Modeled cost-effectiveness of transforaminal lumbar interbody fusion compared with posterolateral fusion for spondylolisthesis using N²QOD data

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OBJECTIVE Transforaminal lumbar interbody fusion (TLIF) has become the most commonly used fusion technique for lumbar degenerative disorders. This suggests an expectation of better clinical outcomes with this technique, but this has not been validated consistently. How surgical variables and choice of health utility measures drive the cost-effectiveness of TLIF relative to posterolateral fusion (PSF) has not been established. The authors used health utility values derived from Short Form-6D (SF-6D) and EQ-5D and different cost-effectiveness thresholds to evaluate the relative cost-effectiveness of TLIF compared with PSF.

METHODS From the National Neurosurgery Quality and Outcomes Database (N²QOD), 101 patients with spondylolisthesis who underwent PSF were propensity matched to patients who underwent TLIF. Health-related quality of life measures and perioperative parameters were compared. Because health utility values derived from the SF-6D and EQ-5D questionnaires have been shown to vary in patients with low-back pain, quality-adjusted life years (QALYs) were derived from both measures. On the basis of these matched cases, a sensitivity analysis for the relative cost per QALY of TLIF versus PSF was performed in a series of cost-assumption models.

RESULTS Operative time, blood loss, hospital stay, and 30-day and 90-day readmission rates were similar for the TLIF and PSF groups. Both TLIF and PSF significantly improved back and leg pain, Oswestry Disability Index (ODI) scores, and EQ-5D and SF-6D scores at 3 and 12 months postoperatively. At 12 months postoperatively, patients who had undergone TLIF had greater improvements in mean ODI scores (30.4 vs 21.1, $p = 0.001$) and mean SF-6D scores (0.16 vs 0.11, $p = 0.001$) but similar improvements in mean EQ-5D scores (0.25 vs 0.22, $p = 0.415$) as patients treated with PSF. At a cost per QALY threshold of \$100,000 and using SF-6D–based QALYs, the authors found that TLIF would be cost-prohibitive compared with PSF at a surgical cost of \$4830 above that of PSF. However, with EQ-5D–based QALYs, TLIF would become cost-prohibitive at an increased surgical cost of \$2960 relative to that of PSF. With the 2014 US per capita gross domestic product of \$53,042 as a more stringent cost-effectiveness threshold, TLIF would become cost-prohibitive at surgical costs \$2562 above that of PSF with SF-6D–based QALYs or at a surgical cost exceeding that of PSF by \$1570 with EQ-5D–derived QALYs.

CONCLUSIONS As with all cost-effectiveness studies, cost per QALY depended on the measure of health utility selected, durability of the intervention, readmission rates, and the accuracy of the cost assumptions.

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KEY WORDS transforaminal lumbar interbody fusion; posterolateral fusion; SF-6D; EQ-5D; cost-effectiveness; spinal disorders

ABBREVIATIONS N²QOD = National Neurosurgery Quality and Outcomes Database; ODI = Oswestry Disability Index; PSF = posterolateral fusion; QALY = quality-adjusted life year; TLIF = transforaminal lumbar interbody fusion.

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THE primary goal of lumbar fusion surgery is to improve a patient's quality of life by adequately decompressing the neural structures and achieving a stable arthrodesis. However, the optimal surgical approach to treating degenerative conditions of the lumbar spine remains controversial. Although historically posterolateral spinal fusion (PSF) was the most commonly used procedure, transforaminal lumbar interbody fusion (TLIF) is increasingly becoming more common.²⁹ Theoretical advantages of TLIF over PSF include anterior column support, indirect foraminal decompression, removal of the disc as a pain generator, and restoration of lumbar lordosis.^{3,10,18,30,36} These theoretical advantages, which come at an increased cost, have not consistently translated into better clinical outcomes.^{1,12,19–21,40} A recent study conducting a cost-utility analysis of data from a prospective randomized trial²⁰ reported that TLIF was not a relevant alternative to PSF from a socioeconomic, societal perspective.⁸

Determination of the cost-effectiveness of any intervention requires measures of both the cost and the effectiveness of the intervention. For an intervention to be more cost-effective than another, it either has to cost less and be at least as effective, or has to generate sufficient added value to justify the additional cost. Although a current procedural terminology code for PSF as a stand-alone procedure is still being used, the American Medical Association in 2012 bundled the codes for TLIF and PSF into a single posterior interbody fusion code (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS1253669.html>). This change will reduce both the relative value and the payment rate for this new single current procedural terminology code as compared with the payment rates for the 2 previous codes used to report the procedures. However, because of the additional implant cost and the additional time required to insert an interbody device, TLIF will likely cost more.

The other half of the cost-effectiveness equation is measuring an intervention's effectiveness. Health gains or losses after an intervention are measured as quality-adjusted life years (QALYs),^{11,17} which take into account both the quantity and the quality of life. The QALY is the arithmetic product of life expectancy and a measure of the quality of the remaining life years. Several generic preference-weighted health state classification questionnaires, which combine a health-status measure with a societal value or utility for each health state,⁴ are used in economic studies. The most widely used questionnaires are the EQ-5D¹³ and the Short Form-6D (SF-6D).^{5,6} However, several studies have shown that although both the EQ-5D and SF-6D are psychometrically valid measures of health state utility in patients with low-back pain, they cannot be used interchangeably.^{22,24,25,32,33} Differences in the health state utility values derived from the EQ-5D and SF-6D are substantial enough that several cost-effectiveness studies present their results using both the EQ-5D and the SF-6D as part of the sensitivity analysis.^{34,35}

The purpose of this study was to determine for patients with spondylolisthesis enrolled in the National Neurosurgery Quality and Outcomes Database (N²QOD)^{2,26,27} at what threshold of increased surgical cost TLIF will be-

come cost-prohibitive relative to PSF when both EQ-5D and SF-6D health state utility values are considered.

Methods

In October 2014, the N²QOD database was queried to retrieve the records of those patients who had a diagnosis of spondylolisthesis, a 1-level or 2-level posterior lumbar fusion with or without an interbody graft, and complete baseline and 12-month follow-up data. Only patients with spondylolisthesis were included in this study, as the definition for this pathology is widely accepted, and surgical fusion is considered an effective treatment for this condition. As per the N²QOD registry inclusion criteria, only patients with vertebral slips of Meyerding²⁸ Grade I or lower and who had not previously undergone surgery were included. Delineation between isthmic and degenerative types of spondylolisthesis was not available. Patients who had a concurrent or subsequent anterior procedure, such as an anterior lumbar interbody fusion, or a lateral access procedure, such as an extreme-lateral interbody fusion or direct lateral interbody fusion, were excluded. Patients who underwent a noninstrumented fusion or a greater than 2-level fusion were also excluded.

To control for an individual surgeon selection bias that is inherent in surgical decision making, patients who had undergone PSF were propensity matched to patients who had undergone TLIF; the patients were matched on the following variables: age, sex, body mass index, smoking status, race, educational level, employment status, presence of an anxiety disorder, insurance status, workers' compensation status, symptom duration, American Society of Anesthesiologists grade, number of levels fused, preoperative back and leg pain numeric rating scales (ranging from 0 to 10)²³ and Oswestry Disability Index (ODI)^{14,15} and EQ-5D¹³ scores. The propensity matching allows for matching multiple patient characteristics across groups without one-on-one matching of each case to a control.^{9,31} As none of the short forms (36-Item Short Form Health Survey [SF-36] or Short Form-12)³⁷ are collected as part of the N²QOD registry, the SF-6D scores were estimated from the ODI scores with a previously published logistic regression model.⁷

Statistical analysis was carried out with IBM SPSS software version 21.0. To account for multiple concurrent analyses, statistical significance was set at the $p < 0.01$ level for both the propensity-matching analysis and subsequent comparisons. Student's *t*-test was used to determine any statistical significance of differences between continuous demographic variables and to compare preoperative and postoperative health-related quality of life scores of the PSF group with those of the TLIF groups. The Fisher exact test was used to compare categorical variables of the 2 groups.

Results

The search of the N²QOD database identified 2035 patients who underwent lumbar fusion between the inception of the registry in March 2012 and October 2013. For 1722 of these patients (84.6%), 12-month follow-up data were available. This cohort included 771 patients (44.8%) with

spondylolisthesis, of whom 134 (17.4%) underwent PSF and 637 (82.6%) TLIF. After the propensity matching, 101 cases from each group were included in the analysis.

As expected after propensity matching, the TLIF and PSF cohorts were similar in demographic, health status, and health insurance data (Table 1). Operative time and blood loss, hospital length of stay, and 30-day and 90-day readmission rates were also similar for the 2 groups (Table 2). Both TLIF and PSF improved the scores for back and leg pain, ODI, EQ-5D, and SF-6D at 3 and 12 months after surgery relative to baseline. Twelve months after sur-

TABLE 1. Summary of the demographic, health status, and health insurance data of the patients in this study*

Variable	Treatment		p Value
	TLIF (n = 101)	PSF (n = 101)	
Mean age in yrs (SD)	63.3 (11.1)	65.3 (9.5)	0.186
Male	42	32	0.189
Mean BMI (SD)	31.9 (7.0)	31.3 (6.3)	0.581
Smoking			0.623
Current every-day smoker	12	8	
Current some-days smoker	1	1	
Former smoker	36	31	
Never a smoker	51	58	
Unknown	1	3	
Race			0.540
White	94	97	
Native American	1	0	
African American	5	4	
Asian	1	0	
Education			0.244
< High school	5	8	
High school	35	40	
2-yr college	19	25	
4-yr college	24	18	
Postgraduate	18	10	
Employment status			0.187
Employed, currently working	32	25	
Employed, not currently working	7	3	
Unemployed	62	73	
Anxiety disorder	14	11	0.670
Insurance status			0.535
Uninsured	0	1	
Medicare	47	50	
Medicaid	4	1	
VA/government	2	3	
Private	48	46	
Workers' compensation			0.194
No	99	95	
Yes	2	3	
Unknown	0	3	

BMI = body mass index; VA = Department of Veterans Affairs.

* Data represent number of patients, unless indicated otherwise.

gery, patients who had undergone TLIF had a statistically significantly greater improvement in the mean ODI score than the PSF patients (30.4 vs 21.1, $p = 0.001$). The TLIF patients also had greater improvements in the mean scores for back pain (4.2 vs 3.5, $p = 0.090$) and leg pain (4.6 vs 3.7, $p = 0.096$) than those in the PSF group, but these differences did not reach statistical significance. Both groups had similar gains in the EQ-5D utility scores (mean 0.25 vs 0.22, $p = 0.415$). However, gains in the SF-6D utility scores were statistically significantly greater for the TLIF group than for the PSF group (0.16 vs 0.11, $p = 0.001$) (Table 3).

Both EQ-5D and SF-6D utility values indicated that TLIF gave greater gains in QALYs than PSF. However, according to the EQ-5D utility values, the QALY gain with TLIF relative to PSF was 0.03; in contrast, for the SF-6D utility values, the QALY gain with TLIF relative to PSF was 0.05. Thus, at a cost-effectiveness threshold of \$100,000,³⁸ TLIF would be cost-prohibitive at surgical costs exceeding those of PSF by more than \$4830 ($\$100,000 \times 0.04830$) according to the SF-6D–based QALYs. However, on the basis of EQ-5D–based QALYs, TLIF would become cost-prohibitive when its surgical costs exceeded those of PSF by \$2960 ($\$100,000 \times 0.0296$). When we used the 2014 US per capita gross domestic product of \$53,042 (from <http://data.worldbank.org/indicator/NY.GDP.PCAP.CD>) as a more stringent cost-effectiveness threshold,³⁹ TLIF became cost-prohibitive at surgical costs exceeding those of PSF by \$2562 ($\$53,042 \times 0.0483$) according to the SF-6D–based QALYs or at a surgical costs greater exceeding those of PSF by \$1570 ($\$53,042 \times 0.0296$) according to the EQ-5D–derived QALYs.

TABLE 2. Summary of surgical and discharge data*

Variable	Treatment (SD)		p Value
	TLIF	PSF	
ASA grade			0.106
1	1	3	
2	51	37	
3	49	58	
4	0	3	
No. of levels			0.132
1	74	63	
2	27	38	
Mean EBL in ml	381.5 (361.8)	418.7 (295.1)	0.484
Mean op time in mins	199.0 (91.2)	194.2 (93.0)	0.711
LOS in days	3.74 (2.3)	4.0 (7.6)	0.646
Discharge disposition			0.955
Home routine	71	68	
Home w/ health service	11	11	
Postacute care setting	16	18	
Transfer to acute care	3	4	
Readmission			
w/in 30 days	0	2	0.498
w/in 3 mos	1	4	0.369

ASA = American Society of Anesthesiologists; EBL = estimated blood loss; LOS = length of stay.

* Data represent number of patients, unless indicated otherwise.

TABLE 3. Summary of surgical outcomes data*

Score	Treatment		p Value
	TLIF	PSF	
Back pain			
Baseline	7.1 (2.2)	7.3 (2.4)	0.444
3 mos	4.3 (2.9)	3.9 (3.0)	0.332
12 mos	4.2 (3.1)	3.5 (3.2)	0.090
Leg pain			
Baseline	6.8 (3.1)	6.8 (3.0)	1.000
3 mos	4.9 (3.9)	4.4 (4.1)	0.426
12 mos	4.6 (3.9)	3.7 (3.8)	0.096
ODI			
Baseline	53.6 (15.8)	52.7 (17.4)	0.685
3 mos	25.3 (16.8)	19.8 (19.0)	0.034
12 mos	30.4 (18.6)	21.1 (19.2)	0.001
EQ-5D			
Baseline	0.51 (0.22)	0.51 (0.22)	0.976
3 mos	0.24 (0.25)	0.25 (0.29)	0.760
12 mos	0.25 (0.26)	0.22 (0.25)	0.415
SF-6D			
Baseline	0.51 (0.08)	0.51 (0.09)	0.685
3 mos	0.13 (0.09)	0.10 (0.10)	0.034
12 mos	0.16 (0.10)	0.11 (0.10)	0.001

* Data represent mean scores (SD).

Discussion

The N²QOD is prospective multicenter, multisurgeon quality assurance program with a substantial infrastructure to optimize data integrity and validity.^{2,26,27} Although patient enrollment is based on widely accepted, well-defined etiologic diagnostic criteria, surgical treatment is determined by the standard practice of the individual surgeon. The use of a large registry allows researchers to pragmatically evaluate surgical interventions for a specific diagnostic indication.

Reflective of the increasing use of interbody support with posterior fusions,²⁹ most spondylolisthesis patients in the current study (83%) underwent TLIF, and only 17% PSF. This trend in use of these 2 treatments has been widely observed despite the lack of strong evidence supporting the routine use of TLIF.

Although previous studies^{1,16,20} have shown that TLIF results in longer operative times and greater estimated blood loss than PSF, the current study showed no difference in these surgical parameters between the 2 treatment groups. This lack of a difference may be due to increased surgical proficiency, improvement in surgical techniques and tools, inclusion of only 1-level and 2-level fusions in the present study, and variability in surgical skill. Previous studies have also reported higher complication rates with TLIF,^{19,21,30} but these were not observed in the current study. In addition, the length of stay, discharge disposition, and 30-day and 90-day readmission rates were also similar for the 2 groups. The observed similarities in perioperative parameters and complication and readmission rates suggested no substantial difference in direct costs

between the 2 treatments, except for the interbody implant and graft material.

Patients in the TLIF group had substantially better ODI scores at 3 and 12 months after surgery than those in the PSF group. However, the TLIF and PSF groups had similar improvements in back and leg pain scores. These inconsistencies may be explained by the unidimensional property of the pain scores, which may limit their sensitivity to change, in contrast to the ODI score, which is multidimensional.

Greater health utility gains were observed in the TLIF group than in the PSF group, but these gains were greater when the SF-6D rather than the EQ-5D questionnaire was used. The EQ-5D score is less sensitive to change than that of the SF-6D for patients with low-back disorders.^{22,24,25,32,33} These differences in health utility valuation for the same disease entity in the same cohort have prompted researchers to present the results of cost-effectiveness analyses for both valuation methods. Several studies have shown that whereas the SF-6D and ODI scores are dispersed and normally distributed, the EQ-5D scores tend to cluster and to have a bimodal distribution.^{6,33} The EQ-5D score has also been shown to have a ceiling effect in patients with low-back pain.^{6,24,25,33} In addition, the EQ-5D currently in wide use has 3 choices for each domain and may therefore not be sensitive enough to detect small changes in health status.

Depending on which cost-effectiveness threshold and health utility value were used, the increased surgical cost at which TLIF becomes less cost-effective than PSF varied from \$1570 to \$4830. The use of more expensive bone graft substitutes or enhancers in PSF or TLIF can change this cost-per-QALY ratio. However, the N²QOD registry does not have sufficient granularity to allow analysis of this issue.

There are limitations to this study, some of which are inherent to the use of registry data. Isthmic and degenerative spondylolisthesis types were not delineated in the present study. Information about the proportion of TLIF patients in our cohort who underwent a minimally invasive approach was also not available. The relatively small sample size in the present study may have caused a failure to detect statistically significant differences, especially in the ordinal values of back and leg pain scores. The relatively short length of follow-up precluded any study on the relative durability of TLIF and PSF. Although the SF-6D should ideally be derived from either the Short Form-12 or the SF-36,^{4,5} neither of these 2 forms was administered as part of the N²QOD. Thus, the SF-6D transformed from the ODI was used.⁷ Of note, previous studies have shown no statistically significant difference between the SF-6D score estimated from the ODI and the SF-36–derived SF-6D score in a cohort of patients who underwent lumbar fusion surgery for degenerative conditions.⁷

Conclusions

Using a large national spine registry, we showed here that operative time, length of hospital stay, complication rates, discharge disposition, and readmission rates were similar for both TLIF and PSF. QALY gains with TLIF

calculated with the SF-6D were greater than those calculated with EQ-5D, and these gains may justify the additional costs associated with TLIF compared with PSF. Importantly, this study demonstrates that the cost per QALY depends on the measure of health utility selected, durability of the intervention, readmission rates, and the accuracy of the cost assumptions.

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