

FINAL Key Questions and Background

Surgery for Symptomatic Lumbar Radiculopathy

Background

Radiculopathy is a clinical syndrome characterized by pain, motor weakness, and sensory disturbances in a myotomal or dermatomal distribution. When radicular symptoms are in the low back and legs, this condition is referred to as lumbar radiculopathy or sciatica. Nerve root compression is a common cause of radiculopathy and various pathological processes may be responsible, but most often it results from disc herniation or spondylosis (i.e., degenerative joint and disc disease).¹⁻³ Both processes can cause stenosis of the lateral recesses or neural foramina and resulting spinal nerve root compression.¹⁻³ Degenerative changes can also produce spondylolisthesis, central spinal canal stenosis, and facet joint hypertrophy, which may be associated with nonradicular low back pain.¹ Less common etiologies of radiculopathy include infection, inflammation, neoplasm, vascular disease, and congenital abnormalities.^{1,2} Radiculopathy is a clinical diagnosis because spinal nerve root compression identified with imaging may not always be symptomatic. Thus, correlation of symptoms and physical exam with imaging is usually used to diagnose radiculopathy, with electromyography reserved for selected patients. The lifetime prevalence of lumbar radiculopathy is 3 to 5%.¹

Lumbar radiculopathy is a heterogenous condition that may present acutely (as in the case of an acute disc herniation with chemical radiculitis) or more insidiously (as in the case of spondylosis).^{1,2} Further, radiculopathy may present only with pain or with varying degrees of sensory disturbance or motor weakness.⁴ The objective of treatment for radiculopathy is symptom relief. If pain or neurologic symptoms are severe or nonresponsive to conservative measures, then surgical treatment of the underlying causative mechanism may be warranted.

Policy Context

Numerous surgical and nonsurgical approaches to the management of lumbar radiculopathy have been studied and are routinely used within current clinical practice. In addition to standard open surgical techniques (e.g., discectomy with laminotomy or laminectomy as needed), minimally invasive surgical techniques that use percutaneous or endoscopic approaches are also available. This health technology assessment (HTA) will review the efficacy, safety, and cost-effectiveness of surgical interventions to treat symptomatic lumbar radiculopathy in adults to assist the State of Washington's Health Technology Clinical Committee in determining coverage for selected surgical interventions.

Scope

The proposed research questions, analytic framework, and key study selection criteria are listed in this section.

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

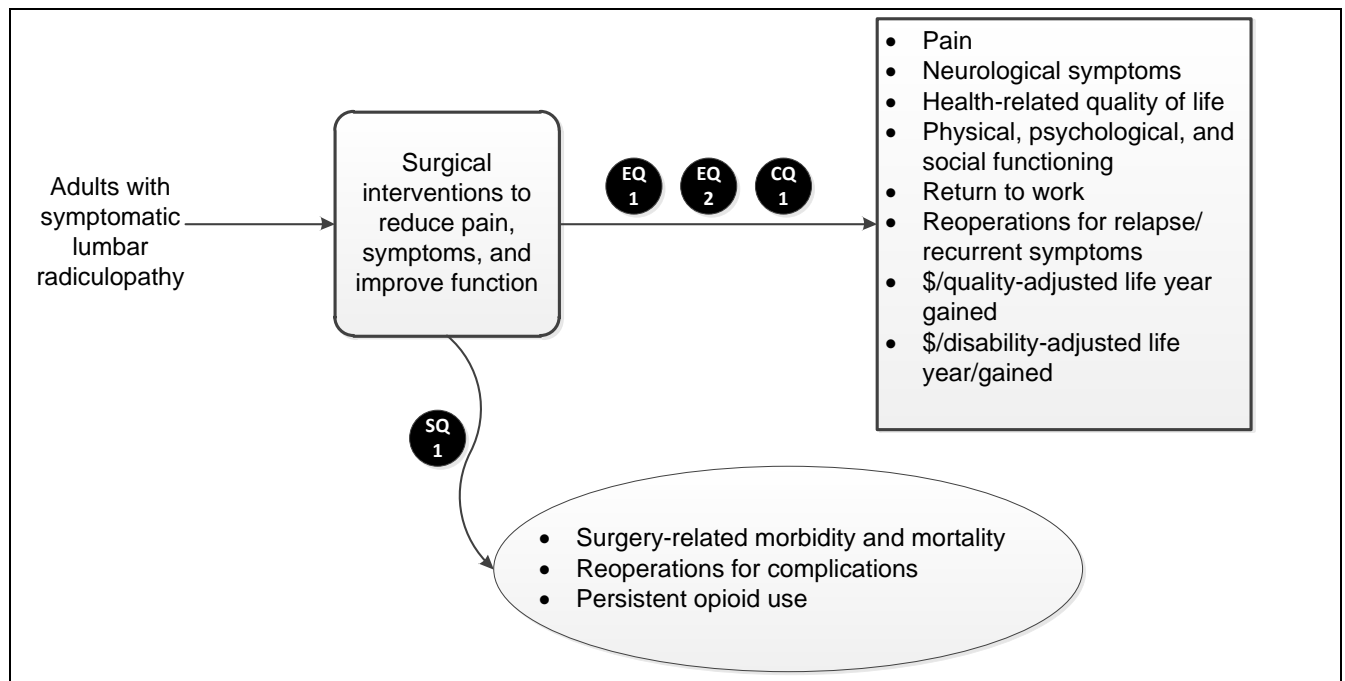
Efficacy Question 2 (EQ2). In adults with symptomatic lumbar radiculopathy, does effectiveness or comparative effectiveness of surgical interventions vary for patients who are not employed because of disability or patients who are undergoing recurrent surgery for relapse?

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

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

Figure 1 depicts the framework of the proposed HTA.

Figure. Analytic Framework Depicting Scope of Proposed Health Technology Assessment



Population: Adults (18 years and over) with symptomatic lumbar radiculopathy are included; adults with cauda equina syndrome, neurogenic claudication, spondylolisthesis, cervical or thoracic symptoms, traumatic or congenital structural abnormalities, or radiculopathy not related to lumbar disc herniation or spondylosis are excluded.

Intervention: The following open surgical interventions are included:

- Discectomy
- Laminectomy, laminotomy
- Foraminotomy
- Nucleotomy
- Sequestrectomy

“Micro” approaches to the above open procedures, which may involve smaller incisions, smaller areas of dissection, and use of a microscope or loupe magnification are also eligible.

Minimally invasive surgical procedures including percutaneous or endoscopic approaches to the above interventions are also eligible.

The following interventions are excluded as they are primarily designed to treat neurogenic claudication because of central spinal stenosis, spinal instability, or nonradicular low back pain.

- Spinal fusion
- Arthroplasty
- Artificial disc replacement
- Interspinous process decompression
- Minimally invasive surgical procedures designed primarily to treat discogenic low back pain or lumbar spinal stenosis

Chemonucleolysis with chymopapain is also excluded because it is a rarely used treatment for lumbar disc herniation and related radiculopathy in current practice.

Comparator: Placebo or no treatment comparators (sham surgery, expectant management); active treatment comparators including nonsurgical management (e.g., physical therapy, chiropractic treatment, epidural injection, medication) or surgical interventions listed above as eligible interventions. Studies without a comparator group, or studies that use active treatment interventions that are listed as ineligible interventions will be excluded.

Outcomes

Efficacy: Pain, neurologic symptoms, health-related quality of life, physical, psychological, and social functioning, return to work, reoperations for relapse; measures of pain, quality of life, and function must be measured using valid and reliable instruments or scales. Only outcomes reported at 4 weeks post-op or later will be included as differences in efficacy before 4 weeks may not be clinically relevant.

Safety: Surgery-related morbidity including venous thromboembolism, paralysis, new onset neurologic symptoms, dural tear, epidural hematoma, surgical mortality, reoperations for complications, persistent opioid use

Cost/Cost-Effectiveness: cost per quality-adjusted life years gained, cost per disability-adjusted life years gained

Setting: Inpatient or outpatient settings in countries categorized as “very high” on United National Human Development Index

Time Period: No restriction on included studies; however, search strategy will use existing systematic reviews to identify potentially relevant studies published prior to 2007.

Other Criteria

Only studies published in English will be included.

For all efficacy and safety research questions, only controlled clinical trials, randomized clinical trials, and systematic reviews of controlled or randomized clinical trials will be included. For active treatment comparisons, only randomized clinical trials or systematic reviews of randomized clinical trials will be included. For cost-effectiveness research question, we will include cost-effectiveness, cost-utility, or cost-benefit analyses performed from payor or societal perspectives.

Studies will be included regardless of risk of bias, however; we will only include studies with a high risk of bias rating in quantitative analysis if fewer than 3 studies are available.

References

1. Tarulli AW, Raynor EM. Lumbosacral radiculopathy. *Neurol Clin.* 2007;25(2):387-405. doi: 10.1016/j.ncl.2007.01.008
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3. Genevay S, Atlas SJ. Lumbar Spinal Stenosis. Best practice & research. *Clinical rheumatology.* 2010;24(2):253-65. doi: 10.1016/j.berh.2009.11.001
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Public comment and response

See *Draft Key Questions: Public Comment & Response* document published separately.