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Diabetic foot ulcers: Lower limb salvage using regenerative therapy

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Background: Treatment modalities that promote wound healing are warranted.

Objectives: To assess the efficacy and safety of regenerative therapy (MEBT/MEBO) regarding healing of chronic diabetic foot ulcers (DFUs), development of new ulcers, and amputation rates.

Subjects and Methods: 109 Patients (with 139 ulcers) were randomized for treatment with MEBT/MEBO (n=56 with 71 ulcers) or saline solution dressing (controls, n=53 with 68 ulcers). Data collected prospectively included patient and ulcer characteristics. Ulcer surface area (SA) and healing index (HI) were calculated at two-week intervals for 12 weeks. Secondary amputations and new ulcers were recorded at 12 months. Adverse effects, if any, were also recorded.

Results: Patients in both groups had similar demographic, clinical and ulcer characteristics. There was a significant increase in HI and reduction in ulcer SA on weeks two and four respectively, that was maintained through 12 weeks in patients treated with MEBT/MEBO ($P<0.01$). More than half of ulcers (59.2%) treated with MEBT/MEBO had complete healing (HI=1) by 12 weeks, as opposed to only 25% of controls ($P=0.000$). None of the patients receiving MEBO had a HI of <0.5 by 12 weeks as compared to 27.4% of those receiving saline ($P=0.0001$). At 12 months post-treatment, 23 patients (21.1%) had undergone various amputations with only two (3.6%) belonging to the MEBT/MEBO Group ($X2= 7.22$, $P=0.008$). No major amputations were required for patients receiving regenerative therapy as compared to 9.4% (5/53) of controls ($X2=4.71$, $p=0.03$). Two patients in each group developed a new ulcer by 12 months ($X2= 0.21$, $P>0.647$). No adverse effects of MEBO were encountered.

Conclusions: (1) In addition to its safety, regenerative therapy with MEBT/MEBO significantly promotes the healing of chronic DFUs with significant increase in HI as early as two weeks and significant reduction of SA starting at 4 weeks, with complete healing of approximately 60% of ulcers by 12 weeks, and (2) Significantly fewer amputations were required by 12 months in patients treated with MEBT/MEBO.

Biography

Mahmoud F Sakr, MD, PhD, FACS (USA), Professor of Surgery, is currently the Chief of the Head, Neck and Endocrine Surgery Department at the Faculty of Medicine, University of Alexandria, Egypt. He is a fellow of the International College of Surgeons and American College of Surgeons. He has published more than 12 surgical books as well as 90 articles in esteemed journals and has been serving as an editorial board member of repute.

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