WOUND HEALING

TOPICAL USE OF AUTOLOGOUS CULTURED BONE MARROW-DERIVED MESENCHYMAL STEM CELLS FOR VENOUS LEG ULCERS: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLINDED, 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 well-controlled clinical trials in order to evaluate the safety and efficacy of MSCs in treating chronic wounds.

Objective: To evaluate the efficacy and feasibility of topically-applied autologous bone marrow-derived mesenchymal stem cells (BM-MSCs) in treating patients with venous leg 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 fibrin spray, and Group C (n=4) received BM-MSCs (active treatment) 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 completely healed. 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. The primary efficacy endpoint of the study is increased wound closure (cm/wk). 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: This exploratory study supports the utility of topical autologous BM-MSCs in

treating patients with venous leg ulcers. The therapeutic effect is demonstrated by superior clinical response when compared with placebo. Our results highlight the promise of BM-MSCs in the treatment of difficult-to-heal wounds. However, larger well-controlled studies are still needed to confirm these findings.