WOUND HEALING

THE TOPICAL USE OF AUTOLOGOUS BONE MARROW-DERIVED MESENCHYMAL STEM CELLS FOR VENOUS ULCERS: A RANDOMIZED, PROSPECTIVE, DOUBLE-BLIND, PLACEBO-CONTROLLED PILOT STUDY

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Introduction: Preclinical studies of mesenchymal stem cells (MSCs) in various animal wound models demonstrate accelerated wound healing through a variety of mechanisms. However, more evidence needs to be generated from adequate well-controlled clinical trials in order to evaluate the safety and efficacy of MSCs in treating chronic wounds.

Objective: To evaluate the feasibility, safety, and efficacy of topically-applied autologous bone marrow-derived mesenchymal stem cells (BM-MSCs) in treating patients with venous ulcers.

Materials and Methods: In this 3-arm study, a total of 11 patients with verified venous ulcers were randomly assigned to one of three groups: Group A (n=4) received control saline spray; Group B (n=3) received control fibrin spray, and Group C (n=4) received BM-MSCs delivered using a fibrin spray. The treatment was applied every three weeks up to a total of three times as long as the wound is not healed completely. Additionally, all subjects received standard conventional therapy for their wounds. The total duration of the treatment was up to 24 weeks. Patients were evaluated weekly. Healing rates (cm/wk) were calculated using Gilman's formula. Data were analyzed by comparing the mean healing rates among groups.

Results: The average healing rate at week-4 for groups A, B, and C was 0.0006, - 0.0522, and 0.1082 cm/wk, respectively. Patients received BM-MSCs (Group C) showed higher mean healing rates when compared to groups A and B at all evaluation time points.

Conclusion: Topical application of autologous BM-MSCs may be an effective treatment of venous ulcers. This effect is demonstrated by rapid onset of response and superior clinical response compared with placebo. Topical autologous BM-MSCs could potentially be a novel option for the treatment of difficult-to-heal wounds. However, larger studies are still

needed to confirm these findings.