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Health state utility of patients with single-level cervical degenerative disc disease: comparison of anterior cervical discectomy and fusion with cervical disc arthroplasty

Clinical article

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Object. Cost-effectiveness analysis (CEA) of medical interventions has become increasingly relevant to the discussion of optimization of care. The use of utility scales in CEA permits a quantitative assessment of effectiveness of a given intervention. There are no published utility values for degenerative disc disease (DDD) of the cervical spine, anterior cervical discectomy and fusion (ACDF), or cervical disc replacement (CDR). The purpose of this study was to define health utility values for those health states.

Methods. The 36-Item Short Form Health Survey data from the ProDisc-C investigational device exemption study were obtained for single-level DDD at baseline and 24 months postoperatively after ACDF or CDR procedures. Patients in the original study were randomized to either ACDF or CDR. Utilizing a commercially available Short Form–6 dimensions program, utility scores were calculated for each health state using a set of parametric preference weights obtained from a sample of the general population using the recognized valuation technique of standard gamble.

Results. The baseline health state utility (HSU) value for a patient with single-level DDD was 0.54 in both the ACDF and CDR groups. Postoperative changes in HSU values were seen in both intervention groups at 24 months. Cervical disc replacement had a HSU value of 0.72. Anterior cervical discectomy and fusion was found to have a postoperative utility state of 0.71. No statistically significant difference was found in the HSU for ACDF and CDR at 24 months of follow-up.

Conclusions. This study represents the first calculated HSU value for a patient with single-level cervical DDD. Additionally, 2 common treatment interventions for this disease state were assessed. Both treatments were found to have significant impact on the HSU values. These values are integral to future CEA of ACDF and CDR.
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Key Words • **degenerative disc disease** • **cervical disc arthroplasty** • **anterior cervical discectomy and fusion** • **health state utility** • **deformity**

Anterior cervical discectomy and fusion (ACDF) is a frequently used procedure for the treatment of cervical disc disease resistant to conservative management. First described in 1955, it has become the gold standard for the treatment of neurological deficits, neck pain, and radiculopathy associated with cervical disc disease.[2,8,12,28] Although some variation exists in reported outcomes, in general a high clinical success rate is reported.[11,13,24,31] Cervical arthroplasty or cervical disc replacement (CDR) is a relatively new procedure that serves as an alternative to ACDF in the treatment of single-level degenerative disc disease (DDD). Cervical disc replacement offers the potential advantage of preserving intervertebral motion, which theoretically may protect adjacent levels from accelerated degeneration.[18,22] Cervical disc replacement also obviates the possibility of pseudarthrosis, which is the most common reason for reoperation at the index level after ACDF.

Four large multicenter national randomized clinical

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; CDR = cervical disc replacement; CEA = cost-effectiveness analysis; DDD = degenerative disc disease; HSU = health state utility; IDE = investigational device exemption; SF-6D = Short Form–6 dimensions; SF-36 = 36-Item Short Form Health Survey.

trials have evaluated the clinical outcomes of CDR compared with ACDF.[18,21–23,26] These trials reported a number of different outcome measures including the neck disability index, 36-Item Short Form Health Survey (SF-36), neurological improvement, and avoidance of subsequent surgery. All 4 trials reported improvement in all outcomes measured in the CDR cohort compared with the preoperative state. The data from these trials also suggest noninferiority of CDR compared with ACDF. Further research aimed toward guiding clinical decision making with regard to using ACDF or CDR for the treatment of cervical disc disease must take into account both the effectiveness of the intervention and its cost.

Cost-effectiveness analysis (CEA) is an instrument increasingly relied upon for usefully comparing 2 interventions. This type of analysis considers the effectiveness or utility of an intervention compared to the intervention's cost. Cost-effectiveness analysis provides valuable information regarding which intervention will lead to a more efficient utilization of health care resources. This type of analysis has had a substantial impact on many health care systems, guiding reimbursement practices. Cost-effectiveness analysis has been applied to a number of spinal surgical interventions. A critical component in the determination of effectiveness is health state utility (HSU). Health state utility values range from 0, representing death, to 1, representing perfect health/function. These values can be determined using information from a number of patient-reported outcomes instruments. Tools are available that convert standardized patient-reported outcomes surveys such as the SF-36 to HSU values. These values provide a quantitative assessment of the health status of a given subject or subjects and allow direct comparison of any number of disease states and interventions.

Cost-effectiveness analysis evaluating CDR and ACDF requires HSU values for the baseline disease state, as well as postoperative values for ACDF and CDR. Carreon et al. recently published HSU values at baseline and after ACDF surgeries.[7] This study aims to determine the baseline HSU values for cervical DDD and as well as postoperative HSU values for ACDF and CDR, allowing for comparison of effectiveness of the 2 procedures. This information is important for future CEA studies of ACDF and CDR.

Methods

The SF-36 data collected during the ProDisc-C (Synthes) investigational device exemption (IDE) trial were used for the calculations of HSU values. In the FDA-regulated IDE study (ProDisc-C IDE #G030059), 209 patients underwent surgery between August 2003 and October 2004 at one of 13 nationwide investigational sites.[23] In the trial, the study population of 209 patients was randomized to the ProDisc-C or ACDF cohorts. The ProDisc-C cohort contained 103 patients, and the ACDF cohort contained 106 patients. The postoperative clinical status of each patient was evaluated for 24 months postoperatively, with SF-36 data collected at 6 weeks and 3, 6, 12, 18, and 24 months.

Disease-state modeling based on a standard gamble analysis was used to calculate HSU values from SF-36 scores. The standard gamble technique presents an individual with a choice between a certain health state (such as back pain) and a gamble that can either improve or worsen the condition. The individual is then asked what probability of improvement would make him or her indifferent to choosing between the current health state and the gamble option. Current applications allow for conversion of SF-36 scores to HSU values using a previously modeled relationship between the health states described by the SF-36 and their values as described by a sample population. This is a well-established method and has been used for a number of topics ranging from heart disease to knee arthritis.[3,5,16]

The Short Form–6 dimensions (SF-6D) is a classification for describing health derived from a subsection of SF-36 items.[4] It is composed of 6 multilevel dimensions. Any patient who completes the SF-36 or the SF-12 can be uniquely classified according to the SF-6D. The SF-6D describes a total of 18,000 unique health states. The SF-6D comes with a set of preference weights obtained from a sample of the general population using the recognized evaluation technique of standard gamble. Members of the general population were asked to assign value to a selection of health states; from these data a model has been generated to predict all the health states described by the SF-6D.

Utilizing a non–commercially licensed application, estimating a preference-based index from the SF-6D, the raw SF-36 data from the IDE trial were used to calculate the baseline HSU for preoperative single-level cervical DDD as well as the HSU of the ACDF and CDR cohorts at 24 months.

Results

In the ProDisc-C IDE study there were no statistically significant differences between the ACDF and CDR cohorts with regard to age, sex, race, smoking status, body mass index, surgical level, length of hospital stay, or prior surgical treatment. In the CDR group, 100 patients had at least 24 months of follow-up. There were 98 patients with 24 months of follow-up in the ACDF group. The SF-36 was one of the outcomes metrics used to quantify surgical success in the study.

The SF-36 success was defined as any improvement from baseline in the composite score of the Mental Component Summary and Physical Component Summary. Both procedures showed a statistically significant improvement in the overall SF-36 scores from baseline ($p < 0.0001$) and at all time points. At 24 months, 80.8% of ProDisc-C patients and 74.4% of ACDF patients showed improvement in the Physical Component Summary of the SF-36. Improvement in the Mental Component Summary was found in 71.8% and 68.9% of the ProDisc-C and ACDF cohorts, respectively.

Individual SF-36 component scores were obtained for each patient in the study. Utilizing the preference-based SF-6D index, HSU values were calculated for the baseline state in both the CDR and ACDF groups (Table 1). The mean baseline HSU value for a person with single-

TABLE 1: Health utility state values for the ACDF and CDR cohorts

Group	No. of Patients	HSU Value		
		Mean ± SD	Minimum	Maximum
CDR				
preop	103	0.54 ± 0.1	0.32	0.92
24 mos	100	0.72 ± 0.15	0.33	0.97
ACDF				
preop	105	0.54 ± 0.08	0.3	0.79
24 mos	98	0.71 ± 0.14	0.38	0.96

level DDD was 0.540 and 0.536 for the CDR and ACDF groups, respectively (p = 0.7442) (Table 2). At 24 months, the mean HSU value of the CDR cohort was 0.724 and that of the ACDF cohort was 0.713 (p = 0.5989). Both the CDR and ACDF groups showed a statistically significant change in HSU from 0 months to 24 months (p < 0.0001 for both).

Discussion

Anterior cervical discectomy and fusion and CDR are 2 surgical alternatives for the treatment of cervical DDD. The 4 randomized controlled trials and a meta-analysis of those trials suggest noninferiority of CDR to ACDF.[18,21–23,26] This study is the first, to our knowledge, to assign HSU values to the preoperative and postoperative states for the 2 procedures. Health state utility values provide a quantified assessment of the overall health state of a patient. These values range from 1 indicating perfect health, to 0 indicating death. This information is pivotal in carrying out future CEAs. In the era of limited health care resources, comparisons of the cost and effectiveness of the various treatment options is a necessary component of well-informed clinical decision making.

Using the data from the ProDisc-C multicenter randomized controlled trial, the preoperative HSU value for single-level DDD was determined to be approximately 0.54. The mean HSU value was 0.540 in the CDR cohort and 0.536 in the ACDF cohort (p = 0.7442). Both procedures demonstrated effectiveness in the treatment of cervical DDD, with mean HSU values at 24 months after surgery of 0.7239 and 0.713 for CDR and ACDF, respectively (p < 0.0001 for both compared with the preoperative state). One procedure did not demonstrate clinical superiority over the other. There was no statistically significant difference in mean HSU value at 24 months in the CDR and ACDF cohorts (p = 0.5989). For the purpose of comparison, HSU values for common health states are available in Table 3.[29,30] Single-level cervical DDD has a lower average HSU value (0.54) than chronic osteoarthritis of the hip (0.60) and heart failure (0.67).

These data suggest that ACDF and CDR are comparable in terms of effectiveness. This is consistent with previously published reports. Randomized controlled trials of the ProDisc-C, PRESTIGE (Medtronic), PCM Cervical Disc (NuVasive), and BRYAN Disc (Medtronic) all showed no statistically significant difference between

TABLE 2: Between-group comparisons using t-tests*

Group 1	Group 2	p Value
preop CDR	postop CDR	<0.0001
preop ACDF	postop ACDF	<0.0001
preop CDR	preop ACDF	0.7442
postop CDR	postop ACDF	0.5989

* All postoperative values were obtained at 24 months of postoperative follow-up.

CDR and ACDF in terms of improvements in the neck disability index or neurological status.[18,22,23,26] Three of the 4 trials found no difference between ACDF and CDR cohorts in survivorship (avoidance of subsequent surgery) and overall success.[18,23,26] A meta-analysis of pooled data from all 4 trials showed superiority of CDR in survivorship, improvement in neurological status, and overall success of procedure.[21] The pooled data showed no difference in improvements in neck disability indices between the two surgical cohorts.

While the HSU values from our analysis are consistent with previously published reports, long-term outcomes are not yet available for CDR. The annual risk of adjacent-level degeneration in patients who have undergone an ACDF is approximately 3%, and about one-quarter of those patients need additional surgery.[15,16,20,21,32] A potential advantage of CDR over ACDF is preservation of the natural mechanics of the cervical spine and a possible reduction in adjacent-level degeneration. No studies to date have shown a lower risk of clinical adjacent-level pathology with arthroplasty compared with ACDF. Pseudarthrosis occurs in between 2.9% and 6.9% of patients who underwent an ACDF.[10] This is the most common reason for revision at the index level: the risk of pseudarthrosis is obviated by CDR.

Most studies comparing radiographic adjacent-level pathology in ACDF and CDR failed to find a difference between the two groups.[6,17,25,27,32] One randomized controlled trial did find a lower rate of radiographic adjacent-level pathology in the CDR group.[9] Long-term studies are necessary to further elucidate whether motion-sparing surgery decreases the rate of clinical adjacent-segment pathology. As more data become available on long-term outcomes, the HSU values of the 2 procedures may change.

TABLE 3: Mean HSU values for a series of common health states*

Health State	Mean HSU Value
single-level cervical DDD	0.54
after CDR	0.72
after single-level ACDF	0.71
chronic OA of the hip	0.60
successful primary THA	0.96
heart failure	0.67
after aortic valve replacement	0.69

* A score of 1 denotes perfect health, and a score of 0 denotes death.
OA = osteoarthritis; THA = total hip arthroplasty.

The current data indicate equal efficacy between CDR and ACDF. Until further evidence supports the superiority of one procedure over the other in terms of efficacy or safety, decisions regarding which surgical option to offer patients should be based primarily on the overall cost of the procedure. Studies comparing the costs of the 2 procedures in the US are lacking. A study from the United Kingdom found a lower total cost of surgery in the arthroplasty group despite the higher cost of the implant.[1] However, procedure costs are specific to health care systems and must be investigated further in the US.

Conclusions

This study based on outcomes from a multicenter randomized controlled trial of the ProDisc-C prosthesis has assigned HSU values to the preoperative single-level cervical DDD state, as well as the postoperative states for CDR and ACDF. This is the first study to assign these values. Health state utility values are integral in future CEAs of the 2 procedures. According to our data both procedures are equally effective in the treatment of single-level cervical DDD. Further research is necessary to determine the total costs of both procedures in the US population.

Disclosure

Dr. Qureshi is a consultant for Stryker, Medtronic, and Orthofix. Dr. Cho is a consultant for Stryker. Dr. Hecht is a consultant for Zimmer Spine and Medtronic Spine.

Author contributions to the study and manuscript preparation include the following. Conception and design: all authors. Acquisition of data: Qureshi, Delamarter, Fehlings. Analysis and interpretation of data: Goz, McAnany. Drafting the article: Qureshi, Goz, McAnany, Hecht, Delamarter. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Goz. Statistical analysis: Goz, McAnany. Administrative/technical/material support: Qureshi, Goz, Cho, Hecht, Fehlings. Study supervision: Qureshi, Cho, Hecht, Delamarter, Fehlings.

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