Meta-analysis of percutaneous kyphoplasty for elderly osteoporotic vertebral compression fractures

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ABSTRACT

Objective: To evaluate the clinical efficacy of percutaneous kyphoplasty (PKP) in the treatment of osteoporotic vertebral compression fractures (OVCF) in the elderly by meta-analysis, and to provide a basis for clinical application. Methods: CNKI, Wanfang, Weipu, CBM, PubMed, the Cochrane Library and EMBase were retrieved by computer from the date of establishment to January 2019. The literature on randomized controlled trials of PKP and conservative treatment of OVCF was collected and diagnosed as thoracolumbar vertebral compression fracture by X-ray, CT, and MRI. Osteoporosis of thoracolumbar vertebrae (T<2.5) was determined by bone mineral density measurements. Age (>50 years old) and course of the disease (<3 months). Postoperative outcome indicators included at least one of the following indicators: visual analogue scale. VAS and Oswestry Dysfunction Index (ODI), changes of Cobb angle of diseased vertebrae and height of the anterior edge of diseased vertebrae. The quality of the included literature was evaluated by referring to the evaluation criteria for randomized controlled trials provided in the Cochrane Systematic Evaluation Manual. Results: Six randomized controlled trials studies were included, all of which were Chinese literature. Five of them had 4 or more points in methodological quality evaluation and one had 3 points in methodology quality evaluation. There were 525 patients in the two groups, 267 in the PKP group and 258 in the conservative treatment group. Meta-analysis showed that the pain visual analogue score in the PKP group was significantly higher than that in the conservative treatment group [MD=2.10, 95%CI (-2.25, -1.95), P<0.0001]. There were significant differences between the PKP group and the conservative treatment (CT) group [MD=8.90, 95%CI (-9.86, -7.94), P<0.0001] in the changes of the Cobb angle of the diseased vertebrae after treatment. There were significant differences in the ODI and the height of the anterior edge of the diseased vertebrae (P<0.05). Conclusion: PKP treatment of OVCF can effectively reduce pain visual analogue score, improve dysfunction index (ODI) and improve the quality of life of patients. It can also effectively restore the height of vertebral loss, correct the Cobb angle of the diseased vertebrae, and reduce the risk of recurrent fracture of the adjacent vertebral body and serious complications.

1. Introduction

In recent years, with the development of China’s social economy and the aging of the population, the incidence of osteoporosis is also increasing year by year, and the risk of fractures is gradually increased[1]. Osteoporosis is a systemic disease characterized by decreased bone mass and changes in bone microstructure, resulting in increased bone fragility and increased risk of fracture. The most important complication is osteoporotic vertebral compression fracture (OVCF) that has become an important factor that jeopardizes the lives of the elderly. Fractures can cause pain and limited mobility, which seriously reduce the quality of life of the elderly, and increase the social burden[2,3]. Percutaneous
kyphoplasty (PKP) is an emerging procedure for the treatment of senile OVCF. Due to its unique advantages, it has been widely used in clinical practice[4]. However, there is still no valid basis for the clinical efficacy and safety evaluation of PKP and conservative treatment. This study aimed to systematically study the effectiveness and safety of the two treatment methods through the meta-analysis method, and provide a reference for the clinical treatment of OVCF to select the appropriate treatment plan to better solve the pain for the patient.

2. Materials and methods

2.1. Selection criteria

2.1.1 Inclusion criteria
Randomized controlled trial (RCT) of PKP and conservative in the treatment of OVCF published at home and abroad; patients diagnosed as thoracolumbar vertebral compression fractures by X-ray, CT, or MRI; bone mineral density measurement measured the presence of thoracolumbar osteoporosis, T ≤ -2.5; gender is not limited, age≥50 years, duration<3 months; observation group was treated with PKP, and the control group was treated conservatively; outcome indicators included: Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI), changes in the Cobb angle of the diseased vertebrae and the height of the diseased vertebrae.

2.1.2 Exclusion criteria
Non-RCTs and repeated studies; fractures with nerve damage, vertebral body infections, tumors; patients with severe medical conditions such as cardiopulmonary disease and coagulopathy; Studies with obvious data errors and inability to extract relevant data.

2.2 Search strategy
Relevant studies were published since the establishment of the library in March 2019 on the Electric database, including CNKI, Wanfang, Weipu, CBM, PubMed, Cochrane, EMbase, and search language was not limited. Subjects were searched using the following keywords: osteoporosis, vertebral compression fractures, percutaneous kyphoplasty, PKP, osteoporotic vertebral compression fractures. According to the characteristics of different databases, the retrieval of subject words and free words were chosen, such as percutaneous kyphoplasty OR PKP AND osteoporosis OR vertebral compression fractures OR osteoporotic vertebral compression fractures OR OVCF.

2.3. Studies selection and data extraction
The two reviewers first read the title and abstract, select the documents, extracted the data and cross-check. If there is any disagreement, the third party would be involved to solve the problem. After excluding the obviously unrelated studies, then the reviewers read the full text to determine the final inclusion. Data extraction content mainly includes title, author, grouping method, type of study, age and gender of patients, number of patients in the observation group and the control group, outcome index, baseline status, presence or absence of fall-off, fund support, etc. The information should be supplemented with the author as much as possible, and finally, the EXCEL software was used to set up the data extraction table.

2.4. Studies quality assessment
The quality of the included studies was evaluated with reference to the evaluation criteria for RCTs provided by the Cochrane Collaboration. 1 to 3 points were considered the low quality and 4 to 7 points were considered the high quality. The specific evaluation contents are as follows: (1) random method: correct (2 points), unclear (1 point), incorrect (0 points); (2) Distribution concealment: appropriate (2 points), unclear (1 point), inappropriate (0 points); (3) Blind method: appropriate (2 points), unclear (1 point), inappropriate (0 points); (4) Whether there was loss of follow-up and whether the intentional analysis was used: described (1 point), not described (0 points). The evaluation was performed by two reviewers in accordance with the Cochrane Collaboration’s bias risk assessment tool for RCTs. If there was a disagreement, it would be resolved by a third party.

2.5. Statistical analysis
Heterogeneity test and meta-analysis were performed using RevMan 5.3 Version. The study used a fixed-effect model and a random effect model to analyze the data. First, the statistical heterogeneity analysis was performed. If I²<50%, there was no statistical heterogeneity or heterogeneity between the studies. The data were combined using the fixed effect model. If I²>50%, there is a certain heterogeneity between the studies. The random-effects model was used to combine the effect quantities. If heterogeneity was found, sensitivity analysis or subgroup analysis was performed to determine the heterogeneity; If there are more than 10 studies included in an outcome indicator, the inverted funnel plot was used to analyze whether there was publication bias; the mean difference (MD) was used for the same measurement data of the unit and the measurement method. If the measurement method was different or the unit was inconsistent, the standardized mean difference (SMD) would be used; At the same time, a 95% confidence interval (CI) was given, P<0.05, indicating that the difference between the two groups was statistically significant.
3. Results

3.1. Studies selection results

A total of 1 301 related documents were retrieved through our initial search. After reading articles and screening in accordance with inclusion and exclusion criteria, 6 studies were included in our meta-analysis. The flow chart of the screening process is described in Figure 1.

3.2. Studies characteristics and quality assessment

Among the six studies included, all were Chinese, with one of which was from 2018 \cite{15}, three from 2017 \cite{6,7,14}, and two from 2016 \cite{19,20}. A total of 525 patients were included, of which 267 were in the observation group and 258 in the control group. The average sample size was 87.5. The maximum sample size of the observation group was 55 cases, and the minimum sample size was 30 cases; the maximum sample size of the control group was 55 cases, and the minimum sample size was 30 cases. Methodological quality evaluation of the 5 articles was 4 points or more, with 1 document 3 points, and the overall quality was higher. The specific results are shown in Table 1, 2. The risk assessment results of bias are shown in Figure 2.

3.3. Meta-analysis results

3.3.1 Visual analogue scale

Five articles \cite{7,14,15,19,20} compared the VAS scores in patients after the treatment, a total of 431 patients, including 216 patients in the PKP group and 215 patients in the conservative treatment group. There was no heterogeneity between the studies (\(P=0.19, I^2=35\%\)), so a fixed effect model was used. The results showed that PKP was significantly different from conservative treatment [MD = -2.10, 95%CI (-2.25, -1.95), \(P<0.00001\)]. It showed that kyphoplasty was more advantageous in reducing pain in patients (Figure 3).

<table>
<thead>
<tr>
<th>References</th>
<th>year</th>
<th>Study Design</th>
<th>Cases (n)</th>
<th>Age (year)</th>
<th>Genders</th>
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<tr>
<td>Lyu, et al.\cite{5}</td>
<td>2018</td>
<td>RCT</td>
<td>30</td>
<td>30</td>
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<tr>
<td>Liu, et al.\cite{6}</td>
<td>2017</td>
<td>RCT</td>
<td>59</td>
<td>43</td>
<td>70.8±4.9</td>
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<td>Gao, et al.\cite{7}</td>
<td>2017</td>
<td>RCT</td>
<td>55</td>
<td>55</td>
<td>70.8±4.6</td>
</tr>
<tr>
<td>Liu, et al.\cite{8}</td>
<td>2017</td>
<td>RCT</td>
<td>42</td>
<td>41</td>
<td>70.2±2.5</td>
</tr>
<tr>
<td>Guo, et al.\cite{9}</td>
<td>2016</td>
<td>RCT</td>
<td>48</td>
<td>48</td>
<td>65.9±3.7</td>
</tr>
<tr>
<td>Yang, et al.\cite{10}</td>
<td>2016</td>
<td>RCT</td>
<td>41</td>
<td>41</td>
<td>70.5±8.5</td>
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</tbody>
</table>

CT: Conservative treatment.

Table 2.

Evaluation of the quality of the study.

<table>
<thead>
<tr>
<th>References</th>
<th>Follow-up time</th>
<th>Lost to follow-up (n)</th>
<th>Random methods</th>
<th>Allocation concealment</th>
<th>Blind method</th>
<th>Lost to follow-up</th>
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<td>Lyu, et al.</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
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<td>Liu, et al.</td>
<td>12</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Gao, et al.</td>
<td>12</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
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<tr>
<td>Liu, et al.</td>
<td>12</td>
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<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Guo, et al.</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Yang, et al.</td>
<td>12</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>
3.3.2 Osseous disability index

Three articles[6,14,15] compared the ODI scores of patients after treatment, a total of 237 cases, including 123 cases in the PKP group and 114 cases in the conservative treatment group. The heterogeneity test was first performed, showing that there was heterogeneity between the two groups (P=0.006, I2=80%), so a random-effects model was used. There was a statistically significant difference in ODI scores between the two methods after treatment [MD=-9.01, 95%CI (-9.86, -7.94), P<0.0001], indicating that kyphoplasty was superior to conservative treatment in improving the quality of life of patients (Figure 4).

3.3.3 Cobb angle change

Two articles[19,20] mentioned changes in cobb angle before and after treatment, and a total of 178 cases were included. Heterogeneity analysis showed no significant heterogeneity (P=0.53, I2=0%), using a fixed-effect model. The results showed that there was a statistical difference in the change of cobb angle between the two methods after treatment (MD=-8.90, 95%CI (-9.86, -7.94), P<0.0001), indicating that kyphoplasty was superior to conservative treatment (Figure 5).

3.3.4 Vertebral body height

Two articles[6,15] compared the height of the anterior border of the vertebral body after treatment, a total of 154 cases, including 81 cases in the PKP group and 73 cases in the conservative treatment group. There was significant heterogeneity between the studies (P<0.0001, I2=94%), so a random-effects model was used. There was a statistically significant difference in ODI scores between the two methods after treatment [MD=-11.57, 95%CI (-12.72, -10.39), P<0.0001], it showed that kyphoplasty was more effective than conservative treatment in improving the quality of life of patients (Figure 4).

4. Discussion

OVCF has become one of the major orthopaedic diseases affecting the health and quality of life of the elderly. It not only causes pain and activity limitation, but also reduces the quality of life of patients, and also returns to the family. And it brings a huge economic burden[3]. At present, the clinical intervention for OVCF is mainly to relieve pain, promote vertebral fracture healing, and improve patient function and improve quality of life. Conservative treatment in the traditional sense applies anti-osteoporosis and drugs for promoting fracture healing, combined with lumbar back function exercise and strict bed rest. However, due to the long treatment period, the patient’s compliance is low, which seriously affects the treatment effect[8]. On the one hand, long-term bed rest will further aggravate the degree of osteoporosis, and prone to complications such as hemorrhoids and hypostatic pneumonia, and even serious life-threatening[9]. On the other hand, because the height of the vertebral body cannot be effectively restored, it can lead to the collapse of the vertebral body, and the change of the kyphosis angle, so that the uneven force between the vertebral bodies will increase the fracture of the patient adjacent to the vertebral body and then The risk of convex deformity causes the disease to fall into a vicious circle[10]. With the continuous advancement of science and technology, the continuous exploration of human medicine, pelvic kyphoplasty (PKP) has been widely used in clinical treatment because of its short course of treatment, fewer side effects and good curative effect[11]. PKP cures the fractured vertebral body by means of imaging technique, placing the puncture needle on the diseased vertebra and then injecting the bone cement into the puncture channel. During the cement injection process, more heat is generated at the same time of curing, which destroys the pain nerve endings in the region. The expansion of the balloon also causes the vertebral body to open, thereby stabilizing the fractured vertebral body and changing the trabecular bone crossover phenomenon[12]. At the same time, it can effectively restore the height of the fractured vertebral body and maintain the anatomical shape and function of the spine, thereby reducing the original dysfunction. After the addition, the convex deformation correction is remarkable, and the stability of the vertebral body is greatly reduced, which greatly reduces the pain of the patient and improves the quality of life of the patient. PKP operation time is shorter, the trauma is lighter, most patients can relieve pain, and can get out of bed 1 d after surgery, which is beneficial to early recovery of patients[13].

The study found that VAS and ODI, the change of Cobb angle and the height loss rate of the diseased vertebra were lower in the observation group than in the control group (P<0.05). ). Especially in improving the patient’s pain symptoms and improving the quality of life of patients. Liu, et al.[14] reported a statistically significant difference in VAS scores between the PKP group and conservative treatment. Lu et al. [15] considered that the VAS and ODI of the experimental group were significantly better than the control group after treatment, and the difference was statistically significant. At present, most studies have shown that the application of PKP can quickly relieve the pain of patients. The mechanism of action is that the bone cement keeps the fractures in the vertebral body fixed, which reduces the stimulation of the nerves, and damages the sensory nerves in the vertebral body through the cytotoxic effect and...
the polymerization heat effect. The tip helps relieve the pain[16,17]. Therefore, PKP can reduce the pain level of patients in a short period of time, improve activity limitation, reduce ODI score, and improve the quality of life of patients. Percutaneous kyphoplasty (PKP) can effectively relieve the pain of patients with fractures and improve the quality of life of patients, and also effectively restore the height of the compressed vertebral body and correct kyphosis[18]. Guo et al.[19] considered that the height of vertebral body loss and Cobb angle in the PKP group were significantly better than those in the control group, which were statistically significant. Yang et al.[20] considered that compared with conservative treatment, Cobb angle was significantly different from that before treatment in the observation group at 1 month and 12 months after treatment. The difference between the two groups was statistically significant. It is indicated that vertebral kyphoplasty in patients with an osteoporotic compression fracture can effectively restore the height of the compressed vertebral body and improve the Cobb angle, thus maintaining the stability of the spine and reducing the risk of recurrence of the fracture.

At present, the treatment methods for OVCF patients mainly include conservative treatment and PKP. The conservative treatment period is too long, while the curative effect is too slow, so the complications are easy to occur. PKP has obvious advantages in reducing pain and improving quality of life, but there is a risk of bone cement injection. It is prone to bone cement leakage, etc., and the technical requirements for the operator are relatively high[21]. Therefore, clinical patients with OVCF should choose a reasonable treatment method, clearly grasp the surgical indications, and strive to reduce the risk of surgery and improve the clinical efficacy of patients. Although this study confirms that PKP has obvious advantages in the treatment of OVCF compared with conservative treatment, it also has certain limitations: (1) the sample size is small, and the literature is insufficient, especially the lack of foreign literature. (2) There are too few references to literature allocation and blind methods, and there is a lack of high-level RCTs. Some of the literature only mentions “random” and does not specify specific random methods. (3) Measurement of the height of the compressed vertebral body and the Cobb angle of the vertebral body may be biased.

In summary, in the future, for the meta-analysis of domestic and foreign literature, we should focus on large-scale, multi-center, high-quality RCTs. At the same time, for the selection of outcome indicators, we should try to adopt internationally recognized indicators; strictly follow the CONSORT standard to improve the scientific, credible and normative results of the report.

References