AN INNOVATIVE ANTIBACTERIAL DRESSING, KERRACONTACT AG, IN THE MANAGEMENT OF VENOUS LEG ULCERS

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Introduction

Chronic venous leg ulcers have a prevalence estimated at 1 to 3 per 1000 of the UK population. The prevalence increases with age, rising to 20 per 1000 in people over 80 years of age. Signs of an infected venous leg ulcer include: enlarged ulcer, increased exudate, increased pain, pyrexia, foul odour, and cellulitis. The aims of this study are to assess the clinical reduction of signs and symptoms of infection such as pain, odour, and exudation in venous leg ulcers following the use of an innovative silver dressing, KerraContact Ag (Crawford Healthcare). Secondary objectives include the ease of use of the dressing, feedback from study participants, and assessment of the secondary dressing used will also be evaluated. The case report form has been designed to enable statistical analysis of outcome data.

Method

A clinical evaluation study was undertaken on 7 patients with venous leg ulcers, who had clinical signs of infection over a 4 week period in the community. The study included male and female subjects aged more than 18 years of age, with adequate perfusion (ABPI>0.7), and who are able to ambulate in their home environment or in an outpatient clinic, with or without mobility aids. Participants included in the study all had ulcer sizes between 1 to 20 cm^1. Clinical diagnosis of infection or suspicion of infection was confirmed by at least 2 of the following criteria: increased exudation, purulence, odour, pain caused by wound, friable dull granulation tissue, or erythema >1 to 2 cm from the wound margin.

Following informed consent, the wound was assessed and photographed once a week, and all relevant data recorded. Patient details, treatment for the previous 12 weeks, wound size and type were also recorded. A Doppler assessment was obtained if not already recorded, and the skin photographed with a patient identifier and ruler to assess changes in skin condition. The patient's pain level was recorded along with any other relevant observations. KerraContact Ag was applied as per the manufacturer's instructions.

Data was collected assessing the wound size, progress, level and type of exudate, level of odour, type of pain, integrity of the surrounding skin, and wound management objectives. In addition, the appearance of the dressing on removal, pain level associated with the application, wear, and removal of the dressing (1=no pain and 10=worst pain), and ease of application and removal of the dressing was assessed. The length of wear time of the dressing, frequency of dressing change, and the absorption, and fluid handling of the secondary dressing was also recorded.

Results

The results from weekly assessment of the clinical signs and symptoms of infection; exudate level/type, odour, pain and condition of the surrounding skin are all shown in Tables 1-4.

Exudate Level / Exudate Type					
Patient	Time 0	1 week	2 week	3 week	4 week
FF	M / P	M / P	M / P	L / S	L / S
HP	M / HM	M / HM	L / S	L / S	L / S
JM	M / P	H / P	M / P	L / S	L / S
JM (2)	M / P	M / P	M / S	L / S	L / S
KS	M / P	M / P	L / S	L / S	L / S
MH	M / P	M / P	M / S	M / S	L / S
RM	M / P	M / P	L / S	L / S	L / S

Table 1 - Exudate level: L = Low, M = Moderate, H = High. **Exudate Type**: S = Serous, HM = Haemoserous, P = Purulent

Odour					
Patient	Time 0	1 week	2 week	3 week	4 week
FF	S	S	N	N	N
HP	N	N	N	N	N
JM	S	S	S	N	N
JM (2)	S	S	N	N	N
KS	S	S	N	N	N
MH	S	N	N	N	N
RM	S	S	N	N	N

Table 2 - Odour: N = None, S = Some, M = Significantly Malodorous

Pain					
Patient	Time 0	1 week	2 week	3 week	4 week
FF	4	6	None	None	None
HP	2 + 5	2 + 5	3 + 5	None	None
JM	1 + 2	2	1 + 5	1 + 5	1 + 5
JM (2)	None	None	None	None	None
KS	2 + 6	2 + 6	2 + 5	2 + 5	2 + 5
MH	None	None	None	None	None
RM	None	None	None	None	None

Table 3 - Pain: 1 = Burning, 2 = Stabbing, 3 = Aching, 4 = Continuous, 5 = Intermittent, 6 = Itching

Surrounding Skin					
Patient	Time 0	1 week	2 week	3 week	4 week
FF	6	6	4	4	4
HP	3	7 (callus)	1	1	1
JM	3	1	1	1	1
JM (2)	7 (Eczema)	7 (Eczema)	7 (Eczema)	7 (Eczema)	7 (Eczema)
KS	7 (Fragile)	7 (Fragile)	1	1	1
MH	1	1	1	1	1
RM	1	1	1	1	1

Table 4 - Surrounding Skin: 1 = Healthy, 2 = Breaking down, 3 = Macerated, 4 = Erythema 1-2cm, 5 = Erythema <1-2cm, 6 = Oedematous, 7 = Other (specify)

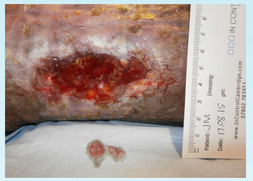

Image 1: Time 0 (JM)

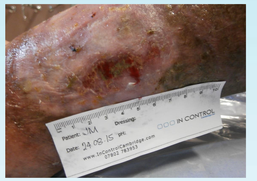

Image 2: 1 week (JM)

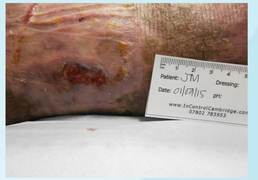

Image 3: 2 week (JM)

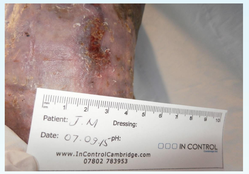

Image 4: 3 week (JM)

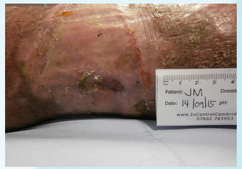

Image 5: 4 week (JM)

All 7 wounds recorded a reduction in size following the weekly assessments. At time 0 all wound measurements combined equal 100%, each week the combined results show a reduction against the figure as a mean score, Mean result at week 1 = 78.81%, mean score at week 2 = 63.32%, mean score at week 3 = 43.23% and mean score by week 4 = 30.85%. From time 0 to week 4 a combined wound reduction of 69.15%.

Discussion

KerraContact Ag is an enhanced activity silver dressing with Ag Oxysalt technology. The Ag Oxysalt technology has higher oxidation states (Ag2+ and Ag3+) that have increased activity at lower concentrations than other silver dressings. The silver Oxysalt dressing proved very effective (4 x log^{10} reduction in ≤4 hours) against all tested wound pathogens in planktonic cultures *in vitro* and demonstrated sustained activity against common wound pathogens in simulated wound fluid over 7 days, demonstrating superior performance compared with competitor dressings.[1]

A previous clinical study evaluating KerraContact Ag in chronic foot and leg ulcers showed that mean pain scores reduced over an 8 week period (n=20). KerraContact Ag was also clinically effective in reducing wound size in 16 out of 20 stalled chronic wounds with critical colonisation.[2]

Conclusion

The objective in managing infected venous ulcers is to reduce the signs and symptoms of infection allowing compression to treat the underlying cause. The reduction in wound area over a short time with KerraContact Ag dressings show that these symptoms are being managed. This study will be expanded to a further 8 patients to confirm the results produced so far.

References

(1) Lemire JA, Kalan L, Bradu A, Turner RJ (2015) Silver oxynitrate, an unexplored silver compound with antimicrobial and antibiofilm activity. Antimicrobial Agents and Chemotherapy 59(7):4031-9

(2) Sibbald R et al. (2012) A 20 patient case series to explore new ionized silver dressing for critically colonized, stalled chronic leg and foot ulcers. Poster presentation at Symposium of Advanced Wound Care