

## Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 3: assessment of economic outcome

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### Recommendations

*Standards.* There is insufficient evidence to recommend a standard for assessment of economic outcome following lumbar fusion for degenerative disease.

*Guidelines.* There is insufficient evidence to recommend a guideline for assessment of economic outcome following lumbar fusion for degenerative disease.

*Options.* It is recommended that valid and responsive economic outcome measures be included in the assessment of outcomes following lumbar fusion surgery for degenerative disease. Return-to-work rates and termination of disability compensation are two such measures. It is recommended that cost analyses related to lumbar spinal fusion include perioperative expenses as well as expenses associated with long-term care, including those incurred in both the operative and nonoperative settings.

### Rationale

Lumbar fusion is commonly performed as an adjunct to the surgical treatment of patients with low-back pain due to degenerative lumbar disease. Using data from the National Hospital Discharge Survey, both Deyo, et al.,<sup>4</sup> and Davis<sup>3</sup> observed a dramatic increase in the frequency of

lumbar fusion procedures in the 1980s. Lumbar fusion has been undertaken in the setting of degenerative disc disease, spinal stenosis, spondylolisthesis, and degenerative scoliosis and is commonly supplemented with internal fixation involving a variety of devices. As the frequency and complexity of lumbar fusion surgery increases, there is a tendency for costs and complication rates to follow.<sup>9</sup> In a time of contracting hospital resources, it is important to understand the economic impact of lumbar fusion. The purpose of this review is to examine the economic impact of lumbar fusion for degenerative lumbar spine disease as assessed by cost, complication rates, and rates of reoperation. These expenses of lumbar fusion must be contrasted with the return-to-work rate and the potential for improved productivity following treatment. These end points will be examined as economic outcome measures following lumbar fusion.

### Search Criteria

A computerized search of the National Library of Medicine database of the literature published between 1966 and 2001 was performed. A search using the subject heading "lumbar fusion" yielded 3708 citations. The following subject headings were combined: "lumbar fusion and outcomes." Approximately 204 citations were acquired. Only citations in English were selected. A search of this set of publications with the key words "employment status," "mortality," "medical care costs," "cost containment/com-

Abbreviations used in this paper: CI = confidence interval; LOS = length of stay; QOL = quality of life; RR = relative risk.

parison," or "cost effectiveness" resulted in 58 matches. Titles and abstracts of the articles were reviewed. Clinical series dealing with adult patients who had lumbar fusion for degenerative disease were selected. Additional references were culled from the reference lists of remaining articles.

Among the articles reviewed, 13 studies were included that dealt with lumbar fusion, complication rates, reoperation rates, and costs. Six of these articles were cohort studies that examined the economic impact of lumbar fusion compared with surgery for degenerative lumbar disease that did not involve fusion. One article was a cohort study investigating fusion with and without fixation. Two studies examined the cost benefit or cost effectiveness of lumbar fusion compared with decompression alone. The remaining study examined the responsiveness of returning to work as an economic indicator in a large series. These articles are summarized in Table 1.

### Scientific Foundation

One of the more difficult results to ascertain following a medical or surgical treatment is economic outcome. Typical medical economic analyses seek to ascertain whether a given treatment-related benefit accrues in light of the expenditures required to provide that treatment. With regard to lumbar fusion procedures, benefits from treatment may include an overall improvement in low-back pain and function, an increased return-to-work rate, and/or improved patient satisfaction. The expenses of the procedures are the measured costs of the surgery, the devices implanted, and operative time. Other measurable outlays include the cost of complications and time and expenses associated with reoperation. Deyo and colleagues<sup>4</sup> examined data concerning lumbar spinal disease and lumbar spinal fusion from the National Hospital Discharge Survey between 1979 and 1987. In addition to a 200% increase in spinal fusion procedures performed during this period, the authors reported significant regional variations in the performance of lumbar fusion procedures as reflected by a ninefold regional variation in frequency between the northeastern US (four/100,000) and the western US (35/100,000). Because of the increasing incidence of lumbar fusion procedures in the treatment of degenerative spine disease, it is important to examine the economic impact of lumbar fusion as a specific outcome measure.

#### *Costs, Complications, Hospitalizations, and Reoperations*

Malter and colleagues<sup>12</sup> performed a population-based study of patients who underwent lumbar surgery for degenerative disease in Washington state in 1988. The study was not prospective, nor was it clear that all patients were eligible for all therapies. Using diagnosis and procedure codes from the Washington State Department of Health's computerized system, the authors obtained data on 6376 patients of whom 1041 underwent lumbar fusion. Rates of reoperation, complications, and associated costs (in 1988 US dollars) were examined through the next 5 years. The complication rates associated with lumbar arthrodesis procedures were 18% compared with a 7% complication rate following lumbar surgery without arthrodesis (chi-square test,  $p < 0.001$ ). The LOS was significantly longer for

fusion-treated patients (7 days compared with 5.1 days;  $p < 0.001$ ). In 1988 dollars, hospital costs averaged \$7101 per patient treated with fusion and \$4161 per patient treated without fusion ( $p < 0.001$ ). These authors examined reoperation rates to determine if fusion reduced the need for repeated lumbar surgery within 5 years. Reoperation rates were similar between those treated with fusion (RR 1.1; 95% CI 0.9–1.3) and those not. Because the indications for surgery were not examined, the only conclusions that could be drawn from this study were that lumbar fusion procedures are associated with increased costs and complications.

Using similar methods and a hospital discharge registry in Washington state, Deyo and colleagues<sup>5</sup> examined 18,122 hospitalizations for lumbar surgery between 1986 and 1988. The majority (84%) of cases requiring surgery involved spinal stenosis or disc displacement. Excluded were cases involving malignant lesions, infection, or fractures. Approximately 15% of patients in this cohort underwent arthrodesis in addition to decompression. The reported mortality rate was less than 1%. The complication rate was 17.4% among patients treated with fusion compared with a 7.6% rate for those with lumbar disease treated surgically without fusion (chi square test,  $p < 0.0005$ ). The LOS among patients who were treated with fusion was approximately 7.6 days compared with 5.4 days for those who did not undergo fusion ( $p < 0.0005$ ). In 1986 to 1988 dollars, the cost of hospitalization was \$6491 for fusion-treated patients compared with \$3793 for patients treated surgically without fusion ( $p = 0.0005$ ). Logistic-regression models were used to examine the risk of complications or prolonged hospitalization and indicated that the RR for a complication or prolonged hospitalization with any type of lumbar fusion procedure was 2.7 (95% CI 1.5–4.9). The lack of information regarding the indications for surgery and the clinical outcome following surgery limit the usefulness of this information.

Deyo, et al.<sup>6</sup> examined lumbar surgery data for 1985 obtained from the Health Care Financing Administration for all Medicare recipients, excluding those on Medicare for chronic renal failure or Social Security Disability. Using ICD-9-CM diagnosis and procedure codes, data were accrued on the frequency of lumbar surgery performed with or without fusion and the incidence of associated complications. The study was not undertaken prospectively nor was it certain that all patients were eligible for all therapies. Specific data were obtained for 6-week mortality rates, requirements for assisted living, and the need for blood transfusion. An economic analysis was completed for LOS and cost. These data were compared with similar data from 1 year prior to 4 years after the study date. A study population of 27,111 patients was obtained of whom 1524 (5.6%) underwent lumbar fusion. For patients treated surgically with fusion, the mean hospital costs (1985 US dollars) were \$10,091 compared with \$6754 for patients treated without fusion (chi-square test,  $p < 0.0005$ ). A logistic regression was completed to determine RR and (95%) CIs for several variables. In the fusion group, the RR was 1.9 (95% CI 1.6–2.2) for the presence of complications, 5.8 for blood transfusion (5.2–6.6), 2.0 for 6-week mortality (1.2–3.4), and 2.2 for discharge to a nursing home (1.7–3.0). This cohort study revealed that lumbar surgery with fusion was more expensive and

TABLE 1

Summary of studies involving assessment of economic outcome after lumbar spinal surgery\*

Authors & Year	Class	Description	Results	Conclusions
Tunturi, et al., 1979	III	133 patients underwent lumbosacral fusion w/ 118 FUs including 2 deaths. Costs were calculated in 1976 US dollars based on periop hospitalization & FUs. Benefit was defined as the time over the mean FU (4.8 yrs) for which the patient was employed & was calculated based on mean salary during this period.	The cost/benefit ratio for lumbosacral fusion was 1:2.9 w/ the cost in 1976 US dollars as \$5569 & benefit as \$16,075.	Lumbosacral fusion in a selected population has a positive cost/benefit ratio.
Deyo, et al., 1991	III	All Medicare recipients undergoing lumbar op in 1985. Data provided from HCFA on these patients from 1 yr preop to 4 yrs postop. 27,111 patients were studied of whom 5.6% (1524) received lumbar fusion. Hospitalizations examined for complications, mortality at 6 wks, need for blood transfusion, & requirements for assisted living. Economic analysis was complete for LOS & costs.	For the fusion group, RR w/ 95% CI for complications was 1.9 (1.6–2.2), blood transfusion 5.8 (5.2–6.6), 6-wk mortality 2.0 (1.2–3.4), assisted living 2.2 (1.7–3.0) (p < 0.05). These results were consistent btwn spinal stenosis & spondylolisthesis w/ hospital costs of \$10,091 (fusion) vs \$6754 (w/o) in 1985 dollars & a significantly shorter LOS (p < 0.05 in each category).	A greater economic cost of fusion in the Medicare population. Lumbar fusion is associated w/ greater morbidity, mortality, & use of hospital resources in older adults. No clear cohort of lumbar degenerative population defined for cost comparison.
Deyo, et al., 1992	III	18,122 hospitalizations for lumbar spine op (84% involved spinal stenosis or disc displacement) from 1986–1988. 15,280 surgeries w/o arthrodesis & 2785 included arthrodesis. Hospitalizations examined for complications. Economic analysis was complete for LOS & costs.	~15% of patients underwent arthrodesis. The complication rate was 17.4% w/ fusion & 7.6% w/o (p < 0.0005). The LOS was 7.6 days w/ fusion & 5.4 w/o (p < 0.0005). The cost in 1986–1988 dollars was \$6491 w/ fusion & \$3793 w/o (p < 0.0005). No details were given for mortality.	Patients who undergo fusion in a broad population are more apt to have longer LOSs w/ greater complication rates & utilization of healthcare resources. No clear cohort of lumbar fusion population defined for cost comparison.
Franklin, et al., 1994	III	388 patients in Workers' Compensation system in Washington state (1986–1987) who underwent fusion. Patient satisfaction studied along w/ economic recovery by patient. Simple satisfaction survey examined back/leg pain, QOL, decision to undergo op, & employment at 2 yrs.	Employment was 16, 32, & 49% over 1, 2, & 3 yrs. It was less likely to occur in this cohort than historical controls (RR = 0.66, 0.88, & 0.93) at 1, 2, & 3 yrs; 23% required reop & instrumentation doubled this risk.	Employment as an economic indicator may be used as an outcome measure but other control groups should be considered.
Katz, et al., 1997	III	272 patients w/ degenerative lumbar stenosis. Surgery: decompression (194), decompression w/ arthrodesis (37), & decompression w/ arthrodesis/fixation (41). Outcomes assessed w/ respect to walking capacity, back/leg pain, satisfaction, health status (SF-36), & hospital cost.	Individual surgeon was predictor for arthrodesis. Hospital costs were \$12,615 (no arthrodesis), \$18,495 (arthrodesis), \$25,914 (arthrodesis/fixation) (p < 0.0001). No reliability given for walking, satisfaction, or health status.	Hospital costs of arthrodesis/fixation are highest w/ no clear defined benefit. Arthrodesis alone showed improved relief of lumbago at 6 & 24 mos w/o reliability. Significant variability introduced by surgeon choice for arthrodesis.
Malter, et al., 1998	III	6376 patients had op for lumbar degenerative disease (1041 for op including arthrodesis, 5335 for op w/o arthrodesis). Economic analysis of hospitalization.	Complication rate: 18% (arthrodesis) to 7% (none) (p < 0.001). Hospital costs greater w/ fusion (\$7101 & \$4161 in 1988 dollars) (p < 0.001). Reop rate similar btwn groups, RR 1.1 (95% CI 0.9–1.3).	The economic costs of lumbar arthrodesis in the setting of stenosis, disc displacement, spondylolisthesis, & degeneration are greater. No clear cohort of lumbar degenerative patients used for comparison.
Kuntz, et al., 2000	III	A cost-effectiveness study of laminectomy, laminectomy w/ noninstrumented fusion, & laminectomy w/ instrumented fusion. Outcome was assessed at 6 mos & long term & based on prior reports. Periop complications & costs & reop rates were all based on prior reports.	The QALYs & costs were calculated & found to be \$56,500 for laminectomy w/ noninstrumented fusion compared w/ laminectomy alone. Instrumented fusion was substantially higher (\$3,112,800). Improved outcome w/ instrumentation (90 vs 80%) reduced the relative cost of fixation.	Lumbar laminectomy w/ noninstrumented fusion compared favorably w/ decompression. Not enough data existed on outcome w/ fixation to present it positively on an economic scale.
Moller & Hedlund, 2000	II	111 patients w/ spondylolisthesis who underwent fusion (77) or exercise (34). Patients were randomized to these groups if they had ≥ 1 yr of pain/sciatica. Evaluation was completed at 1 & 2 yrs using the DRI, a satisfaction survey (much better, better, unchanged, worse: would you repeat op?), & RTE.	The fusion & exercise groups had similar numbers of patients on disability at 2 yrs (46 vs 45%); however, the overall reduction was greater for fusion (p < 0.0001) compared w/ exercise (p = 0.23). The satisfaction survey showed good responses to be significantly higher in the op group (p < 0.01).	RTE appears to be an indicator of improvement. A satisfaction survey was not reliably studied but did appear to be a responsive indicator for outcome & satisfaction had improved more after fusion.

Continued

TABLE 1 Continued

Authors & Year	Class	Description	Results	Conclusions
Slosar, et al., 2000	III	141 patients underwent circumferential lumbar instrumented fusion, either primary (31%) or secondary (69%). FU averaged 37 mos & was done by a basic satisfaction survey: 1) op met expectations; 2) op improved my condition; 3) op improved but would not redo; 4) op worsened condition.	133 FU patients (10.5% = 1, 51.1% = 2, 19.5% = 3, & 18.8% = 4). RTE occurred in 38% of patients; it was more likely in those not involved w/ Workers' Compensation (57 vs 22%; p < 0.001). There was a 20% complication rate included transient weakness, infection, & graft extrusion.	Satisfaction appears to be a responsive outcome measure at 37 mos; however, its reproducibility was not tested. RTE is a responsive measure & improves in the noncompensation patients. A complication rate of 20% was seen, suggesting a negative economic impact.
Fritzell, et al., 2001	II	294 patients w/ L4-S1 disc degeneration & LBP who underwent op (222) or expectant (72) management over a 6-yr period. Evaluation was completed at 6, 12, & 24 mos using the ODI, Million, & general function score along w/ patient assessment. RTE was also monitored.	w/ overall assessment, 63% in the op group indicated they were better or much better compared w/ 29% in the nonop group (p < 0.0001). The net RTE rate was higher in the op group (36%) than the nonop group (13%, p < 0.002).	Satisfaction surveys seem to be responsive over the same time interval, & RTE indicates responsiveness at 24 mos.
Christensen, et al., 2002	III	148 patients underwent lumbar fusion w/ 73 in PLF group and 75 in ALIF/PLF group. Three patients were lost to FU. RTE was also followed at 2 years. FU performed at 0, 1, & 2 yrs.	RTE was similar in both groups but improved from 24% to 36% (no statistics used to analyze) w/ no difference bwn subgroups.	RTE did not appear to work as a responsive indicator of improvement, & RTE seemed to correlate w/ an improvement in DPQ score. No controls were used.
Christensen, et al., 2002	II	129 patients w/ chronic LBP & isthmic spondylolisthesis, primary degeneration, or secondary degeneration who underwent instrumented or noninstrumented fusion. Outcome at 5 yrs was done using functional questionnaires along with rates of RTE & reop.	The instrumented group had a 28% reop rate compared w/ 14% for the noninstrumented group (p < 0.03). Op time 212 vs 127 min (p < 0.0001) w/ greater periop blood loss (p < 0.01).	Medical outcome by reop & op time may be a responsive indicator w/in 5 yrs of lumbar fusions w/ instrumentation.

\* ALIF = anterior lumbar interbody fusion; DPQ = Dallas Pain Questionnaire; FU = follow up; HCEFA = Health Care Financing Administration; LBP = low-back pain; ODI = Oswestry Disability Index; PLF = posterolateral fusion; QALY = quality-adjusted life year; QOL = quality of life; RTE = return to employment; SF-36 = Short Form-36.

associated with higher risk for complications than lumbar surgery without fusion.

Katz and colleagues<sup>10</sup> completed a prospective observational study of 272 patients with radiographically and clinically documented lumbar stenosis. Patients were treated at four centers by eight surgeons over a 4-year period. Surgical treatment included decompression (194 cases), decompression with fusion (37 cases), or decompression with fusion and internal fixation (41 cases). Patients were followed for 24 months and assessed for walking capacity, back and leg pain, satisfaction, and health status based on the Sickness Impact Profile. Internal reliability was calculated for the walking, pain, and satisfaction scales. Hospital costs were analyzed for each group. The individual surgeon, in this study, was the greatest predictor for the performance of a fusion, with an RR of more than 10 based on logistic regression. At 6 and 24 months, decompression and fusion without internal fixation resulted in better relief of back pain (p < 0.004 at 6 months; p < 0.01 at 24 months) compared with the other treatment groups. With multivariate analysis, a trend was evident but did not reach statistical significance. The reoperation rates were similar in all three groups (p = 0.15). Mean hospital costs were \$12,615 per patient for decompression without fusion, \$18,495 per patient for decompression with fusion, and \$25,914 per patient for decompression with fusion and internal fixation (p < 0.0001). This study indicated that increased costs for lumbar fusion may be offset by significant functional gains in the patients who undergo fusion without instrumentation. The medical evidence cited in this report is considered Class III because of the retrospective nature of the study and selection bias by the operating surgeons as to which patients were treated with internal fixation.

Return to Employment

Two studies described resumption of employment among patients with low-back pain and compared those treated with lumbar fusion with those treated nonoperatively. Moller and Hedlund<sup>13</sup> examined 111 patients over a 5-year period who had chronic low-back pain or sciatica for a minimum of 1 year as a result of isthmic spondylolisthesis. Treatments included arthrodesis with internal fixation (37 cases), arthrodesis without internal fixation (40 cases), or exercise (34 cases). Evaluation was performed at 1 and 2 years by using a Disability Rating Index, a satisfaction survey, and return-to-work rates. In the fusion and exercise groups there were similar numbers of patients receiving disability payments at 2 years (46 and 45%, respectively); however, the surgical group had a greater degree of improvement (75 and 46%, respectively; p < 0.0001) compared with the exercise group (61 and 45%, respectively; p = 0.23). Fritzell, et al.,<sup>8</sup> reported a study of 294 patients with lumbar degenerative disease involving chronic lumbago of at least 2 years' duration due to L4-5 and/or L5-S18 disc degeneration. Patients were randomized to surgical or nonsurgical groups. Patients in the surgical group underwent posterolateral fusion (73 cases), posterolateral fusion with internal fixation (74 cases), or interbody fusion with internal fixation (75 cases). Seventy-two patients received medical management including physical therapy. Evaluation was accomplished at 6, 12, and 24 months by using functional out-

## Economic Outcome

come questionnaires and return-to-work status. In an overall assessment, 63% in the surgical group indicated they were better or much better following treatment compared with 29% in the nonsurgical group ( $p < 0.0001$ ). The net return-to-work rate was 39% in the surgical group and only 23% in the nonsurgical group ( $p < 0.05$ ). These two studies suggest that the resumption of employment is a responsive economic outcome measure for patients with low-back pain who may be considered surgical candidates.

In the study by Franklin and colleagues<sup>7</sup> of Workers' Compensation patients, the end of total disability was monitored in patients who underwent lumbar fusion between 1986 and 1987. The termination of total disability as an end point occurred in 16% of treated patients at 1 year, 32% at 2 years, and 49% at 3 years; however, compared with historical controls for Workers' Compensation patients, the RR of ending total disability was less likely among patients treated with lumbar fusion (0.66 at 1 year, 0.88 at 2 years, and 0.93 at 3 years) compared with Workers' Compensation patients as a whole. In contrast, Christensen, et al.,<sup>1</sup> examined 148 patients who underwent lumbar fusion over a 3-year period: posterolateral fusion (73 cases) or a combination of posterolateral and anterior interbody fusion procedures (75 cases). Outcome was assessed over 2 years. Overall improvement was greatest in the circumferential treatment group, with a lower reoperation rate (22% compared with 7%,  $p < 0.009$ ). The return-to-work rate improved in both groups from 24 to 36% with no difference between subgroups. No statistical analyses were used to assess the overall return-to-work rate. Slosar, et al.,<sup>14</sup> reported on 133 patients who underwent circumferential fusion during a 2-year follow-up period. In this group, 50 patients (38%) returned to work; 16 (22%) of the 73 injured workers resumed work compared with 34 (57%) of the 60 patients who were not receiving Workers' Compensation (chi-square test,  $p < 0.001$ ). These studies indicated that return to work and/or termination of disability payment are responsive measures for economic outcome after lumbar fusion procedures. They further indicate that the presence of a compensable injury is associated with a lower rate of return to work.

### Cost-Benefit Analysis

Kuntz and colleagues<sup>11</sup> undertook a cost-effectiveness analysis of lumbar fusion by constructing a hypothetical model based on historical reports in prior clinical studies. They examined lumbar laminectomy, laminectomy with noninstrumented fusion, and laminectomy with instrumented fusion. Rates of clinical improvement and return to employment were culled from series reported in the literature as were costs, complication rates, fusion rates, reoperation rates, and the incidence of clinical worsening. Each negative and positive outcome was assigned a relative value pertaining to quality of life, which the authors adjusted according to hypothetical outcomes.

The authors determined that laminectomy with noninstrumented fusion cost \$56,500 per quality-adjusted year of life compared with laminectomy alone.<sup>11</sup> The addition of instrumentation to lumbar fusion procedure cost \$3,112,800 per quality-adjusted year of life. The authors concluded that laminectomy with noninstrumented fusion

compared favorably with decompression alone; however, improvement in outcome associated with instrumentation was not well defined enough to accrue a benefit. The authors noted that a hypothetical rate of 90% symptom relief for patients treated with instrumented fusion compared with 80% for noninstrumented patients would reduce the quality-adjusted year of life cost to \$82,400.

Tunturi and colleagues<sup>15</sup> analyzed 133 consecutive patients who underwent lumbosacral fusion between 1968 and 1975. Results were reported for 116 patients in whom the mean follow-up period was 4.8 years. These authors calculated the mean expense of the hospital stay and postoperative visits in 1976 dollars. Economic benefits were calculated based on return-to-employment rates compared with the costs of continued disability. The rate of return to employment was approximately 31%. The mean cost in 1976 US dollars for a lumbosacral fusion was \$5569. The mean economic benefit in 1976 US dollars for the same period was \$16,075. The calculated cost/benefit ratio was therefore 1:2.9 for lumbosacral arthrodesis. The authors concluded that lumbosacral fusion had a positive cost-benefit ratio when return-to-employment status and the termination of disability payment were considered as indices of economic outcome.

### Summary

Lumbar fusion may be associated with a high short-term cost, especially if instrumentation is placed; however, there appear to be long-term economic benefits associated with lumbar fusion including resumption of employment. To describe the economic impact of lumbar fusion for degenerative disease adequately, it is important to define the patient population treated with fusion and to compare efficacy as well as the costs of other treatment alternatives. Any such analysis should include both short- and long-term costs and benefits.

### Key Issues for Future Investigation

The application of valid and reliable outcome measures in conjunction with a complete short- and long-term economic analysis will be necessary to assess fully the economic impact of lumbar fusion. To reach meaningful conclusions, it is imperative to compare the economic outcomes of patients treated with lumbar fusion with those in patients with similar disease treated without fusion and to include all relevant costs. This analysis should include subsequent operative and nonoperative medical care, ongoing disability costs, and the costs of loss of productivity. Measures such as return-to-work status and quality-adjusted life years must be included in to allow the development of meaningful data.

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