Systematic Review

The Role of Unilateral Balloon Kyphoplasty for the Treatment of Patients with OVCFS: A Systematic Review and Meta-Analysis

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Background: An increasing number of studies have been conducted to apply unilateral balloon kyphoplasty in the treatment of ostroporotic vertebral compression fractures (OVCFs). However, the efficacy and safety of unilateral kyphoplasty and whether a unilateral or a bilateral approach is superior is controversial.

Objectives: The purpose of this study was to evaluate the role of unilateral balloon kyphoplasty and use meta-analysis to compare the efficacy and safety of unilateral and bilateral kyphoplasty in patients with OVCFs.

Study Design: A systematic literature search was conducted from 1970 to April 2017 using Medline database and the Cochrane Central Register of Controlled Trials. Articles were limited to those published in English. Randomized controlled trials and nonrandomized comparative studies were also included.

Setting: The following search terms were used: "osteoporotic vertebral compression fractures," or "OVCF," and "unilateral kyphoplasty," or "unipedicular approach," or "single balloon kyphoplasty," or "one balloon kyphoplasty." A comprehensive search of reference lists of retrieved articles and previous published reviews was also performed to ensure inclusion of all possible studies.

Methods: All potential articles were independently reviewed by 2 investigators for inclusion into the final analysis. MINORS score was used for nonrandomized studies, and Detsky quality index was applied for prospective randomized controlled trials. Systematic review and meta-analysis was performed for the included studies.

Results: After unilateral balloon kyphoplasty the mean postoperative visual analog score (VAS) was from 1.74 to 4.77, mean postoperative kyphotic angle was from 5.9° to 11.22°, and complications involving cement leaks was from 6.8 to 21.9% or adjacent level fractures was from 0 to 5.6%). Unilateral kyphoplasty had significantly lower operative time, and less bone cement volume; however, the postoperative VAS, Oswestry Disability Index (ODI), vertebral height restoration rate, and cement leakage and adjacent vertebral fracture rate, were similar to bilateral kyphoplasty.

Limitations: Only 6 randomized controlled trials and 3 retrospective comparative studies were selected for analysis. Heterogeneity was detected among the studies when we pooled the outcomes.

Conclusions: Based on the available evidence, the clinical and radiological results of unilateral balloon kyphoplasty were as good as those of bilateral balloon kyphoplasty for the treatment of OVCFs. And unilateral kyphoplasty had advantages in terms of operation time, radiation exposure, and cost.

Key words: Unilateral balloon kyphoplasty, bilateral balloon kyphoplasty, osteoporotic vertebral compression fractures, complications of balloon kyphoplasty, meta-analysis

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Vertebral compression fractures constitute a major health problem affecting more than 1.4 million people each year worldwide, leading to pain, significant morbidity, and healthcare expenses (1-2). Minimally invasive techniques, such as percutaneous balloon kyphoplasty, have been employed to treat osteoporotic vertebral compression fractures (OVCFs). Studies have shown that balloon kyphoplasty provides satisfactory clinical outcomes and better efficacy than conservative treatment (3-9). The standard technique for kyphoplasty involves cannulating both pedicles and placing 2 balloons into the vertebral body (bipedicular approach) (10). But recently a unipedicular approach has been advocated, reducing the operating time, radiation exposure, and complications, and increasing the cost-effectiveness of the procedure (11,12). An increasing number of studies have been conducted to apply unilateral balloon kyphoplasty in the treatment of OVCFs (13-19). Scholars have compared the clinical and radiological results of unilateral and bilateral kyphoplasty approach (20-28). However, the efficacy and safety of unilateral kyphoplasty, or whether a unilateral or a bilateral approach is superior, have been controversial. In the current study, we reviewed the literature evaluating the role of unilateral balloon kyphoplasty and used meta-analysis to compare the efficacy and safety of unilateral and bilateral kyphoplasty in patients with OVCFs.

Methods

Searching and Selection

A systematic literature search was conducted up to April 2017 using the Medline database and the Cochrane Central Register of Controlled Trials. Articles were limited to those published in English. Because only a small number of randomized controlled trials were available in the literature, nonrandomized comparative studies (prospective and retrospective) were also included. The following search terms were used: "osteoporotic vertebral compression fractures," or "OVCF," and "unilateral kyphoplasty," or "unipedicular approach," or "single balloon kyphoplasty," or "one balloon kyphoplasty." A comprehensive search of reference lists of retrieved articles and previous published reviews was also performed to ensure inclusion of all possible studies.

The following inclusion criteria were used 1) The study population consisted of patients with OVCFs; 2) The patients received surgeries through unilateral kyphoplasty or bilateral kyphoplasty; 3) At least one of the following outcomes was reported: operative time, x-ray exposure time, cement volume, visual analog score (VAS), Oswestry Disability Index (ODI), kyphotic angle, restoration rate, and loss reduction or height loss rate after the operation, the incidence of the adjacent vertebral fracture, and cement leakage. All potential articles were independently reviewed by 2 investigators (X.G.H, T.M.J) for inclusion into the final analysis.

Data Extraction

Data were collected based on following categories where available: 1) published year and study design; 2) basic characteristics including inclusion/exclusion criteria, age, gender proportion, enrolled number, surgical modalities, and follow-up duration; 3) baseline comparison information of confounding factors, such as gender, age, surgical level, and concomitant diseases; 4) surgical information, including operative time, intraoperative and postoperative blood loss, intraoperative x-ray exposure time, and bone cement volume; 5) preoperative and postoperative outcomes such as VAS, ODI, kyphotic angle, and height loss rate; 6) outcomes improvement at last follow-up including VAS, ODI, kyphotic angle, and height restoration rate; 7) complication types and complication rates.

Quality Assessment

We applied 2 assessing tools to analyze both the randomized and nonrandomized studies included. MINORS score was used for nonrandomized studies, and Detsky quality index was applied for prospective randomized controlled trials (29,30). Based on the previous published papers, studies scoring ≥ 75 % of the maximum MINORS or Detsky score were designated high quality. Each eligible study was independently reviewed by 2 raters for methodological quality (X.G.H, T.M.J). Inconsistencies were resolved through discussion until a consensus was reached.

Meta-Analysis

For continuous data (operative time, bone cement volume, VAS, ODI, height restoration rate), the inverse variance method was used for the combination of standardized mean differences (SMD). Binary data (adjacent vertebral fracture, cement leakage) were summarized as risk ratios (RR) and combined using the Mantel–Haenszel method. Heterogeneity was evaluated using the χ^2 test and I^2 statistics (considered significant when P value for χ^2 test < 0.10 or I^2 > 50%). Random-effect

models were applied if the heterogeneity was significant; otherwise fixed-effect models were used. The sensitivity analysis was performed to test the strength and robustness of pooled results by sequential omission of individual studies when necessary. Forest plots were used for the graphical display. The analysis was carried out using the statistical software Review Manager Version 5.0 (Cochrane Collaboration, Oxford, UK).

Results

Literature Search

The search strategy (Fig. 1) yielded 16 studies on the use of unipedicular balloon kyphoplasty in the treatment of patients with OVCFs, including 6 randomized controlled trials, 3 retrospective comparative studies, and 7 case series (13-28). Characteristics of each article were given in Table 1 and Table 2.

Risk of Bias Assessment

MINORS score was used for nonrandomized studies, and Detsky quality index was applied for randomized controlled trials. The scores vary from 15 to 20 (Table 2). According to the previous published papers scoring > 75% of the maximum score (15/20 or 18/24) were designated high quality, there were 8 high quality studies.

Patients Undergoing Unilateral Percutaneous Kyphoplasty

Seven studies reported 409 patients undergoing unilateral percutaneous kyphoplasty (13-19). We used a descriptive method for these reports (Table 2). The patient mean age range was 60.3–74 years, and 292 patients were women. The surgical techniques including unilateral transpedicular approach (13,14), unilateral extrapedicular approach (15-19). The mean operative time was 25–37.4 minutes (14,15,17). The mean cement

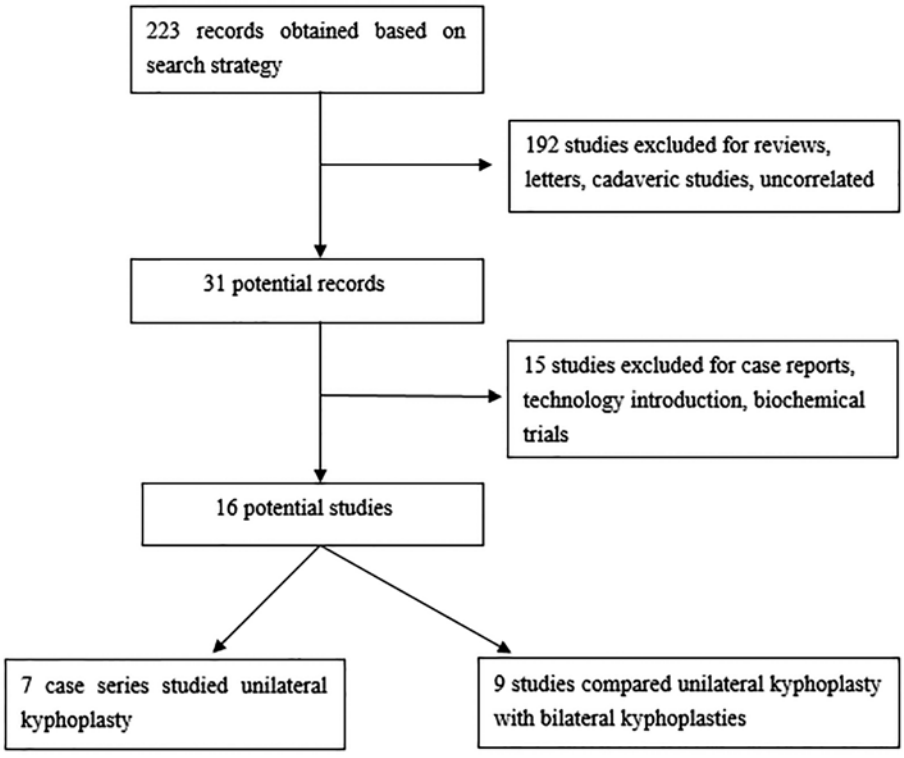

Fig. 1. *The search strategy.*

Table 1. *Evidence for the use of unilateral balloon kyphoplasty in treatment of OVCFs.*

Characteristic	Ryu et al (15)	Lee et al (13)	Sun et al (14)	Papadopoulos et al (19)	Ryu et al (16)	Cho et al (18)	Ge et al (17)
No. of patients	31	105	36	142	29	28	38
Mean age (y)	70	71.6	73.8	74	68.8	72	60.3
Gender (F:M)	27:4	80:25	26:10	110:32	23:6	_	26:12
BMD (T)	-3.95 ± 0.97	_	_		_	-3.24 ± 1.05	_
Follow-up (mo)	8.6	15.3	9.2	7.25	_	17.5	9.5
Operative time (min)	25	< 35	37.4	_	_	_	30
Cement volume (mL)	4.57 ± 1.03	_	3.1	_	4.90 ± 1.13	5.12 ± 1.47	3.2 ± 1.4
Kyphotic angle (°)							
Pre-	16.06 ± 5.24	12.8 ± 6.1	_	_	15.23 ± 5.12	11.6 ± 7.90	19.52 ± 4.79
Post-	8.84 ± 3.89	7.1 ± 4.7	_	_	8.01 ± 4.82	5.9 ± 6.35	11.22 ± 6.51
Cobb angle (°)							
Pre-	_	14.8 ± 8.1	23.43 ± 5.00	_	_	_	_
Post-	_	11.8 ± 9.0	16.16 ± 2.77	_	_	_	_
VAS score							
Pre-	8.58 ± 1.86	8.7 ± 1.4	7.27 ± 1.02	7.02 ± 2.21	9.24 ± 1.22	7.7 ± 1.01	8.92 ± 0.68
Post-	1.78 ± 1.47	2.3 ± 0.9	2.71 ± 0.75	4.77 ± 2.6	1.74 ± 1.85	2.0 ± 1.28	2.80 ± 0.34
Cement leaks (n/%)	7/21.9%	9/6.8%	_	10.73%	15.6%	3/10.7%	3/7.9%
Adjacent level fractures (n/%)	_	_	0	8/5.6%	_	0	_
Ha (mm)	Mean restoration rate was 31.72 ± 20.98%		Postoperation Ha gained 4.3 mm	Mean restoration rate was 48.9 ± 36.0%	Mean restoration rate was 30.34 ± 20.98%	Mean restoration rate was 11.1 ±15.1%	
Pre-		19.8 ± 0.24					18.55 ± 4.32
Post-		22.1 ± 0.16					21.54 ± 4.32
Hm (mm)						Mean restoration rate was 12.8 ± 12.2%	
Pre-		18.5 ± 0.18					15.87 ± 4.43
Post-		22.5 ± 0.15					21.52 ± 3.41

Pre-: Preoperative; Post-: Postoperative; Ha: Height of anterior vertebral body; Hm: Height of middle vertebral body; VAS: Visual Analog Scale.

Table 2. *Characteristics of studies comparing unilateral versus bilateral balloon kyphoplasty.*

Study	Years	Study design	Quality scale[a]	Gender (F:M)	Follow-up (mo)	Patients
Chung HJ et al (24)	2008	RCT	14/20	49:3	≥12	T11–L2 OVCFs
Song BK et al (22)	2009	RCS	16/24	29:16	3	T6-L4 OVCFs
Chen C et al (28)	2010	RCT	16/20	58:0	0.5	-
Chen C et al (21)	2011	RCT	16/20	50:0	24	T12 or L1 OVCFs
Chen L et al (27)	2011	RCT	16/20	41:8	33.5	T6-L4 OVCFs
Wang Z et al (25)	2012	RCS	18/24	32:30	≥15.9	T9-L5 OVCFs
Rebolledo BJ et al (26)	2013	RCT	15/20	38:6	12	T5–L5 OVCFs
Bozkurt M et al (23)	2014	RCS	20/24	124:76	42.2	T4–L5 OVCFs
Yan L et al (20)	2014	RCT	17/20	220:89	16.8	L1-L5 OVCFs

RCS: Retrospective Comparative Study; RCT: Randomized Controlled Trial; OVCFs: Osteoporotic Vertebral Compression Fractures;
a RCT was assessed using Detsky score and non-RCT was assessed using MINORS score

volume was 3.1-5.12 mL (14-18). The mean postoperative VAS score was from 1.74 to 4.77 (14-19), and the mean postoperative kyphotic angle was from 5.9° to 11.22° (13,15-18). There were 7 case series reported complications involving cement leaks (6.8-21.9%) or adjacent level fractures (0-5.6%) (13-19).

Table 3. *Main characteristics of the identified studies pooled in the meta-analysis.*

Characteristic	Chung HJ et al (24)		Song BK et al (22)		Chen C et al (28)		Chen C et al (21)		Chen L et al (27)		Wang Z et al (25)		Rebolledo BJ et al (26)		Bozkurt M et al (23)		Yan L et al (20)	
	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-	Uni-	Bi-
No. of patients	24	28	15	30	33	25	27	23	24	25	31	31	23	21	116	84	158	151
Mean age (y)	66.8	68.9	63.60	69.57	67.73	68.52	68.37	69.43	70.4	72.4	68.3	69.2	78.7	79.3	57	58	71.9	71.1
Operative time (m)	_	_	_	_	33.84	59.39	34.12	57.33	87	120	45	68	47.6	71.4	_	_	33.2	52.5
Cement volume (mL)	3.44	6.43	_	_	_	_	4.11	5.82	3.9	5.5	3.5	7.5	4.8	6.3	1.5	3.0	3.4	5.5
VAS score																		
Pre-	8.1	7.9	8.7	7.0	7.79	7.36	7.74	7.35	7.8	7.9	8.4	8.6	_	_	8.30	8.27	8.1	7.9
Post-	1.9	1.8	2.8	2.8	2.82	2.76	3.93	4.09	3.1	2.7	1.9	2.1	_	_	2.84	2.66	2.6	2.9
ODI																		
Pre-	_	_	44.67	41.17	40.94	39.32	40.56	39.52	_	_	_	_	_	_	73.45	73.8	_	_
Post-	_	_	20.8	19.77	19.85	21.32	22.33	24.35	_	_	_	_	_	_	26.25	26.01	_	_
Cement leaks (n/%)	2/8.3	0	_	_	2/6.1	0	_	_	2/8.3	4/16	4/12.9	5/16.1	2/7.1	7/25	13/7.2	9/7.7	12/7.6	22/14.6
Adjacent level fracture (n/%)	–	_	2/13.3	4/13.3	_	_	4/14.8	2/8.7	0	2/8	2/6.5	3/9.7	_	_	4/3.4	2/2.3	4/2.5	5/3.3
Height restoration rate (%)	_	_	_	_	25.84	32.32	24.97	34.16	_	_	28.5	32.5	20.5	14.8	24.25	37.05	_	_
Kyphotic angle (°)																		
Pre-	17.6	18.5	11.96	8.60	_	_	_	_	24.3	27.2	_	_	26.5	24.0	_	_	18.83	17.98
Post-	Mean restoration was 41.3±8.9%	Mean restoration was 67.8±8.6%	8.17	4.97	_	_	_	_	17.2	19.8	_	_	21.7	19.3	_	_	9.25	12.29

Uni-: Unilateral; Bi-: Bilateral; Pre-: Preoperative; Post-: Postoperative; VAS: Visual Analog Scale; ODI: Oswestry Disability Index.

Comparison of Unilateral and Bilateral Percutaneous Kyphoplasty

Nine studies reported a total of 451 patients in the unilateral kyphoplasty group and 418 in the bilateral kyphoplasty group (20-28). The clinical data of included studies was presented in Table 3.

Operative Time

Six of them provided adequate data about the mean and SD. The weighted mean difference (WMD) was statistically significant (WMD = -23.13, $P < 0.00001$, 95% CI: -26.68 to -19.58; $I^2 = 71\%$, Fig. 2) in favor of the unilateral kyphoplasty group.

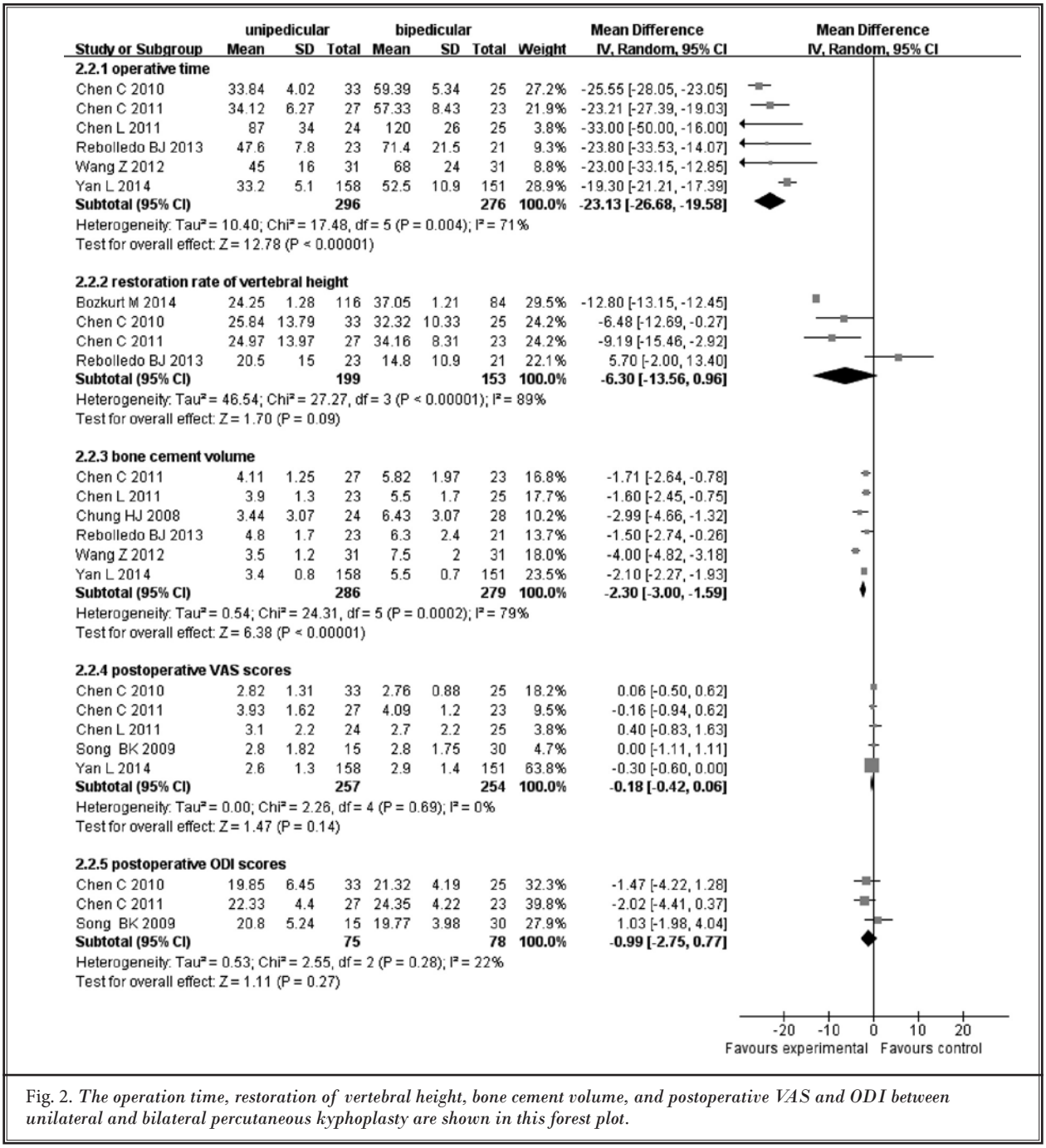

Fig. 2. *The operation time, restoration of vertebral height, bone cement volume, and postoperative VAS and ODI between unilateral and bilateral percutaneous kyphoplasty are shown in this forest plot.*

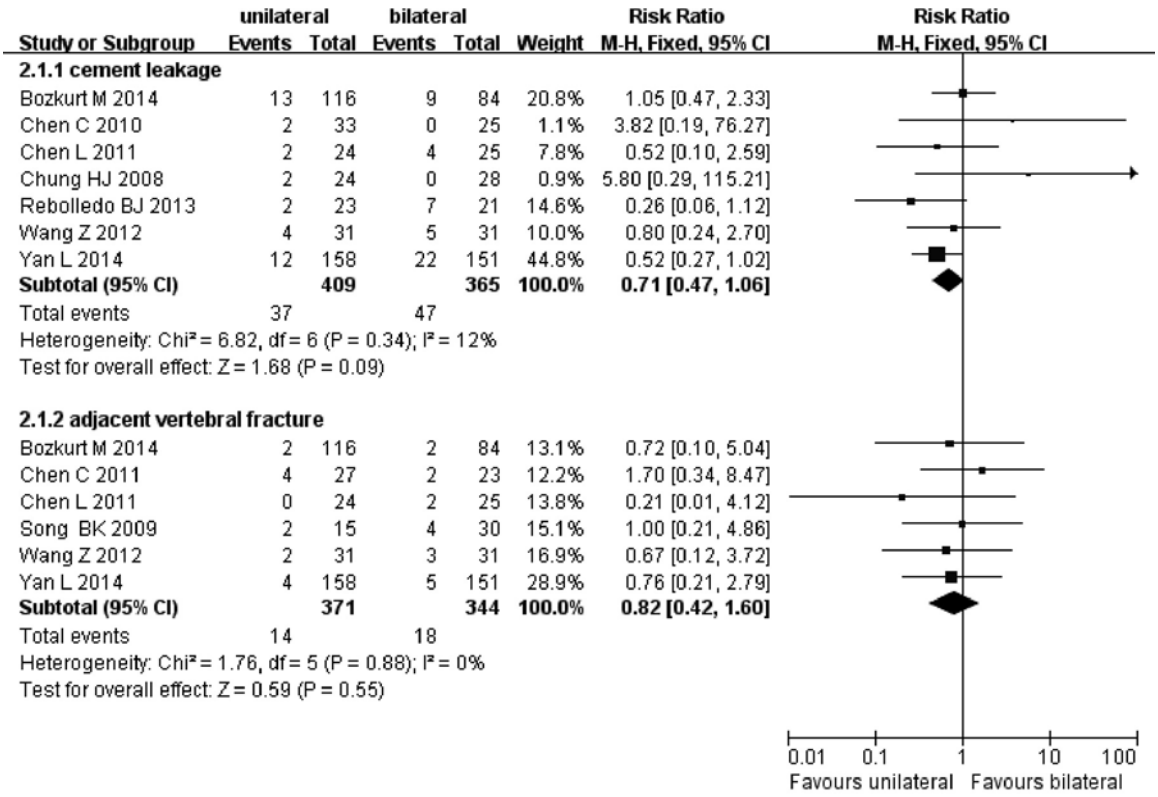

Fig. 3. *The cement leakage and adjacent vertebral fracture rate between unilateral and bilateral percutaneous kyphoplasty are shown.*

Restoration Rate of Vertebral Height

Adequate vertebral height restoration data were available in 4 studies. Pooled data indicated a higher restoration rate of vertebral height in the bilateral group, however, the difference was not statistically significant (WMD = -6.30, P = 0.09, 95% CI: -13.56 to 0.96; I^2 = 89%, Fig. 2).

Bone Cement Volume

Six studies provided adequate data about the mean and SD. Compared with bilateral kyphoplasty group, pooled estimate showed that the unilateral kyphoplasty group used significantly less bone cement volume (WMD = -2.30, P < 0.00001, 95% CI: -3.00 to -1.59; I^2 = 79%, Fig. 2).

Postoperative VAS and ODI

Five studies contributed to a summative outcome. The unilateral and bilateral percutaneous kyphoplasty group obtained similar VAS after surgery (WMD = -0.18, P = 0.14, 95% CI: -0.42 to 0.06; I^2 = 0%, Fig. 2). Three studies reported the results of postoperative ODI, outcomes revealed no difference between unilateral and bilateral percutaneous kyphoplasty (WMD = -0.99, P = 0.27, 95% CI: -2.75 to 0.77; I^2 = 22%, Fig. 2).

Complications

Data regarding complications were available in 9 studies. Seven studies reported cement leakage, and 6 studies reported adjacent vertebral fracture. The pooled estimate showed that the bilateral group was associated with a higher, but statistically insignificant cement leakage and adjacent vertebral fracture rate when compared with the unilateral group. (RR = 0.71, 95 % CI: 0.47–1.06, P = 0.09, I^2 = 12%; RR = 0.82, 95 % CI: 0.42–1.6, P = 0.55, I^2 = 0%; Fig. 3). No heterogeneity existed among the studies.

Publication Bias

The funnel plot showed a fairly symmetrical distribution of the studies that reported complication rate.

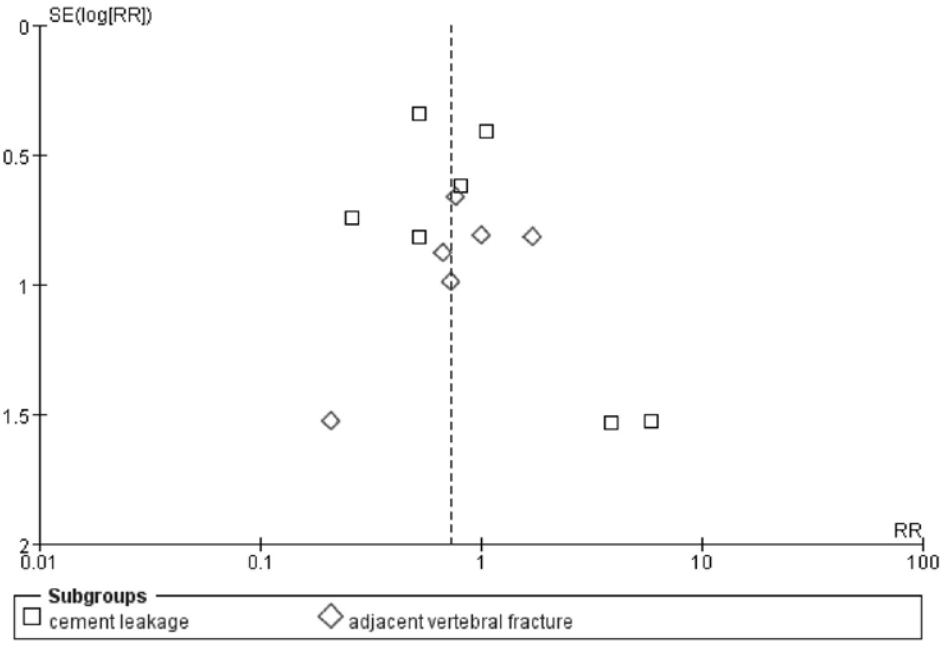

Fig. 4. *The funnel plot.*

All studies fell within the 95% CI and were distributed evenly about the vertical, implying minimal publication bias (Fig. 4).

Discussion

Hoh et al (11) introduced the use of balloon kyphoplasty via a unilateral transpedicular approach in the treatment of a T11 OVCF patient. They deemed that the advantages of a unilateral approach included, reducing the risk of pedicle fracture, nerve injury and cement leakage. Additionally, operative and radiation exposure time were decreased as well as the costs of balloon tamps, cannulas, and needles. The biomechanical tests studied by Steinmann et al (31) showed that unipedicular kyphoplasty was comparable to bipedicular kyphoplasty in the restoration of vertebral body strength, stiffness, and height in experimentally induced vertebral compression fractures. Chen et al (32) found that the restoration of biomechanical balance depends on the distribution of cement in unipedicular percutaneous kyphoplasty (PKP). Asymmetrical strengthening in a fractured vertebra may result in unbalanced lumbar mechanics and clinical efficacy will be influenced. However, when cement augmentation crosses the midline and increased stiffness is obtained on both sides, there is a strong potential for biomechanical balance to be achieved. Wang et al (33) introduced the transverse process-pedicle approach, which allowed an easy puncture to meet or surpass the midline of the lumbar vertebral body.

Several studies (34-36) compared clinical outcomes of unilateral and bilateral percutaneous kyphoplasty, but these studies included small sample sizes and some methodological errors. Therefore, we reviewed the literature evaluating the role of unilateral balloon kyphoplasty and used meta-analysis to compare the efficacy and safety of unilateral and bilateral kyphoplasty in patients with OVCFs.

Recently, many reviewers have reported the application of unilateral balloon kyphoplasty in OVCFs (13-19). The results showed that the mean postoperative VAS was from 1.74 to 4.77, and the mean postoperative kyphotic angle was from 5.9° to 11.22°. These studies also demonstrated complications involving cement leaks (6.8-21.9%) or adjacent level fractures (0-5.6%). The clinical and radiographic results confirmed that unilateral balloon kyphoplasty was an effective procedure for the treatment of OVCFs.

Our meta-analysis suggested that: 1) unilateral kyphoplasty had significantly lower operative time, and

less bone cement volume; 2) the postoperative VAS and ODI were similar between these 2 groups; 3) there was no significant difference in vertebral height restoration; 4) there was no significant difference in cement leakage or adjacent vertebral fracture rate. Owing to the use of only one balloon, cannula, and needle, the cost was less for the unilateral kyphoplasty group.

Limitations

There are several limitations in this meta-analysis. First, only 6 randomized controlled trials and 3 retrospective comparative studies were selected for analysis. Therefore, the level of evidence for this meta-analysis was not high. Second, heterogeneity was detected among the studies when we pooled the outcomes. The heterogeneity could be explained by various study qualities, study designs, and patients' baselines. Third, incomplete data recording was observed when we extracted clinical outcomes. Pooling of such data might lead to bias. Despite these weaknesses, our study can still provide some value for clinical reference.

Conclusions

Based on the available evidence, the clinical and radiological results of unilateral balloon kyphoplasty were as good as those of bilateral balloon kyphoplasty for the treatment of OVCFs. Unilateral kyphoplasty had advantages in terms of operation time, radiation exposure, and cost. More randomized controlled trials are needed to compare these 2 surgical options.

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