

Extrapedicular vs Transpedicular Percutaneous Kyphoplasty for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-analysis

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Abstract: *Background:* Osteoporotic Vertebral Compression Fractures (OVCFs) are one of the most common health problems in the elderly population. Percutaneous kyphoplasty is a minimally invasive technique that has gained widespread recognition. Transpedicular and extrapedicular are two approaches for kyphoplasty. But over the last decade, the safety and effectiveness of two approaches have remained unclear, and there is still a lack of evaluation of their therapeutic effects. *Objectives:* To assess the efficacy and safety of the two approaches as a treatment for patients with OVCF. *Methods:* The study searched CENTRAL, MEDLINE, EMBASE, Chinese Biological Medicine Database, VIP Journals Database, Wan-fang database, CNKI and Chinese Evidence-Based Medicine Database from their inception to December 2020 in both English and Chinese. The study searched Chinese-language journals and conference proceedings. Randomised-controlled trials that compared any form of the transpedicular approach to any form of the extrapedicular approach control intervention in the treatment of osteoporotic vertebral compression fracture patients were included. Two review authors (Wu and Huang) independently determined the studies to be included in the review based on inclusion and exclusion criteria and the extracted data were analysed by RevMan 5.3, and the level of evidence was assessed by the GRADE system. *Results:* Six randomised controlled trials with a total sample size of 395 patients were included; all of them were from Asian countries. Meta-analysis showed that the extrapedicular approach kyphoplasty is superior to the transpedicular approach kyphoplasty for less radiology exposure time, less cement volume, and a lower leakage rate. But there is no difference between the extrapedicular approach kyphoplasty and the transpedicular approach kyphoplasty with postoperative VAS scores and ODI scores. *Conclusion:* Based on the evidence of 6 RCTs, the effectiveness of extrapedicular kyphoplasty for the treatment of osteoporotic vertebral compression fracture patients is suggestive. Extrapedicular kyphoplasty has less radiology exposure time, cement volume and a lower leakage rate than transpedicular kyphoplasty, and there is no significant difference in VAS and ODI after surgery. With the methodological quality and the small number of the included studies taken into consideration, furthermore high quality and large-scale randomized controlled trials are needed.

Keywords: Extrapedicular percutaneous; Transpedicular percutaneous; Kyphoplasty; Osteoporotic vertebral compression fracture; Systematic review

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1. Introduction

Osteoporotic vertebral compression fractures (OVCFs) are common in the elderly population, with an estimated 1.4 million new fractures occurring every year worldwide^[1]. OVCFs cause a substantial economic burden, which will markedly increase over the coming decades^[2-4]. OVCFs have been traditionally treated with conservative management, such as bed rest, analgesics, braces, taking anti-osteoporotic agents, etc.^[5,6] However, in cases with persistent pain or being refractory to conservative management, percutaneous kyphoplasty (PKP) has been traditionally adopted^[7-9]. This minimally invasive technique has gained widespread recognition, effectively reducing pain both in the short and long term^[10,11]. Numerous clinical studies^[12,13] 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 literature, many studies^[14,15] have reported the disadvantages of surgery, such as the augmented vertebrae with significant vertebral height loss and aggravation of kyphotic deformity after surgery. There are still some reports of percutaneous injury to nerves or spinal cords in the surgery of percutaneous kyphoplasty^[16,17].

How to reduce intraoperative injury to nerves or spinal cords in the surgery of percutaneous kyphoplasty has become an important issue for clinicians to improve. Some research shows both the transpedicular approach and extrapedicular approach are relatively safe, but in the upper and middle thoracic spine, the risk of intraspinal mispositioning seems to be lower when using the extrapedicular approach^[18,19]. Due to the variable pedicle anatomy, two different approaches, the transpedicular and the extrapedicular approach, have been established. In particular, in the middle and upper thoracic spine, percutaneous procedures are challenging because of the difficult visualization of anatomical landmarks and a more unfavorable anatomy with smaller and differently orientated pedicles^[20]. But the actual effect and safety of extrapedicular kyphoplasty compared to transpedicular kyphoplasty is still unclear. As we know, this is the first Meta-analysis to discuss the effect of the extrapedicular approach kyphoplasty and transpedicular approach among treating OVCFs.

2. Methods

2.1. Search strategy and selection criteria

The study searched CENTRAL, MEDLINE, EMBASE, Chinese Biological Medicine Database, VIP Journals Database, Wan-fang database, CNKI, and Chinese Evidence-Based Medicine Database from their inception to December 2020. The search terms used were: the transpedicular approach and extrapedicular approach for treating OVCF in both English and Chinese. The study also searched files manually for relevant articles. The study searched Chinese-language journals and conference proceedings. The study included dissertations and abstracts, provided they contained sufficient detail for critical evaluation. The study submitted the details in the INPLASY register (registration number is INPLASY202330048).

The studies that met the following criteria were included: (1) the study evaluated the extrapedicular

kypthoplasty for treating OVCF and PKP; (2) the study must be conducted through case control design; and (3) the study provided sufficient raw data for the weighted mean difference (MD) with 95% confidence intervals (CI). Articles were excluded from our meta-analysis if they were duplicate publications or did not contain raw or usable data. Data from the included studies were extracted and summarized independently by two of the authors. Any disagreement was resolved by the adjudicating senior authors (D.L.).

2.2. Data analysis

For meta-analysis, the total effectiveness rates of dichotomous data were pooled using risk ratios (RRs). The aggregated results and 95% CIs for effect size were calculated using inverse-variance weighted random-effects meta-analysis. I^2 was used to assess heterogeneity across studies, with I^2 values of 0%, 25%, 50% and 75% representing no, low, moderate and high heterogeneity, respectively. Meta-regression was conducted to investigate the potential covariates that might have substantial impacts on between-study heterogeneity. Influence analysis was also conducted to determine whether an individual study affected the aggregate result or not. Subgroup analyses were performed according to the type of study design.

3. Results

The study identified 231 potentially relevant articles, and 225 articles were excluded for reasons given in **Figure 1**. Six studies, involving a total of 395 participants, met our inclusion criteria ^[21–26]. Key data are summarized in Table 1. All of them were from Asian countries, and 6 trials were from China and published in Chinese ^[21–26].

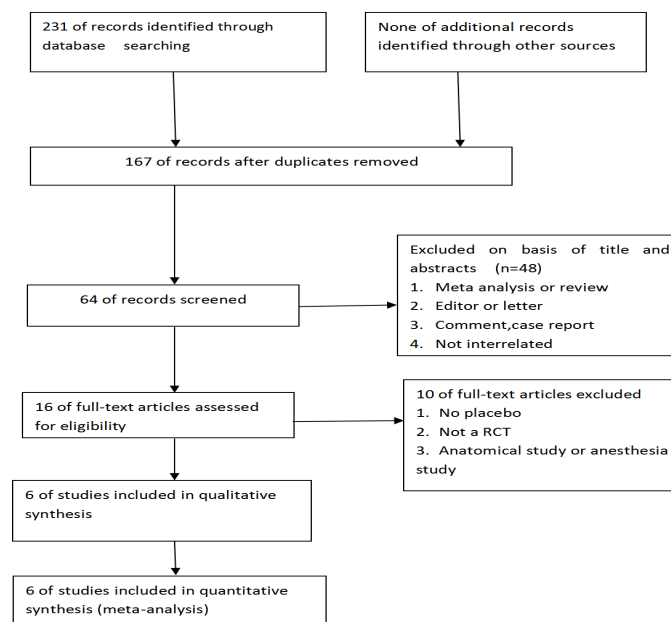


Figure 1. Flowchart of trials selection process.

Table 1. Summary of randomized controlled trials on the two approaches for treating OVCF

First author/year	Type of surgery	Intervention experimental	Intervention control	Outcomes
Chen, 2018 ^[21]	PKP	22	25	VAS, Surgery time, Cement volume, Leakage rate
Huang, 2019 ^[22]	PKP	60	60	VAS, ODI, Surgery time, Radiology exposure time, Leakage rate
Ma, 2019 ^[23]	PKP	30	28	VAS, ODI, Surgery time, Radiology exposure time, Cement volume, Leakage rate
Wang, 2012 ^[24]	PKP	28	26	VAS, Surgery time, Radiology exposure time, Cement volume
Yang, 2016 ^[25]	PKP	24	24	VAS, ODI, Cement volume, Leakage rate
Zhu, 2020 ^[26]	PKP	34	34	ODI, Surgery time, Radiology exposure time, Cement volume

PKP: percutaneous kyphoplasty, VAS: visual analogue scale, ODI: oswestry disability index

3.1. Study quality

Three articles of six trials were non-randomized control groups, and three trials were described as randomized, while one of the trials ^[22] had no detailed description of the method, and two of the trials ^[23,26] reported appropriate randomization, in which researchers used numerical table randomization method for randomization.

While all included trials reported favorable effects of extrapedicular kyphoplasty on treatment to osteoporotic vertebral compression fractures, none of the included trials reported the implementation of allocation concealment. All of the six studies did not mention either subjects or assessor blinding. And three reported follow up ^[22,23,26], none of the included trials reported dropout. Two of the included trials reported the ethical approval ^[21,23]. Three of the six trials showed a high risk of bias ^[21,24,25], while the other three trials showed a unclear risk of bias ^[22,23,26] (**Figure 2** and **Figure 3**). Based on GRADE system, all the evidences were level C and weak recommendation (2C). There was good agreement between the two reviewers.

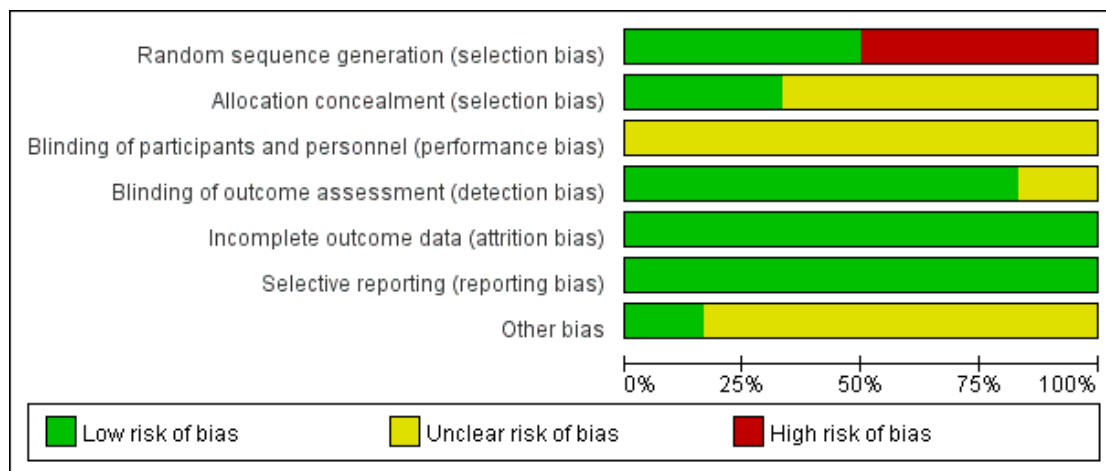


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
2018	+	?	?	+	+	+	?
2019	+	?	?	+	+	+	?
2019	+	+	?	+	+	+	+
2012	+	?	?	+	+	+	?
2016	+	?	?	?	+	+	?
2020	+	+	?	+	+	+	?

Figure 3. Risk of bias summary: Review authors' judgments about each risk of bias item for each included study.

3.2. Outcomes

3.2.1. Fluoroscopy times

Adequate time of intraoperative fluoroscopy data were available in 4 studies ^[22–26]. Pooled data indicated a lower radiology exposure time of operation in the extrapedicular approach group, the difference was statistically significant (MD = -9.85, $P < 0.00001$, 95%CI -13.54 to -6.16, $I^2 = 96\%$, **Figure 4**).

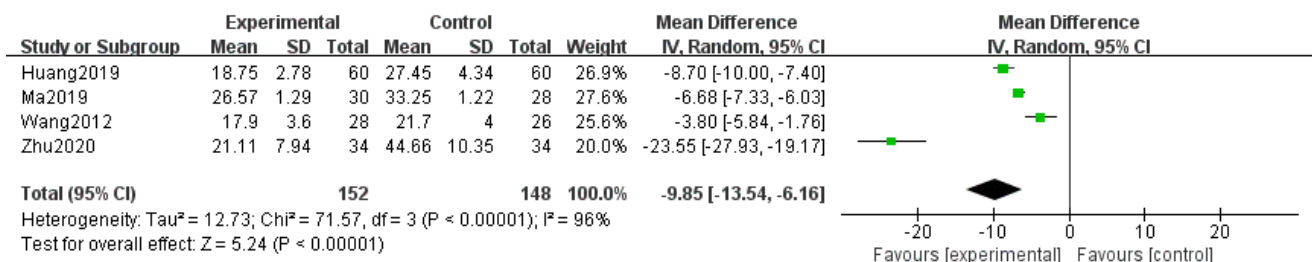


Figure 4. Meta-analyses of the radiology exposure time.

3.2.2. Bone cement injection volume

Five studies ^[21–26] provided adequate data about the mean and SD of the cement injection volume. Compared with the transpedicular approach group, the pooled estimate showed that the extrapedicular approach group used significantly less bone cement volume (MD = -0.96, $P = 0.003$, 95%CI -1.58 to -0.33, $I^2 = 95\%$, **Figure 5**).

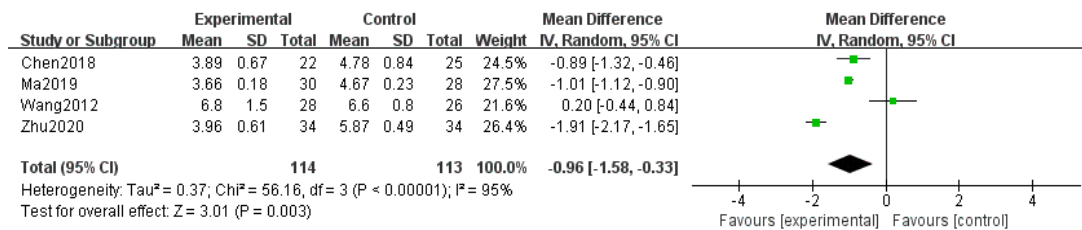


Figure 5. Meta-analyses of the bone cement injection volume.

3.2.3. Postoperative VAS and ODI

Five included articles ^[21–25] reported the VAS score at the time points of preoperative and postoperative. The meta-analysis found no significant differences in VAS after surgery between the extrapedicular approach group and the transpedicular approach group for OVCFs (MD = 0.04, $P = 0.43$, 95%CI -0.05 to 0.13, $I^2 = 66\%$, **Figure 6**). Four included studies ^[22,23,25,26] evaluated surgical outcomes by the ODI scores before and after the treatments. Result of pooled data indicated no statistical difference between the extrapedicular approach group and the transpedicular approach group with postoperative ODI (MD = -0.76, $P = 0.60$, 95%CI -3.60 to 2.08, $I^2 = 85\%$, **Figure 7**).

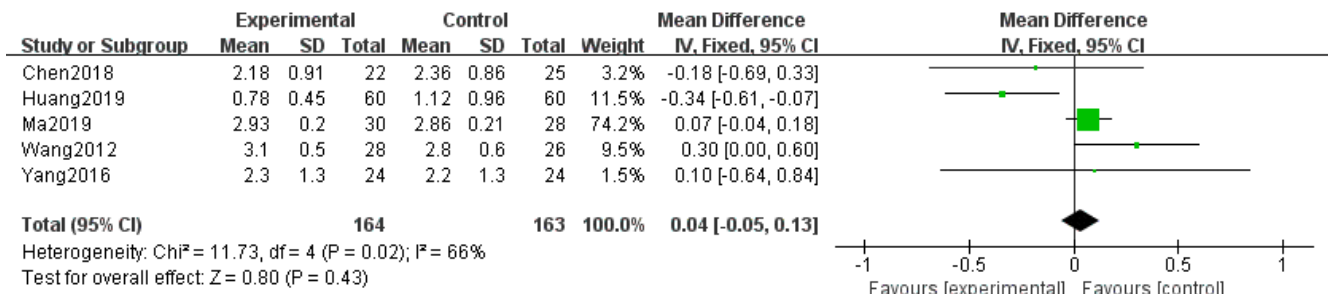


Figure 6. Meta-analyses of the VAS after surgery.

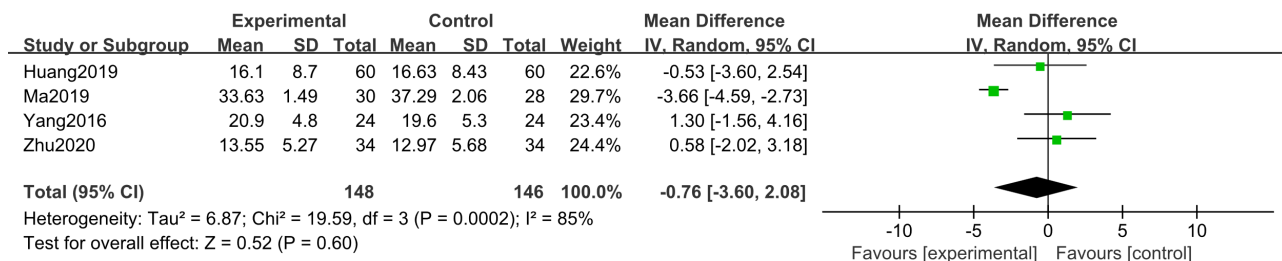


Figure 7. Meta-analyses of the ODI after surgery.

3.2.4. Complications

Four studies ^[21–23,25] provided relevant data on cement leakage, with 272 patients (135 in the extrapedicular approach group and 137 in the transpedicular approach group). The meta-analysis of the four studies showed that the transpedicular approach group had a significantly higher risk of cement leakage than the extrapedicular approach group (OR = 0.34, $P = 0.005$, 95%CI 0.16 to 0.73, $I^2 = 0\%$, **Figure 8**).

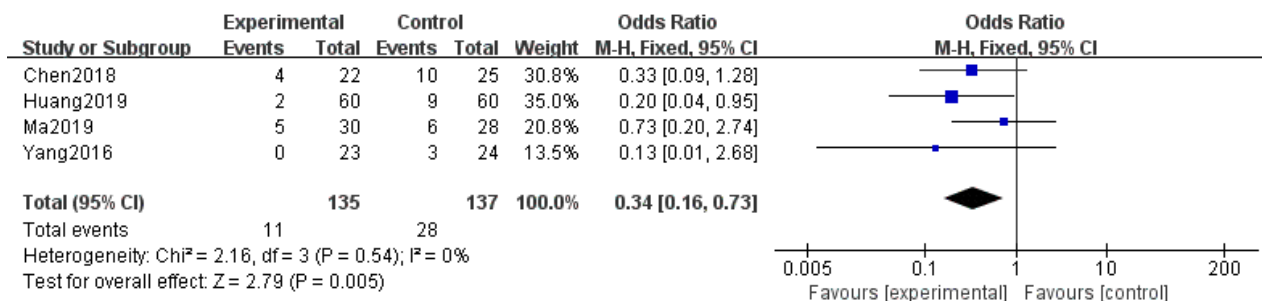


Figure 8. Meta-analyses of the cement leakage rate.

3.2.5. Adverse events

None of the 6 included trials mentioned adverse events at all.

4. Discussion

OVCFs are very common in elderly people, causing intractable pain, kyphosis and greatly impairing the quality of a patient's life. Percutaneous kyphoplasty is a minimally invasive operation used in the treatment of patients with OVCFs who have no improvement after 4 weeks of conservative therapy ^[27–29]; it involves the insertion of the balloon plate into the vertebral body, followed by the injection of cement for the fixation of the vertebral body. Percutaneous kyphoplasty can provide rapid and constant pain relief, reduce the kyphosis deformity and improve the quality of life; thus, it has been regarded as one of the standard operations during the last decade.

Kim *et al.* ^[30,31] described that a unilateral extrapedicular approach to kyphoplasty or vertebroplasty offers several benefits, including shorter operative time, which reduces perioperative risks that are considerable in seniors with multiple medical issues. Andrew *et al.* ^[32] first reported step-by-step the percutaneous techniques used in the lumbar and thoracic extrapedicular approaches and the thoracic infrapedicular approach, with depiction in an accompanying video presentation. Liu *et al.* ^[33,34] introduced the puncture methods in different extrapedicular approaches and recommended appropriate extrapedicular puncture methods for thoracolumbar PVP (PKP). However, the complications between two different approaches of percutaneous kyphoplasty were the main points that attracted the attention of those making the decisions. Cement leakage is a very serious and common complication. These controversial conclusions confused the clinical decision makers and did not standardize the therapy effectively.

Meta-analyses and systematic reviews were confirmed as the evidence with the highest quality in evidence-based medicine ^[35]. This is the first systematic review of meta-analyses to compare the extrapedicular approach to the transpedicular approach in kyphoplasty for OVCFs. The study concluded that the extrapedicular approach kyphoplasty could reduce the radiology exposure time, cement volume, and cement leakage rate compared to that of the transpedicular approach kyphoplasty, while there were no differences in VAS scores, ODI scores. These findings are consistent in all included research, indicating that the extrapedicular kyphoplasty can significantly reduce the cement leakage rate and the radiology exposure time. The possible reason is that the extrapedicular approach is easier to puncture than the transpedicular approach, and there is no need to adjust the puncture too much during the operation ^[36–38].

The study also found that the extrapedicular kyphoplasty group needed less bone cement than the

transpedicular kyphoplasty group. Yan *et al.* ^[39,40] described that, facing the small pedicle of the thoracic spine and the small included angle between the longitudinal axis of the pedicle and the sagittal plane, it is difficult for the pedicle approach to reach the target with a large lateral angle. These reasons may be causing the amount of bone cement injected in the extrapedicular kyphoplasty group to be usually less than the transpedicular kyphoplasty group. The pool analysis also suggests that there is no difference between the extrapedicular kyphoplasty group and the transpedicular kyphoplasty group with postoperative VAS and ODI scores. These results confirm that both extrapedicular kyphoplasty and transpedicular kyphoplasty can improve function and ease the pain of patients.

5. Limitations

There are several limitations in this meta-analysis. First, the search for studies those published in Chinese, so it may be difficult for English readers to assess. Second, several articles were excluded because they did not meet our inclusion criteria, so it is hard to conduct a global summary of all the evidence. Third, there was a high risk of bias attributable to the lack of blinding of participants and personnel due to both being involved directly in the treatment.

6. Conclusion

Although there is controversy, this systematic review comparing the extrapedicular approach kyphoplasty and the transpedicular approach kyphoplasty for treating OVCs demonstrates that the two minimally invasive procedures, extrapedicular approach kyphoplasty, are superior to the transpedicular approach kyphoplasty for less radiology exposure time, less cement volume, and a lower leakage rate. But in the future, large-volume, well-designed RCTs with extensive follow-up are awaited to confirm and update the findings of this analysis.

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Disclosure statement

The authors declare no conflict of interest.

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