International Journal of Surgery 40 (2017) 17–23

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

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.

ARTICLE INFO

Article history:
Received 12 August 2016
Received in revised form
14 February 2017
Accepted 14 February 2017
Available online 17 February 2017

Keywords:
Intravertebral vacuum cleft
Osteoporotic vertebral compression fractures
Percutaneous vertebral augmentation
Meta-analysis

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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http://dx.doi.org/10.1016/j.ijsu.2017.02.019
1743-9191/

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