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Cost-utility analysis modeling at 2-year follow-up for cervical disc arthroplasty versus anterior cervical discectomy and fusion: A single-center contribution to the randomized controlled trial

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Abstract

Background: Patients with cervical disc herniations resulting in radiculopathy or myelopathy from single level disease have traditionally been treated with Anterior Cervical Discectomy and Fusion (ACDF), yet Cervical Disc Arthroplasty (CDA) is a new alternative. Expert suggestion of reduced adjacent segment degeneration is a promising future result of CDA. A cost-utility analysis of these procedures with long-term follow-up has not been previously reported.

Methods: We reviewed single institution prospective data from a randomized trial comparing single-level ACDF and CDA in cervical disc disease. Both Medicare reimbursement schedules and actual hospital cost data for peri-operative care were separately reviewed and analyzed to estimate the cost of treatment of each patient. QALYs were calculated at 1 and 2 years based on NDI and SF-36 outcome scores, and incremental cost effectiveness ratio (ICER) analysis was performed to determine relative cost-effectiveness.

Results: Patients of both groups showed improvement in NDI and SF-36 outcome scores. Medicare reimbursement rates to the hospital were $11,747 and $10,015 for ACDF and CDA, respectively; these figures rose to $16,162 and $13,171 when including physician and anesthesiologist reimbursement. The estimated actual cost to the hospital of ACDF averaged $16,108, while CDA averaged $16,004 (p = 0.97); when including estimated physicians fees, total hospital costs came to $19,811 and $18,440, respectively. The cost/QALY analyses therefore varied widely with these discrepancies in cost values. The ICERs of ACDF vs CDA with Medicare reimbursements were $18,593 (NDI) and $19,940 (SF-36), while ICERs based on actual total hospital cost were $13,710 (NDI) and $9,140 (SF-36).

Conclusions: We confirm the efficacy of ACDF and CDA in the treatment of cervical disc disease, as our results suggest similar clinical outcomes at one and two year follow-up. The ICER suggests that the non-significant added benefit via ACDF comes at a reasonable cost, whether we use actual hospital costs or Medicare reimbursement values, though the actual ICER values vary widely depending upon the CUA modality used. Long term follow-up may illustrate a different profile for CDA due to reduced cost and greater long-term utility scores. It is crucial to note that financial modeling plays an important role in how economic treatment dominance is portrayed.
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Keywords: Anterior cervical discectomy and fusion; Cervical disc arthroplasty; Cost-utility analysis

Introduction

Although patients presenting with cervical spondylotic radiculopathy (CSR) can often be treated nonoperatively with successful results, the reality remains that many will eventually require surgical intervention. The indications for surgical treatment of single-level cervical radiculopathy have been extensively studied and discussed in the existing medical literature.[1–9]

Recently, guidelines have been published regarding the natural history and predictive prognostic features of CSR, including surgical indications for radiculomyelopathy and means for assessing functional outcomes.[4,7,8,10–12] Studies suggest that many patients with CSR secondary to herniated nucleus pulposus may experience spontaneous symptom resolution; therefore, both operative and nonoperative management may produce a similar clinical outcome at 16 months.[7,12–14] Other literature, however, would support early intervention as being beneficial for both pain relief and functional outcome.[6,10,15,16] The timing of intervention can introduce additional economic factors that are often

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overlooked, such as the productivity of a patient returning to gainful employment.

Significant controversy still remains with regard to the most appropriate method of surgical intervention. The 2 most common and heavily debated procedures approached anteriorly for patients with single-level disc disease and otherwise normal spinal alignment are anterior cervical discectomy and fusion (ACDF) and cervical disc arthroplasty (CDA). ACDF is widely viewed as the gold standard,[17,18] yet the emerging significance of motion preservation and the desire for reduced adjacent segment degeneration call this standard into question. Several randomized controlled trials (RCTs) have demonstrated that CDA achieves similar, and in some cases superior, results to ACDF when considering short-term clinical outcome.[19–22] Drawbacks, such as autograft donor site morbidity, pseudarthrosis, and adjacent segment degeneration, that necessitate revision surgery are commonly cited reasons for driving spine surgeons to consider arthroplasty, and positive findings, such as reduced rates of revision, are being demonstrated with longer periods of follow-up for the patients enrolled in the Prodisc-C RCT.[17,18,23,24] Long-term follow-up is required to better evaluate the durability of CDA procedures and to allow spine surgeons to more confidently choose the appropriate surgical technique. Consideration of unexpected or complicating factors in an idealized cost-utility evaluation may lead to inappropriate conclusions, and as such economic modeling attempts to control for unexpected events.

Long-term outcomes, additional nonoperative health interventions, and unexpected events can also exert considerable influence upon the economic effect of a surgical intervention; increased scrutiny of expensive advanced technologies is forcing clinicians to understand the relative advantages of new devices and techniques beyond theoretical benefits and outcomes. Therefore, the cost-effectiveness of a procedure is increasingly relevant to clinical decision making. Several models for illustrating cost-effectiveness have been reported in the past, but the unpredictable influences of long-term events require any such model to rely upon an idealized setting to exclude various positive and negative economic externalities that may arise.[25–27]

Despite the importance of reducing costs while maintaining the best possible outcomes, existing literature evaluating the relative cost-effectiveness of various procedures to treat pathology in the cervical spine is limited.[23,28,29] We report a retrospective cost-effectiveness comparison of ACDF and CDA, considering data from a previously conducted prospective, RCT and utilizing Medicare reimbursement rates to represent the costs of the 2 procedures, with awareness of the shortcomings of an idealized clinical patient cohort.

Methods

Study design

We performed a retrospective review of single institution data from a prospective multicenter, RCT to compare the efficacy of ACDF and CDA in the treatment of symptomatic cervical disc disease.[21] Over the course of the Prodisc-C IDE study, 31 patients were enrolled at our institution; inclusion criteria for this prospective study were limited to patients undergoing surgery on 1 vertebral level for single-level cervical radiculopathy, without adjacent segment degeneration or prior fusion. Two patients were excluded from the study because of motor vehicle crashes, which was likely to skew their self-reported quality of life during the follow-up period, and another elected to be removed from the study. Therefore, after applying these exclusion criteria, there were 28 patients included in our analysis; all 28 patients met the inclusion criteria of the RCT.[21] These criteria were implemented to isolate patients undergoing single-level ACDF and CDA without associated short- or long-term complications, in order to examine the direct costs associated with each procedure. This represents a controlled clinical scenario and does not account for indirect financial factors, such as loss of productivity.

Additionally, institutional cost figures were of interest for further comparison of these patients. However, financial data on the initial study cohorts were not deemed representative of the true procedural costs, due to the fact that the implanted devices were provided to patients by the medical device companies at no cost. Alternatively, the financial records of 2 separate cohorts of single-level ACDF ($n = 15$) and CDA ($n = 13$) patients operated on between 2008 and 2010 were retrospectively reviewed and used to represent hospital costs of ACDF and CDA patients. These patients all underwent single-level procedures for radiculopathy and served as replica patients for the purpose of direct hospital cost modeling.

Outcome scores

Clinical outcome was monitored by recording health-related quality of life outcome scores (HRQOL) from both the disease-specific Neck Disability Index (NDI) and the general-health measure Short Form-36 (SF-36). Preoperative and postoperative monitoring included 6-, 12-, 18-, and 24-month time points. Utility values were derived from the NDI and the SF-36 at 12 and 24 months based on accepted literature and based on validated mathematical modeling.[30–33] A calculation of cumulative quality-adjusted life years (QALYs) was gained at time points 1 and 2 years after surgery was performed. There were 2 patients that had only 1-year follow-up; these were included only in the 1-year cost analysis. Within each treatment group, patients with and without complete follow-up data were compared for utility scores at each time point, as well as for cumulative QALYs gained at 1 and 2 years.

Economic modeling

Cost data were estimated using Medicare reimbursement values. All reported dollar values are based on current USD.

Hospital reimbursement was calculated according to diagnosis-related group (DRG) codes as part of the Medicare prospective payment system. DRG reimbursement includes coverage for the cost incurred by the hospital in the provision of surgical and perioperative services inclusive of implants and medical devices (the cost of devices is often prohibitive, as the DRG is based on diagnosis and does not change based on intervention). DRG payments are significantly altered to account for disproportionate numbers of sick patients, teaching hospitals, geographic location, and other influential factors; the DRG reimbursements utilized for this study were applicable to a large urban environment. In the present study, CDA patients were assigned DRG code 491 to represent back and neck procedures except spinal fusion without major or minor comorbidities and complications. With the exception of 1 patient, all ACDF patients were assigned DRG code 473 to represent cervical spinal fusion without major or minor complications and comorbidities; the remaining patient was assigned DRG 472 for cervical spinal fusion with complication/comorbidity.

Physician reimbursement was calculated based on CPT coding according to the Medicare physician fee schedule.[34] In summary, each CPT code was broken down into 3 categories: physician work or the amount of effort/work needed to perform the service; malpractice or the cost of malpractice associated with the procedure in question; and practice expense or the cost of maintaining a practice that provides the service in question. Each of these elements is assigned relative value units (RVUs), which are then multiplied by a geographic price-cost index that is specific to the location of treatment to adjust for differences based on location. These are then summed to determine the total RVUs for the CPT code. This RVU total is then multiplied by a national-standard, "conversion factor" that is dependent upon the relevant fiscal year to determine the total Medicare reimbursement for the given CPT code. Multiple CPT codes may be combined for 1 procedure by utilizing modifiers; relevant to this study was Modifier 51, which requires additional CPT reimbursement values to be halved to prevent redundancy in physician reimbursement.

In the present study, CDA patients were represented with CPT codes 22856 (CDA) and 76001 (fluoroscopy >1 hour); ACDF patients were represented with CPT codes 63075 (anterior discectomy for decompression), 22551 (interbody fusion, anterior, cervical, below C2) with Modifier 51, 20931 (structural allograft), 22854 (anterior instrumentation, cervical, 2–3 levels), and 76000 (fluoroscopy <1 hour). Although CDA is currently considered an experimental procedure, it is not universally covered by Medicare. However, evidence in favor of CDA as a Medicare procedure is continually increasing, and the provision of CPT codes with corresponding RVUs allows interested parties to justifiably evaluate what is likely to become a competitive procedure from a Medicare cost perspective.

Implant costs for procedures are accounted for within the DRG. Services rendered beyond those considered standard for the index hospitalization costs, such as outpatient healthcare resource utilization and lost or gained patient economic productivity, were not included in this investigation.

Institutional financial economic modeling

With regard to institutional costs, direct care cost has been defined in the literature as the cost directly associated with intervention (ie cost of perioperative inpatient management).[36] Like DRG coverage, this excludes both the utilization of outpatient healthcare resources and consideration of lost or gained economic productivity. The medical record numbers of the patients selected for the financial modeling cohorts were used to identify the relevant financial records of each patient; these records were used to build a data set of the overall hospital cost (HC) associated with patients of both procedures. Surgeon, neuromonitoring and anesthesiologist fees comprised the physician's cost and were based on Medicare reimbursement schedules, as specific contractual information regarding employee pay is confidential. The CPT codes used for calculating physician fees were taken from the *Current Procedural Terminology 2009 Professional Edition*, and the Manhattan health referral region adjustment factor was applied to all fees.[37]

Cost-utility analysis (CUA)

The cost utility of each procedure was determined by dividing Medicare-based cost data by the cumulative QALYs (QALYs are alternatively termed Utility values) gained at 1 and 2 years by each patient. This provides a cost/QALY ratio (Cost-utility in USD) that indicates the cost of each QALY gained by a particular procedure. The cost and outcome data were then used to complete a CUA and incremental cost-effectiveness ratio (ICER). This ratio is determined by dividing the difference in cost of the 2 procedures by the difference in the overall utility gains of the 2 procedures [(cost ACDF−cost CDA)/(utility ACDF −utility CDA)]. This ratio reflects the actual cost of the additional gain in QALYs of 1 procedure in comparison to the other; in this context, it was used to express the additional cost of the added or lost QALYs following ACDF in comparison to those afforded by CDA. The ICER was calculated using utility values 1- and 2-year time points to illustrate the influence that additional postoperative time can have upon this value. For the institutional financial data, the difference in total cost (composed of both hospital costs and estimated physician costs) was used for the ICER calculation.

Where applicable, Pearson chi-squared, Fischer's Exact, or Student *t* tests were used to determine statistically significant differences in demographic, cost, and utility values between treatment groups. A *p* value of $\leq .05$ (2 sided) was

considered significant. SPSS Statistics 17.0 software package (SPSS Inc, Chicago, IL) was used to perform statistical analysis. The same statistical analysis was repeated for all institutional financial data.

Results

Demographic data

Twenty-eight patients that were contributed to the RCT from our institution were included in this analysis (ACDF $n = 10$, CDA $n = 18$). Overall, there were no significant differences in preoperative or operative parameters between the 2 groups, taking into account gender, age, and body mass index, ASA status, operative time, and length of stay (Table 1). The average age for ACDF patients was 40.3 years, compared with 41.9 years for CDA. The ACDF group consisted of 60% men, versus 50% for CDA. Body mass index averaged 26.2 for ACDF and 26.9 for CDA. Both groups were composed of healthy patients, with the ACDF group being composed of 9 ASA 2 patients and 1 ASA 1 patient and the CDA group was composed of 15 ASA 2 patients and 3 ASA 1 patients. Mean operative time for ACDF was 195.7 minutes, versus 204.8 minutes for CDA. Similarly, the mean length of stay for ACDF was only slightly less at 1.2 days, versus 1.4 for CDA. The majority of patients were operated at the C5-6 and C6-7 levels. Only 2 patients were operated at another cervical level, both in the CDA group and both at C4-5.

Clinical outcome

The 2 treatment groups recorded similar preoperative NDI scores, with ACDF averaging 29.0 versus 27.8 for CDA (Table 2). Both groups displayed a noticeable improvement after surgery. For the ACDF group, mean NDI values at 12 and 24 months were 9.4 and 7.9, respectively. For the CDA group, the corresponding NDI scores were 13.1 and 14.2; there were no statistically significant differences in improvement between the 2 groups

The 2 treatment groups also reported similar preoperative and postoperative scores with the SF-36 surveys (Table 3).

Table 2
Summary of NDI scores

	ACDF ($n = 10$)*	CDA ($n = 18$)*	*P*-value
Preoperation NDI	29.0 ± 7.7	27.8 ± 6.5	0.66
12 months	9.4 ± 8.6	13.1 ± 11.4	0.52
24 months	7.9 ± 6.7	14.2 ± 11.3	0.09

*Values given as mean ± standard deviation.

For ACDF, the mean PCS score improved from 33.9 preoperatively to 40.4 and 43.5 at 12 and 24 months, respectively; the mean MCS score for ACDF patients improved from 26.7 to 47.4 and 44.3 at the same time points. For CDA, preoperative PCS was 34.3 and improved to 43.1 and 42.4 at 12 and 24 months, respectively; MCS scores improved from 31.4 to 38.9 and 38.6 at the same time points. Again, there were no significant differences between ACDF and CDA for any postoperative PCS or MCS scores.

Health utility scores

The preoperative health state utility value, when calculated based on NDI (Table 4), was 0.49 for ACDF and 0.50 for CDA. At 12 and 24-month time points, ACDF patients achieved mean postoperative utility scores of 0.61 and 0.70, respectively. These results translate to QALYs gained at 1 year of 0.16 and at 2 years of 0.37. CDA had similar values of 0.65 and 0.64 at 12 and 24 months, respectively; the 1- and

Table 3
Summary of SF-36 scores

	ACDF ($n = 10$)*	CDA ($n = 18$)*	*P*-value
Preoperation PCS	33.9 ± 7.7	34.3 ± 7.1	0.88
12 months	40.4 ± 8.5	43.1 ± 9.0	0.57
24 months	43.5 ± 8.5	42.4 ± 8.6	0.72
Preoperation MCS	26.7 ± 11.8	31.4 ± 9.2	0.25
12 months	47.4 ± 6.2	38.9 ± 13.6	0.07
24 months	44.3 ± 7.2	38.6 ± 12.2	0.20

*Values given as mean ± standard deviation.

Table 1
Summary of demographics

	ACDF ($n = 10$)	CDA ($n = 18$)	*P*-value
Gender distribution (M,F)	6,4	9,9	0.71
Age*	40.3 ± 6.5	41.9 ± 9.1	0.63
BMI*	26.2 ± 4.0	26.9 ± 4.2	0.63
ASA (1,2)	1,9	3,15	0.55
Operative time (min)*	195.7 ± 24.5	204.8 ± 24.4	0.36
Length of stay (days)*	1.2 ± 0.4	1.4 ± 0.6	0.39
Level operated			
C4-5	0	2	
C5-6	7	10	
C6-7	3	6	

*Values given as mean ± standard deviation.

Table 4
Summary of utility values

	ACDF ($n = 10$)*	CDA ($n = 18$)*	*P*-value
NDI			
Preoperation utility	0.49 ± 0.1	0.50 ± 0.1	0.66
12 months	0.61 ± 0.21	0.65 ± 0.12	0.56
24 months	0.70 ± 0.1	0.64 ± 0.11	0.11
Total QALYs 1 year	0.16 ± 0.15	0.13 ± 0.11	0.57
Total QALYS 2 years	0.37 ± 0.23	0.27 ± 0.2	0.27
SF-36			
Preoperation utility	0.47 ± 0.10	0.51 ± 0.12	0.34
12 months	0.72 ± 0.13	0.68 ± 0.17	0.52
24 months	0.71 ± 0.13	0.68 ± 0.16	0.69
Total QALYs 1 year	0.23 ± 0.16	0.15 ± 0.13	0.15
Total QALYS 2 years	0.47 ± 0.30	0.32 ± 0.26	0.19

*Values given as mean ± standard deviation.

Table 5
Procedure costs and cost-utility analysis

	ACDF (*n* = 10)	CDA (*n* = 18)	*P*-value
Medicare cost*			
Hospital	$11,747 ± $1,343	$10,015 ± $0	<0.00‡
Surgeon	$3107 ± $0	$1826 ± $0	<0.00‡
Anesthesia	$596 ± $37	$610 ± $37	0.94
Neuromonitoring	$710 ± $57	$720 ± $72	0.70
Total cost*†	$16,162 ± $1337	$13,171 ± $106	<0.00‡
NDI			
Cost/QALY—Year 1	$101,013	$101,315	
Cost/QALY—Year 2	$43,681	$48,781	
ICER ACDF vs CDA—Year 1	$99,700		
ICER ACDF vs CDA—Year 2	$18,593		
SF-36			
Cost/QALY—Year 1	$70,269	$87,806	
Cost/QALY—Year 2	$34,387	$41,159	
ICER ACDF vs CDA—Year 1	$37,387		
ICER ACDF vs CDA—Year 2	$19,940		

Statistically significant.
  *Values given as mean ± standard deviation.
  †Hospital cost plus and CPT-based fees for surgeon, anesthesia and neuromonitoring.
  ‡Statistically significant.

2-year QALYs gained were 0.13 and 0.27, respectively. There were no statistically significant differences in utility scores or QALYs gained between the 2 treatment groups.

When calculated based on SF-36, there were again no statistically significant differences in utility scores or QALYs gained. The preoperative utility scores were 0.47 for ACDF and 0.51 for CDA; for ACDF, this improved to 0.72 and 0.71 at 12 and 24 months, respectively. The postoperative utility scores for CDA were 0.68 and 0.68 at 12 and 24 months, respectively. These values generated a 1-year cumulative QALYs gained of 0.23 for ACDF and 0.15 for CDA; at 2 years, cumulative QALYs gained were 0.47 and 0.32, respectively. There were no significant differences between patients with and without complete follow-up information regarding utility scores or QALYs gained at all time points.

Cost and CUA—medicare data

Applying Medicare reimbursements yielded an average overall cost of $16,162 for ACDF and $10,015 for CDA (Table 5). The cost/QALY values obtained at 1 year, based on this Medicare modeling and when utility values are obtained from the NDI, were $101,013 for ACDF and $101,315 for CDA. At 2 years these values were reduced to $43,681 and $48,781 for ACDF and CDA, respectively. When QALYs were based on SF-36 scores, ACDF provided benefit to patients at a cost utility of $70,269 at 1-year follow-up, whereas CDA averaged $83,806. At 2 years, ACDF averaged $34,387, compared with $41,159 for CDA. When the ICER was performed based on NDI, the 1- and 2-year incremental cost-effectiveness of ACDF came at a 1-year cost of $99,700 and a 2-year cost of $18,593. When the same calculation was performed utilizing SF-36, the

results demonstrated that, when compared with CDA, the benefit afforded to patients by ACDF came at an additional cost-utility of $37,387 at 1 year and $19,940 at 2 years.

Demographics: cohorts reviewed for institutional financial modeling

The records of 28 patients of either ACDF (*n* = 15) or CDA (*n* = 13) were identified for use in our financial model based on hospital cost (Table 6). The only significant difference within this group and between procedures was the mean age of patients; ACDF patients averaged 53 years, whereas CDA patients averaged 44 years (*P* = .02). The ACDF group was comprised of 10 men (67%) and 5 women (33%), whereas the CDA group had 7 men (54%) and 6 women (46%). The average length of stay within these groups was identical, at 1.3 ± 0.6 days (*P* = .9). These patients were considered to be reasonable financial representations of both ACDF and CDA.

Table 6
Demographics: Single institution patients reviewed for financial modeling

	ACDF (*n* = 15)	CDA (*n* = 13)	*P*-value
Age (y)*	53 ± 9	44 ± 10	0.02†
Gender distribution			0.51
Male	10	7	
Female	5	6	
Length of Stay (d)*	1.3 ± 0.6	1.3 ± 0.6	0.9
ORRC total	$11,785 ± $1991	$11,847 ± $6904	0.97
PORC total	$4,451 ± $1694	$7385 ± $5732	0.52
Hospital cost (HCost)	$16,108 ± $2935	$16,004 ± $7865	0.97

  *Values given as the mean ± standard deviation.
  †Statistically significant.

Table 7
Cost-utility analysis based on institutional financial modeling

	ACDF (n = 15)		CDA (n = 13)	P-value
Hospital cost (HCost)*	$16,108 ± $2935		$16,004 ± $7865	0.97
Physician cost—Surgeon*	$3107 ± $0		$1826 ± $0	<0.01‡
Physician cost—Anesthesia*	$596 ± $37		$610 ± $37	0.94
Total cost (TCost)†*	$19,811 ± $2935		$18,440 ± $7865	0.56
NDI				
HCost/QALY—Year 1	$100,674		$123,104	
HCost/QALY—Year 2	$43,535		$59,272	
TCost/QALY—Year 1	$123,818		$141,842	
TCost/QALY—Year 2	$53,543		$68,295	
ICER ACDF vs CDA—Year 1		$45,700		
ICER ACDF vs CDA—Year 2		$13,710		
SF-36				
HCost/QALY—Year 1	$70,034		$106,690	
HCost/QALY—Year 2	$34,272		$50,011	
TCost/QALY—Year 1	$86,134		$122,930	
TCost/QALY—Year 2	$42,151		$57,624	
ICER ACDF vs CDA—Year 1		$17,138		
ICER ACDF vs CDA—Year 2		$9140		

*Values given as mean ± standard deviation.
†Hospital cost plus CPT-based fees for surgeon and anesthesia.
‡Statistically significant.

Cost and CUA: institutional financial modeling

We found no statistically significant differences in hospital cost between ACDF and CDA (Table 7). Mean hospital cost for ACDF averaged $16,108 ± 2935, whereas the mean cost for CDA was $16,004 ± $7865 (P = .97). The surgeon physician costs, calculated from CPT coding procedures, were significantly different between the 2 procedures; ACDF physician cost was reimbursed at $3107 whereas CDA physician cost was reimbursed at $1826 (P < .01). Physician cost for anesthesia, however, was not significantly different between the 2 procedures ($596 ± $37 for ACDF vs $610 ± $37 for CDA). The total costs for the 2 procedures were also not significantly different, as the mean total cost for ACDF was $19,811 ± $2935 and the total cost of CDA was $18,440 ± $7865 (P = .56).

When utility values were obtained from the NDI, the hospital cost/QALY values obtained at 1 year were $100,674 for ACDF and $123,104 for CDA; when considering total cost, the cost/QALY values at 1 year were $123,818 and $141,842, respectively. At 2 years, the hospital cost/QALY values were reduced to $43,535 for ACDF and $59,272 for CDA, whereas total cost/QALY values at 2 years were $53,543 and $68,295, respectively. When QALYs were based on SF-36 scores, ACDF patients at 1-year follow-up had benefited at a hospital cost of $70,034/QALY, whereas CDA averaged $106,690/QALY; total cost/QALY at 1 year was $86,134 and $122,930, respectively. At 2 years, ACDF averaged $34,272/QALY for hospital costs compared with $50,011/QALY for CDA. When using total cost at 2 years, ACDF averaged $42,151/QALY whereas CDA averaged $57,624/QALY. Therefore,

though ACDF was more expensive, it provided a greater (though nonsignificant, in direct comparison with CDA) average benefit in terms of QALYs gained.

When the ICER was based on NDI, the 1- and 2-year incremental cost-effectiveness of ACDF came at costs of $45,700/QALY and $13,710/QALY, respectively. When the same calculation was performed utilizing SF-36, the results demonstrated that the added benefit afforded to ACDF patients came at a cost of $17,138/QALY at 1 year and $9,140/QALY at 2 years.

Discussion

The management of CSR has taken many forms over time, though considerable debate persists regarding which procedure is most appropriate. The degenerative effect of spinal fusion procedures has been developed as an important topic of research, with focus on adjacent segment degeneration. Implant technology and surgical techniques with the combined goals of neurologic decompression and preservation of cervical motion have therefore followed suit as a therapeutic strategy; included in this spectrum is total disc replacement (TDR), also known as CDA. Several randomized clinical trials and observational studies have compared the efficacy of ACDF and CDA in the treatment of single-level cervical radiculopathy, with or without myelopathy and utilizing differing implant technologies.[19–21] Three specific devices evaluated in this manner include the Prodisc-C (Synthes Spine), the Bryan Cervical Disc (Medtronic Sofamor Danek), and The Prestige ST cervical disc system (Medtronic Sofamor Danek).

The RCT for Prodisc-C that compared CDA vs. ACDF in single-level DDD with radiculopathy included 106

ACDF and 103 CDA patients with 2-year follow-up.[21] Both groups improved significantly but comparably in NDI, SF-36, and neck and arm pain scores, and there were no differences between the treatment groups. It is noteworthy that ACDF patients had a significantly higher rate of reoperation and higher use of strong narcotics at 2 years, and device success (when there is no need for revision, removal or reoperation) was significantly greater for Prodisc-C. The RCT for Bryan also had 2-year follow-up for CDA versus ACDF for single-level cervical disc disease (radiculopathy or myelopathy)[19]; again, both groups improved on all clinical outcome measures at 2 years, though CDA patients had significantly greater improvement in NDI scores and neck pain, and had greater "Overall Success." Lastly, the RCT for Prestige demonstrated that CDA patients had a significantly higher rate of neurological success (based on motor, sensory, and deep tendon reflex evaluations) and significantly lower rates of secondary revision surgeries and supplemental fixation than ACDF patients. CDA patients had a significantly lower rate of adjacent segment reoperations, and maintained near-normal range of motion in the cervical spine. The importance of long-term follow-up and the results with respect to clinical and radiographic outcomes for each of these studies will be crucial to developing an understanding of whether or not such motion-preserving technologies are actually efficient in the long run.

There has been minimal evaluation of the relative cost utility of these interventions considering only the up-front intervention cost at the time of the index procedure, despite growing interest in the cost-effectiveness of comparable technologies. Such analysis is dependent upon patient-reported utility values, through which patients express preferences for various health states; 3 of the most common methods for obtaining these values are the rating scale, standard gamble, and time trade-off techniques.[35] Once determined, utility scores can then be converted to QALYs, which demonstrate the influence that utility scores will have upon the quality of life a patient can expect to have for extended periods of time.[26,36,37]

The most common method for obtaining such a HRQOL in the European Literature is through use of the EQ-5D, whereas in North American literature the SF-36 is more commonly utilized.[38,39] The SF-36 can be converted to SF-6D to generate utility scores; disease-specific clinical outcome scores such as the NDI, can also be converted through regression into the SF-6D[31–33] Most recently, Richardson and Berven endorsed the conversion of NDI scores into SF-6D using data from the Prodisc IDE trial,[33] lending support to the presently reported method of comparing utility scores calculated from NDI and SF-36 outcomes. Subsequently, these HRQOL scores can be converted into QALYs through existing mathematical models.

Once QALYs are calculated, they can be used to determine the number of QALYs gained by a patient as a result of a particular intervention. Cost utility is determined simply by dividing cost by QALYs gained. Relative

analysis is performed through CUA, alternatively termed an incremental cost-effectiveness ratio (ICER), in which 2 interventions for the same condition can be compared. The largest advantage of calculating QALYs is their ability to make comparisons across disease interventions between which a common outcome score may not exist.

We have first established Medicare rates for the surgical management of CSR without adjustment for specific Health Referral Regions, followed by an investigation of institutional financial costs. When Medicare coding is dissected to determine the source of reimbursed costs, ACDF is significantly more expensive than CDA in hospital reimbursement costs; therefore, ACDF appears to be more costly to society than CDA when considering initial hospitalization costs. However, when institutional costs are evaluated, it is apparent that ACDF and CDA incur comparable costs upon the hospital itself, significantly differing only in the cost of the physician. The discrepancies between Medicare and institutional financial data reflect the importance of modeling strategies when developing cost-effectiveness research; in this case, whereas ACDF appears significantly more expensive than CDA to society via Medicare, the 2 procedures are not significantly different in cost for the hospital itself.

There was no overall difference in QALYs gained between the ACDF and CDA at either 1 or 2 years after surgery. That there is no major significant difference in the outcome scores of patients of both groups translates into a nondifference in utility. All Medicare cost-utility values at 2 years, regardless of procedure, fall below the often-suggested limit of $50,000 per QALY to achieve cost-effectiveness; in contrast, the corresponding cost-utility values were higher when evaluating institutional costs, with CDA consistently exceeding $50,000 per QALY at 2 years. However, regardless of the financial model used, ACDF generates lower cost-utility values (cost/QALY) with both NDI and SF-36 at all time points (Tables 5 and 7). These results suggest that ACDF may be more cost effective over time than CDA, though none of the patients enrolled in the study underwent revision and such potential costs are not considered. Additionally, this is limited to the time period of 2 years and the likely durability of these procedures is longer. As time passes, the direct cost of up-front surgical intervention becomes lower with a maintained clinical outcome benefit. This information may be more glaring if compared with ongoing "less costly" nonoperative management in another study in which patient does not experience as great a clinical outcome benefit.

The ICER, an alternative method for a CUA, is useful for directly identifying the absolute cost per QALYs gained by a procedure in comparison with alternative treatment strategy for the same condition or disease state. The ICER at 1 year based on the NDI indicates that the utility afforded by ACDF in comparison with CDA comes at an additional Medicare cost of $99,700. When this same set of patients is considered over a 2-year time period, the ICER declines to $18,593. This

represents a relatively high price to pay for a nonsignificant increase in utility, particularly when considering that this model evaluates only the cost of the index procedure. When the general-health outcome measure (SF-36) is utilized, the cost utility gained by ACDF over CDA equates to 1- and 2-year additional costs of $37,387 and $19,940, respectively (Table 5). The marked discrepancies in the ICER calculations that result from differing HRQOL scales again raise the issue of which are the best HRQOL scores to apply.

Furthermore, the impactful role of which financial model is utilized is highly apparent when the ICER for institutional cost data is considered in contrast with that for Medicare data. The institutional cost ICERs based on the NDI at 1 and 2 years were $45,700 and $13,710, respectively, whereas ICERs using SF-36 were $17,138 and $9,140, respectively (Table 7). The USD values for this financial model are not prohibitive from a relative cost perspective, as they suggest that the gain in utility with performing an ACDF instead of CDA might be worthwhile for the much lower additional cost in the acute setting.

Both the financial model and outcome scoring method chosen therefore have significant effect on what a cost-effectiveness evaluation suggests. Our findings dramatically illustrate the various results that can be found with varying combinations of cost and utility; Medicare data do not support the use of ACDF over CDA because of a high added cost for insignificant gain in outcome, whereas institutional data suggest that both procedures provide comparable outcomes at comparable costs. Once again, these both represent effective operative interventions with high up-front cost relative to nonoperative strategies yet may have more durable benefit eliminating the need for ongoing healthcare consumption and lesser economic productivity within a nonoperative patient population. Such a cost comparison may prove more valuable in defining the economic effect of operative versus nonoperative strategies rather than comparing 2 highly effective operative ones.

This cost analysis is, of course, somewhat artificial; there is a lack of cost information for nonhospital-based healthcare resource utilization to apply. Furthermore, the improvements in NDI and SF-36 scores are greater than both the minimal clinically important difference (MCID), as well as the significant clinical benefit (SCB) threshold reported by Carreon et al.[32] The latter suggests that either procedure will result in the consumption of fewer health care resources and greater improvements in economic productivity following surgical intervention. The prospective collection of data regarding episodes of healthcare utilization in patients managed nonoperatively will become increasingly important. This is especially relevant, because we as a surgical community are constantly facing situations in which we have to define the values of our therapeutic modalities.

Financial data for these types of analyses can be particularly difficult to define and acquire, and the cost modeling can change the results of such studies. The application of Medicare coding for hospital and physician payment may be utilized as a model for the relative cost, though it presents a set of limitations. The first limitation is that Medicare charges and reimbursement are not representative of all methods of payment. Medicare coding also changes periodically, which may result in variable relative USD values for comparable procedures. This may change the cost model of ACDF versus CDA to one in which ACDF is less costly. As a result, the ICER would have an absolute value representing additional QALYs gained through incremental savings. Furthermore, this type of modeling may not account for a discrepancy in nonhospital-based healthcare resource utilization between comparison groups. A final consideration of such perioperative cost modeling is the neglect of individual patient economic productivity, which is dependent upon their ability to return to work. As this type of research develops, these limitations will continue to be problematic with Medicare and non-Medicare economic modeling.

Likewise, there are limitations to the institutional cost model used in this study. First, it contains a very small sample with significant variability in values on a case-by-case basis that is being applied to an entirely separate population of patients. We must therefore emphasize the conceptual role that these data play in the current study; although the data are limited, they efficiently portray how much the chosen financial model affects a CUA. The lack of nonhospital-based healthcare utilization costs again applies to these data. Institutional financial data-based modeling also varies in pricing and services by region and provider, and is therefore not always universally applicable.

Conclusion

We confirm the efficacy of ACDF and CDA in the treatment of cervical disc disease. Overall, based on our patients at a 2-year time point, we demonstrate that ACDF delivers similar outcomes at a greater relative cost, though the cost-utility (cost/QALY) values appear to be in favor of ACDF. However, based on the financial model used for CUA, the greater utility may come at a significant price. Long-term follow-up with more intensive financial review and outcome scoring will allow for a better understanding of adjacent segment degeneration, revision surgery rates, clinical significance, and the relative cost-effectiveness of alternative strategies. Both procedures demonstrate cost-effectiveness when compared with the literature-based threshold of $50,000 at a 2-year time point; these dollar amounts will surely drop for patients that go on with no further therapeutic interventions as the durability of their operative intervention is sustained.

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