USE OF A NEW SURFACTANT GEL WITH SILVER SULPHADIAZINE IN THE TREATMENT OF CHRONIC LEG ULCERS AND DIABETIC FOOT

ITALIAN MULTICENTRIC EXPERIENCE: PALUMBO F.P.¹ – SERANTONI S.² – ABBRITTI F.³

SLIDE 2
• A new technological advanced device (Silver Sulphadiazine Gel) was tested on 58 lesions selected in 43 patients in a multicentric observational study.
• 180 days follow-up results are reported and discussed.

SLIDE 3
METHODS
• Patients were selected according to conditions of the injury at time T0, regardless of time of onset and treatment prior to enrollment date.
• All patients underwent to an anamnestic and clinical and instrumental evaluation (when required).
• Data were collected using a schedule to detect wound characteristics. QL index was administered to all patients.
• Dressing changes were performed from one to three times a week, depending on the characteristics of the lesions.
• In selected patients, a multilayer, multicomponent, inelastic bandage was applied.
• The study was completed in 30 days.
• Our preliminary report was presented at EWMA 2012.

SLIDES 4 & 5

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The coordinators of the study all received the same training in vulnology and are all vascular surgeons.

RESULTS
• In all almost patients an improvement of objective data was observed. Reduction of exudation and of inflammation in the skin around the ulcers were observed since the first week of gel application. These were accompanied by reduction of average wound areas and of pain.
• After 60 days, rates reduction of area were respectively of 78,1% in Group A, of 75,89% in Group B and of 66,63% in Group D. In Group C was observed a decreasing rate of 67,7% after 180 days.
• Pain percentages decreased respectively of 50% in Group A, 76,8% in Group B and of 87,7% in Group D after 60 days. We observed a decrease of 82,8% in Group C patients after 180 days.
• Pain data were correlated to exudation rate that decreased respectively of 57,1% in Group A, 71,4%. In Group B and of 66,6% in Group D after 60 days. In Group C we observed a reduction rate of 60,8% after 180 days.
• A very important data was collected by QL-index administration. Increase of QL-Index was respectively of 35,2% in Group A, of 44,9% in Group B and of 20,9% in Group D after 60 days. An increase of 20,9% was reported in Group C after 180 days.

FOLLOW UP AT 180 DAYS
• All lesions < 20 cm² (30) healed in about 60–75 days. Two lesions > 100 cm² (Group D) underwent to surgical implant of homologous skin graft. 3 patients were treated successfully for 5 weeks with autologous platelet gel (5 lesions).
• The others lesions (16) were treated with gel application once a week to complete healing.
• At 180 days only 4 lesions were not healed.
• Drop out 2 patients (1 hearth failure, 1 stroke).

POSTER #1 1 – LABORATORIO DI VULNOLOGIA – PALERMO; 2 – CASA DI CURA “VILLA FIORITA” – PRATO; 3 – U.O. CHIRURGIA VASCOLARE – A.O. G. SALVINI, GARBagnate MILANESE
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REFERENCES


DISCUSSION

• Aim of this study was to test the effectiveness of SSD-Gel in all types of leg ulcers.

• Thanks to its properties (it can solidify at body temperature) this device may conform to the bottom of the ulcer and exert its antibacterial activity taking advantages of its features on the surface tension (action on biofilm). In this way it is possible to explain its anti-inflammatory activity due to the antibacterial and the sense of freshness that every patient has reported from the first application.

• The follow-up to 180 allowed to observe in the lesion resistant to therapy a progressive improvement in symptoms and an increase of the scores of the QL-index reducing the discomfort associated with excessive exudation and malodor and thus allowing the recovery of the social life, which is especially important in the elderly.

• The SSD-Gel interacts with the surface of “non-healing” ulcers probably through a mechanism of reducing the surface tension of the biofilm and thus allowing the exposure to the action of the bacterial wall to Silver Sulphadiazine linked to it.

• In our experience, the disappearance of the sign of infection and growth of tissue proliferation was observed with greater frequency in small lesions. Many of the injuries that are larger than 20 cm² were treated by skin grafts. Their engraftment in all cases showed indirectly the antibacterial efficacy of the product.