

# Cost-Effectiveness of Single-Level Anterior Cervical Discectomy and Fusion for Cervical Spondylosis

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**Study Design.** Cost-effectiveness analysis with retrospective cost analysis and literature review.

**Objective.** To determine the relative cost-effectiveness of anterior cervical discectomy and fusion (ACDF) with autograft, allograft, and allograft with plating for single-level anterior cervical spondylosis.

**Summary of Background Data.** There are several accepted methods of surgically treating single-level cervical spondylosis anteriorly. No study has clearly demonstrated the superiority of one method over the alternatives. The techniques may differ in their operative risks and resource use, perioperative complications, short-term outcome, and long-term outcome and complications. Formal cost-effectiveness analysis (CEA) provides a structure for analyzing many variables and comparing different treatment outcomes. Sensitivity analysis is used to test the robustness of the model and to determine variables that have significant effects on the results. Future areas of research and refinements of the CEA model can be developed from these findings.

**Methods.** A retrospective review of hospital charges was performed for 78 patients who underwent single-level ACDF with allograft alone or ACDF with allograft and plating (ACDFP). The charges were converted to estimated costs for fiscal year 2000 using the ratio of costs to charges method. A CEA model was developed consisting of a decision-analysis model for the first year postsurgery and a Markov model for the next 4 years after surgery. Probabilities and outcome utilities were estimated from the literature. Outcome was measured in quality-adjusted life years (QALYs), and incremental CEA was performed. Several variables were tested in one-way sensitivity analysis.

**Results.** Compared with ACDF with autograft, ACDF with allograft offered an improvement in quality of life at a cost of \$496 per QALY. ACDFP provided additional gains in quality of life compared with ACDF with allograft at a cost of \$32,560 per QALY in the base case analysis. In sensitivity analysis, these estimates varied between \$417 and \$741 per QALY and between \$19,090 per QALY and domination of ACDFP by ACDF with allograft, respectively. The results were most sensitive to assumptions regarding differences in the length of the postoperative recovery period.

**Conclusions.** ACDF with allograft offers a benefit relative to ACDF with autograft at a cost of \$496 per QALY. ACDFP has a benefit relative to ACDF with allograft at an approximate cost of \$32,560 per QALY. CEA provides a method for comparing the benefits and risks of these three procedures. Further research needs to be performed regarding these procedures, particularly examining the postoperative recovery period.

**Key words:** cost-effectiveness analysis, anterior cervical discectomy, fusion. *Spine* 2005;30:1989–1997

Cervical disc disease accompanied by spondylosis may cause neurological dysfunction via ventral compression of the spinal cord or nerve roots, neck pain, or a combination of symptoms.<sup>1–5</sup> Unlike soft cervical disc herniation without accompanying spondylosis or facet arthrosis, in which the necessity of bone fusion continues to be debated, cervical spondylosis is often considered an indication for anterior cervical discectomy and fusion.<sup>6,7</sup>

The original techniques for anterior cervical discectomy and fusion (ACDF) described by Cloward<sup>8</sup> and Smith and Robinson<sup>9</sup> included harvesting of autograft iliac crest for interbody grafting. Concerns about donor site morbidity and the structural characteristics of autograft subsequently stimulated investigations of alternative graft materials, particularly allograft bone.<sup>5,10</sup> Some studies of ACDF with allograft have reported lower fusion rates than with autograft, however, and raised concerns about pseudarthrosis and graft complications.<sup>11–14</sup> Allograft may also cost more than autograft, and the use of cadaveric material introduces a risk of disease transmission.<sup>7</sup> To increase fusion rates and decrease graft complications, some investigators supplement allograft fusion with an anterior cervical plate, a technique initially described by Bohler and Gaudernak<sup>15</sup> and Caspar<sup>16</sup> for the treatment of cervical trauma. Plating also provides immediate rigidity to the spine, allowing earlier mobilization of the patient and eliminating the need for an external orthosis.<sup>17,18</sup> A shorter recovery time may allow patients to return to normal activities or to work and thereby potentially offset any increased cost of the procedure.<sup>10,19</sup>

Concerns about the necessity of instrumentation for single-level anterior cervical discectomy and fusion and about safety and expense were raised as the use of cervical plates increased and the indications for their use broadened.<sup>18,20–23</sup> The advent of the locking screw obviated the need for bicortical screw purchase and increased the safety of anterior cervical plating.<sup>24</sup> Cost concerns remained, however, and often have been cen-

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tral to debates over the surgical treatment of cervical spondylosis.<sup>7,10,19,25</sup>

Single-level ACDF has a high fusion rate by any technique, and some authors suggest that, whereas internal fixation may be appropriate for multilevel procedures, plating adds little to one-level operations.<sup>21,23,26</sup> On the other hand, recent papers have reported increased fusion rates with plating, even at one level, compared with autologous and allogeneic grafts without plating.<sup>10,17</sup> Although differences in the fusion rates of these procedures have been reported, they seem to be similar in their effectiveness of symptomatic relief.<sup>10,26–29</sup> Differences in their complication profile, fusion rate (and therefore reoperation rate), and cost are the main distinguishing factors.<sup>11,14</sup> Several commentators have advocated for cost-effectiveness analysis to help determine the appropriate procedure when a one-level ACDF is indicated.<sup>30,31</sup>

Decision analysis and cost-effectiveness analysis (CEA) are useful techniques for formalizing the decision-making process and combining cost and outcome data into a single model. These techniques are particularly useful when there are real choices among which a clearly superior option does not exist.<sup>32</sup> Data from different studies may be integrated into a single CEA model and the importance of various factors on the relative cost-effectiveness of the operations tested. Results reported in standard units, such as cost per quality-adjusted life year (QALY) gained, may be compared with other interventions. Sensitivity analysis may be used to test the effect of varying estimates on the results of model. Parameters that, when varied within a reasonable range, induce relatively large changes in the results are identified as particularly influential within the model and as areas in need of further research. This information may be used to guide decisions by physicians, policy makers, and insurers.

Two published studies of ACDF with allograft and plating (ACDFP) have included cost analysis, but no formal CEA of procedures for single-level cervical spondylosis has been performed.<sup>10,33</sup> The purpose of this study was to determine the relative cost-effectiveness of ACDF with autograft, ACDF with allograft, and ACDFP among the typical patient population undergoing surgery for one-level cervical spondylotic disease from a societal perspective. A retrospective review of 78 patients who underwent one-level ACDF with allograft or ACDFP for cervical disc disease and spondylosis was performed to determine the costs associated with these procedures. Additional cost data and outcomes were determined from the literature. These data were entered into a cost-effectiveness model and analyzed for a 5-year time period. The results are reported as cost per QALY gained, and their sensitivity to model variables was tested extensively.

## Materials and Methods

A two-part analytic model was developed to evaluate the costs and benefits associated of ACDF with autograft, ACDF with allograft, and ACDFP from a societal perspective for the first 5

**Table 1. Model Variables: Base Case Analysis Values Common to All Procedures (ACDF-Autograft, ACDF-Allograft, and ACDFP)**

Variable	Base Value
Perioperative and first-year event probabilities	
Death <sup>35</sup>	0.0022
Cord injury <sup>36</sup>	0.0016
Root injury <sup>36</sup>	0.0019
Reoperation other than graft or hardware complication <sup>35</sup>	0.0028
Infection <sup>35</sup>	0.017
Dysphagia <sup>74</sup>	0.0073
Probability of clinical improvement	0.85
Probability of improvement after reoperation	0.70
Health state utilities	
Preoperative <sup>75</sup>	0.81
Improved <sup>75</sup>	1.0
Not improved	0.81
Markov model variables	
Annual probability of adjacent segment degeneration <sup>45</sup>	0.029
Probability of reoperation for adjacent segment degeneration <sup>45</sup>	0.67
Probability of symptomatic improvement after reoperation <sup>40,41</sup>	0.70

years after surgery. The perioperative period and first year after surgery were analyzed in a decision tree model. A Markov model was used to analyze health status and reoperations between 1 and 5 years after surgery. Patients were assumed to enter the state-transition model in either “good” or “fair” condition. The patients were then assigned probabilities of remaining in their initial state or of developing symptomatic adjacent level disease. Patients that developed adjacent level disease were assigned a probability of undergoing reoperation. After reoperation, patients were assigned a probability of symptomatic improvement on the basis of published data.

Costs were determined from a retrospective analysis of 78 patients and from previously published studies. Decision tree probabilities, Markov state-transition probabilities, and health state utilities were estimated from the literature. Analyses were performed using DATA, version 4.0 (TreeAge Software, Williamstown, MA).

## Base Case Analysis

**Perioperative Risks.** The risks of perioperative complications were determined from the literature and are summarized in Tables 1 and 2. In the base case analysis, the risks of several complications common to all procedures, such as death, spinal cord injury, nerve root injury, infection, or dysphagia, were assumed to be equal among all operations.<sup>34</sup> The probability of several perioperative complications were derived from a retrospective database review of elective cervical discectomy opera-

**Table 2. Model Variables: Base Case Values by Procedure**

Variable	ACDF-Autograft	ACDF-Allograft	ACDFP
Total cost	\$9650	9710	11670
Chronic donor site pain <sup>12</sup>	0.028	0.0	0.0
HIV from graft <sup>76</sup>	0.0	$1.0 \times 10^{-6}$	$1.0 \times 10^{-6}$
Graft complication <sup>38</sup>	0.0	0.048	0.0
Hardware complication <sup>17</sup>	0.0	0.0	0.0
Return to work <sup>10</sup>	10 week	7 week	4 week

tions performed in California in 1990 and 1991.<sup>35</sup> Estimates of the risks of spinal cord and root injury were also obtained from the literature.<sup>36</sup>

Risks specific to ACDF with autograft include infection of the iliac crest incision and a higher probability of blood loss attributed to the harvesting procedure. No data were available that allowed an accurate estimate of the magnitude of the difference, and these probabilities were not included in the model.

Procedures using allograft bone have an increased risk of transmission of disease, notably HIV, compared with procedures with autograft. In the base case model, the risk of HIV transmission was set at 1 in 1 million for ACDF with allograft and ACDP.<sup>37</sup>

**First Year Complications.** Rates of delayed complications requiring reoperation during the first year for the base case analysis were estimated from the literature. These included graft complications, plate complications, symptomatic nonunion, and persistent symptoms requiring reoperation. For each procedure, a summary rate of reoperation was estimated incorporating all indications.

The reoperation rate for graft complications for ACDF with autograft was estimated from several large series. Geisler *et al*<sup>38</sup> report a rate of approximately 4.8%; Bishop *et al*<sup>13</sup> report that 1 patient out of 60 required reoperation after single-level ACDF with autograft, a rate of 1.7%. In a head-to-head comparison, An *et al*<sup>14</sup> found a reoperation rate of 13.1% for ACDF with autograft. In the base case analysis, the rate reported by Geisler *et al*, 4.8%, was used as it represented a middle value from the literature.

A similar range of rates for reoperation for graft complications in ACDF with allograft bone was found. While Martin *et al*<sup>39</sup> reported no reoperations among 269 patients undergoing single-level ACDF with fibula allograft, another study reported a rate of 12.5%.<sup>13</sup> A rate of 7.7% was reported by An *et al*<sup>14</sup> in a head-to-head comparison of autologous iliac crest to allogeneic iliac crest tricortical grafts. In the base case analysis, the rate of reoperation in the first year for ACDF with allograft was assumed to be equal to that of ACDF with autograft, 4.8%. This assumption was tested in sensitivity analysis.

In the study by Geisler *et al*,<sup>38</sup> there were no reoperations for plate or graft complications during the first year. A recent study by Kaiser *et al*<sup>17</sup> also reported no reoperations in a large series of patients undergoing ACDP. The base case rate of reoperation in the first year for ACDP was zero; this assumption was tested in sensitivity analysis. In all cases, reoperations were assumed to be ACDP.<sup>40,41</sup> Patients were assigned the cost of that operation and a disutility as described below.

The reported rate of chronic iliac crest harvest site pain varies widely. Schnee *et al*<sup>12</sup> reported that 2.8% of patients have chronic pain at the donor site. Silber *et al*<sup>42</sup> reported a rate of chronic pain of 26%, and Sawin *et al*<sup>43</sup> reported a rate of 17%. A rate of 10% for chronic donor site pain was used in the base case analysis.

Bertalanffy and Eggert<sup>44</sup> reported a rate of deep wound infection of 0.7%. There are no studies documenting differences between the procedures with regard to this complication. Patients with a deep wound infection were assigned the cost of reoperation and a disutility as described below.

**Long-Term Probabilities.** Rates of development of adjacent level disc degeneration and reoperation for the base case analysis were estimated from the report by Hilibrand *et al*.<sup>45</sup> Reoperation rates were converted into yearly probabilities and

entered into the Markov model.<sup>46</sup> The annual probability of symptomatic worsening in the base case model was 0.029; approximately two-thirds of patients with symptomatic worsening were assumed to undergo reoperation each year.<sup>45</sup> Although the study of Hilibrand *et al* did not include patients who had undergone ACDP, the same rate of adjacent segment disease was assumed for all three groups. This was based on the assumption that adjacent level disease is secondary to increased biomechanical stress and range of motion next to a fused segment and that the method of fusion does not affect this process.<sup>47,48</sup> Changes in the probability of the development of adjacent level disease were tested in sensitivity analysis.

All delayed reoperations were assumed to be ACDPs, and the appropriate cost, discounted for time, was assigned.<sup>40,41</sup> The probability of symptomatic improvement was assumed to be lower in reoperations (70%) than in first-time operations.<sup>40,41</sup>

**Outcomes.** There are no published studies of ACDF with health state utility measures. Utilities were derived from a study of ACDF that reported pre- and postoperative SF-36 scores.<sup>2</sup> SF-36 scores were converted into utilities using an algorithm based on the Health Utility Index (HUI2).<sup>49</sup> The mean estimated preoperative utility was 0.81. This value was also assigned to “unimproved” postoperative health states. The mean calculated postoperative utility, based on the results of Klein *et al*,<sup>2</sup> was 1.0, which was assigned to all “improved” health states. Because this postoperative score, equivalent to perfect health, likely overestimates the benefit of surgery, a range of utilities was tested in sensitivity analysis.

Patients who underwent an early reoperation for any complication were assigned a disutility for a 4-week convalescence with a utility of 0.81, equivalent to the recovery after ACDP. Following the method of Kuntz *et al*, utilities of patients who had a nonoperative complication of surgery (including donor site pain and postoperative dysphagia) were reduced by 4% for the first year. Patients who suffered a nerve root injury were assigned the “unimproved” utility of 0.81 for the remainder of the study period. Those who had a spinal cord injury were assigned a utility equivalent to that of a moderate stroke (0.39).<sup>50,51</sup>

No data were available regarding the rate of recovery following each procedure; the rate of postoperative recovery after each procedure was estimated using published studies of return-to-work data. In a study by Shapiro, patients who underwent ACDF with autograft returned to employment at a mean of 10 weeks after surgery, whereas patients who had ACDP returned at a mean of 4 weeks.<sup>51a</sup> The mean time to return to work was used in the current model as the time at which the transition from the preoperative health state to the postoperative health state was made. For the ACDP cohort, a utility of 0.81 was assigned for the first 4 weeks after surgery, after which time a value of 1.0 was assigned. For the autograft ACDF patients, a quality score of 0.81 was given for 10 weeks after surgery followed by a value of 1.0. On the basis of the evidence from a study of patients undergoing two-level allograft ACDF and ACDP, it was assumed that the allograft ACDF group also had a longer recovery compared with ACDP.<sup>33</sup> This period was assumed to be 7 weeks, intermediate between the ACDP and autograft ACDF recoveries. To test the effect of these assumptions the lengths of recovery time were varied in the sensitivity analysis.



**Table 3. Results of Primary Charge and Cost Analysis, 2000 U.S. Dollars**

	ACDF w/Allograft	ACDFP
Primary cost analysis		
n	31	47
Mean total charges (\$)	9634	12040
Mean total cost (\$)	7011	8503
95% CI cost (\$)	6617–7405	7963–9042

**Costs.** A retrospective study was performed to determine the base case costs for the analysis. Itemized hospital bills for 78 patients undergoing treatment for single-level degenerative cervical disease at one institution were reviewed. Thirty-one patients underwent ACDF with allograft and 47 underwent ACDFP. Hospital charges were converted to approximate costs using specific cost to charge ratios from the Institutional Cost Reports prepared for the Health Care Financing Administration. The results of this analysis are shown in Table 3.

From these base costs, the cost of ACDF with autograft was estimated by subtracting the approximate cost of cadaveric fibula (\$320).<sup>10</sup> Other operating room or hospital resource use, including additional time necessary for harvesting or postoperative analgesics, were not included in the ACDF with autograft estimate as there are no published reports of these data. All costs were updated to 2000 U.S. dollars using the medical care component of the Consumer Price Index.<sup>52</sup>

Medicare physician fee reimbursements were used to estimate the cost of the surgeon's time for each procedure. The year 2000 region-specific rates for the appropriate Current Procedural Terminology codes for each procedure were added to the hospitalization costs (Table 4).

Patients undergoing a reoperation for a graft or hardware complication were assigned the cost of ACDFP. Reoperations for other complications such as hematomas and deep wound infections requiring reoperation were assigned the cost of an operation without any grafting procedure.

Costs of spinal cord injury were estimated to be \$200,000 for the first year for rehabilitation and \$24,000 per year for the next 4 years.<sup>53</sup> Costs for patients who were infected with HIV were estimated to be \$77,300 for the study period.<sup>54</sup>

Because no data are available regarding posthospitalization resource use, the postdischarge costs for all procedures were omitted from the cost estimates.

**Discounting.** In the base case analysis, both costs and benefits were discounted at a rate of 3% per year. This rate was varied in the sensitivity analysis from 0 to 10%.

**Sensitivity Analysis.** Extensive sensitivity analysis was performed to determine the effect of the base case assumptions on

the results. Where possible, the plausible ranges of sensitivity analysis testing were determined from the literature; otherwise ranges were determined as a percentage of the base case values to determine the sensitivity of the results to variation. Key variables tested and the sources for the ranges tested are given in Table 3.

Plausible ranges of rates of graft- and hardware-associated complications were determined from the literature. Recently published large studies of ACDF with allograft and ACDFP both reported no reoperations for graft or hardware complications; this was used as the low value for each range.<sup>17,39</sup> The upper limit tested for graft complications was 8.7%, and for hardware complication was 4.8%.<sup>55,56</sup> The latter rate was twice that reported for two-level ACDFP; the paucity of data for single-level procedures necessitated the use of these data. The value was doubled to test the impact of this potentially important variable on the results.

## ■ Results

### Base Case Analysis

The results of the base case analysis are shown in Table 5. Over a 5-year period, ACDF with allograft had an increased cost of \$60 and an incremental gain in effectiveness of 0.121 QALYs compared with ACDF with autograft; the incremental cost-effectiveness ratio was \$496 per QALY. ACDFP resulted in an increased effectiveness of 0.043 QALYs at an incremental cost of \$1,400 compared with ACDF with allograft. The incremental cost-effectiveness ratio (ICER) for ACDFP compared with ACDF with allograft was \$32,560 per QALY.

### Sensitivity and Threshold Analysis

Assuming equal postoperative recovery periods of 4 weeks for all procedures resulted in ICERs of \$741/QALY for ACDF with allograft compared with ACDF with autograft and the domination of ACDFP by ACDF with allograft. Sensitivity testing of probabilities of delayed reoperation and hardware and graft complications resulted in ICERs of ACDFP compared with ACDF with allograft between \$19,090 and \$60,000 per QALY (Table 6).

Varying the utilities for the pre- and postoperative health states altered the ICERs. In general, larger effect sizes (lower symptomatic utilities or higher asymptomatic utilities) resulted in smaller ICERs, whereas narrowing the difference between the symptomatic and asymptomatic states increased the ICERs. The cost per QALY increased to \$547 for ACDF with allograft compared with ACDF with autograft and increased to \$68,250 for ACDFP compared with ACDF with allograft if the post-

**Table 4. Medicare Physician Reimbursement for Relevant Procedures**

Procedure	Current Procedural Terminology Code	HCFA Reimbursement Manhattan, 2000
Anterior cervical discectomy	63075	1788.43
Anterior cervical arthrodesis	22554	1802.23
Anterior instrumentation	22845	943.48
Autograft harvest	20938	264.91

**Table 5. Results of Base Case Analysis**

Procedure	Cost	QALYs	DCost	DQALYs	ICER *
ACDF-auto	\$11230	4.365			
ACDF-allo	11290	4.486	60	0.121	496
ACDFP	12690	4.529	1400	0.043	32560

\*Incremental cost-effectiveness ratio ( $\Delta\text{Cost}/\Delta\text{QALY}$ )

**Table 6. Sensitivity Analysis for Selected Variables**

Procedure	Cost		QALYs	ΔCost ΔQALYs	ICER*
Equal postoperative recovery periods (4 week)					
ACDF-auto \$11,230	4.448				
ACDF-allo	11290	4.529	60	0.081	741
ACDFP	12690	4.529	1400	0.0	dominated
Symptomatic health state utility 0.70					
ACDF-auto \$11,230	4.191				
ACDF-allo	11290	4.335	60	0.144	417
ACDFP	12690	4.404	1400	0.069	20290
"Improved" health state utility 0.90					
ACDF-auto \$11,230	4.048				
ACDF-allo	11290	4.149	60	0.101	544
ACDFP	12690	4.169	1400	0.020	70000
Maximum probability of hardware complication (0.048), baseline probability of graft complication (0.048)					
ACDF-auto \$11,230	4.365				
ACDF-allo	11290	4.486	60	0.121	496
ACDFP	13250	4.529	1960	0.043	45580
Baseline hardware complication rate (0.0), maximum graft complication rate (0.087)					
ACDF-auto \$11,790	4.364				
ACDF-allo	11850	4.485	60	0.121	496
ACDFP	12690	4.529	840	0.044	19090
Maximum probability of hardware complication (0.048), minimum probability of graft complication (0.0)					
ACDF-auto \$10,670	4.365				
ACDF-allo	10730	4.487	60	0.122	450
ACDFP	13250	4.529	2520	0.042	60000
Annual probability of delayed symptomatic worsening twice baseline					
ACDF-auto \$11,230	4.365				
ACDF-allo	11750	4.467	55	0.120	458
ACDFP	13150	4.509	1400	0.042	33310

\*Incremental cost-effectiveness ratio (ΔCost/ΔQALY).

operative improved utility was assumed to be 0.90 rather than 1.0.

Two-way sensitivity analysis of the postoperative period and the probability of adjacent level degeneration was performed for ACDF-allo compared with ACDFP. The results are given in Table 7.

The discount rate was also tested in sensitivity analysis. The ICERs for both ACDF with allograft and ACDFP were very stable for discount rates between 0 and 10% (ICER \$446–468 for ACDF with allograft; \$30,910–35,530 for ACDFP).

## ■ Discussion

The results of this study indicate, based on a review of the published literature and a primary cost analysis, that

ACDF with autograft, ACDF with allograft, and ACDFP have similar cost-effectiveness ratios and that the results are particularly sensitive to the costs of the procedures and to the rate of postoperative recovery of patients undergoing these operations. In the base case analysis, ACDFP yielded a benefit compared with ACDF with allograft at an incremental cost of \$32,560 per QALY. These results are largely based on a secondary analysis of the literature and are subject to several limitations and assumptions. Several key areas of potential difference between these operations have been identified, and the effect of varying the assumptions in the base case analysis has been tested in sensitivity analysis.

## Outcome

There is no compelling evidence in the literature that, for the relief of symptoms, one procedure is significantly superior to another.<sup>10,26–29</sup> Most studies have focused on differences in fusion rate that may affect outcome through differences in symptomatic pseudarthrosis and reoperation rates. On the basis of published studies, however, it seems that there may be differences between the procedures in the rate and length of the postoperative recovery. Patients who undergo ACDF with autograft likely take longer to resume normal activities because of the additional discomfort associated with the harvesting procedure.<sup>42,57</sup> Most reports of ACDF with autograft or

**Table 7. ICER Results of Two-Way Sensitivity Analysis of ACDF-allo and ACDFP With Equal Postoperative Recovery Periods and Annual Probability of Delayed Symptomatic Worsening Twice Baseline (ICER of ACDFP Compared With ACDF-allo)**

		Recovery Period, ACDF-allo	
		4 Week	7 Week
Annual probability of delayed	0.029	dominated	32560
Symptomatic worsening	0.058	dominated	33310

allograft indicate that a rigid cervical orthosis is used after surgery, usually for 6 to 12 weeks.<sup>10,13,14,17,39,58,59</sup> Wearing the rigid collar may be expected to affect patients' quality of life and resumption of daily activities. After ACDFP a rigid cervical orthosis is not necessary; this may reduce the recovery time and lead to QOL gains.<sup>10,17,33,59</sup> These differences in postoperative QOL were estimated from the literature using return-to-work data, a problematic method of estimating recovery.<sup>60</sup> Many factors, including economic, legal, and personal, may play roles of equal or greater importance than health status in determining whether and when a patient returns to work.<sup>60,61</sup> This method was used despite its potential limitations in the absence of any other available measure with which to capture the differences in postoperative recovery between the procedures that have been noted by several authors.<sup>10,17,19,33</sup> To determine the impact of these assumptions on the results, we tested effect of equal postoperative recovery periods (4 weeks) for all procedures, which resulted in the domination of ACDFP by ACDF with allograft. The sensitivity of the results to these assumptions indicates that further study of patients' QOL after surgery is warranted.

The rate of symptomatic improvement in published series of ACDF with autograft or allograft or ACDFP in most studies ranges from 65 to 97%, but no large, comparative study of the clinical outcomes of these procedures has been published.<sup>10,26,29,56,58,62–66</sup> The rate and degree of recovery may vary on the basis of the presenting symptoms (radiculopathy, myelopathy, axial pain, or a combination) and their duration.<sup>67</sup> It was therefore assumed in the base case analysis that the effectiveness of all three procedures for symptomatic relief was conservatively estimated to be 85%.

Fusion status was not directly included in the model. Studies have been published comparing fusion rates of autograft with allograft ACDF and allograft ACDF with ACDFP.<sup>17,56</sup> There are no published data, however, that can be used to correlate fusion rates with rate of clinical improvement.<sup>27,58,64,68,69</sup> Some pseudoarthroses may be asymptomatic and not require reoperation.<sup>14,70</sup> In this model it was assumed that all patients who underwent reoperation between 1 and 5 years after surgery either had not improved after surgery or had worsened after experiencing an initial benefit from surgery. In the base case analysis, it was assumed that the probability of clinical worsening, including recurrent symptoms, symptomatic pseudoarthrosis, and adjacent level disease, was 0.029, based on Hilibrand *et al*;<sup>45</sup> approximately two-thirds of patients with recurrent or new symptoms were assumed to undergo reoperation. Changing the probability of symptomatic recurrence for one procedure relative to the others changed the model's results to a large degree. Doubling the annual probability of symptomatic worsening for ACDFP but not for ACDF with allograft increased the ICER from \$32,560/QALY to \$80,870/QALY.

This study may have underestimated autograft harvest morbidity. A single term with a modest utility reduction for harvest site pain was included. Other potential complications of bone harvesting, such as wound infection and hematoma, were omitted. Despite these simplifying assumptions, however, the incremental cost-effectiveness ratios between ACDF with allograft and autograft were less than \$1,000 per QALY. Assuming that the true disutility of the harvest procedure may be higher than in the model would decrease the cost-per-QALY further and might result in the domination of the autograft procedure by ACDF with allograft.

### **Complications and Reoperations**

The results of this study are sensitive to the reoperation rate for each procedure. There are no prospective, comparative, long-term studies of the rate of reoperation at the same or adjacent levels that allow accurate estimates to be made for this parameter. Studies report higher rates of graft complications requiring revision for both autograft and allograft, and large series of ACDFP report no reoperations for plate complications.<sup>13,14,17,38,71</sup> There is likely bias in the studies that are published, resulting in extreme values (either positive or negative) in the literature. The true complication rates, of both grafts and plates, probably lie in the middle of published values.

The long-term rate of symptomatic deterioration and reoperation, both for recurrent same-level disease and for adjacent-level symptoms, also affect the results of this analysis if a difference exists between the procedures. No prospective, comparative study of these procedures has been published reporting the delayed reoperation rate.

Reported rates of graft and hardware complications vary widely.<sup>10,13,14,17,19,21,39,66</sup> Recent large reports of ACDF with allograft and ACDFP have both demonstrated very low reoperation rates for these complications.<sup>17,39</sup> In sensitivity analysis, the ICER of ACDFP compared with ACDF with allograft was \$60,000 per QALY assuming a plate complication of 4.8% and a 0.0% rate of graft complication. Therefore, the results are robust for these variables over a plausible range of values.

### **Cost**

Although the costs used in the base case analysis were from a single center and may therefore not be representative of costs at other hospitals, comparison to costs reported in other studies provides some evidence of their generalizability. McLaughlin *et al*,<sup>33</sup> reported the total charges for 2-level ACDF and ACDFP; the results were comparable to those of the current study. In that study, the difference in total charges between ACDF with allograft and ACDFP was \$2,474, similar to the difference in charges in this study of \$2,406. The possibility of error is greatest in the estimate of cost of ACDF with autograft. As no autograft procedures were performed at our institution, it was not possible to determine the costs directly. Instead, previously reported costs of allograft fibula and autograft harvesting were used to approximate the cost

of the procedure. In this model, any change in cost that resulted in a greater cost for the autograft procedure compared to ACDF with allograft resulted in the domination of the former by the latter procedure. Studies in which the cost of each procedure is directly measured should be performed to obtain the most accurate estimates possible. It is possible that the relative cost-effectiveness of the procedures may change from institution to institution depending on the relative cost of resources used in these procedures. Less likely, however, is a significant increase (or decrease) in the cost of one procedure relative to the other procedures.

Postdischarge costs were not included in this model as no data were available. Outpatient physical therapy or home health aides, if used, would be expected to increase the total cost of these procedures. Ignoring differences in the posthospitalization costs of each procedure biases the results toward a procedure that requires more postoperative care than the others. In this study, such bias would tend to favor ACDF with autograft, which may induce greater short-term pain and disability secondary to graft harvesting relative to the alternative procedures.<sup>12,26,42,43</sup> The results may also be biased, although probably to a lesser extent, toward ACDF with allograft, because the hard collar usually used for a period of time after noninstrumented fusion may increase patient discomfort and reliance on the assistance of others. Even if care after hospital discharge is provided by family members, an estimate of the resource utilization should be made and included in the total cost of the procedure.

Although a previously published analysis of the costs and effectiveness of ACDF and ACDFP included lost wages in the costs of surgery, there is not a consensus among cost-effectiveness experts whether lost productivity should be included in formal CEA. Some experts believe that health state utilities may implicitly account for this lost productivity and including lost wages in the numerator leads to double counting. The recommendation of the Panel on Cost-Effectiveness in Health and Medicine is not to include these costs in the numerator in the base case analysis.<sup>72</sup>

Cost-effectiveness analysis is not a tool to determine the “best” treatment for a given disease or pathologic entity. It is an analytical technique of combining many variables in a single model that allows systematic testing of the effect of each variable on outcome. In the case of anterior cervical discectomy and fusion factors such as short-term risks, costs, graft and hardware complications, outcome, and long-term reoperation rates must be considered in trying to determine the relative cost-effectiveness of the alternative procedures. This study demonstrates that, in the base case analysis, ACDF with allograft provides a benefit relative to ACDF with autograft with an incremental cost of \$496 per QALY; compared with ACDF with allograft, ACDFP provides an additional benefit at a cost of \$32,560 per QALY. By comparison, a previously published study reported that

lumbar discectomy provided a benefit in the treatment of herniated intervertebral disc of \$39,500 per QALY.<sup>73</sup>

Sensitivity analysis is used to test the effect of changing the input variables on the CEA model's results. This provides information regarding the stability of the model. The results of the sensitivity analysis also may help to develop a research agenda based on particularly important variables. The current analysis, for example, demonstrated that, of the variables tested, the cost-effectiveness of ACDF is most sensitive to the postoperative recovery period. There are few data in the literature regarding this aspect of the procedure. Future studies should be directed toward delineating the relative rates of postoperative recovery and the magnitude of any disutility associated with a cervical hard collar.

Because this study used data from previously published reports, costs, outcomes, and probabilities were not measured in the same patient population. Costs were determined in part by a retrospective analysis of patients at a single institution undergoing ACDF with allograft and ACDFP, and the cost of ACDF with autograft was estimated using previously published figures. Estimates of the rate and degree of clinical improvement were also derived from published studies. Future studies are necessary to confirm these results using cost and effectiveness data from a single patient population.

This study provides evidence that, although the short-term costs of ACDFP may be higher than those associated with ACDF with autograft or allograft, the 5-year cost-effectiveness of these procedures is similar. ACDFP was found to offer a benefit relative to the other procedures at a cost-per-QALY similar to that of other commonly provided treatments. This benefit was largely driven by a shorter postoperative recovery period ascribed to the elimination of an external cervical orthosis and autograft harvest procedure. The results are sensitive to other assumptions of the model, including reoperation rate and cost. Further prospective, comparative studies of these procedures with particular attention to these parameters need to be conducted to determine more accurately their relative cost-effectiveness.

### ■ Key Points

- Cost-effectiveness analysis provides a structure for comparing different treatments with different costs, benefits, and risks.
- ACDFP offers benefits relative to ACDF with autograft and ACDF with allograft at a cost of approximately \$32,560 per QALY in base case analysis.
- The CEA results are sensitive to variable estimates, particularly regarding postoperative recovery.



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