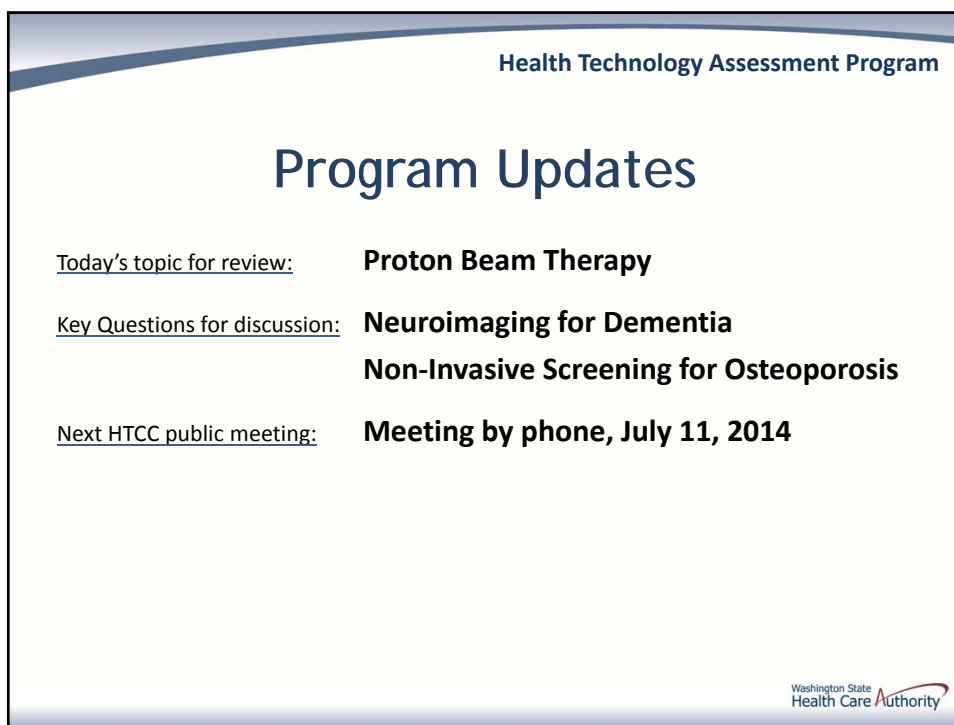


Washington State  
**Health Care Authority**  
*Health Technology Assessment*

## Program Overview

Josh Morse, Program Director  
Health Technology Assessment  
May 16, 2014



Health Technology Assessment Program

## Program Updates

Today's topic for review: **Proton Beam Therapy**

Key Questions for discussion: **Neuroimaging for Dementia**  
**Non-Invasive Screening for Osteoporosis**

Next HTCC public meeting: **Meeting by phone, July 11, 2014**

Washington State  
Health Care Authority

Health Technology Assessment Program

## Background

- The Health Technology Assessment Program (HTA) is located within the Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
  - Safety
  - Efficacy/ Effectiveness
  - Cost-Effectiveness

Washington State  
Health Care Authority

Health Technology Assessment Program

## Background

- Multiple state agency programs participate to identify topics and implement policy decisions:
  - Health Care Authority
    - Uniform Medical Plan
    - Medicaid
  - Labor and Industries
  - Corrections
- Implementation:

Agencies implement determinations of the HTA program within their existing statutory framework.

4

Washington State  
Health Care Authority

Health Technology Assessment Program

## Purpose: Pay for What Works

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners to determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.

Washington State Health Care Authority 5

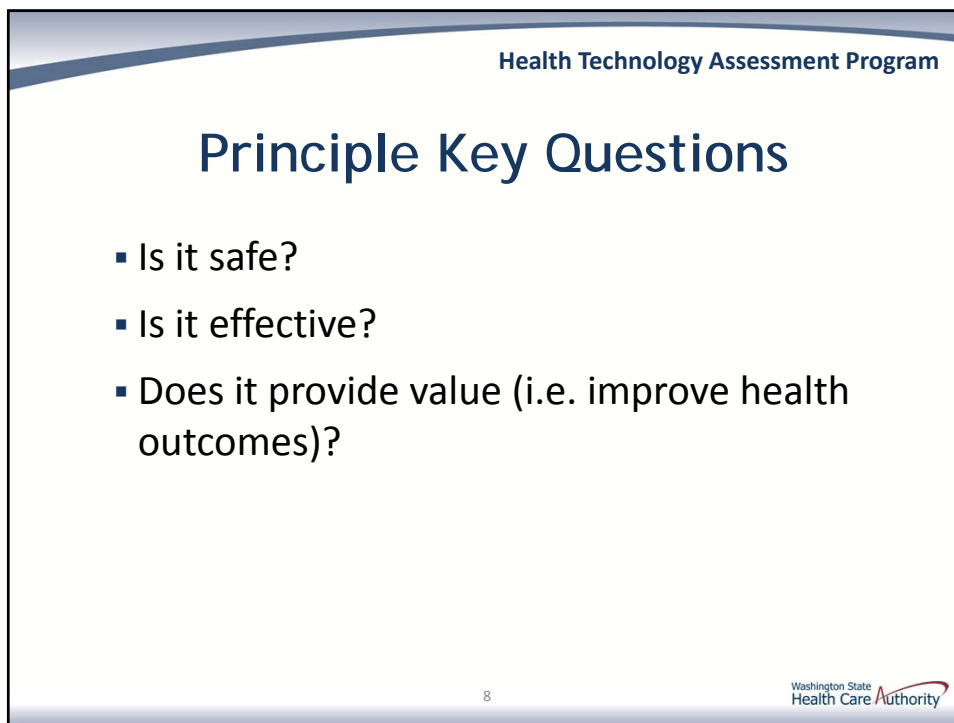
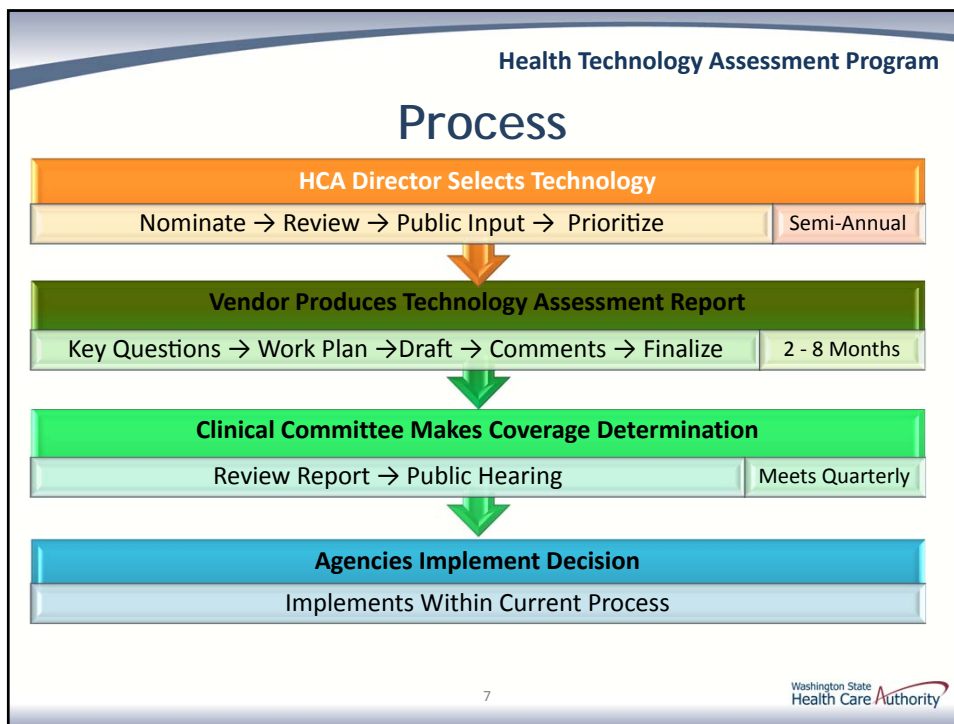
Health Technology Assessment Program

## Objectives

```
graph TD; A[Minimize Bias: Independent decisions considering evidence from all] --> C((Better Health for Washington Citizens: Proven Healthcare)); B[Consistency: Single source of scientific evidence] --> C; D[Evolving & Flexible: Keeps pace with technical innovations] --> C; E[Transparency: Published process open to public input] --> C; F[Cyclic: Regularly assess new evidence on reviewed technologies] --> C;
```

6

Washington State Health Care Authority 6



Health Technology Assessment Program


## Values

**Transparency:** Publish topics, criteria, reports, conduct open meetings

**Best Evidence:** Formal, systematic process for review of selected health care technologies.

**Independent Decisions:**  
Committee of practicing clinicians make decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.

9




Health Technology Assessment Program

## Decision Basis

Clinical Committee decisions must give greatest weight to most valid and reliable evidence.

- **Objective Factors for evidence consideration**
  - Nature and source of evidence
  - Empirical characteristics of the studies or trials upon which evidence is based
  - Consistency of outcomes with comparable studies
- **Additional evaluation factors**
  - **Recency** (date of information)
  - **Relevance** (applicability of information to the key questions presented or participating agency programs and clients)
  - **Bias** (conflict of interest or political considerations)

10




Health Technology Assessment Program

## Technology Topics 2014-15

- Facet Neurotomy for Treatment of Facet Joint Pain
- Nonpharmacological Treatments for Treatment-resistant Depression
- **Proton Beam Therapy**
- ~~Thyroid Ultrasound for Screening and Assessment of Goiter~~
- Neuroimaging for Primary Degenerative Dementia & Mild Cognitive Impairment
- Non-Invasive Screening for Osteoporosis

11




Health Technology Assessment Program

## How To Participate

- Visit the HTA Web site: <http://www.hca.wa.gov/hta> (**NEW URL!**)
- Join the HTA stakeholder distribution list: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)  
Stakeholders notified of all program publications and meetings.
- Comment on:
  - Proposed topics
  - Key questions
  - Draft & final reports
  - Draft decisions
- Attend HTCC public meetings.  
All meeting materials posted on the web.
- Present comments at Clinical Committee meetings.
- Nominate health technologies for review.

12



Health Technology Assessment Program

## Contact Information

**Josh Morse, Program Director**  
(360) 725-0839  
[Josh.Morse@hca.wa.gov](mailto:Josh.Morse@hca.wa.gov)

**New Web Address:** [hca.wa.gov/hta](http://hca.wa.gov/hta)

HTA program email: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

13

Washington State  
Health Care Authority

## Health Technology Clinical Committee

Date: March 21, 2014  
Time: 8:00 am – 5:00 pm  
Location: SeaTac Airport Conference Center  
Adopted:

Meeting materials and transcript are available on the HTA website at:

<http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx>

### HTCC DRAFT MINUTES

**Members Present:** C. Craig Blackmore, MD, MPH; Marie-Annette Brown, PhD, RN; Joann Elmore, MD MPH; David McCulloch, MD; Carson E. Odegard, DC, MPH; Richard C. Phillips, MD, MS, MPH; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh, MD

### HTCC FORMAL ACTION

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. November 15, 2013, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.  
*Action: Ten committee members approved the November 15, 2013 meeting minutes. One member was absent.*
- 3. Hyaluronic Acid/ Viscosupplementation Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. Three comments were received on the draft decision.  
*Action: Six committee members approved the Hip Resurfacing Findings & Decision document. Five members disapproved.*
- 4. Hip Resurfacing Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision.  
*Action: Eleven committee members approved the Hip Resurfacing Findings & Decision document.*
- 5. Nonpharmacological Treatments for Treatment-resistant Depression**  
**Scheduled and Open Public Comments:** The Chair called for public comments. Open public comments were presented by:

Draft



WA - Health Technology Clinical Committee Meeting  
March 21, 2014

- John Neumaier, MD, PhD
- Anna Borisovskaya, MD
- Farrokh Farrokhi, MD, Vice President, WA State Association of Neurological Surgeon Vice President, WA State Association of Neurological Surgeons
- Mercy Yule, EAMP

Presentation materials and conflict of interest forms are available with [March 21, meeting materials](#).

**Agency Utilization and Outcomes:**

Charissa Fotinos, MD, MSc, Deputy Chief Medical Director, WA Health Care Authority presented the state agency utilization rates for Nonpharmacological Treatments for Treatment-resistant Depression to the committee. The full presentation is published with [March 21, meeting materials](#).

**Vendor Report and HTCC Q & A:**

The Chair introduced the clinical expert for Nonpharmacological Treatments for Treatment-resistant Depression, David H. Avery, MD, Professor Emeritus, University of Washington School of Medicine.

Teresa L. Rogstad, MPH, of Hayes, Inc, presented the evidence review addressing Nonpharmacological Treatments for Treatment-resistant Depression. The full presentation is published with [March 21, meeting materials](#).

**Committee Discussion and Decision:**

The HTCC reviewed and considered the Nonpharmacological Treatments for Treatment-resistant Depression technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Electroconvulsive Therapy	0	10	1
Repetitive Transcranial Magnetic Stimulation	0	9	2
Deep Brain Stimulation	11	0	0
Transcranial Direct Current Stimulation	11	0	0

***Discussion***

The committee determined a vote of coverage for electroconvulsive therapy (ECT) and repetitive transcranial magnetic stimulation (RTMS), each without conditions. The committee discussed the application of this determination for only treatment-resistant depression of condition as this was the defined scope of the review.

**Limitations of Coverage:**

Electroconvulsive Therapy is a **covered benefit**.

Repetitive Transcranial Magnetic Stimulation is a **covered benefit**.

**Non-Covered Indicators:**

Deep Brain Stimulation is **not covered**.

Transcranial Direct Current Stimulation is **not covered**.

***Action***

The committee checked for availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Electroconvulsive Therapy, Repetitive Transcranial Magnetic Stimulation, Transcranial Direct Current Stimulation or Deep Brain Stimulation. The committee reviewed selected payer policies for Aetna, Oregon Health Evidence Review Commission and the New England Comparative Effectiveness Public Advisory Council. The committee also reviewed practice guidelines from The American Psychiatric Association, Canadian Network for Mood and Anxiety Treatments, Institute for Clinical Systems Improvement, National Institute for Health and Care Excellence and Veteran's Affairs and the Department of Defense.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Nonpharmacological Treatments for Treatment-resistant Depression reflective of the majority vote for final approval at the next public meeting.

**6. Facet Neurotomy**

Scheduled and Open Public Comments: The Chair called for public comments. Open public comments were presented by:

- Paul Dreyfuss, MD, EvergreenHealth Sport & Spine Care
- Alison Stout, DO, EvergreenHealth Sport & Spine Care
- Ryan Zehnder, MD, EvergreenHealth Sport & Spine Care
- Brandon Messerli, DO, EvergreenHealth Sport & Spine Care
- Doug Burns, MD, EvergreenHealth Sport & Spine Care
- Kevin VorenKamp, MD, Virginia Mason Medical Center

Presentation materials and conflict of interest forms are available with [March 21, meeting materials](#).

**Agency Utilization and Outcomes:**

Gary Franklin, MD, MPH, Medical Director, and Lee Glass, MD, JD, Associate Medical Director, both of WA Department of Labor and Industries presented the state agency utilization rates for Facet Neurotomy to the committee. The full presentation is published with [March 21, meeting materials](#).

**Vendor Report and HTCC Q & A**

Clinical expert, Jason G. Attaman, DO, FAAPMR, was introduced by the Chair.

Robin Hashimoto, PhD, of Spectrum Research, Inc, presented the evidence review addressing Facet Neurotomy. The full presentation is published with [March 21, meeting materials](#).

**Committee Discussion and Decision:**

The HTCC reviewed and considered the Facet Neurotomy evidence review report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Facet Neurotomy, Cervical C3/4 thru C6/7	4	0	7
Facet Neurotomy, Thoracic	11	0	0
Facet Neurotomy, Lumbar	4	0	7
Facet Neurotomy, Cervical spine for headache	10	0	1

**Limitations of Coverage:**

Lumbar Facet Neurotomy is a **covered benefit with conditions:**

- Patients over 17 years of age
- At least six months of continuous low back pain referable to the facet joint
- Non-radicular pain
- Unresponsive to other therapies/ failure of conservative therapies
- No other clear structural cause of back pain
- No other pain syndrome affecting the spine
- Patient selected by 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
- One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy.

Cervical Facet Neurotomy for cervical pain is a **covered benefit with conditions:**

- Patients over 17 years of age
- At least six months of continuous neck pain referable to the facet joint
- Non-radicular
- Unresponsive to other therapies/ failure of conservative therapies

- No other clear structural cause of neck pain
- No other pain syndrome affecting the spine
- Patient selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
- One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy.

**Non-Covered Indicators:**

Thoracic Facet Neurotomy **is not covered.**

Cervical Facet Neurotomy for headache **is not covered.**

**Action**

The committee checked for availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Facet Neurotomy. The committee reviewed selected payer coverage policies from Aetna, Cigna and Health Net. The committee also reviewed practice guidelines from The American Pain Society, National Institute for Health and Clinical Excellence/ National Collaborating Centre for Primary Care, American College of Occupational and Environmental Medicine; American Society of Interventional Pain Physicians; Colorado Division of Workers' Compensation, American College of Occupational and Environmental Medicine, Institute of Health Economics, Work Loss Data Institute, Institute for Clinical Systems Improvement and American Society of Regional Anesthesia and Pain Medicine.

The Chair directed HTA staff to prepare a draft coverage determination document for the topic.

The Chair called for further comments. No further comments on Facet Neurotomy.

**7. Meeting adjourned.**

**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Nonpharmacological Treatments for Treatment-resistant Depression  
**Meeting Date:** March 21, 2014  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website at:  
[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

**Number and Coverage Topic:**

20140321A – Nonpharmacological Treatments for Treatment-resistant Depression (TRD)

**HTCC Coverage Determination:**

Nonpharmacological Treatments for Treatment-resistant Depression are **covered benefits with conditions** consistent with the criteria identified in the reimbursement determination.

**HTCC Reimbursement Determination:**

**Limitations of Coverage**

Electroconvulsive Therapy is a **covered benefit**.  
Repetitive Transcranial Magnetic Stimulation is a **covered benefit**.

**Non-Covered Indicators**

Deep Brain Stimulation is **not covered**.  
Transcranial Direct Current Stimulation is **not covered**.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

**HTCC Coverage Vote and Formal Action*****Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Nonpharmacological Treatments for Treatment-resistant Depression demonstrates that there is sufficient evidence to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Nonpharmacological Treatments for Treatment-resistant Depression.

**Nonpharmacological Treatments for Treatment-resistant Depression**

<b>HTCC Committee Coverage Determination Vote</b>			
	<b>Not Covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
Electroconvulsive Therapy	0	10	1
Repetitive Transcranial Magnetic Stimulation	0	9	2
Deep Brain Stimulation	11	0	0
Transcranial Direct Current Stimulation	11	0	0

***Discussion***

The committee determined a vote of coverage for electroconvulsive therapy (ECT) and repetitive transcranial magnetic stimulation (RTMS), each without conditions. The committee discussed the application of this determination for only treatment resistant depression of condition as this was the defined scope of the review.

**Limitations of Coverage**

Electroconvulsive Therapy is a **covered benefit**.

Repetitive Transcranial Magnetic Stimulation is a **covered benefit**.

**Non-Covered Indicators**

Deep Brain Stimulation is **not covered**.

Transcranial Direct Current Stimulation is **not covered**.

***Action***

The committee checked for availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Electroconvulsive Therapy, Repetitive Transcranial Magnetic Stimulation, Transcranial Direct Current Stimulation or Deep Brain Stimulation. The committee reviewed selected payer policies for Aetna, Oregon Health Evidence Review Commission

**Draft**

and the New England Comparative Effectiveness Public Advisory Council. The committee also reviewed practice guidelines from The American Psychiatric Association, Canadian Network for Mood and Anxiety Treatments, Institute for Clinical Systems Improvement, National Institute for Health and Care Excellence and Veteran's Affairs and the Department of Defense.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Nonpharmacological Treatments for Treatment-resistant Depression reflective of the majority vote for final approval at the next public meeting.

### **Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

**Nonpharmacological Treatments for Treatment-resistant Depression**

*Draft Findings & Decision*

*Timeline and Overview of Comments*

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Nonpharmacological Treatments for Treatment-resistant Depression.

<b>Category</b>	<b>Comment Period April 7 - 22, 2014</b>	<b>Cited Evidence</b>
Patient, relative, and citizen	1	0
Legislator and public official	1	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
<b>Total</b>	<b>2</b>	<b>0</b>

<b>Technology Assessment Timeline</b>		
<b>Study Stage</b>	<b>Date</b>	<b>Public Comment Days</b>
Technology recommendations published	November 19, 2012	
<b>Public comments due</b>	December 3, 2012	<b>15</b>
Selected technologies published	December 6, 2012	
<b>Public comments due</b>	January 7, 2013	<b>32</b>
Draft Key Questions published	September 19, 2013	
<b>Public comments due</b>	October 3, 2013	<b>16</b>
Final Key Questions published	November 8, 2013	
Draft report published	December 19, 2013	
<b>Public comments due</b>	January 24, 2014	<b>36</b>
Final report published	February 24, 2014	
Public meeting date	March 21, 2014	
Findings & decision published	April 7, 2014	
<b>Public comments due</b>	April 22, 2014	<b>16</b>



**Public Comments:**

**Nonpharmacological Treatments for Treatment-resistant  
Depression**

Name	
1	Carolyn Madsen, parent
2	Lee Glass, MD, JD Associate Medical Director, Washington State Department of Labor and Industries

From: [REDACTED]  
Sent: Monday April 21, 2014 4:21 PM  
To: HCA ST Health Tech Assessment Prog  
Cc:  
Subject: Comment to HCA's 03/21/2014 Decision to Cover TMS for Persons with Treatment Resistant Depression (TRD)

Dear HCA: Please accept this email in support of your 03/21/2014 decision to cover TMS for persons with TRD.

Our daughter has struggled with severe recurrent major depression since she was 16. For four years, she tried over 15 different antidepressant medications and add-ons and years of talk therapy, including weekly cognitive behavioral therapy (individual and group) and intensive interpersonal talk therapy (4 sessions/week). Nothing worked as we watched our daughter slip deeper into a depression that robbed her of any semblance of a normal life. She received failing grades at school, lost all of her friends, slept 18 hours a day, and suffered panic attacks when she left the house.

When our daughter was 20 years old, our health provider (Group Health Cooperative) began discussing ECT, but our daughter strongly resisted ECT due to its invasive nature, medical complications, and side effects. Our daughter repeatedly asked Group Health about TMS but they refused to cover it, saying that TMS was not as safe or effective as ECT. A few months before her 21st birthday, our daughter sought an independent medical opinion from Dr. Kenneth Melman, medical director of the Seattle Neuropsychiatric Treatment Center which is affiliated with Swedish Medical Center. Dr. Melman specializes in treating persons with TRD and provides both TMS and ECT. Because our daughter was not suicidal, Dr. Melman recommended that she try TMS, the least invasive of the two most commonly used non-pharmacologic therapies for TRD, and she agreed.

Our daughter began TMS in August 2013 with a Quick Inventory of Depressive Symptomatology score of 21 (very severe depression) and completed TMS treatment in December 2013 with a score of 4 (remission from depression). Our daughter's depression remains in remission today, 4 months after completing TMS treatment.

Though our daughter's depression is in remission, she has not recovered from suffering severe recurrent major depression throughout her teen years. Thanks to Dr. Melman and TMS, however, our daughter is in recovery and will recover.

No one should suffer through years of TRD. Thanks to HCA, TMS will now be available to persons with TRD in Washington State who have publicly-funded health plans. We trust that HCA's decision to cover TMS will influence private health plans in Washington State to change their non-coverage policies.

Thank you for expanding treatment options for persons with TRD!

[REDACTED]

Comment regarding draft nonpharmacological treatments for treatment-resistant depression coverage decision:

To facilitate implementation of the decision, we recommend HTCC clarify the coverage determination in two areas.

1. Since the definition for treatment-resistant depression (TRD) is not standardized, it would be helpful for HTCC to define TRD for the purpose of implementation of the decision. We recommend the following definition that is used commonly in the community: **failure of  $\geq 2$  adequate trials (6 to 12 weeks for each trial) of different antidepressants.**
2. Based on our understanding of the review and FDA approvals, the coverage determination applies only to TRD related to major depression disorder or bipolar depression. We recommend modify the wording of the determination to further clarify the intended use of the treatments. We recommend the following modified wording: Nonpharmacological Treatments for Treatment-resistant Depression **related to major depressive disorder (MDD) or bipolar depression** are covered benefits with conditions consistent with the criteria identified in the reimbursement determination.

Thank you for your consideration of the recommendations.

Office of the Medical Director  
Department of Labor and Industries.

## Health Technology Clinical Committee Draft Findings and Decision

**Topic:** Facet Neurotomy  
**Meeting Date:** March 21, 2014  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website at:  
[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

### Number and Coverage Topic:

20140321B – Facet Neurotomy

### HTCC Coverage Determination:

Facet Neurotomy is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

### HTCC Reimbursement Determination:

Lumbar Facet Neurotomy is a **covered benefit with the following conditions:**

- Patient(s) must be over 17 years of age, and:
- Has at least six months of continuous low back pain referable to the facet joint
- The pain is non-radicular pain
- Condition is unresponsive to other therapies including conservative care
- There are no other clear structural cause of back pain
- There is no other pain syndrome affecting the spine.
- For identification, diagnosis, and treatment:
  - Patient must be selected by at least 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
  - One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.

Cervical Facet Neurotomy for cervical pain is a **covered benefit with the following conditions:**

- Limited to C3 - 4, through C6 -7
- Patient(s) over 17 years of age, and:
- Has at least six months of continuous neck pain referable to the facet joint
- The pain is non-radicular
- Condition is unresponsive to other therapies including conservative care
- There are no other clear structural cause of neck pain
- No other pain syndrome affecting the spine

Draft

- For identification, diagnosis, and treatment:
  - Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
  - One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.

**Non-Covered Indicators**

Facet Neurotomy for the thoracic spine **is not covered**.

Facet Neurotomy for headache **is not covered**.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

## HTCC Coverage Vote and Formal Action

### *Committee Decision*

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Facet Neurotomy demonstrates that there is sufficient evidence to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Facet Neurotomy.

### Facet Neurotomy

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Facet Neurotomy, Cervical C3/4 thru C6/7	4	0	7
Facet Neurotomy, Thoracic	11	0	0
Facet Neurotomy, Lumbar	4	0	7
Facet Neurotomy, Cervical spine for headache	10	0	1

### *Discussion*

The Chair called for discussion of conditions of coverage for Facet Neurotomy following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

#### **Limitations of Coverage**

Lumbar Facet Neurotomy is a **covered benefit with conditions**:

- Patients over 17 years of age
- At least six months of continuous low back pain referable to the facet joint
- Non-radicular pain
- Unresponsive to other therapies/ failure of conservative therapies
- No other clear structural cause of back pain
- No other pain syndrome affecting the spine
- Patient selected by 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
- One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy.

Cervical Facet Neurotomy for cervical pain is a **covered benefit with conditions**:

- Patients over 17 years of age

**Draft**

- At least six months of continuous neck pain referable to the facet joint
- Non-radicular
- Unresponsive to other therapies/ failure of conservative therapies
- No other clear structural cause of neck pain
- No other pain syndrome affecting the spine
- Patient selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
- One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy.

#### **Non-Covered Indicators**

Thoracic Facet Neurotomy **is not covered.**

Cervical Facet Neurotomy for headache **is not covered.**

#### **Action**

The committee was provided information about the availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Facet Neurotomy, but has a decision on nerve ablation. The committee considered this decision and determined there was no data shown supporting the decision, and HTCC's determination did not conflict with this NCD.

The committee reviewed selected payer coverage policies from Aetna, Cigna and Health Net. The committee also reviewed practice guidelines from The American Pain Society, National Institute for Health and Clinical Excellence/ National Collaborating Centre for Primary Care, American College of Occupational and Environmental Medicine; American Society of Interventional Pain Physicians; Colorado Division of Workers' Compensation, American College of Occupational and Environmental Medicine, Institute of Health Economics, Work Loss Data Institute, Institute for Clinical Systems Improvement and American Society of Regional Anesthesia and Pain Medicine.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Facet Neurotomy reflective of the majority vote for final approval at the next public meeting.

#### **Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence

**Draft**

of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.



**Facet Neurotomy**  
*Draft Findings & Decision*  
*Timeline and Overview of Comments*

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Facet Neurotomy.

Category	Comment Period <i>April 7 - 22, 2014</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	1	0
Health care professional	5	4
Industry & manufacturer	0	0
Professional society & advocacy organization	3	3
<b>Total</b>	<b>9</b>	<b>7</b>

<b>Technology Assessment Timeline</b>		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 19, 2012	
<b>Public comments due</b>	December 3, 2012	<b>15</b>
Selected technologies published	December 6, 2012	
<b>Public comments due</b>	January 7, 2013	<b>32</b>
Draft Key Questions published	August 2, 2013	
<b>Public comments due</b>	August 16, 2013	<b>15</b>
Final Key Questions published	August 29, 2013	
Draft report published	December 19, 2013	
<b>Public comments due</b>	January 27, 2014	<b>38</b>
Final report published	February 24, 2014	
Public meeting date	March 21, 2014	
Findings & decision published	April 7, 2014	
<b>Public comments due</b>	April 22, 2014	<b>16</b>

Draft Coverage Criteria Comment Summary.

The following table is assembled to highlight aspects of the draft coverage decision addressed in included comment letters.

HTCC DRAFT Coverage Criteria	Summary
<b>Lumbar Facet Neurotomy is a covered benefit with the following conditions:</b>	
<ul style="list-style-type: none"> <li>• Patient(s) must be over 17 years of age, and:</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• Has at least six months of continuous low back pain referable to the facet joint</li> </ul>	Multiple comments. Recommended changes include pain and functional limitation for > 3 months.
<ul style="list-style-type: none"> <li>• The pain is non-radicular pain</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• Condition is unresponsive to other therapies including conservative care</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• There are no other clear structural cause of back pain</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• There is no other pain syndrome affecting the spine.</li> </ul>	Multiple comments. Recommended change includes that concomitant disease in other parts of the spine are common and should not prevent treatment with facet neurotomy for those that meet other criteria.
<ul style="list-style-type: none"> <li>• For identification, diagnosis, and treatment:               <ul style="list-style-type: none"> <li>○ Patient must be selected by at least 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting</li> <li>○ One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.</li> </ul> </li> </ul>	<p><b>First bullet:</b> one comment to include agency discretion to include anesthetic and/or placebo MBBs in diagnostic workup.            “Patient must be selected by at least 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting</p> <ul style="list-style-type: none"> <li>• <i>If covered by the payer, a placebo medial branch block with insignificant improvement in pain “</i></li> </ul> <p><b>Second bullet:</b> multiple comments:</p> <ol style="list-style-type: none"> <li>1. This is a “reasonable approach”.</li> <li>2. Seek clarification of coverage for bilateral facet arthropathy.</li> <li>3. Coverage of multiple level RF neurotomy in appropriately selected pts (ISIS).</li> </ol>

Draft Coverage Criteria Comment Summary.

The following table is assembled to highlight aspects of the draft coverage decision addressed in included comment letters.

HTCC DRAFT Coverage Criteria	Summary
<b>Cervical Facet Neurotomy for cervical pain is a covered benefit with the following conditions:</b>	
<ul style="list-style-type: none"> <li>• Limited to C3 - 4, through C6 -7</li> <li>• Patient(s) over 17 years of age, and:</li> </ul>	Multiple comments. Recommended coverage of C2-C3 for headache.
<ul style="list-style-type: none"> <li>• Has at least six months of continuous neck pain referable to the facet joint</li> <li>• The pain is non-radicular</li> </ul>	Multiple comments. Recommended change to include pain and functional limitation for > 3 months.
<ul style="list-style-type: none"> <li>• Condition is unresponsive to other therapies including conservative care</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• There are no other clear structural cause of neck pain</li> </ul>	No comments
<ul style="list-style-type: none"> <li>• No other pain syndrome affecting the spine</li> </ul>	Multiple comments. Recommended change includes that concomitant disease in other parts of the spine are common and should not prevent treatment with facet neurotomy for those that meet other criteria.
<ul style="list-style-type: none"> <li>• For identification, diagnosis, and treatment:               <ul style="list-style-type: none"> <li>○ Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting</li> <li>○ One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.</li> </ul> </li> </ul>	<p><b>First bullet:</b> multiple comments.</p> <ol style="list-style-type: none"> <li>1. Comments suggest 100% “sets unrealistic standard...”</li> </ol> <p><b>Second bullet:</b> multiple comments:</p> <ol style="list-style-type: none"> <li>1. Multiple comments suggest too restrictive. Agree that patients should achieve at least 6 months improvement before consideration of repeat.</li> </ol>
Facet Neurotomy for the thoracic spine is not covered.	Multiple comments. Suggest thoracic pathology and pain is less common. Suggest application of identical criteria for thoracic coverage as for lumbar with >80% relief from dual MBBs.

Draft Coverage Criteria Comment Summary.

The following table is assembled to highlight aspects of the draft coverage decision addressed in included comment letters.

HTCC DRAFT Coverage Criteria	Summary
Facet Neurotomy for headache is not covered.	Multiple comments suggest coverage and/or Include evidence summary.
<b>Additional Comments</b>	
Guideline Review	
<p>Excerpt from letter: Jeffery Summers, MD, President, International Spine Intervention Society</p> <p><i>“disappointed to find that among the guidelines reviewed by the Committee, the list did not include those published by ISIS. This, despite the fact that we specifically suggested the review of those guidelines in our letter dated January 17, 2014. Additionally, with our comment letter submitted on January 10, 2013, we included a copy of a pre-publication excerpt containing the summary of evidence relative to facet neurotomy from the 2nd Edition ISIS Practice Guidelines.<sup>15</sup> The ISIS Practice Guidelines provide a comprehensive review of the evidence related to medial branch blocks and radiofrequency neurotomy, as well as specific recommendations relative to techniques that have been used to achieve successful outcomes. We encourage the Committee to review the guidelines, and would be happy to provide a copy to the appropriate individual, if interested.”</i></p>	<p><i>HTA response:</i> The January 17, 2014 letter is included in the Draft Report – Comments &amp; Response and is included below. The January 10, 2013 letter and attachment is also included below. This letter was provided to the review authors for consideration in the review draft.</p>

**Draft Findings & Decision**

**Public Comments: Facet Neurotomy**

Name	
1	Jane C K Fitch, MD President, American Society of Anesthesiologists
2	Paul Dreyfuss, MD                      EvergreenHealth Sport & Spine Care Tanya Cabrita, MD                      EvergreenHealth Sport & Spine Care Jason Attaman, DO                      EvergreenHealth Sport & Spine Care Douglas Burns, MD                      EvergreenHealth Sport & Spine Care Alison Stout, DO                      EvergreenHealth Sport & Spine Care Ray Baker, MD                      EvergreenHealth Sport & Spine Care Ryan Zehnder, MD                      EvergreenHealth Sport & Spine Care Cory Burch, PA                      EvergreenHealth Sport & Spine Care Jeff Roh, MD                      EvergreenHealth Sport & Spine Care Scott Price, MD                      EvergreenHealth Sport & Spine Care Mark Freeborn, MD                      EvergreenHealth Sport & Spine Care Addison Stone, MD                      EvergreenHealth Sport & Spine Care
3	Kevin E. Vorenkamp, MD Associate, Anesthesiology & Pain Medicine Virginia Mason Medical Center
4	Brandon Messerli, DO Diplomate, American Board of PM&R EvergreenHealth Sport & Spine Center
5	<b>Virtaj Singh, MD</b> Seattle Spine and Sports Medicine Ben Snyder, MD                      Seattle Spine and Sports Medicine Alma Garcia, MD                      Seattle Spine and Sports Medicine Richard Seroussi, MD                      Seattle Spine and Sports Medicine Yung Lee, DO                      Evergreen Sports and Spine Andrew Lynch, MD                      Swedish Spine and Sports Andrew Cole, MD                      Swedish Spine and Sports Gary Chimes, MD                      Lake Washington Spine Garret Hyman, MD                      Lake Washington Spine Brandon Messerli, DO                      Evergreen Sports and Spine Ryan Zehnder, MD                      Evergreen Sports and Spine Michael Hatzakis Jr, MD                      Rehab Options of Issaquah Marla Kaufman, MD                      Harborview Spine and Sports Medicine Andrew Friedman, MD                      Virginia Mason Medical Center Ali Putnam, DO                      Virginia Mason Medical Center Niriksha Malladi, MD                      Pacific Rehabilitation Kathy Burgess, MD                      Rehabilitation Institute of Washington Natalia Murinova, MD                      University of Washington

Name	
	Mitch Owens, PT
	Elisa Scherb, DPT
	Charles Naussbaum, MD                      Virginia Mason Medical Center
	Sai Mannem, MD                                Overlake Hospital
	Alexandre De Moraes, MD                    Overlake Hospital
	Kaj Johansen, MD, PhD                      Polyclinic
	Mark Freeborn, MD                            Evergreen Sports and Spine
	Jeffrey Roh, MD                                Evergreen Sports and Spine
	Addison Stone, MD                            Evergreen Sports and Spine
<b>6</b>	Richard Seroussi, MD Seattle Spine and Sports Medicine
<b>7</b>	Jeffery Summers, MD President, International Spine Intervention Society
<b>8</b>	Joseph M Neal, MD President, American Society of Regional Anesthesia and Pain Medicine Professor, Department of Anesthesiology, Virginia Mason Medical Center Asokumar Buvanendran, MD ASRA Treasurer and Executive Committee Member Professor of Anesthesiology and Pain Medicine, Rush University Medical College
<b>9</b>	Lee Glass, MD, JD Associate Medical Director, Washington State Department of Labor and Industries



April 16, 2014

Washington State Health Care Authority  
626 8th Avenue SE  
Olympia, WA 98501

**SUBMITTED VIA EMAIL TO: [SHTAP@HCA.WA.GOV](mailto:SHTAP@HCA.WA.GOV)**

Dear Health Technology Clinical Committee:

We are writing on behalf of the more than 52,000 members of the American Society of Anesthesiologist (ASA) to express our concerns regarding the recently published draft findings and decision of the Washington State Healthcare Authority Health Technology Assessment Health Technology Clinical Committee regarding facet neurotomy.

#### Lumbar Facet Neurotomy

1. The decision to cover lumbar facet neurotomy is reasonable and appropriate. However, the conditions regarding its use are too limited and may limit appropriate use that will help to reduce pain, improve function and decrease time away from work. The following specific items are of concern:
  - a. *Has at least six months of continuous low back pain referable to the facet joint.* **ASA Comment: Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for >3 months despite conservative measures.**
  - b. *There is no other pain syndrome affecting the spine.* **ASA Comment: Degenerative changes that occur with age, trauma and overuse are rarely limited to a single anatomic structure and frequently involve multiple sites. Patients who meet criteria for facet neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as part of an overall treatment plan.**
  - c. *One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.* **ASA Comment: This is a reasonable approach. It is common for degenerative changes to occur bilaterally, e.g. L4-5 and L5-S1. Please clarify if treatment for bilateral facet arthropathy is covered.**

## Cervical Facet Neurotomy

2. Regarding coverage for cervical medial branch neurotomy, there are 4 major areas of concern.

- a. *Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting.* **ASA Comment:** Although optimal results are reported when selecting patients with complete relief, excellent results have also been demonstrated with more traditional guidelines of patient selection. Using 50-80% pain relief, 74% of patients obtain at least 75% pain relief at 6 months (Shin 2006, Speldewinde 2011) or >50% relief at 12 month follow-up (Sapir 2001). Patients who obtain >50-80% pain relief following dual medial branch blocks demonstrated sustained relief beyond months with neurotomy. Selecting patients who only have 100% relief sets an unrealistic standard that neither has evidence in the medical literature nor allows for persistent pain that may be present from contralateral disease or associated myofascial pain. This standard will result in an inappropriate restriction in access to a valuable pain relieving technique for a large number of patients who may receive significant pain relief and functional improvement for >6-12 months.
- b. *One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.* **ASA Comment:** This restriction has no foundation in the medical literature and is inconsistent with the natural history of cervical facet arthropathy, which is commonly present in more than one joint. Of all the studies listed, only the Govind study restricted treatment to a single joint (C2-3 joint/third occipital nerve) and it was designed for the treatment of third occipital headache and not neck pain. All of the other studies listed and published allowed for treatment of additional levels when indicated. When involvement of more than 1 joint is present clinically, and when diagnostic blockade confirms the clinical diagnosis, then neurotomy of more than 1 cervical facet joint should be approved. In addition, it is common for disease to occur bilaterally and it should be clarified that bilateral treatment is acceptable when all other criteria are met. We agree that patients should achieve a minimum of 6-months improvement in pain and function before consideration of repeat neurotomy.
- c. *Has at least six months of continuous neck pain referable to the facet joint.* **ASA Comment:** Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for >3 months despite conservative measures.
- d. *There is no other pain syndrome affecting the spine.* **ASA Comment:** Although less common, some patients have concomitant disease in multiple spine areas, just as patients may have pain arising from multiple joints such as



the hip and the knee. Excluding patients from treatment when alternative treatments are ineffective does not target functional restoration. Patients who meet criteria for facet neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as degenerative changes of the spine are rarely limited to a single region of the spine.

#### Facet Neurotomy for the Thoracic Spine

3. *Non-coverage of thoracic facet neurotomy.* **ASA Comment:** Thoracic pathology and pain are far less common than conditions affecting other portions of the spine. Not surprisingly, there are limited studies evaluating response to thoracic facet neurotomy. The only study with proper selection technique (dual diagnostic medial branch blocks) did demonstrate significant improvement with thoracic facet neurotomy. Stolker et al studied 40 patients with thoracic facet joint pain confirmed by diagnostic blocks. They reported positive results with 47.5% of patients being pain-free and an additional 35% having relief greater than 50% at 2-months follow-up. After a follow-up of 18-54 months, they reported 83% of the patients with greater than 50% benefit. Similarly, Speldewinde showed 68% of patients benefitted from thoracic facet neurotomy, with an average percentage and duration of relief of 85% and 9 months, respectively. Thoracic facet pain is far less common than lumbar or cervical facet pain; however, thoracic facet neurotomy may benefit those patients with refractory thoracic pain who meet identical criteria to those applied to the lumbar region including >80% relief with dual medial branch blocks.

#### Cervical Facet Neurotomy for Headache

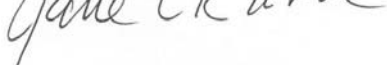
4. *Cervical Facet Neurotomy for headache is not covered.* **ASA Comment:** Non-coverage of neurotomy for the third occipital nerve (TON)/C2-3 facet joint is unreasonable. This treatment has demonstrated a high degree of effectiveness in several studies. Three prospective studies have demonstrated a high level of effectiveness when patients are selected with diagnostic blockade of the third occipital nerve. Govind (2003) published the results of a revised technique for percutaneous radiofrequency neurotomy for third occipital headache and found that 88% of 49 patients obtained COMPLETE relief of pain and had a successful outcome for a median duration of 217 days. Repeat neurotomy when symptoms returned again resulted in COMPLETE relief in 86% of patients. Both Barnsley (2005) and Macvicar (2012) demonstrated comparable relief, namely 60% at 44 weeks and 61%/74% respectively at 17-20 months. Macvicar's success was defined as COMPLETE relief of pain for >6 months WITH restoration of activities, return to work (if applicable) and no need for further health care visits regarding their neck pain. They also demonstrated similar response with repeat treatment. Third occipital neurotomy has demonstrated benefit providing COMPLETE pain relief in patients with pain relieved by diagnostic blockade of the TON. This is a valuable technique for the treatment of intractable headache in a subset of patients and should be approved for use.

In conclusion, we recommend the following changes to the draft findings and decision on facet neurotomy:

1. General: Eligibility should be pain > **3** months duration and not responsive to conservative measures.
2. General: There should **NOT** be an exclusion statement for more than 1 spinal segment pain (i.e. patients may receive both cervical and lumbar neurotomy if other criteria are met).
3. Patient selection: Patients should demonstrate **≥80%** relief with dual diagnostic blocks for all regions of the spine. Treatment coverage may cover 1 or 2 joints, bilaterally when indicated.
4. Third occipital neurotomy: Patients should be eligible for third occipital (C2/3) neurotomy if strict selection criteria are met for the treatment of intractable headache.
5. Thoracic facet neurotomy is indicated for patients with thoracic facet pain when proper selection criteria are met.

On behalf of the ASA, we appreciate the opportunity to provide feedback to the committee regarding the draft findings and decision regarding facet neurotomy. We would be happy to meet with you to provide further information or enter into discussion with the committee to develop safe and effective coverage policies related to the care of patients with spine related pain treated with facet neurotomy.

Respectfully yours,



Jane C.K. Fitch, M.D.

President

American Society of Anesthesiologists

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4.18.14

Regarding: 20140321B – Facet Neurotomy and proposed non-coverage of cervical facet neurotomy for headache

Craig Blackmore, MD, MPH  
Chair  
WA State Health Technology Clinical Committee  
PO BOX 42712  
Olympic, WA 98504-2712

Dear Dr. Blackmore:

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. (Barnsley,1995, Cooper,2007, Lord,1996, Manchukonda, 2007, Yin,2008) In patients who prove positive to controlled medial branch blocks, the segments most commonly positive are C2,3 and C5,6. (Cooper,2007) In 1994, a substantive study, using controlled diagnostic blocks of the third occipital nerve, (which is the innervation to the C2-3 zygapophysial joint) (Bogduk, 1982) reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint. (Lord,1994) RF neurotomy of this joint is performed via third occipital nerve (TON) neurotomy in the treatment of headache originating from the cervical spine aka cervicogenic headache.

The seminal RCT on cervical medial branch neurotomy demonstrated the positive outcome of the procedure at C3-4 to C6-7 is clearly not due to placebo effects and some 60% of patients can be expected to have a successful outcome. (Lord,1996) This study did not evaluate 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. (Lord,1995) More recently, subsequent to the Lord RCT, these RF technical limitations have been addressed. (Govind,2003)

Although there have been three RCTs on the treatment of cervicogenic headache these studies do not provide credible evidence in the evaluation C2-3 facet denervation. (van Suijlekom,1998, Stovner,2004, Haspelagh,2006) In these studies patients were selected on clinical criteria only and not with controlled medial branch or third occipital nerve blocks. Thus, 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, as these studies used invalid methodology no scientifically valid conclusions can be drawn except that poorly selecting patients for RF and performing RF inappropriately will yield results that are no better than sham treatments, as expected.

There is no RCT on third occipital nerve RF for C2-3 facet pain. However, one important consideration has been often overlooked. It would be impossible to perform a true blinded RCT on C2-3 facet RF. Those that receive an effective third occipital nerve neurotomy also develop time limited neuropathic symptoms followed by cutaneous numbness in the distribution of the nerve. The active arm would clearly be aware of such symptoms and know they received the treatment and those that receive the sham would not have such symptoms. Additionally, those that receive the diagnostic third occipital nerve blocks also receive numbness in the same distribution and learn that such is associated with an active block and this would be an expectation following a technically well performed active C2-3 facet neurotomy.

Additionally, 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. (Lord,1996)

Despite the inability to perform a blinded RCT on C2-3 facet RF there is additional evidence that was inappropriately excluded by Spectrum that deserves consideration by the HTCC.

Evidence based medicine dictates evaluation of all available evidence and not only RCTs. This is exemplified by Sackett who stated: "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." Also, Dr. Cancato, stated in the New England Journal of Medicine, "Carefully conducted, observational analyses are at least as reliable as small RCTs and that "ignoring the evidence from observational studies is not a viable option".

The HTCC has made prior coverage decisions when RCTs were lacking or not of adequate quality. The committee appropriately evaluated the next best evidence; prospective trials. We trust the committee is willing to evaluate such evidence in regards to third occipital nerve neurotomy.

There are three prospective trials that provide insight into the effectiveness of denervation of this joint via third occipital nerve neurotomy.

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 (Govind,2003) 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 (Barnsley,2005) or one of the most predominant levels treated. (Macvicar,2012)

Govind selected patients with comparative blocks who had complete pain relief following each block. Anatomically sound RF lesions were performed. 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. (Govind,2003)

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. (Barnsley,2005)

In the study by Macvicar two practitioners reported the outcomes of all their consecutive patients over five years in their respective practices. (Macvicar,2012) 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 (Macvicar,2012)

### **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. These results are far superior to known cervical interventional placebo rates such as from RF at other levels, epidural injections, zygapophysial joint injections or trigger point injections. Furthermore, non-invasive conservative care options (manipulation, physical therapy, drug treatment, psychological care and massage therapy) are employed before one considers the role of C2-3 facet RF. These services are accepted and covered yet no such treatment has been shown via any prospective trial to be capable of achieving complete relief of pain, accompanied by restoration to normal life, and cessation of health care in those with C2-3 facet pain as established by controlled third occipital nerve blocks.

In light of the above we propose the following coverage guidelines:

C2-3 facet RF Neurotomy is a covered service for the treatment of cervicogenic headache provided the following conditions are met:

- Pain is chronic in nature (>6 months of pain)
- No evidence of radicular pain or other obvious co-pain generators
- Failure of non-invasive conservative care
- Diagnosis established by 80-100% relief of the patient's index pain with controlled third occipital nerve blocks
- RF cannot be repeated unless the patient obtained at least 50% improvement in their index pain after third occipital nerve RF for a minimum of 6 months accompanied by functional gains.

Such a coverage policy would be consistent with the current proposed "National LCD" on facet joint interventions. Creation of the recommendations within this national LCD was a collaborative effort between 13 pain, spine, radiological, surgical and other specialty societies treating spine pain and appointed medical directors from Noridian. This national facet LCD is in effect in Noridian and CGS states with other contractors matriculating this LCD through the public comment and CAC process.

#### Additional Considerations:

The HTCC has determined that cervical and lumbar neurotomy is a covered benefit with conditions.

Two conditions include "at least 6 months of continuous neck or back pain referable to the facet joint" and "no other pain syndrome affecting the spine".

For clarification neck or back pain does not refer to the facet joint, but the facet joint can cause referred pain that is non-radicular in nature and consistent with known somatic referred pain patterns.

The condition of "pain syndrome affecting the spine" defines further clarification as it is open to a very broad interpretation. There are patients with chronic pain and patients with chronic pain syndromes. These are significantly different entities. A patient who happens to have minor focused neck pain should not be denied an appropriate lumbar facet neurotomy for significant pain that has a negative impact on their quality of life and function. However, a patient with diffuse, non-anatomic total spine pain with symptom amplification, major depression, a hypersensitivity state and is on long-term disability might not be expected to respond to RF neurotomy in the same positive manner as an individual with a focused, anatomic pain source in a separate region of the spine other than that being addressed by the RF neurotomy. I do not expect the committee wishes to deny an appropriate RF neurotomy because the patient happens to be unfortunate enough to have some degree of spine pain elsewhere. Pain in one region of the spine should not negate the validity of the pain in a separate region of the spine.

Respectfully submitted,

Paul Dreyfuss, MD  
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Douglas Burns, MD  
Alison Stout, DO  
Ray Baker, MD  
Ryan Zehnder, MD  
Cory Burch, PA  
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Scott Price, MD  
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Washington State Health Care Authority  
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Olympia, WA 98501

April 20, 2014

SUBMITTED VIA EMAIL TO: [SHTAP@HCA.WA.GOV](mailto:SHTAP@HCA.WA.GOV)

Dear Health Technology Clinical Committee:

I am writing to express my concerns regarding the recently published draft findings and decision of the Washington State Healthcare Authority Health Technology Assessment Health Technology Clinical Committee regarding facet neurotomy. As background, I am a board certified anesthesiologist and pain medicine physician. I currently serve as faculty at Virginia Mason Medical Center and I actively perform and instruct pain medicine fellows on the proper performance of all of the facet neurotomy treatments that are under review. I believe the shortcomings of the Spectrum group report have been outlined in prior communications and therefore I will focus on the importance of modifying the current terms of the draft findings.

Although I recognize the importance of cost-containment measures, excluding effective procedures is not in the best interest of the patients that will be affected. As presented at the meeting on March 21, these treatments are beneficial to patients and insurance providers when proper patient selection criteria and procedural techniques are used. Also, as commented on by a committee member following the presentations of Drs. Franklin and Glass, the utilization has actually *decreased* over the past few years. Let us now focus on the benefits of the procedures and discrepancies with the current draft recommendations.

Cervical Facet Neurotomy for Headache

1. One of the most successful treatments in all of interventional pain medicine is neurotomy of the third occipital nerve (TON)/C2-3 facet for headache. There are not any other treatment with a similar safety profile that can achieve COMPLETE relief of pain in the majority of patients.

**Non-coverage of neurotomy for the third occipital nerve (TON)/C2-3 facet joint is unreasonable.** This treatment has demonstrated a high degree of effectiveness in several studies. Three prospective studies have demonstrated a high level of effectiveness when patients are selected with diagnostic blockade of the third occipital nerve. Govind (2003) published the results of a revised technique for percutaneous radiofrequency neurotomy for third occipital headache and found that 88% of 49 patients obtained COMPLETE relief of pain and had a successful outcome for a median duration of 217 days. Repeat neurotomy when symptoms returned again resulted in COMPLETE relief in 86% of patients. Both Barnsley (2005) and Macvicar (2012) demonstrated comparable relief, namely 60% at 44 weeks and 61%/74% respectively at 17-20 months. Macvicar's success was defined as COMPLETE relief of pain for >6 months WITH restoration of activities, return to work (if applicable) and no need for further health care visits regarding their neck pain. They also demonstrated similar response with repeat treatment. Third occipital neurotomy has demonstrated benefit providing COMPLETE pain relief in patients with pain relieved by diagnostic blockade of the TON. **This is a valuable technique for the treatment of intractable headache in a subset of patients and should be approved for use.**



## Cervical Facet Neurotomy

2. Regarding coverage for cervical medial branch neurotomy, there are 4 major areas of concern.
  - a. *Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting.*

Although optimal results are reported when selecting patients with complete relief, excellent results have also been demonstrated with more traditional guidelines of patient selection. Using 50-80% pain relief, 74% of patients obtain at least 75% pain relief at 6 months (Shin 2006, Speldewinde 2011) or >50% relief at 12 month follow-up (Sapir 2001). Patients who obtain >50-80% pain relief following dual medial branch blocks demonstrated sustained relief beyond months with neurotomy. In the lumbar spine, Cohen (2013) concluded that there was no significant difference in outcome in patient outcomes with facet neurotomy for patients having at least 50% pain relief, leaving them to conclude ***“Establishing more stringent selection criteria...is likely to result in withholding a beneficial procedure from a substantial number of patients, without improving success rates.”***

**Selecting patients who only have 100% relief sets an unrealistic standard that neither has evidence in the medical literature nor allows for persistent pain that may be present from contralateral disease or associated myofascial pain. This standard will result in an inappropriate restriction in access to a valuable pain relieving technique for a large number of patients who may receive significant pain relief and functional improvement for >6-12 months.**

- b. *One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.*

**This restriction has no foundation in the medical literature and is inconsistent with the natural history of cervical facet arthropathy, which is commonly present in more than one joint.** Of all the studies listed, only the Govind study restricted treatment to a single joint (C2-3 joint/third occipital nerve) and it was designed for the treatment of third occipital headache and not neck pain. All of the other studies listed and published allowed for treatment of additional levels when indicated. **When involvement of more than 1 joint is present clinically, and when diagnostic blockade confirms the clinical diagnosis, then neurotomy of more than 1 cervical facet joint should be approved.** In addition, it is common for disease to occur bilaterally and it should be clarified that bilateral treatment is acceptable when all other criteria are met. We agree that patients should achieve a minimum of 6-months improvement in pain and function before consideration of repeat neurotomy.

- c. *Has at least six months of continuous neck pain referable to the facet joint.*

Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for **>3 months** despite conservative measures.

- d. *There is no other pain syndrome affecting the spine.*

Although less common, some patients have concomitant disease in multiple spine areas, just as patients may have pain arising from multiple joints such as the hip and the knee. Excluding patients from treatment when alternative treatments are ineffective does not target functional restoration. **Patients who meet criteria for facet neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as degenerative changes of the spine are rarely limited to a single region of the spine.**

### Lumbar Facet Neurotomy

3. The decision to cover lumbar facet neurotomy is reasonable and appropriate. However, the conditions regarding its use are too limited and may limit appropriate use that will help to reduce pain, improve function and decrease time away from work. The following specific items are of concern:

- a. *Has at least six months of continuous low back pain referable to the facet joint.*

Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for **>3 months** despite conservative measures.

- b. *There is no other pain syndrome affecting the spine.*

Degenerative changes that occur with age, trauma and overuse are rarely limited to a single anatomic structure and frequently involve multiple sites. **Patients who meet criteria for facet neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as part of an overall treatment plan.**

- c. *One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.*

This is a reasonable approach. It is common for degenerative changes to occur bilaterally, e.g. L4-5 and L5-S1. **Please confirm that bilateral facet neurotomy is covered when indicated.**

### Facet Neurotomy for the Thoracic Spine

4. *Non-coverage of thoracic facet neurotomy.*

Thoracic pathology and pain are far less common than conditions affecting other portions of the spine. Not surprisingly, there are limited studies evaluating response to thoracic facet neurotomy. The only study with proper selection technique (dual diagnostic medial branch blocks) did demonstrate significant improvement with thoracic facet neurotomy. Stolker et al studied 40 patients with thoracic facet joint pain confirmed by diagnostic blocks. They reported positive results with 47.5% of patients being pain-free and an additional 35% having relief greater than 50% at 2-months follow-up. After a follow-up of 18-54 months, they reported 83% of the patients with greater than 50% benefit. Similarly, Speldewinde

showed 68% of patients benefitted from thoracic facet neurotomy, with an average percentage and duration of relief of 85% and 9 months, respectively. Thoracic facet pain is far less common than lumbar or cervical facet pain; however, **thoracic facet neurotomy should be a covered treatment for those patients with refractory thoracic pain who meet identical criteria to those applied to the lumbar region including >80% relief with dual medial branch blocks.**

In conclusion, I recommend the following changes to the draft findings and decision on facet neurotomy:

1. General: Eligibility should be pain > **3** months duration and not responsive to conservative measures.
2. General: There should **NOT** be an exclusion statement for more than 1 spinal segment pain (i.e. patients may receive both cervical and lumbar neurotomy if other criteria are met).
3. Third occipital neurotomy: Patients should be eligible for third occipital (C2/3) neurotomy if strict selection criteria are met for the treatment of intractable headache.
4. Patient selection: Patients should demonstrate **≥80%** relief with dual diagnostic blocks for all regions of the spine. Treatment coverage may cover 1 or 2 joints, bilaterally when indicated.
5. Thoracic facet neurotomy is indicated for patients with thoracic facet pain when proper selection criteria are met.

I appreciate the opportunity to provide feedback to the committee regarding the draft findings and decision regarding facet neurotomy. I would be happy to meet with you to provide further information or enter into discussion with the committee to develop safe and effective coverage policies related to the care of patients with spine related pain treated with facet neurotomy.

Sincerely,



Kevin E. Vorenkamp, M.D.  
[kevin.vorenkamp@gmail.com](mailto:kevin.vorenkamp@gmail.com)

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April 21, 2014

Regarding: 20140321B – Facet Neurotomy

Dear HTA committee members,

I am a board-certified physiatrist practicing at EvergreenHealth Sport & Spine Center. I am writing this letter to express my significant concern for the decision by the HTCC to not cover facet neurotomy at the C2-3 joint, or, third occipital neurotomy (TON). I believe this decision was based on an inadequate and partial analysis of the body of literature and current standard of care. Significant emphasis in the Spectrum analysis was placed on the seminal study by Lord in 2006. This study purposely excluded the C2-3 facet joint, and included only the lower cervical facet levels, because the anatomy and technique for blockage of the third occipital nerve was not adequately defined at that time. Using modern techniques that are now the standard of care, subsequent well-designed prospective trials by Govind, 2003, Barnsley, 2005, and MacVicar, 2012 showed consistently good to excellent results (I defer to my colleagues who have reported on the details of these studies). No randomized controlled trial has been done because, firstly, it is impossible to blind a placebo treatment (subjects know from the diagnostic blocks that they should have subsequent skin numbness), and, secondly, the current evidence, expert opinion, and practical experience is that the procedure is efficacious, and withholding treatment is not warranted.

Non-coverage decisions cannot be simply dictated by showing a lack of randomized controlled trials. This has not been the case with prior HTCC coverage decisions, and it should not be the case now. Additionally, I am not aware of any other conservative treatment options (i.e. PT, manual therapy, massage, medications) that have been studied with a RCT for cervical facet-mediated pain, yet these treatments are covered.

Rather than focusing on the details of the research for this topic, as my colleagues have done, I would like to share my clinical experience. I treat patients with Medicaid and L&I who present with sub-occipital neck pain and cervicogenic headaches. Whiplash-associated disorder from motor vehicle accidents and direct trauma is a common risk factor, but C2-3 facet-mediated pain can also occur due to degenerative disease, chronic postural dysfunction, and repetitive stress injury. C2-3 facet-mediated cervicogenic headaches can be debilitating. They can also contribute to headaches with migrainous features, via trigeminal convergence. A detailed and precise history and physical examination can often clinically select patients with presumed C2-3 facet-mediated pain. It is standard of care to treat these patients first with conservative therapies, and many of my patients do adequately improve, such as to not require further treatment. Some patients become dependent on daily pain medications, including opioids, which are limited by side-effects and are very expensive in the long-term if no definitive treatment is achieved. Some patients have such intense headaches that they frequently miss work, use short-term disability, or apply for SSDI. Just this week, I saw a dental hygienist with over 10 years of C2-3 facet-mediated headaches that have slowly and progressively worsened. She has been unable to work for a number of months due to the pain and has applied for SSDI. She has tried an extensive amount of (expensive) conservative treatment in past years, never with any marked or sustained effect. If dual comparative TON blocks are positive, her C2-3 facet joint will be proven to be the pain generator, and the chance of clinically-significant benefit from TON RFN is high.

I have seen countless patients achieve complete or near-complete pain resolution, and subsequent improvement in quality of life. In fact, compared to the spinal interventions that I personally perform (including lumbar facet RFN), I see the most markedly positive responses with TON RFN. The treatment

of TON RFN can make the difference between chronic disability versus resolution of the headaches and return to full-time employment. The repercussions of a non-coverage decision can have a significant financial impact at the state and federal level as well, as those suffering may lose their employment and not contribute income taxes, and instead collect disability payments and other types of welfare.

I understand that cost containment is required for the system as a whole, and there are difficult coverage decisions pending in most fields of medicine. However, it is our duty to use sound judgement in our decision-making, and not deprive people of a proven treatment. Although this non-coverage decision may help the Washington State budget in the short-term, I believe that the long-term repercussions would have a net negative effect. There are other methods to reduce costs. Unfortunately, there are a small subset of physicians that do not practice evidence-based medicine or follow published guidelines. These faulty practice patterns can be controlled by setting more stringent criteria for insurance pre-approval; criteria that most other doctors are already following. My colleague, Dr Paul Dreyfuss, in his own response letter, has proposed a coverage guideline that I agree is reasonable and prudent, and will help to control utilization of the procedure.

Washington State and physicians have a responsibility to treat our citizens and patients, respectively. It would be a tragedy to neglect people of this proven treatment.

Sincerely,

Brandon Messerli, DO  
EvergreenHealth Sport & Spine Center  
Diplomate, American Board of PM&R

**Virtaj Singh, MD**  
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Dear HTA committee members,

I am a board-certified physiatrist, currently practicing at Seattle Spine and Sports Medicine. I am writing this letter to express concern about the committee's recent non-coverage decision for facet neurotomy at the C2/3 joint level (also known as third occipital nerve neurotomy).

I want to begin by stating my understanding for the difficulty inherent in attempting to use the best medical evidence available to guide decisions regarding which procedures should be covered by L&I. As a taxpayer, I appreciate your role in this valiant effort to protect our limited state-funded health care dollars. Indeed, my concern regarding the C2/3 facet joint non-coverage decision arises from the standpoint of trying to protect our limited resources. To be clear, I do not personally perform C2/3 (or any other level) facet joint neurotomy. Hence, I personally do not stand to lose income if this procedure is not covered. I do, however, take care of quite a few injured workers (I estimate that 1/3-1/2 of my practice are patients covered by L&I), and fear that the decision for non-coverage of this procedure will have significant unintended consequences.

I suspect you are aware that the C2/3 facet joint is considered the most likely cause of chronic headaches in patients who have suffered "cervical strain" injuries and experience cervicogenic headaches. When these headaches become unremitting, managing them without C2/3 facet joint neurotomy becomes almost impossible. Without access to C2/3 facet joint neurotomy, these patients may require daily treatments such as chiropractic care and massage to achieve even a minimal level of function. Many patients become dependent on daily medications, including opioid medications. Patients may find themselves in a vicious cycle of treating headaches regularly with medications that ultimately leads to the development of rebound headaches. Due to their uncontrolled pain, patients often miss work and, when the headaches cannot be terminated, patients may become chronically disabled. These potential long-term outcomes and their sequelae certainly cost the state significantly more than a simple C2/3 facet joint neurotomy would. I have managed many L&I cases that included complaints of cervicogenic headache and have observed that headaches are difficult to disprove and, therefore, it is often not possible to close an injured worker's claim due to lack of objective evidence.

As a provider, I have found no greater satisfaction than when I am able to help someone get rid of their daily headaches by referring them on for C2/3 facet joint neurotomy. With a simple outpatient procedure, these headaches can be reliably terminated, thereby facilitating not only relief from suffering but also rehabilitation and eventual return to work and claim closure. This outcome is the ultimate "win-win" for all parties involved. In my experience caring for injured workers with cervicogenic headaches, the C2/3 facet joint neurotomy has made this desirable outcome a reality on many occasions. Because of my observations of the profound positive impact this procedure can engender, it is easy for me to say, without reservation, that if I could ask for L&I to cover facet neurotomy for just one joint in the entire spine, I would choose the C2/3 facet joint.

I am, of course, just one practitioner. Thus, I asked many colleagues from a variety of backgrounds who treat patients with cervicogenic headaches to see if their sentiments are consistent with my

own. To ensure that I collected endorsements from practitioners who are familiar with the relevant patient population and who do not stand to benefit financially as a function of the coverage status of the procedure, I asked practitioners to endorse the following statement:

“I am a licensed healthcare practitioner in the state of Washington. I do not personally perform C2/3 facet joint neurotomy, but I do believe this procedure is valuable and would request that the non-coverage decision be reversed.”

Please consider both the human suffering and downstream financial costs that the C2/3 facet joint neurotomy procedure can alleviate and reverse this one aspect of your decision. If I can provide any further information, please do not hesitate to contact me.

Sincerely yours,



Virtaj Singh, MD

The following practitioners have agreed to co-sign this letter as detailed above.

Name	Specialty
Ben Snyder, MD	Physiatrist, Seattle Spine and Sports Medicine
Alma Garcia, MD	Physiatrist, Seattle Spine and Sports Medicine
Richard Seroussi, MD	Physiatrist, Seattle Spine and Sports Medicine
Yung Lee, DO	Physiatrist, Evergreen Sports and Spine
Andrew Lynch, MD	Physiatrist, Swedish Spine and Sports
Andrew Cole, MD	Physiatrist, Swedish Spine and Sports
Gary Chimes, MD	Physiatrist, Lake Washington Spine
Garret Hyman, MD	Physiatrist, Lake Washington Spine
Brandon Messerli, DO	Physiatrist, Evergreen Sports and Spine
Ryan Zehnder, MD	Physiatrist, Evergreen Sports and Spine
Michael Hatzakis Jr, MD	Physiatrist, Rehab Options of Issaquah
Marla Kaufman, MD	Physiatrist, Harborview Spine and Sports medicine
Andrew Friedman, MD	Physiatrist, Virginia Mason
Ali Putnam, DO	Physiatrist, Virginia Mason
Niriksha Malladi, MD	Physiatrist, Pacific Rehabilitation
Kathy Burgess, MD	Physiatrist, Rehabilitation Institute of Washington
Natalia Murinova, MD	Neurologist, University of Washington
Mitch Owens, PT	Physical Therapist, specializes in cervicogenic headaches
Elisa Scherb, DPT	Physical Therapist, specializes in cervicogenic headaches
Charles Naussbaum, MD	Neurosurgery Spine Surgeon, Virginia Mason
Sai Mannem, MD	Internal Medicine, Overlake
Alexandre De Moraes, MD	Family Medicine, Overlake
Kaj Johansen, MD, PhD.	Vascular Surgeon, Polyclinic
Mark Freeborn, MD	Orthopedic Spine Surgeon, Evergreen
Jeffrey Roh, MD	Orthopedic Spine Surgeon, Evergreen
Addison Stone, MD	Orthopedic Spine Surgeon, Evergreen



**Richard E. Seroussi M.D., M.Sc.**  
**Diplomate, American Board of PM&R with subspecialty certification in Pain Medicine.**  
**Diplomate, American Board of Electrodiagnostic Medicine.**

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April 6, 2014

**RE: HTA Decision Not to Cover C2-3 Facet Joint Neurotomy**

Dear HTA Committee Members:

**I am urging you to reverse your decision to not cover C2-3 facet joint neurotomy for patients with documented C2-3 facet joint injuries in the Workmen's Compensation setting in Washington State.** In order to improve the clarity of my appeal letter, I will divide my opinions into separate sections as follows:

**My Qualifications and Professional Background**

I am writing as a board-certified physiatrist, practicing at Seattle Spine & Sports Medicine, and on the courtesy clinical faculty at the University of Washington Department of Rehabilitation Medicine. I have over almost 20 years experience as an attending physiatrist treating patients with spinal injuries within the Workmen's Compensation system, as well as patients under private insurance and patients who have been involved in motor vehicle crashes.

I am also subspecialty board-certified in pain medicine and board-certified in electrodiagnostic medicine. I have lectured extensively regarding the nature of spinal injuries in the Workmen's Compensation setting as well as for patients who have sustained so-called "whiplash" injuries.

**Please understand I do not perform this procedure, I do not in any way "profit" within my practice from this procedure, but I will fight for the welfare of injured patients, including in the Workmen's Compensation setting when the guidelines are clearly wrong.**

**Brief Literature Review on the Prevalence of C2-3 Facet Joint Injury**

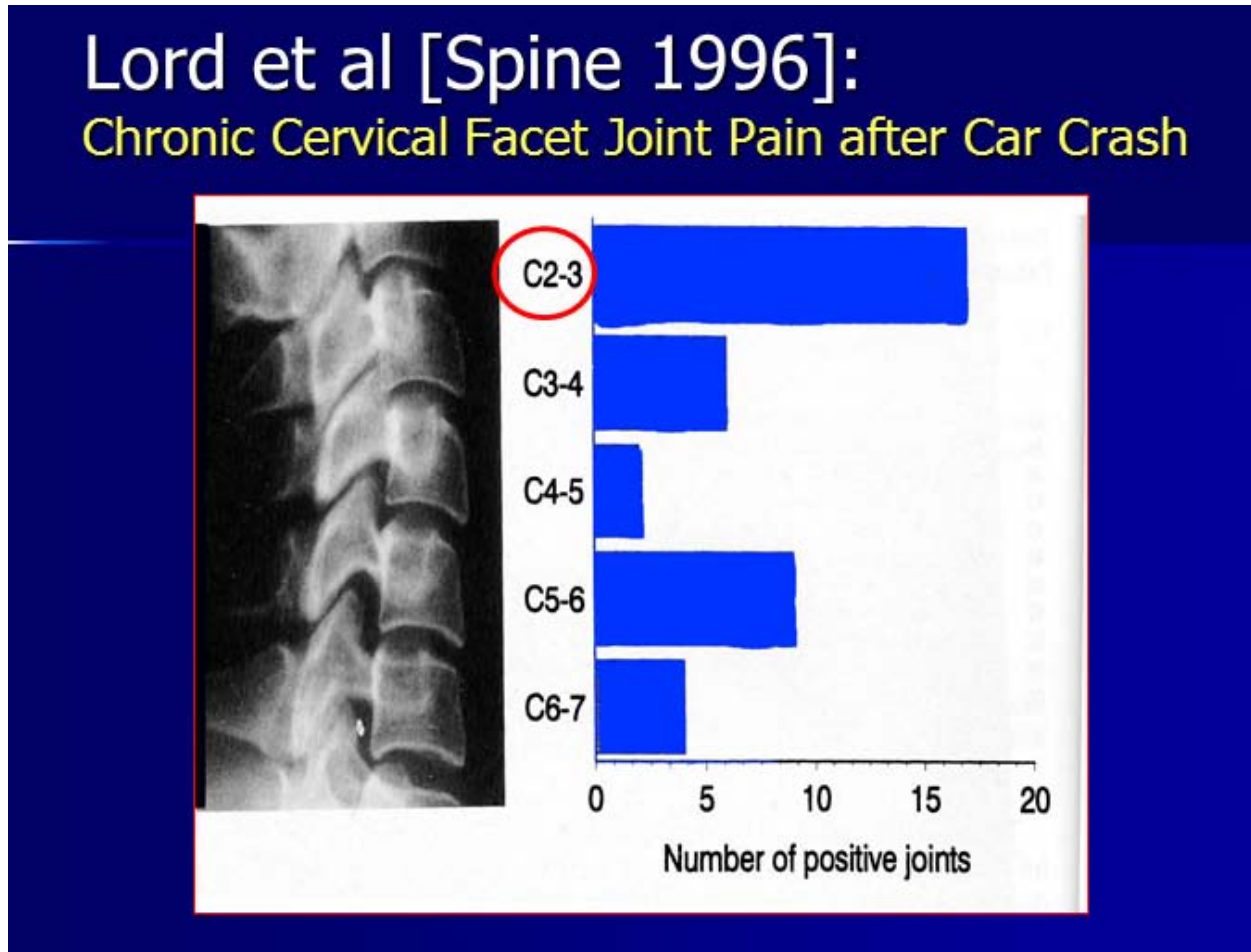
Please note the following about the peer-reviewed literature regarding C2-3 facet joint injury. This joint was identified as a major source of whiplash injury dating back to 1994, with this peer-reviewed article from Susan Lord and others:<sup>1</sup>

**Lord, S. M., L. Barnsley, et al. (1994). "Third occipital nerve headache: a prevalence study." J Neurol Neurosurg Psychiatry 57(10): 1187-1190.**

A consecutive series of 100 patients was studied to determine the prevalence of third occipital nerve headache in patients with chronic neck pain (> three months in duration) after whiplash. Seventy one patients complained of headache associated with their neck pain. Headache was the dominant complaint of 40 patients, but was only a secondary problem for the other 31. Each patient with headache underwent double blind, controlled diagnostic blocks of the third occipital nerve. On two separate occasions the nerve was blocked with either lignocaine or bupivacaine, in random order. The diagnosis of third occipital nerve headache was made only if both blocks completely relieved the patient's upper neck pain and headache and the relief lasted longer with bupivacaine. The prevalence of third occipital nerve headache among all 100 whiplash patients was 27% (95% confidence interval (95% CI) 18-36%) and among those with dominant headache the prevalence was as high as 53% (95% CI 37-68%). There were no distinguishing features on history or examination that enabled a definitive diagnosis to be made before the nerve blocks. Those patients with a positive diagnosis, however, were significantly more likely to be tender over the C2-3

zygapophysial joint ( $p = 0.01$ ). Third occipital nerve headache is a common condition in patients with chronic neck pain and headache after whiplash. Third occipital nerve blocks are essential to make this diagnosis.

This was groundbreaking research coming from the Cervical Spine Research Unit in Australia, headed by Nikolai Bogduk, MD PhD. This group went on to perform further high-quality studies showing that the C2-3 level was the most common source of chronic cervical pain after whiplash injury. The following is a histogram of their study results from their landmark 1996 paper,<sup>2</sup> which I routinely use in my lectures regarding this subject:



You will see that the C2-3 level is by far the most prevalent level of injury for patients who have had chronic whiplash injuries.

Please also understand that “whiplash” is more formally called “whiplash associated disorder” or WAD. **This refers to any acute acceleration-deceleration injury to the torso and head-neck apparatus, something that commonly occurs in the workplace, for example with falling on the job, being hit by a falling objects on the job, or sustaining motor vehicle crashes while working.**

**This is not a rare disorder. Patients suffering from C2-C3 facet-mediated pain represent a significant proportion of injured workers in the state of Washington and elsewhere.** If you deny treatment for these patients, you are doing a clear disservice to the injured workers in the state of Washington. **It would be embarrassing at the minimum—and tragic at a broader level—to deny radiofrequency neurotomy for injuries at the C2-C3 level.**

**1996 New England Journal of Medicine Article on Facet Joint Neurotomy**

I do understand that the landmark paper by the Cervical Spine Research Unit, published in the New England Journal of Medicine in 1996 excluded the C2-3 level. However, this needs to be understood within a historical context and within the limitations of a double blinded-placebo-controlled clinical trial involving a physical intervention rather than a medication. Please note the following:

1. **The C2-3 facet joint level could not have been placebo-controlled. This is because when a patient receives a C2-3 facet joint neurotomy, they also sustain cutaneous alteration at the back of the head.** They develop numbness or dysesthesias at the back of the head from a real neurotomy, but they would not sustain this from a placebo neurotomy. This would have destroyed the double blinded placebo-controlled experimental design. The Cervical Spine Research Unit has been internationally famous for its serious rigor to experimental design. This is one reason why the C2-3 facet joint level was excluded, despite the clear prevalence of injury at this level.
2. **The second major reason that this joint was excluded was that at the time of this landmark work, C2-3 facet joint neurotomy had not yet been perfected.** This was a more technically challenging level to perform neurotomy, and the authors, to my understanding, therefore steered clear of including this level for their seminal work.

**Nonetheless, in the few years that this landmark publication, the C2-3 level was not only perfected for neurotomy, but was also very commonly used, for understandable reasons, given the histogram of injured vertebral levels shown above.**

**If you deny C2-3 facet joint neurotomy within your guidelines, it would be analogous to excluding a nerve graft procedure for the small digit of the hand and for the thumb, given that prior research only was done for the ring, middle, and index fingers.** This is a ridiculous concept, and unconscionable in my opinion as we think of what is appropriate treatment for injured workers.

Please reverse your decision immediately. I would appreciate a detailed and prompt response from the committee regarding my comments and the need for reversal of your plan of action. Thank you in advance of your consideration. I have also attached as an addendum a brief discussion of the peer-reviewed literature regarding the nature of facet joint injuries for whiplash-associated disorders. This discussion is relevant for your consideration here.

Sincerely yours,


Richard Seroussi MD, M.Sc.

**Diplomate, American Board of PM&R with subspecialty certification in Pain Medicine.**

**Diplomate, American Board of Electrodiagnostic Medicine.**

**M.Sc. Degree in Mechanical Engineering**

**Clinical Faculty, University of Washington, Department of Rehabilitation Medicine**

**Addendum: Prepared Discussion regarding the Nature of Neck Injuries after Trauma**

The peer-reviewed literature supports the existence of cervical facet joint and discoligamentous injuries as causes for chronic neck pain after motor vehicle crashes. The upper cervical region, including the craniocervical junction, has been implicated as particularly susceptible to injury from motor vehicle crashes. The peer-reviewed literature contains diagnostic studies and treatment studies, including descriptions of surgery and injections in the upper cervical spine.<sup>1-7</sup> In addition, there are postmortem studies and biomechanical studies further supporting upper cervical injury.<sup>8-12</sup>

According to landmark, peer-reviewed musculoskeletal literature, the main cause of neck pain and headache among patients with chronic motor vehicle crash-related injuries is injury to the cervical facet joint.<sup>1,2,13-19</sup> As a good example of this literature, a **strict double blinded, randomized controlled trial**—published in the prestigious journal, *Spine* in 1996—reported that 60% of chronic neck pain after motor vehicle crash-related injuries was due to cervical facet joint injury, most commonly the C2-C3 facet joint level, but also throughout other levels of the cervical spine.<sup>2</sup>

It is notable that biomechanical and post-mortem (i.e. cadaveric) studies also clearly document the presence of facet injuries after simulated or actual motor vehicle crash exposure. These studies clearly help demonstrate the inadequacy of current imaging technologies for detecting these pathoanatomical lesions.<sup>11,20-25</sup>

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April 22, 2014

C. Craig Blackmore, MD, MPH  
Chair  
Washington State Health Technology Clinical 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 comment on the draft findings and decision on facet neurotomy.

We would like to commend the Committee for efforts to implement reasonable coverage guidelines to help assure appropriate care. We share the Committee's commitment to utilizing facet neurotomy in appropriately selected patients to achieve pain relief and functional improvement. To this end, however, we ask that the Committee reconsider six very important issues:

1. inclusion of treatment at the C2-3 level;
2. coverage of cervical facet neurotomy for cervicogenic headache;
3. revision of patient selection criteria for cervical radiofrequency neurotomy to require 80% relief of index pain from dual, comparative medial branch blocks;
4. coverage of multiple-level radiofrequency neurotomy in appropriately selected patients;
5. treatment after three months of continuous pain; and
6. treatment with facet neurotomy in the presence of concomitant spinal conditions.

Please note that the sole innervation of the C2-3 facet joint is the third occipital nerve, and C2-3 facet neurotomy and third occipital neurotomy are therefore synonymous. Our request for coverage of facet neurotomy for headache applies only to treatment at the C2-3 level.

### **Cervicogenic Headache**

We are extremely concerned that the Committee voted not to cover facet neurotomy for headache. Pain from the C2-3 facet joint is common in patients with post-traumatic neck pain,<sup>1,2,3,4</sup> and this joint is the most common source of referred pain from the neck to the head following whiplash injuries<sup>1,4</sup>. Non-coverage would be a catastrophe for those

patients with cervicogenic headache in the State of Washington who could greatly benefit from this procedure, and we urge the Committee to reconsider this decision.

Although some early studies either did not find improvements in outcomes from third occipital neurotomy<sup>5,6,7</sup> or found that this procedure provided unreliable outcomes<sup>8</sup>, it was due to the fact that proper patient selection through diagnostic blocks and/or proper technique were not assured.

Using a large gauge electrode, holding the electrode in place during coagulation and ensuring that multiple lesions are made in order to encompass all possible locations of the nerve, Govind *et al* showed that complete relief of pain could be achieved in 88% of patients. The median duration of relief was 297 days, and some patients still reported having continued relief at the time of review<sup>9</sup>. These results have been corroborated by two independent studies, in which the level that was most frequently treated was C2-3<sup>10,11</sup>.

Furthermore, 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<sup>9,11</sup>.

Treatment of C2-3 facet pain is as effective as treatment at other levels of the cervical spine and there is no good reason to exclude treatment at this particular level. If this treatment has been excluded because a randomized controlled trial of third occipital neurotomy has not been done, **it is important to understand that conducting a double-blind, randomized controlled trial of third occipital neurotomy is not logistically possible.** The third occipital nerve provides innervation to an area of skin near the occipito-cervical junction, and an unavoidable side-effect of the treatment is cutaneous numbness. 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<sup>12</sup>, it is reasonable to assume that it is not a placebo when the third occipital nerve is the target.

Evidence-based medicine requires consideration of the **best available evidence**, not restricting evidence review to randomized controlled trials. Excluding well-executed, high quality research from consideration represents a fundamental misunderstanding of the tenets of evidence-based medicine and a lack of appreciation of some important limitations inherent in applying randomized controlled trials to all research.

The information outlined above is sufficiently compelling to provide coverage for C2-3 facet neurotomy for treatment of cervicogenic headache. We respectfully ask that the coverage decision be revised to include this crucial, demonstrably effective treatment.

### **Percentage of Relief from Medial Branch Blocks**

We note that in its decision, the Committee voted to implement inconsistent criteria for percentage of relief obtained through dual, comparative medial branch blocks between lumbar and cervical regions. There is no justification for this discrepancy. We suggest

revising the criteria to require 80% improvement in index pain for both cervical and lumbar regions.

### **Multiple-Level Radiofrequency Neurotomy**

We do not support the practice of routine treatment of more than one level, but we urge the Committee to reconsider the current restriction to one cervical level and two lumbar levels. While the majority of patients require treatment at one level only, a significant percentage of patients do have pain at more than one level. Cooper *et al* reported that 52% of patients who had positive responses to controlled cervical medial branch blocks had a single symptomatic level, but multiple symptomatic joints occurred in various combinations in the remaining patients.<sup>13</sup> In consecutive patients who have been treated with radiofrequency neurotomy, treatment has been required at more than one level in 9%<sup>10</sup>, 16%<sup>11</sup>, and 30%<sup>14</sup> of patients. When pain has been identified as arising from more than one joint, with at least 80% pain relief from dual, comparative medial branch blocks, patients can be appropriately treated by neurotomy at multiple levels. Restricting treatment to one cervical level or two lumbar levels per six months will leave these patients with significant pain and functional limitations. We ask that you revise the coverage decision to allow for treatment at multiple levels in appropriately selected patients. This is consistent with CPT coding for diagnostic facet medial branch (nerve) blocks (CPT codes 64490-64494). It is inconsistent to limit neurotomy to one cervical level and one or two lumbar levels, and arbitrary to limit a neurotomy to one or two facet joint levels when more than one level was determined to be a pain generator based on prior diagnostic medial branch blocks.

### **Treatment After Three Months of Continuous Pain**

Pain that has persisted for three months is unlikely to resolve spontaneously, and we recommend revision of the guidelines to allow treatment of patients who have had continuous pain for three months, that has been relieved by cervical or lumbar medial branch blocks, and which has not responded to conservative treatment.

### **Concomitant Spinal Pain**

We do not support exclusion of treatment for patients with other pain syndromes affecting the spine. This would deny treatment, for example, for a patient with neck pain following a whiplash injury in a motor vehicle accident, who has a pre-existing lower back pain condition. We recommend inclusion of patients with other pain syndromes affecting the spine if it has been demonstrated in these patients that functional improvement as well as pain relief has been achieved with diagnostic medial branch blocks.

### **Guideline Review**

Finally, we were very disappointed to find that among the guidelines reviewed by the Committee, the list did not include those published by ISIS. This, despite the fact that we specifically suggested the review of those guidelines in our letter dated January 17, 2014. Additionally, with our comment letter submitted on January 10, 2013, we included a copy of a pre-publication excerpt containing the summary of evidence relative to facet neurotomy from the 2<sup>nd</sup> Edition ISIS Practice Guidelines.<sup>15</sup> The ISIS Practice Guidelines provide a comprehensive review of the evidence related to medial



branch blocks and radiofrequency neurotomy, as well as specific recommendations relative to techniques that have been used to achieve successful outcomes. We encourage the Committee to review the guidelines, and would be happy to provide a copy to the appropriate individual, if interested.

We continue to extend to the Committee an offer to provide national and international expert input as a resource in this process. If you have any questions or wish to discuss any of our suggestions, please contact please contact Margaret Klys, Director of Health Policy, at [mklys@spinalinjection.org](mailto:mklys@spinalinjection.org) or 708-505-9416.

Sincerely,


Jeffrey Summers, MD  
President  
International Spine Intervention Society

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April 21, 2014

Washington State Health Care Authority  
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Olympia, WA 98501

SUBMITTED VIA EMAIL TO: [SHTAP@hca.WA.GOV](mailto:SHTAP@hca.wa.gov)

Dear Health Technology Clinical Committee:

We are writing on behalf of the 4,500 members of the American Society of Regional Anesthesia and Pain Medicine (ASRA) to express our concerns regarding the recently published draft findings and decision of the Washington State Healthcare Authority Health Technology Assessment Health Technology Clinical Committee regarding facet neurotomy. ASRA represents one of the largest number of pain physicians in the country.

Lumbar Facet Neurotomy

1. The decision to cover lumbar facet neurotomy is reasonable and appropriate. However, the conditions regarding its use are too limited and may limit appropriate use that will help to reduce pain, improve function and decrease time away from work. The following specific items are of concern:
  - a. *Has at least six months of continuous low back pain referable to the facet joint.*  
**ASRA Comment: Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for >3 months despite conservative measures.**
  - b. *There is no other pain syndrome affecting the spine.*  
**ASRA Comment: Degenerative changes that occur with age, trauma and overuse are rarely limited to a single anatomic structure and frequently involve multiple sites. Patients who meet criteria for facet neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as part of an overall treatment plan.**
  - c. *One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.*  
**ASRA Comment: This is a reasonable approach. It is common for degenerative changes to occur bilaterally, e.g. L4-5 and L5-S1. Please clarify if treatment for bilateral facet arthropathy is covered.**

## Cervical Facet Neurotomy

2. Regarding coverage for cervical medial branch neurotomy, there are 4 major areas of concern.

- a. *Patient must be selected by 100% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting.*

**ASRA Comment:** Although optimal results are reported when selecting patients with complete relief, excellent results have also been demonstrated with more traditional guidelines of patient selection. Using 50-80% pain relief, 74% of patients obtain at least 75% pain relief at 6 months (Shin 2006, Speldewinde 2011) or >50% relief at 12 month follow-up (Sapir 2001). Patients who obtain >50-80% pain relief following dual medial branch blocks demonstrated sustained relief beyond months with neurotomy. Selecting patients who only have 100% relief sets an unrealistic standard that neither has evidence in the medical literature nor allows for persistent pain that may be present from contralateral disease or associated myofascial pain. This standard will result in an inappropriate restriction in access to a valuable pain relieving technique for a large number of patients who may receive significant pain relief and functional improvement for >6-12 months.

- b. *One joint per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.*

**ASRA Comment:** This restriction has no foundation in the medical literature and is inconsistent with the natural history of cervical facet arthropathy, which is commonly present in more than one joint. Of all the studies listed, only the Govind study restricted treatment to a single joint (C2-3 joint/third occipital nerve) and it was designed for the treatment of third occipital headache and not neck pain. All of the other studies listed and published allowed for treatment of additional levels when indicated. When involvement of more than 1 joint is present clinically, and when diagnostic blockade confirms the clinical diagnosis, then neurotomy of more than 1 cervical facet joint should be approved. In addition, it is common for disease to occur bilaterally and it should be clarified that bilateral treatment is acceptable when all other criteria are met. We agree that patients should achieve a minimum of 6-months improvement in pain and function before consideration of repeat neurotomy.

- c. *Has at least six months of continuous neck pain referable to the facet joint.*

**ASRA Comment:** Early restoration of function is critical to returning to work and functional activity. Diagnostic blocks and facet neurotomy should be considered for patients whose pain and functional limitation persists for >3 months despite conservative measures.

- d. *There is no other pain syndrome affecting the spine.*

**ASRA Comment:** Although less common, some patients have concomitant disease in multiple spine areas, just as patients may have pain arising from multiple joints such as the hip and the knee. Excluding patients from treatment when alternative treatments are ineffective does not target functional restoration. Patients who meet criteria for facet

neurotomy should be eligible for treatment regardless of concomitant disease in other spinal regions as degenerative changes of the spine are rarely limited to a single region of the spine.

#### Cervical Facet Neurotomy for Headache

##### 3. *Cervical Facet Neurotomy for headache is not covered.*

**ASRA Comment:** Non-coverage of neurotomy for the third occipital nerve (TON)/C2-3 facet joint is unreasonable. This treatment has demonstrated a high degree of effectiveness in several studies. Three prospective studies have demonstrated a high level of effectiveness when patients are selected with diagnostic blockade of the third occipital nerve. Govind (2003) published the results of a revised technique for percutaneous radiofrequency neurotomy for third occipital headache and found that 88% of 49 patients obtained COMPLETE relief of pain and had a successful outcome for a median duration of 217 days. Repeat neurotomy when symptoms returned again resulted in COMPLETE relief in 86% of patients. Both Barnsley (2005) and Macvicar (2012) demonstrated comparable relief, namely 60% at 44 weeks and 61%/74% respectively at 17-20 months. Macvicar's success was defined as COMPLETE relief of pain for >6 months WITH restoration of activities, return to work (if applicable) and no need for further health care visits regarding their neck pain. They also demonstrated similar response with repeat treatment. Third occipital neurotomy has demonstrated benefit providing COMPLETE pain relief in patients with pain relieved by diagnostic blockade of the TON. This is a valuable technique for the treatment of intractable headache in a subset of patients and should be approved for use.

In conclusion, we recommend the following changes to the draft findings and decision on facet neurotomy:

1. General: Eligibility should be pain > **3** months duration and not responsive to conservative measures.
2. General: There should **NOT** be an exclusion statement for more than 1 spinal segment pain (i.e. patients may receive both cervical and lumbar neurotomy if other criteria are met).
3. Patient selection: Patients should demonstrate **≥80%** relief with dual diagnostic blocks for all regions of the spine. Treatment coverage may cover 1 or 2 joints, bilaterally when indicated.

4. Third occipital neurotomy: Patients should be eligible for third occipital (C2/3) neurotomy if strict selection criteria are met for the treatment of intractable headache.

On behalf of the ASRA, we appreciate the opportunity to provide feedback to the committee regarding the draft findings and decision regarding facet neurotomy. We would be happy to meet with you to provide further information or enter into discussion with the committee to develop safe and effective coverage policies related to the care of patients with spine related pain treated with facet neurotomy.

Sincerely,



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## References:

Barnsley L. Percutaneous radiofrequency neurotomy for chronic neck pain: outcomes in a series of consecutive patients. *Pain Medicine* 2005; 6:282-286.

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.

MacVicar J, Borowczyk JM, MacVicar AM, Loughnan B, Bogduk N. Cervical medial branch neurotomy in New Zealand. *Pain Medicine* 2012;13:647-654.

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Stolker RJ et al. Percutaneous facet denervation in chronic thoracic spinal pain. *Acta Neurochir (Wien)* 122:82-90, 1993

Comment regarding draft facet neurotomy coverage decision:

Because of the diagnostic and treatment advantages that follow from a determination that a patient's response to a placebo medial branch block exceeds that of a block in which an anesthetic is actually used, I recommend that the following text be inserted into the draft decision.

The committee agreed with the value of placebo injections, but in discussion of whether to include a placebo requirement was concerned about requiring agencies to pay for additional injections. However, this concern can be mitigating by allowing (but not requiring) agencies to include the placebo injection as a condition. The following language is offered as an addition to conditions of coverage:

“An agency, in its discretion, may require that the workup for a potential facet neurotomy include a series of three medial branch blocks, that include, in no particular order, a short acting anesthetic, a long acting anesthetic, and a placebo.” OR

Add to the following condition (*italics*):

For identification, diagnosis, and treatment:

- o Patient must be selected by at least 80% improvement in pain after each of two differential medial branch blocks, one short-acting; one long-acting
  - *If covered by the payer, a placebo medial branch block with insignificant improvement in pain*
- o One or two joints per each intervention, with documented, clinically significant improvement in pain and/or function for six months before further neurotomy at any level.

Thank you for your consideration of this recommendation.

Lee Glass, MD  
Associate Medical Director  
Department of Labor and Industries





January 17, 2014

C. Craig Blackmore, MD, MPH  
Chair  
Washington State Health Technology Committee  
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Olympia, WA 98504-2712

**via Email**

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<sup>1,2</sup>.

**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.

### *References*

1. International Spine Intervention Society. Lumbar medial branch thermal radiofrequency neurotomy. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2<sup>nd</sup> edn. International Spine Intervention Society, San Francisco, 2013:601-641.
2. International Spine Intervention Society. Lumbar medial branch blocks. In: Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures, 2<sup>nd</sup> edn. International Spine Intervention Society, San Francisco, 2013: 559-599.

## 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<sup>1</sup> 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, 2<sup>nd</sup> 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.

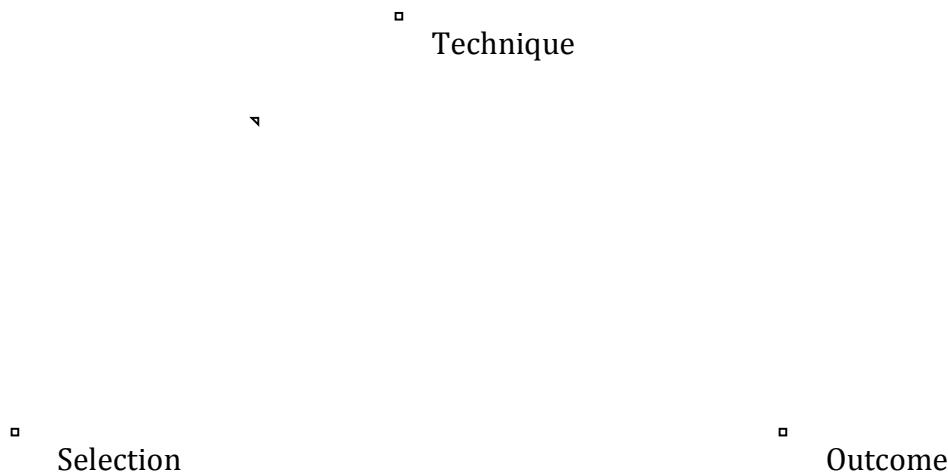
Armed with such information, a review would not pool all data and diseases indiscriminately, while simultaneously not distinguishing the effectiveness of oral antibiotics and intravenous antibiotics, full-strength antibiotics, or even diluted antibiotics. Yet, in the case of facet neurotomy this is what 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 <sup>1,2,3</sup>;
- preferring techniques according to their inventor or country of origin, such as the Dutch technique or the Australian technique <sup>1,2,3</sup>;

- 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 <sup>4</sup>, 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 <sup>4,5,6</sup>. 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 <sup>5,7</sup>. 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 <sup>8</sup>. Similarly, the study of Leclaire *et al* <sup>9</sup> 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 <sup>10</sup>.

The study of Wijk *et al*<sup>11</sup> illustrated the technique used. It is patently inaccurate as pointed out by a letter to the editor.<sup>12</sup> 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
<b>Parallel</b>	Valid  Dreyfuss <sup>19</sup> MacVicar <sup>20</sup> Gofeld <sup>21</sup> Burnham <sup>22</sup> Speldewinde <sup>23</sup> Schofferman <sup>24</sup> Rambaransingh <sup>25</sup> Nath <sup>26</sup> Tekin <sup>27</sup> Lakemeier <sup>28</sup>	
<b>Perpendicular</b>	Questionable  Tzaan <sup>13</sup> Civelek <sup>14</sup> Son <sup>15</sup> Chakraverty <sup>16</sup> Kroll <sup>17</sup> Van Kleef <sup>18</sup>	Inadmissible  Gallagher <sup>8</sup> Leclaire <sup>9</sup> Wijk <sup>11</sup>

**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<sup>13-18</sup> 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<sup>19-28</sup>. Of these, some provide evidence of outcomes<sup>19-23</sup>; others provide data on repeat treatment<sup>20,23,24,25</sup>; two are controlled trials<sup>26,27</sup>; and one was a comparison study<sup>28</sup>.

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<sup>1-7</sup>, 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<sup>8</sup>. 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<sup>9-14</sup>, in accordance with the guidelines of the International Spine Intervention Society<sup>15</sup>. The one exception is the study of Tzaan and Tasker<sup>16</sup> 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<sup>17</sup>. Consequently, the data of Tzaan and Tasker<sup>16</sup> 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<sup>9</sup>; the others have been long-term outcome studies<sup>9-14</sup>. The controlled trial showed conclusively that the outcomes of cervical medial branch neurotomy cannot be attributed to placebo effects<sup>9</sup>. The long-term outcome studies<sup>10-13</sup> corroborate the results of the controlled trial<sup>9</sup>, 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<sup>10,13,14</sup>.

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<sup>15</sup>, 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<sup>1,2,3</sup>. In all studies patients were selected on clinical criteria. Diagnostic blocks were performed in one study<sup>1</sup>, 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<sup>3</sup>. In the second study, outcomes were no different in patients who received active lesions from those who received sham lesions<sup>1</sup>. In the third, outcomes from neurotomy were no different from those of an injection of local anesthetic onto the greater occipital nerve<sup>2</sup>.

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<sup>4</sup>. 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 <sup>5</sup>, 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 <sup>5</sup>. These results have been corroborated by two independent studies <sup>6,7</sup>.

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 <sup>5,7</sup>.

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 <sup>8</sup>, 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<sup>1</sup>. 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<sup>2</sup>.

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<sup>3</sup>, and patients were selected using comparative local anesthetic blocks<sup>4</sup>.

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%<sup>5</sup> or 35%<sup>6</sup> 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<sup>1-6</sup>. 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<sup>1,2,4,5</sup>, return to work<sup>1,2,5</sup>, and no need for other health care<sup>1,2,5,6</sup>. These outcomes are statistically not significantly affected by a compensation claim or ongoing litigation<sup>1,3,6</sup>.

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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<sup>1,2,3</sup>. 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<sup>4</sup>, 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<sup>5</sup>.

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<sup>1,2,3,6</sup>.

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<sup>1,7</sup>. 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<sup>1,3</sup> (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%<sup>8</sup>. They become

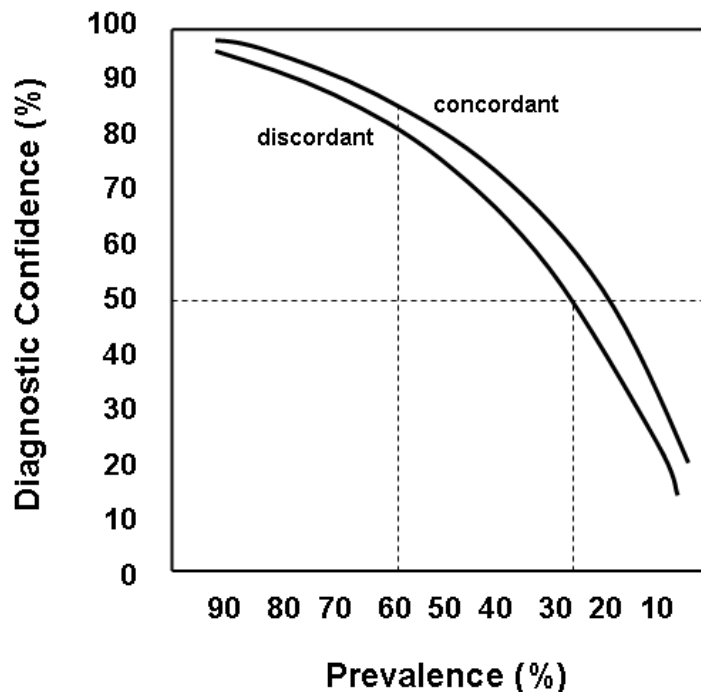


less suitable for the diagnosis of lumbar zygapophysial joint pain, depending on what is accepted as the prevalence of this condition. Estimates have ranged from 40% to less than 10% or 5% <sup>3,9,10</sup>.

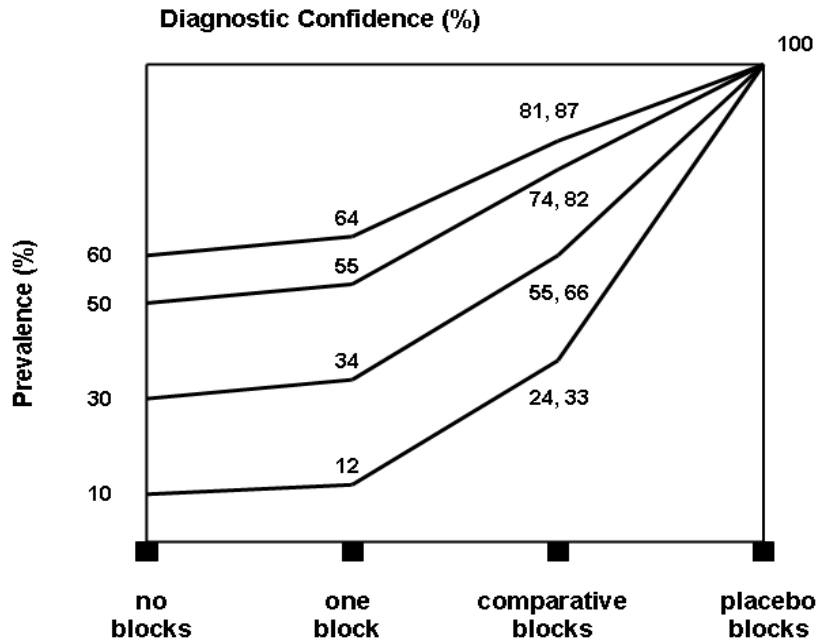
Single diagnostic blocks, even if they provide complete relief, are not a dependable diagnostic tool, for they have an unacceptably high false-positive rate. Various, the false-positive rate has been measured as between 25% and 45% <sup>6,7,11-16</sup>. Such high values generate uncertainty as to whether 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.

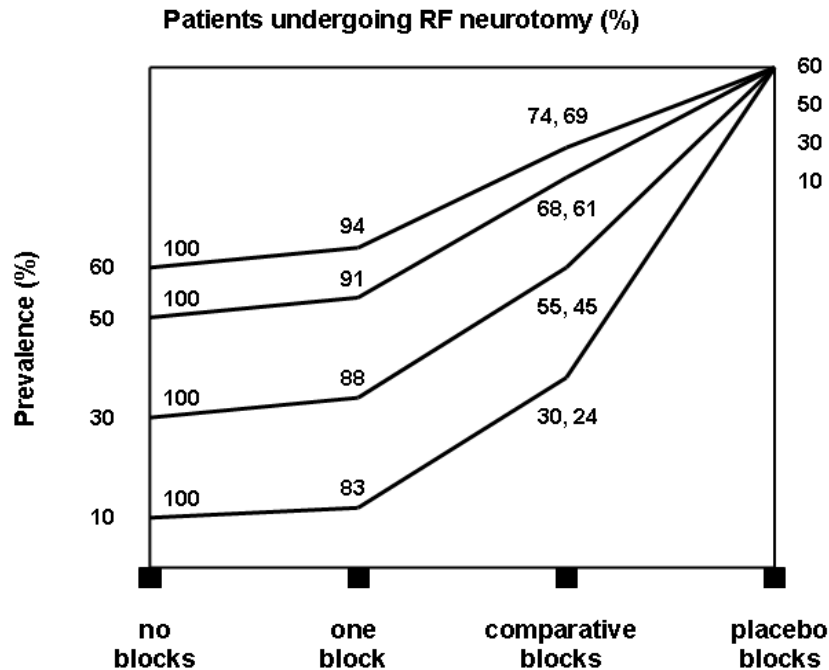


**Figure 2.** A graph of the relationship between diagnostic confidence, *i.e.* post-test probability, and the prevalence of the condition being diagnosed, for either discordant or concordant positive responses to comparative local anesthetic blocks.



**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.

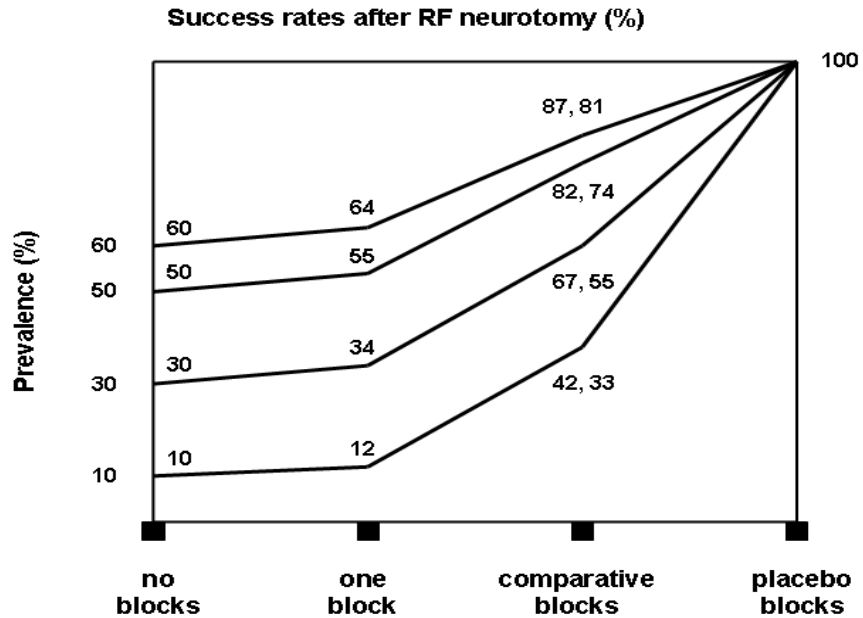
Figure 4 shows the numbers of patients who would undergo radiofrequency neurotomy depending on if the indication was response to no blocks, a single block, comparative blocks, or placebo-controlled blocks. The graph shows that if no blocks are used, all patients undergo treatment. Those numbers reduce 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<sup>1</sup> and its effectiveness in clinical practice<sup>2,3,4,5,6</sup> 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<sup>1,2,4,5</sup>.

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<sup>1,2</sup> the singular indication was a positive response to comparative local anesthetic blocks. The earlier study used a relaxed criterion of 80% relief<sup>1</sup>, whereas the later study required complete relief<sup>2</sup>. 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<sup>1</sup>. 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<sup>2</sup>.

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<sup>3,4</sup>.

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<sup>5</sup>. 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<sup>1</sup> and cervical thermal radiofrequency neurotomy<sup>2</sup>, as well as guidelines for the conduct of lumbar medial branch blocks<sup>3</sup>, third occipital nerve blocks<sup>4</sup>, and cervical medial branch blocks<sup>5</sup>, 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<sup>6</sup>.
- 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<sup>7</sup>.
- In the event of recurrence of pain, complete relief can be reinstated by repeating the treatment<sup>6,7</sup>.

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](mailto:bduszynski@spinalinjection.org) or 815.200.9590.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Summers MD". The signature is cursive and somewhat stylized.

Jeffrey Summers, MD  
President  
International Spine Intervention Society

January 10, 2013



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

Submitted electronically: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

**Re: 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, would like to comment on the topic of Facet Neurotomy for Cervical and Lumbar Pain, selected by the Washington State Health Technology Authority (HTA) for review this year.

We commend the HTA for looking at these procedures to ensure appropriate coverage policies are in place. ISIS has a long record of work dedicated to eliminating fraudulent, unproven and inappropriate procedures; while assuring that appropriate, effective and responsible practices are preserved so that patients are not deprived of reasonable and effective diagnostic and therapeutic spine intervention options. As such, we would like to offer information to assist the HTA in designing appropriate policies.

Numerous publications exist on the topic of radiofrequency neurotomy (RFN) for facet pain. At this time we would like to share with the HTA several publications, which offer extremely valuable information, and which may be missed at the present time, as they are in the process of being published.

1. Efficacy of Cervical Thermal Radiofrequency Neurotomy: Excerpt from Draft 2<sup>nd</sup> Edition ISIS Practice Guidelines (Publication Pending in 2013)
2. Efficacy of Lumbar Medial Branch Thermal Radiofrequency Neurotomy: Excerpt from Draft 2<sup>nd</sup> Edition ISIS Practice Guidelines (Publication Pending in 2013)
3. Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand: [Pain Med.](#) 2012 Dec 28. doi: 10.1111/pme.12000. [Epub ahead of print]

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As you can see, the attachments on the efficacy of cervical and lumbar thermal RFN from the ISIS practice guidelines provide an excellent overview of these procedures and the existing evidence base. An important point, which deserves special emphasis, is that the success of the treatment, in both the lumbar and cervical region, is dependent upon **both** proper patient selection as well as proper technique as outlined in the ISIS guidelines. Failure to adhere to both of these will significantly compromise the results and reputation of lumbar and cervical medial branch neurotomy; whereas, complying with both will significantly improve the outcome of these procedures as has been borne out in the literature. Patients deserve the best possible care and outcomes, and insurers should expect and demand no less.

The attached article by MacVicar also supports this point. MacVicar et al. concluded that lumbar RFN can be very effective when performed in appropriately selected patients by physicians trained in the techniques described in the ISIS guidelines. Chronic back pain that is mediated by the lumbar medial branch nerves can be effectively treated and patients fully restored to normal living, if treated with RFN.

This was a prospective, outcome study of 106 consecutive patients with chronic back pain treated in a community setting and selected on the basis of complete relief of pain following controlled, diagnostic, medial branch blocks. The patients were treated with RFN according to the ISIS guidelines. Successful outcome was defined as complete relief of pain for at least six months, with complete restoration of activities of daily living, no need for any further health care, and return to work. Patients who failed to meet any of these criteria were deemed to have failed treatment. Successful outcome was achieved in 58% and 53% of patients in the two practices. Duration of relief was 15 months from the first RFN and 13 months for repeat treatments. Patients receiving a repeat treatment maintained relief for a median duration of 17–33 months, with some 70% still having relief at follow-up.

It is important to understand that prior to the decision to perform an RFN, diagnostic medial branch blocks are performed. As noted in the attachments referenced above, the interpretation of these results by the practitioner is a key factor in the selection criteria for patients to undergo an RFN. At the very least, it is recommended that patients undergo comparative local anesthetic blocks using two local anesthetics with different durations. A concordant response is one in which the patient reports long-lasting relief when the long acting agent is used but short lasting relief when the short acting agent is used. Discordant responses can also occur - in which case, the patient obtains complete relief of pain on each occasion, but the response to the short acting agent is longer than to the long acting agent. Concordant responses have a sensitivity of 54% but a specificity of 88%. Discordant responses have a sensitivity of 100% but a specificity of only 65%.<sup>1</sup>

Multiple independent studies have shown that the prevalence of cervical facet joint pain is of the order of 60% in patients with chronic neck pain.<sup>2,3,4,5,6,7</sup> This makes it the most common basis of chronic neck pain. Consequently, cervical medial branch blocks should be the foremost investigation for patients with neck pain once serious causes have been excluded. When applying the prevalence rate of 60% with the responses of a specificity of 65% and sensitivity of 100% (as noted above) an operator can be 81% certain that a positive response to comparative blocks (either concordant or discordant) is a true positive.

For patients with positive response to cervical medial branch blocks, radiofrequency neurotomy is the treatment of choice. It is the only treatment of neck pain that has been validated in a placebo-

controlled trial;<sup>8</sup> it is the only treatment that has been shown to produce complete relief of pain<sup>9</sup> together with resolution of psychological distress<sup>10</sup>.

The lower prevalence of lumbar facet joint pain translates to a higher false positive rate of comparative lumbar medial branch blocks. However, it has been shown that patients who obtain at least 80% relief of their pain after comparative blocks can be treated by lumbar medial branch radiofrequency neurotomy, using correct techniques - 60% of patients can expect to have at least 80% relief of their pain sustained at 12 months and 80% can expect at least 60% relief.<sup>11</sup>

Finally, we would like to mention that in 2009, Noridian Administrative Services, the Medicare Administrative Contractor for Washington State, extensively reviewed lumbar RFN – an effort which brought together top experts from 12 national, spine and pain medical societies\*. We are enclosing a consensus document, which was developed as a result of the process. Noridian has since developed comprehensive policies for facet joint injections and RFN, which currently apply to Medicare beneficiaries in Washington and 10 other states.

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

Sincerely,



Ray Baker, MD  
President  
International Spine Intervention Society (ISIS)

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\*American Association of Neurological Surgeons (AANA), American Academy of Pain Medicine (AAPM), American Academy of Physical Medicine and Rehabilitation (AAPMR), American Academy of Orthopaedic Surgeons (AAOS), American College of Radiology (ACR), American Society of Anesthesiologists (ASA), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Congress of Neurological Surgeons (CNS), International Spine Intervention Society (ISIS), North American Spine Society (NASS), Society of Interventional Radiology (SIR)

**Attachments:**

1. Efficacy of Cervical Thermal Radiofrequency Neurotomy: Excerpt from Draft 2<sup>nd</sup> Edition ISIS Practice Guidelines. (Publication Pending in 2013)
2. Efficacy of Lumbar Medial Branch Thermal Radiofrequency Neurotomy: Excerpt from Draft 2<sup>nd</sup> Edition ISIS Practice Guidelines. (Publication Pending in 2013)
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## **EFFICACY OF CERVICAL THERMAL RADIOFREQUENCY NEUROTOMY**

### **HISTORICAL BACKGROUND**

Since the pioneering work of White and Sweet in 1969<sup>1</sup>, radiofrequency neurotomy has been used successfully for the treatment of trigeminal neuralgia<sup>2</sup>. That success inspired its application for the treatment of spinal pain. It was first used to treat low back pain stemming from the lumbar zygapophysial joints<sup>3-6</sup>. Rapidly, its use was extended to treat neck pain<sup>7,8</sup>.

Early descriptive studies<sup>7,8</sup> mentioned the treatment of neck pain almost parenthetically in the course of reports on the treatment of low back pain. Studies explicitly describing percutaneous radiofrequency neurotomy for the treatment of neck pain appeared in 1980<sup>9,10</sup> and 1981<sup>11</sup>. Further descriptive studies appeared<sup>12-14</sup> over the following 10 years.

When this descriptive literature was reviewed in 1995, it was found that the studies varied with respect to selection criteria, technique used, and outcome achieved<sup>15</sup>. In particular, not all studies had selected patients on the basis of diagnostic blocks of the cervical medial branches; or when used, such blocks were not controlled; and the surgical technique used did not accurately target the cervical medial branches. These factors may have explained why the reported results were only fair, in terms of the proportions of patients relieved, and the degree of relief that they obtained.

A pilot study<sup>15</sup> reported that, if an accurate technique was used, complete relief of pain could be achieved in a large proportion of patients treated for lower cervical pain. That study, however, found that results were poor when the third occipital nerve was targeted for the treatment of cervical pain and headache; and it cautioned against the use of radiofrequency neurotomy of the third occipital nerve until technical problems with the conduct of this procedure at this level were overcome.

Since then, the efficacy of cervical medial thermal radiofrequency neurotomy has been validated by a randomized, placebo-controlled trial, and its effectiveness established in several prospective outcome studies.

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## **EFFICACY**

Early descriptive studies<sup>1-7</sup> claimed that between 50% and 90% of patients treated by medial branch radiofrequency neurotomy obtained at least 40% relief of their pain<sup>8,9</sup>, but few studies reported achieving complete relief. Most defined good or excellent relief as greater than 66% or 70% relief of pain. Only one study reported that 37% of patients treated were pain-free at two months<sup>7</sup>.

To be consistent with the rationale for the procedure, complete relief of pain should be the standard outcome. If diagnostic blocks produce complete relief of pain, so should radiofrequency neurotomy. If complete relief is not achieved, either the patient was incorrectly selected or the technical execution of the procedure was imperfect.

Subsequent studies adhered to these standards. They required that patients be selected on the basis of complete relief of their pain following controlled diagnostic blocks of the

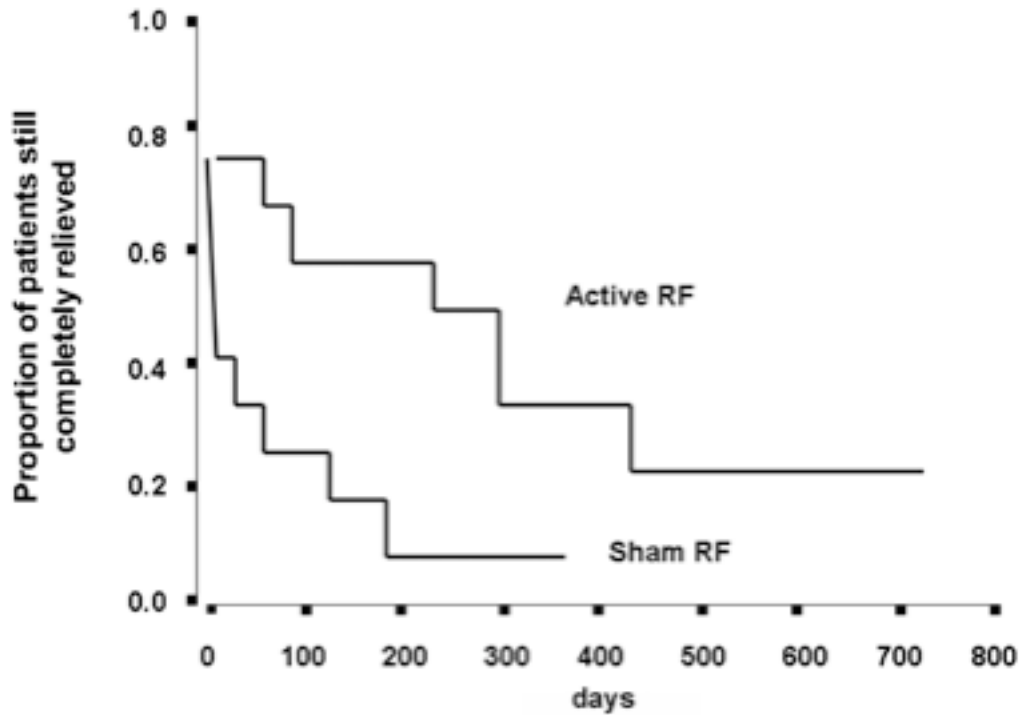
target medial branches, and that meticulous technique be used for the coagulation of those nerves.

A pilot study was conducted on 20 patients who had been diagnosed as having cervical zygapophysial joint pain by controlled diagnostic blocks<sup>8</sup>. Of the 10 patients whose pain was mediated by the third occipital nerve, only four obtained complete, long-lasting relief. Pain recurred in the other six patients within a matter of days. The investigators considered that some form of unrecognized technical error prevented adequate coagulation of the third occipital nerve, and advised against performing radiofrequency neurotomy at this level until those technical errors were overcome. However, of the 10 patients with pain mediated by lower cervical medial branches, seven obtained complete relief of pain lasting for between six months and two years. These latter results justified and prompted a controlled trial.

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 blocks<sup>10</sup>. 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. Twelve were allocated to undergo exactly the same procedure, for exactly the same duration (three hours), save 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 (Figure 1). 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<sup>10</sup>. Although the sample sizes in this study were small, the difference in outcome was so great that the study had 100% power to exclude a placebo effect.





**Figure 1.** Survival curves of the placebo-controlled study of cervical radiofrequency neurotomy<sup>10</sup>.

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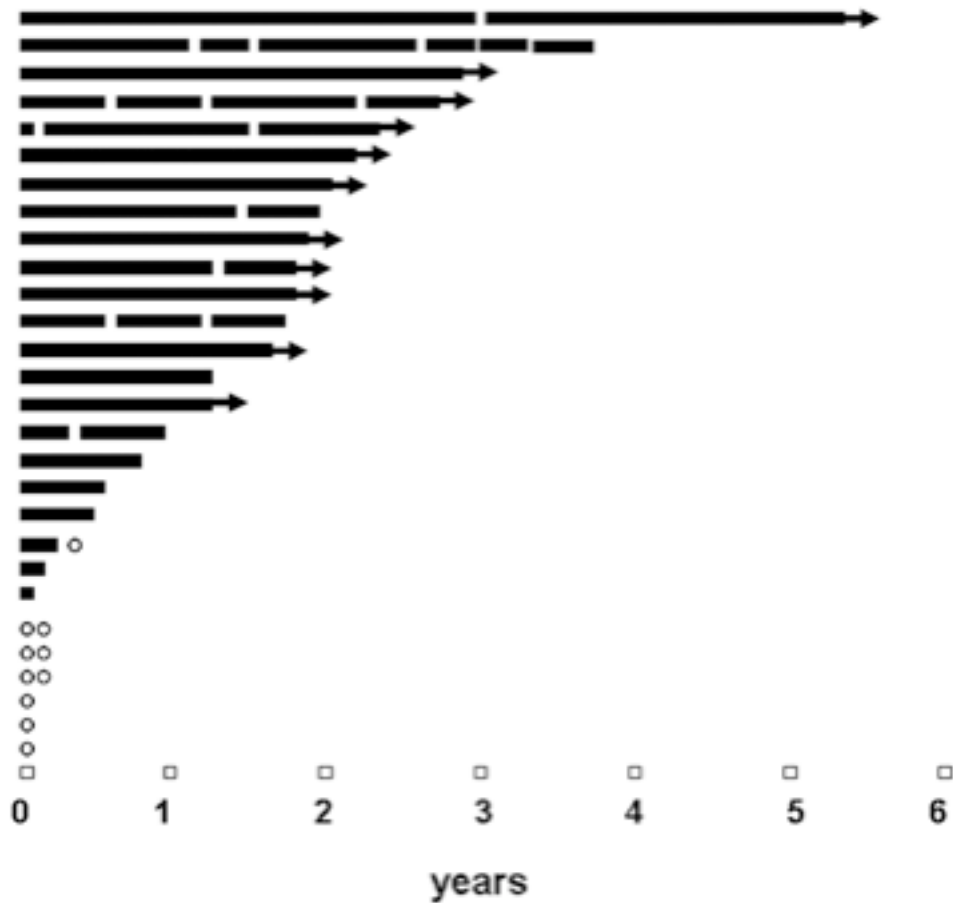
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## **EFFECTIVENESS**

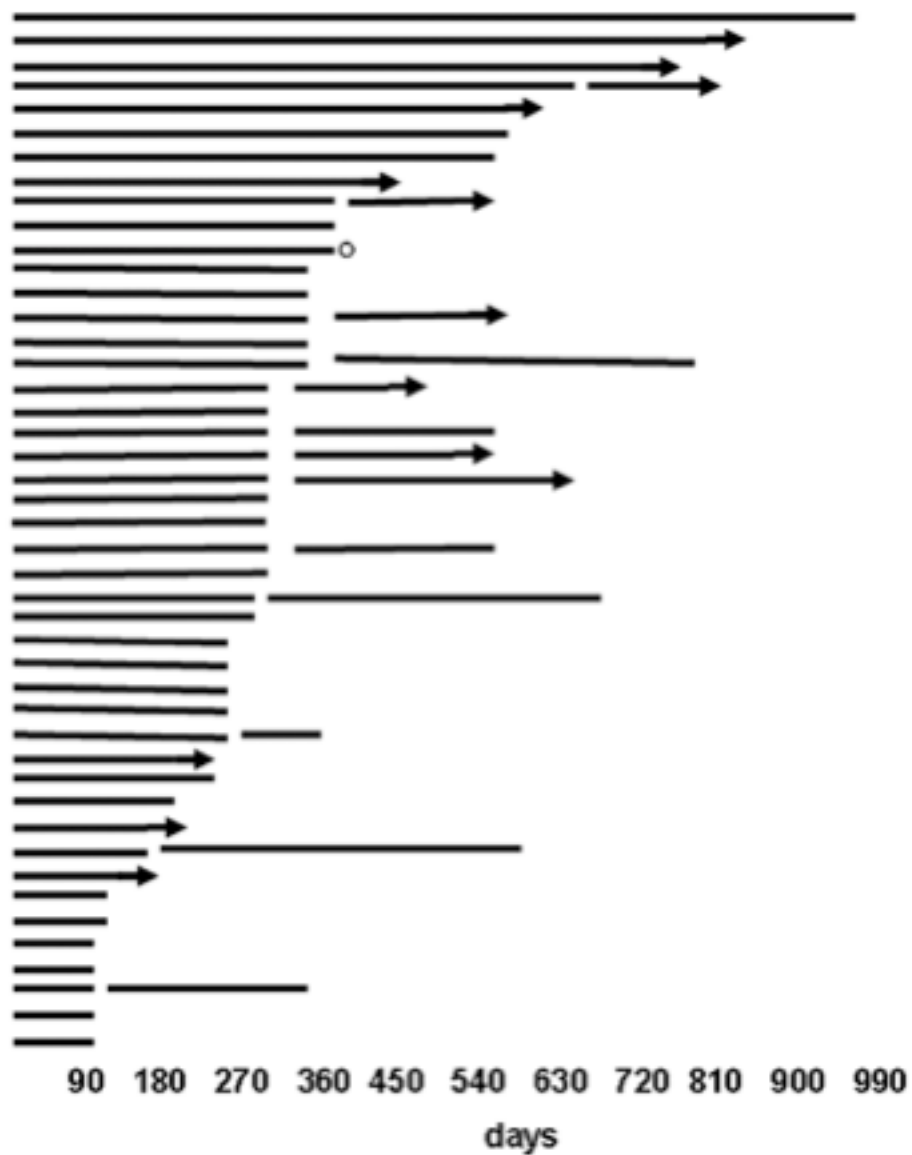
The effectiveness of cervical medial branch radiofrequency neurotomy has been demonstrated by three families of studies. The first was a long-term observational study of the patients enrolled in the randomized controlled trial<sup>1</sup> to which were added patients treated after the conclusion of the trial. The second was an outcome study that described an improved technique for third occipital neurotomy. The third family consists of two studies in which investigators sought to determine if outcomes achieved in conventional practice matched those reported in research studies from the original academic group.

The long-term outcome study, comprised of the patients who participated in the controlled trial along with others enrolled after the conclusion of the trial, showed that of 28 patients treated, 18 (64%) obtained complete relief of pain that lasted for a median duration of 421.5 days (interquartile range: 223 to 730 days)<sup>2</sup>. Furthermore, it showed that if pain recurred, complete relief could be reinstated by repeat neurotomy, with some patients having four and up to six successful repetitions (Figure 2). Analysis of the data showed that there was no significant difference in outcomes achieved by different physicians<sup>2</sup>. Outcomes were not significantly different if placebo-controlled blocks or comparative blocks were used to select patients<sup>2</sup>. Nor did litigation affect the outcome<sup>2</sup>. This latter feature was confirmed by another study that specifically addressed outcome versus litigation<sup>3</sup>.



**Figure 2.** The outcomes of a long-term observational study of cervical radiofrequency neurotomy<sup>2</sup>. Each bar represents a patient who obtained complete relief of pain for the duration depicted. Interruptions indicate that relief ceased but was reinstated by repeat neurotomy. Arrowheads indicate ongoing relief at the time of study. Circles indicate patients who did not obtain complete relief.

A study specifically investigated the efficacy of radiofrequency neurotomy of the third occipital nerve for the treatment of headache<sup>4</sup>. Modifications to the technique used were: using a large gauge electrode; holding the electrode firmly in place throughout the period of coagulation; and placing consecutive lesions no further than one electrode-width apart. As a result of these modifications, previous results of third occipital neurotomy were reversed. Instead of four out of 10 patients obtaining relief<sup>5</sup>, 86% of 49 patients obtained complete relief of pain. 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.



**Figure 3.** The outcomes of a long-term observational study of third occipital radiofrequency neurotomy for cervical headache<sup>4</sup>. Each bar represents a patient who obtained complete relief of pain for the duration depicted. Interruptions indicate that relief ceased but was reinstated by repeat neurotomy. Arrowheads indicate ongoing relief at the time of study. Circles indicate patients who did not obtain complete relief.

The first replication study was undertaken explicitly to test if the outcomes reported in the controlled trial could be replicated in conventional practice<sup>6</sup>. It showed that they

were. Of 35 patients treated, 21 (60%) obtained complete relief of pain for at least 12 weeks in the first instance, and for a median duration of 44 weeks.

The second replication study was commenced to determine if novice practitioners, trained according to the ISIS guidelines, could achieve the same outcomes as reported in previous research studies<sup>7</sup>. Two practitioners were trained, and the outcomes of all their consecutive patients over five years in their respective practices were audited. 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 (Figure 4).

All of these outcome studies used the same technique, viz. that described in the ISIS guidelines.<sup>8</sup> Therefore, the outcomes achieved apply only to that technique. Those outcomes cannot be generalized to other versions of cervical radiofrequency neurotomy. Moreover, the outcomes apply only to patients who were selected using controlled, comparative, local anesthetic blocks of the target nerves, with the criterion for a positive response being complete relief of pain. Conspicuously, no study that has followed these protocols has ever shown cervical medial branch thermal radiofrequency neurotomy not to be effective.

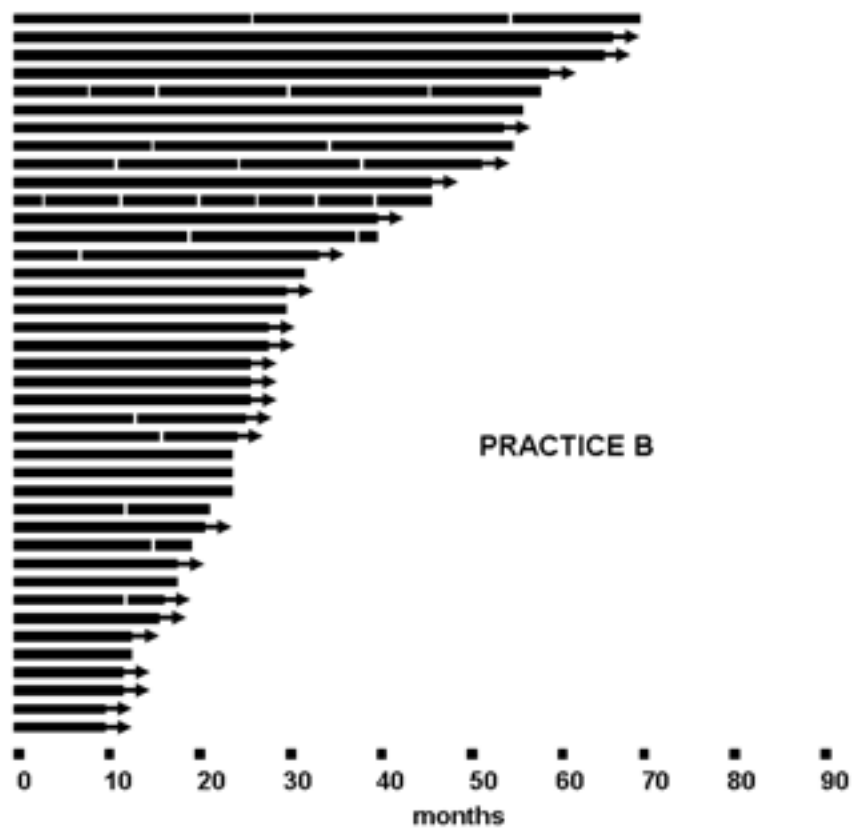
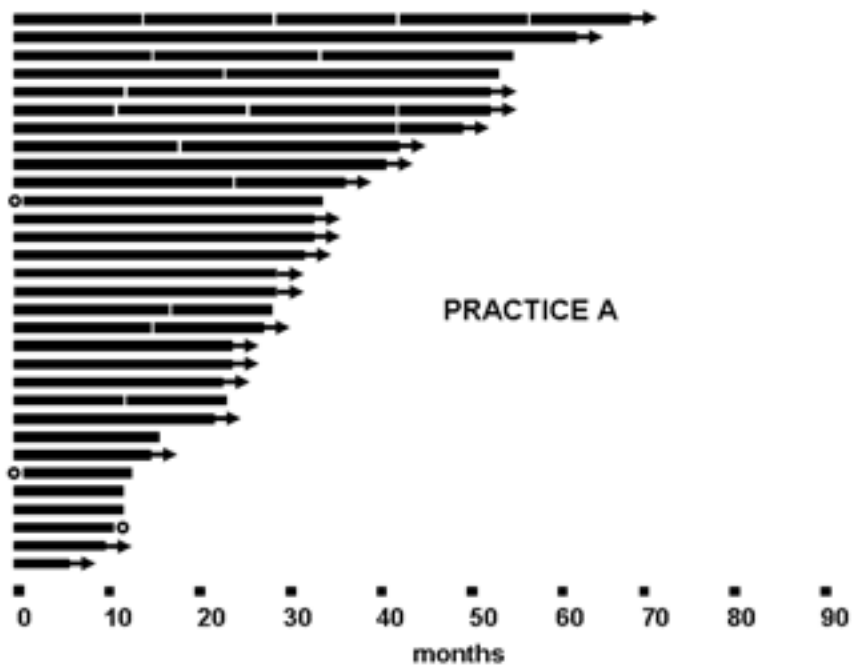
There is no evidence of efficacy or effectiveness of any other variant of the procedure, or for patients selected according to less stringent criteria.

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**DRAFT: For Limited Distribution**



**Figure 4.** The duration of complete relief of neck pain after radiofrequency medial branch neurotomy in patients treated in either or two practices<sup>7</sup>. Each bar represents a patient who obtained complete relief of pain for the duration depicted. Interruptions

indicate that relief ceased but was reinstated by repeat neurotomy. Arrowheads indicate ongoing relief at the time of study.

## **REPETITIONS**

Radiofrequency medial branch neurotomy is not curative. It does not resolve the lesion that causes pain from the zygapophysial joints. It does not permanently destroy the medial branches of the dorsal rami. The cell bodies of these nerves remain intact, and the nerves regenerate. As they regenerate the pain can recur. Nevertheless, on average, patients can expect a period of about 400 days of complete relief of pain<sup>1</sup> following an initial, successful neurotomy. Actions that might be taken when the pain recurs depend on the intensity of the recurrent pain and the disability that it causes.

In some patients the pain that recurs is of less intensity than their original pain. They may be able to cope with this pain, and do not require further treatment. In other patients the pain that recurs requires treatment.

If prognostic blocks are performed and demonstrate that the recurrent pain is mediated by the same nerves that were originally targeted, complete pain relief can be reinstated by repeating the neurotomy<sup>1-5</sup>. There appears to be no limit to the number of times that neurotomy might be successfully repeated. Patients have successfully undergone multiple repetitions over periods of five years or more in order to maintain complete relief of pain and complete rehabilitation<sup>1,4</sup>.

Repetition should not be undertaken presumptively. Whereas it is likely that the recurrent pain stems from the same segmental level, this should always be confirmed by prognostic blocks, lest the recurrent pain happens to arise from another segmental level or a source other than the zygapophysial joints. If the recurrent pain is from another source, it should be diagnosed and treated as a new pain.

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## **Litigation**

Although patients with medicolegal claims have a reputation of responding less well to treatment than patients with legal burden, this prejudice does not apply to cervical radiofrequency medial branch neurotomy. The influence of litigation has been repeatedly tested<sup>1-5</sup>. Although there have been tendencies for patients subject to litigation to have lesser success rates or to have lesser durations of relief, none of these has been found to be statistically significant<sup>1-5</sup>. The differences in outcome are too small to justify denying treatment to patients because they have a medicolegal claim.

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## **EFFICACY OF LUMBAR MEDIAL BRANCH THERMAL RADIOFREQUENCY NEUROTOMY**

### **HISTORICAL BACKGROUND**

The history of lumbar medial branch thermal radiofrequency neurotomy is a saga of errors and misconceptions. Some have been corrected, others not.

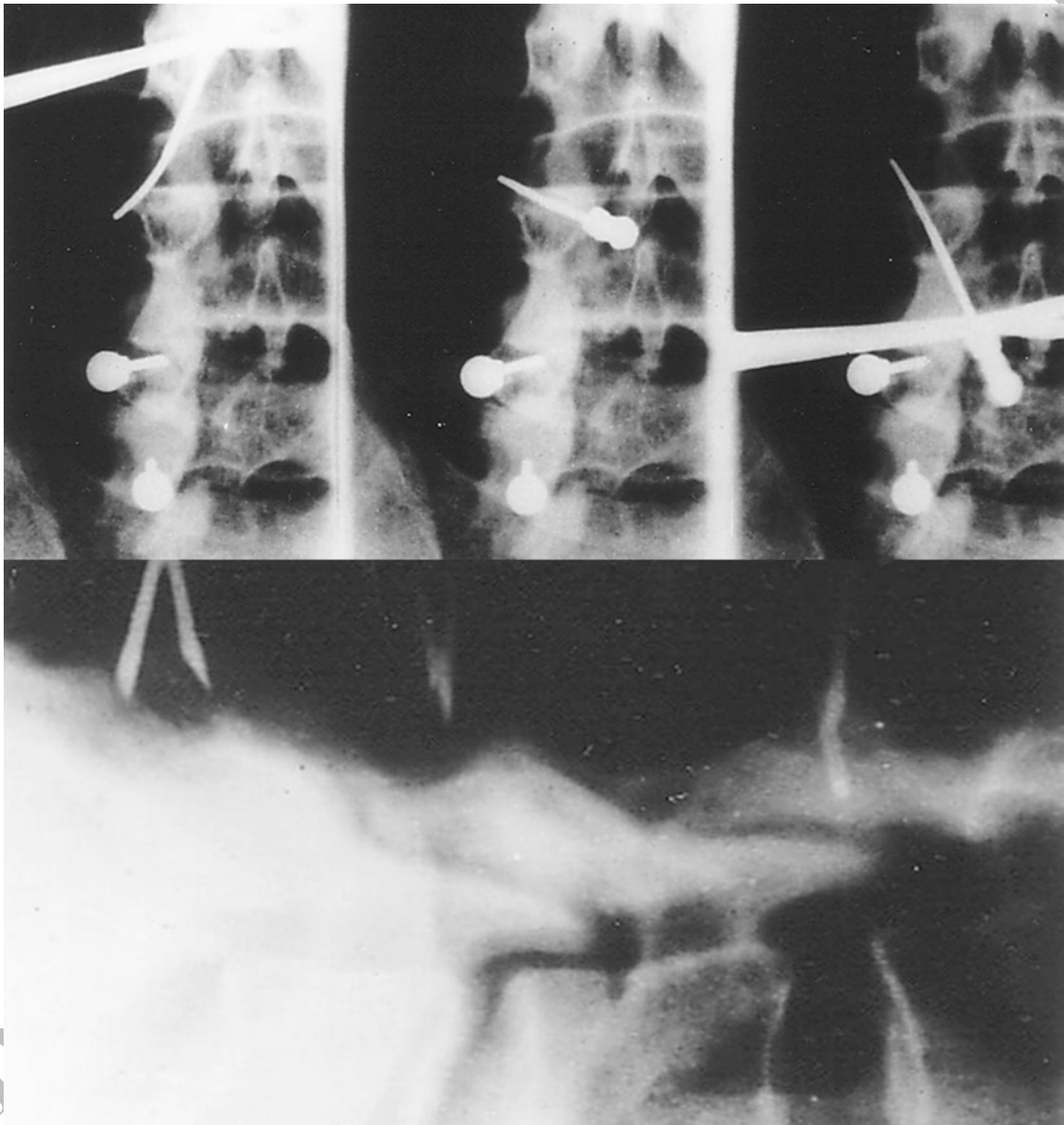
CN Shealy was the first to apply thermal radiofrequency technology to the treatment of low back pain. Between 1974 and 1976 he published several papers<sup>1-4</sup> that proclaimed the success of a procedure that, in the United States, became known as “facet denervation”. In the ensuing years, a large body of literature emerged that echoed Shealy’s claims<sup>5-18</sup>.

Eventually, however, studies showed that Shealy’s technique was anatomically inaccurate<sup>19,20</sup>. Where he placed his electrodes did not coincide with the location of any nerves that innervated the lumbar zygapophysial joints (Figures 1 and 2). Surgically, the procedure amounted to no more than a sham procedure. Consequently the large body of literature pertaining to facet denervation provides no evidence in support of a genuine treatment for back pain stemming from the lumbar zygapophysial joints.

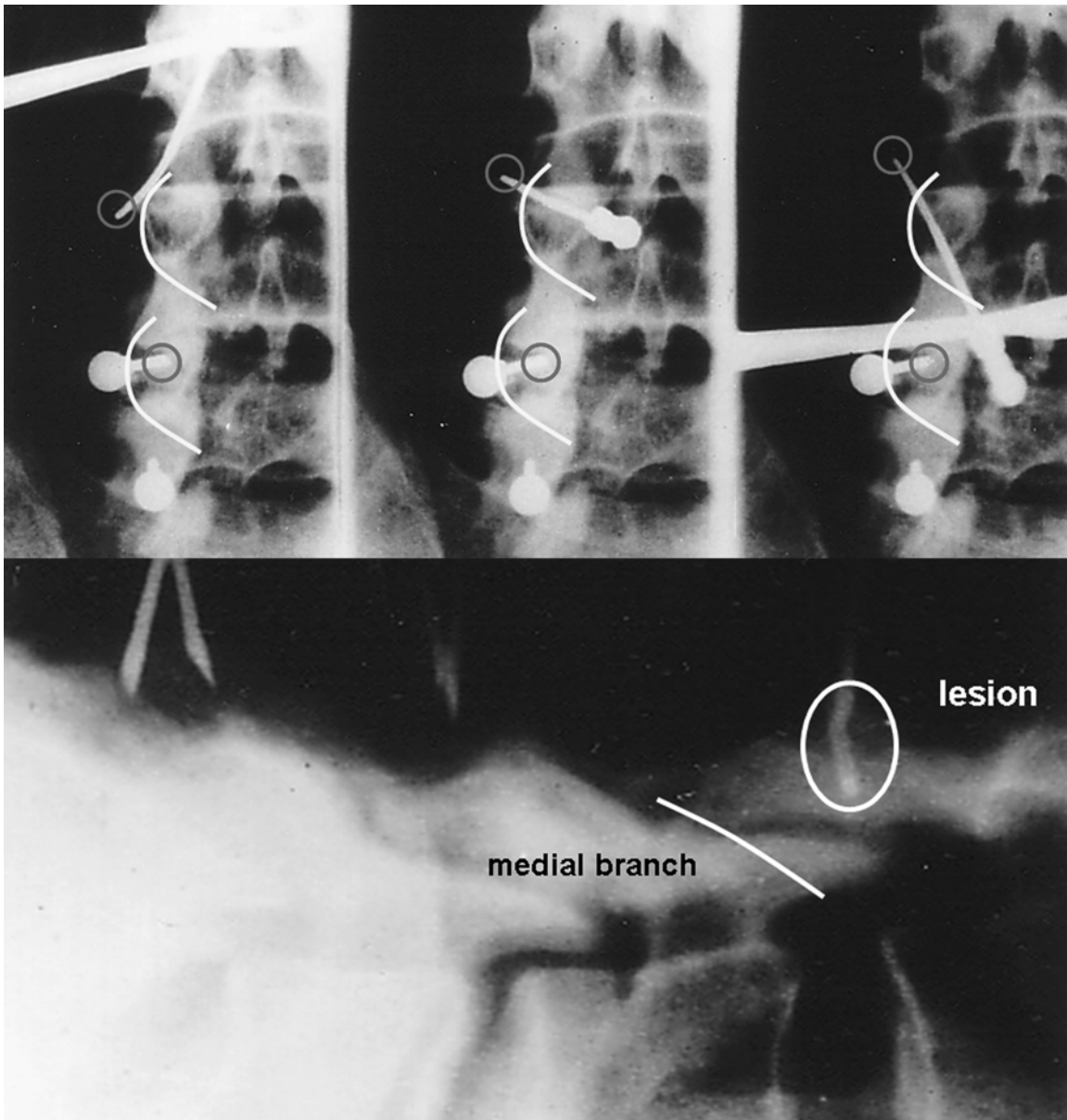
Parallel but separate developments arose in the Netherlands. Success was claimed for a procedure by which lumbar zygapophysial joints could be denervated using thermal lesions<sup>21,22</sup>. Explicit descriptions of the technique, however, are hard to find in the English-language literature. Such evidence that is available<sup>22</sup> suggests that the original technique was flawed (Figure 3). A later version of the technique, said to be commonly practised in the Netherlands<sup>23</sup>, is clearly inaccurate<sup>24</sup> (Figure 4).

Two major reforms occurred to the practice of facet denervation. The first was the clarification of the anatomy of the lumbar medial branches and their role in the innervation of the lumbar zygapophysial joints<sup>19,20</sup>. This changed the focus of denervation procedures from non-existent articular nerves to the medial branches of the lumbar dorsal rami, and changed the name of the procedure from facet denervation to lumbar medial branch neurotomy<sup>20</sup>.

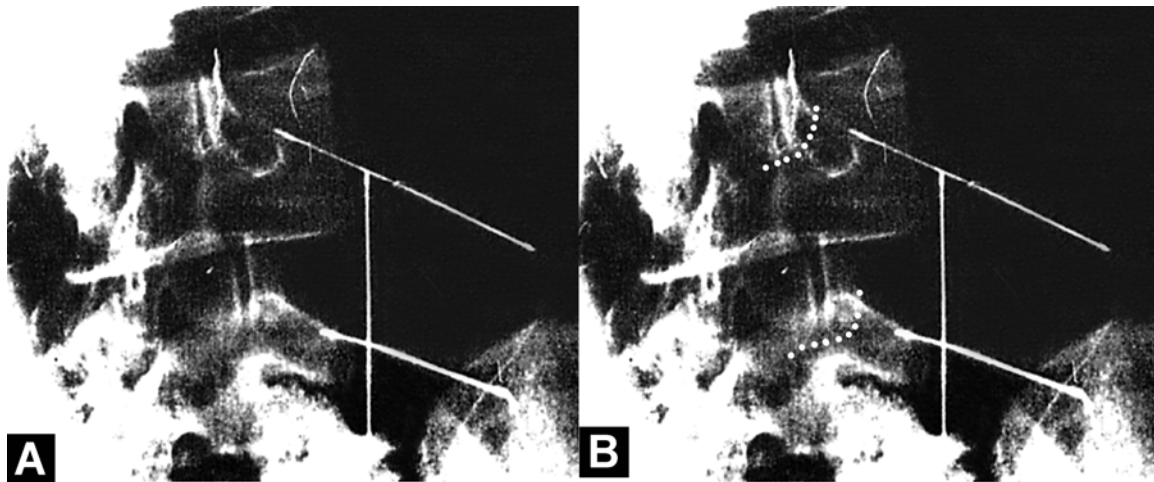
The second reform arose from the demonstration that thermal radiofrequency electrodes do not coagulate distal to their tip, but instead coagulate radially around their tip<sup>25</sup>. This meant that electrodes must be placed parallel to the target nerves, not perpendicular to them.



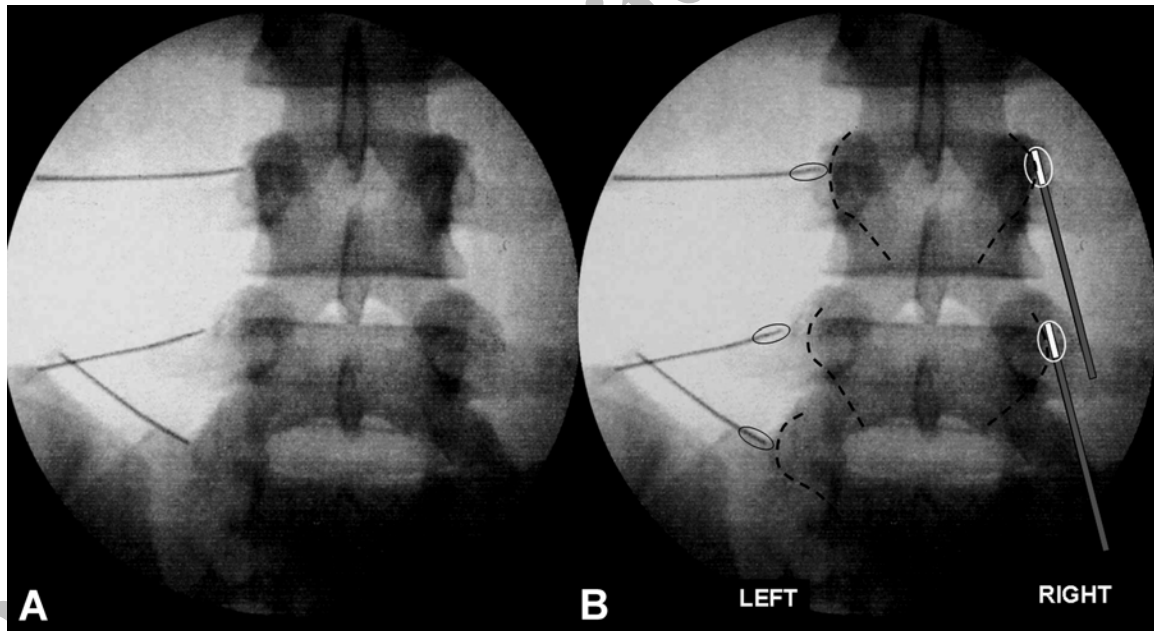
**Figure 1.** Radiographs showing the placement of electrodes for facet denervation as described by Shealy in *Technique for Percutaneous Spinal Facet Rhizotomy*, Radionics Inc, Burlington Massachusetts, 1974. (Illustration prepared by Professor Nikolai Bogduk, Newcastle, Australia.)



**Figure 2.** Radiographs showing the placement of electrodes for facet denervation as described by Shealy, onto which the locations of the medial branches and the locations of the lesions made have been drawn. The lesions do not capture the medial branch, or any other nerve. (Illustration prepared by Professor Nikolai Bogduk, Newcastle, Australia.)



**Figure 3.** An illustration of the technique described by Sluiter and Mehta <sup>22</sup>. **A:** The original radiograph as published showing an oblique view in which two electrodes have been placed. **B:** The same radiograph onto which the courses of the nearest medial branches have been drawn. The tips of the electrodes lie substantially lateral to the course of the nerve. (Illustration prepared by Professor Nikolai Bogduk, Newcastle, Australia.)



**Figure 4.** An illustration of the technique used by van Wijk et al <sup>23</sup>. **A:** The original illustration showing an antero-posterior view of three electrodes in place. **B:** The same radiograph onto which have been drawn the courses of the medial branches. On the left the location of the lesions made are shown. The lesions either do not encompass the nerves or encompass them only partially. On the right the accurate placement of

electrodes and the lesions made have been drawn for comparison. (Illustration prepared by Professor Nikolai Bogduk, Newcastle, Australia.)

These reforms qualify the evidence on lumbar medial branch thermal radiofrequency neurotomy. Studies that used anatomically inaccurate techniques cannot be invoked as evidence for or against the effectiveness of lumbar medial branch thermal radiofrequency neurotomy. Only studies that used anatomically correct techniques qualify as evidence.

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## **EFFICACY**

### **Reviews**

Various clinical guidelines<sup>1-4</sup> and systematic reviews<sup>5-10</sup> have concluded unfavorably on the efficacy and utility of lumbar medial branch neurotomy. However, these publications lacked discrimination on two counts.

First, they did not distinguish between studies that used flawed techniques and those that used correct technique. They admitted as evidence a study<sup>11</sup> that used the discredited technique of Shealy and one<sup>12</sup> whose technique was ill-defined and bears little resemblance to the technique recommended in the ISIS Practice Guidelines.<sup>14</sup> A more discriminating review<sup>13</sup> found that, if only those studies 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.

A second factor confounding the conclusions of some reviews involves the indications used for surgery. 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 will have less than impressive success rates, even if they used correct surgical technique. The effects of poor indications and incorrect procedural technique on success rates are clear when individual studies are examined in detail but nonetheless they have been missed by several review authors.

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## **The Evidence**

The studies that used reasonable surgical technique differ both in design and in how they selected patients. Some have been observational studies. Others have been pragmatic (comparison) studies or explanatory (sham-controlled) studies. All have differed with respect to the types of diagnostic blocks used to select patients, and the criteria used for a positive response.

The original benchmarking study<sup>1</sup> used comparative local anesthetic blocks to select patients. To be eligible for treatment, patients had to report at least 80% relief of their back pain following diagnostic blocks. The study used the technique described in the ISIS Practice Guidelines.<sup>2</sup> In essence 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. Relief of pain was associated with reduction of disability. The number of patients treated was small. So, this study did not provide generalizable evidence as to how effective lumbar medial branch neurotomy is in practice, but it did show how successful the treatment could be if correct technique was used in correctly selected patients.

A contemporary study<sup>3</sup> was conducted as a randomized, placebo-controlled trial. Patients were selected on the basis of single medial branch blocks. Therefore, many would have been included on the basis of false-positive responses; and therefore, the success rate of treatment would have been compromised. The surgical technique used was suboptimal. Although electrodes were placed accurately on the target nerves, they were placed perpendicular, not parallel, to them. Therefore, duration of relief would be expected to be compromised. All of these expectations emerged in the results. Only a small proportion of patients had a successful outcome, and few had 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.

A later placebo-controlled trial<sup>4</sup> carefully selected patients by using controlled diagnostic blocks, and used meticulous surgical technique. It found that active treatment produced greater reductions in pain than did sham treatment. However, this study was conducted in patients who had other pain problems, such as radicular pain. Therefore, a success rate for the elimination of pain could not be determined.

A comparison study sought to compare the efficacy of thermal radiofrequency neurotomy with that of pulsed radiofrequency<sup>5</sup>. However, it included a nested 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, uncontrolled, diagnostic medial branch blocks. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. For thermal radiofrequency a correct technique was used. The electrode was placed parallel to the target nerves. 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. 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% (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.

Collectively, the 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 studies were so designed. Three practice audits have reported the experience of physicians with the routine conduct of lumbar medial branch neurotomy.

The first study<sup>6</sup> selected patients on the basis of at least 50% relief of pain following both an intra-articular block and a medial branch block. It found that 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.

The second study<sup>7</sup> selected patients on the basis of at least 70% relief of pain following comparative medial branch blocks. During a 10-year period, 209 patients were treated by lumbar medial branch neurotomy, and 174 were reviewed. 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. 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.

The third study<sup>8</sup> enrolled patients only if they had complete relief of pain following controlled diagnostic blocks. A total of 106 consecutive patients was recruited in two neighboring practices. All patients were treated strictly according to the technique described in the ISIS Practice Guidelines<sup>2</sup>. 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.**

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.** The subsequent histories of the patients who had successful outcomes are summarized in Figure 5. 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. Practice A performed few repeat treatments, and achieved an aggregate of 575 months of complete relief of pain, in 29 patients, using 35 treatments,

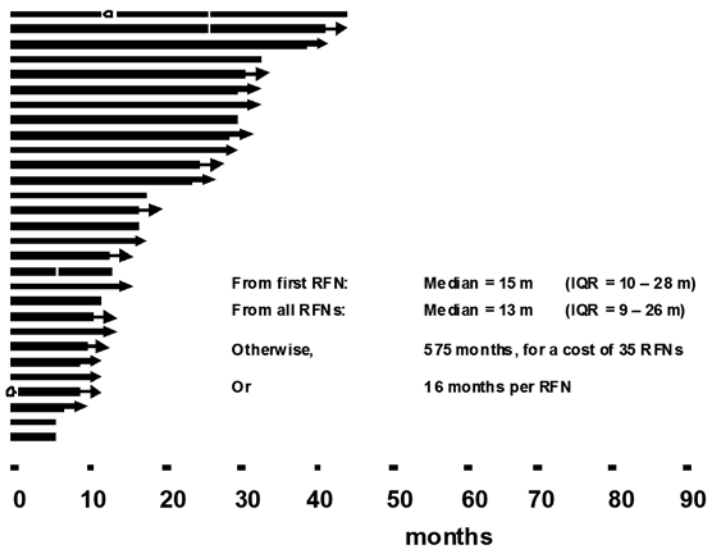
which amounts to a median duration of cumulative relief of 17 (11 – 30) months, and a median duration of 13 months per treatment. Practice B performed more repeat procedures, and kept patients free of pain for a longer period. It achieved an aggregate of 1,067 months of complete relief in 30 patients, using 66 treatments, which amounts to a median duration of cumulative relief of 33 (19 – 46) months, and median duration of 13 months per treatment. In both practices, two-thirds of patients successfully treated still had ongoing relief of pain at the time of follow-up. So, the figures above constitute worst-case values for the duration of relief achieved by radiofrequency neurotomy.

When the outcomes of these three practice audits are plotted, an intriguing trend emerges (Figure 6). The quality of outcomes seems to be related to the criteria used to select patients for treatment.

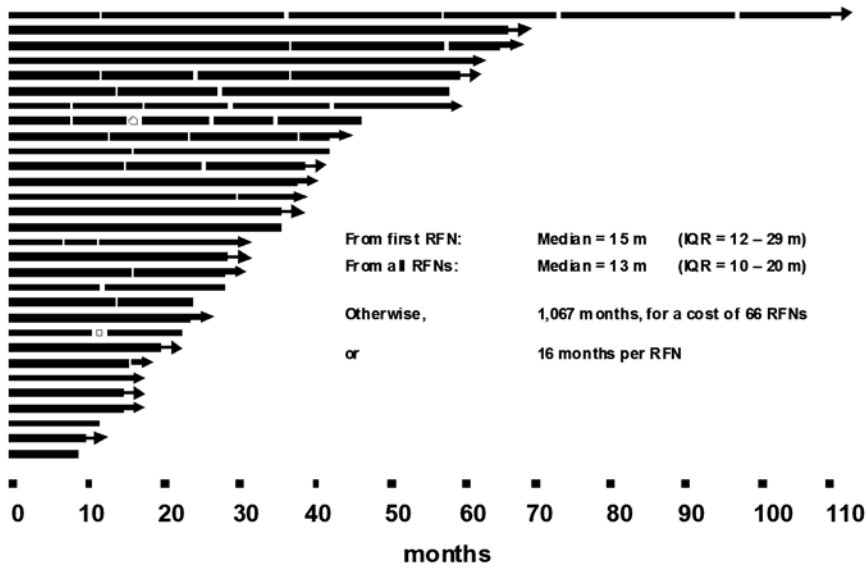
When the criterion for a positive response to diagnostic blocks was 50% relief of pain <sup>6</sup>, the success rate was modest ( $39 \pm 14\%$ ), but the definition of success was only 50% relief of pain. No patients were reported as achieving complete relief of pain.

When the criterion for a positive response to diagnostic blocks was 70% relief of pain, the success rate, for 50% relief of pain after treatment, was 35% ( $\pm 6\%$ ), but an additional 22% ( $\pm 6\%$ ) of patients had complete relief.

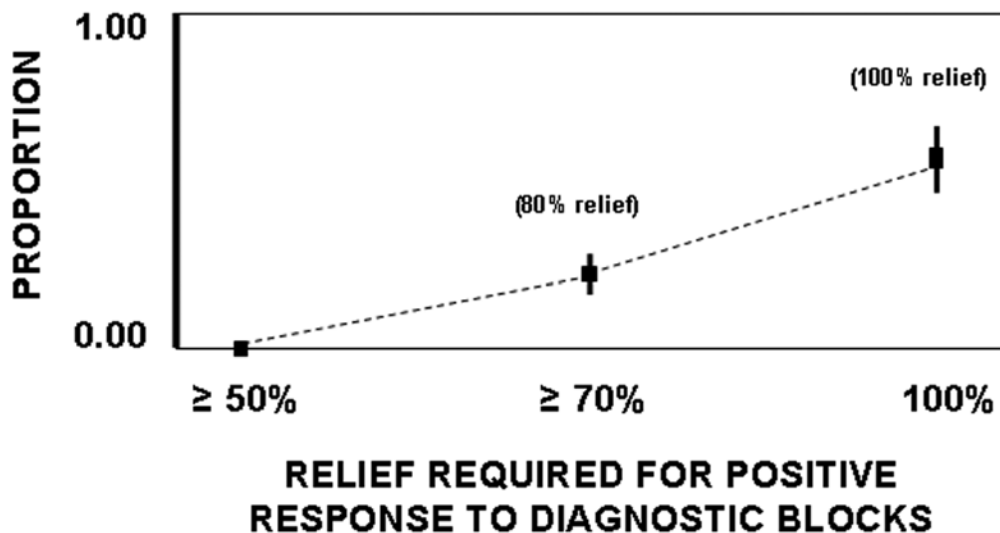
PRACTICE A



PRACTICE B



**Figure 5.** The results of lumbar medial branch neurotomy reported by MacVicar et al<sup>8</sup>. The graphs show the results achieved in two practices. Each bar represents a single patient. The length of the bar indicates the duration of successful outcome. An interruption indicates recurrence of pain. A second bar represents the response to repeat treatment. An arrow indicates ongoing relief at the time of review. Circles indicate no relief following an attempted treatment. **RFN:** radiofrequency neurotomy. **IQR:** interquartile range.



**Figure 6.** The proportion (95% confidence interval) of patients achieving 80% or 100% relief after lumbar radiofrequency medial branch neurotomy, as reported in the literature<sup>6,7,8</sup>, plotted against the criteria used to define a positive response to controlled diagnostic blocks. (Illustration prepared by Professor Nikolai Bogduk, Newcastle, Australia.)

When the criterion for a positive response to diagnostic blocks was complete relief of pain, the success rate for complete relief of pain was 56% ( $\pm 9\%$ ).

These differences strongly suggest that more stringent diagnostic criteria are associated with greater proportions of patients achieving complete relief of pain. Indeed, the authors of the first-mentioned practice audit acknowledged that their lesser success rate might be attributable to their less stringent diagnostic criteria<sup>6</sup>. Reciprocally, the authors of the third audit emphasized that their success rate applied only to patients who reported complete relief to controlled diagnostic blocks<sup>8</sup>. Furthermore, they argued that, despite the quality of their outcomes, their modest success rate probably related to the high false-positive rate of comparative local anesthetic blocks<sup>9</sup>.

## Discussion

The available data vindicate the use of lumbar medial branch neurotomy provided that correct surgical technique is used. There are no data that vindicate any other technique. All studies have consistently shown positive benefits. No studies have shown otherwise. Where the data differ is with respect to selection criteria and definitions of success.

If the criterion for a positive response to diagnostic blocks is 50% relief of pain, some 40% of patients obtain 50% relief after treatment. Their disability improves, and they reduce their need for analgesics.

**If the criterion for a positive response to diagnostic blocks is raised to complete relief, some 56% of patients achieve complete relief of pain. They restore their normal activities, and the need for other health care is eliminated.**

The available data allow physicians to choose which operational criteria they care to follow. Each has implications for practice.

Adopting lesser diagnostic criteria admits more patients for treatment, but the outcomes are poorer. The implication is that physicians will be treating more patients but not achieving optimal outcomes.

Adopting more stringent diagnostic criteria admits fewer patients for treatment, but the outcomes achieved are of greater quality.

A factor to consider in choosing between the options is the reputation of lumbar medial branch neurotomy. Profligate use of the treatment, inadequate technique and mediocre outcomes do not serve its reputation well, particularly in the eyes of those who pay for the treatment, and pose threats to continuation of funding for it. In contrast, outstanding outcomes, resulting from correct technique applied in rigorously selected cases, is what patients need, and is also what serves the reputation of spine intervention procedures well.

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## Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand

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### Abstract

**Objective.** This study aims to determine the effectiveness of lumbar medial branch radiofrequency neurotomy (RFN) performed by two practitioners trained according to rigorous guidelines.

**Design.** Prospective, outcome study of consecutive patients with chronic back pain treated in a community setting.

**Interventions.** A total of 106 patients, selected on the basis of complete relief of pain following controlled, diagnostic, medial branch blocks, were treated with RFN according to the guidelines of the International Spine Intervention Society.

**Outcome Measures.** Successful outcome was defined as complete relief of pain for at least 6 months, with complete restoration of activities of daily living, no need for any further health care, and

return to work. Patients who failed to meet any of these criteria were deemed to have failed treatment.

**Results.** In the two practices, 58% and 53% of patients achieved a successful outcome. Relief lasted 15 months from the first RFN and 13 months for repeat treatments. Allowing for repeat treatment, patients maintained relief for a median duration of 17–33 months, with some 70% still having relief at follow-up.

**Conclusion.** Lumbar RFN can be very effective when performed in a rigorous manner in appropriately selected patients. Chronic back pain, mediated by the lumbar medial branches, can be stopped and patients fully restored to normal living, if treated with RFN.

**Key Words.** Chronic Pain; Back Pain; Radiofrequency; Neurotomy

### Introduction

Lumbar medial branch radiofrequency neurotomy (RFN) is a treatment for a specific subgroup of patients with low back pain: those whose pain is mediated by medial branches of the lumbar dorsal rami and which ostensibly arises from the zygapophysial joint or joints innervated by these nerves [1,2]. The paradigm of lumbar RFN is that if controlled, diagnostic blocks of lumbar medial branches completely relieve the patient's pain temporarily then coagulation of those nerves should provide complete relief of pain for an extended period. Pain may recur if and when the nerves regenerate, but in that event, relief can be reinstated by repeating the neurotomy [3].

Several controlled trials have shown that the effects of lumbar RFN cannot be dismissed as placebo [4–6]. However, for various reasons, these studies did not demonstrate the optimal effectiveness of the procedure [7], nor did certain observational studies [8,9]. Some did not use controlled, diagnostic blocks to select patients [4,5,9]; some did not use optimal surgical technique [4]; some accepted patients with less than complete relief of pain following diagnostic blocks [5,8,9]; or they used patients with concomitant conditions that complicated long-term assessment [6]. To date, only one small study has established the benchmark of outcomes for lumbar RFN [10]. It showed that 60% of patients should expect at least 80% relief of pain at 12 months, or 80% of patients should expect at least 60% relief for the same period.



The present study was undertaken as a prospective audit of outcomes to determine if lumbar RFN in conventional practice achieved benchmark outcomes. In accordance with the paradigm of lumbar RFN, patients were selected for treatment only if they had complete relief of their pain followed controlled, diagnostic, medial branch blocks. Diagnostic blocks were performed using either lignocaine or bupivacaine, and the physician, the assessor of the response, and the patient were all blinded as to which local anesthetic was used. A positive response was confirmed by repeating the blocks with the local anesthetic that was not used for the first procedure. Patients selected for treatment had complete relief from pain on both occasions and were able to perform without restriction movements and activities that would usually aggravate their pain. Duration of relief following each block was not a criterion for eligibility for treatment, because the diagnostic confidence (posttest probability) of comparative blocks is only marginally superior when duration of relief is added as a criterion [11]. The exact number of patients screened with medial branch blocks is unknown because some records were lost as a result of earthquake damage but, from data that is available, it is estimated that 575 patients were screened. For outcomes of lumbar RFN to be classified as successful, pain had to be completely relieved. The results obtained provide a new benchmark for outcomes of lumbar RFN.

## **Methods**

During 2004, two of the authors (JM and JB) were trained by the fifth author (NB) in the rigorous performance of lumbar RFN according to the standards prescribed by the International Spine Intervention Society [1,2,12]. All procedures were carried out with 16 gauge (1.6 mm diameter) Cosman RRE electrodes (Cosman Medical Inc., Burlington, MA, USA), and either 10 cm or 15 cm electrodes were used, depending on the size of the patient. Electrodes with either 5 mm or 10 mm exposed tips were placed parallel to the medial branches, across the necks of the superior articular processes, and sufficient lesions were created to cover the likely location of the nerves. All consecutive patients who underwent lumbar RFN after the period of training until December 2009 were prospectively followed. The patients were assessed and treated in each of two suburban practices conducted by practitioners with a vocational interest in musculoskeletal medicine. The outcomes were assessed, at various times after treatment, at each of the practices respectively by one of two primary care physicians (AM and BL) who were not involved in the treatment of the patients. The data collected were independently assessed and analyzed by the fifth author (NB).

Before treatment, patients recorded their pain score using a visual analog scale or verbal, numerical pain-rating scale [13–15]; they nominated four activities of daily living that were impeded by their pain and which most dearly they would want restored [16–18]; and they recorded their work status and what health care they were using for their pain. Follow-up was undertaken either during subsequent face-to-face consultations or by telephone, at which time

patients were asked to report their pain scores, their activities of daily living and work status, and their use of other health care.

Outcomes were defined categorically. In order to be rated as having a successful outcome, patients had to report complete relief of pain, or at least 80% relief, for at least 6 months; restore all of their desired activities of daily living; require no other health care for their back pain; and return to work if they had not previously been working. Any other combination of response was considered a failure. Occasional exceptions were indulged. For example, return to work was excused if the patient could not work for socioeconomic reasons or for other health reasons but provided that pain was completely relieved, all activities had been restored, and no other health care was required. Patients were allowed to use analgesics if they had some other health problem that was not treated. Patients were allowed to use over-the-counter analgesics for any remnant pain, but they were deemed a failure if they required any prescription medications for their index pain.

The numbers and proportions of patients achieving various grades of outcome were tallied. The median duration (and interquartile range) of complete relief following the first RFN was calculated. Allowing for repeat treatment, the total duration of relief achieved by each patient was calculated by summing all periods of relief achieved for that patient. The median duration of cumulative relief across all patients was calculated as the median of all summed periods for individual patients. Also calculated were the median and average durations of complete relief achieved by all initial and repeat treatments.

## **Results**

In the two practices, a total of 106 consecutive patients were treated. Their presenting demographic features are summarized in Table 1, and their presenting clinical features are shown in Table 2. The patients from the two practices were reasonably similar, demographically, although Practice B saw somewhat more patients with work-related injuries, whereas Practice A saw more patients whose back pain was attributed to other injuries such as falls, lifting, or being hit by moving objects. Clinically, the segments diagnosed and treated were similar in the two practices, but Practice A treated patients with a longer duration of pain (Table 2).

Of the patients for whom treatment was categorized as having failed, the largest subgroup were those who were outright failures; they obtained no relief of their pain (Table 3). Others were relieved of the pain for which they were treated but still had pain from other sources that impaired their recovery. Some patients were completely relieved of their pain, but for reasons not disclosed to the investigators, they were not able to restore their activities of daily living. Others were relieved of their pain and restored their activities, but the duration of relief did not last 6 months. A few patients restored their activities of daily living but did not have complete relief of their pain;

## Lumbar Medial Branch Radiofrequency Neurotomy

**Table 1** Demographic features of patients treated with lumbar radiofrequency neurotomy

Feature	Practice A	Practice B
Gender		
Male	23	33
Female	27	23
Age (years)		
Median	50	45
Interquartile range	30–56	35–56
Range	19–77	15–80
Occupation		
Tradesman	7	15
Manual worker	5	11
Retail	2	6
Professional	6	4
Manager	3	2
Retired	2	3
Domestic duties	3	3
Student	4	2
Not recorded	11	2
Clerical	5	6
Service industry	5	2
Work status		
Working full time	15	16
Working part time	6	11
Not working	26	24
Not applicable	3	5
Injury		
Work-related	7	27
Sport	4	7
Motor vehicle accident	7	5
Other (e.g., fall, hit, lifting)	18	9
None	9	4
Not recorded	5	4

variously they reported 50% or 70% relief, but not complete relief, as required by the outcome criteria. One patient died before follow-up, and two from Practice A were lost to follow-up. Two patients from that practice had complete relief of pain and had restored their activities of daily living, but they had only recently been treated and, therefore, had not reached the required 6 months duration of relief. They portend to become successful outcomes but, for present purposes they were, on technical grounds, classified as not successes.

All other patients satisfied the criteria for successful outcome. They had complete relief of pain for at least 6 months; they restored their activities of daily living; they required no other health care (apart from over-the-counter medications, if at all); and they returned to work. Concessions applied to only five patients. In Practice A, one patient reported 90% relief of pain, and in Practice B, one reported 90%, two reported 95%, and one reported 80% relief, but all of these patients completely restored their activities of daily living, required no other health

**Table 2** Presenting clinical features of patients treated with lumbar radiofrequency neurotomy

Feature	Practice A	Practice B
Duration of pain (months)		
Median	60	17
Interquartile range	36–82	10–75
Range	9–418	5–300
Numerical pain rating (0–100)		
Median	60	50
Interquartile range	50–70	40–65
Nerves treated		
T11,12	1	1
T12, L1	1	3*
T12, L1,2	0	2
L1,2,3	0	2
L2,3	4	4
L2,3,4	0	2
L3,4	11	12
L4,5	18	19*
L3,4,5	9	3
Bilateral T11,12	1	0
Bilateral T12, L1	0	2
Bilateral L1,2,3	0	1
Bilateral L2,3	0	1
Bilateral L3,4	2	1
Bilateral L4,5	3	3

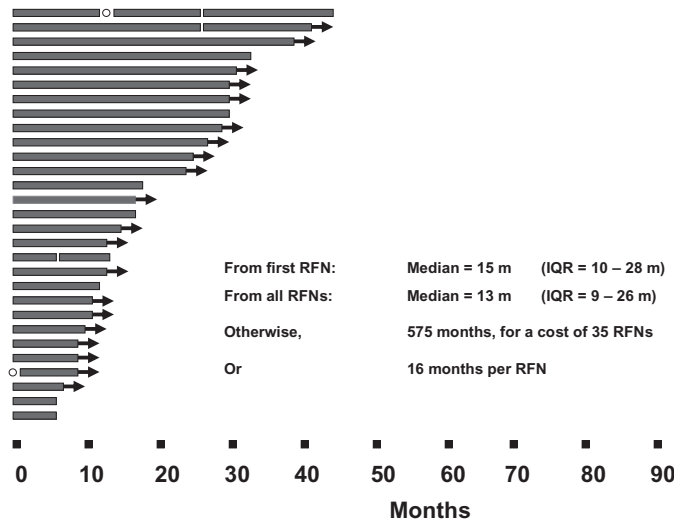
\* One patient was treated on separate occasions for separate complaints mediated by T12,L1 and L4,5.

**Table 3** Outcomes of patients treated with lumbar radiofrequency neurotomy

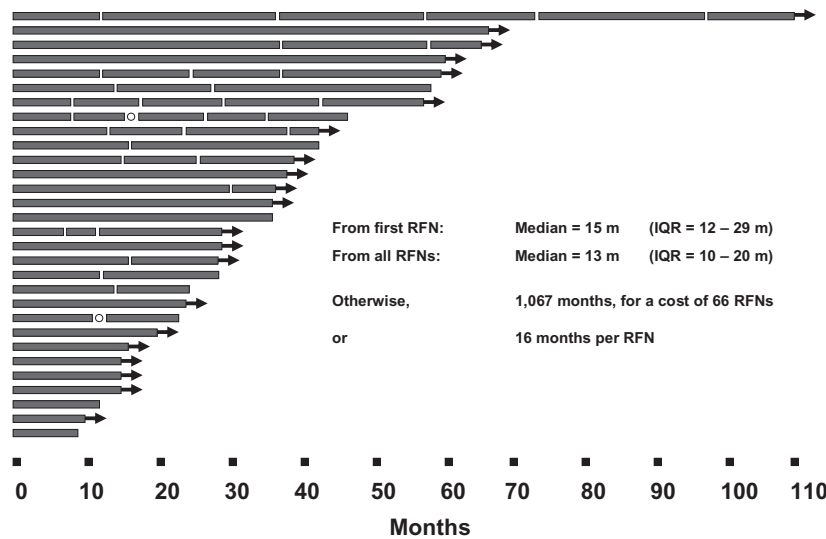
Outcome	Practice A	Practice B
Failure		
Outright; no relief	9	13
Other pain	4	6*
Pain relieved; activities not restored	0	2
Pain recurred, before 6 months	2	0
Not complete relief of pain	2	5
Deceased	0	1
Lost to follow-up	2	0
Not yet reached 6 months	2	0
Success		
Complete relief of pain	29	30
Activities restored		
No other health care	58%	53%
Return to work	(44–72)	(40–66)

\* Includes the patient treated successfully for pain at T12,L1 but without relief at L4,5.

**PRACTICE A**



**PRACTICE B**



**Figure 1** Duration of relief reported by patients treated with lumbar radiofrequency neurotomy. Each line represents one patient. Each bar indicates the duration of relief following a single treatment. Interruptions indicate that relief ceased, followed by repeat treatment. Arrowheads indicate that complete relief was continuing at the time of follow-up. Circles indicate an RFN that was not successful. The insets summarize the statistical parameters of each set of outcomes. IQR = interquartile range; RFN = radiofrequency neurotomy.

care, returned to work, and were very satisfied with their outcome. All other patients had complete relief of pain. The proportions of patients who achieved successful outcomes in the two practices were similar, (58%, 53%) and were not significantly different statistically.

Among the patients with a successful outcome, some requested, and underwent, repeat treatment; others are awaiting repeat treatment, or have not requested it. Figure 1 shows the number of treatments undertaken to achieve and maintain complete relief of pain over an extended period.

The median duration of complete relief of pain following the first successful RFN was 15 months in Practice A (interquartile range: 10–28 months) and 15 months (12–29 months) in Practice B. Practice A performed few

repeat treatments and achieved an aggregate of 575 months of complete relief of pain, in 29 patients, using 35 treatments, which amounts to a median duration of cumulative relief of 17 (11–30) months, and a median duration of 13 months per treatment, or an average of 16 months per treatment. Practice B performed more repeat procedures, and thereby kept patients free of pain for a longer period. It achieved an aggregate of 1,067 months of complete relief in 30 patients, using 66 treatments, which amounts to a median duration of cumulative relief of 33 (19–46) months, and median duration of 13 months per treatment, or an average of 16 months per treatment. In both practices, two-thirds of patients successfully treated still had ongoing relief of pain at the time of follow-up. So, the figures above constitute worst case values for the duration of relief achieved by RFN.

## Lumbar Medial Branch Radiofrequency Neurotomy

### Discussion

Remarkable in the results of the present study are the consistencies between the operators in the two practices. Each practice obtained virtually identical success rates, and the median durations of relief, achieved by the first RFN, and by all RFNs, were essentially the same. This consistency confers internal validity to the study and predicates external validity. Both operators used the same diagnostic protocol and the same operative technique [1,2]. Others who do so should expect the same outcomes.

The outcome measures used in the present study were unusual but deliberately so. The paradigm of lumbar RFN predicts that if patients achieve complete relief of pain following controlled, diagnostic blocks, they should achieve complete relief following RFN. Therefore, complete relief of pain was adopted as the cardinal criterion for successful outcome. This had to be accompanied by complete restoration of activities in daily living, and no need for any other health care. These latter measures were used not only to corroborate the relief of pain but also to indicate that lumbar RFN is a restorative treatment. Without any other intervention, lumbar RFN completely relieves over 50% of patients of their pain and restores them to normal life. No other treatment for low back pain has ever been shown to achieve such outcomes.

Previous studies of lumbar RFN used generous definitions of success. They have reported 20–70% of patients achieving at least 50% relief of pain for 3, 6, 12, or 24 months [4–6,8,9], but they did not report the proportions of patients achieving complete relief of pain, which implies that few, if any, patients did so. The results of the present study are distinctly different, both in terms of the number of patients who achieved complete relief of pain and the duration over which that relief lasted. The possible reasons for these differences bear consideration.

In the present study, patients were selected for treatment if their pain was relieved by controlled, comparative local anesthetic blocks [11,19,20]. Others do not use controlled blocks.

Patients were selected for treatment only if their pain was completely relieved by diagnostic blocks. Others accept 50% relief as constituting a positive response.

Rigorous and meticulous operative technique was used. Large 16G electrodes were used. Others use 21G or 22G electrodes, which can fail to incorporate the target nerve into a lesion [12]. Multiple lesions were made in order to encompass all possible locations of the target nerve [1,12]. Others use an expeditious, single lesion, which can fail to incorporate the nerve, or can fail to incorporate an adequate length of nerve [1,12]. The electrodes were placed parallel to the target nerve. Others use perpendicular placements, which can fail to coagulate the nerve, or might coagulate an insufficient length of nerve [1,12]. No personal or arbitrary variant of lumbar RFN has been shown to be as effective as the method prescribed by the

International Spine Intervention Society and used in the present study [12].

New Zealand patients were unambiguous about their outcomes. Either the procedure worked or it did not. Only six of the 106 patients treated reported only partial relief of pain; the majority clearly had no relief or complete relief of their pain. This contrasts with outcomes reported in North America, where partial relief of pain appears to be reported more commonly. This difference might be due to the lesser selection criteria used in North America, or there might be psychosocial differences between New Zealand patients and North American patients in the way that they respond to treatment.

Of some concern is why the success rate in the present study was only 53–58%. The paradigm of lumbar RFN expects a far greater success rate. Several explanations apply.

First, among the failures were patients whose pain was not completely relieved by diagnostic blocks. For example, their pain scores fell from 50 to 5, but not to zero. The operator nevertheless optimistically ventured to perform RFN, which did not succeed. All patients who did have a successful outcome from RFN had complete relief of pain from their diagnostic blocks. This suggests that complete relief of pain following diagnostic blocks is mandatory for complete relief of pain following RFN.

Second, the responses of several patients were confounded by other sources of pain. As a result, although their index pain was completely relieved, the persistence of the other pain prevented them from restoring the activities of daily living. Thus, RFN was intrinsically successful but could not be shown to be so given the criteria for success that were set a priori. A morality debate arises as to whether or not patients should be relieved of some of their pain when they suffer from other sources of pain that prevent their complete rehabilitation.

Enigmatic are those patients who reported complete relief of pain during diagnostic blocks but did not restore their activities of daily living following apparently successful RFN. This combination suggests a false-positive response both to treatment and to the original, diagnostic blocks.

Comparative local anesthetic blocks are not an ideal diagnostic test. Although their sensitivity is high, their specificity is modest (65%) [11,19,20]. Therefore, it is possible that some the patients treated had false-positive responses to diagnostic blocks. Either this possibility can be accepted, together with the attendant failure rate of treatment, or it can be reduced, and the success rate of RFN improved, by using placebo-controlled blocks to select patients for treatment [11].

Notwithstanding these limitations, the results of the present study demonstrate that lumbar RFN can be a very successful treatment. The patients in the study were not “highly selected” in the sense that prognostically they were

## MacVicar et al.

somehow destined to recover. They were highly selected for having a particular form of back pain, diagnosed by controlled, medial branch blocks. In such patients, the present study shows that lumbar RFN is not curative but can be highly restorative. The initial yield of RFN of about 10% is reasonable, and success can be maintained by repeating the procedure, over multiple years. For patients with this form of back pain, no other treatment has been shown to be effective; no other treatment eliminates pain, restores function, and eliminates the need for other health care. There is no alternative or rival treatment for these patients.

The present study echoes and extends the benchmark originally set by Dreyfuss et al. [10]. They showed that 60% of patients could expect at least 80% relief at 12 months. The present study shows that a similar proportion maintain complete relief of pain for over 12 months, and for much longer if RFN is repeated. This benchmark is achieved by using rigorous protocols for diagnosis [2] and for treatment [1]. It raises serious questions about operators who claim that 50% relief at 3 months with a 20% reduction in use of opioids constitutes a success [21]. Complete relief of pain with no need for other health care is the benchmark for successful lumbar RFN.

## Acknowledgments

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## **Lumbar Medial Branch Radiofrequency Neurotomy**

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November 17, 2009

Bernice Hecker, MD, M.H.A., F.A.C.C.  
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William Mangold, M.D. JD  
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RE: Response to the discussions of telephone conference and your letter with questions.

Dear Drs. Hecker, Waldmann, and Mangold:

The North American Spine Society (NASS), International Spine Intervention Society (ISIS), American Society of Anesthesiologists (ASA), American Academy of Pain Medicine (AAPM), American Academy of Physical Medicine and Rehabilitation (AAPM&R), Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Spine Radiology (ASSR), American Society of Neuroradiology (ASNR), and American Academy of Orthopaedic Surgeons (AAOS), appreciate the opportunity to work with you in addressing your questions with regard to lumbar facet interventions.

The above-noted twelve stakeholder societies, representing over 140,000 practicing physicians, have worked diligently to reach a consensus response to the questions raised. We trust that the results of our cooperation will lead to a coverage Noridian LCD with appropriate restrictions as outlined within this response. (The questions posed by Noridian are in bold and the consensus responses follow).

**A schemata for the use of these blocks in the assessment and treatment of LBP. Ideally, the flow chart would include any time frequencies.** A defined flow chart does not allow for individual variation and physician judgment in the diagnosis and management of patients. It is preferable, and befits good clinical care to allow the physician to determine the appropriate plan of care within the allowable limits for diagnostic and therapeutic options defined below. The myriad of potential variations possible – especially in the elderly – do not permit the formulation of a detailed schemata to be presented for the evaluation and treatment of low back pain in general, or lumbar facet pain in particular. The multi-society consensus regarding indications and inclusion/exclusion criteria for performing facet joint interventions is presented below.

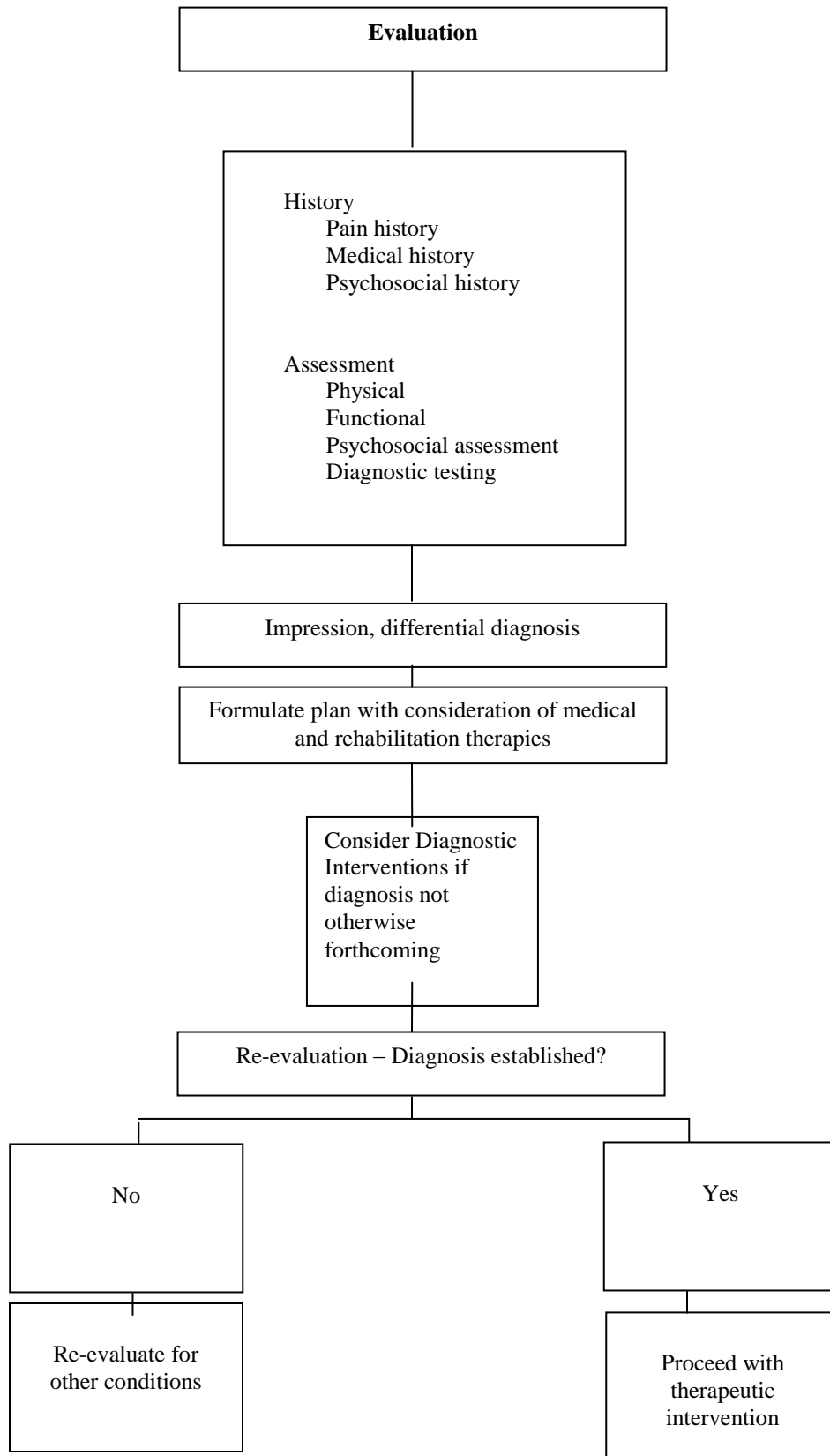
Documentation of medical necessity is considered mandatory. Medical necessity must be documented for lumbar facet joint blocks as follows:

1. Complete initial evaluation including history and physical examination, appropriate imaging performed and reviewed, functional and psychological assessment (as necessary and feasible), diagnostic or treatment plan (not necessarily by the same physician assigned to perform the procedure).
2. Indications, medical necessity, and appropriate prerequisites should address:
  - ◆ Clinical suspicion of somatic low back pain
  - ◆ Pain refractory to conservative modalities of treatment
    - Contraindications or inability to undergo physical therapy, mobilization/manipulation or inability to tolerate non-steroidal anti-inflammatory drugs.
  - ◆ Pain and disability of moderate to severe degree or intermittent or continuous pain causing functional disability.
  - ◆ Absence of obvious non-facet pain pathology that would explain the symptom(s) of low back pain
  - ◆ Absence of “red flag” conditions, such as tumor, fracture, or infection
  - ◆ Absence of psychogenic pain, progressive radiculopathy or other neurological deficits.
  - ◆ Responsiveness to prior interventions with improvement in physical and functional status for repeat facet injection.

### *Evaluation and Management*

An approach to evaluation and management of chronic low back pain includes the following overview schemata:





**The place, if any, of these blocks in the treatment of LBP when other pain generators are present, i.e., the marginal utility.**

The primary utility of facet injections in the context of potential multiple pain generators is diagnostic. When a diagnosis is made, then specific treatment can be provided or, at times, a particular treatment may be identified that should actually be avoided. If a substantial portion of low back pain is demonstrated to arise from the facet joints ( $\geq 50\%$  relief from diagnostic facet blocks) then therapeutic procedures aimed at treating this component of the pain is appropriate.

When there are potentially multiple pain generators, it is necessary to allow the physician to determine the appropriate plan of care within the allowable limits and restrictions for diagnostic and therapeutic options defined below.

**The place of intra-articular blocks (IA) in the diagnosis or treatment of LBP. The literature fails to demonstrate clear evidence of utility in even selected groups.**

*Diagnosis*

Medial branch blocks (MBBs) are the preferred method to diagnose facet pain. Intra-articular blocks are widely considered less specific than MBBs (to “rule-in” facet joint pain) in routine situations. In part this stems from technical issues in their performance. In some very arthritic joints (common in the Medicare population) it can be very difficult or impossible to obtain access to the joint itself. However, intra-articular facet blocks (using local anesthetic) have utility in certain clinical situations to “rule out” facet joint pain.

An intra-articular L5-S1 facet block may be more specific than an L4 medial branch and a L5 dorsal ramus block. Anatomical studies have demonstrated that the L5 dorsal ramus has two divisions, with the medial division supplying innervation to the L5-S1 facet joint, and the lateral division supplying the dorsal sacro-iliac joint complex. Due to the proximity of the lateral branch of the L5 posterior primary ramus, injection of local anesthetic over the L5 dorsal ramus in patients who may have sacro-iliac joint pain may contribute to false positive findings, suggesting facet joint pain, when in fact, sacro-iliac joint pain is present (*Yin, Spine 2003; Willard, Pain Med 2009*). Additionally, when a posterior fusion is present, one cannot routinely block both the appropriate medial branches that innervate the involved joint due to anatomical limitations imposed by the fusion; in this context an intra-articular block has a defined diagnostic role.

*Therapeutic*

The routine use of intra-articular facet injections as a therapeutic modality is not endorsed. Intra-articular steroid injections (used as a presumptive *therapeutic* procedure) to treat *non-degenerative* facet joint pain have not been conclusively established to be superior to placebo or local anesthetic injection in randomized trials. However, there is emerging evidence that in certain clinical scenarios facet joint injections may have a valuable therapeutic role.

The efficacy of intra-articular steroid injected with local anesthetic in patients with proven symptomatic *degenerative* lumbar facet joint pain has not been specifically evaluated in randomized trials. There is emerging evidence from largely prospective trials that in the elderly with facet joint arthropathy with or without synovitis (positive SPECT), intra-articular corticosteroid injections may be a reasonable palliative option. (*Dolan, Br J Rheumatology 1996; Pneumatics, Radiology 2006*). Intra-articular

facet joint aspirations have a role in potential facet-related effusions, infections and abscesses. Corticosteroid injections are appropriate in the evaluation and/or treatment of facet joint effusions and facet synovial cysts resulting in central, foraminal or lateral recess stenosis causing associated focal neural compression and radiculopathy. (*Parlier-Cuau C, Radiology 1999; Bureau NJ, Radiology 2001*) Additionally, in patients with symptomatic facet joint cysts, evidence suggests that purposeful iatrogenic synovial cyst rupture via an intra-articular injection and joint space over-pressurization can be beneficial. (*Allen, Spine J 2009, Martha Spine J 2009*)

In some patients who are not candidates for radiofrequency neurotomy or who do not desire radiofrequency treatment, injection of local anesthetic with steroid into the facet joint represents a reasonable alternative as a palliative measure that is associated with minimal risk of morbidity.

### **Fluoro or CT? If CT, when and why? Restriction on total time?**

It should be the choice of the physician performing the facet injection procedures which imaging modality (fluoroscopy or CT) they feel most comfortable or confident utilizing as they are both appropriate. (*Brook AL et al, JVIR 2008;19:725-735*) With the availability of CT-fluoroscopy and employing ‘quick check’ techniques, the radiation dose to both the patient and physician when performing interventional spine procedures is low. (*Paulson EK et al Radiology 2001;220:161-176, Wagner AL. AJNR Am J Neuroradiol 2004;25:1821-1823*) There is no evidence that fluoroscopy exposes patients to dangerous levels of radiation when used in the performance of facet injection procedures as limited by the recommendations contained herein.

Intra-articular access can often be more confidently achieved with CT, in particular when severely degenerative facet joints, significant anatomic anomalies or variations in joint anatomy exist since direct visualization of the posterior facet surface allows for more confident targeting. Additionally, CT-fluoroscopy is often essential when prior fusion has been performed and bone graft material obscures target access.

**Sedation – none, minimal or moderate? When and in whom?** Sedation is not routinely required for the performance of medial branch or intra-articular zygapophysial joint blocks. It is often provided when performing radiofrequency neurotomy. It should be an option available, at the discretion of the physician, to those patients who have positioning issues related to pain, significant needle anxiety/phobia or substantial paravertebral muscle hypertonicity limiting needle placement with reasonable comfort. If sedation is used, minimal or “conscious” sedation is usually adequate. There are rare circumstances that may necessitate the use of monitored anesthesia care including in those with a poor health status in which increased sedation risk exists. There is no role for general anesthesia in the performance of any of these procedures.

### **Contrast – when? amount/volume?**

For intra-articular injection, contrast arthrography is required to confirm that the subsequently applied injectate will be delivered within the target joint. Further, contrast arthrography is required to assure the subsequent injectate remains confined to the joint space and does not extravasate to the epidural space or adjacent spinal nerve to maintain the diagnostic specificity of the injection. The volume of contrast required to opacify or fill the synovial component of a lumbar facet joint is less than 0.5 mL, although larger volumes may be used when performing a facet cyst rupture.

There are differing opinions between the stakeholder societies as to whether contrast should be mandated during the performance of medial branch blocks as there are no definitive comparative studies. The use of contrast is encouraged, however, by the majority of stakeholder societies as the validating index studies of medial branch blocks used contrast as a means to identify vascular uptake or inadequate flow over the target nerve. (*Dreyfuss, Spine 1997; Kaplan, Spine 1998*) Vascular uptake can occur in light of a negative flash or aspiration at an incidence of 5-8% while performing medial branch blocks. Although intravascular uptake of local anesthetic would not be expected to result in systemic toxicity, undetected intravascular uptake would negate the diagnostic value and purpose of the procedure performed potentially contributing to false-negative results. Additionally, contrast use is beneficial to assure flow is over the target nerve and not peripherally into the paraspinous musculature or tissue cleavage planes.

However, the societies all recognize that the cost of contrast has never been included in the valuation of these procedures and therefore should not be mandated by Noridian unless the carrier also mandates in the LCD that it will pay for its use (e.g., a J code or other supply code such as Q9965, Q9966 or Q9967).

#### **Diagnostic Blocks: Controlled blocks – sham vs. LA or short and long-acting LA?**

Although intra-articular blocks and single medial branch blocks should not be used to select patients for RF neurotomy, is there an optimal methodology for using controlled blocks to select patients for subsequent RF neurotomy?

Direct comparative effectiveness research does not currently exist specifically addressing outcome differences from *lumbar* medial branch RF associated with true concordant responses to controlled comparative blocks (longer relief bupivacaine vs lidocaine) *versus* modified comparison (a minimal defined duration of relief with lidocaine (e.g  $\geq 1$  hr) vs. bupivacaine (e.g.  $\geq 3$  hrs) *versus* placebo controlled (single anesthetic compared to a true placebo (i.e. saline)) medial branch injections used to document the presence of lumbar facet joint pain. The absolute analgesic duration of any particular local anesthetic over the medial branches has not been studied in the lumbar spine. As the duration of nerve blocks are very much dependent on site of injection, minimal duration thresholds (e.g. 1 hour vs. 3 hours) are here extrapolated from studies of duration of subcutaneous local anesthetics.

Genuine controlled comparative blocks or placebo controlled blocks would enhance specificity while limiting sensitivity. Modified comparative blocks improve specificity over single uncontrolled blocks, and would be expected to improve sensitivity over true comparative blocks and placebo-controlled blocks. (*Lord, Clin J Pain, 1995*)

Pending definitive CER literature, recommendations to limit the number of diagnostic lumbar facet joint/medial branch blocks (so as to decrease expense and limit the risk attendant to invasive procedures) must be balanced against the risk of treating patients who do not have facet joint pain. The optimal selection process should be left to the discretion of individual specialists who are provided with the options to use one of three methods; 1) true controlled comparative blocks, 2) modified comparative blocks or 3) placebo-controlled blocks. Each option would only employ two medial branch injections.

Using a criterion of at least 80% relief with these three options could enhance specificity, but potentially limit sensitivity, especially in patients who may have multiple discreet pain generators or in those who cannot discriminate various degrees or locations of pain relief adequately. Using a criterion of a minimum of 50% relief, sensitivity would be enhanced in these conditions at the expense of specificity; more patients who have facet joint pain would have access to definitive therapy (RF neurotomy), but more patients without facet joint pain would also undergo RF neurotomy. At this point, no mandate regarding which level of relief should be achieved is yet appropriate, pending further study and publication.

When performing diagnostic facet blocks, no other diagnostic procedure should be performed concomitantly until the patient is reexamined and it is then determined that the block was negative. Only then may another diagnostic block be performed on the same or another day.

### **How many joints in one person over time? At one session? When bilateral?**

The question regarding how many lumbar joints could or should be injected in one person during one session was thoroughly discussed and incorporated into a multi-society CPT proposal that was presented and subsequently revised and approved at the February 2009 AMA-CPT meeting. This resulted in the development of three new lumbar facet injection CPT codes (64493-64495) which will be implemented as of January 1, 2010. Although the literature has shown that the vast majority of facet pain exists at the L4-5 and/or L5-S1 levels, there are circumstances in which three or more facet joints can be arthritic and appropriate to block. The current CPT codes are billed per joint blocked without limit, however the new CPT codes basically “cap” billing to 3 levels (64493 for first joint/level blocked, 64494 for second joint/level blocked, 64495 for the third and any additional levels blocked; this code is billed only once regardless of the number of additional joints blocked after the second level). We recommend that the Noridian LCD reflect the proper billing of these procedures as defined by the AMA-CPT regardless of the number of levels blocked. Pain can be unilateral or bilateral and use of the appropriate “-50” modifier should be applied to any procedure performed bilaterally at the same joint-level.

RF neurotomy is usually performed at one or two joint levels unilaterally or bilaterally. There is no indication to perform RF neurotomy targeting denervation of more than three joint levels per treatment session.

### **Total cc’s drug injected per level?**

For a medial branch block the validated volume that maintains target specificity is  $\leq 0.5$  cc. (*Dreyfuss, Spine 1997; Kaplan, Spine 1998*) For intra-articular injection, unpublished data suggest that the volume of the lumbar facet joints varies by level; a precise volume or range of volumes has not been validated as with medial branch blocks. Given the size of the lumbar facet joints, intra-articular injections should be limited to less than 1.0 mL, in order to minimize extra-articular extravasation (except when attempting to rupture a facet cyst, in which case no specific limitation is appropriate).

### **Ever appropriate to repeat a diagnostic block for same joint?**

A repeat medial branch block in the context of performing controlled blocks (comparative or saline placebo) is appropriate. Repetition of diagnostic intraarticular blocks is not routinely indicated, but exceptions exist, including but not limited to, technical limitations from the first

injections, a substantial more recent change in the patient's clinical presentation or the first procedure was aborted.

In the instance of a patient who has previously been successfully treated with lumbar medial branch RF who has recurrence of identical pain, repeat diagnostic blocks are not routinely necessary, but their use would improve diagnostic specificity, as other structural sources of pain can mimic lumbar facet joint pain. If the patient with recurrent pain demonstrates symptoms or signs obviously different from their prior symptoms, then additional diagnostic testing would be indicated. In this context, if positive, one medial branch block would usually suffice before repeating a RF neurotomy.

**Electrical stimulation with medial branch block (MBB)? If so, electrical parameters (frequency amps).**

Electrical stimulation is not needed to define the proximity of the needle to the target medial branch before injection of anesthetic in the lumbar spine. Sufficient reports in the peer-reviewed literature support that fluoroscopy and CT each produce appropriate radiological coordinates and view of injection of contrast that demonstrates lack of venous uptake and appropriate target flow near the nerve are sufficient when performing this injection. (*Dreyfuss, Spine 1997; Kaplan, Spine 1998*)

**For RF, what temp(s); how long (secs.), number of lesions (what is adequate lesion volume)?**

Anatomic studies demonstrate that lesions with monopolar needle-type electrodes should be created in an axis parallel to the length of the nerve. Lesions should be performed proximal to the mamillo-accessory ligament and distal to the lateral and intermediate branches of the dorsal rami along the medial branch. The lesion volume should be able to lesion the target volume between the superior articular process and transverse process (or sacral ala in the case of the L5 dorsal ramus) and at the lateral neck of the superior articular process in the case of the L1-4 medial branches. This target volume can be adequately reached with as little as a single lesion with an appropriately placed (along the axis or length of the median branch) larger gauge RF electrode, or multiple overlapping parallel lesions as the width of the needle decreases to create the same target lesion volume. (*Lau, Pain Medicine, 2004*) Validating literature has used temperatures of 80-90° C for 60-120 seconds to create the RF lesion. RF lesion temperature less than 80° is not endorsed. (*Bogduk, Pain Medicine 2009*)

**Therapeutic Blocks (facet/RF): Steroids? Phenol? When? Amount/volume? Frequency?**

*IA steroid injections:* When performing an intra-articular block for diagnostic purposes one should not inject more than 1.0 cc.

The use of intra-articular steroids has been previously addressed. There is no validated therapeutic dose/volume, but injection of 10-20 mg (0.25-0.5 cc) of triamcinolone or equivalent dose of an alternate corticosteroid has commonly been performed.

*IA injection of neurolytic agents:* There are no validated outcome studies supporting the injection of intra-articular phenol or ethanol. Significant safety concerns surround the inherent risks associated with the injection of neurolytic agents near the spinal nerve roots, and thecal sac.

*RF neurotomy*: Radiofrequency neurotomy should only be repeated if there was adequate pain relief ( $\geq 50\%$  relief with functional improvement) for at minimum of 6 months. In this situation, should facet joint pain recur, RF neurotomy may be repeated. There is no rationale for performing more than 2 RF neurotomies per year per level.

**Total Interventions per summary recommendations above:**

**Routine**

Two diagnostic medial branch blocks/level to determine if patient has facet mediated pain. This may include two controlled comparative or modified comparative anesthetic injections or an anesthetic injection and a blinded saline placebo injection.

Following positive diagnostic blocks, patient may receive maximum of two RF neurotomies/year/level.

One therapeutic facet joint injection procedure/level/year

A patient may receive one additional therapeutic facet injection procedure/level/year only if 50% or greater sustained relief and functional improvement occurs for at least 3 months and either RF neurotomy is contraindicated, unavailable, or patient prefers to avoid such due to extended relief from a therapeutic facet injection procedure or specific conditions exist (i.e, presence synovial cyst) for which RF neurotomy is not appropriate.

**Special circumstances**

After the two initial diagnostic medial branch blocks, one may have a repeat diagnostic medial branch in the case where a prior RF neurotomy was effective ( $\geq 50\%$  sustained relief for a minimum of 6 months) and there is change in the patients clinical presentation; a single medial branch block will help define the appropriateness of a repeat RF neurotomy in this context.

If a patient has been seen by a different provider from a different medical practice and is no longer under his or her care, and the validity of the diagnostic blocks is in question, one additional medial branch block is reasonable for diagnostic confirmation.

**A mechanism to recover the patient outcomes of these interventions that includes assessment of change in functional status over time.**

We agree that collection of valid outcome data for facet injections is important on a routine basis.

Following a facet block and prior to facility discharge, providers should at a minimum, document whether relief is apparent when patients perform maneuvers that typically exacerbate their index pain. At a minimum, for diagnostic procedures, this should include an analogue pain diary which records pain levels before and for a minimum of six hours following the procedure, at intervals of 30-60 minutes, either in the form of percentage of index pain relieved, or in the form of a visual analog scale or numeric rating scale.

There is no universally accepted or validated formal functional outcome tool for facet blocks. Individual practitioners should assess functional outcome before and at intervals following the procedure. Until such time as a single outcome instrument can be universally recommended and validated, practitioners should utilize outcome tools according to their practice needs from a menu of individually validated options which may include, but are not limited to, ODI, SF-36, SF-12, EQ-5D, RMDQ, Global Perceived Effect, 3-4 question patient specific functional improvements or a QOL scale. It is the responsibility of the physician to provide the outcome tools to the patient, but ultimately the responsibility of the patient to complete the materials, if they decide to comply.

For therapeutic facet joint injection procedures, pain levels should also be recorded at intervals following the procedure for a minimum of 7-10 days. Thereafter, assessment of pain (e.g. VAS, VIS, percent relief against baseline) and a functional outcome tool as described above should be documented at a minimum of 3 and 6 months.

Following radiofrequency neurotomy, assessment of pain (e.g. VAS, VIS, percent relief against baseline) and a functional outcome tool as described above should be documented at follow-up after the patient has recovered from the neurotomy (e.g. 4 – 6 weeks). Pain relief and functional outcomes should be assessed at a minimum of 3 and 6 months following the RF neurotomy.

The collected outcomes data for each individual patient should be reviewed by the individual physician to assess treatment results for that patient. In any field of medicine, outcomes data from any index therapeutic intervention should ideally be reviewed by individual practitioners on a periodic basis, and compared to literature established benchmarks to make adjustments in practice patterns and technique if needed to improve quality. (Although several “center of excellence” practices currently track consecutive outcomes prospectively, these outcomes tracking activities are not reimbursed, and have historically been maintained only for the purposes of clinical research.)

We are concerned about the scientific validity of any conclusions of efficacy drawn from pooled outcome data using the current collection methods. Creation of multi-specialty prospective spine outcomes registries are under development and will certainly be helpful in addressing these questions in the future. The logistical and financial challenges coupled with the administrative burdens associated with maintaining such a registry – which would require a standard EMR platform across providers as well as third-party payors wishing to access such data – are daunting.

Despite the financial, logistical, and legal challenges that must be overcome prior to the deployment of such a registry, we are committed to making such a historic registry project a reality in the near future. We look forward to working with Noridian to refine the ideal outcome assessment tools to ensure that the data collected with such a registry is accurate, informative, and that conclusions drawn from such registry data are valid.

Pending definitive development and the universal adoption of cross-specialty outcomes measurement tools and data collection and infrastructure between providers and payors, the



recommendations for lumbar facet joint interventions have been crafted to minimize inappropriate utilization of procedures for lumbar facet joint pain through objective documentation of outcomes, not only for diagnostic blocks, but for RF. These documentation requirements are reasonable. Limiting the number of procedures that may be paid for over the course of a year in the LCD proposal is inherently based on outcomes, and although crude and inferred, would nevertheless effect a reasonable and practical alternative to a true prospective auditable outcomes process implemented among all providers performing interventions for lumbar facet joint pain.

We also look forward to working with Noridian to help identify funding and reimbursement strategies to address the additional physician work and expense required for collection and analysis of outcome data. Changes to the current CPT descriptor and coding manual will need to be implemented if the proposed LCD becomes effective. These changes would detail clinical and documentation requirements for these injections and facilitate collection of outcome data.

Finally, to our knowledge, the required collection and analysis of outcome data by Medicare as a condition of coverage is rare. We would request Noridian's assistance in identifying existing procedures in other fields of care where coverage has been linked to prospective outcomes data. This would greatly facilitate our ability to provide more focused responses to the current questions, and help us incorporate appropriate design features to the prospective spine outcomes registries currently under development. At the same time, we appreciate the importance of outcome measurement for facet injections and for all of medicine. We should proceed both rapidly yet carefully, understanding the full implications of this historic new policy.

We collectively trust the responses above are helpful in your upcoming decision. We remain available to you if there are further questions or if additional clarification is required to the consensus material presented within.

Sincerely,



Way Yin, MD, President  
International Spine Intervention Society



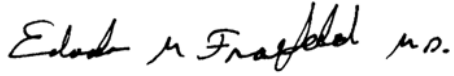
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