FOR OSTEOPOROTIC

**HIGH- VS. LOW-VISCOSITY** 

**CEMENT VERTEBROPLASTY** 

VERTEBRAL COMPRESSION

FRACTURE: A META-ANALYSIS

# INPLASY PROTOCOL

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## Corresponding author: Qiang Wang

13810717309@126.com

Author Affiliation: Beijing Hospital

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#### Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

## **INTRODUCTION**

**Review question / Objective:** To compare high vs. low viscosity bone cement on the clinical outcomes and complications in patients with OVCFs who underwent PVP or PKP. Condition being studied: PubMed, Embase, and the Cochrane Library were searched for papers published from inception up to February 2021 for potentially eligible studies comparing high- vs. low-viscosity cement for PVP/PKP. The outcomes were the leakage rate, visual analog scale (VAS), and Oswestry Disability Index (ODI).

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Wang, Q<sup>1</sup>; Sun, C<sup>2</sup>; Zhang, L<sup>3</sup>; Wang, L<sup>4</sup>; Ji, Q<sup>5</sup>; Min, N<sup>6</sup>; Yin, Z<sup>7</sup>.

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**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 June 2021 and was last updated on 29 June 2021 (registration number INPLASY202160110).

#### **METHODS**

Participant or population: Osteoporotic compression fracture patients.

Intervention: PKP or PVP surgery.

**Comparator:** The patients undergone PKP or PVP use high vs. low viscosity bone cement.

Study designs to be included: RCT or cohort study.

Eligibility criteria: 1) population: patients with OVCF, 2) exposure: treated with PVP/ PKP and high-viscosity bone cement, 3) non-exposed control: treated with PVP/ PKP and low-viscosity bone cement, 4) outcomes: leakage rate, VAS, and ODI, and 5) full-text published in English.

Information sources: PubMed, Embase, and the Cochrane Library were searched for papers published from inception up to February 2021 for potentially eligible studies using the MeSH terms "Osteoporotic Fractures" and "high viscosity cement", as well as relevant key words, followed by screening based on the eligibility criteria. The literature search and study selection process were performed independently by two investigators according to a pre-specified protocol.

Main outcome(s): There were lower cement leakage rates in PVP/PKP with highviscosity bone cement than with lowviscosity bone cement. The 2 groups have similar results in ODI, but the VAS score results favor high-viscosity bone cement. Therefore, the administration of high viscosity bone cement in PVP/ PKP could be a potential option for improving the complications of leakage in OVCFs, while the clinical efficacy of relieving pain are not certain.

Quality assessment / Risk of bias analysis: This study has limitations. Most of the included studies were single-center studies, and the bone cement materials they used might be different and have certain heterogeneity. This study direction is relatively new, so the number of reports was small, and there is a lack of highquality RCT evidence. The included patients have certain heterogeneity, possibly biasing the results. Finally, as for any meta-analysis, the quality of this metaanalysis is limited to the quality of the included studies. Indeed, no cohort study scored higher than 8 points on the NOS, and no RCT scored higher than 5 points on the RoB 2. In addition, one study used high-viscosity cement for PVP and lowviscosity cement for PKP, which is bound to bias the results.

Strategy of data synthesis: For continuous outcomes, the mean values and standard deviations (SD) were used to compute the odds ratios (ORs) and weighted mean d iff e r e n c e s (WMDs) a n d th e i r corresponding 95% confidence intervals (CIs). The data were analyzed according to the exposure of PVP/PKP with high- vs. low-viscosity bone cement.

Subgroup analysis: High-viscosity Group: PKP group, PVP group; low-viscosity Group: PKP group, PVP group.

Sensitivity analysis: The sensitivity analyses showed that the meta-analyses for the total leak rate, VAS, and ODI use CI.

Country(ies) involved: China.

Keywords: osteoporotic fractures; spine; vertebroplasty; kyphoplasty; bone cement; viscosity.

#### **Contributions of each author:**

Author 1 - Qiang Wang. Author 2 - Changtai Sun. Author 3 - Liang Zhang. Author 4 - Lin Wang. Author 5 - Quan Ji. Author 6 - Nan Min. Author 7 - Zilong Yin.