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Safety and Efficiency of Cervical Disc Arthroplasty in Ambulatory Surgery Centers vs. Hospital Settings

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ABSTRACT

Background: Outpatient surgery has been shown safe and effective for anterior cervical discectomy and fusion (ACDF), and more recently, for 1-level cervical disc arthroplasty (CDA). The purpose of this analysis is to compare the safety and efficiency of 1-level and 2-level CDA performed in an ambulatory surgery center (ASC) and in a hospital setting.

Methods: The study was a retrospective collection and analysis of data from consecutive CDA patients treated in ASCs compared to a historical control group of patients treated in hospital settings who were classified as outpatient (0 or 1-night stay) or inpatient (2 or more nights). Surgery time, blood loss, return to work, adverse events (AEs), and subsequent surgeries were compared.

Results: The sample consisted of 145 ASC patients, 348 hospital outpatients, and 65 hospital inpatients. A greater proportion of 2-level surgeries were performed in hospital than ASC. Surgery times were significantly shorter in ASCs than outpatient or inpatient 1-level (63.6 ± 21.6, 86.5 ± 35.8, and 116.7 ± 48.4 minutes, respectively) and 2-level (92.4 ± 37.3, 126.7 ± 43.8, and 140.3 ± 54.5 minutes, respectively) surgeries. Estimated blood loss was also significantly less in ASC than outpatient and inpatient 1-level (18.5 ± 30.6, 43.7 ± 35.9, and 85.7 ± 98.0 mL, respectively) and 2-level (21.1 ± 12.3, 67.8 ± 94.9, and 64.9 ± 66.1 mL). There were no hospital admissions and no subsequent surgeries among ASC patients. ASC patients had 1 AE (0.7%) and hospital patients had 10 AEs (2.4%). Working patients returned to work after a similar number of days off, but fewer ASC patients had returned to work by the end of the 90-day period.

Conclusions: Both 1- and 2-level CDA may be performed safely in an ASC. Surgeries in ASCs are of shorter duration and performed with less blood loss without increased AEs.

Cervical Spine

Keywords: ambulatory surgery center, outpatient surgery, cervical disc arthroplasty, total disc replacement

INTRODUCTION

Bolstered by trends toward less invasive surgery, as well as modified anesthetic and pain management techniques, surgical procedures are increasingly performed as outpatient procedures across all surgical fields.[1] Concomitantly, ambulatory surgery centers (ASCs) have rapidly multiplied in the United States, so that outpatient surgeries are increasingly performed in an ASC.[2,3]

Similarly in relatively healthy patients, spine surgery has increasingly been performed in outpatient settings including ASCs since the 1980s.[1,4] Surgeons have analyzed spinal surgeries performed in patient cohorts ranging in size from less than 100 to over 1000 patients.[5–20] Furthermore, the comparative safety and effectiveness of spine surgery performed on an outpatient versus inpatient basis have been evaluated for a variety of procedures: lumbar discectomy,[21,22] lumbar decompression,[23,24] lumbar interbody fusion,[25,26] anterior cervical discectomy and fusion (ACDF),[27–32] and cervical disc arthroplasty (CDA).[33] The complexity of outpatient spine surgeries has also increased from microdiscectomy and decompression, to single-level fusion and multi-level fusion using an anterior approach.

Evidence of the safety of ACDF as an outpatient procedure has accumulated.[34] Indeed, surgeons have reported safely performing not only 1-level

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but 2-level[14–16,28,30,32] and 3-level ACDF.[11] In contrast, there is little published evidence of the safety of outpatient CDA despite the growing use of CDA as an alternative treatment to ACDF. Beyond the many published Food and Drug Administration (FDA) Investigational Device Exemption (IDE) studies of CDA, which included but did not separately subanalyze and report outpatient outcomes, only 2 studies, based on small patient samples, supported the safety of outpatient 1-level CDA.[33,35] Hence, the purpose of this analysis is to compare the safety and efficiency of 1-level and 2-level CDA performed in an ASC and hospital settings.

MATERIALS AND METHODS

Patient Sample

Surgeons retrospectively reviewed the charts of 213 patients who had undergone cervical arthroplasty at 1 or 2 levels with a specific artificial disc (Mobi-C, Zimmer Biomet, Westminster, Colorado). Consecutive patients who met all the inclusion criteria and none of the exclusion criteria were enrolled in this study. Patients had to be treated at 1 or 2 contiguous levels (C3-C7) for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a 1- or 2-level abnormality localized to the level of the disc space, and with a diagnosis of at least 1 of the following conditions: herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels. The surgery had to occur in an ASC (defined as a distinct financial entity that operates exclusively to provide outpatient surgical services) at least 6 months prior to enrollment in the study. The patients were treated at 9 ASCs across the United States from August 2013 to December 2015. Each study center received approval from a central institutional review board.

Historical Control

The study patients were compared to a historical control group composed of the patients from the FDA IDE trials of the same artificial disc (NCT00389597). Patients in the clinical trial suffered from symptomatic degenerative disc disease (DDD) with radiculopathy or myeloradiculopathy at 1 or 2 adjacent levels. The inclusion and exclusion criteria of the IDE trials were similar to the criteria of the ASC cohort. The clinical trial surgeries were performed at 24 clinical sites between April 2006 and March 2008.[36,37] None of the centers nor surgeons who participated in the FDA trials were part of this ASC study.

Patients Groups

The historical control hospital patients were further divided into inpatient and outpatient groups, based on the length of hospital stay. Hence, this study compares 3 patient groups:

- *ASC*: patients who underwent surgery in a distinct administrative and financial facility, operating exclusively for providing outpatient services.
- *Hospital Outpatient*: patients with 1 night or less stay in a hospital-administrated facility (per the Medicare definition).
- *Hospital Inpatient*: patients admitted for 2 or more nights of stay in a hospital-administrated facility (per the Medicare definition).

Demographic and Medical Data

The following information was collected from the patients' medical records: basic demographics (age, height, weight, and gender), work status, and workers' compensation status.

Safety Data

Adverse events (AEs) and subsequent surgeries were collected from the period after surgery to 90 days' postsurgery, corresponding to the Medicare-defined global period for major procedures. A complication was any adverse effect that was determined to be related or might have been related to the device or the cervical spine surgery. For the purposes of this study, this is defined as an event that caused a life-threatening illness, even if temporary in nature; or resulted in permanent impairment of a body function or permanent damage to a body structure; or necessitated medical or surgical intervention to preclude life-threatening illness, permanent impairment of a body function or permanent damage to a body structure (corresponding to the World Health Organization [WHO] classification of Grades 3 and 4 serious AEs).

Data were collected on secondary surgeries occurring on the day of surgery (admission to the ASC) or at any time during the 90-day period

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Table 1. Demographic characteristics: mean ± standard deviation or number (percent) of patients. Bold text indicates significance.

	ASC, N = 145	Hospital Outpatient, N = 348	*P* Values[a]	Hospital Inpatient, N = 65	*P* Values[b]
Age (range)	43.9 ± 9.5	44.1 ± 8.6	.88	45.5 ± 8.6	.82
Male (%)	60 (41.4%)	176 (50.6%)	.06	27 (41.5%)	.98
BMI (kg/m^2)	28.6 ± 6.3	27.4 ± 4.5	.20	27.9 ± 4.5	.93
Obese (BMI ≥ 30)	47 (32.4%)	101 (29.0%)	.45	22 (33.9%)	.84
Worker's compensation	29 (20.0%)	11 (3.2%)	**<.0001**	8 (12.3%)	.18
Preoperative work status			.73		.22
Working	96 (66.2%)	232 (66.7%)		35 (53.9%)	
Unable or not working	34 (23.5%)	73 (21.0%)		20 (30.8%)	
Retired/full time student	15 (10.3%)	43 (12.4%)		10 (15.4%)	

Abbreviations: ASC, ambulatory surgery center; BMI, body mass index.
[a]Adjusted *F*-tests and χ^2 comparison ASC to hospital outpatient.
[b]Adjusted *F*-tests and χ^2 comparison ASC to hospital inpatient.

postsurgery. Secondary surgeries are defined as any additional operation of the cervical spine. Data collected included the diagnosis, treatment, relation to index surgery, and the relation to the device. Additional information collected for subsequent surgeries included level(s) involved and type of surgery performed. Hospital admissions and emergency room visits were noted in the ASC group only.

Surgical Data

The following surgical data were collected: number of devices implanted, level of surgery, surgical time, and estimated blood loss. Anesthesia time was recorded for the ASC group only.

Return-to-Work Data

In the 90 days postsurgery, the number of patients who returned to work and the number of days of missed work were collected on patients who were working at the time of surgery.

Statistical Methods

The study was designed to test the noninferiority of ASC outcomes versus the historical controls in a hospital setting. The sample size calculation used an assumption of a 2% rate of complications for the ASC patients,[16,29,30] and a 4.3% rate of complications for hospital patients from the results of the Mobi-C IDE trial. Assuming a 1:3 sampling proportion with 80% power, $\alpha = 0.05$, and a minimum clinically significant difference of 3.5%, the minimum number of subjects needed was 440 (ASC, 110; hospital, 330).

Continuous variables were compared with ANOVA and categorical variables with χ^2. Due to the small number of AEs and secondary surgeries, Clopper-Pearson Exact binomial confidence intervals were calculated for each group. Statistical tests were 2-sided and *P* values ≤.05 were considered significant. Statistical analyses were performed with SAS (version 9.4, SAS Institute, Inc, Cary, NC).

RESULTS

A total of 145 patients were treated in ASCs. Of the 413 historical controls, 348 were outpatients and 65 inpatients. Table 1 reports the demographic and baseline characteristics of the 3 groups. The ASC group had more workers' compensation patients than the hospital groups. The 3 groups were similar in all other demographic characteristics. A greater proportion of 2-level surgeries were performed in the hospital groups than the ASC group (Table 2). For that reason, the efficiency, safety, and return-to-work analyses are reported separately for 1- and 2-level surgeries.

In the 90-day period after surgery, only 1 device- or surgery-related AE was reported in the ASC group (0.7%), compared to 10 events reported in the hospital cohort (2.4%). The overall rate of AEs was 2.0% (7/348) for hospital outpatients and 4.6% (3/65) for hospital inpatients. These AE rates are lower than those assumed for the sample size calculations. Therefore, we applied a more conservative noninferiority margin to compare the ASC group to the hospital group. Using a noninferiority margin of 2%, the ASC group was noninferior to all hospital patients and to each hospital subgroup ($P < .05$). Due to the greater proportion of 2-level surgeries performed in the hospital group, further comparisons of AEs are reported separately for 1- and 2-level surgeries (Table 3).

The 1 AE reported in an ASC patient was a wound dehiscence. The wound dehiscence was superficial and treated in an emergency room but

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Table 2. Surgical procedures: number (percent) of patients. Bold text indicates significance.

	ASC	Hospital Outpatient	*P* Values[a]	Hospital Inpatient	*P* Values[b]
Procedure					
1-level	99 (68.3%)	160 (46%)	**<.0001**	19 (29.2%)	**<.0001**
2-level	46 (31.7%)	188 (54%)		46 (70.8%)	
Operated segments					
C3-C4	2 (2.0%)	1 (0.6%)	.73	0 (0%)	.24
C4-C5	8 (8.1%)	11 (6.9%)		0 (0%)	
C5-C6	50 (50.5%)	86 (53.8%)		14 (73.7%)	
C6-C7	39 (39.4%)	62 (38.8%)		5 (26.3%)	
C3-C5	1 (2.2%)	1 (0.5%)	.46	0 (0%)	.59
C4-C6	10 (21.7%)	50 (26.6%)		11 (23.9%)	
C5-C7	35 (76.1%)	137 (72.9%)		35 (76.1%)	

Abbreviation: ASC, ambulatory surgery center.
[a]χ^2 comparison ASC to hospital outpatient.
[b]χ^2 comparison ASC to hospital inpatient.

did not require surgery. Altogether, the ASC patients experienced 1 (0.7%) AE, 1 (0.7%) emergency room visit, no hospital readmission and no secondary surgery. The AEs reported in hospital patients (1-level [1] and 2-level [9]) were as follows: neck and/or arm pain (5), dysphagia (2), hematoma (2), and incorrectly placed device (1). Four hospital patients required a secondary surgery: 2 hematoma drainage, 1 laminectomy for radiculopathy, and 1 disc replacement to correct position.

Average surgical times (Table 4) were significantly shorter in ASCs than hospital outpatient and hospital inpatient times for both 1-level (63.6 vs. 86.5 vs. 116.7 minutes for ASC, outpatient, and inpatient, respectively) and 2-level (92.4 vs. 126.7 vs. 140.3 minutes, respectively). Similarly, estimated blood loss was significantly lower in the ASC than the 2 hospital groups for both 1-level (18.5 vs. 43.7 vs. 85.7 mL) and 2-level (21.1 vs. 67.8 vs. 64.9 mL) procedures. Anesthesia times (recorded in the ASC group only) were 110.1 ± 39.3 for 1-level CDA and 139.6 ± 53.9 for 2-level CDA.

Working patients returned to work after a similar number of days off work. However, a greater proportion of ASC patients had not returned to work in the 90-day postoperative period (Table 5). For 1-level CDA, the average numbers of days off work were 28.6, 23.4, and 41.6 (ASC, outpatient and inpatient, respectively). The percentages of 1-level patients who returned to work in the 90-day postoperative period were 47.0%, 82.0%, and 80.0%, respectively. For 2-level CDA the average numbers of days off were 38.4, 24.8, and 26.4, respectively. The percentage of 2-level patients who returned to work were 66.7%, 78.5%, and 72.0%, respectively.

DISCUSSION

The results of this study confirm the safety and efficiency of 1-level and 2-level CDA performed in the ASC setting. CDA in an ASC had a lower incidence of AEs and secondary surgeries than when performed in hospital. Surgeries in an ASC were of shorter duration and had less blood loss than in the hospital. While other factors may contribute to lower estimated blood loss (EBL) in an ASC, shorter surgery duration was significantly correlated with reduced EBL ($r = 0.45$; $P < .001$).

Past studies reporting on outpatient surgical procedures did not typically distinguish between hospital outpatient departments (HOPDs) and ASCs, so that either 1 or both settings were included in their reports. Indeed, in the only 2 studies of

Table 3. Adverse events and secondary surgeries: number (percent) of patients.

	ASC	95% CI[a]	Hospital Outpatient	95% CI	Hospital Inpatient	95% CI
1-level	N = 99		N = 160		N = 19	
Adverse events	1 (1.0%)	0.03%–5.5%	1 (0.6%)	0.02%–3.4%	0 (0.0%)	0%–17.6%
Secondary surgeries	0 (0.0%)	0%–3.7%	1 (0.6%)	0.02%–3.4%	0 (0.0%)	0%–17.6%
2-level	N = 46		N = 188		N = 46	
Adverse events	0 (0.0%)	0%–7.7%	6 (3.2%)	1.2%–6.8%	3 (6.5%)	1.4%–17.9%
Secondary surgeries	0 (0.0%)	0%–7.7%	2 (1.1%)	0.1%–3.8%	1 (2.2%)	0.06%–11.5%

Abbreviations: ASC, ambulatory surgery center; CI, confidence interval.
[a]Clopper-Pearson Exact binomial confidence intervals.

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Table 4. Surgical outcomes: mean ± standard deviation. Bold text indicates significance.

	ASC	Hospital Outpatient	*P* Values[a]	Hospital Inpatient	*P* Values[b]
1-level	N = 99	N = 160		N = 19	
Surgery time (min)	63.6 ± 21.6	86.5 ± 35.8	**.002**	116.7 ± 48.4	**.037**
Estimated blood loss (mL)	18.5 ± 30.6	43.7 ± 35.9	**.037**	85.7 ± 98.0	**.004**
2-level	N = 46	N = 188		N = 46	
Surgery time (min)	92.4 ± 37.3	126.7 ± 43.8	**<.0001**	140.3 ± 54.5	**<.0001**
Estimated blood loss (mL)	21.1 ± 12.3	67.8 ± 94.9	**<.0001**	64.9 ± 66.1	**.022**

Abbreviation: ASC, ambulatory surgery center.
[a]Adjusted *F*-tests comparing ASC to hospital outpatient.
[b]Adjusted *F*-tests comparing ASC to hospital inpatient.

outpatient CDA, the surgery was performed in HOPDs in 1 study[33] and ASCs in the other.[35] However, a difference in the safety of procedures performed in HOPDs and ASCs has been reported. A study compared 175,288 surgical procedures performed on Medicare patients at ASCs and 360,780 at HOPDs.[38] The following rates per 100,000 procedures were found: 30-day mortality rate (13.5 at outpatient hospital and 8.7 ASC), 30-day emergency room visit (365.7 vs. 183.2), and 30-day inpatient hospital admissions (548 vs. 165.3). This suggests that procedures were safer when performed in an ASC than an HOPD. Similarly, the current study also observed fewer AEs and secondary surgeries in ASC patients than our hospital outpatient cohort. Patient selection may have impacted the greater safety of CDA in ASCs in our study, given that ASC patients had fewer comorbidities and underwent fewer 2-level procedures than hospital outpatients.

Procedure costs and reimbursement were not analyzed in the present study but financial considerations may have influenced the choice of ASC versus hospital. This study observed a greater proportion of 2-level CDA performed in hospital: reimbursement may have been a factor influencing surgery location.

It should be noted that in the original FDA trial, 84% of the CDA patients required only a 1-night hospital stay or were discharged the same day as surgery. Hence, the standard for CDA may already be to perform this procedure in an outpatient setting. What this study demonstrates is that performing CDA in an ASC has no greater risk than CDA performed in the hospital. Similar levels of improvement have already been reported for 1- and 2-level ACDF in an ASC compared to the hospital.[31] The surgery and anesthesia times in this study are comparable to those reported in other outpatient cervical surgery studies.[15,16,19] As in most studies of outpatient cervical surgery, very few patients experienced AEs, needed to be readmitted, or underwent secondary surgery.[16,29–31,33]

More than 90% of existing ASCs are to some extent owned by physicians and 65% of ASCs are wholly owned by physicians.[39] Ownership of an ASC has been called a conflict of interest for surgeons, and is said to influence physician practice patterns and increase their rate of surgical procedures.[40,41] In an article, concern was expressed regarding the possible underreporting of postoperative morbidity of cervical spine surgery in ASCs (0.8% to 6%), while comparable inpatient cervical procedures reported a morbidity rate of up to 19.3%.[42] This reported difference in postoperative

Table 5. Return to work: mean ± standard deviation or number (percent) of patients. Bold text indicates significance.

	ASC	Hospital Outpatient	*P* Values[a]	Hospital Inpatient	*P* Values[b]
1-level	N = 99	N = 160		N = 19	
Working preoperatively[c]	66/99 (66.7%)	111/160 (69.4%)	.90	10/19 (52.6%)	.34
Returned to full time work within 90 days	31/66 (47.0%)	91/111 (82.0%)	**<.0001**	8/10 (80.0%)	.09
Days until returned to full time work	28.6 ± 23.2	23.4 ± 17.3	.76	41.6 ± 28.0	.51
2-level	N = 46	N = 188		N = 46	
Working preoperatively[c]	30/46 (65.2%)	121/188 (64.4%)	.74	25/46 (54.3%)	.56
Returned to full time work within 90 days	20/30 (66.7%)	95/121 (78.5%)	.17	18/25 (72.0%)	.77
Days until returned to full time work	38.4 ± 23.1	24.8 ± 18.0	.06	26.4 ± 20.4	.39

Abbreviation: ASC, ambulatory surgery center.
[a]Adjusted *F*-tests and χ^2 comparisons of ASC to hospital outpatient.
[b]Adjusted *F*-tests and χ^2 comparisons of ASC to hospital inpatient.
[c]Working full or part time preoperatively.

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morbidity could logically result if surgeons carefully select patients with fewer comorbidities in order to safely perform surgery at an ASC.[39] Patient selection in this study and choice of procedures (fewer 2-level CDAs) may have positively affected the safety of ASC surgeries.

Factors intrinsic to an ASC have been shown to improve its efficiency independently of financial interests. In this prior study, the efficiency of a hospital inpatient facility was found to be inferior to that of its own ASC.[43] Orthopedic procedures by the same surgeon were performed more efficiently and more rapidly at the ASC than the inpatient facility. In this reported scenario, both the inpatient and ambulatory facilities were owned and operated by the same hospital without financial incentive to the operating surgeon. Other studies also have found that having dedicated staff and operating rooms improves efficiency and reduces surgical time.[44,45] Furthermore, infection rates were found to be significantly lower in single specialty ASCs compared to multispecialty ASCs.[46] Similarly, this study shows that surgical times and estimated blood loss are lower in ASC patients than hospital outpatients, supporting the greater efficiency of ASCs.

While patients in the 3 groups returned to work after a similar number of days, a greater proportion of hospital patients than ASC patients had returned to work by 90 days after surgery for the single-level CDA case. A greater proportion of ASC than hospital patients were workers' compensation cases. Previous studies have shown a delay in return-to-work for workers' compensation patients.[47] The physically demanding nature of the work is assumed to be responsible for the delay in return-to-work, given that the workers' compensation patients are predominantly employed in heavy labor industries. However, in this study, nonworkers' compensation patients returned to work at a much lower rate in ASC surgeries (59.0%) than hospital outpatient (93.4%) and hospital inpatient surgeries (91.2%). We do not know what factors are responsible for this reported difference, although how this information was collected may have contributed to the difference.

Two key limitations of this study are the use of a historical control and a retrospective chart review. While ASC patients' charts were methodically and thoroughly reviewed, it is possible that patients may not have communicated all pertinent information to their physicians. Additionally, the type and definitions of data collected did not always match between IDE trial patients and the ASC cohort. Hence the number of comparisons between the ASC and hospital cohorts was limited by the availability of comparable data.

Although there are inherent limitations to retrospective studies, the available data support a conclusion of greater efficiency and safety of 1-level and 2-level CDA performed in an ASC compared to hospital settings.

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