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A comparison of high viscosity bone cement and low viscosity bone cement vertebroplasty for severe osteoporotic vertebral compression fractures

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ABSTRACT

Objective: To compare the clinical outcome and complications of high viscosity and low viscosity polymethyl methacrylate bone cement PVP for severe OVCFs.
Methods: From December 2010 to December 2012, 32 patients with severe OVCFs were randomly assigned to either group H using high viscosity cement ($n = 14$) or group L using low viscosity cement ($n = 18$). The clinical outcomes were assessed by the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Short Form-36 General Health Survey (SF-36), kyphosis Cobb's angle, vertebral height, and complications.
Results: Significant improvement in the VAS, ODI, SF-36 scores, kyphosis Cobb's angle, and vertebral height were noted in both the groups, and there were no significant differences between the two groups. Cement leakage was seen less in group H. Postoperative assessment using computed tomography identified cement leakage in 5 of 17 (29.4%) vertebrae in group H and in 15 of 22 (68.2%) vertebrae in group L ($P = 0.025$).
Conclusions: The PVP using high viscosity bone cement can provide the same clinical outcome and fewer complications compared with PVP using low viscosity bone cement.

1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) are the most common types of osteoporotic fracture in the elderly population, causing back pain and loss of mobility due to the resulting spinal deformities [1–4]. Traditional conservative therapy includes bed rest, use of analgesics, physiotherapy, and external bracing. However, many patients may still complain of severe pain not responding to these therapies and even exhibiting progressive kyphosis and collapse of the vertebral body [5–7]. The classical open surgery with different types of metal implants is not an optimal treatment for a majority of patients due to the poor quality of osteoporotic bone and associated comorbidities. Percutaneous vertebroplasty (PVP) has gained popularity as a treatment modality for OVCFs, providing nearly immediate pain relief and mechanical strengthening of the vertebral body with low incidence of adverse events and morbidity [8–10].

The severe OVCF, refers to part of the vertebral body collapsed to less than one-third of its original height, has been cited as relative or even absolute contraindication by many authors for technical difficulties to perform and resultant high risk of cement leakage [11–14]. Some studies have reported the sustained efficacy of PVP treating severe OVCFs with advances in medical devices and imaging [11,12,15,16]. However, cement leakage, ranging from 43% to 45% detected by an X-ray to 78% to 91.9% detected by computed tomography (CT) scan, is still the main risk of complication for PVP with conventional low viscosity cement [11,16,17]. While most leakages are clinically asymptomatic, serious complications occurred in 3.9–7.5% of the patients who underwent PVP. If the cement leakages cause neurologic deficits, abdominal thromboembolisms, and pulmonary embolism, induction of new adjacent vertebral fractures by intradiscal cement leakage is suggested [18–21].

To reduce cement leakages, adequate patient selection, technical improvement, and its implementation such as accurate imaging in the hands of skilled operators were recommended, but the results were not conclusive [11,12,22]. Viscosity, the main characteristic parameter of the polymethyl methacrylate (PMMA) bone

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cement, has been demonstrated to be the key influencing factor for leakage when PVP technique and radiological equipment are optimal. High viscosity cements have been demonstrated to effectively reduce the risk for extravasation, thereby improving overall clinical safety, and improve infiltration and restore height. Baroud et al. demonstrated that cement leakage ceased completely when its viscosity was very high in their experimental model [23]. Georgy and Anselmetti further confirmed that high viscosity cement is safe in application and may increase the safety of vertebral augmentation techniques compared with less viscous cements, in a prospective clinical study [24,25]. These cements reach a constant putty-like viscosity immediately after mixing, without a waiting period of few minutes as in other cements, and remain consistently injectable for 8–10 min before these cements solidify.

The objective of this prospective randomized controlled study was to evaluate and compare the clinical outcomes and cement leakage of high viscosity PMMA bone cement versus low viscosity cement PVP in treating severe OVCFs. To our knowledge, no other report has been published on this comparison.

2. Materials and methods

This was a prospective randomized controlled study, approved by the Institutional Review Board. From December 2010 to December 2012, a total of 32 patients with severe OVCFs adopting PVP were included in the present study. Written consent to participate in the study was obtained from each patient.

Patients were included in the study if they (1) were aged above 50 years, (2) had severe OVCFs (part of the vertebral body collapsed to less than one-third of their original height), (3) had focal back pain without definite radicular signs and symptoms unresponsive to at least 8 weeks of appropriate conservative treatment, (4) had back pain related to the location of the OVCF on spinal radiographs, (5) were diagnosed to have an apparent bone edema in the fractured vertebra on magnetic resonance imaging (MRI) T2-weighted short tau inversion recovery sequences, and (6) had decreased bone mineral density (T scores < -1). Patients were excluded if they (1) had ordinary OVCFs (vertebral body collapsed to more than one-third of their original height), (2) had spinal cord compression or stenosis of the vertebral canal >30% of the local canal diameter, (3) had neurologic deficits, (4) had uncorrectable bleeding disorders, (5) had systemic or local spine infections, and (6) had severe comorbidity in the heart, liver, kidney, and lung intolerance to surgery.

After enrollment, the patients were given a serial number according to the consecutive sequence of hospitalization and were assigned to either group H (used high viscosity cement) or group L (used low viscosity cement) randomly by computer according to the serial number. The study population consisted of 14 patients in the group H (mean age, 75.5 ± 9.3 years) and 18 patients in the group L (mean age, 75.8 ± 9.3 years). All procedures were performed by the same surgeon.

2.1. Radiological evaluation

All patients underwent preoperative plain radiography, CT construction, MRI, and dual-energy X-ray absorptiometry for testing bone mineral density. Changes in marrow signal were assessed using MRI to determine the symptomatic levels of the fracture. Bone scans were used in cases where MRI was contraindicated (e.g. presence of a pacemaker). All radiological assessments were evaluated by two radiologists who were unaware of the clinical presentation and its outcome in the patients.

The extent of vertebral body collapse was measured from the height of the maximum collapse on lateral radiographs. The percentage of collapse, compared with the normal vertebral body height, was then calculated. Anterior and middle vertebral heights were defined as the distance between the upper and lower endplates at the anterior vertebral body wall and in the centre of the vertebral body, respectively. Normal heights of the anterior and midvertebra were defined as the mean of the equivalent values for the adjacent superior and inferior nonfractured vertebrae. Variation in vertebral body height was then calculated by fractured vertebral body height/normal vertebral body height $\times$ 100%. The kyphosis Cobb's angle was assessed by measuring the kyphotic angle from the superior endplate of the vertebral body one level above the injury to the inferior endplate of the vertebral body one level below.

2.2. Procedural technique

The procedure was performed under general anesthesia to provide a certain comfort, especially during the progression of the trocar, which can be painful. Patients were placed in a prone position and monitored by electrocardiograph and oxygen saturation during the procedures. After localizing the fractured vertebra using fluoroscopy, the surgeon placed overlapping palm on the vertebral spinous process to push toward ventral slowly for partial reduction of the fractured vertebra.

Through a 0.5-cm-sized skin incision, the vertebroplasty needles were advanced to obtain bilateral transpedicular access until its tip reached the junction of the anterior and middle one-third of the vertebral body under C-arm fluoroscopic guidance. In cases where pedicles were not visualized on fluoroscopy, the parapedicular or unipedicular approach was used. Once the needle position was satisfactory, high viscosity cement (Confidence; DePuy Spine, Raynham, MA) or low viscosity cement (Vertebroplastic; DePuy Acromed, Raynham, MA) was injected into the vertebral body using continuous fluoroscopic guidance. Depending on the ambient temperature of the operation room, the time from the beginning of mixing to the beginning of application of low viscosity cement was 4–8 min, while high viscosity cement could be applied immediately after mixing for 30 s. The injection of cement was stopped whenever epidural or paravertebral opacification was observed or the cement reached the dorsal quarter of the vertebral body. The needles were not removed before the end of polymerization to prevent spreading of low viscosity cement, while the needles were removed immediately after the application of high viscosity cement (due to its high viscosity there was no possibility of cement leakage from the needles into the surrounding area).

2.3. Assessment of outcomes

Patients were followed up postoperatively, and at 3 days, 3, 12, and 18 months after surgery. The Visual Analog Scale (VAS) score was used to evaluate back pain, Oswestry Disability Index (ODI) was used as a functional assessment, and Short Form-36 General Health Survey (SF-36) was used to evaluate the quality of life. Any clinical complications were recorded immediately after the procedure. Cement leakage, defined as the presence of any extravertebral cement, was assessed independent of the treating physician by two investigators using the CT scan. The position of any cement leakage was noted and was correlated with any symptoms reported during the follow-up period.

2.4. Statistical analysis

Data were presented as the mean $\pm$ standard deviation. The SPSS for Windows Version 13.0 (SPSS, Chicago, IL) was used for the analysis. Intergroup comparisons were made using the Student's paired t-test or Chi-square test. Comparisons between before and after operation were made using the Student's paired t-test. The