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Cost-effectiveness of Cervical Total Disc Replacement vs Fusion for the Treatment of 2-Level Symptomatic Degenerative Disc Disease

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Abstract

Importance Cervical total disc replacement (CTDR) was developed to treat cervical spondylosis, while preserving motion. While anterior cervical discectomy and fusion (ACDF) has been the standard of care for 2-level disease, a randomized clinical trial (RCT) suggested similar outcomes. Cost-effectiveness of this intervention has never been elucidated.

Objective To determine the cost-effectiveness of CTDR compared with ACDF.

Design, Setting, and Participants Data were derived from an RCT that followed up 330 patients over 24 months. The original RCT consisted of multi-institutional data including private and academic institutions. Using linear regression for the current study, health states were constructed based on the stratification of the Neck Disability Index and a visual analog scale. Data from the 12-item Short-Form Health Survey questionnaires were transformed into utilities values using the SF-6D mapping algorithm. Costs were calculated by extracting Diagnosis-Related Group codes from institutional billing data and then applying 2012 Medicare reimbursement rates. The costs of complications and return-to-work data were also calculated. A Markov model was built to evaluate quality-adjusted life-years (QALYs) for both treatment groups. The model adopted a third-party payer perspective and applied a 3% annual discount rate. Patients included in the original RCT had to be diagnosed as having radiculopathy or myeloradiculopathy at 2 contiguous levels from C3-C7 that was unresponsive to conservative treatment for at least 6 weeks or demonstrated progressive symptoms.

Main Outcomes and Measures Incremental cost-effectiveness ratio of CTDR compared with ACDF.

Results A strong correlation ($R^2 = 0.6864$; $P < .001$) was found by projecting a visual analog scale onto the Neck Disability Index. Cervical total disc replacement had an average of 1.58 QALYs after 24 months compared with 1.50 QALYs for ACDF recipients. Cervical total disc replacement was associated with \$2139 greater average cost. The incremental cost-effectiveness ratio of CTDR compared with ACDF was \$24 594 per QALY at 2 years. Despite varying input parameters in the sensitivity analysis, the incremental cost-

effectiveness ratio value stays below the threshold of \$50 000 per QALY in most scenarios (range, −\$58 194 to \$147 862 per QALY).

Conclusions and Relevance The incremental cost-effectiveness ratio of CTDR compared with traditional ACDF is lower than the commonly accepted threshold of \$50 000 per QALY. This remains true with varying input parameters in a robust sensitivity analysis, reaffirming the stability of the model and the sustainability of this intervention.

Introduction

Cervical total disc replacement (CTDR) was developed to treat neck pain and neurologic sequelae associated with cervical disc disease, while preserving motion. The technology is available worldwide and has become increasingly common in the United States since 2007 as several CTDR devices have been approved for use. Several large-scale Food and Drug Administration–regulated Investigational Device Exemption clinical trials consistently demonstrated that CTDR is at least as safe and effective as anterior cervical discectomy and fusion (ACDF) for the treatment of symptoms associated with cervical spondylosis and degenerative disc disease (DDD). However, until now, these trials were limited to the treatment of single-level disease.

Patients often experience multilevel pathology and, although the data appear equivocal, there is some evidence that multilevel fusion constructs are biomechanically more demanding on adjacent levels than single-level fusions.^{1,2} Lopez-Espina et al³ showed that as the number of fused levels increases from 1 to 2, stress on the inferior adjacent intervertebral discs increases during flexion, lateral bending, and torsion by as much as 17%. Davis et al⁴ published results from a prospective, multicenter randomized Food and Drug Administration Investigational Device Exemption trial that demonstrated superiority of the Mobi-C Cervical Artificial Disc over ACDF for 2-level DDD. The Food and Drug Administration subsequently approved Mobi-C as the first CTDR for 2-level indications. However, the cost-effectiveness of 2-level CTDR compared with ACDF and the assessment of quality-of-life changes have never been fully elucidated.

Two approaches are commonly used to conduct a cost-effectiveness analysis (CEA) for a clinical trial: simple incremental calculation vs decision analytical modeling. The simple calculation method uses quality-of-life data collected during the trial to calculate the aggregate for each arm to make comparisons between arms. Decision analytical modeling involves transforming the quality-of-life data into input parameters that are used to inform a decision model about the likelihood of clinical events occurring to trial participants. The advantage of the latter is its flexibility. Decision analysis allows for time-frame extrapolation, subgroup analysis, and more robust sensitivity analyses to test generalizability. Obvious disadvantages include the exactitude required to derive input parameters from the original trial data and the mathematical assumptions needed to generate the model.⁵

With the intention to (1) understand how patients with multilevel cervical spine disease progress beyond the primary study end point (24 months), (2) clarify the variables affecting utilities and disutilities, and (3) make conclusions that can extend beyond the trial setting, we proposed using decision analysis to evaluate the cost-effectiveness of CTDR vs ACDF for 2-level DDD.

Methods

Study Design

We used decision analytical modeling to evaluate the cost, changes in quality of life, health outcomes, and cost-effectiveness of 2 comparison treatment strategies, CTDR vs ACDF, for 2-level symptomatic disc disease.⁶⁻⁹ Data were initially derived from a published randomized clinical trial (RCT)⁴ that tested the noninferiority of CTDR when compared with ACDF for 2-level DDD. Patients included in the trial (N = 330) had to be diagnosed as having radiculopathy or myeloradiculopathy at 2 contiguous levels from C3-C7 that was unresponsive to conservative treatment for at least 6 weeks or demonstrated progressive symptoms. Patient demographics in the RCT were well-balanced, without statistically significant differences. The specific method from the RCT is not included here for brevity.⁴ The entire RCT patient cohort was used for the CEA. To conduct the CEA, the cohort Markov model was chosen instead of simple decision tree because a Markov model incorporates the temporal element essential in quantifying patient progress postoperatively. Corresponding to the available follow-up data from the RCT, 2 years was set as the time horizon for the model in the base-case analysis; this was varied from 1 to 10 years in the sensitivity analysis. Cost was calculated from a societal perspective in the base case including both direct medical costs and productivity loss due to disease-associated disabilities. Similarly, costs from a health system single-payer perspective (ie, inclusion of only direct medical costs) were explored in the sensitivity analysis. Cost-effectiveness of the 2 treatment strategies was measured using incremental cost-effectiveness ratios (ICERs). All data were analyzed using SAS version 9.3 (SAS Institute Inc) and TreeAge Pro 2013 (TreeAge Software Inc).

All sites where new cost data were collected had institutional review board approval.

Model Description

An illustrative example of the model schematic can be found in the eFigure in the [Supplement](#). Each comparison strategy was constructed as a Markov model, which contains 6 discrete health states in ascending order of pain severity: mild disability, moderate disability, severe disability, crippled, bedbound, and death. The 5 health states, excluding death, were established by creating a composite disability score from the 2 major quantitative measurements used in the RCT,⁴ the Neck Disability Index and a visual analog scale for neck and arm pain. The composite score was stratified into 5 subgroups based on the established Neck Disability Index¹⁰ classification method.⁸ Patients could experience postsurgical complications within each

transition cycle. Every health state had an assigned medical cost and utility value per specified period. The total cost and quality of life associated with the cohort were calculated by aggregating the probability-weighted per-period values over the entire time span. An annual discount rate of 3% was applied to both costs and quality of life.¹¹

Transition Probabilities

By convention, transition probabilities in a cohort Markov model are irrespective to time. To account for the fact that clinical recovery after these procedures is usually exponential, initially dramatic during the early postoperative period with differences slowing over time, we split the follow-up time (from enrollment to 24 months) into 4 segments: 0 to 6 weeks, 6 weeks to 6 months, 6 months to 1 year, and 1 year to 2 years. Transition probabilities were independently calculated for each segment using the longitudinal trial data. In the case of missing health states at certain points (approximately 7% of the data set), these were imputed assuming a gradual recovery over time. For example, if a patient's health state was crippled at 6 weeks and mild disability at 2 years, with interval missing data, then health states of severe disability and moderate disability were imputed for 6 and 12 months, respectively. Missing health states were not imputed in instances where patients were lost to follow-up. Time-specific transition probabilities for both ACDF and CTDR procedures are illustrated in [Table 1](#). Transition probabilities from disability states to death were based on 2010 national age-specific mortality rates.¹²

Quality-of-Life Value Derivation

Utility values were derived from the 12-item Short-Form Health Survey (SF-12)¹³ questionnaires collected preoperatively and at each follow-up visit. Two methods exist for converting SF-12 data into single-utility values on a scale from 0 to 1. The first and most commonly used algorithm is the EQ-5D index score. The second method uses aspects of the SF-12 to compose the SF-6D index score. This index has been shown to correlate with US preference-based utility measurements.¹⁴ The latter was used owing to a ceiling effect, with the EQ-5D mapping algorithm at low-utility levels (mild medical problems, slight depression, and minimal disability).¹⁵ The SAS-based mapping algorithm used to convert SF-12 to SF-6D was obtained from the University of Sheffield.¹⁶ The SF-6D index scores were used as the measure of quality-adjusted life-years (QALYs). Mean QALYs and SDs were computed for each of the 5 health states ([Table 2](#)).

Risk for Complications

Based on the RCT data, patients could experience 4 types of postsurgical interventions including supplemental fixation, revision, reoperation, and device removal. There were 20 (6.1%) postsurgical interventions (12, or 3.63%, in the ACDF arm and 8, or 2.42%, in the CTDR arm) that occurred within the 2-year follow-up. There was no clear trend in terms of improvement in patients' health state after receiving any of the postsurgical interventions or higher likelihood of having a postsurgical intervention given a poorer health state. However, analysis did reveal that 18 of 20 (90%) postsurgical interventions occurred after

6 months from the initial surgery. Therefore, the model assumed that the postsurgical complications could happen in any transition regardless of what health state patients transitioned from but the risk for having an intervention were time specific. The time-specific probabilities of postsurgical complications are listed in [Table 2](#).

Cost

Costs were calculated by extracting *Current Procedural Terminology*, Healthcare Common Procedure Coding System, and Diagnosis-Related Group codes directly from institutional billing data and then applying 2012 Medicare reimbursement rates. Direct medical costs of the initial surgery; subsequent complications, such as revisions; medications; ancillary services; and productivity loss were also included. The costs of medications and ancillary services were health state specific. We estimated the average quantity of pain medication use and frequency of office visits per 6-week interval for each disability health state based on clinical consensus among surgeons participating in this study. We then applied 2012 Medicare per-unit reimbursement rates to calculate health state–specific total cost per 6-week interval. Productivity loss in monetary terms was calculated by using 2013 national average wage data and by associating our derived health states with commensurate proportions of time off from work and work-related activities.¹⁷ All cost items are listed in [Table 2](#).

Sensitivity Analyses

Three types of sensitivity analyses were conducted to comprehensively evaluate the uncertainty and generalizability of the model output. First, the scenario sensitivity analysis was used to test the model outputs under different analytical settings. This included varying the time horizon from 1 to 10 years and addressing an alternative costing method from a health system single-payer perspective in which productivity loss was excluded. Second, we used subgroup sensitivity analysis to assess the generalizability of the model output. The cost and effectiveness of both procedures were reevaluated for specific cohorts of patients and for patients 45 years or younger, the median age of our sample. Age group–specific distributions of health state prior to surgery are shown in the eTable in the [Supplement](#). Third, we tested the robustness of the results against the variation in values of input parameters using a univariate sensitivity analysis. In the univariate sensitivity analysis, 1 input value was varied at a time. Cost items and complication risks were varied up to 20% and quality-of-life values up to 95% CI limits. The result was summarized in a tornado diagram ([Figure](#)).

Results

Base-Case Result

The model demonstrates that in a theoretical cohort of 100 patients in need of 2-level surgery for symptoms associated with DDD, CTDR costs \$4 305 995 compared with \$4 092 030 for ACDF over a 24-month period, a cost savings of \$213 965, or \$2139 per patient, favoring ACDF ([Table 3](#)). Those in the CTDR cohort were projected to have higher total QALYs of 158.7 than those in the

ACDF group (total QALYs of 150.0), an increase of 8.7 QALYs, or 0.087 QALY per person. Therefore, the ICER of CTDR over ACDF is \$24 594 per QALY, lower than the commonly used US ICER threshold of \$50 000 per QALY,¹⁸ suggesting that the strategy of CTDR is a highly cost-effective treatment option.

Sensitivity Analyses

Scenario sensitivity analysis suggests that CTDR becomes less cost-effective (ie, a higher ICER) only when costs and quality of life during the first 12 months after surgery are considered ([Table 4](#)). Cervical total disc replacement is also shown to dominate (ie, less costly yet more effective) compared with ACDF when an extended time horizon is considered such as 4 and 10 years after surgery. When disability-related productivity loss is not accounted for, ICER for CTDR vs ACDF at 2 years increased to \$100 257 per QALY. This indicates that at least part of the benefit of CTDR is realized outside of the health sector (ie, return to work).

In the subgroup sensitivity analysis, CTDR has an ICER below \$50 000 per QALY for patients in the worst health states (ie, bedbound and crippled) preoperatively, suggesting that CTDR is more cost-effective in the most disabled patients with 2-level cervical disc disease ([Table 4](#)). Additionally, CTDR is cost-effective in both the 45 years and younger and 46 years and older age cohorts, although a lower ICER was calculated for the younger stratum (eTable in the [Supplement](#)).

The tornado diagram in the [Figure](#) illustrates how changes in probability, utility, and cost parameters affect the ICER. The most-sensitive parameter is the utility value of minimal disability health state group; when the utility of being in the least-severe health state is valued less, it becomes less favorable to use CTDR. The second most-sensitive parameter is the device cost; the less expensive the device, the more cost-effective it becomes. Despite these input parameter variations, with the exception of the value placed on the minimal disability health state, the ICER value stays below the threshold of \$50 000 per QALY in each instance,¹⁹ affirming the stability of the result that CTDR is a cost-effective treatment option.

Discussion

Assuming a \$50 000 per QALY willingness-to-pay threshold, our CEA suggested that CTDR is not only a cost-effective option for 2-level cervical disc disease, but from a societal perspective, it dominates ACDF after 4 years. When an intervention dominates in CEA, it imparts a greater quality of life at less cost and thus is the treatment of choice. We feel that including productivity loss in the model was essential when assessing QALYs and economic sustainability. Examination of the transition probabilities within the Markov model suggests that cost-effectiveness of CTDR may be, in part, secondary to a faster recovery or earlier transition to improved health states compared with the ACDF group ([Table 1](#)). This disparity seems to be realized after 1-year of follow-up, with CTDR patients being in superior health states and ostensibly

returning to their regular activities at that time. This may also explain why CTDR was more cost-effective in the younger cohort because they are, in general, more active and likely to perceive a greater benefit from the earlier return to societal functioning. Whether the believed increased range of motion with CTDR contributed to the increased QALYs observed in the younger cohort remains equivocal. Because CTDR patients appear to recover faster, they may use fewer health care resources, such as physical therapy and other ancillary services that are not being captured, implying that an even greater cost difference over time has yet to be appreciated. This suggests that our initial analysis is likely conservative and further supports the conclusion that CTDR is a cost-effective intervention compared with ACDF.

The ICER of CTDR for 2-level disease compares favorably with those of other surgical interventions. A publication looking at single-level CTDR found that it became cost-effective compared with ACDF after 11 years.²⁰ At 20 years, single-level CTDR dominated ACDF (ICER, -\$2394 per QALY).²⁰ Similarly, total ankle arthroplasty demonstrated an ICER of \$18 419 per QALY as compared with ankle fusion; antibiotic-impregnated hip arthroplasty, an ICER of \$37 595 per QALY; and lumbar discectomy vs nonoperative management, an ICER of \$69 403 per QALY.²¹⁻²³ Although these and other published reports have looked at cost and quality of life in similar patient populations,^{24,25} to our knowledge, this is the first article of its kind to create unique health states and use Markov modeling to thoroughly assess cost-effectiveness in multilevel cervical disc disease. This novel approach allowed for extrapolation and accounted for the temporal component inherent in the disease process and patients' recovery.

Our analysis was based on RCT data with specific inclusion/exclusion criteria, thus we recognize that not all patients with 2-level cervical disc disease are appropriate for the CTDR technology. The CEA was conducted using decision analytical modeling and, as a result, has several inherent limitations. By definition, the Markov model is supposed to be conditional on the present state alone; future and past events are assumed independent. With disease processes, it is rarely plausible to assume that a patient's transition to another health state was not in some way dependent on the prior health state. Furthermore, our extrapolation to 4 and 10 years in our sensitivity analysis assumed linearity in QALY and health states. Despite this, no better analytical modeling tool exists for health care economic valuation. We also recognize that some cost data were simply unascertainable. For example, because it is conventionally unacceptable to use hospital charge data to conduct a CEA, we used Medicare rates for Diagnosis-Related Groups (see the Methods section). As a result, differences in parameters, such as operating room time and length of stay, were not captured in the analysis. However, it is likely that the marginal increases in operating room time associated with CTDR, and the resultant increased cost, is obviated by the shorter length of stay observed in this same group when compared with ACDF. Furthermore, transportation costs, caregiver time/responsibilities, and willingness-to-pay data were neither available nor captured.

Additional indirect costs, such as the average quantities of pain medications and average frequency of office visits per 6-week interval for each disability health state, were estimated based on clinical experience. Medicare per-unit reimbursement rates were then applied to these estimates to calculate health state-specific total cost per 6-week interval. Productivity loss in monetary terms was calculated by using 2013 national average wage data and by associating our derived health states with commensurate proportions of time off from work and work-related activities. It is unclear how these estimates may bias our conclusion. However, we contend that both groups were treated similarly based on sound and collaborative clinical judgment.

Conclusions

Taken together, CTDR appears to be a highly cost-effective surgical modality compared with ACDF for 2-level cervical disc disease. In all sectors of society, we are inevitably faced with limited resources. In the United States alone, health care costs are projected to reach about 20% of gross domestic product by 2021.²⁶ When a new intervention has the potential over time to dominate conventional management, yielding greater improvement in quality of life at a lower total cost, it deserves serious attention. The safety and efficacy for treating 2-level cervical disc disease with CTDR have been demonstrated. This is the first instance where a comprehensive economic model has established cost-effectiveness. Therefore, adoption of this technology seems advisable for the US market. We plan to continue this research, ensuring that spine surgery continues to move toward sustainability and cost-effectiveness, while concomitantly offering our patients a chance at a better quality of life.

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Study concept and design: Ament, Yang, Kim.

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