



Risk factors and score for recollapse of the augmented vertebrae after percutaneous vertebroplasty in osteoporotic vertebral compression fractures

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Abstract

Summary Our study demonstrated a high incidence of recollapse of the augmented vertebrae after PVP treatment for OVCFs. A risk score based on all significant factors can predict the rate of recollapse and gain clinical benefits to prevent recollapse in patients at high risk.

Background Recollapse of the augmented vertebrae after percutaneous vertebroplasty (PVP) treatment for osteoporotic vertebral compression fractures (OVCFs) has obtained much attention. However, little is known about risk factors and score for recollapse of the augmented vertebrae.

Objective To determine risk factors and furthermore develop a risk score related to recollapse of the augmented vertebrae after PVP treatment for OVCFs.

Methods Patients who were treated with PVP for single OVCFs and met this study's inclusion criteria were retrospectively reviewed. The follow-up period was at least 2 years. Associations of recollapse with co-variables (age, gender, bone mass density [BMD] with a T-score, fracture level, intravertebral cleft [IVC], fracture type, cement volume, cement leakage, leakage into a disc, cement distribution pattern, Non-PMMA-endplate-contact [NPEC], preoperative fracture severity, reduction rate [RR], reduction angle [RA]) were analyzed and a risk score for recollapse was further developed to predict recollapse.

Results A total of 152 patients were included. Recollapse group was found in 42 (27.6%) patients. Preoperative IVC, solid lump cement distribution pattern, more RR (a cutoff value of 7%) and larger RA (a cutoff value of 3°) was significantly associated with increased risk for recollapse of the augmented vertebrae. A risk score was developed based on the number of risk factors present in each patient. Patients with a score of 4 had an approximately ninefold increased risk of developing recollapse over patients with a score of 0. The receiver operating characteristic curve of the risk score generated an area under the curve of 0.899 (95% CI 0.642–0.836, $P = 0.000$).

Conclusion A risk score based on preoperative IVC, cement distribution pattern, reduction rate, and reduction angle predicts the rate of recollapse. Additional studies should aim to validate this score and inspect clinical benefits of recollapse prophylaxis in patients at high risk.

Keywords Augmented vertebrae · Osteoporotic vertebral compression fracture · Percutaneous vertebroplasty · Recollapse · Risk score

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Introduction

Osteoporotic vertebral compression fractures (OVCFs) are very common in the elderly with an estimated 1.4 million of new fractures occurring every year worldwide [1]. OVCFs may cause pain, limited physical function, decreased quality of life, and increased mortality [2–4]. OVCFs have been traditionally treated with conservative managements, such as bed rest, analgesics, braces, taking anti-osteoporotic agents, et al. [5]. However, such treatments are only partially effective, and

about one third of patients have been reported to suffer from persistent pain and progressive functional limitation [6–8]. Hence, in cases with persistent pain or being refractory to conservative managements, percutaneous vertebroplasty (PVP) has been traditionally adopted. PVP is a minimally invasive technique for treating painful osteoporotic vertebral fractures (OVCFs). Numerous clinical studies [9–11] demonstrated that the treatment could rapidly relieve the pain of patients, restore vertebral height partially, and provide biomechanical stability by injecting bone cement into the fractured vertebrae.

However, in light of previous literatures, many studies [12–14] have reported recollapse of the augmented vertebrae with significant vertebral height loss and aggravation of kyphotic deformity after postoperative follow-up period, which usually required further treatment. Some researchers [13, 14] believed that previous intravertebral cleft (IVC) might be an important predisposing factor to recollapse. Lin et al. [15] reported that cement distribution patterns might have a significant effect on stability of the augmented vertebrae over the long term and an insufficiently diffused pattern might be another important risk factor, but they could not find a significant relationship with recollapse. Thus, the purpose of the present study was to identify risk factors and further develop a risk score for recollapse of the augmented vertebrae after PVP treatment for OVCFs.

Materials and methods

This study was designed to be performed retrospectively at our institute between January 2011 and December 2014.

Selection of patients

Eight hundred forty-five consecutive patients who underwent PVP to treat OVCFs were initially investigated during this interval. The inclusion criteria were as follows: (1) single-level symptomatic OVCF treated with PVP and without evidence of a previous osteoporotic vertebral fracture; (2) treatment via bilateral portals; (3) no complication after surgery, including leakage of PMMA into the spinal canal, or postoperative neurologic deficit; (4) follow-up period of at least 2 years; (5) no additional history of trauma after surgery; (6) regular radiologic studies including preoperative, postoperative (immediately, 1 years and 2 years); (7) regular anti-osteoporotic treatment for all patients during the follow-up period after PVP (0.5 mg/day for 1 α -hydroxy vitamin D and 70 mg weekly tablet for alendronate). The exclusion criteria were as follows: (1) multiple-level PVP patients; (2) non-osteoporotic vertebral compression fractures or compression fractures secondary to other factors, such as pathologic fractures due to metastasis or symptomatic hemangioma; (3) poor

medication compliance to anti-osteoporotic drugs during the follow-up period. Finally, a total of 152 patients were enrolled in our study (137 women, 15 men).

Operative procedure

All of PVP procedures were performed by three more than 10 years experienced spinal surgeons with standard training of PVP techniques. The PVP technique was adopted by a transpedicular approach (bipedicular needle insertion) in an extended posture under local anesthesia (1% lidocaine). According to Jensen's technique [16, 17], with the guidance of fluoroscopic C-arm, 11 to 13-gauge bone biopsy needles were inserted parallel to the superior and inferior edges of the pedicle, or in a slightly descending course through the pedicle. The stylet was removed from the trocar when the needle tip was optimally positioned. Then, polymethylmethacrylate (PMMA) powder with sterile barium sulfate (Tianjin Synthetic Material Research Institute, Tianjin, China) would be inserted into the vertebral body when it was thicker than a toothpaste-like consistency. The cement injection process was monitored continuously under C-arm fluoroscope in the lateral plane. Injection was temporarily halted when initial cement leakage without any discomfort complained by the patients was noted and terminated on the reoccurrence of it or when bone cement reached the posterior quarter of the vertebral body, to avoid cement leakage into spinal canal or neural foramina. After PVP, all patients were enforced bed rest for a few hours.

Radiological assessment

All the radiological parameters were measured twice by 2 more than 10 years experienced spinal surgeons individually and independently to eliminate intra- and inter-observer bias. In our study, for the measurement of all radiological parameters, the intra- and inter-observer correlation coefficient (ICC) was all excellent (ICC > 0.82). However, eight cases had a noticeable difference in preoperative and immediately postoperative vertebral height between both observers. In order to manage the bias, a third experienced evaluator was involved to have deciding vote. Additionally, radiological reports were also used to assist in the decision-making process if necessary. All radiologic measurements were checked digitally through the picture archiving and communication system (PACS) and its related computer software at our department (M-viewTM, Marotech, Seoul, Korea).

An evaluation of preoperative IVC

To evaluate preoperative IVC within the affected vertebrae, preoperative magnetic resonance imaging (MRI), or computed tomography (CT) was used to observe and reveal the

presence and location of IVC. The IVC sign was detected as a radiolucent shadow on lateral radiography and sagittal CT, hypointense signal on T1-weighted images and hypointense/hyperintense on T2-weighted images. Additionally, a peripheral zone of hypointensity can be seen surrounding the hyperintensity on T2-weighted images (Fig. 1) [18, 19].

An evaluation of cement distribution pattern

The immediately postoperative radiological assessment on the sagittal CT was performed to evaluate cement distribution patterns within the affected vertebrae. According to the cement distribution through the cancellous bone, two patterns were distinguished: group 1: solid lump distribution pattern; group 2: the sufficiently diffused distribution pattern [12].

An evaluation of fracture severity of the affected vertebrae

Based on the percentage of preoperative vertebrae collapse, the fracture severity was classified as follows: group 1: mild (< 2–5% collapse); group 2: moderate (26–40%)—severe (> 40%), respectively [17, 20].

An evaluation of preoperative T-score in bone mineral density (BMD)

On the day of admission, BMD scores of the lumbar vertebrae (L2–4) were determined using dual X-ray absorptiometry (DXA) (Hologic, Waltham, MA, USA), and when the fracture was at L2–L4 the respective vertebrae were excluded at T-score evaluation.

An evaluation of non-PMMA-endplate-contact (NPEC)

NPEC was determined when postoperative plain radiograph and sagittal CT revealed that the inserted PMMA did not come into contact with superior portion of the endplate [21].

An evaluation of reduction rate (RA) and reduction angle (RA)

We retrospectively measured preoperative and postoperative (first day, 1 year, and 2 years) radiological parameters, including vertebral height and kyphotic angle from lateral plain radiographs. The vertebral height and kyphotic angle were measured according to previous literatures described by Linn et al. [19] and Kim et al. [21]. Vertebral height was measured at the point of maximal compression of the augmented vertebrae. Vertebral compression rate (CR) was measured as the rate of vertebral height of the augmented vertebrae to the mean vertebral height of the upper and lower vertebrae at the same site. RR was calculated by the difference between preoperative and immediate postoperative CR. Kyphotic angle (KA) was measured using Cobb's method, considering the angle between the

upper endplate of the upper vertebra and the lower endplate of the lower vertebra. RA was calculated using the difference between the preoperative and immediate postoperative KA.

An evaluation of recollapse of the augmented vertebrae

In conjunction with prior reports [17, 21], two conditions were defined as progression of the augmented vertebrae: (1) $\geq 15\%$ progression of CR between the immediately postoperative and last follow-up period; (2) $\geq 10^\circ$ progression in local KA between the immediately postoperative and last follow-up period.

Factors evaluated

In total, 14 risk factors including age, gender (male/female), preoperative T-score in BMD, fracture level, preoperative IVC, fracture type, cement volume, cement leakage, leakage into a disc, cement distribution pattern, NPEC, preoperative fracture severity (mild vs. moderate-severe), reduction rate, and reduction angle were evaluated. Additionally, clinical efficacy was assessed by one author through the visual analogue scale (VAS) scores for back pain evaluation (range, 0–10; 0, no pain at all; 10, worst pain imaginable). Preoperative and postoperative VAS scores were performed on the day of admission and on the first postoperative day, respectively; Final follow-up VAS scores were performed in outpatient clinic.

Statistical analysis

Quantitative variables were described by means and standard deviations, whereas frequencies were reported for qualitative variables. Univariate analysis was used to assess clinical outcome of preoperative, immediately postoperative and final follow-up VAS scores of back pain and risk factors associated with recollapse. In addition, a multivariate stepwise logistic regression analysis was performed to identify which independent factors helped to predict recollapse of the augmented vertebrae, with adjustments made for other potential confounding factors. Then, a receiver operating characteristic (ROC) curve was created to determine the cutoff values of all significant risk factors with quantitative data. Then, each independent factor was converted to a binary variable. The presence of each independent factor was considered 1 point. Finally, the factors were used collectively to calculate a patient's risk score for recollapse. Recollapse risk scores for all patients entered into a ROC curve, which yielded an area under the curve (AUC) value to grade the predictability of the model. SPSS 20.0 statistical software (SPSS, Inc., Chicago, IL, USA) was used for analysis.

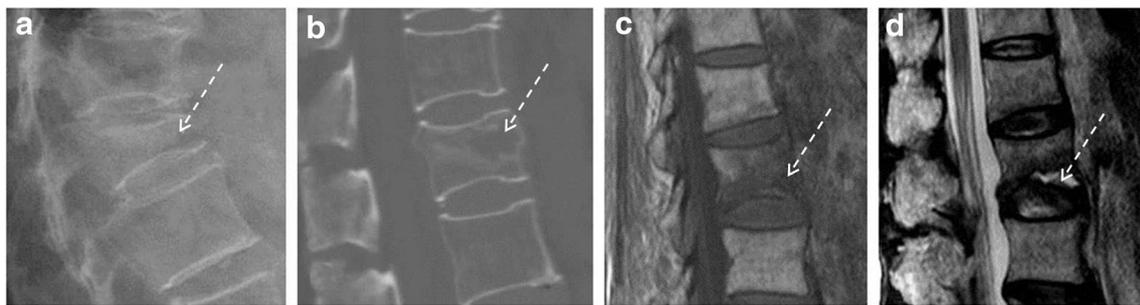


Fig. 1 The imaging manifestation of preoperative IVC. **a** Lateral radiograph demonstrates a radiolucent shadow in T12; **b** sagittal CT demonstrates a T12 superior endplate IVC; **c** sagittal T1W MRI

demonstrates fluid within a L1 hypo-sign IVC; **d** sagittal T2W MRI demonstrates fluid within a L1 hyper-sign IVC. IVC, intravertebral cleft

Results

In total, 152 patients (M/F = 15:137) were reviewed. The average age of the patients was 70.22 ± 7.35 and the mean follow-up period ranged from 24 to 33 months (median, 26 months). During the follow-up period, conservative treatments were followed for all patients in recollapse group after detection of recollapse of the augmented vertebrae, and no additional surgical intervention was needed for our included patients. Recollapse group was found in 42 (27.6%) patients. Postoperative back pain scores in both groups were significantly lower in comparison of preoperative back pain score ($P < 0.001$). The VAS scores of back pain at final follow-up period, however, were significantly higher in recollapse group than those in well-maintained group ($P < 0.001$). At preoperative and immediately postoperative evaluation, there was no significant difference in VAS scores of back pain between the two groups (Table 1).

Non-adjusted comparisons using univariate analysis between patients with and without recollapse showed that there were no significant differences between the two groups regarding age, gender, BMD T-score, fracture level, fracture type, cement volume, cement leakage, leakage into a disc, NPEC, and fracture severity ($P > 0.05$). Univariate analysis revealed that four risk factors were significantly associated with increased risk of developing recollapse, including preoperative IVC ($P = 0.014$), solid lump cement distribution pattern ($P = 0.010$), more reduction rate ($P = 0.024$), and larger reduction angle ($P = 0.019$) (Table 1). Multivariate stepwise logistic regression analysis also further revealed significant difference in preoperative IVC (OR = 2.40, 95% CI 1.07–5.36, $P = 0.003$), solid lump cement distribution pattern (OR = 3.15, 95% CI 1.26–7.89, $P = 0.014$), more reduction rate (OR = 1.03, 95% CI 1.01–2.03, $P = 0.041$), and larger reduction angle (OR = 5.36, 95% CI 2.32–12.41, $P = 0.000$) (Table 2).

The ROC curve for RR as a predictor for recollapse had an AUC of 0.618, indicating moderate accuracy ($p = 0.024$). A cutoff value of 7% demonstrated a sensitivity of 81.0% and a specificity of 67.3%. Hence, more than 7% for RR was

assigned 1 point. Similarly, the ROC curve for RA as a predictor for recollapse had an AUC of 0.699, indicating moderate accuracy ($p = 0.000$). A cutoff value of 3° demonstrated a sensitivity of 76.2% and a specificity of 62.7%. Hence, more than 3° for RA was assigned 1 point. Finally, patients were assigned a total score for risk of recollapse, and scores ranged from 0 to 4. The risk score for recollapse showed high predictability of recollapse, with incidence rates of 10% for those with a score of 0 and 87.5% for those with a score of 4 (Fig. 2). The recollapse risk score's ability to predict recollapse was further assessed by using a ROC curve, which had a cutoff value of 2.5 score with a sensitivity of 76.2% and a specificity of 65.5%. The AUC was 0.739 (95% CI 0.642–0.836, $P = 0.000$, Fig. 3). Progression of recollapse of the augmented vertebrae with a score of 4 was shown in Fig. 4 by analysis of radiological films from serial follow-ups.

Discussion

Use of PVP as an alternative treatment for some OVCFs refractory to conservative managements is controversial, primarily due to two previous independent level 1 trials, as both of which found that patients randomized to PVP did not experience decreases in pain or disability in comparison to patients in the placebo arm [22, 23]. Furthermore, although the two studies have been criticized for a variety of reasons, the American Academy of Orthopedic Surgeons believed that they did have sufficient power to detect the minimal clinically important difference in pain, and clinical practice guideline issued by the American Academy of Orthopedic Surgeons strongly recommended against PVP for symptomatic OVCFs [24]. Despite of these controversies, increased use of PVP for managing OVCFs has been the trend, likely due to the individual physician experience on the efficacy of this procedure. Nowadays, some guidelines are recommending PVP and numerous studies are showing its benefits [5, 25–27].

To the best of our knowledge, this is the first study conducted to identify risk factors and further develop a risk score

Table 1 Characteristics of recollapse group and comparison with well-maintained group

	Recollapse group (n = 42)	Well-maintained group (n = 110)	P values
Age (years) ^a	68.88 ± 7.60	70.73 ± 7.22	0.167
Sex (female, %)	39 (92.9%)	98 (89.1%)	0.761
BMD T-score ^a	- 3.17 ± 0.75	- 3.02 ± 0.72	0.270
Thoracolumbar (T11–L2) (yes, %)	34 (90.0%)	83 (75.5%)	0.472
Fracture severity (mild, %)	23 (54.8%)	61 (55.5%)	0.939
Preoperative IVC (yes, %)	22 (52.4%)	34 (30.9%)	0.014
Fracture type (wedge, %)	23 (54.8%)	56 (50.9%)	0.671
Cement volume (ml) ^a	5.59 ± 0.57	5.06 ± 0.77	0.435
Cement leakage (yes, %)	10 (23.8%)	25 (22.7%)	0.887
Leakage into disc space (yes, %)	3 (7.1%)	4(3.6%)	0.396
Cement distribution pattern (solid lump, %)	15 (35.7%)	18 (16.4%)	0.010
NPEC (yes, %)	9 (21.4%)	18 (16.4%)	0.465
Reduction rate (%) ^a	12.3 ± 9.5	10.5 ± 10.6	0.024
Reduction angle (°) ^a	4.59 ± 5.76	2.75 ± 3.56	0.019
VAS scores ^a			
Preoperative	8.27 ± 0.65	8.14 ± 0.35	0.967
Postoperative	1.78 ± 1.94	1.72 ± 0.98	0.989
Last	5.15 ± 2.12	2.37 ± 1.05	0.000

BMD bone mineral density, IVC intravertebral vacuum cleft, NPEC non-PMMA-endplate-contact, VAS visual analogue scale score

^a Quantitative variables are expressed as mean ± SD

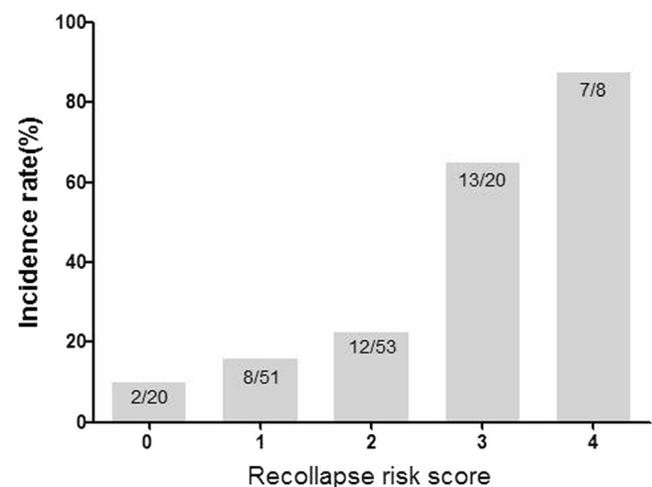
for recollapse of the augmented vertebrae after PVP treatment for OVCFs. In addition to osteoporosis as fracture etiology, we restricted the analysis to patients with a single-level fracture for creating a uniform cohort and simplifying the interpretation. Our current study found that four independent risk factors, including preoperative IVC, solid lump cement distribution pattern, more reduction rate (a cutoff value of 7%), and larger reduction angle (a cutoff value of 3°) were significantly associated with recollapse of the augmented vertebrae. The ROC curve for recollapse risk score had an AUC of 0.739, while a cutoff value of 2.5 score showed a sensitivity of 76.2% and a specificity of 65.5%. Therefore, in cases with more than 2 as a score, the possibility of recollapse might be greater. Patients with a score of 4 had an approximately ninefold increased risk of developing recollapse over patients with a score of 0.

Table 2 Outcome of multivariate logistic regression analysis

	OR (95% CI)	P value
Preoperative IVC	2.40 (1.07–5.36)	0.033
Cement distribution pattern	3.15 (1.26–7.89)	0.014
Reduction rate	1.30 (1.01–2.03)	0.041
Reduction angle	5.36 (2.32–12.41)	0.000

IVC intravertebral vacuum cleft

Several studies have investigated the effect of preoperative IVC on recollapse of the augmented vertebrae. It could be possibly due to two reasons. Firstly, most studies considered that the presence of preoperative IVC was mainly related with cement distribution pattern. When the IVC within the affected vertebrae appeared, cement injected was mainly filled with solid lump into the IVC area under low pressure. Solid lump cement may act to both concentrate stress on the surrounding

**Fig. 2** Rates of recollapse grouped according to recollapse risk score

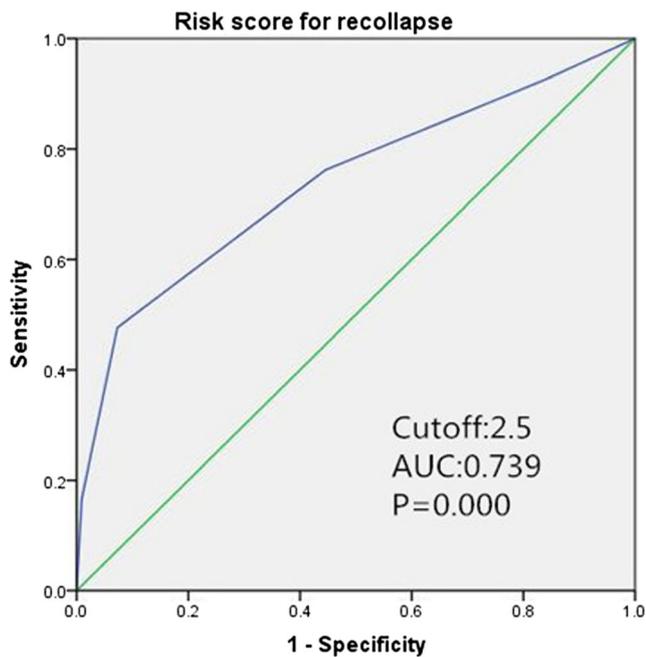


Fig. 3 Receiver operating characteristic curve for recollapse risk score

fragile bones and intercept mechanical interlock with surrounding cancellous bones for lack of contiguous interdigitation with surrounding cancellous bones [28, 29]. Thus, the recollapse in PMMA-unsupported areas is easily developed during daily activity. Secondly, in light of prior biomechanical study, Kim et al. [20] and Chen et al. [30] demonstrated that the load could be transferred from upper endplate to the PMMA column and then to the lower endplate if the PMMA could be diffused throughout the cancellous portion of the affected vertebrae. However, the weaker cancellous bone would be not loaded in series under the condition that the PMMA mass was not diffused while consisted of one- or two-solid masses, if it was like so, greater height loss and kyphotic deformity would occur.

In our study, more reduction rate and larger reduction angle were considered to be other risk factors for recollapse of the augmented vertebrae. Most studies [13, 14, 31, 32] were compatible with our current results. They demonstrated that too much restoration of vertebral height might cause increased paravertebral soft tissue tension which then led to increased mechanical loading on the augmented vertebrae or more instability in the fractured segment. Consequently, recollapse of the augmented vertebrae increased with a greater degree of vertebral height restoration. Another reason might be also associated with the presence of preoperative IVC and solid lump cement. Heo et al. [13] reported that re-expansion rate of vertebrae by volume-pressure effect produced by solid lump cement in the IVC area was higher in collapse group than that by contiguous bone interdigitation in well-maintained group. They thought that this type of re-expansion by volume effect might aggravate the process of osteonecrosis instead of contiguous bone interdigitation.

Finally, we believe that our development of a risk score is meaningful in prevention for recollapse of the augmented vertebrae and preoperative IVC can be considered as the most important risk factor. The identification of preoperative IVC is also very important to clinicians because surgical management can be adjusted to prevent recollapse. According to our prior clinical study [33], the cement mass injected can be sufficiently interdigitated with peripheral cancellous bone and form sufficiently diffused distribution pattern when the proposed target puncturing technique was chosen. Briefly, the needle tip is placed at the peripheral cancellous bone around the IVC area instead of being traditionally placed in the IVC area. Then, PMMA cement can be infiltrated into the cleft area through peripheral cancellous bone under great injection pressure. By this method, the PMMA cement in the IVC can make a better interdigitation with peripheral cancellous bone, and gain better mechanical stability. Meanwhile, excessive restoration of the affected vertebrae in the operative procedure should be possibly avoided, especially for the existence of

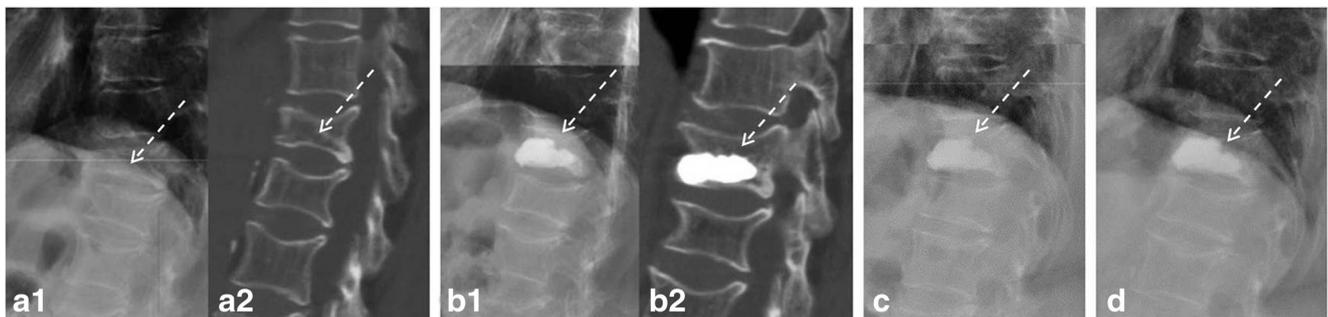


Fig. 4 A 76-year-old female patient with a T12 osteoporosis vertebral compression fracture with risk score of 4. A1–A2 Preoperative sagittal x-ray and CT image demonstrates preoperative IVC (1 point); B1–B2 Immediately postoperative sagittal x-ray and CT image demonstrate solid lump cement distribution pattern (1 point), 31.5% for RR (more than 7%

for RR, 1 point) and 8° (more than 3° for RA, 1 point); C–D a severe recollapse of the augmented vertebrae developed at 1 year (C) and 2 years (D) follow-up period. IVC, intravertebral cleft; RR reduction rate; RA, reduction angle

preoperative IVC. When the patients have a high-risk score of recollapse (more than 2 as a score), careful observation is also necessary to prevent deterioration of their clinical course.

A major limitation to this study was that the number of cases was not large. We used strict criteria for patient selection. We sought to evaluate results associated with the bony condition itself and to minimize extravertebral factors. Our efforts resulted in well-selected but small patient groups. Another limitation was that there was no gold standard to evaluate the recollapse of the augmented vertebrae. Although we employed previous classification of Kim et al. [21], we believe that different classification criteria such as McKiernan's method [34], in which more than 4 mm anterior vertebral height loss was defined as recollapse, might lead to different classification results for some cases. However, we believed that final results would be not significant. Another limitation was the inconsistency of last follow-up period for every subject in our study, widely ranging from 24 to 37 months. Another limitation was that although 1α -hydroxy vitamin D and alendronate were regularly taken for our patients and BMD T-score all showed no significant difference on the day of admission and final follow-up, those patients treated with more effective anti-osteoporotic agents, such as zoledronate, denosumab, or teriparatide, et al., may not respond the same to PVP regardless of the similar BMD. Finally, some other influencing factors were not taken into consideration, such as adjacent cancellous bone edema within the affected vertebrae, et al. Hence, validation of this study might be achieved through repeating this risk-factor analysis with data from other national databases and with newer data to compare the significant risk factors. In addition, well-designed and prospective studies analyzing various recollapse-prophylaxis strategies in patients were thought to be at high risk for recollapse under the condition that the score presented here would be a reasonable next step for further validation.

Conclusion

According to our results, four independent risk factors were significantly associated with recollapse of the augmented vertebrae after PVP, that is, preoperative IVC, solid lump cement distribution pattern, more reduction rate, and larger reduction angle. A risk score for recollapse based on those factors could predict the incidence of recollapse. Additional studies should aim to validate this score and inspect the clinical benefits of recollapse prophylaxis in patients at high risk.

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Compliance with ethical standards

Conflicts of interest None.

Statement of informed consent For this type of study formal consent is not required.

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