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Liu, LC; Peng, B.

Corresponding author:
Lvchen Liu

1147380993@qq.com

Author Affiliation:
Hunan University of Chinese
Medicine.

ADMINISTRATIVE INFORMATION

Support - None.
Review Stage at time of this submission - Data analysis.
Conflicts of interest - None declared.

INPLASY registration number: INPLASY202540063

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2025 and was last updated on 19 April 2025.

INTRODUCTION

Review question / Objective We aimed to analyze all published studies using intradiscal injection of autologous mesenchymal stem cells for the treatment of discogenic low back pain and summarize the evidence-based medical evidence for the effectiveness of this biologic treatment for discogenic low back pain.

Condition being studied The team consists of 2 medical professors and 3 medical doctors, with strong scientific research ability, and I can complete this work full time. Paper search and data extraction have now been completed.

METHODS

Participant or population Patient with discogenic low back pain.

Intervention Intradiscal injection of autologous mesenchymal stem cells.

Comparator This study was a single-arm meta-analysis, the incidence rate was not controlled, and the Visual Analogue Scale(VAS) and Oswestry Disability Index(ODI) were compared before and after treatment.

Study designs to be included Prospective single-arm study.

Eligibility criteria 1. Recurrent lower back pain with a course of more than 3 months; 2. No lumbar spondylolisthesis, spondylolisthesis and lumbar instability were found in X-ray examination; 3. CT scan showed no lumbar disc herniation, lumbar spinal stenosis and other abnormalities; 4. MRI examination showed that the lesioned intervertebral disc nucleus pulposus showed low signal changes in T2-weighted images; 5. Lumbar intervertebral disc angiography showed rupture of the annulus fibrosus. Induced reproduction of the same lower back pain as in the past. At the same time, the above five points were met, and the diagnosis was discogenic low back pain.

Information sources English databases included PubMed, Embase, Cochrane Library and ClinicalTrials database.

Main outcome(s) The changes of Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) compared with the baseline after 1 month, 3 months, 6 months, and 12 months of treatment.

The incidence rates of the VAS scores decreasing by more than 30% and 50% compared with the baseline after 1 month, 3 months, 6 months, and 12 months of treatment.

In the group treated with autologous mesenchymal stem cells combined with hyaluronic acid, the incidence rate of the VAS scores decreasing by more than 30% compared with the baseline after 6 months and 12 months of treatment; the incidence rates of the VAS scores decreasing by more than 50% compared with the baseline after 3 months, 6 months, and 12 months of treatment.

In the group treated with autologous mesenchymal stem cells alone, the incidence rate of the VAS scores decreasing by more than 30% compared with the baseline after 6 months and 12 months of treatment; the incidence rates of the VAS scores decreasing by more than 50% compared with the baseline after 3 months, 6 months, and 12 months of treatment.

Safety analysis of autologous mesenchymal stem cells in the treatment of degenerative disc disease.

Quality assessment / Risk of bias analysis The quality of non-randomized controlled trials were evaluated using the Newcastle Ottawa Scale (NOS) scale.

Strategy of data synthesis All statistical analyses were performed with Review Manager v.5.4 (The Cochrane Collaboration, Software Update, Oxford, United Kingdom). The incidence rate (odds ratio, OR) was calculated by analyzing dichotomous variables, and the interval estimation was expressed using 95% confidence interval (CI) with the conversion formula: incidence = $OR/(1+OR)$, LL (lower limit) = $LLOR/(1+LLOR)$, and UL (upper limit) = $ULOR/(1+ULOR)$. The mean difference (MD) was calculated for continuous variables, and interval estimates were expressed using 95% CI, with P 50%. The test level of Meta-analysis was $\alpha = 0.05$. All statistical analyses were performed with Review Manager v.5.4 (The Cochrane Collaboration, Software Update, Oxford, United Kingdom).

Subgroup analysis Follow-up time subgroup analysis: four time points of 1, 3, 6 and 12 months were studied. Efficacy subgroup analysis: greater

than 30% or 50% improvement in pain scores compared to baseline.

Sensitivity analysis Sensitivity analysis was performed in the revman software to reflect the sensitivity of the articles by the change in effect size after the removal of one of the articles.

Country(ies) involved China.

Keywords Discogenic low back pain; Autologous mesenchymal stem cells; Visual Analogue Scale; Oswestry Disability Index; Intervertebral disc injection.

Contributions of each author

Author 1 - Ivchen Liu.

Author 2 - bing Peng.