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Hard-to-heal venous leg ulcers: Results from a double-blind RCT of a silver foam dressing*

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Introduction

Hard-to-heal' ulcers are frequently inflammatory and often highly colonized. Ionised silver has anti-inflammatory and antibacterial properties. Previous studies have shown that a silver foam dressing* provides a faster reduction in wound area of infected wounds than a dressings without silver[1,2].

Aim

To investigate the efficacy of a silver foam dressing* in comparison with a foam dressing without silver+ for the treatment of hard-to-heal venous leg ulcers.

Methods

This is a subgroup analysis of the French patient group (n=75) from a 10-week, multinational, double-blind randomised, controlled trial (RCT) of patients with a venous or predominantly venous leg ulcer that had failed to heal despite appropriate therapy, including compression therapy, in the 4 weeks prior to inclusion.

The patients were centrally randomized and allocated to treatment with the silver foam or the comparator foam for 6 weeks by an interactive voice response service (IVRS). Thereafter both groups continued with the comparator foam for 4 weeks.

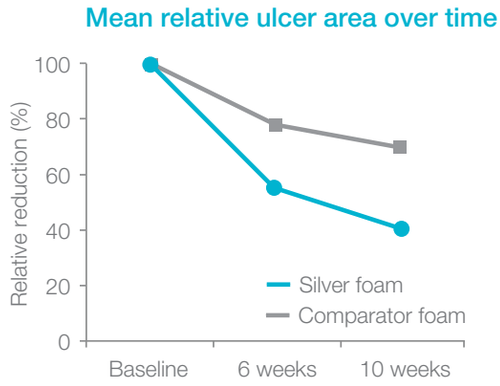
The primary endpoint was relative reduction in ulcer area at week 6. Data from week 10 are also presented. Wound size and area were measured by planimetry. Data were analysed on the intention-to-treat (ITT) population with last observation carried forward (LOCF) using ANCOVA with baseline area, age and BMI as covariates and gender, ulcer age and treatment as fixed effects.

Results

Baseline parameters were comparable in the two treatment groups.

Baseline parameters	Biatain	Biatain Ag	p-value
N	38	37	
Gender	23 /15	22/15	0.92
Female / Male			
Age (years) Mean (SD)	76.2 (9.5)	80.4 (7.8)	0.04
Ulcer area (cm^2, planimetry) Mean (SD)	18.5 (15.8)	17.1 (13.7)	0.69
Ulcer duration (years) Mean (SD)	3.1 (3.9)	3.0 (5.3)	0.90
Ankle/Brachial/Index (ABI) Mean (SD)	1 (0.1)	1 (0.2)	0.25
Ulcer origin (N, %)			
Deep venous insufficiency	24 (64.9%)	21 (56.8%)	0.48
Superficial venous insufficiency	16 (43.2%)	14 (37.8%)	0.81
History of phlebitis	14 (37.8%)	17 (45.9%)	0.64

Figure 1. After 6 weeks ulcer area was reduced by 44% with the silver foam and by 22% with the comparator (p=0.0229). After 10 weeks (when comparator foam had been applied on both groups for 4 weeks) the ulcer area was reduced by 60% in the silver foam group and by 30% in the comparator group (p=0.0262).



The linear wound healing rate (Gilman) was 0.63 mm/week for the silver foam and 0.33 mm/week for the comparator.
Two adverse events possibly related to treatment were registered. In the silver foam group, one patient had pain in the study ulcer (severe) and in the comparator group one patient had pruritus (itching) (moderate).

Conclusions

In this subgroup analysis of the French patient group from a double-blind RCT, a silver foam dressing was effective for the treatment of hard-to-heal venous leg ulcers in comparison with a similar foam dressing without silver. This effect was still significant after 10 weeks, 4 weeks after treatment was switched from the silver foam to the comparator foam.

References

1. Jørgensen et al. Int Wound J 2005;2(1):64-73. 2. Münter et al. J Wound Care 2006;15(5):199-206.

*Biatain Ag, +Biatain, Coloplast A/S

Biatain® Ag
– superior absorption for infected wounds

New evidence

Hard-to-heal venous leg ulcers: Results from a double-blind RCT of a silver foam dressing. Senet and Petersen. EWMA 2012

Superior absorption for faster healing

Key findings

- Biatain Ag effectively started healing of hard-to-heal venous leg ulcers
  - ➔ Wound area was reduced by 44% at week 6
- The effect persisted even after Biatain Ag was switched to Biatain without silver after 6 weeks
  - ➔ Wound area was reduced by 60% at week 10
- Healing was twice as fast with Biatain Ag during the full 10 weeks study period

Description of Biatain Ag

Biatain Ag is a soft and conformable silver foam dressing with superior absorption that helps infected wounds heal faster[1,2]. Major independent studies have proven that Biatain Ag is the only wound dressing that is effective on all bacteria commonly found in infected wounds[3,4].

References: 1. Jørgensen et al. International Wound Journal 2005;2(1):64-73 **2.** Münter et al. Journal of Wound Care. 2006;15(5):199-206 **3.** Ip et al. Journal of Medical Microbiology 2006;55:59-63 **4.** Basterzi et al. Wounds July 2010.

Biatain® Silicone Ag

Size	Itemno.	National code
7.5x7.5	39636	
10x10	39637	
12.5x12.5	39638	

Biatain® Ag Non-Adhesive

Size	Itemno.	National code
5x7	5105	
10x10	9622	
10x20	9623	
15x15	9625	
20x20	9626	
Soft Cavity	9628	

Biatain® Ag Adhesive

Size	Itemno.	National code
7.5x7.5	9631	
12.5x12.5	9631	
15x15	3484	
18x18	9635	
17x17 Sacral	9641	
19x20 Heel	9643	

Ostomy Care
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Coloplast

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