RESEARCH PAPER

Prospective, Descriptive Study of Critically Colonized Venous Leg Ulcers Managed With Silver Containing Absorbent Dressings and Compression

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Abstract Chronic non-healing venous ulcers are by their very nature colonized with bacteria. The amount and make up will vary based on many variables. The transition from colonization to contamination, critical colonization, and infection complicates the treatment of these ulcers. Silver has been shown to be an effective antimicrobial agent with a diverse antimicrobial footprint, minimal allergic reactions, and has been employed for over twenty-five years with little resistance being encountered. Based on these factors, this study was initiated to evaluate the impact of silver containing absorbent dressings on critically colonized venous leg ulcers.

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Introduction

Chronic non-healing ulcers are colonized by a variety of bacterial organisms which can change and vary with the duration of the ulcer. The bacterial makeup of the ulcer will also vary based on etiology and anatomical location of the ulcer. Assessing the bacterial makeup of a chronic non-healing ulcer by standard swab cultures is not recommended unless there are clinical signs that the ulcer is infected; as standard ulcers swab cultures will only confirm the colonization of the ulcer. Such cultures can lead to the initiation of antimicrobial treatment that is not indicated

and could lead to increasing resistance by the bacteria colonizing the ulcer.

The transition of a chronic ulcer from colonization to active infection is problematic and if not diagnosed and treated can lead to increased morbidity and mortality. Tissue cultures of ulcers suspected of being infected are recommended however such cultures take time and may allow for further bacterial proliferation if empirical antimicrobial intervention is not initiated. Empirical intervention however contributes to the potential of facilitating increasing resistance and the enhancement of biofilm formation. Topical antimicrobial agents can help in treating and reducing the bacterial burden inherent in chronic non-healing ulcers; however, increasing resistance is associated with both topical antimicrobials and systemic antimicrobials and recent reviews showed that the routine use of systemic antibiotics did not improve healing rates.¹

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Table 1 Study Participant Inclusion and Exclusion Criteria

Included	Excluded
Age 18 or older	Has an allergy to one of the components of the dressings
Venous ulcer 5 cm ² –40 cm ²	Taking antibiotics at the time of enrollment
Ulcer duration less than 2 years	Venous duplex findings negative for reflux
Using compression therapy	Unable to tolerate compression
Ankle Brachial Index ≥ 0.8	Is unwilling or unable to comply with the study protocol
Non-infected (off antibiotics at least 2 weeks)	Is unable to continue contact with the investigator for a period of at least two weeks
Critically colonized at time of enrollment	

Silver has been shown to be an effective antimicrobial agent in preventing bacterial proliferation in burns as well as non-healing chronic ulcers.² Silver has a diverse antimicrobial footprint with minimal allergic reactions and has employed for over 25 years with little resistance being encountered.³ Chronic venous stasis ulcers are known to harbor a variety of gram negative and positive organisms. Previous analysis of such ulcers revealed that 88.46% of the ulcers revealed the presence of bacteria with *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Escherichia coli* being the most common and most resistant to therapy.⁴ Silver has been shown to significantly reduce colony forming units of these bacteria and has been incorporated into a number of ulcer dressings based on these studies.⁵

Critical colonization varies based on the bacteria being present and leads to stagnation of the healing process. The diagnosis that a chronic non-healing ulcer is critically colonized is a clinical diagnosis based on the failure of the ulcer to progress. In prior work, Lazareth et al⁶ have used five clinical signs to assess for the presence of critical colonization in venous leg ulcers. Ulcers were considered critically colonized if three out of five of the following signs were present:

1. Severe pain between two dressing changes,
2. Perilesional erythema,
3. Local edema,
4. Malodor, and
5. The presence of heavy exudate.

The aim of this clinical study was to assess signs of critical colonization and healing among participants with

venous leg ulcers who were managed with one of two silver containing absorbent dressings that are currently on the market in the US.

Objectives

The primary objective of the study was to compare Restore[®] Calcium Alginate Dressing, Silver (Hollister Incorporated, Libertyville, IL) to AQUACEL[®] Ag Hydrofiber[®] Ulcer Dressing (ConvaTec Inc., Skillman, NJ) using the following signs: progression toward infection, ease of dressing application and removal, and percent progression to ulcer closure. Due to low sample size caused by slow enrollment the results are descriptive rather than comparative in nature.

Methods

This was a randomized, prospective, multi-center, open label clinical evaluation conducted under IRB approval at U.S. outpatient ulcer centers. Following informed consent and screening for inclusion and exclusion criteria (Table 1), participants were randomized by order of enrollment by site to use one of the two products for up to six weeks.

At the first study visit the ulcer was debrided as clinically indicated, photographed, and measured using a disposable ruler. The study dressing was applied, covered with a gauze secondary dressing, and a multilayer compression wrap dressing was applied. The same procedure was followed during weekly study visits for up to six weeks

Table 2 Changes in the Number of Clinical Signs Present by End of Study Period When Compared to First Rating

Trend	Product			
	A-Restore Silver		B-AquaCel Ag	
	n	Percent	n	Percent
No Increase	6	60.0	5	71.4
Increase with Subsequent Decrease	3	30.0	0	0.0
Increase with no Subsequent Decrease	1	10.0	2	28.6
Total	10	–	7	–

Table 3 Clinician Satisfaction With Product Attributes

Item	Group A	Group B
Ease of application (1 – Very Easy to 10 – Very Difficult)	1.0	1.0
Ease of removal (1 – Very Easy to 10 – Very Difficult)	2.0	2.0
Absorption (1 – Excellent to 10 – Poor)	3.0	5.0
Wear time (1 – Completely Satisfied to 10 – Dissatisfied)	3.0	4.0

Table 4 Combined Chart of Percent Progression to Closure

unless ulcer closure occurred. A final study visit was conducted at the end of the sixth week (so there were seven possible visits per person). One additional interim dressing change was allowed per week if needed due to excessing drainage (conducted by home health nurse or in the outpatient site). In addition to measuring and assessing the ulcer, at each study visit the clinician completed a questionnaire about the study dressing.

Results

The final analysis included data from 19 participants from five study sites. Eleven were enrolled in Group A (Restore) and eight were enrolled in Group B (AQUACEL). There were two discontinuations, thus results are shown for 17 participants. Three participants missed one visit.

Progression Toward Infection

None the ulcers became clinically infected during the period of the study, as determined by the treating investigators. Most participants either showed no increase in the number of clinical signs of colonization or showed an increase followed by a decrease by the end of the study, as shown in Table 2.

Ease of Dressing Application and Removal

The investigators ranked both dressing favorably on ease of use, absorbency, wear time, and adherence to the ulcer bed. The median scores are displayed in Table 3.

Ulcer Closure

Three subjects in each arm of the study went on to complete closure within the study period. Percent progression to closure by week is shown in Table 4.

Discussion and Conclusions

Both dressings were viewed as acceptable for use as part of a comprehensive treatment plan incorporating debridement and compression dressings. The ulcers improved over time with the use of such dressings, none of the ulcers became clinically infected, and the closure rates of the ulcers were consistent with results reported by other researchers.⁷

The number of enrollees in the study was too small to draw conclusions concerning the advantage of one dressing over the other.

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