

Percutaneous vertebroplasty versus balloon kyphoplasty for treatment of osteoporotic vertebral compression fracture: a meta-analysis of randomised and non-randomised controlled trials

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Received: 13 March 2011 / Accepted: 15 May 2011 / Published online: 3 June 2011
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Abstract

Purpose There is still debate over whether vertebroplasty (VP) or kyphoplasty (KP) is superior for the treatment of osteoporosis vertebral compression fractures (VCFs). We performed a systematic review and meta-analysis of randomised and non-randomised controlled trials comparing VP with KP to reach a relatively conclusive answer.

Methods We searched computerised databases comparing efficacy and safety of VP and KP in osteoporotic fractures. These trials reported pain relief (Visual Analogue Scale), disability (Oswestry disability score) and complications (i.e., cement leakage, incident fractures) as the primary outcome.

Results Eight studies involving 848 patients were identified. The outcome showed that VP is more effective in the short-term (no more than seven days) pain relief. Kyphoplasty had a superior capability for intermediate-term (around three months) functional improvement. As for long-term pain relief and functional improvement, there is no significant difference between these two interventions. Consistently, both interventions have similar risk for subsequent fracture and cement leakage.

Conclusion Thus considering the higher cost of the KP procedure, we recommend VP over KP for the treatment of osteoporotic VCFs.

Abbreviation

VCFs	Vertebral compression fractures
VP	Vertebroplasty
KP	Kyphoplasty
RCTs	Randomised controlled trials
NRTs	Non-randomised controlled trials
CCTs	Clinical controlled trials
VAS	Visual analog scale
ODI	Oswestry disability score
RR	Relative risks
WMD	Weighted mean difference

Introduction

Vertebral compression fractures (VCFs) constitute a major health care problem of osteoporosis worldwide. Due to the increasing ageing of the population there has been a constant rise in osteoporotic VCFs during the last decade [1]. It is estimated that 750,000 new vertebral fractures occur in the United States each year. Although only about one-third of these fractures become symptomatic, they can result in height loss, spinal deformity, acute and chronic pain, restriction of thoracic and abdominal contents, impaired mobility and disability.

Different approaches for the management of painful osteoporotic VCFs are currently available. Standard medical therapy includes bed rest, analgesia, bracing, external fixation, rehabilitation and a combination of these treatments [2]. However, there are still limitations of these methods. Long-term bed rest often leads to further demineralisation and may predispose the patients to future VCFs. As for medication of anti-inflammatory drugs and

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certain types of analgesics, it may be difficult for patients, especially the older ones, to tolerate the side effects. And medical management does not reverse kyphotic deformity. The surgical treatment for VCFs, refractory to medical therapy, involves surgical stabilisation via dorsal instrumentation [3]. However, because of the poor quality of osteoporotic bone, surgical fixation often fails and open surgical treatment is reserved to the rare cases of neurological deterioration or to the more frequent cases of persistent intractable pain. What's more, such treatments are only partially effective in relieving symptoms. About one-third of patients have been reported to suffer from persistent pain and progressive functional limitation [4].

As we know, percutaneous vertebroplasty (VP) was first performed to treat patients with extreme pain caused by a haemangioma [5]. Kyphoplasty (KP) as a modified procedure of VP which aims at restoration of the vertebral body height. Both have become widely accepted and routine procedures for the management of pain associated with osteoporotic VCFs. Recently, two RCTs comparing KP or VP versus conservative treatments confirmed that immediate pain relief can be achieved with the help of both of these two minimally invasive treatments [6, 7]. Consistently, systemic reviews have indicated that both VP and KP were effective and safe medical interventions to control the pain of osteoporotic VCFs [8–10].

However, which of these interventions provides a better outcome than the other and whether the long-term outcomes are as favourable as the short-term outcomes remains unclear [11]. Although several systemic reviews have been performed to compare the efficacy and safety of VP versus KP in patients with symptomatic VCFs from osteoporosis, almost all of them only reported case series studies examining VP and KP for VCF as a result there is little literature directly comparing VP and KP [12–15]. There is only one systematic review to date by Taylor et al. reporting one article directly comparing these two interventions for treatment of VCFs from myeloma and other malignancies [15].

Recently, several studies directly comparing VP and KP, both randomised controlled trials (RCTs) and non-randomised controlled trials (NRTs), have been published. We therefore performed this meta-analysis to check if either of these two minimally invasive operations is superior to the other.

Materials and method

We conducted a computerised search of the electronic databases OVID MEDLINE, PubMed MEDLINE, and ISI web of knowledge MEDLINE. Searches were conducted from 1983 onwards until October 2010. Search terms were selected in order to maximise both the search sensitivity

and specificity. Additionally, a manual search of peer-reviewed English documents was performed by cross-checking the bibliographies of selected articles. If multiple studies of the same patient population were identified, we only included the published report with the largest sample size. We did not seek unpublished investigations.

Inclusion criteria

Studies were included in this review if they met the following criteria:

1. Experimental studies (i.e., randomised or quasi-randomised trials) or observational studies (i.e., cohort or case-control studies) comparing balloon KP versus VP for treatment of patients with VCFs of osteoporotic a etiology.
2. Report of at least one of the following outcomes: efficacy, pain relief (visual analogue scale) or disability (Oswestry disability score); safety, cement leakage or incident fractures.

The two investigators (Shiliang Han and Shuanglin Wan) independently selected the documents according to the criteria described above. Consensus was reached by negotiation.

Assessment of risk of bias

We applied the “assessing risk of bias” table recommended in the Cochrane handbook 5.0.2 to assess the risk of bias of the articles included. There were several reasons for using this method. First, the key consideration in a Cochrane meta-analysis is the extent to which results of included studies should be believed. No such tools for assessment of methodological quality of the document can target this question squarely except for the “assessing risk of bias” table. Second, both randomised and non-randomised studies can be assessed for risk of bias by this method. We avoided assessing the quality of the studies in two different ways for randomised and non-randomised studies respectively.

The two investigators (Shiliang Han and Shuanglin Wan) assessed studies for “risk of bias” in strict accordance with the introduction of the Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.0.

Data extraction

First, two investigators (Shiliang Han and Shuanglin Wan) independently tabulated the data. A double-check procedure was performed to make sure of the accuracy of the data extracted. Then, a manager inputted the extracted data into a spreadsheet. The following information was abstracted from the studies: the first author, publishing year, study design, sample volume, patients lost to follow-up, baseline

demographic characteristic of patients and any possible data on efficacy (i.e., visual analog scale, Oswestry score) and safety (i.e., cement leakage and incident fractures).

Data analysis

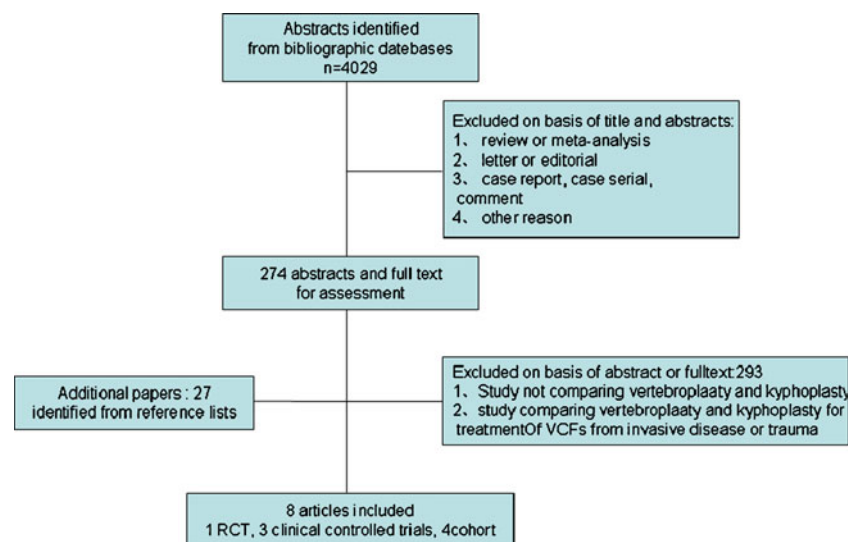
The following methods were conducted and reported in strict accordance with the “2009 Updated Method Guidelines for Systematic Reviews in the Cochrane Back Review Group” [16] and “Cochrane Handbook for Systematic Reviews of Interventions 5.0.2”.

For dichotomous data, we calculated the crude RR (relative risks) and 95% CI for each study whenever possible. And the meta-analysis was performed on crude data extracted from the text. For continuous outcomes, we pooled data by employing weighted mean differences (WMD) of the final value across groups to check which one was superior to the other.

In instances in which a standard error for the final value outcome was not reported, we calculated the standard error of mean differences across groups by converting the p value to a z -score and solving for the standard error with the formula: $z = \text{mean difference} / \text{standard error}$ [17]. In instances in which a study did not report the outcome at the exact time supposed, we took the one closest to the time examined for pooling [16].

Prior to analysing the data, Q statistics test was employed for the assessment of heterogeneity. The fixed-effects model (inverse-variance model) was used when the effects were assumed to be homogenous ($p > 0.05$), while the random-effects model (inverse-variance model) was used when they were heterogeneous ($p < 0.05$). Subgroup analysis was performed according to the study design. Sensitivity analysis was performed by excluding the study with obvious methodological heterogeneity.

Fig. 1 Flow chart summarised the selection process of trials



Publication bias was assessed with funnel plots, in which the outcome (e.g. intervention effect) is plotted on the vertical axis and the covariate (e.g. the standard error of the logarithm of intervention effect) is plotted on the horizontal axis. Bias is revealed if the plots are asymmetrical about the pooled RR, whereas a plot resembling a symmetric funnel shows that no bias is present.

In addition, all statistical tests for this meta-analysis were performed with STATA Version 11.0. However, “risk of bias” assessment was realised by employing the Review Manager Version 5.0.

Results

Identification and selection of studies

A total of 4,029 citations (1271 from OVID MEDLINE, 1822 from Pubmed MEDLINE, 936 from ISI web of knowledge MEDLINE) were obtained from searches of the various electronic bibliographies. A further 29 papers were obtained from the citation list of included studies. All the documents were selected strictly according to the criteria described. Ten articles comparing VP and KP were identified. One article was excluded because they employed these two interventions for treatment of VCFs due to either osteoporosis or trauma [18]. The other article was excluded because they compared the effect of these interventions for malignant cancer [19]. The study selection process and reasons for exclusions are summarised in Fig. 1.

Study characteristics and quality

Eight articles directly comparing KP and VP were included in this meta-analysis: one randomised controlled trial [20],

three clinical controlled trials [21–23] and four cohorts [24–27] (three prospective cohorts [24–26] and one retrospective cohort [27]). These studies were evaluated with the help of the “assessing risk of bias” table and the exact outcome was summarised in Fig. 2.

All of these articles were aimed at assessing efficacy and safety of VP and KP for treatment of osteoporotic VCFs, although not all of them reported the method for diagnosis of osteoporosis. Altogether, 848 patients were involved in this review. The sample sizes of the trials ranged from 51 to 244. The mean duration between injury and surgery varied greatly across the studies. VP or KP were the only procedures recommended to patients. PMMA was the only type of cement for the treatment of VCFs, although the volume used was not included in most of the articles. The demographic characteristic of the studies without significant difference between these two groups is summarised in Table 1.

In particular, there were two studies needing special attention. One reported the number of vertebra being treated but not the exact allocation of patients [21]. While in the other study more than 20% of the patients were lost to follow-up [27].

Visual analogue scales (VAS)

The pain intensity measured by VAS pain score was extracted and summarised as short-term (no more than seven days), mediate-term (closest to six months) and long-term (closest to one year) follow-ups. And then we pooled mean differences across the group.

	Adequate sequence generation?	Allocation concealment?	Blinding? (Self-reported outcomes)	Blinding? (Objective outcomes)	Incomplete outcome data addressed?	Free of selective reporting?	Free of other bias?
Grohs et al	●	?	?	?	?	+	+
KUmar et al	●	●	?	?	?	+	?
Liu et al	+	+	?	+	?	+	+
Lovi et al	●	●	?	?	?	+	●
Rollinghoff et al	●	+	?	+	?	+	?
Santiago et al	●	●	?	+	?	+	?
Schofer et al	●	?	?	?	?	+	?
Yan et al	●	●	?	?	?	+	?

■ Yes (low risk of bias)
■ Unclear
■ No (high risk of bias)

Fig. 2 Risk of bias assessment of included studies

The overall pooled WMD on VAS pain score was 0.37 (95% CI: -0.27 to 1.02, $p=0.25$) at short-term follow-up. Subgroup analysis of CCTs and cohorts showed that there was no significant difference across the VP and KP groups. However, subgroup analysis of a randomised controlled trial (RCT) [20] showed that VP was more effective than KP with the pooled WMD value of -0.30 (95% CI: -0.52 to -0.08, $p=0.01$) as shown in Fig. 3.

As for mid- and long-term follow-up, outcomes revealed statistically no significant difference between these two interventions, with the overall pooled WMD value of 0.05 (95% CI: -0.30 to 0.40, $p=0.77$) and 0.99 (95% CI: -0.01 to 1.98, $p=0.05$), respectively. Furthermore, the outcome was relatively stable when subgroup analysis was performed according to the study design. No statistically significant difference was defined either, except for the subgroup analysis of cohort studies for long-term results with the pooled WMD of 1.39 (95% CI: 0.10–2.67) as summarised in Table 2.

Oswestry disability score (ODI)

Disability measured by ODI was extracted and summarised as intermediate-term (closest to three months) and long-term (closest to one year). And then we pooled the data across the group.

As for intermediate-term follow-up, an overall pooled WMD value of 3.33 (95% CI: -0.17 to 6.84, $p=0.06$) was obtained, indicating that there is no difference between VP and KP for the functional improvement of patients with osteoporotic VCFs. Subgroup analysis of the cohorts still showed no difference [24–26]. However, with a pooled WMD value of 4.86 (95% CI: 0.63 to 9.08, $p=0.02$) for subgroup analysis of the CCTs [21, 22, 26], it was manifested that KP had a superior capability for intermediate-term functional improvement to VP as shown in Fig. 4.

As for long-term follow-up, with an overall pooled mean difference value of (95% CI: 0.35–7.91, $p=0.03$), it appeared that KP had a superior capability for the functional improvement to the VP. However, with pooled mean difference values of 2.69 (95% CI: -2.28 to 7.6, $p=0.29$) and 4.81 (95% CI: -0.19 to 9.81), respectively, for subgroup analysis of the CCTs [21, 22, 26] and cohorts [24–26], there appeared to be no difference across VP and KP for long-term functional improvement of patients with osteoporosis VCFs as summarised in Table 3.

Complications

As cement leakage and subsequent VCFs were the only complications included in the article, safety assessment for these two interventions was realised by extracting and pooling relative data.

Table 1 Description of the studies included in the meta-analysis

Author, year, country	Study design	SS	Age (years): VP/KP	Gender (M/F)	Volume of cement injected		Length of follow-up	Lost to follow-up
					VP	KP		
Liu et al., 2009, Taiwan	RCT	100	74.3±6.4/72.3±7.6	23/77	4.91±0.65	5.56±0.62	6 months	NR
Lovi et al., 2009, Italy	Prospective cohort	164	67.6 (53–95)/67.6 (53–95)	56/98	2.5	3.2	33 months	10
Röllinghoff et al., 2009, USA	CCT	90	68.9±10.4/68.9±10.4	1/4.3	NR	NR	12 months	10
Grohs et al., 2009, Austria	CCT	51	70 (64–77)/70 (65–74)	12/39	NR	NR	24 months	NR
Kumar et al., 2010, Canada	Prospective cohort	52	78 (57–94)/73 (52–89)	16/36	3.2 (1.0-7.0)	1.8 (0.75-5.0)	42.2 months	6
Schofer et al., 2009, Germany	CCT	60	73.8±6.4/72.5±5.7	14/46	4.9±1.2	>12 months	>12 months	11
Santiago et al., 2010, Spain	Prospective cohort	60	73.0±1.5/65.9±1.9	14/46	NR	NR	12 months	NR
Yan et al., 2010, China	retrospective cohort	244	77.2±10.3/76.9±11.5	80/112	NR	NR	>12 months	52

SS sample size, M/F male/female, RCT randomised controlled trial, CCT clinical controlled trial

In the seven studies providing cement leakage data, 748 patients were involved in this assessment [21–27]. And there were no significant difference between these two interventions, with the pooled RR values of 1.31 (95% CI:

0.95–1.78, $p=0.13$), 1.19 (95% CI: 0.73–31.95, $p=0.10$), and 1.39 (95% CI: 0.92–2.08, $p=0.19$), respectively, for overall analysis and subgroup analysis of CCTs [21–23] and cohort [24–27] analysis as shown in Fig. 5.

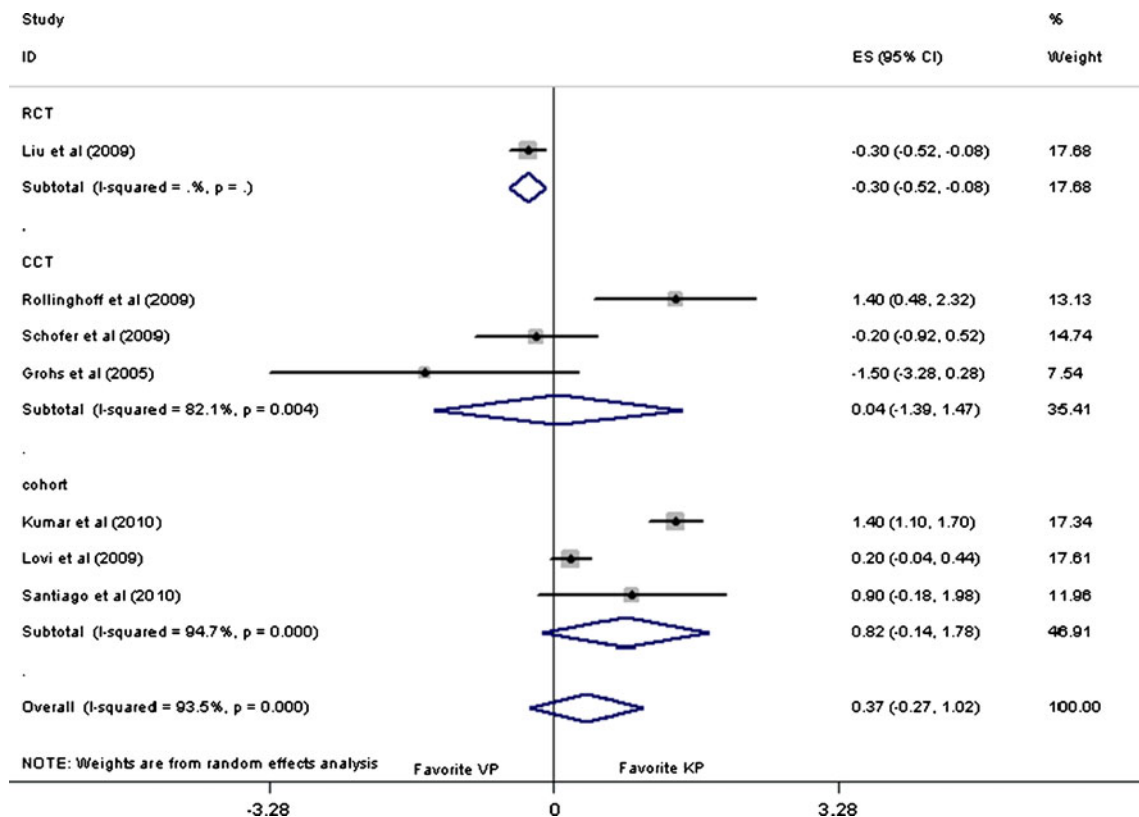


Fig. 3 Forest plot: mean difference in VAS and 95% CI for short-term follow-ups

Table 2 The pooled outcome for VAS pain score

Outcome	VAS (short-term follow-up)			VAS (mediate-term follow-up)			VAS (long-term follow-up)		
	n	WMD (95% CI)	Heterogeneity	n	WMD (95% CI)	Heterogeneity	n	WMD (95% CI)	Heterogeneity
All studies	5	0.37 (-0.27 to 1.01)	$p=0.00$	5	0.05 (-0.30 to 0.40)	$p=0.05$	7	0.99 (-0.01 to 1.98)	$p=0.00$
RCT only	1	-0.30 (-0.52 to -0.08)	NA	1	0.00 (-0.24 to 0.24)	NA	0	NA	NA
CCT only	2	0.05 (-1.39 to 1.48)	$p=0.00$	1	-1.40 (-3.07 to 0.27)	NA	3	-0.03 (-0.92 to 0.87)	$p=0.17$
Cohort only	2	0.82 (-0.14 to 1.78)	$p=0.00$	3	0.23 (-0.35 to 0.82)	$p=0.04$	4	1.39 (0.10 to 2.67)	$p=0.00$

WMD weighted mean difference, CI confidence interval, NA not applicable

short-term follow-up: no more than 7 days; mediate-term follow-up: close to 6 months; long-term follow-up: close to 1 year

In the seven studies providing subsequent fracture, 788 patients were involved in this assessment. With the pooled RR values of 1.15 (95% CI: 0.68–1.95, $p=0.61$), 0.20 (95% CI: 0.01–4.06, $p=0.30$), 0.54 (95% CI: 0.21–1.43, $p=0.22$), and 1.75 (95% CI: 0.91 to 3.35, $p=0.09$), respectively, for overall analysis and subgroup analysis of RCT [20], CCT [21–23] and cohort [24–27] analysis, it was indicated that these two interventions had similar risk for subsequent fracture as shown in Fig. 6.

Sensitivity analysis was performed by excluding the study which only reported the number of vertebra being treated but not the exact allocation of patients [21]. With the overall pooled outcome value of 1.12 (95% CI: 0.54–2.66, $p=0.66$) and 1.47 (95% CI: 0.88–2.43, $p=0.14$) for

subsequent fracture and cement leakage, respectively, it appeared that there were no significant differences between these two methods. Further subsequent analysis according to study design showed that the outcome was relatively stable.

Publication bias

Figure 7 shows a funnel plot for studies reporting the RRs of subsequent fracture as a measure of treatment effect. The plot is symmetrical, and all studies fall within the 95% CI axis for a given standard error. There may be few studies missing from the search strategy, and so there is minimal evidence of publication bias.

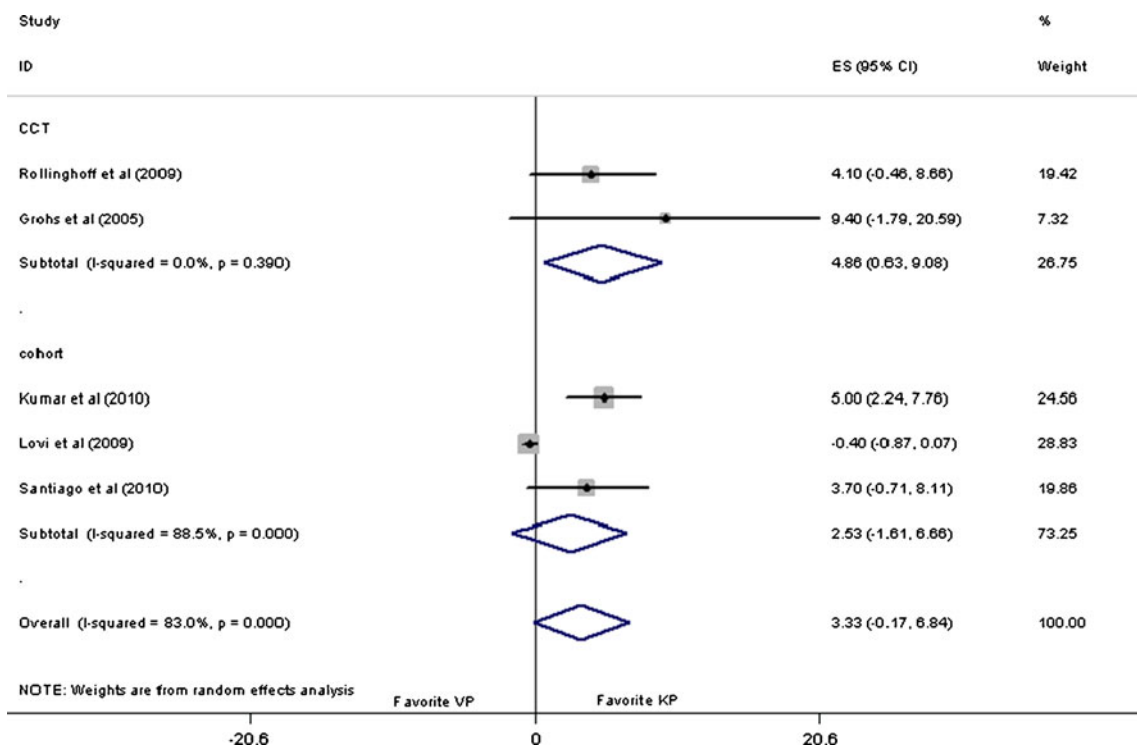


Fig. 4 Forest plot: mean difference in ODI and 95% CI for intermediate-term follow-ups

Table 3 The pooled outcome for Oswestry disability score

Outcome	VAS (mediate-term follow-up)			VAS (long-term follow-up)		
	<i>n</i>	WMD (95% CI)	Heterogeneity	<i>n</i>	WMD (95% CI)	Heterogeneity
All studies	5	3.33 (−0.17 to 6.8)	<i>p</i> =0.00	5	4.13 (0.35 to 7.91)	<i>p</i> =0.00
CCT only	2	4.86 (0.63 to 9.08)	<i>p</i> =0.39	2	2.69 (−2.28 to 7.67)	<i>p</i> =0.27
Cohort only	3	2.53 (−1.61 to 6.66)	<i>p</i> =0.00	3	4.81 (−0.19 to 9.81)	<i>p</i> =0.00

WMD weighted mean difference, CI confidence interval, NA not applicable

Intermediate-term follow-up: close to 3 months; long-term follow-up: close to 1 year

Discussion

To our knowledge, this is the first quantitative comparative meta-analysis of studies directly comparing kyphoplasty and vertebroplasty for the treatment of osteoporotic VCFs. Ultimately, eight studies in the literature—one randomised controlled trial [20], three clinical controlled trials [21–23] and four cohorts [24–27] (three prospective cohorts [24–26] and one retrospective cohort [27])—were included in our systematic review. In order to assess the efficacy and safety of VP and KP, we extracted relative data as much as possible and we pooled the outcome whenever possible.

First, we took the outcome of VAS pain score and ODI for efficacy assessment. As for VAS, overall outcome showed that

there was no significant difference across these two interventions, with the pooled WMD of 0.37 (95% CI: −0.27 to 1.02, *p*=0.25), 0.05 (95% CI: −0.30 to 0.40, *p*=0.77) and 0.99 (95% CI: −0.01 to 1.98, *p*=0.05), respectively, for short-term, mediate-term and long-term follow-ups. As a result of the weakness of the study design of the observational study, results of experimental studies such as RCT and CCT are more credible, as shown in the “risk of bias” table (Fig. 2). And after subgroup analysis of outcome of RCT or CCT, it was shown that VP is more effective for short-term pain relief of patients with the pooled outcome of −0.30 (95% CI: −0.52 to −0.08, *p*=0.01) [20]. As for mid- and long-term follow-ups, no significant difference across these two interventions was identified.

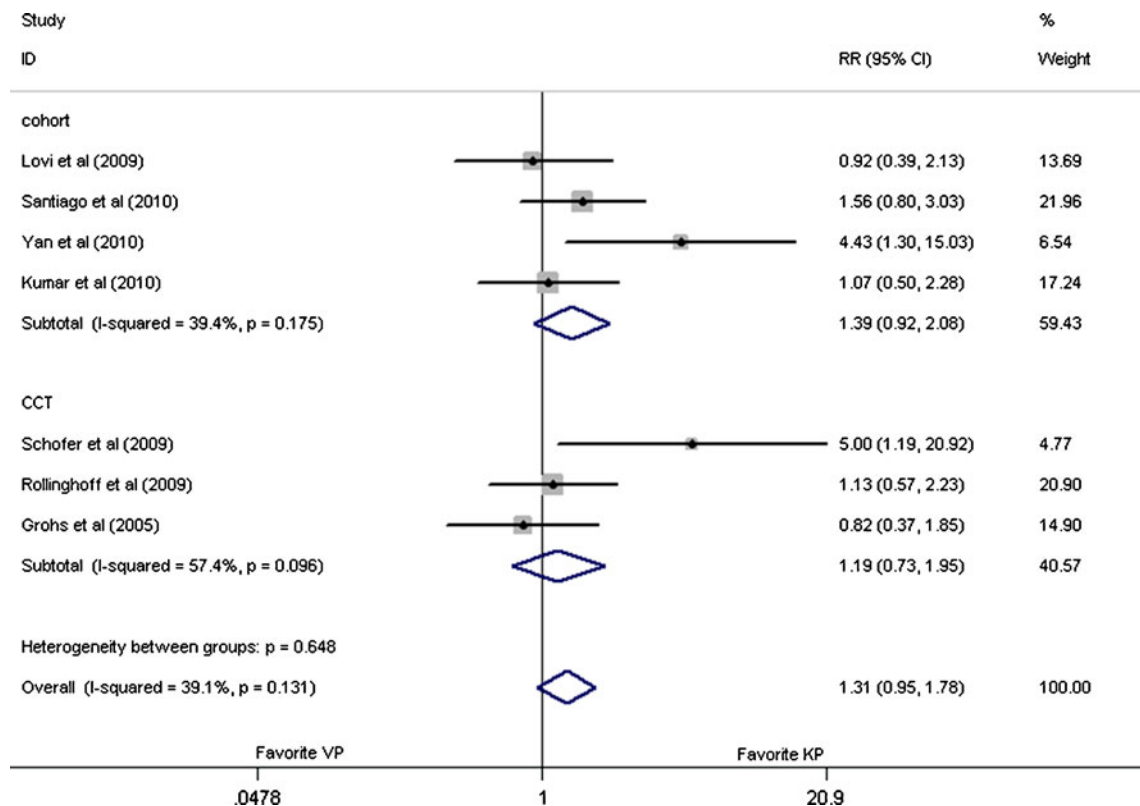


Fig. 5 Forest plot: relative risks in cement leakage and 95% CI

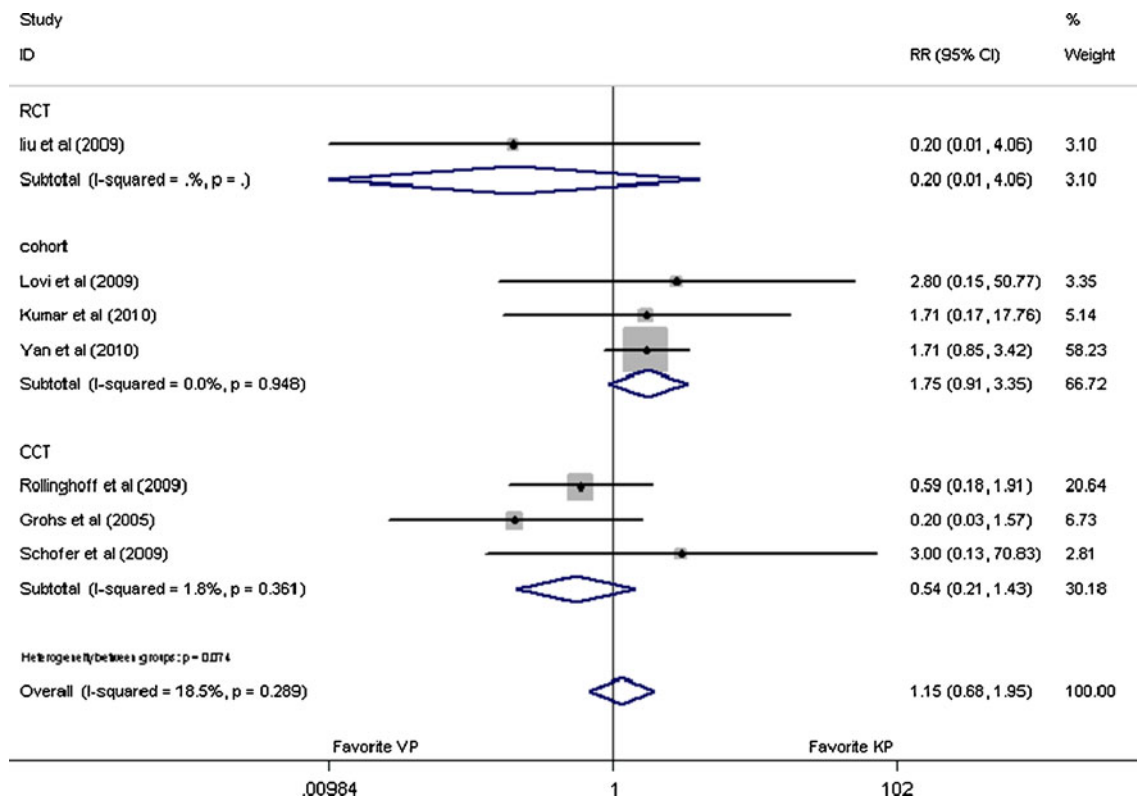


Fig. 6 Forest plot: relative risks in subsequent fracture and 95% CI

A similar trend was also found when assessing for ODI. With the pooled outcome of 4.86 (95% CI: 0.63–9.08, $p=0.02$) for subgroup analysis of the outcomes of intermediate-term follow-ups of the CCTs [21, 22, 26], KP appears more effective for intermediate-term functional improvement. As for long-term follow-ups, no significant difference between these two interventions was identified either.

As for safety assessment, we just analysed the most common complications, namely, subsequent VCF and cement leakage, for they were the only complications reported in studies. Again the outcomes show that there was no significant difference between these two interventions. What's more, subgroup analysis and sensitive analysis did not detect any differences either.

As a meta-analysis for randomised and non-randomised studies, there are several limitations to our studies. First, almost all of the studies included in this meta-analysis are NRTs, such as clinical controlled trial, prospective or retrospective cohort and as a result of study design limitations, these studies were more likely to suffer from various kinds of bias. Furthermore, confounding factors which were balanced by randomisation in RCTs often disturbed the observation of effect of the intervention in NRTs. Thus it was not surprising that almost all of them were at relatively high risk when we assessed the risk of bias for the studies included (Fig. 2).

Second, heterogeneity was statistically significant across several outcomes. Although we employed the subgroup and sensitivity analysis according to the study designs, the heterogeneity can be only partially resolved. Potential explanations for such heterogeneity might be that it is more likely to encounter greater heterogeneity in a systematic review of NRTs than that of RCTs. This is due to the increased potential for variation in the way in which

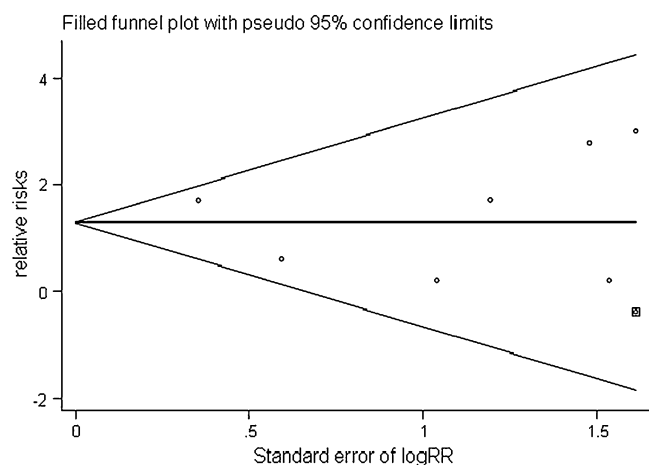


Fig. 7 Funnel plot for the outcome of subsequent vertebral compression fractures

confounding is considered in the analysis and greater risk of all kinds of biases through poor design of NRTs. However, there is still no way for controlling for these biases in the analysis of primary studies and no established method for assessing how these biases affect primary studies.

Third, no authors were contacted for further information. We extracted the data either directly from the article or by extrapolation. Taking the “effect size”, for instance, although the method of “change from baseline” is more credible, we took the final outcome as “effect size” while rejecting the method of “change from baseline”. Because all documents have given standard deviations for the baseline and the final measures but not the standard deviation for the mean difference of the pre- and post-operative, it is impossible for us to calculate the standard deviation of mean difference with the data extracted from the text. However, if we chose the final outcome as the “effect size”, it would be expected to give a relatively wider confidence interval especially for repeated measurement of the outcome on the same patient. It is therefore necessary for us to interpret the outcome carefully.

Forth, the mean duration between injury and surgery varied greatly between the studies included. There were studies aimed to clarify whether VP and KP had additional value for patients with acute or fresh vertebral compression fractures [21–23]. There were also studies assessing the treatment value of these two minimally invasive operations for chronic VCFs (more than three months). It is well known that the natural history for spontaneous pain reduction is three months [28]. When the duration of fracture is as long as the natural healing time, it is difficult for us to distinguish the effect of intervention from the natural resolution. A plausible explanation might be that these interventions can also be recommended to patients, refractory to medical therapy.

Finally, both of these two interventions can restore vertebral body height and kyphotic wedge angle [29]. However, KP involves the use of an inflatable bone tamp which can be introduced into the vertebral body and help restore vertebral height by forming a space into which acrylic cement can be injected [30, 31]. Theoretically, KP is more effective for vertebral height restoration. Nevertheless, the literature included in this meta-analysis only reported limited information on kyphotic restoration. It is therefore impossible for us to assess the radiological result of these two minimally invasive surgeries.

In summary, we believe that this meta-analysis, comparing VP versus KP for treatment of osteoporotic VCFs, offers useful conclusions and shows that both interventions have similar risk for subsequent fracture and cement leakage. VP is more effective for short-term (no more than seven days) pain relief. KP had a superior capability for

intermediate-term (close to three months) functional improvement to VP. As for long-term pain relief and functional improvement, there is no significant difference between these two interventions. Thus, considering the higher cost of the KP procedure, we recommend VP over KP for the treatment of osteoporotic VCFs.

Acknowledgements The intent of this statement is to display our idea on osteoporotic vertebral compression fracture. All the authors state that there are no outside grants in support of this research this work. There is no financial and personal relationships with other people or organisations that could inappropriately influence (bias) our work.

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