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Original Article

Clinical comparison of Zero-profile interbody fusion device and anterior cervical plate interbody fusion in treating cervical spondylosis

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Abstract: Objective: the aim of the study was to compare the clinical effect of Zero-profile interbody fusion device (Zero-P) with anterior cervical plate interbody fusion system (PCB) in treating cervical spondylosis. Methods: a total of 98 patients with cervical spondylosis (110 segments) in February 2011 to January 2013 were included in our hospital. All participants were randomly divided into observation group and control group with 49 cases in each group. The observation group was treated with Zero-P, while the control group received PCB treatment. Comparison of the two groups in neurological function score (JOA), pain visual analogue scale (VAS), the neck disability index (NDI), quality of life score (SF-36) and cervical curvature (Cobb angle) change were recorded and analyzed before and after treatment. Results: The observation group was found with 90% excellent and good rate, which was higher than that of the control group (80%). Dysphagia rate in observational group was 16.33% (8/49), which was significantly less than that in control group (46.94%). Operation time and bleeding volume in the observation group was less than those in control group. Postoperative improvements of JOA score, VAS score, and NDI in observational group were also significantly better than that in control group ($P<0.05$). Conclusion: The clinical effect of Zero-P and PCB for the treatment of cervical spondylosis was quite fair, but Zero-P showed a better therapeutic effect with improvement of life quality.

Keywords: Cervical spine, Zero-profile device, anterior, intervertebral fusion, plate

Introduction

Cervical vertebra disease is a common spine disease that torments thousands of patients, and patients with this disease will be likely to choose conservative treatment to relieve their pains [1]. However, for those with severe cases, surgery was a prior choice. Anterior cervical discectomy and interbody fusion have become a widely accepted surgical procedure for the treatment of cervical degenerative diseases and they have been well validated in clinical practices [2]. However, this procedure has disadvantages on postoperative dysphagia and stability. With the development of interbody fusion technique, anterior cervical interbody fusion system Zero-profile device comes into use in clinical works [3]. As we notice, there were no head-to-head comparison of Zero-P and anterior cervical plate interbody fusion system (PCB) in clinical practice. Hence, we conducted a comparative study to analyze the clinical effect of Zero-P and PCB for the treatment of cervical spondylosis.

Materials and methods

Patient demographics

A total of 98 consecutive patients (110 segments) with cervical degenerative disc disease who underwent the anterior cervical discectomy and fusion either the Zero-P or PCB between February 2011 and January 2013 were enrolled. There were 86 cases of patients with monosegmental cervical spondylosis and 12 cases of patients with bisegmental cervical spondylosis. The numbers of involving surgical levels of C3/C4, C4/C5, C5/C6, and C6/C7 were 23, 47, 28 and 12, respectively. Preoperatively, radiculop-

Table 1. Demographics of subjects

	Observational group	Control group	*P* value
Patient no.	49	49	-
Sex (male/female)	29/20	29/20	-
Age (year)	43.1±5.3	43.3±5.2	0.853

athy was detected in 10 patients, myeloradiculopathy in 25 patients, and traumatic cervical disc protrusion in 63 patients. There were 58 males and 40 females and the average age was 43.2±5.2 years (range 38-61 years). These patients were divided into two groups: the observational group (49 cases) and control group (49 cases). There were 29 males and 20 females in observational group, and the average age was 43.1±5.3 years (range 38-60 years). There were 29 males and 20 females in control group, and the mean age was 43.3±5.2 years (range 38-61 years). No significant differences of basic information in age, gender and so on were observed between two groups (**Table 1**).

Methods [4]

The patients in the observational group received anterior cervical interbody fusion system Zero-P and those in the control group underwent anterior cervical plate interbody fusion system. The operation time and blood loss in two groups were recorded and analyzed. All participants were followed for 6 months.

Zero-P surgery: After successful general anesthesia, the basic techniques for exposure, discectomy and decompression were performed using a right-sided skin incision. Then, intervertebral space was located by the fluoroscopy of C-arm X-ray machine. Using anterior distraction device, the intervertebral disc and herniated nucleus pulposus were extirpated. Extensive decompression was performed, including removal of the osteophytes. The appropriate size of the anchored intervertebral fusion cage was determined by both preoperative templating and intraoperative evaluation using a trial cage to confirm initial stability. Suitable Zero-P (Johnson & Johnson, USA) was selected and autologous chip bone and recombinant human bone were exclusively placed in the center of a cage. Using an impactor, the cage was inserted into the disc space and then the location of the cage was identified using C-arm X-ray machine. The right place was as follows: C-arm X-ray machine fluoroscopy showed that anteroposterior position of the cage was located in the center of the vertebral body. In lateral projection, front edge of the cage was 2 mm after anterior vertebral body and its trailing edge was not over 5 mm before posterior vertebral body. After implantation of the cage, two cervical anchoring clips were placed into the lower and upper vertebra through the anterior part of the cage to ensure primary stabilization by self-locking function of anchoring clips. The incision was closed in layers in the usual manner. The drain tube was removed at 24 hours after operation. The neck was fixed with neck splint for 3 months. The represented medical images were seen in **Figure 1**.

PCB surgery: Patients with general anesthesia were kept in supine position. Exposure of intervertebral space was performed in a standard manner of discectomy. Extensive decompression was conducted, including removal of intervertebral disc, herniated nucleus pulposus and osteophytes. Then, suitable PCB was selected and fitted tightly together with intervertebral space. C-arm X-ray machine fluoroscopy confirmed that cervical anchoring clips were placed safely. Autologous chip bone was placed into hollow vertebral cage through oval foramen and compressed. The incision was closed in a regular manner. The neck was fixed with neck splint for 3 months.

Outcome assessment [5]

(1) Japanese Orthopaedic Association Scores (JOA) has been widely used and it indicates the objective function of spinal cord. JOA scores were calculated for upper limb function (0-4 scores), lower-extremity function (0-4 scores), sensory level (upper limb: 0-2 scores, Lower limb: 0-2 scores, trunk: 0-2 scores) and bladder function (0-3 scores). The JOA recovery rate, which suggested the degree of postoperative improvements, was calculated using Hirabayashi's formula: (postoperative score-preoperative score) × 100/[17 (full score)-preoperative score]. Excellent, good, fair, poor were defined as JOA recovery rate >75%, 50%-74%, 25%-49%, <25%, respectively. (2) The inci-

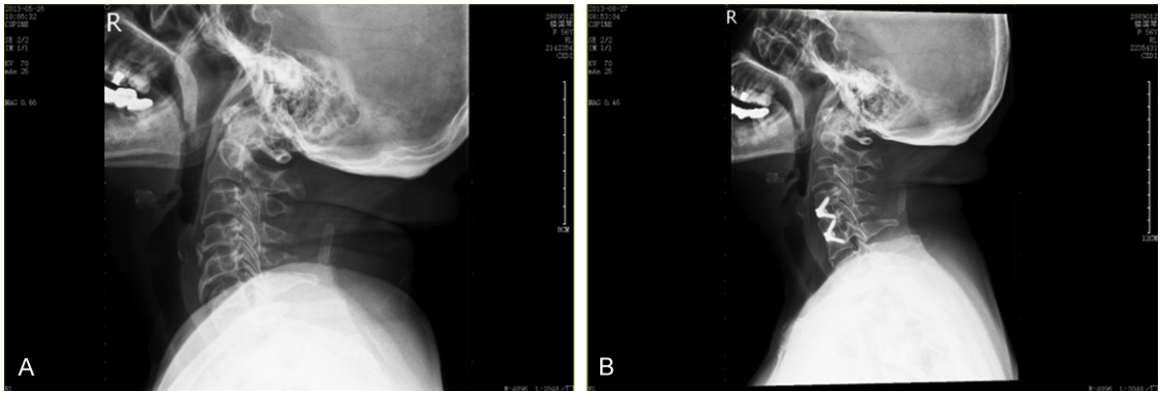

Figure 1. Preoperative and postoperative plain radiographs of cervical vertebral in patients with Zero-P treatment. A. Preoperative x-ray showed degeneration and abnormal physiology curvature of cervical vertebra. B. Postoperative x-ray showed good internal fixation and physiological curvature improvement.

Table 2. Postoperative JOA recovery rate and dysphagia percentage in 2 groups

Group	Case	JOA recovery rate (%)	Postoperative dysphagia (n, %)
Observational group	49	44 (90%)	8 (16.33%)
Control group	49	39 (80%)	13 (26.53%)
x^2 value	-	4.346	10.616
P value	-	0.037	0.001

Table 3. Comparison of operative time and blood loss between two groups (mean ± SD)

Group	Case	Operative time (min)	Amount of bleeding (ml)
Observational group	49	70±17.3	49.5±17.23
Control group	49	87±23.4	65.2±25.33
T value	-	4.089	3.587
P value	-	0.000	0.001

dence of dysphagia was recorded by using the system defined by Bazaz. Severity of dysphagia, which was graded as none (liquid food: none; solid food: none), mild (liquid food: none; solid food: rare), moderate (liquid food: none or rare; solid food: occasionally with specific food) and severe (liquid food: none or rare; solid food: frequently with majority of solid). (3) The quality of life was evaluated by using SF-36. (4) Cervical lordosis was defined as the angle between the lower endplate of C2 and the upper endplate of C7 by using Cobb's method.

Statistical analysis

Statistical analysis was achieved by using SPSS 13.0 software. Enumeration data was analyzed by using Chi-Square test. Measurement data was expressed as mean ± SD. The statistical significance was defined as $P<0.05$.

Results

The JOA recovery rate and dysphagia percentage after surgery in 2 groups

All patients were followed up. The JOA recovery rate was 94% (Excellent 90%, Good 4%, Fair 6%, Poor 0%) in Observational group and 80% (Excellent 77%, Good 3%, Fair 2%, Poor 0%) in Control group. There was significant difference in the JOA recovery rate between two groups ($P<0.05$). In the six months of follow-up, there were 8 (16.33%) patients who complained of dysphagia in Observational group. Among them, 1 patient complained about mild dysphagia and 7 patients complained of moderate dysphagia. There were 13 (26.53%) patients who complained of dysphagia in Control group. 11 patients complained about mild dysphagia and 2 patients complained of moderate dysphagia. And there was statistical significance in the dysphagia percentage between two groups ($P<0.05$), seen **Table 2**.

Outcome results on operation time and blood loss in two groups

The operation time (70±17.3 min) and the amount of bleeding (49.5±17.23) in Observational group were significantly less than those in Control group and the results were statistically significant ($P<0.05$), seen in **Table 3**.

Table 4. Outcomes on JOA, VAS, NDI, SF-36 and Cobb Angle between observational group and control group (mean ± SD)

Parameters	Time	Zero-P (n=49)	PCB (n=49)	T value	*P* value
JOA Score	Pre	8.9±3.1	8.8±3.2	0.157	0.876
	Post	15.3±5.3	10.2±3.9	5.425	0.000
VAS Score	Pre	5.9±2.2	5.8±2.1	0.230	0.819
	Post	1.8±0.73	4.5±1.74	10.016	0.000
NDI (%)	Pre	39.5±13.65	39.8±13.72	0.109	0.914
	Post	13.8±8.75	27.5±11.92	6.486	0.000
SF-36 (%)	Pre	31.9±6.74	32.1±6.54	0.149	0.882
	Post	53.4±10.29	51.2±8.52	0.563	0.234
Cobb Angle (°)	Pre	8.6±5.3	8.7±5.2	0.094	0.925
	Post	15.3±8.7	14.6±6.5	0.550	0.283

PCB: Control group; Zero-P: observational group.

The comparison of the preoperative and postoperative data on JOA score, VAS score, NDI, SF-36 and Cobb Angle between observational group and control group

No significant difference on preoperative JOA scores, VAS scores, NDI, SF-36, and Cobb Angle between the 2 groups was observed (P>0.05). After surgery, the improvements in Observational group were better than those in Control group, particularly in the terms of JOA scores, VAS scores and NDI, seen in **Table 4**.

Discussion

Cervical spondylosis was a common disease as the result of hyperostosis and degenerative change of intervertebral disc, which was often seen in elderly patients [6]. Patients with cervical spondylosis usually suffered from neck and shoulder pain. The compression of adjacent tissue (e.g. nerve root, spinal cord) caused by the degenerative changes of cervical intervertebral disc brought great suffering to patients. As internal fixation system in spine surgery progresss, the effect of anterior cervical discectomy and fusion in treating cervical spondylosis has obtained experimental and clinical verification. Anterior cervical discectomy and fusion was an effective surgical procedure for treatment of cervical spondylosis. PCB was a common clinical anterior surgery based on the technique of anterior cervical discectomy and fusion. However, PCB could lead to different degree of complications in long-term follow-up [7]. Moreover, it was reported that most of patients have clinical symptoms of dysphagia and esophageal injury after PCB [8]. With the increasing development of the requirements for the treatment of cervical spondylosis, Zero-P began to be used in clinical practices. Zero-P not only had the advantages of little trauma and easy recovery, but was with higher fusion rate and less complications compared with PCB.

The comparisons of Zero-P and PCB for the treatment of cervical spondylosis showed as follows: The JOA recovery rate in observational group was 90%, which was better than that in Control group (80%). The operation time and the amount of bleeding in observational group were less than those in Control group. The percentage of dysphagia in the observational group was 16.33% (8/49) and lower than that in Control group. This finding was consistent with the report by Healy et al [9]. They indicated that Zero-P had better clinical effect on cervical spondylosis with less invasive surgical treatments compared with PCB. The surgical procedure of Zero-P system was very simple with relatively short time, which just needed to be fixed by tightening the screws up after placement. In addition, the fixation system was placed in the intervertebral space during Zero-P, which might reduce the incidence of dysphagia caused by protrudent vertebral body. Last but not least, Zero-P was far away from intervertebral space to the greatest extent, which could decrease to the maximum of interference of intervertebral disc. Therefore, postoperative fusion rate was relatively high and Zero-P was highly valued with high stability and easy recovery. The comparisons of related indexes between pre-operation and post-operation showed that there were not significant differences in preoperative parameters such as JOA scores, VAS scores, NDI, SF-36, and Cobb Angle between two groups. However, the postoperative improvement in observational group was better than that in Control group, particularly in JOA scores, VAS scores and NDI. These result were in consistent with the findings reported by Njoku et al [10]. This also indicated that Zero-P could significantly improve neurological function and relieve patients' pain in the

treatment of cervical spondylosis. We considered that interbody fusion cage of Zero-P not only promoted the bone healing and increased the fusion, but also avoided the sink of cage. Therefore, Zero-P had better effect on human pain relief and neurological function improvement, but had no influence on patients' life. Several points regarding to the usage of Zero-P should be noted as follows [11, 12]: (1) Prevertebral fascia was separated until most part of vertebral body was exposed. It was not necessary to completely expose the whole vertebral body, which could reduce operative wound. (2) Prosthesis was selected as large as possible, and try to avoid the cutting of screws. (3) Screws with appropriate length should be selected and attention should be paid to the direction of screws.

In conclusion, both Zero-P and PCB were found with favorable clinical effect in treating cervical spondylosis. Comparatively speaking, Zero-P might be better because of little trauma, high stability and less incidence of dysphagia. In the aspect of quality life improvement and pain relief degree, Zero-P was also better than PCB. However, further studies with robust evidence are needed to confirm the long-term effect of Zero-P.

Disclosure of conflict of interest

None.

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