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Modified unilateral extrapedicular vertebroplasty for thoracolumbar osteoporotic vertebral compression fractures in a prospective Phase II study

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Article

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Abstract

Background

A unilateral extrapedicular trajectory may facilitate vertebral-midline access, but its feasibility and approach-specific risks require prospective evaluation. This Phase II study assessed a modified extrapedicular technique for thoracolumbar osteoporotic vertebral compression fractures.

Methods

This prospective, single-center, single-arm study enrolled 20 patients aged over 60 years with acute magnetic-resonance-imaging-confirmed fractures at T10-L3 and a pain score greater than 4 on a 0–10 visual analogue scale. The needle was slid along the superior-lateral pedicle surface to the posterosuperior vertebral body. Outcomes included procedure completion, midline access, cement distribution, operative variables, complications, pain, and disability through 1 month. Analyses were descriptive, with exact 95% confidence intervals for participant-level technical success and serious adverse events.

Results

The cohort included 16 women and 4 men with a mean age of 75.2 years (range 60–96); 22 vertebrae were treated. All patients completed the procedure without conversion (20/20; 100%; exact 95% confidence interval 83.2–100%). Midline access and bilateral cement distribution were achieved in all 22 vertebrae. Mean cement volume was 3.9 ± 0.7 mL and operative time was 23.7 ± 6.5 min per vertebra. Mean visual analogue scale scores decreased from 7.8 ± 1.0 before surgery to 2.1 ± 0.7 on day 1 and 1.9 ± 0.6 at 1 month. Mean Roland-Morris Disability Questionnaire scores decreased from 21.5 ± 2.4 to 10.6 ± 1.5 and 9.8 ± 1.6. Three vertebrae (13.6%) had asymptomatic cement leakage. No serious procedure-related adverse event was observed (0/20; exact 95% confidence interval 0-16.8%).

Conclusions

The modified approach was technically feasible in this small T10-L3 cohort and consistently achieved midline access and bilateral cement distribution. The absence of a comparator, limited sample, and short follow-up preclude conclusions about comparative efficacy or uncommon harms.

Trial registration

Chinese Clinical Trial Registry, ChiCTR2000033687; prospectively registered on 9 June 2020.

Background

Osteoporotic vertebral compression fractures are a frequent cause of acute back pain, impaired mobility, and loss of independence in older adults. Percutaneous vertebroplasty is used in selected patients with

persistent severe pain and imaging-confirmed acute fractures [1–3]. The procedure requires a safe working channel and controlled polymethylmethacrylate delivery within the affected vertebral body.

Bipedicular access permits bilateral cement delivery but requires two punctures. Unilateral access may shorten the procedure and reduce the number of punctures [4, 5]. At the thoracolumbar junction, a unilateral transpedicular trajectory is widely used [6], although pedicle width and orientation can restrict the mediolateral angle and make vertebral-midline access difficult. Extrapedicular routes have been described in the thoracic and lumbar spine [7–10], but the optimal entry corridor remains important because segmental vessels and neural structures lie near the lateral vertebral wall.

Anatomical and computed-tomographic-angiography studies indicate that lumbar arteries usually course along the middle or lower lateral vertebral body and that vascular variation becomes more relevant at L4 and L5 [11–13]. These observations informed a modified superior-lateral pedicle margin trajectory in which the needle remains near the superior edge of the transverse-process root before entering the posterosuperior vertebral body. We conducted this prospective Phase II study to evaluate technical feasibility and short-term safety before comparative assessment. Pain and disability outcomes were exploratory.

Methods

Study design setting and registration

This was a prospective, single-center, single-arm Phase II feasibility study conducted at The First Affiliated Hospital of Tsinghua University, also known as Beijing Huaxin Hospital. The Medical Ethics Committee of Beijing Huaxin Hospital approved the study (approval no. 2020-33-R01), and all participants provided written informed consent before enrollment. The clinical research program was prospectively registered in the Chinese Clinical Trial Registry on 9 June 2020 (ChiCTR2000033687). The registry covers the staged clinical program that later proceeded to randomized comparison; this report contains only the preceding 20-patient Phase II feasibility cohort.

Participants

Patients aged over 60 years were eligible if they had an acute osteoporotic vertebral compression fracture causing severe back pain and limitation of daily activities, a visual analogue scale score greater than 4 on a 0–10 scale, a fracture at T10-L3, and magnetic resonance imaging findings consistent with an acute fracture. The imaging criteria included low signal on T1-weighted imaging and high or isointense signal on T2-weighted imaging, with high signal on fat-suppressed sequences.

Exclusion criteria were secondary vertebral compression caused by tuberculosis, infection, or tumor; severe coagulation disorder; unstable fracture; spinal cord or nerve-root injury; a general medical

condition conferring excessive procedural risk; inability to provide informed consent or cooperate with the procedure; and vertebral-body compression greater than 75%.

Procedure

Patients were positioned prone with soft padding beneath the chest and pelvis so that the abdomen remained free. The planned lateral distance from the posterior midline to the skin entry point was measured on preoperative axial magnetic resonance imaging (Fig. 1). Under C-arm fluoroscopy, the needle was advanced to the superior edge of the transverse-process root. It was then kept in contact with bone and slid approximately 1–2 cm along the superior-lateral pedicle surface until it reached the posterosuperior corner of the vertebral body. This maneuver was termed the slide technique (Fig. 2).

Anteroposterior and lateral fluoroscopic views were used to confirm the trajectory (Fig. 3). The needle was advanced until its tip reached approximately the anterior three-quarters of the vertebral body on the lateral view and the vertebral midline, defined by the spinous process, on the anteroposterior view. Approximately 3–5 mL of polymethylmethacrylate cement was injected under intermittent fluoroscopy while cement spread and leakage were monitored [16]. A representative procedure is shown in Fig. 4.

Outcomes and follow up

An observer independent of the operating team prospectively recorded patient characteristics, planned lateral skin-entry distance, operative time per treated vertebra, cement volume, completion of the assigned procedure, needle-tip access to the vertebral midline, bilateral cement distribution, and procedure-related complications. Technical success at the participant level was defined as completion of the planned unilateral extrapedicular procedure without conversion to another access route. Vertebral-level feasibility outcomes were midline access and bilateral cement distribution on anteroposterior imaging.

Back-pain intensity was assessed with a 0–10 visual analogue scale, in which 0 represented no pain and 10 the worst imaginable pain [14]. Disability was assessed with the 24-item Roland-Morris Disability Questionnaire [15]. Scores were recorded before surgery, on postoperative day 1, and at the final scheduled study visit at 1 month. All participants underwent radiography on postoperative day 1. Computed tomography was obtained in a nonprespecified subset to illustrate the puncture trajectory; it was not used as a uniform outcome assessment.

Safety outcomes included cement leakage, symptomatic cement embolism, hematoma, spinal cord or nerve-root injury, infection, and other serious procedure-related adverse events through the 1-month visit.

Sample size

A minimum of 20 participants was planned for this preliminary Phase II cohort. The study was intended to establish procedural feasibility and identify major short-term safety signals before comparative evaluation. It was not designed or powered for confirmatory testing of clinical efficacy.

Statistical analysis

Analyses were performed using SPSS version 23.0 (IBM Corp., Armonk, NY, USA). Categorical data are presented as counts and percentages. Continuous data are presented as means and standard deviations, with ranges where available. Exact two-sided 95% confidence intervals for participant-level technical success and serious procedure-related adverse events were calculated with the Clopper-Pearson method. Patient-reported outcomes were summarized descriptively across the three time points because the study was not powered for efficacy. Participant-level outcomes and vertebral-level technical outcomes are identified separately. No adjustment for clustering was applied to vertebral-level descriptive summaries.

Use of generative artificial intelligence

OpenAI ChatGPT was used after completion of the study analysis for English-language editing, formatting, and internal-consistency checking. It was not used to generate, analyze, or interpret study data. The authors reviewed and verified all AI-assisted text and take responsibility for the final manuscript.

Results

Participant and procedural findings

Twenty patients were enrolled, including 16 women and 4 men. Mean age was 75.2 years (range 60–96). Eighteen patients underwent single-level treatment and two underwent two-level treatment, for a total of 22 treated vertebrae. All 20 patients completed the assigned procedure without conversion (100%; exact 95% confidence interval 83.2–100%). Participant and procedural findings are summarized in Table 1.

Table 1
Participant and procedural findings

Variable	Denominator	Value
Participants	Patients	20
Age	Patients	75.2 years (range 60–96)
Women	Patients	16/20 (80.0%)
Men	Patients	4/20 (20.0%)
Single-level treatment	Patients	18/20 (90.0%)
Two-level treatment	Patients	2/20 (10.0%)
Treated vertebrae	Vertebrae	22
Planned lateral skin-entry distance	Vertebrae	5.2 cm (range 4.0–6.0)
Cement volume	Vertebrae	3.9 ± 0.7 mL
Operative time	Vertebrae	23.7 ± 6.5 min
Midline access	Vertebrae	22/22 (100%)
Bilateral cement distribution	Vertebrae	22/22 (100%)
Cement leakage	Vertebrae	3/22 (13.6%)
Serious procedure-related adverse events	Patients	0/20 (0%)

Values are n/N (%) or mean ± standard deviation unless otherwise stated.

Feasibility and technical outcomes

The needle tip reached the vertebral midline in 21 treated vertebrae and slightly crossed the midline in one; therefore, all 22 vertebrae met the midline-access criterion. Cement was distributed bilaterally in all 22 vertebrae. The mean planned lateral skin-entry distance was 5.2 cm (range 4.0–6.0). Mean cement volume was 3.9 ± 0.7 mL per vertebra, and mean operative time was 23.7 ± 6.5 min per vertebra.

Pain and disability outcomes

Mean pain and disability scores were lower after surgery at both reported assessments (Table 2). The mean visual analogue scale score decreased by 5.7 points from baseline to postoperative day 1 and by 5.9 points from baseline to 1 month. The corresponding mean Roland-Morris Disability Questionnaire reductions were 10.9 and 11.7 points. These single-arm changes are exploratory and cannot distinguish the effect of the access route from the effects of vertebroplasty, concurrent care, or recovery over time.

Table 2
Pain and disability outcomes through one month

Outcome	Preoperative	Postoperative day 1	One month
Visual analogue scale	7.8 ± 1.0	2.1 ± 0.7	1.9 ± 0.6
Roland-Morris Disability Questionnaire	21.5 ± 2.4	10.6 ± 1.5	9.8 ± 1.6

Values are mean ± standard deviation. Visual analogue scale range 0–10; Roland-Morris Disability Questionnaire range 0–24. Outcomes were summarized descriptively.

Safety findings

Three of 22 treated vertebrae (13.6%) had a small, asymptomatic cement leak: two extended into the superior intervertebral disc and one was anterior to the vertebral body. No symptomatic cement embolism, hematoma, spinal cord injury, nerve-root injury, infection, or other serious procedure-related adverse event was observed (0/20 participants; exact 95% confidence interval 0-16.8%).

Discussion

Principal findings

This prospective Phase II cohort showed that the modified unilateral extrapedicular procedure could be completed in all 20 selected patients. The needle reached or crossed the vertebral midline and cement was distributed bilaterally in every treated vertebra. Three small, asymptomatic cement leaks occurred, and no serious procedure-related adverse event was observed through 1 month. Pain and disability scores improved after surgery, but the single-arm design does not establish that these changes were caused by the modified access route.

Interpretation and relation to previous evidence

The transpedicular route constrains needle angulation within the pedicle. By contrast, the slide technique uses the superior edge of the transverse-process root and the superior-lateral pedicle surface as a bony guide before the needle enters the posterosuperior vertebral body. Once the posterior wall is reached, a larger mediolateral angle can be used without deliberately crossing the medial pedicle cortex. This geometric feature offers a plausible explanation for the consistent midline access observed in this cohort and is concordant with previous extrapedicular reports [8–10, 22–24].

Bilateral or more uniform cement distribution has been associated with greater mechanical balance in biomechanical and finite-element studies [17–21]. The present study confirms only that bilateral distribution was technically achievable with this trajectory. It does not show that the distribution pattern improves pain, vertebral height, subsequent-fracture risk, or long-term function. The study also did not record fluoroscopic exposure count or radiation dose. Any claim that this approach reduces radiation exposure would therefore require direct measurement and a concurrent comparator.

Safety considerations

Vascular safety is central to any extrapedicular approach. Lumbar arteries commonly cross the middle or lower portion of the lateral vertebral body, and intersegmental branches are more frequent at L4 and L5 [11–13]. Segmental-artery injury and retroperitoneal hematoma have been reported after extrapedicular vertebroplasty [25]. The present technique therefore keeps the needle close to the superior pedicle-transverse-process junction and was evaluated only at T10-L3. The results should not be extrapolated to L4 or L5. If an extrapedicular route is considered at lower lumbar levels or in altered anatomy, preoperative vascular imaging or a transpedicular route should be considered.

Study limitations

This study has several limitations. The cohort was small, came from one center, and had no control group or randomization. The exact confidence interval around the absence of serious adverse events remains wide, so uncommon complications cannot be excluded. Follow-up was limited to 1 month, precluding assessment of adjacent fractures, delayed cement-related events, or durability of symptom improvement. Pain and disability outcomes were descriptive and susceptible to regression to the mean, placebo effects, concurrent treatment, and natural recovery. Postoperative computed tomography was not obtained systematically. Fluoroscopic exposure and radiation dose were not recorded. Finally, the findings apply to selected T10-L3 fractures with no more than 75% vertebral-body compression and should not be generalized to severe collapse, lower lumbar levels, kyphoplasty, or patients with unstable fractures or neurologic injury.

Conclusions

Modified unilateral extrapedicular vertebroplasty using the superior-lateral pedicle margin slide technique was technically feasible in this 20-patient Phase II cohort and consistently achieved vertebral-midline access and bilateral cement distribution at T10-L3. No serious procedure-related adverse event was observed during 1 month of follow-up, but the sample was too small to exclude uncommon harm. Comparative efficacy, radiation exposure, and longer-term safety require evaluation in a controlled study.

Abbreviations

CI
confidence interval
CT
computed tomography
MRI
magnetic resonance imaging
OVCF
osteoporotic vertebral compression fracture
PMMA

polymethylmethacrylate
PVP
percutaneous vertebroplasty
RDQ
Roland-Morris Disability Questionnaire
VAS
visual analogue scale.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. The Medical Ethics Committee of Beijing Huaxin Hospital approved the study (approval no. 2020-33-R01; approval date: November 2020. All participants provided written informed consent before enrollment.

Consent for publication

Written informed consent for publication of the anonymized clinical and imaging material was obtained from the participants whose images are presented.

Competing interests

The authors declare that they have no competing interests.

Authors' information

Not applicable.

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Author Contribution

JX and YLiu contributed equally to the study and manuscript. JX, BW, and DEP contributed to study conception, design, supervision, and interpretation. JX, YLiu, JG, ZW, YN, NL, YanL, and YY contributed to participant recruitment, clinical procedures, data collection, or data interpretation. JX, YLiu, and DEP drafted or substantively revised the manuscript. All authors read and approved the final manuscript.

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Data Availability

The deidentified data generated and analyzed during the current study are available from the corresponding authors on reasonable request, subject to institutional approval and participant-privacy requirements.

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Figures

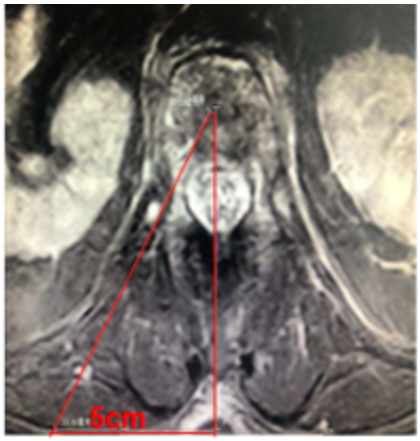


Figure 1

Preoperative planning of the lateral skin entry distance. The planned distance from the posterior midline to the skin entry point was measured on axial magnetic resonance imaging; the example shows a 5-cm distance.

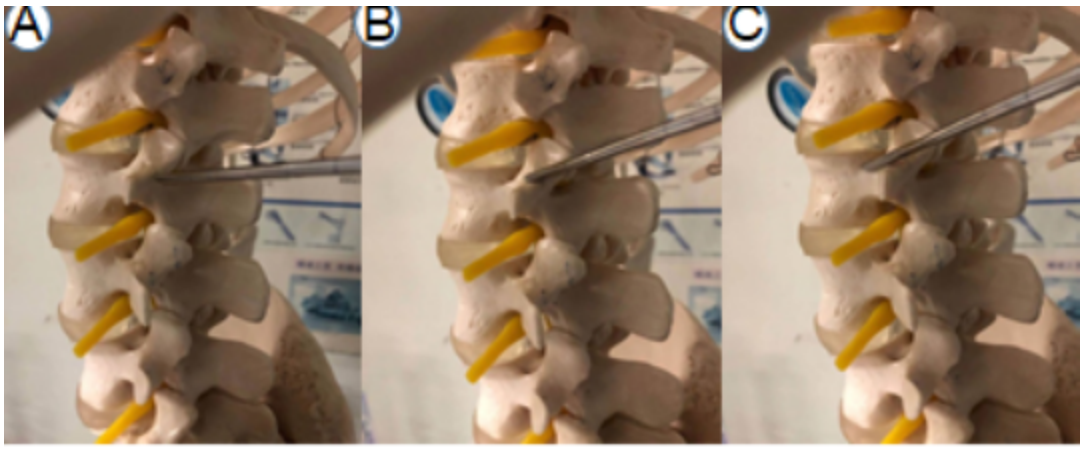


Figure 2

Steps of the superior lateral pedicle margin slide technique. (A) The needle reaches the superior edge of the transverse-process root. (B) The needle slides along the superior-lateral pedicle surface. (C) The needle reaches the posterosuperior corner of the vertebral body.

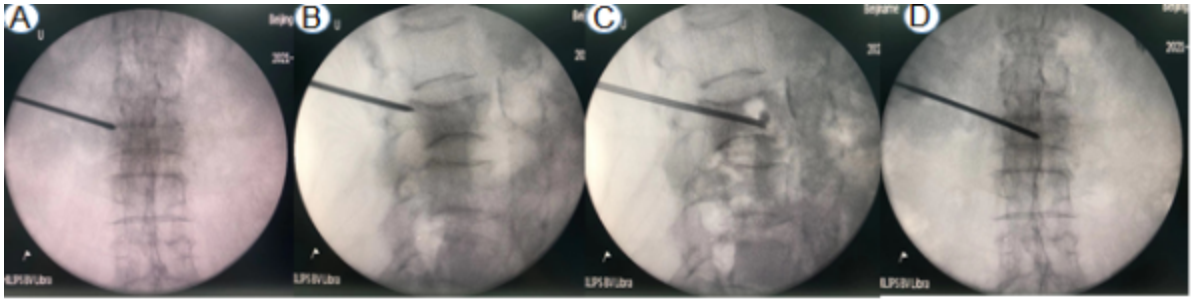


Figure 3

Fluoroscopic needle progression during the modified extrapedicular approach. (A-B) When the needle tip is at approximately the 11-o'clock position relative to the pedicle on the anteroposterior view, it has reached the posterosuperior vertebral-body corner on the lateral view. (C-D) At the final position, the tip reaches the vertebral midline on the anteroposterior view and approximately the anterior three-quarters of the vertebral body on the lateral view.

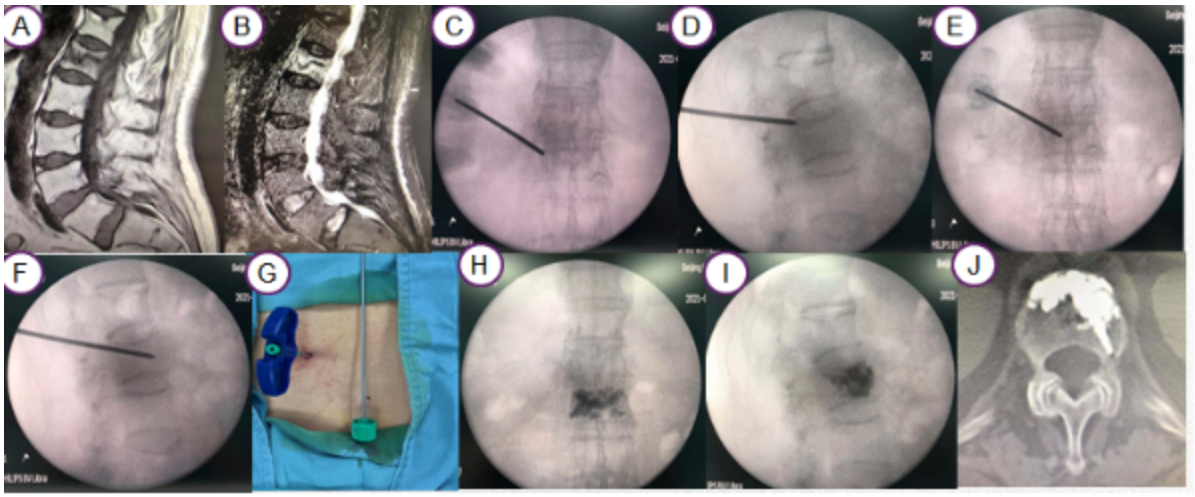


Figure 4

Representative modified unilateral extrapedicular vertebroplasty case. (A-B) Preoperative magnetic resonance imaging demonstrates an acute L1 fracture. (C-D) Initial fluoroscopic needle position at the lateral pedicle margin and posterior vertebral body. (E-F) Final needle position at the vertebral midline and anterior vertebral body. (G) Intraoperative setup. (H-I) Postoperative anteroposterior and lateral radiographs show bilateral cement distribution. (J) Postoperative computed tomography confirms the extrapedicular trajectory and bilateral cement distribution.