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Amniotic Suspension Allograft Injection for the Treatment of Osteoarthritis: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - This study did not receive any financial support from any funding agencies, commercial entities, or not-for-profit organizations.

Review Stage at time of this submission - Data extraction.

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 28 August 2024 and was last updated on 28 August 2024.

INTRODUCTION

Review question / Objective P: osteoarticular defects, osteoarthropathy; I: Amnionic fluid allograft; C: Hyaluronic Acid, Platelet rich plasma, Dextrose Prolotherapy, Wharton's jelly, Stem cell; O: VAS, Major adverse event.

Rationale There is a growing interest in regenerative medicine approaches that have the potential to modify the course of osteoarthritis. Among them, amniotic suspension allograft (ASA) injections have emerged as a promising treatment option due to their anti-inflammatory, anti-fibrotic, and regenerative properties. ASA contains various growth factors, cytokines, and extracellular matrix components that may promote tissue repair and reduce inflammation within the joint. Several clinical studies have already demonstrated promising results with ASA for the treatment of osteoarthritis, with no major adverse events reported. Despite its potential, no systematic review or meta-analysis currently focuses on this topic.
Therefore, a systematic review and meta-analysis of the available studies are warranted to synthesize the existing evidence, assess the clinical effectiveness, and determine the safety profile of ASA injections in patients with OA. The findings of this study will contribute to the understanding of ASA as a therapeutic option for OA and may guide clinical decision-making and future research directions.

Condition being studied Osteoarthritis (OA) is a prevalent and debilitating joint disease characterized by the progressive degradation of articular cartilage, leading to pain, loss of function, and a reduced quality of life. Traditional treatment modalities for OA, such as non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, and physical therapy, often provide only temporary relief and do not address the underlying degenerative processes.

METHODS

Search strategy Six databases, including Embase, Ovid Medline, Cochrane Library, Scopus, the Index to Taiwan Periodical Literature System and Airiti Library, were systematically searched to identify relevant articles published from 1975 to June 2024. Four main concepts, amniotic suspension allograft (ASA) injection, osteoarthritis, pain were used combination with controlled vocabulary.

Participant or population Adults older than 18 years diagnosed with moderate knee OA (grade 2 or 3 on the KL score), or mild hip osteoarthritis (Tonnis grade 1 or 2 changes) Osteoarthritis of knee.

Intervention Amniotic suspension allograft injection.

Comparator This study will include comparisons with the most commonly used regenerative medicine approaches, such as Hyaluronic Acid, Platelet-Rich Plasma (PRP), Dextrose Prolotherapy, Wharton's Jelly, and Stem Cells. Saline injection will be used as the control group.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria This study selection criteria were according to PICOS (Participants, Intervention, Comparison, Outcomes and Study type) and the inclusion criteria included (1) population (P): adults (aged 18 years and over) who had moderate knee OA (grade 2 or 3 on the KL score), or mild hip osteoarthritis (Tonnis grade 1 or 2 changes)Osteoarthritis of knee in which, (2) intervention (I): the experimental group received Amniotic suspension allograft (ASA) once, (3) comparison (C): the control group received saline injection or other regenerative medicine approaches, such as Hyaluronic Acid, Platelet-Rich Plasma (PRP), Dextrose Prolotherapy, Wharton's Jelly, and Stem Cells, (4) outcomes (O): the study outcome must have included a measurement of pain, (5) studies (S): randomized controlled trials and (6) language: publications in either the Chinese or English language. The exclusion criteria were as follows: (1) the experimental group received two or more injections.

Information sources Electronic Databases: Embase, Ovid Medline, Cochrane Library, Scopus, the Index to Taiwan Periodical Literature System and Airiti Library

Contact with authors: We will contact the authors of the identified studies to obtain additional data or clarify study details.
Trial Registers: We will search clinical trial registries such as ClinicalTrials.gov and the WHO ICTRP to identify ongoing or unpublished studies.
Grey Literature: Grey literature, including conference proceedings, theses, and dissertations, will be searched.

Main outcome(s) The primary outcome is the change in pain levels, measured using the Visual Analog Scale (VAS) score, at 3 months post-intervention compared to saline injection.

Additional outcome(s) Additional outcomes include comparing pain levels, as measured by the Visual Analog Scale (VAS) score, to other regenerative medicine treatments such as Hyaluronic Acid (HA), Platelet-Rich Plasma (PRP), and Stem Cell therapies. Functional outcomes will also be reviewed, including scores from the Knee injury and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC) score, Single Assessment Numeric Evaluation (SANE), and Lysholm score.

Data management Two of authors (TYC, CTC) independently screened all articles including titles, abstracts and key word which were imported into EndNote X9 for identification of duplicates study. After removing of duplication, the same two authors (TYC, CTC) extracted the following data from the selected articles: Author, year, country, sample, age, intervention, control and outcome measure. The quality of eligible articles was assessed using the Cochrane Collaboration's tool. The seven domains were rated as either low risk, unclear or high risk (Higgins & Thomas, 2019). Any disagreements were resolved by consensus.

Quality assessment / Risk of bias analysis We assessed the certainty of evidence (CoE) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology (Guyatt et al., 2008). The GRADE main domains included the following factors: risk of bias, consistency, directness, precision and publication bias. The levels of CoE were classified as high, moderate, low and very low certainty (Guyatt et al., 2008).

Strategy of data synthesis We used Review Manager 5.4 to analyze the effect of Amniotic Suspension Allograft (ASA) on pain intensity in patients with osteoarthritis. The mean difference (MD) and 95% confidence intervals (CIs) were calculated to evaluate continuous outcomes of

pain intensity. Heterogeneity was assessed using Cochrane's Q statistic and the I^2 statistic (Melsen et al., 2014). If the I^2 value was greater than 50% or the p-value was less than 0.10, indicating statistical heterogeneity, a random-effects model was selected.We used Review Manager 5.4 to analyse the effect of cold application on pain intensity and anxiety levels in adults after CTR. The mean difference (MD) and 95% confidence intervals (CIs) were used to analyse continuous outcomes of pain intensity and anxiety level. Heterogeneity was assessed using Cochrane's Q statistic and Isquared (Melsen et al., 2014). If the I square value > 50% or p value< 0.10 was defined as statistical heterogeneity, random-effects model was selected.

Subgroup analysis In addition, subgroup analysis was conducted to search for the source of heterogeneity.

Sensitivity analysis We conducted sensitivity analyses for all outcomes where the meta-analysis included trials that were judged to have a high risk of bias in any domain. To assess the robustness of the results, we repeated the meta-analyses, excluding these high-risk studies.

Language restriction Publications in either the Chinese or English language.

Country(ies) involved Taiwan.

Other relevant information Nil

Keywords Amnion, platelet-rich plasma, osteoarthritis.

Dissemination plans We plan to submit the results for publication in a leading journal in the field of orthopedics and regenerative medicine and the results will be presented at national and international conferences.

Contributions of each author

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