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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion

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

References

1. Fager, C.A., *Observations on spontaneous recovery from intervertebral disc herniation.* Surg Neurol, 1994. 42(4): p. 282-6.
2. Weber, H., I. Holme, and E. Amlie, *The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam.* Spine (Phila Pa 1976), 1993. 18(11): p. 1433-8.
3. Kreiner, D.S., et al., *An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy.* Spine J, 2014. 14(1): p. 180-91.
4. Lewis, P.J., et al., *Long-term prospective study of lumbosacral discectomy.* J Neurosurg, 1987. 67(1): p. 49-53.
5. Clark, A.J., et al., *Tubular microdiscectomy: techniques, complication avoidance, and review of the literature.* Neurosurg Focus, 2017. 43(2): p. E7.
6. van den Akker, M.E., et al., *Tubular diskectomy vs conventional microdiskectomy for the treatment of lumbar disk-related sciatica: cost utility analysis alongside a double-blind randomized controlled trial.* Neurosurgery, 2011. 69(4): p. 829-35; discussion 835-6.

7. Righesso, O., A. Falavigna, and O. Avanzi, *Comparison of open discectomy with microendoscopic discectomy in lumbar disc herniations: results of a randomized controlled trial.* Neurosurgery, 2007. 61(3): p. 545-9; discussion 549.
8. Cohen, S.P., et al., *Nucleoplasty with or without intradiscal electrothermal therapy (IDET) as a treatment for lumbar herniated disc.* J Spinal Disord Tech, 2005. 18 Suppl: p. S119-24.
9. Karasek, M. and N. Bogduk, *Twelve-month follow-up of a controlled trial of intradiscal thermal anuloplasty for back pain due to internal disc disruption.* Spine (Phila Pa 1976), 2000. 25(20): p. 2601-7.
10. Hlubek, R.J. and G.M. Mundis, Jr., *Treatment for Recurrent Lumbar Disc Herniation.* Curr Rev Musculoskelet Med, 2017. 10(4): p. 517-520.
11. Dower, A., et al., *Surgical management of recurrent lumbar disc herniation and the role of fusion.* J Clin Neurosci, 2016. 23: p. 44-50.
12. Guan, J., et al., *Comparing clinical outcomes of repeat discectomy versus fusion for recurrent disc herniation utilizing the N2QOD.* J Neurosurg Spine, 2017. 26(1): p. 39-44.
13. Pereira, E.A., M. Farwana, and K.S. Lam, *Extreme lateral interbody fusion relieves symptoms of spinal stenosis and low-grade spondylolisthesis by indirect decompression in complex patients.* J Clin Neurosci, 2017. 35: p. 56-61.
14. Villavicencio, A.T., et al., *The Timing of Surgery and Symptom Resolution in Patients Undergoing Transforaminal Lumbar Interbody Fusion for Lumbar Degenerative Disk Disease and Radiculopathy.* Clin Spine Surg, 2017. 30(6): p. E765-E769.
15. Rao, P.J., et al., *Outcomes of anterior lumbar interbody fusion surgery based on indication: a prospective study.* Neurosurgery, 2015. 76(1): p. 7-23; discussion 23-4.
16. Rouben, D., M. Casnellie, and M. Ferguson, *Long-term durability of minimal invasive posterior transforaminal lumbar interbody fusion: a clinical and radiographic follow-up.* J Spinal Disord Tech, 2011. 24(5): p. 288-96.
17. Hackenberg, L., et al., *Transforaminal lumbar interbody fusion: a safe technique with satisfactory three to five year results.* Eur Spine J, 2005. 14(6): p. 551-8.
18. Alimi, M., et al., *Extreme lateral interbody fusion for unilateral symptomatic vertical foraminal stenosis.* Eur Spine J, 2015. 24 Suppl 3: p. 346-52.
19. Resnick, D.K., et al., *Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: lumbar fusion for stenosis with spondylolisthesis.* J Neurosurg Spine, 2014. 21(1): p. 54-61.
20. Endler, P., et al., *Outcomes of Posterolateral Fusion with and without Instrumentation and of Interbody Fusion for Isthmic Spondylolisthesis: A Prospective Study.* J Bone Joint Surg Am, 2017. 99(9): p. 743-752.
21. Bruggeman, A.J. and R.C. Decker, *Surgical treatment and outcomes of lumbar radiculopathy.* Phys Med Rehabil Clin N Am, 2011. 22(1): p. 161-77.
22. Kerr, D., W. Zhao, and J.D. Lurie, *What Are Long-term Predictors of Outcomes for Lumbar Disc Herniation? A Randomized and Observational Study.* Clin Orthop Relat Res, 2014. 473(6): p. 1920-30.
23. Voorhies, R.M., X. Jiang, and N. Thomas, *Predicting outcome in the surgical treatment of lumbar radiculopathy using the Pain Drawing Score, McGill Short Form Pain Questionnaire, and risk factors including psychosocial issues and axial joint pain.* Spine J, 2007. 7(5): p. 516-24.
24. Madsbu, M.A., et al., *Surgery for Herniated Lumbar Disc in Daily Tobacco Smokers: A Multicenter Observational Study.* World Neurosurg, 2017.
25. Yoo, M.W., et al., *Does obesity make an influence on surgical outcomes following lumbar microdiscectomy?* Korean J Spine, 2014. 11(2): p. 68-73.

26. Fakouri, B., M.G. Stovell, and R. Allom, *A Comparative Cohort Study of Lumbar Microdiscectomy in Obese and Nonobese Patients.* J Spinal Disord Tech, 2013. 28(6): p. E352-7.
27. Tomasino, A., et al., *Tubular microsurgery for lumbar discectomies and laminectomies in obese patients: operative results and outcome.* Spine (Phila Pa 1976), 2009. 34(18): p. E664-72.
28. Adogwa, O., et al., *A prospective, multi-institutional comparative effectiveness study of lumbar spine surgery in morbidly obese patients: does minimally invasive transforaminal lumbar interbody fusion result in superior outcomes?* World Neurosurg, 2014. 83(5): p. 860-6.
29. Ibrahim, M., et al., *Recurrent Lumbar Disc Herniation: Results of Revision Surgery and Assessment of Factors that May Affect the Outcome. A Non-Concurrent Prospective Study.* Asian Spine J, 2015. 9(5): p. 728-36.
30. Sarrami, P., et al., *Spine surgery outcome in patients who sought compensation after a motor vehicle accident: a retrospective cohort study.* BMC Surg, 2016. 16(1): p. 76.
31. Shamji, M.F. and A. Shcharinsky, *Use of neuropathic pain questionnaires in predicting persistent postoperative neuropathic pain following lumbar discectomy for radiculopathy.* J Neurosurg Spine, 2015: p. 1-7.
32. Papavero, L., N. Engler, and R. Kothe, *Incidental durotomy in spine surgery: first aid in ten steps.* Eur Spine J, 2015. 24(9): p. 2077-84.
33. Shriver, M.F., et al., *Lumbar microdiscectomy complication rates: a systematic review and meta-analysis.* Neurosurg Focus, 2015. 39(4): p. E6.
34. Ramirez, L.F. and R. Thisted, *Complications and demographic characteristics of patients undergoing lumbar discectomy in community hospitals.* Neurosurgery, 1989. 25(2): p. 226-30; discussion 230-1.
35. Shamim, M.S., et al., *Microdiscectomy for lumbosacral disc herniation and frequency of failed disc surgery.* World Neurosurg, 2011. 74(6): p. 611-6.
36. Tosteson, A.N., et al., *The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT).* Spine (Phila Pa 1976), 2008. 33(19): p. 2108-15.
37. Parker, S.L., et al., *Cost-effectiveness of multilevel hemilaminectomy for lumbar stenosis-associated radiculopathy.* Spine J, 2011. 11(8): p. 705-11.
38. Hansson, E. and T. Hansson, *The cost-utility of lumbar disc herniation surgery.* Eur Spine J, 2007. 16(3): p. 329-37.