

**Efficacy and Safety of a Novel Super-Oxidized Solution (SOS) in Managing Post-Surgical Lesions of the Diabetic Foot - A Prospective, Randomized Clinical Trial**

Goretti C, Mazzurco S, Leonildi A\*, Scatena A, Tedeschi A, Rizzo L, Tascini C\*, Piaggese A. Diabetic Foot Section, Department of Endocrinology and Metabolism & \*Infectious Diseases Department, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy

**Aim of the Study:** To evaluate the efficacy and safety of SOS in the management of infected lesions of the diabetic foot after surgical debridement. **Study Design:** Adult diabetic patients with surgical outcomes of drainage or partial amputation of the foot on account of an infected lesion distal to the ankle joint (Grade 2B/3B UTC) have been included. All patients have had a lesion  $> 5 \text{ cm}^2$ , an ankle-brachial pressure index  $\geq 0.9$  and the presence of at least two arteries in the ankle documented by palpable pulses or doppler CW. Patients who fulfil the study entry criteria and have written dated, informed consent have been randomized to receive local SOS treatment Group A [N=20, Age  $63.6 \pm 7.7$  yrs, Duration of Diabetes (DD)  $16.6 \pm 2.7$  yrs, Glycated Haemoglobin (HbA1c)  $9.4 \pm 0.4\%$ , Area of Lesion (AL)  $25.3 \pm 15.2 \text{ cm}^2$ ] or standard local treatment with povidone iodine, Group B [N=19, Age  $64.5 \pm 1.9$  yrs, DD  $18.7 \pm 2.6$  yrs, HbA1c  $8.4 \pm 0.4\%$ , AL  $24.7 \pm 11.2 \text{ cm}^2$ ] in addition of metabolic control, systemic antibiotics and off loading, as necessary. All patients enrolled have required to complete acute and long-term clinical follow-up. At baseline and at weekly control visits area of lesions, clinical signs of infection, microbiological sampling eventual new debridement procedures and adverse events were recorded blindly to the local treatment. A subset of patients have also had a pathology analysis of the wound bed. Endpoints at week 24 included healing rate, healing time, time for sterilization of the lesions, number of debridement procedures and number of adverse events. **Results:** 85% of Group A patients healed in 24 weeks compared to 53% of group B ones ( $p < .01$ ); healing time was  $10.5 \pm 1.3$  wks in Group A vs  $16.5 \pm 1.7$  wks in Group B ( $p < .01$ ), time for sterilization was  $5.5 \pm 2.1$  wks in Group A compared to  $16.2 \pm 6.6$  wks in Group B ( $p < .01$ ), further debridement procedures were carried out in 3 patients of group A and in 9 of group B ( $p < .05$ ), no differences were observed in the adverse events occurrence (2 in group A vs 3 in Group B). **Conclusions:** SOS local treatment proved to be as safe as and more effective than standard medication in the management of wide post-surgical infected lesions of the diabetic foot left to heal for secondary intent.