INPLASY PROTOCOL

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None.

Therapeutic efficacy of third-generation percutaneous vertebral augmentation system in osteoporotic vertebral compression fractures: a systematic review and meta-analysis

Dong, C[1]; Wu, D[2]; Qi, Y[3]; Wei, H[4]; Li, C[5].

Review question / Objective: **P: osteoporotic vertebral compression fractures I: third-generation percutaneous vertebral augmentation system C: percutaneous vertebroplasty, percutaneous kyphoplasty O: VAS, ODI, cement leakage, adjacent fractures, vertebral height, local kyphotic angle, Cobb angle S: Interventional studies (RCTs) and observational studies (cohort or case-control studies).**
Condition being studied: **PKP and PVP without stenting are two minimally invasive vertebral augmentation (VA) procedures recommended as options for treating osteoporotic VCFs only in people who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management. Recent studies comparing both procedures demonstrate the advantages of BKP over VP in terms of sagittal balance improvement, cement leakage, improved mortality rates, and cost savings. Thus, PKP appears to be the current standard of care for VCFs, even if recovery of vertebral body (VB) height may be only temporary as there is often a total or partial VB collapse after balloon deflation, prior to cement injection. The third-generation percutaneous VA system has been shown in biomechanical studies to be superior to BKP in terms of sagittal height restoration and height maintenance.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 January 2021 and was last updated on 4 January 2021 (registration number INPLASY202110015).

INTRODUCTION

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METHODS

Participant or population: Osteoporotic vertebral compression fractures.

Intervention: Third-generation percutaneous vertebral augmentation system.

Comparator: Percutaneous vertebroplasty or percutaneous kyphoplasty.

Study designs to be included: Interventional studies (RCTs) and observational studies (cohort or case-control studies).

Eligibility criteria: Inclusion criteria 1. Interventional studies (RCTs) and observational studies (cohort or case-control studies). 2. Studies reported the comparisons between third-generation percutaneous vertebral augmentation system and PVP or PKP for patients with OVCFs 3. Studies reported at least one of the following outcomes: VAS, ODI, cement leakage, adjacent fractures, vertebral height, local kyphotic angle, Cobb angle. Exclusion criteria 1. Pathological fracture due to primary or metastatic tumors, infection, or tuberculosis. 2. Patients complicated with nerve disorder, long-term use of steroidal or nonsteroidal anti-inflammatory drugs, or previous surgery at the diseased vertebra. 3. Non-original articles (case reports, reviews, letters, meta-analyses, and editorials), animal studies, or computational modeling studies.

Information sources: Pubmed: (((((Spinal Fracture*) OR (thoracic fracture*)) OR (lumbar fracture*)) OR (vertebral fracture*)) OR ("Spinal Fractures"[Mesh])) AND ((((((KIVA) OR (spinejack)) OR (vertebral body stent*)) OR (Stentoplasty)) OR (VBS)) OR (OsseoFix)) Embase: No. Query Results #14. #6 AND #13 #13. #7 OR #8 OR #9 OR #10 OR #11 OR #12 #12. 'osseofix' #11. 'vbs' #10. 'stentoplasty' #9. 'vertebral body sent*' #8. 'spinejack' #7. 'kiva' #6. #1 OR #2 OR #3 OR #4 OR #5 #5. 'vertebral fracture*':ab,ti #4. 'lumbar fracture*':ab,ti #3. 'thoracic fracture*':ab,ti #2. 'spinal fracture*':ab,ti #1. 'spine fracture'/exp.

Main outcome(s): VAS, ODI, cement leakage, adjacent fractures, vertebral height, local kyphotic angle, Cobb angle.

Quality assessment / Risk of bias analysis: The methodological quality of the included RCT was assessed using Cochrane review criteria. In contrast to the RCTs, the non-RCTs used a NOS form. studies assigned 7 scores were considered high quality, and the remaining one assigned 6 scores was considered moderate quality.

Strategy of data synthesis: Our meta-analysis was performed through RevMan v5.3 software (Cochrane Collaboration, Oxford, UK). Continuous data, such as VAS, ODI, Cobb angle, VH%, were expressed as mean ± SD and summarized using the mean difference (MD) or standardized mean difference (SMD) with 95% confidence interval (CI). Risk ratio (RR) with 95% CI was calculated for binary outcome data like cement leakage and adjacentlevel fractures.

Subgroup analysis: Different third-generation percutaneous vertebral augmentation systems.

Sensibility analysis: The sensitivity analysis which was performed by omitting 1 study in each turn investigated the influence of a single study on the overall outcome.

Country(ies) involved: China.

Keywords: Third-generation, percutaneous vertebral augmentation system, osteoporotic vertebral compression fractures, meta-analysis.

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