The safety of instrumented outpatient anterior cervical discectomy and fusion

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Abstract

BACKGROUND CONTEXT: Reported hospitalization times after an anterior cervical discectomy and fusion (ACDF) procedure range between 20 hours to 4 days. Reasons for this wide variation are manifold, but the safety of an instrumented ACDF in the setting of a hostile medical-legal climate is most likely the primary concern influencing such a discrepancy.

PURPOSE: The purpose of this study was to evaluate the safety and feasibility of performing single, two- and three-level ACDF with instrumentation on an outpatient or 23-hour observation period basis in order to potentially diminish the additional cost of hardware without compromising the purported benefits of surgery.

STUDY DESIGN/SETTING: A retrospective chart review of patients undergoing instrumented ACDF on an outpatient basis was performed.

PATIENT SAMPLE: A total of 103 patients with neck pain and/or radiculopathy undergoing ACDF were enrolled into this study.

OUTCOME MEASURES: Included the evaluation of intraoperative and perioperative complications, which were reported for a total of 6 months after surgery. Clinical examination and radiographical assessment, including plain radiographs and computed tomography and magnetic resonance imaging (when required), were performed to assess complications.

METHODS: Complications were divided into two groups: major and minor. Major complications included vertebral fracture and dehydration resulting in readmission. Minor complications included allergic reactions to medications that did not require hospitalization, and transient (≤3 months) neurologic deficit. A comprehensive literature search and meta-analysis was performed to generate a large comparison group in order to compare the complication rates in our outpatient series to those reported in the literature.

RESULTS: A total of 99 patients (96.1%) undergoing single and two-level ACDF were discharged less than 15 hours after their surgeries (median time: 8 hours; range: 2–15 hours), and 4 patients (3.9%) were discharged after a 23-hour observation period following three-level ACDF. The overall complication rate in our outpatient series was 3.8% (n=4), including 1.9% (n=2) major and 1.9% (n=2) minor complications. The overall complication rate in the 633 patient meta-analysis derived comparison group was 0.95% (n=6). The difference between overall complication rates was not found to be significantly different (p=.12). The hardware-related complication rate in the meta-analysis comparison group was 0.5% (n=3), and was not found to be significantly different from our rate of 0% (p≤1).

CONCLUSION: Performing ACDF with instrumentation on an outpatient basis is feasible, and it is not associated with higher overall or hardware-related complication rates as compared with complication rates reported in the literature, suggesting that this procedure is safe to perform on an outpatient basis. © 2007 Elsevier Inc. All rights reserved.

Keywords: Anterior cervical discectomy and fusion; Cervical plating; Cervical spine surgery; Complications; Degenerative cervical spine; Fusion; Outpatient surgery

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Introduction

Anterior cervical discectomy and fusion (ACDF) has proven to be a safe and effective procedure for the treatment of a multitude of spinal disorders [1–9]. A considerable controversy exists regarding the necessity of fusion [10–14] and instrumentation [4,15,16]. However, complication rates are low with instrumented ACDF [17–19], and there are substantial benefits that have been reported in adding instrumentation, such as beneficial effects on long-term stabilization [1], increased fusion rates for one- and two-level procedures [18,20], and decreased kyphotic deformity associated with pseudoarthroses [19–21]. Additionally, the use of plating has been demonstrated to significantly reduce convalescent time, thus decreasing the economic impact of undergoing ACDF [6].

One way to potentially reduce the total cost of surgery is to perform procedures on an outpatient basis. There are substantial benefits to outpatient surgeries besides overall reduced costs, including decreased exposure to nosocomial infections [22,23]. In a series of 103 patients, Silvers et al. [22] reported that converting single and two-level noninstrumented ACDF from an admitted to an ambulatory procedure is safe, effective, and can substantially reduce the economic impact of the surgery. However, currently there is only one study which assesses outpatient instrumented ACDF, the investigation by Stieber et al. [24].

The purpose of our study was to evaluate the safety and feasibility of performing single, two- and three-level ACDF with instrumentation on an outpatient basis (including patients who would not have met the outpatient inclusion criteria from the Stieber [24] study), in order to potentially diminish the additional cost of hardware, without compromising the purported benefits of instrumentation.

Methods

Study design

Over a 2-year period from April 2003 to April 2005, 103 patients were enrolled in our study in order to evaluate the feasibility and safety of performing ACDF with instrumentation procedures on an outpatient basis. This study was a retrospective chart review evaluating the safety of outpatient ACDF with plating. The safety and feasibility of performing ACDF as an outpatient procedure were assessed comparing intraoperative and perioperative complications, which were reported for a 6-month follow-up time period. This included reports at discharge, 2- or 3-week postoperative appointments, 3- and 6-month follow-up visits, and any unplanned postoperative visits. Clinical, neurological evaluation and radiological examination, including plain radiographs, computed tomographic and magnetic resonance imaging scans if necessary, were used to assess complications. Complications were divided into two groups: major and minor. Major complications included vertebral fracture,

hardware failure requiring reoperation, and dehydration resulting in readmission. Minor complications included allergic reactions to medications that did not require hospitalization and transient (≤3 months) neurologic deficit. Clinical parameters, such as surgical blood loss and duration of the surgical procedure were reported. A comprehensive literature search and meta-analysis was performed to generate a large comparison group in order to compare the complication rates in our outpatient series to those reported in the literature. Fusion rates and clinical outcomes were not evaluated in this paper.

Demographic data

A total of 103 patients, 43% of them female, average age 50.25 years (range, 19 to 80 years) were enrolled into this study and underwent ACDF surgery planned as an outpatient procedure (Table 1). An extensive preoperative clinical examination was performed to evaluate motor, sensory, and reflex deficits. Clinical findings were consistent with mechanical neck pain with or without radiculopathy, which limited the patient's ability to function. Radiological examination consisting of cervical spine magnetic resonance imaging, computed tomographic scan, and plain X-rays with flexion and extension views were performed to confirm clinical diagnoses. Only those patients whose symptoms did not respond to a minimum of at least 6 weeks of conservative management were offered surgical treatment.

The distribution of surgical levels and the surgical indications of the patient population are presented in Table 2. The patient population consisted of 103 patients who underwent 1–3 level procedures from C2–T1, did not have intraoperative or immediate postoperative complications, and were in a stable clinical condition at time of discharge. Overall, 99 patients were discharged less than 15 hours (median time: 8 hours; range: 2–15 hours) after their surgeries. Fifty-seven percent of all surgeries (n=59) were single-level operations, whereas 39% (n=40) of all surgeries were two-level operations. Four percent (n=4) of all surgeries were three-level operations, and these patients were discharged after a 23-hour observation period. The four patients undergoing three-level ACDF have been included in this study as outpatients. The average number of spinal levels operated on was 1.46 for the patient population.

Surgical procedure

After endotracheal anesthesia was applied, the patient was placed in the supine position with the head in a Halter

Table 1
Demographic data

	n	Females	Average age
Outpatients	103	44 (43%)	50.25 (19–180)

n=number of patients; ranges are presented in parenthesis.

Table 2
Comparison of indications and operative levels

Indications	Outpatient (n)
Herniated disc	41 (40%)
Disc pathology with myelopathy	23 (22%)
Cervical spine stenosis	26 (25%)
Cervical spondylosis	13 (13%)
Single-level	60
C2–3	1 (1.7%)
C3–4	6 (10%)
C4–5	9 (15%)
C5–6	23 (38.3%)
C6–7	19 (31.7%)
C7–T1	2 (3.3%)
Two-level	39
C3–5	1 (2.5%)
C4–6	14 (36.0%)
C5–7	24 (61.5%)
Three-level	4*
C3–6	2 (50%)
C4–7	2 (50%)
C5–T1	0
Average number of levels	1.46

N=number of patients.

* These patients were discharged after a 23-hour observation period.

head distraction holder with 10 pounds of axial distraction. The anterior cervical region was prepared and draped in a sterile fashion. After intraoperative fluoroscopic localization of the correct cervical level, a transverse incision was made at the level of the interspace that was to be treated. All patients had a left-sided Smith–Robinson [25] approach unless there was a contra-indication, such as previous left-sided anterior cervical surgery. Banked allograft bone and an anterior cervical plate were used in all cases. The details of a standard approach to the anterior cervical spine have been described in detail elsewhere [25,26]. After adequate decompression of the thecal sac and neural foramen, the end plates were prepared accordingly. The disc spaces were sized, and cortical allograft anterior cervical fusion spacers (Synthes, West Chester, PA or Lanx, Boulder, CO) were filled with autogenous bone from the osteophytectomy, which was sometimes supplemented with demineralized bone matrix, and then placed into the disc space. An appropriately sized anterior cervical plate was then placed and secured with 14-mm (female) or 16-mm (male) self-drilling screws (Atlantis or Zephir, Medtronic Sofamor Danek, Memphis, TN).

Meta-analysis

A comprehensive MEDLINE database search was performed to generate a comparison group for our outpatient complication rates. All English-language records from 1966 to March 2006 were searched using the key words "anterior cervical discectomy and fusion". Studies that were to be included in the comparison group were subjected to the following inclusion criteria. Studies that had a minimum of 30 inpatients or outpatients undergoing 1–

3 level ACDF with allograft and instrumentation as the only procedure were included in the comparison group. A minimum of 6 months of follow-up was also a requirement. Of the studies that met these initial inclusion criteria, only those that specifically reported intraoperative and perioperative (hardware-related and overall) complications were retained. Cases of transient hoarseness or dysphagia were not included as complications within the comparison group. In studies that contained both plated and nonplated groups or autograft and allograft groups, data pertaining to patients undergoing instrumented ACDF with allograft were specifically extracted when possible.

Statistical methods

Fisher exact test was used to compare complication rates between the comparison group and our outpatient series. Significance was defined at p=.05.

Results

Complications

Incidences of complications in the patient population are presented as major and minor (Table 3) according to the criteria described in the Methods section. The overall complication rate was 3.8% (n=4), including 1.9% (n=2) major and 1.9% (n=2) minor complications. Six patients (5.8%) in the study had dysphagia, and four (3.9%) had hoarseness of voice. These complications were transient, did not require any treatment, and were not included in the analysis of complication rates. One adverse reaction to medication (Hydrocodone) occurred, did not require medical treatment, and then resolved. The Hydrocodone course was discontinued.

There was one occurrence of a nerve root injury at C5, which was treated conservatively with medications and epidural steroid injections; this resolved completely within 2 months. One patient had a left anterior vertebral body fracture at C5, which was diagnosed at a 3-month follow-up visit. The patient was asymptomatic, did not require surgical intervention, and the fracture healed before a 6-month follow-up visit. Another patient who had a single-level

Table 3
Complications

Complications	Outpatient (n)
Minor	
Reaction to medications	1
Radiculopathy	1
Total minor complications	2 (1.9%)
Major	
Hardware failure	0
Dehydration	1
Vertebral fracture	1
Total major complications	2 (1.9%)
Total	4 (3.8%)

surgery was readmitted into the hospital several days after surgery for dehydration and moderate chest pain. The patient was treated with intravenous fluids and was discharged the following day without further incident.

Clinical and surgical data

The average hospitalization time was 8 hours (range 2-15 hours) for 99 patients (96.1%) undergoing single and two-level ACDF. Four patients (3.9%) who underwent three-level ACDF were discharged after a 23-hour observation period.

The average operative time for ACDF with instrumentation and average blood loss for the entire cohort is presented in Table 4.

Meta-analysis

In order to compare the incidence of complications in our outpatient series, a comprehensive literature search and meta-analysis was performed. A total of 251 articles were initially located, nine of which met all of the inclusion criteria. These nine studies generated a 633 patient comparison group [3,6,18–21,24,27,28]. There were three hardware-related and six overall complications identified in the comparison group. The hardware-related complications identified in the comparison group consisted of one plate and two screw migrations. The overall complications identified in the comparison group consisted of one new radiculopathy, a laryngeal nerve palsy, an epidural hematoma, and two misplaced screws. The rate of complications was compared with that of our outpatient series.

Statistical analysis

A comparison of the complication rates in both the outpatient and meta-analysis derived comparison group was carried out using Fisher exact test. The difference in hardware-related complication rates was not found to be statistically significant ($p \leq 1$) between the meta-analysis comparison and outpatient groups (0.5% and 0%, respectively). The difference in overall complication rates between the meta-analysis comparison and outpatient groups (0.95% and 3.8%, respectively) was not statistically significant ($p = .12$). Given that the studies included in the meta-analysis comparison group were not specifically evaluating safety, they more than likely did not report incidences of adverse reactions to medications, as we did in

our series. Thus, our single instance of an adverse reaction to medication was excluded from the statistical analysis of overall complication rates between groups.

Discussion

Anterior cervical discectomy and fusion has long been the treatment of choice for many different spinal disorders. Since originally described by Smith and Robinson [25] and Cloward [26], the ACDF procedure has evolved to include plating. The addition of instrumentation has been shown to be safe, with a low hardware-related complication rate that varies from 0 to 5% [3,5,6,18–21] for a wide range of clinical indications. There are substantial clinical and financial benefits to adding plating to an ACDF surgery. The increased surgical cost of hardware is offset by the lower rate of pseudoarthrosis [20,21].

Previous studies regarding lumbar microdiscectomy, laminotomy, and root decompressive procedures have demonstrated that the overall cost of a surgery can be reduced by performing the procedure on an outpatient basis [29–31]. Similar results have been reported regarding noninstrumented ACDF. Silvers et al. [22] reported in 1996 that converting noninstrumented single and two-level ACDF to an ambulatory procedure is safe, effective, and provides substantial savings in hospital and economic costs, along with high patient satisfaction and good clinical outcomes. They reported a 45% savings rate between inpatient and outpatient groups, and a potential $90–140 million economic savings due to reduced convalescent time. However, with respect to the literature, it is not clear that performing ambulatory ACDF is standard practice. Since the Silvers et al. [22] study in 1996, the reported hospitalization times for ACDF with and without instrumentation have widely varied in literature published from 1997 to 2004. The reported average lengths of stay range between 20 hours to 4 days for single and multilevel procedures [1,3,17,28,32–34]. The reason for this wide variation in average length of stay is unclear, but the discrepancies most likely arise from individual physician or patient preferences, complications, or Medicare reimbursement requirements. Further investigation into the safety and complication rates of converting to ambulatory surgery will undoubtedly increase surgeon confidence in discharging their patients the same day of surgery.

This study appears to be one of the first few investigations into the safety of performing single-level, two-level, and three-level ACDF procedures with instrumentation as ambulatory procedures. Stieber et al. [24] published a report in 2005 that compared complication rates of 30 outpatients undergoing instrumented ACDF to two inpatient cohorts, each comprised of 30 patients. The outpatient inclusion criteria in the study were strictly defined, as they only included patients who were undergoing one- and two-level instrumented ACDF from C4–C5 to C6–C7, had no

Table 4
Operative data*

	Outpatient
Operative time (min)	90.0 (40–240)
Estimated blood loss (mL)	103.8 (25–200)

  * Range values are presented in parentheses.

evidence of myelopathy, and whose operations were estimated to last less than 2 hours. Our outpatient population included 9 patients outside of the Stieber operative level criteria, 18 patients who underwent two-level surgeries that lasted 120 minutes or longer (average: 141.7 minutes; range: 120–240), and included patients with myelopathy as candidates for outpatient ACDF. None of our patients outside of the Stieber inclusion criteria were found to have complications.

To evaluate the safety of a broad patient population undergoing outpatient instrumented ACDF, we performed a retrospective chart review seeking to identify hardware-related, perioperative, and intraoperative complications. In our series, the total hardware-related complication rate (0%) compares favorably with previously reported rates identified through our meta-analysis (0.5%). Thus, the trend of typically low hardware-related complication rates can be extrapolated to ambulatory ACDF.

Our overall outpatient complication rate is also low (3.8%), which was not found to be significantly different compared with the 0.95% rate observed in the meta-analysis comparison group (p=.12). McLaughlin et al. [6] reported a case of epidural hematoma, a complication associated with ACDF which ought to be of primary concern when considering converting instrumented ACDF to ambulatory practice. Fortunately, there were no instances of epidural hematoma in our series, which has been noted in a single study to occur in approximately 0.9% of ACD without fusion cases [35]. Thus, overall complication rates are typically low, and our low outpatient complication rate, similar to the results of the Stieber et al. [24] study, lends weight to the argument that instrumented ACDF is safe as an ambulatory procedure.

Converting instrumented ACDF to an outpatient procedure has the potential to lower hospital reimbursements, as such a conversion will lower the average length of stay for ACDF, and thus reduce length of stay cost considerations in the determination of reimbursement amounts. While hospitalization cost data for ACDF is not consistently reported in studies regarding cost effectiveness and is thus sparse, hospitalization costs that are reported vary. In a 2000 study, Castro et al. [36] reported a $6,739 total hospitalization cost for two- and three-level instrumented ACDF, whereas McLaughlin et al. [6] reported a $9,701 mean length of stay charge for two-level ACDF in 1997. Thus, converting to outpatient ACDF has the potential to lower the overall cost of surgery. Further studies that properly assess the specific cost/reimbursement reduction and the economic impact of such a conversion are needed.

Although the low overall and hardware-related complication rates in this study suggest that instrumented ACDF is safe to perform as an outpatient procedure, it does not make a blanket statement regarding the safety of ACDF with instrumentation for every patient. As is true for any surgical procedure, proper patient selection, patient education, and meticulous surgical technique are necessary for successful outcomes [22,29–31].

The decision to discharge on the same day of surgery ought to be a mutual decision made by the patient and physicians, including both the surgeon and the anesthesiologist. This study did not expressly evaluate clinical outcome. However, noninstrumented ACDF has been reported to have positive clinical outcomes in both inpatient and outpatient populations [22]. Similarly, inpatient single and multilevel ACDF with instrumentation has been reported to produce excellent and good clinical outcomes [37,38].

Although this study suggests that outpatient instrumented ACDF is safe, there are several limitations to our study. A large prospective, randomized study is needed to identify acceptable co-morbidities and determine the limits of outpatient candidacy for this procedure, as well as to confirm our initial findings along with those of Stieber et al. [24]. Additionally, further studies would be useful to evaluate long-term clinical outcomes after outpatient instrumented ACDF.

Conclusion

Performing ACDF with instrumentation on an outpatient basis is feasible, and it is not associated with higher overall or hardware-related complication rates as compared with a meta-analysis comparison group, suggesting that this procedure is safe to perform on an outpatient basis.

Acknowledgment

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