Randomized Trial

# The Potential Impact of Venobasillar System Morphology and Applied Technique on Epidural Cement Leakage with Percutaneous Vertebroplasty

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**Background:** Bone cement leakage during vertebroplasty is a frequently reported complication with the potential for neural injury.

**Objective:** To assess risk factors for epidural cement leakage during vertebroplasty.

**Setting:** Neurosurgical department of a scientific research institute.

**Study Design:** This is a prospective cross-sectional randomized trial.

**Methods:** Seventy-five patients with intractable pain due to low energy vertebral compression fractures between T11 and L5 were treated with vertebroplasty at 150 vertebral levels. Preoperative computed tomography (CT) scans were utilized to characterize vertebral parameters including the type of nutrient foramena in the posterior vertebral cortex. Following vertebroplasty, distance from the needle tracts to the midline and the presence and type of any epidural cement leakage were determined. Using logistic regression analysis, significant risk factors for cement leakage were determined.

**Results:** A smaller distance between the tip of the needle and the midline and a magistral type of venobasillar system were found to be significant risk factors for epidural cement leakage ($P < 0.0001$). Use of a bipedicular vs. monopedicular technique did not significantly affect the rate of epidural cement leakage ($P = 0.3869$).

**Limitations:** This study is limited because of the relatively small number of patients and the lack of any patients who had clinical consequences as a result of extensive epidural cement leakage.

**Conclusion:** The type of venobasillar system should be taken into account when planning a vertebroplasty procedure as a magistral type of venobasillar system is associated with the increased rate of epidural cement leakage. It is important to try and achieve a large distance between the needle tip and the midline, especially when a magistral type of venobasillar system is present, to reduce the risk of epidural cement leakage.

**Key words:** Vertebroplasty, intracanal cement leakage, low energy vertebra fracture

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Low energy vertebral fracture is one of the most frequent causes of disability in older patients (1). Vertebroplasty, originally reported in the 1980s, has been widely used to treat low energy vertebral fractures and has a reported rate of success of up to 97% in select patients (2-6). A major complication rate of 1 – 6% has been reported for percutaneous vertebroplasty (2,7). Although vertebroplasty has been considered relatively safe, epidural cement leakage remains a frequent occurrence and carries the potential for temporary or permanent loss of neurological functioning (2,8-10). The mechanisms of

neurological injury in cases of epidural cement leakage are believed to be due to either direct mass effect of the neural elements or thermal injury from cement polymerization (8,11).

Yeom et al (12) divided cement leakage into 3 types: type B – intracanal leakage through venobasillar system, type B – cement leakage through cortical clefts, and type S – cement leakage via the segmental veins. Type B has been reported to be the most neurologically risky (2,3). Some risk factors for epidural cement leakage have been identified including the use of low viscosity cement, the presence of a posterior cortical defect, a severe vertebral body compression deformity, and the use of a larger volume of injected cement (13,14). The use of a mono- vs bipedicular approach have been debated as a risk factor with various authors reporting opposing opinions (15,16). The aim of this study was to determine if other risk factors such as the type of venobasillar system or the position of the needle were independent risk factors for epidural cement leakage during vertebroplasty.

## Methods

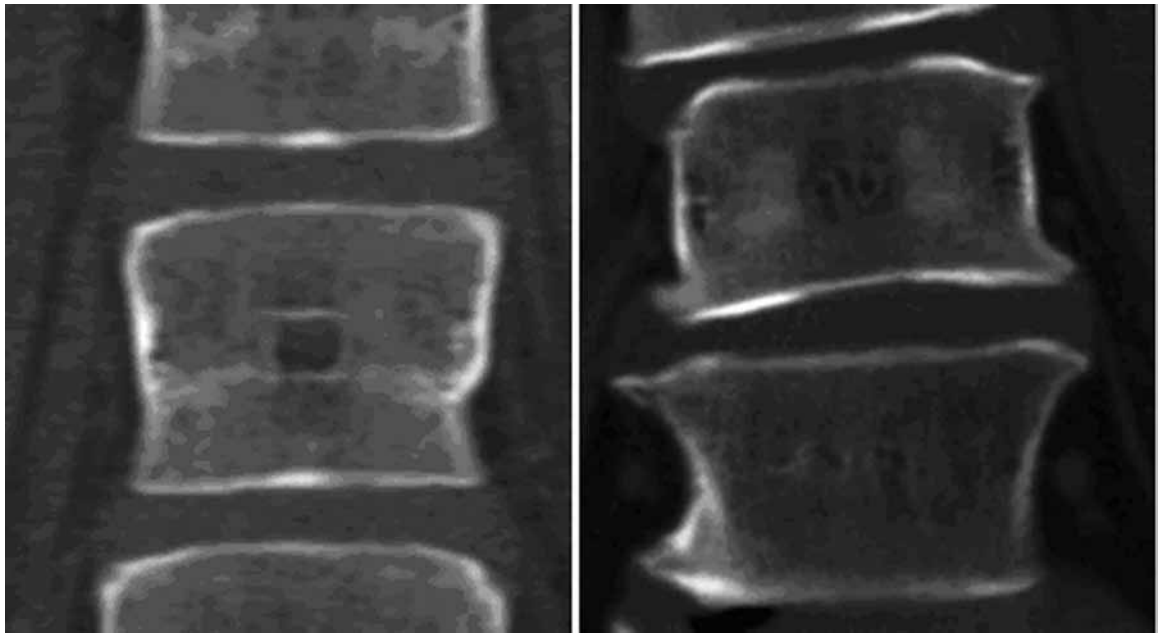
This is a prospective cross-sectional randomized study of 75 patients with low energy vertebra fractures. After obtaining institutional ethics board approval, a consecutive cohort of patients with low energy vertebral compression fractures (T11-L5), who were interested in study participation and signed an informed consent documents, were enrolled in this study. Study inclusion criteria were compression fractures due to osteoporosis and low energy trauma. Exclusion criteria included patients with a fracture compromising the posterior cortex of the vertebra, those with vertebral height loss of greater than 60%, and those with any evidence of neoplastic involvement of the spine. All patients had intractable back pain that was unresponsive to a minimum of 4 weeks of conservative treatment consisting of rest, bracing, and oral analgesic medications prior to vertebroplasty.

Before undergoing the vertebroplasty procedures, all patients underwent a non-contrast computed tomography (CT) scan (Aquilion 32, Toshiba Corporation). The scans utilized a slice thickness was 0.5 mm, covering a scan area of 50 cm. The scan parameters included tube voltage 120 kV, tube current 300 mA, auto mAs range 180 – 400; 1.0 sec/3.0mm/0.5x32, helical-pitch 21.0. Integrated software was utilized for CT scans assessment (Vitrea Version 5.2.497.5523) incorporating a window width/window level ratio of 2000/500. The CT scans were evaluated independently by 2 radiologists. The fractures were classified according to the classification system of Genant et al (17). Other imaging characteristics were also analyzed including the morphology of the posterior cortical nutrient foramena (venobasillar system). Specifically, the vertebra were classified according to whether they had a magistral type venobasillar system (a large, single centrally located posterior nutrition foramen) or a dispersed type venobasillar system with multiple small nutrient foramena (Fig. 1a and 1b).

The vertebroplasty procedures were performed using a standardized technique under sterile conditions using fluoroscopic guidance. Patients were first anesthetized with intravenous sedation (Midazolam 5 mg) and local anesthesia at the skin puncture site and bone periosteum (Lidocain 2% 20 mL). Next, either one (monopedicular cases) or 2 (bipedicular cases) pedicles were cannulated under fluoroscopic guidance using a 10 G bone biopsy needle which was advanced into the anterior one third of a vertebral body on the lateral fluoroscopic view.

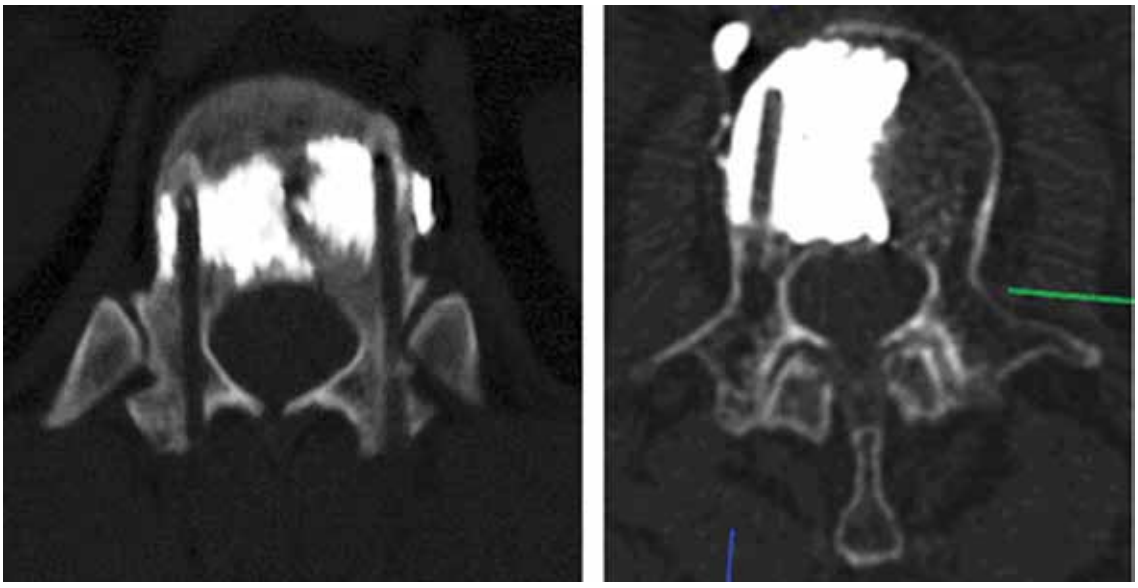
A high viscosity methyl methacrylate bone cement (Vertecem V+, Synthes) was utilized in all cases. This type of cement is doughy immediately after mixing and has an elongated polymerization time. The cement was allowed to cure for 6 – 7 minutes to increase viscosity. Then the cement was then injected into the vertebral body under continuous fluoroscopic guidance until at least the anterior ¾ of vertebra body was filled up with cement on lateral fluorogramms. In cases of cement spread to the posterior wall and signs of a cement drain, the vertebroplasty procedure was interrupted regardless the volume of the injected cement. The cement was then allowed to cure while leaving the needle(s) in place and gently and continuously moving the needle to needle to prevent incarceration within the cement.

Postoperatively, non-contrast CT scans were performed in all cases using the same protocol as for the preoperative CT scans. All scans were assessed independently by 2 radiologists and the following variables were collected: the distance of a needle tip from midline (Fig. 2a and 2b) and the presence, type, and severity of any epidural cement leakage. Images where epidural cement leakage was observed were further categorized into one of 2 groups: those with local epidural cement leakage (cement meniscus only at the nutrition foramen) (Fig. 3a) and those with extensive epidural cement leakage (cement mass within the spinal canal) (Fig. 3b). Patients with evident vio-



*A* *B*

Fig. 1. *The posterior vertebral body in a coronal CT images. A. magistral type of venobasillar system.B. disperse type of venobasillar system.*



*A* *B*

Fig. 2. *Location of needle tracks seen on an axial CT image A) following a bipedicular vertebroplasty; B) following a monopedicular vertebroplasty, red line shows a midline, green line shows a distance between a needle tip and midline of a vertebra body.*

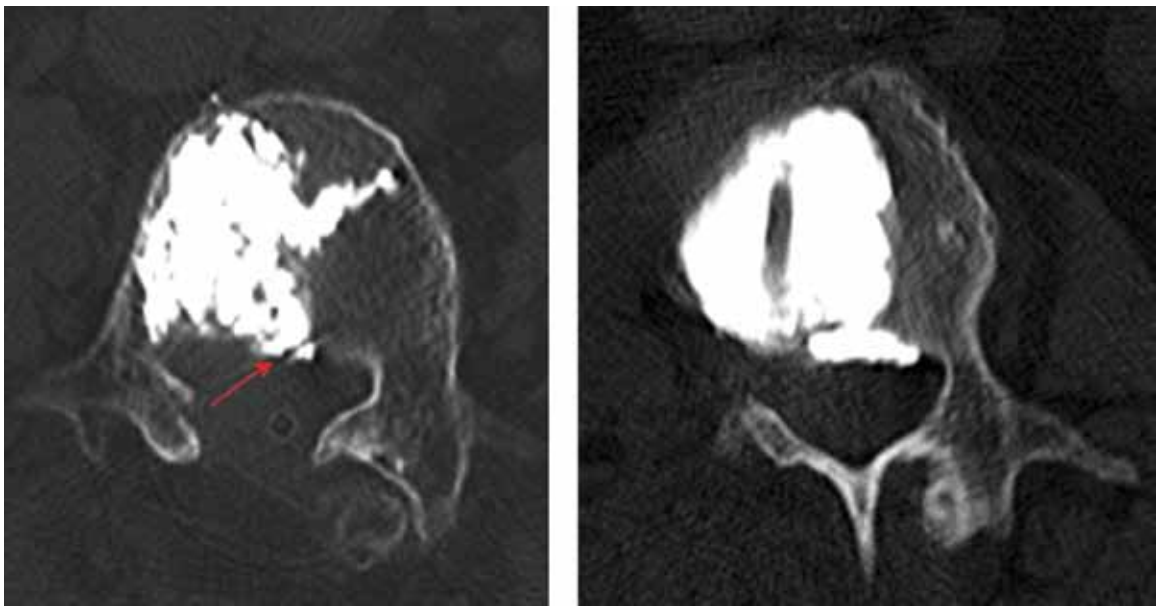


Fig. 3. A. Local epidural cement leakage on axial CT image (red arrow). B. Extensive epidural cement leakage on axial CT image (red arrow).

lation of needle placement were excluded from this study.

### Statistical Analysis

A power analysis was performed prior to the study using data from a small pilot sample to determine the necessary sample size for patient recruitment. Fisher's exact test was used to assess the statistical significance of dichotomous variables. A logistic regression analysis was performed to assess the association between cement leak and needle position, venobasillar system type, and the mono- vs bipedicular technique.

## Results

A total of 75 patients, ages 57 – 82 (mean 65) were enrolled in this study including 57 women (76%) and 18 men (24%). Thirty-seven patients (43%) had a single level fracture and 43 (57%) had multi-level fractures. A total of 150 vertebroplasty procedures were performed including 56 (37%) with a bipedicular technique and 94 (62%) with a monopedicular technique.

Extensive epidural cement leakage was observed in 28 cases (19%), although all patients were asymptomatic. A magistral type of venobasillar system was observed in 65 (43%) of the 150 treated vertebral levels and of these 22 (34%) demonstrated extensive epidural cement leakage. A disperse type of venobasillar system was observed in 85 (57%) of the 150 treated vertebral levels, of these 6 (7.1%) demonstrated extensive epidural cement leak. These differences were analyzed using Fischer's exact test and found to be statistically significant with a $P < 0.0001$.

Using logistic regression analysis, the relationship between extensive epidural cement leakage and the distance from the needle tip to the midline was explored (Fig. 4). The analysis demonstrated a strong relationship between these factors with a smaller needle distance to the midline significantly favoring a higher rate of extensive epidural cement leakage. The parameters of general logistic regression that includes type of venobasillar system and a distance of a needle tip from a midline were B0 = -1.487795, $P = 0.0118$; B1 = -0.1375676, $P = 0.01786$; and B2 = 1.9034 (B0 is an intercept coefficient, B1 is a slope coefficient for a distance of needle from a midline, and B2 is the slope coefficient for a venobasillar system type).

The odds ratio (OR) for the distance of a needle from a midline per unit change was OR = 0.8715, 95% confidence interval [0.7770; 0.9775]; OR range 0.0841; 95% CI [0.0106; 0.6635]. OR for the presence of a ma-

gistral type of venobasillar system equaled 6.7084; 95% CI [2.4574; 18.3129]. The value for calculated coefficient of correlation for the former was r = -0.6888; for the latter – r = 0.5622. Calculated from those figures determination coefficients show that almost 79% of changes in rate of intracanal cement leakage can be explained by detected risk factors. The predictive value of the estimated general model was 84% (percent of correctly predicted values for dependent variable). Goodness of fit for the estimated regression model was Chi square = 23.65705, $P < 0.0001$.

The influence of the applied technique on epidural cement drain rate was also studied (mono- vs. bipedicular). Extensive epidural cement leakage was observed in 20 of 94 procedures for a rate of 21.3% using the monopedicular approach. Extensive epidural cement leakage was observed in 8 of 56 procedures for a rate of 14.3% using the bipedicular technique. The difference in rate of epidural cement drain between those 2 subgroups did not show statistical significance using Fischer's exact test ($P = 0.3869$). Addition of the mono- vs bipedicular technique factor to the presented previously general logistic regression model did not produce a significant change in the quality of the estimated regression model. The statistical significance of the observed differences between 2 models that include only distance from a midline and venobasillar system type and that one with the additional factor of the applied technique type accounted for only $P = 0.8903$.

## Discussion

Cement leakage into the venous system is a common complication with vertebroplasty, although it is rarely associated with neurologic consequences (2). Unfortunately, fluoroscopic guidance is not able to prevent or even detect many cases of epidural cement leakage, as the findings on postoperative CT are considerably higher than detected by intraoperative fluoroscopy (2,3). It is therefore useful to have thorough understanding of the preoperative factors that can be used to predict the risk of epidural cement leakage, as well as, technical strategies that can be used to reduce the rate of epidural cement leakage.

Others, including Georgy (18), have classified cement leakage, however the clinical significance of this grading system remains unclear. For this reason, we chose to focus on the extensive type of cement leakage as this type of leakage is the one at risk for neurologic compromise.

Our finding that the mono- vs. bipedicular technique did not have a significant effect on the rate of extensive epidural cement leakage is in contrast to other authors who have advocated one technique or the other as being associated with a lower rate of cement leakage (15,16). We believe the discrepancy in our findings are due to the inclusion of the additional variables of this study which have a much greater effect on the risk of epidural cement leakage compared to whether a mono- vs bipedicular technique was utilized.

Our findings are in agreement with those of Kasó et al (19), who observed that a lateral position of the vertebroplasty needle was associated with a decreased rate of epidural cement leakage. Our study has added the morphology of the venobasillar system as another clinically significant factor to consider with the magistral type of venobasillar system being associated with a much higher risk of extensive epidural cement leakage.

Other recent studies have demonstrated that the cement leakage rate is dependent on the volume of cement injected, with a larger volume being associated with a higher risk of leakage. In addition, there is not a strong relation between volume of the injected cement and clinical result (14,20). Filling of the just 24% of intertrabecular space with bone cement has been associated with favorable clinical and biomechanical results following vertebroplasty (14). This study would add additional support to the hypothesis that attempts to achieve a maximum fill of the vertebral body, especially if this required placing the needle close to the midline or in the setting of a magistral venobasillar system, are unjustified.

The limitations of this study must be acknowledged and include the relatively small number of patients and the lack of any patients who had clinical consequences as a result of the extensive epidural cement leakage. Nonetheless, the benefits of this study are the fact that it highlights clinical relevant findings to reduce the rate of extensive epidural cement leakage.

This study suggests that the morphology of the venobasillar system should be evaluated and taken into account when planning a vertebroplasty intervention due to the increased rate of extensive epidural cement leakage seen with the magistral type of venobasillar system. In addition, the surgeon should strive to keep the needles far from the midline during cement injection to reduce the rate of epidural cement leakage.

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