

Original Article

Influence of one-level cervical disc arthroplasty and anterior cervical decompression and fusion on adjacent segment degeneration: a comparative study with two-year follow up

Ruiduan Liu^{1,2}, Anmin Jin³, Caijun Liu³, Rongchi Xiao⁴, Zhihong Tang⁴

¹Department of Spinal Surgery, Affiliated Hospital of Guilin Medical University, Guilin, China; ²Zhujiang Hospital of Southern Medical University, Guangzhou, China; ³Department of Spinal Surgery, Zhujiang Hospital of Southern Medical University, Guangzhou, China; ⁴Department of Spinal Surgery, Affiliated Hospital of Guilin Medical University, Guilin, China

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Abstract: To compare the morbidity of adjacent segment degeneration (ASD) in patients who underwent cervical disc arthroplasty (CDA) and anterior cervical decompression and fusion (ACDF). ACDF used to be considered as the best treatment of cervical degenerative disc disease. It's controversial when ASD was reported as complication after ACDF. CDA was believed to maintain the physiological motion pattern and reduce intervertebral stress. There are few reports comparing the results of two surgeries. Patients undergoing CDA or ACDF from February 2007 to August 2008 got a minimum follow-up of 4 years. The cohort consisted of 150 patients (69 men and 81 women) with an average age of 46.7 ± 6.5 years. 45 patients were treated with CDA and 105 patients underwent ACDF. The efficacy was evaluated with the visual analog scale (VAS), the neck disability index (NDI), Japanese Orthopaedic Association (JOA) score and the range of motion (ROM). The anteroposterior and lateral radiographs and over flexion-extension lateral radiographs were obtained. Cervical CT and MRI were obtained if persistent discomforts or new symptoms were claimed. The revised Hilibrand method was adopted to assess the level of ASD. All the 150 patients complete the clinical and radiological follow-up interval (48 months). From investigation, the preservation of motion was notably maintained in the CDA patients. However, there were no statistically significant difference of the ASD incidence based on the VAS, NDI and JOA scores between the two groups. Therefore, the role of CDA in ASD incidence remains unclear unless more randomized controlled trials are conducted and definitive evidence is achieved. CDA significantly increased ROM comparing to ACDF. However, the other scores were not significant different between two groups. More data are needed for solid conclusion.

Keywords: Adjacent segment degeneration, cervical disc arthroplasty, anterior cervical decompression and fusion, prospective cohort study, neck disability index, visual analog scale, Japanese orthopedic association score, range of motion

Introduction

The invention of anterior cervical decompression and fusion (ACDF) in 1950's was considered as a milestone for the treatment of the cervical Degenerative Disc Disease (DDD). Since the first report of Smith and Robinson in 1958 [1], ACDF is regarded as the golden standard surgical treatment of the cervical DDD, while it is also used to treat herniated discs to reduce pain when conservative treatments have failed [2]. However, in recent years, adjacent segment degeneration (ASD), which may be caused by the increase of motion load or adjacent-level stresses, has been reported as a

complication to the surgery [3]. Hilibrand et al. [4] reported that ASD were detected in about 18% of patients with single-level ACDFs and this data might be increased to 25.6% in 10 years after the initial procedure. Moreover, Goffin et al. [5] reported that 6.11% of the patients need a secondary surgical procedures at 60 months post the initial one because of ASD. Randomized controlled trails (RCTs) evidence in Level I has not been specifically studied. Hilibrand et al. [6] described this phenomenon as a natural degeneration in their following study. Recently, Helgeson et al. [7] described the ASD as a result caused by natural history, fusion, local surgery and etc.

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Table 1. Patients' demographics

	CDA	ACDF	p-values
Number of patients	45	105	N/A
Age (average \pm S.D.)	45.9 \pm 6.0	46.9 \pm 6.9	0.30
Gender			
Male	18 (40.0%)	51 (48.6%)	
Female	27 (60.0%)	54 (51.4%)	0.39
Operated segment			
C3/4	1 (2.2%)	2 (1.9%)	
C4/5	4 (8.8%)	12 (11.4%)	
C5/6	27 (60.0%)	68 (64.5%)	
C6/7	13 (29.0%)	23 (22.2%)	0.16
Types of disease			
Nerve root	24 (53.3%)	53 (50.5%)	
Spinal cord	7 (15.6%)	19 (18.1%)	
Hybrid	14 (31.1%)	33 (31.4%)	0.29

Meanwhile, cervical disc arthroplasty (CDA) has been regarded as a potential surgical method to maintain the physiological motion pattern, reduce intervertebral stress and delay the onset of DDD [8]. In some studies, CDA treatments were described for the application of improvement of sagittal balance of the cervical spine and spinal reconstruction [9]. However, there are some other researchers claimed that there was no sufficient evidence supporting a decrease of ASD when comparing the CDA group with ACDF group [10, 11].

When comparing the ACDF and CDA, it remains controversial which surgical treatment gives better outcomes. Therefore, this study was performed to compare the morbidity of ASD in patients who underwent CDA or ACDF.

Patients and methods

Patient cohort

This patient cohort contains patients who underwent CDA or ACDF from February 2007 to and August 2008 with a minimum follow-up of 2 years. The cohort consisted of 150 patients (69 men and 81 women) with an average age of 46.7 \pm 6.5 years, including 45 patients were treated with CDA and 105 patients underwent ACDF. Patients' demographics were listed in **Table 1**.

Inclusion and exclusion criteria

Patients in the cohort were included in the study with single level symptomatic degenera-

tive disc disease (DDD) between C-3 and C-7, as demonstrated by symptoms of radiculopathy or/and myelopathy. Non-response to conservative treatments after 3 months or a new neurologic deficit secondary to myelopathy were reported among the patients. After informed consents were obtained, the participating patients were assigned to receive CDA or ACDF, based on patients' opinion. This study was approved by the Medical Ethics Committee.

Patients who were younger than 18 years of age were excluded from this study. In addition, the patients would not be included if there were the evidence of cervical vertebral malformation (loss of lordotic curvature on radiographs), cervical instability (defined as horizontal displacement of 2 mm or more or a range of angular intervertebral mobility of 11° or more was observed in any segment of the cervical [12]), severe cervical spondylosis consisting in osteophytosis, 50% or more intervertebral height loss or disc-space narrower than 2 mm. More exclusion criteria included uncovertebral joint hypertrophy, decreased bone density, tumor, metabolic bone disease and bone fusion problems caused by smoking and intemperance.

Surgical technique and postoperative course

The standard right-sided anterolateral approach of discectomy and decompression were performed by the same surgeon after cervical and tracheoesophageal pulling extension. The posterior longitudinal ligament was removed in all cases. External fixation of neck was underwent in ACDF group for 6 weeks, while functional exercise was underwent in ADR group under the guidance of medical staff. Postoperative anti-infection treatment was administered for 24-48 h, without non-steroidal anti-inflammatory drugs (NSAID). Here, the prosthesis of CDA group adopted was ProDisc C, while the prosthesis of ACDF group was dynamic titanium plate. The surgery was performed by three steps, including osteophytes removal, titanium mesh and bone graft fusion.

Follow-up procedures

Follow-up procedures of all patients in this study were assessed at 3, 6, 12 and 24 months post-surgery by one independent evaluator with a completed record of VAS, NDI, JOA and ROM. We obtained the anteroposterior and lateral

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Figure 1. X-ray of typical patients before and after CDA at C6/7.

radiographs and over flexion-extension lateral radiographs of the study point for radiographic assessments. A cervical CT and MRI were obtained if persistent discomforts or new symptoms were claimed. All the CT and MRI result were evaluated by two independent researchers. And the difference of evaluation would be discussed by the research group.

The evaluation of radiological evidence of adjacent-disc disease was based on the criteria of Hilibrand as follows; new anterior osteophyte formation or enlargement of existing osteophytes, increased or new narrowing of a disc space (>30%), new or increased calcification of

the anterior longitudinal ligament and the formation of radial osteophytes. CT and MRI results, local symptoms and signs were also taken into consideration.

Statistical analysis

The measures of VAS, NDI, JOA and ROM were evaluated by the central tendency and dispersion (\pm SD). The parametric and non-parametric inferential statistic was employed by t test and X^2 test respectively. IBM SPSS statistical package 20.0 was used for the analysis, and a probability value of less than 0.05 was set for the level of significance.

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Figure 2. X-ray of typical patients before and after CDA at C5/6.

Results

All the 150 patients complete the clinical and radiological follow-up interval (48 months). Among the patients, there were 69 men and 81 women with an average age of 46.7 ± 6.5 years. Here, 45 patients were treated with CDA and 105 patients underwent ACDF. X-ray of typical patient cases before and after CDA are shown in **Figures 1 and 2**.

Clinical features, including VAS, NDI, JOA and ROM scores were illustrated in **Table 2** for detailed comparison in many respects. Each score was evaluated in both postoperative and preoperative periods for both CDA and ACDF

groups. From our results, the VAS scores, which were used to evaluate the arm pain intensity, evaluated at 3 (CDA 3.0 ± 0.5 vs. ACDF 3.0 ± 0.6 , t test $P = 0.432$), 12 (CDA 3.2 ± 1.1 vs. ACDF 2.9 ± 1.3 , t test $P = 0.516$) and 24 months (CDA 3.5 ± 1.2 vs. ACDF 3.0 ± 1.0 , t test $P = 0.589$) after surgery were comparable. The similar results were achieved in NDI score, which is the most commonly used self-report measure for neck pain [13], and JOA score, which was developed for assessment of cervical myelopathy [14]. While, from our investigation, the preservation of motion were notably maintained in the CDA patients, which were 8.8 ± 0.8 , 7.3 ± 0.5 , 7.1 ± 0.7 in 3, 12, and 24 months respectively, compared to the ACDF group, which were

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Table 2. The comparison of the two groups in VAS, NDI, JOA and ROM score

	CDA	ACDF	p-values
VAS Score			
Preoperative	7.92±0.9	7.95±1.0	0.512
3-6 months postoperative	3.0±0.5	3.0±0.6	0.432
12 months postoperative	3.2±1.1	2.9±1.3	0.516
24 months postoperative	3.5±1.2	3.0±1.0	0.589
NDI Score			
Preoperative	41.4±7.0	42.8±6.5	0.607
3-6 months postoperative	15.0±5.0	15.4±4.5	0.589
12 months postoperative	13.0±3.4	13.5±2.5	0.556
24 months postoperative	18.09±5.8	18.4±5.4	0.597
JOA Score			
Preoperative	8.2±0.5	8.1±0.4	0.658
3-6 months postoperative	14.5±0.4	14.7±0.3	0.532
12 months postoperative	15.0±0.1	15.3±0.4	0.586
24 months postoperative	15.0±0.3	15.1±0.2	0.498
ROM Score			
Preoperative	8.0±0.9	7.9±0.6	0.891
3-6 months postoperative	8.8±0.8	1.3±0.1	0.032
12 months postoperative	7.3±0.5	0.9±0.04	0.029
24 months postoperative	7.1±0.7	0.8±0.1	0.019

Table 3. Comparison of adjacent segment degeneration rates (%)

	CDA	ACDF	P-values
Degeneration rate	12% (8/25)	11% (12/105)	0.632

1.3±0.1 in 3 months, 0.9±0.04 in 12 months and 0.8±0.1 in 24 months. Adjacent segment degeneration rates in two groups are not significantly different (**Table 3**).

CDA treatment could significantly increase ROM compared with ACDF group. However, there were no statistically significant difference of the ASD incidence based on the VAS, NDI and JOA scores between the two groups. Therefore, the role of CDA in ASD incidence will remain unclear unless more randomized controlled trials are conducted and definitive evidence is achieved.

Discussion

Here, we reported that the preservation of motion was notably maintained in the CDA patients. However, there was no statistically significant difference of the ASD incidence between the two groups. The results in this

study improved in the following aspects compared with recent studies.

First of all, scientific and reasonable criteria of ASD are still incomplete. Most of the studies are according to the criteria of Hilibrand, which based on X-ray imaging results. However, CT and MRI were not obtained, and symptoms and signs were not considered, which were compensated in our research.

Secondly, the research design is not convincing enough since the lack of RCTs to compare the effects of ACDF and CDA. Most of the RCTs conducted in the USA as 'Food and Drug Administration investigational device exemption studies' demonstrated significant non-inferiority. This means that the primary outcome measure is not tested for superiority but for equality. Therefore, the results might be questionable since the less stringent for demonstrating efficacy of the non-inferiority design than the standard clinical trial. In addition, study quality is limited due to unblinding of outcome assessors, exclusion of patients after randomization and unclear or no intention-to-treat-analysis [15].

Additionally, the follow-up time and sample size is not convincing enough to draw any conclusion. In most studies, the follow-up time is about 2 years. Nevertheless, Nunley [16] et al. reported that there were no statistically significant difference of the ASD incidence in their 4-year-follow-up study with 170 patients. This result was confirmed by many other studies for long-time and large-sample studies [17-19]. Hence, the lack of long time and enough sample size may be the reason of unstable results. This is also the limitation for our study here due to the small size.

It's been reported that NSAID may reduce the incidence of heterotopic ossification after hip replacement [20]. However, the effects of NSAID are not clear on CDA [21]. Therefore, NSAID was not given to patients in this study.

Conclusion

In this study, we performed a fully comparative study of the ASD in patients who underwent CDA and ACDF. Data from the study indicated

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that CDA treatment could significantly increase ROM compared with ACDF group, while the other scores were not significantly different. Longer follow-up time and more clinical results are needed before drawing further conclusion.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Anmin Jin, Department of Spinal Surgery, Zhujiang Hospital of Southern Medical University, 253 Industrial Road, Guangzhou 510280, China. Tel: +86 20-61643888; Fax: +86 20-62782020; E-mail: anminjin@sina.com

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