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Perspective

Treatment of knee osteoarthritis with amniotic suspension allograft

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Abstract

Osteoarthritis (OA) is a massively prevalent joint disorder that typically affects large weight-bearing joints, affecting over 30 million people in the United States and is expected to reach 67 million by 2030. Its pathophysiology includes synovial tissue inflammation and articular cartilage degeneration, which results in pain and decreased function. Physical therapy, activity modification, pharmacological agents (For example, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), opioids, corticosteroids, viscosupplementation (hyaluronic acid), etc.), and surgery are commonly used to treat OA when other treatment modalities have failed.

Keywords: assistive technology, amputation, hemicorporectomy, rehabilitation, prosthesis, case report

INTRODUCTION

Osteoarthritis (OA) is a massively prevalent joint disorder that typically affects large weight-bearing joints, affecting over 30 million people in the United States and is expected to reach 67 million by 2030. Its pathophysiology includes synovial tissue inflammation and articular cartilage degeneration, which results in pain and decreased function. Physical therapy, activity modification, pharmacological agents (for example, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), opioids, corticosteroids, viscosupplementation (hyaluronic acid), etc.), and surgery are commonly used to treat OA when other treatment modalities have failed. The treatment approaches mentioned above have limitations in that they seek to reduce pain rather than target the underlying pathology. Several molecular targets, including interleukin-1 (IL-1), Transforming Growth Factor- (TGF-), matrix metalloproteinases, and others, have recently been identified. These therapies, however, may have a negative risk-to-benefit ratio. As a result, additional safe and effective treatment options are required to address this unmet medical need. Over the last decade, there has been a surge in interest in the use of biologics, including autologous biologics such as Platelet-Rich Plasma (PRP), bone marrow concentrate, and adipose tissue, as well as allogenic biologics such as perinatal tissue, for regenerative medicine applications, particularly for musculoskeletal disorders. Amniotic tissue (amniotic membrane and/or amniotic fluid) has been used clinically for several years to treat burns, complex wounds, and ophthalmic conditions. Recently, there has been an increase in the use of amniotic tissue for musculoskeletal conditions such as plantar fasciitis, tendinopathies, cartilage defects, and so on. Numerous basic science studies have found anti-inflammatory cytokines in amniotic tissue, including IL-1 receptor antagonist (IL-1RA), MMPs, Hyaluronic Acid (HA), and proteoglycans, indicating a potential role in the treatment of OA. As previously discussed, several preclinical studies in rat and rabbit OA models have yielded positive results. Despite these encouraging findings, there are few high-powered clinical trials demonstrating the safety and efficacy of amniotic tissue in the treatment of knee OA patients. In this Editorial, I will focus on a recent clinical trial titled "Human Amniotic Suspension Allograft Improves Pain and Function in Knee Osteoarthritis: A Prospective Not Randomized Clinical Pilot Study" published by Natali et al. The authors investigated the safety, in this prospective, non-randomized study. The clinical effectiveness and feasibility of intra-articular injections of Amniotic Suspension Allograft (ASA) in patients with unilateral knee OA, with the goal of evaluating the clinical status and delaying any invasive surgical procedures, were investigated. A total of 25 patients (11 males and 14 females) were enrolled in the study based on inclusion criteria (Kellgren-Lawrence (KL) grade 1-3, failure of prior conservative treatments, i.e., NSAIDs, physical therapy, intraarticular injections of corticosteroids, HA, or PRP, etc.) and exclusion criteria (KL grade 4, intra-articular steroid or HA within last 3 months, etc). (homogenized amniotic membrane suspended in physiological solution). The International Knee Documentation Committee (IKDC) and Visual Analogue Scale (VAS) scores were used to assess these patients at baseline (prior to injection) and at 3, 6 and 12 months post-injection. Throughout the study, no serious adverse events were reported. Both IKDC and VAS showed statistically significant improvements (p=0.05) when compared to the baseline at all follow-up time points. Both IKDC and VAS scores regressed by 6 months, indicating that ASA had no long-term effect; however, at the 12-month follow-up, both scores showed significant improvement compared to the baseline. Despite this, the findings of this study showed that a single intra-articular injection of ASA is safe and has positive clinical outcomes. This is consistent with other published clinical trials using ASA to treat knee OA. In addition to the limitations mentioned above, one of the concerns, which is not unique to this study, is a lack of consistency in the composition of similarly named biologics. For example, this study defined ASA as a 'homogenised amniotic membrane suspended in physiological solution,' whereas previously published studies defined ASA as 'amniotic suspension allograft containing human amniotic membrane and human amniotic fluid-derived cells,' with no description of the formulation protocol. As a result, I believe it is critical to maintain consistency in the composition of similarly named biologics and to describe the formulation protocol in order to allow the repeatability and reproducibility of the results of prospective trials assessing the safety and efficacy of these biologics around the world. This study has a few limitations, which the authors also mention. These include small sample size, a lack of a placebo and/or control group, and MRI image analysis.In addition to the limitations mentioned above, one of the concerns, which is not unique to this study, is a lack of consistency in the composition of similarly named biologics. For example, this study defined ASA as a 'homogenised amniotic membrane suspended in physiological solution,' whereas previously published studies defined ASA as 'amniotic suspension allograft containing human amniotic membrane and human amniotic fluid-derived cells,' with no description of the formulation protocol. In conclusion, despite its limitations, I applaud the author's efforts, as this study adds to the current literature suggesting that the administration of amniotic tissue, including ASA, is safe. It also justifies the need for a high-powered, prospective, multi-centre, double-blind, randomised controlled trial with a longer follow-up duration to further establish the efficacy of ASA to alleviate symptoms associated with knee OA, potentially providing a new m On clinicaltrials.gov as of October 13, 2022, there are three ongoing clinical trials (search terms: "knee osteoarthritis" and "amniotic suspension allograft" or "amniotic membrane").