ORIGINAL PAPER

Vertebral body clinico-morphological features following percutaneous vertebroplasty *versus* the conservatory approach

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Abstract

Most percutaneous vertebroplasty procedures are being performed in order to relieve pain in patients with severe osteoporosis and associated stable fractures of one or more vertebral bodies. In addition, vertebroplasty is also recommended for patients suffering from post-traumatic symptoms associated with vertebral fractures, patients with large angiomas positioned inside the vertebral body, with an increased risk for collapse fracture and also patients presenting with pain associated with vertebral body metastatic disease. On another aspect, it is possible that in isolated cases, an orthopedic surgeon confronted with a vertebra plana presentation will recommend bone cement injection into the vertebral bodies adjacent to the fractured one, in order to have a better and more robust substrate for placement of screws or other fixation devices. The aim of our study is to compare results attained by the Department of Interventional Radiology, in performing this procedure, with results attained by following the classical orthopedic treatment procedure, involving non-operative treatment, using medication and bracing varying from simple extension orthoses in order to limit spinal flexion, light bracing for contiguous fractures, presenting either angulation or compression, and for severe cases standard thoracolumbosacral orthoses (TLSOs).

Keywords: vertebral fracture, vertebroplasty, minimally invasive.

⊡ Introduction

The process of injecting bone cement through a percutaneous needle has first been implemented in Europe, at the end of the 80's [1]. Later on, in the early 90's, the United States also adopt the procedure [2].

As far as safety, patient comfort and length of hospital admission, the newly developed procedure showed a rapid increase in frequency, nowadays being performed worldwide in a wide range of health institutions.

Most percutaneous vertebroplasty procedures are being performed in order to relieve pain in patients with severe osteoporosis and associated stable fractures of one or more vertebral bodies. In addition, vertebroplasty is also recommended for patients suffering from post-traumatic symptoms associated with vertebral fractures, patients with large angiomas positioned inside the vertebral body, with an increased risk for collapse fracture and also patients presenting with pain associated with vertebral body metastatic disease.

On another aspect, it is possible that in isolated cases, an orthopedic surgeon confronted with a vertebra plana presentation will recommend bone cement injection into the vertebral bodies adjacent to the fractured one, in order to have a better and more robust substrate for placement of screws or other fixation devices.

Lastly, it is worth noting the prophylactic vertebroplasty

notion that has been vehiculated, based on experimental data that vertebrae adjacent to a cement infused vertebral body receive more structural stress due to the decreased compliance of the local spinal segment [3]. Similar results have been reported in a small clinical study [4] that states that there is a statistically significant higher risk of spinal fracture in the vicinity of the already treated vertebra. Sadly, the paper does not clarify the notion of "vicinity", and moreover several other studies state that 20% of patients treated for stable fracture will have another one in the following year [5].

The aim of our study is to compare results attained by the Department of Interventional Radiology in performing this procedure with results attained by following the classical orthopedic treatment procedure, involving non-operative treatment, using medication and bracing varying from simple extension orthoses in order to limit spinal flexion, light bracing for contiguous fractures, presenting either angulation or compression, and for severe cases standard thoracolumbosacral orthoses (TLSOs) [6–8].

Moreover, we wanted to research and quantify the impact of the treatments on the patient, in consequence we evaluated the patients' wellbeing and overall quality of life before the procedure and at a one month interval after the procedure, using a Ferrans and Powers Quality of Life (QoL) Index© Spinal Cord Injury (SCI) – Version III.

⌕ Patients, Materials and Methods

The study has had a duration of four years and has been developed on a group of 76 patients, referring to the Department of Orthopedic Surgery, University of Medicine and Pharmacy of Craiova, Romania, for symptoms suggesting a spinal fracture.

Soon after admission, each patient underwent a complete history and a physical examination, in order to exclude other possible causes of pain.

Each patient was given a survey developed by Ferrans and Powers, tailored for patients with spinal cord injury: Quality of Life (QoL) Index© Spinal Cord Injury (SCI) – Version III.

If the patients had imaging vertebral column studies performed prior to admission, usually magnetic resonance imaging (MRI), they were considered for the vertebroplasty procedure eligibility.

Patients with no imaging studies were referred for spinal native MRI, requesting T1 and T2 weighted sagittal and axial sequences and also sagittal short *tau* inversion recovery (STIR) sequences for the same segment. All MRI images evaluated during this study were performed with MRI machines with magnetic field intensities of 1.5 to 3 T, ensuring satisfactory resolution of the affected segment (Figure 1). Only a portion of the patients also had computed tomography (CT) scans, the amount of extra information given being minimal. Figure 2 shows a native sagittal CT of the thoracic spine and a three-dimensional (3D) rendering of it.

Figure 1 – *Sagittal T2 weighted and STIR sequence of the lumbar spine. Compression fractures of L3 and L4, associated with vertebral column angulation. STIR: Short tau inversion recovery; Acq Tm: Acquisition time; DFOV: Display field of view.*
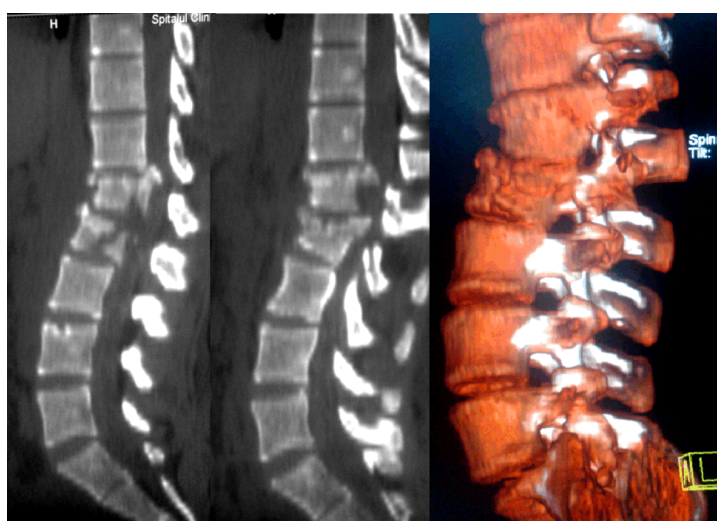
Figure 2 – *Sagittal native CT of the lower thoracic and lumbar spine. Burst fractures of the L2 and L1 vertebrae (left). 3D rendering of the affected segment of the vertebral column. CT: Computed tomography; 3D: Three-dimensional.*

Following clinical, biological and imaging examination, 40 patients have been considered eligible for the procedure. The rest of 36 patients had only relative contraindications, however due to the higher complication risk they opted for the medical approach involving bracing, bed rest and oral analgesic medication.

Relative contraindications were considered:

▪ Retropulsion of bony fragments;

▪ Burst fracture of the posterior wall of the vertebral body;

▪ Severe fracture with more than 70% collapse or greater.

It is worth considering that the literature mentions physicians treating vertebra plana with vertebroplasty and achieving satisfactory results [9–11].

Absolute contraindications include nerve root impingement and spinal cord impingement with the afferent symptoms. This includes radicular pain, decrease of sensitivity and not lastly bladder and bowel deterioration of function. None of the patients enrolled in the study had absolute contraindications.

The percutaneous vertebroplasty has been conducted inside a hybrid operating room, using the floor mounted SIEMENS Axiom Artis dFA monoplane angiograph. The vertebroplasty kits have been supplied by Stryker Medical. A precision cement delivery (PCD) all-in-one mixer and delivery system has been used for 27 patients (manual mixing of cement and manual cement injection), while 13 patients have been treated with the AutoPlex mixer and delivery system, which had an automatic cement mixing and syringe filling function, ensuring longer cement work time.

The bone cement used for all 40 patients was VertaPlex form Stryker Medical – a polymethyl methacrylate with a medium work-time of 10.2 minutes. The cement has been refrigerated prior to the procedure ensuring a small prolongation of the viscous phase.

After the patient has been placed on the table, the affected vertebral body/bodies is/are discovered under fluoroscopy and the C-arm is positioned in such a manner that the X-ray beam passes in the same axis as the vertebral pedicle. A 26G needle and syringe filled with anesthetic is used to numb the area of skin, muscle and periosteum, and also to plot a line from the skin to the pedicle.

After local anesthesia, a vertebroplasty needle of 11G

or 13G is advanced through the pedicle under direct fluoroscopy until the center of the vertebral body is reached.

After verification of correct needle placement in at least two incidences, the cement is taken out of the fridge and mixed with the solvent inside the mixer. After proper homogenization, the cement is manually delivered using a vertebroplasty syringe, as seen in Figure 3, until the vertebral body is completely filled or cement starts escaping from the posterior aspect of the vertebral body.

Usually, 5–9 mL of bone cement are slowly introduced inside each vertebral body under constant fluoroscopic supervision. Each cement dose delivered has been recorded during the procedure, in expectance of further statistical analysis.

After satisfactory opacification of the vertebral body, the cement pump/syringe is disconnected and the needle is rotated 180° around the long axis. After the leftover cement in the vertebroplasty pump has completely dried, the needle is rotated once more 180° and then extracted, maintaining manual local compression for 30 to 60 seconds in order to obtain superficial hemostasis. The aspect of a consolidated vertebral body can be observed in Figure 4.

In conjunction with the data gathered concerning the actual vertebroplasty, we also paid close attention to the radiation dose the patients have been exposed to during the entire procedure. In order to develop a more complex view over this matter, we decided to record not only the name, surname, age, vertebroplasty level/levels associated with cement injection quantity for each vertebra, but also the type of X-ray exposure protocol (usually lumbar, in accordance with SIEMENS Artis dFA available options), total time of fluoroscopy expressed in minutes, radiation dose measured in mGy and also the dose–area product (DAP), which represents a product between the dose, expressed in mGy and a unit of surface [m^2].

The radiation-related data has been generated as a text file by the Leonardo subunit of the Axiom Artis, also reporting live inside the angiography suite information related to patient radiation dose. The file has also been attached to each patient's study CD, for any further medical professional requiring that information.

The patients considered non-eligible for vertebroplasty have received prescriptions for oral analgesic medication and have been fit with an immobilization device in accordance to the severity and level of spinal injury.

Figure 3 – *Vertebroplasty systems: AutoPlex Vertebroplasty System – Stryker Medical (left); PCD Precision Vertebroplasty System – Stryker Medical (right). PCD: Precision cement delivery.*
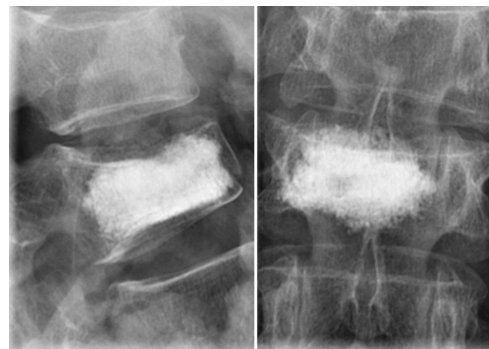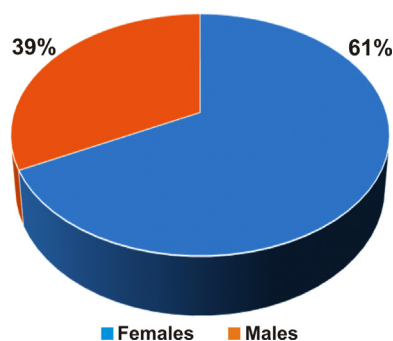

Figure 4 – *Opacified vertebral body in frontal and lateral incidences. Vertebroplasty.*

⊟ Results

The study was based on a cohort of 76 patients, with an average age of 64.22 years, the youngest patient being an 18-year-old female suffering from a spinal column trauma due to a fall, while the oldest was also an 80-year-old female and having multiple compression fractures due to osteoporosis.

As shown in Figure 5, the gender distribution for the total group was 39% males and 61% females.

After patient selection based on clinical and imaging criterion, a group of 40 patients was considered eligible for the procedure, their gender distribution being illustrated in Figure 6. The distribution is similar, women representing 67% of the group.
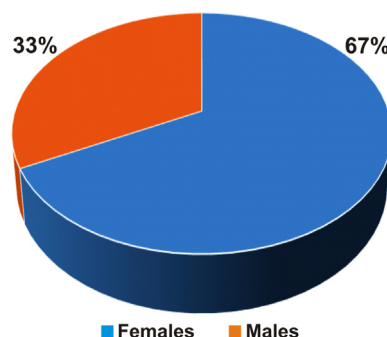
Figure 6 – *Gender distribution in the percutaneous vertebral consolidation group.*

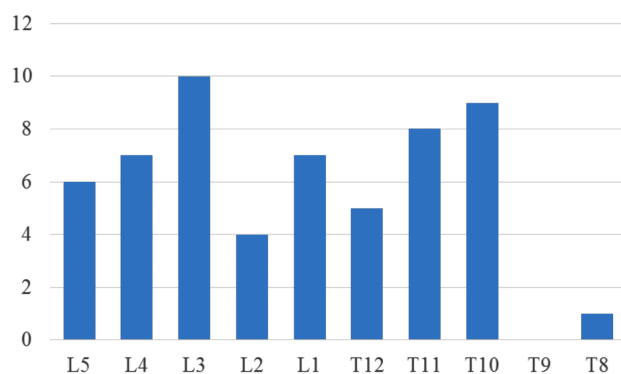**Figure 5 – *Gender distribution for the total group of patients.***

In the case of 17 patients selected for vertebroplasty, more than one vertebra was affected, so in order to maximize the outcome, two vertebrae were consolidated in parallel. The rest of 23 patients had only one vertebral

consolidation each. An analysis of the 57 consolidated vertebrae shows a mean cement volume of 6.76 mL/vertebra, with a standard deviation (SD) of 1.0064. As for the analysis of the site of fracture, results can be found in Figure 7, showing a slight increase in frequency towards the lumbar vertebrae graph area.

Taking into consideration the variable volume of the normal vertebral body in accordance to each region of the vertebral column, we consider that performing an analysis of cement dose distribution over all patient vertebral levels array will somewhat hinder the value of the results. Therefore, during the diagnosis, the vertebral body volume has been determined, resulting in a mean value of 14.5 cm^3 for the thoracic vertebral body volume (ranging from 4.9 to 38.6 cm^3), while values for the lumbar vertebrae has had a mean value of 33.2 cm^3 (ranging from 18 to 59.2 cm^3). It is safe to assume that a lower dose of polymethyl methacrylate will be necessary for consolidation of a thoracic vertebra in comparison to the same type of disease affecting a lumbar one.

Our findings were that a mean volume of 6.76 cm^3 (with a SD of ±1.0064 cm^3) of cement was injected considering the entire array of vertebral bodies treated.

However, considering only the 23 thoracic vertebrae consolidated, the mean value of the cement injected was only 5.34 cm^3 (SD of ±1.3 cm^3), recording a minimum of only 3 mL of cement injected, while the maximum value has been 8 mL. In contrast, considering only the 34 lumbar vertebrae treated during this study, a mean value of 8.02 cm^3 was determined, having a SD of ±1.08 cm^3.

Going even further, we determined the ratio between mean vertebral volume and mean cement injection volume for each of the two regions treated in our Center: for the thoracic vertebroplasty, the bone volume/cement ratio has been of 2.71, where the ratio for lumbar vertebroplasties neared the value of 4.13. This finding leads us to conclude that not only the volume differs between the two values, but also the bone to cement ratio, a smaller quantity (per volume) being necessary for the consolidation of a lumbar vertebra.

If we divide the group of vertebroplasty patients into subgroups, according to their specific etiology for the fracture/fractures, we discover that the vast majority suffers from osteoporosis, followed by the presence of large angiomas. The data can be observed in Figure 8.

Figure 7 – *Distribution of vertebral levels consolidated with bone cement.*

Figure 8 – *Distribution of cases according to vertebral fracture's etiological factor.*

Concerning the other focus of our study, we determined that the mean value for the total radiation dose was 606.43 mGy, with a SD of 233.69 mGy. Concerning the average time our patients were exposed to fluoroscopy, the value obtained was 6 minutes and 42 seconds, with a SD of 2 minutes and 48 seconds.

The average number of image acquisitions has been 26 (SD=7.46), acquisition offering superior image quality in comparison to fluoroscopy.

Not lastly, the mean DAP has had a value of 2294.68 mGy × m^2, with a SD of 1170.3 mGy × m^2.

Plotting a scatter graph containing the representation of fluoroscopy time in conjunction with the total dose (mGy) we can observe a positive correlation between the two, as seen in Figure 9.

At a microscopic level, the bone cement distribution and intercations have been described in Figure 10.

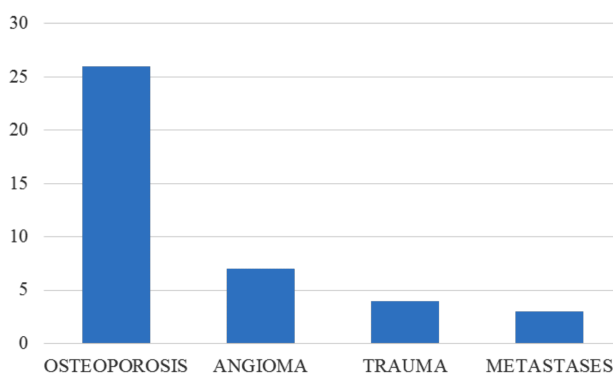A more detailed view of the bone cement compound can be observed in Figure 11.

A closer look to the endosteal interface between the bone cement and the trabeculae is given in Figure 12.

Regarding the QoL survey given to our patients before

the procedure and one month after, we gathered the results indexed in Table 1.

⊟ Discussions

Keeping in mind the vast array of advantages offered by this procedure, it is only fair we also discuss the risks and complications subsequent to percutaneous vertebroplasty. If we were to make a list according to severity, we could divide them into three groups [12].
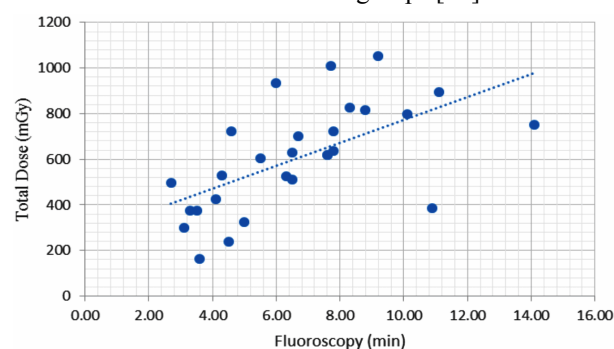
Figure 9 – *Correlation between fluoroscopy and total radiation dose in patients undergoing vertebroplasty.*

Figure 10 – *Normal bone trabeculae surrounding areas of bone marrow. The left of the image contains a few trabecular fragments advanced between the normal ones. Bottom right side shows amorphous material expanding in the bone marrow spaces, containing optically empty gaps of various sizes. There is a clear demarcation area between the bone cement and normal marrow cells. No inflammation present. Hematoxylin–Eosin (HE) staining, ×40.*
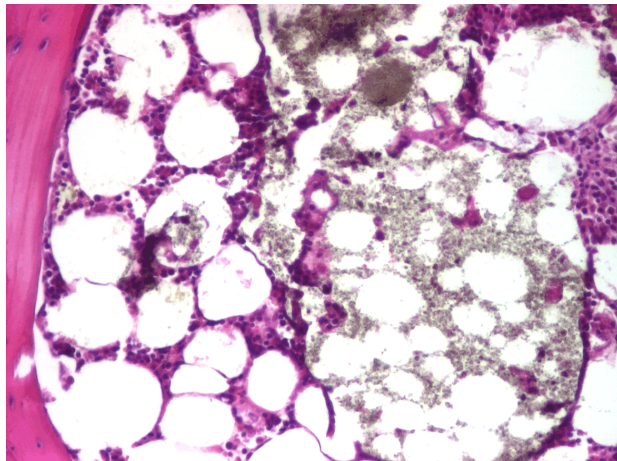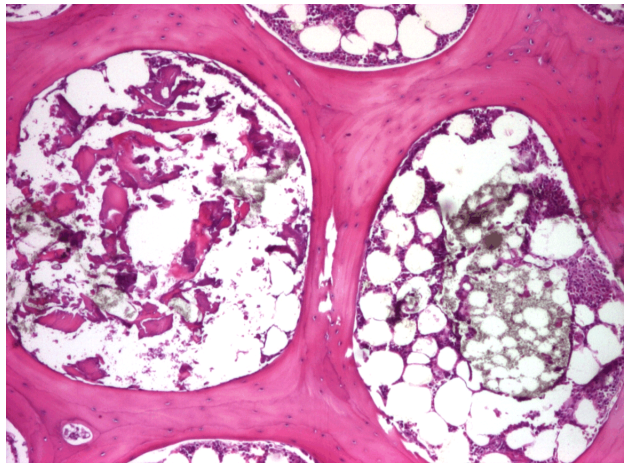
Figure 11 – *Detail of previous figure. The injected bone cement has a granular aspect, presenting homogenous distribution in the medullar space. HE staining, ×100.*
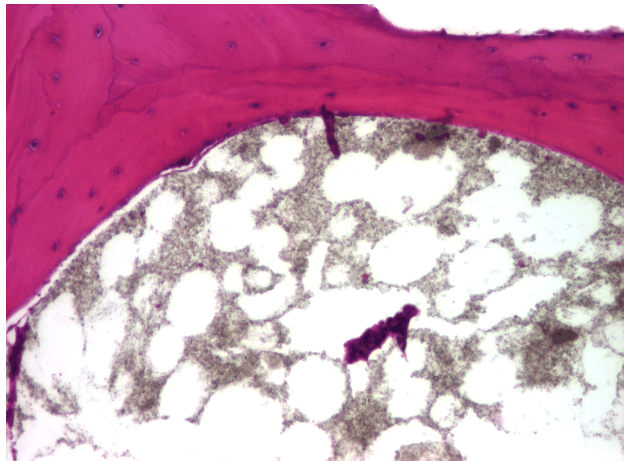
Figure 12 – *Osseous alveolae completely filled with amorphous material. No endosteal inflammatory reaction. HE staining, ×200.*

Table 1 – *Gross results extracted from the QoL questionnaires*

	VPL before	VPL one month after	Medical approach before	Medical approach one month after
Part 1 (Satisfaction)	16.4	24.1	16.7	19.6
Part 2 (Importance)	15.5	26.3	14.3	18.9

QoL: Quality of Life; VPL: Vertebroplasty.

Mild complications

As mild complications, a temporary increase of the local pain level may be experienced, due to an inflammatory reaction in response to the heat released by the polymerization of the bone cement [13]. Although not very frequent, this symptom can easily be controlled with steroids.

Another clinical finding rarely associated with percutaneous vertebroplasty is represented by the onset of transient hypertension, usually easily managed with anti-hypertensive medication [14].

From an imaging point, cement leakage can be observed either during the actual procedure or during a CT or radiographic exam for another disease. Cement leakage occurring in the perivertebral tissues is commonly observed with no real clinical significance. However, cases where leakage appears in the vertebral plateau could dictate cessation of the procedure, the presence of the cement in the intervertebral disc having a significantly increased chance of fracture occurring in the adjacent vertebral body [15].

A better approach for osteoporotic disease is the injection of small amounts of cement, waiting for partial cure before reinjection. In this manner, the vertebral body is sufficiently stable, and the chance for leakage is minimized.

Moderate complications

Findings consider that moderate complications consist of mainly two entities. The first one is infection, the polymethyl methacrylate having a sponge-like structure, being able to harbor a bacterial pathogen. The site of the infectious process can be the disc, the vertebral body itself or the epidural space, the last two having the potential for catastrophic outcomes. Moreover, for infections occurring in the vertebral body, the cement is usually removed surgically [16, 17].

The other complication contained in this category is the permeation of the orthopedic cement into the epidural or foraminal space, most of the cases being clinically uneventful. Moreover, Chiras *et al.* report a rate of paraplegia for percutaneous vertebroplasty of around 0.4% [18].

A particularly bad outcome has the translaminar approach, complication encountered mostly in the thoracic vertebrae, where the pedicles are smaller.

Severe complications

Another significant type of complications is linked to the permeation of the cement into the vertebral veins, causing pulmonary embolism. Although 4.6% of the patients have a small quantity of cement escape the vertebra into the blood stream, most of them are asymptomatic [19, 20]. When symptoms arise, the classical array consisting in dyspnea, chest pain and hypotension can be discovered. The onset of symptoms can either be sudden, either in lysis, in some cases leading to death [21].

⊡ Conclusions

Percutaneous vertebroplasty represents one of the least invasive procedures for treating stable vertebral fractures with or without compression. Due to the minimum requirements of the procedure, not only the procedure is easily accepted by the patient, but also has a positive effect on wellbeing of the patient and inherently on his quality of life. From a clinical perspective, in the first hours after the procedure, the pain either stops completely or it is greatly reduced, the patients being able to revert to the lifestyle before the fracture. Concerning the comparison between the survey results of patient undergoing vertebro-plasty *versus* patients receiving conservative orthopedic treatment, the vertebroplasty has a clear positive impact. The regional characteristics of the affected vertebra must be always taken into account, region related criterion as volume having a significant impact on the volume of cement injected, and thus, the general outcome of the procedure. Radiation dose has to be taken into conside-ration, especially in young fertile patients. Moreover, close monitoring of all patient irradiation parameters helps streamline the workflow of the procedure, optimizing needle placement while minimizing unnecessary exposure.

Conflict of interests

The authors declare that they have no conflict of interests.

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