled by any other intervention for back pain or neck pain. No other intervention has been shown to be capable of achieving complete relief of pain, accompanied by restoration to normal life, and cessation of health care for the condition treated. The available literature shows that these outcomes can be achieved. It also shows how they can be achieved.

Surely the Washington State Health Care Authority would support practices that achieve such outcomes and would ensure that they are available to patients.

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ISIS appreciates the opportunity to provide these comments. If you have any questions or wish to discuss any of our suggestions, please contact Belinda Duszynski, ISIS Director of Research and Quality Improvement, at bduszynski@spinalinjection.org or 815.200.9590.

Sincerely,

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