DRAFT Key Questions and Background

Surgery for symptomatic lumbar radiculopathy

Public comment on the draft key questions will be accepted until: COB, November 27, 2017

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). Both processes can cause stenosis of the lateral recesses or neural foramina and resulting spinal nerve root compression. Degenerative changes can also produce spondylolisthesis, central spinal canal stenosis, and facet joint hypertrophy, which may be associated with nonradicular low back pain. Less common etiologies of radiculopathy include infection, inflammation, neoplasm, vascular disease, and congenital abnormalities. 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%.

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). Further, radiculopathy may present only with pain or with varying degrees of sensory disturbance or motor weakness. 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 surgical techniques (e.g., laminectomy, discectomy), minimally invasive surgical techniques that use percutaneous, endoscopic, or laser-assisted approaches are now 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.

Proposed 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 difficult subpopulations? For example, 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 proposal to HTA.

Figure. 1 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 disc herniation or spondylosis are excluded.

Intervention: The following surgical interventions are included:

- Laminectomy, laminotomy
- Discectomy
- Foraminotomy
- Nucleotomy
- “Micro” approaches to the above procedures, which involve smaller incisions, smaller areas of dissection, or both
Minimally invasive surgical procedures including percutaneous, endoscopic, laser-assisted, and image-guided approaches focused on treating radicular low back or leg pain or neurologic symptoms

Chemonucleolysis

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
- Minimally invasive surgical procedures focused on treated nonradicular low back pain

**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.

**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.

**Safety:** Surgery-related morbidity including venous thromboembolism, paralysis, new onset neurologic symptoms, 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 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 safety research question, in addition to trials and systematic reviews, we will include observational designs with a comparator group. Observational designs without a comparator group will only be included for rare adverse events.

Studies will be included regardless of risk of bias, however; we will synthesize studies with a high risk of bias separately from studies for which the risk of bias is low or cannot be determined.
References


Public comment and response

Submit comments to the HTA program at shtap@hca.wa.gov.

For additional information on public comments.