

# Safety, effectiveness and predictors for early reoperation in therapeutic and prophylactic vertebroplasty: short-term results of a prospective case series of patients with osteoporotic vertebral fractures

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## Abstract

**Introduction** Vertebroplasty (VP) is a cost-efficient alternative to kyphoplasty; however, regarding safety and vertebral body (VB) height restoration, it is considered inferior. We assessed the safety and efficacy of VP in alleviating pain, improving quality of life (QoL) and restoring alignment.

**Methods** In a prospective monocenter case series from May 2007 until July 2008, there were 1,408 vertebroplasties performed during 319 interventions in 306 patients with traumatic, lytic and osteoporotic fractures. The 249 interventions in 233 patients performed because of osteoporotic vertebral fractures were analyzed regarding demographics, treatment and radiographic details, pain alleviation (VAS), QoL improvement (NASS and EQ-5D), complications and predictors for new fractures requiring a reoperation.

**Results** The osteoporotic patient sample consisted of 76.7% (179) females with a median age of 80 years. A total of 54 males had a median age of 77 years. On average, there were 1.8 VBs fractured and 5 VBs treated. The pre-operative pain was assessed by the visual analog scale

(VAS) and decreased from 54.9 to 40.4 pts after 2 months and 31.2 pts after 6 months. Accordingly, the QoL on the EQ-5D measure (−0.6 to 1) improved from 0.35 pts before surgery to 0.56 pts after 2 and to 0.68 pts after 6 months. The preoperative Beck Index (anterior height/posterior height) improved from a mean of 0.64 preoperative to 0.76 postoperative, remained stable at 2 months and slightly deteriorated to 0.72 at 6 months postoperatively. There were cement leakages in 26% of the fractured VBs and in 1.4% of the prophylactically cemented VBs; there were symptoms in 4.3%, and most of them were temporary hypotension and one pulmonary cement embolism that remained asymptomatic. The univariate regression model revealed a tendency for a reduced risk for new or refractures on radiographs (OR = 2.61, 95% CI 0.92–7.38,  $p = 0.12$ ) and reoperations (OR = 2.9, 95% CI 0.94–8.949,  $p = 0.1$ ) when prophylactic augmentation was performed. The final multivariate regression model revealed male patients to have an about three times higher refracture risk (radiographic) (OR = 2.78,  $p = 0.02$ ) at 6 months after surgery. Patients with a lumbar index fracture had an about three to five times higher refracture/reoperation risk than patients with a thoracic (OR = 0.33/0.35,  $p = 0.009/0.01$ ) or thoracolumbar (OR = 0.32/0.22,  $p = 0.099/0.01$ ) index fracture.

**Conclusion** If routinely used, VP is a safe and efficacious treatment option for osteoporotic vertebral fractures with regard to pain relief and improvement of the QoL. Even segmental realignment can be partially achieved with proper patient positioning. Certain patient or fracture characteristics increase the risk for early radiographic refractures or new fractures, or a reoperation; a consequent prophylactic augmentation showed protective tendencies, but the study was underpowered for a final conclusion.

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**Keywords** Osteoporosis · Percutaneous vertebroplasty · Vertebral fractures · Prophylactic augmentation

## Introduction

A painful vertebral fracture can be a significant burden for patients, limiting physical function and quality of life (QoL), and increasing social isolation [1, 2]. The fractures may cause depression and can result in decreased mobility, loss of independence and increased mortality because of a reduction in lung capacity and abdominal space with a consequent loss of appetite [3, 4]. Percutaneous vertebroplasty (VP) has been used for the treatment of osteoporotic compression fractures, aggressive hemangiomas and osteolytic neoplasms. Polymethylmethacrylate bone cement (PMMA) is injected into a fractured vertebral body (VB) through one or two bone biopsy needles [3]. The cement is directly injected into the fractured vertebra without creation of a void unlike in balloon kyphoplasty (BKP). Re-establishment of lost VB height is not possible with the procedure per se, but can possibly be achieved with additional positioning maneuvers [5]. Height restoration, however, is not the main goal of VP, but rather prevention of further segmental or spinal malalignment, pain reduction, increased mobility and improved QoL.

The current article reports on the early results of 233 patients with one or several osteoporotic fractures in an academic center with a high annual volume of VPs.

## Materials and methods

Information was prospectively collected on standardized scannable case report forms in the framework of the research program for the treatment of osteoporotic fractures of the Association for the Study of Internal Fixation (AO/AO-ASIF). The data were then entered into the MEMdoc online database (<http://www.memdoc.org>) of the Institute for Evaluative Research in Medicine (IEFM) at the University of Bern [6].

The following documentation forms and outcome instruments were used: (a) surgeon-administered primary intervention form and follow-up form; (b) for patient assessment, Euroqol-5D, NASS, and comorbidity questionnaire; (c) patient consent form; and (d) one annotation form about the study and its purpose.

At the time of surgery, the primary intervention form was completed by the surgeon. Informed consent about participation had to be given by the patient as well as a completed Euroqol-5D, NASS, and comorbidity questionnaires preoperatively and at every follow-up examination after 8 weeks, 6 months, 1 year and 2 years.

The current article reports on the 6-month follow-up of the study. A total of 636 EQ-5D and 638 NASS forms for the evaluation of general and disease-specific QoL and 175 comorbidity questionnaires were available for analysis.

## Patient sample

### Overall sample

In this prospective case series, 306 patients were treated with a percutaneous VP between May 2007 and July 2008. They underwent a total of 319 VP interventions with 1,408 treated levels; 29 repeat interventions were done in 29 patients for new fractures after primary surgery. Exclusion criteria for the study were VP in combination with a rigid stabilization of the spine and a fracture older than 6 months or without reparative activity on MRI.

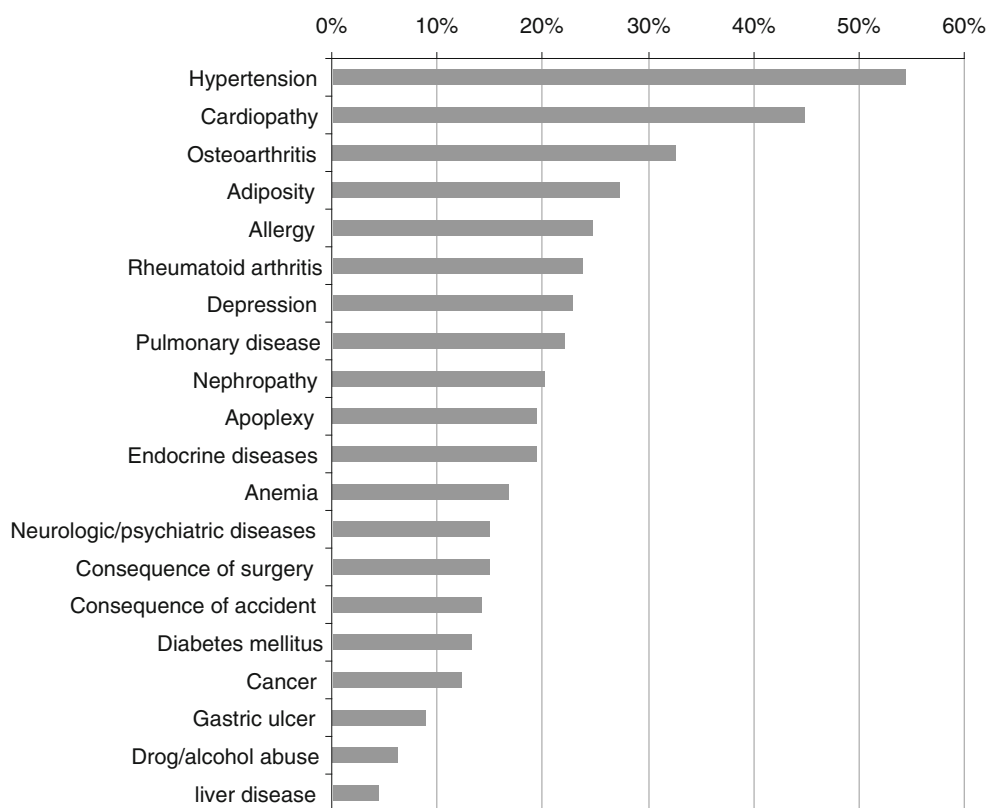
There were 214 (69.9%) females and 92 (30.1%) males with a mean age of 75 years (range 28.3–94.1 years) and 71 years (range 35–92.7 years). The overall distribution of underlying diagnoses was osteoporosis in 73% (233 cases), trauma in 14.7% (47 cases) and lytic lesions in 12.3% (39 cases). Stratified by sex, there was osteoporosis in 83.6% (179 patients), trauma in 7.5% (16 patients) and lytic lesions in 8.9% (19 patients) of females. In the male patient group, there were 58.7% (54 patients) of cases with osteoporosis, 26.1% (24 patients) with trauma and 15.2% (14 patients) with lytic lesions.

### Study sample with osteoporosis

The osteoporotic patient sample consisted of 76.7% (179) females with a median age of 80 years. The 54 males had a median age of 77 years. Figure 1 shows the comorbidities of the osteoporotic patient sample. On average, there were 1.8 VBs fractured, but an average of five levels was augmented. Regarding AO fracture types, there were 19.4% A.1.1, 48.2% A.1.2, 15.8% A.3.1 and 16.5% other fracture types. The most frequently performed cementations were in 6 (30.9%), 3 (21.5%) or 5 (19.74%) levels. About 36.5% of the interventions were localized at the thoracolumbar junction (Th12–L2). MRI was not routinely used for assessing the fracture age, i.e., reparative activity. Only in those cases where multiple old and new fractures were present, the MRI and fracture edema were used for selecting the levels to be augmented.

The preoperative American Society of Anesthesiologists (ASA) status of the osteoporotic patients was ASA 1 or 2 in 25.3% (59 interventions), ASA 3 or 4 in 64.8% (151 interventions), 6.9% (16 interventions) unspecified and not recorded in 3.0%. There were 23 repeat interventions in this group.

**Fig. 1** Comorbidity profile of the patient group with osteoporotic fractures



Osteoporosis was either defined based on dual axial absorptiometry (DXA) conducted during a current treatment in the hospital's department of osteoporosis (internally referred cases, about 50%) or based on anamnesis and risk/comorbidity profile of the patient. The main diagnosis could be specified as "osteoporosis," "trauma", "lytic lesion" or a combination. For the current analysis, only cases with the main diagnosis of "osteoporosis" were considered; this corresponds to a spontaneous or low-energy osteoporotic fracture. Cases with "trauma" and "osteoporosis" marked, e.g., slipping in a bathtub with a consequent fracture, were excluded.

We also divided the osteoporotic group based on the type of prophylactic augmentation into:

- Type 1 (84 cases): cranio/caudal (one or two-sided) augmentation of the directly adjacent vertebral body(ies) and augmentation of the fractured VB. There were 76% females with a mean age of 75 years; males were 73 years old.
- Type 2 (43 cases): one sided multilevel prophylaxis. There were 65% females with a mean age of 78 years; males were 74 years old.
- Type 3 (105 cases): cranio/caudal (two-sided) multilevel prophylaxis. There were 82% females with a mean age of 78 years; males were 79 years old.

#### Statistical analysis

Wilcoxon's rank-sum and signed-rank test were used for comparisons between baseline and follow-up examinations of continuous variables such as the pain visual analog scale (VAS). When comparing proportions, the chi-square test was used and McNemar's test for matched pairs.

For binary outcomes, the search for predictors was conducted with univariate and multivariate logistic regression models with backward elimination of non-significant co-variables and checked with stepwise model selection. Odds ratios and 95% confidence intervals of significant predictors were reported. The  $\alpha$  was set to 0.05 throughout the study. All statistical analyses were conducted using SAS 9.1 (SAS Institute Inc., Cary, NC, USA). Power analyses were conducted with PASS 2008 (NCSS, LLC, Kaysville, UT, USA).

#### Results

##### Pain relief

One of the main advantages of VP is the fast and effective pain reduction. Pain was assessed by VAS scores using the NASS questionnaire.

The mean preoperative back pain was 54.9 points. At the 2 months follow-up it was reduced to 40.4 points and further to 31.2 points at 6 months (both  $p < 0.0001$ ).

#### Reduction in pain medication

A significant reduction in painkiller consumption was revealed. The amount of patients who did not need any pain medication increased from 12.5% preoperative to 52.7% at the 2 months follow-up and 62.2% at 6 months ( $p < 0.0001$ ). The number of patients consuming acetaminophen decreased, from 33.9% before the intervention to 11.6% at 2 months ( $p < 0.0001$ ) and 8.6% at 6 months postoperatively ( $p < 0.0001$ ). The consumption of metamizole decreased from 10.7% preoperatively to 2.2% at the 2 months ( $p < 0.0001$ ) and to 1.72 at the 6 months follow-up ( $p < 0.0001$ ).

The consumption of nonsteroidal anti-inflammatory drugs (NSAIDs) decreased from 9% before the intervention to 3.4% at 2 months postoperatively ( $p = 0.0093$ ) and to 1.7% at 6 months ( $p = 0.0007$ ). Morphine and morphine derivatives were needed by 20.2% of patients before surgery. This number was reduced to 4.3% after 2 months and ( $p < 0.0001$ ) and to 3.4% after 6 months ( $p < 0.0001$ ).

#### Segmental kyphosis and alignment

For the evaluation of the segmental kyphosis and alignment, 162 patients whose 2-month radiographs were available for analysis were radiologically assessed; for the 6 months measurements, 85 patients' radiographs were available.

The average preoperative anterior VB height (AO fracture types 1.2 and 3.1) was 16.7 mm (range 33.6–2.8 mm), improved immediately postoperative to 20.2 mm ( $p < 0.0001$ ) (range 7.7–33.8 mm), and slightly decreased after 2 months with an average of 19.5 mm (range 9.6–33.3 mm) and after 6 months to 20 mm (range 10.0–31.8 mm).

The middle VB height was increased from a preoperative average of 16.8 mm (range 5.3–31.4) to 20.0 mm ( $p < 0.0001$ ) (range 9.1–31.4) postoperatively, and after 2 months to 19.7 mm (range 10.8–29.8) and after 6 months to 20.2 mm (range 10.6–31.6 mm).

The average preoperative Beck Index (anterior height divided by posterior height, AO fracture types 1.2 and 3.1) was 0.64 (range 0.15–1.1); the immediate postoperative one was 0.76 ( $p < 0.0001$ ) (range 0.29–1.4), which decreased slightly to 0.75 (range 0.35–1.51) after 2 months and further to 0.72 (range 0.4–1.0) after 6 months.

Alternative Beck Index (middle height divided by posterior height).

The average alternative preoperative Beck Index was 0.65 (range 0.28–1.3); the immediate postoperative one was 0.7 ( $p < 0.0001$ ) (range 0.37–1.22), 0.74 (range 0.37–1.02) after 2 months ( $p < 0.0001$ ) and 0.74 (range 0.54–0.98) after 6 months.

The preoperative local sagittal angle (angle of the superior and inferior end plates, AO fracture types 1.2 and 3.1) was improved from an average 14.1° (range 0.2°–37.7°) to 10.1° (range 0.2°–30.6°) postoperatively ( $p < 0.0001$ ), 10.7° (range 0.1°–28.6°) after 2 months ( $p < 0.0001$ ) and 11.9° (range 0.9°–23.1°) after 6 months ( $p < 0.001$ ).

#### Fractured VBs—Genant classification

According to the Genant classification, a semiquantitative technique for assessment of fracture-related vertebral deformity [7], no patient had a preoperative class 0 fracture (no deformity); 12.7% (19 VBs) were class 1 (mild deformity), 32% (48 VBs) class 2 (moderate deformity) and 55.3% (83 VBs) class 3 (severe deformity). Postoperatively, 0.9% (2 VBs) were class 0, 20.1% (43 VBs) class 1, 58.9% (126 VBs) class 2 and 20.1% (43 VBs) class 3. Two months postoperatively, there was 1 (0.6%) fracture class 0; 20.5% (33 VBs) were class 1, 64% (103 VBs) class 2, and 15% (24 VBs) class 3. At 6 months, there was one (1.19%) fracture class 0; 25% (21 VBs) were class 1, 58.3% (49 VBs) class 2 and 15.5% (13 VBs) class 3.

#### QoL improvement

Possible values of the EQ-5D range from 1 (best possible QoL) to  $-0.6$  (QoL worse than death). On preoperative examination, the mean EQ-5D score was 0.35 points. It improved to 0.56 points at the 2-month follow-up ( $p = 0.0007$ ) and further to 0.68 ( $p < 0.001$ ) points at the 6-month follow-up. Before the intervention, 23.1% (27 patients) of patients indicated a QoL below zero. At the 2-month follow-up, this percentage was reduced to 5.3% (5 patients) and to 1.19% (1 patient) at 6 months.

#### Cemented levels—fractured levels

In total, 1,121 VBs were cemented in the group with osteoporosis as an underlying diagnosis. The most frequently treated levels were L1 in 14.3% (160 VBs), L2 in 13.3% (149 VBs) and Th12 in 13.1% (147 VBs) of the cases. Of the 1,121 cemented levels, 415 had a fracture (37%). The most frequent fracture locations were L1 (16.9%, 61 cases), L2 (15.2%, 55 cases) and TH12 (14.4%, 52 cases). The other 706 levels (63%) were prophylactically cemented. Hence, with each fractured VB, about two others were prophylactically augmented (Fig. 2).

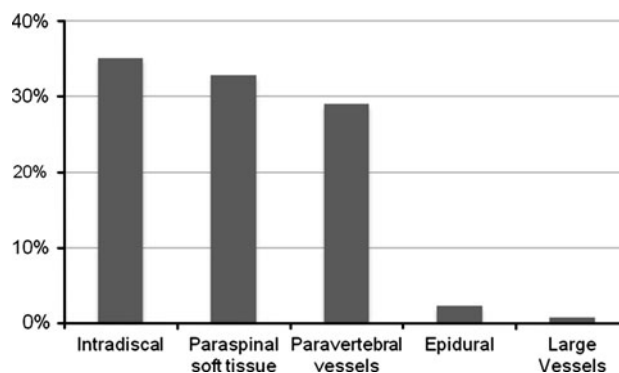
Subsequent new or refractures or reoperations at the 2- and 6-month follow-up

For risk assessment of new fractures or refractures, defined as change of one Genant class on radiographs, or reoperation risks depending on the extent of preventive augmentation, we analyzed the three prophylactic groups with patients who had been radiologically assessed or followed up by telephone. Two-month rates of new fractures or refractures in these three groups were 18.2, 13.0 and 8.5%, respectively. Six-month rates of new fractures or refractures in these three groups were 21.6, 14.3 and 9.6%, respectively. Reoperation rates at 2 months after surgery were 16, 11.7 and 6.4%, and at 6 months after surgery they were 18.9, 11.7 and 7.5, respectively.

### Cement extrusions

There were 1,121 cemented VBs with 415 fractured and 706 prophylactically cemented levels in the osteoporotic patient sample. Overall, 118 (6.3%) cement extrusions were documented, based on the assessment of intraoperative AP and lateral fluoroscopic imaging of each treated level. For the fractured VBs, the extrusion rate was 26% (108/415) and for the prophylactically augmented VBs 1.4% (10/706). The direction of extrusions is displayed in Fig. 3.

Some authors seem to not consider the intradiscal extrusions as true extrusions or even provoke or undertake these “discoplasties” intentionally. If deducting this type of extrusion, the total rate of cement extrusions drops to 15.4% for the fractured VBs. None of these extrusions caused local or systemic symptoms.



**Fig. 3** Direction of cement extrusions

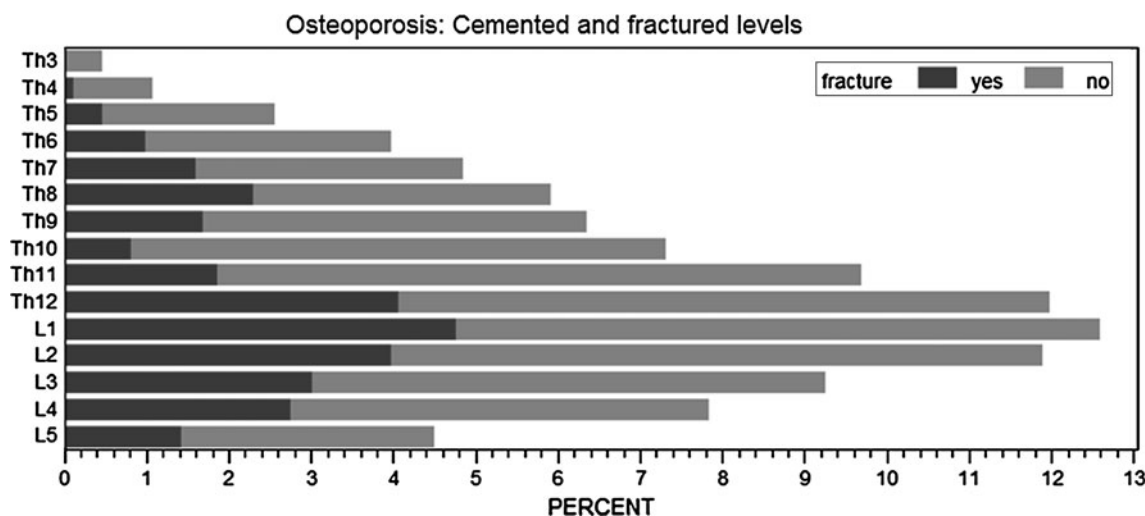
### Intraoperative complications

Intraoperative complications were seen in 4.3% (10 cases). They comprised nine temporary hypotensions after cement injection (3.9%) and one nonsymptomatic cement embolism (0.4%).

### Postoperative experience of a patient with the procedure

At the 2-month follow-up, 69.7% (62 cases) of patients indicated that their condition had improved, 6.7% (6 cases) considered the situation as “stable”, 5.6% (5 cases) had declined, and 18% (16 cases) found the time too early to decide.

A total of 77.6% (76 cases) of the patients would undergo the same operation getting the same result “certainly” or “probably”; 19.4% (19 cases) were not sure and only 3.1% (3 cases) would “probably” or “certainly” not undergo the operation again.



**Fig. 2** Frequency of cemented and fractured vertebral bodies

At the 6-month follow-up, 76.5% (62 cases) of patients indicated that their condition felt “much” or “slightly” better; 12.4% (10 cases) considered the situation as “stable”, 8.6% (7 cases) had declined, and 2.5% (2 cases) found the time too early to decide.

A total of 83.3% (70 cases) of the patients would undergo the same operation getting the same result “certainly” or “probably”; 10.7% (9 cases) were not sure and only 3.6% (3 cases) would “probably” or “certainly” not undergo the operation again.

#### Predictors for new fractures or refractures or reoperation at 6 months after surgery

In a univariate analysis, we searched for predictors of the above events and included the following covariates in the analysis: prophylaxis index new, defined as the number of augmented levels divided by the number of new fractures; prophylaxis index old/new, defined as the number of augmented levels divided by the number of previous but untreated and new fractures; augmentation type 1–3 and level of fracture 1–3 defined as thoracic (Th3–Th11), thoracolumbar (Th12–L2) and lumbar (L3–L5).

In the univariate analysis, the level of fracture was revealed as a significant predictor for reoperation as well as new fracture/refracture (radiographic) at 6 months after surgery. A lumbar index fracture had a three times higher risk for new fracture/refracture compared with a thoracic (OR = 0.3, 95% CI 0.09–0.95) or thoracolumbar (OR = 0.3, 95% CI 0.12–0.74) index fracture. The risk for reoperation was three times higher compared with a thoracic (OR = 0.35, 95% CI 0.11–1.148, n.s.) and five times higher compared with a thoracolumbar (OR = 0.21, 95% CI 0.07–0.62) index fracture. The model gave indications for augmentation type 3 (cranio-caudal multilevel prophylaxis) to have a protective effect. Type 1 patients had a more than twice as high new fracture/refracture (radiographic) risk compared with type 3 patients (OR = 2.61, 95% CI 0.92–7.38,  $p = 0.12$ ). For a reoperation, the same tendencies were revealed. Group 1 had an about three times higher risk compared with group 3 (OR = 2.9, 95% CI 0.94–8.949,  $p = 0.1$ ). Both effects were not significant, but both models lacked power. A total of 485 patients would be necessary for conclusively answering if the non-significant findings would truly remain that way or if we are currently dealing with a beta-error.

The final multivariate model revealed male patients to have an about three times higher new fracture/refracture risk (radiographic) (OR = 2.78,  $p = 0.02$ ) at 6 months after surgery. Similar to the univariate analysis, patients with a lumbar index fracture had an about three to five times higher new fracture/refracture or reoperation risk than patients with a thoracic (OR = 0.33/0.35,  $p = 0.009/0.01$ )

or thoracolumbar (OR = 0.32/0.22,  $p = 0.099/0.01$ ) index fracture.

#### Discussion

Our series reports the short-term results of the treatment of VB compression fractures with percutaneous VP in osteoporotic patients. We found a significant and clinically relevant reduction in back pain, decreased painkiller consumption, increased QoL and vertebral height restoration. The localization of the index fracture and the patient's sex had an influence on the 6-month radiographic new fracture/refracture or reoperation risk. We focused on this seemingly short follow-up interval, since it is known from BKP studies that the majority of new fractures do already occur in the first 60 days after surgery [8]. We found tendencies for the extent of prophylactic augmentation also to have an influence, but because of an underpowered analysis we cannot conclusively answer this question. The underlying disease was osteoporosis, a condition with a reduced bone density and limited skeletal stability.

The current study showed moderate cement extrusion rates, but much lower symptomatic extrusions compared with the literature. Intraoperative hypotension was observed as patients were monitored very closely and the intervention was done under general anesthesia. No clinically symptomatic cement leakages were observed in this series [9–14]. The main reason for this may be our use of high viscosity cement (DePuy Spine, Inc.), which we inject after around 12 min of polymerization time at 19° room temperature. By then, it is already too viscous to be applied by hand with standard syringes. An additional augmentation of adjacent and nonadjacent VBs was used to prevent further fractures and all the related consequences, to minimize the total number of surgeries in this multimorbid patient population and to consequently increase the cost-effectiveness of the index intervention [15–17]. The decision to perform a multilevel preventive augmentation was based on the extent of the presence of risk factors that the WHO FRAX® tool regards as the most important predictors for an osteoporotic fracture (<http://www.shef.ac.uk/FRAX/>). These are the patient's age, gender, comorbidity risk profile (e.g., renal disease, steroid treatment, rheumatoid arthritis, secondary osteoporosis), BMI, BMD, smoking and alcohol consumption, previous osteoporotic VB fractures, previous osteoporotic fractures in other bones, family history of hip fractures, and the number and location of newly fractured VBs. The current 6-month followup analysis of new fractures, refractures or reoperations revealed that cranio-caudal multilevel prophylaxis could be superiorly protective compared with a solely cranial or caudal prophylaxis. The comparisons were,



however, compromised by a lack of power. In the literature, the rate for distant or adjacent fractures is between 17 and 27% depending on the follow-up time [16–18]. Unfortunately, there is no objective parameter yet, which is helpful for assessing the individual fracture risk of the most vulnerable levels.

A significant improvement in the anterior and/or central VB height could be shown. This was also reflected in a significant pre- to postoperative improvement in the Beck Index and local sagittal angle. Percutaneous VP and BKP, both, have the ability to restore vertebral height and to improve alignment [19]. For VP, however, the preoperative dynamic mobility of the fracture is the important predictor for the postoperative height improvement, which is mainly achieved by a correct prone positioning maneuver and not by the procedure itself [20].

A significant back pain reduction from 56.7, preoperatively, to 41.4 at the 8-week follow-up was found. The pain reduction might appear limited, but it is still significant and clinically relevant. However, it also reflects the fact that we are inclined to a rather aggressive approach for the treatment of osteoporotic VB compression fractures to prevent further collapses. Therefore, we consider the intervention as indicated even in cases with an initially moderate pain level. The pain alleviation, reduced need for medication and improved segmental alignment increased the QoL after VP to a great extent.

The significant and clinically relevant pain relief we found is also reported in other observational and randomized controlled study designs [21–23]. In meta-analyses and systematic reviews of the literature, a significantly greater improvement in pain scores was found in patients receiving VP [24]. There was, however, no difference in the clinical significance of pain relief between the two treatments. In comparison to the conservative treatment regimens, both VP and BKP are promising innovations with the benefit of rapidly improved mobility, function and stature, significantly decreased pain-related doctor visits and reduced use of analgetics [25, 26]. This ultimately leads to a prolonged survival of patients who were surgically treated [27]. The increased refracture risk of male patients seems counterintuitive at first. Female patients with their mostly weaker osteoporotic bone stock should have more refractures. The fact that there are no significant differences in reoperation risk. However, these findings may be similarly explained as in total hip arthroplasty. Male patients tend to have higher postoperative activity levels that result in higher component loosening risks [28, 29]. These activity levels may lead to a larger extent of vertebral body sintering which we regarded as a Genant class change of at least one unit, but not necessarily to a manifest symptomatic event that requires reoperation.

## Conclusion

VP results in immediate back pain reduction as well as improvement of local vertebral body alignment, compared to baseline, along with improved QoL and low rates of complications and revisions. The type of preventive augmentation may positively influence the short-term new fracture rate in this osteoporotic patient sample without significantly increasing the complication and extrusion rates. Male patients and patients with a lumbar index fracture are at an increased risk for refractures and/or reoperations at 6 months after surgery.

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**Conflict of interest** None.

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