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Original Research

An updated comparison of high- and low-viscosity cement vertebroplasty in the treatment of osteoporotic thoracolumbar vertebral compression fractures: A retrospective cohort study

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HIGHLIGHTS

- High-viscosity cement can reduce cement leakage, especially in the paravertebral area and peripheral vein.
- High-viscosity cement has satisfactory clinical effect.
- The use of a hydraulic system to inject high-viscosity cement is safe and feasible.

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ABSTRACT

Objective: This study mainly aimed to evaluate complications of cement leakage for osteoporotic thoracolumbar vertebral compression fractures by PVP using HVC, and access the clinical efficacy.
Methods: Between May 2013 and June 2015, 66 patients with osteoporotic thoracolumbar vertebral compression fractures, who underwent PVP (36 HVC and 30 LVC) in our hospital, were enrolled. Cement leakage, Visual Analog Scale (VAS), Oswestry Disability Index (ODI), refracture of the cemented vertebrae, and adjacent vertebral fractures were evaluated. The follow-up time was 1 year.
Results: The overall cement leakage rate was 30.55% in the HVC group, lower than 77.77% obtained in the LVC group ($P = 0.00$). The incidence rates of cement leakage into paravertebral area ($P = 0.02$) and vein ($P = 0.04$) in the HVC group were significantly lower than those of the LVC group; however, no differences were found for disc space ($P = 0.72$) and intraspinal space ($P = 0.58$). There were no differences in VAS, ODI, refracture of cemented vertebrae, and adjacent vertebral fracture between the two groups ($P > 0.05$).
Conclusions: PVP using HVC not only can reduce cement leakage, especially in the paravertebral area and peripheral vein, but also has satisfactory clinical effect.

1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) seriously risk the health of elderly individuals. They cause back pain, loss of mobility, spinal deformities, neural compromise, and even paralysis [1–3]. Traditional therapies include long-term bed rest, suppling by analgesics, physiotherapy, and classical open surgery. However, accompanying complications of long-term bed rest may occur gradually, such as bedsore, urinary tract infection, pneumonia, malnutrition, deep vein thrombosis, and even stroke [4]. Classical open surgery also has the risks. Low tolerance to surgery because of patients' old age might result in multi system damage and slow postoperative recovery. In addition, open surgery may cause screw loosening due to the poor quality of osteoporotic bone; this can increase the patient's pain as well as surgical revision rate.

With the development of OVCFs treatment, percutaneous vertebroplasty (PVP), as a minimally invasive technique, is a preferred choice for treating OVCFs due to low incidence of adverse events and other advantages such as fast recovery, pain relief, and vertebral collapse prevention [5,6]. However, cement leakage is an

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unsolved problem associated with PVP, occurring at a frequency as high as 30%–70% [7]. Cement leakage into the intraspinal space may compress the spinal cord, resulting in functional disorder of spinal segments, or even paralysis; leakage into the vessels can cause thermal damage to the vessels, pulmonary embolism, or even death [8]. Therefore, cement leakage has attracted extensive attention from many researchers. It was proposed that cement viscosity is the main influencing factor of cement leakage, and increasing viscosity greatly reduces cement leakage [9,10]. For instance, Liang Z, et al. [11] prospectively assessed 32 patients with severe OVCFs, and found that high viscosity cement (HVC) has reduced leakage rate compared with low viscosity cement (LVC). In addition, a prospective cohort study revealed that PVP using HVC results in a lower rate of cement leakage in the disc space, but no statistically significant difference was found for the epidural space, paravertebral area and peripheral vein, compared with kyphoplasty using LVC [12]. Wiese D, et al. [13] reported that PVP with HVC in the treatment of OVCFs is significantly effective in reducing the risk of venous cement leakage. However, other researchers insist there is no significant difference in cement leakage rates between HVC and LVC [14,15]. Georgy BA, et al. [15] found no statistically significant differences based on leakage area for the disc space, epidural space, and vein. Besides, similar results were reported in another study [14].

In order to assess the differences in cement leakage between HVC and LVC, and evaluate the clinical effect of HVC, we retrospectively analyzed patients by PVP (Hydraulic Delivery Vertebroplasty System, Shiyitang Medical, China) using HVC (Osteopal V, Heraeus Medical Gmbh, Germany) and LVC (Mendec Spine, Tecres S.P.A. Italy), for the treatment of osteoporotic thoracolumbar vertebral compression fractures.

2. Methods

2.1. Study design

This was a retrospective cohort study, in which 66 PVP procedures with 36 HVC and 30 LVC, at a single center between May 2013 and June 2015, were reviewed. The study was approved by the Ethics Committee of our hospital.

2.2. Patients selection

Patients were selected, with osteoporotic compression fracture of a single thoracolumbar vertebral body (T_{11}-L_2), T-score of bone density below −2.5, Visual Analog Scale (VAS) score above 5 points, absence of spinal cord or nerve compression symptoms preoperatively, PVP procedures within 2 weeks after fracture and complete follow-up data (postoperative 1 month, 6 months and 1 year). The selected patients with PVP should also be limited to hydraulic cement injection by the unipedicular approach.

2.3. Procedural technique

The prone position was adapted for all patients, with shoulder and pelvis slightly elevated with soft pads. Changes of heart rate, blood oxygen saturation, and blood pressure were recorded by an ECG monitor. The fractured vertebrae were located by C-arm fluoroscopy, and markers were used on the skin surface to locate the surface projection of the pedicle. Disinfection and draping were performed conventionally. Local infiltration anesthesia was performed with 1% lidocaine to the depth of the periosteum at the left pedicle for the fractured vertebrae. An incision of about 0.5 mm was made at the level of skin marks. A puncture instrument was delivered to the left pedicle rotationally, and needle orientation was adjusted under C-arm fluoroscopy to avoid damage to the medial wall of the pedicle and endplates. The needle was stopped once reaching the anterior middle portion of the vertebral body. Bone cement was prepared and loaded to the hydraulic pump. When the cement paste was formed, the needle core was removed and the cement slowly injected into the vertebral body with the hydraulic delivery system. The needle was removed rotationally after injection was completed. The incision was bandaged by compression of the puncture site. The patients returned to the ward after stabilization of vital signs.

2.4. Data collection

X-ray or computed tomography (CT) images were postoperatively reviewed to assess cement leakage. Refracture of cemented vertebrae as well as adjacent vertebral fractures were also assessed by CT and magnetic resonance imaging (MRI) during follow-up, independently by two researchers blinded to grouping. Disagreement between the above two researchers was resolved by consensus with the involvement of a third researcher. In addition, leakage locations were recorded and divided into paravertebral area, intraspinal space, disc space and peripheral vein (Fig. 1) [16]. The VAS and ODI for all patients were collected preoperatively and postoperatively, to compare pain relief and life quality improvement between the two groups.

2.5. Statistical analyses

Statistical analyses were performed using the SPSS 24.0 software. Data are mean ± standard deviation (SD). For the VAS and ODI, repeated measures analysis of variance was used to assess differences at various time points between the two groups. Intergroup changes at the same time point were evaluated by independent samples *t*-test. For baseline data (Tables 1 and 2), differences between the two groups were compared by independent samples *t*-test for continuous data, and Chi-square test for count data. Cement leakage rate, refracture of cemented vertebrae and adjacent vertebral fracture in both groups were comparatively assessed by Chi-square test. $P < 0.05$ indicated a statistically significant difference.

3. Results

In this series, all 66 patients with PVP procedures (36 HVC and 30 LVC) were reviewed. Patients' demographics and basic characteristics, including age, gender, weight, height and fracture location, were well matched between the two groups (Table 1). No differences were found in hospital days, operation time, intraoperative blood loss, and injected cement volume between the two groups (Table 2).

3.1. Primary outcome – cement leakage

A statistically significant difference was found in the overall cement leakage rate between the two groups ($P = 0.00$). The overall cement leakage rate was 30.55% in the HVC group, lower than the rate of 77.77% obtained in the LVC group. In addition, cement leakage more commonly involved the paravertebral area ($P = 0.02$) and peripheral vein ($P = 0.04$), rather than the disc ($P = 0.72$) and intraspinal space ($P = 0.58$) (Table 3). No neurological complications occurred in these patients.