Therapeutic effect of kyphoplasty and balloon vertebroplasty on osteoporotic vertebral compression fracture

A systematic review and meta-analysis of randomized controlled trials

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Abstract

Introduction: This study aimed to assess the treatment effects of kyphoplasty (KP) compared with percutaneous vertebroplasty (VP) in patients with osteoporotic vertebral compression fracture, based on evidence from randomized controlled trials (RCTs).

Methods: The electronic databases PubMed (from 1966), EmBase (from 1974), and Cochrane Library (including Cochrane Central Register of Controlled Trials and Cochrane Reviews) were searched systematically to identify relevant studies published up to August 31, 2019. Meta-analyses were conducted for subjective pain as measured using visual analogue scale (VAS), disability function as measured by Oswestry disability index (ODI), and cement leakage. For VAS and ODI, mean change from the baseline and standard deviation were used; for cement leakage, numbers of events and patients in each group were used. The random-effects model was applied to summarize the effects across trials.

Results: Previous reviews and meta-analysis included non-RCTs, which brought (for those studies) a higher risk of bias. Therefore, 6 RCTs involving 1077 patients were included in the meta-analysis. No between-group difference was found. The weighted mean difference was 0.19 (95% confidence interval [CI], 0.39–0.01; P = .057) for VAS and −3.51 (95% CI, −8.70–1.67; P = .184) for ODI. However, KP had numerically lower rates of cement leakage across trials in a consistent fashion (relative risk, 0.83; 95% CI, 0.74–0.94; P = .004).

Conclusions: Both KP and VP had clinically meaningful beneficial effects on pain and disability, and the effects were stable and similar. KP had significantly fewer cement leakages.

Abbreviations: CI = confidence interval, KP = kyphoplasty, ODI = Oswestry disability index, OVCF = osteoporotic vertebral compression fracture, RCTs = randomized controlled trials, RR = relative risk, SD = standard deviation, VAS = visual analogue scale, VCFs = vertebral compression fractures, VP = vertebroplasty, WMD = weighted mean difference.

Keywords: kyphoplasty, osteoporotic vertebral compression fracture, Oswestry disability index, vertebroplasty, visual analogue scale

1. Introduction

Osteoporosis is a bone disorder characterized by a low bone density that leads to fragile bones and higher fracture risks. The most frequent osteoporotic fracture is osteoporotic vertebral compression fracture (OVCF). Vertebral fracture is one of the major healthcare problems all over the world due to their high incidence, adverse consequences on the health-related quality of
life of the patients, and huge expenses.\textsuperscript{1,2} Patients with osteoporosis are subject to multiple incidences of fractures during lifetime, and the risk increases with age. The age-standardized incidence of vertebral fracture was 12.1/1000 person-years in women and 6.8/1000 person-years in men aged more than 50 years in Europe.\textsuperscript{3} The consequences of OVCF can be burdensome to patients and healthcare system if left untreated. The physical symptoms of vertebral compression fractures (VCFs) include chronic back pain, severe vertebral deformity, and disability.\textsuperscript{4} The disability caused by VCFs, in turn, adds to healthcare budgets and social security cost by increasing the use of long-term care facilities, hospitalization, and vertebral augmentation procedures.\textsuperscript{5} VCFs also have a negative impact on mental health. Prolonged VCFs may cause anxiety and depression and impair social functions of patients.\textsuperscript{6}

Different treatment approaches for improving pain control, preventing deterioration and deformity, and treating underlying osteoporosis are currently available. The conventional treatments include medications, bed rest, and bracing. However, they are only partially effective for people suffering from OVCFs.\textsuperscript{4} On the contrary, previous studies have found that conservative treatments often fail to improve pain and mobility.\textsuperscript{7} Minimally invasive approaches have been gradually adopted in recent years.\textsuperscript{8–10} Percutaneous vertebraloplasty (VP) is regarded as an effective and safe treatment for OVCFs. In this procedure, bone cement is injected through the pedicle into a collapsed and porotic vertebral body.\textsuperscript{11–13} As a modification of VP, balloon kyphoplasty (KP) was developed to reduce vertebral deformity, pain, and disability by inserting balloons into the vertebral body and then fixing the fracture fragments through polymethylmethacrylate injection.\textsuperscript{14} Currently, both techniques are widely used clinically as major noninvasive treatments to OVCF. Both are shown to be more effective in providing pain relief and improving daily function and quality of life compared with conservative therapy.\textsuperscript{15} However, the optimal treatment is still controversial.

Previously, systematic reviews and meta-analyses were conducted to tackle this question, but no conclusive agreement was reached due to the following limitations: insufficient number of randomized controlled trials (RCTs), lack of conformity in the duration of follow-up, and heterogeneity mainly among observational studies due to bias.\textsuperscript{11–17} Thus, this systematic review and meta-analysis was conducted to overcome the aforementioned limitations by focusing on RCTs and subgrouping outcomes to compare the effects of KP and VP on patients with OVCF depending on the timing of measurement.

2. Methods

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Statement issued in 2009.\textsuperscript{18} The meta-analysis based on public literature is not applicable for ethical approval

2.1. Literature search

A systematic search was performed to identify relevant studies published up to August 31, 2019, using electronic databases PubMed (from 1966), Embase (from 1974), and Cochrane Library (including Cochrane Central Register of Controlled Trials and Cochrane Reviews). The following key words were used: vertebroplasty, kyphoplasty, compression, fracture, fractures, osteoporotic, and osteoporosis.

2.2. Study selection

Because previous reviews and meta-analysis have included studies with homogeneous methods and high risk of bias, the aim of this study was to draw conclusions from homogeneous studies of the highest available quality. The inclusion criteria for this systematic review were as follows: RCTs on humans; publication in the English or Chinese language; study population with OVCFs; and randomization to VP and KP. The exclusion criteria were as follows: observational study design or interventional study without randomization; inclusion of patients with fractures related to indications other than OVCFs, such as fractures related to cancer; and no explicit comparison between KP and VP. Only RCTs were included to avoid biases common in observational studies. The patient population included only those with OVCFs who underwent VP or KP. If the study included patients with diverse indications, patients with OVCFs were assessed and reported as a subgroup separately to be considered for inclusion. The interventions of interest were KP and VP. Comparisons between 2 interventions were explicitly made. If more than 2 interventions were investigated, only the results on the 2 relevant groups were included. The study outcomes focused on measuring pain, quality of life, or new fractures.

Two reviewers screened the studies to determine eligibility for inclusion. Studies were included when both agreed; in case of any disagreement, a third reviewer made the final decision. The screening included 2 stages. First, all titles and abstracts were reviewed against inclusion and exclusion criteria. In case information was inadequate to make a decision, the full text was retrieved to further examine the eligibility of the study. Systematic reviews that shared the scope similar to this review were also identified during screening, and their reference lists were scanned and added to the screening data set.

2.3. Data extraction and quality assessment

For all included studies, information on study characteristics and outcomes was extracted into summary tables. Specifically, author name, year, sample sizes, patient demographics, pain scores, disability index, and cement leakages were extracted.

The reviewer assessed the methodological quality of the included studies according to the Jadad score. Studies were evaluated in terms of the following 3 key methodological features for an overall score of 0 to 5: randomization, masking, and accountability of all patients; a higher score meant higher quality.\textsuperscript{19} The Cochrane risk-of-bias tool provided a detailed assessment of each aspect of the study design and reporting.\textsuperscript{20} A graph was plotted using Review Manager 5.3 (version 5.3; The Nordic Cochrane Centre, Copenhagen, Denmark, The Cochrane Collaboration, 2014).

2.4. Statistical methods

The commonly reported outcomes were the visual analogue scale (VAS), the Oswestry disability index (ODI), and cement leakage. The pain was assessed using VAS or pain score with a scale of either 0 to 10 or 0 to 100 after 3 days, 1 month, 3 months, 6 months, 12 months, and 60 months. The mean and standard deviation for each group were extracted, and scores on a scale of 0 to 100 were standardized to 0 to 10 by dividing the mean and standard deviation by 10. The level of disability was measured using ODI after 3 days, 3 months, and 12 months. The mean and standard deviation for each group were extracted and then
meta-analyzed. For the main analysis, only the final endpoint (the one with the longest follow-up) from each trial was included. Meta-analyses for pain scores, ODI, and cement leakage were conducted to quantitatively summarize the evidence. For continuous outcomes, weighted mean difference (WMD) and 95% confidence intervals (CIs) were presented. For dichotomous outcomes, risk ratio and 95% CI were presented. The selection between the random-effects model and the fixed-effects model was based on the measure of heterogeneity (the random-effects model was used when the $I^2$ value was $\geq 50%$; otherwise, the fixed-effects model was used).[21] A sensitivity analysis was conducted to evaluate whether outcome measurement instruments and potential publication bias had impacts on the effect estimate. The sensitivity analysis for measurement instruments included pain scores other than the most reported VAS, and the standardized mean difference was estimated to take into account different measurement scales.[20] Funnel plots were generated, and Egger and Begg tests were conducted to detect publication bias.[22,23] The significance level for all tests was set at 0.05. All the analyses were conducted in Stata 13.1 (StataCorp 2013, TX).

3. Results

3.1. Study and patient characteristics

Figure 1 is a flowchart of studies screened and reviewed. A total of 676 studies were identified from the search after duplicates excluded. The exclusion was based on the following criteria: publication types, including letters, reviews, case reports, opinions, book chapters, and protocols (n=103); non-RCT study design (n=369); interventions not of interest or no comparison between KP and VP (n=111); study population, including patients with cancer and trauma (n=37); and nonclinical outcomes such as cost or mechanical properties of cement (n=16). Previous meta-analyses included studies with homogeneous methods and high risk of bias. Therefore, this study aimed to draw conclusions from homogeneous studies of the highest available quality.[15–17] Eventually, 6 RCTs reported by 7 studies[24–30] were included based on the inclusion criteria. The most common reasons for exclusion were non-RCT study design and inappropriate comparison groups. Detailed patient characteristics at baseline in each study are shown in Table 1.

Figure 1. Flowchart of study selection and inclusion process.
| References | Country   | Race          | Sample size  | Mean age (year)   | Gender (M/F) | KP group | VP group | Follow-up (month) | Main outcomes                  |
|------------|-----------|---------------|--------------|-------------------|--------------|----------|----------|------------------|--------------------------------|
| [26]       | Germany   | Caucasian     | 20           | 63 (range: 53–77) | 6/14         | 8/13     |          | 6                | VAS ODI cement leakage         |
|            |           |               | 21           | 71 (range: 63–77) |              |          |          |                  |                                |
|            |           |               | 63 (range: 53–77) |                  |              |          |          |                  |                                |
|            |           |               | 6/14         | 8/13              |              |          |          |                  |                                |
|            |           |               |              |                   |              |          |          |                  |                                |
| [28]       | USA       | Caucasian     | 191          | 75.6 (entire sample) | 77.4% women (baseline) |        |          | 24               | Back pain score ODI cement leakage |
| [29]       | Taiwan    | East Asian    | 50           | 72 (SD: 8)        | 11/39        | 12/38    |          | 60               | VAS                            |
|            |           |               | 50           | 74 (SD: 6)        |              |          |          |                  |                                |
| [27]       | USA       | Caucasian     | 59           | 75 (SD: 10)       | 21/38        | 13/43    |          | 12               | Pain score                     |

(continued)
| References | Country   | Race       | Sample size | Mean age (year) | Gender (M/F) | Follow-up (month) | Main outcomes                                      |
|------------|-----------|------------|-------------|-----------------|--------------|-------------------|---------------------------------------------------|
| [25]       | China     | East Asian | 30          | 70 (SD: 7)      | 7/23         | 0.1               | VAS, ODI, cement leakage                          |
|            |           |            | 30          | 70 (SD: 9)      | 5/25         |                   |                                                   |
|             |           |            |             |                 |              |                   |                                                   |
| [26]       | China     | East Asian | 40          | 66 (SD: 2)      | 10/30        | 12                | VAS, ODI, cement leakage                          |
|            |           |            | 40          | 66 (SD: 2)      | 13/27        |                   |                                                   |

**Table 1 (continued).**

| References | Country   | Race       | Sample size | Mean age (year) | Gender (M/F) | Follow-up (month) | Main outcomes |
|------------|-----------|------------|-------------|-----------------|--------------|-------------------|---------------|
| [25]       | China     | East Asian | 30          | 70 (SD: 7)      | 7/23         | 0.1               | VAS, ODI, cement leakage                          |
|            |           |            | 30          | 70 (SD: 9)      | 5/25         |                   |                                                   |
| [26]       | China     | East Asian | 40          | 66 (SD: 2)      | 10/30        | 12                | VAS, ODI, cement leakage                          |
|            |           |            | 40          | 66 (SD: 2)      | 13/27        |                   |                                                   |

**Main outcomes:**

- VAS: Visual Analogue Scale
- ODI: Oswestry Disability Index
- KP: Kyphoplasty
- VP: Vertebroplasty
- PMMA: Polymethylmethacrylate
- SD: Standard Deviation
- NR: Not Reported

**Key Points:**

- **Kyphoplasty** was performed using a unilateral approach with a unipedicular approach. A drill passing through the cannula created a tract for the balloon to be inserted into the center of the vertebral body. Cement was injected through the needle until the vertebral body was filled or until leakage occurred.

- **Vertebroplasty** was performed using a unipedicular transpedicular approach. Once the needle was in place, polymethylmethacrylate was injected through the needle until the vertebral body was filled or until leakage occurred.

**Notes:**

- KP = Kyphoplasty, NR = not reported, ODI = Oswestry disability index, SD = standard deviation, VAS = visual analogue scale, VP = vertebroplasty.
Sample sizes of the included studies ranged from 41 to 381. The total number of patients was 1077. The Jadad score for most trials was 2 (n = 2)\textsuperscript{[26,29]} or 3 (n = 3),\textsuperscript{[24,25,28]} except 1 trial with a score of 5.\textsuperscript{[27]} This indicated poor to moderate quality of the trials in general. The details on Jadad scores are presented in Table 2. Quality assessment using the Cochrane risk-of-bias tool is presented in Figure 2. Common issues included unclear or high risks in randomization and patient and investigator blinding. All

| References | Randomization | Blinding | An account of all patients |
|------------|---------------|----------|---------------------------|
|            | Appropriate   | Unclear  | Not appropriate | Appropriate | Unclear | Not appropriate | Described | Not described | Total |
| \[26\]     | √             |          |               | √           |          |               |            |                |       |
| \[28\]     |               | √        |               | √           |          |               |            |                |       |
| \[29\]     |               |          |               |             |          |               |            |                |       |
| \[25\]     |               |          |               |             |          |               |            |                |       |
| \[24\]     |               |          |               |             |          |               |            |                |       |
| \[27\]     | √             |          |               | √           |          |               | √          |                | 5     |

Table 2. Methodological quality of studies included in the meta-analysis.

Figure 2. (A and B) Cochrane risk-of-bias evaluations.
the trials measured and reported on pain, while 4 out of 6 reported on ODI or the incidence of cement leakage. All the patients had OVCFs confirmed radiologically. After randomization, patients in the intervention groups were balanced in terms of demographics and clinical manifestation. The results of therapeutic effect of KP and VP on patients with OVCF in the meta-analysis are shown in Table 3.

### 3.2. Clinical outcomes

#### 3.2.1. Pain

Four [24–26, 29] of the 6 trials measured subjective pain using the VAS score on a scale of either 0 to 10 or 0 to 100. The other 2 [27, 28] measured pain scores and a pain intensity numeric rating scale were not included in the main analysis but tested in a sensitivity analysis. The between-group difference in effect was estimated using a meta-analysis (Fig. 3). The final endpoints with the longest length of follow-up from each of the 5 trials were included in the meta-analysis. The overall WMD was not statistically significant (WMD = -0.19; 95% CI, -0.39-0.01; \(P = .057\)). The \(I^2\) value attributed 34.5% variation in WMD to heterogeneity; therefore, a fixed-effects model was applied.

One trial (Liu 2015) included a long-term follow-up after 5 years. The authors claimed no between-group difference without reporting the numeric values. Therefore, the data were not used in the meta-analysis, and the 6-month endpoint was used instead (Liu 2009).

#### 3.2.2. Oswestry disability index

Four [24–26, 28] trials measured the perceived level of disability using the ODI on a scale of 0 to 100. A lower score represented a lower level of disability. The final endpoints from 4 trials were included in the meta-analysis. The overall WMD was not statistically significant (WMD = -3.51; 95% CI, -8.70-1.67; \(P = .184\)). The \(I^2\) value attributed 83.5% variation in WMD to heterogeneity (Fig. 4); therefore, a random-effects model was used.

#### 3.2.3. Cement leakage

Four [24–26, 28] trials measured the rate of cement leakage right after surgery, all showing a nonstatistically
significantly lower rate with KP. A meta-analysis estimated a borderline statistically significant risk ratio of 0.83 (95% CI, 0.74–0.94; \( P = .004 \)), suggesting a lower risk of leakage with KP (Fig. 5). The \( I^2 \) value attributed 23.8% variation to heterogeneity; therefore, a fixed-effects model was used.

3.3. Sensitivity analysis

The 2 trials that measured pain using a pain score instead of VAS were combined with the other 4 in a sensitivity analysis. The overall mean difference remained nonstatistically significant, with a mean of \(-0.05 \) (95% CI, \(-0.19\)–\(-0.10\); \( P = .534 \); Fig. 6). The \( I^2 \) value was 49.3%, so a fixed-effects model was used.

3.4. Publication bias

The review of the funnel plots could not rule out the potential publication bias for VAS, ODI, and cement leakage (Figs. 7–9). The Egger and Begg tests showed no evidence of publication bias for VAS (\( P = .480 \) and .308, respectively), ODI (\( P = .265 \) and .089, respectively), and cement leakage (\( P = .087 \) and .734, respectively).

4. Discussion

A meta-analysis of RCTs showed that both KP and VP had statistically significant and clinically meaningful beneficial effects on pain and disability. KP and VP demonstrated similar treatment effects on pain and disability in patients with OVCF. KP had a lower cement leakage compared with VP. This most-updated systematic review and meta-analysis focused on examining the treatment effects of KP and VP in patients with OVCFs based on evidence from RCTs and specifically stratified on the duration of follow-up. Previous meta-analyses, including observational studies of varied and insufficient quality, have drawn conflicting and ambiguous conclusions. Most studies indicated no differential effects but heterogeneity among individual studies. Some have pointed out the need for more RCTs to be conducted and included in the meta-analysis. Recently, Li et al [25] tried to demonstrate that the bone-filling mesh container with polymethylmethacrylate bone cement for treatment of OVCFs can have a significant result in relieving the pain, lifting the injured vertebral height, and the correction of kyphosis, which can also reduce the leakage rate of bone cement. In addition, Evans et al [27] suggested that VP could be considered as the surgical procedure of choice, apart from mostly asymptomatic cement leakage. However, the results were still unclear and even controversial. Therefore, this comprehensive meta-analysis was conducted to clarify the treatment effects of KP compared with VP in patients with OVCF, based on evidence from RCTs.

This meta-analysis aimed to fill the evidence gap by focusing on RCTs and including trials published recently. The results showed

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**Figure 4.** Forest plot showing the WMD estimates for ODI. KP = kyphoplasty, ODI = Oswestry disability index, VP = vertebroplasty, WMD = weighted mean difference.
that KP and VP both significantly improved pain and disability and had a comparable impact on VAS and ODI. In addition, it also demonstrated that the effects of these 2 procedures were generally consistent among trials and durations of the follow-up. With the source of evidence restricted to RCTs of moderate to high quality, measured and unmeasured confounding factors common in observational studies were minimized. Thus, the results were more consistent among trials. The data were meta-analyzed with the duration of follow-up well controlled in RCTs. The study also found a statistically significant lower rate of cement leakage with KP compared with VP. The mechanism underlying this difference was that KP involved an inflatable bone filling into the vertebral body to form a cavity, consequently contributing to decreased cement extravasation and lower pressure.\[31\]

The evidence suggested a moderate to high heterogeneity for the pain and disability outcomes and a small heterogeneity for the cement leakage outcome. Moderate heterogeneity in VAS has been found across trials because although VAS is a valid tool to measure pain at 1 time point, it may not behave linearly and its responsiveness may vary according to the type of pain.\[32,33\] Therefore, the interpretation of raw change in VAS may be heterogeneous among studies. However, this hypothesis could not be tested in the present study due to the lack of access to patient-level data. On the contrary, little variation in cement leakage rates was anticipated because the detection technique was quite standardized, which was a computed tomography scan immediately after the procedure; also, a binary outcome was determined regardless of the volume of the leakage. It was not clear why much greater heterogeneity was observed for the ODI outcome compared with the other 2 outcomes. However, 1 possibility was that the timing of final endpoint varied greatly among the 4 trials, ranging from 3 days after the procedure to 2 years later. It is possible that the effect size changes with time, which should be further explored in the future. Also noteworthy is the fact that although most researchers agreed that it was appropriate to treat ODI as a continuum having a linear correlation with a disability, the changes should be compared without considering the starting point.\[34\] Little and MacDonald\[35\] suggested that the change should be expressed as a percentage of the original score. This argument might provide another explanation for the observed heterogeneity in ODI because of the variation observed in the baseline ODI (ranging from 60–75). Further validation of the methodology is needed to explain this phenomenon.

The strengths of this systematic review and meta-analysis included relatively homogenous studies due to RCT design, ability to conduct a meta-analysis on multiple follow-up durations, and focus on clinically relevant outcome measures. However, including solely RCTs is not without limitations. Some
important and meaningful outcomes more often measured in liberal settings, such as cohort studies, are not easily measured in a controlled environment in RCTs. For example, quality of life was measured only in 1 trial using SF-36 and EQ-5D, and thus no meta-analysis could be conducted. Some outcomes that required a longer follow-up were not often measured in RCTs either. One example was the incidence of new fractures, which was also measured in only 1 trial, showing similar rates with both interventions. It would be interesting to examine cumulative evidence from more trials on this critical endpoint. Some evidence on other clinical measurements was not summarized in this review due to the lack of uniformity in the measures and the fact

**Figure 6.** Sensitivity analysis of the standardized mean difference estimates for pain. CI = confidence interval, KP = kyphoplasty, VP = vertebroplasty.

**Figure 7.** Funnel plot for publication bias test of VAS outcome. VAS = visual analogue scale, WMD = weighted mean difference.

**Figure 8.** Funnel plot for publication bias test of ODI outcome. ODI = Oswestry disability index, WMD = weighted mean difference.
that they were intermediate outcomes. For example, the regaining of vertebral height would be of less clinical relevance without improvement in function. The measure of height restoration was highly attributable to patient’s position, which varied from site to site, or even patient to patient. As a result, it was believed that this review should prioritize examining the most critical and reliable outcomes. In addition, useful data on the associations among the kind of cement (high or low viscosity), the rates of complications (pulmonary cement embolisms, neurological, restoration of segmental kyphosis), and the risk of osteoporotic vertebral fractures could not be obtained from the included studies.

In summary, this systematic review and meta-analysis provided the most up-to-date evidence on the comparative effect of KP and VP on pain, ODI, and cement leakage. However, more high-quality data are still needed to validate the findings. As more RCTs are conducted and published and the existing ones provide long-term follow-up results, a switch from systematic reviews of observational studies to RCTs and examining a detailed list of outcome measures are expected.

5. Conclusions

Evidence from RCTs showed that both KP and VP had statistically significant and clinically meaningful beneficial effects on pain and disability that was stable over time up to 5 years. KP and VP demonstrated similar treatment effects on pain and disability in patients with OVF. KP probably had a lower cement leakage compared with VP. These conclusions suggested that KP avoided potential risk of cement leakage and exerted treatment effects comparable with those of VP. However, the results of this study need further validation through large-scale RCTs due to the limitation regarding the quantity and quality of the included trials.

Author contributions

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