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Treatment of infected leg ulcers needs as antimicrobial topical agent the silver, it represents actually a topical effective agent against bacterial growth and no bacterial resistance is reported. Usually silver is linked in the advanced dressing or in the ointments. Sulphadiazine with silver is largely used in Italy, but in extensive and in chronic ulcers its effectiveness is reduced both for inappropriate use that for ulcer characteristics as wound biofilm. Therefore use of silver dressings is very expensive and their use is reserved only to the severe infections. In September 2011 a new technological advanced product was presented for tests and we began to use in our patients in an observational study (Silver Sulphadiazine Gel – SSD-gel).

The centers are dislocated in northern, central and southern Italy, but the teams were formed in same center and all procedures were planned to obtain an homogeneous data base.

Aim of this study was to test the effectiveness of this product in a short period of thirty days selecting the patients affected of leg ulcers of various aetiology.

## METHODS

43 patients with 58 lesions (20 males and 23 females – age 26-91 years, average age 70,9 years) were selected in the period October 1st – November 30th 2011 in all centers.

All patients underwent to a general anamnestic and clinical evaluation and to a local evaluation of the lesion/s. In those patients who required an instrumental evaluation (venous, arterial, mixed and diabetic) an echocolor Doppler examination of the venous and arterial leg axis was performed.

According to T.I.M.E. size, exudation, infection and perilesional skin were observed and a photographic relief of each lesion was performed before the application of the product. By a VAS scale pain and malodour were classified in a data base.

On the basis of the wound areas the lesions were divided in four groups (see Tab. 1):

LESIONAL AREA CLASSIFICATION	LESIONAL AREA	N. LESIONS
GROUP A	0-10	30
GROUP B	11-20	10
GROUP C	21-100	16
GROUP D	> 100	2

According with aetiology the classification of the ulcers is reported in Tab. 2

▪ VENOUS	19
▪ ARTERIAL	10
▪ MIXED	5
▪ HYPERTENSIVE	3
▪ UNKNOWN	1
▪ VASCULITIS	3
▪ DIABETIC	9
▪ INFECTION	1
▪ PRESSURE	2
▪ POST-TRAUMATIC	7

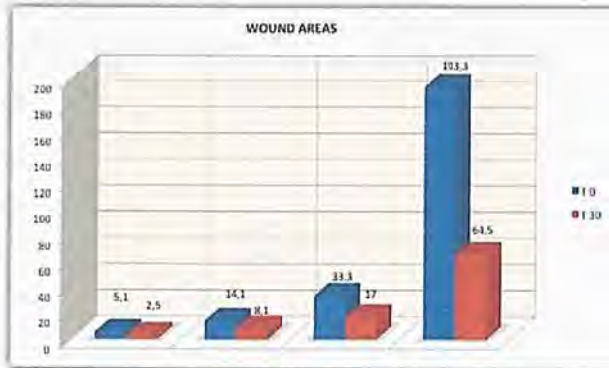
The administration of the product was performed by one to three times a week depending on the characteristics of the lesions and of the center work organization.

In those patients affected of oedema a compressive therapy (multilayer, multicomponent and inelastic bandage) was administered for all entire period of treatment.

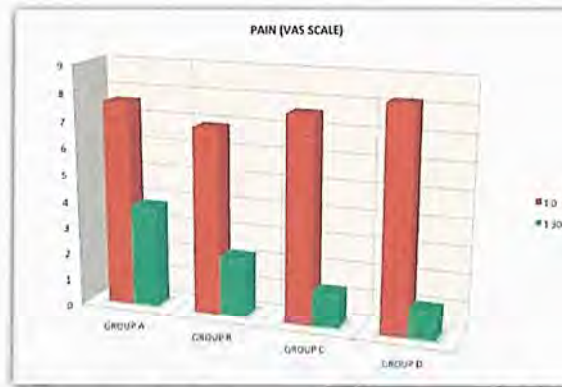
## RESULTS

In all almost patients an improvement of objective data was observed. Reduction of exudation and of perilesional skin inflammation were observed since the first week of gel application. Contemporarily application of gel was accompanied by reduction of pain (in many cases it disappeared) and majority of patients referred a freshness sensation in the wound for one-two days after the change of medication. These data were observed in about 85% of wounds, especially in group A and B.

Reduction of wound areas was calculated by a planimetric method and data are illustrated in Tab. 3



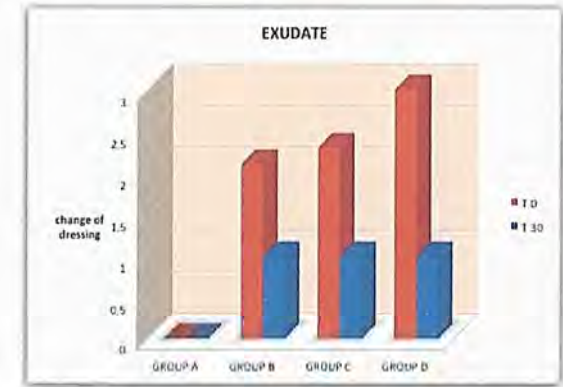
Tab. 3 – Lesional areas before and after the treatment (data expressed in cm<sup>2</sup>)



Tab. 4 – Pain (VAS scale 1-10) before and after the treatment.

To evaluate the reduction of exudate quantity a personal scale based on the need of dressing change was adopted. This scale is not objective and depends also on the lesion size both on the presence of a logistic reason.

This scale was not valid for the lesions in the Group A, so data are referred to the other three groups.



Tab. 5 – Exudate before and after the treatment.

Calculating the average area lesions, we observed a reduction rate of 50,98% in Group A (from 5,1 to 2,5 cm<sup>2</sup>), of 44,89% in Group B (from 14,1 to 8,1 cm<sup>2</sup>), of 48,94% in Group C (from 33,3 to 17 cm<sup>2</sup>) and of 66,63% in Group D (from 193,3 to 64,5 cm<sup>2</sup>) at 30 days.

## DISCUSSION

Aim of this study was to test the effectiveness of a new surfactant gel with silver sulphadiazine in non-selected ulcers including diabetic foot and less common lesions. This new compound is a new generation product in which are present new technologies. The first based on gel properties; it may thicken at body temperature to conform to and protect wound surfaces. It is removable with a water rinse, making care simpler and much less painful for the patient.

## USE OF A NEW ACTIVE SURFACE SURFACTANT GEL WITH SILVER SULPHADIAZINE IN THE TREATMENT OF LEG SKIN ULCERS AND DIABETIC FOOT LESIONS: *PRELIMINARY RESULTS*

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

The limitation of the study was the time, having closed it at 30 days to get more informations as homogeneous as possible.

Application of the product lead to modify as soon as possible the lesions characteristics, especially in Group A and B (from 0 to 20 cm<sup>2</sup>). Reduction of inflammation and of pain was observed in all the patients, majority of them referred a freshness after the application and this sensation was present also in the successive days.

After the first applications in all the ulcers an objective change in ulcer border was observed, maybe as reaction of inflammatory answer or of local infection decrease. In many cases a white alone separated the ulcer border from the healing skin was observed. In small ulcers healing was faster than the biggers, but in these last the insufficient data cannot explain the

product role rather than compressive therapy in the healing process.

Gel application has modified also the bottom of the ulcers, decreasing necrotic and fibrin amount and increasing proliferative tissue. In Group C some non-healing ulcers presented at the end of study a bottom ready for graft tissue implant or for platelet-gel application.

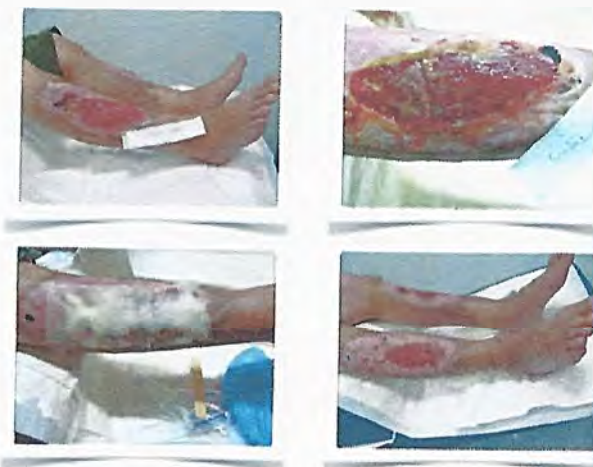
Easy of application and absence of pain during dressing change are reported in all the patients. No complications were referred during the study.

### CONCLUSIONS

- The gel interacts with the wound biofilm, thereby reducing the signs of infection;
- It changes the characteristics of the non healing wounds;
- In the biggest ulcers, it prepares the wound bed to the subsequent skin graft.
- Decreasing wound inflammation and infection, it reduces the pain.



*CASE 1 – Venous ulcer. Compressive therapy and SSD-gel application lead to wound closure in 30 days.*



*CASE 2 – Post-traumatic ulcers in both legs in a 42 years old man. SSD-gel application and result after 30 days.*

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**CASE 3** – Vasculitic ulcer in diabetic woman (81 years old). After the first application of SSD-gel pain disappeared. Result after 60 days of treatment.



**CASE 4** – Vasculitic lesion occurred in a woman affected of rheumatoid arthritis. SSD-gel application allows necrotic tissue removal and growth of new tissue in 60 days.

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