Low-back and leg pain due to degenerative lumbar spondylolisthesis is occurring with increasing frequency and is associated with increasing public health implications as the US population older than 65 years of age grows. A marked increase in spine fusion rates and corresponding aggregate health care costs over the past 2 decades are well documented. Economic value is an increasingly important component of health care policy decision-making. Hence, much attention has recently been given to the cost-effectiveness of lumbar fusion procedures.

In 2000 and 2004, the initial cost-effectiveness studies on lumbar fusion used economic modeling and direct cost comparisons in heterogeneous patient populations to demonstrate that instrumented lumbar fusion may not be cost-effective. In 2008, Tosteson et al. performed the first formal cost-utility analysis on “as-treated” cohorts from the prospective randomized SPORT and demonstrated that lumbar fusion was not very cost-effective when compared with medical management at 2 years ($115,600/QALY gained). However, the fusion cohort underwent various fusion techniques, of which only 78% were instrumented. Furthermore, the medical arm (control group) of this cost-utility analysis comprised only those who remained after patients in whom medical management failed crossed over into the surgery cohort. This inevitably inflated the utility (QALYs gained) of the fusion cohort.

Cost-effectiveness of transforaminal lumbar interbody fusion for Grade I degenerative spondylolisthesis

Clinical article

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Object. Transforaminal lumbar interbody fusion (TLIF) for spondylolisthesis-associated back and leg pain is associated with improvement in pain, disability, and quality of life. However, given the rising health care costs associated with spinal fusion procedures and varying results of recent cost-utility studies, the cost-effectiveness of TLIF remains unclear. The authors set out to assess the comprehensive costs of TLIF at their institution and to determine its cost-effectiveness in the treatment of degenerative spondylolisthesis.

Methods. Forty-five patients undergoing TLIF for Grade I degenerative spondylolisthesis-associated back and leg pain after 6–12 months of conservative therapy were included. The authors assessed the 2-year back pain visual analog scale (VAS) score, leg pain VAS score, Oswestry Disability Index, and total back-related medical resource utilization, missed work, and health-state values (quality-adjusted life years [QALYs]), calculated from EQ-5D with US valuation. Two-year resource use was multiplied by unit costs based on Medicare national allowable payment amounts (direct cost), and patient and caregiver workday losses were multiplied by the self-reported gross-of-tax wage rate (indirect cost). The mean total 2-year cost per QALY gained after TLIF was assessed.

Results. Compared with preoperative health states reported after at least 6 months of medical management, a significant improvement in back pain VAS score, leg pain VAS score, and Oswestry Disability Index was observed 2 years after TLIF; with a mean 2-year gain of 0.86 QALYs. The mean ± SD total 2-year cost of TLIF was $36,836 ± $11,800 (surgery cost, $21,311 ± $2800; outpatient resource utilization cost, $3940 ± $2720; indirect cost, $11,584 ± $11,363). Transforaminal lumbar interbody fusion was associated with a mean 2-year cost per QALY gained of $42,854.

Conclusions. Transforaminal lumbar interbody fusion improved pain, disability, and quality of life in patients with degenerative spondylolisthesis-associated back and leg pain. The total cost per QALY gained for TLIF was $42,854 when evaluated 2 years after surgery with Medicare fees, suggesting that TLIF is a cost-effective treatment of lumbar spondylolisthesis. (DOI: 10.3171/2011.3.SPINE10562)

KEY WORDS • cost-effectiveness • fusion • transforaminal lumbar interbody fusion

Low-back and leg pain due to degenerative lumbar spondylolisthesis is occurring with increasing frequency and is associated with increasing public health implications as the US population older than 65 years of age grows. A marked increase in spine fusion rates and corresponding aggregate health care costs over the past 2 decades are well documented. Economic value is an increasingly important component of health care policy decision-making. Hence, much attention has recently been given to the cost-effectiveness of lumbar fusion procedures.
Cost-effectiveness of transforaminal lumbar interbody fusion

medical treatment cohort measured at 2 years, falsely decreasing the calculated cost-effectiveness of lumbar fusion. Because ethical considerations prohibit withholding surgical treatment from randomized patients in whom the assigned medical management fails, use of an unbiased 2-year medical control group without an inflated QALY gained in future cost-utility studies is unlikely.

To avoid such bias in a control group, Glassman et al. recently performed a post hoc cost-utility analysis of a prospective study evaluating recombinant human bone morphogenetic protein–2 for single level lumbar fusion by using preoperative health states after 6 months of failed medical management as a baseline comparison for postoperative QALYs gained. Contrary to the “as-treated” SPORT cost-utility study, Glassman et al. demonstrated that instrumented lumbar fusion was cost-effective at 5 years after surgery ($50,949/QALY gained) and cost-effective as early as 2 years after surgery ($59,771/QALY gained) when patients presenting with mostly back pain were excluded.

Given the contradicting evidence regarding the cost-effectiveness of lumbar fusion and the heterogeneity of fusion techniques previously studied, we set out to assess the cost-effectiveness of a single lumbar fusion procedure (single-level TLIF) on a homogeneous patient population (Grade I degenerative spondylolisthesis) at a single institution. In a study design similar to that of Glassman et al., we assessed total 2-year back-related costs and 2-year gain in QALYs compared with preoperative health state after single-level TLIF for degenerative spondylolisthesis–associated back and leg pain.

**Methods**

Forty-five consecutive patients undergoing TLIF for Grade I lumbar degenerative spondylolisthesis–associated back and leg pain were included. The institutional review board approved this study. To be included, a patient had to have MR imaging evidence of Grade I degenerative lumbar spondylolisthesis, mechanical low-back pain and radicular symptoms, experienced a failure of conservative therapy after at least 6 months, and an age of 18–70 years. Patients were excluded if they had a history of a previous back operation, an extraspinal cause of back pain or sciatica, an active medical or Workers’ compensation lawsuit, any preexisting spinal pathology, or were unwilling or unable to participate with follow-up procedures. Patients with notable associated abnormalities, such as inflammatory arthritis or metabolic bone disease, were also excluded.

Patients were initially entered into a prospective electronic registry from which preoperative, intraoperative, and perioperative data were recorded. At the initiation of this study, preoperative patient-reported outcome metrics (EQ-SD, ODI, and VAS score) were retrospectively assessed. Two-year resource utilization, occupational disability, and patient-reported outcomes were prospectively assessed by phone interview. Resource utilization was then confirmed via retrospective analysis of hospital records.

**Surgical Technique**

Following midline skin incision, the fascia was incised, and paravertebral muscles were dissected from the spine. Radiographs were obtained to check the appropriate level. Bilateral pedicle screw-rod constructs were implanted, and laminectomy and unilateral facetectomy were then performed. Unilateral anulotomy, discectomy, and placement of polyetheretherketone interbody graft were then achieved. Next, cartilaginous material from the end-plates was removed using an endplate scraper. The interbody graft was placed anteriorly and contralateral to the anulotomy within the interbody space. For posterolateral arthrodesis, local autogenous bone with or without bone extenders (DBX, Lifenet) was used for bone grafting. Finally, the wound was copiously irrigated and closed in successive layers.

**Clinical Outcome Measures and QALY**

To assess pain, disability, and overall health state preoperatively and 2 years postoperatively, outcome questionnaires were completed either during clinic evaluation or via phone interview. Questionnaires were administered by an independent investigator not involved with clinical care. Patient-assessed questionnaires included theVAS for low-back and leg pain, the ODI, and the EQ-SD. The EQ-5D represents the overall cost to the third-party payer, which may be adjusted for quality of life. J Neurosurg: Spine / Volume 15 / August 2011 139

Quality-adjusted life years were calculated from the EQ-5D with US valuation.

**Resource Utilization and Cost**

Resource utilization was determined from patient-reported use and institutional records. Low back–related outpatient visits (surgeons, chiropractor, other physicians, physical therapists, and acupuncturists), diagnostic tests (radiography, CT scanning, MR imaging, and electromyography), devices (braces, canes, and walkers), injections, emergency department visits, back-specific medications (nonsteroidal antiinflammatory drugs, Cox-2 inhibitors, oral steroids, narcotics, muscle relaxants, and antidepressants), and number of physical therapy days were assessed.

The 2-year direct medical costs were estimated by multiplying medical resource use by unit costs based on current Medicare national allowable payment amounts. Surgeon costs were based on Medicare allowable amounts using the resource-based relative value scale. Therefore, the cost analyzed was that to the third-party payer, which represents the overall cost to the medical system. The costs of surgery depends on the procedure being performed (all TLIFs in this series), the severity of the individual case, and whether complications occurred, which collectively determined the diagnosis-related group. Total direct costs comprised institutional, physician, and resource consumption Medicare fees.

**Indirect Costs**

The indirect costs were estimated by assessing the productivity losses due to spine-related problems, such as missed workdays for those employed outside the home. Costs for missed days of unpaid caregivers were estimated based on average gross wages plus nonhealth benefits.
Using the standard human capital approach, costs were estimated by multiplying the change in hours worked by the gross-of-tax wage rate based on self-reported wages at study entry. These calculations of indirect costs have been previously validated by prior studies.\textsuperscript{10,16}

**Cost Per QALY Gained**

Similar to the single cohort cost-utility analysis performed by Glassman et al.,\textsuperscript{7} we used the QALYs obtained after 6–12 months of conservative therapy (preoperative QALY) as a baseline comparison for 2-year QALYs gained from TLIF. The mean total (direct and indirect) 2-year back-related cost of TLIF was then calculated and divided by the mean 2-year gain in QALY. The cost per QALY gained by TLIF was the primary end point of this study.

**Results**

Means are presented as ± SDs or with 95% CIs.

**Patient Population**

A total of 45 consecutive patients (26 women and 19 men) were enrolled in the study over a period of 18 months. During this period, 20 patients with degenerative spondylolisthesis were excluded due to the following: Grade II spondylolisthesis (2 patients), pain not limited to leg/back only (3 patients), age older than 70 years (2 patients), or prior surgery (13 patients). Overall, the mean patient age was 51 ± 11 years. All patients presented with back and leg pain and radiographic evidence of Grade I degenerative spondylolisthesis. Interbody fusion was performed at L4–5 in 30 patients (67%) and L5–S1 in 15 patients (33%). All cases were 1-level fusions. Overall, the mean duration of symptoms was 47 ± 39 months. At presentation, the mean back pain VAS and leg pain VAS scores were 8.91 ± 1.32 and 7.33 ± 3, respectively. The mean preoperative ODI and EQ-5D US scaled index were 36 ± 7.81 and 0.37 ± 0.31, respectively (Table 1). The mean length of hospitalization following surgery was 4.07 ± 1.6 days. No patient developed a surgical site infection, CSF leak, or hardware failure; however, there were 4 cases (9%) of incidental durotomy that were repaired primarily with no subsequent complications. One patient returned to the operating room for evacuation of a perioperative hematoma.

**Two-Year Outcome**

Two-year back pain VAS scores, leg pain VAS scores, and ODI were significantly improved from preoperative levels for all outcome measures (Fig. 1). Two years after surgery, the mean changes in back pain VAS score and leg pain VAS score from baseline were 4.33 (95% CI 3.49–5.17) and 3.78 (95% CI 2.79–4.76), respectively. The mean changes per patient in ODI and EQ-5D US scaled index were 19.51 (95% CI 16.21–22.81) and 0.43 (95% CI 0.30–0.55), respectively. Accordingly, the cumulative health utility value gained over a 2-year interval after TLIF was 0.86 QALY (Table 2).

**Two-Year Resource Use and Cost**

Over a 2-year period after TLIF, the patients’ spine-related physician visits and days of physical therapy were
I degenerative spondylolisthesis–associated back and leg pain, we found that TLIF was cost-effective in our institutional practice using Medicare fee scheduling. While the average 2-year direct health care cost of TLIF was $25,251, the indirect societal costs of missed productivity also contributed significantly, on average $11,584. Even though the total 2-year cost of TLIF was as high as $36,836 (direct + indirect), TLIF resulted in a significant improvement in QALYs gained (0.86 over 2 years), resulting in a favorable cost per QALY gained of $42,854. This cost per QALY gained is under the well-accepted $50,000 cost-effective threshold, suggesting that TLIF is a cost-effective treatment option for patients with back and leg pain caused by Grade I degenerative spondylolisthesis.

Our findings on cost are consistent with those of Tosteson et al. and Glassman et al. Tosteson and colleagues calculated the 2-year direct medical cost of lumbar fusion as $31,938 from the SPORT. Glassman and colleagues calculated the 5-year direct medical cost of single-level lumbar fusion as $20,668 from a prospective FDA recombinant human bone morphogenetic protein trial. In our series, TLIF was associated with a 2-year direct medical cost of $25,251, almost exactly the average of the two prior cost-utility studies. Tosteson et al. and Glassman et al. also reported indirect costs from lost work productivity after fusion to be $10,472 and $14,377, respectively. We observed a similar indirect cost of $11,584, again consistent with prior cost-utility studies. It is important to note that 2- and 5-year costs of lumbar fusion are not only dependent on patient outcomes but also on surgeon practice patterns. Our resource consumption and cost estimates lie well within those previously reported, suggesting that our institution’s practice pattern may be similar to others. For this study, cost analyses were based on the cost to third-party payers, which represent the true overall costs to the medical system. Medicare data were used to place an accurate cost value on resource consumption, as private payers negotiate per medical center and practice group, making private payer cost estimations less accurate for a medical center or practice group interpreting this study. Hence, the published Medicare fee schedule facilitates a more objective cost calculation, particularly as it pertains to policy makers. Also similar to many prior efficacy studies, TLIF was associated with significant improvement in all outcome measures. Back pain, leg pain, disability, and overall health states were markedly improved after TLIF through a 2-year follow-up period. The greatest variability within the literature has been the reported QALYs gained with lumbar fusion. Tosteson et al. reported a 2-year gain of 0.46 QALYs from the “as treated” SPORT. Glassman et al. reported a 2-year gain of 0.26 QALYs and a 5-year gain of 0.68 QALYs. Our patient cohort reported a favorable 2-year gain of 0.86 QALYs. The variability in reported utility after lumbar fusion is likely due to the variation that still exists in patient selection. Patients presenting primarily with back pain can be expected to have less favorable response to surgery than patients with significant radicular symptoms. In fact, when Glassman and colleagues excluded patients with spondylolisthesis who presented primarily with back pain, they found a 2-year cost per QALY gained very similar to ours ($59,771). In our series, all patients undergoing TLIF presented with significant leg pain, a TLIF cohort associated with $42,854/QALY gained. Translumbar interbody fusion for patients primarily with back pain and minimal leg pain may be less cost-effective. The fact that there is consistency in cost estimates but variability in utility reported after lumbar fusion highlights the fact that patient selection and surgi-

### TABLE 2: Mean improvement in scores 2 years after TLIF in 45 patients

<table>
<thead>
<tr>
<th>Rating System</th>
<th>Mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>leg pain VAS</td>
<td>3.78 (2.79–4.76)</td>
</tr>
<tr>
<td>back pain VAS</td>
<td>4.33 (3.49–5.17)</td>
</tr>
<tr>
<td>ODI</td>
<td>19.51 (16.21–22.81)</td>
</tr>
<tr>
<td>cumulative EQ-5D index gain</td>
<td>0.86 (0.60–1.10)</td>
</tr>
</tbody>
</table>

### TABLE 3: Mean 2-year direct and indirect costs of TLIF by type of cost and component per patient

<table>
<thead>
<tr>
<th>Component</th>
<th>Mean Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>direct cost</td>
<td></td>
</tr>
<tr>
<td>op</td>
<td>$21,311</td>
</tr>
<tr>
<td>health care visits</td>
<td>$1,200</td>
</tr>
<tr>
<td>diagnostic imaging</td>
<td>$1,900</td>
</tr>
<tr>
<td>medications, injections</td>
<td>$840</td>
</tr>
<tr>
<td>total direct costs</td>
<td>$25,251</td>
</tr>
<tr>
<td>indirect cost</td>
<td></td>
</tr>
<tr>
<td>patient’s missed work</td>
<td>$11,215</td>
</tr>
<tr>
<td>caregiver’s missed work</td>
<td>$369</td>
</tr>
<tr>
<td>total indirect costs</td>
<td>$11,584</td>
</tr>
<tr>
<td>total 2-yr cost of TLIF</td>
<td>$36,836</td>
</tr>
</tbody>
</table>
cal indication correlates closely with a procedure’s efficacy and therefore cost-effectiveness.

The $42,854 2-year cost per QALY gained for TLIF observed here compares favorably with other well-accepted cost-effective treatments. For total hip arthroplasty, the reported cost per QALY gained ranges between $29,139 and $80,000.3 For total knee replacement, the cost per QALY gained has been reported as $59,262.4 Infliximab, a cost-effective medication for rheumatoid arthritis, was found to have a cost/QALY gained of $30,500 in a prospective randomized trial of 428 patients.21 Given the favorable comparison of our findings and those of Glassman et al.9 with those of other cost-effective treatments, the debate on the cost-ineffectiveness of lumbar fusion requires further investigation.

Highlighting the limitations of our study is important to its interpretation. First, the initiation of the cost-utility study design occurred after patients underwent surgery. While pre- and perioperative variables were recorded into a registry at the time of surgery, these variables were retrospectively assessed at the time of the study’s initiation. While collection of resource utilization and outcomes variables were obtained prospectively and resource utilization was confirmed with medical records, bias inherent to retrospective studies without a priori determination of follow-up assessment should be considered here. Second, patient recall was used as the primary method of recording resource utilization and may have introduced recall bias. Furthermore, similar to Glassman et al.,9 use of a single cohort precluded a direct ICER (incremental cost-effectiveness ratio) comparison with a medical control group. However, our study design was based on a model in which the preoperative QALYs at baseline represented the maximum QALY attained from medical management, and as such, any QALY gained may be attributed to operative care. This was intended to avoid a medically managed control group that by definition experiences a favorable response to conservative management (treatment bias). Such bias was inherent in the SPORT “as treated” cost-utility analysis control group, with an artificially elevated QALYs gained after medical management. In addition, the assessment of pseudarthrosis was not standardized in this observational study and, therefore, was not formally evaluated in this series of patients. However, of patients complaining of persistent back pain, none required further treatment for pseudarthrosis by 2 years. Despite these limitations, this study supports the findings by Glassman et al.9 that single-level TLIF is a cost-effective treatment for low-grade degenerative spondylolisthesis.

Conclusions

The rising health care cost associated with spine surgery highlights the importance of comparative effectiveness research. Our 2-year cost-utility study suggests that TLIF improves pain, disability, and quality of life and was cost-effective in our practice for the treatment of degenerative spondylolisthesis-associated back and leg pain.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: McGirt. Acquisition of data: McGirt, Adogwa, Parker, Davis, Cheng. Analysis and interpretation of data: McGirt, Adogwa, Parker, Davis, Devin. Drafting the article: Adogwa, Parker, Davis, Devin. Critically revising the article: Cheng. Approved the final version of the paper on behalf of all authors: McGirt. Statistical analysis: Adogwa, Parker, Davis, Cheng. Administrative/technical/material support: Aaronson, Devin, Cheng. Study supervision: McGirt, Aaronson, Devin, Cheng.

References


