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Quality of Life in Patients Undergoing Spine Surgery: Systematic Review and Meta-Analysis

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Abstract

Study Design: Meta-analysis.

Objective: Despite the increasing importance of tracking clinical outcomes using valid patient-reported outcome measures, most providers do not routinely obtain baseline preoperative health-related quality of life (HRQoL) data in patients undergoing spine surgery, precluding objective outcomes analysis in individual practices. We conducted a meta-analysis of pre- and post-operative HRQoL data obtained from the most commonly published instruments to use as reference values.

Methods: We searched PubMed, EMBASE, and an institutional registry for studies reporting EQ-5D, SF-6D, and Short Form-36 Physical Component Summary scores in patients undergoing surgery for degenerative cervical and lumbar spinal conditions published between 2000 and 2014. Observational data was pooled meta-analytically using an inverse variance-weighted, random-effects model, and statistical comparisons were performed.

Results: Ninety-nine articles were included in the final analysis. Baseline HRQoL scores varied by diagnosis for each of the 3 instruments. On average, postoperative HRQoL scores significantly improved following surgical intervention for each diagnosis using each instrument. There were statistically significant differences in baseline utility values between the EQ-5D and SF-6D instruments for all lumbar diagnoses.

Conclusions: The pooled HRQoL values presented in this study may be used by practitioners who would otherwise be precluded from quantifying their surgical outcomes due to a lack of baseline data. The results highlight differences in HRQoL between different degenerative spinal diagnoses, as well as the discrepancy between 2 common utility-based instruments. These findings emphasize the need to be cognizant of the specific instruments used when comparing the results of outcome studies.

Keywords

spine surgery, spine outcomes, quality-of-life, EQ-5Q, SF-6D

Introduction

Spine ailments are common causes of lost productivity and diminished health-related quality of life (HRQoL) in the United States. The number of patients seeking treatment for spine-related problems was estimated to be nearly 33 million with a 15-fold increase in the number of complex spinal fusion procedures performed between 2002 and 2007.[1,2] A recent analysis of the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample found that laminectomy/discectomy and spinal fusion were the fifth and sixth most common surgical procedures in the United States, with over 1 million procedures performed annually.[3] Furthermore, spinal fusion represented the single most expensive operative procedure with regard to direct hospital costs, accounting for $12.8 billion per year.[3]

Given the volume and costs associated with these procedures, it is no surprise that spine surgery has been subject to numerous comparative- and cost-effectiveness studies. Such

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studies make use of validated patient-reported outcome measures, which include instruments that quantify global HRQoL, pain, and disease-specific disability. While all 3 categories of patient-reported outcome measures are important in understanding the cumulative effect of a surgical procedure on the patient, global HRQoL is particularly important because it quantifies the overall physical, social, and mental well-being of a patient and can objectively compare a patient's health state across different diseases, not just spinal conditions.

Indirect measures of HRQoL take the form of surveys with standard sets of questions and are generally classified as either "non–preference based," which provide a score based on the assumption that each question within the survey carries equal weight, or "preference based," by adjusting the relative weights of the questions based on population studies of health state preferences. Preference-based instruments derive utility scores, which are anchored at 0 (death) to 1 (perfect health), although negative numbers are possible and reflect health states deemed worse than death. Utility scores may be combined with measures of time for use in comparative-effectiveness and economic studies. The most common unit in such studies is the quality-adjusted life year (QALY), in which time in a given health state is multiplied by the corresponding utility. For example, 10 years at a utility of 0.1 equals 1 QALY, as do 4 years at a utility of 0.25 and a single year in perfect health. Within the spine surgery literature, the most commonly used global HRQoL measures are the EQ-5D and the Short-Form (SF) instruments.

The EQ-5D is a preference-based HRQoL instrument with a 5-domain set of questions regarding mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Scoring of the EQ-5D has been conducted in multiple population samples (eg, US, UK, and Dutch samples) using different valuation methods such as the time tradeoff, standard gamble, or visual analog scale. The minimum and maximum scores of the EQ-5D vary based on the population set being used. For example, the UK population utilities range from −0.594 to 1, while the US population scores range from −0.109 to 1.[4,5]

The SF instruments are based on the RAND Corporation's 1989 Medical Outcomes Study. While there are multiple iterations of the SF, the most widely used version is the non–reference based SF-36, with 36 items across 8 domains on physical functioning, role limitations (2), health perceptions, vitality, social functioning, mental health, and health transition.[6] The results of the SF-36 are usually reported in terms of the 8 separate domain scores and/or 2 summary scores (Physical Component Summary [PCS], Mental Component Summary), each of which ranges from 0 to 100. The shorter, preference-based SF-6D was developed in 1998 for direct utility scoring, and because they use the same questions, the SF-36 can be mapped to the SF-6D to also derive utility scores ranging from .296 to 1.[7]

Ideally, HRQoL instruments should be administered preoperatively and at scheduled time points postoperatively in order to determine QALYs gained (or lost) after an intervention. While an increasing number of single-center and national-level registries have been developed to prospectively track outcomes in spine surgery, many providers had not been routinely recording preoperative HRQoL scores until the development of formal registries, making it difficult to reliably calculate QALYs and conduct cost-effectiveness research using previously operated patients. Such research, even if retrospective, is nevertheless important for both internal quality review and from various stakeholder perspectives.

To help overcome the lack of baseline data in many spine practices, the first goal of this study is to conduct a systematic review and meta-analysis of published studies on spinal surgery for degenerative conditions that report preoperative EQ-5D, SF-6D, or SF-36 PCS scores. A second goal of this study is to assess postoperative HRQoL scores associated with the most common spinal diagnoses to evaluate the average impact of surgical interventions. Findings from this study will provide baseline HRQoL scores associated with common degenerative spinal disorders for providers looking to quantify the impact of their surgeries, and can also serve as a benchmark for average patient improvement following treatment.

Material and Methods

A broad search was conducted to identify studies reporting EQ-5D, SF-6D, and SF-36 PCS HRQoL scores in patients undergoing surgery for degenerative cervical and lumbar spinal conditions. We searched PubMed, EMBASE, and the Cost-Effectiveness Analysis Registry at Tufts Medical Center Institute for Clinical Research and Health Policy. Our search strategy required the combination of anatomic location ("spine," "spinal," "cervical," or "lumbar") in the title and a measure of HRQoL ("quality of life" as a medical subject heading or "utility," "EQ-5D," "SF-36" or "SF-6D" in the title or text). We limited our search to English-language articles that contained preoperative HRQoL scores published between January 2000 and December 2014. We supplemented the search by using the "Related Articles" feature of PubMed and by manually searching the bibliographies of selected articles. We limited articles to those devoted to degenerative spinal diseases and which contained at least 10 operated cases. If multiple studies were published from the same institution or utilizing the same database, only the largest study was included to avoid duplication of data. A single author performed the literature search, and at least 2 authors reviewed each article to obtain pooled data. If a discrepancy arose during the article survey and data collection process, a third author reviewed the article.

Among cervical patients, we subdivided by preoperative diagnoses of radiculopathy, myelopathy, or degenerative disc disease. Among lumbar patients, we subdivided by preoperative diagnoses of radiculopathy, lumbar stenosis (neurogenic claudication), lumbar spondylolisthesis, chronic low back pain, and failed back surgery. Series related to spinal infections, trauma, neoplasia (primary and metastatic), and nonoperative management were excluded. Operative approaches varied for each diagnosis and are detailed in Supplemental Tables S1 to S3, available in the online version of the article. At least

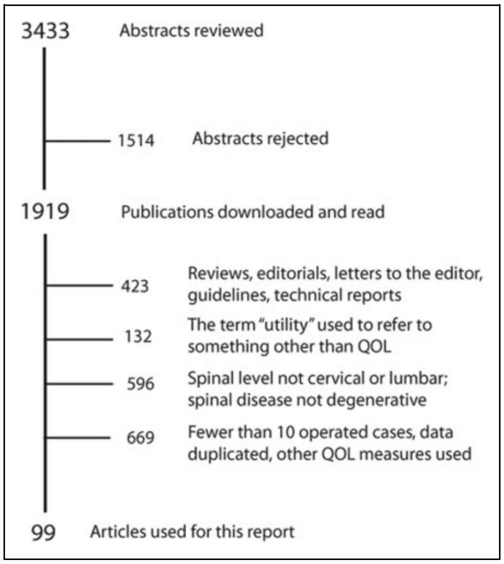

Figure 1. Summary of literature search results, with numbers of articles reviewed and rationale for article exclusion.

2 authors reviewed each article to obtain pooled data for the evidence tables, from which we calculated the mean preoperative and postoperative HRQoL scores based on diagnosis.

Observational data was pooled meta-analytically using an inverse variance-weighted, random-effects model.[8] Data pooling followed the guidelines of the meta-analysis of observational studies in epidemiology group.[9] Statistical comparisons between 2 means employed *t* tests, and comparisons among multiple groups used analysis of variance (ANOVA) with Bonferroni correction for multiple comparisons. We considered differences for which the probability was less than 5% to be significant. All data analysis was performed independently of the article selection by a single author. Meta-analytic pooling and statistical comparisons were performed with Stata (version 12; StataCorp, College Station, TX).

Results

Our initial search yielded 3433 abstracts, of which 1514 were discarded as unsuitable due to language, topic, or irrelevant diagnoses. This left 1919 articles, which were downloaded and reviewed. Figure 1 illustrates the assessment of the literature that resulted in the 99 articles included in the analysis, totaling 22 312 cases for EQ-5D utilities, 2312 cases for SF-6D utilities, and 11 927 cases for SF-36 PCS scores. The articles analyzed are detailed in Supplemental Tables S1 to S3, available online in the online version of the article.

Median follow-up time of the included studies was 12 months. Average age varied by diagnosis among all 3 instruments. Patients with lumbar stenosis were significantly older than all other lumbar disease groups ($P < .01$), and patients with cervical spondylotic myelopathy were likewise significantly older than patients with either cervical radiculopathy or generic degenerative cervical disc disease ($P < 0.05$).

Preoperative EQ-5D utility ranged from .289 to .455 for degenerative lumbar conditions and from .500 to .583 for degenerative cervical conditions (Table 1). Preoperative SF-6D utility ranged from .496 to .555 for degenerative lumbar conditions and from .550 to .575 for degenerative cervical conditions (Table 2). Finally, preoperative SF-36 PCS scores ranged from 26.8 to 28.5 for degenerative lumbar conditions and from 28.3 to 34.7 for degenerative cervical conditions (Table 3).

Surgery was associated with improved HRQoL for all groups in which postoperative scores were measured (range of improvement: .127 to .335 for EQ-5D; .073 to .257 for SF-6D; 8.08 to 15.25 for SF-36 PCS). For each instrument, cervical myelopathy was associated with the smallest mean change from baseline, while lumbar radiculopathy was associated with the greatest mean change from baseline. Differences between pre- and postoperative HRQoL were significant for each diagnosis within each of the 3 instruments ($P < .001$ for each comparison).

There were considerable differences in utility by diagnosis between the EQ-5D and SF-6D (Table 4). While cervical myelopathy utility scores were similar between the 2 instruments, there were statistically significant differences in preoperative utility for all lumbar conditions ($P < .001$ for each comparison).

Discussion

Given the increased focus on patient-reported outcomes and value-based health care, generic HRQoL measures are more commonly being used to demonstrate efficacy of interventions and facilitate comparative- and cost-effectiveness research in spine surgery. In this study, we provide pooled estimates of pre- and postoperative EQ-5D, SF-6D, and SF-36 PCS HRQoL scores for patients undergoing surgery for common degenerative spinal disorders. The results indicate that these patients have variable baseline HRQoL depending on preoperative diagnosis. This variation is more pronounced using the EQ-5D than the SF-36 PCS or SF-6D. Additionally, there were considerable differences in preoperative utility scores between the EQ-5D and SF-6D. While there was heterogeneity among the specific surgical interventions performed for each diagnosis, the pooled postoperative HRQoL scores indicate that the treatments these patients had received were generally quite effective.

In tracking clinical outcomes, the choice of instrument depends on multiple factors, including psychometric validation, burden to patients and clinicians, professional consensus, and use in the published literature. While the EQ-5D and SF surveys both allow for calculation of utility scores, disparate instruments have been shown to produce widely different results, as evidenced by studies on chronic pain, osteoarthritis, and coronary artery disease.[10-13] Sogaard et al studied 275 patients who had undergone surgery for chronic low back pain.[14] Patients completed both the EQ-5D and SF-6D, and the authors found a mean difference of .085 between instruments. Most of the variation was found to be intrinsic to survey questions rather than attributable to covariates of age, sex, preoperative diagnosis, history of previous surgery, or occupational

Table 1. Pooled EQ-5D Utility Scores for Degenerative Cervical and Lumbar Spinal Diagnoses.

	Age			Preoperative Utility			Postoperative Utility		
Disease	n	Mean	SD	n	Mean	SD	n	Mean	SD
L radiculopathy	15 293	44.8	1.86	15 618	0.417	0.135	1621	0.752	0.062
L stenosis	4166	70.9	1.08	4166	0.377	0.116	3772	0.640	0.051
L spondylolisthesis	961	55.3	7.89	815	0.455	0.097	593	0.711	0.102
L DDD/cLBP	628	44.1	4.00	804	0.373	0.035	804	0.664	0.062
Failed back surgery	476	53.4	8.53	476	0.289	0.091	219	0.600	0.049
C radiculopathy	185	47.3	1.07	185	0.500	0.095	185	0.744	0.071
C myelopathy	248	60.0	5.63	248	0.583	0.048	160	0.710	0.092

Abbreviations: L, lumbar; C, cervical; DDD, degenerative disc disease; cLBP, chronic low back pain.

Table 2. Pooled SF-6D Utility Scores for Degenerative Cervical and Lumbar Spinal Diagnoses.

	Age			Preoperative Utility			Postoperative Utility		
Disease	n	Mean	SD	n	Mean	SD	n	Mean	SD
L radiculopathy	148	46.0	4.10	148	0.517	0.122	148	0.774	0.143
L stenosis	256	63.0	1.58	256	0.522	0.029	122	0.688	0.018
L spondylolisthesis	689	59.8	2.31	689	0.555	0.014	401	0.691	0.040
L DDD/cLBP	401	48.9	4.21	401	0.538	0.039	115	0.666	0.007
Failed back surgery	420	55.7	2.83	420	0.496	0.008	25	0.65	0.03
C radiculopathy	ND								
C myelopathy	222	55.3	10.81	70	0.575	0.131	70	0.648	0.148
C DDD[a]	328	48.4	10.70	328	0.55	0.11	ND		

Abbreviations: L, lumbar; C, cervical; DDD, degenerative disc disease; cLBP, chronic low back pain; ND, no data.
[a]Includes cases with neck pain, radiculopathy, myelopathy.

Table 3. Pooled SF-36 Physical Component Summary Scores for Degenerative Cervical and Lumbar Spinal Diagnoses.

	Age			Preoperative Score			Postoperative Score		
Disease	n	Mean	SD	n	Mean	SD	n	Mean	SD
L radiculopathy	1107	44.2	4.12	1107	28.518	3.194	1032	43.764	3.357
L stenosis	886	65.1	8.25	886	26.823	6.932	786	40.205	3.861
L spondylolisthesis	1785	58.6	8.71	4983	29.111	2.732	4808	39.880	5.530
L DDD/cLBP	4983	47.2	6.83	1785	28.395	1.784	1785	38.868	5.234
Failed back surgery	143	42.0	1.44	143	28.331	2.277	143	38.068	9.167
C radiculopathy	688	49.2	8.67	688	33.281	1.767	688	50.918	6.589
C myelopathy	639	53.5	5.92	581	34.685	3.090	566	42.764	17.569
C DDD[a]	1754	48.3	5.81	1754	33.611	2.478	1239	44.827	5.528

Abbreviations: L, lumbar; C, cervical; DDD, degenerative disc disease; cLBP, chronic low back pain.
[a]Includes cases with neck pain, radiculopathy, and myelopathy.

Table 4. Differences in Average Preoperative EQ-5D and SF-6D Utility Values.

Disease	Difference in Utility[a]	*P* Value
Lumbar radiculopathy	0.100	<.001
Lumbar stenosis	0.145	<.001
Lumbar spondylolisthesis	0.100	<.001
Lumbar DDD/cLBP	0.165	<.001
Failed back surgery	0.287	<.001
Cervical myelopathy	−0.008	.428

Abbreviations: DDD, degenerative disc disease; cLBP, chronic low back pain.
[a]Difference represented by SF-6D minus EQ-5D utility scores.

status. Similar findings between the EQ-5D and SF-6D were identified in a study on Spine Patient Outcomes Research Trial (SPORT) participants with lumbar disc herniation.[15] Whitehurst et al compared the 2 scales using standardized valuation exercises and concluded that the differences in scores were based on different descriptive systems.[16] Our study identified differences in the pooled mean values among all included degenerative lumbar diagnoses, providing further evidence that EQ-5D and SF-6D utility scores are not interchangeable.

Among HRQoL measures, the SF instruments appear to be more commonly used as a whole, as demonstrated by the number of publications using the SF-36 reviewed in our study, but given the variation in SF surveys, length (particularly the SF-36), patient/administrative burden, and disparities in reporting results, the EQ-5D seems to be a more sustainable option for long-term outcomes tracking and cross-study comparability. In situations where patients may be compensated for their participation, such as funded clinical trials, the burden of longer or duplicate surveys may be acceptable to both patients and researchers, which may not hold true in routine practice. Additionally, longer surveys have been associated with lower completion rates, detracting from the overall data quality.[17,18] Perhaps for these reasons, multiple national-level surgical registries including the UK National Institute of Clinical Excellence, US-based National Neurosurgery Quality and Outcomes Database, and Swedish National Spine Registry have adopted the EQ-5D as the primary measure of HRQoL.

When evaluating the mean change from baseline score, a common variable to consider is the minimal clinically important difference (MCID), which is a threshold for clinically perceptible change by the patient. The MCID is particularly important in larger studies, where statistically significant changes may be identified despite no perceived clinical benefit. Unfortunately, most studies proposing MCID thresholds have used very specific patient populations, small sample sizes, and variable statistical methods to calculate the MCID; thus, the results have limited generalizability and contribute to a lack of consensus on the topic.

Walters and Brazier initially calculated MCIDs of .081 and .097 for the EQ-5D and SF-6D, respectively, among patients with nonspecific back pain.[19] These values are often extrapolated for use in studies on spine surgery, although subsequent research on specific surgical procedures have reported values as high as 0.46 for the EQ-5D, highlighting the tremendous variability in technique.[20] Copay et al utilized the Lumbar Spine Study Group database to determine an MCID of 4.9 for the SF-36 PCS among patients undergoing lumbar spine surgery for degenerative conditions, consistent with the 5-point MCID used by the Food and Drug Administration for medical device evaluation.[21,22] Compared to commonly cited MCIDs, the results of this study suggest that, on average, the interventions performed for most disease states result in clinically meaningful improvement. The borderline values identified in the cervical myelopathy cohorts highlight the need to concomitantly measure disease-specific disability through instruments such as the Japanese Orthopaedic Association Scale for myelopathy severity, as functional limitations and improvements from baseline may not be adequately reflected in global HRQoL scores in these patients.

Given the high cost of spine surgery, and because changes in utility represent the denominator in cost-effectiveness research, small variations in utility between instruments may lead to erroneous interpretations of the relative efficacy of a procedure and result in vastly different perceived cost-utility ratios. Although comparative-effectiveness and cost-utility studies have thus far played a limited role in resource allocation in the United States, it is plausible that moving forward this data may play a larger role in medical decision-making. To further support efforts in high quality comparative-effectiveness research, the Patient Protection and Affordable Care Act (ACA) of 2010 facilitated the establishment of the independent, nonprofit Patient-Centered Outcomes Research Institute (PCORI).[23]

While a major goal of the ACA is to stem the rising costs of health care, legislation prohibits both public and private insurers from using PCORI-funded research for mandates on coverage or reimbursement decisions.[24] Nevertheless, the ACA emphasizes the Centers for Medicare and Medicaid Services' commitment to value-based purchasing, which has implications for nearly all medical specialties. For example, some private insurers have used cost-effectiveness research in oncology to establish tiered benefit designs that require greater out-of-pocket expenses by patients for certain chemotherapy treatments.[25] Should a similar situation arise within spine surgery, formal patient-reported outcomes may become standard of care to document quality that is not necessarily reflected in administrative databases tracking re-admissions and other reportable complication rates. For these reasons, we believe increased attempts at standardization of instruments within the spine surgery literature will improve the comparability across institutions and registries.

There were multiple challenges and limitations of this study. The most significant challenge was that common registries and data sets are often used by multiple groups and at different time points, resulting in numerous studies with overlapping sample populations and redundant data. We sought to minimize duplicate data by limiting studies utilizing known registries to specific preoperative diagnoses. If multiple studies were identified from the same center or utilizing a common registry for a given diagnosis, we selected the one study with the greatest sample size. Despite our efforts, it is possible that we may have inadvertently excluded unique studies in an attempt to minimize redundancy.

Another limitation in this study is that heterogeneity among baseline patient characteristics and comorbidities was not controlled for, and may have biased average preoperative values and mean changes from baseline. For example, patients who had previously undergone spine surgery at the index level were often not clearly identified. Additionally, follow-up times varied between studies, which may have skewed postoperative averages and limits the generalizability of the pooled results. Most studies used set follow-up time points at 12 or 24 months postoperatively; thus, the data does not provide information on the long-term durability of surgical results. Furthermore, the value sets (eg, the United States vs the United Kingdom) employed to derive utility value were often not noted, which may lead to slightly different utility values between studies. Our results do not control for the procedural heterogeneity within a given diagnosis. For example, chronic low back pain may be treated with a number of different fusion techniques, each of which may have inherently different indications and levels of efficacy. Finally, a subset of studies were industry sponsored, potentially biasing the surgical outcome toward a positive result.

Despite these limitations, the results of this study provide initial, large-scale comparisons between different HRQoL instruments for common spinal diagnoses. The values presented in this study may be used by practitioners who would otherwise be precluded from quantifying their surgical outcomes using patient-reported outcomes and performing cost-utility studies due to a lack of baseline, preoperative data. The findings of the meta-analysis highlight the differences in preoperative quality-of-life experienced by patients with different degenerative spinal disorders, as well as the discrepancy in values obtained by the 2 most common utility-based instruments in spine surgery, the EQ-5D and SF-6D, which emphasizes the need to be cognizant of the specific instruments used when comparing the results of multiple studies. While heterogeneity among patient characteristics and operative procedures necessitate judicious interpretation of the results, we believe the pooled meta-analytic data will be helpful as more centers begin tracking and analyzing their clinical outcomes with validated patient-reported outcomes.

Declaration of Conflicting Interests

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Supplemental Material

The supplemental material is available in the online version of the article.

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