INPLASY PROTOCOL

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None.

Kiva augmentation technique versus balloon kyphoplasty for Osteoporotic vertebral compression fracture

Dong, DP[1]; Huang, JJ[2]; Chen, DX[3]; Li, L[4]; Huang, ZY[5]; Luo, DW[6]; Zhang, WH[7].

Review question / Objective: **Participant: osteoporotic vertebral compression fractures; Intervention: Kiva augmentation technique; Comparison: balloon kyphoplasty; Outcomes: rate of refracture, vertebral height, Cobb angle.**
Condition being studied: **Vertebroplasty and balloon kyphoplasty are the common method to manage OVCF and have gained worldwide acceptance. But these two thechniques increase the risk of refractures adjacent and remote vertebral levels due to PMMA rigidity. Kiva augmentation technique is a new technology for the treatment of OVCFs and a few reports have been shown to have good potential in early investigations. However, potential benefits and possible risks associated with KIVA augmentation technique compared with balloon kyphoplasty in managing OVCFs are not fully understood.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 January 2021 and was last updated on 18 January 2021 (registration number INPLASY202110068).

INTRODUCTION

Review question / Objective: **Participant: osteoporotic vertebral compression fractures; Intervention: Kiva augmentation technique; Comparison: balloon kyphoplasty; Outcomes: rate of refracture, vertebral height, Cobb angle.**

Condition being studied: **A systematic search was performed in PubMed, Medline, Embase, Clinical Trial.gov registry, Cochrane Central Register of Controlled**

Trials (CCTR), and Cochrane Database of Systematic Reviews (CDSR) from their date of inception to December 2020. Medical Subject Headings (MeSH) terms and corresponding keywords were used for search with various combinations of the operators "AND" and "OR": (MeSH exp. "kyphoplasty" and keywords "kyphoplasty," "balloon kyphoplasty," "PKP," and "KP"), (keywords "Kiva," "Kiva technique," and "kiva implant"), and (MeSH exp. "osteoporotic fractures," and keywords "osteoporotic fracture," "osteoporotic vertebral fracture," "OVCF," and "OVF").We also reviewed the reference lists of all retrieved articles for further identification of potentially relevant studies.

METHODS

Participant or population: Patients of OVCFs.

Intervention: Kiva augmentation technique.

Comparator: Balloon kyphoplasty.

Study designs to be included: Comparative trials comparing Kiva augmentation technique with balloon kyphoplasty will be included.

Eligibility criteria: All available comparative trials comparing Kiva augmentation technique with balloon kyphoplasty will be included.

Information sources: A systematic search was performed in PubMed, Medline, Embase, Clinicaltrial.gov registry, Cochrane Central Register of Controlled Trials (CCTR), and Cochrane Database of Systematic Reviews (CDSR) from their date of inception to December 2020.

Main outcome(s): The primary outcome contains rate of refracture, the anterior and mid vertebral height, and Cobb angle.

Additional outcome(s): The operative time, injected cement volume, VAS, ODI and rate of cement leakage are recorded as the secondary outcomes.

Data management: Two reviewers independently extracted the data from each article that met the inclusion criteria. The following data were recorded in a standardized form: name of the first author and published year, study period, country of study, study design, fracture level, sample size(number of vertebral body), and follow-up time. We resolved disagreements by consensus or by consultation with a third review author.

Quality assessment / Risk of bias analysis: Newcastle–Ottawa scale (NOS) and Cochrane review criteria were respectively used to evaluate the quality of the cohort studies and randomized controlled trials(RCTs) in this meta-analysis[19,20]. NOS included three categories with eight items: the selection of the patients (four items), the comparability of the study populations (two items), and the ascertainment of either the exposure or outcome of interest (three items). Nine stars were the highest value for quality assessment. Studies with seven or more stars suggested to be of high quality. The risk of bias was evaluated by the risk of bias tool of the Cochrane Collaboration. It included six domains: random sequence generation; allocation concealment; blinding of participants, providers, data collectors, outcome adjudicators, and data analysts; incomplete outcome data; selective outcome reporting; and other biases. We defined trials as having "low," "high," or "unclear" risk of bias and evaluated individual bias items as described in the Cochrane Handbook for Systematic Reviews of Interventions. Any disagreement was resolved by discussion or by a third reviewer.

Strategy of data synthesis: Review Manager Version 5.3.5 (Cochrane Collaboration, Oxford, UK) was used for all data analysis. The odds ratio (OR) and weighted mean difference (WMD) were used respectively to analyze dichotomous outcome and continuous outcome. Both were reported with 95% confidence interval (CI), and a P value lower than 0.05 or a 95% CI that did not contain unity was considered statistically significant.

Heterogeneity was evaluated with the I2 test, and the I2 > 50% indicated significant heterogeneity.

Subgroup analysis: If there is enough research, subgroup analysis will be carried out based on fracture levels.

Sensibility analysis: If enrolled studies were more than 10, funnel plot will be used to identify the possible publication bias. Additionally, Egg regression and Begg tests will be utilized to detect the funnel plot asymmetry.

Language: English.

Country(ies) involved: China.

Keywords: Kiva technique; balloon kyphoplasty; OVCF.

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