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A systematic review of unilateral versus bilateral percutaneous vertebroplasty/percutaneous kyphoplasty for osteoporotic vertebral compression fractures

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ABSTRACT

Objective: The aim of this study was to compare the unilateral and bilateral approaches in treating osteoporotic vertebral compression fractures.
Methods: Based on the principles and methods of the Cochrane systematic reviews, the records of the Cochrane Library, PubMed, Web of Science, Chinese Bio-medicine database, China Journal Full-text Database, VIP database, and Wanfang database were reviewed until October 2014. The randomized controlled trials on unilateral and bilateral approaches to percutaneous vertebroplasty (PVP)/percutaneous kyphoplasty (PKP) for osteoporotic vertebral compression fractures were included. The risk of bias of included trials was assessed based on the Cochrane Handbook for Systematic Reviews of Interventions Version. The RevMan Software 5.0 was used for meta-analysis.
Results: Fifteen randomized controlled trials with a total of 850 patients were included. Risk of bias in the included studies was inevitable. There was no statistically significant difference in visual analog scale, vertebral height, kyphotic angular, and quality of life. The main operative complications were bone cement leakage and adjacent vertebral fracture, without difference between the two groups.
Conclusions: In view of the current evidence, there is insufficient evidence to show any difference between the unilateral and bilateral approaches in both the PVP and PKP treatment in osteoporotic vertebral compression fractures.
Level of Evidence: Level 1.

Osteoporosis is a skeletal disease with the characteristic of low bone mass and micro architectural deterioration of bone tissue, which increases the risk of fracture.[1] With the aging of society, the incidence rate tends to increase yearly. One of the most common complications,[2] osteoporotic vertebral compression fracture (OVCF), leads to persistent chest and/or waist pain. It has severe consequences for patient quality of life.

Conservative treatment takes a long time to achieve pain relief, while open surgery has slow recovery. In addition, open surgery can have many complications, such as hypostatic pneumonia or urinary tract infection as result of long-term bed rest. Therefore, minimally invasive surgery (MIS) has been increasingly favored. Percutaneous vertebroplasty (PVP) was first used in the 1980s, and was used in OVCF shortly thereafter. Addition of percutaneous kyphoplasty (PKP) represented an improvement that was also applied in clinical practice.[3] PVP and PKP have been shown to be effective in the reinforcement of a fractured vertebral body.[4,5] In addition, quick remission of pain and long-term analgesic effect effectively improve the quality of life of patients.[6,7]

In the early stage, bilateral approach was used for procedure. However, due to advantages of simple surgery and short operative time, unilateral approach has also been widely accepted. Therefore, systematic review was designed to provide the highest level quality of evidence in determination of superior approach in MIS for OVCF.[8] The goal of this systematic review of randomized controlled trials (RCT) was to identify differences between unilateral and bilateral approaches in treating OVCF, and to establish a reference for clinicians.

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Patients and methods

Criteria for considering studies for this review

1 Types of studies

Relevant RCT were included; controlled clinical trials and quasi-randomized studies were excluded.

2 Types of participants

Patients who were diagnosed with OVCF were included without discrimination based on age, sex, or race. Vertebral compression fracture was diagnosed based on imaging. Osteoporosis was defined as decreased bone mineral density diagnosed using World Health Organization guidelines.[9]

3 Types of interventions

Unilateral approach and bilateral approach were compared.

4 Types of outcome measures

Primary outcomes

a) Visual analog scale (VAS) score
b) Vertebral height
c) Kyphotic angle

Secondary outcomes

d) Quality of life
e) Complications

Search method for identification of studies

The Cochrane Library, PubMed, Web of Science, Chinese Biomedicine database, China Academic Journals Full-text Database, VIP database, and Wanfang database were searched using the search terms "osteoporosis," "osteoporoses," "osteoporotic," "fractures, compression," "spinal fractures," "percutaneous vertebroplasty," "percutaneous vertebroplasty," "vertebral plasty," "percutaneous kyphoplasty," "percutaneous kyphoplasty," "unilateral," "unipedicular," "unilateraly," "bilateral," "bipedicular," and "bipediculary." Entries of all databases through October 2014 were searched. The search strategy to identify randomized trials was implemented according to the description in the Cochrane Handbook for Systematic Reviews of Interventions.[10] In addition, references cited in articles were checked manually to identify other eligible studies.

Data collection and analysis

1 Selection of studies

The title, abstract, and keywords of every record were scanned by 2 authors independently to determine whether the studies should be assessed further. The full article was then examined to decide if it met the inclusion criteria. When there was disagreement, the reviewers resolved it through discussion. The reviewers attempted to contact article authors by e-mail if any information was not available.

2 Assessment of risk of bias

Two authors assessed risk of bias of included trials independently as described in the Cochrane Handbook for Systematic Reviews of Interventions[10] using the following criteria: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other sources of bias.

3 Data analysis

Review Manager (RevMan) 5.0 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was used to perform statistical analysis. For dichotomous data, relative risk and associated 95% confidence interval (CI) were calculated, while weighted mean difference and 95% CI were calculated for continuous data. When there was no statistically significant heterogeneity ($p \geq 0.10$, $I^2 \leq 50\%$), meta-analysis was conducted using fixed-effect model; otherwise, possible reasons were explored or random-effect model was used for significant heterogeneity ($p < 0.10$, $I^2 > 50\%$). When data could not be extracted for meta-analysis, the data from these trials were assessed as descriptive data and still considered in the results of the review.

Results

Description of studies

The initial search identified 422 references; 390 articles were subsequently excluded after reading titles and abstracts because they were duplicates or inconsistent with study objectives for the review. Thirty-two references were retrieved for further assessment, and 15 references[11–25] were excluded because they did not meet the inclusion criteria. Two references[26,27] were listed as studies awaiting classification, because those articles lacked information and we could not get in touch with the authors. Finally, 15 studies[28–42] were included. Fig. 1 illustrates flowchart of literature screening as described in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[43]

A total of 850 OVCF patients were included and follow-up period ranged from 2 weeks to 54 months. Groups were well matched at the baseline based on information obtained from studies. Table 1 provides details of the included studies.

Risk of bias in included studies

Table 2 and Fig. 2 are summaries of the risk of bias in the included trials. Only 4 trials indicated that random number table was used to generate allocation sequence, while all trials were described as randomized. Only 1 trial reported blinding to the patients and surgeons. More than half of the trials had missing data or patients lost to follow-up. We tried to get in touch with authors by e-mail, but did not receive any response.

Effects of interventions

Of the 15 included trials, 7 studies[28–34] reported operating method of PVP, 7 articles[36–42] reported operating method of PKP, and 1[35] was a comparison of PVP and PKP.

Effects of PVP

a) VAS score

Seven articles[28–34] reported VAS score from time point of post surgery (in a week) and 3, 6, 12 months after surgery. There was no statistical heterogeneity between trials in results from post surgery and 12 months after surgery ($p = 1.00$, $I^2 = 0\%$; $p = 0.18$, $I^2 = 42\%$). The result of pooled data revealed no statistical difference between unilateral and bilateral PVP for OVCF (Fig. 3).

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