Washington State Health Care Authority
Health Technology Assessment

FINAL key questions and background

Artificial disc replacement – re-review

Background

Back and neck pain due to degenerative disc disease (DDD) is the leading cause of pain and disability in adults in the United States, and as such, a large proportion of health care expenditures is used for the evaluation and treatment of this condition. Because aging is the primary risk factor for development of DDD, as the US population ages, the incidence of DDD is expected to increase.

Initially, treatment of symptomatic DDD typically consists of nonsurgical approaches, such as physical therapy, epidural steroid injections, and medications. However, an estimated 10% to 20% of people with lumbar DDD and up to 30% with cervical DDD are unresponsive to nonsurgical treatment. In addition, cervical DDD may lead to radiculopathy and/or myelopathy; 25% of people with cervical radiculopathy and 50% to 70% of those with cervical myelopathy do not respond to nonsurgical treatment.

Surgery may be considered when nonoperative treatments for at least six months fail to relieve symptoms attributed to spinal DDD or to prevent progression of nerve damage in the case of radiculopathy or myelopathy. Historically, lumbar or cervical fusion (also called arthrodesis) has been offered as a surgical option with the goal of removing the disc and fusing the vertebrae, thereby limiting the motion at the symptomatic segment. Spinal fusion is thought by some to promote the degeneration of the vertebrae above or below the fusion site (adjacent segment disease); however, many uncertainties remain regarding the extent to which this occurs. Guidelines recommend consideration of intensive multidisciplinary rehabilitation and appropriate patient selection as an integral part of decisionmaking particularly for lumbar fusion. For cervical DDD resulting in radiculopathy or myelopathy, the current surgical standard is anterior cervical discectomy and spinal fusion (ACDF), the goal of which is nerve decompression and restoration of spinal alignment and stability.

A surgical alternative to fusion is artificial disc replacement (ADR). Disc prostheses were developed to mimic the decompressive and supportive properties of intervertebral discs as well as to preserve motion at the index level, thereby improving pain and function as well as decreasing stresses on adjacent segment structures and theoretically the risk of adjacent segment disease. Lumbar ADR (L-ADR) is currently indicated in patients with single-level DDD who have failed at least six months of nonoperative care, while cervical ADR (C-ADR) is indicated in patients with radiculopathy or myelopathy secondary to one- or two-level DDD that has not responded to six weeks of nonsurgical treatment.

A Health Technology Assessment titled: *Artificial Disc Replacement*, was published on September 19, 2008 by the Health Care Authority.; the resulting Findings and Coverage Decision were released on October 17, 2008 and adopted on March 20, 2009. Based on a signal update report (1/25/2016), new randomized controlled trials for lumbar and cervical ADR have been published subsequent to the 2008 report. In addition, longer-term follow-up of patients is now available for some of these trials, and at least one device has subsequently received FDA approval for two-level placement.

Policy context

This technology was originally reviewed September 2008 and was selected for re-review based on new literature identified which may invalidate aspects of the previous report.

Objectives

The primary aim of this assessment is to update the 2008 report based on systematic review and synthesis of subsequently published evidence on the efficacy, safety, and cost-effectiveness of artificial disc replacement (ADR) in the cervical and lumbar spine.

Scope

Population:
Lumbar: Patients undergoing primary L-ADR for DDD without neurological compromise and who have not had prior spine surgery at the instrumented level.

Cervical: Patients undergoing primary C-ADR for DDD resulting in radiculopathy or myelopathy and who have not had prior surgery at the instrumented level.

Intervention: L-ADR or C-ADR with commercially available device (defined as FDA-approved devices or unapproved devices in Phase III trials with ≥ 1 year of follow-up data in a peer-reviewed journal)

Comparators: Non-operative treatment, spinal fusion, other spine surgery. Comparator interventions that employ a device not FDA-approved for use in the US will be excluded.

Outcomes:
Studies must report on at least one of the following:

- Physical function/disability (overall clinical success, ODI [L-ADR] or NDI [C-ADR]).
- Pain/pain reduction.
- Device failure (reoperation at the index level, to include revision, reoperation or removal).
- Complications (e.g., migration, subsidence, neurologic injury as well as infection, vascular damage, heterotopic ossification others).

The following secondary outcomes are reported if presented with studies meeting the above criteria:

- Quality of life (SF-36).
- Incidence of adjacent segment disease.

Non-clinical outcomes such as range of motion and alignment are excluded from the scope.

Key questions

1. What is the evidence of efficacy and effectiveness of ADR compared with comparative therapies (including non-operative therapy; spinal fusion; other surgery)?
2. What is the evidence related to the ADR safety profile? (including device failure, reoperation)
3. What is the evidence of differential efficacy or safety issues amongst special populations (including but not limited to the elderly and workers compensation populations)?
4. What are the cost implications and cost effectiveness for ADR?

Study design

This report will focus on evidence that evaluates efficacy and effectiveness and has the least potential for bias. For Key Question 1, only randomized controlled trials (RCTs) and comparative studies with concurrent controls will be considered (N≥50 for lumbar ADR; N≥100 for cervical ADR). For Key Question 2, adverse events or harms reported in the RCTs and nonrandomized studies included for Key Question 1 will be included; in addition, summaries of case series with the evaluation of safety as a primary study objective may be considered and very briefly summarized to provide additional context. High quality systematic reviews will be appraised and incorporated if feasible. RCTs and comparative cohort studies with concurrent controls and low risk of bias published subsequent to such reviews and will be evaluated based on the PICO inclusion/exclusion criteria. As this report serves to update the 2008 assessment, only comparative studies published subsequent to that review will be included and described; results will be described based on the context of previous findings. For Key Question 3, RCTs which stratify on patient or other characteristics and formally evaluate statistical interaction (effect modification) will be sought. For Key Question 4 only full, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies) will be considered.

Analytic framework