

Percutaneous vertebroplasty versus percutaneous kyphoplasty for the treatment of delayed post-traumatic vertebral body collapse (Kümmell's disease) in Chinese patients: a systematic review and meta-analysis[†]



Original article

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Abstract: Objective: To compare the clinical efficacy between percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) in the treatment of Kümmell's disease in Chinese patients.

Methods: The studies using randomized controlled trials to compare clinical efficacy between PVP and PKP in the treatment of Kümmell's disease in Chinese patients were retrieved from Embase, Pubmed, Central, Cinahl, PQDT, CNKI, CQVIP, Wanfang Data, and CBM (from September 2008 to September 2018). Keywords for both Chinese and English search were: percutaneous vertebroplasty, PVP, percutaneous kyphoplasty, PKP, and Kümmell's disease. A total of 132 articles were retrieved based on the search strategy through online database searching and manual searching. Finally, one foreign report and seven Chinese reports were included. After extracting the data, statistical software Review Manager 5.3 was used for data analysis.

Results: Through comparison, Cobb angle (95% CI [0.54, 4.42], $P = 0.01$) and Oswestry Dysfunction Index (ODI) (95% CI [0.21, 2.15], $P = 0.02$) of PKP group was smaller than that of PVP group. Postoperative anterior vertebral body height of the PKP group was better than PVP group (95% CI [-1.27, -0.66], $P < 0.001$). However, the PVP group had shorter operation time than PKP group (95% CI [-13.48, -7.43], $P = 0.001$). In the other outcome measures, including Visual Analogue Scale (VAS) score (95% CI [-0.04, 0.27], $P = 0.15$), cement volume (95% CI [-0.82, 0.32], $P = 0.39$) and cement leakage (95% CI [0.90, 2.76], $P = 0.11$), there was no significant differences between the two procedures.

Conclusions: At this stage, there is sufficient evidence to support that PKP is better than PVP in the treatment of Kümmell's disease in Chinese patients. Although PVP surgery requires much less operation time, PKP has better postoperative radiological results and lower ODI. Moreover, both of them had similar clinical results (e.g., analgesic effects, cement dosage, and leakage rate). Further evidence is dependent on the emergence of randomized controlled trials with higher quality and larger sample sizes in the future.

Keywords: Kümmell's disease • percutaneous vertebroplasty • percutaneous kyphoplasty • post-trauma • vertebral body collapse • meta-analysis • systematic review

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1. Introduction

Kümmell's disease, otherwise known as delayed post-traumatic vertebral collapse and avascular necrosis of the vertebral body, after a mild traumatic experience in an asymptomatic period, was first described by the German surgeon Kümmell in 1895.^{1,2} Due to the rare and complicated conditions, Kümmell's disease has so far been reported few times. Kümmell's disease causes only mild symptoms at an early stage, and the duration of the disease varies, which can delay diagnosis and treatment.³ In the late stage, vertebral body collapse and kyphotic deformity are caused, which often leads to severe intractable back pain.⁴ Some patients even have symptoms of spinal cord compression, which severely impacts the quality of life. Kümmell's disease treatment includes conservative and surgical methods, which includes PVP, PKP minimally invasive surgery, and open surgery. As the vertebral body of Kümmell's patients is destroyed and does not heal itself, conservative treatment is often ineffective for Kümmell's disease and requires surgical intervention.⁵ Surgical treatment of patients with Kümmell's disease results in better clinical outcomes such as good pain relief, functional improvement, and kyphosis correction. Both the PVP and PKP are minimally invasive surgery, which percutaneously injected cement into the vertebral body under local anesthesia and X-ray to enhance the strength and stability of the vertebral body.⁶ Percutaneous vertebroplasty (PVP) and kyphoplasty can effectively relieve fracture pain and even partially restore the height of vertebral body. At the same time, the thermal effect generated by polymerization of bone cement can further alleviate the pain of nerve degeneration and necrosis in and around vertebral body. Therefore, the operation has the advantages of simple operation, exact curative effect, small trauma, and early activity of the patient.^{7,8}

Currently, it is generally believed that PVP surgery is more economical than PKP surgery because there are no consumables such as balloons. Clinical application has confirmed that PVP is a safe and effective surgical procedure;^{9,10} PKP is a better choice for patients with significant vertebral height loss and old fractures with pseudo articular formation. PKP can better restore vertebral height and correct kyphosis.^{11,12} On the other hand, due to the injection of bone cement into the compressed vertebral body under a large pressure, both types of minimally invasive surgery may cause complications such as leakage of bone cement. Reportedly, both procedures can be used for the treatment of Kümmell's disease, but the optimal choice between these two procedures remains controversial.^{13,14} This meta-analysis intends to systematically compare the efficacy between the two procedures in order to provide some theoretical guidance for clinical practice.

2. Materials and methods

2.1. Search strategy

The retrieval was conducted in the online databases include Embase, Pubmed, Central, Cinahl, PQDT, CNKI, CQVIP, Wanfang Data, Cochrane Library, and CBM. We also manually searched some journals' catalog and references, and strive to find gray literature, such as unpublished academic papers and chapters in monographs. Searching all relevant papers without restricting the language and translating if necessary. Keywords searched for both Chinese and English were: Percutaneous Vertebroplasty, PVP, Percutaneous Kyphoplasty, PKP, and Kümmell's disease. Search strategy was: Kümmell's disease AND "Percutaneous Vertebroplasty OR PVP" AND "Percutaneous Kyphoplasty OR PKP."

2.2. Inclusion criteria

Inclusion criteria for the analysis were (1) Chinese adults with phase I and II Kümmell's disease; (2) randomized controlled trials (RCTs), prospective studies, retrospective studies, and cohort studies; (3) Patients received minimally invasive surgery for the treatment of Kümmell's disease; (4) study compared results of PVP and PKP, (5) The outcome being measured by Cobb angle, anterior vertebral body height, Oswestry Dysfunction Index (ODI), Visual Analogue Scale (VAS) score, cement volume, cement leakage, and operation time.

2.3. Exclusion criteria

The exclusion criteria were: (1) letters, comments, editorials, case reports, proceedings, personal communications, or reviews; (2) study objective or intervention measures failed to meet the inclusion criteria; (3) the original documents of experimental design being not precise; and (4) studied with incomplete data.

2.4. Data extraction and quality assessment

Inclusion decisions were made independently by two reviewers participated in according to the pre-stated eligibility criteria. Disagreement between the two reviewers was resolved by discussion or consulting to a third reviewer when necessary. The risk-of-bias assessment tool outlined in Cochrane Handbook was used to measure the methodological quality of case-controlled trials (CCTs). Six domains are evaluated: random sequence generation, allocation concealment, blinding of patients and personal, blinding of outcome assessment, incomplete outcome data, and selective reporting risk.

The Newcastle–Ottawa Scale (NOS) was used to assess the quality of cohort studies, the full score is 9 points. Trials with a score of more than 6 points are considered high-quality study. Relevant data were recorded in this analysis, including: first author's name, published year, sample size of PVP and PKP in the treatment of Kümmell's disease, and so on.

2.5. Statistical analysis

Data were independently entered into RevMan 5.3 software by two reviewers. Dichotomous outcomes were expressed in terms of Odds ratio (OR) and the weighted mean difference (WMD) or the standard mean difference (SMD) was used for continuous outcomes, both with 95% confidence intervals (95% CI). Heterogeneity was tested using both the chi-square test and I^2 test. A fixed-effects model was chosen when there was no statistical evidence of heterogeneity ($I^2 < 50\%$) and random-effects model was adopted if significant heterogeneity was found. If the heterogeneity was found, we checked the study population, treatment, outcome, and methodologies to determine the source of heterogeneity. If it could not be quantitatively synthesized or the event rate was too low to measure, we used qualitative evaluation. By eliminating some of the studies for sensitivity analysis and making funnel plots to assess the bias. The difference was considered statistically significant when $P \leq 0.05$.

3. Results

Based on the above mentioned search strategy, a total of 132 related articles were retrieved. By reading the titles and abstracts, we excluded 55 noncontrolled studies, repeated publications, and 40 articles that are not related to the research purpose. Thirty-seven related studies were screened out preliminarily; further reading the full texts and the screening criteria were strictly followed according to the inclusion and exclusion criteria. Finally, one English article and seven Chinese articles were included. Patient's characteristics and conditions in included study were compared such as age, gender, and so on. The differences were not significant ($P > 0.05$). The literature screening process and the results are shown in Figure 1. Basic characteristics of included literature are indicated in Table 1.

3.1. Cobb angle

To compare preoperative and postoperative Cobb angle changes in PVP and PKP groups of Chinese Kümmell patients, five clinical studies were included. These studies were divided into three subgroups based

on preoperative, postoperative 1–2 days and last follow-up. Random effect model was employed in meta-analysis because the heterogeneity between the studies and subgroups was significant ($I^2 > 50\%$). The results showed that PKP group had less Cobb angle than PVP group 1–2 days after operation (95% CI [0.91, 8.36], $P = 0.01$), but preoperative Cobb angle (95% CI [−1.25, 1.05], $P = 0.86$) and the last follow-up Cobb angle (95% CI [−0.76, 6.41], $P = 0.12$) was similar, and the difference was not statistically significant (Figure 2).

3.2. Anterior vertebral body height

According to the preoperative, 1–2 days after operation, and the last follow-up, data were divided into three subgroups. A total of six trials were included, and preoperative and postoperative vertebral body height of Chinese Kümmell's patients between PVP and PKP groups were compared. Random effect model was employed in meta-analysis because the heterogeneity between the studies and subgroups was significant ($I^2 > 50\%$). The results showed that the height of anterior vertebral body in the PKP group was better than PVP group on 1–2 days postoperative (95% CI [−5.49, −0.26], $P = 0.03$) and the last follow-up (95% CI [−4.7, −0.29], $P = 0.03$), and the difference was statistically significant (Figure 3).

3.3. Oswestry Dysfunction Index

According to the preoperative, 1–2 days after operation, and the last follow-up, data were divided into three subgroups. A total of six trials were included, and preoperative and postoperative ODI of Chinese Kümmell's patients in PVP and PKP groups were compared. Random effect model was employed in meta-analysis because the heterogeneity between the studies and subgroups was significant ($I^2 > 50\%$). The results showed that PKP group had less ODI score than PVP group 1–2 days after operation (95% CI [0.00, 1.81], $P = 0.05$), but preoperative ODI score (95% CI [−0.41, 3.84], $P = 0.11$) and the last follow-up ODI score (95% CI [−0.60, 3.46], $P = 0.17$) was similar, and the difference was not statistically significant (Figure 4).

3.4. VAS score

According to the preoperative, 1–2 days after operation, and the last follow-up, data were divided into three subgroups. A total of eight trials were included, and preoperative and postoperative VAS score of Chinese Kümmell's patients between PVP and PKP groups was compared. Random effect model was employed in meta-analysis because the heterogeneity between the studies and subgroups was significant ($I^2 > 50\%$).

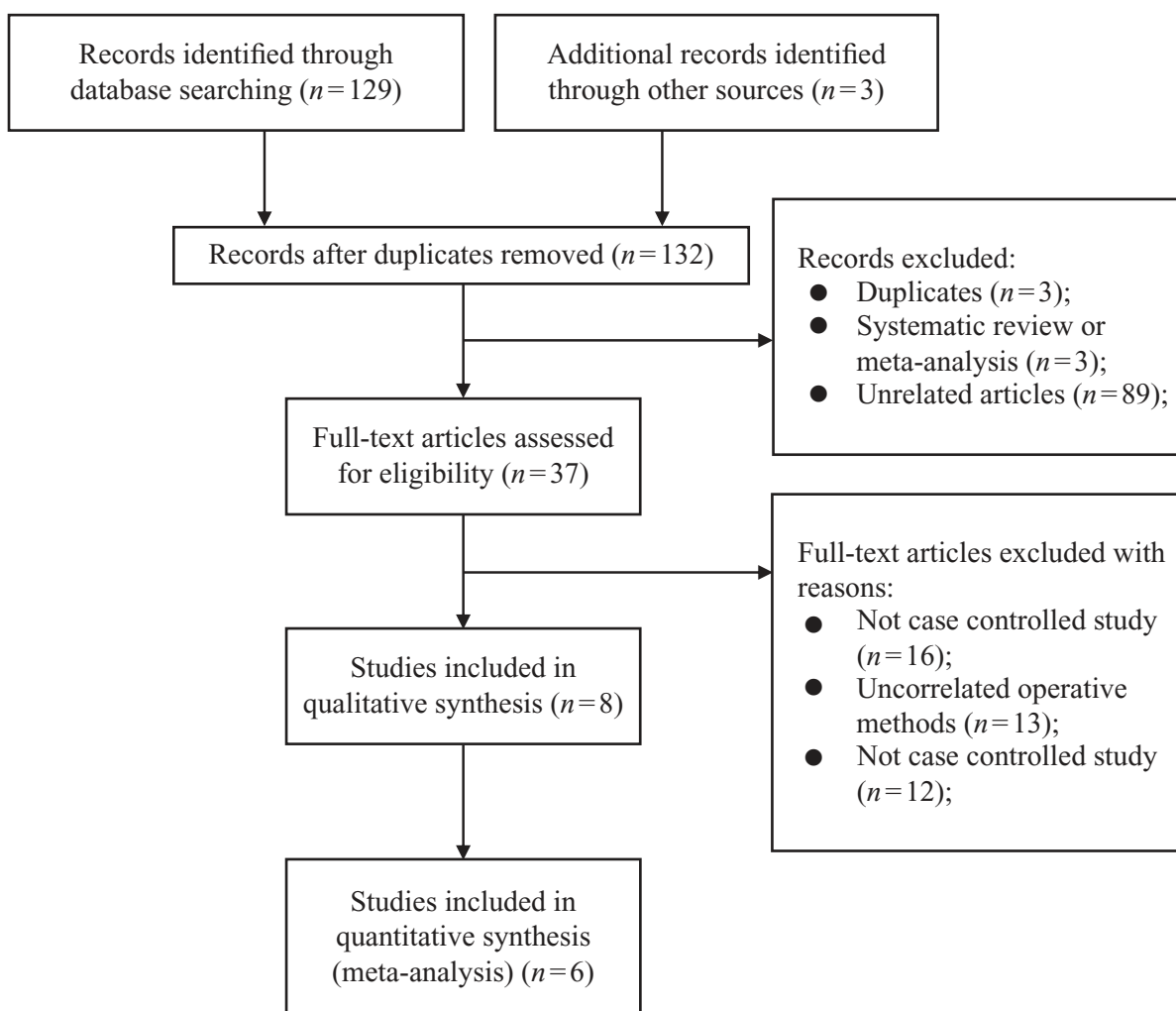


Figure 1. Flow diagram of search strategy.

The results showed that in PVP group and PKP group, preoperative VAS score (95% CI [-0.09, 0.45], $P = 0.19$), VAS score at 1–2 days after operation (95% CI [-0.20, 0.15], $P = 0.79$) and the last follow-up VAS score (95% CI [-0.18, 0.52], $P = 0.35$) was similar, and the difference was not statistically significant (Figure 5).

3.5. Cement volume

For 6 studies included we compared the amounts of cement injected between PVP and PKP procedures. Random effect model was employed in meta-analysis because the heterogeneity between the studies was significant ($I^2 > 50\%$). The meta-analysis showed that amounts of cement injected in PVP and PKP procedures were similar (95% CI [-0.82, 0.32], $P = 0.39$), there was no significant difference between the two groups (Figure 6).

3.6. Cement leakage

Seven studies included have compared the cases of cement leakage of PVP and PKP procedures. Fixed effect model was employed in meta-analysis with the absence of heterogeneity ($I^2 < 50\%$) among the seven study results. The meta-analysis showed that the occurrence of cement was similar between the two groups (95% CI [0.90, 2.76], $P = 0.11$), and the difference was not statistically significant (Figure 7).

3.7. Operation time

Five trials included have compared the operation time between PVP and PKP procedures. Random effect model was employed in meta-analysis because the heterogeneity between the studies was significant ($I^2 > 50\%$). The meta-analysis showed that the operation

Author	Study design	Group	Cases	Age (y)	Gender (M/F)	Outcomes	Newcastle-Ottawa Scale
Chen et al. 2012 ¹⁵	Retrospective	PVP	33	69.2 ± 6.3	4/29	D, E, F, G	★★★★★
		PKP	30	68.7 ± 6.5	3/27		
Feng and Sun 2018 ¹⁶	Retrospective	PVP	20	72.3 ± 5.4	12/28	A, B, C, D, E, F, G	★★★★★
		PKP	20				
Gao et al. 2016 ¹⁷	Retrospective	PVP	38	73 ± 6	20/18	B, C, D, F	★★★★★
		PKP	35	75 ± 6	16/19		
Li 2013 ¹⁸	Retrospective	PVP	7	71.8 ± 7.69	3/4	A, C, D, F	★★★★★
		PKP	5		2/3		
Shi et al. 2017 ¹⁹	Retrospective	PVP	10	75.1 ± 3.6	7/16	A, B, C, D, E, G	★★★★★
		PKP	13				
Yu et al. 2016 ²⁰	Retrospective	PVP	14	74.47 ± 5.79	5/9	A, B, C, D, E, F	★★★★★
		PKP	28	71.56 ± 8.35	9/16		
Yu et al. 2016 ²¹	Retrospective	PVP	48	74.6 (63–85)	10/38	A, B, C, D, E, F, G	★★★★★
		PKP	20	75.9 (65–87)	4/16		
Zhang et al. 2015 ²²	Retrospective	PVP	38	75.58 ± 4.97	10/28	B, D, E, F, G	★★★★★
		PKP	35	73.74 ± 4.35	9/26		

Note: Outcomes: A: Cobb angle; B: Anterior vertebral body height; C: ODI; D: VAS score; E: Cement volume; F: Cement leakage; G: Operation time.

Table 1. General characteristics of included studies.

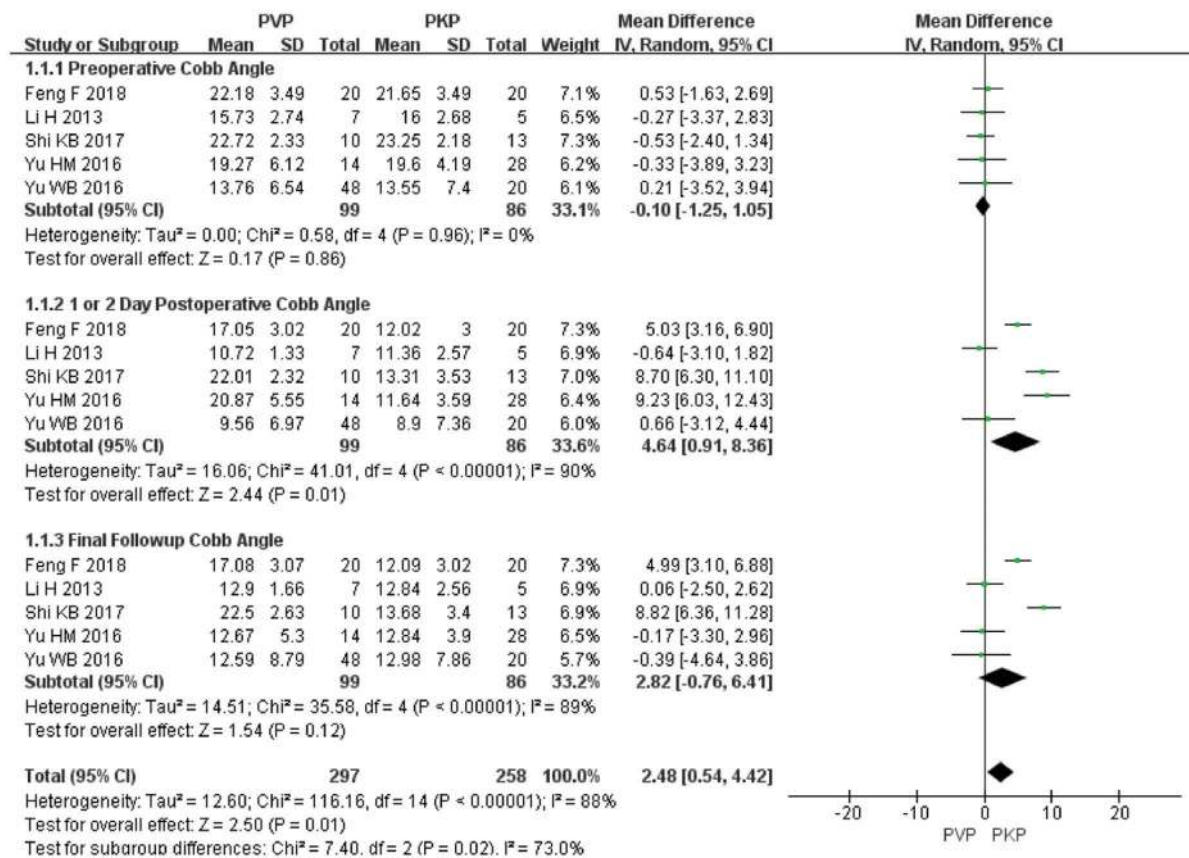


Figure 2. Forest plot to assess Cobb angle between two procedures.

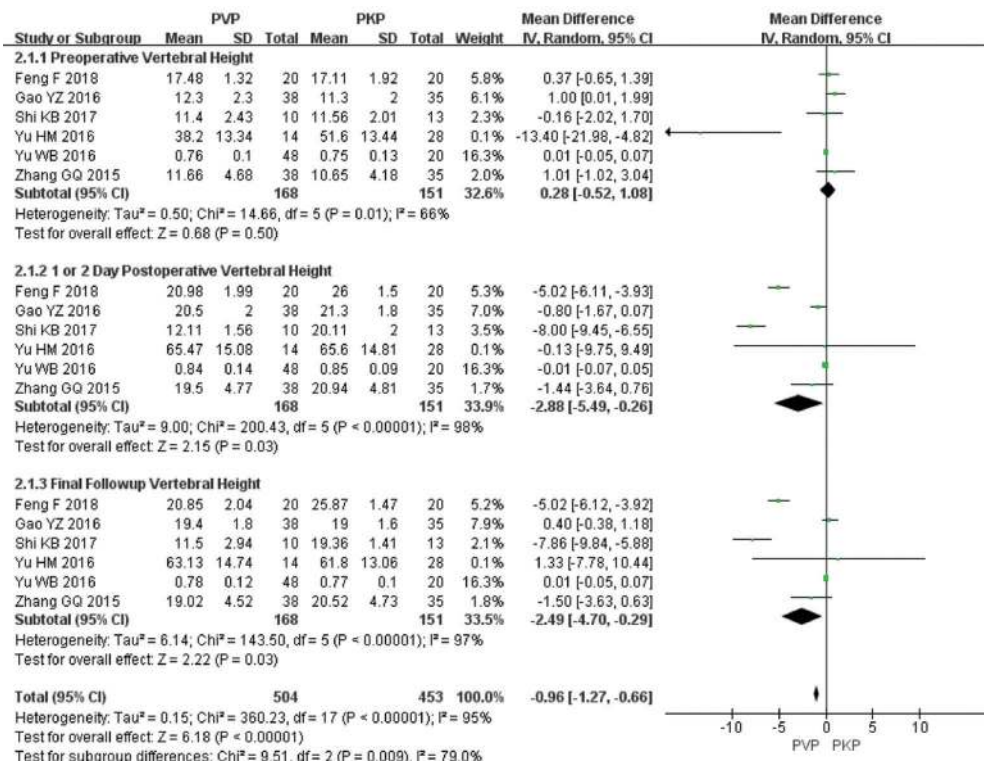


Figure 3. Forest plot to assess anterior vertebral body height between two procedures.

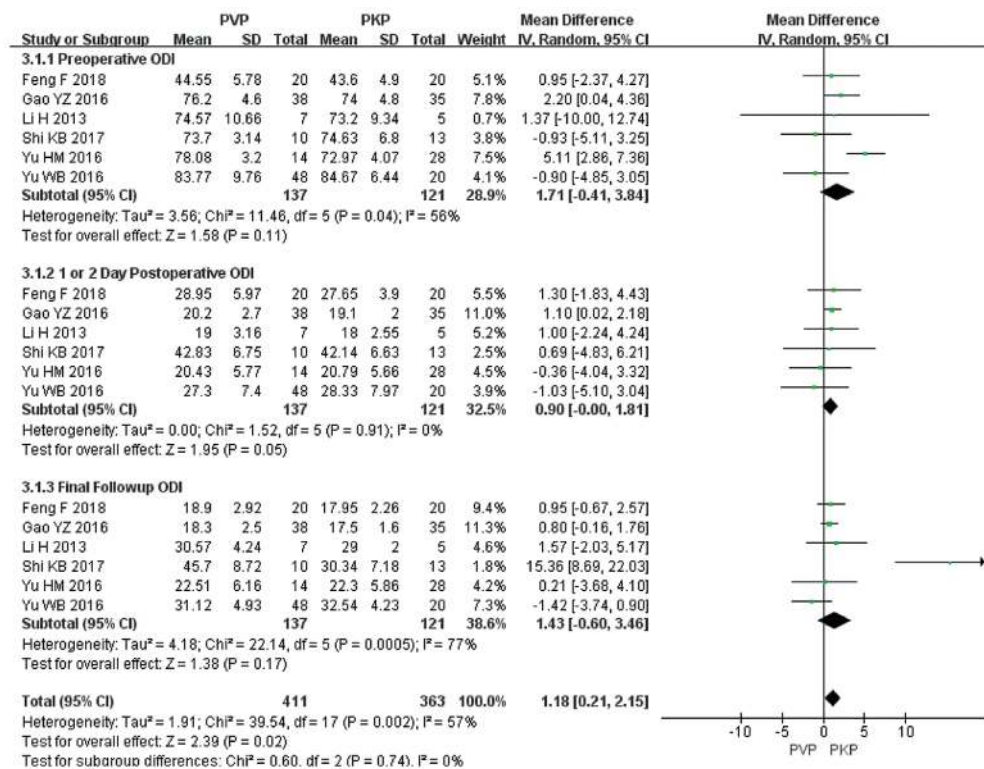


Figure 4. Forest plot to assess ODI between the two procedures.

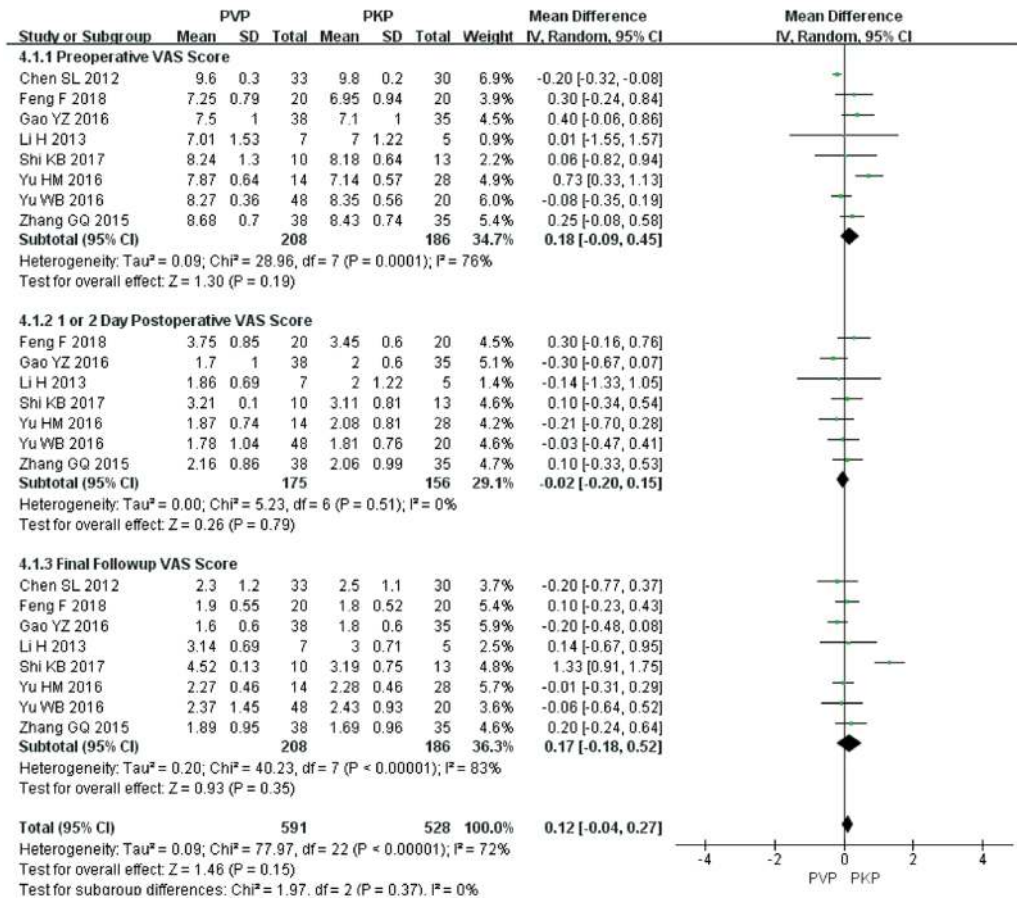


Figure 5. Forest plot to assess VAS score between the two procedures.

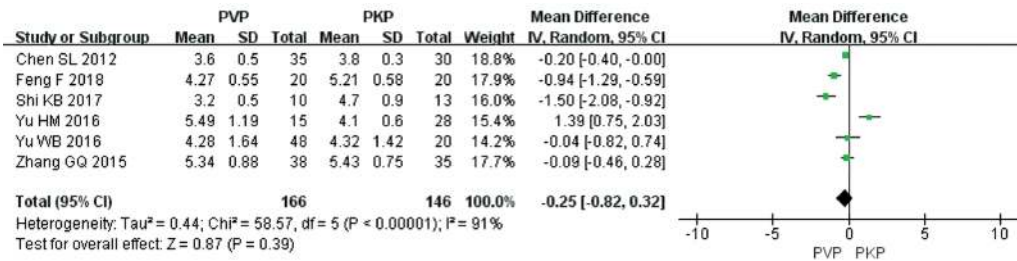


Figure 6. Forest plot to assess cement volume between two procedures.

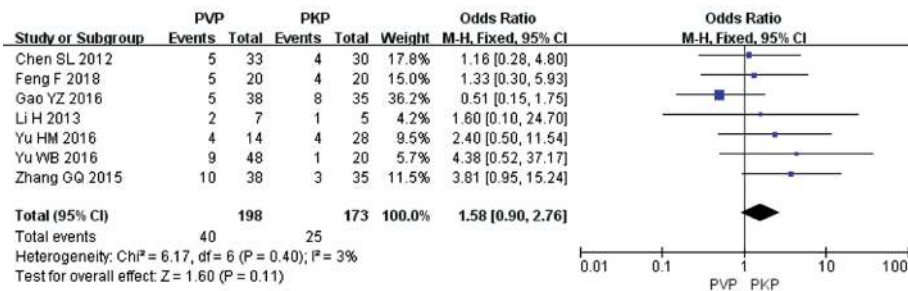


Figure 7. Forest plot to assess cases of cement leakage between the two procedures.

time required for PVP group was less than that in PKP group (95% CI [-13.48, -7.43], $P < 0.001$; Figure 8).

3.8. Publication bias

All the eight studies included in this meta-analysis had gone through a strict quality assessment. All of them were CCTs and the possibility of a bias was low. But the funnel figure showed that there was a small bias, which may be associated with the incomplete collection of relevant literature, insufficient sample size, and the different level of clinical physicians. Sensitivity analysis showed a good overall result (Figures 9 and 10).

Each risk of bias item is presented as a percentage across all included studies and indicates the proportional level for each risk of bias item.

Methodological quality of the included studies. This risk of bias tool incorporates assessment of randomization (sequence generation and allocation concealment), blinding (participants, personnel, and outcome assessors), completeness of outcome data, selection

of outcomes reported, and other sources of bias. The items were scored with “yes,” “no,” or “unclear.”

4. Discussion

Kümmell's disease is a special type of osteoporosis vertebra compressed fracture (OVCF),²³ which accounts for about 10% of OVCF.²⁴ It is reported few times due to the rare incidence and difficult diagnosis. However, as China enters an aging society with the explosion of the elderly population and advancement of imaging diagnostic technology, particularly the popularity of MRI has increased the reports of Kümmell's disease.²⁵ The main symptoms of Kümmell's disease are back pain with or without spinal cord injury.^{26,27} The disease progresses progressively, and due to the obvious vertebral body necrosis and collapse, it can lead to severe kyphotic deformity in the late stage, which has a higher incidence of nerve injury than common OVCF.^{28,29} Li et al. divided Kümmell's disease into three stages: in Stage I, vertebral body height reduction was $< 20\%$ without

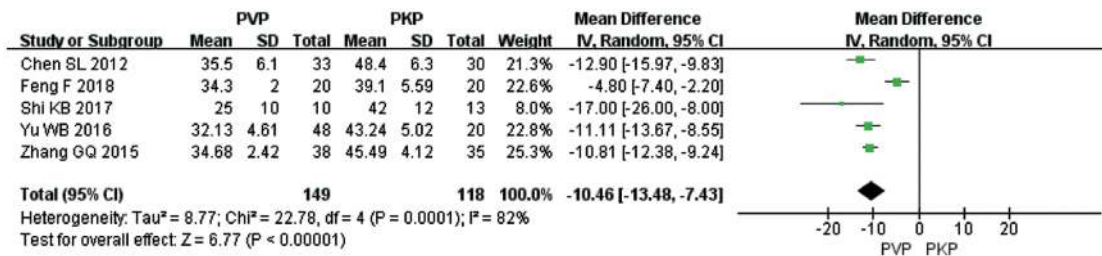


Figure 8. Forest plot to assess the operation time between the two procedures.

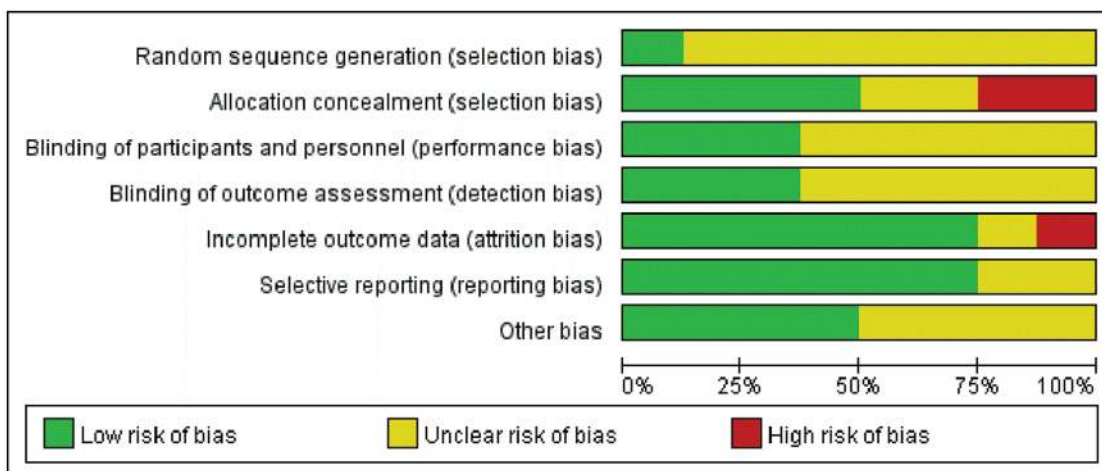


Figure 9. Risk of bias graph.

	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
Chen SL 2012	+	+	?	?	+	+	?
Feng F 2018	?	+	?	?	?	+	?
Gao YZ 2016	?	+	?	?	+	+	+
Li H 2013	?	?	+	+	+	?	+
Shi KB 2017	?	?	?	?	-	+	+
Yu HM 2016	?	-	+	+	+	+	?
Yu WB 2016	?	-	?	?	+	?	?
Zhang GQ 2015	?	+	+	+	+	+	+

Figure 10. Risk of bias summary.

adjacent disc degeneration; in Stage II, vertebral body height reduction was > 20%, often with adjacent disc degeneration; in Stage III, the posterior cortex of vertebrae ruptured with spinal cord compression.¹⁹ For stages I and II, PVP and PKP procedures are often used for vertebral bone cement treatment.^{30–32} But the vertebral body in stage III is incomplete due to posterior cortex collapse, and greater risk of cement leakage in vertebral canal exists during surgery, therefore open surgery is recommended.^{33,34} At present, PVP and PKP have become one of the most effective methods to treat vertebral tumors and OVCF^{35,36} (including Kümmell’s disease).

The purpose of this meta-analysis was to compare the efficacy of PVP and PKP in the treatment of Kümmell’s disease in Chinese patients. We selected seven outcomes including Cobb angle, vertebral body height, ODI, VAS score, amounts of cement injected, cement

leakage, and operation time and strive to fully compare the efficacy between the two procedures. By comparison, Cobb angle (95% CI [0.54, 4.42], $P = 0.01$), ODI (95% CI [0.21, 2.15], $P = 0.02$) and postoperative anterior vertebral body height (95% CI [-1.27, -0.66], $P < 0.001$) of the PKP group was better than PVP group and the difference was statistically significant. It indicates that there is no significant difference between the two groups in pain relief (VAS score), bone cement volume for injection and rate of leakage, but PKP is superior to PVP in terms of better functional improvement (ODI index), vertebral height recovery, and correction of kyphosis. However, the PVP group had less operation time than PKP group (95% CI [-13.48, -7.43], $P < 0.001$). PKP technology is an improved technology for PVP. By correcting kyphosis deformity through balloon dilation, bone cement can be injected at a lower pressure, but the operation time is longer than that of PVP due to the increase of operation steps. In summary, at this stage PKP has a clear edge over PVP in the treatment of Chinese Kümmell’s disease at I and II stage. Although there is no evidence to support that PVP is invalid, in some hospitals with limited technical conditions, PVP is still an effective treatment for Kümmell’s disease.

5. Conclusions

This systematic review included seven Chinese articles and one English article, and the methodological quality evaluation results were all high. Most studies were case–control studies. The purpose of this study is to compare the clinical efficacy of two cement augmentation procedures in Kümmell’s disease treatment at I and II stages in Chinese patients. Therefore, the patient’s informed consent, the choice of a specific treatment plan, the medical ethical issues, and the other inevitable bias also impact the reliability of the meta-analysis. In the same outcome measurements system, we include into the maximum of eight articles least of five and the heterogeneity between groups will increase. Therefore, the above conclusions still need to further verify depending on the emergence of RCTs with higher quality and larger sample sizes in the future.

Ethical approval

This study was approved by the ethics committee of Shanxi Medical University (IRB approval number: 201622083).

Conflicts of interest

All contributing authors declare no conflicts of interest.

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