JOURNAL ARTICLE

Intratendinous Injection of Autologous Adipose Tissue-Derived Mesenchymal Stem Cells for the Treatment of Rotator Cuff Disease: A First-In-Human Trial

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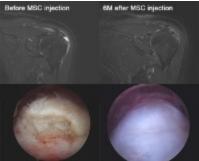
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ABSTRACT

Despite relatively good results of current symptomatic treatments for rotator cuff disease, there has been an unmet need for fundamental treatments to halt or reverse the progress of disease. The purpose of this study was to assess the safety and efficacy of intratendinous injection of autologous adipose tissue-derived mesenchymal stem cells (AD MSCs) in patients with rotator cuff disease. The first part of the study consists of three dose-escalation cohorts; the low- $(1.0 \times 10^7 \text{ cells})$, mid- $(5.0 \times 10^7 \text{ cells})$ \times 10⁷), and high-dose (1.0 \times 10⁸) groups with three patients each for the evaluation of the safety and tolerability. The second part included nine patients receiving the high-dose for the evaluation of the exploratory efficacy. The primary outcomes were the safety and the shoulder pain and disability index (SPADI). Secondary outcomes included clinical, radiological, and arthroscopic evaluations. Twenty patients were enrolled in the study, and two patients were excluded. Intratendinous injection of AD MSCs was not associated with adverse events. It significantly decreased the SPADI scores by 80% and 77% in the mid- and high-dose groups, respectively. Shoulder pain was significantly alleviated by 71% in the high-dose group. Magnetic resonance imaging examination showed that volume of the bursal-side defect significantly decreased by 90% in the highdose group. Arthroscopic examination demonstrated that volume of the articular- and bursal-side defects decreased by 83% and 90% in the mid- and high-dose groups, respectively. Intratendinous injection of autologous AD MSCs in patient with a partial-thickness rotator cuff tear did not cause adverse events, but improved shoulder function, and relieved pain through regeneration of rotator cuff tendon.

Intratendinous injection of adipose tissue-derived mesenchymal stem cells in patients with a partial-thickness rotator cuff tear regenerated tendon defect proved with magnetic resonance imaging and arthroscopy at 6 months after injection.



Keywords: Rotator cuff disease, Rotator cuff tear, Mesenchymal stem cells, Intratendinous injection, Clinical trialIssue Section: TRANSLATIONAL AND CLINICAL RESEARCH

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