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Clinical Study

Utilization trends of cervical artificial disc replacement during the FDA investigational device exemption clinical trials compared to anterior cervical fusion

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ABSTRACT

While anterior cervical discectomy and fusion (ACDF) is the gold standard surgical treatment for cervical disc disease, concerns regarding adjacent segment degeneration lead to the development of cervical disc arthroplasty (CDA). This study compares the utilization trends of CDA *versus* ACDF during the period of the Food and Drug Administration Investigational Device Exemption clinical trials from 2004 to 2007. The Healthcare Cost and Utilization Project Nationwide Inpatient Sample database was used to identify CDA and ACDF procedures performed in the USA between 2004 and 2007. The prevalence of CDA and ACDF procedures was estimated and stratified by age, sex, diagnosis, census region, payor class, and hospital characteristics. The average length of hospital stay, total charges, and costs were also estimated. The number of CDA surgeries significantly increased annually from 2004 to 2007 and mostly took place at urban non-teaching hospitals. There were no regional differences between CDA and ACDF utilization. There was no difference between sex or admission type between CDA and ACDF patients. ACDF patients were older and had more diabetes, hypertension, and chronic obstructive pulmonary disease. CDA patients were more likely to be discharged home and had shorter hospital stays but had a higher rate of deep venous thrombosis than ACDF patients. Significantly more CDA patients had private insurance while more ACDF patients had Medicare. The average cost was higher for ACDF than CDA. While ACDF dominated surgical intervention for cervical disc disease during the trial period, CDA utilization increased at a significantly greater rate suggesting rapid early adoption.

1. Introduction

The gold standard for surgical treatment of cervical disc disease continues to be anterior cervical discectomy and fusion (ACDF).[1–3] Cloward first reported on anterior cervical decompression and fusion in 1958 and, since then, the safety and effectiveness of this procedure has been established and demonstrated throughout the literature.[4,5]

Despite the success of ACDF, concerns regarding pseudoarthrosis, adjacent segment degeneration, and loss of motion at the operated level have led to the development and adoption of cervical disc arthroplasty (CDA).[6] Disc arthroplasty was designed on the premise that it could preserve cervical spinal motion, both at the affected and adjacent levels.[1–3]

The initial development of cervical arthroplasty devices occurred in Europe where the first prospective, randomized trials comparing cervical arthroplasty and fusion were initiated in 2000 to study the Prestige and Bryan devices (Medtronic Sofamor Danek, Inc., Memphis, TN, USA).[7] Following these studies, randomized, prospective studies were initiated in the USA in 2002 under a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) to study the Prestige and Bryan discs.[7] The first ProDisc-C device (DePuy Synthes, West Chester, PN, USA) was implanted in Europe in 2002 and a prospective randomized multi-center IDE study, conducted in the USA between 2003 and 2004, published its results in 2009.[8]

International Classification of Diseases Ninth Revision Clinical Modification (ICD-9-CM) procedure codes were approved for CDA in the last quarter of 2004. After ICD-9-CM approval, the Nationwide Inpatient Sample (NIS) began including information on usage of CDA.

The purpose of this study was to evaluate and analyze the patient populations that were treated in the time period when the trials were conducted, between 2004 and 2007, using ICD-9-CM data. Additionally we sought to highlight trends in the early adoption and usage of CDA and compare the demographics of the patients that underwent CDA and ACDF during the IDE clinical trial period.

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2. Materials and methods

The Healthcare Cost and Utilization Project (HCUP) NIS database was used to analyze the characteristics associated with CDA and ACDF surgeries performed in the USA between October 1, 2004 and December 31, 2007. Revision of cervical disc prosthesis was included in the study. To identify the study population ICD-9-CM procedure codes 84.62 (cervical disc prosthesis), 84.66 (revision of cervical disc prosthesis) and 81.02 (anterior cervical fusion) were used in the primary or secondary position.

Hospitals are stratified within the NIS sample according to ownership, bed size, teaching status, urban/rural location, and USA census region.[9] Hospitals are randomly selected in order to approximate a 20% sample of the total hospitals in each stratum. Thus, the NIS can be weighted to produce national estimates from the 20% sample, with the use of the provided sampling weights. All discharge records from each of the selected hospitals are collected and form part of the NIS file for a given year. In 2007, the NIS had a sample size of 8,043,415 records from 1044 hospitals in 40 states, which represents approximately 20% of all discharges from hospitals in the United States.[9] Excluded from the NIS are short-term rehabilitation hospitals (beginning with 1998 data), long-term non-acute care hospitals, psychiatric hospitals, and alcoholism/chemical dependency treatment facilities.[9]

The prevalence of CDA and ACDF procedures was calculated with use of the NIS for population subgroups stratified by age, sex, diagnosis, census region, primary payor class, and hospital characteristics (size, location, and teaching status). The average length of hospital stay and total charges were also computed.

We used Rao–Scott chi-squared tests for dichotomous variables and *t*-tests for continuous variables. To produce correct national estimation and account for NIS design, we used SAS survey procedures (SAS Institute Inc., Cary, NC, USA). We used HCUP cost-to-charge ratio files to calculate cost from hospital charges and reported results in 2007 US dollars. Comorbid conditions and complications were identified using previously reported methods.[10] For the per capita calculations, annual nationwide census information was obtained from the National Census Bureau for the years 2004 to 2007, and results were expressed as the rate of the variable per 100,000 population.

Statistical significance was expressed as p values, with values of $p < 0.05$ considered significant. Data sets were analyzed with SAS 9.2 software.

3. Results

A total of 321,154 ACDF surgeries and 1715 CDA surgeries were identified between October 1, 2004 and December 31, 2007 (Table 1). From 2004 to 2007, there was a 57-fold increase in the number of CDA surgeries performed (15 *versus* 869, respectively). During that period, ACDF surgery also continued to increase in volume, with almost 14,000 more surgeries performed in 2007 than 2004, an increase of 15%. Figure 1 demonstrates this trend per capita. When comparing ACDF to CDA, it is interesting to note that in 2005 there were 5000 fusions per one artificial disc, but in 2007, this ratio decreased to 100 fusions per one artificial disc.

3.1. Patient characteristics

The six most common diagnoses associated with cervical disc replacement from 2004 to 2007 were cervical disc displacement, disc degeneration, cervical spondylosis, cervical disc displacement with myelopathy, cervical spinal stenosis, and cervical spondylosis with myelopathy. Among these six diagnoses, cervical disc displacement was the most common.

Table 1
Baseline characteristics of patients treated with fusion or artificial disk surgery

	ACDF (n = 321,154)	CDA (n = 1715)	*p* value
Demographics			
Age, years	53.73	49.54	<0.01
Women	51.72%	51.90%	0.66
Race (%)			
White	58.16	63.91	0.44
Black	6.42	4.31	0.25
Hispanic	2.80	3.50	0.99
Asian	0.77	0.82	0.99
Indian	0.31	0.00	1.00
Other	1.60	1.52	0.78
Missing	29.9	25.95	
Admission type (%)			
Elective	80.01	80.98	0.70
Emergent	10.53	6.58	0.23
Trauma	0.1	0.00	1.00
Missing	9.46	12.44	
Comorbid conditions (%)			
DM	13.38	8.63	<0.01
HTN	39.73	31.89	<0.01
COPD	14.26	9.58	<0.01
CAD	8.26	6.90	0.41
Renal	0.80	0.58	0.66
PVD	0.90	0.19	0.08
Cerebral	0.84	0.57	0.57
Lipids	7.88	7.89	0.99
Osteo	2.00	1.42	0.44
Insurance (%)			
Medicare	23.99	18.36	0.03
Medicaid	7.82	6.21	0.31
Private	57.81	65.07	<0.01
Uninsured	1.46	3.11	<0.01
Other	8.92	7.25	0.26

ACDF = anterior cervical discectomy and fusion, CAD = coronary artery disease, CDA = cervical disc arthroplasty, COPD = chronic obstructive pulmonary disease, DM = diabetes mellitus, HTN = hypertension, Osteo = osteoarthritis, PVD = peripheral vascular disease.

The target population for both ACDF and CDA surgical was compared. The average age of patients undergoing ACDF was statistically higher (53.7 years) compared to CDA (49.5 years), although clinically this is likely insignificant. Hospitalizations for surgery did not differ between sex or admission type. Patients who underwent ACDF were significantly more likely to have diabetes, hypertension, and chronic obstructive pulmonary disease (COPD) than

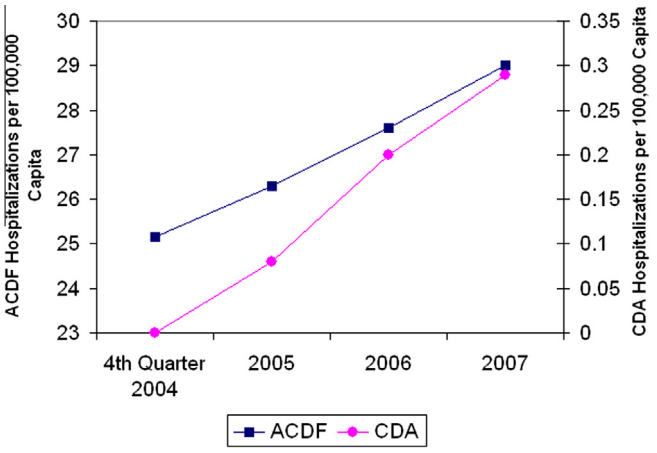

Fig. 1. Graph showing the trend of anterior cervical discectomy and fusion and cervical disc arthroplasty surgeries per 100,000 capita in the USA between 2004 and 2007. ACDF = anterior cervical discectomy and fusion, CDA = cervical disc arthroplasty. (This figure is available in colour at http://www.sciencedirect.com/.)