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Clinical outcomes of stem cell therapy for decompensated liver cirrhosis: a meta-analysis of randomized controlled trials.

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 October 2024 and was last updated on 3 October 2024.

INTRODUCTION

Review question / Objective The aim of this study was to comprehensively evaluate the efficacy of stem cell transplantation in the treatment of decompensated cirrhosis by using meta-analyses of randomized controlled trials.

Condition being studied Liver cirrhosis is a chronic, progressive liver disease with diverse etiologies and ranks as the 11th leading cause of death globally. Orthotopic liver transplantation remains the definitive treatment for decompensated liver cirrhosis, yet it is constrained by the scarcity of donor organs and other practical limitations. In recent years, stem cell transplantation has emerged as a promising therapeutic approach in regenerative medicine. While some clinical studies have preliminarily validated the efficacy and safety of stem cell therapy for decompensated liver cirrhosis, a unified standard for its application and efficacy

evaluation remains elusive. The selection of therapeutic parameters and the assessment of therapeutic outcomes still necessitate robust evidence-based medicine to guide practice. Therefore, we conducted a systematic review and meta-analysis of all available randomized controlled trials (RCTs) to comprehensively evaluate the therapeutic efficacy and safety of stem cell transplantation in the treatment of decompensated liver cirrhosis. Additionally, we analyzed therapeutic parameters, including cell source, infusion route, and delivery frequency, to elucidate the positive and negative impacts of these factors on therapeutic outcomes.

METHODS

Participant or population Patients with decompensated liver cirrhosis.

Intervention Stem cell therapy.

Comparator Conventional symptomatic treatment.

Study designs to be included Randomized controlled trials only.

Eligibility criteria The inclusion criteria were (1) RCTs, (2) patients diagnosed with decompensated cirrhosis, (3) patients in the experimental group received stem cell therapy and patients in the control group were treated with conventional treatment, and (4) availability of clinical outcomes (Primary outcomes were all-cause mortality and adverse events related to stem cell therapy. Secondary outcomes included the model for end-stage liver disease (MELD) score, liver function parameters (ALB, ALT, PTA and INR).

Information sources Medline (PubMed), EMBASE, Cochrane library and ClinicalTrials.gov.

Main outcome(s) All-cause mortality and adverse events related to stem cell therapy.

Additional outcome(s) Model for end-stage liver disease (MELD) score, liver function parameters (ALB, ALT, PTA and INR).

Quality assessment / Risk of bias analysis The risk of bias was assessed using the Cochrane risk-of-bias bias assessment tool.

Strategy of data synthesis For continuous variables, the standardized mean difference (SMD) is employed to assess their effects. In contrast, for dichotomous (or bicategorical) variables, the odds ratio (OR) serves as the metric for evaluating their effects. To quantify the heterogeneity across studies, both chi-square tests and I^2 statistics are utilized. When a notable degree of heterogeneity is observed between studies, specifically when the P-value is less than 0.1 or the I^2 value exceeds 50%, a random-effects model is adopted. Conversely, in the absence of significant heterogeneity, a fixed-effects model is deemed appropriate.

Subgroup analysis Reasons for heterogeneity in study results were further explored using subgroup analyses. Planned subgroup analyses, specified by the stratification factors (cell type, delivery route and frequency of administration), were also conducted.

Sensitivity analysis Sensitivity analyses will be performed by excluding the included studies from the analysis one by one and comparing the results.

Country(ies) involved China.

Keywords Stem cell therapy, decompensated cirrhosis, efficacy, safety, meta-analysis.

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