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Subject: Draft Evidence Report for Cervical Spinal Fusion for Degenerative Disc Disease

Dear Mr. Morse:

On behalf of the Washington State Association of Neurological Surgeons (WSANS), Washington State Orthopaedic Association (WSOA), American Association of Neurological Surgeons (AANS), American Association of Orthopaedic Surgeons (AAOS), AOSpine North America, Cervical Spine Research Society (CSRS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and North American Spine Society (NASS), we would like to thank the Washington State Health Care Authority for the opportunity to comment on the draft Health Technology Assessment (HTA) draft evidence report on "Cervical Spinal Fusion for Degenerative Disc Disease." As leaders in cervical spine care, our organizations have worked with policymakers for many years to help ensure that patients have access to this important treatment when appropriate.

We appreciate the Washington State Health Care Authority's attempt to summarize the literature on surgical treatment of the cervical spine in this draft evidence report. Unfortunately, the technology assessment makes a number of critical errors, which undermine the validity of the report's analysis and strongly questions the quality of the assessment's final conclusions.

Background

Regrettably, cervical DDD is a "catch all" diagnosis, applied to a variety of different cervical degenerative conditions. This illustrates one significant failing of International Classification of Disease-9-Clinical Modification coding used in administrative data, where one code may refer to a variety of different patients. Both a young patient with a small disc bulge and mild radicular symptoms with no motor or sensory deficits, and an elderly patient with severe ossification of the posterior longitudinal ligament and advanced cervical myelopathy who is wheelchair dependent, may each be coded in administrative datasets as having cervical DDD. Hence, any literature review or assessment of administrative data must initially determine how to identify patients with separate categories of cervical symptomatology: axial neck pain, cervical radiculopathy and cervical myelopathy.

Axial neck pain, as noted in the report's Introduction, is very common and often necessitates medical evaluation. Axial neck pain may be present in cases of cervical radiculopathy or myelopathy as well. However, surgical treatment for axial neck pain in isolation is unusual. Sources for axial neck pain include cervical disc degeneration and musculoskeletal injury, as seen in whiplash associated disorders.

Cervical radiculopathy develops from focal impingement upon a nerve root producing radiating pain. While usually following a benign clinical course, cervical radicular symptoms failing to improve with conservative therapy or producing motor deficit may require operative therapy. Interestingly, the report fails to cite multiple reports published from recent randomized, prospective U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials establishing the clinical value of operative treatment in cervical radiculopathy and the maintenance of these beneficial effects at up to 6 years following surgery. These articles share rigorous study design, clear inclusion and exclusion criteria for enrolled patients and excellent follow-up rates (1-4).

Cervical myelopathy classically develops from chronic compression of the spinal cord as a result of cervical degenerative changes. Narrowing of the spinal canal produces both trophic and dynamic effects upon spinal cord morphology and vascular supply, producing neurologic loss of function. The natural history of cervical myelopathy arising from cord compression is one of gradual, steady deterioration (5). In cases of functional loss from myelopathy, recovery is difficult to predict, with many patients continuing to harbor significant deficits after surgery; a prime goal of operative intervention is prevention of further functional loss (5-7). Many operatively treated patient will only see stabilization of their symptoms, with up to 30 percent of patients in prospective studies not enjoying a return of pre-operative lost function (7).

The patient populations, indication for surgery, and goals of treatment in axial neck pain, myelopathy and radiculopathy patients are clearly distinct. Most studies focus on the evaluation and management of one of these patient populations; unfortunately, the draft HTA does not observe these distinctions, and freely mixes between the three groups of patients in their analysis. This inattention to detail and mixing of distinct clinical entities limits the value of the report's conclusions.

For instance, while the report notes that it does not include patients presenting with a primary complaint of myelopathy, a citation from Key Question #4 nevertheless uses results of a myelopathy study to predict outcomes in treatment of cervical radiculopathy patients (7). This approach produces critical errors, using outcomes for surgery from one distinct clinical entity (cervical myelopathy) to construct a value-of-care model on a completely different clinical entity (cervical radiculopathy). Further detail is provided in the comments below on Key Question #4.

Unfortunately, comparable to its lack of attention to detail in consideration of different patient populations, the report also lumps a wide variety of operative treatments for cervical degenerative disc disease together. Operative indications and expectations of patient outcome for a single level discectomy, versus a multiple level laminectomy and fusion, are as different as the patients themselves. Ignoring these clinically vital details introduces further sources of potential selection bias to the report.

Literature Quality

The choice of articles upon which the report is based is curious. There are 15 randomized, controlled trials (RCTs) listed as sources in Appendix C. However, only 6 were published in the last 10 years and most are much older. Only three of the RCTs are from U.S. centers. These unusual choices for foundational data introduce a source of bias in the report's results.

In discussing non-operative treatments, this rigorous approach to assessment of article quality was not applied. In non-operative therapies, observational case series are reported as adequate

foundation for intervention. The rationale for greater leniency in evaluation of the literature in non-operative treatments is not explained in the report. This leads to the unusual situation where uncommon conservative interventions, with limited support in the literature (e.g., chemonucleolysis, coblation nucleoplasty), are placed upon equal literature-based footing with anterior cervical discectomy and fusion -- an operative treatment with over 60 years of clinical experience. This illustration of further potential confirmation bias questions the validity of the report's conclusions.

There have been a number of recent cervical arthroplasty versus cervical fusion prospective, randomized, FDA sanctioned, IDE studies published in the literature. The report notes these were not included in this assessment due to some of these articles being previously reviewed by the Washington State HCA. However, the goal of this report is to evaluate the effect of surgical fusion on the clinical outcomes in patients with cervical degenerative disease, not to update previous Washington State HCA publications. While some of these articles may have been previously reviewed in other HCA processes, they are still material to this assessment and failing to include them is a source of bias in this report.

We believe these findings indicate deficiencies not in the extant literature, but rather in the choice of articles summarized in the report. We feel this represents another potential for confirmation bias.

Moving beyond these preliminary observations, the remainder of our comments will address each of the report's Key Questions.

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Key Question #1: Evidence on Comparative Clinical Effectiveness

Beginning with the language of KQ1, there is significant ambiguity as this is a broad topic: “What is comparative clinical effectiveness of cervical fusion for DDD relative to that of conservative management approaches, minimally-invasive procedures, and other forms of surgery?” Examples of each of these interventions are described in the policy put forth by the HTA, and are further detailed below. Per the HTA brief, the policy presents a consensus where “...the focus of this appraisal was on adults (>17 years of age) with cervical DDD symptoms, including neck pain, arm pain, and/or radiculopathic symptoms...[and] did not include myelopathic patients...” Below, the provided comparators are broken down and medical care concerns identified.

Cervical Fusion

Cervical fusion surgery is not a distinct clinical term. In patients undergoing cervical fusion, many factors may impact clinical outcomes. Not only do the number of levels involved potentially affect patient results, but so do approach (anterior only, posterior only, anterior and posterior), whether procedures are completed with or without discectomy, with or without laminar decompression, with or without interbody fusion, with or without corpectomy, with or without bone fusion and with or without instrumentation. When instrumented, great heterogeneity exists in types of instrumentation employed. For example, in posterior instrumentation there is variability in lateral mass plates versus lateral mass screws, pedicle screws, facet screws and spinous process wiring. The phrase “cervical fusion” is therefore extremely broad and encompasses a huge variety of patients.

Conservative Therapy

Options provided by HTA include physical therapy, cervical collar immobilization, spinal manipulation (chiropractic), medication (analgesics, muscle relaxants, opioids), alternative therapy (yoga, acupuncture) and self-care (educational materials, home stretching). These represent a variety of nonsurgical options available for consideration for the management of cervical spondylosis and radiculopathy. The assertion stated in the HTA that all forms of conservative management (e.g., physical therapy, spinal manipulation) have approximately equal clinical effectiveness is simply not valid.

Spinal Injections

Included options provided by HTA are spinal injections of steroids, nerve blocks, chemonucleolysis and botulinum toxin. The use of epidural steroid injections in the cervical spine is much more technically challenging and involves higher risk due to anatomical concerns. There are very limited numbers of providers able to do cervical epidural steroid injections (ESI), and as such there is significant limitation to patient access. The risks are higher than in the lumbar spine because of the presence of the cervical spinal cord and the smaller allowable volume. Selective nerve root blocks (SNRB) in the cervical spine likewise have high risk challenges for the provider and patient due to anatomy. Additionally, even if a patient consents to this treatment by someone willing and able to provide the cervical steroid injection (whether ESI or SNRB), these often involve multiple injections over the course of a year or more; thus it is not necessarily a one-time cost.

Finally, the risk of steroid injections in the central nervous system was brought into sharp focus recently when a large number of patients died from contaminated product. This has further limited the enthusiasm of patients and providers to use this therapeutic option. Chemonucleolysis, when chosen, is a technique typically used in the lumbar spine to manage disk degenerative issues, and is more akin to the next section, which addresses minimally invasive/percutaneous procedures. While botulinum injection can be very helpful for dystonia/torticollis that can cause neck pain, or even exacerbate cervical degenerative issues including radiculopathy, using botulinum toxin alone is not indicated for classic radicular pain of the arm/hand -- and, in fact, has been cited to cause cervical

radiculopathy as a complication of its use in treatment of dystonia (1). There are no articles in the past decade of PubMed listings to support this use.

Minimally Invasive Procedures

Less invasive procedures listed by the HTA are radiofrequency ablation and coblation nucleoplasty. These listed procedures are better labeled as percutaneous procedures, since they do not have the visualization, intensity, outcomes or acceptance similar to surgical interventions (i.e., open, minimally-invasive and mini-open surgical techniques are much more similar to each other than the percutaneous techniques). Radiofrequency ablation, chemonucleolysis and coblation nucleoplasty are not generally used in the management of cervical disk degeneration with radiculopathy.

In a PubMed search, few recent articles support these treatments for radiculopathy. Rather, these procedures are more typically used, if chosen, in the lumbar spine. Because of the anatomy involved (i.e., spinal cord, vascular anatomy, smaller epidural space and smaller disk space), they are not typically performed in the cervical spine. Radiofrequency ablation therapies may be used in facetogenic pain, which is a potential contributor to neck pain, but this is a scenario different than the one indicated by the HTA. We agree with the statement that “no comparative data were available comparing fusion to minimally-invasive nonsurgical management options such as spinal injections, RFR or coblation nucleoplasty.”

Other Surgeries (Non-fusion Surgeries)

As noted in the HTA, non-fusion surgeries include discectomy, foraminotomy and laminectomy/laminoplasty. The examples given for these procedures in the HTA are, however, confounded by heterogeneity. Discectomy can be achieved ventrally or posteriorly (the latter in very select scenarios). As compared to the lumbar spine, a discectomy via a posterior approach in the cervical spine is a more complex technical issue and entails greater risk given the anatomy of the spinal cord and nerve root in such a small space as the cervical canal. It can therefore only be used in select patients with more laterally-positioned soft discs. Foraminotomy may be a component of laminectomy, laminotomy or laminoplasty, and may or may not also be done with discectomy – in the vignette describing foraminotomy as provided by the HTA, discectomy is described with it. Inconsistencies in describing the procedures, or intent of procedures, muddy the interpretation. Foraminotomies can also be done via a ventral approach. Decompression of the central canal by laminectomy or laminoplasty is not the typical procedure for management of cervical radiculopathy – decompression of the central canal is the typical procedure for cervical stenosis/myelopathy. Laminectomy or laminoplasty combined with foraminotomy and or discectomy is the more typical posterior approach for management of radiculopathy, when a posterior approach is chosen. To combine this variety of “other” non-fusion surgeries into an arbitrarily singular category limits the clinical relevance of these observations.

Some application of the data chosen to support the position statements of the HTA are flawed (see KQ 4). With respect given to ICER’s definitions of quality, the majority of the cited articles are Levels III/IV evidence. Most of the studies cited by the HTA are not RCTs, and none are Level I evidence.

When conservative measures fail, or when significant neurologic impairment exists, surgical intervention is reasonable to consider. Neck pain alone is not considered a typical indication for operative therapy. Anatomic considerations and surgeons’ experiences must factor into decision of approach. The goal of surgical intervention is protection and decompression of neural elements while ensuring spinal stability. The HTA also describes radiographic evidence of radiculopathy: radiculopathy is a clinical diagnosis; radiographic studies can confirm or negate the working hypothesis that a compressive phenomenon exists. When compression of the nerve root is confirmed, surgery can be an appropriate option. Not every radiculopathy co-exists with an

identifiable compressive phenomenon; in such situations, various conservative measures including those listed in the HTA may provide benefit.

While it is true that not all non-surgical measures are equal, so too is it true that not all surgical measures are equal. Having varied approaches for assorted patient needs is of the utmost consideration of a physician/surgeon.

Previously Developed Guidelines

What other information is available? In utilizing evidence-based medicine techniques, in the last three years, there are two major guidelines published regarding the management of cervical radiculopathy, and these are available online from the National Guideline Clearinghouse and the National Quality Measures Clearinghouse/AHRQ. The first is from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS). In August 2009, the AANS and CNS jointly published guidelines regarding the diagnosis and treatment of cervical radiculopathy in patients with degenerative disorders. This squarely fits the stated intentions of this Washington State HTA. Management, surgical and nonsurgical and functional outcomes are analyzed in a consistent and structured fashion, and the data behind the guidelines and recommendations are amassed in the August 2009 issue of the *Journal of Neurosurgery Spine* (2). Additionally, in January 2011, the North American Spine Society (NASS) published additional clinical guidelines entitled "Evidence- Based Clinical Guidelines for Multidisciplinary Spine Care Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders." in the *Spine Journal* (3). The AANS/CNS guidelines report found level 1 literature evidence for superior clinical efficacy of anterior cervical decompression and fusion in comparison to conservative therapy in patients with radiculopathy from cervical degenerative disease. The NASS guidelines detail further literature support for operative treatment of cervical radiculopathy.

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Key Question #2: Adverse Events and Other Harms Associated w/Cervical Fusion

The draft report reviews several RCTs and comparative cohort studies in order to determine the incidence of potential harm after surgical treatment for cervical DDD. While it is clear that surgery of any kind introduces risk, determining the true incidence of adverse events after surgery is complex. This Washington State HTA's approach to addressing surgical risk for cervical DDD is inherently limited as it assumes that cervical DDD is a single disease entity with: a) uniform risk factors for adverse events; and b) that various surgical treatment approaches carry similar and equivalent potential risk.

Cervical DDD is not a singular disease but a diagnosis associated with a larger spectrum of clinical conditions, which can include myelopathy, radiculopathy, axial neck pain, or can be asymptomatic. As such, the underlying patient's condition and pre-existing disability not only factor into the indication for surgery, but also significantly impact surgical morbidity. Wang, et al in a review of 932,009 hospital discharges with the diagnosis of cervical DDD from the Nationwide Inpatient Sample (NIS) found an overall low rate of complications and mortality after cervical spine surgery (1). Notably however, they observed that the most significant factor in determining morbidity and mortality after surgery was associated preoperative myelopathy. The impact of pre-existing disability on surgical morbidity has similarly been reported in other observational studies (2, 3). Therefore, in determining risk of surgery for cervical DDD, combining disparate study populations from multiple RCTs and comparative cohort studies leads to variable, inconclusive results.

There are various potential surgical approaches for patients with symptomatic cervical DDD, with surgical decision-making dependent on the patient's underlying condition, age, comorbidities, spinal alignment, and extent of involved levels (among other factors). Large NIS observational studies confirm that the type of surgery performed is frequently correlated with these patient factors (1, 4, 5), thereby creating uniquely different risk profiles. Surgical risk can be categorized as those inherent to the type of procedure, and those incurred secondary to the severity of the underlying condition. For example, hoarseness is a known, yet infrequent, complication associated with anterior cervical surgery that does not occur after posterior surgery. Alternatively, posterior cervical surgery is often preferred in patients with myelopathy, multilevel disease and advanced age, and is associated with higher risk than anterior surgery for less severe conditions. Therefore, the risk for a given adverse event (e.g. hoarseness) or the overall cumulative surgical risk may be markedly different for anterior versus posterior surgery. Lumping these procedures together when reporting potential harm thus results in misleading and invalid conclusions.

Certain adverse events are unique to fusion surgery and warrant critical evaluation. As this HTA points out, pseudarthrosis is intrinsic to fusion procedures and can be considered a potential harm as it may lead to disability or need for reoperation. The impact of these surgical risks, however, must be weighed against the consequence of the underlying disease if left untreated. In 2009, the AANS/ CNS Joint Section on Disorders of the Spine and Peripheral Nerves performed an evidence-based review and formulated guidelines regarding the management of cervical DDD. They found the natural history of untreated patients with severe, long-standing cervical spondylotic myelopathy demonstrates stepwise worsening deterioration without improvement (6). Progressive myelopathy not only impacts individual disability, it creates a heavy burden on caregivers and society. Therefore, while surgery does carry a small risk of adverse events such as pseudarthrosis and reoperation, this must be viewed in light of the improved quality of life and reduction in socioeconomic costs with proper surgical treatment (7).

Last, this HTA points out the challenge of determining surgical risk using the available literature. RCTs are often too small to capture reliable data on complications that occur infrequently. Traynelis, et al in a review of 720 patients undergoing cervical spine surgery reported only a 0.4 percent risk for new postoperative neurologic deficit (8). The number of subjects necessary to conduct a comparative effectiveness trial with respect to potential harm would be unfeasible at that low incidence. Further, the exclusion criteria of many RCTs eliminates patients with significant disability or who are otherwise at high risk, thereby resulting in a subject group that does not accurately reflect the as-treated patient population. Alternatively, although large administrative patient databases such as the NIS allow for analysis of considerable numbers of cases, they have limitations including variations in reporting, sampling bias, coding inconsistencies, and the inability to determine causal relationships between diagnosis, interventions, and outcomes. Moving forward, multicenter prospective clinical outcomes registries will likely provide us with the necessary information for better defining risk of adverse events with accurate generalizability.

We applaud the efforts of the HTA for reviewing the literature and attempting to ascertain surgical risk associated with cervical DDD. While it is clear that overall complications are rare, based on the reasons outlined above, it is unlikely that we will be able to come to any significant useful conclusions regarding potential harm using the present analysis.

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Key Question #3: Effectiveness and Safety of Cervical Fusion vis-à-vis Certain Factors

Single versus 2-Level Surgery

The authors make reference to a 1976 RCT comparing ACDF to posterior discectomy with foraminotomy, and report the conclusion that for single level disease, the fusion group did better, but for 2 level disease, the posterior non-fusion group did better. It is important to recall that this paper compares the Cloward technique to the posterior decompression. This operative approach to anterior cervical discectomy predates the use of plate fixation and is no longer routinely used. There is a known incidence of cervical kyphosis using the Cloward technique without anterior plate fixation (1). A two-level Cloward operation without a plate could lead to even more kyphosis, perhaps negatively impacting the clinical results in these patients.

This paper does not apply to the current medical practice standards, which includes plating with two-level fusions, and hence the conclusion that posterior decompression is superior to anterior two-level fusion may not be correct using modern techniques.

Gender

Although male gender was found in the Rosensorn study to be associated with better outcomes, it does not make practical sense to favor offering fusion procedures to the male gender. The majority of patients in this study were males; hence an extended sample size and more rigorous analysis will likely rule gender out as a factor to consider in offering fusion procedures to patients. If females are denied equal access to fusion procedures, the social implications will be extreme.

Inpatient versus Outpatient Fusion

The Silvers 1996 study concluded that inpatient surgical candidates were more than twice as likely to require revision operations. There was no statistical testing on this. It makes sense that the inpatients were more likely to have revision surgeries. Most surgeons elect to perform outpatient surgery on healthy individuals with minimal or absent comorbidities (3), while inpatients are those who have multiple comorbidities and hence are more likely to experience complications leading to increased rates of re-operation.

Anterior versus Posterior Fusion

We have reviewed the studies that are reported to describe how anterior fusions lead to fewer complications when compared to posterior fusions. Most surgeons will agree that anterior cervical fusions have superior clinical outcomes when compared to posterior cervical fusions; however the vast majority of posterior cervical fusions are for patients that have 4-8 levels being fused. It is very important to compare fusion levels when making such a comparison. The Shamji study did not evaluate which levels were being fused, and the posterior group is very likely to include patients with more pathological levels and more multiple comorbidities. Most surgeons resort to a posterior approach when more four or levels need be performed, intraoperative time is shorter and dysphagia requiring peg tubes less likely. The Shamji study confirmed the greater incidence of dysphagia in the anterior group (2). There usually are very concrete and distinct reasons to either perform an anterior or posterior fusion or both, and it is extremely difficult to make a blanket statement that favors one approach over another other, as each patients pathology location differs.

Duration of symptoms

We agree that increased duration of symptoms prior to surgery often lead to worsening outcomes. We often recommend surgical intervention prior to the completion of conservative treatment measures for fear of this phenomenon. It is not unusual for us to encourage patients to come to the ER for expedited treatment in the setting of a patient who has been denied coverage for an operation.

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Key Question #4: Cost of Cervical Fusion versus Alternative Treatments

Regarding clinical effectiveness, throughout the draft report, studies examining patients with cervical myelopathy are combined with analyses examining patients with and without radiculopathy (i.e. neck pain only). Combining three very different diseases (radiculopathy, myelopathy and neck pain with radiographic signs of DDD) is not clinically appropriate. In particular, degenerative disc disease (DDD) is a radiographic entity and not a clinical spine diagnosis per se.

Although cervical myelopathy is given as an exclusion criterion, many studies including myelopathy are included in the evidence review and results. Separate reports should be created for these three very distinct diseases; they should not be lumped together.

With regards to the Markov decision model which estimates the probability of events (one of four outcomes) and assigns an estimated utility and cost to those four outcomes, the clinical inputs and evidenced-based assumptions are flawed. The model is only as strong as the evidence that drives the assumption and the likelihood of a particular outcome. Because all other values that are estimated downstream are based on whether one treatment or another makes a patient better, worse, the same, or results in death, these downstream statistical "adjustments" do not overcome the errors made upstream. In fact, this "frame-shifting" leads to a dramatic negative effect on the integrity of the analytical output.

The largest error we have identified relates to the clinical inputs that drive the model on the probability of the four outcomes. The model is based on the assumption that the percentage of patients getting worse, better or same after surgery for DDD (with associated radiculopathy) will be similar to the Kadanka (2002) paper (1). Table 8 is identical to Kadanka 2002. However, the Kadanka paper is a study of myelopathy, not neck and arm pain. Importantly, Kadanka, et. al. reported better, same and worse outcomes for treatment of myelopathy (and based on myelopathy specific -- i.e., spinal cord -- function), not DDD associated neck pain or arm pain. Therefore, the model of probabilities of outcome is based on the wrong disease and the wrong endpoint (spinal cord function) for better/worse/same.

We also note inaccuracies in the assignment or estimations of utility (QALY-gain) for cervical surgery. The QALY health state for pre-treatment DDD (with radiculopathy) associated neck pain is based on population norms for "neck pain" patients in general from large population surveys (2). Again, these are not surgically relevant patients, nor is there any evidence that these patients have DDD or radiculopathy. Based on the prevalence of various forms of cervical disease, this baseline population norm reference more likely reflects "neck strains" than DDD with radiculopathy. Furthermore, the assumed utility or QALY-gain or loss for better/worse/same outcome was based on Van der Velde et al. study (3). The +/-0.9 utility assigned in the model and from the Van der Velde study was what was reported for general neck pain patients in a pain clinic when they were asked whether they had "no troublesome neck pain" = 0.80 QALY or "yes, troublesome neck pain" = 0.71 QALY- regardless of type of medical treatment or whether they ever had neck treatments (Table 1 of Van der Velde). In fact, there is no evidence that this utility was applied in patients with DDD (with or without radiculopathy) associated neck pain. Neck pain does not, by definition, represent the disease being studied in the report. Neck pain is a symptom, not a disease. To further the analogy, "cough" does not necessarily equate to lung cancer. Cough is a symptom of pneumonia, viral flu, allergy, or cancer. Utility of treatment of cough is not a valid proxy for utility of treatment for lung cancer.

The Value of a treatment is most dependent on the effectiveness of that therapy versus that of an alternative. The definition of effectiveness likelihood (Kadanka 2002) and assignment of utility values (Van der Velde) to represent Utility are both flawed in this analysis. The model does not accurately estimate the parameters of benefit in the [benefit/cost] value equation.

The flaws in the benefit estimation are insurmountable and produce extremely misleading results.

References

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Conclusion

On behalf of the undersigned organizations and the surgeons and patients we serve, we thank you for the opportunity to comment on the Washington State Health Care Authority's Health Technology Assessment on Cervical Spinal Fusion for Degenerative Disc Disease. It is imperative that patients have a wide range of treatment options available to them, and so we encourage you to carefully consider our comments and amend the draft report accordingly. **We therefore specifically request that as the Health Technology Clinical Committee considers its recommendations regarding the surgical treatment for cervical degenerative disease, that careful consideration be given to the multispecialty guidelines recently published by the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves and NASS.** These guidelines are referenced in the responses to Key Question #1 above and attached herein.

If you have any questions or need additional information, please do not hesitate to contact us. In the meantime, we look forward to the opportunity to present our views in person at the March 22, 2013 Health Technology Clinical Committee meeting.

Sincerely,



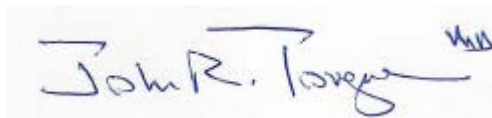
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Indications for anterior cervical decompression for the treatment of cervical degenerative radiculopathy

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Object. The objective of this systematic review was to use evidence-based medicine to identify the indications and utility of anterior cervical nerve root decompression.

Methods. The National Library of Medicine and Cochrane Database were queried using MeSH headings and key words relevant to surgical management of cervical radiculopathy. Abstracts were reviewed after which studies meeting inclusion criteria were selected. The guidelines group assembled an evidentiary table summarizing the quality of evidence (Classes I–III). Disagreements regarding the level of evidence were resolved through an expert consensus conference. The group formulated recommendations that contained the degree of strength based on the Scottish Intercollegiate Guidelines network. Validation was done through peer review by the Joint Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons.

Results. Anterior nerve root decompression via anterior cervical discectomy (ACD) with or without fusion for radiculopathy is associated with rapid relief (3–4 months) of arm/neck pain, weakness, and/or sensory loss compared with physical therapy (PT) or cervical collar immobilization. Anterior cervical discectomy and ACD with fusion (ACDF) are associated with longer term (12 months) improvement in certain motor functions compared to PT. Other rapid gains observed after anterior decompression (diminished pain, improved sensation, and improved strength in certain muscle groups) are also maintained over the course of 12 months. However, comparable clinical improvements with PT or cervical immobilization therapy are also present in these clinical modalities (Class I). Conflicting evidence exists as to the efficacy of anterior cervical foraminotomy with reported success rates of 52–99% but recurrent symptoms as high as 30% (Class III).

Conclusions. Anterior cervical discectomy, ACDF, and anterior cervical foraminotomy may improve cervical radicular symptoms. With regard to ACD and ACDF compared to PT or cervical immobilization, more rapid relief (within 3–4 months) may be seen with ACD or ACDF with maintenance of gains over the course of 12 months (Class I). Anterior cervical foraminotomy is associated with improvement in clinical function but the quality of data are weaker (Class III), and there is a wide range of efficacy (52–99%). (DOI: 10.3171/2009.3.SPINE08720)

KEY WORDS • cervical spine • foraminotomy • practice guidelines •
radiculopathy • surgery

Recommendations

Indications: Cervical Radiculopathy. Anterior surgical nerve root decompression via ACD with or without fusion in patients with cervical radiculopathy is recom-

mended for the rapid relief (within 3–4 months) of arm and neck pain, weakness, and/or sensory loss compared to PT or immobilization with a cervical collar. Anterior surgical nerve root decompression is recommended for longer term (12 months) improvement in wrist extension, elbow extension, and shoulder abduction, and internal rotation compared to PT. Other rapid gains observed after anterior decompression (diminished pain, improved sensation, and improved strength in certain muscle groups) are also maintained over the course of

Abbreviations used in this paper: ACD = anterior cervical discectomy; ACDF = ACD with fusion; ACF = anterior cervical foraminotomy; ADL = activity of daily living; CCI = cervical collar immobilization; NDI = Neck Disability Index; PT = physical therapy; VAS = visual analog scale.

Anterior cervical decompression for radiculopathy

12 months. However, at the 12-month time point, comparable clinical improvements with PT or cervical immobilization therapy are also present in these clinical modalities. One caveat is that this recommendation is based on only 1 of several variables that may be important to the patient. Furthermore, there is insufficient data to factor in the cost of complications and any undesirable long-term effects related to the specific surgical intervention, such as adjacent-segment disease (quality of evidence, Class I; strength of recommendation, B).

Indications: Cervical Radiculopathy. Anterior cervical foraminotomy with attention to disc preservation is recommended in the treatment of cervical radiculopathy for relief of arm/neck pain, weakness, and/or sensory loss. However, conflicting evidence exists as to its efficacy with success rates of 52–99% reported. Recurrent symptoms have been reported in as many as 30% of patients (quality of evidence, Class III; strength of recommendation, D).

Methods. Methods will be addressed in the chapter on surgical techniques to treat anterior cervical radiculopathy.

Timing. There is insufficient evidence to make a recommendation regarding timing.

Rationale

Cervical radiculopathy presents with a combination of arm pain, sensory dysfunction, and motor function loss. Also common is associated neck pain. In the acute phase, nonoperative management is the mainstay, with success rates averaging 90%.¹⁶ Wainner and Gill²⁴ performed a systematic review of the diagnosis and nonoperative management of this disease and found that the course may often be favorable. However, these authors also noted that no clear prognostic factors had been delineated, nor had the efficacy of nonoperative therapy been well defined.²⁴

The purpose of this chapter is to provide an evidence-based review of the efficacy of anterior surgical nerve root decompression for radiculopathy. When clinical cervical radiculopathy is present with active nerve root compression visible on diagnostic imaging, the clinician often recommends surgical decompression if nonoperative measures have failed. Options for decompression include anterior or posterior approaches. The efficacy of posterior cervical nerve root decompression is reviewed elsewhere. The anterior approach has typically involved removal of the vast majority of disc material with or without subsequent fusion.^{3,15} Anterior cervical decompression without substantial disc removal or fusion has also been reported.^{2,9,23}

Search Criteria

We completed a search of the National Library of Medicine (PubMed) and the Cochrane Database for the period from 1966 through 2007 using both key words and associated MeSH subject headings. A search of “intervertebral disk displacement (Mesh)” and “cervical vertebrae (Mesh)” and “decompression, surgical (Mesh)” yielded 63

citations. “Anterior discectomy” and “outcome” yielded 296 citations. “Anterior cervical” and “decompression” yielded 890 citations. “Anterior cervical” and “decompression” and “outcome” yielded 335 citations. “Anterior cervical decompression” and “randomized trial” yielded 18 citations. “Anterior cervical discectomy” and “clinical trial” yielded 100 citations. “Anterior cervical foraminotomy” produced 58 citations.

For literature on cervical radiculopathy, we searched “radiculopathy (Mesh)” and “therapeutics (Mesh)” and “outcome assessment (Health Care),” which produced 83 citations. “Cervical radiculopathy” and “randomized controlled trial” produced 37 citations. We reviewed titles and abstracts with attention to those titles addressing trials comparing surgery to nonoperative management; we also found 1 Cochrane review that addressed the subject.

We selected articles if they clinically compared one treatment pathway to the other. We examined articles that contained information on only 1 technique if large numbers of patients were involved (typically > 40 patients) or if quantitative data were presented; this was decided on an ad hoc basis. We then compiled evidentiary tables (Tables 1 and 2) based on the resulting list of 23 studies that met our criteria. One randomized controlled trial and 1 systematic review examined ACD compared to PT or CCI (Table 1). The remaining studies examined large series pre- and postoperatively. The authors of 6 studies (Table 2) examined the technique of ACF.

Scientific Foundation

Critical Examination With Control Groups

Fouyas and colleagues⁵ completed a systematic review of surgery for cervical myeloradiculopathy. On completion of rigorous search and screening techniques, 2 articles met the criteria, 1 of which dealt with radiculopathy (the other was myelopathy). The authors completed appropriate tests for heterogeneity. The review used the random effects model to weight the treatment effects. It was uncertain how much weighting the random effects model achieved because only 1 study that analyzed radiculopathy was included. With respect to anterior decompression and radiculopathy, surgery appeared to improve pain (current) and sensory dysfunction at 3 and 4 months, respectively, compared to PT ($p < 0.05$) or CCI (pain, $p < 0.001$; sensory, $p < 0.05$). Compared to CCI, improvement was seen for “current” and “worst” pain. These effects dissipated at 1 year ($p = 0.5$) in all categories.⁵

The studies reviewed by Fouyas and colleagues⁵ were those of Persson et al.^{19,20} Using sealed envelopes, this study randomized 81 patients with cervical radiculopathy defined by clinical examination and radiological studies to surgery, PT, or CCI groups, 27 patients per group. Surgery was done via ACD with Cloward fusion. Evaluation was performed at 3–4 months after surgery and 12 months. This study evaluated patients clinically using the Mood Adjective Check List, Hospital Anxiety/Depression Scale, the Coping Strategies Questionnaire, VAS pain score, and the Disability Rating Index. The authors assessed strength using a dynamometer and a device to

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome*

| Authors & Year | Description | Results | Class | Conclusions |
|-----------------------|--|---|-------|--|
| Fouyas et al., 2001 | Systematic review of studies examining surgery for cervical myeloradiculopathy. Rigorous protocol of searching & screening. | 2 studies dealt w/ radiculopathy & 1 w/ myelopathy. W/ respect to radiculopathy, surgery seemed to improve pain & deficits more quickly in the short-term (3 mos; $p < 0.05$) but results equal by 1 yr ($p = 0.2$). | I | Because many of the study parameters were equivalent at 12 mos (despite the significant clinical improvements w/ surgery at 3–4 mos), the authors concluded that the randomized trial did not provide enough reliable evidence on the beneficial effects of surgery for cervical radiculopathy. |
| Persson et al., 1997 | 81 patients w/ cervical radiculopathy (duration >3 mos) followed at 4 & 12 mos w/ VAS, hand strength dynamometer, & sensory testing. Randomized to surgery, PT, or CCI (n = 27). | Surgery group had improvement in mean current pain w/in group ($p < 0.01$); worst pain w/in wk was significantly improved w/ surgery or PT compared to CCI group at 4 mos ($p < 0.01$). No changes at 12 mos. At 4 mos, surgery had improved power relative to non-affected size in several muscle groups compared to PT or CCI. At 12 mos, this was true compared to PT only. Absolute muscle testing showed improvement at 4 mos w/ surgery compared to PT & CCI which did not persist at 12 mos. Paresthesias improved at 4 mos w/ surgery; improvement did not persist at 12 mos. | I | Surgery improves strength, sensation, & pain significantly at 4 mos. Improvement in pain & sensation does not significantly last after 4 mos. Class I: randomization w/ allocation concealment. Reliability for outcome tests. |
| Persson & Lilja, 2001 | 81 patients w/ chronic cervical radiculopathy (>5 mos), FU for 3–12 mos w/ MACL, HAD, CSQ. Pain measured w/ VAS & DRI. Randomized to surgery, PT, or CCI (n = 27 each) w/ FU at 3 & 12 mos. | Intention-to-treat analysis. Groups equivalent, but nonsmokers had less pain intensity ($p < 0.01$). W/ respect to pain intensity, surgery better than CCI at 3 mos ($p < 0.01$) but no group differences at 12 mos. MACL showed no group differences & no improvement. Age & duration did not correlate. Pain correlated w/ anxiety & depression in all groups over all time points. DRI showed surgery improved 'heavy work' & dressing persisting over 12 mos. | I | Chronic radicular pain associated w/ low mood state, anxiety, & depression which persist over 12 mos despite treatment. Coping was also poor. Surgery improved pain compared to collar but differences diminished at 12 mos. Class I study shows that surgery improves pain sooner but results similar at 12 mos w/ diminished chronic mood state. |
| Amasson et al., 1987 | 114 patients underwent either conservative (n = 33), anterior surgery (n = 37), or posterior surgery (n = 44). FU available for conservative (n = 24) or anterior (n = 35). Outcome was better, the same, or worse. Anterior surgery mostly ACD. | Local neck pain improved in 43% of patients w/ conservative & 55% of patients (only present in 29) w/ anterior surgery. Radicular pain improved in 19% of those w/ conservative (only present in n = 15) vs 71% w/ anterior surgery. | III | Anterior surgery is better than conservative therapy for anterior radiculopathy. Class III due to no statistics & selection bias. Surgeon & patients determined grouping & treatment. |
| Sampath et al., 1999 | 246 patients in CSRS study cohort w/ cervical radiculopathy; data were compiled from surveys of patients & physicians w/ outcome compiled from surveys. | Surgery recommended in 35% (86); FU in 155/246. FU in 51 (33%) surgery, & 104 nonoperative (67%). Pain scores improved in surgery & medically treated groups (1.6 vs 1.04). Neurological function improved 0.28 vs 0.64 (significant for surgery). Functional status measures improved in both medical & surgical patients (0.57). ADLs improved significantly in surgery group only. | III | Pain & functional status improves w/ medical & surgical treatment. Neurological function & ADLs improve more this surgery. Excruciating pain persisted in 26% surgery at FU. Class III: patients not randomized, treatment selected by physician. Uncertain whether patients were eligible for same treatment. |

(continued)

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome* (continued)

| Authors & Year | Description | Results | Class | Conclusions |
|---------------------------|---|---|-------|---|
| Klein et al., 2000 | 28 patients underwent ACDF for radiculopathy. Evaluation by Health Systems Questionnaire 2.0 at 21 mos. 1- or 2-level surgery, average age 44. Odom's criteria also used. | Significant improvements in physical function (p = 0.01), social function (p = 0.0004), physical role function (p = 0.0003), fatigue (p = 0.003), bodily pain (p = 0.0001). No difference in general health, mental health, or emotional role function. Good or better result in 93%. | III | Anterior decompression for radiculopathy is associated w/ improvement in physical & social function w/o overall general or mental health change. Class III. No reliability tested; no control group. |
| Bohlman et al., 1993 | 122 patients w/ radiculopathy as defined by arm pain and/or neurological deficit. ~ 60% had spondylosis. All treated w/ ACDF. | 108 patients had good functional improvement w/ 81 having resolution of pain. Age, smoking, & Workers' Compensation status did not affect outcome. | III | Anterior decompression is effective therapy for cervical radiculopathy. Class III due to large case series. |
| Pointhillart et al., 1995 | 68 patients w/ cervical radiculopathy secondary to soft cervical disc herniation treated w/ ACDF. FU in 57 patients averaging 23 mos. Odom's criteria & radiographic outcome. | Good or better outcome in 92%; fusion in 33%; dynamic radiographs indicated only 2° of motion. Complications & reoperations in 3 of 57 who underwent FU. | III | Anterior decompression is effective therapy for radiculopathy from soft disc herniation. Class III due to large case series. |
| Brigham & Tsahakis, 1995 | 43 patients w/ radiculopathy w/ pain, dysesthesia, or weakness (duration 5.8 mos). Surgery ACDF for a mix of spondylosis & soft disc. 1-level (27) & 2-level (16). FU was 14 mos w/ Odom's criteria. | Good or better arm pain relief in 91% (excellent 77%). Neck pain relieved in 32/36 (82%). Minimal functional limitations in 93% (none in 77%). Complications related to graft in 3/43. | III | Arm pain & neck pain significantly improved w/ anterior decompression. Class III due to case series. |
| Heidecke et al., 2000 | 106 patients underwent Cloward fusion (145 levels) for radiculopathy (n = 28) or myeloradiculopathy (n = 78). Outcome 1, 3, 12 mos & 6.5 yrs w/ late questionnaire. Outcome also was judged good, fair, poor based on deficits. | Short-term pain improved in 26/28 (92.1%) & remained improved long-term (6.5 yrs). Satisfaction in 92.1%. Complications mostly pain related due to graft site. | III | Anterior decompression improves radiculopathy pain in >90%. Class III due to case series. |
| Gaetani et al., 1995 | 153 patients w/ cervical degenerative disease. Radiculopathy in 108 the vast majority of whom received ACD. FU 1-10 yrs using Odom's criteria. | Good or better outcome in 90.9%. Age, duration of symptoms, & disc pathology (soft vs rigid) did not affect outcome. | III | Anterior decompression is effective therapy for radiculopathy. Age & duration of symptoms do not correlate w/ outcome. Class III due to large case series. |
| Kozak et al., 1989 | 47 patients w/ cervical spondylosis & radiculopathy underwent ACDF. FU averaged 15 mos w/ 40/47 FUs. | Good or better outcome in 83% w/ fusion in 87%. Fusion status did not correlate w/ outcome. | III | Anterior decompression is effective therapy for cervical radiculopathy from spondylosis. Fusion status does not correlate w/ outcome. Class III due to large series. |
| Ylinen et al., 2003 | 71 patients w/ 1-level cervical disc disease who underwent ACDF; FU in 53 & compared to 53 healthy volunteers. Pain assessed w/ VAS, grip strength w/ dynamometer, & neck power w/ isometric. | Mobility (ROM) & isometric strength was diminished in the ACDF group (p < 0.001) compared to controls. Grip strength no difference (p = 0.16). 43% of ACDF patients had severe pain. Pain was associated w/ diminished ROM & strength. | III | ACDF is associated w/ diminished ROM & strength compared to normal controls. This can, occasionally, be associated w/ prolonged pain. Class III due to case-control series whose control did not have the underlying disease. |
| Lunsford et al., 1980 | 295 patients w/ cervical radiculopathy, soft disc (n = 101) or spondylosis (n = 194) treated w/ anterior decompression (ACD/135 or ACDF/108) w/ 253 FUs. | 67% noted good or better results w/ 16% poor results. Outcome did not differ between soft or hard disc (p = 0.556). Recurrence of symptoms in 38% & did not differ between soft & hard disc (p = 0.897). However, only 4% of patients needed reoperation. | III | Anterior cervical decompression results in generally good improvement but moderate chance of recurrence of symptoms. Class III: selection bias due to uncertainty as to how patients were chosen for ACD or ACDF. Nonvalidated outcome measure w/o blinded observers. |

(continued)

TABLE 1: Evidentiary summary of studies examining anterior decompression through disc removal and outcome* (continued)

| Authors & Year | Description | Results | Class | Conclusions |
|-----------------------------|--|---|-------|---|
| Nandoe Tawarie et al., 2007 | >400 patients w/ cervical radiculopathy who underwent ACD. FU over several years w/ questionnaire & chart review. NDI as FU. | FU at 6 wks indicated >90% of patients satisfied. Late phone survey FU in 102 patients w/ 67.6% having no recurrence of symptoms. However, 11% were worse. Complication rate was 10.3%. NDI would increase 0.75 points/yr on average. | III | ACD improves pain early but slow recurrence of pain develops over years. Class III due to series. |
| Peolsson et al., 2006 | 34 patients w/ cervical disc disease who underwent surgery; FU 6 mos through 3 yrs using VAS, NDI, DRAM. | 28 available at 3 yrs' FU of whom 23 responded to questionnaire. VAS, neck pain, & numbness all improved (p < 0.02). No differences were evident at 3 yr compared to 6- & 12-mo results. | III | Improvement after anterior decompression; outcomes at 6 mos mirror outcomes at 3 yrs. Class III due to case series & poor FU. |

* The criteria for scoring each manuscript into a class are described in *Introduction and Methodology: Guidelines for the Surgical Management of Cervical Degenerative Disease*, which appears in this issue of the *Journal of Neurosurgery: Spine*. Abbreviations: ADL = activity of daily living; CSQ = Coping Strategies Questionnaire; CSRS = Cervical Spine Research Society; DRI = Disability Index Rating; DRAM = Distress and Risk Assessment Method; FU = follow-up; HAD = Hospital Anxiety/Depression Scale; MACL = Mood Adjective Check List; ROM = range of motion.

measure pinch strength. The study used an intention-to-treat analysis and concealed allocation.^{19,20}

With regard to the questionnaires, the groups were homogeneous at the start although nonsmokers had less pain intensity (p < 0.01). Surgery reduced VAS pain intensity at 3 months more than CCI (p < 0.01); this effect was not seen at 12 months. The Mood Adjective Check List survey did not show any differences between groups and did not improve with therapy. The severity of pain correlated with the intensity of anxiety and depression in all groups on the Hospital Anxiety/Depression Scale and Coping Strategies Questionnaire. Finally, the Disability Rating Index showed that surgery improved return to heavy work and dressing ability better than the nonoperative alternatives at 12 months.¹⁹

With regard to current and worst pain, surgery or PT improved the “worst pain in last week” compared to CCI at 4 months (p < 0.01).²⁰ There were no significant differences between the PT, surgery, or CCI groups at 12 months. At 4 months, surgery improved power relative to the unaffected side in several muscle groups compared with PT or CCI. At 12 months, this difference was still present compared with PT. Absolute muscle strength improved with surgery at 4 months compared with both nonoperative alternatives. This difference did not persist at 12 months. A similar result was seen for sensory dysfunction.²⁰ These studies were scored Class I. Appropriate randomization and allocation concealment was undertaken. The groups were homogeneous at the start. The intention-to-treat analysis was used with minimal crossover. Finally, outcome assessments had good external reliability.^{19,20}

Arnasson et al.¹ and Sampath et al.²² completed comparative studies of lower quality. Arnasson and colleagues reported on 114 patients with cervical radiculopathy who underwent nonoperative treatment (33 patients), anterior decompression via ACD (37 patients), or posterior decompression (44 patients). For this review, the posterior decompression group was eliminated. Follow-up was completed in 24 patients in the nonoperative group and 35 in the anterior group. Clinical outcome was classified as better, the same, or worse. In those who had local neck pain, it improved in 43% of patients who received nonoperative treatment and 55% of those who underwent ACD. Radicular pain was only present in 15 of 33 patients who did not receive operative treatment, however, it improved in only 19% compared to 71% of patients who underwent ACD.¹ This study was Class III because of selection bias for each treatment arm, the poor follow-up for nonoperative patients, and the lack of statistical review.

Sampath et al.²² reported on 246 patients included in a cervical spine database from the Cervical Spine Research Society. In this cohort, the surgeons recommended surgery (anterior decompression with or without fusion in > 85%) for 86 patients (35%). Follow-up was only available for 155 patients (51 operative and 104 nonoperative). The study assessed outcome through questionnaires. Pain scores improved in both groups with an aggregate of 1.60 surgery versus 1.04 nonoperative. Neurological function improved 0.28 for the nonoperative group and 0.64 in the surgical group. This improvement was significant for the

Anterior cervical decompression for radiculopathy

surgical group but not for the nonoperative group. Functional status improved in both groups significantly while ADLs significantly improved in the surgery group only ($p < 0.01$). However, the surgery group started with significantly worse ADLs (2.42 vs 1.88). This study was graded Class III due to the absence of randomization and selection bias and heterogeneity of the groups.²²

Case Series for Anterior Decompression

Several authors completed large case series (Class III) that reviewed the pre- and postoperative outcomes after anterior decompression for cervical radiculopathy.^{3,4,8,12,21} Klein et al.¹² reported a small study of 28 patients who underwent ACDF (1- or 2-level, average age 44 years) for radiculopathy. Evaluation was by the Health Systems Questionnaire 2.0 given at an average of 21 months. This study was included due to the quantitative data provided by the questionnaire. Odom's criteria were also used. Significant improvements were seen after surgery for physical function ($p = 0.01$), social function ($p = 0.0004$), physical role function ($p = 0.0003$), fatigue ($p = 0.003$), and bodily pain ($p = 0.0001$). However, no overall differences were seen for general health or mental health. Good or better outcomes were seen in 93% according to Odom's criteria. This study was graded Class III because external reliability was not tested and because there was no control group.

Bohlman et al.³ (122 patients), Pointillart et al.²¹ (68 patients), Brigham and Tsahakis⁴ (43 patients), and Heidecke et al.⁸ (106 patients) all reported series of patients with cervical radiculopathy who underwent anterior decompression surgery. In general, the vast majority of patients (339 total) did well. Odom's criteria were commonly applied, and good or better outcomes were generally seen in most patients (~90%). Complications were minimal in all 3 studies. In the Bohlman series,³ outcome was analyzed with regard to age, smoking status, and Worker's Compensation status. These did not appear to affect outcome.

Gaetani and colleagues⁶ and Kozak et al.¹⁴ also looked at certain prognostic indicators. Gaetani et al.⁶ reported on 153 patients, of whom 108 underwent ACD for cervical radiculopathy. Follow-up was over the course of 1–10 years using Odom's criteria. The authors observed a good or better outcome in 90.9% of patients. Age, duration of symptoms, and pathogenesis of disc herniation did not affect outcome. Because this was a series and it was not certain how homogeneous the cohort was, it was graded Class III.⁶ Kozak and colleagues¹⁴ reported on 47 patients with spondylosis and cervical radiculopathy who underwent ACDF with a 15-month follow-up using Odom's criteria for assessment. Forty of 47 patients responded to follow-up, and 83% were considered to have good or better outcomes. Fusion occurred in 87% of cases but did not correlate with clinical outcome. For similar reasons as the Gaetani et al.⁶ study, this study was scored Class III.

Ylinen et al.²⁶ compared outcomes in patients who had undergone anterior decompression for cervical disc prolapse to a healthy population who did not have radiculopathy or undergo cervical surgery. In this series, 71 patients with cervical radiculopathy underwent ACDF and

follow-up was available in 53. Outcomes in this group were compared to 53 healthy volunteers using a case-control technique. However, because the volunteers did not have the underlying disease, this study was graded Class III. Pain was assessed using the VAS, grip strength with using dynamometer, and neck power with isometric testing. Compared to the results in the healthy volunteers, mobility and isometric strength diminished after ACDF ($p < 0.001$). Grip strength was no different between the groups ($p = 0.16$). In the ACDF group, 43% of patients reported pain that was associated with diminished mobility and strength.

Lundsford and colleagues¹⁵ reported on 295 patients with cervical radiculopathy and soft disc displacement (in 101) or spondylotic ridge (in 194). Anterior decompression via ACD was achieved in 135 patients and ACDF in 108. Follow-up was reported for 253 patients. Using Odom's criteria, the authors reported a good or better outcome in 67% of patients, with a poor outcome in 16%. Outcome did not differ between patients with soft disc displacement and spondylotic ridge ($p = 0.556$). Over the study period, the authors observed recurrent symptoms in 38%, with repeated operations performed in 4%. Recurrence of symptoms did not differ between patients with soft disc and spondylosis ($p = 0.897$). This study was graded Class III because of selection bias as to how patients were chosen for surgery and nonvalidated outcome measures without assessor blinding.

Nandoe Tewarie et al.¹⁷ also reported recurrence of symptoms in a Class III case series. These authors reported on 456 of 551 patients with cervical radiculopathy who underwent ACD. Follow-up was conducted with a chart review, questionnaire, and telephone surveys. After 6 weeks, 90.1% of patients were satisfied with the outcome of surgery. Late follow-up by telephone in 102 patients revealed that 67.6% had no symptom recurrence. In those patients with symptoms, 20.6% (21 patients) had moderate complaints, while 11.8% (12 patients) had severe complaints. There was a postoperative complication rate of 10.5%.

Peolsson and colleagues¹⁸ found that early results at 6 months correlated to long-term outcome at 3 years using the VAS, NDI, and a distress questionnaire. In this Class III series, 34 patients underwent anterior decompression for cervical radiculopathy. Follow-up was available for 23 patients at 3 years. The VAS and NDI scores and numbness improved in all patients ($p < 0.02$). The results at 3 years were similar to those at 6 months. These authors did not report the recurrence rates described by Nandoe Tewarie et al.,¹⁷ however, this series was markedly smaller.

Anterior Cervical Foraminotomy

Jho et al.¹⁰ reported on 104 patients with cervical radiculopathy who underwent ACF. This cohort had an average age of 46 years and duration of symptoms of 17 months. Sensorimotor dysfunction was present in >60%, with similar proportions of soft disc (52%) and spondylosis (42%). The authors assessed outcome using Odom's criteria. The study reported good or better outcome in 99%, with an excellent outcome in 79.8%. The complication rate was ~5%. Using outcome measures from the

TABLE 2: Evidentiary summary of studies examining anterior foraminotomy (disc preservation) and outcome

| Authors & Year | Description | Results | Class | Conclusions |
|--------------------------|---|---|-------|---|
| Jho et al., 2002 | 104 patients w/ cervical radiculopathy who underwent ACF. Age 46 yrs w/ symptoms 17 mos duration. Sensorimotor dysfunction in >60%. Soft disc in 52% & spondylosis in 42%. Odom's criteria used for outcome. | Good or better outcome in 99% (79.8% excellent). Complication rate was ~5%. Using CSRS outcome, pain improved from 3.08 to 1.02 ($p < 0.00001$). Neurological rating improved from 2.97 to 1.68 ($p < 0.00001$). Functional status 1.78 to 2.02 ($p < 0.5$). ADL 1.80 to 1.27 ($p < 0.05$). | III | ACF associated w/ good outcome & improvement in pain & neurological function & ADL. Class III due to series. |
| Johnson et al., 2000 | 21 patients w/ cervical radiculopathy. All underwent ACF. Outcomes 12–42 mos w/ Oswestry Pain, VAS, radiography. | Oswestry improved in 91% from 64 to 83 ($p < 0.05$). Using VAS, good or better outcome in 85% (70% excellent) w/ 5% worse. No instability. Return-to-work of 95% light duty at 3 mos. | III | ACF improves pain in >85%. Class III due to case series. |
| Koc et al., 2004 | 19 patients (14 w/ 1-level op) w/ cervical radiculopathy who underwent ACF. Outcome by Odom's criteria & VAS. | Mean FU was 23.4 mos. Good or better outcome in 89.4% (excellent 78.9%). VAS improved from 5.2 to 1.7. No spinal instability developed. | III | ACF associated w/ improvement in pain & good functional outcome. Class III due to case series. |
| White et al., 2007 | 21 patients w/ 1- (n = 14) or 2-level (n = 7) cervical radiculopathy (1–48 mos duration) who underwent ACF. VAS completed by patient & surgeon for pain, strength, sensation. Patient & surgeon were blinded to each other's results (10–36 mos). | Pre- & postop assessment was fully complete in 67%. Mean VAS reduction in arm pain was 6.9 ($p = 0.0009$). Neck pain reduction 4.0 ($p = 0.0032$). Arm strength improved 3.8 ($p = 0.0086$), arm sensation improved by 3.8 ($p = 0.0032$). Surgeon thought 7.0 improvement in arm w/ minimal in neck. | III | Anterior foraminotomy relieves arm & neck pain subjectively. Class III due to series w/o control group & w/o blinded observation. |
| Aydin et al., 2005 | 216 patients w/ cervical degeneration and 182 w/ radiculopathy as defined by arm pain >3 wks or neurological deficit. Tx was "anterior contralateral approach." Primarily 1 level (75%) w/ soft disc herniation (~60%). Outcome w/ Odom's criteria. | Functional outcome was good or better in 100%. Motor recovery was seen in 92.9% & sensory recovery was 88.5%. 4 patients developed kyphosis & fibrous union w/o instability was seen in 92%. | III | Anterior contralateral limited discectomy is effective at pain relief & functional outcome. Class III due to large series. |
| Snyder & Bernhardt, 1989 | 63 patients w/ degenerative disease underwent anterior cervical fractional interspace decompression. FU averaged 23 mos. Odom's criteria applied. | Good or better results in 64–70% depending upon Worker's Compensation status. 87% returned to work. Spontaneous fusion in only 4%. | III | Anterior cervical decompression results in a good outcome w/ minimal complication. Class III due to case series. |
| Hacker & Miller, 2003 | 23 patients w/ cervical radiculopathy underwent ACF w/ 3-mo min FU. | 7 patients (30%) underwent revision surgery: 4 due to recurrent disc & 3 due to intractable neck pain. Good or better outcome in 12 (52%). | III | ACF for decompression is associated w/ a high-revision rate w/ worse outcome (52%). Class III due to retrospective series. |

Cervical Spine Research Society, pain improved from 3.08 to 1.02 ($p < 0.00001$). The neurological rating improved from 2.97 to 1.68 ($p < 0.00001$), functional status improved from 1.78 to 2.02 ($p = 0.5$), and ADLs improved from 1.80 to 1.27 ($p < 0.05$).¹⁰ This study was graded Class III because it was a case series and lacked a control group.

Johnson et al.,¹¹ Koc et al.,¹³ and White et al.²⁵ each described smaller, Class III series using a similar ACF technique. Johnson and colleagues¹¹ reported on 21 patients with cervical radiculopathy who underwent ACF. Follow-up was 12–42 months using an Oswestry Pain Scale, VAS, and radiographs. Oswestry Pain Scale and VAS scores improved in 85–91% of patients, with Oswestry values increasing from 64 to 83 ($p < 0.05$). The authors reported clinical worsening in only 5%. In the se-

ries of Koc et al.,¹³ 19 patients with cervical radiculopathy underwent 1- or 2-level ACF (14 and 5 patients, respectively). Outcome was evaluated using Odom's criteria and the VAS, with mean follow-up of 23 months. The authors reported good or better outcome in 89.4% (excellent in 78.9%). The VAS score improved from 7.9 to 1.7.¹³ White et al.²⁵ reported on 21 patients with cervical radiculopathy who underwent 1- or 2-level ACF, in 14 and 7 patients, respectively. The authors assessed outcomes by patients and surgeons using the VAS over 10–36 months. Follow-up was available in 67% of patients. The mean arm pain VAS score reduction was 6.9 ($p = 0.0009$), the VAS neck pain reduction was 4.0 ($p = 0.0032$), and arm strength ($p = 0.0086$) and sensation ($p = 0.0032$) each improved by 3.8. The estimate of the surgeon was similar that of the patient for arm pain.

Anterior cervical decompression for radiculopathy

Aydin et al.² and Snyder and Bernhardt²³ described modifications to ACF in 2 Class III series. Aydin and colleagues reported on anterior contralateral limited discectomy in 182 patients with cervical radiculopathy. Surgery was primarily at 1 level (75% of patients) with soft disc displacement in most (~60%). The authors assessed outcome using Odom's criteria, and reported good or better outcome in 100%. The authors reported recovery of motor function in 92.9% and sensory recovery in 88.5%. They reported kyphosis in 4 of 182 patients. The majority of patients (92%) developed fibrous union without instability. Snyder and Bernhardt²³ described 63 patients who underwent anterior fractional interspace decompression. Follow-up averaged 23 months and assessments were done with Odom's criteria. The authors observed good or better outcomes in 64–70% of patients, depending on Worker's Compensation status. The majority (87%) returned to work. Spontaneous fusion was observed in 4%.²³

Hacker and Miller⁷ described a series of 23 patients with cervical radiculopathy who underwent ACF with 3-month minimum follow-up. Seven patients in this series (30%) underwent revision surgery—4 because of recurrent disc displacement, and 3 due to intractable neck pain. Using Odom's criteria, these authors observed good or better outcome in 12 patients (52%). The evidence from this series was graded Class III.⁷

Summary

When comparing the results of anterior decompressive surgery to PT or CCI, Class I data indicates that surgery gives greater relief of neck/arm pain, weakness, and sensory loss at 3–4 months after therapy. Functional improvement appears to be longer lasting. Using Odom's criteria, the authors of multiple Class III series demonstrated good or better outcome in >90% of patients after anterior decompression for cervical radiculopathy. However, Odom's criteria have problematic reliability and may be prone to conformational bias when assessed by the surgeon. Because of their subjective nature, Odom's criteria may not be readily reproduced by the same or different evaluators, leading to poor reliability. Furthermore, improvement or regression in Odom's criteria may not correlate with other outcome measures, resulting in suspect validity. Finally, its broad ranges make it poorly responsive. Accordingly, Odom's criteria are far from an ideal outcome measure.

Age, duration of symptoms, and type of disc pathology do not appear to play a role in outcome (Class III). One Class III study demonstrated that in patients who undergo anterior decompression for cervical radiculopathy, physical and social function—but not general health—appear to improve significantly. Another Class III study revealed that the 6-month outcome is similar to outcome at 3 years. However, the authors of 2 other Class III studies have suggested that recurrence of symptoms after several years is not uncommon in 11–38% of patients.

Multiple Class III series have indicated that ACF improves pain, weakness, and numbness, with neck pain improving in the majority. Good or better outcomes (Odom's criteria) were observed in 85–90% of patients. However,

1 Class III study concluded otherwise with revision surgeries in 30%, and good or better outcomes in only 52%. Given this conflicting data regarding ACF, no firm recommendations can be made.

Key Issues for Future Investigations

The advantage of anterior nerve root decompression lies in an operative approach to the pathology without crossing the neural elements. The theoretical disadvantage is loss of a motion segment if fusion is performed. Key issues include the ability to undertake anterior decompression without disc removal while minimizing the threat to the vertebral artery.

Future investigation should involve the identification of the ideal surgical treatment for soft lateral cervical disc displacement causing radiculopathy. Only 1 of the studies described above was a randomized controlled trial, and it contained only 81 patients. Review of the current peer-reviewed literature does not resolve whether anterior or posterior surgery yields better short- and long-term results, nor are there any trials comparing both of these groups to nonoperative therapy. Performance of a well-designed, randomized clinical trial in patients with this clinical scenario would enable resolution of this question.

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Review Article

An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders

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Abstract

BACKGROUND CONTEXT: The North American Spine Society (NASS) Evidence-Based Clinical Guideline on the Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders provides evidence-based recommendations on key clinical questions concerning the diagnosis and treatment of cervical radiculopathy from degenerative disorders. The guideline addresses these questions based on the highest quality clinical literature available on this subject as of May 2009. The guideline's recommendations assist the practitioner in delivering optimum efficacious treatment of and functional recovery from this common disorder.

PURPOSE: Provide an evidence-based educational tool to assist spine care providers in improving quality and efficiency of care delivered to patients with cervical radiculopathy from degenerative disorders.

STUDY DESIGN: Systematic review and evidence-based clinical guideline.

FDA device/drug status: not applicable.

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BrainLab; relationships outside the one year requirement, DePuy Spine); AKS (speaking/teaching arrangements, Forest Labs [Savella speakers program]).

Disclaimer: This review article summarizes a published evidence-based guideline. It is a product of the NASS Evidence-Based Guideline Development Committee, approved by the NASS Board of Directors and accepted for publication outside The Spine Journal's peer review process.

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METHODS: This report is from the Cervical Radiculopathy from Degenerative Disorders Work Group of the NASS' Evidence-Based Clinical Guideline Development Committee. The work group consisted of multidisciplinary spine care specialists trained in the principles of evidence-based analysis. Each member of the group formatted a series of clinical questions to be addressed by the group. The final questions agreed on by the group are the subjects of this report. A literature search addressing each question using a specific search protocol was performed on English language references found in MEDLINE, EMBASE (Drugs and Pharmacology), and four additional evidence-based databases. The relevant literature was then independently rated by a minimum of three reviewers using the NASS-adopted standardized levels of evidence. An evidentiary table was created for each of the questions. Final recommendations to answer each clinical question were arrived at via work group discussion, and grades were assigned to the recommendations using standardized grades of recommendation. In the absence of Levels I to IV evidence, work group consensus statements have been developed using a modified nominal group technique, and these statements are clearly identified as such in the guideline.

RESULTS: Eighteen clinical questions were formulated, addressing issues of natural history, diagnosis, and treatment of cervical radiculopathy from degenerative disorders. The answers are summarized in this article. The respective recommendations were graded by the strength of the supporting literature, which was stratified by levels of evidence.

CONCLUSIONS: A clinical guideline for cervical radiculopathy from degenerative disorders has been created using the techniques of evidence-based medicine and best available evidence to aid both practitioners and patients involved with the care of this condition. The entire guideline document, including the evidentiary tables, suggestions for future research, and all references, is available electronically at the NASS Web site (www.spine.org) and will remain updated on a timely schedule. © 2011 Elsevier Inc. All rights reserved.

Keywords:

Diagnosis; Imaging; Treatment; Cervical radiculopathy from degenerative disorders; Clinical practice guideline

Introduction

In an attempt to improve and evaluate the knowledge base concerning the diagnosis and treatment of cervical radiculopathy from degenerative disorders, the Cervical Radiculopathy from Degenerative Disorders Work Group of the North American Spine Society (NASS) Evidence-Based Clinical Guideline Development Committee has developed an evidence-based clinical guideline on the topic. The Institute of Medicine has defined a clinical guideline as “systematically developed statements to assist practitioner and patient decisions about health care for specific clinical situations” [1].

The application of the principles of evidence-based medicine (EBM) to guideline development helps create an explicit linkage between the final recommendations in the guideline and the evidence on which these recommendations are based [2]. When using the principles of EBM, the clinical literature is extensively searched to answer specific questions about a disease state or medical condition. The literature that is identified in the search is then rated as to its scientific merit using levels of evidence, determined by specific rule sets that apply to human and clinical investigations. The specific questions asked are then answered using studies of the highest possible levels of evidence that have been obtained from the searches. As a final step, the answers to the clinical questions are reformulated as recommendations that are assigned grades of

strength related to the soundness of the best evidence available at the time of answering each question. The intent of the grade of recommendation is to indicate the strength of the evidence used by the work group in answering the question asked.

Methods

For this clinical guideline, the guideline development process was broken down into 12 steps. In Step 1, guideline participants, trained in the principles of EBM, submitted a list of clinical questions focused on diagnosis and treatment of cervical radiculopathy from degenerative disorders that the guideline should address. In Step 2, multidisciplinary teams composed of surgical, medical, interventional, and radiological specialists were assigned to groups, each of which was assigned a subset of the questions to be answered. Step 3 consisted of each group identifying appropriate search terms and parameters to direct the literature search according to the NASS-instituted Literature Search Protocol. The literature search was then completed in Step 4 by a medical research librarian according to the NASS Literature Search Protocol and stored in a cross-referencing database for future use or reference. The following electronic databases were searched for English language publications: MEDLINE (PubMed), EMBASE (Drugs and Pharmacology), American College of Physicians Journal

Club, Cochrane Database of Systematic reviews, Database of Abstracts of Reviews of Effectiveness, and Cochrane Central Register of Controlled Trials. Work group members then reviewed all abstracts from the literature search in Step 5. The best research evidence available was identified and used to answer the targeted clinical questions. That is, if adequate Level I, II, or III studies were available to answer a specific question, the work group was not required to review Level IV or V evidence. In Step 6, the members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses, and assigning levels of evidence. To systematically control for bias, at least three work group members reviewed each article selected and independently assigned a level of evidence per the NASS Levels of Evidence table. The final level of evidence assigned was that agreed on by at least two-thirds of the reviewers.

To formulate evidence-based recommendations and incorporate expert opinion when necessary, work groups participated in Webcasts in Step 7. Expert opinion was incorporated only where Levels I to IV evidence was insufficient, and the work groups deemed a recommendation was warranted. For transparency in the incorporation of consensus, all consensus-based recommendations in this guideline are clearly stated as such. Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (“extremely inappropriate”) to 9 (“extremely appropriate”) [3]. Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8, or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted. When the recommendations were established, work group members developed guideline content, referencing the literature that supported the recommendations.

In Step 8, the completed guideline was submitted to the NASS Evidence-Based Guideline Development Committee and the NASS Research Council for review and comment. Revisions to recommendations were considered only when substantiated by a preponderance of appropriate levels of evidence. Once evidence-based revisions were incorporated, the guideline was submitted to the NASS Board of Directors for review and approval in Step 9. In Step 10, the NASS Board-approved guideline was submitted for inclusion in the National Guidelines Clearinghouse.

In Step 11, the recommendations will be submitted to the American Medical Association Physician Consortium for Performance Improvement, a multispecialty collaborative group engaged in the development of evidence-based performance measures. In Step 12, the guideline recommendations will be reviewed every 3 years and the literature base updated by an EBM-trained multidisciplinary team with revisions to the recommendations developed

in the same manner as in the original guideline development.

Results

Definition and natural history

Question 1: What is the best working definition of cervical radiculopathy from degenerative disorders?

Cervical radiculopathy from degenerative disorders can be defined as pain in a radicular pattern in one or both upper extremities related to compression and/or irritation of one or more cervical nerve roots. Frequent signs and symptoms include varying degrees of sensory, motor, and reflex changes as well as dysesthesias and paresthesias related to nerve roots without evidence of spinal cord dysfunction (myelopathy).

Workgroup Consensus Statement.

Question 2: What is the natural history of cervical radiculopathy from degenerative disorders?

To address the natural history of cervical radiculopathy from degenerative disorders, the work group performed a comprehensive literature search and analysis. The group reviewed 31 articles that were selected from a search of MEDLINE (PubMed), Cochrane Register of Controlled Trials, and Web of Science and EMBASE (Drugs and Pharmacology). However, all identified studies failed to meet the guideline’s inclusion criteria because they did not adequately present data about the natural history of cervical radiculopathy. The plurality of studies did not report results of untreated patients, thus limiting conclusions about natural history. This includes works that have been frequently cited as so-called natural history studies but are in fact reports of the results of one or more medical/interventional treatment measures [4–8]. In other investigations, data were reported for untreated and conservatively treated patients together without an analysis specific to the untreated group. Other commonly cited studies did not report subgroup analyses of patients with cervical radiculopathy alone and thereby presented generalized natural history data regarding a heterogeneous cohort of patients with isolated neck pain, cervical radiculopathy, or cervical myelopathy.

Because of the limitations of available literature, the work group was unable to definitively answer the question posed related to the natural history of cervical radiculopathy from degenerative disorders. In lieu of an evidence-based answer, the work group did reach consensus on the following statement addressing natural history.

It is likely that for most patients with cervical radiculopathy from degenerative disorders signs and symptoms will be self-limited and will resolve spontaneously over a variable length of time without specific treatment.

Workgroup Consensus Statement.

Diagnosis and imaging

Question 3: What history and physical examination findings best support a diagnosis of cervical radiculopathy from degenerative disorders?

It is suggested that the diagnosis of cervical radiculopathy be considered in patients with arm pain, neck pain, scapular or periscapular pain, and paresthesias, numbness and sensory changes, weakness, or abnormal deep tendon reflexes in the arm. These are the most common clinical findings seen in patients with cervical radiculopathy [9–13].

Grade of Recommendation: B

It is suggested that the diagnosis of cervical radiculopathy be considered in patients with atypical findings such as deltoid weakness, scapular winging, weakness of the intrinsic muscles of the hand, chest or deep breast pain, and headaches. Atypical symptoms and signs are often present in patients with cervical radiculopathy and can improve with treatment [9,11,14–17].

Grade of Recommendation: B

Provocative tests including the shoulder abduction and Spurling's tests may be considered in evaluating patients with clinical signs and symptoms consistent with the diagnosis of cervical radiculopathy [18–22].

Grade of Recommendation: C

Because dermatomal arm pain alone is not specific in identifying the pathologic level in patients with cervical radiculopathy, further evaluation including CT (computed tomography), CT myelography, or MRI (magnetic resonance imaging) is suggested before surgical decompression [9,13,23].

Grade of Recommendation: B

Question 4: What are the most appropriate diagnostic tests (including imaging and electrodiagnostics), and when are these tests indicated in the evaluation and treatment of cervical radiculopathy from degenerative disorders?

Magnetic resonance imaging is suggested for the confirmation of correlative compressive lesions (disc herniation and spondylosis) in cervical spine patients who have failed a course of conservative therapy and who may be candidates for interventional or surgical treatment [24–28].

Grade of Recommendation: B

In the absence of reliable evidence, it is the work group's opinion that CT may be considered as the initial study to confirm a correlative compressive lesion (disc herniation or spondylosis) in cervical spine patients who have failed a course of conservative therapy, who may be candidates for interventional or surgical treatment, and who have a contraindication to MRI [29].

Work Group Consensus Statement

Computed tomography myelography is suggested for the evaluation of patients with clinical symptoms or signs that are discordant with MRI findings (eg, foraminal compression that may not be identified on MRI). Computed tomography myelography is also suggested in patients who have a contraindication to MRI [24,26–28,30–32].

Grade of Recommendation: B

The evidence is insufficient to make a recommendation for or against the use of electromyography for patients in whom the diagnosis of cervical radiculopathy is unclear after clinical examination and MRI [33,34].

Grade of Recommendation: I (Insufficient Evidence)

Selective nerve root block with specific dosing and technique protocols may be considered in the evaluation of patients with cervical radiculopathy and compressive lesions identified at multiple levels on MRI or CT myelography to discern the symptomatic levels. Selective nerve root block may also be considered to confirm a symptomatic level in patients with discordant clinical symptoms and MRI or CT myelography findings [35,36].

Grade of Recommendation: C

Outcome measures for medical/interventional and surgical treatment

Question 5: What are the most appropriate outcome measures to evaluate the treatment of cervical radiculopathy from degenerative disorders?

The Neck Disability Index, Short Form-36, Short Form-12, and Visual analog scale are recommended outcome measures for assessing treatments of cervical radiculopathy from degenerative disorders [37–49].

Grade of Recommendation: A

The modified Prolo, Patient-Specific Functional Scale, Health Status Questionnaire, Sickness Impact Profile, Modified Million Index, McGill Pain Scores, and modified Oswestry Disability Index are suggested outcome measures for assessing treatment of cervical radiculopathy from degenerative disorders [33,42,48–53].

Grade of Recommendation: B

Medical/interventional treatment

Question 6: What is the role of pharmacologic treatment in the management of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of pharmacologic treatment in the management of cervical radiculopathy from degenerative disorders.

Question 7: What is the role of physical therapy/exercise in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of physical therapy/exercise in the management of cervical radiculopathy from degenerative disorders.

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Question 8: What is the role of manipulation/chiropractics in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the role of manipulation/chiropractics in the management of cervical radiculopathy from degenerative disorders. The review did identify several case reports and series describing serious vascular and nonvascular complications and adverse outcomes associated with manipulation including radiculopathy, myelopathy, disc herniation, and vertebral artery compression [55–58]. The true incidence of such complications is unknown, and estimates vary widely. Some complications have occurred in patients with previously unrecognized spinal metastatic disease who did not have premanipulation imaging. Most patients with serious complications of manipulation require emergent surgical treatment.

As the efficacy of manipulation in the treatment of cervical radiculopathy from degenerative disorders is unknown, careful consideration should be given to evidence suggesting that manipulation may lead to worsened symptoms or significant complications when considering this therapy. Premanipulation imaging may reduce the risk of complications.

Work Group Consensus Statement

Question 9: What is the role of epidural steroid injections for the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature revealed limited high-quality studies to address this question. There is Level IV data indicating that transforaminal epidural steroid injections may provide relief for 60% of patients, and about 25% of patients referred with clear surgical indications may obtain at least short-term pain relief negating the need for surgery. Interestingly, there is limited Level II evidence that suggests that the addition of steroid to local anesthetic does not improve pain relief in these patients at 3 weeks postinjection. All the studies that qualified as at least Level IV data used transforaminal epidural injections under fluoroscopic or CT guidance as the method of treatment. For this reason, the work group was unable to make recommendations regarding the safety or efficacy of interlaminar

epidural steroid injections for the treatment of cervical radiculopathy.

The literature search yielded a number of publications demonstrating that transforaminal epidural steroid injections are not without risk and the potential complications, including spinal cord injury and death, need to be considered before performing this procedure [59,60].

Transforaminal epidural steroid injections using fluoroscopic or CT guidance may be considered when developing a medical/interventional treatment plan for patients with cervical radiculopathy from degenerative disorders. Due consideration should be given to the potential complications [61–64].

Grade of Recommendation: C

Question 10: What is the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and transcutaneous electrical nerve stimulation in the treatment of cervical radiculopathy from degenerative disorders?

Ozone injections, cervical halter traction and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated [7,65,66].

Work Group Consensus Statement

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Surgical treatment

Question 11: Does surgical treatment (with or without preoperative medical/interventional treatment) result in better outcomes than medical/interventional treatment for cervical radiculopathy from degenerative disorders?

Surgical intervention is suggested for the rapid relief of symptoms of cervical radiculopathy from degenerative disorders when compared with medical/interventional treatment [67,68].

Grade of Recommendation: B

Emotional and cognitive factors (eg, job dissatisfaction) should be considered when addressing surgical or medical/interventional treatment for patients with cervical radiculopathy from degenerative disorders [54].

Grade of Recommendation: I (Insufficient Evidence)

Question 12: Does anterior cervical decompression with fusion (ACDF) result in better outcomes (clinical or

radiographic) than anterior cervical decompression (ACD) alone?

Both ACD and ACDF are suggested as comparable treatment strategies, producing similar clinical outcomes, in the treatment of single-level cervical radiculopathy from degenerative disorders [48,69–73].

Grade of Recommendation: B

The addition of an interbody graft for fusion is suggested to improve sagittal alignment after ACD [48,69].

Grade of Recommendation: B

Question 13: Does ACDF with instrumentation result in better outcomes (clinical or radiographic) than ACDF without instrumentation?

Both ACDF with and without a plate are suggested as comparable treatment strategies, producing similar clinical outcomes and fusion rates, in the treatment of single-level cervical radiculopathy from degenerative disorders [74–76].

Grade of Recommendation: B

The addition of a cervical plate is suggested to improve sagittal alignment after ACDF [74–76].

Grade of Recommendation: B

Although plate stabilization may be indicated in some patients undergoing multilevel ACDF, there is insufficient evidence that this practice results in significant improvement in clinical outcomes for degenerative cervical radiculopathy.

Work Group Consensus Statement

Question 14: Does anterior surgery result in better outcomes (clinical or radiographic) than posterior surgery in the treatment of cervical radiculopathy from degenerative disorders?

Either ACDF or posterior foraminotomy are suggested for the treatment of single-level degenerative cervical radiculopathy secondary to foraminal soft disc herniation to achieve comparably successful clinical outcomes [73,77,78].

Grade of Recommendation: B

Compared with posterior laminoforaminotomy, anterior cervical discectomy and fusion is suggested for the treatment of single-level degenerative cervical radiculopathy from central and paracentral nerve root compression and spondylotic disease.

Work Group Consensus Statement

Question 15: Does posterior decompression with fusion result in better outcomes (clinical or radiographic) than posterior decompression alone in the treatment of cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately compare the outcomes of posterior

decompression with posterior decompression with fusion in the treatment of cervical radiculopathy from degenerative disorders. Most decompression and fusion appears to be indicated for multilevel stenosis resulting in myelopathy or for instability because of trauma, tumor, or inflammatory disease. Because of limited indications and, thus, limited sample size, there is likely little to gain and a low probability of generating meaningful data to compare effects of posterior decompression alone with posterior decompression and fusion for degenerative disease resulting in cervical radiculopathy.

Question 16: Does ACD and reconstruction with total disc replacement result in better outcomes (clinical or radiographic) than ACDF in the treatment of cervical radiculopathy from degenerative disorders?

Anterior cervical decompression with fusion and total disc arthroplasty are suggested as comparable treatments, resulting in similarly successful short-term outcomes, for single-level degenerative cervical radiculopathy [44,79].

Grade of Recommendation: B

Question 17: What is the long-term result (>4 years) of surgical management of cervical radiculopathy from degenerative disorders?

Surgery is an option for the treatment of single-level degenerative radiculopathy to produce and maintain favorable long-term (>4 years) outcomes [73,80–82].

Grade of Recommendation: C

Question 18: How do long-term results of single-level compare with multilevel surgical decompression for cervical radiculopathy from degenerative disorders?

A systematic review of the literature yielded no studies to adequately address the comparison of long-term results of single-level compared with multilevel surgical decompression in the management of cervical radiculopathy from degenerative disorders. After this review, it is clear that most patients with true radiculopathy suffer from one-level and occasionally two-level disease. The incidence of multilevel disease without the additional presence of myelopathy is rare. Thus, there is likely little to gain and a low probability of generating meaningful data to answer this question.

Discussion

This evidence-based clinical guideline for diagnosis and treatment of cervical radiculopathy from degenerative disorders has several functions. It is an educational tool for both clinicians and patients, and as such this particular guideline is intended to facilitate the diagnosis and treatment of cervical radiculopathy from degenerative disorders. This guideline also serves to focus and rate the clinical data on this topic. An evidence-based guideline such as this

allows a physician access to the best and most current evidence and reduces the burden of “keeping up with the literature” that spans innumerable journals from a broad spectrum of disciplines. In addition, this evidence-based clinical guideline has the potential to improve the appropriateness and effectiveness of patient care by basing decisions on the best evidence available. Finally, the creation of this guideline serves to identify knowledge gaps in the clinical literature on the diagnosis and treatment of cervical radiculopathy from degenerative disorders. High-quality clinical guidelines ideally identify and suggest future research topics to improve guideline development, and thus patient care, as detailed in the current guideline. The NASS Web site, www.spine.org, contains the complete clinical guideline summarized in this article, along with extensive descriptive narratives on each topic outlining the evidence and work group rationale for the answers to each question. In addition, more extensive descriptions are provided of the guideline development process used at NASS, along with all of the references used in this guideline and suggestions for future research studies on the diagnosis and treatment of cervical radiculopathy from degenerative disorders. The core clinical guideline on the Web site is intended to be a “living document” with periodic updates of the literature and recommendations.

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