

Cadaveric device-injected very high-viscosity cement during vertebroplasty

ABSTRACT

Introduction: Cement extravasation during vertebroplasty (VP) is the most commonly reported complication. Cement viscosity is considered the single most important predictor of the risk of extravasation. Certainly, injecting high-viscosity cement (HVC) is difficult to utilize in real practice. We invented a new device capable of injecting high-viscosity with ease and at a distance to avoid radiation. The aim of this study is to confirm the efficacy and safety of the new device on cadaveric vertebrae.

Methodology: A 126 osteoporotic vertebral bodies were harvested from cadavers. Eighty vertebrae were included in the study. Computer-randomization software was used to allocate specimens over two main groups, Conventional VP and New Device. Both groups were further subdivided into two subgroups; high-viscosity and low-viscosity. A custom device was used on each vertebra to induce a compression fracture.

Results: Injecting HVC was associated with a lower leakage volume compared with low-viscosity cement. HVC was associated with no leakage into the spinal canal. It was also associated with a low incidence of vascular extravasation ($P < 0.001$). The mean volume of cement leakage in the low-viscosity group was 0.23 and 0.15 cc, for the Conventional VP and New Device, respectively. In both groups, the most common site for leakage was the vertebral end plate, which was exhibited more in the low-viscosity group (71.5%) compared with the high-viscosity group (42.5%). The preset target amount of cement to be injected was reached in 99% of the time when injecting HVC with the New Device, compared with 62% using the Conventional VP. In both groups, there was no correlation between the amount of cement injected and the amount of leakage.

Conclusion: The new device is capable of injecting HVC easily, with a lower incidence of cement leakage. It also minimized the risk of radiation exposure to the surgeon.

Keywords: Cement, high-viscosity, vertebral compression fracture, vertebroplasty

INTRODUCTION

Vertebral compression fracture (VCF) is a unique type of fracture that results in the loss of vertebral height. These fractures constitute a huge burden on the society, mostly due to their sequelae on the quality of life of affected individuals. Around 1.4 million new cases are diagnosed yearly,^[1] with one quarter are above the age of fifty.^[2] Almost 40% of cases are seen in women in their eighties, with approximately 25% seen in postmenopause.^[3] These pathologic fractures are commonly secondary to the following: osteoporosis, hematopoietic or lymphoid neoplasm, or hematogenous metastasis.^[4] By far, osteoporosis is considered the most common risk factor for VCFs.^[5]

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The presentation of VCFs varies from being completely asymptomatic to having a severe, disabling pain. The resulting pain and deformity could lead to a significant deterioration in the functional and psychological status of the patient.^[5] Moreover, it is associated with high risk of mortality and morbidity, which predisposes patients to develop chronic back pain, decline in pulmonary function, and fractures in the adjacent levels as well as spinal cord compression.^[5,6]

Vertebral augmentation procedures (VAPs) are minimally invasive, percutaneous techniques that involve the injection of a fast-setting polymer into a pathologic vertebral body, with the aim of pain relief and deformity correction.^[4] They are considered less invasive alternatives to the conventional open resection and spinal reconstruction in treating patients with symptomatic VCFs refractory to conservative management.^[7] The main indication for the procedure is to manage painful VCF that fails to heal after 8 weeks of conservative management.^[8] In a systematic review conducted by Robinson and Olerud comparing the outcomes of VAPs with the medical treatment, VAPs were associated with a significantly lesser pain and better functional outcomes.^[9]

Vertebroplasty (VP) and kyphoplasty (KP) are minimally invasive VAPs that involve the percutaneous injection of a polymethylmethacrylate cement through a needle into a fractured vertebral body under radiographic guidance.^[10] KP follows the same principles of VP, with an additional step of percutaneous insertion and inflation of a balloon device into the vertebral body before injecting the cement.^[11] This extra step gives an advantage of reexpanding the vertebral body to gain some height before the introduction of cement. This, in fact, accounts for a better correction of the kyphotic deformity when compared to VP. In addition, by creating a vacancy within the vertebral body, the semisolid cement can be easily injected under low pressure, which contributes to a lower incidence of cement leakage in KP compared to VP.^[12,13]

VAPs have become popular treatment alternatives that are less invasive than open surgery, and yet more effective than conservative management. Both VP and KP are considered minimally invasive procedures, with a relatively good safety profile.^[14] However, they are deceptively intricate and could be dangerous if proper technique is not used.^[15] The overall incidence of clinically evident complications ranges from 1% to 5%.^[10,16] Commonly reported complications include rib fracture (3%),^[17,18] cement extrusion (5%–80%),^[19,20] and fractures of the adjacent vertebrae (8%–27%).^[21] Other less common complications include pyogenic spondylitis,^[22] hemorrhage, cerebrospinal fluid leak,^[23] cauda equina

syndrome,^[24] esophageal perforation,^[25] and fracture of the pedicle or transverse process.^[26]

In fact, rib fractures were the most commonly reported complication in the literature.^[17,18,27] Cement extravasation, however, remains the most serious complication. Although it is clinically silent in the vast majority of cases,^[20,28] cement leakages could lead to potentially harmful consequences. The injected cement may leak from the vertebral body into the paravertebral space, veins and venous plexus, spinal canal, or intervertebral foramen.^[29,30] The leaked cement could lead to serious sequelae such as paraplegia,^[31,32] spinal cord and nerve root compression,^[20,32-34] cardiac perforation,^[35,36] pulmonary embolisms,^[37-40] and even death.^[28] The proper identification and careful avoidance of the risk factors that contribute to cement leakages will help in minimizing the incidence and severity of extravasation. The commonly reported risk factors include improper instrumentation placement,^[28] inadequate cement radio-opacity, high-pressure delivery of cement,^[15] volume of cement injected,^[15,29,32] low cement viscosity,^[41-43] and the type of procedure utilized. It is also important to appreciate that the higher risk procedures performed on patients with metastatic osteolytic tumors or myeloma are associated with a significant risk of cement leakage.^[44-47]

Different experimental studies in the literature agreed that cement viscosity is considered an independent predictor of extravasation.^[48-50] Cement with higher viscosity forms a more clump-like intracorporeal distribution, with trabecular disruption but reduces leakage incidence.^[49] Injection of high-viscosity cement (HVC) can be one of the solutions to avoid cement leakage; however, injecting HVC is difficult due to the high resistance of cement flow. We have invented a new device capable of injecting HVC easily with low force and at a distance to avoid radiation. The aim of this study was to assess the safety and efficacy of the new device with cadaveric comparative tests.

METHODOLOGY

Study design and specimens selection

This was a prospective case–control cohort study conducted on 126 osteoporotic vertebral bodies from 8th thoracic vertebra to 5th lumbar vertebra harvested from 14 fresh whole human cadavers obtained from the postmortem multi-organ donors. The exclusion criteria for this study were a normal vertebral body, vertebral body with pathology other than osteoporosis, a preexisting vertebral fracture, or those with a previous VAP. Dual-energy X-ray absorptiometry scan and simple radiographs were performed on all the

vertebral bodies to confirm the diagnosis of osteoporosis and to rule out any preexisting pathologic compression fractures. Osteoporosis is defined by the World Health Organization as a bone mineral density (BMD) that lies of 2.5 standard deviations or less below the average of a young healthy reference population of the same gender. A total of 80 vertebral bodies matched the inclusion criteria and were included in this study. Before the start of the procedure, a metal plate with identification number was attached to each vertebra. The anterior and posterior heights of each vertebra were recorded radiographically and clinically. Each vertebra was submerged in a sterile distilled water and the volume of each one was measured using Archimedes method.

Specimen allocation and preparation

The specimens were stored at -2°C before testing. Vertebral bodies were stratified based on their size, volume, and BMD. Based on our pretesting results, we empirically set the targeted low and high cement viscosity at 60 and 300 Pas, respectively. A computer-generated randomization schedule was used to assign each vertebral body to one of two groups, Group 1 (G1) "Syringe VP" or Group 2 (G2) "New Device VP." The total number of vertebrae allocated in each group was 40. Each group was further subdivided into two subgroups; the low-viscosity cement (LVC) and HVC. At the end, the baseline characters of specimens were almost the same between the two groups for each vertebral level. A custom jig (device) was used to apply an axial force on the anterior segment of each specimen to create a standardized anterior compression fracture [Figure 1]. Each vertebra lost around 40% of its anterior body height, with no loss of the posterior height. After creating the fractures, specimens were returned back to storage until the day of the procedure.

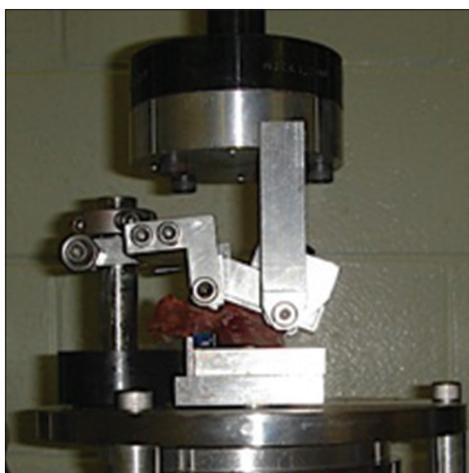


Figure 1: A custom jig (device) used to create standardized anterior vertebral compression fracture

Surgical procedure

Cement injections were done simultaneously as a pair by two senior spine surgeons. To prevent operator-dependent variability, all procedures were done by the same surgeons. Each vertebra was submerged into a 37°C water bath and cement was injected under direct visualization following a transpedicular approach. The amount of cement to be injected was calculated as 25% of the initial vertebral body volume, yielding an average target volume of 6.3 cc per vertebra. All augmentations were done following the same method commonly practiced in clinical treatment. Parameters including cement viscosity, volume, distribution, speed of injection, and needle placement were measured accordingly. The cement distribution within the body is measured and compared between groups using two-view radiographs [Figure 2].

Data analysis

Data were collected and entered using Microsoft Excel and analyzed using Predictive Analytical Software version 18.1 (PASW, IBM, Chicago, Illinois, USA). The mean was calculated and the level of significance was determined between groups using parametric and nonparametric statistical tests ($P < 0.05$). Z-test was used to determine the significance between two proportions.

RESULTS

Eighty vertebrae were included in the study (mean age, 70.6; range: 54–81). The majority of the vertebrae were harvested from female cadavers (73.75%). The mean volume, BMD, anterior height for each group and subgroup were calculated.

Force required for cement injection

From a pilot study using a FlexiForce sensor, we measured the force required to inject cement at different viscosities using different delivery systems. The possible maximal sustained loading force with one hand was 30–35 N. The estimated maximal cement viscosity that can be injected using the new device, 1 and 2 cc syringes were 1000 Pas, 350 Pas, and 110 Pas, respectively. Unlike the new device, it

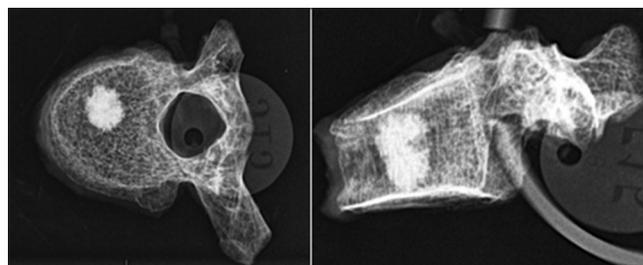


Figure 2: Measurement of cement distribution within the body using two-view radiographs

was impossible to inject cement with viscosity above 500 Pas when using either 1 cc or 2cc syringes. Furthermore, cement had a consistent shape when injected at a higher viscosity.

Procedure duration

The mean procedure duration for high-viscosity VP using 1 or 2 cc syringe was 148.75 min ($n = 20$; 95% confidence interval [CI] 129.61–167.89). On the other hand, the mean procedure duration for high-viscosity VP using the new device was 141.25 min ($n = 20$; 95% CI 123.48–159.02). The mean difference in procedure duration between the new device and the syringes was 7.5 min ($P = 0.64$).

Volume of cement injected

The target volume of cement for injection was calculated using Archimedes method. For each vertebral body, the aim was to inject cement volume, that is, 25% the original vertebral body volume. When injecting HVC with 1 or 2 cc syringes, the total injected cement volume was only 61.59% of the target volume (95% CI: 50.39–72.78). With the new device, the injected volume was 98.88% of the target volume (95% CI: 95.63–102.14). Furthermore, the target cement volume was fully reached in 85% of samples when injecting a HVC using the new device, compared to only 20% when using syringes ($P < 0.0001$). The new device was more efficient in delivering the predetermined target volume of HVC ($P < 0.001$).

Vertebral height restoration

The average vertebral height correction when injecting HVC was 2.54 cm (95% CI: 2.05–3.04), which represents 29.03% of the original vertebral height (95% CI: 23.49–34.57). On the contrary, injecting LVC led to an average height correction of 1.9 cm (95% CI: 1.61–2.24), which accounts for 21.84% of the original vertebral height (95% CI: 17.99–25.69). There was a statistically significant difference in vertebral height correction when using a HVC injection ($P < 0.05$). Cement viscosity was directly proportional to vertebral height gain.

Risk of cement leak

The risk of accidental cement leak was inversely related to cement viscosity (relative risk = 0.667). The incidence rate of cement leak when injecting HVC was 52.5%, compared to 77.5% with LVC. There was a 25% absolute risk reduction in cement leak when injecting HVC. In addition, the volume of leaked cement was also higher in the LVC, with a mean leak volume of 0.19 ml with LVC compared to only 0.07 ml with HVC ($P = 0.012$).

Site of cement leak

Cement leak was observed from the fracture site, vessels of the upper and lower vertebral endplates, and anterior

and lateral walls of the spinal canal. Overall, the vertebral endplates were the most common sites for cement leak in all groups, which occurred more frequently in the low-viscosity group (71.5%) compared to the high-viscosity group (42.5%). When using HVC, there was no incidence of cement leak into the spinal canal. In addition, the risk of cement leakage through blood vessels was significantly reduced when injecting HVC, whether with the new device or when using a syringe ($P < 0.0001$).

DISCUSSION

VCFs constitute huge burden on the society, mostly due to their sequelae on the quality of life of affected individuals.^[1] While conservative management remains the first line of treatment for VCFs,^[10] VAPs are associated with significantly lesser pain and better functional outcomes.^[9] Cement extravasation is a major complication associated with VP. In this study, we showed that high cement viscosity is associated with a significant reduction in the risk of extravasation. We also showed that a custom-made injection device was more superior for injecting HVC compared to injection syringes.

A major limiting factor when injecting HVC is the high force required for efficient cement delivery. When we used a FlexiForce sensor device, we found that the maximum force the surgeon can generate with one hand was 35 N. According to Poiseuille law, syringe length and diameter are important factors in determining the force required for high cement viscosity injection.^[51] When we injected HVC (300 pas) using a 2-cc syringe, the force generated was 11 times higher compared to the new device. When we used a 1-cc syringe, however, the force decreased three folds compare to a 2-cc syringe. This reduction in the force is explained by the smaller diameter of the 1-cc syringe, which was illustrated earlier by the Poiseuille law. Nevertheless, the new device was superior to the 1-cc syringe and was associated with the least amount of force required for HVC injection.

Percutaneous VP involves injecting cement under direct intraoperative fluoroscopic visualization, which poses a great risk for radiation hazard to the operator and the patient.^[52] The minimum radiation dose to induce early transient skin erythema and main erythema is 2 Gy and 6 Gy, respectively.^[53] Wagner *et al.* has found an average radiation dose of 1.97 and 0.27 mSv, to the patient and the operator, respectively, when performing VP using one-fluoroscopic technique.^[53] The amount of radiation exposure is influence by multiple factors, including: imaging technique, procedure duration, and operator location from the radiation source.^[54,55] When we used the new device to inject HVC, not only was

the surgeon able to inject at a distance from the radiation site but also the procedure time was reduced by an average of 7 min. This could have a tremendous impact on reducing the risk of radiation exposure associated with the procedure.

The ultimate goal when managing VCFs is to provide rapid pain relief while correcting the kyphotic deformity. In a retrospective study on vertebral deformity correction, VP was associated with 29% restoration of the anterior vertebral height and 4.3° reduction in the kyphotic angle.^[56] This is comparable to the percentage of anterior vertebral height restoration we obtained in this study with high-viscosity VP (29.03%). Furthermore, the percentage of anterior vertebral height correction was 32.9% higher with high-viscosity compared to low-viscosity VP.

Cement extravasation is a major complication associated with VP, accounting for 5%–80% of the overall complications.^[19,20,57,58] Cement viscosity is considered a major factor in predicting the risk of cement extravasation.^[48-50] When we used HVC, we observed a 25% reduction in the risk of cement leak. Furthermore, the volume of leaked cement decreased by three folds compared to LVC. Vertebral endplates were the most common sites for cement leak in all groups, which may increase the risk of adjacent vertebral fracture. High-viscosity VP was associated with a significantly reduced risk of blood vessels extravasation, which may reduce the risk of thromboembolic events. Cement leak into the spinal canal is a serious complication that could lead to a potentially irreversible damage to the spinal cord. We observed no incidence of the spinal canal extravasation when we used high-viscosity VP.

CONCLUSION

High-viscosity VP contributes to lower risks and decreased volume of cement extravasation. Despite the difficulty with HVC injection, the new device is capable of injecting HVC up to 1000 Pas. Furthermore, it was efficient in delivering the intended target cement volume, while minimizing the risk of cement leak and radiation exposure.

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Conflicts of interest

There are no conflicts of interest.

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