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Safety of Vertebral Augmentation with Cranio-Caudal Expandable Implants in Vertebral Compression Fractures with Posterior Wall Protrusion

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ABSTRACT

Objectives

Vertebral augmentation (VA) has become routinely used in vertebral compression fractures (VCFs). VCFs are often associated with posterior wall protrusion (PWP), which theoretically contraindicates vertebroplasty due to a higher risk of neurological complications. Latest generation of VA devices uses intravertebral cranio-caudal expandable implants to improve the correction of structural deformities but could also be used to prevent further PWP during cement injection. The aim of this study was to evaluate the safety of VA with expandable implant for VCFs with PWP.

Methods

All consecutive patients treated with expandable implants were considered eligible for inclusion if they met the following criteria: 1) Non-neurological VCF 2) Considered unstable (A3-A4 in AOSpine classification) 3) Significant PWP (>2mm) 4) Back pain with a visual analogue scale (VAS) ≥4. PWPs were independently measured by two investigators; Pearson's statistics were used for interobserver reproducibility.

Results

Fifty-one consecutive patients, with a mean age of 75±8.3 years (range:50-92), were included. There was a slight decrease between mean preoperative (6.7±2.2mm) and postoperative PWP (6.5±2.2mm) (p=0.02), with an excellent interobserver reproducibility (Pearson correlation coefficient=0.92). A mean kyphosis reduction of 34.9% (±28.4) was observed (p<0.001). 42 patients (82.4%) had significant pain improvements (mean

preoperative VAS=6.9 [±1.7] versus 3.1 [±2.0] postoperatively [p<0.001]). Secondary adjacent level fractures were noted in 16 patients (31.4%), with a reduction of that risk down to 18.8% if a preventive adjacent vertebroplasty was performed, without reaching the significance threshold (p=0.14).

Conclusions

VA with expandable implants appeared safe for non-neurological VCFs with PWP, while allowing satisfactory pain relief.

KEY POINTS

1. Vertebral augmentation with cranio-caudal expandable implants is safe for non-neurological vertebral compression fractures with posterior wall protrusion.

2. Vertebral augmentation with cranio-caudal expandable implants might increase the occurrence of secondary adjacent level fractures.

3. Adjacent level vertebroplasty might be helpful to prevent secondary adjacent level fractures.

Keywords: Spinal Fractures; Vertebroplasty; Osteoporotic Fractures; Back Pain

ABBREVIATIONS AND ACRONYMS

BKP: Balloon Kyphoplasty

CT: Computed Tomography

MRI: Magnetic Resonance Imaging

PMMA: Poly-Methyl-Methacrylate

PVP: Percutaneous Vertebroplasty

PWP: Posterior Wall Protrusion

SALF: Secondary Adjacent Level Fracture

SD: Standard Deviation

VA: Vertebral Augmentation

VAS: Visual Analogue Scale

VCF: Vertebral Compression Fracture

VKA: Vertebral Kyphotic Angle

INTRODUCTION

Vertebral Compression Fractures (VCFs) are an important health issue in Western countries, affecting mostly an elderly population [1]. Many adverse events may occur following VCFs, from the consequences of heavy pain medication use to bedsore complications, eventually leading to a twofold higher mortality rate in patients with VCFs [2]. Osteoporotic VCF may also adversely impact the quality of life and represent a considerable economic burden.

Historically, the treatment of VCFs was divided into surgical management with anterior or posterior stabilization and conservative treatment that relied on rest and immobilization.

Although urgent decompression surgery is clearly required in cases of neurological deficits [3], the decision is usually more balanced in non-neurological but symptomatic VCFs [4]. In spite of many controversies [5–9], minimally invasive percutaneous procedures such as percutaneous vertebroplasty (PVP), have arguably found their place and became, among other Vertebral Augmentation (VA) techniques, a first line treatment for non-neurological but symptomatic VCFs, even for elderly patients [10].

During PVP, cement is injected under pressure, which exposes to a double risk of cement leakage and bone fragment protrusion into the spinal canal. Cement leakage results from the propensity of the cement to reach the areas of lower pressure; for instance through a cortical wall rupture or in a venous compartment. Although most of cement leakage are well-tolerated, even when intra-cardiac embolism occurs [11], the risk of neurological compression is the most feared [12]. Thus, Posterior Wall Protrusions (PWPs) are classically considered as contraindication for PVP in most of recent guidelines, including those of the Society of NeuroInterventional Surgery (SNIS) [13] and Cardiovascular and Interventional Radiological Society of Europe (CIRSE) [14].

To improve the correction of structural deformities, newer VA techniques have been designed. They basically involve the creation of a cavity inside the vertebral body; either by using the exocentric expansion of a balloon in Balloon Kyphoplasty (BKP), or by deploying an intravertebral implant. Even if BKP allows for such cavity creation; and thereby a low-pressure cement injection; there is an added risk of promoting a posterior wall fragment protrusion due to the balloon expansion [15], which still constitutes an inherent limit and a relative contra-indication to this technique [16].

One of the most recent VA techniques uses an intravertebral cranio-caudal expandable implant called the SpineJack®, that is designed to provide sustainable height restoration and kyphosis correction [17, 18], which has an efficacy at least comparable with other VA techniques as BKP [19]. Henceforth, these techniques are widely shared among spine specialists and considered first-line options for the treatment of symptomatic VCFs.

Considering that VCFs are commonly associated with PWP, the SpineJack® could be useful because of its ability to sustainably correct the structural modifications with a likely limited risk of posterior wall fragment mobilization due to the low pressure cement injection. The purpose of this study was to assess the safety of vertebral augmentation with the SpineJack® in VCFs with PWP, by evaluating its impact on PWP measurements before and after the procedure.

MATERIALS AND METHODS

The manuscript was prepared according to the STROBE guidelines.

Population

Data of all consecutive patients who underwent a VA with the SpineJack® for osteoporotic VCFs from January 2012 to January 2019 were retrospectively reviewed. The cohort of patients used for this study includes 7 patients whose data were already analyzed in a previous study about VA with the SpineJack® in chronic vertebral compression fractures with major kyphosis [20].

Patients were considered eligible for inclusion if all following criteria were present: 1) Non-neurological VCF 2) considered unstable (grade A3 or A4 according to AOSpine's classification [21]) 3) Significant PWP (superior to 2 mm) 4) Back pain with a visual analogue scale (VAS) ≥ 4.

Patients were excluded if any of the following was present: 1) Confirmed malignancy on the pathologic examination of the per-procedural vertebral biopsy 2) Unavailability of preoperative imaging (Computed Tomography [CT] or Magnetic Resonance Imaging [MRI]) on the picture archiving and communication system.

Device

The only intra-vertebral implant used in this study was the Spinejack® (Stryker, USA). The SpineJack® is an intra-vertebral titanium implant with two end-plates that can be gradually deployed in the cranio-caudal direction. The device exists in 3 dimensions (4.2 mm, 5.0 mm and 5.8 mm) corresponding to the insertion's size of the device, before its deployment, this choice being limited by the pedicle's diameter.

Procedures

All interventions were performed under general anaesthesia, bone needles (Thiebaud Biomedical Device, France) were inserted under fluoroscopic X-ray guidance via a bilateral transpedicular approach to the vertebral body. By performing an exchanging manoeuvre over the Kirschner's needle, the working cannulas with the reamer were placed into the vertebral body. After the creation of the central cavity with the template, the SpineJack® implants were inserted and deployed inside the vertebral body until suitable kyphosis reduction and height restoration were reached. Then, the implants were detached. And finally, Poly-Methyl-Methacrylate (PMMA) bone cement (Bone Cement V, Zimmer Biomet, USA) was gently injected under fluoroscopy control until the vertebral body filling was judged satisfactory or interrupted in cases of cement leakages. Adjacent PVP was performed at the operator's discretion, either preventively or for adjacent fractures. A systematic post-operative unenhanced CT-scan was performed directly in the procedure room, in order to find and characterize cement leakages and to control the PWP.

Radiological measures and follow-up

VCFs were categorized according to the AOSpine's classification [21], and specifically the subgroup of compression fractures with posterior wall involvement (A3 and A4, respectively incomplete and complete burst fracture). PWP and vertebral kyphotic angle (VKA) were measured on the most recent pre-operative CT or MRI and then on the post-operative CT scan that is systematically performed in our institution.

PWPs were measured on a sagittal plane reconstruction, by drawing a line between the posteroinferior corner of the upper vertebra and the posterosuperior corner of the vertebra

below. Then, the maximal protrusion of the posterior wall bone fragment was perpendicularly measured rearward from this line (as shown in **Figure 1**). PWP measures were performed at the same time by two independent assessors (one junior radiologist [L.M], three years of experience; and one senior reviewer [M.E] 10 years of experience, blinded from the first analysis), both blinded on clinical data.

Additional imaging examinations were performed during the follow-up in case of persistent and intractable back pain or in case of pain recurrence and were also reviewed in search of delayed complications. On follow-up imaging, Secondary Adjacent Level Fractures (SALFs) were defined as any new vertebral fracture occurring at a directly adjacent level of treated vertebra(e), in the year following the procedure. When preventive PVPs were performed at an adjacent level, we counted as a SALF any new VCF at the level adjacent to the PVP.

Clinical follow-up

A systematic clinical examination of each patient was carried out between 4 and 6 weeks after the intervention including pain evaluation using VAS as well as functional improvements. The examination was led by the same operator who performed the VA. Additional consultations were undertaken only in case of persistent pain or occurrence of new symptoms.

Patients lost to follow-up, were kept in the analysis of clinical outcomes.

Complications

Periprocedural and delayed complications were systematically assessed and categorized according to the CIRSE classification [22]. Technical complications without clinical impact were classified as grade 1. Minor local hematoma or reversible nerve root compression were classified as grade 2. Hematoma requiring surgery or blood transfusion, life-threatening decompensation of a comorbidity or neurological deficit was classified as grade 3 to 5 depending to the level of sequelae. Procedure related-death was classified as grade 6.

On follow-up imaging, Secondary Adjacent Level Fractures (SALFs) were defined as any new vertebral fracture occurring at a directly adjacent level of treated vertebra(e), in the year following the procedure. When preventive PVPs were performed at an adjacent level, we counted as a SALF any new VCF at the level adjacent to the PVP.

Ethical Statement

Neither approval of the institutional review board nor patient informed consent was required by the ethics committee of our Institution for retrospective analyses of patients' records and imaging data.

Statistical analysis

All analysis was performed using the open source software R (version 3.5.2).

Comparisons of means were performed using a Student-t test or, if the Shapiro-Wilk test rejected the normality of the studied variables' distribution, with a Wilcoxon test. The χ^2 test

was used for comparisons of proportions. Results were considered statistically significant when p-values were inferior to 0.05.

Inter-observer reproducibility was evaluated using the Pearson correlation coefficient, interpreted as follows: poor (< 0.20), fair (0.21-0.40), satisfactory (0.41-0.60), good (0.61-0.80), and excellent (0.81-1.00).

RESULTS

One hundred twenty-eight patients underwent VA with the SpineJack® during the study period and were screened. Finally, 51 patients (40 females, 11 males), with an average age of 75±8.3 years (range: 50-92) were kept for the analysis (**Figure 2**). Forty-eight fractures (94.1%) were caused by minor trauma with underlying osteoporotic condition and 3 fractures (5.9%) were caused by high kinetic trauma. Baseline characteristics of the patients are shown in **Table 1.**

Six patients (11.8%) were lost to the clinical follow-up, but radiological measurements were available for every patient. VA with the SpineJack® was performed at one level in each case and the most frequently affected vertebra was L1 (n=23, 45.1%). In 32 cases (62.7%) a simultaneous complementary PVP was performed and in half of those cases (31.4%) for preventive purposes.

Mean preoperative PWP was 6.7 mm (± 2.2; range: 2.5 – 13.0) and mean postoperative

PWP was 6.5 mm (± 2.2; range: 3.0 – 13.0). Comparison between pre and post-operative PWP showed a slight reduction of the PWP (p=0.02), even if clinically negligible. There was an excellent interobserver reproducibility with a correlation coefficient of 0.92. Mean VKA was -17.5° (± 7.9) pre-operatively and decreased to -11.1° (± 6.9) post-operatively ($p < 0.001$), averaging 34.9% (± 28.4) of kyphosis reduction. Forty-two patients (82.4%) had pain improvements with a mean VAS decreasing from 6.9 (± 1.7) preoperatively to 3.1 (±2.0) postoperatively ($p < 0.001$). Among 31 patients with significant walking disorders before the procedure, 12 showed a complete regression of these troubles (38.7%), 10 incomplete

resolution (32.3%), 5 patients experienced no functional improvements (16.1%) and 4 were lost to follow-up (12.9%).

Cement leakages occurred in 21 cases (41.2%) and were intra-discal in 12 cases (23.5%). Other cement leakages mostly affected the venous system: epidural vein in 4 cases (7.8%), para-vertebral vein in 3 cases (5.9%) and foraminal vein in 1 case (2.0%). In only 1 case (2.0%), a posterior cement leakage inside the fracture site was observed (**Figure 3**). All of them were asymptomatic. One patient (2.0%) presented a minor cement pulmonary embolism that remained asymptomatic. Procedure-related complications are summarized in **Table 2.**

In the year following SpineJack® implantation, 21 SALFs occurred in 17 patients (33.3%). The rate of SALF seemed lower in the group with preventive adjacent PVP (18.8%) versus 40.0% when no preventive PVP were performed, without reaching the significance threshold ($p=0.14$). Of note, no SALF occurred at a level adjacent to a discal cement leakage. In subgroup analysis, SALFs were significantly more likely to occur when a complete burst fracture (grade A4) was present ($p < 0.05$). Subgroup analysis of SALFs is shown in **Table 3.**

DISCUSSION

This study is the one of the first to focus on VA with latest generation devices, such as the SpineJack®, in VCFs with PWP. The results of this work suggested that this technique is safe in this indication; allowing slight improvement of the posterior wall bulging, thus preventing neurological complications. We also confirmed its effectiveness, by providing satisfactory pain relief, substantial improvements of walking disability and significant kyphosis correction.

PVP is classically considered contraindicated in VCFs with PWP, as both the risks of displacement of the posterior wall fragment and cement leakage due to the posterior wall injury may lead to neurological complications [12]. BKP may also seem dangerous when a PWP is present considering that this technique requires balloon inflation for the expansion of the vertebra that could also promote bone fragment mobilization. Thus, VA with the Spinejack® appeared to be a valuable alternative, as the expansion force is only applied in the cranio-caudal direction, which could limit an unintended thrust force against the posterior wall and its potential consequences. Furthermore, the cavity creation allow a low-pressure cement injection and thus reducing the risk of leakage, that can explain the rate of cement leakage found in our study, which is comparable to other studies of VA for burst fracture [23].

Another limitation of BKP is the lack of sufficient vertebral height restoration or pathological angulation correction. Indeed, some studies, such as the Kaviar Trial, found that the improvement of the kyphosis was weak and similar to those of the PVP [24]. It is possible that height restoration and kyphosis correction cannot be sustained after the deflation of the balloon prior to cement injection [25]. In this indication, VA with SpineJack® seems more

effective with better results on height restoration and kyphosis correction [26, 27], considering that the implant may help to hold the thrust force and provide a more sustainable expansion [17], either in acute or in chronic vertebral fracture [20].

This study seemed to show that VA with the Spinejack® was efficiently able to prevent further PWP. The same observations were made by a recently published study by Venier et al [28], which also explored the impact of VA technique on PWP, finding a significant reduction of postoperative PWP that they explained by the ligamentotaxis effect of the posterior longitudinal ligament. Besides undeniable resemblances with our work, one asset of our cohort is its homogeneity, with the use of a single kind of implant, without any surgical stabilization associated to VA. Both studies adds to the body of literature that PWPs without neurological deficits may not be any more considered as absolute contraindications to reinforced VA techniques such as the SpineJack® or other armed cementoplasty techniques.

The other subject disclosed by this study is the high rate SALFs (31.4%) recorded during the follow-up, that seemed higher than the risk of SALF after PVP (estimated at 13.7% in a recent meta-analysis [29]). SALFs are allegedly consecutive to the altered biomechanical properties induced by cementation, which increases the stiffness of the treated vertebra and reports unusual constraints to the adjacent levels [30]. One of the weaknesses in our study is the absence of control group, which do not allow to eliminate the effect of possible confounding factors on these finding, as could be the severity of osteoporosis.

The risk of secondary fractures after VA procedures has been scantly studied. Possibly, the important modifications of local constraints due to the cranio-caudal expansion of the device could explain an increase of that risk. We also noted that complete burst fractures were

significantly associated with the onset of SALFs, which may be explained by both an increase of the load transfer to the adjacent vertebra or by the fact that burst fractures may reflect profound osteopenia. PVP was regularly employed along this study to prevent such complications, particularly in case of severe osteoporosis. This technique, already performed for the prevention of new fracture after PVP [31], should be even more interesting in VA with the SpineJack® due to a potential higher risk of SALF. Even if our results suggested a possible effectiveness of this preventive PVP, the low number of patients and the design of this study do not permit to definitively confirm it. Another potential solution to reduce the rate of SALF could be the use of silicone elastomeric material instead of PMMA cement [32], but needs to be weighed against a potentially higher risk of cement leakage and pulmonary embolism [33].

Targeted studies exploring this specific topic are awaited and could help elucidate the implication of the VA with the SpineJack® in these SALFs. Nevertheless, the high rate of SALF suggested that operators should be particularly careful during the follow-up of these patients. Furthermore, optimal medical management of osteoporosis remains critical, as anti-osteoporotic medications have been shown to reduce the risk of subsequent vertebral fractures by 40 to 70% [34].

This study entails several limitations. Firstly, the monocentric and retrospective nature of data collection is source of multiple biases. Moreover, the low number of patients included and the scarcity of neurological complications after percutaneous procedures may explain these results of our study. The primary endpoint, based on a radiological measure, was evaluated by two non-blinded investigators, with the aim to reduce the impact linked to potential measurement bias. The clinical endpoints, even more subjective, may have been

influenced by the non-controlled non-blinded evaluation of the results by the operator during the follow-up.

Nevertheless, this study is one of the largest cohorts to date to emphasize the SpineJack® technique in this subset of patients and suggested that VA with the SpineJack® for VCFs with PWP is a safe procedure that prevents neurological complications while providing satisfactory pain relief and functional improvements.

However, all the advantages that could be expected from the SpineJack®, either in terms of effectiveness (analgesia, functional improvements and structural deformities' correction) or safety needs to be confirmed in a larger population.

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FIGURES AND TABLES

Figure 1.

Seventy-year-old patient with past history of osteoporosis presenting a painful L1 vertebral compression fracture, graded A4 according to the AOSpine classification, without any neurological deficit. (A) Preoperative CT, sagittal reconstructions, vertebral kyphotic angle (VKA) and posterior wall protrusion (PWP) (8.0 mm). (B) Peroperative plain X-ray, lateral projection, showing adequate deployment of both implants. (C) Post-procedure control plain X-ray displaying optimal filling of the vertebral body. (D) Postoperative CT, sagittal reconstruction: Restoration of vertebral height and correction of local kyphosis without increasing the PWP (7.5 mm).

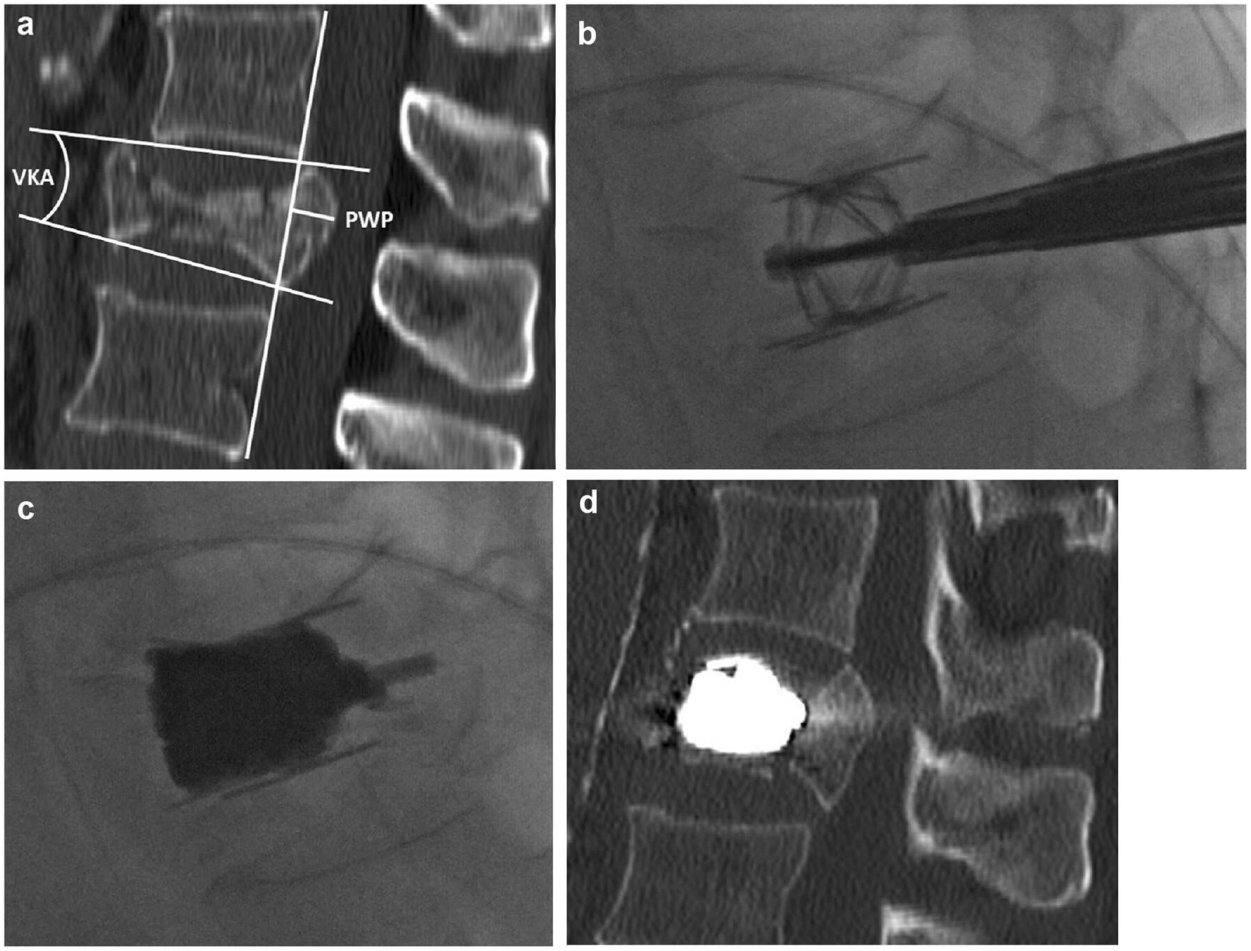

Figure 2.

Study Flowchart.

PWP: Posterior Wall Protrusion; CT: Computed Tomography; MRI: Magnetic Resonance Imaging

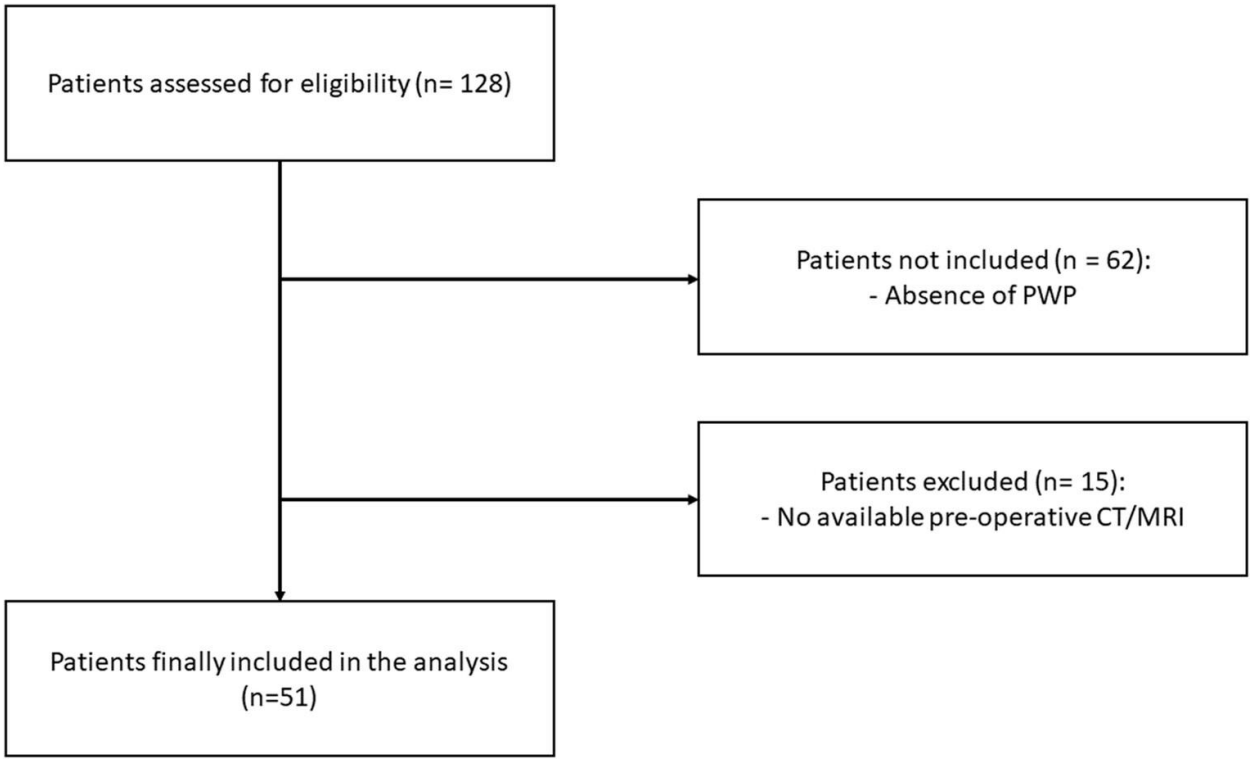

Figure 3.

Seventy-year-old patient with osteoporosis presenting a symptomatic T12 VCF, classified A4, with a complete involvment of the posterior wall and osteonecrosis (A). Preventive PVPs were performed at the adjacent levels. (B) Control CT scan, axial slice on T12 showing posterior cement leakage restrained inside the fracture site without any majoration of canal narrowing. (C, D) Preoperative and postoperative MRIs showing no modification of the PWP. The patient was discharged symptoms-free at day 1.

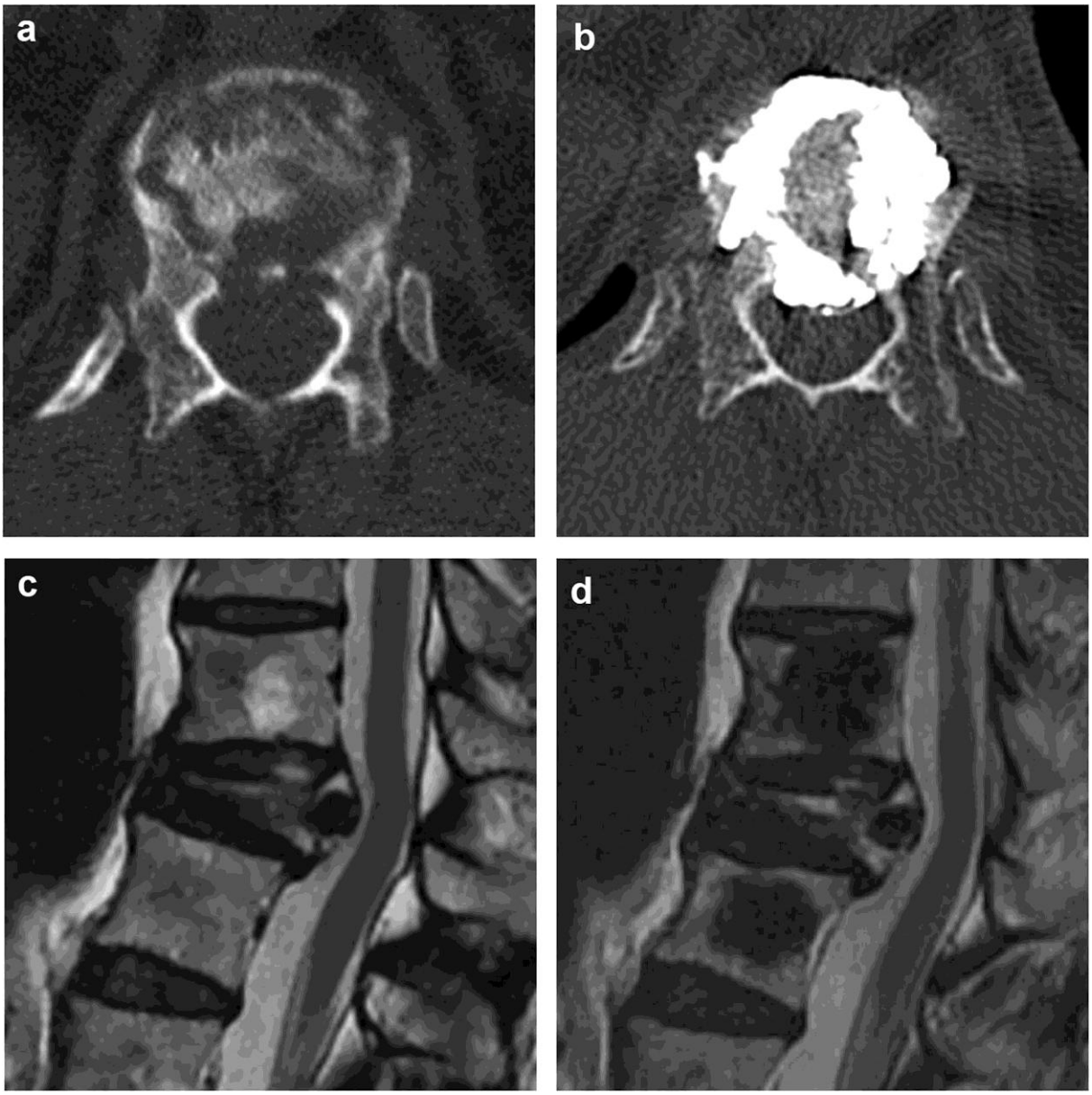

Table 1. Patients' baseline characteristics

[1] According to the AOSpine classification.

Characteristic	**n (%)**
Sex	40 Females (78.4%), 11 Males (21.6%)
Age	75 (50-92)
Treated level **- T12** **- L1** **- L2** **- L3** **- L4**	 19 (37.3%) 23 (45.1%) 6 (11.8%) 2 (3.9%) 1 (2.0%)
Type of fracture[1] **- A3** **- A4**	 12 (23.5%) 39 (76.5%)
Type of traumatism **- Minor traumatism** **- High kinetic traumatism**	 48 (94.1%) 3 (5.9%)
Type of SpineJack® **- 4.2mm** **- 5.0mm**	 34 (66.7%) 17 (33.3%)
Associated vertebroplasty	32 (62.7%)
Adjacent level vertebroplasty	16 (31.4%)

Table 2. Procedure-related complications

SALF: Secondary Adjacent Level Fractures ; S.D : Standard Deviation

Characteristic	**n (%)**
Patients with SALFs	17 (33.3%)
Number of SALFs	21 (41.2%)
Cement leakage: **- Foraminal** **- Para-vertebral** **- Epidural** **- Intra-discal**	21 (41.2%) 1 (2.0%) 3 (5.9%) 5 (9.8%) 13 (25.5%)
Cement volume injected (±S.D)	5.7 (±1.2)

Table 3. Exploratory analysis of secondary adjacent level fractures

S.D: Standard Deviation

Parameter	**Patients with SALF (n=17)**	**Patients without SALF (n=34)**	**P-value**
Mean age (±S.D)	78 (± 8.4)	74 (± 8.0)	0.14
Intradiscal leaks (n; %)	3 (17.6%)	9 (26.5%)	0.48
Mean cement volume (mL ±S.D)	5.7 (± 1.4)	5.8 (± 1.1)	0.85
Complete burst fracture	17 (100.0%)	22 (64.7%)	**<0.05**
Preventive adjacent vertebroplasty	3 (17.6%)	13 (38.2%)	0.14
Mean vertebral kyphotic angle correction (%; ±S.D)	32.4% (± 26.5)	34.1% (± 27.8)	0.68