



## PERCUTANEOUS RADIOFREQUENCY NEUROTOMY FOR TREATMENT OF CHRONIC PAIN FROM THE UPPER CERVICAL (C2-3) SPINE

### *A Technology Assessment*

#### INTRODUCTION

The California Technology Assessment Forum has been asked to review the peer reviewed scientific literature on the efficacy and safety of percutaneous radiofrequency neurotomy in the treatment of chronic neck and head pain thought to derive from the upper cervical (C2-3) spine.

#### BACKGROUND

Chronic spinal pain is common among medical patients, and results in significant disability, morbidity and direct and indirect health care costs<sup>1</sup>. Although chronic spinal pain is most frequently due to lower back pathology, chronic neck pain has been reported in up to one-third of the adult population, and is usually thought to originate either from the facet joints or the intervertebral discs<sup>2</sup>. The facet (or zygapophyseal) joints are paired, posterior articulations between adjacent vertebrae, and based on studies of controlled diagnostic blocks have been shown to be a common source of pain in the neck and of referred pain to the head and upper extremities<sup>1</sup>. Chronic neck pain occurs commonly after a whiplash injury<sup>3</sup> and in about half of patients with chronic neck pain of this sort, the pain originates in the cervical zygapophyseal joints<sup>3,4</sup>. While this type of pain cannot be diagnosed clinically or radiographically, it can be identified with use of local anesthetic injections to block the nerves supplying the painful joint<sup>5-7</sup>. The facet joints are innervated by the medial branches of the dorsal rami, so interventional techniques to control pain have often focused on treating these nerves.

Cervicogenic headache is a vexing disorder consisting of refractory head pain thought to originate from the cervical spine. It is most often caused by trauma such as a whiplash injury, but may also occur in the absence of trauma. While diagnostic criteria have been developed<sup>8,9</sup> there is still controversy over the exact etiology and presentation of the disorder. Patients with cervicogenic headache experience a variety of pain complaints but it usually entails pain from the cervical spine



that may be referred to the occipital, fronto-temporal and peri-orbital regions and may mimic a migraine, though it does not respond well to migraine medications<sup>10</sup>. The pain is generally unilateral, may be intermittent or constant, and can be triggered or worsened by neck movement, direct pressure to the cervical spine or Valsalva maneuver<sup>10</sup>. The prevalence of cervicogenic headache is reported to be from 0.7% to 13.8% in the general population and significantly higher in patients with chronic headache referred to pain clinics<sup>11, 12</sup>. Referred pain from the C2-3 zygapophyseal joint (also known as the “third occipital headache”) is part of the syndrome of cervicogenic headache, but cervicogenic headache can also include neck and head pain that is derived from lower in the cervical spine (i.e. C3 - C6,7 level). The diagnosis of C2-3 cervicogenic headache can be confirmed by anesthetizing the third occipital nerve which innervates this joint. If the patient’s pain is relieved as a result of this procedure, and there is no response to a placebo saline injection, it is thought to confirm the diagnosis<sup>13</sup>.

### **Percutaneous Radiofrequency (RF) Neurotomy**

Radiofrequency is an alternating electric field that produces heat around the introduced electrode when the body tissue acts as a resistor. When the electrode is in proximity with neural tissue, destruction of this tissue will take place at temperatures above 60° C<sup>14</sup>. Shealy (1975) was the first to employ RF energy for denervation of the lumbar zygapophyseal joints<sup>15</sup>. He reported pain relief in greater than 70% of treated patients. During the past two decades, percutaneous RF neurotomy has been used in the treatment of chronic neck and low back pain, when this pain is thought to stem from the cervical and lumbar zygapophyseal joints, among other conditions. This procedure offers temporary relief; from pain secondary to a denaturing of the nerves that innervate the painful joint. The rationale for this technique is that nociceptive transmission from the cervical or lumbar zygapophyseal joint can be blocked by coagulating the medial branches of the dorsal ramus nerves that innervate the joint. In the procedure, a 10-cm, 22-gauge electrode with a 2-15-mm exposed tip is introduced percutaneously under fluoroscopic guidance so that it contacts each of the nerves supplying the painful joint. Typically, the electrode is introduced repeatedly at various angles and multiple lesions are made to accommodate possible variations in the course of the nerves. To generate the lesions, RF energy is applied to produce a temperature of 80° C. for 60-90 seconds<sup>16</sup>. The plane of insertions of the electrodes is critical, in that electrodes must lie parallel



to, and within one mm to two mm of, the nerve in order for the nerve to be adequately coagulated<sup>17</sup>. RF neurotomy is technically demanding and the procedure may require two to three hours of operating time. It is typically performed under regional or general anesthesia<sup>18</sup>. More recently, pulsed RF neurotomy has been introduced which allows for the application of RF current at markedly lower tissue temperatures thus theoretically minimizing the risk of adverse events<sup>19</sup>.

A prior review of “Percutaneous RF Neurotomy of Cervical and Lumbar Zygapophyseal Joints for Chronic Neck and Low Back Pain” was completed in 2001. At that time, the committee voted to approve the technology for treatment of chronic lower cervical (C3-4 and below) or lumbar zygapophyseal joint pain confirmed by preoperative anesthetic nerve blocks. It voted, however, that percutaneous RF neurotomy for treatment of chronic upper cervical (C2-3) zygapophyseal joint pain did not meet criteria. The current assessment is requested to reevaluate the data on percutaneous RF neurotomy for treatment of chronic upper cervical (C2-3) zygapophyseal joint pain with an emphasis on the peer reviewed research published since the last review.

## TECHNOLOGY ASSESSMENT (TA)

**TA Criterion 1 Does the technology have final approval from the appropriate government regulatory bodies?**

Several manufacturers have received FDA 510(k) clearance for their radiofrequency generators and probes. Among them are Smith & Nephew (Andover, MA), Stryker Instruments (Kalamazoo, MI), Diros Technology Inc. (Markham, ON, Canada) and Radionics Inc. (Burlington, MA). These devices were determined as substantially equivalent to devices marketed in interstate commerce prior to the May 28, 1976 enactment date of the Medical Devices Amendment. The Radionics device was used in most of the studies reviewed.

All devices are indicated for the treatment of pain.

TA Criterion 1 is met



**TA Criterion 2** The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words “neck pain”, “cervical pain” and “cervicogenic headache” cross referenced with the keywords “percutaneous neurotomy” and “percutaneous RF neurotomy” from 1966 to April 2007. The bibliographies of systematic reviews and key articles were manually searched for additional references. Abstracts of citations were reviewed and all relevant articles reviewed in full.

Inclusion criteria varied among the trials identified. However, in general, patients were identified for inclusion in the trials if they met clinical criteria for cervical headache (as defined by Sjaastad<sup>8</sup>), if they had been previously evaluated by a specialist and other pathology had been excluded and had failed conventional therapy. The diagnosis of cervicogenic headache was confirmed if the patient had complete relief of symptoms after temporary blockade of the third occipital nerve with infusion of topical anesthetic. Outcomes assessed in the various clinical trials include: procedural success, usually defined as relief of patients’ accustomed pain; intensity of pain rated on a 100-mm visual analog scale or on the McGill Pain Questionnaire; duration of pain relief; measures of psychological distress such as the SCL-90-R; global perceived effect, scored by the patients on a seven-point scale; analgesic intake; disability, most frequently assessed by the Oswestry disability scale (a questionnaire containing 60 items on limitations in various daily activities); quality of life by various questionnaires; and side effects such as numbness, dysesthesias, and ataxia. The criteria for success has generally been the complete elimination or a >50% subjective reduction of pain; treatment is considered to have failed if the patient reports no relief of the accustomed pain immediately after the procedure or when the pain returns to at least 50 percent of its preoperative level. In the various trials, assessments have been conducted at one, two, three, six, and 12-month intervals after the procedure.

Most of the published literature regarding percutaneous RF neurotomy has been uncontrolled clinical trials. However, two randomized controlled trials (RCTs) comparing outcomes following RF



neurotomy procedures in patients with cervicogenic headache have been published<sup>20 21</sup>. One of these trials<sup>21</sup> was designed as a randomized, blinded, sham controlled trial with the primary outcome variable being patient report of “days of intense pain” defined as the number of days per two weeks with pain intensity 2 (moderate) or 3 (severe) which was meant to be a reflection of the degree of disability caused by the headache pain. They arbitrarily defined as a “meaningful clinical response” a reduction of at least 30% of days with a significant headache. This outcome has not been validated in previous clinical trials. In the second RCT<sup>20</sup> patients were randomized to receive either percutaneous RF or steroid/anesthetic injection plus treatment with a transcutaneous electrical nerve stimulation (TENS) unit. Outcomes assessed in this trial included visual analogue scores for pain, global perceived effects scores, quality of life scores and a headache diary. Methodological issues in this trial include the fact that they did not establish the diagnosis of cervicogenic headache in their subjects by controlled diagnostic blocks (as is the standard protocol in most trials) among other problems.

Because of the lack of sufficient number of rigorous trials and methodologic flaws in existing trials, it is not possible to sufficiently evaluate the efficacy and safety of percutaneous RF neurotomy in the treatment of cervicogenic headache or chronic neck pain.

Level of Evidence: 1, 5

TA Criterion 2 is not met.

TA Criterion 3 The technology must improve the net health outcomes.

#### Uncontrolled Case Series

Barnsley (2005) report on a study of consecutive patients with chronic neck pain treated by a single rheumatologist in Australia between 1998 and 2000<sup>22</sup>. Of the 35 patients enrolled in the study, 23 had pathology localized to the C2-3 joint by having “definite or complete” relief of pain after block of the third occipital nerve and no response when placebo infusion was used. The primary end-point was duration of relief from pain (as reported by the patient to an “independent assessor”. They



performed 47 procedures on the 35 patients (12 patients had repeat procedures due to initial failure or return of pain). Twenty-six patients obtained complete relief from pain for a median duration of 35 weeks. Most patients reported “significant” post-operative pain; this lasted three months in one patient. One patient developed a serious local wound infection. They report that the overall duration of relief following third occipital neurotomy was less than at other levels, though this did not meet statistical significance.

Van Zundert (2003) report on a study conducted in Belgium of the first 18 patients treated with percutaneous pulsed RF of the cervical dorsal root ganglion<sup>2</sup>. Patient selection for treatment followed the standard protocol of diagnostic segmental nerve blocks. Overall, they report that 13 of 18 patients had  $\geq 50\%$  reduction in pain over short term follow up (mean of 9.2 months). Only six patients with chronic cervicogenic headache were treated at the C2-3 level; and it is not clear how many of these patients were included in the 13 patients who improved.

Govind<sup>13</sup> report on the effectiveness of a revised technique of percutaneous RF neurotomy for treatment of third occipital headache. The revised technique consisted of use of a large gauge electrode (a Ray electrode, Radionics, Burlington, Massachusetts), holding the electrodes in place by hand and ensuring minimum separation between the three electrode placements. The study was conducted in a single pain clinic in Newcastle, Australia between 1998 and 2001. They recruited 120 patients with complaint of headache associated with neck pain or a history of neck injury. All patients underwent a third occipital nerve block using standard double blind techniques in order to definitively diagnose 49 patients as suffering from third occipital headache. The primary outcome measure was complete relief of pain and restoration of normal activities of daily living for a period initially lasting 90 days. Patients with recurrent symptoms were offered repeat neurotomy procedures. Of the 49 patients treated, 43 patients had pain relief and restoration of function for at least 90 days. (As nerves eventually regenerate and this procedure targets the peripheral axons and not the cell body it is not unexpected that patients will have recurrence of pain as the nerves grow back). Eight patients had long-term relief and 14 patients underwent repeat neurotomy with 12 of them achieving relief beyond 90 days. Litigation status did not influence response to treatment. Adverse effects included numbness, ataxia and dysesthesia in the majority of patients,



lasting seven to ten days in most, and not longer than four weeks. Ataxia arises since the third occipital nerve innervates much of the Semispinalis capitis muscle in the upper and back part of the neck, the tendons of which pass upward and insert into the occipital bone, resulting in loss of proprioception. The authors conclude that: “third occipital neurotomy offers the prospect of complete relief of pain.” They concede, however, that “the skills and patience required to perform (third occipital neurotomy) correctly would limit its appeal to aficionados with a special interest in the problem.”

Royal (2002) report on a retrospective case series on 148 patients who underwent RF neurotomy at a private practice pain clinic in the US; 63 of these patients had cervical facet procedures, but it is not clear what proportion of these had neurolysis of the third occipital nerve so results will not be reported here<sup>16</sup>.

Lord<sup>23</sup> report on an uncontrolled case series of 19 patients seen from 1991-1994 at a cervical spine research unit in Australia. Diagnosis was based on comparative local anesthetic blocks per usual protocol. (In addition to pain relief, third occipital nerve pain was confirmed by the presence of cutaneous anesthesia in the distribution of the third occipital nerve). Ten patients had percutaneous RF neurotomy for C2-3 facet joint pain; of these only three patients achieved satisfactory pain relief. In contrast, seven of ten patients who had treatment of lower cervical facet joints had complete relief of pain for several months. The authors report that they “temporarily abandoned” third occipital neurotomies after this pilot study and excluded the procedure from the randomized trial they then planned and executed following these results<sup>3</sup>.

### Randomized Clinical Trials

Haspeslagh<sup>20</sup> (2006) report on a randomized controlled trial of cervical radiofrequency (RF) “lesioning” of 30 patients seen at a single pain and research center in the Netherlands with cervicogenic headache identified according to the Sjaastad diagnostic criteria, which are based on expert consensus developed by the Cervicogenic Headache International Study Group<sup>9</sup>. Patients did not undergo the usual pre-treatment diagnostic protocol of controlled diagnostic nerve blocks. Inclusion criteria included age between 20 and 65 years, an initial visual analogue pain scale (VAS)



of more than 50 mm and significant pain during at least two days per week. Fifteen patients were randomized to receive RF percutaneous facet denervation (they targeted dorsal root ganglion and cervical facet joints and not the occipital nerves) and 15 received steroid/anesthetic injections followed by TENS treatment. They report that there was no statistically significant difference in outcomes between the two groups, leading them to conclude that they did not find evidence that RF treatment of cervical facet joints is effective. It is not clear from the study description how many patients, if any, were thought to have third occipital headache (i.e. the pain derived mainly from the C2-3 joint) so results from this trial may not be relevant to this patient population. In addition, it is not clear why they used TENS plus steroid injection as the comparative treatment as it is not the established 'gold standard' treatment for cervicogenic headache.

Stovner<sup>21</sup> report on a randomized, sham-controlled, double-blinded study of 12 patients (only six in each arm) with disabling, chronic, treatment resistant cervicogenic headache. Their aim was to study the effects of RF denervation of facet joints C2-6 on the side of the pain in patients presenting to a Neurology clinic at the Norwegian National Headache Centre. Patients were enrolled in the study based on clinical criteria<sup>8</sup> and not their response to controlled nerve blocks. In addition, inclusion criteria were age 25-65 years, pain for at least one year not relieved with medication and brain and cervical imaging without "significant pathology". Patients were excluded if they had prior surgery or pending litigation, among other factors. Outcome measures included a patient pain diary, range of motion in the neck and number of days of intense pain over two weeks. Patients randomized to the treatment arm received medial branch neurotomies on facet joints C2-6 on the symptomatic side using fluoroscopic guidance. For patients with pain thought to originate in the C2-3 facet joint, the electrode was directed at an oblique and sagittal direction towards the third occipital nerve and two to three lesions (85° C for 60 seconds) were given to denervate the facet joint. Patients randomized to the sham arm went through the same operation except that they received only local anesthesia (as did the treatment arm patients) but no RF was applied after the electrodes were inserted. Both procedures lasted about 90 minutes. Following the procedure, more patients in the RF group (four of six) than in the sham group (one of six) reported short-term neck pain. The authors report that the study was sufficiently powered to detect > 50% improvement in the treatment arm in spite of the small numbers. However, they did not find a consistent significant



difference between the groups in pain or range of motion beyond three months. They conclude that “RF-treatment for CeH (cervicogenic headache) is not performed on a routine basis, but is restricted to research protocols”.

### Systematic Reviews

Niemisto<sup>24</sup> (2003) in a Cochrane Collaborative review concluded that there is “limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophyseal joint origin”. This conclusion was based on the RCT by Lord<sup>3</sup> which did not include patients with C2-3 pathology.

### Patient Safety

Potential complications of percutaneous RF neurotomy include possible vascular or neural injury (this has not been reported); post-operative pain, ataxia, spatial disorientation, cutaneous numbness, dysesthesia, local infection and transient neuritis<sup>17</sup>. Overall, the procedure seems to be safe with no serious complications reported in the literature. Ataxia is a routine side effect of third occipital neurotomy procedures; and postoperative pain (less than up to ten days) requiring oral analgesic medications has been noted. No deaths have been reported in the published trials.

TA Criterion 3 is not met.

TA Criterion 4:           The technology must be as beneficial as any established alternatives.

There is no established “gold standard” in the treatment of chronic neck and head pain thought to derive from the C2-3 zygapophyseal joint. In a recent review, Martelletti and van Suijlekom<sup>12</sup> concluded that consensus on a standard treatment for cervicogenic headache does not exist. The established alternatives to percutaneous RF neurotomy include pharmacologic treatment and non-pharmacological treatments including interventional and surgical. Pharmacologic treatments commonly used are analgesics and anti-inflammatory medication such as acetaminophen, non-



steroidal anti-inflammatory drugs (NSAIDs) and opioids; muscle relaxants; anti-seizure drugs such as gabapentin; and tricyclic antidepressants such as amitriptyline. Pharmacologic treatment should generally be used as first line therapy for neck pain. Interventional techniques include anesthetic blocks, trigger point injections, and a recent study investigated intraarticular regeneration injection therapy (RIT) (a.k.a. prolotherapy) for treatment of chronic neck pain related to whiplash<sup>25</sup>. Although widely used, the evidence for efficacy is not clear<sup>26</sup>. Non-pharmacological treatments such as manipulative therapies, physical therapy, biofeedback and TENS are also widely used for chronic neck pain; there are no studies comparing their effectiveness to percutaneous neurotomy<sup>10</sup>. In addition, several surgical procedures aimed at reducing the nociceptive input on the cervical level have been tested. These include operative decompression of occipital nerves and cervical nerve roots, occipital neurectomy, cervical epidural injections, radiofrequency denervations of the periosteum of the occipital bone and botulinum toxin injections. Level one evidence supporting their effectiveness is lacking.

TA Criterion 4 is not met.

TA Criterion 5:           The improvement must be attainable outside the investigational settings.

Percutaneous radiofrequency neurotomy of the C2-3 zygapophyseal joint has not been shown to be beneficial in investigational settings so no improvement can be obtained outside of these settings. It is clear that radiofrequency neurotomy at any level of the spine is a “highly specialized field of practice” (Lord, 2002) so even if proven to be efficacious it should not be performed outside of the research or specialty practice setting.

TA Criterion 5 is not met

## CONCLUSION

To date, only one well done randomized controlled trial has documented a clinically significant effect of radiofrequency cervical facet joint neurotomy in patients with chronic neck pain, with significant reduction of pain compared with a sham procedure<sup>3</sup>. This trial excluded patients with C2-3 facet joint pathology as an earlier pilot conducted by this investigator had found that the procedure was ineffective in this patient population<sup>23</sup>. Experts agree that treatment of the third occipital nerve (C2-3 facet joint) is technically more complicated than other spinal radiofrequency neurotomy procedures<sup>16</sup>.

The case series and RCTs reviewed above examining percutaneous RF neurotomy for chronic upper cervical (C2-3) neck pain were all limited by significant methodological shortcomings including varied methods for identifying the target population of interest, lack of agreement and uniformity regarding the ideal RF neurotomy technique to be employed and lack of standardization of the relevant outcome measures. Future RCTs on RF procedures should include sufficiently homogeneous patient populations and standard techniques. Uniform inclusion and exclusion criteria for appropriate patient selection are important. Meticulous descriptions of techniques are necessary, and a draft of international guidelines on adequate and preferably validated techniques would be helpful. Such arrangements, in combination with basic research into underlying mechanisms, will lead to more uniformity and higher quality research studies. Only under these conditions will it then be possible to adequately assess the efficacy of RF techniques in specific spinal pain syndromes<sup>27</sup>.

## RECOMMENDATION:

It is recommended that the use of Percutaneous Radiofrequency Neurotomy does not meet TA criteria 2 through 5 for safety, effectiveness and improvement in health outcomes for the treatment of chronic upper cervical (C2-3) neck pain or headache.

*The CTAF panel voted unanimously in favor of the recommendation.*

June 20, 2007



## RECOMMENDATIONS OF OTHERS

### Blue Shield Blue Cross Association (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

### Centers for Medicare and Medicaid Services (CMS)

The CMS does provide for denervation procedures when used in selected cases to treat chronic pain. CMS does not provide guidance as to spinal level.

### Association of California Neurologists (CAN)

ACN was invited to provide an opinion regarding the use of this technology and testimony at the meeting.

### California Association of Neurological Surgeons (CANS)

CANS was invited to provide an opinion regarding the use of this technology and testimony at the meeting.

### California Academy of Pain Medicine (CAPM)

The CAPM does not have an opinion specific to the use of this technology.

### California Society of Anesthesiologists (CSA)

CSA was invited to provide an opinion regarding the use of this technology and testimony at the meeting.

### California Orthopaedic Association (COA)

The COA does not have an opinion specific to the use of this technology.

### American Society of Interventional Pain Physicians (ASIPP)

The ASIPP practice guideline, Interventional techniques in the management of chronic spinal pain: an evidence-based practice guideline is available at [www.guideline.gov](http://www.guideline.gov). This guideline was published in the journal Pain Physician in 2005. This guideline indicates that “the evidence for radiofrequency neurotomy of medial branches was moderate to strong for short-term and long-term relief of lumbar and cervical facet joint pain”. There is no reference to specific spinal level.



## American Society of Anesthesiologists (ASA)

The ASA Practice Guidelines for Chronic Pain Management were developed by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section in 1997. Under the heading: XII: Neuroablative Techniques it is stated that “Neuroablative techniques should be used as part of a comprehensive approach to managing pain and applied only as a last resort after failure of other therapies”. There is no reference to specific spinal level. The guideline is available at <http://www.asahq.org/publicationsAndServices/ChronicPainMgmt.pdf>.

## ABBREVIATIONS USED IN THIS ASSESSMENT

RF: Radiofrequency  
DARE: Database of Abstracts of Reviews of Effects  
RCT's: Randomized Controlled Trials  
TENS: Transcutaneous Electrical Nerve Stimulation  
VAS: Visual Analogue Pain Scale  
CeH: Cervicogenic headache  
NSAID's: Non-Steroidal Anti-inflammatory Drugs  
RIT: Regeneration Injection Therapy

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