

Comparison between unilateral and bilateral percutaneous kyphoplasty in the treatment of osteoporotic vertebral compression fracture: A meta-analysis and systematic review

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Abstract. The present study collected retrospective research data and compared the safety and efficacy of unilateral and bilateral percutaneous puncture kyphoplasty for the treatment of vertebral fractures caused by osteoporosis, to guide the selection of clinical surgical methods. In the present meta-analysis, PubMed, Embase and the Cochrane Library were searched from the establishment of the databases to March 2023. Studies that reported differences in the efficacy and safety between the unilateral and bilateral approaches in the treatment of osteoporotic vertebral compression fractures were included in the analysis. Duplicate published studies, unpublished studies, studies with incomplete data, animal experiments, literature reviews and systematic studies were excluded from the analysis. All data were processed using STATA 15.1 statistical software. The pooled results demonstrated that there were no significant differences between the unilateral and bilateral approaches in the visual analog scores, Oswestry disability index, height restoration rate or incidence of cement leakage. However, the post-kyphotic angle of the unilateral approach was significantly lower than that of the bilateral approach (standardized mean difference, -0.41; 95%

confidence interval, -0.68 to -0.14; $P=0.003$). Furthermore, the pooled results demonstrated that the unilateral approach required less operative time and a lower volume of injected cement, which is safer for elderly patients who are more likely to have underlying diseases.

Introduction

Elderly and postmenopausal middle-aged women are prone to osteoporosis, with a large amount of bone loss occurring due to a decline in body function and bone microenvironment changes (1). One of the hallmarks of the disease is a loss of bone strength, which can lead to fractures (2). Osteoporotic vertebral compression fractures (OVCFs) are the most serious result of osteoporosis (3,4). While most OVCFs are benign, some can lead to serious morbidity and socioeconomic costs, as well as a reduced quality of life and productivity in the growing elderly population (5). Conservative management (the patient should rest in bed and apply appropriate medication to relieve pain; after the fracture has healed initially, the patient should wear a brace and start to get out of bed) and vertebral cemented augmentation (a technique for strengthening a diseased vertebra by injecting bone cement into it) are the two most common treatments for OVCF. In vertebral cement augmentation, there are two mainstream minimally invasive surgical procedures: Percutaneous vertebroplasty (PVP) (after the puncture, bone cement was injected directly into the diseased vertebra) and percutaneous kyphoplasty (PKP) (after the puncture was completed, the bone cement was injected by balloon dilation) (6,7). Following technological improvements and developments, PKP has been recommended as an advanced method for treating OVCF (7). It has been demonstrated that PKP has a potential advantage over PVP in restoring compressed vertebral and spinal deformities without increasing the cement leakage rate and fracture risk of adjacent segments (8). PKP involves two different surgical approaches with either a unilateral or bilateral puncture. Certain studies suggest that bilateral puncture PKP can make the sides of the diseased vertebra symmetrical

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Abbreviations: SMD, standardized mean difference; CI, confidence interval; KPA, kyphotic angle; VAS, visual analogue score; ODI, Oswestry disability index; OVCFs, osteoporotic vertebral compression fractures; PVP, percutaneous vertebroplasty; PKP, percutaneous kyphoplasty; RCT, randomized controlled trial

Key words: percutaneous kyphoplasty, unilateral approach, bilateral approach, osteoporotic vertebral compression fracture, meta-analysis, systematic review

and evenly distribute the bone cement in the compressed vertebral body by avoiding unevenly applied force, thus it is more effective for the recovery of the compressed vertebral body (9,10). However, Steinmann *et al* (11) reported no significant differences in the vertebral strength, stiffness or height recovery between patients treated with unilateral or bilateral PKP. The present study collected a large amount of retrospective research data and evaluated the safety and efficacy of the two types of PKP for the treatment of vertebral fractures caused by osteoporosis to guide the selection of clinical surgical methods.

Materials and methods

Literature inclusion and exclusion criteria. The literature inclusion criteria were as follows: i) Study object: Patients with OVCFs; ii) intervention measures: Unilateral approach; iii) control: Bilateral approach; iv) outcome indicators: Operative time, cement injection, visual analog score (VAS), Oswestry disability index (ODI), post-kypnotic angle (KPA), height restoration rate and incidence of cement leakage; and v) study design: Randomized controlled trials (RCTs) or non-RCTs. Only studies published in English were included in the analysis. The exclusion criteria were duplicate published studies, incomplete studies, studies with incomplete or unavailable data, animal testing, reviews and systematic reviews.

Search strategy. In the present meta-analysis, PubMed (<https://pubmed.ncbi.nlm.nih.gov/>), Embase (<https://www.embase.com/>) and the Cochrane Library (<http://www.cochranelibrary.com>) were searched from the establishment of the databases to March 2023. In addition, additional records were identified through other sources (Reference lists of relevant studies). The search terms used were as follows: [osteoporotic vertebral compression fracture (Title/Abstract)] and [percutaneous kyphoplasty (Title/Abstract)].

Literature screening and data extraction. The literature searches, data screening and data extraction were conducted by two researchers. Any questions or disputes were addressed after consultation with a third party. The extracted study contents included the author, publication year, country, study design, sample size, sex, age, post-KPA status, mean follow-up duration and outcome indicators.

Literature quality assessment. The quality of the studies was independently assessed by two researchers (QZ and ZZ). The Cochrane Collaboration's Risk of Bias Tool was used to assess literature quality for RCTs (12), whereas the Newcastle-Ottawa Scale (NOS) was used to evaluate cohort studies (13). Disagreements were addressed through consultation or deliberation by a third party (GL). The meta-analysis was performed according to the reported and relevant items in the meta-analysis checklist (the PRISMA checklist), which are preferred for systematic evaluations (14).

Data synthesis and statistical analysis. All data were processed with the statistical analysis software, STATA 15.1 (StataCorp LP) (15). Standardized mean difference (SMD) with 95% confidence interval (CI) were used to analyze continuous variables and odds ratio (OR) with 95% CI was used to analyze categorical

Table I. Baseline characteristics and quality assessment of the included studies.

First author, year	Country	Study design	Sample size, n		Sex, no. of male/female	Age, years [median (range) or mean \pm standard deviation]		Post-KPA ($^{\circ}$)		Mean follow-up, months			NOS score	(Refs.)
			U	B	U	U	B	U	B	U	B			
Chung <i>et al</i> , 2008	South Korea	RCT	24	28	2/22	1/27	66.8 (57-80)	68.9 (57-83)	17.6 (13-25)	18.5 (12-27)	17.8	16.6	-	(16)
Chen <i>et al</i> , 2010	China	RCT	33	25	-	-	67.7 \pm 7.1	68.5 \pm 7.3	-	-	-	-	-	(17)
Chen <i>et al</i> , 2011	China	RCT	24	25	4/20	4/21	70.4 (52-91)	72.4 (54-87)	24.3 \pm 13.7	27.3 \pm 12.1	31.8	35.2	-	(18)
Wang <i>et al</i> , 2012	China	Cohort	31	31	13/18	17/14	68.3 (59-78)	69.2 (62-79)	-	-	16.7	15.9	7	(19)
Rebollo <i>et al</i> , 2013	USA	RCT	23	21	4/19	2/19	78.7 \pm 7.8	79.3 \pm 6.5	26.5 \pm 10.3	24.0 \pm 9.9	12	12	-	(20)
Yan <i>et al</i> , 2014	China	RCT	158	151	46/112	43/108	71.9 \pm 4.2	71.1 \pm 3.7	18.83 \pm 8.22	17.98 \pm 7.18	12	12	-	(21)
Zhang <i>et al</i> , 2022	China	Cohort	29	38	10/19	12/26	73.6 \pm 5.7	74.1 \pm 4.9	-	-	17.1	-	8	(22)
Zhu <i>et al</i> , 2022	China	Cohort	34	42	5/29	8/34	70.1 \pm 6.8	71.4 \pm 8.7	-	-	16.6	-	8	(23)

RCT, randomized controlled trial; NOS, Newcastle-Ottawa scale; U, unilateral; B, bilateral; KPA, kypnotic angle.

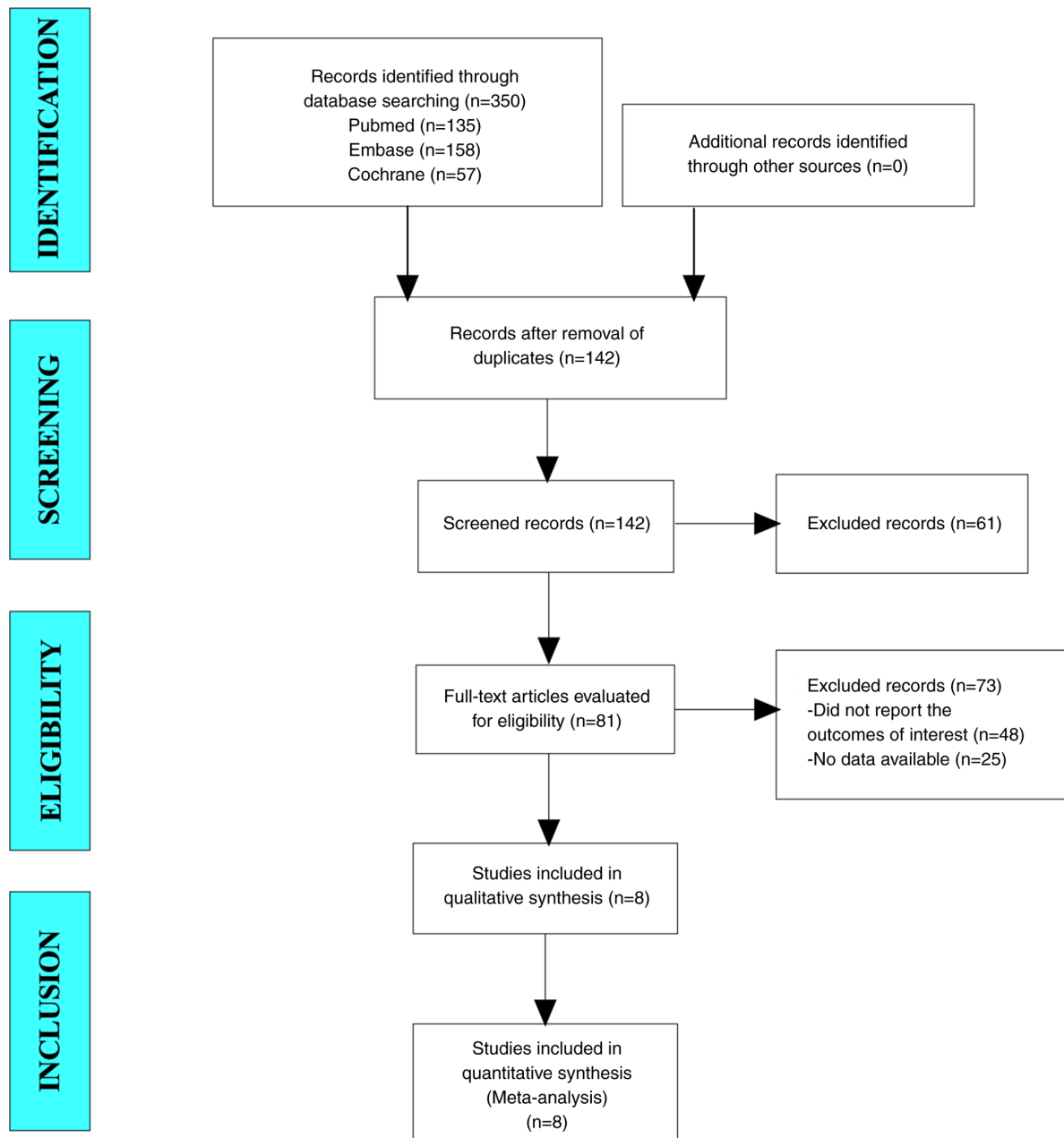


Figure 1. Flow diagram for the selection of studies.

variables. A heterogeneity result of $P > 0.1$ and $I^2 < 50\%$ indicated that all studies were homogeneous. $P < 0.1$ and $I^2 > 50\%$ indicated that the studies differed and a difference sensitivity analysis (conducted by excluding each trial individually and then performing a combined analysis of the remaining trials) was performed to identify the sources of the difference. Subsequently, a random-effects model was applied or a descriptive analysis was conducted instead of a pooled analysis. Funnel plots and Egger's test were used to investigate publication bias. $P < 0.05$ was considered to indicate a statistically significant difference.

Results

Literature search results. A total of 350 articles were collected for the present study. After excluding duplicate studies, 142 articles remained. From this pool, 81 articles were

identified following eligibility screening of titles and abstracts. After reading the full text, 48 studies that didn't report the outcomes of interest and 23 studies with no data available were excluded. Finally, eight studies were included in the present meta-analysis (Fig. 1).

Baseline characteristics and quality assessment of the included studies. A total of eight studies (five RCTs and three cohort studies) were included in the present meta-analysis (16-23). The patient sample size ranged from 44 to 309, with a total of 717 patients, including 356 in the unilateral group and 361 in the bilateral group. A single study included patients from the USA and all other studies included patients from Asia. The age range of patients was 52-91 years, all of whom were aged. The NOS scores (used for quality assessment) of the three cohort studies were all > 7 and met the quality requirements (Table I).

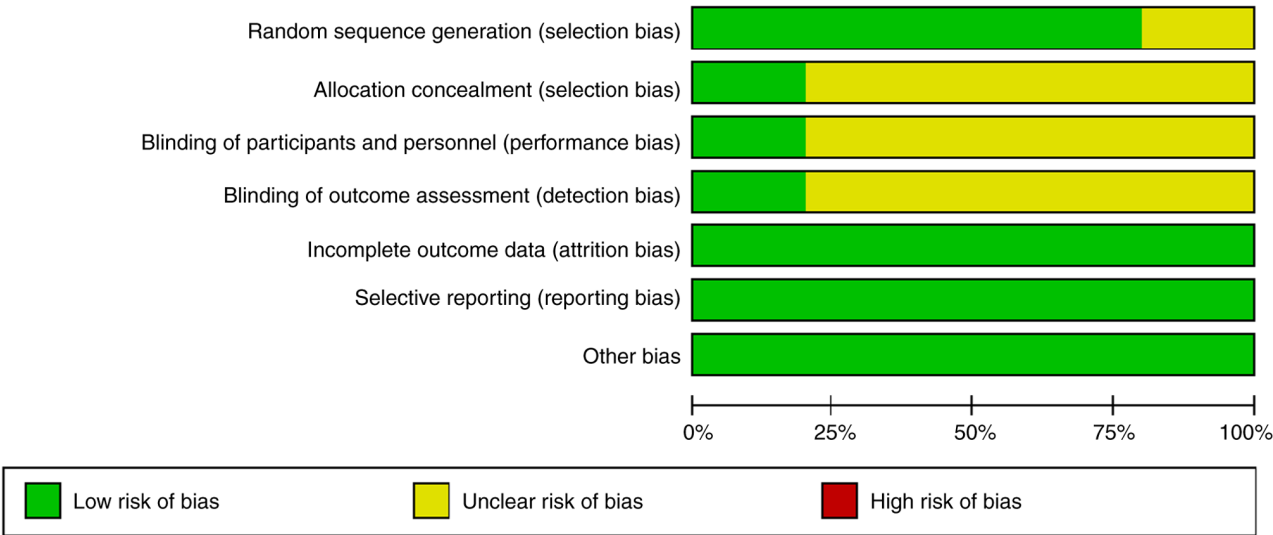


Figure 2. Risk of bias graph for the randomized controlled trials.

The quality assessment results of the five RCTs are shown in Figs. 2 and 3. The results indicated that four studies included in the present review utilized random sequences for patient group allocation and only one conducted double-blinding (Figs. 2 and 3).

Analysis of the operative time. A total of six studies compared the operative time in the unilateral and bilateral surgical approaches. Owing to significant heterogeneity ($I^2=80.8\%$; $P<0.001$; Fig. S1), sensitivity analyses were performed, and it was found that the study by Yan *et al* (21) had a significant impact on the results (Fig. S2). After excluding this article, a noTable reduction in heterogeneity was found ($I^2=54.4\%$; $P=0.067$; Fig. 4) and the effect sizes were pooled using a random-effects model. The pooled results demonstrated that the operative time of the unilateral approach was significantly reduced compared with the bilateral approach (SMD=-1.48; 95% CI, -1.87 to -1.09; $P<0.001$; Fig. 4).

Analysis of cement injection volume. A total of five studies compared the cement injection volume in the unilateral and bilateral surgical approaches. Owing to significant heterogeneity ($I^2=96.6\%$; $P<0.001$; Fig. S3), sensitivity analyses were performed, and it was found that the study by Yan *et al* (21) and Zhang *et al* (22) had significant impact on the results. After excluding the two studies, a noTable reduction in heterogeneity was found ($I^2=85.5\%$; $P=0.001$; Fig. 5) and the effect sizes were pooled using a random-effects model. The pooled results demonstrated that the cement injection volume of the unilateral approach was significantly reduced compared with the bilateral approach (SMD=-1.51; 95% CI, -2.40 to -0.61; $P=0.001$; Fig. 5).

Analysis of the VAS. A total of five studies compared the VAS (a scale used to evaluate pain) in the unilateral and bilateral surgical approaches. A meta-analysis of the results of these studies was conducted using a random-effects model. The pooled results demonstrated that there was no

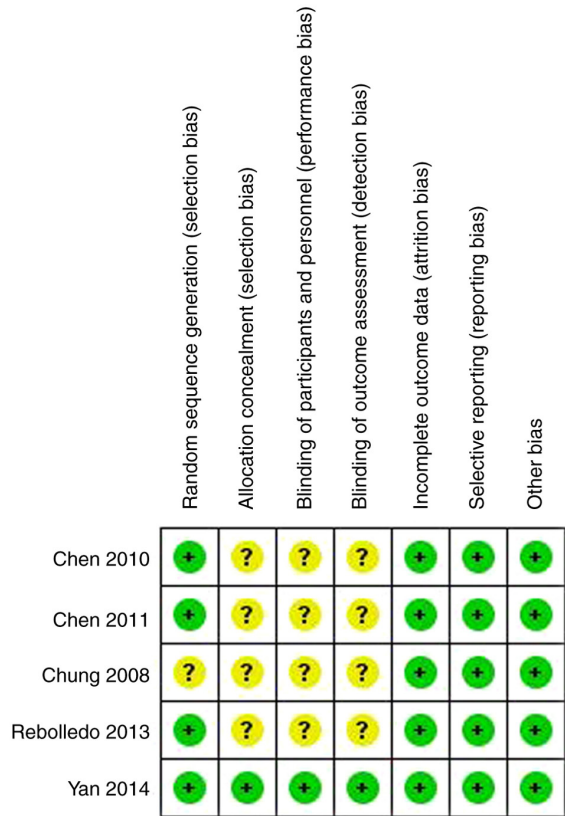


Figure 3. Risk of bias summary for the randomized controlled trials.

significant difference in the VAS between the unilateral and bilateral surgical approaches (SMD=-0.08; 95% CI, -0.25-0.09; $P=0.362$; Fig. 6).

Analysis of the ODI. A total of two studies compared the ODI (one of the principal condition-specific outcome measures used in the management of spinal disorders) in the unilateral and bilateral surgical approaches. A meta-analysis of the results of these studies was conducted using a random-effects

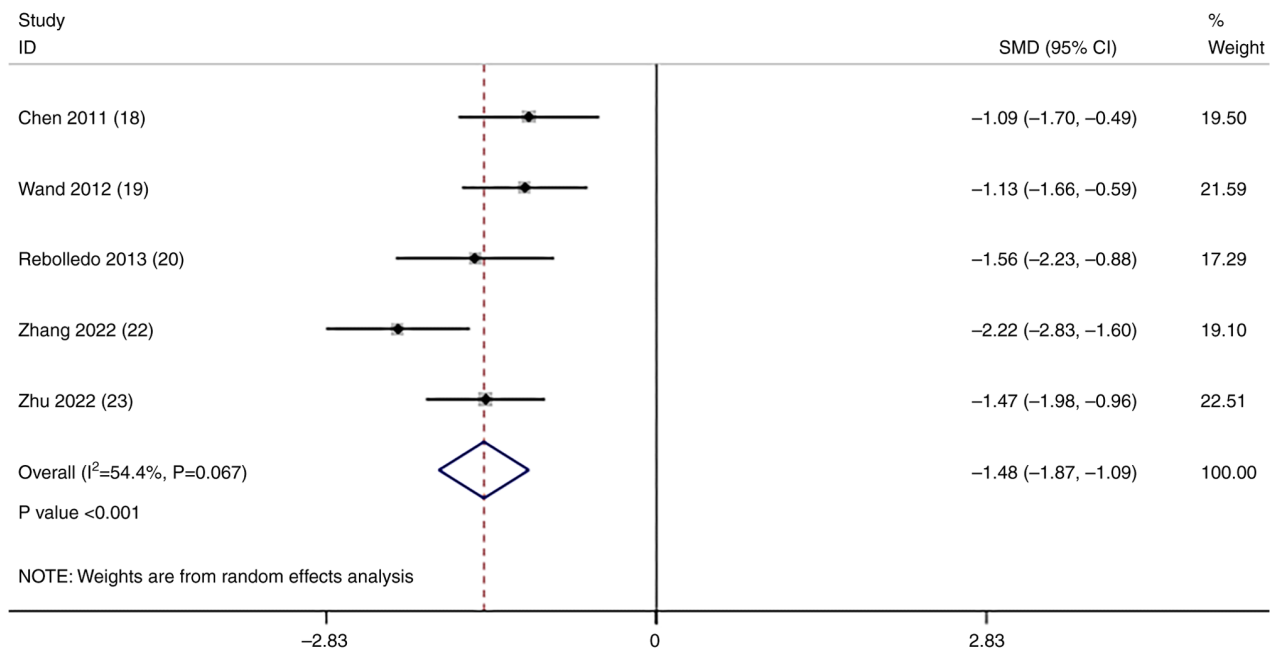


Figure 4. Comparison of the differences in the operative times between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval.

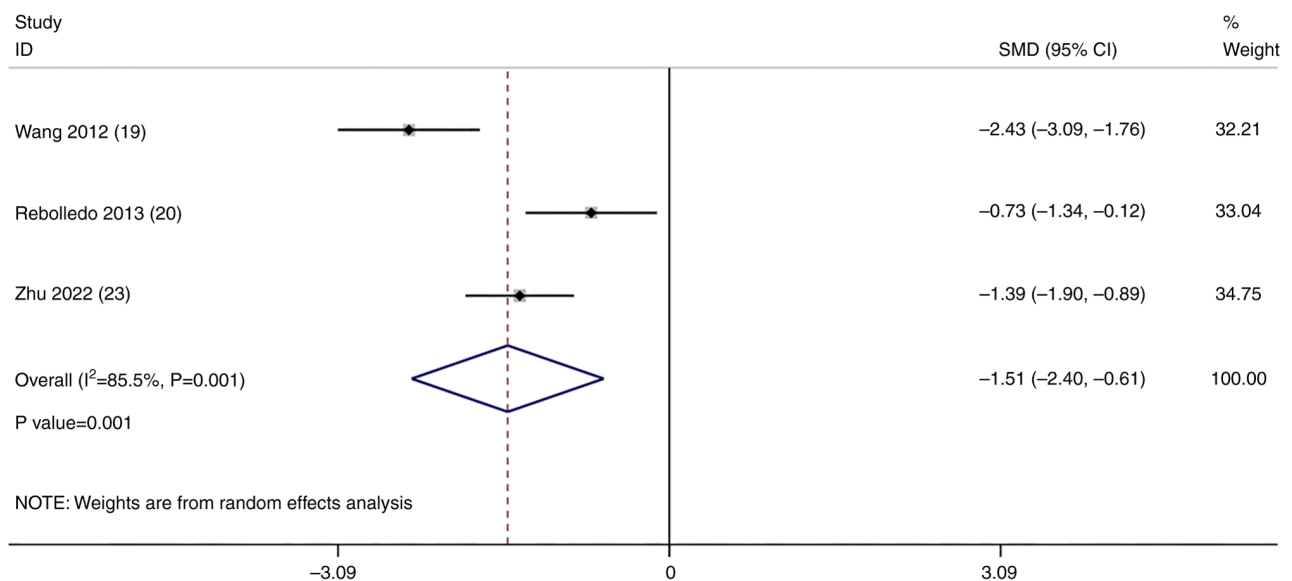


Figure 5. Comparison of the differences in the cement injection volumes between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval.

model. The pooled results demonstrated no significant difference in the ODI between the unilateral and bilateral surgical approaches (SMD=-0.05; 95% CI, -0.41-0.31; $P=0.769$; Fig. 7).

Analysis of the post-KPA. A total of three studies compared the post-KPA in the unilateral and bilateral surgical approaches. A meta-analysis of the results of these studies was conducted using a random-effects model. The pooled results demonstrated that the post-KPA of the unilateral approach was significantly lower than that of the bilateral approach (SMD=-0.41; 95% CI, -0.68 to -0.14; $P=0.003$; Fig. 8).

Analysis of the height restoration rate. A total of five studies compared the height restoration rate in the unilateral and bilateral surgical approaches. A meta-analysis of the results of these studies was conducted using a random-effects model. The pooled results demonstrated that there was no significant difference in the height restoration rate between the unilateral and bilateral surgical approaches (SMD=-0.60; 95% CI, -1.51-0.30; $P=0.193$; Fig. 9).

Analysis of cement leakage incidence. A total of six studies compared the incidence of cement leakage in the unilateral and bilateral surgical approaches. A meta-analysis of the

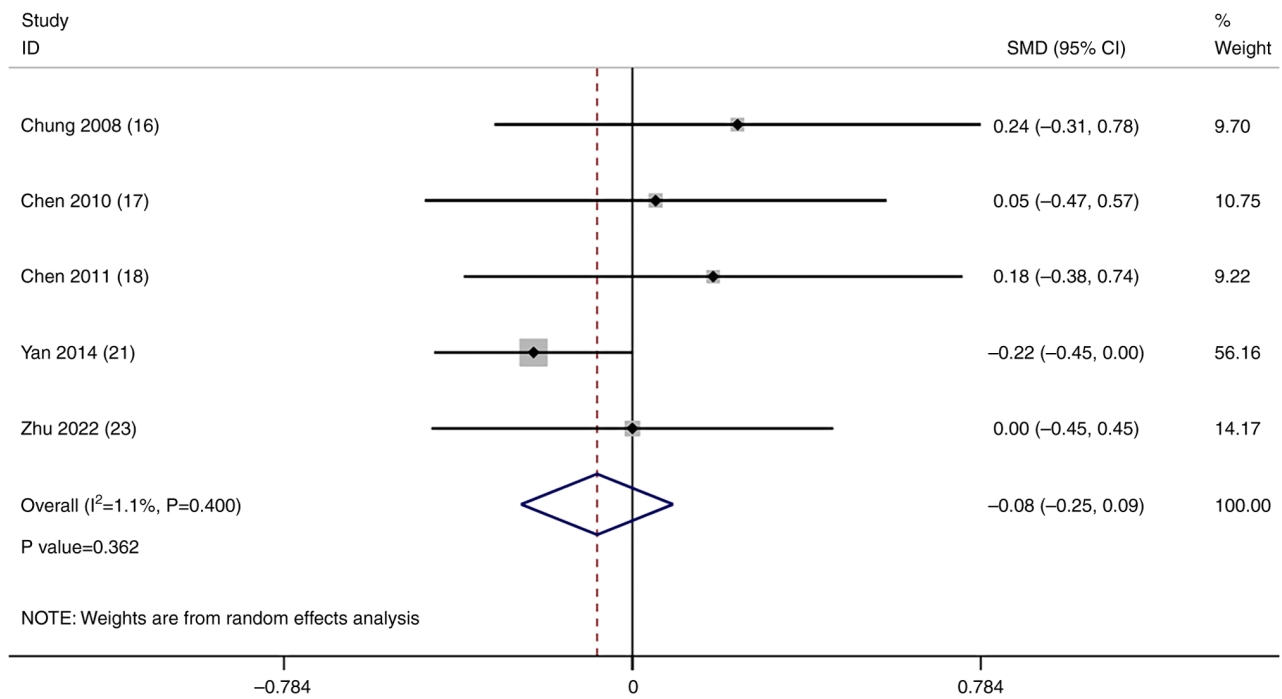


Figure 6. Comparison of the differences in the VASs between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval; VAS, visual analogue score.

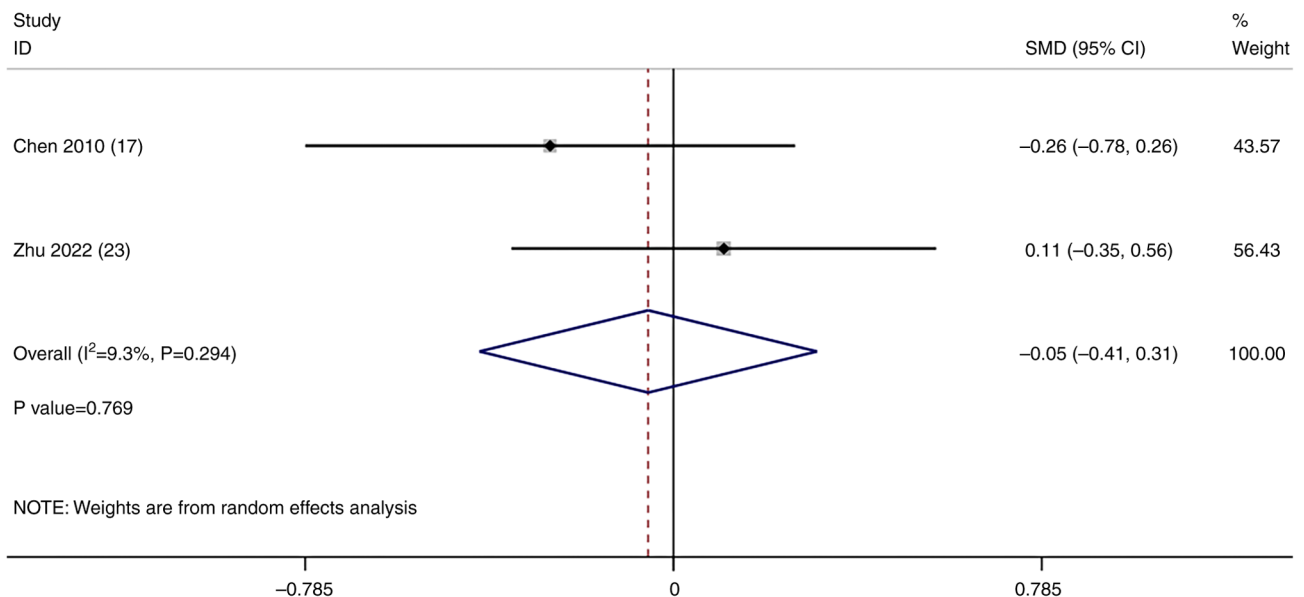


Figure 7. Comparison of the differences in the ODIs between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval; ODI, Oswestry disability index.

results of these studies was conducted using a random-effects model. The pooled results demonstrated that there was no significant difference in the incidence of cement leakage between the unilateral and bilateral surgical approaches [odds ratio (OR)=0.60; 95% CI, 0.29-1.24; $P=0.166$; Fig. 10].

Sensitivity analysis. A sensitivity analysis was performed to exclude each trial individually and then a combined analysis of the remaining trials was performed. Following the subsequent meta-analyses, it was found that the study by Yan *et al* (21) had

a large impact on the results of the surgery time; Yan *et al* (21) and Zhang *et al* (22) had a large impact on the results of the cement injection volume analyses; no other articles significantly impacted the results of the other outcomes (Figs. S3-S8).

Publication bias. Fig. 11 presents the publication bias funnel plot. The funnel plot was symmetrical and the result of the Egger's tests was $P=0.205$, which indicated that there was no significant publication bias in the studies analyzed in the present study.

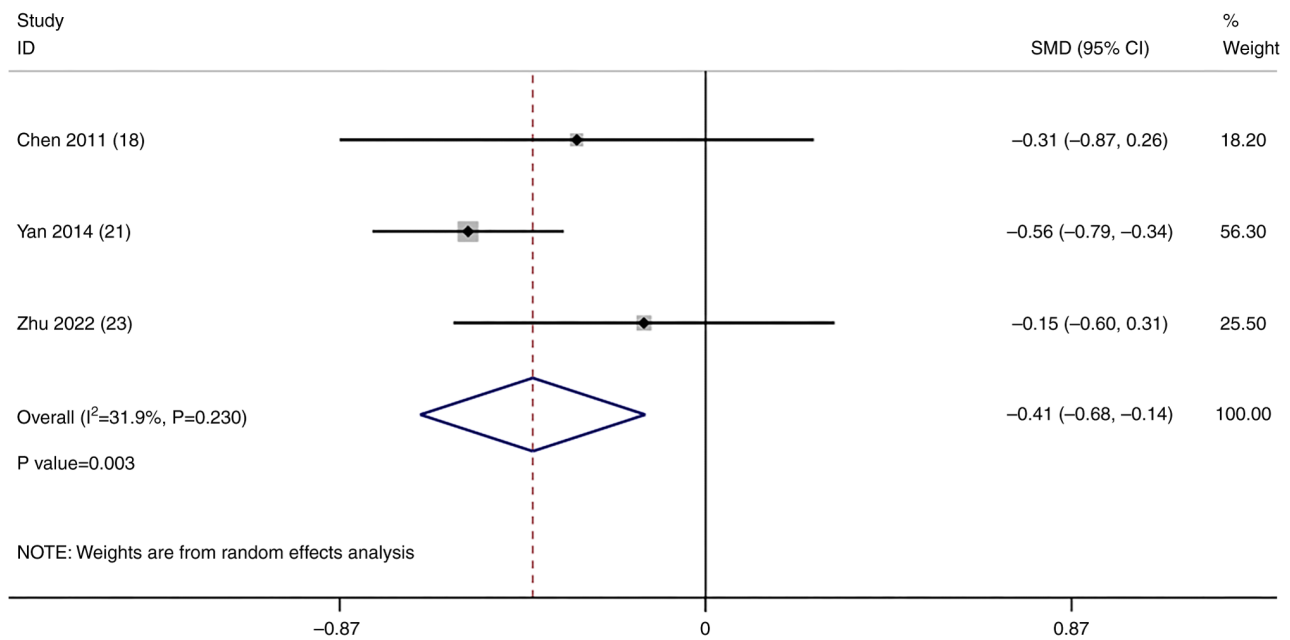


Figure 8. Comparison of the differences in the post-KPAs between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval; KPA, kyphotic angle.

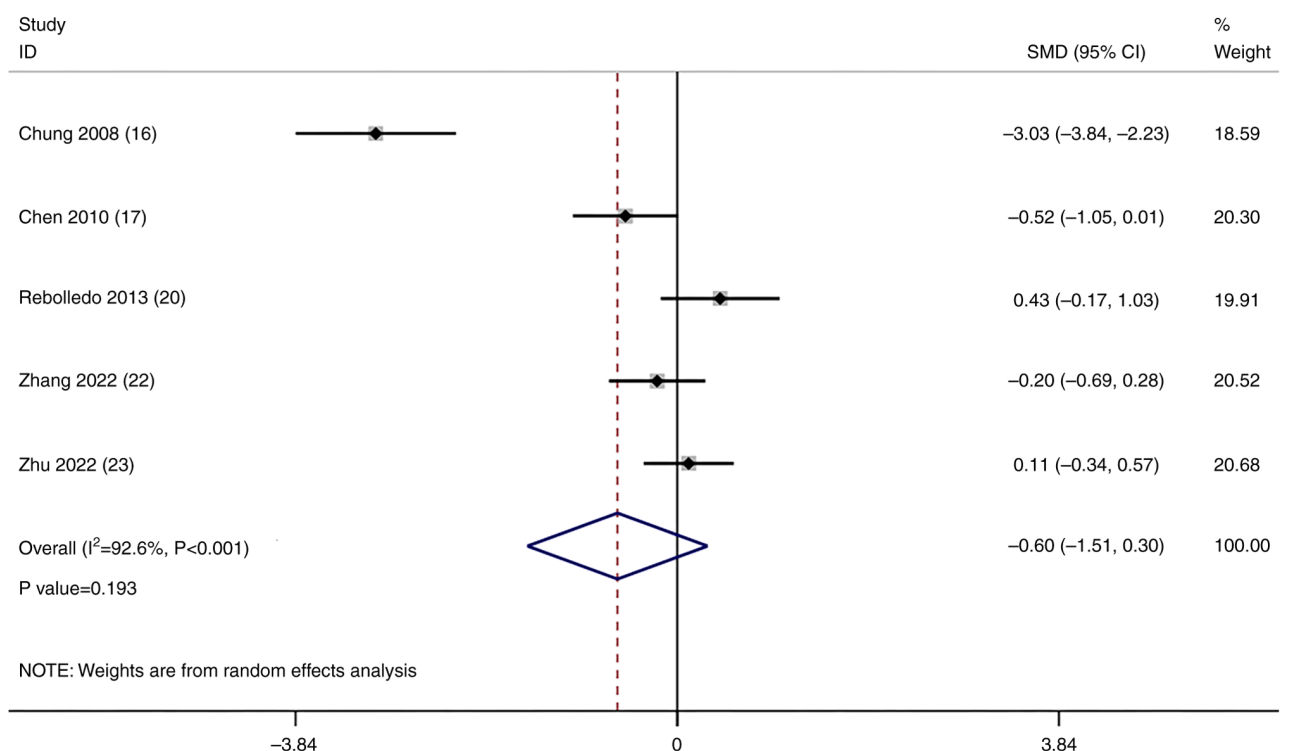


Figure 9. Comparison of the differences in the height restoration rates between the unilateral and bilateral surgical approaches in different studies. SMD, standardized mean difference; CI, confidence interval.

Discussion

Osteoporosis often leads to vertebral fractures that seriously affect the health and quality of life of the elderly (24). Symptom relief is mainly achieved through conservative or surgical treatment (25). PKP is a minimally invasive procedure and an effective treatment for OVCF that is divided

into two surgical approaches: Unilateral or bilateral pedicle puncture (26). Previous studies have suggested that the latter should be the mainstay treatment for OVCF (27,28). However, with advances in technology, previous studies have shown that a unilateral pedicle puncture can produce the same clinical and radiological improvements (20,29). The present meta-analysis included eight studies involving

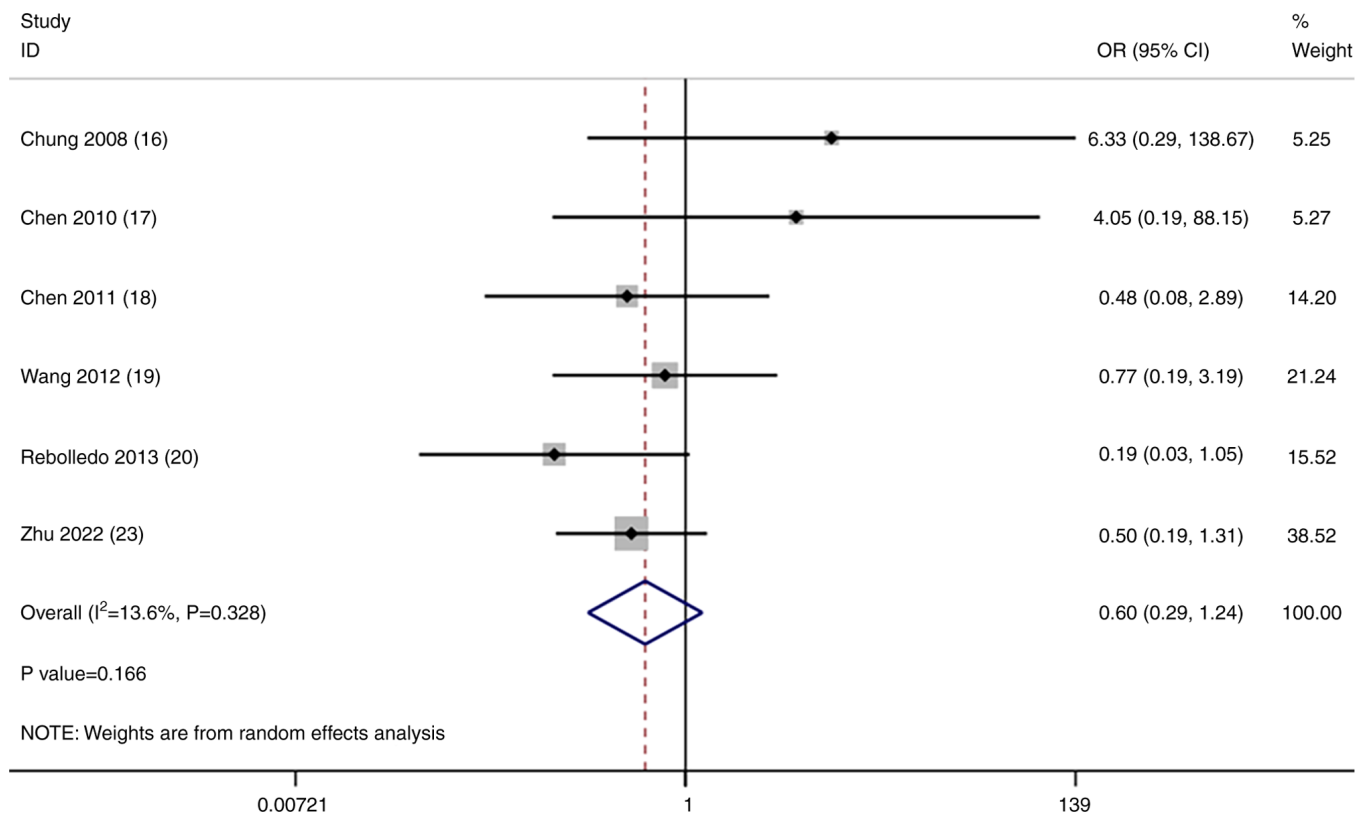


Figure 10. Comparison of the differences in the incidence of cement leakage between the unilateral and bilateral surgical approaches in different studies. OR, odds ratio; CI, confidence interval.

717 patients and evaluated the safety and efficacy of the two types of PKP in the treatment of vertebral fractures caused by osteoporosis to guide the selection of clinical surgical methods.

In the present study, the VAS and ODI results were used for the assessment of clinical effectiveness. The pooled results demonstrated that there were no significant differences in the VAS and ODI scores between the unilateral and bilateral surgical approaches, which was consistent with the results of the included studies. Findings of present study showed that once a certain amount of properly distributed cement was reached, no matter the puncture approach used, pain was alleviated and the functional status was promoted. Of note, the present study demonstrated that the post-KPA of the unilateral surgical approach was significantly lower than that of the bilateral approach. Although the findings of the present study indicated that there was no clear difference between the two surgical approaches for improving vertebral height, the improved KPA observed with the unilateral approach could aid decision making amongst clinicians. In addition, the pooled results demonstrated that the operative time and cement injection volume using the unilateral approach were significantly lower compared with the bilateral approach. The short operation time may be due to the simplicity of the unilateral approach.

To evaluate safety, the occurrences of cement leakage were analyzed. The pooled results demonstrated no significant difference in the incidence of cement leakage between the unilateral and bilateral surgical approaches. However, an OR value of 0.62 indicated that the unilateral approach may be

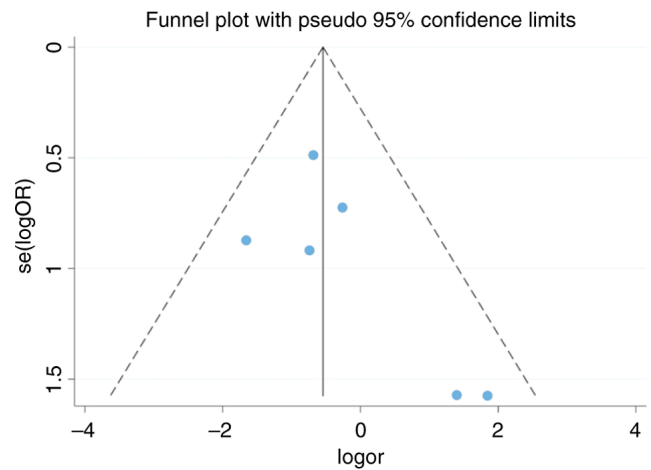


Figure 11. Funnel plot evaluating the publication bias of the studies included in the present meta-analysis. OR, odds ratio; se, standard error.

potentially safer than the bilateral approach, but this conclusion requires further validation in the future.

The present meta-analysis had certain limitations. First, the included studies had small sample sizes. Therefore, the objectivity of the meta-analysis results may be reduced despite data pooling and further studies are required. Second, although the aggregated data contained greater statistical power, the included prospective randomized studies had various types of biases, such as selection, performance and detection bias, which lowered the quality of the evidence.

In conclusion, there were no significant differences in the VAS and ODI between the unilateral and bilateral surgical approaches. However, the pooled results indicated that the unilateral method had a more significant effect on improving KPA and required less operative time and a lower cement injection volume. This approach may therefore be safer for elderly patients, who are more likely to suffer from a greater number of underlying diseases.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

JZ and GL conceived the study. ZZ and QZ analyzed data and wrote the manuscript. ZZ and GL participated in literature review and figure drawing. JZ participated in the revision of the article. JZ and GL checked and confirm the authenticity of all the raw data. All authors have read and approved the final manuscript. ZZ and GL agree to be 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.

Ethics approval and consent to participate

Not applicable.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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