Is Unilateral Kyphoplasty as Effective and Safe as Bilateral Kyphoplasties for Osteoporotic Vertebral Compression Fractures? A Meta-analysis

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Abstract

Background An osteoporotic vertebral compression fracture is a common condition in elderly people, especially women. The percutaneous kyphoplasty is an effective treatment for osteoporotic vertebral compression fractures. Controversy remains regarding whether a unilateral or a bilateral approach is superior, and to our knowledge, there have been no large studies comparing these two approaches, therefore a meta-analysis synthesizing the data on this question is warranted.

Questions/purposes We asked the following questions: (1) Is there evidence to suggest a benefit in clinical outcome as assessed by the VAS and Oswestry Disability Index of a unilateral kyphoplasty or bilateral kyphoplasties? (2) Are the complications associated with the two approaches different? (3) Do the procedures result in different kyphosis angle reduction or anterior vertebral height restoration? (4) Is the surgical time for the procedures different?

Methods We searched the Cochrane Library, PubMed MEDLINE, EMBASE, Web of Knowledge MEDLINE (January 1980 to June 2013), and reference lists of eligible prospective studies. The levels of the evidence and

recommendations were assessed using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system. Five studies encompassing 253 patients met the inclusion criteria.

Results The short- and long-term clinical outcomes as assessed by the VAS and Oswestry Disability Index showed no differences between unilateral and bilateral kyphoplasties ($p = 0.41$, $p = 0.60$ for VAS; $p = 0.10$, $p = 0.36$ for Oswestry Disability Index). There were no differences in complications such as cement leakage and adjacent vertebral fractures associated with the two approaches ($p = 0.43$ and $p = 0.95$). The kyphosis angle reduction and anterior vertebral height restoration showed no difference between the two approaches ($p = 0.34$ and $p = 0.46$). The unilateral approach was shorter in terms of surgical time (mean difference, -24.98 ; $p < 0.0001$). The overall GRADE system evidence quality was very low, with only high evidence for operation time, which lessens our confidence in recommendations.

Conclusions Unilateral and bilateral percutaneous kyphoplasties appear to be safe and effective for treating osteoporotic vertebral compression fractures. No clinically important differences were found between them. Considering less operation time and less cost, we suggest that a unilateral percutaneous kyphoplasty is advantageous, but because of the poor quality of the evidence, high-quality randomized controlled trials are required to resolve this issue.

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Introduction

An osteoporotic vertebral compression fracture is a common condition in elderly people, especially women. The National Osteoporosis Foundation released updated prevalence data estimating that approximately 9 million adults

in the United States have osteoporosis and an additional 43 million have low bone mass (indicated by T-scores between -1.0 and -2.5), placing them at increased risk for osteoporosis and fractures [29]. Fractures may result in functional limitations, chronic pain, loss of independence, and pulmonary dysfunction [10, 36]. Initial treatment of an osteoporotic vertebral compression fracture should include pain control with resumption of activity as quickly as possible and physical therapy [1]. For patients who do not have any improvement in pain after 4 weeks of conservative treatment such as oral analgesics and nasal calcitonin, or for patients who are unable to tolerate oral analgesics, procedures such as percutaneous vertebroplasty and percutaneous kyphoplasty are alternatives.

Debate increased after two randomized controlled studies were published comparing outcomes after percutaneous vertebroplasty and a sham procedure [3, 18], followed by comments on these two studies defending the role of percutaneous vertebroplasty [12, 30]. However, two Level I studies have reported substantial benefits from percutaneous vertebroplasty compared with conservative treatments [11, 21]. Shi et al. [37] conducted a meta-analysis showing that percutaneous vertebroplasty relieved pain better and improved quality of life without increasing the risk of new fractures. Several comparative studies reported that percutaneous vertebroplasty and percutaneous kyphoplasty result in similar pain control and improvement in physical function [24, 27, 35, 42]. In addition, Eck et al. [9] conducted a meta-analysis comparing all studies of percutaneous vertebroplasty and percutaneous kyphoplasty in osteoporotic vertebral compression fractures. Their study showed there was less cement leakage, fewer new compression fractures, and fewer pulmonary embolisms with a percutaneous kyphoplasty compared with a percutaneous vertebroplasty [9].

Traditional bilateral percutaneous kyphoplasties were shown to be safe and effective for treatment of pain associated with osteoporotic vertebral compression fractures [22, 33]. Nevertheless, a unilateral percutaneous kyphoplasty would be an attractive alternative to the traditional bilateral percutaneous kyphoplasties owing to theoretical speed, safety, and less expense. Two meta-analyses compared unilateral with bilateral percutaneous kyphoplasties for osteoporotic vertebral compression fractures [26, 43]. We believe those reviews need to be updated because they did not include the data reported by Chung et al. [8] owing to the absence of needed standard deviations, which would have resulted in statistical bias and publication bias; however, the data can be used with methods introduced in the Cochrane Handbook [17]. In 2013 another prospective study was published that met the original published inclusion criteria [32], which may add some important information. There were some methodologic errors in the

meta-analyses by Lin et al. [26] and Yang et al. [43]: there were no definitions of short- and long-term in the study by Lin et al. and the inclusion and exclusion criteria were not well established. Therefore, we conducted this meta-analysis to assess the safety and efficacy of unilateral and bilateral percutaneous kyphoplasties for treatment of osteoporotic vertebral compression fractures.

We asked: (1) Is there evidence to suggest a benefit in clinical outcome as assessed by the VAS and Oswestry Disability Index of unilateral or bilateral kyphoplasties? (2) Are the complications associated with the two approaches different? (3) Do the procedures result in different kyphosis angle reduction or anterior vertebral height restoration? (4) Is the time to perform the procedures different?

Materials and Methods

Search Strategy and Criteria

PRISMA-compliant searches of The Cochrane Library, PubMed MEDLINE, EMBASE, and the Web of Knowledge MEDLINE were performed for all peer-reviewed studies published until the end of June 2013 that compared unilateral percutaneous kyphoplasty with bilateral percutaneous kyphoplasties in patients with osteoporotic vertebral compression fractures. The following search terms were used for the database search: kyphoplasty, vertebral compression fracture, and osteoporosis. Broad MeSH terms and Boolean operators were used to maximize the search sensitivity and specificity. The reference lists of all the full-text papers were examined to identify any initially omitted studies. We restricted the search to English language publications. Studies were considered eligible for inclusion if they met the following criteria: (1) randomized controlled trials (RCTs) and prospective comparative studies; (2) had patients with primary osteoporotic vertebral compression fractures; (3) unilateral and bilateral percutaneous kyphoplasties were performed; and (4) reported at least one of the following results: VAS, Oswestry Disability Index, incidence of adjacent vertebral fractures, cement leakage, vertebral body height restoration, operative time, or local kyphosis angle. Studies were excluded if (1) they were retrospective studies, case reports, or reviews; (2) they enrolled patients with neoplastic etiology (ie, metastasis or myeloma), infection, neural compression, invasive disease, traumatic fracture, neurologic deficits, spinal stenosis, previous surgery at the vertebral body in question, or long-term use of steroids; (3) they did not report any result mentioned in the inclusion criteria. Two reviewers (ZBH, SLW) independently screened the titles and abstracts for the eligibility criteria. Full-text articles were read when the studies met the

Fig. 1 A summary of the study selection and exclusion process is shown.

inclusion criteria, and the literature was reviewed to determine the final inclusion. We resolved disagreements by discussion to reach a consensus. A total of 594 titles and abstracts were preliminarily reviewed, and five prospective comparative studies eventually satisfied the eligibility criteria [5–8, 32] (Fig. 1). A total of 131 patients underwent a unilateral percutaneous kyphoplasty and the remaining 122 received bilateral percutaneous kyphoplasties. The population, volume of polymethylmethacrylate, operation time, and followup period were recorded as the demographic characteristics of the included studies (Table 1).

Data Extraction and Analysis

Two of the authors (ZBH, SLW) independently extracted the following data: study characteristics, sample size, age, sex, types of interventions, and outcome parameters. The extracted data were rechecked by one of the authors (ZBH). We defined short term as occurring within 4 weeks, mid-term as occurring between 4 weeks and 6 months, and long term as occurring after 6 or more months [13]. We performed all of the meta-analyses with Review Manager software (RevMan Version 5.1; The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark). For continuous outcomes, the means and standard

deviations were pooled to a mean difference (MD) and 95% CI. For dichotomous outcomes, the risk ratio (RR) and 95% CI were assessed. A probability value less than 0.05 was regarded as statistically significant. Statistical heterogeneity was assessed using Q statistics. A fixed-effects model was used when the effects were assumed to be homogeneous ($p > 0.05$); otherwise, a random effects model was used when the probability was less than 0.05, which implied statistical heterogeneity. The sensitivity analysis was performed by rejecting the studies with higher statistical heterogeneity when necessary. For the studies offering final means without relevant standard deviation, we calculated the standard deviation by the calculator in the Review Manager software. For the studies that did not provide exact data, providing only graphs for the results, we estimated from the graphs in the studies.

Assessment of Methodologic Quality and Evidence Synthesis

The risk of bias in the included studies was assessed independently by two authors (ZBH, SLW) in accordance with the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1 [17]. Any disagreements were resolved by discussion. A third author (SLH) was the

Table 1. Characteristics of studies included in the meta-analysis

Study	Number of patients		Sex (male/female) Number		Volume of polymethylmethacrylate (mL)		Operation time (minutes)		Followup (months)	
	Unilateral	Bilateral	Unilateral	Bilateral	Unilateral	Bilateral	Unilateral	Bilateral	Unilateral	Bilateral
Chung et al. [8]	24	28	2/22	1/27	3.44	3.43	NR	NR	17.8	16.6
Chen et al. [5]	33	25	0/33	0/25	NR	NR	33.84	59.69	0.5	0.5
Chen et al. [6]	27	23	0/27	0/23	NR	NR	34.12	57.33	24	24
Chen et al. [7]	24	25	4/20	4/21	3.9	5.5	32.1	50.8	35.5	31.8
Rebolledo et al. [32]	23	21	4/19	2/19	4.8	6.3	47.6	71.4	> 12	> 12

NR = not reported.

adjudicator when no consensus could be achieved. We evaluated the included studies using the “Cochrane collaboration’s tool for assessing the risk of bias” [17]. The five included studies mentioned randomization of sequence generation, but none offered details regarding how randomization was conducted [5–8, 32]. No studies reported allocation concealment, and none used blinding of performance and outcome assessment. All of the included studies had a low risk of reporting bias and other bias, and four of the five had a low risk of attrition bias. Only the study by Rebolledo et al. [32] had a high risk of attrition bias owing to the high proportion of patients lost to followup (Fig. 2).

Owing to the limited number of included studies, it was difficult to explore publication bias. A funnel plot might not be appropriate to evaluate or explain publication bias with only five studies.

The evidence grade was determined using the guidelines of the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) working group [2]. The GRADE system uses a sequential assessment of the evidence quality that is followed by an assessment of the risk-benefit balance and subsequent judgment on the strength of the recommendations. The evidence quality was graded using the GRADE pro software (GRADEpro. Version 3.2 for Windows. Jan Brozek, Andrew Oxman, Holger Schünemann, 2008. <http://tech.cochrane.org/revman/other-resources/grade-pro/download>). The strengths of the recommendations were based on the quality of the evidence.

Results

VAS and Oswestry Disability Index Clinical Endpoints

Three studies reported the VAS scores at short-term followup [5, 7, 8]; showing similar VAS improvement between unilateral and bilateral percutaneous kyphoplasties (MD, 0.19; 95% CI, −0.26 to 0.63; $p = 0.41$) (Fig. 3). Long-term VAS scores were available for four studies [6–8, 32], and the

Fig. 2 The methodologic quality of the included studies is shown.

pooled results showed no differences between the two groups (MD, 0.12; 95% CI, −0.33 to 0.56; $p = 0.60$) (Fig. 4). As for Oswestry Disability Index, outcomes revealed no differences between unilateral and bilateral percutaneous kyphoplasties for short- (MD, −1.98; 95% CI, −4.36 to 0.39; $p = 0.10$) and long-term results (MD, −1.38; 95% CI, −4.31 to 1.55; $p = 0.36$) (Table 2).

Complications

Four studies reported complications related to cement leakage after percutaneous kyphoplasty [5, 7, 8, 32], and no difference was found between the two approaches (RR,

Fig. 3 The short-term VAS scores between unilateral and bilateral percutaneous kyphoplasties are shown in this forest plot.

Fig. 4 The long-term VAS scores between unilateral and bilateral percutaneous kyphoplasties are shown.

Table 2. Results of Oswestry Disability Index and radiographic assessment

Assessment tool	Number of studies	Number of patients (unilateral/bilateral)	Effect	95% CI	p value
Short-term Oswestry Disability Index	2	45/41	-1.98	-4.33 to 0.39	0.10
Long-term Oswestry Disability Index	2	41/38	-1.38	-4.31 to 1.55	0.36
Kyphosis angle reduction	3	62/68	-1.91	-5.8 to 1.98	0.34
Anterior vertebral body height restoration	2	71/65	0.47	-0.77 to 1.72	0.46

0.72; 95% CI, 0.32–1.63; $p = 0.43$) (Fig. 5). No difference was found in the postoperative adjacent-level fracture rate between the two approaches (RR, 0.96; 95% CI, 0.27–3.42; $p = 0.95$), which was reported in two studies [6, 7] (Fig. 6).

Kyphosis Angle Reduction and Anterior Vertebral Height Restoration

Three studies reported the results of kyphosis angle reduction [7, 8, 32], indicating no difference for the mean kyphosis angle reduction between the two groups (MD, -1.91; 95% CI, -5.8 to 1.98; $p = 0.34$; $I^2 = 85\%$, random effect model used) (Table 2). Sensitivity analysis showed that one study was the main cause of heterogeneity [8]; no difference was found when this study was rejected. Because of postoperative anterior vertebral height restoration percentage, no difference was found between the two groups (MD, 0.47; 95% CI, -0.77 to

1.72; $p = 0.46$; $I^2 = 91\%$, random effect model used) (Table 2).

Operation Time

Adequate operative time data were available in four studies [5–7, 32], showing that unilateral percutaneous kyphoplasty had a shorter operative time than bilateral percutaneous kyphoplasties (MD, -24.98; 95% CI, -27.04 to -22.91; $p < 0.00001$) (Fig. 7).

Quality of the Evidence and Recommendation Strengths

The outcomes in this systematic review were evaluated using the GRADE system. The evidence quality for each outcome was low or very low, except for the outcome of operation time with high evidence quality (Table 3). Therefore, we

Fig. 5 The risk ratio for cement leakage between unilateral and bilateral percutaneous kyphoplasties is shown in this forest plot.

Fig. 6 The forest plot shows data for postoperative adjacent-level fractures between unilateral and bilateral percutaneous kyphoplasties.

Fig. 7 The forest plot shows data for the operation times between unilateral and bilateral percutaneous kyphoplasties.

agreed that the overall evidence quality was very low, which may decrease confidence in any recommendations.

Discussion

An ideal treatment for an osteoporotic vertebral compression fracture should result in lasting improvement in symptoms, durable kyphosis deformity correction, and prevention of new fractures. Currently, percutaneous kyphoplasty and percutaneous vertebroplasty are not recommended as the preferred treatments for osteoporotic vertebral compression fractures, but for patients with failed conservative treatment or who cannot tolerate the adverse effects of oral analgesics, percutaneous kyphoplasty and percutaneous vertebroplasty are alternatives [19, 34]. These procedures have been effective for rapid and lasting pain reduction and improved quality of life [16, 41]. The

benefits of percutaneous kyphoplasty regarding pain relief, low rates of cement leakage, and height restoration have been documented, but the evidence in support of percutaneous kyphoplasty was collected in studies of bilateral kyphoplasties [14, 28]. Several of the comparative studies concluded that a unilateral percutaneous kyphoplasty can provide similar results for clinical and radiographic outcomes as bilateral percutaneous kyphoplasties [31, 38, 39]. However, it is not known which is better. Therefore, an evidence base is needed to help surgeons make clinical decisions, and for this reason, we performed a meta-analysis of prospective comparative trials. We found that: (1) the clinical results were similar (such as VAS and Oswestry Disability Index improvement) between unilateral percutaneous kyphoplasty and bilateral percutaneous kyphoplasties; (2) a unilateral percutaneous kyphoplasty has a lower rate of cement leakage compared with bilateral kyphoplasties (RR, 0.72); (3) there were no differences for

Table 3. Evidence quality for each outcome

Quality assessment		Summary of findings					Importance	
		Number of patients			Effect		Quality	
		Unilateral kyphoplasty	Unilateral kyphoplasty	Other considerations	Relative (95% CI)	Absolute		
Short-term VAS (followup 2–4 weeks; measured with VAS; range of scores, 0–10; better indicated by lower values)								
3	Randomized trials	81	78	None	–	MD 0.19 higher (0.26 lower to 0.63 higher)	Low	Critical
Long-term VAS (followup mean 12–36 months; measured with VAS; range of scores, 0–10; better indicated by lower values)								
4	Randomized trials	89	91	None	–	MD 0.12 higher (0.33 lower to 0.56 higher)	Low	Critical
Mid-term Oswestry Disability Index (followup median 6 months; measured with Oswestry Disability Index; range of scores, 0–50; better indicated by lower values)								
2	Randomized trials	45	41	Reporting bias	–	MD 1.98 lower (4.36 lower to 0.39 higher)	Very low	Critical
Long-term Oswestry Disability Index (followup median 12–36 months; measured with Oswestry Disability Index; range of scores, 0–50; better indicated by lower values)								
2	Randomized trials	41	38	None	–	MD 1.38 lower (4.31 lower to 1.55 higher)	Very low	Critical
Cement leakage (followup 12–36 months; x-ray)								
4	Randomized trials	8/104 (7.7%)	11/99 (11.1%)	None	RR, 0.72 (0.32–1.63)	31 fewer per 1000 (from 76 fewer to 70 more)	Low	Critical
Adjacent-level fractures rate (followup 12–36 months)								
3	Randomized trials	4/51 (7.8%)	4/50 (8%)	None	RR, 1.10 (0.44–2.77)	8 more per 1000 (from 45 fewer to 142 more)	Low	Critical
Operation time (followup 12–36 months; measured with operating time; range of scores, 32–71; better indicated by lower values)								
4	Randomized trials	107	96	Strong association ⁷	–	MD 24.98 lower (27.04 to 22.91 lower)	High	Important
Kyphosis angle reduction (followup 12–33 months; measured with kyphosis angle reduction after operation; range of scores, 0–180; better indicated by higher values)								
3	Randomized trials	62	68	None	–	MD 1.91 lower (5.8 lower to 1.98 higher)	Low	Important
Postoperative anterior vertebral body height restoration (followup 12 months; measured with 0–100%; range of scores, 0–100%; better indicated by higher values)								
3	Randomized trials	71	65	None	–	MD 0.47 higher (0.677 lower to 1.72 higher)	Very low	Important

¹ Without concealment; ²no details of randomization; ³Chung et. al did not report SD of VAS resulting in wide 95% CI; ⁴limited sample size; ⁵no exact data in one study, only a figure to estimate the data; ⁶result is inconsistent; ⁷effect is really stable; MD = mean difference; RR = risk ratio.

the radiographic results (such as kyphosis angle reduction and vertebral height restoration); and (4) operation time is much less for a unilateral percutaneous kyphoplasty compared with bilateral percutaneous kyphoplasties.

There are some limitations of this systematic review. First, the sample size of the included studies was small, so despite data pooling, our meta-analysis might be underpowered to answer some important questions. Larger studies are needed. Second, although aggregate data contained larger statistical power, the included prospective randomized studies had various types of biases, such as selection bias, performance bias, and detection bias, which would lower the quality of evidence. Third, the SD data for the VAS were not reported in one study [8]; by converting the reported data to SD, statistical biases were produced in this meta-analysis. Fourth, the overall GRADE quality of evidence was very low, which lowers confidence in any subsequent recommendations. Moreover, owing to the limited number of included studies, publication bias was difficult to evaluate and sensitivity was impossible to evaluate even with obvious heterogeneity.

We took the results of the VAS and Oswestry Disability Index for clinical effectiveness assessment. The results of the short-term and long-term VAS outcomes revealed no significant differences between unilateral and bilateral percutaneous kyphoplasties. The result was consistent, because all the included studies showed that unilateral and bilateral percutaneous kyphoplasties were effective for pain control, and no differences were found among them [5–8, 32]. Two studies reported short- and long-term Oswestry Disability Index improvement, and no difference was found between the two groups [6, 32]. Because of the weakness of the study design and the limited sample size, together with other biases, the GRADE evidence quality for the VAS and Oswestry Disability Index outcomes were low or very low.

In our safety assessment, we took the results of the cement leakage rate and postoperative adjacent-level fracture rate, because they were the only complications reported in these studies. With the numbers available, we found there was little difference in cement leakage rate between unilateral and bilateral percutaneous kyphoplasties (RR, 0.72; 95% CI, 0.32–1.63; $p = 0.43$). Bilateral percutaneous kyphoplasties might increase the rate of cement leakage because two pedicles are punctured, but the data do not confirm this. The aggregate cement leakage rates were 10% for unilateral percutaneous kyphoplasty and 16% for bilateral percutaneous kyphoplasties [15, 25, 31], and as our meta-analysis showed, the aggregate cement leakage rates were 7.7% and 11.1% respectively. For postoperative adjacent-level fracture rates, the pooled outcome analysis showed no significant differences between the unilateral and bilateral percutaneous kyphoplasties (RR, 0.96; 95%

CI, 0.27–3.42; $p = 0.95$). However, the GRADE evidence quality for safety assessment was low. No accidental pulmonary cement embolism was reported in the included studies. Kim et al. [20] reported that pulmonary cement embolisms were detected in 23% of patients who had percutaneous vertebroplasties. Other systematic reviews reported rates ranging from 2.1% to 26% for percutaneous kyphoplasty and percutaneous vertebroplasty [23, 40]. Because there is no clear diagnostic standard for pulmonary cement embolism, this complication might be underreported with radiographic assessment.

We used kyphosis angle reduction and anterior vertebral height restoration for radiographic outcomes assessment. Random effects model analysis was performed and showed no difference between the treatment approaches (MD, -1.91 ; 95% CI, -5.8 to 1.98 ; $p = 0.34$; $I^2 = 85\%$). The GRADE evidence quality for kyphosis angle reduction outcome was low. Regarding anterior vertebral height restoration, with the numbers available there was no difference between the unilateral and bilateral approaches (MD, 0.47 ; 95% CI, -0.77 to 1.72 ; $p = 0.46$; $I^2 = 91\%$, random effects model used). The GRADE evidence quality was low. Some in vitro studies showed that a unilateral percutaneous kyphoplasty is comparable to bilateral percutaneous kyphoplasties in restoration of vertebral body strength, stiffness, and height in experimentally induced vertebral compression fractures [4, 38], but a unilateral percutaneous kyphoplasty requires the augmentation be extended across the midline and both sides of the vertebral body must be filled with polymethylmethacrylate to avoid imbalance of stress on the vertebral body.

Adequate operative time data were available in four of the trials [5–7, 32]. The pooled outcome showed a shorter operative time favoring unilateral groups (MD, -24.98 ; 95% CI, -27.04 to -22.91 ; $p < 0.00001$). The GRADE evidence quality was high even with serious limitations in design and performance of the included studies. We accept that there was high evidence that a unilateral percutaneous kyphoplasty needs less operation time than bilateral percutaneous kyphoplasties.

Conclusion

This meta-analysis comparing unilateral and bilateral percutaneous kyphoplasties for treating osteoporotic vertebral compression fractures showed that unilateral and bilateral percutaneous kyphoplasties are safe and effective surgical procedures. Considering less operation time and less cost, we suggest that a unilateral percutaneous kyphoplasty is advantageous, but because of the poor quality of the evidence, high-quality randomized controlled trials are required to resolve this issue definitively.

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