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Retrospective Evaluation

Feasibility, Safety and Cement Leakage in Vertebroplasty of Osteoporotic and Malignant Compression Fractures Using Ultra-Viscous Cement and Hydraulic Delivery System

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Background: The major complications arising from vertebroplasty or kyphoplasty are related to leakage of cement beyond the confines of the collapsed vertebral body. Traditionally, a liquid (low viscosity) cement is used in most vertebroplasty systems available on the market, coupled with mechanical injection devices or one mL syringes.

Objectives: The purpose of this study is to evaluate the feasibility and safety, as well as study cement leakage patterns, in vertebroplasty performed for both osteoporotic and malignant vertebral compression fractures using ultraviscous cement injected by the hydraulic CONFIDENCE Vertebral Augmentation System.

Study Design: Retrospective evaluation of postoperative images.

Setting: Single center inpatient and outpatient population.

Methods: A retrospective evaluation of clinical charts and postoperative X-ray imaging was performed in 122 cases; a total of 214 levels were treated. The study group comprised a total of 163 levels of benign osteoporotic fractures and 51 levels of various malignant lesions. The degree of leakage, seen in postoperative films, was assessed at each treated level using a strict 4-point scale (none, mild, moderate, severe).

Results: For benign lesions, there was no leakage in 82 levels (50%), mild venous leakage in 38 levels (23%), moderate venous leakage in 4 levels (2%), mild disc leakage in 28 levels (17%), moderate disc leakage in 7 levels (4%), mild paravertebral leakage in 2 levels (1%), and moderate paravertebral leakage in 2 levels (1%). No severe leakage or epidural leakage were seen. For malignant lesions, there was no leakage in 25 levels (49%), mild venous leakage in 12 levels (24%), moderate venous leakage in 4 levels (8%), mild disc leakage in 7 levels (14%), moderate disc leakage in one level (2%), mild paravertebral leakage in one level (2%), and one level showed a mild epidural leakage (2%).

Limitations: Retrospective study, single center.

Conclusion: Percutaneous cement augmentation in osteoporotic and malignant compression fractures using a highly viscous cement that can be safely controlled and injected via a hydraulic system can be performed safely without significant complications. The leakage rate and patterns were similar in both benign and malignant compression fractures. The use of highly viscous cement may decrease the complication rate in malignant lesions that has been traditionally described to exhibit more cement leakage with low viscosity cement.

Institutional Review: This study was approved by the Institutional Review Board

Key words: Vertebroplasty, high viscosity cement, CONFIDENCE system, hydraulic injection.

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The major complications arising from vertebroplasty or kyphoplasty are related to leakage of cement beyond the confines of the collapsed vertebral body. The rate of local bone cement leakage was reported to be up to 80% for percutaneous vertebroplasty in postoperative X-ray images (1). Traditionally, a liquid (low viscosity) cement is used in most vertebroplasty systems available on the market, coupled with mechanical injection devices or one mL syringes. The purpose of this paper is to investigate the feasibility and safety, as well as study cement leakage patterns, in vertebroplasty performed for both osteoporotic and malignant vertebral compression fractures using ultraviscous cement injected by the hydraulic CONFIDENCE Vertebral Augmentation System (DePuy Spine, Raynham, MA) to further control cement deposition in a large cohort of patients. We will also evaluate the effect of using high viscosity cement in the treatment of malignant lesions against its effect on benign compression fractures.

Methods

Study Design

Institutional review board permission was obtained for this retrospective study to evaluate postoperative images as well as radiology and medical chart review. This is a single center retrospective study. All patients had initially presented with painful collapsed vertebrae that had not responded to conventional therapy. Radiographic work-up included magnetic resonance imaging (MRI) and plain films for all patients. Computed tomography (CT) evaluation was also available for all malignant lesions. All cases were performed using the CONFIDENCE spinal cement system.

Procedural Technique

The surgical approach for all treated patients was as follows: Patients were placed in the prone position and were given conscious sedation, consisting of multiple doses of midazolam and fentanyl. The patient's heart rate, blood pressure, Po2, and level of consciousness were measured with electronic monitors throughout the procedure. The procedure was performed under strict antiseptic conditions and intravenous coverage of antibiotics. The levels requiring treatment were identified under fluoroscopy. The skin was then prepped and draped by using standard antiseptic techniques. The periosteum was anesthetized with 1% lidocaine. Levels treated ranged from T1 to L6. Bipedicular access was used to treat 178 levels; unipedicular access was used to treat 36 levels. The needle placement was checked by fluoroscopy, after which cement was injected using a proprietary hydraulic system. The volume of injected cement was approximately 2–4.5 mL per level. Patients were monitored postoperatively to ensure full recovery and were discharged the same day.

Radiographic Analysis

Postoperative radiographs for all patients were reviewed in a blinded manner by a single reviewer. All preoperative radiographs were characterized for percentage compression. These data were collected to ensure that the nature and severity of compression fractures were comparable for both groups. The degree of compression was calculated from plain films, obtained anterior and/or central to the vertebral body. The amount of leakage was then characterized postoperative as none, mild, moderate, or severe using a grading system described by Georgy (2). In addition, the location of the leakage was also recorded. The following locations were subject to leakage: the disc space, the epidural space, the paravertebral areas, and the peripheral veins.

Cement Injection End Point

The end point of cement injection for both types of patients was the presence of radiologically adequate filling, the start of extravasation, or alarming increased pressure during injection. The hydraulic delivery system will allow almost immediate cessation of cement injection after reverse rotation of the handle.

Results

Demographics

The study included 122 patients who had 214 levels treated by vertebroplasty. The study group was composed of 94 cases (163 levels) of benign osteoporotic fractures and 28 cases (51 levels) of different malignant metastatic lesions. There were a total of 89 women and 33 men with a median age of 81 years (range 44 to 99 years). The primary malignant lesions included cases of breast cancer, multiple myeloma, leukemia and lymphoma, prostate, lung, liver, and renal cancers. Levels treated ranged from T1 to L6 levels. The most frequently treated levels in descending order were L1, T11, T12 (Fig. 1). The distribution of treated levels was similar in the 2 groups.

The preoperative degree of vertebral collapse was comparable for benign and malignant lesions. For benign lesions, the mean degree of preoperative vertebral collapse was 29% and for malignant lesions, the mean degree of vertebral collapse was 21%.

The distribution of surgical approaches was similar; however, a bipedicular approach was used more frequently on malignant lesions. In benign lesions, a bipedicular approach was used for 82% (133/163) levels and a unipedicular approach in 18% (30/163). In malignant lesions a bipedicular approach was used for 88% (45/51) levels, and a unipedicular approach in 12% (6/51).

Leakage Rates and Locations

The location and degree of leakage was similar regardless of the presenting indication for vertebroplasty. Figure 2 shows that a similar proportion of patients in both the benign and the malignant groups were free of leakage (50% and 46% respectively) and that the pattern of leakage was similar in both location and degree between the 2 groups.

For benign lesions, there was no leakage in 82 levels (50%), mild venous leakage in 38 levels (23%), moderate venous leakage in 4 levels (3%), mild disc leakage in 29 levels (18%), moderate disc leakage in 8 levels (5%), mild paravertebral leakage in 2 levels (1%), and moderate paravertepral leakage in 2 levels (1%). No severe leakage or epidural leakage was observed. Multiple leaks (2 locations each) were noted in 2 patients with benign lesions. A total of 83 leakages were detected in 163 levels of benign compression fractures treated.

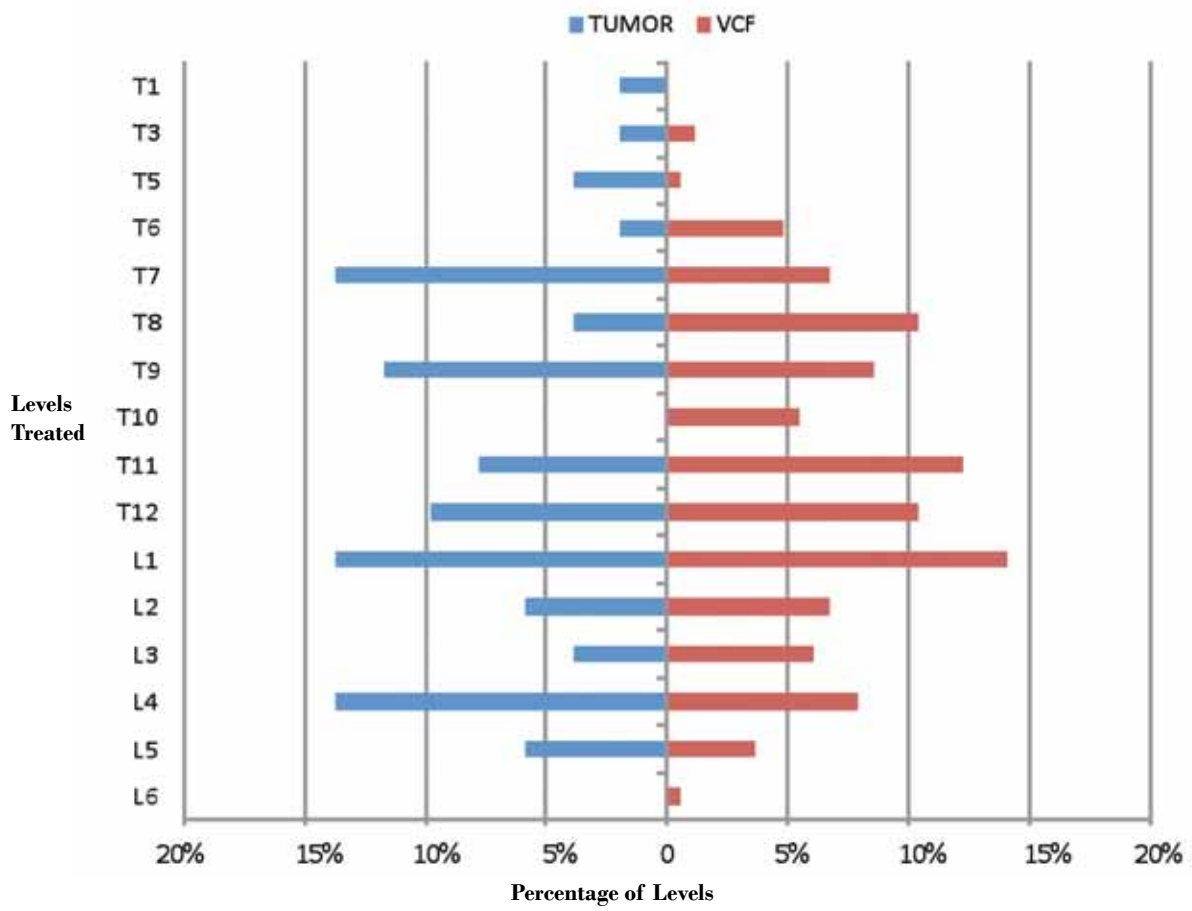

Fig.1. Distribution of levels treated by indication. The distributions of treated levels of benign and malignant lesions in this report are similar.

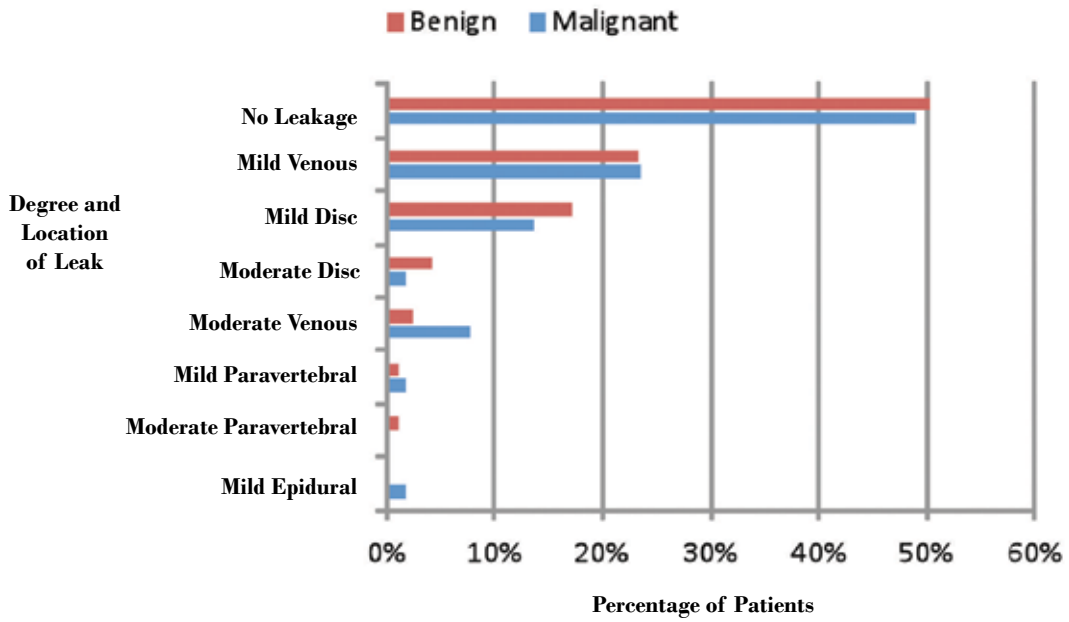

Fig.2. Degrees and location of leak. The distribution and degree of leakage are similar for cases of benign and malignant lesions treated with high viscosity cement with no leak seen in between 46% and 50% of cases.

For malignant lesions, there was no leakage in 23 levels (45%), mild venous leakage in 12 levels (24%), moderate venous leakage in 4 levels (8%), mild disc leakage in 8 levels (16%), moderate disc leakage in one level (2%), mild paravertebral leakage in 2 levels (4%), and mild epidural leakage in one level (2%). No moderate paravertebral leakage and no severe leakage of any type was seen. There were no symptomatic leaks that required surgical intervention. In the one case of mild epidural leakage, some cement was seen in a neural foramen; however, it was asymptomatic and required no treatment. Multiple leaks were noted in one patient with malignant lesions; these leaks were present at 2 locations. A total of 28 leakages were detected in 51 levels of malignant compression fractures treated.

Discussion

This study evaluated the safety profile and feasibility of using ultraviscous cement injected by a hydraulic device, the CONFIDENCE Vertebral Augmentation System to further control cement deposition in a large cohort of patients. The leakage rate and the distribution pattern were similar to those in previously published reports comparing vertebroplasty and kyphoplasty using the same cement type (2). The rate of local bone cement leakage was reported to be up to 87.5% for percutaneous vertebroplasty, as detected by CT imaging (3). The CT imaging date from this study illustrates the fact that leakage is well underreported using plain films.

The use of cement that may be too viscous to flow freely outside of the injection site has recently raised significant interest in the scientific and medical community, especially because of the availability of devices that can safely deliver these cements to a fracture site. Baroud et al evaluated the impact of cement viscosity on leakage rates in vitro (4). This study demonstrated the effect of increased viscosity on cement leakage through a laboratory model of vertebral fracture. In this model, higher viscosity cements were shown to result in significantly lower leakage rates. The clinical relevance of this finding is significant, considering the rare yet potentially serious risks of cement leakage for patients undergoing percutaneous vertebroplasty. In another study, the same high-viscosity cement was

found to have significantly lower extravasation rates compared with normal low-viscosity cement (5).

Baroud and coworkers (4), however, concluded that delivery of high-viscosity cement might approach or exceed the human physical tolerance limit to injection forces. However, the hydraulic cement delivery system enables the introduction of constant high-viscosity cement immediately after mixing the cement components during an 8- to 10-minute injection. Use of a system with high-viscosity polymethylmethacrylate demonstrates a highly significant reduction of extravasation into the vein and, consequently, into the systemic venous circulation (6). This difference was demonstrated to occur in comparison to standard percutaneous vertebroplasty (PV) with low-viscosity vertebroplasty-designed bone cement ($P < 0.001$), but also when gelfoam embolization preceded standard PV ($P = 0.0303$). The same authors (6) also showed that there was no significant difference in the clinical outcomes between patients treated with high viscosity and low viscosity cement using the Visual Analog Score and the Oswestry Disability Self-Evaluation Questionnaire.

Vertebroplasty of malignant compression fractures is associated with 4 times as many complications as benign compression fractures (6), and many authors have reported higher leakage rates when treating these malignant lesions. Chiras et al (7) reported an extravasation rate of up to 10%, compared to 1-2% in osteoporotic fractures. However, Mousavi et al (8) reported that the risk of cement leakage during percutaneous vertebroplasty in the metastatic spine is significant, with 85.7% of procedures resulting in cement extravasations outside of the vertebral body. These publications all reported using a standard, more liquid, cement material than the current study. The results of this work show that highly viscous cement can be potentially beneficial to decrease the leakage rate when treating malignant compression fractures.

The higher risk of extravasations in patients with spinal malignancy, compared with patients with osteoporotic vertebrae, may be attributed to the increased in situ pressures generated during the procedure (9). Injection of bone cement into a vertebral body with a resident tumor is more difficult than injection into an osteoporotic vertebral body.

Nieuwenhuije et al (1) identified the risk factors of cement leakage in vertebroplasty cases based on postoperative CT images. High fracture grade and low viscosity cement are general, strong, and independent risk factors for cement leakage. Using MRI assessment, cortical disruption and the presence of intervertebral cleft were identified as additional strong risk factors. The authors described 3 different types of cement leakages. A Type B leak represents cement leakage following the basivertebral veins and anterior internal venous plexus into the epidural space. Using low-viscosity bone cement increases the risk of this type of leakage by approximately a factor of 2 compared with usage of medium-viscosity bone cement. A Type S leak compromises cement leakage via the segmental vertebral veins and anterior external vertebral venous plexus. This type of leakage is related to the occurrence of pulmonary cement emboli. Type C leakages are intradiscal in nature 95% of the time, and are highly associated with cortical disruption on preoperative MRI.

The hydraulic injection device has many advantages over the most commonly used mechanical injectors. In this system, the cement container is attached to the needle hub. Cement is injected via a hydraulic injector that is connected to the cement container by a flexible small diameter tube by using a pressurized sterile saline. Hydraulic pressure using saline can be transmitted over long distances and allows injection of highly viscous cement more efficiently than a direct mechanical system. The flexible, small diameter tube in the hydraulic system does not transmit forces to the needle tip during injection and does not interfere with the imaging equipment. A rigid mechanical injection device connected directly to the needle can apply undesirable forces during injection inside the vertebral body. Also, the flexible hydraulic tubing can bend around obstructions in between the needle and the pump without interfering with imaging equipment; it also allows the physician to inject cement while standing outside the radiation field. A more rigid mechanical system would restrict where one can be positioned during injection.

Limitations of this study include that it was conducted retrospectively; however, a comprehensive analysis of all data was performed. In addition, this study was conducted at a single site only and may, therefore, not reflect possible interoperator variability, which is typical for surgical devices. Further studies with larger sample sizes would also address the issue of the relatively small sample size included in this evaluation. Despite all the limitations, observational studies are the mainstay of the literature for initial reports and for complications in general. Considering that there have not been any studies in this area, this retrospective

evaluation should provide a foundation for future controlled prospective studies.

Conclusion

In this study, we evaluated the feasibility, safety and radiographic evidence of leakage in both benign and malignant compression fractures using high viscosity cement injected by a hydraulic system. Leakage rates and locations were found to be closely equivalent between both benign and malignant compression fracture. No leakage or mild leakage was noted in 92% of the osteoporotic compression fractures and 90% of malignant lesions treated. No clinically significant leakage that required further intervention was reported in this patient cohort. The use of a hydraulic system to inject highly viscous cement is safe and feasible and may be useful for treatment of malignant compression fractures, as it results in a leakage rate almost equal to that of benign lesions. High viscosity cement may be helpful to decrease the leakage rate in malignant compression fractures. Further prospective studies are needed to confirm this finding.

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