

CRITICAL COLONIZATION AND A NEW ABSORBENT DRESSING IMPREGNATED WITH SILVER SALTS*: RESULTS OF A CLINICAL STUDY IN THE MANAGEMENT OF LEG ULCERS.

AUTHORS

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INTRODUCTION

The vast majority of leg ulcers are colonized by micro-organisms (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus beta hemolytica*, etc.), which, in some cases, possess documented infective potential. No precise therapeutic strategy has yet been established for wounds of this type which, though not clinically infected, nevertheless present signs of "critical colonization" (perilesional erythema, painful or malodorous lesion, edema, heavy exudate).

The aim of this clinical study is to evaluate the performance (efficacy, safety) of a new **absorbent dressing impregnated with silver salts*** in the management of venous leg ulcers presenting clinical signs of critical colonisation.

MATERIALS AND METHODS

A phase III, an open-label, multicentre clinical study was conducted in 12 sites including dermatology, vascular medicine hospital wards and private physicians (angiologists and dermatologists).

Patients presenting critically colonized leg ulcers on average 12cm² in size were included in this study. They were followed up to 4 weeks on a weekly basis, including a clinical examination (based on the clinical signs suggesting critical colonization), area tracing and photographs. Acceptability was documented by the nursing staff when dressings were changed.

RESULTS

45 patients were included in the study. The baseline characteristics of the patients and wounds are summarized in Table 1. Compared with baseline, the mean reduction in ulcer area was of 35,0± 58,0% (median: 33%, $p < 0.001$) after the 4 weeks treatment (Figure 1) and the mean number of clinical signs of critical colonization per ulcer decreased from 3,6± 0,7 to 1,2± 1,2 at the end of the 4th week of follow-up ($p = 0.001$) (Figure 2). Oedema, malodorous wounds, erythema and spontaneous pain disappeared at the 4th week in 80%, 70%, 69% and 65% of the treated ulcers respectively. Granulation tissue covered a mean 77% of the ulcer surface area at week 4, compared with 41% at baseline. Details of the acceptability are summarized in Table 2. Only three local events were documented in this trial: a contact dermatitis, a burning sensation and an erythema.



Initial aspect



After 4 week treatment



Initial aspect: D0



Wound at week 2



Final aspect: W4

Figure 1 : Percentage reduction in ulcer surface area over the four weeks of treatment

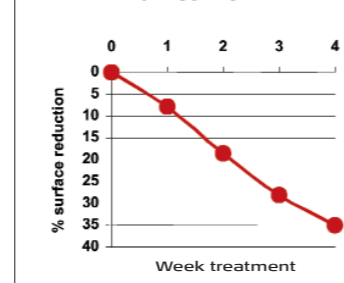


Figure 2 : Evolution of the clinical score

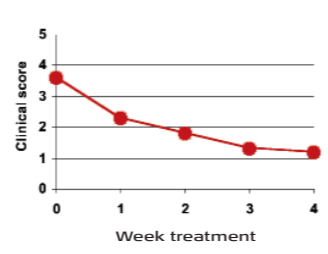


Table 1 : Baseline characteristics of the patients and wounds

Gender	Female	31 (69 %)
	Male	14 (31 %)
Age (years)		76 ± 11 [48;92]
Duration of the ulcers (months)		15.2 ± 18.5 [1;96] median = 9
Surface area (cm ²)		12.6 ± 10.0 [2.6;47.9] median = 9.4
Number of local sign of critically colonization (Clinical Score on 5)		3.6 ± 0.7 [3;5] median = 3.0

Table 2 : Acceptability of tested dressing

Ease of dressing application Female		
Very easy		83.7 %
Easy		13.2 %
Difficult or very difficult		3.0 %
Conformability to the wound bed		
Good or very good		93.1 %
Poor or very poor		6.9 %
Ease of dressing removal		
Easy or very easy		99.6 %
Difficult or very difficult		0.4 %
Pain at removal		
Absent or minor		98.1 %
Moderate or important		1.9 %
Adherence at removal		
Absent or minor		99.4 %
Moderate or important		0.6 %
Odour		
Absent or minor		91.6 %
Moderate or nauseating		8.4 %

CONCLUSION

The results of this clinical trial suggest that a new absorbent dressing impregnated with silver salts* had a favorable influence on the wound prognosis (considering the reduction of clinical score and the surface area), is well tolerated and well accepted in the treatment of venous leg ulcers presenting clinical signs of critical colonization.

* UrgoCell® Silver/Cellosorb® Ag trademark by the Laboratoires URGO (France), in Europe / Restore® Foam Dressing Silver, trademark by Hollister Wound Care LLC in the Northern America
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