The Performance of Fusion Procedures for Degenerative Disease of the Lumbar Spine

DRAFT KEY QUESTIONS (KQs)

KQ1: In adult patients with symptomatic, non-mobile degenerative spondylolisthesis, how effective is fusion with decompression compared to decompression alone for:

KQ1A: Reduction in back pain and symptoms associated with neural compression

KQ1B: Rates of re-operation within 12 months

KQ2: In adult patients with degenerative lumbar spondylolisthesis undergoing spinal fusion, does addition of an interbody cage to pedicle screw instrumentation affect:

KQ2A: Rates of arthrodesis

KQ2B: Postoperative outcomes [as measured by Oswestry Disability Index (ODI), SF-36, SF-12]

KQ3: Are lumbar epidural steroid injections, medial branch blocks, or radio frequency ablation effective for improving symptoms in patients with chronic low-back pain resulting from degenerative disease of the lumbar spine?

KQ4: Among patients with chronic low-back pain resulting from degenerative disease of the lumbar spine, does symptomatic improvement to therapeutic challenge with lumbar facet injections, medial branch blocks or radio frequency ablation predict positive outcomes after lumbar fusion surgery?

KQ5: Does the use of intraoperative monitoring decrease perioperative neurological injuries for lumbar fusion?

KQ6: For adult patients undergoing lumbar fusion, do clinical outcomes vary between the use of autografts compared to the use of bone graft extenders and biologic substitutes (demineralized bone matrix, cadaveric allograft, cortical fibers, bone morphogenic protein, cellular allografts)?

BACKGROUND

The Patient-Centered Outcomes Research Institute (PCORI) is partnering with the Agency for Healthcare Research and Quality (AHRQ) to develop a systematic evidence review on the performance of fusion procedures for degenerative disease of the lumbar spine. The Congress of Neurological Surgeons (CNS) nominated the topic to PCORI in anticipation of the systematic review informing a future guideline.

Degeneration of the intravertebral disks of the lumbar spine and other spinal support structures occurs as a normal result of aging. This degeneration can lead to a host of problems, including spondylolisthesis

(the slippage of one vertebra over another), which can cause neural compression and pain, mobility issues, and can impact quality of life.[1] Degenerative disease of the lumbar spine is common, with up to 27% of adults in the United States experiencing degeneration by age 65 and prevalence increasing with age.[2]

Patients with degenerative disease of the lumbar spine experiencing symptoms can be treated with conservative nonsurgical therapies including pain medication, back braces, or physical therapy. Other treatments like epidural steroid injections, medial branch blocks, or radiofrequency ablation may also be used to target affected nerves and provide pain relief. In some cases, patients may remain symptomatic following conservative treatment, and as a result, may choose to undergo surgery in hopes of reducing pain or improving other neurological symptoms.[3] Surgical treatment involves fusing the affected vertebrae of the lumbar spine, connecting them to prevent further movement and alleviate symptoms. The rates of elective lumbar spinal fusion for spondylolisthesis are increasing dramatically in the United States, up 110% from 2004 to 2015, with increases greatest for patients aged 65 or older.[4] While lumbar fusion procedures have demonstrated benefit for many patients,[5] they have not been effective for all and surgical approaches continue to evolve, leaving questions around what works best and for whom.[6]

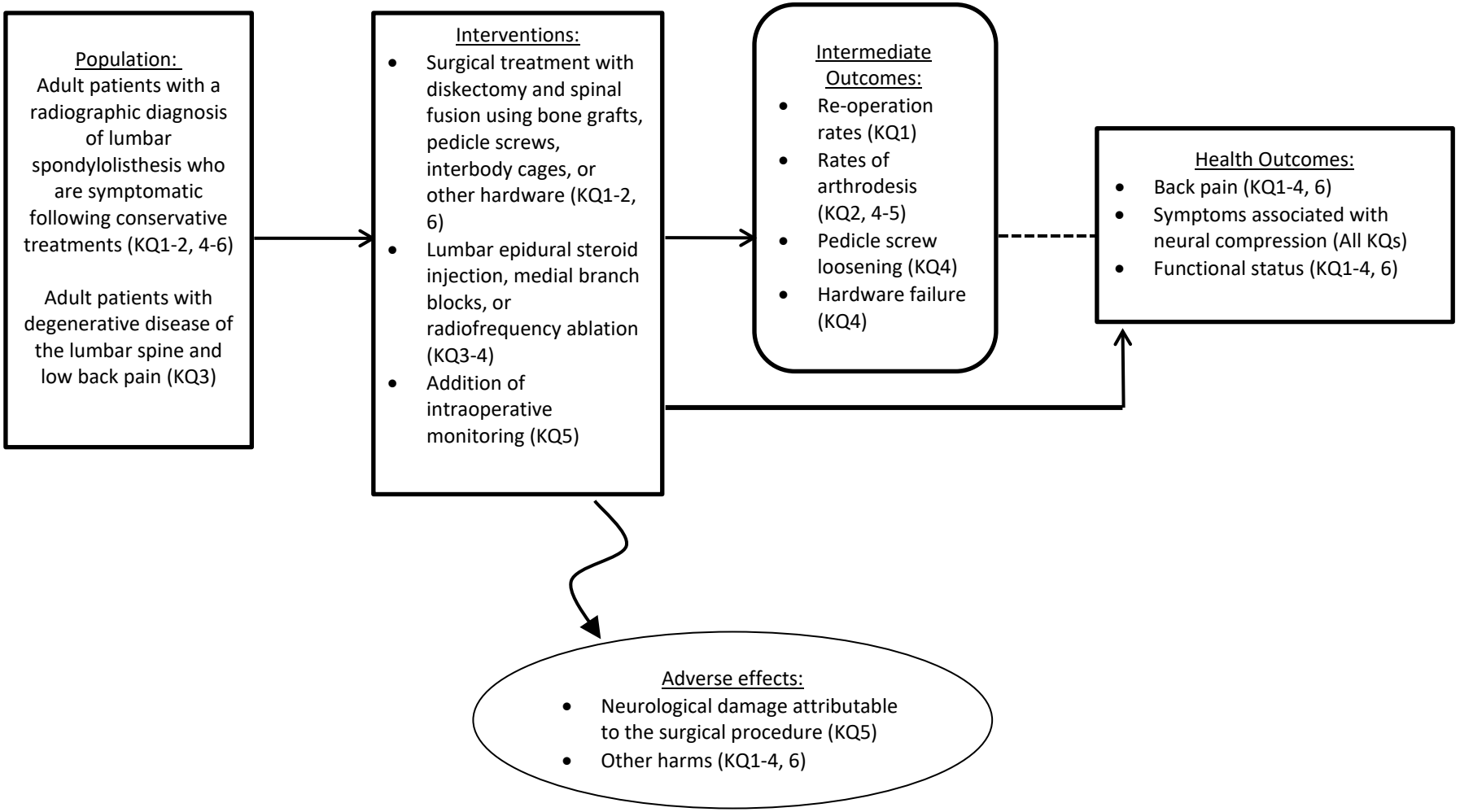
In 2014, the CNS Spine Section, a collaboration with the American Association of Neurological Surgeons, published an updated clinical practice guideline on the performance of lumbar fusion procedures for degenerative disease of the lumbar spine.[5,7] The guideline made recommendations for patients with different clinical presentations, specific approaches to fusion and hardware, nonsurgical therapies, use of autografts, bone growth extenders and biological substitutes, and intraoperative monitoring. While the North American Spine Society also published a guideline on diagnosis and treatment of degenerative lumbar spondylolisthesis in 2014 and the Enhanced Recovery After Surgery (ERAS®) Society developed a consensus statement on perioperative care during lumbar fusion in 2021, there are no other recent clinical practice guidelines or statements related to the topic.[8,9]

Since the publication of the CNS guideline, randomized controlled trials and observational studies assessing fusion procedures for degenerative disease of the lumbar spine have accumulated but there are no recent comprehensive systematic reviews synthesizing the new evidence. One systematic review assessing surgical fusion and decompression compared with decompression alone is dated and only includes studies published prior to mid-2016.[10] Five recent systematic reviews evaluated different fusion techniques and hardware, but none directly compare the use of pedicle screws alone with the addition of an interbody cage.[11–15] An additional five systematic reviews assessed the effectiveness of a key nonsurgical alternative, radiofrequency ablation, but have drawn mixed conclusions.[16–20] Other important questions, such as whether the response to therapeutic challenges of nonsurgical treatments can predict lumbar fusion surgical outcomes and the effectiveness of intraoperative monitoring approaches, are not addressed in recent reviews.

A new systematic review of fusion procedures for degenerative disease of the lumbar spine is warranted. CNS plans to use the findings of the review to update their 2014 guideline. The systematic review may serve to reaffirm existing clinical recommendations and offer an up-to-date overview of the state of the science and identify evidence gaps for future research.

DRAFT ANALYTIC FRAMEWORK

Figure 1. Preliminary Analytic Framework



SCOPE

Table 1. PICOTSS Framework (population, interventions, comparators, outcomes, timing, settings, study design) for KQ1-6

	KQ1 (Effectiveness of Fusion)	KQ2 (Interbody Cage to Pedicle Screw)	KQ3 (Epidural Steroid Injection)	KQ4 (Therapeutic Challenge)	KQ5 (Intraoperative Monitoring)	KQ6 (Autografts, Extenders, and Biologic Substitutes)
POPULATIONS	Adult patients with a radiographic diagnosis of non-mobile lumbar spondylolisthesis who are symptomatic following conservative treatments	Adult patients with a radiographic diagnosis of lumbar spondylolisthesis who are symptomatic following conservative treatments	Adult patients with chronic low back pain and degenerative lumbar spine disease.	Adult patients with a radiographic diagnosis of lumbar spondylolisthesis who are symptomatic following conservative treatments	Adult patients with a radiographic diagnosis of lumbar spondylolisthesis who are symptomatic following conservative treatments undergoing lumbar spine fusion surgery	Adult patients with a radiographic diagnosis of lumbar spondylolisthesis who are symptomatic following conservative treatments
INTERVENTIONS	Surgical treatment with diskectomy and spinal fusion using bone grafts, pedicle screws, interbody cages, or other hardware	Surgical treatment with diskectomy and spinal fusion using pedicle screws with addition of interbody cage (expandable/ static; ALIF; TLIF; LLIF)	Lumbar epidural steroids (ESI), medial branch blocks, or radio frequency ablation (RFA)	Therapeutic challenge with lumbar facet injections, medial branch blocks or radiofrequency ablation before lumbar fusion surgery	Intraoperative monitoring using neurophysiological monitoring or other techniques	Surgical treatment with diskectomy and spinal fusion using autografts
COMPARATOR	Surgical treatment with diskectomy alone	Surgical treatment with diskectomy and spinal fusion using pedicle screws alone	Alternative form of treatment of non-operative treatment or no specific treatment	Measures of low back pain/patient functional status measured by ODI, EQ5D, and the SF-36, symptoms associated with neural compression, successful arthrodesis [as radiographically determined via x-ray/computed tomography or by proxy (ex. lack of revision)], pedicle screw loosening Results are to be stratified according to patient response to	No use of intraoperative monitoring or use of an alternative form of monitoring	Surgical treatment with diskectomy and spinal fusion using bone graft extenders and biologic substitutes (demineralized bone matrix, cadaveric allograft, cortical fibers, bone morphogenic protein, cellular allografts)
OUTCOMES	(1A) Reduction in back pain and symptoms associated with neural compression using a defined scoring system (ODI, SF-36, SF-12) and	(2A) Rates of arthrodesis (2B) Postoperative outcomes of low back pain and	Measures of low back pain and patient functional status measured by ODI, EQ5D, and the SF-36		Neurological damage attributable to the surgical procedure	Measures of low back pain and patient functional status measured by ODI, EQ5D, and the SF-36. Successful arthrodesis

	minimum detectable change (MDC) (1B) Rates of re-operation Harms of treatment	patient functional status as measured by ODI, SF-36, or SF-12 Harms of treatment	Harms of treatment	therapeutic challenge (i.e. - improvement of symptoms vs. non-improvement of symptoms) Harms of treatment		Harms of treatment
TIMING	(1A) Outcomes measured at least 12 months after surgical procedure (1B) Within the 12 months after surgical procedure	Outcomes measured at least 12 months after surgical procedure	Outcomes measured over a 6-month period following the procedure	Outcomes measured at least 12 months after surgical procedure	Outcomes measured at any time during post-operative follow-up	Outcomes measured at least 12 months after surgical procedure
SETTINGS	Inpatient care followed by care in specialty and primary care clinics		Outpatient care	Outpatient care for therapeutic challenge. Inpatient care followed by care in specialty and primary care clinics for surgical procedure.	Inpatient care	Inpatient care followed by care in specialty and primary care clinics.
STUDY DESIGN	Randomized controlled trials. Controlled trials and observational studies as determined during Topic Refinement					

KQ = Key Question; ODI = Oswestry Disability Index; SF-36 = 36-Item Short Form Survey; SF-12 = 12-Item Short Form Survey; EQ5D = EuroQol standardized measure of health-related quality of life; ALIF = Anterior lumbar interbody fusion; TLIF = Transforaminal lumbar interbody fusion; LLIF = Lateral lumbar interbody fusion; PROMs = patient-reported outcome measures

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