J Exp Pathol. 2026;7(1):12–17.

Journal of Experimental Pathology | Commentary

Metrics and Confounders of Vertebral Augmentation on Malignant Spine Fractures

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Received date: March 30, 2026, **Accepted date:** May 08, 2026

Citation: Copeland R, Roldan SP, Roldan CJ. Metrics and Confounders of Vertebral Augmentation on Malignant Spine Fractures. J Exp Pathol. 2026;7(1):12–17.

Introduction

Vertebral augmentation (VA) encompasses percutaneous vertebroplasty and kyphoplasty, with or without the integration of expandable intravertebral implants (EII), is a primary intervention for the management of painful vertebral compression fractures, including those of a pathologic nature secondary to cancer. The procedure involves the targeted injection of polymethylmethacrylate (PMMA) or analogous bone cement into the fractured vertebral body to achieve mechanical stabilization and subsequent analgesia.

Precise image guidance is paramount to ensure the optimal delivery of PMMA, typically targeting the anterior third of the vertebral body. Fluoroscopy remains the most prevalent imaging modality utilized for this purpose. The image-guided VA is a technically demanding intervention that can result in extended fluoroscopy times (FT) and higher cumulative fluoroscopy doses (FD) relative to standard interventional spinal procedures. These radiation metrics are often amplified in academic tertiary care centers where procedures are performed by trainees under the guidance of experienced interventionalists [1].

While existing literature has quantified radiation exposure during fluoroscopically guided procedures for non-malignant spinal pain, such as epidural steroid or facet joint injections, there remains a significant paucity of data specifically addressing radiation exposure in oncology patients undergoing VA for pathologic fractures [2,3]. Furthermore, the clinical implications and potential long-term risks associated with such exposure for both the patient and the proceduralist remain inadequately defined.

Consequently, this study sought to evaluate radiation exposure levels during VA procedures in a cancer-specific cohort by retrospectively analyzing documented FT and FD metrics. Additionally, it analyzed characterized procedural and demographic variables, including vertebral levels, augmentation techniques, and pedicle approaches. These data aimed to provide interventional pain specialists with a benchmark for assessing radiation risk and to facilitate the development of protocols to reduce ionizing radiation exposure for both patients and healthcare personnel within the procedural suite.

Participating patients

The study included patients that received care from various oncology subspecialists. Eligibility criteria included a cancer diagnosis; evidence of stable thoracic or lumbar vertebral compression fracture upon computed tomography (CT) or magnetic resonance imaging (MRI) of the spine; a clinical evaluation by pain specialists confirming axial pain originating from compression fracture(s) and supporting the need for VA; and a VA procedure performed in an operating room.

Statistical analysis

Summary statistics, including mean, SD, median, and range, for continuous variables, such as age as well as frequency counts and percentages for categorical variables, such as sex, were provided. The Wilcoxon signed-rank test was used to evaluate statistical differences in pain scores before and after VA. The Fisher's exact or the chi-square test was used to assess associations between categorical variables. The Wilcoxon rank-sum test was used to assess the difference in a continuous variable between patient groups. SAS, version 9.4 (Cary, NC), was used for all the analyses.

Variables measured

The study described patient demographics, including sex, age, and cancer diagnosis. FT was measured from initial to final fluoroscopy during the procedure, and FD was measured as the total radiation dose used (these variables are automatically recorded in the fluoroscopy database as part of the medical records). To determine what variables, if any, were associated with increased VA radiation exposure, data on body mass index (BMI) was collected as a general medical assessment on all patients; a BMI of 25 or higher was considered overweight, and a BMI of 30 or higher was considered obese. The review included the vertebral levels augmented, the type of procedure performed (i.e., vertebroplasty or kyphoplasty with or without expandable intravertebral implants), the approach used (i.e., unipedicular, bipedicular, or extra-pedicular), the volume of PMMA injected, and any immediate reported complications.

Demographic data

Demographic data for 140 patients was included and summarized in **Table 2**. The median age was 69 years (range, 38–92). There were 61 women and 79 men. Most patients (77.9%) were white. The most common diagnoses were multiple myeloma (n=58, 41.4%) and lung cancer (n=12, 8.6%), with the remaining diagnoses comprising solid and liquid cancers such as Leukemia of diverse etiologies.

None of the patients had a documented osteoporosis-related fracture or other factors that might have contributed to the vertebral injury (e.g., trauma). Most patients had a single compression fracture of the lumbar spine (n=39, 27.9%) or of the thoracic spine (n=29, 20.7%). The spine levels augmented included those from the thoracic spine (cephalad to T4) to the sacral spine (caudad to the sacrum). In most cases, either one or two levels at the lumbar spine were augmented per procedure (n=52, 37.1%). The most common techniques used were percutaneous vertebroplasty (n=65, 46.4%) and balloon kyphoplasty (n=55, 39.29%), and most patients (n=81, 57.86%) underwent an unipedicular VA approach (**Table 3**). Patients older than 60 years were more likely to undergo unipedicular VA compared to patients younger than 60 years (n=68 [48.6%] and n=13 [9.3%], respectively).

Table 1. Variables affecting FT & FD in vertebral augmentation.

Higher FT & FD	Lower FT & FD
• Kyphoplasty	• Vertebroplasty
• Multi-level	• Single level
• Malignant fractures (Sclerotic > Lytic lesions)	• Non-malignant
• Higher BMI, especially >30	• Normal or lower BMI
• Male gender	• Female gender
• C-arm technology	• O-arm technology • Biplanar fluoroscopy
• Continuous fluoroscopy	• Pulsed fluoroscopy
• C-arm operated by hand	• C-arm operated by foot switch
• Trainees-assisted	• Experienced proceduralists

Table 2. Patients' characteristics (N=140).

Characteristic	n	%
Age		
<60	26	18.6
≥60	114	81.4
Sex		
Male	79	56.4
Female	61	43.6

Characteristic	n	%
Race		
White	109	77.9
Black	13	9.3
Asian	7	5
Other	11	7.9
Cancer diagnosis		
Multiple myeloma	58	41.4
Pancreatic	4	2.9
Gastro-esophageal	4	2.9
Gynecologic	4	2.9
Thyroid	1	0.7
Other cancers	20	14.3
Prostate	9	6.4
Lung	12	8.6
Breast	6	4.3
Renal	8	5.7
Colorectal	5	3.6
Melanoma	5	3.6
Hepatobiliary	4	2.9

Table 3. Vertebral augmentation levels, technique and approach used.

Characteristic	n	%
Levels augmented		
L1–2	52	36.4
L3–4	10	7.1
S1	1	0.7
T1	29	20.7
T1, L1–2	14	9.9
T1, L3–5	8	5.7
T2	5	3.6
T2, L1–2	9	6.4
T2, L3	1	0.7
T3	3	2.1
T3, L1–2	2	1.4
T3, L3	2	1.4
T4, L1	2	1.4
Technique		
Kyphoplasty	57	40.7
Vertebroplasty	66	47.1
EII	17	12.1
Pedicle approach		
Unipedicular	81	57.9
Bipedicular	48	34.3
Combined	11	7.9

Abbreviation: EII: Expandable Intravertebral Implants.

Discussion

VA is a minimally invasive technique for percutaneous stabilization of painful vertebral fractures, including those caused by malignancy. There is variability in adverse events caused by VA, due in part to the need for intraoperative fluoroscopic visualization, differences in the proceduralist's experience level, fracture morphology, and vertebral level, among other factors [5–9].

Clinical efficacy

The patients' baseline demographic and clinical characteristics were generally similar. The mean pain score (as measured on the numerical rating scale) decreased by 3.56 (SD, 2.58) after the VA procedure. The median pain score was reduced by 4 (range, -3–10) (P<0.0001). These findings suggest that the VA procedures were effective for pain control.

Metrics of the procedure

Due to this complexity and the time required for such procedures, examination of ionizing radiation exposure is imperative, as potential deterministic (harmful effects likely to occur after exceeding dose thresholds) and non-deterministic (stochastic) effects from such exposure are concerned for the patient and the proceduralist. For instance, latent effects seen from ionizing radiation exposure include the development of cataracts after a fractionated or cumulative dose of 800 rem (0.01 rem = 0.1 mGy), with a latency period of 8 years, with concerns that lens opacification may occur with even lower cumulative doses [10–12]. The International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements define dose limits for VA procedures to protect both workers and patients from the harmful effects of ionizing radiation [13–15].

In comparison to non-malignant conditions, VA procedures performed in cancer-related fractures expose some differences that might be reflected in a higher FT and FD. Here we discuss some factors that might contribute to the findings of the study.

Technique related confounders

Current literature reflects a significant lack of data regarding radiation exposure during vertebral augmentation (VA) for pathologic vertebral fractures, with most existing studies focusing exclusively on non-malignant populations. For instance, a meta-analysis published in 2021excluded oncology patients, it reported a mean fluoroscopy time (FT) of 294 ± 198 seconds for vertebroplasty; notably, this modality demonstrated lower radiation exposure for both the operator and patient relative to kyphoplasty [16]. A separate study of non-cancer patients reported a mean FT per level of 124 seconds (range, 36–258 s) for single fractures and 102 seconds (range, 36–174 s) for multiple fractures [17]. In contrast, this study revealed a prolonged overall mean FT of 233.8 seconds and a higher mean fluoroscopy dose (FD) of 157.98 mGy for VA procedures in the oncology setting.

Patient related confounders

Consistent with previous observations, this study identified a significant correlation between increased radiation exposure and overweight status, defined as a Body Mass Index (BMI) of 25 or above (study mean BMI: 26.67) [3]. FT was particularly extended in patients with a BMI >30.45, a finding that may be idiosyncratic to our specific patient cohort.

Furthermore, the structural distortion of vertebral anatomy inherent in malignant lesions including posterior wall disruption, osteolysis, and pedicle destruction necessitates a highly tailored procedural approach to maintain clinical efficiency [18]. In the present study, an unipedicular VA approach was utilized in most cases (57.86%). Of clinical significance is the presence of sclerotic bone lesions, which unlike lytic lesions, frequently require extended FT due to the increased bone density that instrumentation must penetrate [19]. This relationship appears to correlate with the increased FT observed in our sub-60-year-old demographic. This subgroup exhibited a higher prevalence of sclerotic lesions secondary to diverse etiologies, including prostate and breast cancer, carcinoid tumors, medulloblastoma, neuroblastoma, gastrointestinal adenocarcinoma, Hodgkin lymphoma, small cell lung cancer, pulmonary adenocarcinoma, and medullary thyroid carcinoma. Finally, the higher average bone density in males relative to females may account for the association with elevated FD, a trend observed in both existing literature and our current findings [4].

Equipment related confounders

The utilization of simultaneous biplanar fluoroscopy has been associated with a reduction in cumulative radiation exposure, as it facilitates a consistent, optimal imaging configuration throughout the procedure and obviates the requirement for manual repositioning between orthogonal planes [20]. Furthermore, the implementation of O-arm technology, a mobile imaging system providing real-time two-dimensional (2D) and three-dimensional (3D) visualization has demonstrated superior diagnostic precision and procedural accuracy. This modality is further associated with a decreased necessity for surgical revisions or supplemental imaging, while effectively eliminating radiation exposure for the surgical personnel [21]. Within the study's institution, both advanced imaging technologies are integrated into the neurosurgical and interventional radiology suites but remain inaccessible in the interventional pain management department.

Optimization of fluoroscopic metrics (FT and FD) may be achieved through surgeon-controlled C-arm operation via foot switches, a practice shown to significantly reduce total radiation exposure [22]. However, these specific procedural configurations are frequently unavailable in many clinical settings. Furthermore, balloon kyphoplasty presents inherently greater technical demands relative to percutaneous vertebroplasty due to the multi-step requirement of inflatable bone tamp (IBT) deployment; consequently, this technique necessitates more frequent fluoroscopic assistance for precise structural monitoring.

Proceduralist related confounders

Reviewed data suggests a discernible learning curve effect among clinical trainees, which persisted despite direct supervision by an experienced interventionalist. This phenomenon is illustrated by the significantly elevated fluoroscopic metrics recorded in July and August, the initial months of the academic cycle. During this introductory phase of fellowship training, the mean fluoroscopy time (FT) was 265.80 seconds, and the mean fluoroscopy dose (FD) was 165.90 mGy. In contrast, a longitudinal reduction in these parameters was observed during May and June, toward the conclusion of the fellowship term, with the mean FT and FD decreasing to 225.75 seconds and 145.85 mGy, respectively. These findings underscore the impact of accumulating technical proficiency on procedural efficiency and radiation safety within an academic teaching environment.

Safety of the procedure

The incidence of complications on the VA procedure was reported to be 10%, mainly from mild PMMA extravasation, and without clinical implications. This did not reach statistical significance between the groups with and without complications, as the P values for FD and FT were 0.5205 and 0.4637, respectively.

Limitations

Several limitations inherent to this study warrant consideration. The retrospective design precluded the ability to address certain inconsistencies or inadequacies in data acquisition that occurred at the point of care. Furthermore, the single-center nature of the data limits the generalizability of the findings, as fluoroscopy time (FT) and dose (FD) are highly dependent on institutional protocols, specific clinical settings, and varying levels of procedural expertise among clinicians. These external variables significantly influence radiation metrics and may not be fully captured within the scope of this analysis.

Conclusions

The findings of this study indicate that vertebral augmentation (VA) procedures in the oncology population are associated with significantly higher radiation exposure compared to established non-malignant cohorts. Consequently, interventionalists must exercise heightened vigilance regarding radiation safety protocols when managing cancer-related vertebral fractures. The elevation in fluoroscopy time (FT) and fluoroscopy dose (FD) is multifactorial, predicated upon a complex interplay of patient-specific variables, pathologic fracture morphology, procedural technique, and the technical proficiency of the operator. Furthermore, the availability of advanced imaging infrastructure remains a critical determinant of cumulative radiation delivery. These results emphasize the necessity of tailored radiation mitigation strategies in the treatment of vertebral augmentation for malignant vertebral body fractures.

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