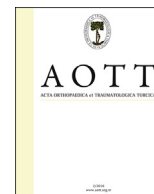


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A systematic review of unilateral versus bilateral percutaneous vertebroplasty/percutaneous kyphoplasty for osteoporotic vertebral compression fractures



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ABSTRACT

Objective: The aim of this study was to compare the unilateral and bilateral approaches in treating osteoporotic vertebral compression fractures.

Methods: Based on the principles and methods of the Cochrane systematic reviews, the records of the Cochrane Library, PubMed, Web of Science, Chinese Bio-medicine database, China Journal Full-text Database, VIP database, and Wanfang database were reviewed until October 2014. The randomized controlled trials on unilateral and bilateral approaches to percutaneous vertebroplasty (PVP)/percutaneous kyphoplasty (PKP) for osteoporotic vertebral compression fractures were included. The risk of bias of included trials was assessed based on the Cochrane Handbook for Systematic Reviews of Interventions Version. The RevMan Software 5.0 was used for meta-analysis.

Results: Fifteen randomized controlled trials with a total of 850 patients were included. Risk of bias in the included studies was inevitable. There was no statistically significant difference in visual analog scale, vertebral height, kyphotic angular, and quality of life. The main operative complications were bone cement leakage and adjacent vertebral fracture, without difference between the two groups.

Conclusions: In view of the current evidence, there is insufficient evidence to show any difference between the unilateral and bilateral approaches in both the PVP and PKP treatment in osteoporotic vertebral compression fractures.

Level of Evidence: Level I, Therapeutic study.

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Osteoporosis is a skeletal disease with the characteristic of low bone mass and micro architectural deterioration of bone tissue, which increases the risk of fracture.¹ With the aging of society, the incidence rate tends to increase yearly. One of the most common complications,² osteoporotic vertebral compression fracture (OVCF), leads to persistent chest and/or waist pain. It has severe consequences for patient quality of life.

Conservative treatment takes a long time to achieve pain relief, while open surgery has slow recovery. In addition, open surgery can have many complications, such as hypostatic pneumonia or urinary tract infection as result of long-term bed rest. Therefore, minimally invasive surgery (MIS) has been increasingly favored. Percutaneous

vertebroplasty (PVP) was first used in the 1980s, and was used in OVCF shortly thereafter. Addition of percutaneous kyphoplasty (PKP) represented an improvement that was also applied in clinical practice.³ PVP and PKP have been shown to be effective in the reinforcement of a fractured vertebral body.^{4,5} In addition, quick remission of pain and long-term analgesic effect effectively improve the quality of life of patients.^{6,7}

In the early stage, bilateral approach was used for procedure. However, due to advantages of simple surgery and short operative time, unilateral approach has also been widely accepted. Therefore, systematic review was designed to provide the highest level quality of evidence in determination of superior approach in MIS for OVCF.⁸ The goal of this systematic review of randomized controlled trials (RCT) was to identify differences between unilateral and bilateral approaches in treating OVCF, and to establish a reference for clinicians.

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Patients and methods

Criteria for considering studies for this review

1 Types of studies

Relevant RCT were included; controlled clinical trials and quasi-randomized studies were excluded.

2 Types of participants

Patients who were diagnosed with OVCF were included without discrimination based on age, sex, or race. Vertebral compression fracture was diagnosed based on imaging. Osteoporosis was defined as decreased bone mineral density diagnosed using World Health Organization guidelines.⁹

3 Types of interventions

Unilateral approach and bilateral approach were compared.

4 Types of outcome measures

Primary outcomes

- a) Visual analog scale (VAS) score
- b) Vertebral height
- c) Kyphotic angle

Secondary outcomes

- d) Quality of life
- e) Complications

Search method for identification of studies

The Cochrane Library, PubMed, Web of Science, Chinese Biomedicine database, China Academic Journals Full-text Database, VIP database, and Wanfang database were searched using the search terms “osteoporosis,” “osteoporoses,” “osteoporotic,” “fractures, compression,” “spinal fractures,” “percutaneous vertebroplasty,” “percutaneous vertebroplasty,” “vertebral plasty,” “percutaneous kyphoplasty,” “percutaneous kyphoplasty,” “unilateral,” “unipedicular,” “unilateraly,” “bilateral,” “bipedicular,” and “bipedicular.” Entries of all databases through October 2014 were searched. The search strategy to identify randomized trials was implemented according to the description in the Cochrane Handbook for Systematic Reviews of Interventions.¹⁰ In addition, references cited in articles were checked manually to identify other eligible studies.

Data collection and analysis

1 Selection of studies

The title, abstract, and keywords of every record were scanned by 2 authors independently to determine whether the studies should be assessed further. The full article was then examined to decide if it met the inclusion criteria. When there was disagreement, the reviewers resolved it through discussion. The reviewers attempted to contact article authors by e-mail if any information was not available.

2 Assessment of risk of bias

Two authors assessed risk of bias of included trials independently as described in the Cochrane Handbook for Systematic Reviews of Interventions¹⁰ using the following criteria: sequence

generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias.

3 Data analysis

Review Manager (RevMan) 5.0 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was used to perform statistical analysis. For dichotomous data, relative risk and associated 95% confidence interval (CI) were calculated, while weighted mean difference and 95% CI were calculated for continuous data. When there was no statistically significant heterogeneity ($p \geq 0.10$, $I^2 \leq 50\%$), meta-analysis was conducted using fixed-effect model; otherwise, possible reasons were explored or random-effect model was used for significant heterogeneity ($p < 0.10$, $I^2 > 50\%$). When data could not be extracted for meta-analysis, the data from these trials were assessed as descriptive data and still considered in the results of the review.

Results

Description of studies

The initial search identified 422 references; 390 articles were subsequently excluded after reading titles and abstracts because they were duplicates or inconsistent with study objectives for the review. Thirty-two references were retrieved for further assessment, and 15 references^{11–25} were excluded because they did not meet the inclusion criteria. Two references^{26,27} were listed as studies awaiting classification, because those articles lacked information and we could not get in touch with the authors. Finally, 15 studies^{28–42} were included. Fig. 1 illustrates flowchart of literature screening as described in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.⁴³

A total of 850 OVCF patients were included and follow-up period ranged from 2 weeks to 54 months. Groups were well matched at the baseline based on information obtained from studies. Table 1 provides details of the included studies.

Risk of bias in included studies

Table 2 and Fig. 2 are summaries of the risk of bias in the included trials. Only 4 trials indicated that random number table was used to generate allocation sequence, while all trials were described as randomized. Only 1 trial reported blinding to the patients and surgeons. More than half of the trials had missing data or patients lost to follow-up. We tried to get in touch with authors by e-mail, but did not receive any response.

Effects of interventions

Of the 15 included trials, 7 studies^{28–34} reported operating method of PVP, 7 articles^{36–42} reported operating method of PKP, and 1³⁵ was a comparison of PVP and PKP.

Effects of PVP

a) VAS score

Seven articles^{28–34} reported VAS score from time point of post surgery (in a week) and 3, 6, 12 months after surgery. There was no statistical heterogeneity between trials in results from post surgery and 12 months after surgery ($p = 1.00$, $I^2 = 0\%$; $p = 0.18$, $I^2 = 42\%$). The result of pooled data revealed no statistical difference between unilateral and bilateral PVP for OVCF (Fig. 3).

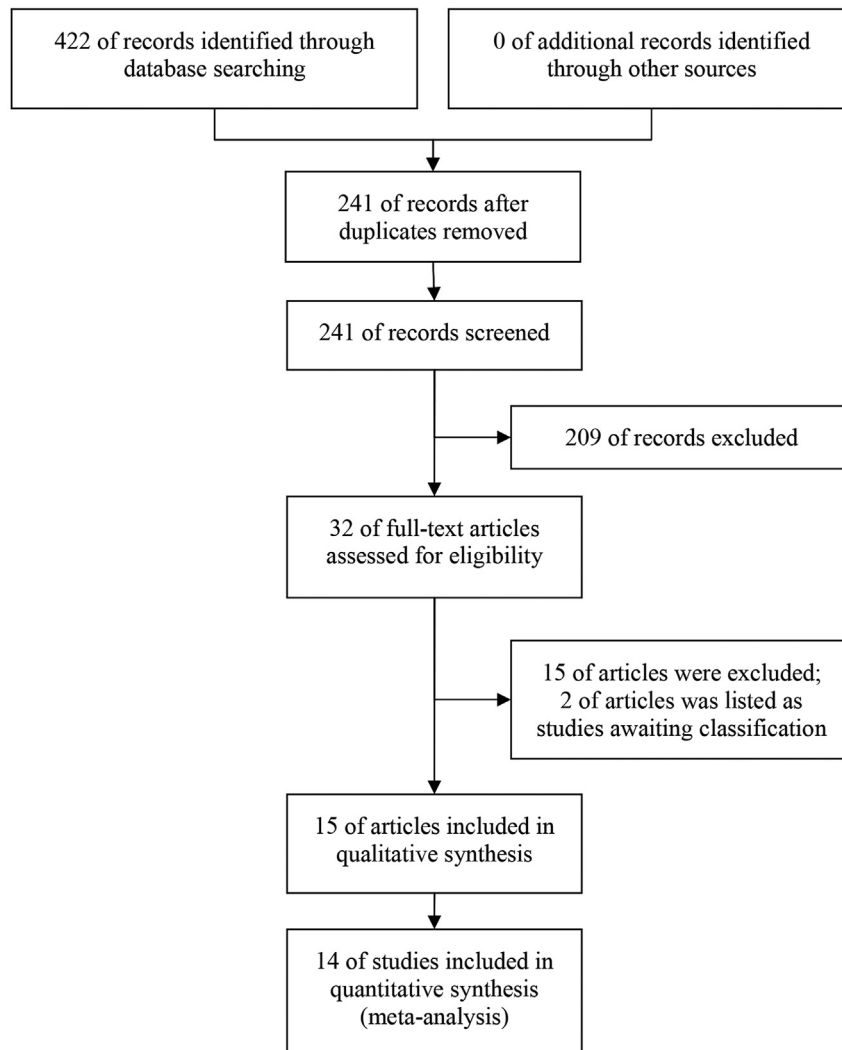


Fig. 1. Flowchart of literature screening.

b) Vertebral height

Four articles^{28,30,34,35} reported vertebral height at time point of post surgery (in a week) and at 6, 12, 18, 24, 30, and 36 months after the surgery. Pooled data from 3 studies at post surgery (in a week)^{28,30,34} and 2 studies at 12 months after the surgery^{30,35} yielded no statistical difference between unilateral and bilateral PVP for OVCF (SMD [standardized mean difference] = -0.10 , 95% CI, -0.42 to 0.23 ; SMD = 0.10 , 95% CI, -0.35 to 0.55). The only one reporting data at 6, 18, 24, 30, and 36 months, conducted by Zeng,³⁵ also presented the same results.

c) Kyphotic angle

Only 1 article²⁸ reported the outcome of kyphotic angle post surgery (in a week). There was no statistical difference in unilateral and bilateral PVP for OVCF in this report.

d) Quality of life

Quality of life measure was reported in 5 studies.^{30,32,33,35,37} The Oswestry Disability Index (ODI) was used at the time point of post surgery (in a week) and at 1 year after the surgery by Huang.²⁸ The

Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) was used at post surgery point (in a week) in 2 studies^{30,31} and at 1 year after surgery in Wang's study.³⁰ The Quality of Life Questionnaire of the European Foundation for Osteoporosis was used post surgery (in a week) and 3, 6, and 12 months after the surgery by Zhang.³³ The Modified Barthel Index of activities of daily living (MBI of ADL) was used at 6, 12, 18, 24, 30, and 36 months after the surgery by Zeng.³⁵ Significant difference only could be seen at 3, 6, and 12 months after surgery in the study conducted by Zhang,³³ while there was no significant difference between 2 groups in the other studies.

Effects of PKP

a) VAS score

Seven articles^{36–42} reported VAS score at the time point of post surgery (in a week) and at 2 weeks, and at 1 and 3 months after the surgery. There was no statistical heterogeneity between trials at post surgery (in a week) and 2 weeks after the surgery ($p = 1.00$, $I^2 = 0\%$; $p = 0.75$, $I^2 = 0\%$). Result of pooled data indicated no statistical difference between unilateral and bilateral PKP for OVCF (Fig. 4).

Table 1
Characteristics of included studies.

Study	Year	Operative methods	Groups	Number of patients (male/female)	Number of vertebrae	Age, mean (SD), yrs	BMI, mean (SD), kg/m ²	Follow-up	Outcomes*
Huang S ²⁸	2013	PVP	Unilateral	9/13	22	67.9 (9.6)	NR†	(25.0 ± 8.1) months	a, b, c, d, e
			Bilateral	11/13	24	65.7 (10.0)	NR	(26.9 ± 8.1) months	
Kong JJ ²⁹	2012	PVP	Unilateral	26/20	NR	63.5 (14.5)	NR	NR	a
			Bilateral	25/21	NR	64.5 (15.5)	NR	NR	
Wang W ³⁰	2013	PVP	Unilateral	10/15	51	66.9	NR	1 year	a, b, d, e
			Bilateral	8/14	45	68.7	NR		
Zhang CL ³¹	2013	PVP	Unilateral	7/21	NR	65.68 (5.31)	NR	NR	a, d
			Bilateral	6/18	NR	65.13 (5.26)	NR		
Zhang JX ³²	2009	PVP	–	11/32	NR	71.4	NR	NR	a, e
Zhang LG ³³	2014	PVP	Unilateral	36	NR	70.0 (2.9)	NR	1 year	a, d, e
			Bilateral	32	NR	70.7 (2.5)	NR		
Zhang X ³⁴	2014	PVP	–	25/28	62	70 (0.27)	NR	1 year	a, b, e
Zeng ZJ ³⁵	2013	PKP, PVP	–	27/33	NR†	64.26 (3.37)	NR	3 years	b, d
Chen CM ³⁶	2010	PKP	Unilateral	33	38	67.73 (7.05)	–3.08 (0.47)	2 weeks	a, b, d, e
			Bilateral	25	28	68.52 (7.26)	–2.89 (1.38)		
Chen L ³⁷	2011	PKP	Unilateral	4/20	NR	70.4	NR	2 years	a, b, c, d, e
			Bilateral	4/21	NR	72.4	NR		
Gu XH ³⁸	2009	PKP	–	17/35	52	71.3	NR	(10–18) months	a, b, c, e
Li GZ ³⁹	2012	PKP	–	11/29	55	69.3	NR	(6–22) months	a, b, c, e
Mao JG ⁴⁰	2013	PKP	Unilateral	34/16	56	64.2 (1.7)	NR	3 months	a, c
			Bilateral	31/19	52	61.3 (1.9)	NR		
Zhang QG ⁴¹	2012	PKP	–	6/17	32	76.4	NR	1 month	a, b, d, e
Zhou MW ⁴²	2013	PKP	–	36/31	97	67.1	NR	(18–54) months	a, b, c, d

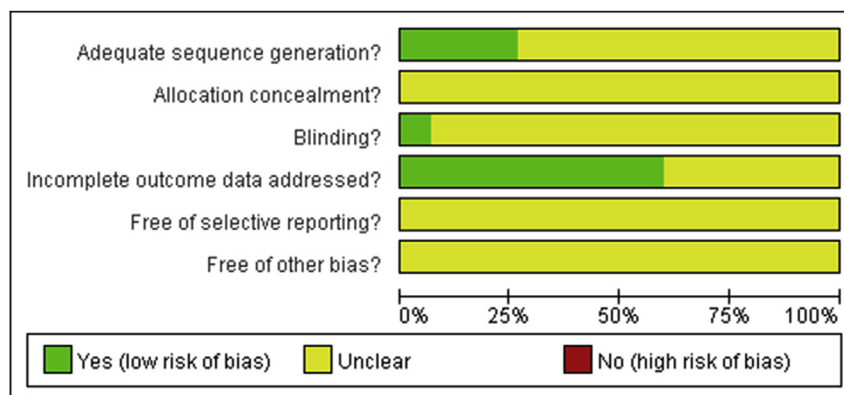
*: a: VAS; b: vertebral height; c: kyphotic angular; d: quality of life; e: complications.

†: NR: no report.

Table 2
Risk of bias in included studies.

Study	Sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Huang S ²⁸	Yes (random number table)	Unclear	Unclear	Yes	Unclear	Unclear
Kong JJ ²⁹	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Wang W ³⁰	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Zhang CL ³¹	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Zhang JX ³²	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Zhang LG ³³	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Zhang X ³⁴	Yes (random number table)	Unclear	Unclear	Yes	Unclear	Unclear
Zeng ZJ ³⁵	Yes (random number table)	Unclear	Yes	Yes	Unclear	Unclear
Chen CM ³⁶	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Chen L ³⁷	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Gu XH ³⁸	Unclear	Unclear	Unclear	Yes	Unclear	Unclear
Li GZ ³⁹	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Mao JG ⁴⁰	Yes (random number table)	Unclear	Unclear	Yes	Unclear	Unclear
Zhang QG ⁴¹	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Zhou MW ⁴²	Unclear	Unclear	Unclear	Yes	Unclear	Unclear

Yes: 'Low risk' of bias; No: 'High risk' of bias; Unclear: 'Unclear risk' of bias.

**Fig. 2.** Risk of bias graph.

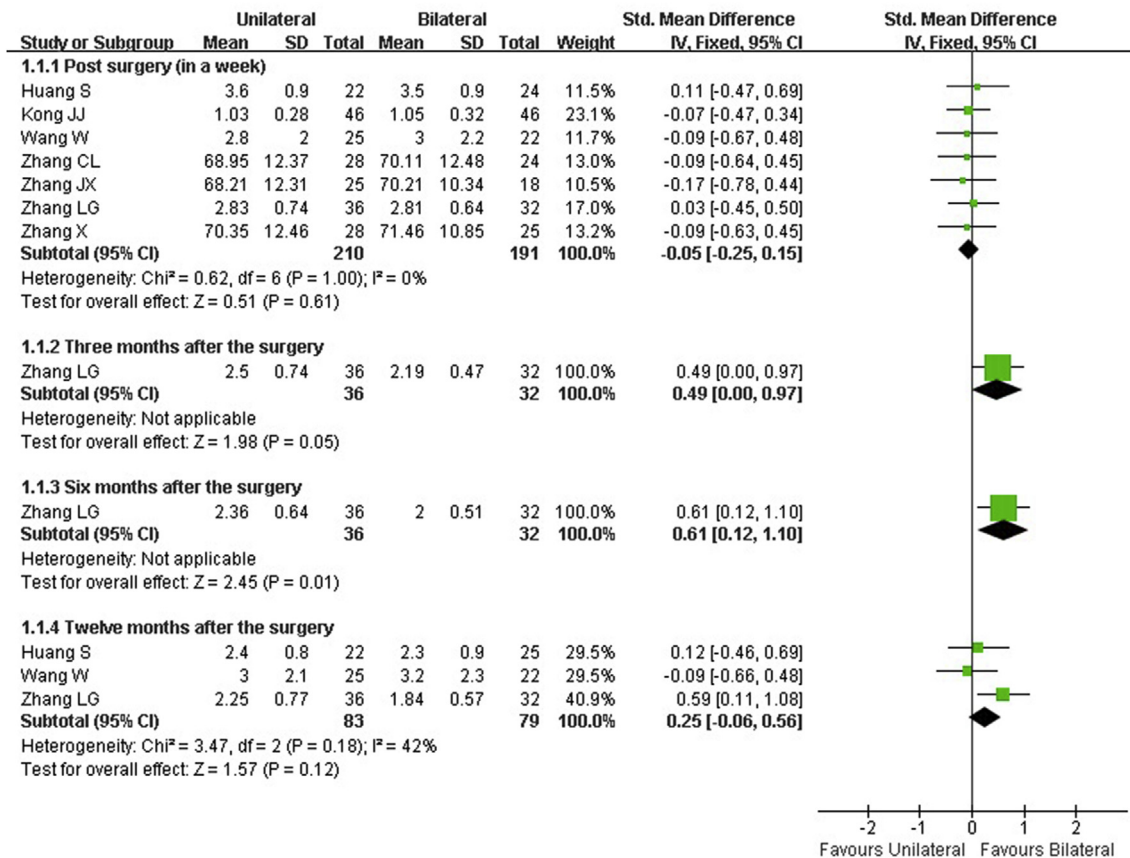


Fig. 3. Unilateral versus bilateral percutaneous vertebroplasty, results for visual analog score.

b) Vertebral height

Six articles^{35–37,39,41,42} reported vertebral height at the time point of post surgery (in a week) and at 2 weeks and 1, 6, 12, 18, 24, 30, and 36 months after surgery. The pooled data from 4 studies at post surgery (in a week)^{37,39,41,42} revealed no statistical difference between unilateral and bilateral PKP for OVCF (SMD = -0.13 , 95% CI, -0.43 to 0.17). There was no statistical difference between the 2 operative methods at 2 weeks after surgery in the report by Chen,³⁶ or at 1 month after the surgery in the report by Zhang.⁴¹ Zeng³⁵ reported the same results at 6, 12, 18, 24, 30, and 36 months.

c) Kyphotic angle

Five articles^{37–40,42} reported kyphotic angle at the time point of post surgery (in a week) and 3 months after the surgery. The result of pooled data showed that there was no statistical difference between unilateral and bilateral PKP for OVCF (SMD = -0.05 , 95% CI, -0.28 to 0.18). Mao⁴⁰ reported that there was no statistical difference between unilateral and bilateral PKP for OVCF at 3 months after the surgery.

d) Quality of life

Quality of life was reported by 4 studies.^{37–39,43} ODI was used 2 weeks after the surgery by Chen³⁶ and at 1 month after the surgery by Zhang.⁴¹ The SF-36 was used post surgery (in a week) by Chen.³⁷ MBI of ADL was used at 6, 12, 18, 24, 30, and 36 months after the surgery by Zeng.³⁵ There was no significant difference between the 2 groups in any of the reports.

Complications

Twelve of the included studies described the outcome of complications.^{28,30,32–39,41,42} Four studies^{32,35,38,39} reported that there were no complications in the follow-up period. The most common complication, bone cement leakage, was reported in 8 studies,^{28,30,33,34,36,37,41,42} although there were no neurological symptoms or other clinical consequences. Adjacent vertebral fracture was another complication described.^{28,34,37,41}

Publication bias

Funnel graph plots SMD against the standard error of SMD for VAS score. The open circles indicate individual studies. The line in the center represents the pooled SMD. Asymmetry in the funnel plot indicates a risk of publication bias (Fig. 5).

Discussion

Differences in results of 15 RCT examining unilateral and bilateral approaches in treating OVCF were summarized in this systematic review. Based on the outcomes of VAS score, vertebral height, kyphotic angle, quality of life, and complications, this review demonstrated that there was no difference between unilateral and bilateral approaches at different time points. However, because of the low quality of this evidence, further research is very likely to impact our confidence level in the estimate of effect and is likely to change the estimate.

This review identified 15 RCT. Approximately one-quarter of included studies detailed the method of randomization and none of them described allocation concealment. Therefore, there is a possibility of selection bias. Only 1 reported the implementation of

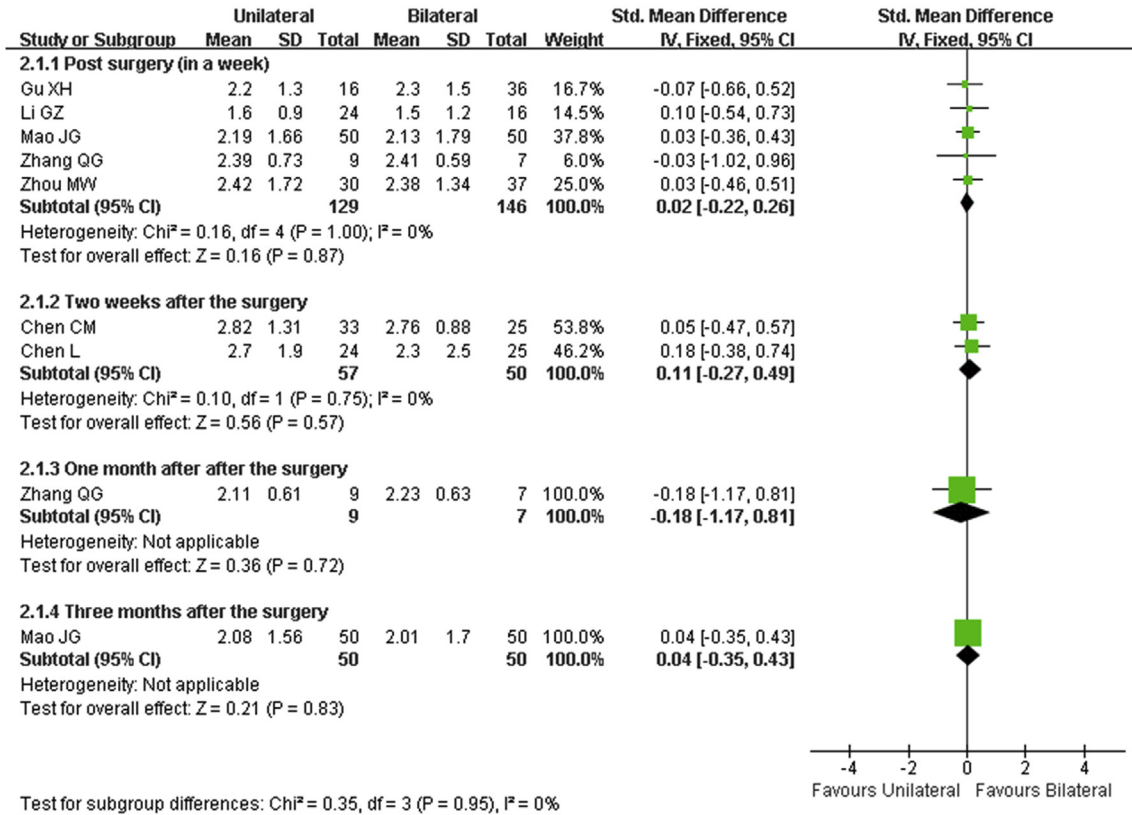


Fig. 4. Unilateral versus bilateral percutaneous kyphoplasty, results for visual analog score.

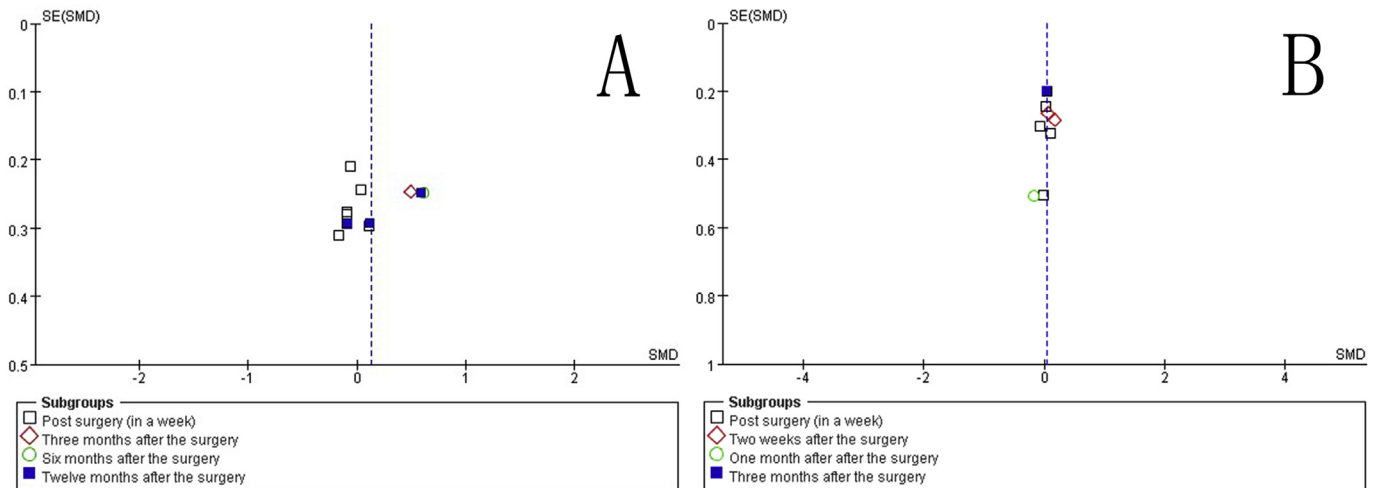


Fig. 5. Funnel plot of included studies. (a) Funnel graph for visual analog score of percutaneous vertebroplasty. (b) Funnel graph for visual analog score of percutaneous kyphoplasty. Asymmetry in the funnel plot indicates a risk of publication bias.

blinding. Thus, performance bias was inevitable. We contacted the authors by e-mail for unavailable information; however, we did not receive any response. Publication bias is indicated by the funnel plot. The overall quality of the reports in general was poor.

The patients in the included studies were predominantly elderly women. Previous studies^{44,45} also support this finding that osteoporosis is predominantly a condition of the elderly and significantly higher in women.

A study on cadavers about biomechanics⁴⁶ demonstrated that there was no difference in the restoration of vertebral body strength, stiffness, or height in experimentally induced vertebral

compression fractures between unilateral kyphoplasty and bilateral kyphoplasty. Using virtual vertebroplasty on damaged model, Liebschner⁴⁷ found both unilateral and bilateral approaches to have effect on recovery of vertebral stiffness and strength after fracture; however, unilateral vertebroplasty may not be as effective as vertebroplasty in recovering vertebral body stability, i.e., the unsupported side preferentially deformed when uniaxial compressive stress boundary conditions were applied.

The most common complication reported in most studies was bone cement leakage. Previous reports have indicated high incidence of 19%–65%.⁴⁸ There is no correlation between perfusion of

bone cements and analgesic effect. However, with increasing injection volume, risk of leakage also increases.⁴⁹ The increased stiffness of vertebral body with bone cement perfusion may be one of the reasons for adjacent vertebral fracture. Osteoporosis and bone cement leakage into the intervertebral disc space have also been considered predictive factors affecting adjacent vertebral fracture.⁵⁰

Cement dosage is also an important variable in outcome. Retrospective analysis of 158 patients treated with PVP yielded result that there was no significant association between cement dosage and post surgery pain.⁵¹ Thus, it is unnecessary to achieve particular cement volume. Therefore, the outcomes we chose to analyze were mainly view of clinical patients and outcome of cement dosage was not included. Systematic review and meta-analysis of unilateral versus bilateral PKP for OVCF indicated that unilateral PKP used smaller quantity of cement than bilateral PKP.⁵²

For this secondary document, the main limitation is that the authenticity of this study depends on original articles. Another limitation is that about half of included studies were in Chinese, which is difficult for English readers to assess.

In view of the low quality of evidence currently available, there is insufficient data to demonstrate if there are any differences between unilateral and bilateral approaches in both PVP and PKP treatment of OVCF. In clinical setting, selection of operative method may depend on patient's condition, including such factors as age, degree of osteoporosis, and fracture type.

Ethical approval

For this secondary document, formal consent is not required.

Conflicts of interest

The authors declare that they have no conflict of interest.

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