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Safety of Anterior Cervical Disc Arthroplasty in the Ambulatory Setting: an Eastern European Experience

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ABSTRACT

Background: *Spine surgery has been gradually transitioning from the inpatient setting into ambulatory surgery centers (ASC) and as such, the safety of treating patients on an outpatient basis needs to be validated.*

Objective: *In this study, we aimed to evaluate the safety of anterior cervical disc arthroplasty (CDA) performed in an ambulatory setting in an Eastern European population. All existing studies evaluating safety and efficiency of outpatient CDA have originated from high-volume ASCs from the USA.*

Methods: *We retrospectively reviewed 103 consecutive patients who underwent outpatient CDA between January 2018 and February 2020 in order to assess the safety of outpatient single- and multi-level CDA procedures. Various operative data was collected, including adverse events.*

Results: *One patient required reintervention for reposition of the implant, resulting in a reoperation rate of 0.97%. Of the total 149 levels treated, the risk of readmission per level treated was 0.67%. Other AEs included prolonged postoperative hoarseness (laryngeal nerve dysfunction) in two (1.94%) patients, which for one patient resolved within one year. There were no other cases of reintervention, hospital readmission, or postoperative emergency visits.*

Conclusion: *To our knowledge, this is the first study to evaluate the safety of CDA in the ambulatory setting in an Eastern European population. Our data suggests that CDA may be considered safe in the outpatient setting in appropriately selected patients. The 30-day reintervention rate was 0.97%, while AE rate was 1.94%. The reoperation and AE rates were similar to or lower than the complication rates reported by large US outcome studies.*

Keywords: ambulatory surgery, outpatient surgery, disc arthroplasty, cervical discectomy.

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INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) has been the gold standard for treating cervical disc herniation and/or cervical radiculopathy failing nonsurgical treatment for over 60 years. Limitations of this procedure included adjacent segment disease (ASD) and reduced cervical range of motion, especially in an increasingly young and active patient population, have contributed to the development of anterior cervical disc arthroplasty (CDA) (1). The goal of successfully mitigating patient morbidity from ASD, as well as reducing the need for future surgical intervention for ASD have contributed to CDA becoming an increasingly acceptable treatment option to ACDF in well-selected patients (2).

With advances in surgical techniques and rising healthcare costs, the number of spinal procedures performed in ambulatory surgical centers (ASCs) has drastically increased to over 54 million procedures annually (3). Spinal disorders are associated with high financial burden and the transition of spinal procedures to ASCs represents a popular cost saving measure (4). However, life-threatening complications like retropharyngeal hematoma formation, as well as limited sufficient postoperative monitoring have all been well-referenced concerns for performing CDA in a hospital setting (5). Although there is increasing evidence in the literature supporting the safety and efficacy of this shift, the majority of the studies originated from large-volume centers in the United States (6). Our objective is to evaluate the safety of outpatient single- and multi-level anterior CDA procedures in a well-selected Eastern European cohort of patients where anterior cervical surgery is not typically performed in an ASC setting. ❑

METHODS

We retrospectively reviewed 103 consecutive patients who underwent elective CDA from January 2018 and February 2020 with the Mobi-C (Zimmer Biomet, Indiana, USA) cervical disc prosthesis. The inclusion and exclusion criteria for patient selection were comparable to the investigational device exemption (IDE) United States Food and Drug Administration trial (NCT00389597) that used the same prosthesis. Indications for surgery in our study consisted of cervical radiculopathy and/or myelopathy treated with one-, two-, or three-level surgery (7). A total of 149 levels were treated. All patients had preoperative imaging (MRI and CT) of affected levels, intraoperative fluoroscopy (Figure 1), and CT scan postoperative day 30 to evaluate implant position. Charts were reviewed to define patient demographics and medical comorbidities.

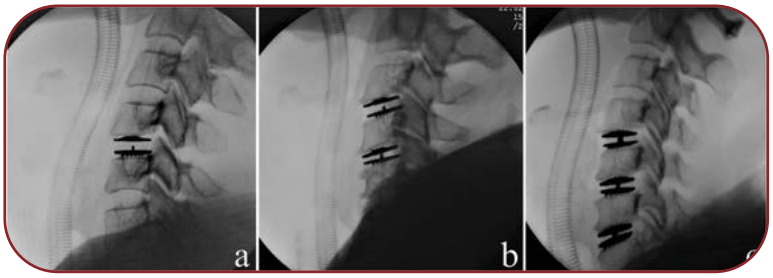

FIGURE 1. Intraoperative tluoroscopy verifying implant positioning for one-level (la), two-level (lb), and three- level (lb) cervical disc arthroplasty

Patients underwent the procedure in an outpatient setting, meaning they were discharged within 23 hours after admission. An adverse event (AE) was defined as any unintended physical injury that was determined to be or might have been related by cervical spine surgery that required additional care. Adverse events were graded according to a contracted Clavien-Dindo classification of surgical complications (8). Grade I AEs included any deviation from the expected postoperative course and did not require pharmacologic (excluding analgesics, diuretics, antipyretics, antiemetics, and physiotherapy), radiological, endoscopic, or surgical intervention. Grade II AEs required pharmacologic treatment with drugs other than the ones allowed for grade I AEs. Finally, grade III AEs required surgical intervention under general anesthesia. ❑

RESULTS

The 103 patients included in this study, of which 35 (33.9%) were identified as males and 68 (66.1%) as females, had an average age of 42 ± 9.4 and an average BMI of 27.2 ± 6.1. Patient demographics are presented in Table 1. By number of levels operated, the majority of patients (58.25%) had a one-level intervention (Table 2). Of the 37 patients (35.92%) who un-

Variable	Average ± SD	Min	Max
Age (years)	42 ± 9.4	27	76
Gender	Nr. of cases	Percentage	
Male	35	33.9%	
Female	68	66.1%	
Body mass index (average ± SD)	27.2 ± 6.1		
	Nr. of cases	Percentage	
Smokers	37	35.9%	
Diabetes	11	10.6%	
Indication for surgery			
Cervical radiculopathy	88	85.5%	
Myelopathy	15	14.5%	
Total patients	103		

TABLE 1. Demographic data of the patients included in this study

derwent two-level CDA, all of them were operated for contiguous levels. Additionally, five (4.85%) patients underwent three-level CDA. Indications for surgery consisted of cervical radiculopathy (85.5%) and myelopathy (14.5%). The 30-day reintervention rate was 0.97% and per level treated, the risk of readmission was 0.67%. Two AEs (1.94%) were observed in our cohort (Table 3), which included hoarseness that resolved within two months (Grade I) and one reoperation for implant repositioning (Grade III). There were no cases of dysphagia requiring treatment with nasogastric feeding tube or parenteral nutrition. After reoperation, the patient also experienced hoarseness, which resolved after one year with otolaryngologic care. ❑

DISCUSSION

Our study suggests that outpatient CDA can be performed safely in low-volume ASCs in a well-selected Eastern European population. Cervical disc arthroplasty is a surgical technique that was developed to address the shortcomings of ACDF, namely adjacent segment disease (ASD), the incidence of which has been observed to be as high as 92% (1). Anterior cervical discectomy and fusion has a profoundly negative impact on the kinematic profile at the index level, which is the driving force behind the prevalence of ASD in ACDF (9). Conversely, the association of ASD and decreased range of motion (ROM) is explicitly lower in CDA (2, 10, 11). The kinesiologic explanation for this observation was explored through the use of a finite element modeling studies – CDA introduces smaller disturbances in range of motion and column load sharing, which contributes to preserving adjacent segment biomechanics, thus limiting accelerated degeneration (12).

The goal of CDA was to treat patients with similar indications for ACDF, while avoiding these long-term complications. Cervical disc arthroplasty is still a relatively new procedure and as a result, there is considerably more high-quality evidence available which validates the safety and efficiency of ACDF in the ambulatory setting, like a recent 2000 patient study by McGirt *et al* (13). While searching the PubMed, Scopus, and Web of Knowledge databases, we have identified four studies that validated one-level CDA to be safe and efficient when performed in an outpatient setting (14-17). There is a clear paucity of evidence – only two studies evaluated

TABLE 2. Surgical procedures perfonned and their corresponding levels

Procedure	Number of patients	Number of levels
1 - level	60 (58.25%)	60
2 - level	37 (35.92%)	74
3 - level	5 (4.85%)	15
Total	103	149
Operated segments		
One-level		
C4 - C5	8 (13.3%)	
C5 - C6	26 (43.3%)	
C6 - C7	26 (43.3%)	
Total	60	
Two-level		
C4 - C6	12 (32.43%)	
C5 - C7	25 (67.56%)	
Total	37	
Three-level		
C4 – C7	5 (100%)	
Total	5	
Total levels		
C4 - C5	25 (16.77%)	
C5 - C6	68 (45.63%)	
C6 - C7	56 (37.58%)	

two-level CDA and no studies examined the safety of three-level CDA in the ambulatory setting (18, 19).

As mentioned earlier, the primary concern regarding the transition of anterior cervical spinal procedures to an outpatient setting revolves around decreased postoperative monitoring. Life-threatening complications, like retropharyngeal hematoma formation with soft tissues swelling and subsequent airway compromise can rapidly develop and place patients at risk. For ACDF, the incidence of postoperative hematoma formation varies from 1.3-5.6% and, while the incidence of this complication is significantly lower in CDA, it can still occur – of the six outpatient CDA studies found, two patients (from one study) were reported to develop this complication and required reoperation for drainage (5, 19). Other examples of dangerous postoperative complications include, but are not limited to, intractable pain, new deficits, vascular or esophageal injury, and high-volume cerebrospinal fluid leaks.

The demographics for this study were comprised by a standard patient population. The 30-day reoperation rate of 0.97% is comparable to other studies, both ambulatory and inpatient. The reported reoperation rate for CDA is approximately 2.0-5.2% (20-22). The largest cohort of examined patients to date reported perioperative readmission rates of 2.11% and a 90-day reoperation rate of 2.04% (23). The rate of AEs observed in our study (1.94%) is also consistent with other ambulatory CDA studies (14-16, 19). The major AEs in our cohort included hoarseness – one case which resolved spontaneously within two months and another which resolved after one year with otolaryngologic care. However, the previous operation and the existing scar tissue may have played a role in the evolution of this AE. Goffin et al reported a similar complication of hoarseness and dysphonia arising in a patient who was reoperated for a CDA procedure (1). Generally, single-level or multi-level CDA may be performed after previous spinal surgery safely; however, preoperative hypermobility should be approached with caution (24).

Procedure done	Grade I	Grade II	Grade III
One-level CDA	0	0	1 (0.97%)
Two-level CDA	1 (0.97%)	0	0
Three-level CDA	0	0	0
Hybrid surgery	0	0	0

TABLE 3. Adverse events: number (percent) of patients. (CDE: cervical disc arthroplasty)

Multi-level disease in spondylosis is common and, despite the clear benefits of CDA, patients may have contraindications to CDA, as did a subset of patients in our study (25). Translational instability, disc space collapse, facet joint arthropathy are examples where ACDF may be a safer option than CDA. In order to mitigate the long-term complication profile of two-level ACDF, ACDF was combined with CDA to develop hybrid surgery (HS) (26). A dynamic construct improves functional outcomes through preservation of cervical spine curvature and ROM, while the bone graft allows to fuse bone where indicated (27, 28). Hybrid surgery has been showed to be a safe procedure, although there is a lack of evidence on 30-day outcomes for HS performed in an ambulatory setting (29). In our small HS patient subgroup, the intervention was performed safely, without any AEs noted in the immediate or 30-day postoperative periods.

Lastly, when comparing preoperative variables of inpatient and ambulatory CDA patients, the former cohort was found to have higher rates of obesity and insulin dependent diabetes (18). While no studies directly link obesity or diabetes to patient safety, these factors should nevertheless be given careful consideration during patient selection. In their ambulatory patient group, Gornet et al reported the rate of AEs to increase from one-level (0.6%) to two-level CDA (3.2%), thus suggesting that the numbers of levels treated should have a greater impact when considering the inpatient versus ambulatory setting (19). From our study, we would also add that, in addition to BMI, attention should be given to patient proportions, as a shorter neck and more muscle mass may obscure implant borders during intraoperative visualization, increasing the risk for implant misplacement, which will require reoperation.

The limitations of this study include its retrospective nature, relatively small sample size, and that the patient safety experience is reported from a single-center. In addition, unfortunately due to our modest sample size, it may be difficult to observe other rare complications in which early discharge my lead to poor outcome. Furthermore, the patient population of our study is likely different from that of other studies, as patients who undergo elective surgical procedures in private clinics tend to be of higher socio-economic status, which positively correlates with involvement in their care. ❑

CONCLUSION

Low incidence of AEs in both, the immediate and 30-day periods support the safe practice of outpatient single- and multi-level CDA in ASCs in well-selected patients. Despite the fact that the CDA procedure has been evaluated to be safe in various studies in the US, no previous studies have evaluated its safety in an Eastern European population. Our study demonstrates that CDA can be performed safely and with a low complication profile in well-selected patients by experienced spine surgeons in an Eastern European patient population. ❑

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