

ORIGINAL ARTICLE

Comparison of the efficacy and safety of unilateral and bilateral approach kyphoplasty in the treatment of osteoporotic vertebral compression fractures: A meta-analysis

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Osteoporosis, a metabolic bone disease, has attracted widespread attention globally in recent years. It often stems from osteopenia, involves changes in bone microstructure, and makes bones prone to fracture.^[1] Osteoporotic vertebral compression fractures (OVCFs) commonly occur in the lower thoracic and lumbar vertebrae.^[2] As a prevalent complication of osteoporosis, the incidence of OVCFs is increasing annually in tandem with societal ageing.^[3] The incidence in women is 8% at the age of 50 and rises to 27% by the age of 80.^[4] Patients with OVCFs receiving conservative treatment are not exempt from complications that can substantially impact

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ABSTRACT

Objectives: The study aimed to compare the efficacy and safety of unilateral versus bilateral percutaneous kyphoplasty (PKP) in treating osteoporotic vertebral compression fractures.

Materials and methods: Adhering to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, three English-language databases were systematically reviewed: PubMed, Web of Science, and the National Library of Medicine. The search was conducted between their inception and January 1, 2023. Studies that were replications or that used regression analysis were excluded. Randomized controlled trials and cohort studies that met the criteria were included, and a meta-analysis was performed.

Results: The mean follow-up duration was 17.9 ± 9.7 months for the unilateral group and 18.4 ± 8.3 months for the bilateral group. Eight randomized controlled trials and four cohort studies were included, comprising a total of 1,391 patients (499 males, 697 females; 195 cases did not report sex; mean age: 70.9 years; range, 45 to 82 years). Of these patients, 710 underwent the unilateral surgical approach and 681 the bilateral approach. The meta-analysis revealed that the long-term VAS was marginally higher in the unilateral PKP group (mean difference [MD]=0.09; 95% confidence interval [CI]: 0.06-0.13; p<0.001). The unilateral group also demonstrated a greater recovery rate in the postoperative kyphosis angle (MD=2.27; 95% CI: 0.67-3.87; p=0.006), shorter operation duration (MD=18.56 min; 95% CI: 8.96-28.17; p<0.001), and a lower bone cement dosage (MD=1.20 mL; 95% CI: 0.39-2.01; p=0.004).

Conclusion: Unilateral PKP appears equally effective as bilateral PKP for treating osteoporotic vertebral compression fractures but with advantages in terms of procedure time, cement use, and pain reduction.

Keywords: Bilateral approach; kyphoplasty; osteoporosis; unilateral approach, vertebral compression fracture.

their health.^[5] Two-thirds of these patients find symptom relief after four weeks of conservative treatment,^[6] whereas those who do not find relief may require further surgical intervention. Currently, in treating OVCFs, percutaneous vertebroplasty and percutaneous kyphoplasty (PKP) are prominent minimally invasive surgical techniques. Both procedures are comparable in terms of pain relief. However, research indicates that PKP has a lower bone cement leakage rate and achieves better kyphosis angle recovery than percutaneous vertebroplasty.^[7,8] Consequently, PKP is increasingly recognized in spine surgery for its precision advantages and is now considered the preferred solution for OVCFs.^[9]

Traditional PKP is often performed using a bilateral double-balloon technique.^[10] Recently, the unilateral single-balloon technique has been developed and is considered to offer similar vertebral height and hardness recovery as the bilateral method.^[11] It also provides the benefits of a shorter operation time and reduced bone cement consumption.^[12] A meta-analysis by Qiao et al.^[13] reported that compared to the bilateral approach, the unilateral method reduces operation time and cement injection, making it a safer option for elderly patients; however, the analysis of other outcome indicators remains inconclusive.

There is currently considerable debate in clinical practice regarding whether it is preferable to establish a channel through one pedicle (the unilateral approach) or two pedicles (the bilateral approach).^[14] Each approach has its own set of advantages and disadvantages, and no consensus has been reached.^[15] Consequently, this paper aimed to collect and analyze published PKP-related literature, updating it to encompass a broader range of outcome indicators. The objective is to conduct a comprehensive systematic evaluation and meta-analysis of the efficacy and safety of both unilateral and bilateral approaches in treating OVCFs through kyphoplasty. This will provide robust medical evidence to inform clinical practice.

MATERIALS AND METHODS

Literature search strategy

Adhering to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, three English-language databases were systematically searched: PubMed, Web of Science, and the National Library of Medicine. The search covered the period between their inception and January 1, 2023. We used a combination of subject words and free words for the search. The keywords included the following: "kyphoplasty OR percutaneous kyphoplasty," "unilateral approach," "bilateral approach," and "compression fracture OR vertebral compression fracture OR OVCF OR spinal fracture OR vertebral fractures."

Literature inclusion and exclusion criteria

The inclusion criteria included the following: (i) randomized controlled trials (RCTs) and cohort studies comparing the unilateral versus bilateral PKP techniques for treating OVCFs; (ii) individuals diagnosed with OVCFs via relevant imaging examinations; (iii) undergoing kyphoplasty; and (iv) having evaluated operation time, bone cement injection volume, Visual Analog Scale (VAS) score, Oswestry Disability Index (ODI) score, the recovery rate of the kyphosis angle, the recovery rate of anterior vertebral height, vertebral height loss rate, bone cement leakage, or postoperative adjacent segment fractures. The exclusion criteria included the following: (i) studies involving infection, tumor-derived fractures, nerve compression, nerve injury, spinal stenosis, secondary surgery at the same segment, and long-term use of steroids or similar drugs in described cases; (ii) studies on vertebral fractures caused by combined nerve injury and nonosteoporotic fractures; (iii) studies lacking specific outcome measures; (iv) review studies; (v) animal studies and replication studies.

Literature screening and data extraction

The literature was independently screened by two investigators. The initial screening involved reviewing titles and abstracts, followed by a secondary screening, which entailed a full-text reading and evaluation against the inclusion and exclusion criteria. In cases of disagreement, a third investigator's opinion was sought to reach a consensus through discussion. Following the literature screening, data such as the first author, year of publication, country of publication, study type, number of cases (unilateral/bilateral), basic patient characteristics (sex and age), follow-up time, and outcome measures were independently extracted by the two investigators.

Outcome measures

The primary outcome measures included shortand long-term VAS scores, bone cement leakage rate, postoperative adjacent segment fractures, and recovery rates of anterior vertebral height and kyphosis angle. The secondary outcome measures included operation time, bone cement injection volume, and medium- and long-term ODI scores. In cases where data were not available in a conventional format in the original text, data conversion was performed following the

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guidelines in the Cochrane Handbook. Short-term follow-up was defined as <4 weeks, medium-term follow-up as four weeks to six months, and long-term follow-up as >6 months.

Literature quality assessment

The quality of the literature was assessed using the Jadad scale. Studies with a score >3 were considered to meet the inclusion criteria, whereas studies with a score of <3 were deemed low quality and excluded.^[16] Literature meeting the inclusion criteria was classified and further assessed.

The Newcastle-Ottawa Scale (NOS) was employed for the quality evaluation of the included cohort studies, focusing on selection, comparability, and exposure or outcome. The total possible score on this scale is 9 points, with 1 point awarded for meeting specific scoring criteria. Studies scoring <5 were classified as low quality, whereas those with scores >5 were considered high quality. Studies with NOS scores <5 were excluded from the metaanalysis.^[17]

Statistical analysis

The meta-analysis was conducted using Review Manager version 5.3 software. For measurement data, the mean difference (MD) was used as the effect indicator, whereas for count data, the relative risk was employed. Effect sizes were presented as point estimates with 95% confidence intervals (CIs). The I^2 test assessed heterogeneity, with $I^2 < 50\%$ or p>0.1 suggesting homogeneity in the included literature, which was then analyzed using the fixed effects model (Mantel-Haenszel). Conversely, values of $I^2 > 50\%$ or p<0.1 indicated heterogeneity among the studies, prompting analysis using the random effects model (DerSimonian-Laird). The significance level for the meta-analysis was set at p<0.05.

RESULTS

Literature search results

In total, 437 literature items were retrieved from the databases. Of these, 45 replication studies and 276 systematic reviews, case reports, and other studies were excluded. Following the inclusion and exclusion criteria, studies lacking clear diagnostic criteria were also excluded after reviewing the full text. Consequently, 12 literature items were ultimately included in the meta-analysis.^[6,18-28] The flowchart of the literature screening process is depicted in Figure 1.

Basic characteristics of the literature and assessment of literature quality

The 12 included literature items were published between 2008 and 2022; eight of these were RCTs,

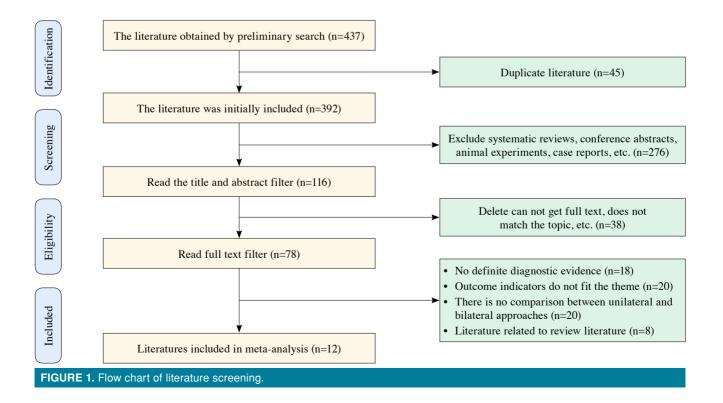


						TABLE	Ū.						
			Basic chara	cteristic indi	cators and	literature qu	uality evalu	Basic characteristic indicators and literature quality evaluation level included in the study	Included in t	he study			
	Year of publication	Study design	Country of publication	Number of cases	of cases	Sex (male/female)	ex emale)	Age (year)	year)	Follow-up time (months)	up time nths)	Outcome indicators	Literature quality rating
Literature included				Unilateral	Bilateral	Unilateral	Bilateral	Unilateral	Bilateral	Unilateral	Bilateral		
Chung et al. ^[18]	2008	RCT	South Korea	24	28	2/22	1/27	66.8	68.9	17.8	16.6	1,2,3,6,8	ო
Chen et al. ^[19]	2010	RCT	China	33	25	0/33	0/25	67.7	68.5	0.5	0.5	1,3,5,7	4
Chen et al. ^[20]	2011	RCT	China	24	25	4/20	4/21	70.4	72.4	31.8	35.2	1,2,3,4,6,7,8,	£
Yan et al. ^[6]	2014	RCT	China	158	151	46/112	43/108	71.9	71.1	12	12	1,2,3,4,5,6,7,8	4
Yan et al. ^[21]	2016	RCT	China	55	53					12	12	5,7,8,9	e
Yilmaz et al. ^[22]	2018	Cohort	Türkiye	36	51			ı		12-83	12-83	1,2,5,3,7,9,10	7
Chen et al. ^[23]	2011	RCT	China	27	23	0/27	0/23	68.37	69.43	0.5-24	0.5-24	2,4,5,7,8,9,10	5
Rebolledo et al. ^[24]	2013	RCT	NSA	23	21	4/19	2/19	78.7	79.3	42	12	2,3,5,6,7,8,9,10	ო
Wang et al. ^[25]	2019	RCT	China	151	140	115/36	119/31	68.5	69.4	0.25-6	0.25-6	1,2,3,4,7,8,10	5
Bozkurt et al. ^[26]	2014	Cohort	Türkiye	116	84	73/43	51/33	57	58	41.8	43.4	3,4,5	7
Zhang et al. ^[27]	2022	Cohort	China	29	38	10/19	12/26	73.6	74.1	17.1	2,5,7,8	ω	
Zhu et al. ^[28]	2022	Cohort	China	34	42	5/29	8/34	70.1	71.4	16.6	1,2,7,8,10	8	
1: Short term VAS score; 2: Long term VAS score; 3: Leakage rate of bone cement; 4: Postoperative adjacent segment fracture; 5: Recovery rate of anterior edge height of vertebral body; 6: Recovery of rear convex angle; 7: Surgical time; 8: Amount of bone cement used; 9: ODI (medium-term follow-up); 10: ODI (long-term follow-up).	; 2: Long term VAS cement used; 9: O	S score; 3: Le DI (medium-t	akage rate of bon term follow-up); 10	le cement; 4: Pc): ODI (long-terr	ostoperative ac n follow-up).	ljacent segment	: fracture; 5: Re	covery rate of a	nterior edge he	ight of vertebra	l body; 6: Recov	very of rear convex an	jle; 7: Surgical

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and the remaining four were retrospective cohort studies. Geographically, two studies were from Türkiye, one from South Korea, one from the USA, and eight from China. The total patient count was 1,391 (499 males, 697 females; 195 cases did not report sex; mean age: 70.9 years; range, 45 to 82 years), comprising 710 patients treated with the unilateral surgical approach and 681 with the bilateral approach. The mean follow-up duration was 17.9±9.7 months for the unilateral group and 18.4±8.3 months for the bilateral group. According to the Jadad scale, the RCTs required a score >3 for inclusion, and the cohort studies needed a score >7. Yan et al.^[21] provided detailed information on sequence generation. Rebolledo et al.^[24] reported a high loss-to-follow-up rate, potentially introducing bias. After the exclusion of studies without clear diagnostic criteria, 12 literature items were finalized for meta-analysis. Table I presents additional details.

Meta-analysis results

The short-term postoperative VAS score was reported in eight literature items. The metaanalysis revealed heterogeneity among the studies $(I^2=70\%)$; consequently, a random effects model was utilized for the analysis, as illustrated in Figure 2. The findings demonstrated that the shortterm postoperative VAS score in the unilateral approach group was marginally higher than that in the bilateral approach group, showing a difference of 0.05 points. This suggested that the short-term pain relief experienced by the unilateral approach group was comparable to that of the bilateral approach group. The observed difference might be attributable to chance, as it was not statistically significant (MD=0.05; 95% CI: -0.20-0.30; p=0.69). This indicated parity in short-term VAS scores between the two groups.

The long-term postoperative VAS score was reported in nine literature items. The meta-analysis

	Un	ilatera	I	Bi	lateral	ſ		Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
CHUNG HJ 2008	2.1	0.96	24	1.7	0.96	28	11.5%	0.40 [-0.12, 0.92]	2008	
CHEN C 2010	2.82	1.31	33	2.76	0.88	25	10.6%	0.06 [-0.50, 0.62]	2010	• • • • • • • • • • • • • • • • • • •
CHEN C 2011	7.74	1.23	27	7.35	0.98	23	9.7%	0.39 [-0.22, 1.00]	2011	
CHEN L 2011	2.7	1.9	24	2.3	2.5	25	3.5%	0.40 [-0.84, 1.64]	2011	
YAN L 2014	3.7	1.1	158	4	1.2	151	18.6%	-0.30 [-0.56, -0.04]	2014	_
YILMAZ A 2017	3.2	1.7	36	4.1	1.6	51	8.1%	-0.90 [-1.61, -0.19]	2017	· · · · · · · · · · · · · · · · · · ·
Wang WT 2018	3.1	0.5	151	2.9	0.3	140	22.4%	0.20 [0.11, 0.29]	2018	• • • • • • • • • • • • • • • • • • •
Zhu Di 2022	3.1	0.8	42	2.9	0.8	34	15.6%	0.20 [-0.16, 0.56]	2022	· +
Total (95% CI)			495			477	100.0%	0.05 [-0.20, 0.30]		+
Heterogeneity: Tau ² =	= 0.07; C	hi ² = 2	3.05, di	f=7(P:	= 0.00	2); l² = 1	70%			
Test for overall effect:	Z = 0.40) (P = ().69)							Unilateral Bilateral

FIGURE 2. Forest plot of postoperative short-term VAS scores in the unilateral approach group versus the bilateral approach group. SD: Standard deviation; CI: Confidence interval; VAS: Visual Analog Scale.

	Un	ilatera	I	Bi	lateral			Mean Difference			Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% Cl	Year		IV, Fixed, 95% CI	
CHUNG HJ 2008	1.9	0.48	24	1.8	0.48	28	1.8%	0.10 [-0.16, 0.36]	2008		- -	
CHEN C 2011	2.82	1.31	27	2.76	0.88	23	0.3%	0.06 [-0.55, 0.67]	2011			
CHEN L 2011	3.1	2.2	24	2.7	2.2	25	0.1%	0.40 [-0.83, 1.63]	2011			
Rebolledo BJ 2013	3.51	2.45	23	3.35	2.74	21	0.1%	0.16 [-1.38, 1.70]	2013	-		-
YAN L 2014	2.6	1.3	158	2.9	1.4	151	1.3%	-0.30 [-0.60, 0.00]	2014			
YILMAZ A 2017	2.2	1.2	36	2.6	1.4	51	0.4%	-0.40 [-0.95, 0.15]	2017		<u> </u>	
Wang WT 2018	2	0.2	151	1.9	0.1	140	95.0%	0.10 [0.06, 0.14]	2018			
Zhang YT 2022	1.8	1.1	29	1.7	1.3	38	0.4%	0.10 [-0.48, 0.68]	2022		<u> </u>	
Zhu Di 2022	2.1	1	42	2.1	0.9	34	0.7%	0.00 [-0.43, 0.43]	2022			
Total (95% CI)			514			511	100.0%	0.09 [0.06, 0.13]			•	
Heterogeneity: Chi ² =	10.21, 0	if = 8 (i	P = 0.2	5); I² = 2	2%					-2		
Test for overall effect:	Z= 5.15	5 (P < 0	0.00001	1)						-2	Unilateral Bilateral	2

FIGURE 3. Forest plot of postoperative long-term VAS scores in the unilateral approach group versus the bilateral approach group. SD: Standard deviation; CI: Confidence interval; VAS: Visual Analog Scale. indicated low heterogeneity among the studies (I^2 =22%); thus, a fixed effects model was employed in the analysis, as depicted in Figure 3. The results revealed that the long-term postoperative VAS score in the unilateral approach group exceeded that in the bilateral approach group, with a statistically significant difference in long-term postoperative VAS scores between the two groups (MD=0.09; 95% CI: 0.06-0.13; p<0.001). However, despite the statistical significance, the difference in the long-term postoperative VAS score between the groups was minimal.

The bone cement leakage rate was a major postoperative complication associated with both procedures. Postoperative bone cement leakage was reported in nine literature items. The total incidence of bone cement leakage was 23.7%, with 23.8% in the unilateral approach group and 23.6% in the bilateral

approach group. The meta-analysis indicated low heterogeneity among the studies (I^2 =45%); hence, a fixed effects model was adopted for the analysis, as shown in Figure 4. The findings indicated no statistically significant difference in the postoperative bone cement leakage rate between the unilateral and bilateral approach groups (odds ratio [OR]= 0.97 mL; 95% CI: 0.70-1.33; p=0.84).

Adjacent segment fractures were a major postoperative complication associated with both procedures. Postoperative adjacent segment fractures were reported in five literature items. The total incidence of postoperative adjacent segment fractures was 12.0%, with 12.6% in the unilateral approach group and 11.4% in the bilateral approach group. The meta-analysis revealed homogeneity among the studies (I^2 =0%); therefore, a fixed effects model was employed in the analysis, as illustrated

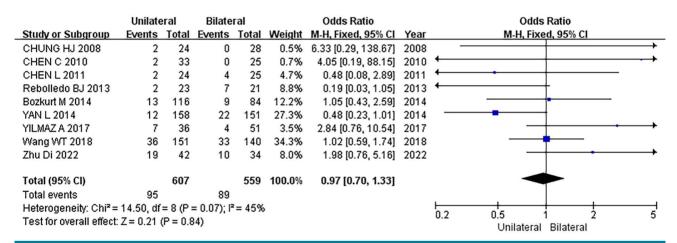


FIGURE 4. Forest plot of postoperative bone cement leakage rate in the unilateral approach group versus the bilateral approach group. Cl: Confidence interval.

Ci. Conndence interval.

	Unilate	eral	Bilate	ral		Odds Ratio			Odds	Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	Year		M-H, Fixe	d, 95% Cl		
CHEN L 2011	0	24	2	25	9.2%	0.19 [0.01, 4.21]	2011	←				
CHEN C 2011	4	27	2	23	7.1%	1.83 [0.30, 11.02]	2011			•	-	
YAN L 2014	4	158	5	151	19.2%	0.76 [0.20, 2.88]	2014					
Bozkurt M 2014	4	116	2	84	8.6%	1.46 [0.26, 8.19]	2014			-		
Wang WT 2018	19	151	16	140	55.9%	1.12 [0.55, 2.27]	2018		-			
Total (95% Cl)		476		423	100.0%	1.04 [0.61, 1.79]						
Total events	31		27									
Heterogeneity: Chi ² =	1.93, df=	4 (P =	0.75); l ² =	= 0%					-		+	100
Test for overall effect:	Z=0.15	(P = 0.8	38)					0.01	0.1 Unilateral	Bilateral	10	100

FIGURE 5. Forest plot of postoperative adjacent segment fractures in the unilateral approach group versus the bilateral approach group. Cl: Confidence interval. in Figure 5. The results indicated no statistically

significant difference in the rates of postoperative

adjacent segment fractures between the unilateral

and bilateral approach groups (OR=1.04; 95% CI: 0.61-

imaging techniques. Recovery of the anterior

vertebral height was reported in eight literature

items. The meta-analysis demonstrated high

heterogeneity among the studies $(I^2=100\%)$;

consequently, a random effects model was utilized,

as shown in Figure 6. The findings indicated that

the bilateral approach group exhibited a higher

recovery rate in postoperative anterior vertebral

height than the unilateral approach group, although

the difference was not statistically significant

angle was reported in four literature items. The

meta-analysis revealed high heterogeneity among

the studies (I^2 =78%); thus, a random effects model

The recovery rate of the postoperative kyphosis

(MD=-2.40; 95% CI: -8.74-3.93; p=0.46).

Postoperative recovery of anterior vertebral height and kyphosis angle was assessed using

1.79; p=0.88).

was adopted, as depicted in Figure 7. The results demonstrated that the unilateral approach group had a higher recovery rate of the postoperative kyphosis angle compared to the bilateral approach group, with the difference being statistically significant (MD=2.27;

Operation time was reported in 10 literature items. The meta-analysis showed high heterogeneity among the studies ($I^2=99\%$); therefore, a random effects model was used, as presented in Figure 8. The findings revealed that the unilateral approach group had a shorter operation time compared to the bilateral approach group, with a statistically significant difference (MD=–18.56 min; 95% CI: –28.17- –8.96; p=0.0002).

95% CI: 0.67-3.87; p=0.006).

The bone cement injection volume was reported in nine literature items. The meta-analysis demonstrated high heterogeneity among the studies $(I^2=99\%)$; thus, a random effects model was applied, as shown in Figure 9. The results indicated that a lower volume of bone cement was used in the unilateral approach group compared to the bilateral

Mean Difference Unilateral Bilateral Mean Difference Study or Subgroup Mean SD Total Mean SD Total Weight IV, Random, 95% Cl Year IV, Random, 95% CI 25 CHEN C 2010 25.84 13.79 33 32.32 10.33 11.9% -6.48 [-12.69, -0.27] 2010 CHEN C 2011 24.97 13.97 27 34.16 11.8% -9.19 [-15.46, -2.92] 2011 8.31 23 Rebolledo BJ 2013 20.5 15 23 14.8 10.9 21 11.2% 5.70 [-2.00, 13.40] 2013 Bozkurt M 2014 24.25 1.28 116 37.05 1.21 84 13.4% -12.80 [-13.15, -12.45] 2014 YAN L 2014 29.07 7.25 158 19.88 8.43 151 13.3% 9.19 [7.43, 10.95] 2014 YAN L 2016 9.3 5.1 55 11.5 3.8 53 13.3% -2.20 [-3.89, -0.51] 2016 YII MA7 A 2017 23.3 1 36 23.8 1 51 134% -0.50 [-0.93, -0.07] 2017 -2.80 [-9.10, 3.50] 2022 Zhang YT 2022 44.9 14.2 34 47.7 13.6 42 11.8% Total (95% CI) 482 450 100.0% -2.40 [-8.74, 3.93] Heterogeneity: Tau² = 77.99; Chi² = 2321.13, df = 7 (P < 0.00001); l² = 100% -20 10 20 -10 ń Test for overall effect: Z = 0.74 (P = 0.46) Unilateral Bilateral

FIGURE 6. Forest plot of the postoperative recovery rate of anterior vertebral height in the unilateral approach group versus the bilateral approach group.

SD: Standard deviation; CI: Confidence interval

	Uni	latera	1	Bi	lateral	l		Mean Difference		Mean Dr	ference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Rando	m, 95% Cl	
CHUNG HJ 2008	4.7	2.9	24	1.6	1.1	28	30.2%	3.10 [1.87, 4.33]	2008		-	
CHEN L 2011	7.2	4.9	24	7.3	5.9	25	15.8%	-0.10 [-3.13, 2.93]	2011			
Rebolledo BJ 2013	4.8	4	23	4.7	4.6	21	19.0%	0.10 [-2.46, 2.66]	2013		<u> </u>	
YAN L 2014	9.34	3.16	158	5.55	2.11	151	35.0%	3.79 [3.19, 4.39]	2014		•	
Total (95% CI)			229			225	100.0%	2.27 [0.67, 3.87]			◆	
Heterogeneity: Tau ² =	1.81; C	hi² = 1	3.38, di	f=3(P:	= 0.00	4); l² = 1	78%			-20 -10 () 10) 20
Test for overall effect:	Z= 2.77	' (P = ().006)							-20 -10 Unilateral		5 20

FIGURE 7. Forest plot of the postoperative recovery rate of kyphosis angle in the unilateral approach group versus the bilateral approach group.

approach group, with a statistically significant difference (MD=-1.20 mL; 95% CI: -2.01--0.39; p=0.004).

The medium-term postoperative ODI score was reported in four literature items. The meta-analysis indicated high heterogeneity among the studies (I^2 =89%); thus, a random effects model was employed,

as depicted in Figure 10. The results showed that the medium-term ODI score in the unilateral approach group was marginally lower than that in the bilateral approach group. However, this difference was not statistically significant (MD=-0.57; 95% CI: -3.13-1.99; p=0.66). This suggested that the differences in the degree of postoperative disability,

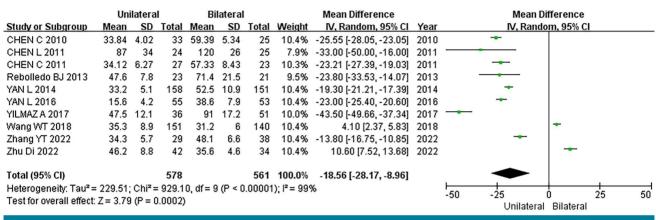


FIGURE 8. Forest plot of operation time between the unilateral approach group versus the bilateral approach group. SD: Standard deviation; CI: Confidence interval.

	Un	ilatera	I	Bi	lateral	(Mean Difference		Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl	
CHUNG HJ 2008	3.44	3.07	24	6.43	3.07	28	8.1%	-2.99 [-4.66, -1.32]	2008		
CHEN C 2011	4.11	1.25	27	5.82	1.97	23	10.6%	-1.71 [-2.64, -0.78]	2011		
CHEN L 2011	3.9	1.3	24	5.5	1.7	25	10.9%	-1.60 [-2.45, -0.75]	2011		
Rebolledo BJ 2013	4.8	1.7	23	6.3	2.4	21	9.6%	-1.50 [-2.74, -0.26]	2013		
YAN L 2014	3.4	0.8	158	5.5	0.7	151	12.3%	-2.10 [-2.27, -1.93]	2014	+	
YAN L 2016	6.2	0.6	55	8.5	0.8	53	12.2%	-2.30 [-2.57, -2.03]	2016	-	
Wang WT 2018	4.5	0.3	151	5	0.5	140	12.4%	-0.50 [-0.60, -0.40]	2018	•	
Zhang YT 2022	4.3	1.1	29	4.1	1.3	38	11.7%	0.20 [-0.38, 0.78]	2022		
Zhu Di 2022	5.2	0.8	42	4.2	0.6	34	12.2%	1.00 [0.69, 1.31]	2022		
Total (95% Cl)			533			513	100.0%	-1.20 [-2.01, -0.39]		•	
Heterogeneity: Tau ² =	= 1.39; C	hi² = 5	36.04,	df = 8 (F	< 0.0	0001);1	l² = 99%			-+ $+$ $+$ $+$ $+$ $+$ $+$ $+$ $+$ $+$	
Test for overall effect:	Z= 2.89) (P = ().004)							Unilateral Bilateral	4

FIGURE 9. Forest plot of bone cement injection volume between the unilateral approach group versus the bilateral approach group. SD: Standard deviation; CI: Confidence interval.

	Uni	ilatera	I	Bi	lateral			Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
CHEN C 2011	22.33	4.4	27	24.35	4.22	23	25.6%	-2.02 [-4.41, 0.37]	2011	
Rebolledo BJ 2013	16.59	9.59	18	16.09	8.84	18	11.7%	0.50 [-5.53, 6.53]	2013	3
YILMAZ A 2017	18.8	2.5	36	20.8	4.2	51	30.0%	-2.00 [-3.41, -0.59]	2017	·
Wang WT 2018	21.6	2.2	151	20.1	1.5	140	32.7%	1.50 [1.07, 1.93]	2018	3
Total (95% Cl) Heterogeneity: Tau² = Test for overall effect:				f= 3 (P	< 0.001		100.0 % = 89%	-0.57 [-3.13, 1.99]		
										Unilateral Bilateral

FIGURE 10. Forest plot of medium-term postoperative ODI score in the unilateral approach group versus the bilateral approach group.

SD: Standard deviation; CI: Confidence interval; ODI: Oswestry disability index.

	Uni	ilatera	I	Bi	lateral			Mean Difference		Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	Year	IV, Random, 95% Cl
CHEN C 2011	19.85	6.45	27	21.32	4.19	23	19.0%	-1.47 [-4.45, 1.51]	2011	
Rebolledo BJ 2013	14.4	8.89	14	12.81	7.65	15	11.3%	1.59 [-4.47, 7.65]	2013	
YILMAZ A 2017	16.2	1.2	36	18.4	1.7	51	24.0%	-2.20 [-2.81, -1.59]	2017	
Wang WT 2018	20.1	1.3	151	18	1.1	140	24.3%	2.10 [1.82, 2.38]	2018	
Zhu Di 2022	22.6	5	42	23.1	4.2	34	21.4%	-0.50 [-2.57, 1.57]	2022	
Total (95% Cl) Heterogeneity: Tau² = Test for overall effect:				df= 4 (F	° < 0.0I	263 0001);1		-0.23 [-3.00, 2.55]		-20 -10 0 10 20 Unilateral Bilateral

FIGURE 11. Forest plot of long-term postoperative ODI score in the unilateral approach group versus the bilateral approach group. SD: Standard deviation; CI: Confidence interval.

functional impairment, and medium-term ODI scores between the unilateral and bilateral approach groups might be attributable to chance.

The long-term postoperative ODI score was reported in five literature items. The meta-analysis

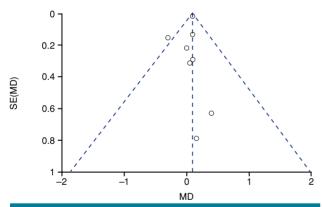


FIGURE 12. Publication bias in bone cement leakage rate. SE: Standard error; MD: Mean difference.

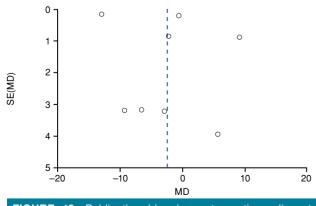


FIGURE 13. Publication bias in postoperative adjacent segment fractures. SE: Standard error; MD: Mean difference.

revealed high heterogeneity among the studies (I^2 =98%); therefore, a random effects model was used, as shown in Figure 11. The findings indicated that the long-term ODI score for the unilateral approach group was slightly lower than that for the bilateral approach group, but this difference was not statistically significant (MD=-0.23; 95% CI:-3.00-2.55; p=0.87). This implied that the differences in postoperative disability, functional impairment, and long-term ODI scores between the unilateral approach group and the bilateral approach group might also be due to chance.

Publication bias assessment

Publication bias analysis was conducted for outcome measures from literature items numbering more than five, including short- and long-term VAS scores, bone cement leakage rate, recovery rate of anterior vertebral height, operation time, and bone cement injection volume. Some publication bias was observed in the long-term VAS scores, recovery rate of anterior vertebral height, operation time, and bone cement injection volume, as depicted in Figures 12 to 15.

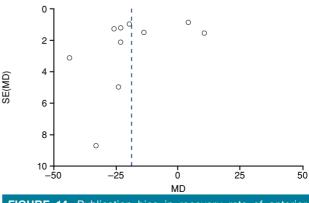
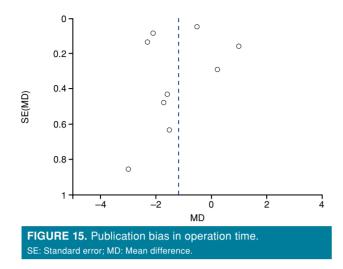


FIGURE 14. Publication bias in recovery rate of anterior vertebral height. SE: Standard error; MD: Mean difference.



DISCUSSION

The results of this study show that the long-term VAS was marginally higher in the unilateral PKP group. However, the results show that the reason for the small MD in the VAS score may be that the VAS score itself is small, and the longterm VAS score is a subjective evaluation tool, so it may be affected by the patient's emotions, cultural background, and other factors, with no clinical significance. In addition, the postoperative kyphosis angle recovery rate in the unilateral approach group was better than that in the bilateral approach group. In addition, the unilateral approach group had shorter operative time and less bone cement consumption. However, there was no statistically significant difference in the short-term VAS score, postoperative bone cement leakage rate, postoperative adjacent segment fracture rate, anterior vertebral body height recovery rate, and postoperative kyphosis angle recovery rate between the two groups. This similarity extended to the mid- to long-term ODI scores as well.

Several meta-analyses have been published evaluating the efficacy of unilateral versus bilateral PKP in treating OVCFs, although they present inconsistent conclusions and methodological flaws.^[29-32] The results of this study show that although there are statistical differences between unilateral and bilateral vertebroplasty in VAS scores and other indicators, the clinically significant difference is less than 0.5. This is consistent with the findings of existing literature. For example, the systematic review and meta-analysis by Zhiyong et al.^[29] and Xiang et al.^[30] also showed that there is no significant difference between unilateral and bilateral vertebroplasty in terms of pain relief. The studies by Tan et al.^[31] and Zhang et al.^[32] further support this view. These findings suggest that unilateral and bilateral vertebroplasty may be equally effective in patients with OVCFs. The choice of surgical procedure may require a combination of other factors, such as surgical time, risk of complications, and the patient's specific circumstances. Chen et al.[33] and Chang et al.[34] determined that unilateral PKP is more effective than bilateral PKP. However, the inclusion of non-RCTs in these studies reduced the reliability of their meta-analysis results. Furthermore, Chang et al.^[34] did not adhere to the PRISMA guidelines. In this study, we modified the previously published meta-analysis and included only high-quality RCTs to analyze the efficacy of both procedures. Additionally, we incorporated a variety of analysis indicators to provide a more comprehensive comparison and evaluation of the two methods. A recent meta-analysis, which included 10 articles, indicated that the postoperative kyphotic angle with the unilateral approach was substantially lower than that with the bilateral approach and required less operative time and a lower volume of injected cement.^[13] Our results align with these findings in terms of operative time and cement volume; however, our meta-analysis, based on comparative data between the two groups, revealed differences in long-term VAS scores and the recovery rate of the postoperative kyphosis angle.

The meta-analysis of this study indicated that in terms of surgical prognosis, the long-term VAS was marginally higher in the unilateral PKP group. However, since the difference in MD was only 0.09 points, this may not be clinically significant. Caution is advised in interpreting this result due to potential accidental differences in data; thus, it is currently unclear whether the bilateral approach group achieves better long-term postoperative pain relief. This conclusion aligns with the findings of Chen et al.^[33] and Chang et al.^[34] who reported no difference in long-term VAS scores between the unilateral and bilateral approach groups. This could be attributed to variations in long-term VAS scores, limited inclusion of literature quality, different literature sources, or possibly no real difference between the two groups, as indicated in previous studies. The ODI is a key clinical efficacy assessment indicator. This study concluded that postoperative disability and dysfunction were lower in the unilateral approach group compared to the bilateral approach group based on medium- and long-term ODI scores; however, no substantial differences were found.^[35,36] Similar results for medium- and long-term ODI scores between the unilateral and bilateral approach groups were not observed in the studies by Chen et al.^[33] and Chang et al.^[34]

The meta-analysis of this study also showed that in terms of imaging assessment results, the postoperative recovery rate of anterior vertebral height was higher in the bilateral approach group compared to the unilateral approach group. This finding aligns with the meta-analysis by Feng et al.,[37] which included 12 RCT studies of high methodological quality. It was observed that bone cement is primarily distributed in the anterior and middle parts of the vertebral body, leading to a better recovery rate of anterior vertebral height in the unilateral approach group due to more bone cement distribution. Additionally, this study found no notable difference in the postoperative kyphotic angle recovery rate between the unilateral and bilateral surgical approach groups, contrasting with the findings obtained by Yan et al.,[21] whose evaluation was based on a 12-month follow-up rather than a short-term follow-up. Yan et al.'s^[21] results suggest that unilateral approach PKP has better long-term kyphotic angle recovery.

Regarding operation time, the unilateral approach group had a shorter duration, making it more suitable for elderly patients or those with certain underlying diseases who cannot tolerate lengthy surgeries. In contrast, the bilateral approach offers no distinct advantages for these patients. Concerning bone cement injection volume, it was lower in the unilateral approach group. An increase in bone cement volume not only raises the surgical cost for patients but also places a greater financial burden on their families. Hence, in terms of cost-effectiveness, the unilateral approach may be preferable, potentially influencing patients' choice of surgical approach.

Postoperative bone cement leakage and adjacent segment fractures are two substantial postoperative complications. The meta-analysis in this study indicated no statistically significant difference in the rates of bone cement leakage and adjacent segment fractures between the unilateral and bilateral approach groups. This finding aligns with the meta-analysis results of Feng et al.^[37] Contrary to some research suggesting that the risk of cement leakage in bilateral PKP is twice that of unilateral PKP,^[38] our findings do not support this claim. Bone cement leakage can occur in areas adjacent to the intervertebral disc, the affected vertebra, paravertebral soft tissue, paravertebral veins, the spinal canal, and the nerve root canal. Leakage into paravertebral veins can lead to severe complications such as pulmonary embolism. If it enters the spinal canal and nerve root canal, it could cause spinal cord and nerve root damage due to the cement's thermal and compression effects. However, clinical symptoms are rare when bone cement enters the adjacent intervertebral disc and paravertebral soft tissue.^[39] Feng et al.^[37] posited that postoperative complications of PKP might largely depend on surgical technique; properly executed surgery can minimize these risks. Thus, it appears that postoperative complications are less related to the choice of unilateral or bilateral surgical approaches, with the specific relationship requiring further exploration in future studies.

In conclusion, unilateral PKP demonstrates a superior recovery rate of the kyphosis angle. Additionally, it presents benefits in terms of operation time and bone cement injection volume. Notably, no significant correlation was observed between postoperative complications and the chosen surgical approach. Nevertheless, this study refrains from definitively asserting that the bilateral approach yields better long-term pain alleviation following PKP, underscoring the imperative for further investigation in this area.

Ethics Committee Approval: The study protocol was approved by the Xiyuan Hospital of CACMS Ethics Committee (date: 26.07.2023, no: WJEC-KT-2017-018-P002). The study was conducted in accordance with the principles of the Declaration of Helsinki.

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

Author Contributions: Conception and design, Manuscript writing, Final approval: Y.S., X.L.; Collection and assembly of data, Manuscript writing, Final approval: S.M., H.C., T.C.C., K.M.L.; Provision of study materials or patients, manuscript writing; J.L.F.; Data analysis and interpretation, manuscript writing, final approval: Y.Y.S.

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