**Search strategy for cost-effectiveness of surgical treatment for lumbar degenerative disease.**

**PubMed Search**

Date: 11-8-2013

Completed by: KEM

(((("Intervertebral disc disease" [Supplementary Concept]) OR (disk OR disc OR joint) OR ("Spinal Stenosis"[Mesh])) AND (lumbar OR lumbosacral OR thoracolumbar)) AND (("Cost-Benefit Analysis"[Mesh]) OR "Quality-Adjusted Life Years"[Mesh] OR "cost utility"))

|  |  |  |
| --- | --- | --- |
| 1 | "Intervertebral disc disease"[Supplementary Concept] | 71 |
| 2 | disk OR disc OR joint | 637 |
| 3 | “Spinal Stenosis"[Mesh] | 3,986 |
| 4 | #1 OR #2 OR #3 | 4,672 |
| 5 | Lumbar or lumbosacral or thoracolumbar | 98,184 |
| 6 | #4 AND #5 | 2,775 |
| 7 | "Cost-Benefit Analysis"[Mesh] | 57,477 |
| 8 | "Quality-Adjusted Life Years"[Mesh] | 6,415 |
| 9 | "cost utility" | 2,398 |
| 10 | #7 OR #8 OR #9 | 60,295 |
| 11 | #6 AND #10 | 75 |
|  | Abstract available and Human and English | 59 |
|  | Abstract available and Human and non-English | 5 |

**EMBASE Search**

Date: 12-5-2013

Completed by: KEM

|  |  |  |
| --- | --- | --- |
|  | *Abstract available and Human and English, all explosive keywords* |  |
| 1 | “Intervertebral disk disease” OR “vertebral canal stenosis” | 18,856 |
| 2 | “Thoracolumbar spine” OR “lumbar spine” OR “lumbosacral spine” | 22,785 |
| 3 | “Cost effectiveness analysis” OR “cost utility analysis” OR “cost benefit analysis” OR “quality adjusted life year” | 75,235 |
| 4 | #1 AND #2 AND #3 AND #4 | 24 |

**Cochrane Search**

Date: 12-12-2013

Completed by: KEM

|  |  |  |
| --- | --- | --- |
| 1 | “intervertebral disc degeneration” [MeSH] | 56 |
| 2 | “spinal stenosis” [MeSH] | 155 |
| 3 | “lumbar vertebrae” [MeSH] | 1,885 |
| 4 | “thoracolumbar” [exact word] | 164 |
| 5 | “lumbosacral region” [MeSH] | 274 |
| 6 | “cost-benefit analysis” [MeSH] | 14,660 |
| 7 | “quality-adjusted life years” [MeSH] | 3,329 |
| 8 | “cost utility” [MeSH] | 3,732 |
| 9 | #1 OR #2 | 210 |
| 10 | #3 OR #4 OR #5 | 2,236 |
| 11 | #6 OR #7 OR #8 | 15,569 |
| 12 | #9 AND #10 | 140 |
| 13 | #12 AND #11 | 15 |

**CEA Registry**

Date: 12-16-13

Completed by: KEM

Search “lumbar” – found 28 studies, 0 unique (duplicates from EMBASE, Cochrane or PubMed)

**University of York, Centre for Reviews and Dissemination**

Date: 12-16-13

Completed by: KEM

Search (intervertebral disc disease) OR (spinal stenosis) AND (lumbar OR lumbosacral OR thoracolumbar)

Found 60 studies, 0 unique (duplicates from EMBASE, Cochrane or PubMed)

**DETAILED METHODS DESCRIPTION:**

*Electronic Literature Search*

A systematic search of PubMed, EMBASE, the Cochrane Collaboration data base, University of York, Centre for Reviews and Dissemination (NHS-EED and HTA), and the Tufts CEA Registry was conducted to identify full economic studies conducted through December 16, 2013 based on the key questions and inclusion/exclusion criteria established *a priori* (Table 1). For key question one, we attempted to identify studies that compared lumbar spine surgery with nonoperative care. In key question two, we sought to identify studies comparing decompression and lumbar fusion with decompression surgery alone. In key question three, we attempted to identify studies that compared the use of instrumentation in lumbar fusion procedures. Search terms included lumbar degenerative diseases (stenosis, spondylolisthesis and lumbar disc or joint) combined with terms specific to economic studies such as cost benefit, cost effectiveness, cost utility and quality adjusted life years. The search strategy is further documented in the supplementary digital material. Studies published in peer reviewed journals or contained within health technology assessments (HTAs) were considered. Abstracts that did not overtly describe cost effectiveness were excluded. Only economic studies that evaluated and synthesized the costs and consequences of spinal surgery (i.e. cost-minimization, cost-benefit, cost-effectiveness or cost-utility) were considered for inclusion.

*Data Extraction*

 From the included articles, the following data were extracted: study design, patient demographics, inclusion and exclusion criteria, treatment interventions, perspective of economic model, type of economic model (if used), follow-up duration and the rate of follow-up for each treatment group (if reported or calculable), time horizon of economic model, assumptions and specifications of the model, cost sources, discounting and currency type, source of clinical and utility data, primary findings (including costs, quality adjusted life years, incremental cost effectiveness ratios, sensitivity analysis, cost effectiveness information e.g. cost per surgery avoided) and limitations or risk of bias within the study.

*Data Analysis*

Data and economic findings were reported as presented in the articles.

*Critical appraisal*

The Quality of Health Economic Studies (QHES) instrument developed by Ofman et al. was used to provide an initial basis for critical appraisal of included economic studies[1](file:///C%3A%5CUsers%5Cjoe%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAOUOVJU8%5COriginal%20Methods%20%28long%29%20%282%29.docx#_ENREF_1). QHES is a sixteen 'yes' or 'no' question instrument that assesses multiple aspects of economic study design, modeling and reporting to determine internal validity (See Supplemental Digital Material). QHES was assessed prospectively[1](file:///C%3A%5CUsers%5Cjoe%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAOUOVJU8%5COriginal%20Methods%20%28long%29%20%282%29.docx#_ENREF_1),[2](file:///C%3A%5CUsers%5Cjoe%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAOUOVJU8%5COriginal%20Methods%20%28long%29%20%282%29.docx#_ENREF_2) for content and construct validity by the developers and has been evaluated externally as well[3](file:///C%3A%5CUsers%5Cjoe%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAOUOVJU8%5COriginal%20Methods%20%28long%29%20%282%29.docx#_ENREF_3). Components are weighted by importance (as concluded by expert health economists) to yield a score from 0 (lowest quality) to 100 (highest quality). Items that are considered most important (based on their weighting) include:

* use of data from best available sources (e.g. RCT),
* statistical analysis to address random events and use of sensitivity analysis to explore model,
* use of appropriate sources and methodologies for measuring and estimating costs,
* use of valid and reliable outcomes measures,
* transparent description of economic modeling used including delineation and justification of main assumptions and limitations of the model,
* extent to which conclusions and recommendations were justified and based on study results.

Some have suggested that a score of 75-100 points indicates a high quality economic study[4](file:///C%3A%5CUsers%5Cjoe%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAOUOVJU8%5COriginal%20Methods%20%28long%29%20%282%29.docx#_ENREF_4). The QHES does not provide insight into study external validity (generalizability) nor does it directly assess the validity of clinical assumptions and inputs. A study may receive a high score based on factors assessed in QHES, but ultimately may not be applicable to a broader range of clinical populations. Thus, in addition to assessment of criteria in the QHES, other factors are important in critical appraisal of studies from an epidemiologic perspective to assist in evaluation of generalizability and consideration of potential sources of bias related to clinical inputs into the economic model.

Two reviewers (KEM, JRD) independently applied the QHES to included studies. Discrepancies in ratings were discussed so that consensus could be reached and a final score obtained.

**Table 1. Studies excluded at full text and reasoning for exclusion.**

|  |  |
| --- | --- |
| **Citation** | **Reason for exclusion** |
| Deyo, R. A., B. I. Martin, et al. (2013) Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the medicare population (Provisional abstract). Spine 865-872. | Excluded at full text, authors did not synthesize the costs and benefits of the treatment. |
| Tso, P., K. Walker, et al. (2012). "Comparison of lifetime incremental cost utility ratios of surgery relative to failed medical management for the treatment of hip, knee and spine osteoarthritis modelled using 2-year postsurgical values." Can J Surg 55(3): 181-190. | Excluded at full text, comparison not of interest. |

**Table 2. Detailed table of included studies.**

| **Author (year)** **Country****Funding**  | **Population** **Interventions** | **Design****Perspective****Time horizon****Model** | **Assumptions** | **Model specifications** | **Currency****Cost Sources****Discounting** | **Clinical Data Source** (e.g Utility, other)source  | **Primary Findings**(ICER; dominance, Sensitivity analysis range of ICERs) | **Limitations, risk of bias** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Burnett (2010)USAIndividual author discloses no conflicts of interest**Funding of work:** NRPrimary comparison between XSTOP and laminectomy | *Retrospective review of 6 studies used in model***Conservative (nonsurgical) management:**n = NRmales: NRage: NR**Laminectomy:**n = NRmales: NRage: NRsingle level: 20.3%**Inclusion:*** Patients with spinal stenosis and spondylolisthesis

**Exclusion:*** NR
 | CUASocietal2 & 4 year F/U2-year time horizonDecision Tree, Monte-Carlo | * Laminectomies are performed as inpatient surgeries
* All nonoperative patients incur the same costs for nonsurgical care (medication, physical therapy, other rehab costs, medical devices – not included in calculation)
 | Decision Tree, Monte-Carlo* Monte-Carlo simulation, 1000 trials
* Hypothetical patient could receive 1 of three treatments (nonop, XSTOP or laminectomy)
* Each treatment was a success or failure, failure leads to additional laminectomy (QALYs reduced by 10%, costs of laminectomy added)
* Model was run three times, once as all 1-level procedures, then all 2 level, then actual levels treated
* Primary analysis used 2-yr F/U period
 | 2008 $USA**Cost source:** * + 2008 Medicare national average reimbursements
	+ Anesthesia costs (Fleiss et al.)

**Costs used for analysis:*** Direct costs: Medicare DRG and anesthesia
* Indirect costs: excluded from analysis

**Cost and QALY discounted** 3% per year | **Outcome measures** * Revision rates, 2 yr failure rates, requiring additional surgery (Anderson et al., Atlas et al., Fenwick et al., Fleiss et al.)

**Utility measures** * SF-36/HRQOL (Fenwick et al., Fleiss et al., Gold et al., Hsu et al.)

SF-36 scores taken before treatment and at 6, 12, and 24 mos. | **Mean case:** Costs (± SD):(Details NR) costs per patient ($ US)* Nonsurigcal: 3,453.82 ± 427
* Laminectomy: 9,349.03 ± 2,045
* ∆ Cost: $5,895

QALYs:(Details NR) QALYs per patient: * Nonsurigcal: 0.0660 ± 0.0400
* Laminectomy: 0.1651 ± 0.0363
* ∆ QALY: 0.0991

**ICER: ∆$US/∆QALY** 59,487.49**1-Way Sensitivity Analysis Variables*** Cost of laminectomy
* Utility of laminectomy
* Others NR

**ICER ranges from sensitivity analysis:** NR*ICER most sensitive to utility score variation and cost variation* | * Costing data not well documented, specifically for nonoperative care
* LOS not calculated in the analysis
* No indirect costs, direct costs are not reported
* Per authors, assumptions were made that were neutral or favored XSTOP or nonoperative care over laminectomy
 |
| Kim (2012)CanadaIndividual author disclosures related to industry**Funding of work:** Supported by the W. Garfield WestonFoundation and the Toronto General and Western HospitalFoundation.QHES: 76 | *Retrospective cohort*N= 150 assessed n = 115 included% F/U: 76.7%**Decompression alone:**n = 57males: 56%age: 67.1 ± 9.7**Decompression with instrumented fusion:**n = 58males: 27%age: 63.7 ± 9.7**Inclusion:*** DLS as primary diagnosis
* SF-6D score at 1 year
* Failed conservative management (symptomatic ≥ 12 mos.)

**Exclusion:*** + - Index procedure involved a revision or previous surgery at an adjacent level
 | CUASingle provider perspective (Hospital)F/U time NR10-year time horizon Markov Model | * Patients were assumed to be surgical candidates and opted for surgery over continued nonoperative care
* Exclusion of healthcare utilization costs or out-of-pocket expense outside of hospital stay
* No history of prior spinal surgery
* No direct consideration of adverse events except perioperative mortality
* Patients failing surgery or symptom recurrence have chance for re-op after 1 year in “no improvement” state
 | Markov model * 1 year cycle simulations over 10 year period
* 4 transition states – well, unwell, no improvement, death
* Hypothetical cohort of 1000 (all start as “unwell”)
* Separate simulations for decompression and decompression w/fusion cohorts
 | 2010 $CDN**Cost source:** * + Hospital financial department, average cost from prospective cohort cases over 4 years
	+ Physician reimbursement not included

**Costs used for analysis:*** Direct costs (including but not limited to: labor, operating room hours, surgical implants, disposables, recovery room hours, ward nursing and allied health care, inpatient diagnostic testing, laboratory charges)
* Indirect costs (including but not limited to: administration, facilities)

**Cost discounted** 3% per year | **Outcome measures** * Revision rates (Martin et al.)
* Relapse rates (Martin et al.)
* Perioperative death rate (Deyo et al.)
* General death rate (Statistics Canada)
* Clinical improvement rate (overall patient satisfaction from SPORT)
* Choice to reoperate (Martin et al., Kuntz et al.)
* Clinical worsening (source NR)

**Utility measures** * SF-6D (cohort data and SPORT)
 | **Base case:** Costs:10 yr. cumulative costs per patient (K$ CND)* Decom: 6,514
* Decomp/Fusion: 20,797
* ∆ Cost: $14,283

QALYs:10 yr. cumulative QALYs per 1,000 patients: * Decom: 6,263
* Decomp/Fusion:6,340
* ∆ QALY: 0.077/patient

**ICER: ∆$CDN/∆QALY** 185, 878**1-Way Sensitivity Analysis Variables:*** Utility score
* Utility score annual discount rate
* Surgery effectiveness
* Revision rate
* Inpatient ratio
* Decomp/Fusion cost
* Cost annual discount rate

**ICER ranges from sensitivity analysis:** $15,492 – $275,191 *ICER most sensitive to utility score variation and revision rate variation* | * Costing data not well documented
* Complications were not included in analysis
* Physician reimbursement not included
* 1-way sensitivity analysis only
 |
| Kuntz (2000)USA**Funding of work:** Supported NIH grants and Clinical Science Grant from the Arthritis Foundation | *Number of studies NR***Laminectomy w/o fusion:**n = NRmales: NRage: NR**Laminectomy w/ noninstrumented fusion:**n = NRmales: NRage: NR**Laminectomy w/ instrumented fusion:**n = NRmales: NRage: NR% F/U: NR **Inclusion:*** Patients with degenerative lumbar spondylolisthesis and stenosis

**Exclusion:** * NR
 | CUASocietal (no morbidity costs)F/U time NR10 yr time horizonMarkov Model | * Assumptions were made about the number of patients who experienced complications, improvement, etc. based on literature values
* Probability of a patient experiencing clinical improvement was independent of whether fusion healed by 6 mos.
* Long term survival was assumed equivalent across all surgical procedures
* All surgery-related complications could have QoL effects only during the first year after surgery (except for SCI, cauda equina, or root injury)
* Utility associated with moderate stroke was assigned to patients with cord or cauda injury
* Only two distinct health states related to back pain, symptomatic or asymptomatic
 | Decision Analytic Model* 3 time intervals, perioperative, 6 mos. post-op and f/u at 10 yrs.
 | Costs from 1990-1993, updated to 1997 U.S. dollars**Cost source (Katz et al.):*** + Boston hospital cost accounting system
	+ Physician reimbursement not included

**Costs used for analysis:** Costs of the operation and reoperation**Cost discounted** 3% per year | **Outcome measures (from literature):*** Symptom relief (Herkowitz et al., Fischgrund et al., Katz et al., Thomsen et al., Turner et al., Yuan et al.)
* Fusion healing (Turner et al.)
* Revision rates (source NR)
* Complications:
* Death (Deyo et al.)
* Deep wound infection (Turner et al.)
* Cord injury (Esses et al., Turner et al.)
* Nerve root injury (Torrance et al.)
* Dural tear (Turner et al.)
* Donor site pain (Thomsen et al.)
* Medical (eg. pneumonia, pulmonary embolism) (Ciol et al., Deyo et al.)

**Utility measures (from literature):*** Time-trade off from Beaver Dam Health Outcomes study (Fryback et al.)
 | **Base case:** Costs of laminectomy w/:10 yr. cumulative costs, not discounted ($ US)* Laminectomy: 21,025
* Noninstrum fusion: 26,965
* Instrum fusion: 35,669

∆ Cost (compared to laminectomy)* Noninstrum fusion: 5,940

∆ Cost (compared to fusion w/o instrum)* Instrum fusion: 8,704

QALYs:10 yr. cumulative QALY, not discounted (yrs)* Laminectomy: 7.938
* Noninstrum fusion: 8.053
* Instrum fusion: 8.056

∆ QALY (compared to laminectomy)* Noninstrum fusion: 42 days

∆ QALY (compared to fusion w/o instrum)* Instrum fusion: 1 day

**ICER: ∆$US/∆QALY (compared to laminectomy)*** Noninstrum fusion: 56,500

**ICER: ∆$US/∆QALY (compared to fusion w/o instrum)*** Instrum fusion: 3,112,800

**2-Way Sensitivity Analysis Variables (noninstrumented fusion vs. laminectomy w/o fusion):*** Cost of noninstrumented fusion
* Short term complication rate
* Long term utility reduction for donor site pain
* Symptom relief rate
* Utility of severe symptoms of stenosis
* Annual rate of symptom recurrence
* Reoperation rate
* Rate of reoperation success

**ICER ranges from sensitivity analysis:** $24,600 – $585,800 *ICER most sensitive to symptom relief rate, utility of severe symptoms of stenosis and short term complication rate***Sensitivity Analysis Variables (noninstrumented fusion vs. instrumented fusion):** NR | * Patient demographics not reported
* Outcome measures are from different literature sources, not associated with cost source
* Authors state these findings should not be applied to patients with stenosis w/o spondylolisthesis
 |
| Tosteson (2009)USAIndividual author disclosures related to industry**Funding of work:** National Institute of Arthritis and Musculoskeletal and Skin Diseases; Office of Researchon Women’s Health, National Institutes of Health; and the National Institute of OccupationalSafety and Health, Centers for Disease Control and Prevention | *Prospective cohort study - SPORT***Stenosis only: Overall**n = 634males: 61%age: 64.6 years**Surgery:**n = 394males: 61%age: 63.6 ± 12.2**Decompression:**n = 320**Fusion:**n = 43**Nonoperative:**n = 240males: 60%age: 66.3 ± 10.5**Deg. Spondylo.: Overall**n = 601males: 31%age: 66.1 years**Surgery:**n = 368males: 31%age: 64.7 ± 10.1**Decompression:**n = 19**Fusion:**n = 344**Noninstrument:**n = 75**Instrumentation:**n = 269**Pedicle:**n = 209**Circumfren.:**n = 60**Nonoperative:**n = 233males: 33%age: 68.2 ± 10.3**Inclusion:*** Patients image-confirmed stenosis, w/ or w/o DLS
* Patients with neurogenic claudication or radicular leg pain associated with neurologic signs for ≥ 12 weeks
* All patients were judged to be surgical candidates

**Exclusion:** * Patients with lumbar instability (> 4mm or 10° angular motion between flex/extension)
 | CUASocietal2 yr F/U2 yr time horizonLongitudinal regression models fitted with generalized estimating equations | * For each participant, medical resource use by unit was multiplied by unit costs to estimate total direct medical cost at each time point
* Surgery costs were dependent on procedure performed, complications occurred
* Anesthesiology costs were estimated with operative time
* Surgeon costs were estimated with Medicare allowable amounts, according to the resource-based relative value scale
* If data were missing, baseline variables were associated with missing data
* Estimates of cost and QALY differences assumed no deaths over 2 yrs
 | Longitudinal regression models fitted with generalized estimating equations* Separate models for EuroQol EQ-5D and costs
* 5 time intervals, 6 weeks, 3, 6, 12, 24 mos.
* To estimate confidence interval for cost per QALY gained, a bootstrap method using 1000 samples taken with replacement from the original sample with the individual as the unit of observation was used
 | Costs from 2004 U.S. dollars* + **Cost source:** Medicare allowable amounts (direct), standard human capital approach (indirect)
	+ Physician reimbursement not included
	+ Costs were collected from patient health care diaries via questionnaires at 6 weeks, 3, 6, 12 and 24 mos. (6 week or 1 mo. recall period – care involving hospitalization, surgery and devices were not confined to recall window)

**Costs used for analysis:*** Direct costs (including emergency dept. or outpatient visits, spine-related diagnostic tests, injections, devices and rehab or nursing home days)
* Indirect costs (based on patient-reported time away from work or usual activities, including homemaking, because of spine-related problems)

**Costs and QALYs discounted** 3% per year | **Outcome measures (from cohort):*** Resource utilization
* Work loss

**Utility measures (from cohort):*** EuroQol EQ-5D (baseline, 6 weeks, 3, 6, 12, 24 mos.)
 | **Base case:** Costs:2 yr. cumulative costs per patient ($US)**Stenosis:*** Nonop: 13,519
* Surgical: 26,222
* ∆ Cost: $12,703
* Decom: 22,404
* Fusion: 39,949
* ∆ Cost: $17,545

**Deg. Spondyl:*** Nonop: 16,046
* Surgical: 42,081
* ∆ Cost: $26,035
* Decom: 22,012
* Fusion: 42,979
* ∆ Cost: $20,967
* Non-instrum: 40,858
* Instrum: 43,116
* ∆ Cost: $2,258

QALYs (details NR):**Stenosis:*** Nonop: 1.37
* Surgical: 1.54
* ∆ QALY: 0.17
* Decom: 1.54
* Fusion: 1.53
* ∆ QALY: -0.01

**Deg. Spondyl:*** Nonop: 1.33
* Surgical: 1.55
* ∆ QALY: 0.22
* Decom: 1.53
* Fusion: 1.55
* ∆ QALY: 0.02
* Non-instrum: 1.54
* Instrum: 1.56
* ∆ QALY: 0.02

**Mean ICER: ∆$US/∆QALY (Surgical treatment vs. nonoperative care)**Stenosis * All surgery: $77,600
* Decom: $47,900
* Fusion: $258,200

Deg. Spondyl * All surgery: $115,600
* Decom: $38,900
* Fusion: $120,200
* Noninstrum: $119,900
* Instrum: $118,100

**1-Way Sensitivity Analysis Variables:*** Restricting to RCT or observational cohort
* Limiting cost type
* Increasing surgery costs
* SF-6D to estimate effectiveness
* Accounting for observed mortality

**Mean ICER ranges from sensitivity analysis (stenosis only):** $70,900 – $139,000**ICER ranges from sensitivity analysis (stenosis and spondylolisthesis):** $107,800 – $206,600 *ICER most sensitive to increasing surgery costs or estimating effectiveness with SF-6D* | * Complications NR
* Medical costs were calculated based on Medicare national allowables
* Medication based on wholesale prices
* Randomized and observational cohorts were pooled
* Patient reported resource utilization and productivity loss
 |
| Udeh (2014)USAIndividual author discloses no conflicts of interest**Funding of work:** Outcomes Research Dept. of Cleveland ClinicPrimary comparison between minimally invasive lumbar decompression | *Retrospective literature review*N= NR% F/U: NR **ESI (non-op):**n = NRmales: NR age: NR**Laminectomy:**n = NRmales: NR age: NR**Inclusion:*** Patients who have symptomatic from lumbar spinal stenosis
* Failed conservative treatment
* Fulfilled clinical criteria for the *mild* (details NR)

**Exclusion:*** Fusion or instrumentation surgeries
 | CUAInsurer/Payer (Medicare)F/U time NR2-year time horizon Decision Analytic Model | * Patients who had no to minimal relief of symptoms anytime in the 2 yrs after *mild* procedure proceeded to surgical intervention
* Patients who had no to minimal relief of symptoms anytime in the 2 yrs after the surgical procedure assumed to have a repeat procedure
* No further treatment for ESI patients as the population considered for this study already assumes failed conservative therapy
* Symptomatic ESI patients would receive only minimal relief from ESI, but that it was the best treatment option available to them
* Assumed 75% of patients had 2-level laminectomy, 25% had 1-level
* Assumed ESI patients would continue with injections annually (6 per yr), 80% with lumbar interlaminar approach, 20% caudal approach
 | Decision Analytic Model* QALY gain calculated for each intervention, to provide year 1 and year 2 totals
* QALY reductions were calculated for complications attributable to the intervention, based on severity and duration of the complication
* QALY gains for ESI were reduced 25% from lit values to reflect “failed” conservative treatment
* QALY gains for surgery were reduced 25% due to the level of stenosis assumed for the population
 | 2013 $USA**Cost source:** * + Centers for Medicare/ Medicaid, Reimbursement Schedule 2013
	+ Laminectomy costs (also Kim et al., Tosteson et al.)

**Costs used for analysis:*** Direct costs (including but not limited to: cost of initial intervention, cost of any repeat or revision procedure, cost of any alternative treatment if the initial treatment failed w/in 2 yr time frame, complications reimbursable w/in 90 days of intervention)
* Indirect costs: NR

**Cost and QALYs discounted** 3% per year (Weinstein et al.) | **Clinical measures** * QALY gains for ESI (Whynes et al.)
* QALY gains for surgery (Glassman et al., Tosteson et al.)
* Baseline QoL (Kuntz et al.)
* Symptom relief (NR)
* Revision surgery (Kim et al., Malter et al.)
* Complications:
* Death (Kuntz et al.)
* Deep wound infection (Kuntz et al.)
* Postlumbar puncture headache (Kuntz et al., Manchikanti et al.)
* Cord or cauda equina injury (Kuntz et al.)
* Nerve root irritation (Kuntz et al., Manchikanti et al.)
* Nerve root injury (Kuntz et al.)
* Dural tear (Kuntz et al.)
* Dural puncture (Manchikanti et al.)
* Medical (Kuntz et al.)
 | **Base case:** Costs:2 yr. cumulative costs per patient ($US)* ESI: 7,887.98
* Laminectomy: 13,770.72
* ∆ Cost: $5,882.74

QALYs:2 yr. cumulative QALYs per patient: * ESI: 0.19
* Laminectomy: 0.11
* ∆ QALY: -0.08/patient

**ICER: ∆$US/∆QALY** $-73,739Nonoperative care dominates laminectomy alone**ICER ranges from sensitivity analysis**: NR **1 and 2-Way Sensitivity Analysis Variables:*** QALY gains
* Intervention costs
* Surgical revision rates
 | * Based on Medicare reimbursement model
* Additional costs for complications after 90 days from the intervention were excluded (since outside Medicare reimbursement)
* Short time horizon, especially for a chronic condition
* Lack of data on QoL for LSS patients with moderate to severe symptoms after ESI or surgery
 |

CUA: cost utility analysis; DLS: degenerative lumbar spondylolisthesis; DRG: diagnosis-related group; ESI: epidural steroid injections; HRQOL: health related quality of life; ICER: incremental cost effectiveness ratio; LOS: length of stay; LSS: lumbar spinal stenosis; *mild*: minimally invasive lumbar decompression; NR: not reported; QALY: quality-adjusted life years; QoL: quality of life

**Table 3. Quality of Health Economic Studies (QHES) score of included articles**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **QHES Question (pts possible)** | **Burnett 2010** | **Kim 2012** | **Kuntz 2000** | **Tosteson 2008** | **Udeh 2014** |
| 1. Was the study objective presented in a clear, specific, and measurable manner? (7 pts)
 | 7 | 7 | 7 | 7 | 7 |
| 1. Were the perspective of the analysis (societal, third-party payer, etc.) and reasons for its selection stated? (4 pts)
 | 0 | 4 | 0 | 4 | 4 |
| 1. Were variable estimates used in the analysis from the best available source (i.e. randomized controlled trial = best, expert opinion = worst)? (8 pts)
 | 0 | 0 | 0 | 8 | 0 |
| 1. If estimates came from a subgroup analysis, were the groups prespecified at the beginning of the study? (1 pt)
 | 1 | 1 | 1 | 1 | 1 |
| 1. Was uncertainty handled by (1) statistical analysis to address random events, (2) sensitivity analysis to cover a range of assumptions? (9 pts)
 | 9 | 0 | 9 | 9 | 9 |
| 1. Was incremental analysis performed between alternatives for resources and costs? (6 pts)
 | 6 | 6 | 6 | 6 | 6 |
| 1. Was the methodology for data abstraction (including the value of health states and other benefits) stated? (5 pts)
 | 5 | 5 | 0 | 5 | 0 |
| 1. Did the analytic horizon allow time for all relevant and important outcomes? Were benefits and costs that went beyond 1 year discounted (3% to 5%) and justification given for the discount rate? (7 pts)
 | 7 | 7 | 7 | 7 | 7 |
| 1. Was the measurement of costs appropriate and the methodology for the estimation of quantities and unit costs clearly described? (8 pts)
 | 8 | 8 | 0 | 8 | 8 |
| 1. Were the primary outcome measure(s) for the economic evaluation clearly stated and did they include the major short-term, long-term and negative outcomes included? (6 pts)
 | 6 | 6 | 6 | 0 | 0 |
| 1. Were the health outcomes measures/scales valid and reliable? If previously tested valid and reliable measures were not available, was justification given for the measures/scales used? (7 pts)
 | 7 | 7 | 7 | 7 | 0 |
| 1. Were the economic model (including structure), study methods and analysis, and the components of the numerator and denominator displayed in a clear, transparent manner? (8 pts)
 | 8 | 8 | 8 | 8 | 8 |
| 1. Were the choice of economic model, main assumptions, and limitations of the study stated and justified? (7 pts)
 | 7 | 7 | 7 | 7 | 7 |
| 1. Did the author(s) explicitly discuss direction and magnitude of potential biases? (6 pts)
 | 0 | 6 | 6 | 6 | 0 |
| 1. Were the conclusions/recommendations of the study justified and based on the study results? (8 pts)
 | 8 | 8 | 8 | 8 | 8 |
| 1. Was there a statement disclosing the source of funding for the study? (3 pts)
 | 0 | 3 | 3 | 3 | 3 |
| **Total score:** | **79** | **83** | **75** | **94** | **68** |