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VERTEBROPLASTY IN BONE FRAGILITY FRACTURES AND TUMOR FRACTURES: RISKS AND BENEFITS

VERTEBROPLASTIA EM FRATURAS POR FRAGILIDADE ÓSSEA E TUMORAIS: RISCOS E BENEFÍCIOS

VERTEBROPLASTIA EN FRACTURAS POR FRAGILIDAD ÓSEA Y TUMORALES: RIESGOS Y BENEFICIOS

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ABSTRACT

Objective: To evaluate the results of percutaneous vertebroplasty (PV) in spinal fragility fractures (osteoporosis/tumor), analyzing possible complications. Method: We evaluated 33 patients with spinal fractures (FXV) due to osteoporosis or tumor who underwent PV between January and November 2021. A physical examination was performed, obtaining the history and risk factors for bone fragility/tumor and a radiological evaluation of the spine to verify FXV. Genant's semiquantitative method was used for postoperative classification, the VAS score, and a disability questionnaire (ODI). A radiologist evaluated tomographic control to quantify vertebral filling and extravasation, determining where they occurred. Results: 46 vertebrae of 33 patients were operated on, with a mean age of 71 years, and 11 patients with more than one level of surgery. Of the total, 13 patients had tumor fractures, and 20 had fractures due to insufficiency. PMMA extravasation was observed in 31 vertebrae, most frequently in the External Vertebral Venous Plexus (23), Discal Body (9), Anterior Epidural Recess (4), Pulmonary Vessels (4), Internal Vertebral Venous Plexus (3), Inferior Cava (2), Adipose Plane (2) and Azygos Vein (1). No patient had clinical complications. Furthermore, the mean preoperative VAS was eight, the postoperative one was 3, the mean preoperative ODI was 56, and the postoperative one was 30. Conclusion: PMMA extravasation was frequent in several locations and levels without any clinical complications. VP proved to be effective in improving pain and function. ***Level III; Longitudinal Retrospective Cohort Study.***

Keywords: Spine; Osteoporosis; Tumor; Vertebroplasty; Pathological Fracture.

RESUMO

*Objetivo: Avaliar os resultados da vertebroplastia percutânea (VP) em fraturas por fragilidade da coluna (osteoporose/tumoral), analisando possíveis complicações. Método: Foram avaliados 33 pacientes com fratura da coluna vertebral (FXV) por osteoporose ou tumor, entre janeiro e novembro de 2021, submetidos à VP. Foi realizado exame físico junto à obtenção da história e fatores de risco para fragilidade óssea / tumor, além de avaliação radiológica da coluna para constatação de FXV. O método semiquantitativo de Genant foi empregado para a classificação no pós-operatório, além do score EVA e do questionário de incapacidade (ODI). O controle tomográfico foi avaliado por médico radiologista para quantificação do preenchimento vertebral e extravasamento, determinando para onde ocorreram. Resultados: Foram operadas 46 vértebras de 33 pacientes, como média de idade de 71 anos, sendo 11 pacientes com mais de um nível operado. Do total, 13 pacientes apresentavam fraturas tumorais e 20 possuíam fraturas por insuficiência. Observou-se extravasamento do PMMA em 31 vértebras, mais frequentemente para Plexo Venoso Vertebral Externo (23), Corpo Discal (9), Recesso Epidural Anterior (4) Vasos Pulmonares (4), Plexo Venoso Vertebral Interno (3), Cava Inferior (2), Plano Adiposo (2) e Veia Ázigos (1). Nenhum paciente apresentou complicações clínicas. Ainda, o EVA pré-operatório médio foi 8 e o pós-operatório de 3, enquanto o ODI pré-operatório médio foi de 56 e o pós-operatório de 30. Conclusão: O extravasamento de PMMA foi frequente em diversos locais e níveis, sem nenhuma complicação clínica. A VP mostrou-se eficaz na melhora de dor e função. **Nível III; Estudo Longitudinal Coorte Retrospectivo.***

Descritores: *Coluna Vertebral; Osteoporose; Tumor; Vertebroplastia; Fratura Patológica.*

RESUMEN

Objetivo: Evaluar los resultados de la vertebroplastia percutánea (PV) en fracturas por fragilidad de columna (osteoporosis/tumor), analizando posibles complicaciones. Método: Se evaluaron 33 pacientes con fractura de columna (FXV) por osteoporosis o tumor, entre enero y noviembre de 2021, que fueron sometidos a PV. Se realizó examen físico junto con obtención de antecedentes y factores de riesgo de fragilidad ósea/tumor, además de evaluación radiológica de columna para verificar FXV. Para la clasificación postoperatoria se utilizó el método semicuantitativo de Genant, además de utilizar la escala EVA y un cuestionario de discapacidad (ODI). El control tomográfico

Study conducted by the Medical Center of Campinas Foundation, Campinas, São Paulo, Brazil.
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fue evaluado por un radiólogo para cuantificar el llenado vertebral y la extravasación, determinando dónde se producían. Resultados: Se operaron 46 vértebras de 33 pacientes, con una edad promedio de 71 años, 11 pacientes con más de un nivel de cirugía. Del total, 13 pacientes presentaron fracturas tumorales y 20 fracturas por insuficiencia. Se observó extravasación de PMMA en 31 vértebras, con mayor frecuencia en el Plexo Venoso Vertebral Externo (23), Cuerpo Discal (9), Receso Epidural Anterior (4), Vasos Pulmonares (4), Plexo Venoso Vertebral Interno (3), Cava Inferior (2), Plano Adiposo (2) y Vena Azygos (1). Ningún paciente presentó complicaciones clínicas. Además, la EVA preoperatoria media fue de 8 y la postoperatoria de 3, mientras que la ODI preoperatoria media fue de 56 y la postoperatoria de 30. Conclusión: La extravasación de PMMA fue frecuente en varias localizaciones y niveles, sin complicaciones clínicas. VP demostró ser eficaz para mejorar el dolor y la función. ***Nivel III; Estudio de cohorte retrospectivo longitudinal.***

Descriptores: *Columna vertebral; Osteoporosis; Tumor; Vertebroplastia; Fractura patológica.*

INTRODUCTION

Over the years, Vertebroplasty (VP) has become a widely used treatment alternative for treating vertebral fractures refractory to drug therapy. PV is an image-guided, minimally invasive procedure that involves injecting bone cement into a vertebral body fracture to improve the fracture's pain and stability.[1]

PV has historical prominence in the spine surgery scenario, where it aims to relieve pain secondary to vertebral fracture (VF), either due to fragility or secondary to neoplastic lesions, to provide better recovery and reduce disability.[2–4] Compared to radiation therapy alone, PV also provides stabilization of the spine, considerable improvement in pain, and strengthens weakened bone, leading to improved quality of life and quick return to chemo/radiation therapy.[3–6] Although it is a minimally invasive procedure, complications can still occur, the most feared of which is polymethylmethacrylate (PMMA) leakage, which can occur both through blood vessels and into the spinal canal.[7] However, most patients do not present any symptoms.

Vertebral fragility fractures are the most common consequence of osteoporosis. After a spinal fracture occurs, many patients experience severe debilitating back pain, causing a reduction in quality of life and physical function. Conservative treatment consists of analgesia, bed rest, and orthosis, although patients resistant to this treatment, or even those with contraindications or side effects to analgesic treatment, may be candidates for PV.[8]

Tumor-related spinal fractures often require surgical treatment. The most critical factors influencing the need for any type of surgery are the degree of spinal cord compression, the radiosensitivity of the tumor, the presence of spinal instability, and the patient's clinical status and estimated survival. There is a wide spectrum of therapeutic options, such as decompression and fusion in non-radiosensitive tumors with spinal cord compression, followed by adjuvant radiation therapy (RT) and vertebroplasty for stable compression fractures, among other options.[9] In neoplastic spinal lesions, spinal collapse leads to refractory pain due to several factors, such as bone destruction, altered biomechanics, spinal instability, compression of neural structures, and tumor inflammatory mediators.[10]

Most fractures can be treated conservatively due to stability or wedging of less than 50%. However, unstable fractures, such as those with involvement greater than 50% or in a lower percentage but with progression, canal stenosis, or neurological involvement, as well as cases of intractable pain, often require a surgical approach, which, depending on the case, can be open or percutaneous.[2]

Vertebral fractures are usually related to osteoporosis, representing one of the disease's main clinical manifestations.[11] Patients with vertebral fractures are five times more likely to have other vertebrae affected by other fractures and twice as likely to have fractures of the proximal femur and other appendicular bones, usually occurring between the first and third year after the first bone injury.[11]

Osteoporosis has been defined by the *World Health Organization* (WHO) as a disease in which there is a decrease in bone mass and a change in the microarchitecture of the bone, as measured by bone mineral density. It is characterized by a T-score of -2.5 or lower and is one of the causes of fractures, even in low-energy trauma.[11,12] It is estimated that more than 200 million women worldwide suffer from osteoporosis.[13] According to IBGE data, in Brazil, approximately two--thirds of the population have decreased bone mass or osteoporosis, and estimates of vertebral fractures due to insufficiency will increase from 60,000 in 2013 to more than 188,000 in 2060.[13]

This study aims to evaluate the results of percutaneous vertebroplasty (PV) in fragility fractures of the spine (osteoporosis/tumor), analyzing possible complications.

METHODOLOGY

This cohort study was registered (CAAE number 55858622.0.0000.5412) and duly authorized by the local Ethics Committee (consubstantiated opinion number 5.324.341 dated March 31, 2022). The sample consisted of patients who met the following inclusion criteria: the presence of vertebral fracture due to osteoporosis or tumor causing insufficiency of vertebral bone mass; the presence of intractable pain; failure of conservative drug treatment and other therapies; failure of spontaneous fracture healing after two months of drug treatment; age over 50 years. All volunteer patients agreed to participate in the study by signing an Informed Consent Form (ICF). Exclusion criteria included high-energy trauma fractures, history of congenital spinal diseases, and patients and/or caregivers with cognitive impairment verified during anamnesis.

The participants were evaluated preoperatively: medical history, physical examination, analog pain scale (VAS), disability questionnaire (ODI), and imaging examinations, which should contain at least two of the following diagnostic tests: MRI, CT scan, bone scan, and X-ray.

In the postoperative evaluation, the following parameters were considered: pain assessment by VAS in the first seven days after the procedure, computed tomography (CT) of the operated spine segment, chest CT, and the disability questionnaire (ODI) within two weeks. The same radiologist evaluated and quantified the extravasation and the filling of the vertebral body with cement.

Surgical technique

The procedure is done under general anesthesia in ventral decubitus; the patient is supported on cushions to release the abdomen. Locate the vertebral level to be treated with the aid of fluoroscopy. A 15-gauge disposable bone marrow needle *(Johnson Confidence Kit*) was positioned with its distal end at the level of the lateral border of the pedicle and advanced until its distal end was at the level of the medial border of the pedicle under anteroposterior fluoroscopic vision. The needle was advanced through the cortex by tapping its rear end with a hammer under fluoroscopy aid until it reached the medial limit of the pedicle, where fluoroscopy was positioned for lateral control. Minor adjustments were necessary as the needle advanced through the pedicle to direct its tip as close as possible to the junction of the anterior and middle third of the vertebra in the vertebral body. The same steps were followed for the contralateral pedicle (bilateral puncture). Intracorporeal phlebography *(Ominipaque GE HealthCare*) was performed before the injection of the acrylic cement to determine the intraoperative location of possible extravasation sites (Figure 1). After injection of the contrast agent, the vertebral body was washed with saline solution, which was injected into one cannula and aspirated into the contralateral one. After these procedures, the PMMA was prepared and injected slowly with fluoroscopic control in real--time to control possible extravasation paths, always avoiding that the PMMA exceeded the limit in the posterior wall. Due to the anatomical

variations of the different levels approached and the typical characteristics of each fracture, we did not try to predetermine the amount of PMMA to be injected at each level. Still, we tried to inject a sufficient volume to fill 50% of the vertebral body operated.

Post-operative follow-up

After the procedure, the patients were submitted to postoperative exams and consultations two weeks after the surgeries to evaluate the level of satisfaction with the procedure employing VAS and ODI questionnaires and postoperative CT scan analysis to evaluate the percentage of vertebra filling. Also, the same licensed radiologist evaluated possible sites of extravasation (Figure 2).

Data Analysis

The results were presented based on descriptive statistics, including relative and absolute frequency, using a bar graph, pie chart, histogram, *box plot*, and *heatmap*. *Fisher*'s exact test, *Wilcoxon*'s test, and the proportion test were also employed, as well as the libraries *gplots, dplyr, and plotly*, in the statistical program *R Studio*.

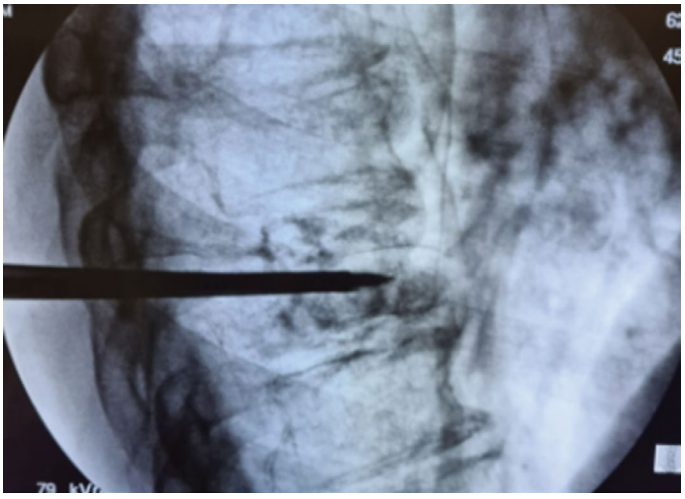

Figure 1. Intraoperative phlebography showing possible sites of extravasation.

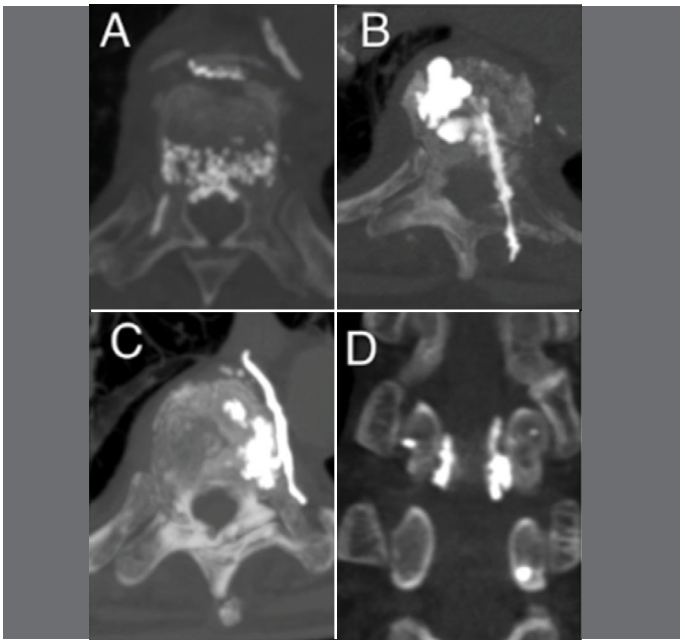

Figure 2. Postoperative tomographic control, showing: epidural recess extravasation through the posterior wall defect (A); epidural recess through the pedicle (B); external vertebral venous plexus (C) on axial sections; epidural recess extravasation (D) on coronal section.

RESULTS

We evaluated 33 patients who underwent PV by the same team of surgeons from January 2019 to November 2021 at the Spine Institute of Campinas - SP. A total of 46 vertebral bodies were treated in these patients, 20 patients with fragility fractures and 13 with pathological tumor fractures (Table 1). As for sex, the sample was composed of 20 women and 13 men, with a mean age of 71 ± 15 years. Of the total, 11 patients had more than one level operated on, ranging from 2 to 3 levels).

Before the intervention, the fractures were classified using Genant's semiquantitative method, 17 Genant 1, 12 Genant 2, and 17 Genant 3. There was a balance of extravasation episodes between the classifications (Figure 3).

When analyzing PMMA extravasation using the control CT scans, 15 vertebrae had no detectable extravasation, and 31 had one or more extravasation sites (Figure 4).

Among the vertebrae that showed signs of extravasation, the most frequent sites were, respectively, the External Vertebral Venous Plexus (23), Discal Body (9), Anterior Epidural Recess (4) Pulmonary Vessels (4), Internal Vertebral Venous Plexus (3), Inferior Cava (2), Adipose Plane (2), Azygos Vein (1). The distribution of overflow by most frequent level and location is shown in Figure 5.

As for the percentage of PMMA filling, in 16 vertebrae, it was less than 50%, and in 30, it was more than 50%. Among the fractures that presented extravasation, 66% had more than 50% filling of

Table 1. Demographic Analysis.

Variable	Absolute Fr.	Relative Fr.
Gender		
Female	20	60,61%
Male	13	39,39%
Tumor		
Yes	13	39,39%
No	20	60,61%

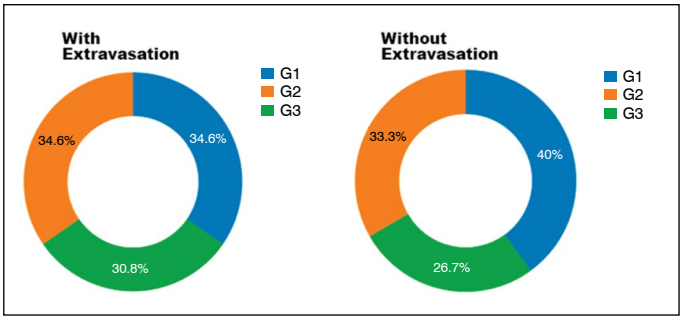

Figure 3. Genant extravasation classification.

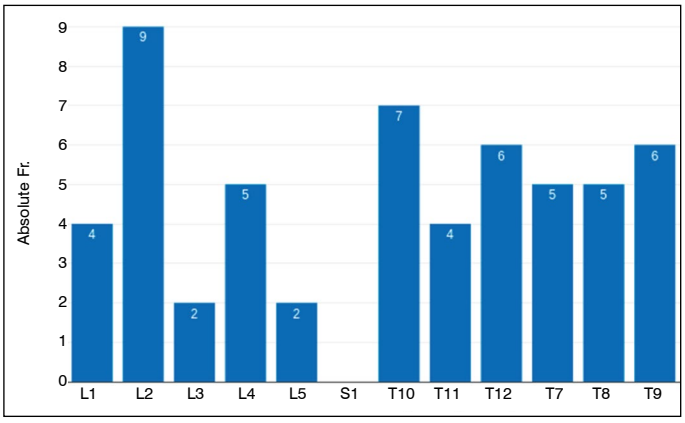

Figure 4. Amount of overflow per operated level.

the vertebral body and 34% less than 50%, showing a tendency to increase extravasation when a larger amount of PMMA was injected (p = 0.0038) (Figure 6).

Regarding the correlation of extravasation frequency between osteoporotic fractures compared to tumor fractures, it was observed that in the osteoporotic fracture etiology group, this percentage was approximately 57%. In the tumor patients' group, leakage was present in 75% of the vertebrae analyzed (Figure 7), with a difference of 18% more leakage in the tumor patients group. Applied the tests of Association and Proportion, the p-values of 0.33 and 0.42 were observed, respectively.

When we observe the VAS and ODI scores, the patients showed significant improvement in pain, evolving from severe to moderate disability after the procedure, with statistical significance (p = 0.000016 and 0.00003.5, respectively) (Figures 8 and 9).

No patient had clinical repercussions related to the extravasation.

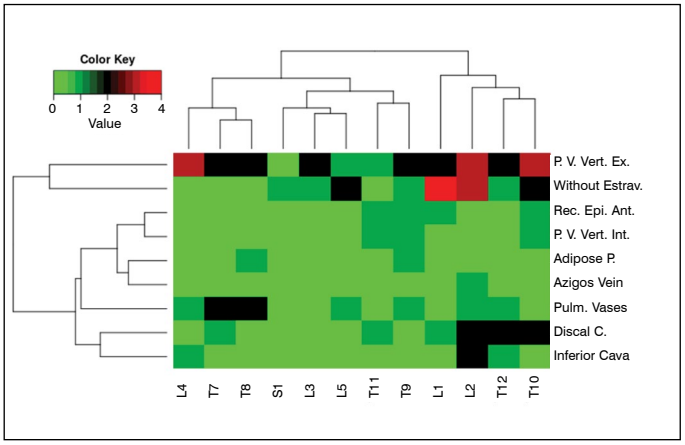

Figure 5. Heat map by level and most frequent overflow location.

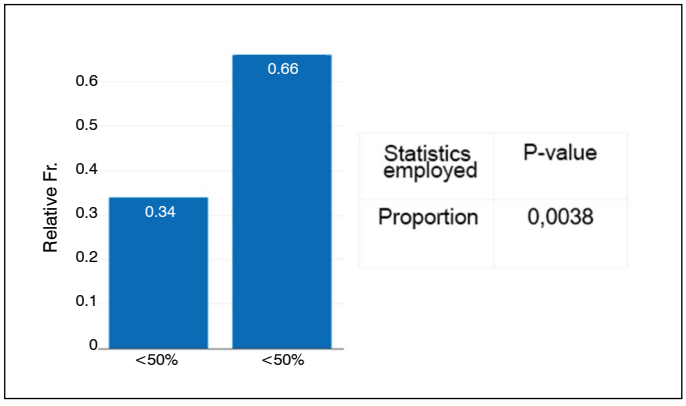

Figure 6. Percentage Extravasation x Percentage Filling of the Vertebra.

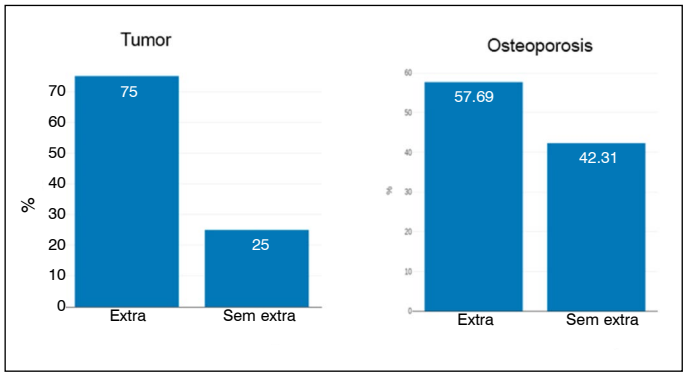

Figure 7. Percentage of PMMA extravasation in patients with tumor pathology x osteoporosis.

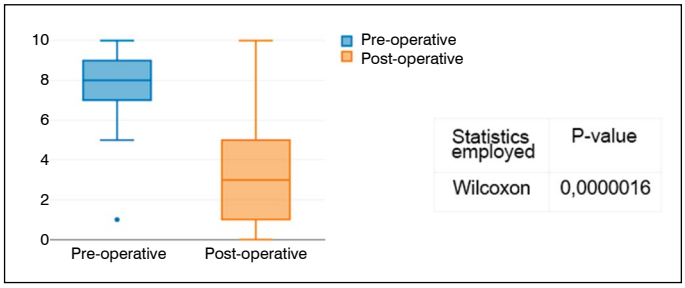

Figure 8. Pre- and post-operative VAS score analysis.

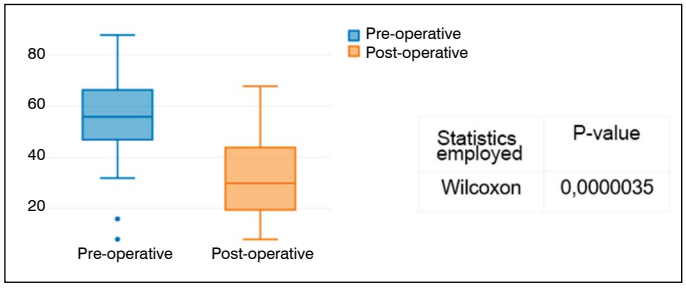

Figure 9. Analysis of the Oswestry Disability Index (ODI) score.

DISCUSSION

In the present study, we found an absolute extravasation rate of 67%, similar to the rate of 63% found by Yeom et al.[14] and 81% by Schmidt et al.[15] When we try to observe which are the main factors that lead to this outcome, we have that the cause is multifactorial. The PMMA can extravasate either through the bone flaw of the posterior wall, the pedicle pathway, or the anterior vertebral venous plexus.[16] Such extravasations can also be explained by the fluid consistency of PMMA during its application, especially when the needle is positioned close to the basivertebral vein.[17] Some authors, such as Gangi et al.,[18] recommend real-time follow-up during PMMA injection, both tomographically and by fluoroscopy. In our clinical practice, and the great majority of the Services in Brazil, such a recommendation would make the procedure unfeasible, and phlebography with the aid of conventional fluoroscopy is routinely used during the PMMA injection.

A factor that showed significance for this occurrence was the percentage of vertebra filling, where we observed that, among the vertebrae that presented extravasation, 66% corresponded to vertebrae with more than 50% of body filling, which may lead to the direct interpretation that, the greater the volume used, the greater the chance of some extravasation occurring.

Interpretations on the volume of cement injected about pain improvement vary in the literature, and from 2 to 15ml of injected volume can be found.[19–21] In this study, we opted for a more practical evaluation where, according to the vertebra analyzed, the volume was evaluated as less than 50% filling of the vertebral body. In this way, we could evaluate both vertebrae with a minimal degree of wedging (Genant 1) and fully collapsed vertebrae. What we observed was that regardless of the lower or higher fill rate, the VAS pain scores (average of 8 preoperatively and three postoperatively) and ODI function scores (average of 56 preoperatively and 30 postoperatively), evolving from severe to moderate disability, were significantly improved (Figures 8 and 9). These results were similar to the study by Alvarez et al.,[19] with no differences observed in the tumor/osteoporosis groups. These findings support the applicability of the technique in both osteoporotic and tumor fragility fractures.[2,3]

When comparing the extravasation of PMMA between the tumor and osteoporosis groups, 75% of the vertebrae showed some type of extravasation in the group of patients with tumor pathology versus 57% in the patients with osteoporosis fractures. This finding corresponds to the proportion found by Barragán-Campos

et al.,[22] who identified a rate of PMMA extravasation in patients with tumor pathology of 78.5% of the 117-patient sample. The higher proportion of extravasation in tumor pathology fractures is due to the presence of larger lytic lesions/cavities and increased local circulation.[23]

When we talk about complication rates, these were not observed in our study, whether due to neurological or painful alterations, epidural/radicular extravasation, or even in cases of extravasation in pulmonary vessels (Figure 10), in agreement with the literature, which shows rates of less than 10%.[15,16,24] This result may have been influenced by the study's small sample size. It can be inferred that due to the rarity of the complications, a larger sample size, perhaps, could have influenced the appearance of clinical complications.

Figure 10. Extravasation of PMMA in bilateral pulmonary vessels.

CONCLUSION

PV was shown to be an effective procedure for its goal of improving pain and function (VAS and ODI). Extravasation of PMMA content was frequent at various sites and levels but without any related clinical complications. Increased filling of the vertebral bodies is an important factor in increasing the occurrence of extravasation.

All authors declare no potential conflict of interest related to this article.

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