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Re: Adoption of ACOEM Guidelines on Cervical and Thoracic Spine Disorders

To Whom It May Concern:

The Spine Intervention Society (SIS), a multi-specialty association of over 2,800 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 your adoption of the American College of Occupational and Environmental Medicine (ACOEM) guidelines addressing cervical and thoracic spine disorders.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. 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 and often unnecessary surgical procedures.

We commend ACOEM on their extensive work on the Cervical and Thoracic Spine Disorders Guideline. This was clearly a massive undertaking and the authors should be congratulated. SIS agrees with many of the conclusions in these guidelines; however, we do wish to address concerns regarding several recommendations.

We agree with the panel’s conclusions that were drawn against recommendations for myeloscopy (endoscopic examination of the epidural space), diagnostic ultrasound for facet joint pain, diagnostic fluoroscopic evaluation for facet joint pain, cervical epidural steroid injections in the treatment of non-radicular pain, continuous epidural infusion of corticosteroids and local anesthetic for acute, subacute, or chronic cervicothoracic pain with or without radiculopathy, dorsal root ganglia radiofrequency lesioning, intra-articular facet joint hyaluronic acid injections, cervical intradiscal electrothermic therapy (IDET), cervical percutaneous intradiscal radiofrequency thermocoagulation.
(PIRFT), and prolotherapy injections. However, we believe that the conclusions that were drawn on other topics are not supported by careful evaluation of the literature.

First, the panel has recommended the use of oral steroids for acute cervical radicular pain. The panel has referenced the literature on lumbar radicular pain and concluded that the use of oral steroids is supported by this literature. However, the two studies that were referenced show clinically insignificant improvement in function without improvement in pain (1) and clinically insignificant improvement in pain without improvement in function for less than three days (from IV steroids) (2). A systematic review and meta-analysis concluded that there is no benefit of systemic steroids over placebo, and there are more side effects when they are used (3). Epidural steroid injections, however, were not recommended for acute, subacute, or chronic cervical radicular pain due to insufficient evidence. The SIS Standards Division reviewed the published literature on cervical transforaminal epidural steroid injections for the treatment of cervical radicular pain and concluded that approximately 50% of patients experience at least 50% relief of pain for at least four weeks and that there may be surgery-sparing effects (4). While the evidence in support of cervical epidural steroid injections is not robust, and in fact, was graded as very low quality in the SIS review (4), the evidence against the use of systemic steroids is strong (3). Therefore, it is perplexing why the conclusion of this panel was to recommend for the use of oral steroids, yet against the use of cervical epidural steroid injections.

Another area of concern is the lack of a recommendation (for or against) regarding percutaneous radiofrequency neurotomy (RF) for the treatment of chronic cervical/thoracic pain confirmed by diagnostic medial branch blocks. On page 304 of the guidelines, the document states that, “Radiofrequency lesioning is invasive, has adverse effects, and is costly. There is evidence of a lack of efficacy for treatment of lumbar pain, thus there is an unreconciled dispute in the literature (ineffective in the lumbar spine, but perhaps some efficacy in the cervical spine).” We strongly disagree with this interpretation of the literature. The literature regarding RF neurotomy in the lumbar spine has demonstrated lack of benefit from the procedure when the procedure is performed on inappropriately selected patients using improper technique (5-7). However, when dual diagnostic medial branch blocks are used to select patients, and when the procedure is performed in accordance with the technical standards recommended by the Spine Intervention Society, the procedure is effective both in the lumbar spine (8,9) and the cervical spine (10). In fact, no other procedure has approached the same level of success – elimination of pain, complete restoration of activities, no need for additional health care, and return to work – that has been demonstrated by RF neurotomy.

Similarly, we have concerns about the recommendation against percutaneous radiofrequency neurotomy for the treatment of cervicogenic headache. The studies referenced to support this decision contain major flaws. One cited study reported minimal benefit of RF neurotomy in 12 patients diagnosed by clinical evaluation (11).
SIS agrees that patients should not be selected for RF neurotomy based on clinical evaluation alone. Lack of demonstrated benefit from a study that selects its patients in this manner does not add meaningful information to the literature. Dual diagnostic blocks are required to establish an accurate diagnosis of facet joint pain. In fact, the authors of this study concluded that, “a consistent and marked (close to 100%) effect of facet joint blockade should probably be among the inclusion criteria” (11). The second study that was used to support the decision to recommend against percutaneous RF neurotomy for cervicogenic headache also selected patients based on clinical features (12). Additionally, this study used small (22 gauge) needles, inadequate lesion temperature (60-67°C) for an unspecified amount of time, and only treated the C3-4 through C5-6 facet joints (thereby missing the most commonly involved facet joint in cervicogenic headache – the C2-3 facet joint). The above-referenced studies therefore add nothing to the literature about the effectiveness of RF neurotomy for cervicogenic headache in properly selected patients, and should not be used to determine policy.

Specifically, we wish to highlight strong evidence in support of third occipital nerve (C2-3) RF neurotomy. For patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using appropriate techniques, third occipital nerve RF neurotomy is a proven, effective procedure.

In patients with chronic neck pain, the representative prevalence of cervical zygapophysial joint pain is in the order of 60% in patients (13-17). This makes it the single most common basis for chronic neck pain, and the only condition that can be diagnosed using validated diagnostic tests. No other causes of neck pain have diagnostic tests that have been validated, and there has been no other cause in which the prevalence has been determined. In patients with positive responses to controlled, medial branch blocks, the segments most commonly positive are C2-3 and C5-6 followed by C6-7 (17).

In 1994, a substantive study using controlled diagnostic blocks of the third occipital nerve, which is the innervation to the C2-3 zygapophysial joint (18), reported their yield in patients with headache after whiplash (19). It reported a prevalence of 54% of headache stemming from the C2-3 zygapophysial joint.

It should be apparent that the C2-3 zygapophysial joint is a substantial pain generator not only in those with neck pain but in those with cervicogenic headache as well (20). If non-invasive conservative care fails to provide adequate pain relief for those with pain originating from this articulation, then C2-3 zygapophysial joint denervation via third occipital nerve thermal RF neurotomy should remain a viable option for this substantial subset of patients rather than relegating these patients to continued suffering or reliance on analgesics.
There has been a seminal RCT on cervical medial branch neurotomy that demonstrates that the positive outcome of the procedure is clearly not due to placebo effects (21). This study did not access the C2-3 level due to documented technical limitations of RF neurotomy of this level (at the time of the study) attributable to anatomic variation of its nerve supply (third occipital nerve) (22). More recently, following the Lord RCT, the technical limitations of the RF technique have been addressed, which compensates for the unique anatomy of the third occipital nerve (23).

Prospective observational evidence outside of RCTs can demonstrate the effectiveness of a procedure. In fact, when the outcomes of well-performed prospective trials demonstrate dramatic and sustainable results that are reproducible across studies, one could argue that the need to demonstrate that the effects of the procedure are not due to placebo effects alone are seriously minimized. This is more so the case when the procedure itself is in the same region of the spine for essentially the same anatomical condition (zygapophysial joint pain) and when the index procedure has already been shown to be effective in an RCT, for which the results cannot be attributed to a placebo effect (21). This is indeed the case for C2-3 zygapophysial joint denervation, as compared to other cervical zygapophysial joints (23).

Since the third occipital nerve RF technique has been appropriately modified following the seminal Lord RCT, three studies evaluating the effectiveness of third occipital nerve neurotomy have been published (23-25). In a prospective trial, Govind specifically investigated the efficacy of radiofrequency neurotomy of the third occipital nerve for the treatment of headache via a modified technique (23). Modifications to the technique used included: using a large gauge electrode; holding the electrode firmly in place throughout the period of coagulation; and placing consecutive, parallel 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 (22), 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. Of the 14 patients who underwent repeat neurotomy when their pain recurred, 12 (86%) regained complete relief. In regards to the safety profile of third occipital nerve neurotomy, it should also be noted that there were no major complications, and side effects (dysesthesia, ataxia, local itchiness) were self-limited and resolved within 7-10 days, apart from one patient having a side effect for 4 weeks.

Another study was undertaken to explicitly test if the outcomes reported in the controlled trial could be replicated in conventional practice; it showed that they were (24). 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. In this study, treatment was provided at the C2-3 level in 50% of the patients.

In the third study, two clinicians evaluated their outcomes after being trained in proven technically effective lesioning techniques (25). The outcomes of all their consecutive
patients over five years in their respective practices were audited. Treatment was provided at all levels from C2-3 to C6-7, and C2-3 was the most common level treated. 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 further need for any other health care for their index pain. In the two practices, 74% and 61% of patients achieved a successful outcome. Relief lasted a median duration of 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.

These studies clearly demonstrate that 60-86% of patients with C2-3 facet pain can be effectively rendered pain free for a duration of relief from 10-17 months. No other non-surgical treatment in the cervical spine can rival this degree and duration of relief. There are minimal to no high-quality rigorous trials of non-invasive conservative care (*i.e.* physical therapy, chiropractic, medications) for sub-occipital neck pain or cervicogenic headache, to aid in drawing comparisons to third occipital nerve neurotomy regarding efficacy or cost-effectiveness. When considering potential surgical treatments, cervical fusion is the only valid consideration. However, fusion is rarely indicated; primarily when there is C2-3 segmental instability or spondylolisthesis. Even in properly selected patients, surgery of the upper cervical spine has a relatively high morbidity and mortality, and surgery may be contraindicated in some patients. Preservation of access to a proven, effective treatment is particularly critical when there are few valid, proven, and equally safe alternative options.

An RCT establishing that the results of third occipital nerve RF neurotomy are not due to placebo effects as an absolute condition of coverage is not necessary in light of the magnitude of effects for this intervention when appropriately performed on the correct patients (26-28), but one important consideration has been often overlooked. It would be impossible to perform a true blinded RCT on C2-3 facet RF. Patients who receive an effective third occipital nerve neurotomy 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 diagnostic third occipital nerve blocks also develop temporary 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.

It is our recommendation, consistent with local coverage determinations proposed by the Multisociety Pain Workgroup and adopted by several Medicare Contractors, that for patients with suspected pain arising from the C2-3 zygapophysial joint, who have achieved greater than 80% relief of index pain with dual diagnostic blocks using previously described techniques, third occipital nerve RF neurotomy should be a covered procedure.
In summary:

1. Evidence does suggest that cervical epidural steroid injections are effective for many patients with cervical radicular pain, providing short-term relief with demonstrated surgery-sparing effects.
2. Cervical medial branch RF neurotomy is an effective treatment for patients with chronic axial neck pain who experience significant relief from dual medial branch blocks.
3. TON RF neurotomy is a very effective treatment for appropriately selected patients with cervicogenic headache.

We hope that this information, as well as any dialogue and collaboration between the California Division of Workers’ Compensation and the Spine Intervention Society, will lead to the establishment of reasonable coverage policies that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@SpineIntervention.org.

Sincerely,

Timothy Maus, MD
President
Spine Intervention Society

References: