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Review

The therapeutic effect of intravertebral vacuum cleft with osteoporotic vertebral compression fractures: A systematic review and meta-analysis

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HIGHLIGHTS

- The IVCs were very common in OVCFs.
- The IVCs have an important effect on therapeutic efficacy in percutaneous PVA for the treatment of OVCFs.
- It is important to have a strict observation and follow-up for OVCFs with IVCs after PVA.

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ABSTRACT

Background: To date, there has been ongoing debate over whether intravertebral vacuum cleft (IVC) has the effect of therapeutic efficacy in percutaneous vertebral augmentation (PVA) for the treatment of osteoporotic vertebral compression fractures (OVCFs).
Objective: The aim of this meta-analysis was to calculate a pooled estimate of the IVCs on the effect of therapeutic efficacy of PVA for the treatment of OVCFs.
Methods: A systematic electronic literature search was performed using the following databases: PubMed, Embase and Cochrane Library; the databases were searched from the earliest available records up to June 2016. Pooled risk ratio (RR) or a mean difference (MD) with 95% confidence interval (CI) was calculated using random- or fixed-effects models. The RevMan 5.2 was used to analyze the data.
Results: In the immediate postoperative period, pooled results showed that vertebral height and VAS scores of the IVC patients were significantly lower than those of the non-IVC patients. However, pooled results showed there was no significant difference in kyphotic angle and ODI indices between the two groups. At final follow-up period, significant difference was observed in all the radiological and clinical parameters for the IVC patients with compared to the non-IVC patients in our pooled results. Pooled results showed significant difference with respect to the rate of cement leakage between the two groups.
Conclusion: The IVCs had an important effect of therapeutic efficacy in PVA for the treatment OVCFs. Therefore, we strongly recommend its strict observation and follow-up for the IVCs patients.

1. Introduction

Percutaneous vertebral augmentation (PVA) refers to percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP). It is a minimally invasive technique for treating painful osteoporotic vertebral fractures (OVCFs). Numerous clinical studies [1,2] have demonstrated that this treatment could rapidly relieve the pain of patient, restore vertebral height partially, and provide biomechanical stability by injecting bone cement into fractured vertebrae. In addition, PVA [3–5] has been also recommended for OVCFs with intravertebral vacuum cleft (IVC) and achieved good outcomes. However, there is debate over whether intravertebral vacuum cleft (IVC) has the effect of therapeutic efficacy in percutaneous

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vertebral augmentation (PVA) for the treatment of osteoporotic vertebral compression fractures (OVCFs).

Therefore, we performed a meta-analysis of observational studies to calculate a pooled estimate of the IVCs on the effect of therapeutic efficacy of PVA for the treatment of OVCFs.

2. Materials and methods

2.1. Literature search

We systematically searched Pubmed, EMBASE, and Cochrane Library for studies published up to May 2016. The keywords for the study object (MeSH words or free words) included (“vertebral fractures” or “osteoporosis”) AND (“Intravertebral cleft” or “intravertebral pseudarthrosis” or “avascular necrosis” or “vertebral osteonecrosis” or “intraosseous vacuum phenomena” or “Kümmell's disease”). For the intervention strategy, the keywords were “vertebroplasty” or “kyphoplasty,” or “vertebral augmentation.” The reference lists of selected articles and reviews were manually reviewed for potential relevant citations until no additional articles were found. When required, the authors of the articles were contacted. All analyses were based on previous published studies; thus, no ethical approval and patient consent are required.

2.2. Inclusion and exclusion criteria

Two independent reviewers screened titles and abstracts of the studies to determine the relevance of each study to this review. The following criterions were used to select a study for our meta-analysis. Firstly, the study must be conducted through case-control design; Secondly, the intervened subjects were patients suffering from osteoporotic vertebral compressive fractures; Thirdly, all subjects were intervened by PVA (PVP or PKP); Fourthly, the study was a comparative study between patients with IVC and those without IVC; Finally, published sufficient data to estimate an risk ratio (RR) or a mean difference (MD) with 95% confidence interval (CI).

The studies were excluded from our meta-analysis if they were not conducted through a comparative trial; the intervention strategy or grouping settings were not in accordance with our selection criterion. The articles that did not report outcomes of interest were excluded.

2.3. Data extraction

After removing duplicates and completing the study selection process, data extraction was conducted by two independent reviewers by adapting the predetermined standardized procedure. All data were checked for internal consistency, and controversies were settled by discussion with a third author. Baseline data were extracted from eligible studies including first author and year of publication, country, study design, type of surgery, sample size (case/control), mean age and outcome. Additionally, several primary outcomes were evaluated, including vertebral height, kyphotic angle, visual analogue scale (VAS) and Oswestry Disability Index (ODI) at the immediate postoperative and final follow-up period. Moreover, the rate of cement leakage would be also estimated by pooled analysis.

2.4. Quality assessment

To assess the quality of the studies, the Newcastle–Ottawa Scale (NOS) with a 9-point system [6] was used to assess each study with respect to the following three broad perspectives: the selection of the study groups (0–4 points); the comparability of the groups (0-2points); and the determination of either the exposure or the outcome of interest (0–3 points). The studies with $\geq$7 points were considered high quality. Those two evaluators also independently performed methodological quality evaluations and then cross-validated the results. When disagreement occurred between the 2 evaluators, a third evaluator (X.B.J.) was involved.

2.5. Statistical analysis

The RevMan 5.2 software program of the Cochrane Collaboration was employed to analyze the data. We assessed the efficacy and safety of PVA treatment for OVCFs with or without IVC based on the data from 9 observational studies. Vertebral compression rate, VAS was treated as continuous variables, and they were expressed as MD with 95% CI for each study; the cement leakage rate was treated as dichotomous variables, thus they were expressed as risk ratio (RR) with 95% confidence intervals (CIs). Before the original data were synthesized, the Q-test and I^2 value calculations were adopted to assess the heterogeneity of the data. A random effects model would be used as meta-analysis when P value is <0.1 and I^2 value > 50%; otherwise, a fixed-effects model (Mantel–Haenszel method) was used for analysis.

3. Results

3.1. Identification of eligible studies

The results of the search strategy and study selection process were detailed in Fig. 1. A total of 236 reports were identified by the initial database search. Of these, 108 were excluded for duplicate records and 99 were excluded after scanning the titles and abstracts. After reviewing the full text of the remaining 29 studies, we excluded 21additional full-text articles and one record from reference lists was included. Finally, nine (7–15) studies that met the selection criterion were included in this meta-analysis.

3.2. Study characteristics and the quality assessment

Table 1 presented the basic information of the nine selected studies. The articles were published between 2003 and 2015. Each study involved 43 to 388 patients, involving a total of 1484 patients, which were composed of 400 IVC patients with and 1084 non IVC patients. Of these, three were conducted in china, three in Korea, one in Taiwan, one in Japan and one in Germany. Seven of nine studies adopted PVP as an intervention strategy, one adopted PKP and one adopted either PVP or PKP. For all included studies, five [7,8,11–13] provided the different data of vertebral height and kyphotic angle in the immediate postoperative period; three studies [8,11,12] provided the data of vertebral height and kyphotic angle at final follow-up; three [14,17,18] provided the different data of VAS scores and ODI indices at the immediate postoperative and final follow-up period; six [9–12,14,15] provided the different data of cement leakage rate.

The results of the quality assessment were shown in Fig. 2. Two studies [7,9] received a score of 9, three studies [8,11,14] received a score of 8, three studies [10,12,15] received a score of 7 and one studies [13] received a score of 6.

3.3. Pooled analysis of vertebral height

Five studies [7,8,11–13] reported the data of vertebral height at the immediate postoperative period. Heterogeneous test also showed no heterogeneity among the 5 studies ($P = 0.3$, $I^2 = 18\%$). The fixed-effects model showed the immediate postoperative vertebral height of the IVC patients was significantly lower than

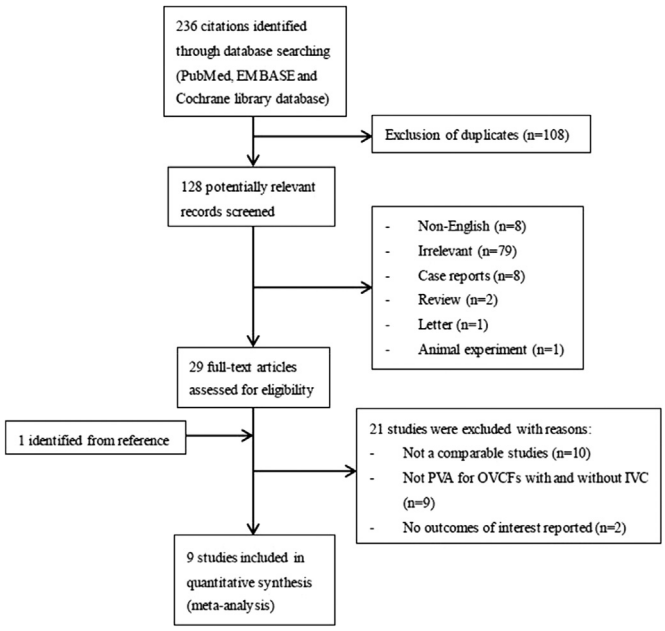

Fig. 1. Literature search methodology.

that of non IVC patients (MD = −4.68, 95% CI [-6.50, −2.87], P < 0.0001). Three studies [8,11,12] provided the data of vertebral height at final follow-up period. There was also no heterogeneity (P = 0.23, I^2 = 32%). The fixed-effects model showed the final follow-up vertebral height of the IVC patients was still lower than that of non IVC patients (MD = −5.82, 95% CI [-7.93, −3.72], P < 0.0001), as shown in Fig. 3. No publication bias was observed with respect to vertebral height; the funnel plots were symmetric about the mean standardized difference (Fig. 4).

3.4. Pooled analysis of kyphotic angle

Five studies [7,8,11–13] reported the data of kyphotic angle at the immediate postoperative period. Heterogeneous test also showed no heterogeneity among the 5 studies (P = 0.17, I^2 = 38%). The fixed-effects model showed that there was no significant difference in the immediate postoperative kyphotic angle between the IVC patients and the non IVC patients (MD = 0.48, 95% CI [-0.23, 1.18], P = 0.19). Three studies [8,11,12] provided the data of kyphotic angle at final follow-up period. There was also no heterogeneity (P = 0.74, I^2 = 0%). The fixed-effects model showed the final follow-up kyphotic angle of the IVC patients was lower than that of non IVC patients (MD = 1.65, 95% CI [0.47, 2.84], P = 0.006), as shown in Fig. 5.

3.5. Pooled analysis of visual analogue scale (VAS) scores

Three studies [14,17,18] reported the data of VAS scores at the immediate postoperative period. Heterogeneous test showed no heterogeneity among the 3 studies (P = 0.97, I^2 = 0%). The fixed-effects model showed that the immediate postoperative VAS scores of the IVC patients was significantly higher than that of non IVC patients (MD = 0.32, 95% CI [0.09, 0.55], P = 0.007). Three studies provided the data of VAS scores at final follow-up period. There was also no heterogeneity (P = 0.15, I^2 = 47%). The fixed-effects model showed the final follow-up VAS scores of the IVC patients was lower than that of non IVC patients (MD = 1.31, 95% CI [1.02, 1.60], P = 0.006), as shown in Fig. 6.

3.6. Pooled analysis of Oswestry Disability Index (ODI) indices

Three studies [14,17,18] reported the data of ODI indices at the immediate postoperative period. Heterogeneous test showed no heterogeneity among the 3 studies (P = 0.55, I^2 = 0%). The fixed-effects model showed that there was no significant difference in the immediate postoperative ODI indices between the IVC patients and the non IVC patients (MD = 1.53, 95% CI [-0.01, 3.07], P = 0.05). Three studies provided the data of ODI indices at final follow-up period. There was also no heterogeneity (P = 0.36, I^2 = 2%). The fixed-effects model showed the final follow-up VAS scores of the IVC patients was lower than that of non IVC patients (MD = 9.86, 95% CI [7.97, 11.76], P < 0.0001), as shown in Fig. 7.

3.7. Pooled analysis of the rate of cement leakage

Six studies [9–12,14,15] reported the data of cement leakage rate. There was heterogeneity for cement leakage rate among the 6 studies (P = 0.003, I^2 = 72%). Based on the origins of patients, the studies were divided into 2 groups. The Asian group included 5 studies [10–12,14,15] with no heterogeneity (P = 0.15, I^2 = 40%).

Table 1
Baseline characteristics of patients in the trials included in the meta-analysis.

Author/Year	County	Study design	Type of surgery	Sample size (case/control)	Mean age (years)	Outcomes
Sun et al.,/2011 [7]	China	Retrospective study	PVP	232(49/183)	64.4	Vertebral height, Kyphotic angle
Fang et al.,/2015 [8]	China	Retrospective study	PVP PKP	388(47/341)	72.3	Vertebral height, Kyphotic angle, VAS, ODI
Krauss et al.,/2006 [9]	Germany	Retrospective study	PVP	192(44/148)	72.3	Cement leakage rate
Jung et al.,/2006 [10]	Korea	Retrospective study	PVP	85(36/49)	70	Cement leakage rate
Ha et al.,/2006 [11]	Korea	Retrospective study	PVP	58(12/46)	70.9	Vertebral height, Kyphotic angle, VAS, ODI Cement leakage rate
Wu et al.,/2013 [12]	China	Retrospective study	PKP	113(48/65)	72.7	Vertebral height, Kyphotic angle, VAS, ODI Cement leakage rate
Teng et al.,/2003 [13]	Taiwan	Retrospective study	PVP	73(39/34)	75.5	Vertebral height, Kyphotic angle,
Tanigawa et al.,/2009 [14]	Japan	Retrospective study	PVP	300(107/193)	73	Cement leakage rate
Xuee et al.,/2008 [15]	Korea	Retrospective study	PVP	43(18/25)	74.2	Cement leakage rate

VAS, visual analogue scale; ODI, Oswestry Disability Index.

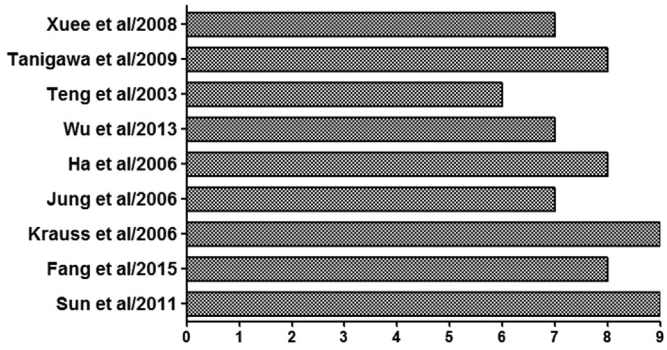

Fig. 2. The quality assessment of nine included studies.

The fix-effects model in the 5 studies showed that the rate of cement leakage was significantly higher in the IVC patients than that in the no IVC patients (RR = 1.19, 95% CI [1.01, 1.40], P = 0.04). The European group included one study (9), and there was lower in the IVC patients than that in the no IVC patients (RR = 0.40, 95% CI [0.21, 0.76], P = 0.005), as shown in Figs. 8.

4. Discussion

The IVCs [16–18] refer to a prominent radiolucency (gas containing), located centrally or adjacent to the vertebral body endplates as seen on computed tomography (CT) or plain radiographs. On magnetic resonance imaging (MRI), it usually shows as low signal intensity on T1-weighted images, high or low signal on T2-weighted images, which mainly depends on whether fluid or gas fills the cleft. McKiernan et al. [19] reported that the IVCs also indicated instability within the fracture in different body postures. Hence, vertebral height loss and kyphotic deformity could be easily corrected by PVA. The non IVC fractures usually could not appreciable correction of vertebral height and kyphotic deformity because of their immobility. However, Carlier et al. [20] and Cawley et al. [21] demonstrated that the localized kyphosis could be still corrected for some non IVC patients under intraoperative spinal hyperextension. In addition, McKiernan and Faciszewski [22] reported the difference of cement distribution patterns between the IVC patients and the non IVC patients. When the IVCs appeared, it was served as a confluent reservoir, and cement injected could be filled with uniform opacity and sharp radiological margins. In the absence of the IVCs, the cement injected was interspersed throughout the trabecular space in a more even manner. To date, a few studies have been conducted to demonstrate the difference of the effect of therapeutic efficacy for PVA for the treatment of OVCFs with and without the IVCs. However, their results were inconsistent.

To the best of our knowledge, this is the first comprehensive meta-analysis to assess difference of effect of therapeutic efficacy for PVA for the treatment of OVCFs with and without the IVCs. In this study, we attempted to include all related comparative studies about PVA for the treatment of OVCFs with and without the IVCs. Five studies reported the data of vertebral height and kyphotic angle in the immediate postoperative period. Combining the results of 5 studies, we found that vertebral height of the IVC patients was significantly lower than that of the non IVC patients. As compared to our pooled results of vertebral height, most included studies were inconsistent, in which vertebral height of the IVC patients was numerically lower than that of the non IVC patients. Such discrepancies may be due to small sample size which ranged from 58 to 388 in their studies. Moreover, the relatively low incidence of the IVCs could be another reason, also causing very small sample size (ranging from 12 to 48) in the IVC groups. In the study, pooled analysis of VAS scores showed the same pattern in the immediate postoperative period.

In this study, pooled analysis showed that there was no significant difference between the IVC patients and the non IVC patients. This result was also consistent with all selected studies. The kyphosis angle is affected by the relative position of adjacent vertebral bodies and intervertebral disc spaces, in addition to the individual wedge angle induced by vertebral height loss. Therefore, the IVCs showed no significant impact on the correction of kyphotic angle in the immediately postoperative period. In addition, our pooled analysis of ODI indices also showed there was no significant difference between the two groups in the immediate postoperative period.

Our pooled analysis also demonstrated that all radiological and clinical parameters of the IVC patients were statistically different from the non IVC patients. Significant recollapse was observed in the IVC groups at the final follow-up period. These results were

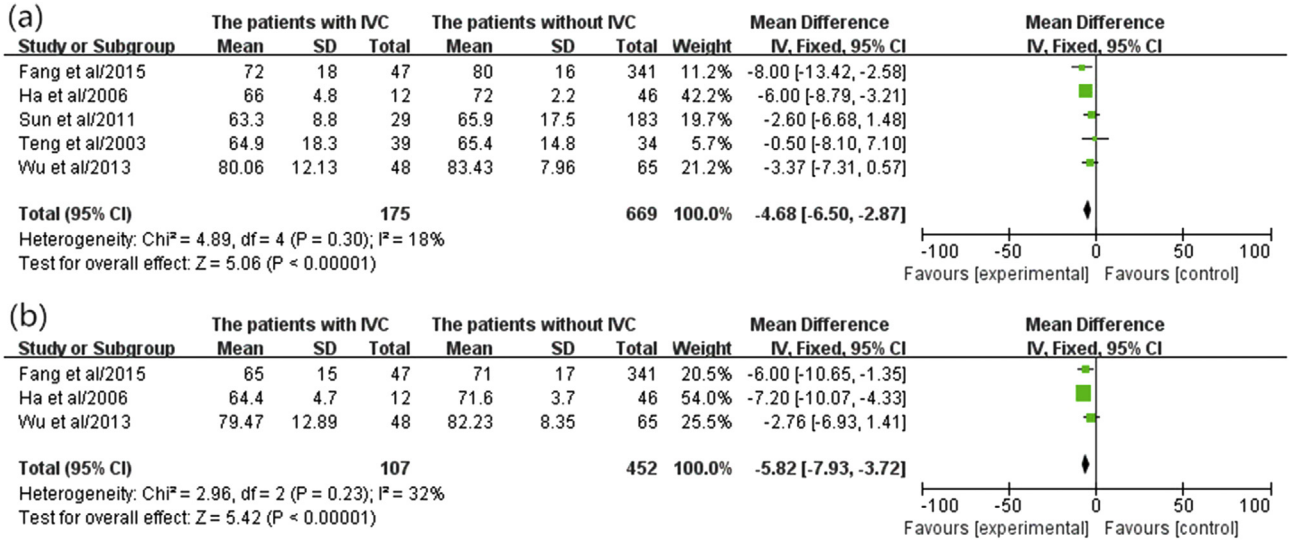

Fig. 3. Forest plot of comparison: vertebral height at the immediate postoperative **(a)** and final follow-up period **(b)**.

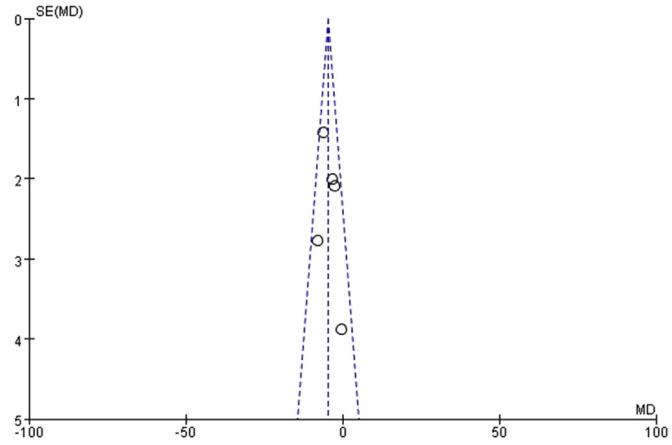

Fig. 4. Funnel plot symmetrically distributed around the standardized mean difference.

similar with all included studies. The distribution pattern of PMMA cement might be an important predisposing factor. In the IVC groups, PMMA cement injected is mainly filled with solid lump into the IVC area. Solid lump cement may act to both concentrate stress on the surrounding fragile bones, and to intercept mechanical interlock with surrounding trabecular bones [22]. Moreover, severe demineralization in the IVC groups could also increase the fracture risk of the unaugmented trabecular bones. Hence, significant recollapse was observed in 'PMMA-non supported area' in the IVC patients.

The rate of cement leakage has also drawn great attention in OVCFs with and without the IVCs. Among the selected studies, six studies reported the difference of cement leakage rate with and without the IVCs. Considering the apparent heterogeneity among the studies, two subgroups were formed according to the origins of patients. The Asian group consists of 5 studies, which showed cement leakage rate of the IVC patients is significantly higher than that in the non IVC patients. However, one study of the European group showed lower cement leakage rate of IVC patients than that of the non IVC patients. The main bias reason might be that the

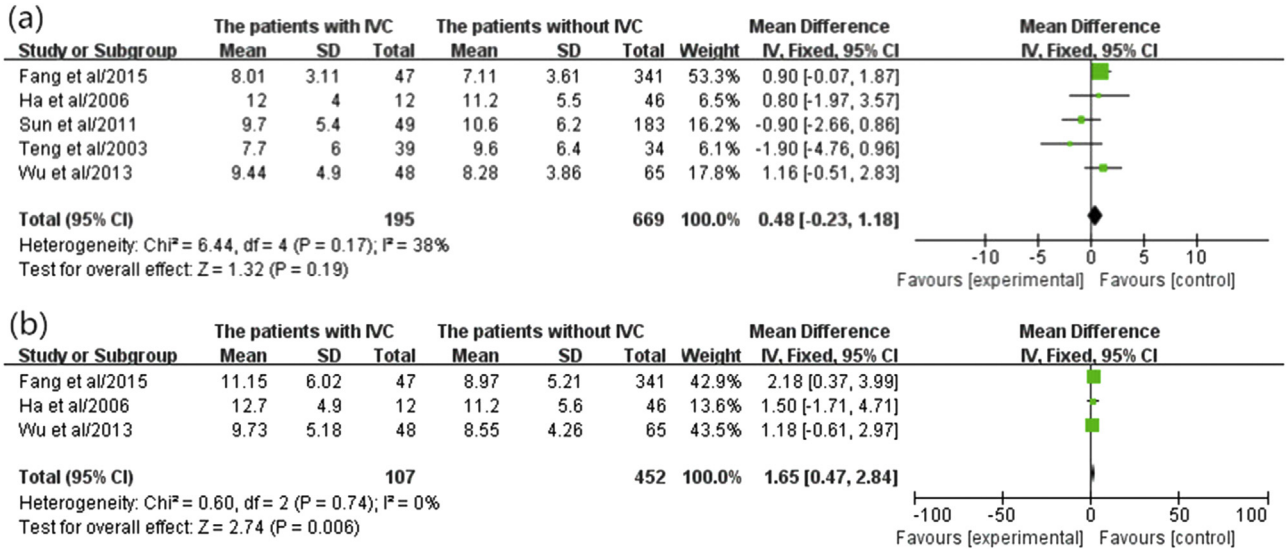

Fig. 5. Forest plot of comparison: kyphotic angle at the immediate postoperative **(a)** and final follow-up period **(b)**.

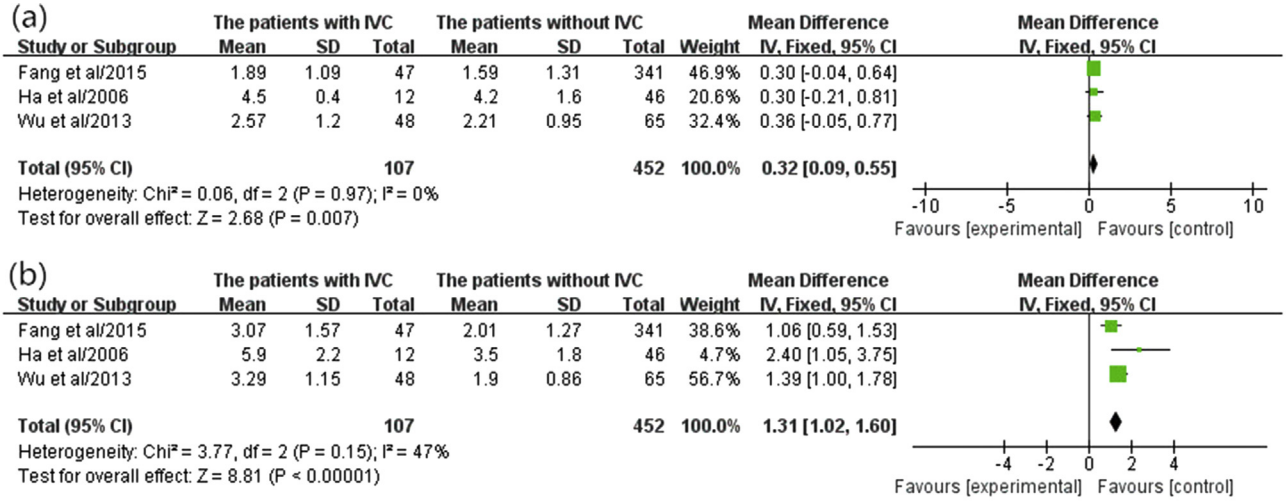

Fig. 6. Forest plot of comparison: visual analogue scale scores at the immediate postoperative **(a)** and final follow-up period **(b)**.

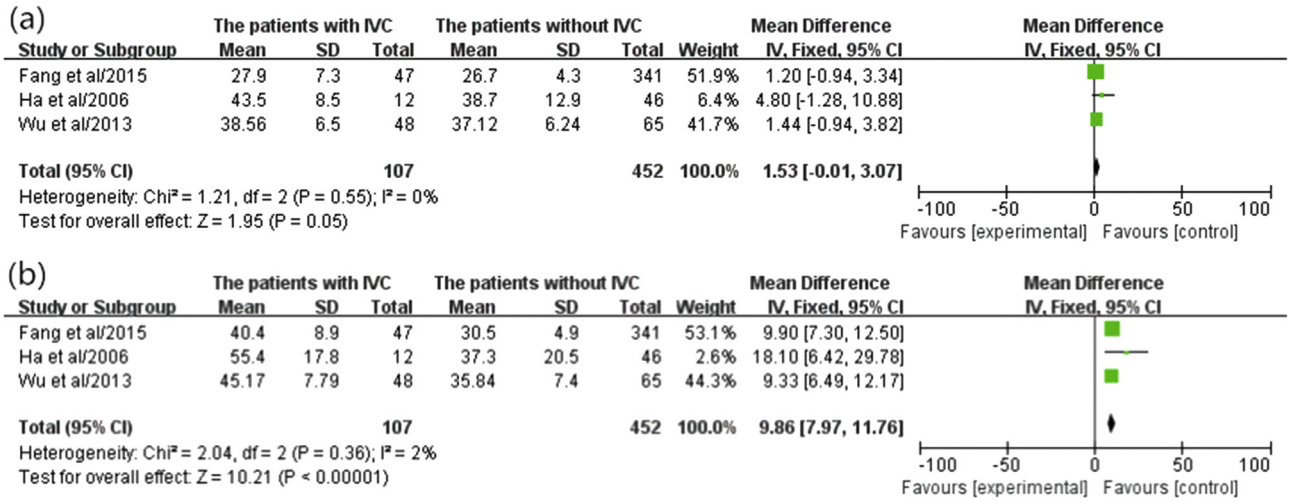

Fig. 7. Forest plot of comparison: Oswestry Disability Index indices at the immediate postoperative (**a**) and final follow-up period (**b**).

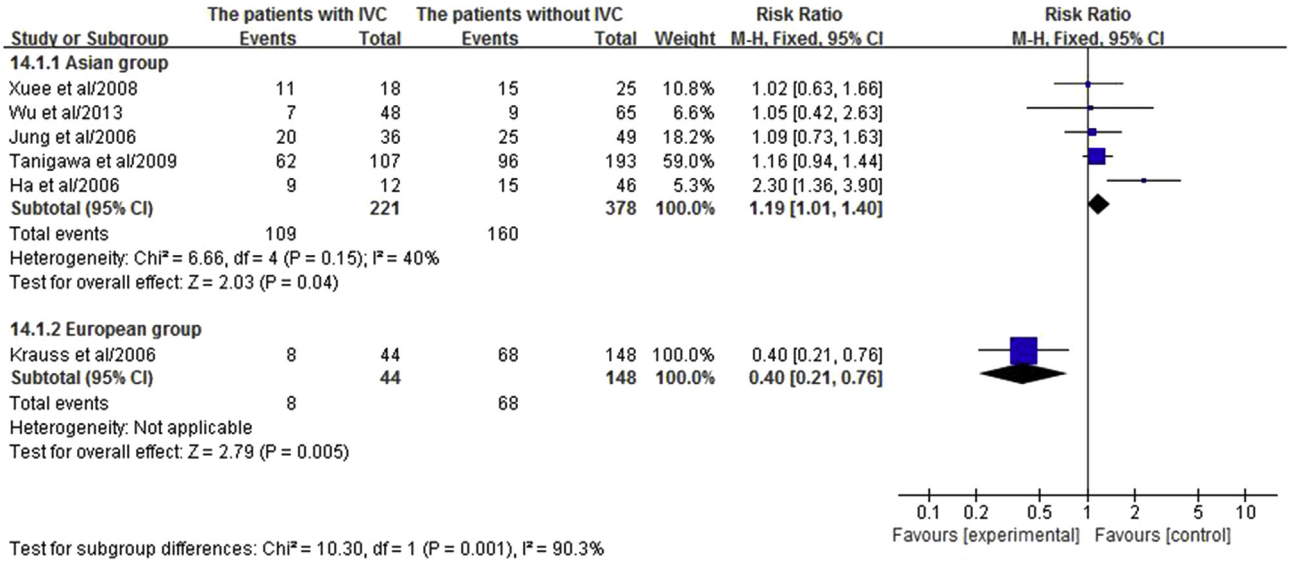

Fig. 8. Forest plot of comparison: the rate of cement leakage intraoperatively.

mean volume of cement injected in the study of Krauss et al. (3.1 ml) [9] was significantly less than all other 5 studies (ranged from 4.0 ml to 6.2 ml) [10–12,14,15]. When low volume cement was injected, the cement could be locally filled in the IVC area and meanwhile, the fibrocartilaginous membrane around the IVC area [9] could prevent the cement extrusion into paravertebral veins; however, when more volume cement continued to be injected, additional cement could not be interspersed through the membrane into peripheral trabecular space, and possibly extruded into paravertebral veins under high pressure.

This meta-analysis has several limitations. First, almost all of the studies included in this meta-analysis are retrospective cohort, and as a result of study design limitations, these studies were more likely to suffer from various kinds of bias. Second, follow-up times were different among the studies, and such differences affected the argumentation and reliability of radiological and clinical outcomes at final follow-up period to a certain extent. Finally, given the limited number of the included studies in the analysis, the findings should be confirmed in future research with more relative studies and prospective randomized controlled trials to obtain more conclusive data.

5. Conclusion

Overall, the IVCs had an important effect of therapeutic efficacy in PVA for the treatment OVCFs, especially at final follow-up period. Most of the studies selected in this study showed that higher rate of cement leakage in the IVC group than that in the non IVC group. However, one study showed lower rate of cement leakage in the IVC patients.

Ethical approval

No ethical approval and patient consent are required.

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Author contribution

Weibo Yu, De Liang and Xiaobing Jiang contributed to conceiving and designing the study. Weibo Yu, Zhensong Yao, Ting Qiu performed the experiment. Weibo Yu, De Liang, Xiaobing Jiang analyzed the data. Weibo Yu played main role in writing the manuscript.

Conflicts of interest

The authors declare that they have no conflict of interest.

Research registration unique identifying number (UIN)

This study has been registered on the Review Registry. Reference is reviewregistry209.

Trial registry number

No.

Guarantor

Weibo Yu, De Liang, Zhensong Yao, Ting Qiu, Linqiang Ye, Xiaobing Jiang accept full responsibility for the work.

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