



Comparison of clinical and radiological outcomes of vertebral body stenting versus percutaneous kyphoplasty for the treatment of osteoporotic vertebral compression fracture: A systematic review and meta-analysis

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Osteoporotic vertebral compression fractures (OVCFs) are common in the aging population, and there are approximately 1.7 million cases of OVCF in the USA and Europe annually. Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are well-established methods for treating OVCFs.^[1-3] Percutaneous kyphoplasty is considered a second-generation minimally invasive alternative to PVP due to its advantages in correcting Cobb angle and reducing cement leakage.^[4-6] However, studies have shown that PKP does not significantly improve vertebral body height and Cobb angle in

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ABSTRACT

Objectives: The study aimed to compare the efficacy and safety of percutaneous kyphoplasty (PKP) and vertebral body stenting (VBS) in the treatment of osteoporotic vertebral compression fractures (OVCFs) and evaluate the clinical efficacy, Cobb angle correction, and cement leakage associated with both methods for OVCFs.

Materials and methods: A systematic search was conducted in PubMed, EMBASE, Cochrane Library, Medline, China National Knowledge, and Wanfang Data for clinical studies comparing VBS with PKP for OVCF up to May 2023. The meta-analysis was performed using Review Manager 5.3, with a focus on evaluating clinical and radiologic outcomes.

Results: A total of eight eligible clinical studies were included in this meta-analysis. In terms of clinical outcomes, VBS was found to have a longer surgical time compared to PKP (standard mean difference [SMD]=1.06 min; 95% confidence interval [CI]: 0.20, 1.92; p=0.02). However, VBS demonstrated comparable blood loss to PKP (SMD=0.00 mL; 95% CI: -0.45, 0.45; p=0.99). Additionally, VBS showed slight superiority in alleviating back pain as measured by the Visual Analog Scale (VAS) (SMD=-0.38; 95% CI: -0.63, -0.12; p=0.004), as well as in improving functional disability based on the Oswestry Disability Index (ODI) (SMD= -0.28; 95% CI: -0.54, -0.03; p=0.03). Radiographically, VBS achieved better Cobb angle correction compared to PKP (SMD= -1.00; 95% CI: -1.48, -0.51; p<0.0001), while there was no significant difference in cement leakage between VBS and PKP (odds ratio=0.81; 95% CI: 0.21, 3.14; p=0.76).

Conclusion: The findings suggest that VBS has a comparable clinical outcome to PKP based on operation time, intraoperative blood loss, VAS, and ODI. Furthermore, VBS showed slightly better maintenance of Cobb angle correction, whereas VBS did not demonstrate a significant advantage over PKP in terms of cement leakage.

Keywords: Meta-analysis, osteoporosis vertebral compression fracture, percutaneous kyphoplasty, vertebral body stenting.

OVCF due to the deflation of the balloon before cement perfusion.^[7,8] Additionally, PKP is not effective in reducing endplate fractures, which are an independent risk factor for adjacent segment degeneration and the development of new symptomatic OVCF.^[3,9]

Muto et al.^[10] first reported the use of a vertebral body stenting (VBS) system for treating OVCF. They discovered that VBS effectively reduced vertebral body collapse and achieved significant height restoration (Figure 1). However, the superiority of VBS over PKP remains controversial. Several studies have demonstrated that VBS outperforms PKP in terms of kyphosis correction and reduction of vertebral body height.^[11-15] Nonetheless, Werner et al.^[16] conducted a randomized trial and found no beneficial effect of VBS over PKP regarding kyphotic correction, cement leakage, radiation time exposure, or neurologic injury. Hence, we performed a meta-analysis to

evaluate whether VBS is indeed superior to PKP in the treatment of OVCF, with the aim of providing substantial evidence for clinical decision-making.

MATERIALS AND METHODS

Search strategy

A systematically literature search was conducted in PubMed, EMBASE, Cochrane Library, Medline, China National Knowledge Internet, and Wanfang Data up to May 2023. The study was registered with PROSPERO (registration number CRD42023430990). No other systematic reviews focusing on VBS and PKP for OVCF were found in the PROSPERO database. The search strategy used the following formula: (((((vertebral body stenting system[Title/Abstract]) OR (VBS[Title/Abstract])) OR (vertebral body stenting[Title/Abstract])) OR (vertebral stenting[Title/Abstract])) OR (vertebral body stent system[Title/Abstract])) AND (((((percutaneous kyphoplasty[Title/

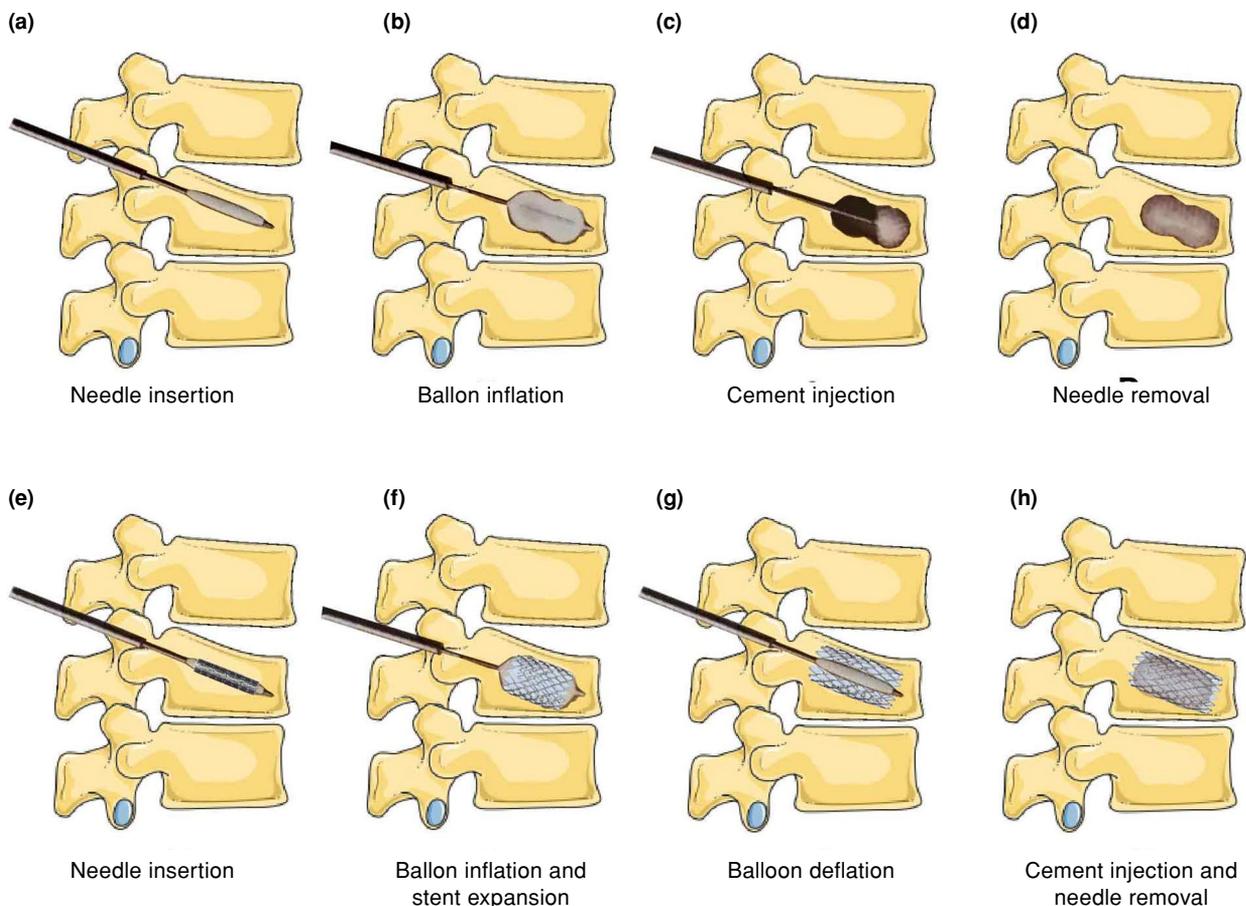


FIGURE 1. Schematic diagram illustrating PKP and VBS surgical procedures. (a-d), schematic diagram of PKP surgical steps. (e-h), schematic diagram of VBS surgical steps.

PKP: Percutaneous kyphoplasty; VBS: Vertebral body stenting.

Abstract)) OR (PKP[Title/Abstract])) OR (percutaneous balloon kyphoplasty[Title/Abstract])) OR (BKP[Title/Abstract])) OR (kyphoplasty[Title/Abstract])) OR (vertebral balloon plasty[Title/Abstract])) AND ((((((osteoporosis vertebral compression fracture[Title/Abstract]) OR (OVCF[Title/Abstract])) OR (OVF[Title/Abstract]))OR(osteoporosiscompressionfracture[Title/Abstract])) OR (osteoporotic fracture[Title/Abstract])) OR (osteoporotic vertebral fracture[Title/Abstract])).

The inclusion criteria for the publications were as follows: (i) participants were aged ≥ 18 years with OVCF, excluding non-OVCF or traumatic vertebral fracture; (ii) a comparison was made between the intervention methods of VBS and PKP; (iii) outcome parameters included operation time, blood loss, Oswestry Disability Index (ODI), Visual Analog Scale (VAS), Cobb angle, and cement leakage; (v) the study design was either a randomized controlled trial (RCT) or a cohort study. The exclusion criteria were as follows: (i) a comparison between VBS and PVP; (ii) duplicate articles or articles including the same patients and results; (iii) studies conducted on animals or cadavers.

Data extraction

According to the inclusion and exclusion criteria, two researchers independently screened the literature

by reviewing titles, abstracts, and full texts, and any disagreements were resolved through discussion. If there were any missing data, we contacted the corresponding author to obtain further information by email.

Statistical analysis

All extracted data were analyzed using Review Manager (RevMan version 5.3; Cochrane Collaboration, Oxford, UK). Heterogeneity was assessed using the I^2 statistic. An $I^2 < 50\%$ indicated no significant homogeneity among studies, and a fixed-effects model was used for analysis. An $I^2 < 50\%$ indicated homogeneity among studies, and a random-effect model was used for the analysis. Outcomes for continuous variables were expressed as standard mean difference (SMD) with 95% confidence interval (CI), and outcomes for dichotomous variables were expressed as odds ratio (OR) with 95% CI. A p -value < 0.05 was considered statistically significant.

RESULTS

Search results

A total of 237 studies were identified, with 228 acquired from the databases and nine from other sources. After screening for duplication, nonclinical

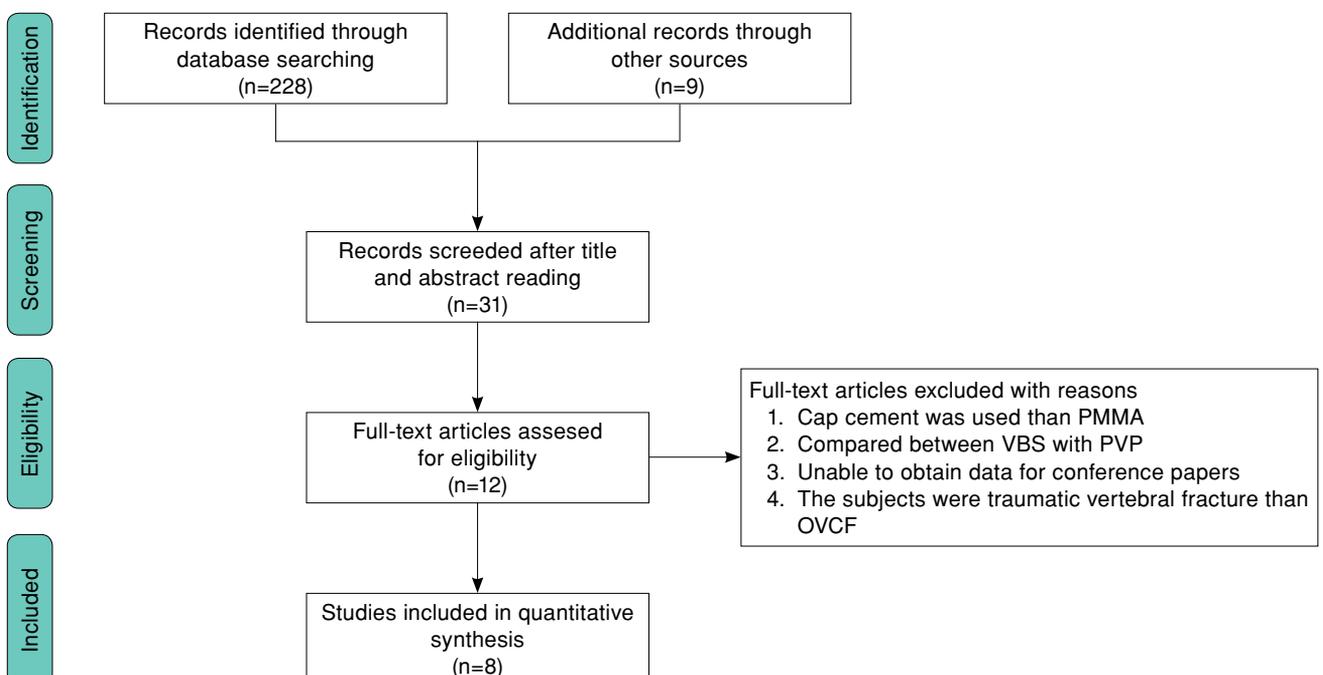


FIGURE 2. Flowchart of the study selection process in the meta-analysis.

PMMA: Poly (methyl methacrylate); VBS: Vertebral body stenting; PVP: Percutaneous vertebroplasty; OVCF: Osteoporotic vertebral compression fractures.

TABLE I
Characteristics of the included studies in the meta-analysis

Study and year	Location	Study period	Study design	Diagnosis	Sample size (n)			Mean age (year)		Follow up (month)	NOS
					VBS	PKP	VBS	VBS	PKP		
Werner et al. ^[16] (2014)	Switzerland	ND	Randomized control trial	OVCf	50	50	ND	ND	ND	Postoperation	NA
Jia et al. ^[22] (2018)	China	2014.1-2017.12	Retrospective cohort study	OVCf	20	24	65.50±7.98	69.67±6.98	6	6	6*
Ma et al. ^[11] (2020)	China	2017.1-2018.12	Retrospective cohort study	OVCf	15	25	76.8±9.92	72.84±7.53	ND	ND	7*
Xia et al. ^[23] (2022)	China	2020.1-2022.1	Retrospective cohort study	OVCf	40	40	72.3±9.7	74.6±9.4	6	6	6*
Zhang et al. ^[24] (2022)	China	2019.1-2020.12	Retrospective cohort study	OVCf	19	19	76.28±3.7	77.03±3.0	6	6	7*
Zhao et al. ^[12] (2022)	China	2019.1-2020.1	Retrospective cohort study	OVCf	30	32	69.00±2.63	68.41±2.30	14	14	7*
Wang et al. ^[21] (2023)	China	2019.7-2020.12	Retrospective cohort study	OVCf	36	47	68.78±6.281	67.81±6.233	>12	>12	7*
Zhao et al. ^[25] (2023)	China	2020.3-2022.3	Retrospective cohort study	OVCf	55	55	74.61±3.38	75.02±3.95	ND	ND	7*

VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; NOS: Newcastle-Ottawa Scale; ND: No described; NA: No applicable; OVCf: Osteoporotic vertebral compression fracture.

trials, reviews, meta-analyses, and other criteria, 236 studies were excluded based on title and abstract.

The full text of the remaining 31 studies was reviewed, and 19 additional studies were excluded for various reasons. Ultimately, eight studies were included in the present study. The flowchart depicting the literature selection process is presented in Figure 2.

Characteristics of studies

The eight included studies, published between 2014 and 2023, comprised one RCT and seven retrospective cohort studies. Based on the Newcastle-Ottawa Scale (NOS) assessment, all the studies were considered moderate-to-high quality. The total sample size consisted of 557 patients, with 265 in the VBS group and 292 in the PKP group. All patients were diagnosed with OVCf. The basic characteristics of the included studies are summarized in Table I.

Evaluation of literature quality

The quality of RCTs was evaluated using a modified version of the generic assessment tool as outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Figure 3). The NOS system was used to assess the quality of non-RCTs based on study population selection, comparability of parameters, and outcomes evaluation. Studies with more than five “stars” were included in the analysis (Table I).

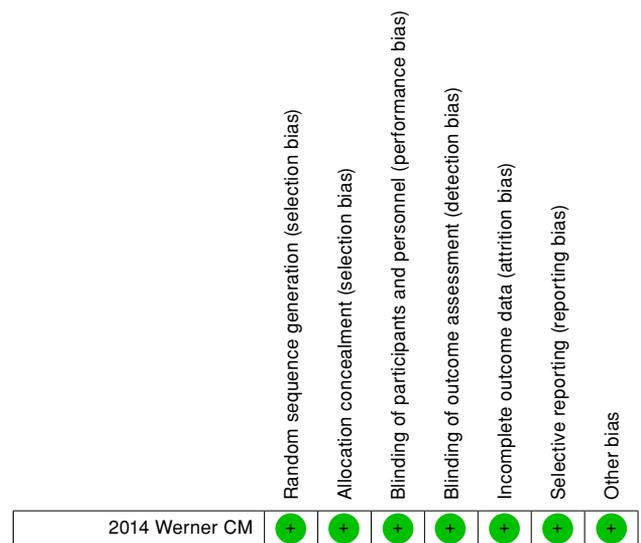


FIGURE 3. The summary of bias risk of RCTs.
RCTs: Randomized controlled trials.

Meta-analysis results

Clinical outcomes

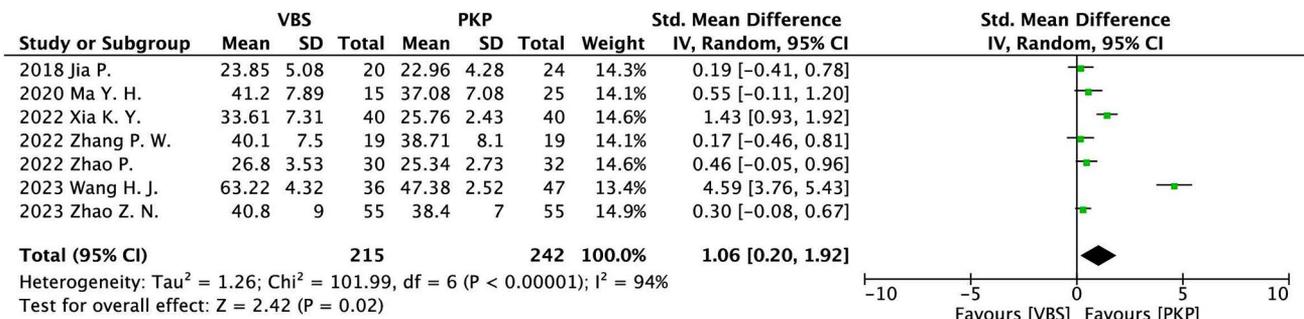
In terms of clinical outcomes, among the seven articles comparing the operation time of VBS and PKP, the meta-analysis included 215 patients in the VBS group and 242 patients in the PKP group. Vertebral body stenting was found to have a slightly longer surgical time compared to PKP (SMD=1.06 min; 95% CI: 0.20, 1.92; p=0.02; heterogeneity: Tau²=1.26, Chi²=101.99, degrees of freedom [df]=6, p<0.01, I²=94%; Figure 4a). In the five articles comparing intraoperative blood loss between VBS and PKP, a total of 165 patients were included in the VBS group and 186 patients in the PKP group. The results of the meta-analysis revealed no significant difference in blood loss between the two groups (SMD=0.00 mL; 95% CI: -0.45, 0.45; p=0.99; heterogeneity: Tau²=0.20, Chi²=16.85, df=4, p<0.01, I²=94%; Figure 4b).

Visual Analog Scale for back pain was reported in seven articles. Among the six studies reporting preoperative VAS for back pain, no significant difference was observed (SMD= -0.03; 95% CI: -0.22, 0.16; p>0.05; heterogeneity: Tau²=0.00, Chi²=2.52, df=5, p>0.05, I²=0%). There were five, two, two, and

seven studies that reported VAS for back pain at three postoperative days, one postoperative month, three postoperative months, and the final follow-up, respectively. Meta-analysis showed no significant difference at any of these time points. However, when tested for the overall effect, VBS showed slight superiority in alleviating back pain as measured by VAS (SMD= -0.38; 95% CI: -0.63, -0.12; p=0.004; Figure 5).

There were two, three, five, and two studies that reported outcome data for ODI at three postoperative days, one postoperative month, three postoperative months, and the final follow-up time, respectively. Meta-analysis revealed no significant difference at three days, three months, and the last follow-up postoperatively. However, VBS showed a slight improvement in ODI compared to PKP at one month (SMD= -0.81; 95% CI: -1.27, -0.35; p<0.05; heterogeneity: Tau²=0.03, Chi²=1.35, df=1, p>0.05, I²=26%). In the test for overall effect, VBS demonstrated a slight advantage in improving functional disability as measured by the ODI (SMD= -0.28; 95% CI: -0.54, -0.03; p=0.03; Figure 6). Clinically, the slight difference in operation time, VAS, and ODI between the two methods was almost negligible.

(a) Operation time (minutes)



(b) Blood loss (mL)

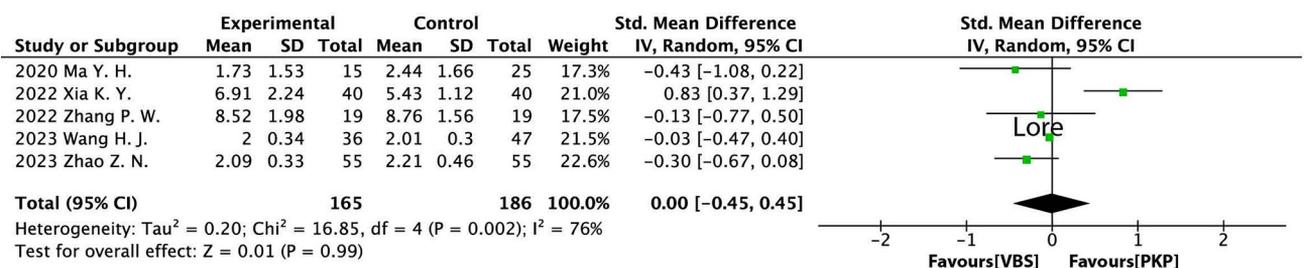


FIGURE 4. Forest plots comparing the operation time and blood loss between VBS and PKP.

VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; SD: Standard deviation; CI: Confidence interval.

Radiologic outcomes

Cobb angle was reported in six articles, with Cobb angle measurements available at different time points. Specifically, six articles reported Cobb angle before the operation, four articles at three postoperative days, two articles at one postoperative

month, three articles at three postoperative months, and six articles at the last follow-up. There was no significant difference in Cobb angle at one month and three months. However, VBS showed better Cobb angle correction at three days (SMD= -0.73; 95% CI: -0.98, -0.48; p<0.01; heterogeneity: Tau²=0.00,

VAS

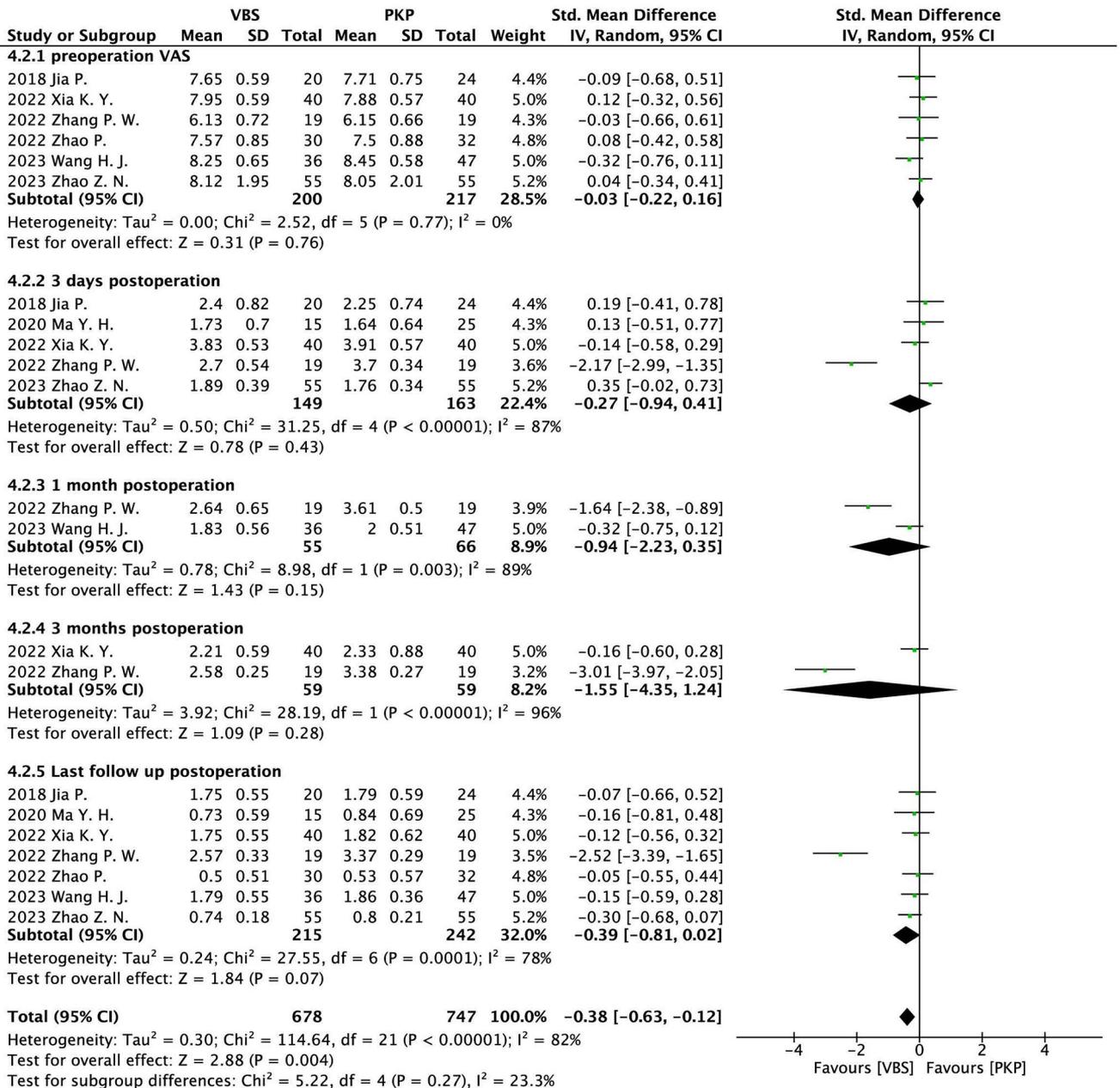


FIGURE 5. Forest plots comparing improvement in VAS for pain before the operation, three postoperative days and at one postoperative month, three postoperative months, and the last follow-up time between VBS and PKP.
 VAS: Visual Analog Scale; VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; SD: Standard deviation; CI: Confidence interval.

Chi²=2.13, df=3, p>0.05, I²=0) and the last follow-up (SMD= -1.76; 95% CI: -3.06, -0.46; p<0.01; heterogeneity: Tau²=2.52, Chi²=125.21, df=5, p<0.05, I²=96%; Figure 7). The difference in Cobb angles at the final follow-up between the two operations can be considered clinically significant, although the precise cut-off is unknown.

In addition, cement leakage was reported in three studies, and the analysis showed no significant difference between VBS and PKP (OR=0.81; 95% CI:

0.21, 3.14; p>0.05; heterogeneity: Tau²=0.09, Chi²=5.34, df=2, p>0.05, I²=63%; Figure 8).

Publication bias and sensitivity analysis

Funnel plots were constructed to assess publication bias for all the parameters and all funnels were relatively asymmetric (Supplementary Figures 1-3). Sensitivity analysis was performed by randomly excluding one study at a time, and the results remained stable after removing any of the included studies.

ODI (%)

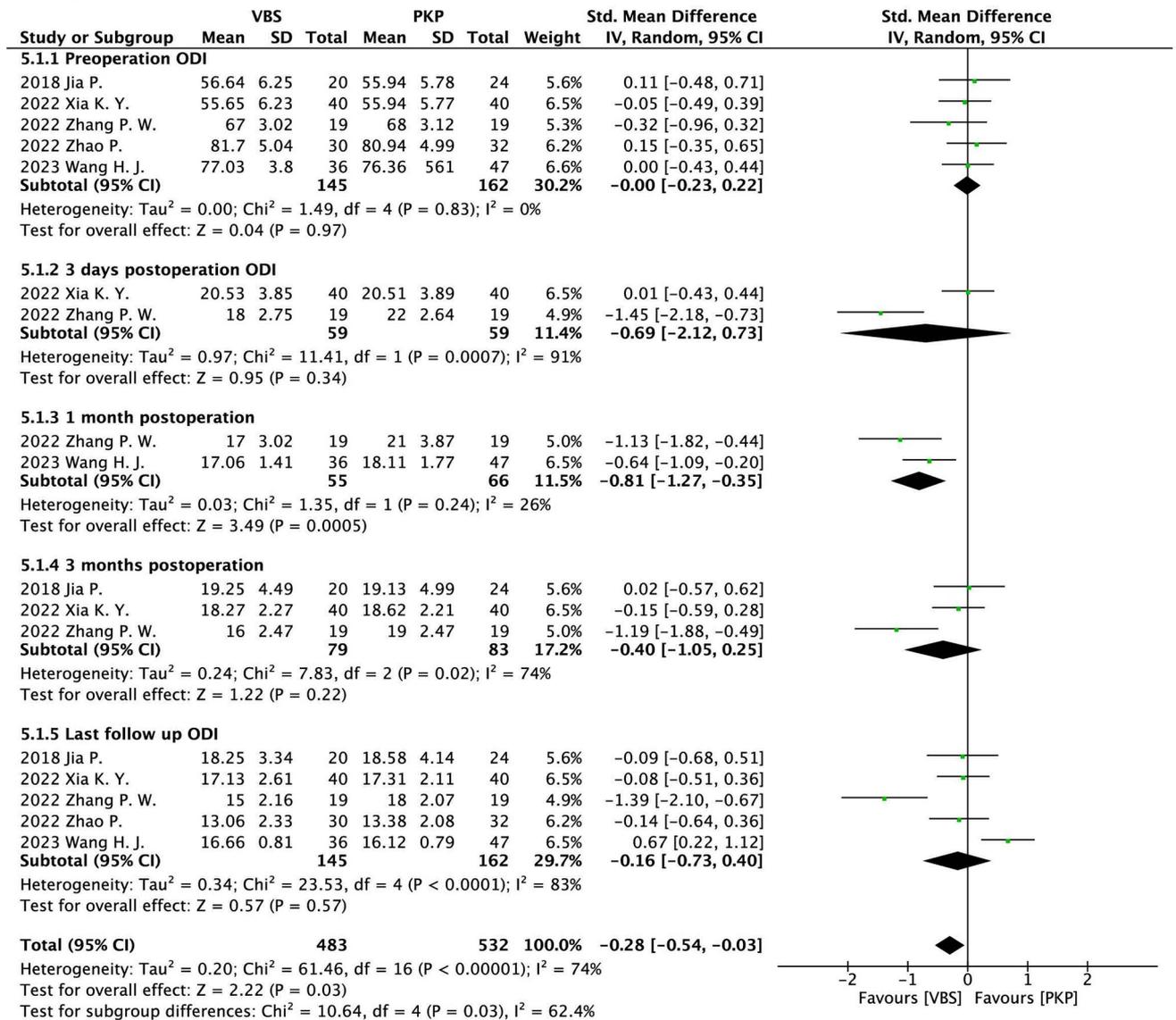


FIGURE 6. Forest plots comparing improvement in ODI for functional disability before the operation and at three postoperative days, one postoperative month, three postoperative months, and the last follow-up time between VBS and PKP. ODI: Oswestry Disability Index; VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; SD: Standard deviation; CI: Confidence interval.

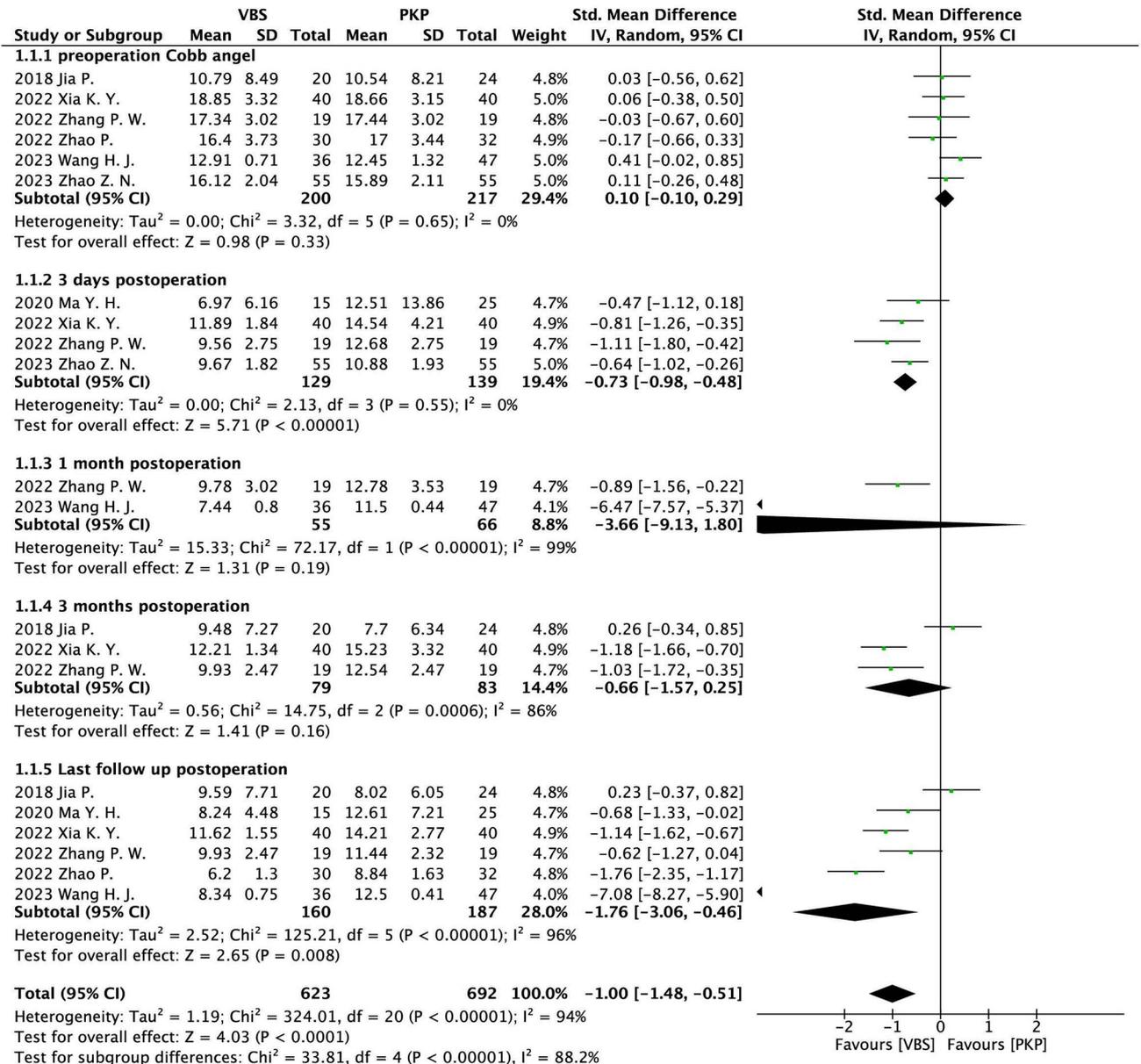


FIGURE 7. Forest plots comparing improvement in Cobb angle before the operation and at three postoperative days, one postoperative month, three postoperative months, and the last follow-up time between VBS and PKP.

VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; SD: Standard deviation; CI: Confidence interval.

Cement leakage

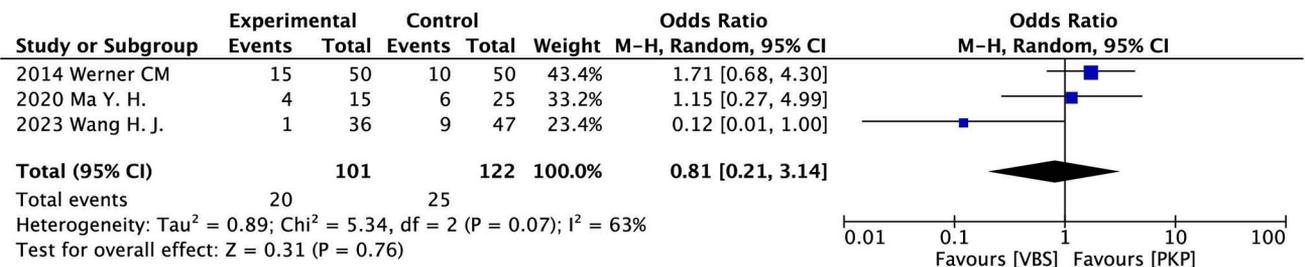


FIGURE 8. Forest plots comparing bone cement leakage between VBS and PKP.

VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; CI: Confidence interval.

DISCUSSION

Percutaneous kyphoplasty has been widely utilized as a popular minimally invasive treatment for OVCF and has demonstrated favorable clinical outcomes.^[17] In theory, PKP offers advantages, such as reduced cement leakage, increased vertebral body height, and improved Cobb angle correction, attributed to the use of balloon inflation before cement perfusion compared to PVP. However, studies have reported unsatisfactory Cobb angle correction and limited vertebral body height reduction with PKP due to balloon deflation before cement perfusion.^[7,9,18,19] Feltes et al.^[7] conducted a retrospective study evaluating pain relief and vertebral body height restoration through PKP, finding excellent pain relief but limited improvement in vertebral body height restoration. Voggenreiter^[18] also observed a significant loss of fracture reduction after balloon tamp deflation and removal, as assessed by kyphosis angle, anterior height, and medial height of the fractured vertebral body. Therefore, the expected spinal realignment cannot be well achieved by PKP,^[14] resulting in a higher risk of adjacent vertebral body fracture recurrence.^[19] In response to these drawbacks, various efforts have been made to develop new devices that prevent the loss of restored fractured vertebral body height after balloon deflation during PKP.^[14,20] A cadaver study has shown better results for a metallic implant known as VBS in terms of vertebral augmentation and height restoration compared to PKP.^[14] Vertebral body stenting uses a specially designed catheter-mounted stent that can be implanted and expanded within the vertebral body, remaining in place after balloon deflation to prevent collapse of the vertebral body height.

Wang and Wang^[21] reported a significantly longer operation time for VBS compared to PKP. Although other studies found no significant difference in operation time between VBS and PKP for OVCF, the mean operation time recorded in all these studies was longer for VBS than for PKP.^[11,12,22-25] In our meta-analysis, the operation time for VBS is slightly longer than that of PKP. This finding is expected since the VBS procedure involves a thicker puncture needle and a metal bracket on the sleeve, which requires surgeons to exercise greater caution when placing the catheter and expanding the balloon compared to PKP. While the blood loss in VBS was comparable to that in PKP, in our opinion, the thicker puncture needle and cannula used in VBS, along with the longer operation time, may result in slightly more bleeding compared to PKP. Surprisingly, the meta-analysis did not show a significant difference in blood loss

between VBS and PKP. Only Xia et al.^[23] reported a slightly higher mean bleeding volume in VBS (6.9 mL) compared to PKP (5.43 mL), while the difference was not statistically significant. This discrepancy may be attributed to both VBS and PKP being minimally invasive surgeries with minimal bleeding, and the estimation of bleeding volume by surgeons may be subjective and prone to significant error.

Despite both VBS and PKP being widely used for the management of painful OVCF, it remains uncertain whether VBS achieves comparable clinical outcomes to PKP. Unlike PKP, VBS retains the expanded metallic stent within the fractured vertebral body after balloon deflation and withdrawal. Zhang et al.'s^[24] study showed that VBS acquired better clinical outcomes than PKP based on the evaluation of VAS and ODI. However, several other studies have shown no significant difference in clinical outcomes between VBS and PKP.^[11,12,21,22,25] Our meta-analysis indicated that the clinical effect of VBS is equivalent to that of PKP, which is consistent with the majority of the previous cohort studies.

Currently, the existence of significant differences between VBS and PKP in kyphosis correction remains controversial. Werner et al.^[16] found no superior benefits of VBS over PKP regarding kyphotic correction, and VBS was associated with higher pressures during balloon inflation and increased material-related complications. Conversely, Ma et al.^[11] found that VBS achieved better kyphosis correction compared to PKP, consistent with several other studies.^[12,21,24] Our analysis revealed that VBS achieved better Cobb angle correction at three postoperative days and the last follow-up compared to PKP, which had statistically significant differences. However, no significant difference was observed at one month and three month postoperatively. In VBS, the stent expands along with the balloon inflation. After the balloon is withdrawn, the stent still plays a supporting role inside the vertebral body, maintaining the height of the vertebral body.^[14,26] Once the stent is reinforced with bone cement, its strength significantly increases, reducing the risk of postsurgical vertebral collapse.^[27] Although PKP is an effective surgical method for correcting vertebral kyphosis, the reduction achieved cannot be sustained after balloon deflation due to the presence of osteoporosis, resulting in "secondary collapse" and partial loss of vertebral height.^[14] Therefore, VBS may surpass PKP in terms of vertebral height restoration and kyphosis deformity correction.

While PKP was designed to reduce the incidence of cement leakage observed in PVP,^[4] instances of cement leakage still occur in PKP.^[28-30] Whether VBS could decrease the incidence of cement leakage is controversial. Werner et al.^[16] found no significant advantage of VBS over PKP with regard to cement leakage. Ma et al.^[11] also found that although VBS can inject a larger volume of bone cement than PKP, there is no difference in the incidence of cement leakage. However, Wang and Wang^[21] discovered that compared to PKP, the VBS group had a higher amount of bone cement injection and a significantly reduced bone cement leakage rate. In our meta-analysis, cement leakage was observed in 19.8% of the vertebral levels treated with VBS and 20.5% of those treated with PKP, but this difference was not significant. The included literature in our study recorded cement leakage rates ranging from 2.8 to 30% in the VBS group and from 19.1 to 24% in the PKP group. These discrepancies may stem from the different evaluation methods used in different studies. Werner et al.^[16] used CT evaluation, while Ma et al.^[11] and Wang and Wang^[21] utilized X-ray evaluation. The viscosity of bone cement is closely related to the leakage rate. Wang et al.^[31] found that high-viscosity bone cement led to a lower cement leakage rate in PVP/PKP compared to low-viscosity bone cement in any location, including disc space, epidural space, paravertebral area, and peripheral vein. Other complications were only reported in one study,^[16] which identified that VBS had more complications than PKP, with most of the complications in VBS being material-related, such as failure of the working cannulas, incomplete or no opening of the stent, and balloon rupture. Notably, no postoperative neurologic sequelae were observed in either the VBS or PKP group.

This meta-analysis has certain limitations. First, all the studies included in this analysis were single-center cohort studies, primarily conducted in China, which limits their generalizability to other ethnic groups. Second, there was significant heterogeneity among several parameters across the included studies. Third, there is a lack of high-quality RCTs in this paper. Considering these limitations, further research involving high-quality multicenter studies is necessary to more comprehensively compare the differences between VBS and PKP.

In conclusion, the findings suggest that although there is a statistically significant difference in VAS and ODI, the differences are very minor. Only the Cobb angle correction between the two methods at the last follow-up time has clinically significant difference. No difference was observed in operation

time and cement leakage with VBS compared to PKP. The findings suggest that both VBS and PKP yield similar clinical outcomes in terms of VAS and ODI. However, VBS exhibits an advantage in maintaining Cobb angle correction despite its longer operation time.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Participated in the study conception and design: T.Z., J.L.; Performed the systematic literature search, analyzed the data, drafted the manuscript and conducted the statistical review: T.Z., Y.X.P.; Critically reviewed the manuscript. All authors read and approved the final manuscript: J.L.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

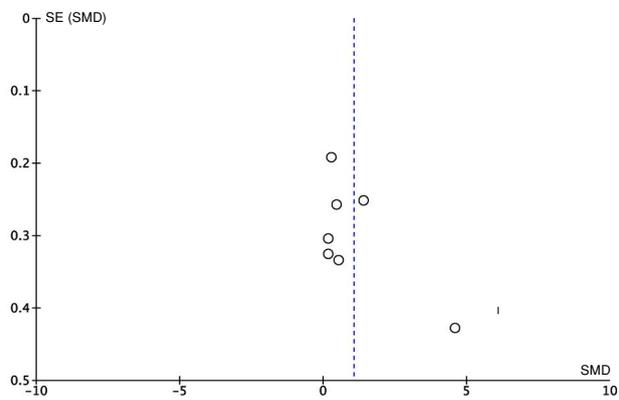
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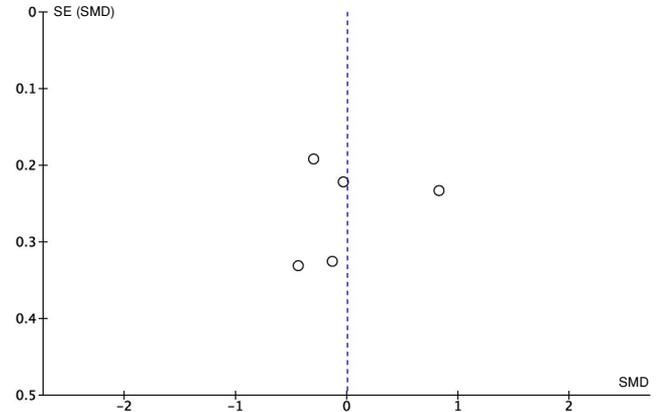
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(a) Operation time



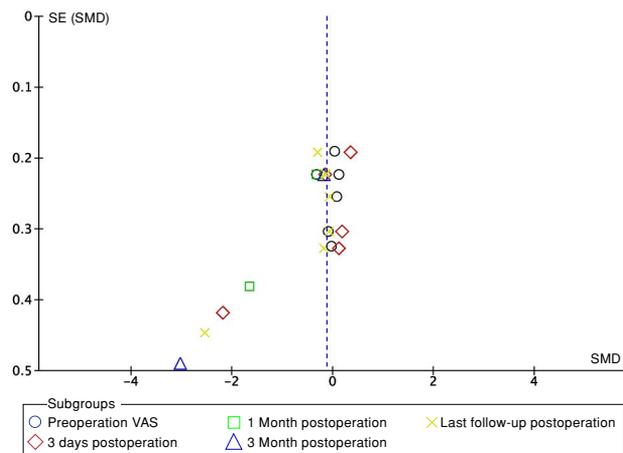
(b) Blood loss



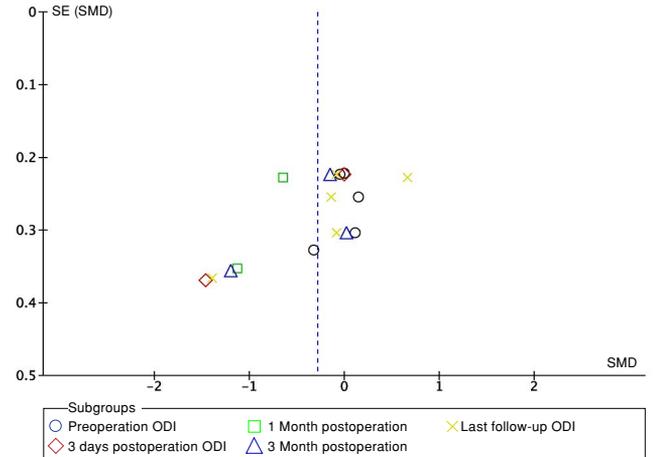
SUPPLEMENTARY FIGURE 1. Funnel plots of publication bias in operation time and intraoperative blood loss between VBS and PKP.

SE: Standard error; SMD: Standard mean difference; VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty.

(a) VAS



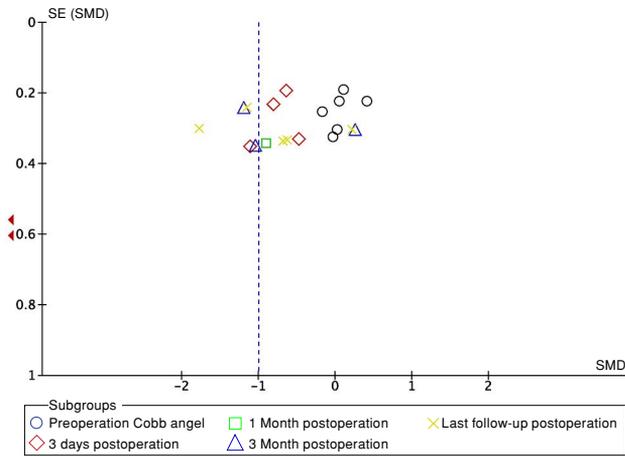
(b) ODI



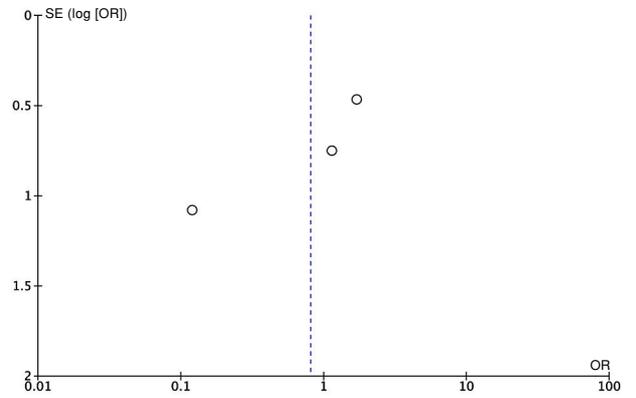
SUPPLEMENTARY FIGURE 2. Funnel plots of publication bias in improvement in VAS for pain and improvement in the ODI scores for functional disability between VBS and PKP.

VAS: Visual Analog Scale; ODI Oswestry Disability Index; SE: Standard error; SMD: Standard mean difference; VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty.

(a) Cobb angle



(b) Cement leakage



SUPPLEMENTARY FIGURE 3. Funnel plots of publication bias in the correction of the Cobb angle and bone cement leakage between VBS and PKP.

SE: Standard error; SMD: Standard mean difference; VBS: Vertebral body stenting; PKP: Percutaneous kyphoplasty; OR: Odds ratio.