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ORIGINAL STUDY

Early results of one-level cervical discectomy and fusion with stand-alone cervical cage and bone marrow soaked tricalcium phosphate

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Cervical disc prolapse has been traditionally treated with anterior discectomy and fusion, with good results ; however autogenous bone graft and instrumentation remain a limiting factor. To avoid this, a stand-alone cage with bone marrow soaked tricalcium phosphate was used for single level cervical disc disease. Fifteen consecutive patients with single level cervical disc disease operated with the above technique were prospectively followed at six weeks, six and twelve months post-surgery. Clinical improvement was assessed by VAS and Odom's criteria. CT and plain radiography were used to assess fusion. Mean duration of symptoms was 7.2 months (SD : 4.14, range : 1-18 months). Mean preoperative VAS was 7 (SD : 1.31, range : 5-10) which improved to 1.4 (SD : 0.63, range : 1-3) at 6 weeks post op, 0.93 (SD : 0.80, range : 0-3) at 6 months and 0.80 (SD : 0.77, range : 0-3) at final follow-up. Similarly Odom's criteria were excellent in ten, good in three and satisfactory in 2 patients at six weeks. Results were rated excellent in eleven patients, good and satisfactory in two patients each respectively at six months and final follow-up. All patients had radiological fusion with no sign of cage extrusion.

Results with this technique in terms of fusion, pain relief and overall functional outcomes were found to be good in this small patient population and warrant a larger sample size randomized long-term study.

Keywords : cervical discectomy ; stand alone cage ; bone graft substitute.

INTRODUCTION

Where conservative management has failed, a symptomatic prolapsed cervical disc has been treated traditionally with anterior discectomy and fusion, with good results. However, the bone graft remains the limiting factor with problems of fracture, arterial and nerve injury while harvesting bone graft ; and infection, herniation, non union, collapse and extrusion in the follow-up period *(22)*. Bone grafting causes significant donor site morbidity in the long run, with up to 25% of patients reporting

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chronic pain refractory to treatment (*28*). This was seen even when the graft was taken for a single-level cervical discectomy and many patients reported functional impairment leading to restriction of daily activities (*25*). Anterior plate stabilization of grafted bone was introduced to reduce complications of graft extrusion and enhance fusion. However, in spite of newer low-profile plates, the possibility of implant failure (*3*) and injury to anterior structures such as trachea, oesophagus, and carotid arteries still remain (*10,21*). Application of these plates also entails additional operative time for the surgeon and extra cost for patients, both of which are valuable in a developing country scenario (*11*).

Insertion of bone graft into the intervertebral space acts as a spacer which leads to increased foraminal height, better sagittal alignment of the cervical spine with overall superior functional outcomes (*1,26*). With the intention of preserving the benefits of spacer effects while reducing dependency on bone graft and avoiding anterior implant associated complications, stand-alone cages were introduced, first for the lumbar spine and subsequently for the cervical spine. Stand-alone cages have been shown to be reliable for one or two-level cervical discectomy procedures with restoration of disc height and immediate load bearing, with shorter hospital stays and lesser pain scores (*6,8,13,18,19,30*). These cages are usually filled with cancellous bone graft from osteophytes and body of vertebrae obtained during the surgical procedure. The quantity of this locally harvested graft may be insufficient even in single level disc disease, due to the effort to save the bony end plates to prevent long term subsidence (*9*), especially in younger patients. Due to these problems, an attempt was made to replace autologous bone graft with banked allograft bone. However bone allografts reportedly had problems of pseudoarthrosis, decreased fusion and potential risk of disease transmission (*29*). In light of these shortcomings, bone graft substitutes were explored for use in anterior cervical discectomy and fusion (ACDF). Many reports of use of bone substitutes such as hydroxyapatite (HA) with augmented plate fixation and cages (*12*) have appeared in literature, with a few reports on use of beta-tricalcium phosphate (β-TCP) (*4*). Studies show that β-TCP may allow better bony replacement when compared to HA (*32*). Further it has been shown in a canine lumbar spine model that use of β-TCP in cages yields fusion results comparable with those obtained using autograft-filled cages, which obviated the need for harvesting autograft (*16*). Later in another canine model study it was also shown that, rh-bmp-2 (recombinant bone morphogenetic protein-2) mixed β-TCP had best fusion quality and quantity of fusion mass amongst autograft, β-TCP alone and rh-bmp-2 mixed β-TCP for cages (*17*). We present our early experience with stand-alone cervical cage (Syncage®, Synthes) filled with bone substitute β-TCP (Chronos™, Synthes) soaked in autologous bone marrow aspirate for single-level disc disease in the cervical spine.

MATERIALS AND METHODS

After approval, this prospective study was carried out in 15 consecutive patients with prolapse of a single cervical disc. Patients were enrolled after informed written consent.

Strict inclusion criteria were followed which consisted of patients having clinically and radiologically documented single-level prolapsed cervical disc with monoradicular signs which failed to respond to conservative management. Patients with diabetes mellitus, peripheral neuropathy, multiple level disc prolapse, canal stenosis, myelopathic signs, recurrent disc, and those with involvement in litigation, any known psychiatric illness or previous surgery on the cervical spine were excluded from the study.

Preoperative workup

Detailed preoperative work up including history, neurological examination and routine laboratory investigations was done. Radiological examination consisted of cervical spine AP and lateral radiographs including flexion extension views taken within the comfort range. All cases correlating clinically with radiological signs were included in the study. The procedure was explained to the patient and written consent was obtained. Pre operative visual analogue scale which is an effective instrument for pain quantification (*20*) was explained to the patient and readings were obtained for clinical assessment of pain.

Operative technique

We used Robinson's technique (*27*) of anterior cervical discectomy. The patient was placed supine after induction of general anaesthesia, with a folded cloth under the interscapular region to keep the neck extended. The disc level was checked under image intensifier and a vertical incision was made along the medial border of the left sternocleidomastoid. The platysma was incised in line with the skin incision. The incision was extended to the superficial layer of the deep cervical fascia, then the carotid was palpated and the carotid sheath retracted laterally while the rest of the structures – sternohyoid, sterno - thyroid, omohyoid muscles, the oesophagus, trachea and thyroid gland – were retracted medially. Following this, the vertebral body was exposed after vertically incising the prevertebral fascia. With cervical retractors in place the discectomy was done thoroughly, taking care to excise all bony spurs at that level and reconfirming the decompression. The cartilaginous endplates were carefully removed with the help of a high-speed diamond tip burr, preserving the bony end plate. Sizing was done by trials to ascertain the proper size of cage which would maintain the tension of residual soft tissue supporting structures. A Syncage® filled with Chronos™ along with locally harvested bone graft mixed with bone marrow aspirate, was implanted in the intervertebral disc space. The wound was closed in layers, over a suction drain.

Post operative Management

The patients were given a hard cervical collar in the immediate postoperative period and usually were allowed to ambulate on the second postoperative day after drain removal. The cervical collar was continued for 6 weeks to provide minimal restraint to the neck and remind the patient to avoid strenuous activities.

Follow-up protocol

All operated patients were followed at 6 weeks, 6 and 12 months after surgery. The variables observed at regular intervals were visual analogue scale, Odom's criteria (*15*) for clinical improvement and plain radio - graphs and CT scan for radiological fusion. Fusion was identified as continuous bridging bone seen in sagittal sections of the CT scan.

Statistical analysis

The data was entered in Excel sheet for evaluation and SPSS software was used to carry out analysis of data.

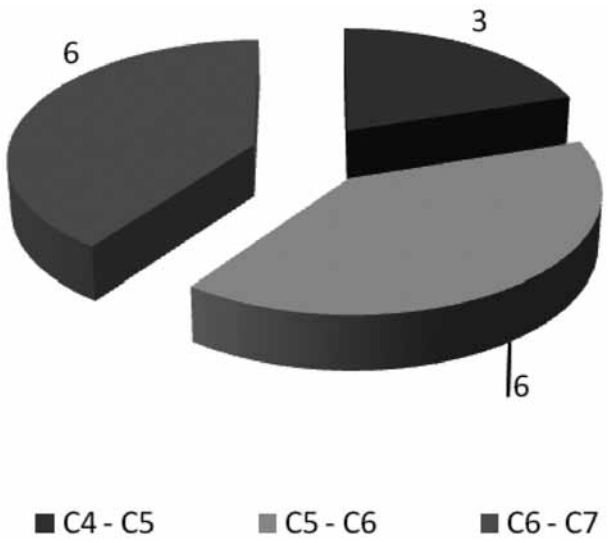

Fig. 1. — Distribution of patients according to the site of lesion

Student's t-test was carried out to analyze the data and test significance. P values smaller than 0.05 were considered significant.

RESULTS

This study included 15 patients (9 males, 6 females), with a mean age of 45.3 years (SD 6.18, range : 32-56). The most common levels of cervical disc prolapse were C5-C6 and C6-C7 as shown in Fig. 1. Most patients (12/15) had spontaneous onset of symptoms with only three having a history of trauma (20%). The mean duration of symptoms was 7.2 months (SD 4.14, range : 1-18 months). The main symptom was radiating pain into either arm (13/15 patients) ; no patient had bilateral radiation. However paraesthesia was present in 11 patients whereas mild weakness in one upper limb was present in only 3 patients. All patients with weakness had 4/5 power in the upper limb with hyperreflexia. Six patients had some sensory loss in the dermatome compressed by the disc. Preoperative visual analogue scale (VAS) was measured for all patients in the preoperative period and follow-up period with values as mentioned in Fig. 2. The mean preoperative VAS score for pain was 7 (SD 1.31, range : 5-10) which improved to

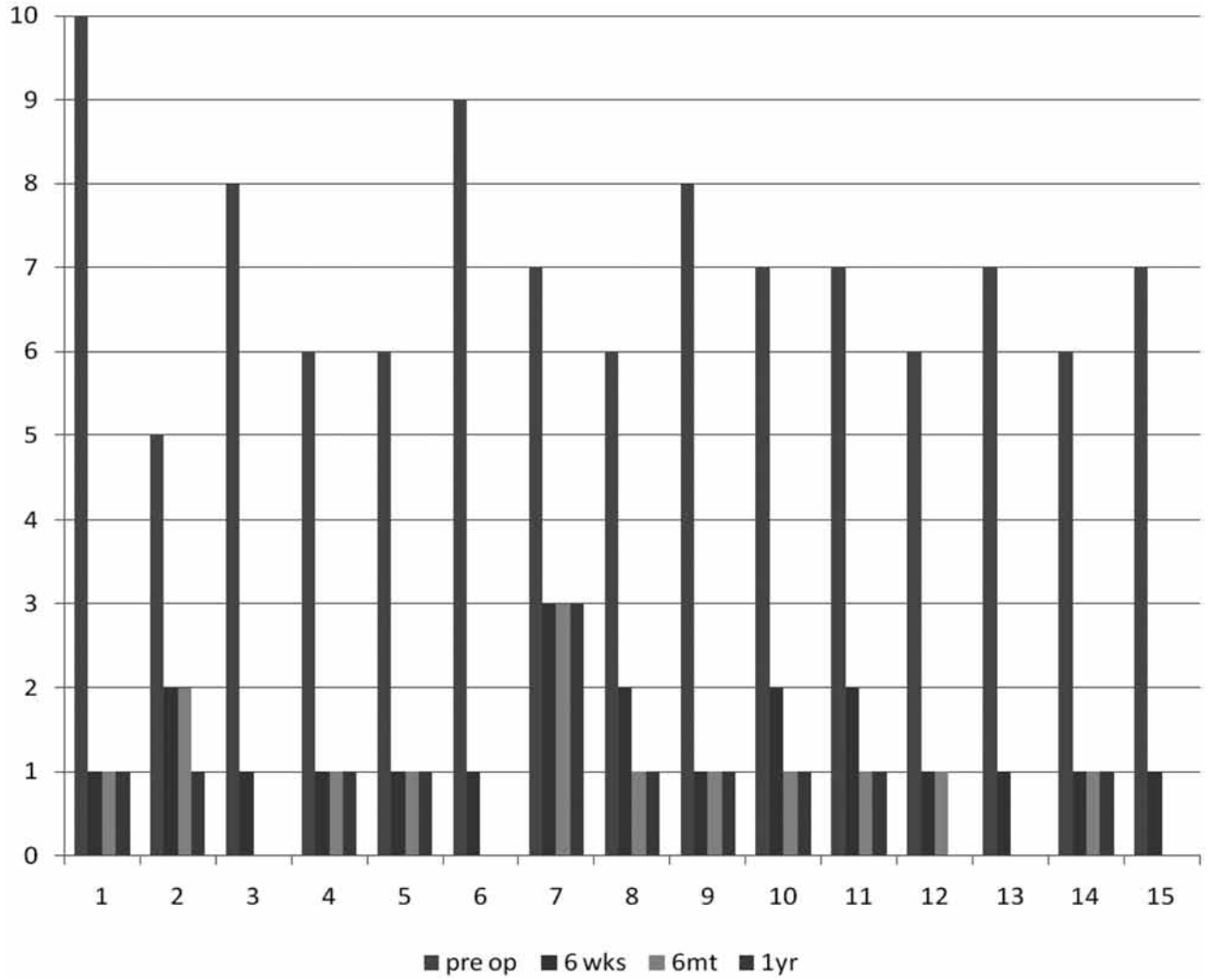

Fig. 2. — Visual analogue scale (VAS) values for all patients in the preoperative and follow-up periods

1.4 (SD 0.63, range 1-3) at 6 weeks post operatively. The VAS score for pain further improved, to a mean value of 0.93 (SD 0.80, range : 0-3) at six months and 0.80 (SD 0.77, range 0-3) at final follow-up. Similarly the outcome based on Odom's criteria was excellent in ten, good in three and satisfactory in two patients at six months, which improved to excellent results in eleven patients, good and satisfactory in two patients each at six months. The grading for Odom's criteria at final follow-up was the same as at six months in all patients. Bony fusion was not seen at six weeks in all patients. However, at six months 14 out of 15 patients had bony fusion bridging the two vertebrae on sagittal cuts of the CT scan. The one patient who did not have signs of union at 6 months ultimately had fusion at final follow-up. No major complication was reported except one superficial infection which resolved with a week of iv antibiotics (cefoperazone & sulbactam) followed by oral antibiotics for the next 3 weeks.

DISCUSSION

Multicenter prospective studies have established the safety of stand-alone cervical cage. Our study

included patients with single-level prolapsed cervical intervertebral disc treated by discectomy and a stand-alone cage filled with beta tricalcium phosphate and bone marrow aspirate. The main presenting symptom in our series was radiating pain (86.7%) to either arm. This was similar to Clement *et al*'s (*2*) observation of unilateral pain as the most common symptom in 87% of patients in their study group of 94 patients. The most common operative disc levels were C5-C6 (55%) and C6-C7 (35%) as reported by Hacker *et al* (*6*) whereas in our study the majority of patients were equally distributed at these disc levels. The results of this study show that stand-alone cages provided relief of symptoms. The VAS score dramatically dropped from a mean value of 7 to 1.6 at six weeks, a significant improvement ($p < 0.05$), similar to the findings of Vicario *et al* (*31*). The VAS further improved marginally at six months and one year. At final follow-up all patients had a VAS of less than or equal to 3. Pain relief coincided with overall improvement in Odom's criteria with excellent or good results in 86.6% of patients. Hwang *et al* (*7*) reported 92% excellent and good results with titanium cages, versus 75% and 77.77% respectively for Vicario *et al* (*31*) and Schroder *et al* (*24*). The fusion rate in our study was 93.3% at six months and 100% at one year, in line with the 95% fusion rate noted by Hwang *et al* (*7*) and Moreland *et al* (*14*) at six months, and 98% after two years reported by Schmeider *et al* (*23*).

The early results of this technique in terms of fusion, pain relief and overall functional outcomes were found to be good in this small patient population, comparable to established techniques of anterior cervical disk fusion, with minimal complications. This can be a viable alternative in the management of single-level cervical disc disease in a properly selected patient. A randomized controled study based on these results on a larger sample size is being planned.

REFERENCES

1. **Bohlman HH, Emery SE, Goodfellow DB, Jones PK.** Robinson anterior cervical discectomy and arthrodesis for cervical radiculopathy. *J Bone Joint Surg* 1993 ; 75-A : 1298-1307.
2. **Clements DH, O'Leary PF.** Anterior cervical discectomy and fusion. *Spine* 1990 ; 15 : 1023-1025.
3. **Coe JD, Vaccaro AR.** Complications of anterior cervical plating. In : Clark CR, Benzel EC, Currier BL et al (eds). *The Cervical Spine*. 4th ed. Lippincott Williams & Wilkins, Philadelphia, 2005.
4. **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.
5. **Hacker RJ.** A randomised prospective study of an anterior cervical fusion device with a minimum of 2 years follow-up results. *J Neurosurg (Spine 2)* 2000 ; 93 : 222-226.
6. **Hacker RJ, Cauthen JC, Gilbert TJ.** A prospective randomized multicenter clinical evaluation of an anterior cervical fusion cage. *Spine* 2000 ; 25 : 2646-2655.
7. **Hwang SL, Hwang YF, Lieu AS *et al.*** Outcome analysis of interbody titanium cage fusion used in the anterior discectomy for cervical degenerative disc disease. *J Spinal Disorder Tech* 2005 ; 18 : 326-331.
8. **Kadziora F, Pflugmacher R, Schafer J *et al.*** Biomechanical comparison of cervical spine interbody fusion cages. *Spine* ; 2001 ; 26 : 1850-1857.
9. **Kettler A, Wilke HJ, Claes L.** Effects of neck movements on stability and subsidence in cervical interbody fusion : An in vitro study. *J Neurosurg* 2001 ; 94 (1 Suppl) : 97-107.
10. **Lee MJ, Bazaz R, Furey C, Yoo J.** Influence of anterior cervical plate design on dysphagia : a 2-year prospective longitudinal follow-up study. *J Spinal Disord Tech* 2005 ; 18 : 406-409.
11. **Lowery GL, McDonough RF.** The significance of hardware failure in anterior cervical plate fixation. Patients with 2 to 7 year follow-up. *Spine* 1998 ; 23 : 181-186.
12. **McConnell JR, Freeman BJ, Debnath UK *et al.*** A prospective randomized comparison of coralline hydroxyapatite with autograft in cervical interbody fusion. *Spine* 2003 ; 28 : 317-323.
13. **Meier U, Grave A, Hajdukova A.** Clinical experience with Cespace, the new intervertebral disc spacer by Aesculap for spondylodesis of the cervical spine in comparison with similar products by Weber, Intromed and AcroMed. *Neurosurg Q* 2003 ; 13 : 40-50.
14. **Moreland DB, Asch HL, Clabeaux DE *et al.*** Anterior cervical discectomy and fusion with implantable titanium cage : initial impression, patient outcomes and comparison to fusion with allograft. *Spine J* 2004 ; 4 : 184-191.
15. **Odom GL, Finney W, Woodhall B.** Cervical disc lesions. *JAMA* ; 1958 ; 166 : 23-28.
16. **Ohyama T, Kubo Y, Iwata H, Taki W.** Beta-tricalcium phosphate as a substitute for autograft in interbody fusion cages in the canine lumbar spine. *J Neurosurg* 2002 ; 7 (3 Suppl) : 350-354.
17. **Ohyama T, Kubo Y, Iwata H, Taki W.** Beta-tricalcium phosphate combined with recombinant human bone morphogenetic protein-2 : a substitute for autograft, used for

packing interbody fusion cages in the canine lumbar spine. *Neurol Med Chir (Tokyo)* 2004 ; 44 : 234-240 ; discussion 241.

18. **Payer M, May D, Reverdin A, Tessitore E.** Implantation of an empty carbon fibre composite frame cage after single-level anterior cervical discectomy in the treatment of cervical disc herniation : preliminary results. *J Neurosurg (Spine 2)* 2003 ; 98 : 143-148.
19. **Profeta G, de Falco R, Ianniciello G *et al.*** Preliminary experience with anterior cervical microdiscectomy and interbody titanium cage fusion (Novus CT-Ti) in patients with cervical disc disease. *Surg Neurol* 2000 ; 53 : 417-426.
20. **Revill SI, Robinson JO, Rosen M, Hogg MI.** The reliability of a linear analogue for evaluating pain. *Anaesthesia* 1976 ; 31 : 1191-1198.
21. **Sahjpaul RL.** Esophageal perforation from anterior cervical screw migration. *Surg Neurol* 2007 ; 68 : 205-209.
22. **Sawin PD, Traynelis VC, Menezes AH.** A comparative analysis of fusion rates and donor-site morbidity for autogeneic rib and iliac crest bone grafts in posterior cervical fusions. *J Neurosurg* 1998 ; 88 : 255-265.
23. **Schmieder K, Wolzik-Grossmann M, Pechlivanis I *et al.*** Subsidence of the Wing titanium cage after anterior cervical interbody fusion : 2-year follow-up study. *J Neurosurgery Spine* 2006 ; 4 : 447-453.
24. **Schröder J, Grosse-Dresselhaus F, Schul C, Wassmann H.** PMMA versus Titanium mesh cage after anterior cervical discectomy – A prospective randomized trial. *Zentralbl Neurochir* 2007 ; 68 : 2-7.
25. **Silber JS, Anderson DG, Daffner SD *et al.*** Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. *Spine* 2003 ; 28 : 134-139.
26. **Simmons EH, Bhalla SK.** Anterior cervical discectomy and fusion. *J Bone Joint Surg* 1969 ; 51-B : 225-237.
27. **Smith G, Robinson R.** The treatment of certain cervical spinal disorders by anterior removal of the intervertebral disc and interbody fusion. *J Bone Joint Surg* 1958 ; 40-A : 607-624.
28. **Summers BN, Eisenstein SM.** Donor site pain from the ilium : a complication of lumbar spine fusion. *J Bone Joint Surg* 1989 ; 71-B : 677-680.
29. **Tomford WW, Starkweather RJ, Goldman MH.** A study of the clinical incidence of infection in the use of banked allograft bone. *J Bone Joint Surg* 1981 ; 63-A : 244-248.
30. **Vavruch L, Hedlund R, Javid D, Leszniewski W, Shalabi A.** A prospective randomised comparison between the Cloward procedure and a carbon fiber cage in the cervical spine : a clinical and radiological study. *Spine* 2002 ; 27 : 1694-1701.
31. **Vicario C, Lopez-Oliva F., Sanchez-Lorente T. *et al.*** [Anterior cervical fusion with tantalum interbody implants. Clinical and radiological results in prospective study.] (in Spanish). *Neurocirugia* 2006 ; 17 : 132-139.
32. **Xie Y, Chopin D, Hardouin P, Lu J.** Clinical, radiological and histological study of the failure of cervical interbody fusions with bone substitutes. *Eur Spine J* 2006 ; 15 : 1196-1203.