Washington State Health Care Authority

Surgery for Symptoms of Lumbar Radiculopathy

Draft key questions: public comment and response

December 14, 2017

Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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The information in this document is intended to help the Washington HCA make well-informed coverage determinations and thereby improve the quality of health care services. This document is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this document in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

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Public Comments Submitted

The State of Washington's Health Technology Assessment Program posted for public comment the draft key questions and proposed scope for a health technology assessment (HTA) on the topic of "Surgery for Lumbar Radiculopathy" between November 14, 2017 and November 27, 2017. Table 1 lists the comments received and submitting individual/organization.

Table 1. Comments Received on Draft Key Questions on Surgery for Lumbar Radiculopathy HTA

Number	Name and Title	Organization	Location
1	Daniel Cher, MD Vice President of Clinical Affairs	SI-BONE	San Jose, California
2	Trent Tredway, MD FAANS Neurosurgeon	Tredway Spine Institute	Seattle, Washington
3	Catherine Jeakle Hill Senior Manager Regulatory Affairs	On behalf of: • American Association of Neurological Surgeons • Congress of Neurological Surgeons • American Academy of Orthopaedic Surgeons • International Society for the Advancement of Spine Surgery • North American Spine Society • Washington State Association of Neurological Surgeons	Various

Summary of Main Themes from Comments

- Two of the comments expressed concerns over the selection of this topic for an HTA given that decompressive surgery for lumbar radiculopathy is a standard clinical practice.
- One comment requested the scope of the review to be expanded to diagnostic accuracy of lumbar radiculopathy and sacroiliac joint pain.

Detailed Comments and Response

Comment 1.

Submitted by Daniel Cher, MD Vice President Clinical Affairs at SI-BONE

From: Daniel Cher [mailto:DCher@si-bone.com]
Sent: Thursday, November 23, 2017 8:55 AM
To: HCA ST Health Tech Assessment Prog <SHTAP@HCA.WA.GOV>
Subject: comment on lumbar radiculopathy

I commend the Washington State Health Care Authority on its mission to evaluate the effectiveness of various treatments for lumbar radiculopathy. https://www.hca.wa.gov/about-hca/health-technology-assessment/surgery-for-symptomatic-lumbar-radiculopathy

However, the document's scope is incomplete. I suggest an additional scope question, namely: what proportion of patients with lumbar radiculopathy seeking surgical or non-surgical treatments are misdiagnosed and instead have pain emanating from the sacroiliac (SI) joint?

SI joint pain commonly manifests as buttock pain with radiation into the upper legs and can easily be mistaken for lumbar radiculopathy. Studies show that 15-30% of chronic low back pain may have a contribution from the SI joint,[1-5] it is obvious that interventions aimed at the lumbar spine will be expensive and ineffective if the pain source is outside of the lumbar spine. Such interventions confer only risk and not benefit. This is especially important given the well-known poor correlation between MRI findings and radicular pain.

Regards,

Daniel Cher

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Comment 1 Response

We agree with the commenter that diagnosing the precise source of low back and leg pain can be challenging. Evaluating the diagnostic test accuracy of symptoms, signs, physical exam findings, or imaging for lumbar radiculopathy or for pain attributed to the sacroiliac joint is outside of the scope of the proposed HTA, which is focused on interventions for diagnosed lumbar radiculopathy. We anticipate that most trials evaluating surgical interventions for radiculopathy will use study entry criteria requiring

correlation of symptoms with physical exam findings and imaging findings suggestive of nerve root compression.

Comment 2

Submitted by Trent Tredway, MD, Neurosurgeon at Tredway Spine Institute

From: trent tredway [mailto:ttredway@hotmail.com]
Sent: Monday, November 27, 2017 6:14 PM
To: HCA ST Health Tech Assessment Prog <SHTAP@HCA.WA.GOV>
Subject: Comments Regarding Lumbar Decompression

Dear Josh,

Please find my comments regarding the Key Questions attached to this email. I have also included commentary in this email regarding the actual process that the HTA has utilized in regard to choosing this topic as I strongly believe this is completely out of the scope of the HTA's review of "new technology". This information contained in this email should also be included in the comments for this topic. This topic that was reviewed is the standard of care for many of our patients that fail conservative management. It could be said that the entire Practice of Neurosurgery is based on decompression of neural elements. This is evident in cranial procedures where we decompress the offending agent (tumor, infection, traumatic injury, edema, hematoma, etc.) so that the neural elements are not under direct compression causing injury to the brain and cranial nerves. Decompression of nerve roots is the mainstay of surgery of the peripheral nerves including surgery for carpal tunnel syndrome and ulnar entrapment injury, to name the most common procedures. The same principle applies for decompression of the nerve roots in the neuroforamen in cervical, thoracic, and lumbar disease. Therefore, as you can see, I find this review topic to be useless and an actual attack on the Practice of Neurosurgery.

1

I have pointed out earlier in the comments I posted when this topic was first being evaluated that the decision by Dorothy Teeter was wrong and beyond the scope of the HTA committee. I also find that the inquiry that "lumps" together various adjuncts for surgery to be a prime example of the misunderstanding by Dorothy Teeter and individuals on this committee. I find it insulting that one of the Key Questions and Comments on the HTA website suggests that minimally invasive procedures, "micro" procedures, image guided surgery, and laser-assisted surgery are grouped together. To set the record straight, all lumbar decompression surgeries require access to the spinal elements. This requires performing a surgical incision and the use of a retractor system. It is true that surgeons are trying to use smaller incisions and retractors to minimize the trauma to the normal surrounding tissue. It is also true that we have better visualization modalities including use of microscopes and endoscopes to help assist us in performing the laminoforaminotomies and microdiscectomies. These modifications are only to help in achieving better patient outcomes and safer procedures

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Also, the coding for these procedures are also the same (CPT codes 63030 for microdiscectomy, 63047 and 63048 for laminectomies and laminotomies, additional level (63048) and thus are essentially the same in regard to decompression of the nerve roots. I find it insulting as well that the HTA is questioning the use of "image guidance" in performing these procedures. It is absolutely malpractice and against standard of care to perform a lumbar decompression without documenting the correct level. The use of C-arm fluoroscopy or CT and/or Fluroscopic navigation to help document this does not have a cost impact and is not billable under the current CMS guidelines, so I am perplexed as to why the HTA would confuse this matter. Can you imagine performing a surgery and not documenting the appropriate level? Futhermore, the use of lasers in neurosurgery have been utilized since the 1980's in treating tumors of the brain and spine as well as lipomyelomeningoceles is children and adults and has been a useful tool. In regard to its role in the treatment of lumbar decompression, there is limited evidence that it is helpful in actually performing the procedure as it is often used for the approach on the soft tissue dissection. The majority of surgeons utilize electrothermal coagulopathy (bipolar or monpolar) in our dissection. Once again, the use of a laser is not billable for our decompressive surgeries as outlined above (CPT 63030, 63047, 63048) and I find it strange that the HTA is grouping this into a procedure for treatment of lumbar radiculopathy.

If Dorothy Teeter or the HTA has a specific "new technology" that it believes requires evaluation by the HTA committee, then the Director and the committee should be more direct and stop performing "fishing expeditions" for procedures that have been the standard of care in neurosurgery for many decades.

I look forward to the HTA Committee's response to our comments as I often believe these comments are not even read or taken seriously.

Thank you for your time.

Sincerely,

Trent L. Tredway, MD FAANS
Neurosurgeon
Tredway Spine Institute

Sent from Windows Mail

Additional Attachment Submitted

EQ1/EQ2

Lumbar spinal stenosis (LSS) is one of the most common diseases of the spine that affects the elderly population. Verbeist first described this syndrome in the early 1950's; however, controversy exists in regard to symptomatology, diagnosis (clinical versus radiological), as well as choice of treatment.[1] The syndrome is a result of multitude of degenerative changes that occur as the body ages. The combination of disc degeneration, facet arthropathy, and ligamentum flavum hypertrophy leads to a narrowing of the spinal canal causing compression of the neural elements. Patients with lumbar stenosis may present

symptoms that include low back pain, radiculopathy, motor or sensory deficits, and/or intermittent claudication that usually worsens with walking.[2] Since this condition occurs gradually over years, it rarely will lead to acute neurological deficits.

Initially, most patients can be managed with conservative non-operative therapy. Aggressive physical therapy regimens, epidural steroid injections, and weight loss may provide some patients with significant relief of their symptoms.[3, 4] If conservatively treated patients do not exhibit improvement, then decompressive surgery may be considered. Traditional surgical treatment includes posterior decompressive laminectomy. This procedure involves surgical resection of the spinous process, lamina, part of the facet, as well as disruption of the supraspinous and interspinous ligaments. The development of novel minimally invasive approaches that limit the disruption of the surrounding tissue has become an increasingly popular treatment option in patients with symptomatic lumbar stenosis.

Historical Perspective of Spinal Stenosis and Treatment

Perhaps one of the earliest examples of an operation to relieve spinal stenosis was reported my Arbuthnot Lane in 1893 when he successfully decompressed a patient with cauda equina syndrome secondary to spondylolisthesis.[5] In 1913, Elsberg also documented an early case of a patient with lower extremity pain and left leg weakness that was cured after he performed a laminectomy.[6] It was more than thirty years after these early reports that Verbeist finally described the syndrome associated with the narrowing of the lumbar spinal canal.[1] In order to delineate the etiology, Arnoldi devised an international classification of lumbar stenosis that consists of: 1) degenerative, 2) congenital, 3) combined, 4) spondylolytic spondylolisthesis, 5) iatrogenic, and 6) post-traumatic stenosis.[7]

There are numerous case series that report a high success rate in patients undergoing an open decompressive laminectomy, but the results appear to lessen over time.[8-10] One prospective,

observational cohort study is the Maine lumbar spine study. The study enrolled 148 patients, of which 81 were treated surgically and 67 treated non-surgically. Atlas reported 28% of non-surgically patients and 55% of surgically treated patients reported a definite improvement in their predominant symptoms. The maximal benefit was observed at three months. [11] A report of this group after evaluation at four years demonstrated that 70% of the surgically treated and 42% of the non-surgically treated patients reported improvement in their predominant symptom.[12] Of the 148 patients enrolled, 105 were alive at ten years. Eight to ten year follow-up data was available 56 of the 63 surgically treated patients and 41 of the 60 non-surgically treated patients. A similar percentage of surgical and non-surgical patients reported that their back pain was improved, 53% and 50%, respectively. Interestingly, by ten years, 23% of surgical patients undergone at least one lumbar spine operation and 39% of non-surgical patients had at least one lumbar spine surgery.[13]

Patients that undergo an open decompressive laminectomy may develop worsening of their symptoms requiring another operation. The re-operation rate has been reported to be approximately 10-23%.[14-16] Jansson et al reported a 1, 2, 5, and 10-year re-operation rate of 2 ,5 ,8 , and 11%, respectively, in 9,664 patients that underwent decompression for stenosis in Sweden.[16] The procedure has also been reported to be safely performed older, medically frail population.[17-19]

Less Invasive Modifications for Decompression

The emphasis on reducing the iatrogenic damage to the surrounding soft tissue as well as preserving the supporting ligaments and paraspinal musculature led to the development of various “less invasive” procedures. The preservation of the supraspinous ligament by performing bilateral laminotomy as well as unilateral approaches was reported by Joson et al in 1987.[20] Modifications of this “less invasive” approach have been well documented in the literature with reported excellent clinical results and low morbidity.[21-30] Unique techniques including “spinous process-plasty” and spinous process osteotomies

have also been reported to offer a "less invasive" treatment option with a purported stabilizing effect. These procedures have also been reported to offer a good clinical outcome.[31-34]

Technological advances have paved the way for novel less invasive surgical treatments for spinal stenosis. Improvements in fiber optic and endoscopic technology have provided surgeons with an alternative method of visualization through smaller surgical corridors. One of the pioneers in minimally invasive spinal arthroscopy, Parviz Kambin, reported his results in patients suffering from lateral recess stenosis. Of the 40 patients treated, 38 were available for follow-up and a "satisfactory" result was obtained in 31 patients (82%) with minimal complications.[35] In addition, surgeons have also reported excellent results in large case series utilizing percutaneous approaches combined with laser application.[36, 37]

Minimal Access Technology and the MicroEndoscopic Tubular Retractor System

Access to the spine has traditionally relied on wide exposure with paraspinal muscle retraction. Studies have demonstrated a loss of density in the lumbar spinal muscles on review of postoperative CT imaging as well as increases in intramuscular pressure (IMP) and intramuscular perfusion pressure (IPP) recorded intra-operatively during decompressive surgery.[38-43] In order to reduce this iatrogenic damage caused by the traditional retractors, a tubular retractor system was designed. This minimal access system was first utilized to treat patients with lumbar disc herniations and offered a safe and effective alternative to the "gold standard" microdiscectomy.[44, 45]

The MetRx system was used in a cadaveric study to assess the feasibility of performing a decompressive laminectomy from a unilateral approach with microendoscopic technique. In this study, the L1-L4 laminae of four cadavers underwent one of four procedures consisting of: 1) unilateral microscopic laminotomy, 2) bilateral microendoscopic laminotomy, 3) unilateral open laminotomy, and 4) bilateral open laminotomy. Guiot et al demonstrated through computed tomography that excellent

decompression of the neural elements could be achieved with microendoscopic laminotomy and was as effective as open laminotomy.[46]

This technique was employed to treat a series of 25 consecutive patients with classic symptoms of lumbar radiculopathy by one of the leading experts in the field of minimally invasive spine surgery, Richard G. Fessler. The patients were compared to a second group of 25 patients treated with open decompressive laminectomy. Patients undergoing the minimally invasive procedure reported a 16% resolution of back pain, 68% improvement of symptoms, but 16% remained unchanged in regard to symptomatology. The results were similar to the open decompression group. In the minimally invasive group, the average blood loss was 68 mL and postoperative hospitalization was 42 hours compared to 193 mL and 94 hours, respectively, in the open group. The authors noted an increase in operative time in the minimally invasive group, 109 minutes/level, compared to the open group, 88 minutes/level. The increase in operative time is likely due to the learning curve associated with performing the new minimally invasive procedure.[47] There have been other reports of excellent results with only slight modifications of the technique.[48, 49]

Instability associated with Stenosis

Lumbar stenosis is commonly associated with patients that have evidence of spondylolisthesis. Many of these patients present with symptoms consistent with intermittent claudication or radiculopathy as well as axial low back pain and may be candidates for minimally invasive decompression with fusion. Controversy exists when determining the indication for fusion and usually depends on the surgeon's training.[50-55] It is my preference to perform only decompression in patients with radicular symptoms and no evidence of instability as assessed on dynamic imaging. Patients that have a major component of back pain with evidence of instability are usually treated with a minimally invasive transforaminal lumbar interbody fusion (MI-TLIF).

Adjacent Level Stenosis

Iatrogenic lumbar stenosis may result at levels adjacent to previous surgical fusions. The factors associated with the development of adjacent segment stenosis are not well established. It is reasonable that the additional stress that is transferred to the adjacent level leads to accelerated changes within the disc and facet complex.[56] Although the rate of degeneration at levels adjacent to fusions in the cervical spine have been well documented, the rate of lumbar degeneration is less clear.[57, 58]

Aiki et al retrospectively analyzed 117 patients who had undergone posterior fusion and were followed for a minimum of two years. Nine patients (7.7%) required a second operation secondary to adjacent level stenosis with neurological symptoms. Although this represents a small population, the only variable associated with a high rate of re-operation was multilevel fusion.[59] In another retrospective study, adjacent segment degeneration was evaluated and found to occur in 17 (35%) out of the 49 patients analyzed.[60]

Patients that develop stenosis adjacent to previous fusion surgery are candidates for further decompression. Phillips et al reported the results of 33 patients that underwent surgical decompression at adjacent levels to previous fusion. In this retrospective review, 26 of the 33 were followed for 3-14 years, mean of 5 years, and were evaluated with an outcome questionnaire. Of the 26 patients, 15 rated their surgery as completely satisfactory, 6 neutral toward the surgery, and 5 considered their surgery a failure. Interestingly, six of the patients required another surgical procedure during the follow-up period.[61]

Minimally invasive treatment options can be employed in the treatment of adjacent segment disease. The feasibility of performing a microendoscopic decompression may rely on the ability to negotiate the working channel around the posterior instrumentation during the approach. The 18mm

working channel can usually be docked overlying the level of stenosis. Extension of the fusion at the adjacent level may be recommended if symptoms develop in the postoperative phase.

Treatment of Synovial Cysts with MEDS Procedure

Degenerative lumbar stenosis may also be associated with the formation of synovial cysts.[62-64] The term juxta-facet cyst may be more appropriate since the entity includes the synovial cyst that arise from the degeneration of the facet joint and the ganglion cyst that arise from the mucinous degeneration of the periarticular connective tissue. Although these cysts are relatively rare, reportedly occurring in 1% of 2898 patients that underwent MRI of the lumbar spine in one study, they can frequently be associated with clinical symptoms.[65]

The most common presentation in patients harboring a synovial cyst is painful radiculopathy. Neurogenic claudication, sensory deficits, and motor weakness are also observed in patients with symptomatic synovial cysts.[66] These lesions have been successfully treated through numerous percutaneous procedures.[67-70] However, surgical resection may offer the best and most definitive outcome.[71-73]

A retrospective study of 194 patients treated with open decompression at the Mayo Clinic has been reported with excellent clinic results and a low morbidity. Of the 194 patients evaluated, follow-up data was available for 147 patients and 134 (91%) reported good relief of their pain and 82% experienced improvement in their motor deficits. Although concomitant fusion was performed in 18 patients demonstrating evidence of instability, subsequent fusion was required in only four patients that developed symptomatic spondylolisthesis after decompression.[66]

Synovial cysts have also been treated using minimally invasive techniques. Sandhu et al reported their results of 17 patients treated for symptomatic synovial cysts using the MetRx tubular retraction system. In their hands, the procedure could be performed in an average of 97 minutes with average

minimal blood loss of 35 mL. Excellent or good results were observed in 94% of patients using the modified MacNab criteria. The authors observed a grade I spondylolisthesis in 47% of the patients; however, only one patient required a subsequent fusion secondary to symptomatic spondylolisthesis. The authors concluded that this type of minimally invasive surgery may minimize the risk of progressive instability in patients with synovial cysts and concomitant spondylolisthesis.[74]

A New Option in the Treatment of Lumbar Stenosis

Although my main objective is to address minimally invasive decompression for stenosis, there are minimally invasive techniques under evaluation that may offer symptomatic relief for patients with lumbar spinal stenosis without undergoing a decompressive surgery. An interspinous distraction device has been available in Europe since June 2002 and has also been evaluated in clinical trials in the United States. The device can be placed through minimal access techniques and has demonstrated radiographic as well as clinical improvement. Lee et al. have reported a cross-sectional increase in postoperative versus preoperative imaging of an average 22.3% and an intervertebral foramina increase of a average 36.5% in 10 consecutive cases.[75] A prospective, randomized multi-center study involving 191 patients (100 received X STOP and 91 were in the non-operative control group) has been reported with 1-year success rates of 59% and 12%, respectively.[76] This trend was also observed at two years with a satisfaction rate of 73.1% in patients receiving the X STOP compared to 35.9% in the control group.[77]

Summary

With the increasing elderly population, the number of patients presenting with symptoms secondary to lumbar stenosis will increase accordingly. Therefore, treatment of this disease process will become more prevalent and the minimally invasive techniques will offer another treatment option. With increasing experience in minimally invasive techniques, the reported advantages of the minimal access surgery including reduction in soft tissue injury, less blood loss, shorter hospitalization and faster recovery

will make this an attractive alternative to traditional open surgery. Continuing efforts in the minimally invasive field will undoubtedly yield new and potentially less invasive and possibly more efficacious treatment options in the future.

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Comment 2 Response

The main sentiment expressed in the comments submitted in email is that this topic is not a new technology, that decompressive surgery is standard clinical practice, and therefore should not be within scope for review by the HTA Program. We appreciate the additional information supplied in the attachment from this commenter, though it appears that this attachment summarizes clinical, epidemiological, and treatment information from various study designs related to degenerative lumbar spinal stenosis and does not specifically address the key questions or scope proposed for this HTA.

We clarify several specific issues raised in the commenters email in Table 2.

Table 2. Concerns and Response to Comment 2

Concern About Proposed Scope	Response
Concern that the various procedures "micro", image guided surgery, laser-assisted surgery are grouped together.	The proposed scope lists interventions that are eligible for this HTA. This list is not meant to be exhaustive or to suggest that these are different kinds of surgeries, but to communicate the variations of decompressive surgery that we will be including in the HTA.
Concern that HTA is questioning the use of "image guidance" in performing these procedures and that is malpractice to consider a decompression without documenting the correct level.	We note that most trials of decompressive surgery do require imaging for correlation of symptoms prior to study entry; and we agree that imaging to document the level of involvement is standard clinical practice. We believe the commenter may be referring to the part of the proposed scope table that lists the mild® procedure (image-guided minimally invasive lumbar decompression) as an ineligible procedure for inclusion in this HTA. Studies evaluating this procedure are not eligible for inclusion in the HTA because this procedure indicated for patients with lumbar spinal stenosis (central canal stenosis).

Comment 3

Submitted by:

- American Association of Neurological Surgeons
- Congress of Neurological Surgeons
- American Academy of Orthopaedic Surgeons
- International Society for the Advancement of Spine Surgery
- North American Spine Society
- Washington State Association of Neurological Surgeons

November 27, 2017

Josiah Morse, MPH, Program Director
Washington State Healthcare Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

SUBJECT: Washington State HTA Key Questions for Review of Surgery for Symptomatic Lumbar Radiculopathy

Dear Mr. Morse:

The American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), Congress of Neurological Surgeons (CNS), International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS) and the Washington State Association of Neurological Surgeons (WSANS) appreciate the opportunity to provide feedback on the draft key questions for consideration of surgery for symptomatic lumbar radiculopathy.

We have attached a document presenting the consensus views of our organizations on each of the draft key questions and including a robust review of the relevant literature. We must reiterate our view that spine surgery seems to have been disproportionately selected as a review topic by the Health Technology Assessment Program. Collectively, our organizations do not agree with the need to review surgery for symptomatic lumbar radiculopathy at this time. The surgical treatment of lumbar radiculopathy in patients refractory to nonoperative measures or with a neurological deficit has been the standard of care for decades. We hope that the review will be based on the strength of the evidence and availability of care in the state of Washington. Our organizations are concerned that some past decisions regarding spine care were based on studies conducted outside the United States and thus not relevant to the population covered by the programs in the purview of the Washington State Health Care Authority — resulting in fewer effective treatment options for those patients.

Thank you for the opportunity to provide our comments.

Sincerely,
American Academy of Orthopaedic Surgeons
American Association of Neurological Surgeons
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
Congress of Neurological Surgeons
International Society for the Advancement of Spine Surgery
North American Spine Society
Washington State Association of Neurological Surgeons

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The American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), AANS/CNS Section on Disorders of the Spine and Peripheral Nerves (DSPN), Congress of Neurological Surgeons (CNS), International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS), and Washington State Association of Neurological Surgeons (WSANS)

Responses to Key Questions for Washington State Health Care Authority Health Technology Assessment of Surgery for Symptomatic Lumbar Radiculopathy

Efficacy question 1 (EQ1). In adults with symptomatic lumbar radiculopathy, what is the effectiveness and comparative effectiveness of surgical interventions?

Lumbar radiculopathy is caused by nerve root compression in the lumbar spine. Symptoms include neuropathic pain, sensory dysfunction, and motor deficits. Treatment for acute radicular pain, in the absence of neurologic deficit, begins with nonoperative management including medication, physical therapy, and injections. Nonoperative management is effective for acute radicular pain in approximately 70-85% of cases at an average of 4-6 weeks.[1, 2]

Surgery for lumbar radiculopathy is considered in several scenarios: 1) when nonoperative management of radicular pain fails to improve symptoms after 6+ weeks, 2) if there is acute and/or progressive motor deficit, and 3) pain is so severe and debilitating that nonoperative management is not possible. The appropriate surgical intervention depends primarily on the location and the source of nerve root compression/irritation. There are four primary locations for nerve compression: central canal, lateral recess, the neural foramen, and the far lateral/ extraforaminal region. The source of the compression can either be from 1) direct encroachment from displaced material, such as disc herniation, hypertrophic facet, and buckled/hypertrophic ligament; or 2) narrowed corridors as a result of abnormal alignment, such as spondylolisthesis and scoliosis.

Decompressive procedures for lumbar radiculopathy are most effective for pathology caused by disc herniation, hypertrophic facet, and buckled/hypertrophic ligament. Stenosis of the central canal, lateral recess, proximal foramen is easily accessed through a laminectomy/laminotomy. Far lateral disc herniation and distal foraminal stenosis require a lateral, extraforaminal approach. Surgical treatment of lumbar radiculopathy has proven to be highly effective in a multitude of studies.[3] In a series of 100 patients undergoing discectomy, at one-year post-op, 73% had complete relief of leg pain, and 63% had complete relief of back pain. At a minimum of 5 years postoperatively, 62% of patients had complete relief of back pain, and 62% had complete relief of leg pain. Ninety-six percent were pleased that they the surgery performed and 93% were able to return to work.[4] Minimally invasive techniques, such as percutaneous endoscopic lumbar discectomy, appear to achieve equivalent clinical outcomes compared

to more traditional open techniques.[5-7] Other, less conventional, strategies for treatment of disc herniation have been introduced, such as nucleoplasty, intradiscal endothermal therapy, and laser spine surgery, which have generated variable results. With studies demonstrating less favorable outcomes than more orthodox treatments, these techniques have not gained universal acceptance.[8,9]

Recurrent disc herniation occurs postoperatively in 5-18% of patients.[10] Surgical treatment options for recurrent disc herniation include repeat discectomy or decompression with fusion; favorable clinical outcomes have been reported with both treatment strategies.[11] Results from a national registry study demonstrated similar improvement in ODI, VAS, and QALY at 3 and 12 months with both repeat discectomy and fusion.[12]

When lumbar radiculopathy is caused primarily by spinal malalignment, such as spondylolisthesis and scoliosis, fixation and fusion is often necessary to adequately decompress the affected nerve(s).[1315] Fusion is effective at improving radicular symptoms in this setting and leads to clinical success rates of 81-89% when used for this purpose.[15, 16] All fusion techniques (transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, lateral lumbar interbody fusion, and posterolateral fusion) appear to be equally effective in improving lumbar radiculopathy in this setting.[15, 17-20] The duration of preoperative symptoms appears to influence the resolution of lumbar radiculopathy after fusion surgery. In a study by Villavicencio et al., 89% of patients with radiculopathy reached the minimal clinically important difference (MCID) for self-reported leg pain postoperatively when symptoms were present <24 months, while only 71% of patients reached the MCID with symptoms >24 months ($p=0.032$).[14] It is not unusual to have radiculopathy from severe foraminal stenosis. Sometimes the nature of this foraminal stenosis is such that a complete facetectomy is required to address the radiculopathy adequately. Because this category of patients requires a complete facetectomy with resultant iatrogenic instability, fusion is required under these circumstances. [21]

In summary, spine surgery is highly effective at improving symptoms of lumbar radiculopathy. Both decompression alone and fusion surgery result in favorable clinical outcomes when these procedures are used for the appropriate patients.

Efficacy Question 2 (EQ2). In adults with symptomatic lumbar radiculopathy, does effectiveness or comparative effectiveness of surgical interventions vary for difficult subpopulations?

Symptomatic lumbar radiculopathy is caused by compression of a lumbar nerve root. Compression of the nerve may have a variety of causes including a herniated lumbar disc, synovial cyst, ligamentous hypertrophy, foraminal stenosis, or instability. Ultimately, the goal of surgical intervention is to decompress the nerve root to relieve the radicular complaint. There are a variety of methods to achieve this goal depending on the specific pathology which can include direct decompression alone, direct

decompression and fusion, and indirect decompression and fusion. The most common etiology of lumbar radiculopathy is a herniated lumbar disc, and the most basic surgical treatment for this pathology is a laminotomy with discectomy. To simplify the question of whether the effectiveness of surgical intervention varies for different subpopulations, it is necessary to discuss the literature concerning laminotomy with discectomy.

There are three major studies that address outcomes from surgical treatment for herniated lumbar discs. The Weber trial in the 1980s followed 126 patients with lumbar disc herniation treated surgically for 10 years. The Maine Lumbar Spine study in the 1990s followed 389 patients (219 treated with surgery) for five years. Most recently, the SPORT trial in the 2000s followed 501 patients randomized into surgical and non-surgical groups as well as following an observational cohort of 743 patients for eight years. Overall, patients had improvement in their symptoms over time, with the surgical cohort having an advantage over the non-operative cohort and the surgical cohort having faster initial improvement.[21, 22]

When analyzing for subgroups performance, there were only a few notable subgroups that did not respond as well to surgical intervention. The Weber trial noted patients with psychosocial comorbidities tended to have poorer outcomes. The Maine study showed that patients on worker's compensation represented the only group that did not have a statistically significant benefit over the non-surgical cohort. The SPORT trial's analysis of patients on worker's compensation found initial benefit from surgery early but no benefit over the non-surgical cohort after two years. Importantly, no other subgroups concerning patient demographics or comorbidities demonstrated poor responses to surgery. When comparing the subgroups of tobacco use, depression, and comorbid joint disease, there were worse outcomes for both surgical and non-surgical cohorts. Nevertheless, there remained a significant treatment benefit for the surgical cohort in these subgroups.

There are a few other studies in the literature that address possible subgroups that may respond less well to surgical decompression for radiculopathy. Voorhies et al. studied 121 patients treated with decompression for lumbar radiculopathy. They also noted the poor response to surgery for patients with psychosocial comorbidities as well as for those with axial joint pain. They found no impact on the effectiveness of surgery for comorbidities including diabetes, narcotic dependence, obesity, osteoporosis, smoking status, or prior surgery in the affected area. While this study identified two subgroups that did not respond as well to surgery, there was not a non-surgical cohort to determine whether these groups still experienced a treatment effect from surgery.[23]

Similarly, Madsbu reported that at one year following single-level lumbar microdiscectomy, nonsmokers experienced a greater improvement in ODI and other functional outcome compared with smokers. Nonetheless, smokers also experienced significant improvements.[24]

For patients with morbid obesity, Yoo et al. reported that despite an increase in operation time and EBL, there were no differences in surgical outcomes.[25] Fakouri et al. also reported no difference in radicular leg pain between obese and non-obese patients after lumbar microdiscectomy.[26] Tomasino et al. also reported that using tubular microsurgery, obese patients have similar surgical outcomes compared to non-obese patients for lumbar discectomies and laminectomies.[27] In addition, a prospective, multi-institutional comparative study showed significant improvement of pain and functional level with lumbar arthrodesis for low back pain and/or radiculopathy for morbidly obese patient, either with open transforaminal lumbar interbody fusion or minimally invasive transforaminal lumbar interbody fusion.[28]

Ibrahim et al. studied the incidence of recurrent lumbar disc herniation and factors that might predispose patients to have poor outcomes due to recurrent symptoms. No major subgroups of patients were more likely to have recurrent disc herniation with the biggest factor seeming to be the morphology of the disc herniation. Patients demonstrating a large extruded disc fragment with large annular defects were more prone to recurrent disc herniation. In managing patients with recurrent disc herniation, patients with poorly controlled diabetes tended to respond poorly to subsequent surgical interventions for recurrent disc herniation including decompression and fusion alike.[29]

Sarrami et al. evaluated outcomes in patients seeking compensation after motor vehicle collisions. While this study evaluated patients undergoing all types of lumbar surgery as a treatment for a variety of pain complaints after injury, 41% of claimants complained of ongoing radicular symptoms after surgery. This compares unfavorably with an estimated 90% success rate for treating disc herniation with microdiscectomy. However, this study is limited by analyzing a complicated population of patients with axial and radicular pain complaints treated with both decompression alone and combined decompression and fusion.[30]

Shamji et al. evaluated patients with persistent neuropathic pain following lumbar discectomy for radiculopathy. In a series of 250 patients, similar to other reports, 88% had a substantial (>50%) reduction in leg pain severity. Patients with persistent radicular complaints after surgery tended to be younger and presented with motor or sensory deficits, but there were no differences in subgroups of sex or smoking status. Importantly, even those patients with persistent radicular complaints showed clinically significant improvement in disability status.[31]

In the many studies analyzing the response of lumbar radiculopathy to surgical decompression, nearly all groups of patients show statistically significant improvement in pain and disability after surgery with advantages over non-surgical management. There is no agreement of any patient demographic groups or medical comorbidities that eliminates the treatment effect of the surgical intervention. The only exception that appears to bear out in multiple analyses is the subgroup of patients seeking or receiving

compensation after an injury. Looking at this subgroup, the most positive response to surgical treatment was in the SPORT trial showing statistically significant improvement over the nonsurgical cohort early but losing this treatment effect after two years. Several other studies show this subgroup having only mild benefits from surgery with many patients complaining of persistent pain and remaining unable to return to work. This finding suggests that patients with secondary gain tend to have relatively poor responses to surgical intervention which should play a role in the decision to perform surgery for this subgroup. However, the underlying pathology and disease process is no different from the rest of the population that responds well to this pathology. While one must be wary of this subgroup as being less likely to improve with surgery, patients with severe pathology and certain physical examination findings of sensory or motor deficits should still be considered for surgical intervention.

Safety question 1 (SQ1). In adults with symptomatic lumbar radiculopathy, what are the adverse events associated with surgical interventions?

Surgical intervention for adults with symptomatic lumbar radiculopathy is a low-risk procedure with an overall complication rate of less than 10% and less than 10% of patients requiring revision surgery. As with any operation, adverse events depend on the pathology, surgical technique (open microscopic vs. endoscopic vs. minimally invasive), as well as the number of levels treated, and revision vs. initial surgery.

The most common complication associated with the surgery itself is a CSF leak secondary to a dural tear, seen in 0.9-4.5% of cases. Durotomy is well known to increase in frequency when operating on patients with a history of previous decompression surgery and may be as high as 14.5%.[32] Other adverse events related to the surgery itself include injury to the nerve root (0.9-2.6%); new neurologic deficit (1.3-3%); surgical errors including wrong level/negative exploration (1-3%); post-operative wound complications include; hematoma (0.5-1.2%); and wound infections (0.5-2.1%). Medical complications such as MI, stroke, DVT, PE, acute kidney injury, and UTI are also reported but with a low incidence (0-3%).[33]

Recurrent disc herniation are possible following decompressive operations without fusions and have been reported to occur in 1.8-6.1% of cases. The overall reoperation rate for all causes ranges from 3.7-10.2%. Some patients may also re-present with a recurrent disc but may be managed conservatively and may improve without requiring a revision operation.[34, 35]

Complications from surgical treatment of radiculopathy are low and have decreased over the years with advancements in surgical technology and techniques. It remains a safe and viable option for patients who have failed conservative treatment options.

Cost question 1 (CQ1). In adults with symptomatic lumbar radiculopathy, what is the costeffectiveness of surgical interventions?

Surgical intervention in adults with symptomatic lumbar radiculopathy is a cost-effective intervention. The cost-effectiveness of surgical versus non-operative treatment for lumbar disc herniation, a common cause of lumbosacral radiculopathy, has been evaluated previously. Tosteson et al. evaluated the cost-effectiveness of surgical versus non-operative treatment for lumbar disc herniation over two years from the Spine Patient Outcomes Research Trial (SPORT).[36] The study was designed to limit some of the crossover problems with SPORT and utilized an as-treated methodology. Using Medicare surgery costs, a cost per quality-adjusted life years (QALY) was calculated. Costs were higher in those treated surgically than those treated conservatively, but outcomes over two years were better in the operative group. Estimated costs per QALY gained with surgery were $34,355 with an incremental Cost-Effectiveness Ratio (ICER) of $33,176. As the authors point out the QALY gained compares very favorably with other established medical and surgical interventions.

The cost-effectiveness of surgery in patients with radiculopathy with lumbar stenosis who underwent multilevel hemilaminectomy has also been evaluated. Parker et al. reported an economic analysis of fifty-four consecutive patients undergoing multilevel hemilaminectomy for stenosis-related radiculopathy after at least six months of conservative management.[37] At two years there was a mean two-year gain of 0.72 QALY. The total cost per QALY gained for multilevel hemilaminectomy was $33,700. The cost per QALY for radiculopathy secondary to stenosis at multiple levels is very similar when compared to the cost per QALY for lumbar radiculopathy secondary to disc herniation.

Hansson et al. studied the cost-utility of lumbar discectomy relative to conservative treatment. While the medical costs were higher in the surgical group when examining treatment costs in isolation of other indirect costs, when examining total cost, including disability cost, costs were lower in the surgical group. Hansson attributed this decreased cost in the surgical group to fewer recurrences and fewer permanent disability benefits. The gain in QALY was ten times higher in the patients who underwent surgery. This resulted in better cost utility for surgical treatment relative to the conservative group.[38]

Conclusion

In conclusion, surgery in patients with symptomatic lumbar radiculopathy secondary to disc herniation or stenosis represents a cost-effective treatment and compares very favorably with other accepted medical and surgical interventions. As more focus is shifted towards these procedures being performed in more cost-effective settings such as outpatient surgical centers, the cost per QALY is likely to be even lower.

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Comment 3 Response

We thank the commenters for their consensus assessment of the literature on the effectiveness, safety, and cost-effectiveness of surgery for lumbar radiculopathy. We address one specific concern raised in the cover letter in Table 3.

Table 3. Concern and Response to Comment 3

Concern About Proposed Scope	Response
Concern about the potential inclusion of studies conducted outside of the United States.	Limiting the scope to studies conducted only in the US may lead to a limited evidence base for consideration by the HTCC. Unless there is a specific rationale for why the clinical course of radiculopathy, interventions applied, or postoperative care are dissimilar between the US and other highly developed countries, we would not *a priori* exclude studies conducted in non-US settings.

From:	Daniel Cher
To:	HCA ST Health Tech Assessment Prog
Subject:	comment on lumbar radiculopathy
Date:	Thursday, November 23, 2017 8:55:03 AM
Attachments:	image001.png

I commend the Washington State Health Care Authority on its mission to evaluate the effectiveness of various treatments for lumbar radiculopathy. https://www.hca.wa.gov/about-hca/health-technology-assessment/surgery-for-symptomatic-lumbar-radiculopathy

However, the document's scope is incomplete. I suggest an additional scope question, namely: what proportion of patients with lumbar radiculopathy seeking surgical or non-surgical treatments are misdiagnosed and instead have pain emanating from the sacroiliac (SI) joint?

SI joint pain commonly manifests as buttock pain with radiation into the upper legs and can easily be mistaken for lumbar radiculopathy. Studies show that 15-30% of chronic low back pain may have a contribution from the SI joint,[1-5] it is obvious that interventions aimed at the lumbar spine will be expensive and ineffective if the pain source is outside of the lumbar spine. Such interventions confer only risk and not benefit. This is especially important given the well-known poor correlation between MRI findings and radicular pain.

Regards,

Daniel Cher

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From: trent tredway
To: HCA ST Health Tech Assessment Prog
Subject: Comments Regarding Lumbar Decompression
Date: Monday, November 27, 2017 6:14:23 PM
Attachments: Tredway Comments for HTA Lumbar Decompression 11-27-2017.doc

Dear Josh,

Please find my comments regarding the Key Questions attached to this email. I have also included commentary in this email regarding the actual process that the HTA has utilized in regard to choosing this topic as I strongly believe this is completely out of the scope of the HTA's review of "new technology". This information contained in this email should also be included in the comments for this topic. This topic that was reviewed is the standard of care for many of our patients that fail conservative management. It could be said that the entire Practice of Neurosurgery is based on decompression of neural elements. This is evident in cranial procedures where we decompress the offending agent (tumor, infection, traumatic injury, edema, hematoma, etc.) so that the neural elements are not under direct compression causing injury to the brain and cranial nerves. Decompression of nerve roots is the mainstay of surgery of the peripheral nerves including surgery for carpal tunnel syndrome and ulnar entrapment injury, to name the most common procedures. The same principle applies for decompression of the nerve roots in the neuroforamen in cervical, thoracic, and lumbar disease. Therefore, as you can see, I find this review topic to be useless and an actual attack on the Practice of Neurosurgery.

I have pointed out earlier in the comments I posted when this topic was first being evaluated that the decision by Dorothy Teeter was wrong and beyond the scope of the HTA committee. I also find that the inquiry that "lumps" together various adjuncts for surgery to be a prime example of the misunderstanding by Dorothy Teeter and individuals on this committee. I find it insulting that one of the Key Questions and Comments on the HTA website suggests that minimally invasive procedures, "micro" procedures, image guided surgery, and laser-assisted surgery are grouped together. To set the record straight, all lumbar decompression surgeries require access to the spinal elements. This requires performing a surgical incision and the use of a retractor system. It is true that surgeons are trying to use smaller incisions and retractors to minimize the trauma to the normal surrounding tissue. It is also true that we have better visualization modalities including use of microscopes and endoscopes to help assist us in performing the laminoforaminotomies and microdiscectomies. These modifications are only to help in achieving better patient outcomes and safer procedures.

Also, the coding for these procedures are also the same (CPT codes 63030 for microdiscectomy, 63047 and 63048 for laminectomies and laminotomies, additional level (63048) and thus are essentially the same in regard to decompression of the nerve roots. I find it insulting as well that the HTA is questioning the use of "image guidance" in performing these procedures. It is absolutely malpractice and against standard of care to perform a

lumbar decompression without documenting the correct level. The use of C-arm fluoroscopy or CT and/or Fluroscopic navigation to help document this does not have a cost impact and is not billable under the current CMS guidelines, so I am perplexed as to why the HTA would confuse this matter. Can you imagine performing a surgery and not documenting the appropriate level? Futhermore, the use of lasers in neurosurgery have been utilized since the 1980's in treating tumors of the brain and spine as well as lipomyelomeningoceles is children and adults and has been a useful tool. In regard to its role in the treatment of lumbar decompression, there is limited evidence that it is helpful in actually performing the procedure as it is often used for the approach on the soft tissue dissection. The majority of surgeons utilize electrothermal coagulopathy (bipolar or monpolar) in our dissection. Once again, the use of a laser is not billable for our decompressive surgeries as outlined above (CPT 63030, 63047, 63048) and I find it strange that the HTA is grouping this into a procedure for treatment of lumbar radiculopathy.

If Dorothy Teeter or the HTA has a specific "new technology" that it believes requires evaluation by the HTA committee, then the Director and the committee should be more direct and stop performing "fishing expeditions" for procedures that have been the standard of care in neurosurgery for many decades.

I look forward to the HTA Committee's response to our comments as I often believe these comments are not even read or taken seriously.

Thank you for your time.

Sincerely,

Trent L. Tredway, MD FAANS
Neurosurgeon
Tredway Spine Institute

EQ1/EQ2

Lumbar spinal stenosis (LSS) is one of the most common diseases of the spine that affects the elderly population. Verbeist first described this syndrome in the early 1950's; however, controversy exists in regard to symptomatology, diagnosis (clinical versus radiological), as well as choice of treatment.[1] The syndrome is a result of multitude of degenerative changes that occur as the body ages. The combination of disc degeneration, facet arthropathy, and ligamentum flavum hypertrophy leads to a narrowing of the spinal canal causing compression of the neural elements. Patients with lumbar stenosis may present symptoms that include low back pain, radiculopathy, motor or sensory deficits, and/or intermittent claudication that usually worsens with walking.[2] Since this condition occurs gradually over years, it rarely will lead to acute neurological deficits.

Initially, most patients can be managed with conservative non-operative therapy. Aggressive physical therapy regimens, epidural steroid injections, and weight loss may provide some patients with significant relief of their symptoms.[3, 4] If conservatively treated patients do not exhibit improvement, then decompressive surgery may be considered. Traditional surgical treatment includes posterior decompressive laminectomy. This procedure involves surgical resection of the spinous process, lamina, part of the facet, as well as disruption of the supraspinous and interspinous ligaments. The development of novel minimally invasive approaches that limit the disruption of the surrounding tissue has become an increasingly popular treatment option in patients with symptomatic lumbar stenosis.

Historical Perspective of Spinal Stenosis and Treatment

Perhaps one of the earliest examples of an operation to relieve spinal stenosis was reported my Arbuthnot Lane in 1893 when he successfully decompressed a patient with cauda equina syndrome secondary to spondylolisthesis.[5] In 1913, Elsberg also documented an early case of a patient with lower extremity pain and left leg weakness that was cured after he performed a laminectomy.[6] It was more than thirty years after these early reports that Verbeist finally described the syndrome associated with the narrowing of the lumbar spinal canal.[1] In order to delineate the etiology, Arnoldi devised an international classification of lumbar stenosis that consists of: 1) degenerative, 2) congenital, 3) combined, 4) spondylolytic spondylolisthesis, 5) iatrogenic, and 6) post-traumatic stenosis.[7]

There are numerous case series that report a high success rate in patients undergoing an open decompressive laminectomy, but the results appear to lessen over time.[8-10] One prospective, observational cohort study is the Maine lumbar spine study. The study enrolled 148 patients, of which 81 were treated surgically and 67 treated non-surgically. Atlas reported 28% of non-surgically patients and 55% of surgically treated patients reported a definite improvement in their predominant symptoms. The maximal benefit was observed at three months. [11] A report of this group after evaluation at four years demonstrated that 70% of the surgically treated and 42% of the non-surgically treated patients reported improvement in their predominant symptom.[12] Of the 148 patients enrolled, 105 were alive at ten years. Eight to ten year follow-up data was available 56 of the 63 surgically treated patients and 41 of the 60 non-surgically treated patients. A similar

percentage of surgical and non-surgical patients reported that their back pain was improved, 53% and 50%, respectively. Interestingly, by ten years, 23% of surgical patients undergone at least one lumbar spine operation and 39% of non-surgical patients had at least one lumbar spine surgery.[13]

Patients that undergo an open decompressive laminectomy may develop worsening of their symptoms requiring another operation. The re-operation rate has been reported to be approximately 10-23%.[14-16] Jansson et al reported a 1, 2, 5, and 10-year re-operation rate of 2 ,5 ,8 , and 11%, respectively, in 9,664 patients that underwent decompression for stenosis in Sweden.[16] The procedure has also been reported to be safely performed older, medically frail population.[17-19]

Less Invasive Modifications for Decompression

The emphasis on reducing the iatrogenic damage to the surrounding soft tissue as well as preserving the supporting ligaments and paraspinal musculature led to the development of various "less invasive" procedures. The preservation of the supraspinous ligament by performing bilateral laminotomy as well as unilateral approaches was reported by Joson et al in 1987.[20] Modifications of this "less invasive" approach have been well documented in the literature with reported excellent clinical results and low morbidity.[21-30] Unique techniques including "spinous process-plasty" and spinous process osteotomies have also been reported to offer a "less invasive" treatment option with a purported stabilizing effect. These procedures have also been reported to offer a good clinical outcome.[31-34]

Technological advances have paved the way for novel less invasive surgical treatments for spinal stenosis. Improvements in fiber optic and endoscopic technology have provided surgeons with an alternative method of visualization through smaller surgical corridors. One of the pioneers in minimally invasive spinal arthroscopy, Parviz Kambin, reported his results in patients suffering from lateral recess stenosis. Of the 40 patients treated, 38 were available for follow-up and a "satisfactory" result was obtained in 31 patients (82%) with minimal complications.[35] In addition, surgeons have also reported excellent results in large case series utilizing percutaneous approaches combined with laser application.[36, 37]

Minimal Access Technology and the MicroEndoscopic Tubular Retractor System

Access to the spine has traditionally relied on wide exposure with paraspinal muscle retraction. Studies have demonstrated a loss of density in the lumbar spinal muscles on review of postoperative CT imaging as well as increases in intramuscular pressure (IMP) and intramuscular perfusion pressure (IPP) recorded intra-operatively during decompressive surgery.[38-43] In order to reduce this iatrogenic damage caused by the traditional retractors, a tubular retractor system was designed. This minimal access system was first utilized to treat patients with lumbar disc herniations and offered a safe and effective alternative to the "gold standard" microdiscectomy.[44, 45]

The MetRx system was used in a cadaveric study to assess the feasibility of performing a decompressive laminectomy from a unilateral approach with microendoscopic technique. In this study, the L1-L4 laminae of four cadavers underwent

one of four procedures consisting of: 1) unilateral microscopic laminotomy, 2) bilateral microendoscopic laminotomy, 3) unilateral open laminotomy, and 4) bilateral open laminotomy. Guiot et al demonstrated through computed tomography that excellent decompression of the neural elements could be achieved with microendoscopic laminotomy and was as effective as open laminotomy.[46]

This technique was employed to treat a series of 25 consecutive patients with classic symptoms of lumbar radiculopathy by one of the leading experts in the field of minimally invasive spine surgery, Richard G. Fessler. The patients were compared to a second group of 25 patients treated with open decompressive laminectomy. Patients undergoing the minimally invasive procedure reported a 16% resolution of back pain, 68% improvement of symptoms, but 16% remained unchanged in regard to symptomatology. The results were similar to the open decompression group. In the minimally invasive group, the average blood loss was 68 mL and postoperative hospitalization was 42 hours compared to 193 mL and 94 hours, respectively, in the open group. The authors noted an increase in operative time in the minimally invasive group, 109 minutes/level, compared to the open group, 88 minutes/level. The increase in operative time is likely due to the learning curve associated with performing the new minimally invasive procedure.[47] There have been other reports of excellent results with only slight modifications of the technique.[48, 49]

Instability associated with Stenosis

Lumbar stenosis is commonly associated with patients that have evidence of spondylolisthesis. Many of these patients present with symptoms consistent with intermittent claudication or radiculopathy as well as axial low back pain and may be candidates for minimally invasive decompression with fusion. Controversy exists when determining the indication for fusion and usually depends on the surgeon's training.[50-55] It is my preference to perform only decompression in patients with radicular symptoms and no evidence of instability as assessed on dynamic imaging. Patients that have a major component of back pain with evidence of instability are usually treated with a minimally invasive transforaminal lumbar interbody fusion (MI-TLIF).

Adjacent Level Stenosis

Iatrogenic lumbar stenosis may result at levels adjacent to previous surgical fusions. The factors associated with the development of adjacent segment stenosis are not well established. It is reasonable that the additional stress that is transferred to the adjacent level leads to accelerated changes within the disc and facet complex.[56] Although the rate of degeneration at levels adjacent to fusions in the cervical spine have been well documented, the rate of lumbar degeneration is less clear.[57, 58]

Aiki et al retrospectively analyzed 117 patients who had undergone posterior fusion and were followed for a minimum of two years. Nine patients (7.7%) required a second operation secondary to adjacent level stenosis with neurological symptoms. Although this represents a small population, the only variable associated with a high rate of re-operation

was multilevel fusion.[59] In another retrospective study, adjacent segment degeneration was evaluated and found to occur in 17 (35%) out of the 49 patients analyzed.[60]

Patients that develop stenosis adjacent to previous fusion surgery are candidates for further decompression. Phillips et al reported the results of 33 patients that underwent surgical decompression at adjacent levels to previous fusion. In this retrospective review, 26 of the 33 were followed for 3-14 years, mean of 5 years, and were evaluated with an outcome questionnaire. Of the 26 patients, 15 rated their surgery as completely satisfactory, 6 neutral toward the surgery, and 5 considered their surgery a failure. Interestingly, six of the patients required another surgical procedure during the follow-up period.[61]

Minimally invasive treatment options can be employed in the treatment of adjacent segment disease. The feasibility of performing a microendoscopic decompression may rely on the ability to negotiate the working channel around the posterior instrumentation during the approach. The 18mm working channel can usually be docked overlying the level of stenosis. Extension of the fusion at the adjacent level may be recommended if symptoms develop in the postoperative phase.

Treatment of Synovial Cysts with MEDS Procedure

Degenerative lumbar stenosis may also be associated with the formation of synovial cysts.[62-64] The term juxta-facet cyst may be more appropriate since the entity includes the synovial cyst that arise from the degeneration of the facet joint and the ganglion cyst that arise from the mucinous degeneration of the periarticular connective tissue. Although these

cysts are relatively rare, reportedly occurring in 1% of 2898 patients that underwent MRI of the lumbar spine in one study, they can frequently be associated with clinical symptoms.[65]

The most common presentation in patients harboring a synovial cyst is painful radiculopathy. Neurogenic claudication, sensory deficits, and motor weakness are also observed in patients with symptomatic synovial cysts.[66] These lesions have been successfully treated through numerous percutaneous procedures.[67-70] However, surgical resection may offer the best and most definitive outcome.[71-73]

A retrospective study of 194 patients treated with open decompression at the Mayo Clinic has been reported with excellent clinic results and a low morbidity. Of the 194 patients evaluated, follow-up data was available for 147 patients and 134 (91%) reported good relief of their pain and 82% experienced improvement in their motor deficits. Although concomitant fusion was performed in 18 patients demonstrating evidence of instability, subsequent fusion was required in only four patients that developed symptomatic spondylolisthesis after decompression.[66]

Synovial cysts have also been treated using minimally invasive techniques. Sandhu et al reported their results of 17 patients treated for symptomatic synovial cysts using the MetRx tubular retraction system. In their hands, the procedure could be performed in an average of 97 minutes with average minimal blood loss of 35 mL. Excellent or good results were observed in 94% of patients using the modified MacNab criteria. The authors observed a grade I spondylolisthesis in 47% of the patients; however, only one patient required a subsequent fusion secondary to symptomatic spondylolisthesis. The authors

concluded that this type of minimally invasive surgery may minimize the risk of progressive instability in patients with synovial cysts and concomitant spondylolisthesis.[74]

A New Option in the Treatment of Lumbar Stenosis

Although my main objective is to address minimally invasive decompression for stenosis, there are minimally invasive techniques under evaluation that may offer symptomatic relief for patients with lumbar spinal stenosis without undergoing a decompressive surgery. An interspinous distraction device has been available in Europe since June 2002 and has also been evaluated in clinical trials in the United States. The device can be placed through minimal access techniques and has demonstrated radiographic as well as clinical improvement. Lee et al. have reported a cross-sectional increase in postoperative versus preoperative imaging of an average 22.3% and an intervertebral foramina increase of a average 36.5% in 10 consecutive cases.[75] A prospective, randomized multi-center study involving 191 patients (100 received X STOP and 91 were in the non-operative control group) has been reported with 1-year success rates of 59% and 12%, respectively.[76] This trend was also observed at two years with a satisfaction rate of 73.1% in patients receiving the X STOP compared to 35.9% in the control group.[77]

Summary

With the increasing elderly population, the number of patients presenting with symptoms secondary to lumbar stenosis will increase accordingly. Therefore, treatment of this disease process will become more prevalent and the minimally invasive techniques will offer another treatment option. With increasing experience in minimally invasive techniques, the reported advantages of the minimal access surgery including reduction in soft tissue injury, less blood loss, shorter hospitalization and faster recovery will make this an attractive alternative to traditional open surgery. Continuing efforts in the minimally invasive field will undoubtedly yield new and potentially less invasive and possibly more efficacious treatment options in the future.

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November 27, 2017

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

SUBJECT: Washington State HTA Key Questions for Review of Surgery for Symptomatic Lumbar Radiculopathy

Dear Mr. Morse:

The American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), Congress of Neurological Surgeons (CNS), International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS) and the Washington State Association of Neurological Surgeons (WSANS) appreciate the opportunity to provide feedback on the draft key questions for consideration of surgery for symptomatic lumbar radiculopathy.

We have attached a document presenting the consensus views of our organizations on each of the draft key questions and including a robust review of the relevant literature. We must reiterate our view that spine surgery seems to have been disproportionately selected as a review topic by the Health Technology Assessment Program. Collectively, our organizations do not agree with the need to review surgery for symptomatic lumbar radiculopathy at this time. The surgical treatment of lumbar radiculopathy in patients refractory to nonoperative measures or with a neurological deficit has been the standard of care for decades. We hope that the review will be based on the strength of the evidence and availability of care in the state of Washington. Our organizations are concerned that some past decisions regarding spine care were based on studies conducted outside the United States and thus not relevant to the population covered by the programs in the purview of the Washington State Health Care Authority — resulting in fewer effective treatment options for those patients.

Thank you for the opportunity to provide our comments.

Sincerely,
American Academy of Orthopaedic Surgeons
American Association of Neurological Surgeons
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
Congress of Neurological Surgeons
International Society for the Advancement of Spine Surgery
North American Spine Society
Washington State Association of Neurological Surgeons

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The American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), AANS/CNS Section on Disorders of the Spine and Peripheral Nerves (DSPN), Congress of Neurological Surgeons (CNS), International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS), and Washington State Association of Neurological Surgeons (WSANS)

Responses to Key Questions for Washington State Health Care Authority Health Technology Assessment of Surgery for Symptomatic Lumbar Radiculopathy

Efficacy question 1 (EQ1). In adults with symptomatic lumbar radiculopathy, what is the effectiveness and comparative effectiveness of surgical interventions?

Lumbar radiculopathy is caused by nerve root compression in the lumbar spine. Symptoms include neuropathic pain, sensory dysfunction, and motor deficits. Treatment for acute radicular pain, in the absence of neurologic deficit, begins with nonoperative management including medication, physical therapy, and injections. Nonoperative management is effective for acute radicular pain in approximately 70-85% of cases at an average of 4-6 weeks.[1, 2]

Surgery for lumbar radiculopathy is considered in several scenarios: 1) when nonoperative management of radicular pain fails to improve symptoms after 6+ weeks, 2) if there is acute and/or progressive motor deficit, and 3) pain is so severe and debilitating that nonoperative management is not possible. The appropriate surgical intervention depends primarily on the location and the source of nerve root compression/irritation. There are four primary locations for nerve compression: central canal, lateral recess, the neural foramen, and the far lateral/ extraforaminal region. The source of the compression can either be from 1) direct encroachment from displaced material, such as disc herniation, hypertrophic facet, and buckled/hypertrophic ligament; or 2) narrowed corridors as a result of abnormal alignment, such as spondylolisthesis and scoliosis.

Decompressive procedures for lumbar radiculopathy are most effective for pathology caused by disc herniation, hypertrophic facet, and buckled/hypertrophic ligament. Stenosis of the central canal, lateral recess, proximal foramen is easily accessed through a laminectomy/laminotomy. Far lateral disc herniation and distal foraminal stenosis require a lateral, extraforaminal approach. Surgical treatment of lumbar radiculopathy has proven to be highly effective in a multitude of studies.[3] In a series of 100 patients undergoing discectomy, at one-year post-op, 73% had complete relief of leg pain, and 63% had complete relief of back pain. At a minimum of 5 years postoperatively, 62% of patients had complete relief of back pain, and 62% had complete relief of leg pain. Ninety-six percent were pleased that they the surgery performed and 93% were able to return to work.[4] Minimally invasive techniques, such as percutaneous endoscopic lumbar discectomy, appear to achieve equivalent clinical outcomes compared to more traditional open techniques.[5-7] Other, less conventional, strategies for treatment of disc herniation have been introduced, such as nucleoplasty, intradiscal endothermal therapy, and laser spine surgery, which have generated variable results. With studies demonstrating less favorable outcomes than more orthodox treatments, these techniques have not gained universal acceptance.[8,9]

Recurrent disc herniation occurs postoperatively in 5-18% of patients.[10] Surgical treatment options for recurrent disc herniation include repeat discectomy or decompression with fusion; favorable clinical outcomes have been reported with both treatment strategies.[11] Results from a national registry study demonstrated similar improvement in ODI, VAS, and QALY at 3 and 12 months with both repeat discectomy and fusion.[12]

When lumbar radiculopathy is caused primarily by spinal malalignment, such as spondylolisthesis and scoliosis, fixation and fusion is often necessary to adequately decompress the affected nerve(s).[13-

15] Fusion is effective at improving radicular symptoms in this setting and leads to clinical success rates of 81-89% when used for this purpose.[15, 16] All fusion techniques (transforaminal lumbar interbody fusion, anterior lumbar interbody fusion, lateral lumbar interbody fusion, and posterolateral fusion) appear to be equally effective in improving lumbar radiculopathy in this setting.[15, 17-20] The duration of preoperative symptoms appears to influence the resolution of lumbar radiculopathy after fusion surgery. In a study by Villavicencio et al., 89% of patients with radiculopathy reached the minimal clinically important difference (MCID) for self-reported leg pain postoperatively when symptoms were present <24 months, while only 71% of patients reached the MCID with symptoms >24 months (p=0.032).[14] It is not unusual to have radiculopathy from severe foraminal stenosis. Sometimes the nature of this foraminal stenosis is such that a complete facetectomy is required to address the radiculopathy adequately. Because this category of patients requires a complete facetectomy with resultant iatrogenic instability, fusion is required under these circumstances. [21]

In summary, spine surgery is highly effective at improving symptoms of lumbar radiculopathy. Both decompression alone and fusion surgery result in favorable clinical outcomes when these procedures are used for the appropriate patients.

Efficacy Question 2 (EQ2). In adults with symptomatic lumbar radiculopathy, does effectiveness or comparative effectiveness of surgical interventions vary for difficult subpopulations?

Symptomatic lumbar radiculopathy is caused by compression of a lumbar nerve root. Compression of the nerve may have a variety of causes including a herniated lumbar disc, synovial cyst, ligamentous hypertrophy, foraminal stenosis, or instability. Ultimately, the goal of surgical intervention is to decompress the nerve root to relieve the radicular complaint. There are a variety of methods to achieve this goal depending on the specific pathology which can include direct decompression alone, direct decompression and fusion, and indirect decompression and fusion. The most common etiology of lumbar radiculopathy is a herniated lumbar disc, and the most basic surgical treatment for this pathology is a laminotomy with discectomy. To simplify the question of whether the effectiveness of surgical intervention varies for different subpopulations, it is necessary to discuss the literature concerning laminotomy with discectomy.

There are three major studies that address outcomes from surgical treatment for herniated lumbar discs. The Weber trial in the 1980s followed 126 patients with lumbar disc herniation treated surgically for 10 years. The Maine Lumbar Spine study in the 1990s followed 389 patients (219 treated with surgery) for five years. Most recently, the SPORT trial in the 2000s followed 501 patients randomized into surgical and non-surgical groups as well as following an observational cohort of 743 patients for eight years. Overall, patients had improvement in their symptoms over time, with the surgical cohort having an advantage over the non-operative cohort and the surgical cohort having faster initial improvement.[21, 22]

When analyzing for subgroups performance, there were only a few notable subgroups that did not respond as well to surgical intervention. The Weber trial noted patients with psychosocial comorbidities tended to have poorer outcomes. The Maine study showed that patients on worker's compensation represented the only group that did not have a statistically significant benefit over the non-surgical cohort. The SPORT trial's analysis of patients on worker's compensation found initial benefit from surgery early but no benefit over the non-surgical cohort after two years. Importantly, no other subgroups concerning patient demographics or comorbidities demonstrated poor responses to surgery. When comparing the subgroups of tobacco use, depression, and comorbid joint disease,

there were worse outcomes for both surgical and non-surgical cohorts. Nevertheless, there remained a significant treatment benefit for the surgical cohort in these subgroups.

There are a few other studies in the literature that address possible subgroups that may respond less well to surgical decompression for radiculopathy. Voorhies et al. studied 121 patients treated with decompression for lumbar radiculopathy. They also noted the poor response to surgery for patients with psychosocial comorbidities as well as for those with axial joint pain. They found no impact on the effectiveness of surgery for comorbidities including diabetes, narcotic dependence, obesity, osteoporosis, smoking status, or prior surgery in the affected area. While this study identified two subgroups that did not respond as well to surgery, there was not a non-surgical cohort to determine whether these groups still experienced a treatment effect from surgery.[23]

Similarly, Madsbu reported that at one year following single-level lumbar microdiscectomy, nonsmokers experienced a greater improvement in ODI and other functional outcome compared with smokers. Nonetheless, smokers also experienced significant improvements.[24]

For patients with morbid obesity, Yoo et al. reported that despite an increase in operation time and EBL, there were no differences in surgical outcomes.[25] Fakouri et al. also reported no difference in radicular leg pain between obese and non-obese patients after lumbar microdiscectomy.[26] Tomasino et al. also reported that using tubular microsurgery, obese patients have similar surgical outcomes compared to non-obese patients for lumbar discectomies and laminectomies.[27] In addition, a prospective, multi-institutional comparative study showed significant improvement of pain and functional level with lumbar arthrodesis for low back pain and/or radiculopathy for morbidly obese patient, either with open transforaminal lumbar interbody fusion or minimally invasive transforaminal lumbar interbody fusion.[28]

Ibrahim et al. studied the incidence of recurrent lumbar disc herniation and factors that might predispose patients to have poor outcomes due to recurrent symptoms. No major subgroups of patients were more likely to have recurrent disc herniation with the biggest factor seeming to be the morphology of the disc herniation. Patients demonstrating a large extruded disc fragment with large annular defects were more prone to recurrent disc herniation. In managing patients with recurrent disc herniation, patients with poorly controlled diabetes tended to respond poorly to subsequent surgical interventions for recurrent disc herniation including decompression and fusion alike.[29]

Sarrami et al. evaluated outcomes in patients seeking compensation after motor vehicle collisions. While this study evaluated patients undergoing all types of lumbar surgery as a treatment for a variety of pain complaints after injury, 41% of claimants complained of ongoing radicular symptoms after surgery. This compares unfavorably with an estimated 90% success rate for treating disc herniation with microdiscectomy. However, this study is limited by analyzing a complicated population of patients with axial and radicular pain complaints treated with both decompression alone and combined decompression and fusion.[30]

Shamji et al. evaluated patients with persistent neuropathic pain following lumbar discectomy for radiculopathy. In a series of 250 patients, similar to other reports, 88% had a substantial (>50%) reduction in leg pain severity. Patients with persistent radicular complaints after surgery tended to be younger and presented with motor or sensory deficits, but there were no differences in subgroups of sex or smoking status. Importantly, even those patients with persistent radicular complaints showed clinically significant improvement in disability status.[31]

In the many studies analyzing the response of lumbar radiculopathy to surgical decompression, nearly all groups of patients show statistically significant improvement in pain and disability after surgery with advantages over non-surgical management. There is no agreement of any patient demographic groups or medical comorbidities that eliminates the treatment effect of the surgical intervention. The only exception that appears to bear out in multiple analyses is the subgroup of patients seeking or receiving compensation after an injury. Looking at this subgroup, the most positive response to surgical treatment was in the SPORT trial showing statistically significant improvement over the non-surgical cohort early but losing this treatment effect after two years. Several other studies show this subgroup having only mild benefits from surgery with many patients complaining of persistent pain and remaining unable to return to work. This finding suggests that patients with secondary gain tend to have relatively poor responses to surgical intervention which should play a role in the decision to perform surgery for this subgroup. However, the underlying pathology and disease process is no different from the rest of the population that responds well to this pathology. While one must be wary of this subgroup as being less likely to improve with surgery, patients with severe pathology and certain physical examination findings of sensory or motor deficits should still be considered for surgical intervention.

Safety question 1 (SQ1). In adults with symptomatic lumbar radiculopathy, what are the adverse events associated with surgical interventions?

Surgical intervention for adults with symptomatic lumbar radiculopathy is a low-risk procedure with an overall complication rate of less than 10% and less than 10% of patients requiring revision surgery. As with any operation, adverse events depend on the pathology, surgical technique (open microscopic vs. endoscopic vs. minimally invasive), as well as the number of levels treated, and revision vs. initial surgery.

The most common complication associated with the surgery itself is a CSF leak secondary to a dural tear, seen in 0.9-4.5% of cases. Durotomy is well known to increase in frequency when operating on patients with a history of previous decompression surgery and may be as high as 14.5%.[32] Other adverse events related to the surgery itself include injury to the nerve root (0.9-2.6%); new neurologic deficit (1.3-3%); surgical errors including wrong level/negative exploration (1-3%); post-operative wound complications include; hematoma (0.5-1.2%); and wound infections (0.5-2.1%). Medical complications such as MI, stroke, DVT, PE, acute kidney injury, and UTI are also reported but with a low incidence (0-3%).[33]

Recurrent disc herniation are possible following decompressive operations without fusions and have been reported to occur in 1.8-6.1% of cases. The overall reoperation rate for all causes ranges from 3.7-10.2%. Some patients may also re-present with a recurrent disc but may be managed conservatively and may improve without requiring a revision operation.[34, 35]

Complications from surgical treatment of radiculopathy are low and have decreased over the years with advancements in surgical technology and techniques. It remains a safe and viable option for patients who have failed conservative treatment options.

Cost question 1 (CQ1). In adults with symptomatic lumbar radiculopathy, what is the cost-effectiveness of surgical interventions?

Surgical intervention in adults with symptomatic lumbar radiculopathy is a cost-effective intervention. The cost-effectiveness of surgical versus non-operative treatment for lumbar disc herniation, a common cause of lumbosacral radiculopathy, has been evaluated previously. Tosteson et al.

evaluated the cost-effectiveness of surgical versus non-operative treatment for lumbar disc herniation over two years from the Spine Patient Outcomes Research Trial (SPORT).[36] The study was designed to limit some of the crossover problems with SPORT and utilized an as-treated methodology. Using Medicare surgery costs, a cost per quality-adjusted life years (QALY) was calculated. Costs were higher in those treated surgically than those treated conservatively, but outcomes over two years were better in the operative group. Estimated costs per QALY gained with surgery were $34,355 with an incremental Cost-Effectiveness Ratio (ICER) of $33,176. As the authors point out the QALY gained compares very favorably with other established medical and surgical interventions.

The cost-effectiveness of surgery in patients with radiculopathy with lumbar stenosis who underwent multilevel hemilaminectomy has also been evaluated. Parker et al. reported an economic analysis of fifty-four consecutive patients undergoing multilevel hemilaminectomy for stenosis-related radiculopathy after at least six months of conservative management.[37] At two years there was a mean two-year gain of 0.72 QALY. The total cost per QALY gained for multilevel hemilaminectomy was $33,700. The cost per QALY for radiculopathy secondary to stenosis at multiple levels is very similar when compared to the cost per QALY for lumbar radiculopathy secondary to disc herniation.

Hansson et al. studied the cost-utility of lumbar discectomy relative to conservative treatment. While the medical costs were higher in the surgical group when examining treatment costs in isolation of other indirect costs, when examining total cost, including disability cost, costs were lower in the surgical group. Hansson attributed this decreased cost in the surgical group to fewer recurrences and fewer permanent disability benefits. The gain in QALY was ten times higher in the patients who underwent surgery. This resulted in better cost utility for surgical treatment relative to the conservative group.[38]

Conclusion

In conclusion, surgery in patients with symptomatic lumbar radiculopathy secondary to disc herniation or stenosis represents a cost-effective treatment and compares very favorably with other accepted medical and surgical interventions. As more focus is shifted towards these procedures being performed in more cost-effective settings such as outpatient surgical centers, the cost per QALY is likely to be even lower.

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