Section: Orthopaedics

Original Research Article

SECONDARY VERTEBRAL FRACTURES AFTER PERCUTANEOUS VERTEBROPLASTY: INCIDENCE, PRECIPITATING TRAUMA, AND AN EXPLORATORY ANALYSIS OF CEMENT VOLUME AND LEAKAGE IN A SINGLE-CENTRE PROSPECTIVE STUDY

Vipin Dev M[1], Binu Alex[2], Kuriakose K Karammen[3]

[1]Assistant Professor, Department of Orthopaedics, Palakkad Institute of Medical Sciences, Walayar, Palakkad, Kerala, India.
[2]Senior Consultant & Head, Department of Orthopaedics, Little Flower Hospital & Research Centre, Angamaly, Cochin, Kerala, India.
[3]Consultant, Department of Orthopaedics, Little Flower Hospital & Research Centre, Angamaly, Cochin, Kerala, India.

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Corresponding Author:
Dr. Kuriakose K,
Consultant, Department of Orthopaedics, Little Flower Hospital & Research Centre, Angamaly, Cochin, Kerala, India.
Email: kavinyuvanraja@gmail.com

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ABSTRACT

Background: Secondary (incident) vertebral fractures and cement-related events are key safety concerns following percutaneous vertebroplasty (PVP) for osteoporotic vertebral compression fractures (OVCFs). Prospective, single-centre data that foreground incident fractures, precipitating trauma, and cement parameters (volume, leakage) remain valuable for counselling and quality improvement in routine practice. **Objectives:** To (i) estimate the incidence, timing, and pattern (adjacent/remote) of incident vertebral fractures after PVP; (ii) document precipitating trauma; and (iii) provide an exploratory description of cement volume and leakage in the cohort.

Materials and Methods: Prospective single-centre cohort of 20 consecutive adults with OVCFs who underwent PVP (September 2017–September 2019). Clinical and radiographic assessments were performed immediately post-procedure, at ~6 months, and ~1 year. Safety outcomes included incident vertebral fractures, cement leakage, embolic/infectious events, and kyphotic progression. Cement volume per level was recorded from operative notes. Analyses are descriptive, given the low event counts. The Institutional Ethics Committee approved the protocol, and all participants gave written informed consent.

Results: One patient (5%) developed a symptomatic new fracture at a remote level (L4) about 6 months after PVP following a fall; two patients (10%) had radiographic cement leakage without clinical sequelae; one patient (5%) had increased kyphotic angle at later imaging; no infections or cement embolization were observed. Cement volumes ranged from 2.0 to 3.5 mL (most 2.5 to 3.0 mL). Pain/disability trajectories and adjacent-level height maintenance have been reported in the companion article from this cohort; the present analysis focuses on safety endpoints.

Conclusion: In this prospective cohort, incident symptomatic fracture after PVP was uncommon and occurred in the setting of precipitating trauma. Cement leakage was infrequent and clinically silent. These findings support the provision of explicit counseling on refracture risk and reinforce the importance of fall prevention and osteoporosis management after PVP; larger cohorts with standardized leakage sub-classification are needed.

Keywords: osteoporotic vertebral compression fracture; vertebroplasty; secondary fracture; precipitating trauma; cement leakage; cement volume; prospective cohort.

INTRODUCTION

Osteoporotic vertebral compression fractures (OVCFs) are common fragility injuries that cause pain, deformity, and functional decline in older adults. Percutaneous vertebroplasty (PVP) is widely used for selected, painful OVCFs to stabilize the vertebral body and facilitate early mobilization. While rapid analgesia is typical, safety endpoints—particularly incident vertebral fractures and cement-related sequelae—remain areas of clinical concern. Published reports cite a wide range of new fractures after vertebroplasty (≈8–52%), and observational data have linked intradiscal cement spread and higher injected volumes to an increased risk of refracture, although the findings are heterogeneous.

Despite the expanding literature, there are relatively few prospective, single-centre datasets from Indian practice that focus on the incidence and timing of incident fractures after PVP, while also describing procedure-level parameters (cement volume and leakage) collected uniformly across the cohort. Additionally, leakage morphology is not consistently subclassified in routine clinical archives, limiting inferences about intradiscal extension. Practice-proximal evidence that isolates safety outcomes can support transparent counselling and procedural audit.

Accordingly, this companion paper to our previously published outcomes article reports the incidence, patterns, and precipitating trauma associated with incident vertebral fractures, as well as documents cement volume/leakage from the same prospectively enrolled cohort. The specific objectives were: (i) estimate incidence, timing, and pattern of incident fractures after PVP; (ii) document precipitating trauma; and (iii) explore cement volume and leakage as descriptive correlates.

MATERIALS AND METHODS

Study design and setting: Prospective, single-centre observational cohort at a tertiary academic centre. Consecutive adults with painful osteoporotic OVCFs undergoing PVP were enrolled and followed according to a predefined protocol.

Study period and participants: September 2017–September 2019; N = 20. Inclusion: radiographically confirmed OVCFs selected for PVP per institutional practice. Exclusions: neurological deficit, systemic/spinal infection, pregnancy, and unstable fractures.

Procedure: PVP was performed under fluoroscopic guidance with polymethylmethacrylate (PMMA). Cement volume per level was recorded from operative notes.

Follow-up and outcomes: Assessments were scheduled immediately post-procedure, at ~6 months, and at ~1 year. Primary safety outcome: incident vertebral fracture (adjacent or remote) confirmed clinically and radiographically; precipitating trauma recorded—other endpoints: cement leakage, embolic/infectious complications, and kyphotic progression.

Definitions and analysis: 'Cement leakage' denoted any extravasation seen intraoperatively or on immediate postoperative imaging. Analyses are descriptive (counts, proportions, medians, and ranges) given low event counts.

Ethics approval and consent: The study protocol received approval from the Institutional Ethics Committee of Bharati Vidyapeeth Medical College & Hospital, Pune. All participants provided written informed consent.

RESULTS

Cohort and procedural profile: twenty adults were enrolled (mean age 66.7 ± 10.99 years; 16/20 [80%] women). Index fractures clustered at the thoracolumbar junction—L1 (35%) and T12 (30%). Per-level PMMA volumes ranged 2.0–3.5 mL, most commonly 2.5–3.0 mL.

Table 1 (Baseline characteristics) summarizes demographics and co-morbidities: hypertension (50%), diabetes mellitus (45%), and hyperlipidemia (30%) were most prevalent; 25% each reported smoking and alcohol use—typical of a fragility-fracture profile.

Table 1: Baseline characteristics (n = 20)

Age, years (mean ± SD)	**66.7 ± 10.99**
Sex, n (%)	Female 16 (80); Male 4 (20)
Co-morbidities, n (%)	Hypertension 10 (50); Diabetes 9 (45); Hyperlipidemia 6 (30)
Addictions, n (%)	Smoking 5 (25); Alcohol 5 (25)
Index levels (most common)	L1 7 (35); T12 6 (30)
Follow-up schedule	Immediate post-op, ~6 months, ~1 year

Table 2 (Distribution of index vertebral level) shows thoracolumbar predominance with L1 in 7/20 (35%) and T12 in 6/20 (30%), followed by L3 (3/20, 15%), L2 (2/20, 10%), and single cases at L4 and T11 (each 5%).

Table 2: Distribution of index vertebral level (n = 20)

Level	n (%)
T11	1 (5)
T12	6 (30)
L1	7 (35)
L2	2 (10)
L3	3 (15)
L4	1 (5)

Table 3 (Pain and disability trajectories) demonstrates prompt and sustained clinical improvement. Mean VAS fell from 7.55 pre-op to 4.75 immediately post-op, then to 3.05 at ~6 months and 2.47 at ~1 year; mean RMDQ declined from 16.5 to 15.05, 8.3, and 7.36, respectively. Two individuals showed transient score increases—one aligned with a new remote L4 fracture that occurred after a fall at ~6 months.

Table 3: Pain and disability trajectories

Timepoint	VAS (0–10)	RMDQ (0–24)
Pre-op	7.55	16.50
Post-op	4.75	15.05
6 months	3.05	8.30
1 year	2.47	7.36

Table 4 (Adverse events and sequelae) indicates a low event rate: radiographic cement leakage in 2/20 (10%) without sequelae; one symptomatic incident fracture at a remote level (L4) following a fall (5%); one case with kyphotic-angle progression (5%); and no infections or cement embolization.

Table 4: Adverse events and sequelae

Event	n (%)	Notes
Incident vertebral fracture	1 (5)	Remote L4 ~6 months; fall reported; symptomatic
Cement leakage	2 (10)	Radiographic: no embolic/infectious sequelae
Kyphotic angle increase	1 (5)	Seen on later imaging
Infection	0 (0)	None observed
Cement embolization	0 (0)	None observed

Table 5 (Adjacent vertebral body heights, pre-op vs last follow-up) shows no systematic change in the heights of vertebrae immediately above or below the treated level across the cohort, supporting structural stability at adjacent levels over routine follow-up.

Table 5: Adjacent vertebral body heights: pre-operative vs last follow-up

Level	Upper (pre-op), cm	Upper (last), cm	Lower (pre-op), cm	Lower (last), cm
T11	2.12	2.12	1.94	1.94
T12	2.28	2.28	2.37	2.37
L1	2.35	2.35	2.27	2.27
L2	2.54	2.54	2.70	2.70
L3	2.77	2.77	2.57	2.57
L4	2.80	2.80	2.75	2.75

Figure 1 (VAS trajectory) visualizes the stepwise pain reduction across time points, with the mid-term outlier corresponding to the patient who sustained a remote post-fall L4 fracture.

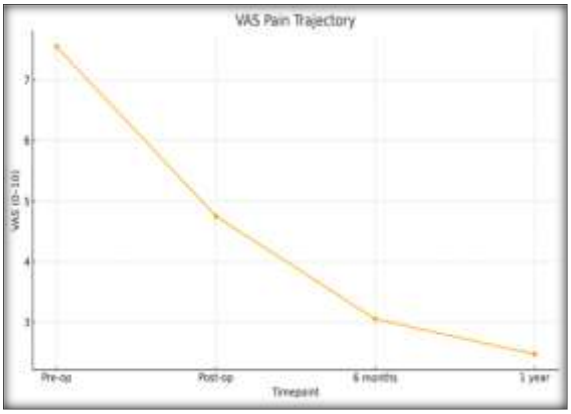

Figure 1: VAS pain trajectory across scheduled follow-up visits (pre-op, post-op, 6 months, 1 year)

Figure 2 (RMDQ trajectory) mirrors the VAS trend, showing functional gains that consolidate by

~6 months and are maintained mainly at ~1 year; the same outlier pattern is noted.

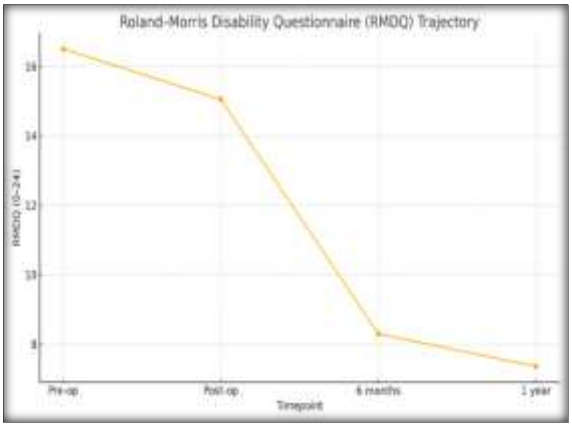

Figure 2: Roland–Morris Disability Questionnaire (RMDQ) trajectory across scheduled follow-up visits

Figure 3 (Index-level distribution) graphically emphasizes thoracolumbar clustering, consistent with the known biomechanical vulnerability around T12–L

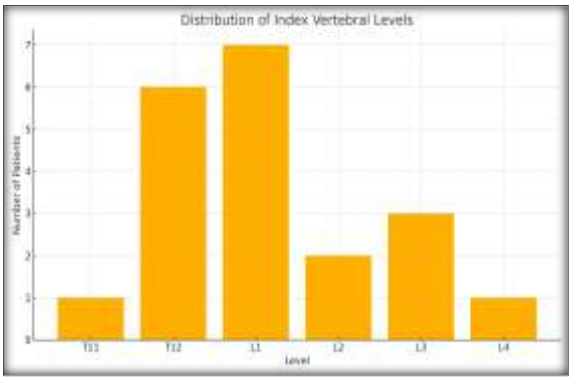

Figure 3: Distribution of index vertebral levels in the cohort

DISCUSSION

In this prospective single-centre cohort of 20 OVCF patients treated with PVP, symptomatic incident fracture occurred in 5% at a remote level after a precipitating fall; radiographic cement leakage occurred in 10% and was clinically silent; one patient showed kyphotic-angle progression; and no embolic or infectious events were observed. Pain (VAS) and disability (RMDQ) improved promptly and were sustained to ~1 year, while adjacent-level vertebral heights remained stable on serial radiographs.

Contemporary guidance and reviews emphasizethe careful selection of augmentation and comprehensive secondary prevention.[1,2,11] Meta-analyses over the last three years report heterogeneous risks of new fractures after augmentation compared with non-operative care, reflecting variations in study design and leakage patterns; pooled estimates range from a higher risk to comparable or lower risk in randomized data.[4,5,6] Patient- and procedure-level correlates of refracture include low bone mineral density and intradiscal cement spread, with single-center series highlighting modifiable technique factors.[3,7] Comparative syntheses suggest that BKP may be more effective in restoring height, while PVP and BKP achieve broadly similar clinical improvements when patients are appropriately selected.[8] Our low incidence of fractures (5%) and its temporal link to a documented fall align with the view that ongoing osteoporosis and falls remain dominant drivers of refracture. In contrast, modest cement volumes and the absence of clinically significant leakage likely contributed to a benign safety profile.

Strengths of our study include a prospective design, uniform single-centre technique, predefined clinical and radiographic follow-up, and systematic recording of cement volume. Limitations are the small sample size, absence of a concurrent control group, and incomplete leakage subclassification (e.g., intradiscal versus epidural). Longitudinal bone health (repeat densitometry) and pharmacotherapy were not tracked, which limited the ability to adjust for osteoporosis severity and fall risk.

Within the constraints of a small, prospective series, incident symptomatic fracture after PVP was uncommon and associated with precipitating trauma; cement leakage was infrequent and clinically silent. These data support counseling focused on falls prevention and osteoporosis management after PVP and motivate larger studies with standardized leakage subclassification and longitudinal bone health assessment to identify modifiable predictors of refracture.

CONCLUSION

In this single-centre prospective cohort, incident symptomatic fracture after PVP occurred in 5% and followed a fall at a remote level; cement leakage (10%) was clinically silent. Pain and disability improvements were sustained, and adjacent-level heights remained stable. Further adequately powered, multicenter studies are needed to clarify modifiable predictors and optimize selection and technique.

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Conflict of interest: None declared.

Data availability: De-identified data are available on reasonable request to the corresponding author.

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