Kyphoplasty versus percutaneous posterior instrumentation for osteoporotic vertebral fractures with posterior wall injury: a propensity score matched cohort study

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Background: Osteoporotic vertebral fractures (OVFs) that present with posterior wall cortical injury pose a higher risk for instability. Surgical management includes standard cement augmentation techniques like balloon kyphoplasty (BKP) or percutaneous posterior instrumentation with pedicle screws (PS) or both. Neither treatment has yet demonstrated superiority, and posterior cement leakage is of special concern in these fractures.

Methods: At a single tertiary care center, 25 patients with 32 OVFs with posterior wall injury treated with percutaneous instrumentation and cement augmentation (PS group) were retrospectively included and matched (1:1) using propensity scores to 25 patients with 29 OVFs with posterior wall injury treated with standalone BKP (BKP group) from 2010 to 2018. Our primary study aim identified 30-day morbidity rates using a 4-point grading system by comparing BKP with and without percutaneous instrumentation with PS for the treatment of OVFs with posterior wall injury. Our secondary aims evaluated cement leakage, radiographic results, surgical time, length of stay (LOS), pain relief, and subsequent fractures.

Results: Overall 30-day morbidity was 34% and did not differ between groups (24% BKP *vs.* 44% PS groups, P=0.136). Most complications were mild (82.4%), requiring no interventions beyond drug treatment. In the PS group, a trend towards more mild complications was observed (16% *vs.* 40%, P=0.059). Moderate and severe complications affected 17.6% of all morbidity cases and were comparable between groups. Asymptomatic cement leakage into the spinal canal was noted in 2 (8%) BKP patients and symptomatic pulmonary cement embolism in 1 (4.8%) PS patient. Compared with baseline, all radiographic parameters significantly improved in both groups. In the BKP group, mean surgical times (52±32.9 *vs.* 164.9±48.4 minutes, P<0.001) and LOS (4.3±2.5 *vs.* 7±2.9 days, P<0.001) were significantly shorter, and use of opioids at discharge was significantly lower (52% *vs.* 84%, P=0.015). At 3-month follow-up, no differences between groups were seen in back pain, use of opioids, and occurrence of subsequent OVFs. Follow-up averaged 8.4 months.

Conclusions: Standalone BKP may be a viable option for the treatment of OVFs even in the presence of posterior wall cortical injury.

Keywords: Osteoporosis; vertebral fracture; posterior wall injury; kyphoplasty; cement augmentation

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Introduction

Vertebral compression fractures represent the most common type of fracture resulting from osteoporosis, affecting 30–50% of people over the age of 50 (1). Patients with osteoporotic vertebral fractures (OVFs) face significant impairment to quality of life and increased overall mortality risk for up to 5 years after initial fracture diagnosis (2-4). Balloon kyphoplasty (BKP) is considered a standard surgical procedure for the treatment of painful OVFs (5-7). Randomized controlled trials (RCTs) and prospective open-label studies have demonstrated the safety and superiority of BKP compared with non-surgical management in improving pain, function, quality of life, and patient satisfaction (8-11). Immediate reduction in pain, promoting early mobilization, and improvement of vertebral body deformity and angular kyphosis are the goals of surgery. However, a more severe subtype of OVF shows cortical defects of the posterior vertebral wall (12), potentially resulting in a segmental instability. In these cases, a reasonable apprehension exists among surgeons regarding the risk of posterior cement leakage into the spinal canal during augmentation and subsequent neurologic deficits (13-15). Although percutaneous fixation with pedicle screws (PS) might be performed under such circumstances, concerns exist regarding implant-related complications (i.e., screw pull-out, subsidence) because of poor bone quality (16). Furthermore, posterior instrumentation, which must include several vertebral levels for adequate fixation (17), requires longer constructs in osteoporotic patients that presumably results in longer surgical times and a higher probability of perioperative complications given their advanced age and morbidity. Standalone BKP still can be an option for the treatment of OVFs even in the presence of posterior wall injury given that there are relative but no absolute contraindications to the procedure (18). However, no controlled clinical trials have been conducted for the surgical management of OVFs with posterior wall injury, and treatment recommendations for OVFs are often based on expert consensus by different medical societies (19,20).

With the growing healthcare problem of osteoporosis globally and the lack of comparative data on perioperative morbidity of different surgical techniques, this retrospective study evaluated our center's procedural data, surgical results, and perioperative complications in a cohort of patients with OVFs with posterior wall injury who underwent treatment with BKP with or without percutaneous posterior instrumentation. Compared with percutaneous posterior instrumentation, we hypothesized that standalone BKP could be safely performed to achieve both sufficient correction of radiographic parameters and good clinical outcomes. We present the following article in accordance with the STROBE reporting checklist (21) (available at http://dx.doi.org/10.21037/jss-20-625).

Methods

This retrospective study included 50 patients with 61 OVFs of the thoracic or lumbar vertebrae with evidence of posterior wall cortical injury who underwent surgical treatment between January 2010 and December 2018 at a single tertiary care center. Surgical treatment included BKP or percutaneous posterior instrumentation with PS or both. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethical Committee of Northwestern and Central Switzerland (ID number EKNZ BASEC 2018-00185), and individual consent for this retrospective analysis was waived.

Inclusion criteria

Inclusion criteria were the following:
- ❖ Age ≥50 years;
- ❖ OVFs occurred spontaneously or as a result of low-energy trauma;
- ❖ One to three OVFs of the thoracic and/or lumbar vertebrae with cortical disruption and morphological alterations of the posterior wall in at least one vertebra identified on preoperative sagittal computed tomography (CT) imaging;
- ❖ Fracture age <8 weeks;
- ❖ Evidence of vertebral body edema on magnetic resonance imaging (MRI) with fat suppression sequences suggestive of acute or subacute fractures in two- or three-level fractures.

Exclusion criteria

Exclusion criteria were the following:
- ❖ Posterior tension band injuries according to AOSpine thoracolumbar injury classification system (22);
- ❖ High-energy trauma identified as the mechanism of injury;
- ❖ Simple bulging of the posterior wall with no obvious cortical disruption on sagittal CT imaging;

❖ Symptomatic spinal canal stenosis requiring decompression;
❖ Metastasizing malignancy, myeloproliferative disorder or multiple myeloma;
❖ Ankylosing spondylitis or diffuse idiopathic skeletal hyperostosis;
❖ Parkinson's disease;
❖ Degenerative scoliosis with a Cobb angle >20°;
❖ Prior arthrodesis or cement augmentation of adjacent segments.

Surgical technique

The kit used for percutaneous instrumentation was Viper® 2 (DePuy Synthes Spine, Oberdorf, Switzerland) until 2015, and the CD Horizon® Longitude® II (Medtronic Spinal and Biologics, Memphis, TN, USA) from 2016 to 2018. The kit used for BKP was Confidence Spinal Cement System® (DePuy Synthes Spine, Oberdorf, Switzerland), and Kyphon® Express and Express II (Medtronic Spinal and Biologics, Memphis, TN, USA). Bone cement used for screw augmentation and BKP was Confidence® (DePuy Synthes Spine, Oberdorf, Switzerland), and Kyphon® Xpede (Medtronic Spinal and Biologics, Memphis, TN, USA). Both cements were composed of polymethylmethacrylate (PMMA), mixed during surgery, and set to reach an appropriate viscosity for injection. In a stepwise approach from both sides under fluoroscopy, the cement was injected slowly through the cannulated screws or into the void created by the balloons using the Confidence Spinal Cement System® (DePuy Synthes Spine), the Kyphon® bone-filling devices, or the Kyphon® Cement Delivery System (Medtronic Spinal and Biologics). In the PS group, BKP was performed only after screw placement, insertion and reduction of the rods and final closure of the system to prevent disruption of the bone-cement-interface at the index level.

Group formation

We identified two study groups based on the surgical treatment received. First, the PS group included 25 patients with 32 OVFs with posterior wall injury who underwent percutaneous placement of cannulated and fenestrated PS and rod constructs with additional cement augmentation techniques (*Figure 1*). Very few patients who underwent percutaneous instrumentation without BKP, but cement augmentation of PS, were also included in this group for the
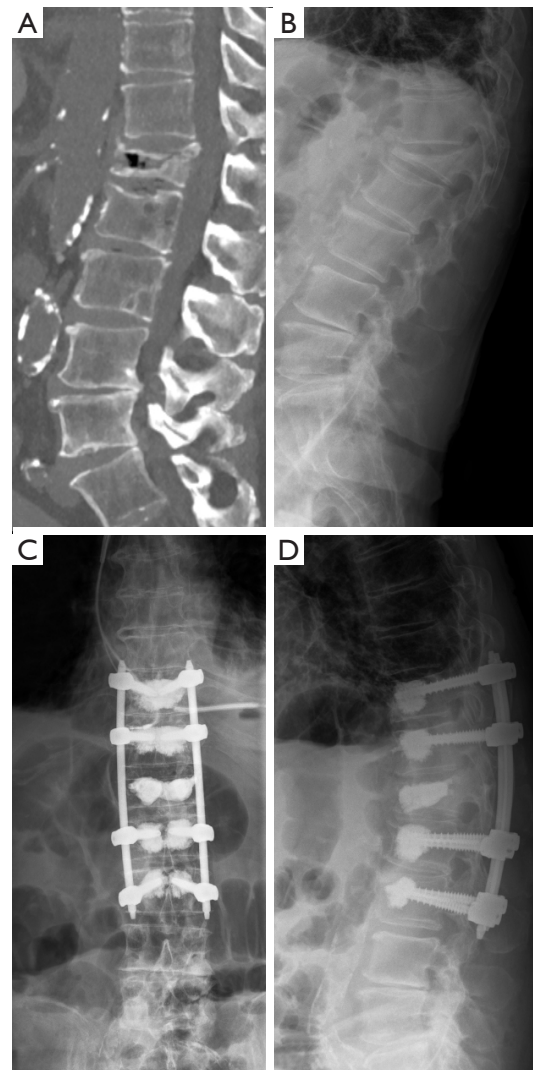
Figure 1 Preoperative and postoperative imaging of an 86-year-old male with an osteoporotic vertebral fracture of L1 who underwent percutaneous instrumentation and cement augmentation techniques (PS group). (A) Preoperative sagittal computed tomography imaging showing posterior wall injury and an intravertebral cleft with vacuum phenomenon; (B) preoperative lateral standing radiograph showing severe kyphotic deformity of the thoracolumbar junction and significantly decreased anterior vertebral height of L1; (C) postoperative anteroposterior standing radiograph after percutaneous instrumentation with cement augmented pedicle screws two levels above and two levels below L1 and balloon kyphoplasty of L1; cardiac pacemaker electrodes are overlapping with T11 and T12; (D) postoperative lateral standing radiograph showing good correction of kyphotic deformity, restoration of vertebral body height, adequate cement augmentation of L1 and pedicle screws, and no signs of posterior cement leakage.

ease of analysis. Second, the BKP group was selected based on comparable propensity scores (23) from our previously reported study of 214 patients who underwent BKP for OVFs at our institution (24). Of these, 46 patients met the inclusion criteria of posterior wall cortical injury detected on CT imaging and were further screened with propensity scoring. With propensity scores matched to each PS patient (1:1) as closely as possible, the BKP group consisted of 25 patients with 29 OVFs with posterior wall injury (*Figure 2*). Propensity scores were calculated and matched based on the treatment and the covariates of: age, sex, number of fractured vertebrae, fracture etiology (spontaneous or low-energy trauma), fracture age, involvement of the thoracolumbar junction (T11–L2), sagittal Cobb angle (angle between the superior endplate from the vertebral body one level above the injured vertebral body and the inferior endplate of the vertebral body one level below) (25), vertebral wedge angle (angle between superior and inferior endplate of the injured vertebral body), posterior cortical wall height loss >1/5, and additional presence of pincer-type injury (focal cortical injury of the upper and lower endplate without fracture dislocation).

Surgical and clinical decisions were made by attending spine surgeons on a case-by-case series or by team consensus. Procedures were performed under general anesthesia with the patient positioned prone, and with the use of two image intensifiers (anteroposterior and lateral views). Standing radiographs after surgery were obtained as soon as the patients were mobilized, normally on the first postoperative day, and at every follow-up visit. Patient and radiological data were retrieved from the local patient data management software and Picture Archiving and Communication System (PACS). Radiographic reviews were done by a single board-certified neurosurgeon and attending spine surgeon using PACS viewer Merlin 5.3 (Phoenix-PACS, Freiburg, Germany). After completion of data collection, patient data was encrypted before statistical analysis.

Primary endpoint

The primary endpoint, the occurrence of a postoperative complication, was defined using the 4-point grading system proposed by Landriel Ibañez *et al.* (26). This scale defines the severity of a complication as any deviation from the normal postoperative course that develops within 30 days of surgery. Grades, from mild to severe, were based on the therapy then administered to treat a postoperative adverse event:

- ❖ Grade I (mild): non-life-threating complication not
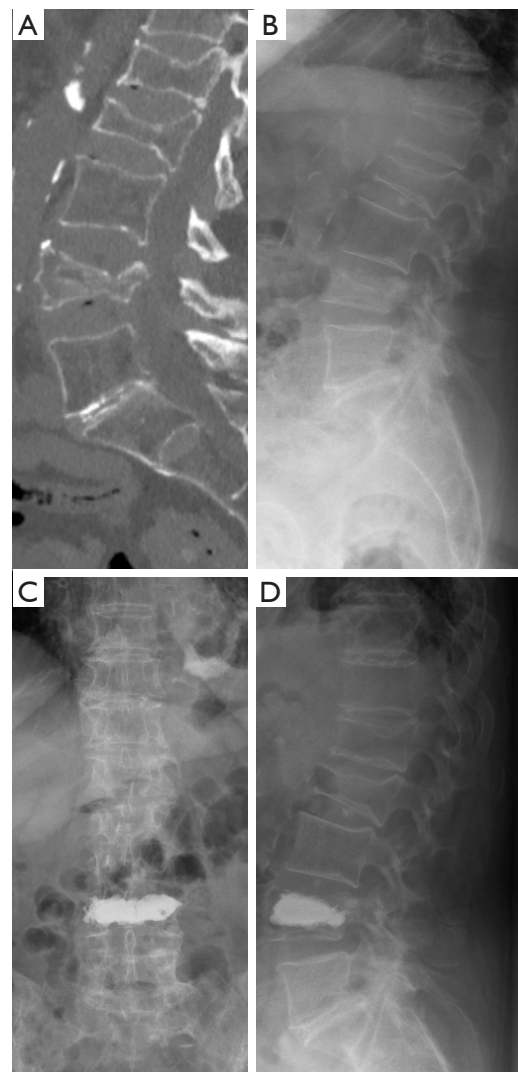
Figure 2 Preoperative and postoperative imaging of a 91-year-old female with an osteoporotic vertebral fracture of L4 who underwent balloon kyphoplasty (BKP group) shows older fractures of L1 and L2. (A) Preoperative sagittal computed tomography imaging showing posterior wall injury and a pincer-type injury in the posterior third of the vertebral body; (B) preoperative lateral standing radiograph showing anterior and posterior vertebral body height loss; (C) postoperative anteroposterior standing radiograph; (D) postoperative lateral standing radiograph showing good restoration of vertebral body height, and no signs of posterior cement leakage.

requiring drug treatment (grade Ia), or requiring drug treatment (grade Ib);
- ❖ Grade II (moderate): complication requiring invasive treatment (surgical, endoscopic, or

endovascular) without general anesthesia (grade IIa), or under general anesthesia (grade IIb);

❖ Grade III (severe): life-threating complication requiring management in intensive care unit (ICU) for a single organ failure (grade IIIa), or multiple organ failure (grade IIIb);

❖ Grade IV (death).

In patients suffering more than one complication within the first 30 days postoperatively, the complication with the highest grade was considered for analysis.

Secondary endpoints

Secondary endpoints were improvements of sagittal radiographic parameters, including Cobb angle for sagittal deformity, vertebral wedge angle, and anterior vertebral height. In multilevel OVFs, radiographic measurements were confined only to the vertebrae with posterior wall injury. Fractures occurring exclusively at the L3–L5 vertebrae were excluded from analysis because of the lordotic orientation of the lower lumbar spine. Radiographic parameters were evaluated by radiographic analysis to compare baseline preoperative images with the first postoperative standing lateral radiographs. Additionally, presence, direction and extent of cement leakage were evaluated on postoperative anteroposterior and lateral radiographs. Potential loss of correction was evaluated by comparing standing lateral radiographs at 3-month follow-up with early postoperative images.

Surgical time and length of stay (LOS) were also assessed. Patient-reported outcomes included initial back pain and at 3-month follow-up rated on a numeric rating scale (NRS) from 0 (no pain) to 10 (worst pain imaginable), and opioid use at discharge, and 3-month follow-up. Minimally clinically significant improvement in back pain was considered an NRS change of 3.5 points (27). Occurrence of any subsequent OVFs was noted in up to 3-month follow-up.

Statistical analysis

Pearson's χ^2 test and Fisher's Exact test were used for the comparison of categorical data. The two-sample t test and Mann-Whitney U test were used for the comparison of means, with the calculation of 95% confidence intervals (CIs), as applicable. Descriptive statistics were used to calculate means, medians, standard deviations, and ranges. Subgroup analysis was performed, if appropriate. Statistical analysis was performed with SPSS Statistics version 23.0 (IBM Corp., Armonk NY, USA). Results at a probability value P<0.05 were considered statistically significant.

Results

Demographic and surgical characteristics

Demographics and baseline characteristics of the study population are reported in *Table 1*. Both groups were comparable for the 10 preoperative covariates rated in propensity score matching, except for the smaller sagittal Cobb angle in the BKP versus PS groups [mean ± standard deviation (SD)] of 15.8°±8.7° *vs.* 22.9°±9°, respectively (95% CI: 1.78–12.386; P=0.010). Of covariates excluded from propensity score matching, differences between BKP and PS groups, respectively, were significant for body mass index (BMI) (24.3±4.5 *vs.* 27.5±5 kg/m^2; 95% CI: 0.4934–5.8826; P=0.021); first manifestation of osteoporosis (80% *vs.* 48%; P=0.018); and American Society of Anesthesiologists (ASA) Class II (64% *vs.* 32%; P=0.024). Surgical characteristics are outlined in *Table 2*. In the PS group, 200 PS were inserted in 105 vertebrae, with instrumentation two levels above and two levels below the index level in 12 (63.2%) of 19 single-level fractures (*Figure 1*). In this group, cement augmentation with PMMA was used for the screws in 21 (84%) of 25 patients, and all but 3 patients had additional BKP of the fracture level, preferably as a single-staged procedure. Follow-up averaged 8.4 months (range, 1–56.4 months).

30-day morbidity

Overall, 17 (34%) of all 50 patients developed a complication within 30 days after surgery, 6 (24%) in the BKP group and 11 (44%) in the PS group (P=0.136) (*Table 3*). Of complications recorded, 14 (82.4%) were mild, 2 (11.8%) were moderate, and 1 (5.9%) was severe; differences between groups were not significant, but a trend towards more mild complications requiring drug treatment (Ibañez Ib) was observed in the PS group (P=0.059). The 30-day mortality was 0%, and no surgical site infections were observed during follow-up. Mild complications commonly included water-electrolyte imbalance, urinary tract infection, delirium, and pulmonary embolism; all were treated with medications (Ibañez Ib). Of note, a 76-year-old woman in the PS group with cement augmentation of PS (1/21; 4.8%) developed symptomatic

Table 1 Demographics and baseline characteristics of the study population

	Total (n=50)	BKP Group (n=25)	PS Group (n=25)	95% CI	P value
Age (years), mean ± SD [range]	74.4±9.5 [51.8–91.9]	74.7±7.8 [64.9–91.1]	74.1±11.2 [51.8–90.3]	−6.1079 to 4.8599	0.820
Female, n [%]	43 [86]	22 [88]	21 [84]		1.000[§]
BMI (kg/m^2), mean ± SD [range]	25.9±5 [18.3–39]	24.3±4.5 [18.3–39]	27.5±5 [19.9–37.6]	0.4934–5.8826	0.021
Medical history, n [%]					
Arterial hypertension	32 [64]	17 [68]	15 [60]		0.556
Diabetes	8 [16]	2 [8]	6 [24]		0.247[§]
Pulmonary disease	9 [18]	4 [16]	5 [20]		1.000[§]
Long-term steroid use (>1 year)	4 [8]	2 [8]	2 [8]		1.000[§]
Anticoagulant or antiaggregant use	26 [52]	10 [40]	16 [64]		0.089
First manifestation of osteoporosis	32 [64]	20 [80]	12 [48]		0.018
Antiresorptive therapy	10 [20]	4 [16]	6 [24]		0.480
Lumbar DXA T-Score[†], mean ± SD [range]	−2.1±1.2 [−5.1 to 0.9]	−2.5±1.3 [−5.1 to −0.2]	−1.8±1.1 [−3.9 to 0.9]	−0.2717 to 1.6410	0.153
ASA class, n [%]					
II	24 [48]	16 [64]	8 [32]		0.024
III	24 [48]	9 [36]	15 [60]		0.089
IV	2 [4]	0 [0]	2 [8]		0.149[§]
Fractured vertebrae, n	61	29	32		
Single level, n [%]	41 [82]	22 [88]	19 [76]		0.463[§]
Two level, n [%]	7 [14]	2 [8]	5 [20]		0.417[§]
Three level, n [%]	2 [4]	1 [4]	1 [4]		1.000[§]
Number of fractured vertebrae, mean ± SD [range]	1.2±0.5 [1–3]	1.2±0.5 [1–3]	1.3±0.5 [1–3]	−0.1690 to 0.4090	0.408
Fracture etiology, n [%]					
Spontaneous	10 [20]	4 [16]	6 [24]		0.480
Low-energy trauma	40 [80]	21 [84]	19 [76]		0.480
Fracture age (weeks), mean ± SD [range]	1.9±1.9 [0.1–7.7]	1.6±1.7 [0.1–7.7]	2.2±2 [0.1–6.7]	−0.4575 to 1.6575	0.260
Fracture localization and morphology, n [%]					
** Thoracolumbar junction (Th11-L2) involved**	40 [80]	21 [84]	19 [76]		0.725[§]
Posterior wall cortical injury on CT	50 [100]	25 [100]	25 [100]		1.000
** Posterior wall height loss >1/5**	23 [46]	12 [48]	11 [44]		0.879
** Additional pincer-type injury**	19 [38]	9 [36]	10 [40]		0.684

Table 1 (*continued*)

Table 1 (*continued*)

	Total (n=50)	BKP Group (n=25)	PS Group (n=25)	95% CI	P value
Baseline mean physiological parameters‡, mean ± SD [range]					
Sagittal Cobb angle (°)	19.3±9.3 [−7 to 40]	15.8±8.7 [−7 to 34]	22.9±9 [5−40]	1.78–12.386	0.010
Vertebral wedge angle (°)	19.1±6.3 [−1 to 30]	17.4±7.3 [−1 to 28]	20.9±4.6 [13−30]	−0.196 to 7.227	0.063
Anterior vertebral height (mm)	13.5±5.2 [5−28]	14.2±5.9 [5−28]	12.9±4.7 [5−26]	−4.503 to 1.887	0.414
Baseline mean NRS [1–10], mean ± SD [range]	6.4±1.5 [3.5–10]	6.3±1.3 [3.5–9.5]	6.5±1.6 [3.5–10]	−0.6688 to 1.0271	0.673
Opioid use at baseline, n [%]	29 [58]	13 [52]	16 [64]		0.296

Covariates in bold were used for propensity score matching. [†], DXA T-scores of the lumbar spine obtained within ± 24 months to surgery were considered for analysis. T-Scores were available from 11 (44%) of patients in the BKP group and 16 (64%) of patients in the PS group. [‡], patients with fractures occurring exclusively at the levels L3–L5 (2 in the BKP group and 3 in the PS group) were excluded from analysis because of the physiological lordotic orientation of the lower lumbar spine. [§], P value from Fisher's Exact test. ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; CT, computed tomography; DXA, dual X-ray absorptiometry; NRS, numeric rating scale; SD, standard deviation.

pulmonary cement embolism that was confirmed by contrast-enhanced chest CT; she was readmitted 4 days after discharge (7 days after surgery) because of progressive dyspnea. After treatment with Rivaroxaban and medications for additional co-morbidities, dyspnea resolved and the patient recovered without further interventions (Ibañez Ib). One 81-year-old woman in the PS group developed transient proximal muscle weakness in her right leg that resolved within a few days after treatment with dexamethasone; this was not attributed to screw misplacement or cement leakage (Ibañez Ib), but was possibly related to a subsequent fracture of the lower endplate of the lower instrumented vertebra L4. No other neurologic complications developed in the study population. Except for placement of a suprapubic catheter under local anesthesia (Ibañez IIa) in one patient in each group, there were no endoscopic or surgical interventions performed within the first 30 days postoperatively.

Secondary endpoints

Secondary endpoints are outlined in *Table 2*, with radiographic parameters before and after surgery shown in *Figures 3-5*. No significant differences in cement leakage were observed between groups; specifically, 7 (28%) in the BKP group and 11 (44%) in the PS group (P=0.196). Most cement leaks occurred ventrally and/or laterally confined to the vertebral level of origin. Asymptomatic cement leakage into the spinal canal contained by the posterior longitudinal ligament occurred in two patients only in the BKP group

(P=0.490).

All radiographic parameters significantly improved compared with baseline measures. Mean preoperative sagittal Cobb angle improved from 15.8°±8.7° (median 16°) at baseline to 11.1°±9.4° (median 8°) after surgery (95% CI: 1.761–7.63; P=0.003) in the BKP group and from 22.9°±9° (median 23°) at baseline to 8.6°±8.4° (median 10°) after surgery (95% CI: 11.809–16.828; P<0.001) in the PS group (*Figure 3*). Mean preoperative vertebral wedge angle improved from 17.4°±7.3° (median 18°) at baseline to 9.1°±6.7° (median 8°) after surgery (95% CI: 5.352–11.083; P<0.001) in the BKP group and from 20.9°±4.6° (median 21°) to 5.5°±5.6° (median 3°) after surgery (95% CI: 12.381–18.437; P<0.001) in the PS group (*Figure 4*). Mean anterior vertebral height improved from 14.2±5.9 mm (median 12 mm) at baseline to 21.5±5.7 mm (median 22 mm) after surgery (95% CI: −9.026 to −5.582; P<0.001) in the BKP group and from 12.9±4.7 mm (median 13 mm) to 24.3±4.2 mm (median 25 mm) after surgery (95% CI: −13.227 to −9.5; P<0.001) in the PS group (*Figure 5*).

At 3-month follow-up, mean sagittal Cobb angle increased to 14.9°±7.4° in the BKP group (average loss of correction 3.8°) and remained stable at 8.2°±9.2° in the PS group. Mean vertebral wedge angle increased to 11.9°±6.4° in the BKP group (average loss of correction 2.8°) and to 7.1°±4.3° in the PS group (average loss of correction 1.6°). Mean anterior vertebral height decreased to 19.3±5.1 mm in the BKP group (average loss of correction 2.2 mm) and to 22±5 mm in the PS group (average loss of correction 2.3 mm). Although no statistical significant differences were

Table 2 Surgical characteristics, secondary endpoints (except physiological parameters) and follow-up of the study population

	Total (n=50)	BKP Group (n=25)	PS Group (n=25)	95% CI	P value
Fractured vertebrae, n	61	29	32		
Number of fractured vertebrae, mean ± SD [range]	1.2±0.5 [1–3]	1.2±0.5 [1–3]	1.3±0.5 [1–3]	−0.1690 to 0.4090	0.408
Number of surgically approached vertebrae, mean ± SD [range]	3.4±2.1 [1–8]	1.6±0.9 [1–3]	5.2±1.1 [3–8]	2.933–4.107	<0.001
Pedicle screws inserted, n	200	0	200		
Extent of instrumentation for single-level fractures, n [%]					
Short fixation (one level above and below index level)	1 [2]		1 [4]		
Short fixation (two level above and one below index level)	4 [8]		4 [16]		
Long fixation (two levels above and below index level)	12 [24]		12 [48]		
Other, n [%]	2 [4]		2 [8]		
Cement augmentation of pedicle screws, n [%]	21 [42]		21 [84]		
Vertebral body augmentation with BKP, n [%]	47 [94]	25 [100]	22 [88]		
Single-staged	48 [96]	25 [100]	23 [92]		
Two-staged	2 [4]	0 [0]	2 [8]		
Protective vertebroplasty of unfractured adjacent vertebrae, n [%]	12 [24]	7 [28]	5 [20]		0.508
Resident involved (teaching case), n [%]	39 [78]	19 [76]	20 [80]		0.733
Intraoperative complications, n [%]	0 [0]	0 [0]	0 [0]		1.000
Cement leakage	18 [36]	7 [28]	11 [44]		0.196
Intraspinal	2 [4]	2 [8]	0 [0]		0.490
Ventral or lateral confined to level	14 [28]	5 [20]	9 [36]		0.208
Ventral or lateral >1 level	1 [2]	0 [0]	1 [4]		1.000‡
Adjacent disc space	1 [2]	0 [0]	1 [4]		1.000‡
Surgical time (min)†, mean ± SD [range]	108.5±70.2 [23–274]	52±32.9 [23–165]	164.9±48.4 [51–274]	89.344–136.416	<0.001
Surgical time (min) per level approached, mean ± SD [range]	32.4±9.5 [15–60]	32.7±10.5 [15–60]	32.2±8.5 [17–54.8]	−5.928 to 4.960	0.859
Length of stay (days), mean ± SD [range]	5.6±3 [1- 16]	4.3±2.5 [1–10]	7±2.9 [3–16]	1.149–4.211	0.001
Opioid use at discharge, n [%]	34 [68]	13 [52]	21 [84]		0.015

Table 2 (*continued*)

Table 2 (*continued*)

	Total (n=50)	BKP Group (n=25)	PS Group (n=25)	95% CI	P value
30-day readmission rate, n [%]	3 [6]	2 [8]	1 [4]		1.000‡
Surgical site infections during follow-up, n [%]	0 [0]	0 [0]	0 [0]		
Follow-up (months), mean ± SD [range]	8.4±11.8 [1–56.4]	8±13.4 [1–56.4]	8.8±10.2 [1.3–43.6]	–6.0165 to 7.5045	0.826
Opioid use at 3-month follow-up, n [%]	7 [14]	3 [12]	4 [16]		1.000‡
NRS (0-10) at 3-month follow-up, mean ± SD [range]	2.4±1.8 [0–5.5]	2.6±1.9 [0–5.5]	2.2±1.8 [0–5.5]	–1.4522 to 0.6522	0.448
Subsequent fractures within 3-month follow-up, n [%]	20 [40]	11 [44]	9 [36]		0.564

†, surgical times were summarized for two-staged procedures in 2 patients in the PS group. ‡, P value from Fisher's Exact test. CI, confidence interval; SD, standard deviation.

seen in radiographic parameters early after surgery between groups (all P>0.05), mean sagittal Cobb angle and mean vertebral wedge angle were significantly greater at 3-month follow-up in the BKP than the PS group, with 14.9°±7.4° *vs.* 8.2°±9.2° (95% CI: –12.227 to –1.212; P=0.018) and 11.9°±6.4° *vs.* 7.1°±4.3° (95% CI: –8.463 to –1.326; P=0.009), respectively.

Surgical times were significantly shorter in the BKP than PS groups at 52±32.9 *vs.* 164.9±48.4 min, respectively (95% CI: 89.344–136.416; P<0.001). Significantly fewer vertebrae per patient were surgically approached in the BKP (1.6±0.9) than PS (5.2±1.1) groups (95% CI: 2.933–4.107; P<0.001). Comparing BKP and PS groups, respectively, mean LOS was significantly shorter at 4.3±2.5 *vs.* 7±2.9 days (95% CI: 1.149–4.211; P=0.001), and opioid use at discharge was significantly less at 52% *vs.* 84% (P=0.015).

At 3-month follow-up, both groups had achieved the minimally clinical important change in NRS score for back pain: improvement averaged 3.7±1.4 in the BKP group versus 4.2±1.5 in the PS group (95% CI: –0.3125 to 1.3925; P=0.209). No differences were observed in final NRS scores between groups (2.6±1.9 *vs.* 2.2±1.8; 95% CI: –1.4522 to 0.6522; P=0.448). Opioid use at 3-month follow-up was equally low in both groups, with no significant difference (12% BKP *vs.* 16% PS groups; P=1.000).

Subsequent fractures occurring within 3-month follow-up affected 20 (40%) of all patients, 11 (44%) in the BKP group and 9 (36%) in the PS group (P=0.564). Fractures were diagnosed an average of 45.7±9.1 in BKP and 47± 18.6 days in PS groups (95% CI: –12.060 to 14.605; P=0.843) after the index procedure. Four patients in the BKP group showed fracture progression of the cement augmented level, which was managed conservatively in all cases. Of two patients in the PS group with a subsequent fracture of the lower instrumented vertebra, both had received instrumentation two levels above and one level below the index level: one was managed conservatively, and another underwent revision surgery with caudal extension of the instrumentation 83 days after the index procedure. Adjacent level fractures, which accounted for 70% of subsequent fractures, equally affected 7 (28%) patients per group (P=1.000).

Discussion

Our retrospective study of 50 patients with 61 OVFs with posterior wall injury provides evidence for the hypothesis that BKP alone was comparable to BKP with percutaneous instrumentation in achieving correction of radiographic

Table 3 Primary endpoint of the study population: 30-day morbidity and severity of complications (Grades I–IV) according to the classification by Landriel Ibañez *et al.* (26) after surgical treatment of osteoporotic vertebral fractures with posterior wall cortical injury

|	Total (n=50)	BKP group (n=25)	PS group (n=25)	P value
30-day morbidity, n [%]	17 [34]	6 [24]	11 [44]	0.136
Mild complications (Ibañez I), n [%]	14 [28]	4 [16]	10 [40]	0.059
Not requiring drug treatment (Ia)	0 [0]	0 [0]	0 [0]	1.000[†]
Requiring drug treatment (Ib)	14 [28]	4 [16]	10 [40]	0.059
Urinary tract infection	3 [6]	1 [4]	2 [8]	1.000[†]
Anemia requiring transfusion of red blood cells	1 [2]	0 [0]	1 [4]	
Delirium	1 [2]	0 [0]	1 [4]	
Fluid overload, hyponatremia	1 [2]	0 [0]	1 [4]	
Hypokalemia	1 [2]	1 [4]	0 [0]	
Hypertensive crisis	1 [2]	1 [4]	0 [0]	
Hypertensive crisis, hyperkalemia, hyponatremia	1 [2]	1 [4]	0 [0]	
Pulmonary cement embolism (dyspnea) requiring anticoagulation, hyponatremia, hypokalemia, anemia requiring transfusion of red blood cells, urinary tract infection	1 [2]	0 [0]	1 [4]	
Pulmonary embolism	1 [2]	0 [0]	1 [4]	
Pulmonary embolism, delirium, pneumonia	1 [2]	0 [0]	1 [4]	
Urinary tract infection, hypokalemia	1 [2]	0 [0]	1 [4]	
Transient proximal muscle weakness in the right leg and subsequent fracture of lower instrumented vertebra (L4)	1 [2]	0 [0]	1 [4]	
Moderate complications (Ibañez II), n [%]	2 [4]	1 [4]	1 [4]	
Requiring invasive treatment without general anesthesia (IIa)	2 [4]	1 [4]	1 [4]	
Obstructive micturition requiring suprapubic catheter	1 [2]	0 [0]	1 [4]	
Complicated urinary tract infection requiring suprapubic catheter	1 [2]	1 [4]	0 [0]	
Requiring invasive treatment with general anesthesia (IIb)	0 [0]	0 [0]	0 [0]	
Severe complications (Ibañez III), n [%]	1 [2]	1 [4]	0 [0]	
ICU treatment because of single organ failure (IIIa)	0 [0]	1 [4]	0 [0]	
Acute pericarditis	0 [0]	1 [4]	0 [0]	
ICU treatment because of multiple organ failure (IIIb)	0 [0]	0 [0]	0 [0]	
Mortality (Ibañez IV), n [%]	0 [0]	0 [0]	0 [0]	

[†], P value from Fisher's Exact test. ICU, intensive care unit.

parameters and yielding good clinical outcomes. Specifically, both BKP and PS groups showed significant improvement in radiographic parameters versus baseline values and similar 30-day morbidity rates. However, the BKP group achieved significantly shorter mean surgical times, shorter LOS, and received less opioid medication at discharge. Potentially life-threatening complications or directly procedure-related complications were minimal, with one patient affected in each group. Significantly more BKP patients were classified as ASA Class II, whereas more (not significant) PS patients were classified as ASA Class III. At 3-month follow-up, loss of correction was more likely to occur in the BKP group, but this did not affect clinical outcome. Findings of this propensity score matched study can add to the discussion
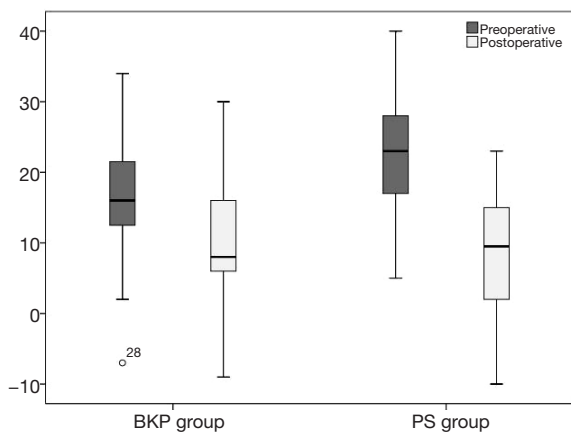
Figure 3 Preoperative and postoperative sagittal Cobb angle (°) in both study groups.
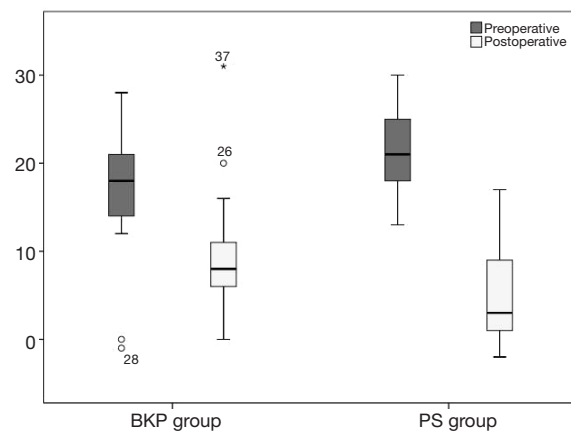
Figure 4 Preoperative and postoperative vertebral wedge angle (°) in both study groups.
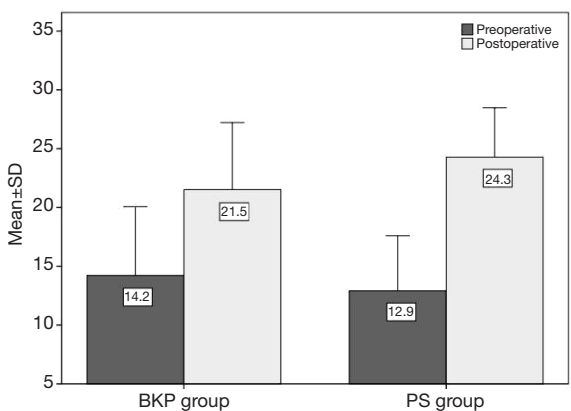
Figure 5 Preoperative and postoperative anterior vertebral height (mm) in both study groups.

when weighing the choice of treatment in aging populations affected by osteoporosis and increasing numbers of OVFs with a higher risk for instabilities.

Complications, cement leakage, and subsequent fractures

In a retrospective, non-matched study of 99 patients that compared PS with instrumentation to BKP for OVFs with posterior wall injury, Tassemeier *et al.* (28) showed that the surgical approach and not the ASA Class was a relevant factor for complications and revision surgery. Similar to our results, the authors found patients with PS averaged longer surgical time (120 min), longer LOS (21 days), and better correction of vertebral wedge angle (7.5°). In the EVOLVE-Trial of 350 patients, Beall *et al.* (11) reported 30-day morbidity after BKP was 24.9%, which aligned with the 24% rate in our BKP group.

Symptomatic pulmonary cement embolism was the only directly procedure-related complication in 1 (2%) patient in our study population. Cement leakage, a common complication of BKP, has a reported incidence ranging from 2.9% to 27% (8,11,29,30). Compared with vertebroplasty, BKP significantly decreases the risk of cement leakage (RR 0.62; 95% CI: 0.47–0.80) (31) because of the lower pressures used to inject the cement into the vertebral body after creating a void with inflatable balloons (5,6). Furthermore, correction of kyphotic deformity and restoration of vertebral height was significantly greater after BKP (31). Cement viscosity, injected cement volume, cortical disruption, and history of pulmonary diseases are factors reported to affect the complications resulting from cement leakage (32).

The risk of cement-related pulmonary embolism after vertebral augmentation techniques for OVFs ranges from 3.5% to 23% (33). In a meta-analysis, Zhan *et al.* (29) noted that cortical disruption posed a more than 5-fold higher risk of cement leakage after vertebroplasty or BKP (OR, 5.56; 95% CI: 1.84–16.81; P<0.01) than no cortical disruption. The question arises, "Should BKP be performed in the presence of posterior wall injury?" In a retrospective series of 97 patients with incomplete osteoporotic burst fractures, Krüger *et al.* (34) reported cement leakage in 47.4% of patients, including leakage into the spinal canal in 7.2% of patients; nonetheless, all cases were clinically unremarkable. In a prospective series of 82 patients with 98 OVFs with posterior wall injury treated with BKP, Abdelgawaad *et al.* (18) found no cement leakage into the spinal canal in any of their patients. The authors attributed this to their

technique modification: after first creating a large void in the anterior two-thirds of the vertebrae using small-sized balloons, they incrementally injected high-viscosity cement in volumes equal to or lower than that of the void created. In cases of posterior wall fractures, Liu *et al.* (35) reported the least cement leakage (3.7%) when using high-viscosity cement and an unilateral approach for BKP, whereas Walter *et al.* (36) noted higher rates of cement leakage into the spinal canal (9.8%) with 2/13 patients undergoing revision surgery. In our study, the 2 (8%) intraspinal cement leaks in the BKP group oriented longitudinally along the posterior vertebral wall, seen on lateral radiography, indicated an intact posterior longitudinal ligament. To avoid unnecessary radiation exposure, no additional CT imaging was performed because these 2 patients were neurologically intact and had an unremarkable postoperative course. Given the available literature, the rate of symptomatic leaks into the spinal canal seems to be low, and modifications in surgical technique may further reduce that risk.

Instrumentation of the osteoporotic spine is a challenging task because of the tendency to instrumentation failure secondary to pull-out and subsidence, leading to revision surgeries (16). In recent years, although cement augmentation of PS has received growing attention and is increasingly performed (37), there is a lack of Level I evidence in the literature and no standardized technique for cement augmentation of PS. The use of cannulated PS for cement augmentation has been investigated in in-vitro pull-out studies (38,39). In fatigue testing in an osteoporotic cadaveric study, Weiser *et al.* (17) reported increased stability of long segment fixation (T11–T12 to L2–L3) compared to short fixation (T12 to L2). However, augmentation with bone cement failed to demonstrate a significant increase in the mean cycles to failure and fatigue force between short- and long-segment fixation. Cement augmentation of PS in long fixation together with vertebral augmentation of the fracture level potentially puts the patient at higher risk of symptomatic cement leakage because of the higher total volumes of cement injected. Janssen *et al.* (40) reported asymptomatic cement leakage in 110 (66.7%) of 165 patients after cement augmentation of PS, while Martín-Fernández *et al.* (41) reported cement leakage in 650 (62.3%) of 1,043 vertebrae instrumented with cement augmented PS. In the former study, the overall symptomatic complication rate was 5.5% (9/165), including symptomatic pulmonary cement embolism in 3% (5/165), and a 30-day mortality rate as high as 1.8% (3/165). Clinically relevant cement leakage after cement augmentation of PS has been reported in 0.6–5.5%

(40-43), which was similar to the 4.8% found in our PS group. Given the high rate of cement leakage reported in the literature, including potentially life-threatening complications and even death, indication to augment PS with bone cement should be cautious and patients should be properly informed about such potential risks.

In a retrospective series of 214 BKPs performed at our institution for OVFs, the 25.7% rate of subsequent fractures in the first year after BKP included 3/4 of those fractures occurring within 12.9 weeks after the index procedure (24). Beall *et al.* reported 36.7% incidence of subsequent fractures within 3 months after BKP in 350 patients (11). In the present study, the rate of subsequent fractures at 3 months was 44% in the BKP group. Only one patient in our PS group showed a subsequent fracture of the lower instrumented vertebra L4 in the first 30 days after surgery. However, the 30-day morbidity does not adequately reflect subsequent fractures. The lower rate of subsequent fractures in the PS group was probably related to better restoration of radiographic parameters; this did not affect the rate of adjacent level fractures, which were equal between the two study groups.

In the results of an international RCT that included 141 patients, Noriega *et al.* (44) demonstrated the non-inferiority of a titanium implantable vertebral augmentation device (TIVAD) compared with BKP for painful OVFs. Compared with BKP, TIVAD achieved better fracture reduction of midline vertebral height, better pain control at 1 and 6 months, and lower incidence of adjacent fractures (all significant). Given the technical advancement in this vertebral augmentation technique, the availability of a new classification-system (12), and classification-based scoring methods for OVFs (20), surgical decision making may be refined and candidates for standalone vertebral augmentation recognized more easily.

Among several limitations, first is the selection bias of this retrospective, single-center study with specified inclusion criteria. Nonetheless, using matching with propensity scores, two comparable groups could be formed in terms of age, sex, osteoporosis severity, and fracture characteristics, although kyphotic deformity at baseline, as measured by sagittal Cobb angle, was significantly greater in the PS group. Second, the indication to perform percutaneous instrumentation did not follow a therapeutic algorithm or classification-based scoring method and was potentially influenced by higher degrees of kyphotic deformity at baseline in the PS group. Rather, based on individual preference, it also resulted in a form of surgical bias and heterogeneity for both groups. Our results may

also be interpreted that for more severe cases of kyphotic deformity, percutaneous instrumentation was feasible and achieved better preservation of deformity correction at 3-month follow-up. Third, classifying posterior wall injury on CT was simplified to mere cortical disruption and morphological changes like height loss >1/5. Whether or not severity and extent of posterior wall injury (e.g., degree, extent of comminution, displacement or angulation) influence the risk for posterior cement leakage cannot be answered and could be further investigated. Fourth, the low sample size with one patient accounting for 2% of overall results and 4% of group results; while not statistically significant, mild complications were more than double the rate in the PS group compared to the BKP group. Considering the primary endpoint, our study has a power (1–β) of 0.386 with an α error probability of 0.136. To achieve an α error probability of 0.05 with the same power, it would have been necessary to include a total of 82 patients (41 patients in each group), which was not possible given the inclusion criteria applied. Fifth, the rather short follow-up, unable to determine long-term outcomes of the study population. Given these limitations, our findings must be interpreted with appropriate caution.

Conclusions

BKP with and without percutaneous posterior instrumentation with PS are both effective techniques in the surgical treatment of OVFs with posterior wall injury. Both techniques had similar 30-day morbidity and achieved significant improvements in early postoperative radiographic parameters versus their baseline values. When compared with percutaneously instrumented OVFs, standalone BKP was a less invasive surgical procedure associated with significantly shorter surgical times, shorter LOS, and less opioid requirement at discharge, that achieved equally good clinical outcomes at 3-month follow-up.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/jss-20-625

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethical Committee of Northwestern and Central Switzerland (ID number EKNZ BASEC 2018-00185), and individual consent for this retrospective analysis was waived.

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