Review Article

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for osteoporotic vertebral compression fracture

A metaanalysis

Guo Shi-Ming, Luo Wen-Juan, Huang Yun-Mei, Wu Yin-Sheng, Huang Mei-Ya, Lin Yan-Ping

Abstract

Background: Osteoporotic vertebral compression fracture (OVCF) is the most common complication of osteoporosis, however, debate persists over which procedure of percutaneous vertebroplasty (PVP) or balloon kyphoplasty (BKP) is a better treatment. We performed a metaanalysis of prospective, randomized controlled and clinical controlled trials of PVP and BKP to determine the efficacy and safety for the treatment of OVCFs to reach a relatively conclusive answer.

Materials and Methods: We searched computerized databases comparing efficacy and safety of PVP and BKP in osteoporotic vertebral compression fractures. These reports included pain relief, functional capacity (Oswestry disability index [ODI] score), anterior vertebral body height (AVBH), kyphotic angle and complications (i.e. cement leakage, incident fractures). Studies were assessed for methodological bias and potential reasons for heterogeneity were explored.

Results: As of March 15, 2013, a PubMed search resulted in 761 articles, of which eleven studies encompassing 789 patients, met the inclusion criteria. The average length of followup is 17 months and 4.6% patients were lost to followup. Results of metaanalysis indicated that BKP is more effective for short term pain relief. In addition, BKP is more effective to restore the AVBH (anterior vertebral body height), ODI and kyphotic angle of OVCFs. Moreover, BKP need more polymethylmethacrylate amount.

Conclusions: In terms of better effectiveness of BKP procedure, we believe BKP to be superior over PVP for the treatment of osteoporotic VCFs.

Key words: Balloon kyphoplasty, metaanalysis, percutaneous vertebroplasty, vertebral compression fracture
MeSH terms: Vertebroplasty, osteoporotic fractures, bone cements

Introduction

Osteoporosis is characterized by low bone density that leads to fragile bones and higher fractures risk.[1] One of the major complications of osteoporosis is vertebral compression fractures (OVCFs), which constitute a major health care problem worldwide. Due to the increasing age of the population, there has been a constant rise in OVCFs during the last decade.[2] These fractures result in a decrease in the anterior vertebral height and cause spinal deformity, reduced pulmonary function, restrict the abdominal and thoracic contents, impair the mobility and cause clinical depression.

Several approaches for the treatment of OVCFs are currently available, such as bed rest, analgesia, bracing, rehabilitation and a combination of these treatments.[3] However, there are limitations of these methods. As we know, it may be difficult for patients, especially the elderlies, to tolerate long term bed rest. Anymore, conservative management cannot reverse kyphotic deformity that causes the biomechanical changes in the spinal segment. Biomechanical changes may be one factor leading to an increased incidence of adjacent vertebral fractures. Surgery fails because of poor quality of osteoporotic vertebral bone. About one third patients have been reported to suffer from persistent pain and progressive functional limitation.[4]

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Two percutaneous treatments have been introduced for OVCF. They are effective surgery, proven by multiple studies, for relieving or decreasing pain and have become an emerging choice for clinical vertebral body compression fractures.[5] Percutaneous vertebroplasty (PVP) was introduced in France by Galibert *et al*. in 1987, first described for the treatment of a hemangioma at the C2 vertebra.[6] It involves percutaneous injection of viscous polymethylmethacrylate (PMMA) into the vertebral body. With kyphoplasty, prior to injecting the cement, balloon is percutaneously inserted into the fractured vertebral body and inflated to create a cavity. The balloon is then deflated and removed and PMMA is injected. Although several systemic reviews have been performed to compare the efficacy and safety of PVP versus balloon kyphoplasty (BKP) in patients with symptomatic OVCFs,[7] it remains debatable over which procedure, PVP or BKP, provides a better outcome.[8] The purpose of this study was to perform a comprehensive review of literature and perform a metaanalysis to compare outcomes with the two techniques.

Materials and Methods

A comprehensive review of literature was performed using the PubMed MEDLINE. Searches were conducted from 1987 till March 15, 2013, for the terms "vertebroplasty and kyphoplasty," in order to maximise both the search sensitivity and specificity, which resulted in 761 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. In addition, we used meta-regression and subgroup analyses to identify potential predictors of outcomes.

Inclusion criteria

Studies were considered eligible if they met the following criteria: (1) Experimental studies (i.e., randomized controlled trials, clinical controlled trials, prospective trials) comparing PVP and balloon BKP for treatment of patients with OVCFs. (2) Studies with at least one of the following outcomes: Visual analog scale (VAS), Oswestry disability index (ODI), cement leakage or incidental fractures.

Exclusion criteria

Patients were excluded from the metaanalysis if they had a neoplastic etiology (i.e., metastasis or myeloma), infection, neural compression, traumatic fracture, neurological deficit or spinal stenosis. Other exclusion criteria were single arm studies, non English studies, systematic reviews, metaanalysis and studies not reporting clinical outcomes.

Study selection

Two investigators independently selected documents according to the criteria described above. We resolved disagreements by discussion to reach a consensus.

Assessment of quality of studies

As there is no accepted instrument or standard approach to the assessment of quality of case series or nonrandomized comparative studies, quality was assessed quantitatively according to the "Downs and Black checklist" table.[9] The Downs and Black checklist includes 5 aspects which consists of 27 questions, the highest total score being 32 points. There were several reasons for using this method. First, the key consideration is the extent to which results of included studies should be believed. The checklist is suitable for both nonrandomized and randomized control trials. Second, score from the checklist was helpful in assessing the quality directly. We can deem it good if the score was more than 15. The two investigators assessed studies for "risk of bias" according to the introduction of the Downs and Black checklist.

Data extraction

First, two investigators independently extracted the data. A double-check procedure was performed to check the accuracy of the extracted data. The following information was abstracted from the studies: First author, publishing year, study design, sample volume, patients lost to followup, baseline demographic characteristic of patients and any possible data on efficacy (i.e. VAS, Oswestry score) and safety (i.e. cement leakage and incident fractures).

Data analysis

We performed all metaanalyses using the Review Manager software (RevMan version 5.2; The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark). For continuous outcomes, means and standard deviations were pooled to a weighted mean difference (WMD) and a 95% confidence interval (CI). For dichotomous outcomes, the risk ratio (RR) and the 95% CI were assessed. $P < 0.05$ was considered to be statistically significant. The assessment for statistical heterogeneity was calculated using the Chi-square and I-square tests. A fixed effects model was used if there was no evidence of heterogeneity between studies ($P > 0.1$); a random effects model was used when $P < 0.1$ implied statistical heterogeneity. The source of heterogeneity was investigated by a subgroup analysis, and the subgroup analyses were stratified by study design in the meta-analysis. This "subgroup analysis" allows exploration of the influence of a variety of potential prognostic factors that might be associated with the efficacy or safety of PVP or BKP.[10]

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 [Figure 1].

Results

A total of 761 articles related to vertebroplasty and kyphoplasty were reviewed. All biomechanical and basic science studies were eliminated. Of the 761 abstracts reviewed, 11 eventually satisfied the eligibility criteria for this study [Figure 2]. Table 1 summarizes the data from these studies.

Study characteristics and quality

Eleven articles directly comparing PVP and BKP were included in this meta-analysis: Three clinical randomized controlled trial,[15,22,23] two randomized controlled trials[14,24] and six prospective cohorts.[11-13,16,25,26] The methodological quality of the included articles is assessed through quality assessment in Tables 2 and 3. "Assessing risk of bias" were evaluated and the exact outcome is summarized in Figure 1. Most studies used validated outcome measures and majority of case series were prospective, so the levels of assessment and selection bias were relatively low.

Visual analogue scales

The pain intensity measured by VAS pain score was extracted and classified as short term (no more than 3 months) and long term (no more than 1-year) followups. And then we pooled mean differences across the group. Nine studies[11-16,22,24,26] reported short term VAS scores. Long term VAS scores were available in seven studies.[11,14,16,22,23,25,26] The short term subgroup found that BKP was more effective than PVP (WMD = −0.21, 95% CI = −0.36 to −0.05; $P = 0.009$), but subgroup analysis of long term did not find a significant difference between the PVP and BKP groups. The overall pooled WMD on VAS pain score was −0.18 (95% CI = −0.33 to −[1,2]0.03, $P = 0.02$) [Figure 3].

Kyphotic angle

Separate subgroup analyses were also performed for the short and long term kyphotic angle outcomes. Four studies[16,22,24,25] reported short term kyphotic angle scores. Two subgroup were employed according to the region: USA subgroup and Europe Asia subgroup. The PVP and BKP patients did not differ significantly in the USA subgroup analysis (WMD = −0.90, 95% CI = −3.01–1.21; $P = 0.40$). However, the Europe Asia subgroup analysis found that BKP was more effective than PVP (WMD = 3.39, 95% CI = 2.43–4.35; $P < 0.00001$) [Figure 4].

Oswestry disability index score

Two subgroup analyses were performed according to published year (2010): A subgroup (before 2010 year)[13,22,25,26]

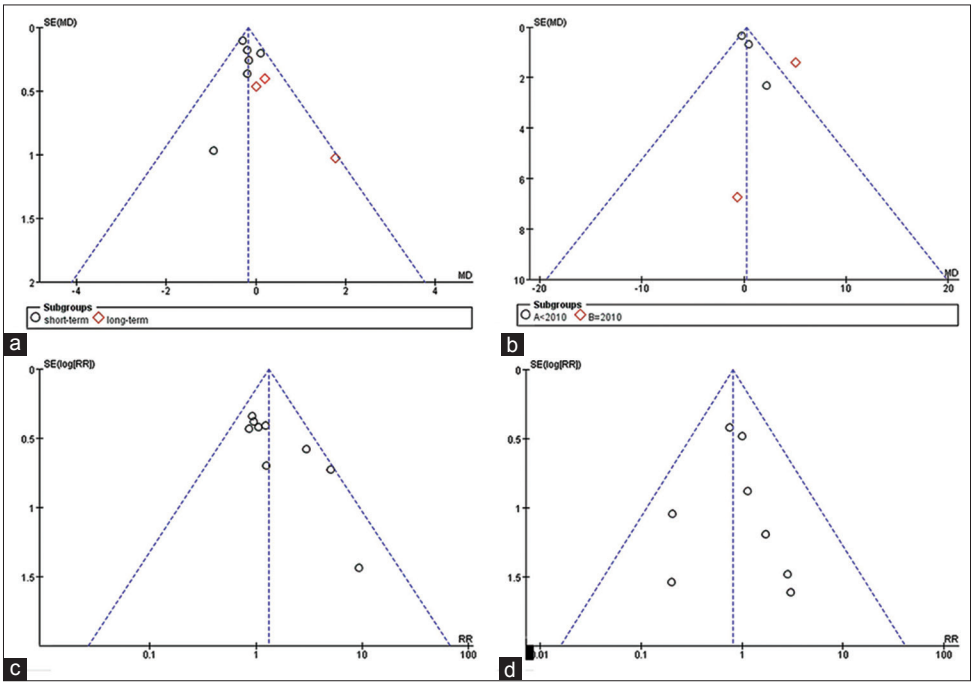

Figure 1: (a) Funnel plot to assess publication bias for the most frequently reported outcome: Visual analogue scale. (b) Funnel plot to assess publication bias for the most frequently reported outcome: Oswestry disability index score. (c) Funnel plot to assess publication bias for the most frequently reported outcome: Cement leakage rates. (d) Funnel plot to assess publication bias for the most frequently reported outcome: Adjacent level fracture rates

and B subgroup (2010 year).[11,12,14] As for A subgroup, an overall pooled WMD value of −0.02 (95% CI = −0.65–0.61, P = 0.95) was obtained, indicating that there was no difference between PVP and BKP before 2010. Subgroup analysis of B showed that overall pooled WMD value was 4.76 (95% CI = 2.06–7.46, P = 0.0006), which implied that BKP provided better functional improvement of patients with osteoporosis VCFs in 2010 [Figure 5].

Anterior vertebral body height

Four studies[11,15,24,25] provided data on the anterior vertebral body height (AVBH) after operation. Our pooled results showed that there was a significant difference between the BKP and PVP groups (WMD = −3.84, 95% CI = −6.05 to −1.64; P = 0.0006). Therefore, patients who underwent BKP had a better anterior height of the vertebral body than those who underwent PVP [Figure 6].

Polymethylmethacrylate amount

The dates of the polymethylmethacrylate (PMMA) amount were available for four trials. Two subgroup were employed according to the region of literature: Developed country subgroup[12,22,24] and developing country subgroup.[16]

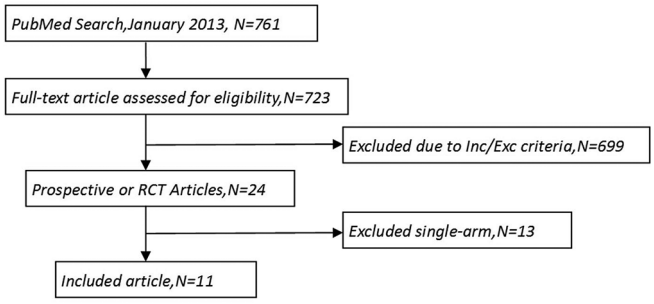

Figure 2: Literature search and selection

The developed country subgroup results showed that BKP needed more PMMA than PVP (WMD = −0.69, 95% CI = –0.92 to −0.46; P < 0.00001), however the developing country subgroup groups show no significantly difference between PVP an BKP in this respect (WMD = 0.3, 95% CI = −0.36–0.96; P = 0.37) [Figure 7].

Complications

Nine studies[11-13,15,22,23,25,26] reported complications related to cement leakage. The pooled analysis [Figure 8] showed that there were no significant difference between these two interventions, with the pooled RR values of 1.31 (95% CI = 0.97–1.78, P = 0.08).

In the eight studies[12,14,16,22-26] providing information about subsequent adjacent level fracture, with the pooled RR values of 0.81 (95% CI = 0.49–1.34, P = 0.42), it was indicated that these two interventions had similar risk for a subsequent fracture [Figure 9].

Discussion

Osteoporosis was defined as 2.5 or more standard deviations decrease in bone mineral density at observation.[17] PVP and BKP have been accepted as a successful procedures for treating OVCFs traditionally, which is a serious complication of osteoporosis. The two minimally invasive procedures can provide rapid and lasting pain reduction and improved quality of life. Although several published studies[18] have demonstrated that PVP and BKP improve preoperative clinical status and quality of life, it is not clear which of these two interventions provides better outcomes. Therefore, there is a need to help surgeons make clinical decisions as to which of these two surgical procedures leads to better outcomes.

Table 1: Studies included in this metaanalysis

Author, year, country	Study design	Quality assessment	Observation index	Length of followup	Lost to followup
Schofer *et al.*, 2009, Germany[22]	CCT	18	VAS score, ODI, kyphotic angle, PMMA amount, cement leakage	12 months	11
Grohs *et al.*, 2005, Austria[23]	CCT	15	VAS score, ODI, kyphotic wedge, cement leakage, AVF	24 months	NR
Liu *et al.*, 2010, Taiwan[24]	RCT	19	VAS score, kyphotic angle, operative time, AVBH, PMMA amount, AVF	6 months	NR
Röllinghoff *et al.*, 2009, USA[25]	Prospective	18	VAS score, kyphotic angle, ODI, AVBH, cement leakage, AVF	12 months	10
Lovi *et al.*, 2009, Italy[26]	Prospective	15	VAS score, ODI, PMMA amount, AVBH, cement leakage, AVF	33 months	10
Santiago *et al.*, 2010, Spain[11]	Prospective	13	VAS score, ODI, cement leakage, AVBH	12 months	NR
Kumar *et al.*, 2010, Canada[12]	Prospective	16	VAS score, ODI, EQ-5D, SF-36, PMMA amount, cement leakage, AVF	42.2 months	6
Negri *et al.*, 2007, Italy[13]	Prospective	14	VAS score, ODI, cement leakage	>6 months	NR
Bae *et al.*, 2010, USA[14]	RCT	14	VAS score, ODI, SF-12, Cortoss amount, leakage, AVF	>24 months	NR
Zhou *et al.*, 2008, China[15]	CCT	11	VAS score, operative time, blood loss, AVBH, cement leakage	12 months	NR
Movrin *et al.*, 2010, Slovenia[16]	Prospective	17	VAS score, BMD, kyphotic angle, PMMA amount, cement leakage, AVF	12 months	NR

RCT=Randomised controlled trial, CCT=Clinical controlled trial, ODI=Oswestry disability index, VAS=Visual analogue scale, AVBH=Anterior vertebral body height, AVF=Adjacent vertebral fracture, NR=Not reported, SF=Short form, PMMA=Polymethylmethacrylate, BMD=Bone mineral density

Table 2: Check list for measuring study quality (Downs and Black check list)

Aspects	Check list term	Schofer *et al.*	Grohs *et al.*	Liu *et al.*	Röllinghoff *et al.*	Lovi *et al.*	Santiago *et al.*
Reporting							
1	Is the hypothesis/aim/objective of the study clearly described?	1	1	1	1	1	1
2	Are the main outcomes to be measured clearly described in the introduction or methods section?	1	1	1	1	1	1
3	Are the characteristics of the patients included in the study clearly described?	1	1	0	1	0	0
4	Are the interventions of interest clearly described?	1	1	1	1	1	1
5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	0	0	0	0	0	0
6	Are the main findings of the study clearly described?	1	0	1	1	0	0
7	Does the study provide estimates of the random variability in the data for the main outcomes?	1	0	1	1	1	0
8	Have all important adverse events that may be a consequence of the intervention been reported?	0	1	1	1	0	0
9	Have the characteristics of patients lost to followup been described?	1	0	0	1	1	0
10	Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is <0.001?	0	0	0	0	0	0
External validity-bias							
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	1	1	1	1	1	1
12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	1	1	1	1	1	1
13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	1	1	1	1	1	1
Internal validity-bias							
14	Was an attempt made to blind study subjects to the intervention they have received?	0	0	1	0	0	0
15	Was an attempt made to blind those measuring the main outcomes of the intervention?	0	0	1	0	0	0
16	If any of the results of the study were based on "data dredging", was this made clear?	1	1	1	1	1	1
17	In trials and cohort studies, do the analyses adjust for different lengths of followup of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	1	1	1	1	1	1
18	Were the statistical tests used to assess the main outcomes appropriate?	1	1	1	1	1	1
19	Was compliance with the intervention/s reliable?	1	1	1	1	1	1
20	Were the main outcome measures used accurate (valid and reliable)?	1	1	1	1	1	1
Internal validity-confounding							
21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	1	1	1	1	1	1
22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	1	1	1	1	1	1
23	Were study subjects randomized to intervention groups?	0	0	1	0	0	0
24	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	0	0	0	0	0	0
25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	0	0	0	0	0	0
26	Were losses of patients to followup taken into account?	1	0	0	0	0	0
Power							
27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is <5%?	0	0	0	0	0	0
	Amount	18	15	19	18	15	13

Yes=1, No=0, Unable to determine=0

Table 3: Check list for measuring study quality according to assessment method of downs and black check list

Aspects	Check list term	Kumar *et al.*	Negri *et al.*	Bae *et al.*	Zhou *et al.*	Movrin *et al.*
Reporting						
1	Is the hypothesis/aim/objective of the study clearly described?	1	1	1	1	1
2	Are the main outcomes to be measured clearly described in the Introduction or methods section?	1	1	1	1	1
3	Are the characteristics of the patients included in the study clearly described?	0	1	1	1	1
4	Are the interventions of interest clearly described?	1	1	1	0	1
5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	0	0	0	0	1
6	Are the main findings of the study clearly described?	1	0	1	0	1
7	Does the study provide estimates of the random variability in the data for the main outcomes?	1	1	1	0	1
8	Have all important adverse events that may be a consequence of the intervention been reported?	1	0	0	0	1
9	Have the characteristics of patients lost to followup been described?	1	0	0	0	0
10	Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is <0.001?	0	0	0	0	0
External validity-bias						
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	1	1	1	1	1
12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	1	1	1	1	1
13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	1	1	1	1	1
Internal validity-bias						
14	Was an attempt made to blind study subjects to the intervention they have received?	0	0	0	0	0
15	Was an attempt made to blind those measuring the main outcomes of the intervention?	0	0	0	0	0
16	If any of the results of the study were based on "data dredging", was this made clear?	1	1	0	0	1
17	In trials and cohort studies, do the analyses adjust for different lengths of followup of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	0	0	0	0	0
18	Were the statistical tests used to assess the main outcomes appropriate?	1	1	1	1	1
19	Was compliance with the intervention/s reliable?	1	1	1	1	1
20	Were the main outcome measures used accurate (valid and reliable)?	1	1	1	1	1
Internal validity-confounding						
21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	1	1	1	1	1
22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	1	1	1	1	1
23	Were study subjects randomized to intervention groups?	0	0	0	0	0
24	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	0	0	0	0	0
25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	0	0	0	0	0
26	Were losses of patients to followup taken into account?	0	0	0	0	0
Power						
27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is <5%?	0	0	0	0	0
	Amount	16	14	14	11	17

Yes=1, No=0, Unable to determine=0

In order to assess the efficacy and safety of PVP and BKP, we extracted published data. Unfortunately, much of the current literature is in the form of retrospective cases series and case reports. Due to the lack of randomized surgical trials and the large number of observational surgical studies, CCT were included in this review. Eleven studies in the literature – three clinical randomized controlled trials,[22,15,23] two randomized controlled trials[14,24] and six prospective cohorts,[11-13,16,25,25] were included in our systematic review, with a total of 789 patients. The average length of followup

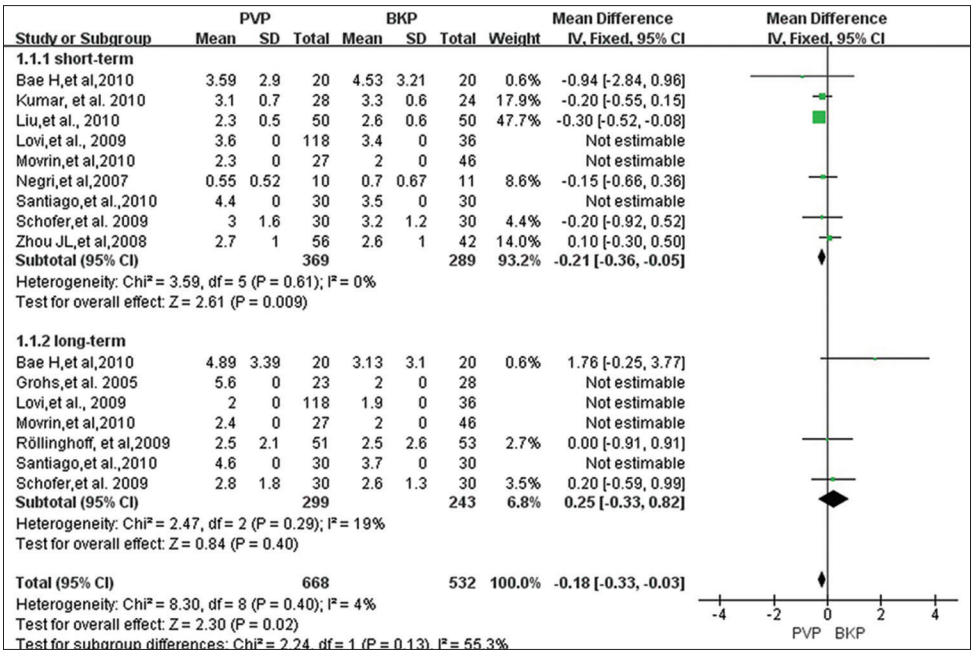

Figure 3: Forest plot and tabulated data illustrating the weighted mean difference in postoperative visual analogue scale (VAS) between the percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP) procedures, showing that patients who underwent BKP relieve pain than patients who underwent PVP postoperatively in the short term. However, the two interventions showed no significant difference in VAS postoperatively in the long term

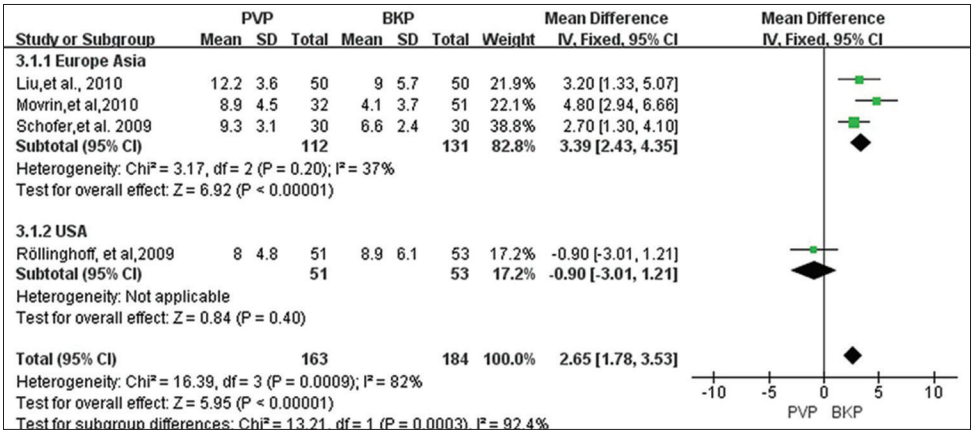

Figure 4: Forest plot and tabulated data illustrating the weighted mean difference in kyphotic angle between percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP) procedures, showing that BKP was more effective than PVP in this respect in Europe Asia subgroup

was 17 months and 4.6% were lost to followup, which had not influenced the result of the metaanalysis. Most studies used validated outcome measures and the majority of case series were prospective and hence the levels of assessment and selection bias were relatively low [Figure 1a-d].

Postoperative pain relief in osteoporotic compression fractures has been shown in the literature using BKP and PVP, which was measured by the VAS pain scale. The combined data revealed that there was no significant difference across these two interventions in the long term. However, the short term subgroup found that BKP was more effective than PVP as shown in Figure 3. Results of experimental studies such as short and long term are credible, as shown in the "risk of bias" table [Figure 1a]. The percentage improvement in VAS pain scores was 67.8% after kyphoplasty and 70.5% after vertebroplasty,[24] so there was no statistically significant difference in pain scores between vertebroplasty and kyphoplasty groups. The potential reason for the similar pain scores is that clinical heterogeneity was induced by a double blind, the duration of illness, types of fractures, gender differences, insufficient sample size bias. As we know, the natural history for spontaneous pain reduction is 3 months.[19] 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 natural resolution.

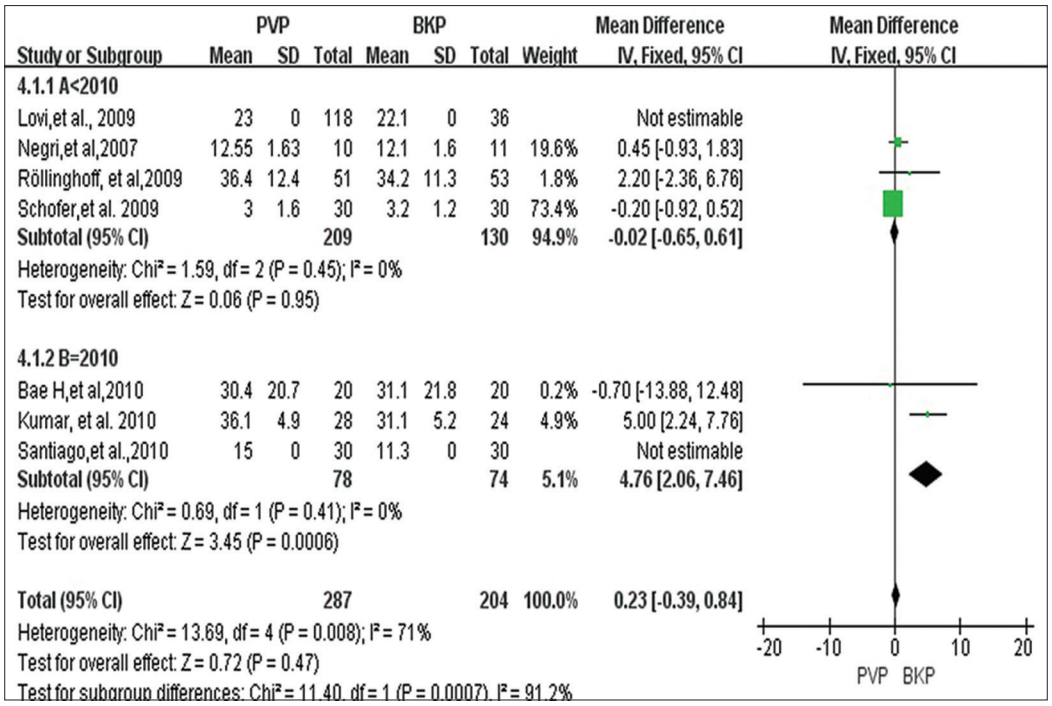

Figure 5: Forest plot and tabulated data illustrating the weighted mean difference in Oswestry disability index scores between the percutaneous vertebroplasty and balloon kyphoplasty (BKP) procedures, showing that there is no significant difference between the two interventions before 2010. However, subgroup analysis of B showed that BKP provided better functional improvement in 2010

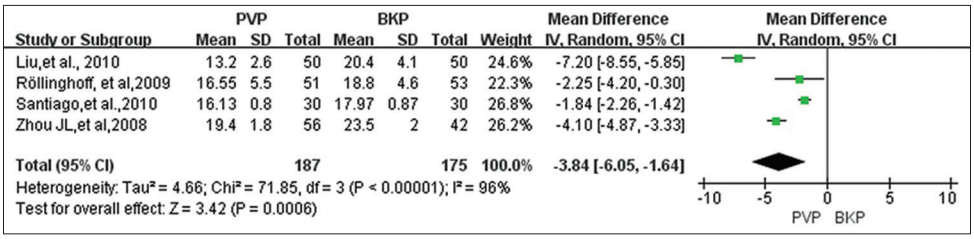

Figure 6: Forest plot and tabulated data illustrating the mean difference (MD) in anterior vertebral body height between the percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP) procedures, showing that BKP is higher than PVP significantly

A similar trend was also found when assessing for ODI. With the pooled WMD value of 4.76 for the B subgroup analysis, BKP appeared more effective for functional improvement in 2010. The overall pooled WMD value obtained from A subgroup indicates that there is no difference between PVP and BKP before 2010. A possible reason is that BKP is more effective in the improvement of ODI with improvement in operative skills in 2010. Previous studies have demonstrated that PVP and BKP significantly improve the quality of life compared with the preoperative status.

In our metaanalysis, Europe Asia subgroup analysis found that BKP was more effective in a reduction of the kyphosis angle than PVP. However, several factors attributed to the measured kyphosis angles. First, patient positioning may influence measurement accuracy. Second, the difference in the results may be attributable to the subsidence of the endplates of the index vertebrae. Detection bias may influence the reliability of the outcomes. The pressure and volume of the injected PMMA helps to preserve positional changes and may further correct the kyphotic angle. Of course, the reduction in angle also depends on the natural healing of the fracture.[20] Direct postoperative kyphosis angle was reduced to 8° for vertebroplasty and 8.9° for kyphoplasty.[25] It was recommended that there was an additive effect from the balloon-inflated restoration. However, the PVP and BKP patients did not differ significantly in the USA subgroup analysis. The potential reason is unclear.

Restoration and repositioning of fractured vertebral body height are easily achieved with low pressure bone cement injection when using BKP. In a systematic analysis, patients who underwent BKP had a better anterior height of the vertebral body than those who underwent PVP. BKP helps restore vertebral height by forming a space into which cement can be injected.[18,21] In comparison to vertebroplasty, kyphoplasty has a potential advantage in that it may partially reestablish vertebral height.[27] Restoration of vertebral body

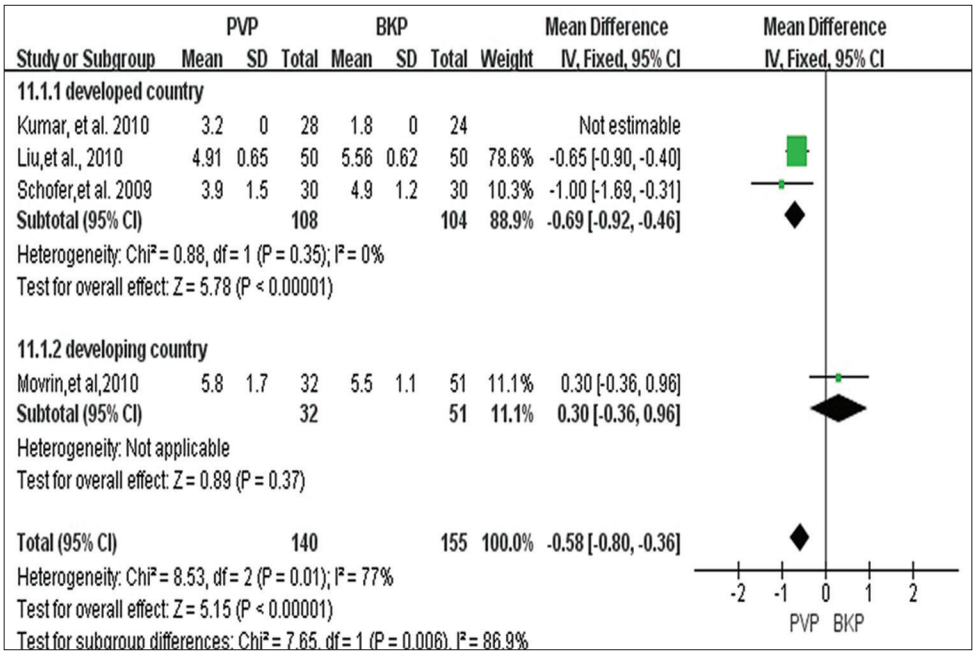

Figure 7: Forest plot and tabulated data illustrating the weighted mean difference in polymethylmethacrylate (PMMA) amount between the balloon kyphoplasty (BKP) and percutaneous vertebroplasty (PVP) procedures, showing that there is no signifi cantly difference between the two group in developing country, but the developed country subgroup results showed that BKP needed more PMMA than PVP

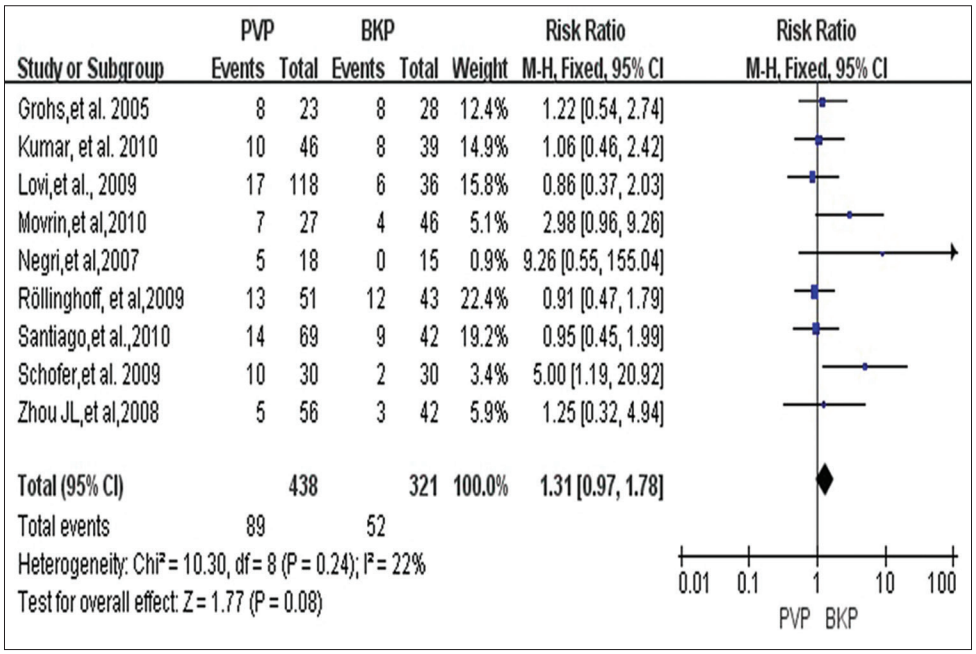

Figure 8: Forest plot and tabulated data illustrating the risk ratio for cement leakage between the balloon kyphoplasty and percutaneous vertebroplasty procedures, showing that there were no significant difference between these two interventions in this respect

height by BKP can be associated with the possibility of restoring the shape of the vertebral body through the balloon. Although there was no relationship between the improved vertebral body height and clinical outcome in either the BKP or PVP groups,[22,25] restoration of vertebral body height associated with OVCF was theoretically better in the BKP group. Therefore, patients with significant height loss of the fractured vertebrae may be better candidates for BKP. Theoretically, BKP is more effective for vertebral height restoration. By comparison, BKP needed more amount of PMMA than PVP in the developed country subgroup. However, in the developing country subgroup, PVP and BKP needed similar amount of PMMA.

As for safety assessment, we analyzed the most common complications. Occurrence of cement leakage is up to 8%

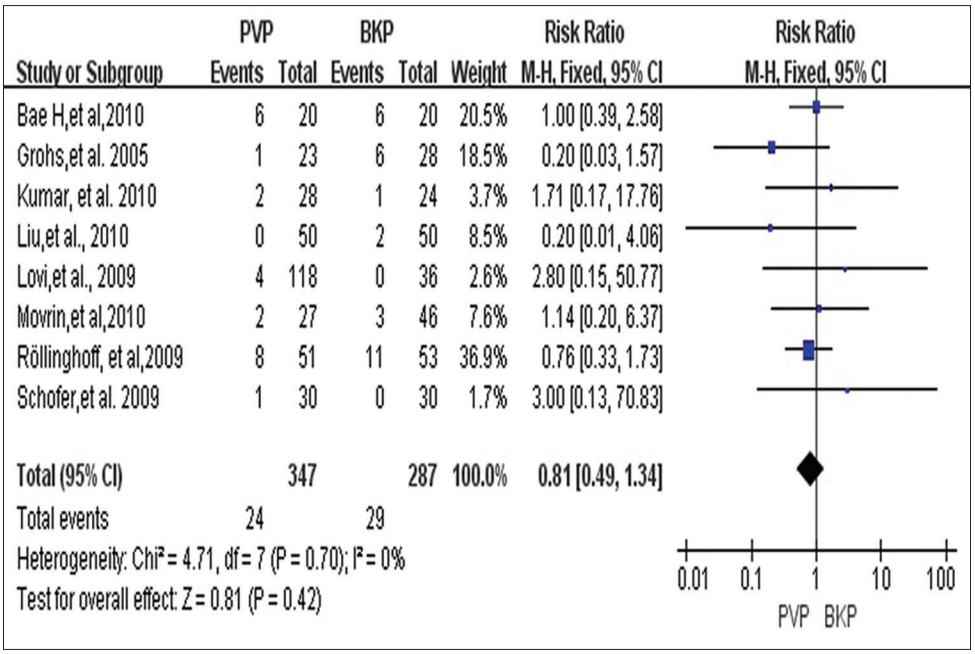

Figure 9: Forest plot and tabulated data illustrating the risk ratio for adjacent-level vertebral fracture between the percutaneous vertebroplasty and balloon kyphoplasty procedures showing that there is no significant difference between the two interventions in this respect

in BKP and PVP patients.[28] However, cement leakage does not usually cause any clinical symptoms. Although all of the included studies reported the incidence of cement leakage, no cases of spinal stenosis and pulmonary embolism due to cement leakage were reported. Further evidence was provided that little cement leakage is found by the standard radiographic imaging, whereas high rates are observed with computed tomography.[28] Some authors do not consider asymptomatic leaks to be a complication. Others have suggested that there are long term sequelae from asymptomatic cement leaks.[29] The pooled analysis showed that there was no significant difference between these two interventions. By contrast, Lovi *et al*.[26] and Lee *et al*.[8] reported that the rate of cement leakage also appeared to be higher for PVP. The potential reason was related to the high risk of publication bias and outcome inconsistencies.

We also examined the rates of adjacent level fracture between PVP and BKP. It appears that there was no statistically significant difference in the incidence of adjacent-level fracture between the two surgical methods based on our analyses. Vertebral augmentation may reduce the risk of subsequent fracture as anterior column support along with a reduction of kyphosis lessens the flexion moment on the surrounding vertebrae, thus reducing the likelihood of further fractures.Variability in fracture reporting can confound these results as only symptomatic fractures are likely to be reported. It can be presumed that BKP involves the similar amount of PMMA with PVP, which results in the similar rigid segmental construct that may subsequently lead to similar junctional stresses adjacent to the treated level.

As with any metaanalysis there are limitations with this study too. This analysis is dependent on the quality of each of the individual studies. Although an effort was made, it is difficult to weigh its influence. Although we employed the subgroup according to the study designs, the heterogeneity can be only partially resolved. There is still no way for controlling these biases in the analysis of primary studies and no established method for assessing how these biases affect primary studies. Owing to the limited number of included trials, we also could not analyze the medical cost for the two groups, which Is essential for establishing the importance of a procedure.

Conclusion

It appears that BKP is a well tolerated, relatively safe and effective technique that provides short term pain relief and improved functional outcomes. BKP also had a superior capability for kyphotic angle and AVBH improvement as compared to PVP. Both interventions have similar risk for subsequent fracture and cement leakage. In terms of better effectiveness of BKP procedure, we believe BKP to be superior over PVP for the treatment of osteoporotic VCFs.

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