Original Article

The Results of Anterior Cervical Fusion Compared between Autologous Iliac Bone Graft and Beta-Tricalcium Phosphate: Clinical and Radiological Results

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Objective: To compare beta-tricalcium phosphate (TCP) with autologous iliac crest bone graft (AIB) by using the results of anterior cervical discectomy and inter-body fusion procedure.

Materials and Methods: The present study was a prospective cohort study of 55 patients suffering from cervical spondylopathy treated at Hatyai Hospital, between January 2015 and December 2018.

Results: All study patients were diagnosed as either cervical spondylosis radiculopathy or myelopathy. They were recruited and divided into two groups: 29 cases of AIB, and 26 cases of TCP. The aims of the present study were to determine inter-vertebral bony fusion, to verify visual analog score and the Japanese Orthopedic Association cervical myelopathy score. Questionnaire and radiographic study were used to evaluate results, which showed no difference. However, patients' post-operative complication and satisfaction were significantly different.

Conclusion: For cervical fusion, both AIB and TCP demonstrated the same results, but TCP had less pain and complication.

Keywords: Anterior cervical spine inter-body fusion, Tricalcium phosphate, Autologous iliac bone graft

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The anterior cervical discectomy and fusion (ACDF) procedure has gained popularity since its introduction in the 1950s by Smith-Robinson and Cloward[1-3]. The autologous iliac crest bone graft (AIB) has been most commonly used as the gold standard[4,5]. Moreover, AIB is used to restore the height of intervertebral space after discectomy. However, there were some reports on adverse effects of the donor site. For example, femero-cutaneus nerve injury, hematoma, infection, and chronic bone pain were found in up to 24%[6,7]. The ideal graft material should be composed of three basic properties, osteo-genicity, osteo-conductivity, and osteo-inductivity. Therefore, the development of alternative graft[8,9] and instruments have been widely studied. As a result, to achieve cervical stability, Polyetheretherketone (PEEK) inter-body cage containing bone graft was used. The cages prevented bone graft collapse and restored disc space height[13-17].

To avoid bone-graft harvesting, bone graft substitute like beta-tricalcium phosphate (TCP) has been used for bone regeneration[10-12].

TCP is an osteo-conduction material that has been used as bone substitute for many years. The clinical results have been reported in many studies[13-17].

The present study aimed to compare autologous tri-cortical iliac crest bone graft with PEEK contained with TCP in cervical spondylosis radiculopathy and myelopathy to evaluate fusion rate, clinical outcomes (VAS, JOA, Odom's score), and radiographic results.

PEEK was obtained from CeSPACE cage, B. Braun (Figure 1).

TCP was obtained from Excelos, Daewoong Pharmaceutical, Korea.

All patients underwent ACDF with "ABC cervical plate" (B. Braun) by Tantammaroj P.

The present study was approved by the Ethics

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Figure 1. Peek and Beta tricalcium phosphate.

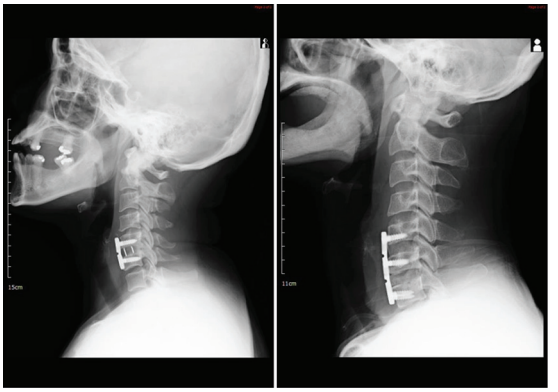

Figure 2. Anterior cervical discectomy and fusion.

Committees of Hatyai Hospital with protocol number 87/2558.

The study design was prospective cohort, conducted between January 2015 and December 2018.

Materials and Methods

The present study was approved by the Committee of Medical Ethics and the Institutional Review Board of the authors hospital. Fifty-five patients who underwent ACDF between January 2015 and December 2018 participated in the present study after their written consent was signed and discussion with the surgeon. Their diagnoses was either cervical spondylosis radiculopathy or myelopathy. They were conventionally treated for at least three months, but the outcome was quite unsatisfactory.

The patient's inclusion criteria were degenerative disc causing radiculopathy or myelopathy. The patient's exclusion criteria were active infection, osteoporosis, gross obesity, ossified posterior longitudinal ligament, prior cervical surgery, and major psychological problems.

ACDF was performed at C3-4 to C6-7.

Surgical procedure

All patients were operated by a certified orthopedic surgeon. The standard left side anterior Smith-Robinson approach was chosen as the surgical procedure under general anesthesia. Surgical level was confirmed by C-arm fluoroscope. The disc space was identified and distracted with Caspar distractor. The pathologic disc and osteophyte were removed until posterior longitudinal ligament was visualized.

The upper and lower cartilage end plates were removed for the optimized bone graft interface.

The inter-body fusion with PEEK case (CeSPACE, B. Braun) containing TCP, 34 levels was performed in 26 patients, and tricortical AIB, 41 levels in 29 patients (Figure 2).

All patients underwent anterior cervical plate fixation (ABC plate, B-braun). The correct position was confirmed by intra-operation C-arm fluoroscope before wound closure. Soft collar was used for four weeks during post-operative period.

Assessment

The operative time, blood loss, and duration of hospital stay were recorded.

After surgery, the radiographic examination was performed on the first day, six weeks, three months, six months, and one year.

The radiographic inter-body bony fusion was evaluated with X-ray cervical spine lateral view. Bony fusion was considered successful if bridging bone incorporating the graft/PEEK and adjoining endplates was apparent[18]. The X-ray was done on digital radiographs using integrated software to measure distance up to 0.01 mm. To validate the assessed data, the measurements were performed independently by two examiners: one orthopedic surgeon and one radiologist.

Statistical analysis

The Student t-test was used for paired comparisons of quantitative data including visual analog score (VAS), the Japanese Orthopedic Association (JOA) cervical myelopathy. The Mann-Whitney U test was used for Odom's criteria. All analyses were performed with computer program. Significance was set to p-value less than 0.05 a priori.

The clinical outcomes were assessed by 1) JOA cervical myelopathy evaluated questionnaire (score 0 to 17), 2) VAS score 0 to 10, 3) Odom's criteria[19], and 4) complications.

Results

Initially, there were 60 cases, but data could be collected on only 55 patients.

In the TCP with PEEK, there were 34 levels in 26 patients (Table 1), and in the autologous iliac crest graft, there were 41 levels in 29 patients.

The average operative time was 61±10.5 minutes for one level surgery and 78±11.8 minutes in two levels surgery of TCP group.

The average operative time 68±11.0 minutes for one level surgery and 85±13.7 minutes in two and three levels bone-graft group. The operative time is significantly longer in autologous bone graft group ($p<0.01$).

In TCP group, the mean blood loss was significantly lower than AIB group (70±15.9 ml) versus (102.5±186 ml). There was no statistically significant difference of hospital stay between the two groups (6.5±1.5 days versus 7±1.8 days, $p<0.05$). However, there was one patient who underwent the second operation due to graft migration.

Table 1. Demographic data

Parameters	TCP group n	AIB group n
No. of cases	26	29
Age (years), Mean±SD	52.6±10.7	54.3±11.5
Sex (female/male)	10/16	12/17
Preoperative pathology radiculopathy	12	13
Myelopathy	14	16
Degenerative segment		
C3 to C4	1	2
C4 to C5	15	15
C5 to C6	17	22
C6 to C7	1	2
Level of fusion		
Single level	18	18
Double level	8	10
Triple level	0	1

TCP=tricalcium phosphate; AIB=autologous iliac bone graft; SD=standard deviation

Visual analog score (score 0 to 10)

In TCP and AIB groups, the post-operative neck and arm pain measured by VAS showed significant relief ($p<0.05$) when compared to pre-operative score (Table 2).

However, no significant difference of improvement in VAS was observed between the two groups ($p=0.1836$). The pre-operative pain of AIB group decreased from 7.8 points, to 2.5 points after post-operative time, and the mean of improvement was 6.5±2.1 points, while TCP group improved from 7.5 to 2.4 points on average, with the mean improvement of 5.6±2.8 points.

No significant differences were found in both the TCP group and the AIB group at any follow-up time.

The JOA scoring system (score 0 to 17)

The average JOA score improved in each case. The pre-operative average JOA score was 13.1±1.8 points in TCP group, and 12.7±1.5 in the autologous bone graft group. At the final follow up, in TCP group, the average JOA score improved significantly ($p<0.01$) to 16.6±0.7 points and 16.5±0.6 in autologous bone graft group (Table 3).

There were no differences ($p>0.05$) when comparing the JOA scores of the two groups at all time intervals. The recovery rate was 83.8% in TCP group, and 83.0% in AIB group.

Radiographic findings

In the AIB group, 97.5% (40/41 levels) fusion rate was achieved in 6-post-operative months and remained unchanged until one year of follow up time. One case demonstrated radiolucent until one year,

Table 2. VAS before and after operation

Measurement time point	Neck pain, Mean±SD			Arm pain, Mean±SD		
	AIB	TCP	p-value	AIB	TCP	p-value
Pre-operative	7.4±2.0	7.2±2.3	0.460	8.1±1.6	7.8±2.0	0.421
Post-operative at discharge	4.5±2.7	4.5±2.6	0.381	3.9±3.5	4.4±2.0	0.355
Three months	3.3±2.2	3.6±2.4	0.405	3.5±2.1	3.4±2.6	0.421
Six months	2.8±1.9	2.6±2.0	0.386	2.6±1.8	2.7±2.0	0.359
12 months	2.6±1.8	2.3±1.8	0.342	2.4±1.9	2.5±1.3	0.370

TCP=tricalcium phosphate; AIB=autologous iliac bone graft; SD=standard deviation

Table 3. JOA score

JOA score	AIB Mean±SD	TCP Mean±SD	p-value
Pre-operative	12.7±1.5	13.1±1.8	0.723
Post-operative	15.2±2.0	14.8±2.5	0.568
Three months	15.7±1.0	15.8±1.2	0.836
Six months	15.9±0.87	16.0±0.9	0.581
12 months	16.5±0.6	16.6±0.7	0.624

TCP=tricalcium phosphate; AIB=autologous iliac bone graft; SD=standard deviation

Table 4. Odom's criteria

Rating	Odom's criteria
Excellent	No complaints referable to cervical disc disease, able to continue daily occupation without impairment
Good	Intermittent discomfort related to cervical disease but not significantly interfering with work
Fair	Subjective improvement but physical activities limited
Poor	No improvement or worse compared with the condition before the operation

Variable	PEEK+TCP (n=26)	AIB (n=29)	p-value
Odom's criteria, n			0.004
Excellent	10	2	
Good	10	10	
Fair	6	17	
Poor	0	0	
Success of surgery, n (%)	20 (76.9)	12 (41.3)	

PEEK=polyetheretherketone; TCP=tricalcium phosphate; AIB=autologous iliac bone graft

but there was no significant motion in flexion and extension view (Figure 2). There were three cases of AIB subsidence and one case of graft migration that required reoperation. However, the fusion rate of the group using PEEK containing TCP was 70% at six months and 96.77% at one year.

Odom's criteria

In the TCP group, 10 of 26 cases were found to be excellent (38.46%), 10 cases of being good (38.46%), and six cases of being fair (16.66%). Meanwhile, in the AIB group, two of 29 cases were found to be excellent (6.89%), 10 cases of being good (34.48%), and 17 cases of being fair (58.62%). According to the Mann-Whitney U test, p-value was 0.004. By conventional criteria ($p<0.05$), this difference is statistically significant (Table 4).

Complications

There were complications in the AIB group, which had three cases of post-operative hematoma and four cases of painful scar, nevertheless, infection was not found in either groups.

Discussion

ACDF is the treatment of choice for cervical radiculopathy and myelopathy patients who did not respond to conservative treatment. Autologous tri-cortical iliac crest graft is considered as the gold standard. The ideal bone graft consists of three main properties, osteo-conduction, osteo-induction, and osteo-genicity. However, problems at the the donor site including pain, nerve injury, infection, fracture etc., had been reported as high as 10% to 24%. Therefore, the fusion materials, such as femoral and tibial allograft were used as surgical fusion material. Allografts obtained from donor has showed many problems, such as infection, non-union, and viral transmission[20-22]. All of these problematic factors have led to importance of research and development of synthetic material to use in spinal fusion.

To solve such the problems, the author used PEEK containing beta-TCP to replace the bone graft for cervical inter-body fusion. This procedure helps avoidance of donor site morbidity and reduce surgical time as well as bleeding. Moreover, this procedure provides immediate stability, restores foramina height and alignment, minimizes operative time, and the most importantly, alleviates donor site pain.

Clinical outcomes were measured with VAS (0 to 10) and the JOA score. Both groups improved significantly. At pre-operative time, neck pain score decreased from 7 to 8 points to 4 to 4.5 points at post-operative time to discharge. Between 6 and 12 months, the average VAS was 2.5. The arm pain showed the same clinical outcomes as the neck pain. Functional outcome was reported with JOA score, and the results of both groups improved immediately. Post-operative score increased from 12 to 13 points to an average of 15 points. At the one year follow-up, it was 16 to 17 points in both groups. In addition, the ACDF surgery directly decompressed pressure on nerve root and spinal cord with radical discectomy. PEEK and Iliac bone graft increased inter-vertebral disc height and nerve root foramen.

Radiographic assessment of fusion rate undertook ACDF with AIB was achieved in 97.5% (40/41 levels) in comparison to inter-body PEEK containing TCP, which was in 96.77% (30/31 levels). There was not statistically significant.

The mean of blood loss was significantly different in both groups where in TCP group it was 70 ml on average versus AIB group, which was 102 ml on average. The operative time of TCP group was 61 minutes on average versus 78 minutes in bone graft. The difference was due to the additional harvesting of bone graft surgery on iliac crest donor site.

Odom's criteria were used to evaluate the patients' satisfaction. In TCP group, 20 patients out of 26 patients expressed satisfaction at the good to excellent level. The patients' satisfaction in AIB was 12 out of 29 patients. The difference was due to bone harvesting. This was considered as an invasive procedure. After the post-operative period, patients complained about donor site pain immediately, and the pain remained through the follow-up period. Moreover, according to Mann-Whitney U test, the difference was statistically significant.

Although the fusion rate in both groups were the same, the surgical time and blood loss was less in the TCP groups.

Limitation

The main limitations of the present study were relatively small population, and inadequate follow up time (12 months). In addition, statistical calculation was hindered by the uneven distribution of patient-groups.

The assessment of inter-body fusion was limited because the present study used plain X-ray lateral view of cervical spine. Computed tomography (CT) scanning fine cut is more reliable and sensitive for diagnosis of pseudarthrosis than plain X-ray. The CT scan fee is too expensive for routine investigation. The economic limitation was a study disadvantage[23].

Conclusion

Based on the present study, with the purpose of avoiding morbidity at iliac crest donor site, the author found that using PEEK containing TCP for ACDF proved to be an effective treatment for cervical spondylosis radiculopathy and myelopathy. No statistically significant difference was found in clinical outcomes (12 months follow-up), compared to the autologous iliac crest graft.

While the results of ACDF with anterior iliac crest bone graft have been considered to be good up to excellent, there are a lot of complications on donor site. Hence, beta-TCP is one of the bone synthetic fusion materials that can be considerably beneficial to bony fusion of cervical spine.

What is already known on this topic?

This study reported similar results of bony fusion in autologous bone graft and beta-tricalcium phosphate groups. Less blood loss, less surgical time, and no donor site complications were consider being advantages of the TCP group.

Based on this study, it is possible to use TCP as bony fusion material for cervical spine in the future.

What this study adds?

Although the results of using TCP and AIB for cervical fusion were found to be similar, TCP was considered more beneficial than AIB with less complications and more patients' satisfaction.

Conflicts of interest

The author declares no conflict of interest.

References

1. Cloward RB. The anterior approach for removal of ruptured cervical disks. J Neurosurg 1958;15:602-17.
2. Ryu SI, Lim JT, Kim SM, Paterno J, Willenberg R, Kim DH. Comparison of the biomechanical stability of dense cancellous allograft with tricortical iliac autograft and fibular allograft for cervical interbody fusion. Eur Spine J 2006;15:1339-45.
3. Smith GW, Robinson RA. The treatment of certain cervical-spine disorders by anterior removal of the intervertebral disc and interbody fusion. J Bone Joint Surg Am 1958;40-A:607-24.
4. Samartzis D, Shen FH, Goldberg EJ, An HS. Is autograft the gold standard in achieving radiographic fusion in one-level anterior cervical discectomy and fusion with rigid anterior plate fixation? Spine (Phila Pa 1976) 2005;30:1756-61.
5. Wright IP, Eisenstein SM. Anterior cervical discectomy and fusion without instrumentation. Spine (Phila Pa 1976) 2007;32:772-4.
6. Silber JS, Anderson DG, Daffner SD, Brislin BT, Leland JM, Hilibrand AS, et al. Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. Spine (Phila Pa 1976) 2003;28:134-9.
7. Younger EM, Chapman MW. Morbidity at bone graft donor sites. J Orthop Trauma 1989;3:192-5.
8. Beaman FD, Bancroft LW, Peterson JJ, Kransdorf MJ. Bone graft materials and synthetic substitutes. Radiol Clin North Am 2006;44:451-61.
9. Ludwig SC, Boden SD. Osteoinductive bone graft substitutes for spinal fusion: a basic science summary.

Orthop Clin North Am 1999;30:635-45.
10. Giannoudis PV, Dinopoulos H, Tsiridis E. Bone substitutes: an update. Injury 2005;36 Suppl 3:S20-7.
11. Chau AM, Xu LL, Wong JH, Mobbs RJ. Current status of bone graft options for anterior interbody fusion of the cervical and lumbar spine. Neurosurg Rev 2014;37:23-37.
12. Cheng L, Ye F, Yang R, Lu X, Shi Y, Li L, et al. Osteoinduction of hydroxyapatite/beta-tricalcium phosphate bioceramics in mice with a fractured fibula. Acta Biomater 2010;6:1569-74.
13. Aunoble S, Clement D, Frayssinet P, Harmand MF, Le Huec JC. Biological performance of a new beta-TCP/PLLA composite material for applications in spine surgery: in vitro and in vivo studies. J Biomed Mater Res A 2006;78:416-22.
14. Burchardt H. The biology of bone graft repair. Clin Orthop Relat Res 1983;28-42.
15. Dai LY, Jiang LS. Anterior cervical fusion with interbody cage containing beta-tricalcium phosphate augmented with plate fixation: a prospective randomized study with 2-year follow-up. Eur Spine J 2008;17:698-705.
16. Dai LY, Jiang LS. Single-level instrumented posterolateral fusion of lumbar spine with beta-tricalcium phosphate versus autograft: a prospective, randomized study with 3-year follow-up. Spine (Phila Pa 1976) 2008;33:1299-304.
17. Hernigou P, Roussignol X, Flouzat-Lachaniette CH, Filippini P, Guissou I, Poignard A. Opening wedge tibial osteotomy for large varus deformity with Ceraver resorbable beta tricalcium phosphate wedges. Int Orthop 2010;34:191-9.
18. Park HW, Lee JK, Moon SJ, Seo SK, Lee JH, Kim SH. The efficacy of the synthetic interbody cage and Grafton for anterior cervical fusion. Spine (Phila Pa 1976) 2009;34:E591-5.
19. Odom GL, Finney W, Woodhall B. Cervical disk lesions. J Am Med Assoc 1958;166:23-8.
20. Bishop RC, Moore KA, Hadley MN. Anterior cervical interbody fusion using autogeneic and allogeneic bone graft substrate: a prospective comparative analysis. J Neurosurg 1996;85:206-10.
21. Delloye C, Cornu O, Druez V, Barbier O. Bone allografts: What they can offer and what they cannot. J Bone Joint Surg Br 2007;89:574-9.
22. Floyd T, Ohnmeiss D. A meta-analysis of autograft versus allograft in anterior cervical fusion. Eur Spine J 2000;9:398-403.
23. Carreon LY, Glassman SD, Djurasovic M. Reliability and agreement between fine-cut CT scans and plain radiography in the evaluation of posterolateral fusions. Spine J 2007;7:39-43.