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Evaluating the safety and efficacy of mesenchymal stem cell-derived exosomes for treatment of refractory perianal fistula in IBD patients: clinical trial phase I

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Abstract

Background: Exosome administration is a novel medical approach that promises excellent immunomodulatory properties without the conventional side effects of current antitumor necrosis factor drugs and stem cells. This study aimed to assess the safety and efficacy of using mesenchymal stem cell (MSC) exosomes to treat refractory fistulas in patients with inflammatory bowel disease.

Methods: MSCs were derived from the umbilical cords and their exosomes were isolated. Five patients with refractory perianal Crohn's disease fistulas with a median age of 35 years (range 31–47 years) were enrolled in the study. Exosome injections were administered in the operating room to patients with refractory fistula (fistulas that are irresponsive to anti-tumor necrosis factor- α administration within 6 months). Six months later, a physical examination, face-to-face interviews, and magnetic resonance imaging were employed to evaluate the therapy responses of patients.

Results: The outcomes within 6 months after initiation of therapy showed that four patients had responded to therapy. Three patients who received exosome injections exhibited complete healing, while one reported no improvement and active discharge from the fistula site. In addition, five patients (100%) reported neither systemic nor local adverse effects.

Conclusions: Injection of exosomes extracted from MSCs demonstrates safety and a satisfactory therapeutic effect, as evidenced in this and other studies, and may play a significant role in the future treatment of gastrointestinal fistulas.

Keywords: Crohn's disease; IBD; MSCs; exosome; fistula.

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