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https://doi.org/10.21608/zumj.2024.346203.3749 Manuscript ID ZUMJ-2412-3749 DOI 10.21608/zumj.2024.346203.3749 SYSTEMATIC REVIEW

Effectiveness and Safety of Surgical Management of Fragility Fractures of Thoraco-lumbar Spine: A Systematic Review and Meta-Analysis Study

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*Corresponding author:	ABSTRACT
Mo'men Abdallah Elsayed	Background: Low bone mass and microarchitectural disturbance are
Alhoot	hallmarks of the common illness osteoporosis. Percutaneous vertebroplasty
	(PVP) is a substitute nowadays. Symptomatic spinal compression fractures
	have been treated using this minimally invasive technique all around the
E-mail:	world. To improve functional disability and the quality of life for patients,
momen.beast@gmail.com	the primary goal of this systemic review and meta-analysis was to evaluate
	the efficacy of vertebroplasty alone (VP) and vertebroplasty with pedicle
	screw fixation (PSF) in treating fragility fractures. The results of both
Submit Date 20-12-2024	modalities were compared in a systematic review.
Accept Date 22-12-2024	Methods: In this Meta-analysis and systematic study, we employed a
	comprehensive search strategy. Our search encompassed the MED-LINE
	database, PubMed, Cochrane Bone and Muscle Trauma Group Specialized
	Register, Cochrane Register of Controlled Trails using the following
	keywords related to Osteoporosis, osteoporotic fractures, vertebral
	compression fractures vertebroplasty, kyphoplasty, pedicular fixation,
	screws augmentation.
	<b>Results:</b> Our analysis for refracture including 3 studies (in case of VP)
	revealed a pooled proportion 0.21 (95% CI (0.10,0.4)). A significant high
	heterogeneity was found (I2=70%, p.value=0.04) & leave one study had
	no effect on lowering it. It's noticed that VP had higher incidence of
	refracture $(0.21)$ than PSF combined with VP $(0.13)$ .
	<b>Conclusion:</b> This systemic review and meta-analysis comparing both PV
	and PV with PSF for treatment of osteoporotic fractures demonstrated that
	both techniques are safe and effective in short and long term pain control,
	vertebral height restoration. However, VP combined with pedicle screw
	was superior to PVP alone for lower cement leakage rate and incidence of
	refracture.
	Keywords: Osteoporosis; vertebroplasty alone; pedicle screw fixation.

#### **INTRODUCTION**

B ecause osteoporotic spine fractures can cause substantial morbidity and even death, they are a growing and significant health care concern. In the senior population, osteoporosis is becoming more and more common. Elderly individuals are primarily affected by osteoporotic vertebral fractures, which are compounded by pre-existing comorbidities, impaired functional reserves, cognitive dysfunction, and frequently several medications [1].

Women are 16% more likely than males to suffer a veretebral fracture in their lifetime among those aged 50 and over [2]. Most spinal fractures are

clinically quiet, in contrast to hip or wrist fractures. According to estimates, only roughly one out of every three vertebral fragility fractures are clinically recognized [3,4], and even fewer need hospitalization. However, the healthcare system is severely burdened by the morbidity and mortality linked to these fractures as well as the failure to identify and treat the underlying osteoporosis [5, 6].

While the majority of fractures are expected to heal, 15% to 35% may result in negative aftereffects, such as fatigue, kyphotic deformity, poor chest function, persistent discomfort, and neurological deficiency with resulting immobility [7, 8].

The conventional approach to treating spinal compression fractures used to be conservative therapy. Physical treatment, bracing, pain medication, and immobility are all included [9]. While the majority of fractures heal naturally, some individuals will experience ongoing pain and disability and need ongoing medical attention [10]. Percutaneous vertebroplasty (PVP) is a substitute nowadays. Symptomatic spinal compression fractures have been treated using this minimally invasive technique all around the world. In order to stabilize the fracture and provide instant pain relief, polymethylmethacrylate (PMMA) bone cement is injected into the vertebral body [11].

A minimally invasive technique for treating painful VCFs brought on by primary or secondary osteoporosis is balloon kyphoplasty (BKP). In contrast to vertebroplasty, BKP is intended to address kyphotic deformity and restore reduced vertebral height [12]. In balloon kyphoplasty, a tamp (balloon) is inserted into the vertebral body, followed by an injection of polymethylmethacrylate (PMMA) to compress the cancellous bone, create a hollow, and, if feasible, realign the vertebral body's endplate [13].

However, problems such cement leakage into the neural foramen, spinal canal, disc space, veins, lungs, or soft tissues can potentially result when injecting bone cement [14]. Percutaneous vertebroplasty has occasionally been linked in the literature to an elevated incidence of nearby new vertebral fractures during the follow-up period [15].

Because percutaneous vertebroplasty with pedicular fixation can reduce vertebral refracture, adjacent vertebral fracture, and kyphosis, pedicle screw fixation is commonly used in conjunction with percutaneous vertebraplasty to minimize the postoperative complications of osteoprotic vertebral fractures [16].

We hypothesize that surgical management of fragility fractures using percutaneous vertebroplasty or kyphoplasty is associated with less pain and improves functional disability and thus patient's quality of life. Therefore, the aim of this study is to assess the effect of vertebroplasty alone (VP) and vertebroplasty with pedicle screw fixation (PSF) in treating fragility fractures and compare the results of both modalities in a systematic review to improve functional disability and patient's quality of life.

## METHODS

We conducted this meta-analysis and systematic review in Orthopedic Surgery, faculty of medicine, Zagazig University according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart we created to depict the study selection process, detailing the number of studies screened, assessed for eligibility, and included in the review. We included clinical trials and observational cohort evaluating the outcomes of effectiveness and safety of surgical management of fragility fractures of thoraco-lumbar spine with at least 3 months follow-up period. The Institutional Review Board of Zagazig, Egypt, provided ethical approval. All techniques were disclosed in conformity with (IRBZU-IRB#11152-24/9-2023) Zagazig's ethical rules.

*Inclusion criteria:* Elderly patients over 50 years old, presented with fragility fractures of spine after minor trauma and fractures of less than one month. *Exclusion criteria:* Patients with pathological fractures due to primary or metastatic tumors, infections or tuberculosis.

*Types of included interventions:* Percutaneous vertebroplasty with or without pedicular fixation. This systematic review and meta-analysis are dedicated for evaluate the outcomes of surgical management of fragility fractures of thoraco-lumbar spine. Considerations were made regarding success rate of the first surgical treatment, duration of the operation, amount of blood loss and postoperative complications.

Selection criteria for studies: Inclusion criteria were Interventional studies Randomized control trails (RCTs), Cohort studies, case control studies, observational studies, and English studies. Case reports, case series studies, cross-sectional studies, animal studies, non-English studies, and articles with only abstracts or no full text as previous papers, conference, editorial, and author responses were all excluded. Studies with long-term followup data were given priority. The methodological quality of each study was rigorously evaluated, clarity in outcome measures, and appropriateness in statistical analysis to ensure the robustness of the findings.

In conducting our systematic review and metaanalysis, we employed a comprehensive search strategy. We used the following osteoporosisrelated keywords to search the MED-LINE database, PubMed, Cochrane Bone and Muscle Trauma Group Specialized Register, and Cochrane Register of Controlled Trails (The Cochrane Library). osteoporotic fractures. vertebral compression fractures vertebroplasty, kyphoplasty, fixation, pedicular screws augmentation. Additionally, we explored references of included articles to identify potentially relevant studies meeting the inclusion criteria that may not have been captured by the electronic search.

To ensure a comprehensive review, full copies of articles from medical and orthopedic journals, as well as other published studies, were obtained. Published case reports and conference proceedings were also reviewed to identify additional relevant studies. The inclusion of studies was determined based on the relevance of their title, abstract, and content to surgical management of fragility fractures of thoraco-lumbar spine.

Study procedure: The study started by searching articles using the ("Success of the surgical treatment"[MeSH Terms] OR "Success of the surgical treatment"[All Fields] OR "Operative duration"[MeSH] Terms] OR "Operative duration"[All Fields] OR "Blood loss" [MeSH Terms] OR "Blood loss" [All Fields], OR "Postoperative complications" [MeSH Terms] OR "Postoperative complications" [All Fields], after which papers that meet the inclusion criteria are downloaded, and papers that meet the exclusion criteria are excluded. After the supervisors reviewed these publications to ensure that the right data source was identified, we began working with the statistical supervisor to place the data on Rbased software for meta-analysis and begin the study.

*Search Strategy and Screening:* the search and screening process were directed towards identifying studies pertinent to evaluate the effectiveness and safety of surgical management of fragility fractures of thoraco-lumbar spine. Duplicates were eliminated, and studies failing to meet the inclusion criteria were excluded. Titles and abstracts were meticulously screened, and subsequently, the full texts of articles that might be useful were evaluated.

*Participant Criteria:* Demographic information of participants was collected, including age, gender, and specific details related to their eligibility for the treatment. Baseline characteristics documented included previous surgeries, comorbidities, and overall health status.

Statistical considerations: The outcomes from the incorporated studies were synthesized using systematic review management software, ensuring adherence to the predefined inclusion criteria. The Cochrane Collaboration's risk of bias tool was utilized to assess potential biases in each included trial, evaluating aspects such as randomization, blinding, and outcome reporting completeness. The relative risk for primary outcome measures was computed. This involved pooling data from various studies and utilizing appropriate statistical models for meta-analysis, such as fixed or random-effects models, based on observed heterogeneity. Heterogeneity among study results was evaluated using I<sup>2</sup> statistics, and sensitivity analyses were

conducted to explore the impact of the used methodologies and participant characteristics on overall results. Publication bias was examined through methods like funnel plots and Egger regression test to assess the potential influence of unpublished studies on the review conclusions.

The Meta-analysis and Systematic Review Manager program was used to incorporate the results from the included studies. A PRISMA flowchart was made using the inclusion/exclusion criteria and the search results. Utilizing a standardized data extraction tool and Microsoft Excel, details such as participant demographics, surgical procedures, and outcomes were extracted. Discussion or consultation with a third author was used to settle disagreements. Authors of the included studies were contacted for additional information when necessary. The data extraction process was meticulous, ensuring comprehensive collection of relevant data, including baseline characteristics and outcomes of each study.

Data were synthesized in a meta-analysis using RevMan V5.4 software. Binary data, such as incidence of treatment success, treatment failure, mortality, and complications, were analyzed using relative risk or odds ratios. 95% confidence intervals were used to present the results, and prediction intervals were supplied for research that used random-effects models. To evaluate the findings' robustness and investigate particular results, sensitivity and subgroup analyses were carried undertaken. Statistical heterogeneity was evaluated using  $\chi^2$  and I2 tests, with funnel plots used to assess publication bias when appropriate.

The GRADE approach was utilized to evaluate the certainty of the evidence. A Summary of Findings (SoF) table was created, including essential information like absolute risks for both groups, relative risk estimations, and the quality of evidence, considering factors such as bias risk and precision.

Missing standard deviations were estimated using available standard errors or 95% confidence intervals. Continuous outcomes were combined using mean differences or standardized mean differences, and dichotomous outcomes were synthesized using relative risk, employing a random-effects approach to accommodate clinical and methodological variability. Heterogeneity was assessed through forest plot examination and chisquare and I2 tests, with sensitivity analyses performed for trials influencing the uniformity of combined estimates.

To measure publication bias, funnel plots were used. The Cochrane collaboration tool was used to assess each study's risk of bias, while the PRISMA flowchart provided specifics on the study selection

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procedure. Following data pooling, each desired outcome measure's relative risk was computed and contrasted.

### Statistical analysis

Using R Studio, version 1.1.463 (package meta), data were entered and examined. CI limits or, in the absence of them, the standard mean difference were used to estimate the standard deviation (SD) of a mean. As recommended by the Cochrane Handbook for Systemic Reviews of Interventions, the SD was calculated by dividing the inter-quartile range by 1.35 for trials that gave medians. A 95% confidence interval (CI) was used to provide the precision of effect size, whereas the mean was used to indicate the effect size of the continuous outcomes. The precision of the effect size was expressed as a 95% confidence interval (CI), and the effect size of the categorical outcomes was expressed as a proportion (%). We assessed the heterogeneity and inconsistency of treatment effects across trials using the Cochrane Q tests and I2 statistics, respectively. For Cochrane Q tests, a P-value of less than 0.01 was considered The statistically significant. degree of heterogeneity and the percentage of treatment variance that is unaffected by sampling error are shown by the I2 statistics. Since I2 ranged from 30% to 60%, moderate heterogeneity was assumed. The Egger's test for publication bias detection was performed for the variables that had more than 9 studies and statistical significance was set at P. value < 0.01. We depend on our results on the random effect model to avoid the effect of variations between the studies conditions.

#### RESULTS

We found 456 research studies in our first search across five databases. After eliminating duplicate studies, 358 unique articles remained for further assessment. During this process, which comprised screening abstracts and titles, 40 studies were found to have potential relevance and merit a thorough full-text evaluation. In the end, 16 studies met the predetermined inclusion requirements. An illustration of this PRISMA flowchart chosen in Figure 1.

Our meta-analysis encompassed 16 studies. In these studies, the follow-up durations ranged from three months up to two years. The baseline summary and characteristics for the included studies are illustrated in Table 1.

*Operative Time (min):* Our analysis for the operative time (min) including 8 studies (in case of pedicle screw fixation combined with VP) revealed a pooled mean 74.76 (95% CI (55.57, 93.94)). A

significant high heterogeneity was found ( $I^2=99\%$ , p.value<0.01) & leave one test had no effect on lowering it (figure 2.1). Our analysis for the operative time (min) including 2 studies (in case of VP) revealed a pooled mean 36.99 (95% CI (23.27,50.71)). A significant high heterogeneity was found ( $I^2=100\%$ , p.value<0.01) & leave one test can't be done here (figure 2.2). It's noticed that of pedicle screw fixation combined with VP had higher mean of operative time (74.76) than VP (36.99).

*VAS Score:* Our analysis for VAS score including 8 studies (in case of pedicle screw fixation combined with VP) revealed a pooled mean 1.81 (95% CI (1.25, 2.36)). A significant high heterogeneity was found ( $I^2=97\%$ , p.value<0.01) & leave one study had no effect on lowering it (figure 3.1). Our analysis for VAS score including 9 studies (in case of VP) revealed a pooled mean 2.38 (95% CI (1.61, 3.16)). A significant high heterogeneity was found ( $I^2=96\%$ , p. value<0.01) & leave one study had no effect on lowering it (figure 3.2). It's noticed that VP had higher mean of VAS score (2.38) than pedicle screw fixation combined with VP (1.81).

*Kyphosis angle After Surgery:* Our analysis for kyphosis angle after surgery including 7 studies (in case of pedicle screw fixation combined with VP) revealed a pooled mean 7.13 (95% CI (4.86, 9.4)). A significant high heterogeneity was found ( $I^2$ =96%, p.value<0.01) & leave one study had no effect on lowering it (figure 4.1). Our analysis for kyphosis angle after surgery including 4 studies (in case of VP) revealed a pooled mean 12.51 (95% CI (7.61, 17.41)). A significant high heterogeneity was found ( $I^2$ =100%, p.value<0.01) & leave one study had no effect on lowering it (figure 4.2). It's noticed that VP had higher mean of kyphosis angle (12.51) than pedicle screw fixation combined with VP (7.13).

**ReFracture:** Our analysis for refracture including 2 studies (in case of pedicle screw fixation combined with VP) revealed a pooled proportion 0.13(95% CI (0.06,0.25)). A non-significant low heterogeneity was found ( $I^2$ = 30%, p.value=0.23) (figure 5.1). Our analysis for refracture including 3 studies (in case of VP) revealed a pooled proportion 0.21 (95% CI (0.10, 0.4)). A significant high heterogeneity was found ( $I^2$ = 70%, p.value=0.04) & leave one study had no effect on lowering it (figure 5.2). It's noticed that VP had higher incidence of symptomatic fracture (0.21) than pedicle screw fixation combined with VP (0.13).

	(1): Summary of the included studies.										
Study No.	Study ID	Site	Study design	Sample size	Sex (F/M)	Mean age (Y)	Type of Surgery	Follow up period			
1	Chen 2014	China	Retropective cohort	46	32/14	65(9.11)	VP	3 Months			
2	Denegri 2007	Italy	Prospective Non-RCT	10	(F) 77.4%	NR	VP	6 Months			
3	Du 2014	China	Prospective randomized comparison	42	NR	72.1(7.9)	VP	2 Years			
4	Griffoni 2020	Italy	Prospective randomized comparison	64	53/11	72(6.4)	VP	12 Months			
5	Gu 2013	Missis sippi	RCT	20	NR	73.6	Pedicle screw fixation combined with VP	26 Months			
6	Gu 2015	China	RCT	68	NR	74.5	Pedicle screw fixation combined with VP	27 Months			
7	Не 2014	China	Retropective cohort	19	12F/7	66.4	Pedicle screw fixation combined with VP	2006 to 2010			
8	Hu 2018	China	Retropective cohort	70	46/24	65	VP	12 months			
9	Kojima 2023	Japan	RCT	14	13F/1	77.3	Pedicle screw fixation combined with VP	2 Years			
10	Li 2020	China	RCT	83	64/16	73.6(11)	Pedicle screw fixation combined with VP	2 Years			
11	Liu 2010	Taiwa n	RCT	50	38/12	74.3(6.4)	VP	6 months			
12	Liu 2022	Taiwa n	Prospective randomized comparison	30	20F/10	69.4	Pedicle screw fixation combined with VP	45 months			
13	Pawar 2022	India	RCT	11	7F/4	75	Pedicle screw fixation combined with VP	18 months			
14	Schofer 2009	Germa ny	Prospective non randomized	30	NR	NR	VP	2002- 2004			

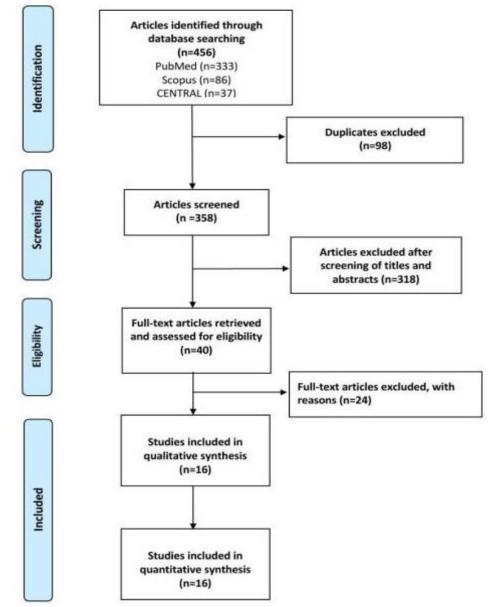
Table (	(1)	):	Summary	of	the	included	studies.

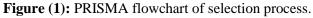
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Study No.	Study ID	Site	Study design	Sample size	Sex (F/M)	Mean age (Y)	Type of Surgery	Follow up period
			cohort					
15	Yang 2015	China	Retropective cohort	56	36/20	77.1(6)	VP	1 year follow up
16	Zhong 2019	China	Prospective randomized comparison	70	49/21	76.1(15.2)	Pedicle screw fixation combined with VP	60.5 Months

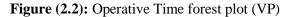




Study	Mean	SD	Total	Weight (common)	•		Mean IV, Fixed + Random, 95% Cl
He 2014	75.40 10		19	3.0%	12.7%	75.40 [ 70.54; 80.26]	+
Kojima 2023	94.50 21	.3000	14	0.6%	12.3%	94.50 [ 83.34; 105.66]	
Liu 2010	44.00 4	.4000	50	47.2%	12.8%	44.00 [ 42.78; 45.22]	-
Liu 2022	83.20 23	.5000	30	1.0%	12.5%	83.20 [ 74.79; 91.61]	<u>↓</u> + -
Pawar 2022	130.00 30	.0000	11	0.2%	11.6%	130.00 [112.27; 147.73]	
Li 2020	59.00 8	.6000	83	20.5%	12.8%	59.00 [ 57.15; 60.85]	
Gu 2013	75.00 25	.0000	20	0.6%	12.3%	75.00 [ 64.04; 85.96]	
Gu 2015	43.40 5	.0000	37	27.0%	12.8%	43.40 [ 41.79; 45.01]	•
Total (common effect, 95% CI)			264	100.0%		48.89 [ 48.05; 49.73]	•
Total (random effect, 95% CI)	2			-	100.0%	74.76 [ 55.57; 93.94]	
Heterogeneity: Tau <sup>2</sup> = 745.7379; Cl	hi <sup>2</sup> = 565.91,	df = 7 (	P < 0.0	1); l <sup>2</sup> = 99%			
							60 80 100 120 140

Figure (2.1): Operative Time forest plot (Pedicle screw fixation combined with VP)

Study	Mean	SD	Total	Weight	Mean IV, Random, 95% Cl		IV, R	Me: andor		% CI	
Hu 2018 Liu 2010		3.4000 4.4000			30.00 [29.20; 30.80] 44.00 [42.78; 45.22]					-	
Total (95% CI) Heterogeneity: Ta	au <sup>2</sup> = 97	7.7238; C	<b>120</b> hi <sup>2</sup> = 3	<b>100.0%</b> 54.85, df =	<b>36.99 [23.27; 50.71]</b> 1 (P < 0.01); I <sup>2</sup> = 100%	<b>2</b> 5	30	35	40	45	50



Study	Mean SD	Total	Weight	Mean IV, Random, 95% C	Mean I IV, Random, 95% CI
Gu 2013	0.70 0.7000		13.2%	0.70 [0.39; 1.01]	
Gu 2015	0.90 1.1000		13.0%	0.90 [0.55; 1.25]	
He 2014 Kojima 2023	2.21 0.9800		12.6% 12.5%	2.21 [1.77; 2.65] 2.00 [1.53; 2.47]	
Liu 2022	1.40 2.2000		10.7%	1.40 [0.61; 2.19]	<b></b>
Pawar 2022	1.70 1.3000	11	10.9%	1.70 [0.93; 2.47]	
Zhong 2019	2.60 0.5500	70	13.6%	2.60 [2.47; 2.73]	
Li 2020	2.80 0.6000	83	13.6%	2.80 [2.67; 2.93]	
Total (95% Cl) Heterogeneity: 1	) [au <sup>2</sup> = 0.5855: Ch	<b>284</b>	<b>100.0%</b>	<b>1.81 [1.25; 2.36]</b> 7 (P < 0.01); I <sup>2</sup> = 97%	
······	,	-	,	(· · · · · /) · · · · · ·	0.5 1 1.5 2 2.5

Figure (3.1): VAS score forest plot (Pedicle screw fixation combined with VP)

Study	Mean	SD Total	Weight (common)	Weight (random)	Mean IV, Fixed + Random, 95% CI	Mean IV, Fixed + Random, 95% Cl
Chen 2014	2.50 0.50	00 46	22.9%	11.4%	2.50 [2.36; 2.64]	
Du 2014	2.70 1.00	00 42	5.2%	11.3%	2.70 [2.40; 3.00]	- <b>-</b> -
Liu 2010	2.60 0.60	00 50	17.3%	11.4%	2.60 [2.43; 2.77]	
Schofer 2009	2.80 1.80	00 30	1.2%	10.6%	2.80 [2.16; 3.44]	- <u>-</u>
Yang 2015	2.00 0.60	00 56	19.4%	11.4%	2.00 [1.84; 2.16]	<b></b>
Griffoni 2020	4.60 2.70	00 64	1.1%	10.6%	4.60 [3.94; 5.26]	<b>-</b>
Hu 2018	0.84 2.78	00 70	1.1%	10.6%	0.84 [0.19; 1.49]	<b>-</b>
Li 2020	3.00 0.70	00 83	21.1%	11.4%	3.00 [2.85; 3.15]	
Gu 2015	0.50 0.60	00 31	10.7%	11.4%	0.50 [0.29; 0.71]	-
Total (common effect, 95% CI)		472	100.0%		2.33 [2.26; 2.40]	
Total (random effect, 95% CI)				100.0%	2.38 [1.61; 3.16]	
Heterogeneity: Tau <sup>2</sup> = 1.3579; Chi <sup>2</sup>	= 469.94, df	= 8 (P < 0	.01); I <sup>2</sup> = 98%			
						1 2 3 4 5

Figure (3.2): VAS score forest plot (VP)

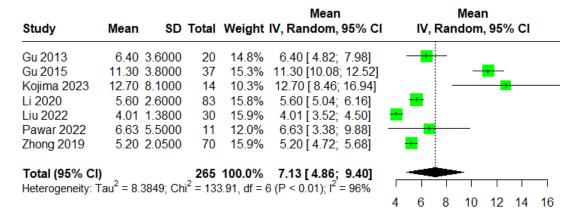
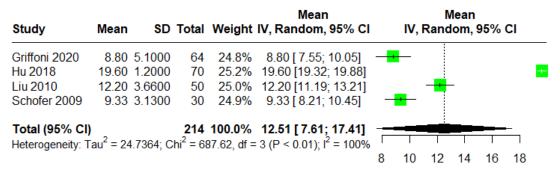
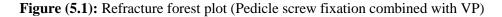


Figure (4.1): Kyphosis angle After Surgery forest plot (Pedicle screw fixation combined with VP)





Study	Events	Total	Weight (common)		IV, Fixed + Random, 95% Cl	IV, Fixe	ed + Randor	n, 95%	% CI
Liu 2022 Zhong 2019	2 11	30 70	16.8% 83.2%		0.07 [0.01; 0.22] 0.16 [0.08; 0.26]				
Total (common effect, 95% CI) Total (random effect, 95% CI) Heterogeneity: $Tau^2 = 0.1385$ ; $Chi^2$		<b>100</b> = 1 (P	<b>100.0%</b>  = 0.23); l <sup>2</sup> = 3	100.0%	0.14 [0.08; 0.22] 0.13 [0.06; 0.25]	0.05			0.25



Study	Events	Total	Weight (common)	-	IV, Fixed + Random, 95% CI	IV, Fixed + Random, 95% CI
 Du 2014	14	42	42.8%	41.8%	0.33 [0.20; 0.50]	
Griffoni 2020	15	64	52.7%	43.6%	0.23 [0.14; 0.36]	
Schofer 2009	1	30	4.4%	14.6%	0.03 [0.00; 0.17]	
Total (common effect, 95% CI)		136	100.0%		0.26 [0.18; 0.34]	
Total (random effect, 95% CI)				100.0%	0.21 [0.10; 0.40]	
Heterogeneity: Tau <sup>2</sup> = 0.3915; Chi <sup>2</sup>	= 6.58, df	= 2 (P	$= 0.04$ ); $I^2 = 7$	70%		
<b>,</b>		,				0.1 0.2 0.3 0.4

Figure (5.2): Refracture forest plot (VP)

#### DISCUSSION

One metabolic condition that commonly affects the elderly is osteoporosis (>60 years of age). With aging, the function and activity of osteoblasts of the patients decrease, while osteoclasts increase under the regulation of hormones, this results in bone loss by decreasing bone production and increasing bone resorption. changes in bone structure, increased bone fragility, and extreme susceptibility to fracture [17].

Osteoporosis vertebral compressed fracture (OVCF) is a common fracture caused by osteoporosis. Thoracic vertebral fractures are manifested as strong pain in the thoracic segment, kyphosis, thoracoabdominal compression, muscle atrophy, loss of self-care ability, and severe cases can cause paralysis and bed rest, or even loss of life [18].

Surgical treatment can restore the physical stability of the thoracolumbar spine, alleviate discomfort, promote function, and improve patients' quality of life. Percutaneous vertebroplasty is currently the most common minimally invasive procedure (PVP) and percutaneous kyphoplasty (PKP) [19].

Both of these procedures enhance the strength and toughness of the vertebral body by injecting fillers usually bone cement materials. polymethylmetaacrylate, (PMMA) into the vertebral body, which is classified as vertebral augmentation (VA) therapy, and can increase the pain relief rate of patients by more than 90% [20]. Operative data: Our analysis showed that PSF combined with VP had higher mean of hospital stay (7.41) than VP (3.25), a higher mean of operative time (74.76) than VP (36.99), and a higher mean of blood loss (76.5) than VP (36.37). Also, we agreed with the study of Gu et al., [21] it showed that patients treated with PVP alone had a far shorter hospital stay than those treated with minimally invasive pedicle screw (MIPS) and PVP. Group 1's hospital stay was  $3.2 \pm 0.4$  days, whereas Group 2's was 5.3  $\pm$  1.0 days. Additionally, the PVP group operated for 43.4  $\pm$ 5.0 minutes, whereas the MIPS combined with PVP group operated for  $74.7 \pm 8.6$  minutes (P = 0.000). Blood loss was also less in PVP group. They found that patients treated with PVP only had significantly less blood loss and shorter operative time than patients underwent MIPS combined with PVP.

Similarly, our study is in line with Li Z et al., [22] that revealed that In PVP with PSF group, The duration of the procedure was  $59.0 \pm 8.6$  minutes, and the recovery period was  $3.3 \pm 0.7$  days. The PVP group had a postoperative bed time of  $1.2 \pm 0.5$  days and an operation time of  $26.6 \pm 5.2$  minutes. Patients in group A saw a statistically

significant difference in operation time and postoperative bed time (P < 0.01) when compared to those in group B that received only PVP treatment.

Similarly, our findings in consistent with Zhong et al. [23] who reported that significant differences were found between the studied groups in terms of operation time, blood loss, and hospitalization time.

Kojima et al. [24] showed that using PPS fixation and percutaneous spinal cement augmentation with BKP combined significantly decreased surgery time and blood loss.

*Clinical data:* Our analysis showed that VP had higher mean of VAS score (2.38) than pedicle screw fixation combined with VP (1.81), while PSF combined with VP had higher mean of ODI score (25.13) than VP (22.83).

In China, a prospective cohort study conducted by Chen et al. [25] compared how well PVP and conservative treatment worked for individuals with chronic compression fractures and chronic, severe pain in terms of pain reduction and functional result. Eighty-nine chronic compression fracture patients who finished the one-year follow-up evaluation were included in their study. These patients were randomized to either CT (n = 43, Group B) or PVP (n = 46, Group A).

Based on visual analogue scale (VAS) and ODI ratings at one week, one month, three months, six months, and one year, they discovered that Group A had considerably superior pain alleviation and functional results than Group B (all p < 0.001).In 39 Group A patients and 15 Group B patients, the last clinical follow-up evaluation showed total pain alleviation (p < 0.001). When compared to conservative treatment, PVP was linked to better pain alleviation and improved functional results at one year for patients with chronic compression fractures and ongoing severe pain. The repair of vertebral fractures following PVP seems to be the primary cause of the notable improvements seen.

In this meta-analysis, Kojima et al. [24] contrasted percutaneous vertebroplasty (PVP) employing hydroxyapatite (HA) block in conjunction with PPS (HAVP + PPS) for thoracolumbar OVF (TLOVF) with balloon kyphoplasty in conjunction with percutaneous pedicle screw (BKP + PPS). They found that the pretreatment VAS of low back pain did not significantly differ across the groups. Also, our work agreed with Gu et al. [26] evaluated the viability and safety of minimally invasive pedicle screw fixation (MIPS) in conjunction with PVP against PVP alone for the treatment of acute thoracolumbar osteoporotic VCF and the prevention of subsequent VCF following PVP. According to their findings, there was no

discernible difference in the preoperative VAS scores between the two groups. In the MIPS and PVP groups, the pain intensity level on the VAS considerably decreased from  $9.1 \pm 1.0$  preoperation to  $2.4 \pm 0.9$  (P < 0.005) right after the procedure, which was comparable to that in the PVP group. At one, two, and three months following surgery, group 2's VAS was considerably lower than that of the PVP group (P < 0.005). Six months, a year, and two years following surgery, group 1's VAS was higher than the PVP group's, but there was no discernible difference between the two groups.

Similarly, this study in line with Zhong et al. [23] who looked into the clinical impact of of 4 in patients with OVCFs receiving PV treatment as opposed to PV plus intermediate bilateral pedicle screw fixation (IBPSF). According to their findings, there was no discernible difference in the preoperative VAS scores between the two groups. At the final follow-up, they discovered that group B's VAS score had dramatically improved when compared to group A's values.

Similarly, in Liu et al. [27] at discharge, the mean pretreatment back pain score on the VAS dropped from  $7.3 \pm 2.2$  to  $2.2 \pm 1.1$  (P<.05), and at the final follow-up, it was  $1.4 \pm 0.3$  (P<.05). At the last follow-up, the mean ODI preoperatively dropped from 84.2± 10.3 to 18.8± 7.5 (P<.05).

*Radiological data:* Our analysis revealed that PSF combined with VP had higher mean of vertebral height (2.51) than VP (1.66), while VP had higher mean of kyphosis angle (12.51) than PSF combined with VP (7.13).

Pawar et al. [28] showed that the average local kyphosis angle was  $15^{\circ}$  before surgery (range 0– $30^{\circ}$ ) and  $7^{\circ}$  after surgery (range 0– $15^{\circ}$ ) (P < 0.001). After surgery, the average anterior vertebral body height rose from 11 mm to 22 mm (P < 0.001). At an average follow-up of 18 months, the correction in AVH and kyphosis remained stable. After kyphosis was corrected and the AVH was reasonably well restored, indirect decompression and vertebroplasty were performed to support the anterior column.

Similarly, in Li Zet al. [22] the postoperative Cobb angle  $(5.6 \pm 2.6, 5.1 \pm 2.0)$  and vertebral anterior height  $(2.8 \pm 0.2, 2.7 \pm 0.3)$  did not differ significantly (P > 0.05). This implies comparable short-term results. However, the PVP group's vertebral anterior height reduced  $(2.3 \pm 0.6, 1.7 \pm 0.5, 1.6 \pm 0.3)$  and their Cobb angle increased (12.4  $\pm 3.2, 17.2 \pm 2.5, 13.2 \pm 2.3)$  during follow-up at 6 months, 12 months, and 24 months following surgery. The vertebral anterior height in the PPSF combined with PVP group  $(2.7 \pm 0.3, 2.6 \pm 0.2, 2.5 \pm 0.7)$  and the Cobb angle  $(4.9 \pm 2.2, 5.5 \pm 2.3, 5.7)$   $\pm$  2.3) showed significant differences (P < 0.05). This suggests that PPSF and PVP together can sustain anterior height for a considerable amount of time following surgery.

Lee et al. [8] discovered that following PKP treatment, the height compression ratio improved from  $24.0 \pm 6.4\%$  prior to surgery to  $66.3 \pm 14.9\%$  following surgery, and the anterior height increased from  $6.4 \pm 2.1$  mm prior to surgery to  $17.2 \pm 4.4$  mm following surgery. They are indicating that PKP is a dependable treatment for individuals with severe OVF compression because it considerably sped up pain recovery and restored anterior height.

According to Gu et al. [21], PPSF in conjunction with PVP can improve anterior height and Cobb angle recovery when compared to OVCF with kyphosis treated by PVP alone. This might have something to do with the pedicle screw being distracted and reduced during surgery.

*Complications:* Our analysis showed that VP had higher incidence of cement leakage (0.19) than PSF combined with VP (0.18), and a higher incidence of refracture (0.21) PSF combined with VP (0.13).

In 2019, a retrospective study conducted by Zhong et al.[23] reported that new fractures occurred in 13 patients (11 patients in VP group and 2 patients in VP with PSF group), cement leakage was observed in 15 patients in group A and 8 patients in group B, and the difference between groups was significant (P < 0.05).

Similarly, in Li Z et al. [22] Twelve cases of bone cement leakage occurred in group B (14.3%) and fourteen cases occurred in group A (17.8%); however, there was no discernible difference between the two groups (P > 0.05). Both groups showed no signs of nerve damage or bone cement leaking in the intraspinal and intervertebral foramina. The two patient groups did not experience pulmonary embolism or bone cement venous leakage.

In this meta-analysis, Griffoni et al. [29] evaluated the safety and effectiveness of balloon kyphoplasty (BKP) and percutaneous vertebroplasty (PVP) in treating osteoporotic vertebral compression fractures. When compared to the balloon kyphoplasty group, they discovered that the vertebroplasty group had a noticeably greater risk incidence of neighboring level fractures. Both groups demonstrated а notable clinical improvement, therefore there were no differences between them in terms of clinical results.

Also, Du et al. [30] revealed that 14 patients (16.3%) experienced a new symptomatic fracture in 16 levels throughout the 2-year follow-up. Eight patients (18.2%) with nine levels in the

kyphoplasty group and six patients (14.3%) with seven levels in the vertebroplasty group were compromised. Three levels (33.3%) of these newly cracked vertebrae in the kyphoplasty group and two levels (28.6%) in the vertebroplasty group were close to the previously treated vertebrae (P =0.677). And within three months of the first fracture therapy, two adjacent level fractures (40%) happened. Ultimately, eight of these 14 patients received conservative treatment, while six of them needed a second operation (2 underwent kyphoplasty and 4 underwent vertebroplasty).

## Limitations

Poor non-RCT research design may have contributed to heterogeneity, which was brought on by differences in bone mineral density, age, gender, follow-up duration, spinal vertebral bodies, unilateral or bilateral surgical procedures, and disease progression. Furthermore, the strength of the results was diminished by the small sample sizes of the few included studies; hence, additional research and RCTs are needed to corroborate these findings in order to have more trustworthy and definitive data. There are also discrepancies amongst research in the selection of outcome indicators.

The main strength of this study is the use of welldesigned and updated database including RCT studies.

## Conclusion

This systemic review and meta-analysis comparing both PV and PV with PSF for treatment of osteoporotic fractures demonstrated that both techniques are safe and effective in short and long term pain control, vertebral height restoration. However, VP combined with pedicle screw was superior to PVP alone for lower cement leakage rate and incidence of refracture.

### **Conflict of interest**

The authors declared that they have no conflicts of interest with respect to authorship and/or publication of this article.

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