Washington State Health Care Authority

Health Technology Assessment

Facet Neurotomy for Treatment of Facet Joint Pain

Final Key Questions: Responses to Public Comments

August 29, 2013

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
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RESPONSES TO PUBLIC COMMENTS

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 periods 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 clinical and peer reviews from the following parties:

Key Questions

1. ISIS (International Spine Intervention Society): Jeffrey Summers, MD (President)
2. Phil Colmenares, MD, MPH
3. Ray Baker, MD and Paul Dreyfuss, MD
4. Chris Standaert, MD (Washington Health Technology Clinical Committee member)

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

	Comment	Response
ISIS (International Spine Intervention Society): *Jeffrey Summers, MD (President)*		
	ISIS has reviewed the Draft Key Questions and we find them to be reasonable.	Thank you, we appreciate your feedback.
	We strongly urge the HTA to assure that the review of literature regarding radiofrequency facet neurotomy for all spinal regions is not grouped together. It is extremely important that the key questions are separated to review the efficacy of the procedure in the cervical, thoracic, and lumbar facet regions, independently.	Thank you. It was our intention to report the results for the cervical, thoracic, and lumbar facet regions separately. We have rephrased all key questions to better reflect these groupings.
Phil Colmenares, MD, MPH		
Outcomes	In order to prioritize findings better between primary outcomes and secondary outcomes, I would recommend limiting the primary outcome to objectively measured functional improvement or QOL determinations and return to work. For example, the SPORT trial (JAMA. 2006;296:2451-2459), the primary end points were 2 scales of the Medical Outcomes Study Short-Form Health Survey (SF-36)—bodily pain scale and physical function scale—and the American Academy of Orthopaedic Surgeons MODEMS version of the Oswestry Disability Index (ODI) as measured at 6 weeks, 3 months, 6 months, and 1 and 2 years. For facet neurotomy, there should be consideration of f/u intervals possibly of 2 weeks, 1 month, 2 months, 3 months, and 6 months. Therefore, primary outcomes should limited to objective measures of true functional improvement. Since it is almost impossible to arrive at a consensus definition of “clinically meaningful pain relief,” this measure as wells as patient satisfaction and psychological measures not included in the above mentioned functional assessment instruments would more logically be considered secondary outcomes. Many of the trials focus on “clinical efficacy” which speaks	Thank you for your comment. The primary outcomes of interest, however, are pain and physical function.

	Comment	Response
	more to the secondary outcome measures that I have proposed, but the trials that should be evaluated first are the ones that speak directly to clinical effectiveness.	
Key Question 1	Since Question #1 becomes essentially nonapplicable if Question #2 is answered negatively, I would recommend switching these the order of the questions.	Thank you for your suggestion.
Key Question 2	I would recommend the following edit to the current 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.)? *Add:* What is the evidence of short- and long-term comparative efficacy? This clearly separates (and puts primacy) on <u>comparative effectiveness</u> which is of most concern to patient outcomes. It also focuses the evidence review first on the issue of clinical effectiveness which has a much higher evidence standard than "efficacy" endpoints which tend to be of varying clinical significance. In order to keep the same methodological rigor throughout the components of question # 2, I would suggest the following: a. What is the evidence of the short- and long-term comparative ~~efficacy and~~ effectiveness of different types of facet neurotomy (e.g., radiofrequency, pulsed (cooled), chemical, cryoablation, laser)? *Add:* Are there differences in clinical efficacy? b. What is the evidence of the short- and long-term comparative ~~efficacy~~ <u>effectiveness</u> of repeat	Thank you. The key question is framed in a standard way and asks about both efficacy (i.e., using evidence from randomized controlled trials) and effectiveness (i.e., using evidence from nonrandomized controlled studies). Efficacy and effectiveness will be evaluated separately.

	Comment	Response
	neurotomy procedures at the same level and the same side as the initial procedure? *Add:* Are there differences in comparative efficacy? c. Is there evidence of differential clinical effectiveness when conducting unilateral versus bilateral facet neurotomy?	
Ray Baker, MD and Paul Dreyfuss, MD		
	The key questions and data scope look great. [We] suggest splitting areas (Cervical, lumbar, etc.) since the studies are different in quality and outcomes. The outcome literature for the cervical spine is different than for the lumbar spine. Furthermore, there is a paucity of literature for thoracic spine facet RF neurotomy in comparison.	Thank you. It was our intention to report the results for the cervical, thoracic, and lumbar facet regions separately. We have rephrased all key questions to better reflect these groupings.
	There is specific literature for treatment of the C2-3 level (third occipital nerve RF) in the cervical spine versus treatment of more inferior levels.	Thank you. We will report on neurotomy of the third occipital nerve separately if literature that meets our inclusion criteria is available.
Chris Standaert, MD (Washington Health Technology Clinical Committee member)		
Introduction	This sentence is confusing- giving finite ranges followed by a statement that the ranges can be very wide is contradictory. The numbers for this vary by the population studied and methodology. "It is estimated that the prevalence of facet joint pain is 10-15% in the low back, 40-50% in the mid-back, and 45-55% in the neck. However, these estimates vary widely with diagnostic methodology employed, with reported estimates ranging from less than 5% to greater than 90%. "	Thank you. We have deleted the last part of the sentence such that it reads: "It is estimated that the prevalence of facet joint pain is 10-15% in the low back, 40-50% in the mid-back, and 45-55% in the neck. However, these estimates vary widely with diagnostic methodology employed."
	"Paraspinal tenderness at the affected facet joints" is not a symptom, it is a physical finding. The dominant symptom is axial spinal pain, which makes it very difficult to identify by symptoms	Thank you. We have changed the sentence to the following: "The primary physical sign

	Comment	Response
	alone.	suggestive of facet joint pain is paraspinal tenderness at the affected facet joints, and the dominant symptom is axial spinal pain."
	Would specify what type of guidance, usually fluoroscopy: "During this procedure, the skin is anesthetized with a local anesthetic and the radiofrequency needles are advanced using guidance to confirm that the needles are properly positioned…"	Thank you. This has been added. The different types of guidance will be described in the full report.
	"The needles are properly positioned at the affected nerve." should be "at the presumed location of the nerves from the affected joint"- it is the joint that is the problem, not the nerves, and we cannot see the nerves in a given person and place the needle based upon the usual location of the nerve.	Thank you. We have made the suggested change.
	I believe the purpose is to actually damage the axons of the sensory nerve so that it cannot function. Either here or elsewhere, it may be worth noting that the medial branch nerves also generally innervate the adjacent paraspinal musculature, and that function, too, is disrupted by the procedure. "A radiofrequency current is then applied to disrupt the ability of the nerves to transmit pain signals to the brain."	Thank you. We will discuss the function of the medial branch nerve in the full report.
Population(s)	"Patients with facet joint pain or facet arthropathy undergoing facet neurotomy." This language presumes that the patient has undergone MBB's and is felt to have facet mediated pain that may be amenable to neurotomy. Is this the population in question or is it those individuals with pain of possible facet	The intended population is patients with possible facet origin being considered for diagnostic and potential therapeutic intervention. As such, we have changed the population of interest to: "Patients being considered for

	Comment	Response
	origin being considered for diagnostic and potential therapeutic intervention?	facet neurotomy due to suspected facet joint pain."
Comparator(s)	Consider including physical therapy, chiropractic, or others, or natural history	Thank you. We have added these to our list of comparator treatments.
Key Questions (general)	Another area to consider exploring is that of predictive factors for positive and negative outcomes from these procedures. Are there things that can predict the likelihood of a positive or negative response to the procedure?	Thank you. This will be considered in Key Question 4, which asks if there is evidence of differential efficacy or safety compared with other treatment options in subpopulations.
Key Question 1	I recommend adding wording to separate out the analysis of MBB's and particularly neurotomy by region of the spine- i.e. cervical, thoracic, and lumbar, as the literature may well differ by region (as evidenced by the differing numbers for prevalence). The vertebrae and related anatomy are distinctly different in different regions of the spine, and the clinical presentation and care may vary by region. "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?"	Thank you. It was our intention to report the results for the cervical, thoracic, and lumbar facet regions separately. We have rephrased all key questions to better reflect these groupings.
Key Question 1e	Consider number of levels, as well- is there data on one level only, two levels, four levels? Does any validity of the procedures change with additional levels included?	Thank you. This had been added to Key Question 1.
Key Question 2	See comment above- I recommend considering the literature by region of the spine (lumbar, cervical, thoracic).	Thank you. It was our intention to report the results for the cervical, thoracic, and lumbar facet regions separately. We have rephrased all key

	Comment	Response
		questions to better reflect these groupings.
Key Question 2	I would also try to address the number of levels performed- if the data supports the use of the procedures, does this apply to one, two, or more levels being treated? The same consideration exists for complications. "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.)?"	Thank you. This had been added to Key Question 2.

August 15, 2013

Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

Submitted electronically: shtap@hca.wa.gov

Re: Draft Key Questions for Facet Neurotomy for Cervical and Lumbar Pain

To Whom It May Concern,

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, is pleased to comment on the topic of Draft Key Questions for Facet Neurotomy for Cervical and Lumbar Pain, posted by the Washington State Health Technology Authority (HTA).

ISIS has reviewed the Draft Key Questions and we find them to be reasonable. However, **we strongly urge the HTA to assure that the review of literature regarding radiofrequency facet neurotomy for all spinal regions is not grouped together. It is extremely important that the key questions are separated to review the efficacy of the procedure in the cervical, thoracic, and lumbar facet regions, independently.**

ISIS appreciates the opportunity to comment. If we may provide any assistance or answer questions, please contact ISIS staff at advocacy@spinalinjection.org or 708-505-9416.

Sincerely,

Jeffrey Summers, MD
President
International Spine Intervention Society

International
Spine Intervention Society

161 Mitchell Blvd, Ste 103
San Rafael, California 94903
415. 457. ISIS (4747) Office
www.spinalinjection.org

Masters, Christine V. (HCA)

From: Phil Colmenares <philcolmenares@gmail.com>
Sent: Friday, August 02, 2013 1:22 PM
To: HCA ST Health Tech Assessment Prog
Subject: Comments on Questions for Facet Neurotomy Evidence Review

Follow Up Flag: Follow up
Flag Status: Completed

Comment on **Outcomes**:

In order to prioritize findings better between primary outcomes and secondary outcomes, I would recommend limiting the primary outcome to objectively measured functional improvement or QOL determinations and return to work. For example, the SPORT trial (JAMA. 2006;296:2451-2459), the primary end points were 2 scales of the Medical Outcomes Study Short-Form Health Survey (SF-36)—bodily pain scale and physical function scale—and the American Academy of Orthopaedic Surgeons MODEMS version of the Oswestry Disability Index (ODI) as measured at 6 weeks, 3 months, 6 months, and 1 and 2 years. For facet neurotomy, there should be consideration of f/u intervals possibly of 2 weeks, 1 month, 2 months, 3 months, and 6 months.

Therefore, primary outcomes should limited to objective measures of true functional improvement. Since it is almost impossible to arrive at a consensus definition of "clinically meaningful pain relief," this measure as wells as patient satisfaction and psychological measures not included in the above mentioned functional assessment instruments would more logically be considered secondary outcomes. Many of the trials focus on "clinical efficacy" which speaks more to the secondary outcome measures that I have proposed, but the trials that should be evaluated first are the ones that speak directly to clinical effectiveness.

Comment on **Question #1**:

Since Question #1 becomes essentially nonapplicable if Question #2 is answered negatively, I would recommend switching these the order of the questions.

Comment on **Question #2**:

I would recommend the following edit to the current 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.)? *Add:* What is the evidence of short- and long-term comparative efficacy?

This clearly separates (and puts primacy) on comparative effectiveness which is of most concern to patient outcomes. It also focuses the evidence review first on the issue of clinical effectiveness which has a much higher evidence standard than "efficacy" endpoints which tend to be of varying clinical significance.

In order to keep the same methodological rigor throughout the components of question # 2, I would suggest the following:

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

cryoablation, laser)? *Add:* Are there differences in clinical efficacy?

b. What is the evidence of the short- and long-term comparative ~~efficacy~~ effectiveness of repeat neurotomy procedures at the same level and the same side as the initial procedure? *Add:* Are there differences in comparative efficacy?

c. Is there evidence of differential clinical effectiveness when conducting unilateral versus bilateral facet neurotomy?versus bilateral facet neurotomy?

Thank you.

Phil Colmenares MD MPH

Masters, Christine V. (HCA)

From: Ray M. Baker, MD <RMBaker@evergreenhealthcare.org>
Sent: Thursday, August 08, 2013 4:59 PM
To: Morse, Josiah (HCA)
Cc: Paul Dreyfuss, MD (pauldreyfuss@gmail.com); Masters, Christine V. (HCA)
Subject: Re: Health Technology Assessment Key Questions

Thanks, Josh. Paul and I have looked them over and the key questions and data scope look great. Paul suggested splitting areas (Cervical, lumbar, etc) since the studies are different in quality and outcomes. Lumping might paint the wrong picture. Paul can add his specifics. Thanks for all your hard work!
Ray

Sent from my iPhone

On Aug 8, 2013, at 16:12, "Morse, Josiah (HCA)" <josh.morse@hca.wa.gov> wrote:

> Drs. Baker and Dreyfus,
>
> Thank you again for your time and input on the HTA review of Facet Neurotomy. We developed and published the draft scope and key questions. It is published and available for comment. Please send any input to our program email , shtap@hca.wa.gov<mailto:shtap@hca.wa.gov> and/or to me directly.
>
> http://www.hta.hca.wa.gov/neurotomy.html
>
> Thanks,
>
> Josh
>
> Josh Morse, MPH
> Program Director
> WA Health Technology Assessment Program
> Josh.Morse@HCA.WA.GOV: 360-725-0839
> http://www.hta.hca.wa.gov
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> <facet_draft_key_questions_080113.pdf>

Washington State Health Care Authority
Health Technology Assessment

Draft Key Questions and Background
Facet Neurotomy for Treatment of Facet Joint Pain

Public comments on the draft Key Questions will be accepted until 5 pm, August 16, 2013

Introduction

A large proportion of the adult population suffers from back or neck pain at some point in life. One of the possible sources of chronic back pain is degeneration of the facet joints. Typically, facet arthropathy (joint disease) develops progressively and the typical patient is over 50 years of age. Whiplash injuries can also result in cervical facet joint pain. It is estimated that the prevalence of facet joint pain is 10-15% in the low back, 40-50% in the mid-back, and 45-55% in the neck. However, these estimates vary widely with diagnostic methodology employed, with reported estimates ranging from less than 5% to greater than 90%.

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. There is no "gold standard" diagnostic tool for facet joint pain. Diagnosis of facet joint pain cannot be accurately made by physical or radiological examination alone and diagnostic nerve blocks may be the most accurate assessment method. Diagnostic medial branch blocks or intra-articular injections involve injection of local anesthetic. A positive block occurs when the patient experiences pain relief that lasts as long as the duration of action of the anesthetic used.

Once the facet joint is determined to be the source of pain as indicated by a positive diagnostic block, then prolonged pain relief may be achieved with destruction of the nerves to the affected joint in a procedure called facet neurotomy. Neurotomy does not cure the source of pain, but instead cuts off the pain signal to the brain by damaging the nerve. Different types of facet neurotomy are available, but the most common type employs radiofrequency needles to destroy the nerve tissue with heat generated by an electric current. During this procedure, the skin is anesthetized with a local anesthetic and the radiofrequency needles are advanced using guidance to confirm that the needles are properly positioned at the affected nerves. A radiofrequency current is then applied to disrupt the ability of the nerves to transmit pain signals to the brain. Other names for this procedure include percutaneous radiofrequency denervation, nerve ablation, neurolysis, medial branch neurotomy, medial branch rhizotomy, and articular rhizolysis.

Comment [C1]: This sentence is confusing- giving finite ranges followed by a statement that the ranges can be very wide is contradictory. The numbers for this vary by the population studied and methodology.

Comment [C2]: This is not a symptom, it is a physical finding. The dominant symptom is axial spinal pain, which makes it very difficult to identify by symptoms alone.

Comment [C3]: Would specify what type of guidance, usually fluoroscopy

Comment [C4]: Should be "at the presumed location of the nerves from the affected joint"- it is the joint that is the problem, not the nerves, and we cannot see the nerves in a given person and place the needle based upon the usual location of the nerve.

Comment [C5]: I believe the purpose is to actually damage the axons of the sensory nerve so that it cannot function. Either here or elsewhere, it may be worth noting that the medial branch nerves also generally innervate the adjacent paraspinal musculature, and that function, too, is disrupted by the procedure

Policy Context

Facet neurotomy aims to treat pain resulting from facet joint disease, but it does not cure the condition. There are significant questions related to the diagnosis of facet joint pain, and treatment of facet joint pain with facet neurotomy.

Scope of this HTA

Population(s):

Patients with facet joint pain or facet arthropathy undergoing facet neurotomy.

Comment [C6]: This language presumes that the patient has undergone MBB's and is felt to have facet mediated pain that may be amenable to neurotomy. Is this the population in question or is it those individuals with pain of possible facet origin being considered for diagnostic and potential therapeutic intervention?

Intervention:

Facet neurotomy using FDA approved devices.

Comparator(s):

Alternative treatments, including sham neurotomy, therapeutic intra-articular injections or medial branch blocks, medical therapy. Different types of facet neurotomy will also be compared if facet neurotomy is found to be effective compared with alternative treatments.

Comment [C7]: Consider including physical therapy, chiropractic, or others, or natural history

Outcomes:

The primary outcomes of interest are clinically meaningful pain relief and functional improvement. Secondary outcomes include health-related quality of life (including psychological status), return to work, patient satisfaction, and opioid use. Outcomes may include composite outcome measures. Additionally, safety and complications outcomes will be reported.

Key Questions

Comment [C8]: Another area to consider exploring is that of predictive factors for positive and negative outcomes from these procedures. Are there things that can predict the likelihood of a positive or negative response to the procedure?

In patients with facet arthropathy or facetogenic pain:

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

Comment [C9]: I recommend adding wording to separate out the analysis of MBB's and particularly neurotomy by region of the spine- ie cervical, thoracic, and lumbar, as the literature may well differ by region (as evidenced by the differing numbers for prevalence). The vertebrae and related anatomy are distinctly different in different regions of the spine, and the clinical presentation and care may vary by region.

Comment [C10]: Consider number of levels, as well- is there data on one level only, two levels, four levels? Does any validity of the procedures change with additional levels included?

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

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

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

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

Comment [C11]: See comment above- I recommend considering the literature by region of the spine (lumbar, cervical, thoracic). I would also try to address the number of levels performed- if the data supports the use of the proceures, does this apply to one, two, or more levels being treated? The same consideration exists for complications.

See *Key Question Public Comment and Response* document published separately.

For additional information on key questions and public comments.