Systematic Review

Is Unilateral Percutaneous Kyphoplasty Superior to Bilateral Percutaneous Kyphoplasty for Osteoporotic Vertebral Compression Fractures? Evidence from a Systematic Review of Discordant Meta-Analyses

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Background: Several meta-analyses have been performed to compare unilateral percutaneous kyphoplasty (PKP) and bilateral PKP in the treatment of osteoporotic vertebral compression fractures (OVCFs), but inconsistencies in the results have led to questions as to which technique is preferable.

Objective: This study was designed to clarify the benefits and disadvantages of unilateral PKP versus bilateral PKP as found in numerous discordant meta-analyses and thereby present surgical treatment recommendations for OVCFs considering the current best evidence.

Study Design: Systematic review/Meta-analysis.

Methods: Meta-analyses on unilateral and bilateral PKP for OVCFs were included by searching Pubmed, Embase, and Cochrane library. Meta-analysis quality was assessed using Oxford Levels of Evidence and Assessment of Multiple Systematic Reviews (AMSTAR). The Jadad decision algorithm was used to identify the best evidence.

Results: Eight eligible meta-analyses were included, 7 of which were Level-II evidence and one was Level-III evidence. The AMSTAR scores varied from 7 to 8. The Jadad decision algorithm suggested that the best meta-analysis should be selected depending upon publication characteristics and methodology of primary studies, language restrictions, and whether data analysis was performed on individual patients. The best available evidence indicated that both unilateral and bilateral PKP could receive similar good clinical and radiological outcomes. However, without increasing the risk of complications, unilateral PKP required shorter surgical time and less cement volume, offering better pain relief and quality of life at post-operative short term follow-ups.

Limitations: Primary studies had defects in their methodologies.

Conclusions: Unilateral PKP appears to be superior to bilateral PKP in the treatment of OVCFs.

Key words: Osteoporotic vertebral compression fractures, percutaneous kyphoplasty, meta-analysis

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Osteoporotic vertebral compression fractures (OVCFs) are common fractures in the elderly, and affect approximately 1.4 million patients, with a predominance in women (1). These fractures frequently lead to decreased mobility and quality of life (2,3). OVCFs have traditionally been managed by conservative treatment such as bed rest. About two-thirds of these patients improve

(2). However, complications from long-term bed-rest can worsen patients` conditions. Moreover, severe pain and progressive deformity are usually reported in patients treated by conservative treatment (2,4). Thus, percutaneous kyphoplasty (PKP) as a safe and effective alternative has been widely performed for OVCFs.

The standard procedure for PKP used a bipedicular approach with two balloon tamps (2,5). PKP using a unipedicular approach has been increasingly performed over the recent years due to reported outcomes comparable to bilateral PKP (6-12). Several randomized clinical trials (RCTs) have been done comparing the effectiveness and safety between unilateral and bilateral PKP, but results have been conflicting (2,13-32). The optimal percutaneous technique for OVCFs remains controversial. Meta-analyses have also been conducted to compare and contrast these 2 techniques. Likewise, results from these meta-analyses have also been conflicting (5-12). Although several studies have reported no differences in treatment effectiveness between unilateral and bilateral PKP in the treatment of OVCFs (7,10,12), other studies have concluded that unilateral PKP is superior to bilateral PKP (5,6,8,9,11). Such conflicting results have created controversy for decision makers(e.g., policy-makers, doctors, patients) who depend on high quality evidence when deciding upon an optimal OVCFs treatment.

In recent years, there has been an increasing number of systematic reviews on discrepant and overlapping meta-analyses (33-38). However, to our knowledge, none of these studies have compared the effectiveness between unilateral and bilateral PKP in the treatment of OVCFs. We conducted such a systematic review in an effort to provide operative recommendations based on the best available evidence.

Methods

This study was performed following the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement (39) and previous similar reports (40-43).

Study Retrieval

A computer search was done using PubMed, Embase, and the Cochrane Library on January 12, 2017. The following key words were used: kyphoplasty, systematic review, and meta-analysis. Two investigators individually performed the computer search. The reference lists of the meta-analyses were used to identify relevant studies. The titles and abstracts were checked for potential eligible studies. The full versions were obtained when the data was insufficient. Any disagreement was resolved by a third investigator.

Selection Criteria

The inlusion criteria were as follows: (1) meta-analyses comparing unilateral PKP with bilateral PKP for OVCFs; (2) articles published in English; (3) comparison of one or more outcomes, such as functional outcomes and complications. Abstracts of meetings, letters to the editor, correspondence, and systematic reviews without meta-analysis were excluded.

Information Extraction

The basic information was independently extracted by 2 investigators: the first author, publication year, database searched, the design of primary trial, the number of included studies and RCTs, I2, and outcomes. Disagreement between the investigators was eliminated by discussion with a third investigator.

Quality Assessment

Two investigators were assigned to evaluate the methodological quality of meta-analysis using Oxford Levels of Evidence (44) and the Assessment of Multiple Systematic Reviews (AMSTAR) tool (45). AMSTAR is thought to be a measurement instrument of study methodology, with reliability, validity, and responsibility (46,47). Any disagreement between the investigators was settled based on discussion and, when necessary, with arbitration by a third investigator.

Implementation of Jadad Decision Algorithm

Jadad et al (48) summarized the sources of disagreement among systematic reviews: comprising clinical questions, inclusion and exclusion criteria, abstracting data, quality evaluation, data synthesis, and statistical analysis. This decision algorithm guides the researchers to find treatment recommendations among discordant meta-analyses (40-43). Three investigators individually assessed the meta-analyses by this algorithm and came to an agreement on which meta-analysis generated the current best evidence.

Results

Study Retrieval

The search strategy found a total of 217 records from the databases. The selection process is shown in

Fig. 1. As a result, 8 meta-analyses were included (5-12). The general information is summarized in Table 1. Three studies were published in 2013 (8,10,11), 2 studies were published in 2014 (9,12), one study was published in 2015 (5), and the other 2 studies were published in 2016 (6,7). The meta-analyses included 3 to 14 primary studies (Table 2).

Search Methodology

Three meta-analyses restricted the publication language to English (5,6,9), while the others reported no language limitation (7,8,10-12). A Cochrane Library search was obtained by all included meta-analyses. However, the use of PubMed, Medline, Embase, OVID, and Web of Science was discordant (Table 3).

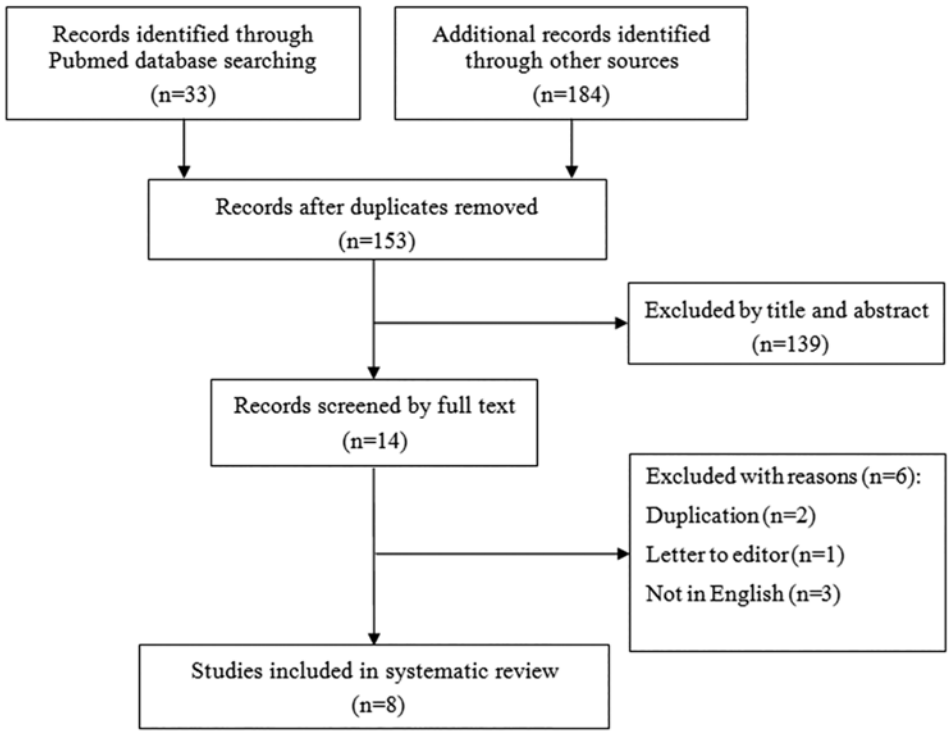

Fig. 1. *The flow chart of study selection.*

Table 1. *Characteristics of the included meta-analyses.*

First author	Date of publication	Journal	Date of last literature search	No. of included studies	No. of included RCTs
Li LH (8)	2013	Chin Med J (Engl)	March, 2013	7	7
Lin J (11)	2013	Pain Physician	July, 2012	3	3
Yang LY (10)	2013	Pain Physician	September, 2012	4	4
Chen H (12)	2014	Orthopedics	April, 2013	14	14
Huang Z (9)	2014	Clin Orthop Relat Res	June, 2013	5	5
Feng H (5)	2015	J Orthop Res	January, 2015	12	12
Cheng X (7)	2016	Eur Spine J	April, 2015	8	5
Sun H (6)	2016	Pain Physician	June, 2015	6	6

Table 2. *Primary studies included in meta-analyses.*

First author (Year)	Li LH (2013)	Lin J (2013)	Yang LY (2013)	Chen H (2014)	Huang Z (2014)	Feng H (2015)	Cheng X (2016)	Sun H (2016)
Chung HJ (2008) (15)	+	+	+	+	+	+	+	+
Gu XH (2009) (22)	+			+				
Chen C (2010) (25)	+		+	+	+	+	+	+
Jiang Y (2010) (24)				+				
Chen L (2011) (28)	+	+	+	+	+	+	+	+
Chen C (2011) (16)	+	+	+	+	+	+	+	+
Zhang B (2012) (30)				+				
Luo XL (2012) (32)	+			+				
Li Q (2012) (31)				+				
Li GZ (2012) (14)				+				
Feng J (2012) (13)				+				
YX H (2012) (19)				+				
Feng J (2013) (18)						+		
Mao JG (2013) (29)						+		
Zhai HL (2013) (20)						+		
Huang S (2013) (17)				+				
Rebolledo BJ (2013) (21)	+			+	+	+	+	+
He CJ (2014) (23)						+		
Lin XL (2014) (27)						+		
XJ L (2014) (26)						+		
Yan L (2014) (2)						+		+

Table 3. *Search methodology of the included studies.*

First author (year)	Restriction of publication language	Restriction of publication status	Search database						
			PubMed	Medline	Embase	Cochrane Library	OVID	Web of Science	Others
Li LH (2013) (8)	No	Yes	+			+			+
Lin J (2013) (11)	No	NR	+	+	+	+			+
Yang LY (2013) (10)	No	NR		+	+	+	+		+
Chen H (2014) (12)	No	NR	+		+	+		+	+
Huang Z (2014) (9)	Yes	Yes	+	+	+	+		+	+
Feng H (2015) (5)	Yes	Yes	+	+	+	+			+
Cheng X (2016) (7)	No	Yes	+	+	+	+	+	+	+
Sun H (2016) (6)	Yes	Yes	+	+	+	+		+	+

Table 4. *Methodological information for the included studies.*

First author (year)	Design of included studies	Level of evidence	Software	GRADE use	Subgroup analysis	Sensitivity analysis
Li LH (2013) (8)	RCT or quasi-RCT	Level II	Stata	No	No	Yes
Lin J (2013) (11)	RCT	Level II	RevMan	No	No	No
Yang LY (2013) (10)	RCT	Level II	RevMan	No	No	Yes
Chen H (2014) (12)	RCT	Level II	RevMan	Yes	No	No
Huang Z (2014) (9)	RCT or PCS	Level II	RevMan	Yes	No	Yes
Feng H (2015) (5)	RCT	Level II	RevMan	No	No	No
Cheng X (2016) (7)	RCT or non-RCT	Level III	RevMan	No	No	No
Sun H (2016) (6)	RCT	Level II	RevMan	Yes	No	Yes

RCT, Randomized clinical trial; PCS, Prospective comparative study

Table 5. *AMSTAR scores for the included studies.*

Items	Li LH (2013) (8)	Lin J (2013) (11)	Yang LY (2013) (10)	Chen H (2014) (12)	Huang Z (2014) (9)	Feng H (2015) (5)	Cheng X (2016) (7)	Sun H (2016) (6)
1. Was an a priori design provided?	0	0	0	0	0	0	0	0
2. Was there duplicate study selection and data extraction?	1	1	1	1	1	1	1	1
3. Was a comprehensive literature search performed?	1	1	1	1	1	1	1	1
4. Was the status of publication (i.e., grey literature) used as an inclusion criterion?	0	0	0	0	0	0	0	0
5. Was a list of studies (included and excluded) provided?	0	1	1	0	0	0	0	1
6. Were the characteristics of the included studies provided?	1	1	1	1	1	1	1	1
7. Was the scientific quality of the included studies assessed and documented?	1	1	1	1	1	1	1	1
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	0	0	0	0	1	1	1	1
9. Were the methods used to combine the findings of studies appropriate?	1	1	1	1	1	1	1	1
10. Was the likelihood of publication bias assessed?	1	0	1	1	0	1	0	0
11. Was the conflict of interest stated?	1	1	1	1	1	1	1	1
Total scores	7	7	8	7	7	8	7	8

Study Quality

In light of Oxford Levels of Evidence, seven studies were evaluated as Level-II (5,6,8-12), while one study was regarded as Level-III (Table 4) (7). The GRADE was applied in 3 studies (6,9,12). The AMSTAR scores ranged from 7 to 8 (Table 5).

Heterogeneity Evaluation

Heterogeneity was evaluated by statistical method using the I^2 statistic value (Table 6). Four meta-analyses performed the subgroup analyses (Table 4) (6,8-10). The I^2 values are shown in Table 6. The heterogeneities are acceptable for most results.

Table 6. *I^2 statistic value of each variable in each meta-analysis.*

Items	Li LH (2013) (8)	Lin J (2013) (11)	Yang LY (2013) (10)	Chen H (2014) (12)	Huang Z (2014) (9)	Feng H (2015) (5)	Cheng X (2016) (7)	Sun H (2016) (6)
Short-term VAS	0%	0%	0%	0%	0%	0%	0%	55%
Middle-term VAS				0%		0%		
Long-term VAS	0%	0%	0%	0%	0%	0%	0%	13%
Short-term ODI	NR			72%	NR	36%	31%	
Middle-term ODI								0%
Long-term ODI	NR			91%	NR			0%
Short-term SF-36 general health benefit						0%		0%
Short-term SF-36 bodily pain relief						9%		
Long-term SF-36						0%		
Surgery time	95%	17%	0%	32%	0%	14%	95%	77%
Cement volume	50%	0%		38%		44%	96%	0%
Cement leakage	40%	45%	28%	27%	41%	0%	23%	22%
Kyphosis angle reduction	0%			42%	85%	85%		93%
Restoration rate	94%					94%	0%	
Short-term anterior vertebral height restoration						0%		
Long-term anterior vertebral height restoration				0%	91%	18%		88%
Middle vertebral height restoration				25%		0%		
Cobb`s angle recovery						50%		
X-ray exposure frequency							98%	
Vertebral height loss			68%			0%		68%
Adjacent vertebral fracture			34%		39%	0%	34%	0%

VAS, Visual analog scale; ODI, Oswestry disability index

Results of Jadad Decision Algorithm

The outcomes of each meta-analysis are listed in Fig. 2. Given that the meta-analyses studied the same question, but did not use the same references or eligibility criteria, the Jadad decision algorithm suggested that the best available evidence should be chosen based upon the publication characteristics of the primary studies, the methodology of the primary studies, the language restrictions, and whether data for analysis were obtained from individual patients (Fig. 3). Hence, a high-quality meta-analysis reported by Feng et al (5) was eventually selected. This study found that unilateral PKP significantly decreased surgery time and cement volume and had a better result of pain relief (visual analog scale (VAS)) as well as quality of life (bodily pain relief and general health benefit of SF-36) at post-operative short-term follow-ups. Bilateral PKP had a better restoration of anterior vertebral height than unilateral PKP in short-term follow-up, while no difference was observed in long-term follow-up. The differences between unilateral and bilateral PKP were not significant in middle- and long-term VAS, short-term Oswestry disability index (ODI), long-term SF-36, cement leakage, long-term kyphosis angle reduction, restoration rate, long-term anterior vertebral height restoration, middle vertebral height restoration, Cobb`s angle recovery, vertebral height loss, and adjacent vertebral fracture.

Discussion

OVCFs can be managed by nonsurgical or surgical procedure (4). Surgical treatments, including unilateral

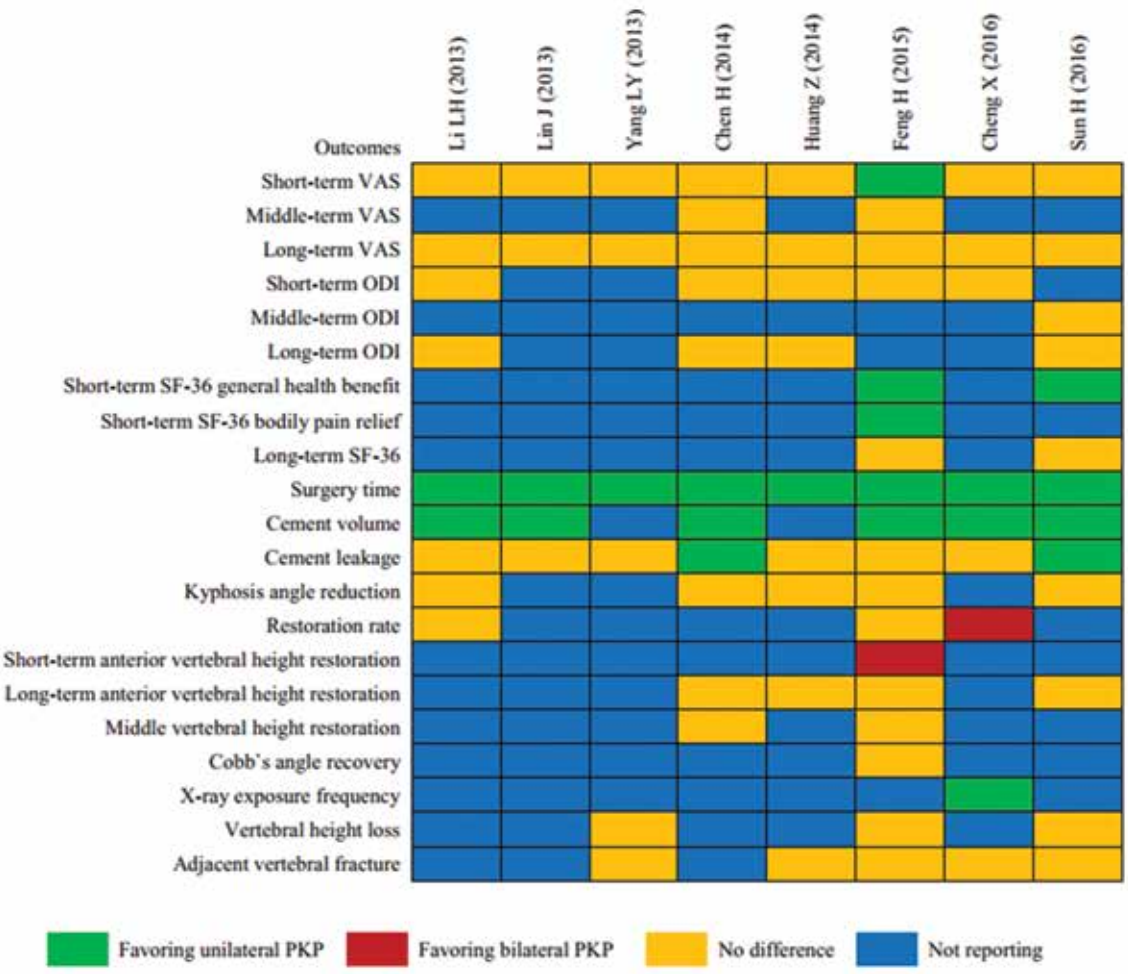

Fig. 2. *Results of the included meta-analyses.*

PKP and bilateral PKP, are widely performed in clinical settings because poor outcomes are reported in patients with conservative treatment (2,13-32). Unilateral PKP has emerged as a promising alternative to bilateral PKP and has been increasingly performed by doctors in recent years (5-12). However, whether unilateral PKP for OVCFs is more beneficial than bilateral PKP is still uncertain.

Meta-analysis of RCTs is considered be the best available source for evidence (36), Decision makers usually refer to meta-analyses to make recommendations on certain clinical topics. In light of this, an increasing number of meta-analyses have been reported to evaluate the differences between unilateral and bilateral PKP. However, discordant results have been found (33-38). These conflicting findings complicate decision making depending on the best available evidence. Systematic reviews of discordant meta-analyses help to interpret and choose the currently discordant available evidence and are increasingly published in medical fields to facilitate decision-making (36,40-43). To the best of our knowledge, this is the first systematic review of discordant meta-analyses regarding unilateral PKP versus bilateral PKP for OVCFs.

Although the computer search of the meta-analyses was performed during a similar period, they did not comprise the same primary studies and did not reach the same conclusions for the treatment selection of OVCFs. The potential reasons for inconsistency amongst systematic reviews have been reported by Jadad et al (48), including the differences in clinical questions, study selection, eligibility criteria, abstracting data,

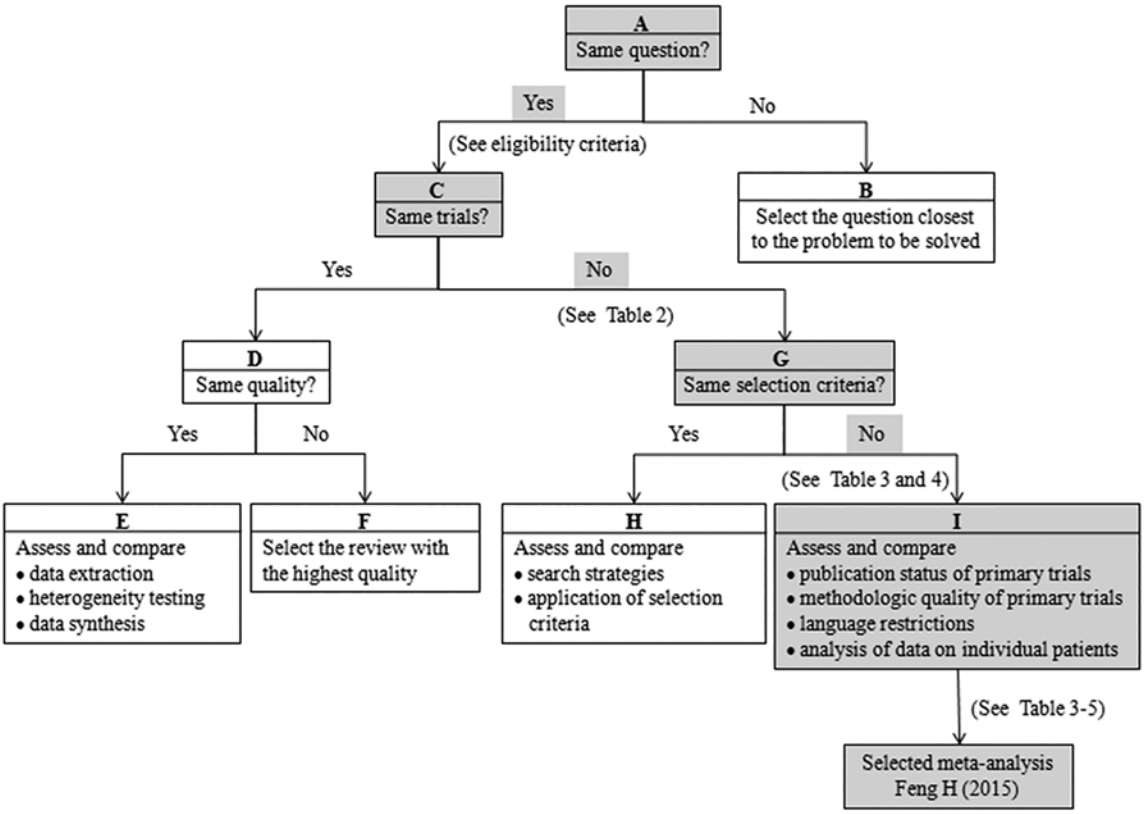

Fig. 3. *The flow chart of Jadad decision algorithm.*

quality evaluation, the ability to pool studies, and data synthesis. Jadad et al (48) designed a decision algorithm to identify high-quality evidence from conflicting meta-analyses. This tool was reported to identify the best evidence among discordant meta-analyses (36,40-43).

On the basis of the Jadad decision algorithm, the meta-analysis reported by Feng et al (5) was chosen in the present study. Their study proved that unilateral PKP had a better degree of pain relief than bilateral PKP at post-operative short-term follow-ups. The radiological outcomes at post-operative short-term follow-ups suggested that bilateral PKP provided a better restoration of anterior vertebral height. Surgical time and cement dosage were lower when unilateral PKP was performed. No differences were found in complications between the groups, such as cement leakage and adjacent vertebral fractures. The findings of life quality suggested that unilateral PKP was better for bodily pain relief and provided general health benefits at post-operative short-term follow-ups. Therefore, we suggest that unilateral PKP may be superior to bilateral PKP for the treatment of OVCFs.

Although this study was strictly conducted following similar publications, several potential limitations may impair the power of the findings. First, this study only included articles in English. Some important articles in other languages were not included. The language bias is inevitable in this systematic review. Second, the primary RCTs had some defects in the methodologies including allocation concealment, inclusion of patients, and outcome assessment, which may result in overestimation of the advantages and/or disadvantages of both procedures.

Conclusions

Based on this systematic review of discordant meta-analyses, the most current evidence suggests that unilateral PKP may be superior to bilateral PKP in the treatment of OVCFs. This study may aid doctors in evidence-based decisions regarding surgical selection of OVCFs treatment. However, high-quality studies should be conducted in the future because of the limitations of the studies included in this review.

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