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A STUDY COMPARING CADEXOMER IODINE AND NANOCRYSTALLINE SILVER ON HEALING OF CHRONIC INFECTED LEG ULCERS

Plastic Surgery

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ABSTRACT

Background: Chronic leg ulcers are a debilitating, often painful and costly condition. Silver and cadexomer iodine primary dressings are commonly used antimicrobial products. **Methods:** After approval from institutional ethical committee, a parallel-group, open label, study design was used to study the patients who were recruited from those visiting Plastic surgery OPD, BHU from January 1, 2019 to February 28, 2019. Forty patients were randomly allocated to each treatment group of antimicrobial agents. **Results:** In each treatment group, a comparable number of patients healed; 70% from the silver group and 67.5% from the iodine group. Mean surface area reduction was noted to be 69.78% in silver group and 65.87% in iodine group. LMM and ANOVA found no significant difference between the treatment groups in the overall wound healing rate, with the exception of the first 2 weeks. **Conclusion:** We conclude that when wanting to achieve an immediate reduction in wound size and when attending clients with large and chronic leg ulcers or a history of protracted healing, a silver antimicrobial can be considered for the first choice.

KEYWORDS

Chronic infected leg ulcers, Cadexomer iodine, Nanocrystalline silver

INTRODUCTION

Chronic leg ulcers are a debilitating, often painful and costly condition.[1] One factor, which may complicate the healing process, is bacterial colonization. It is generally accepted that the use of primary dressings with antimicrobial properties is clinically indicated when a wound becomes critically colonized.[2]

Silver and cadexomer iodine primary dressings are commonly used antimicrobial products. Although evidence for clinical effectiveness has been shown for both these antimicrobial dressings[3,4], data comparing their relative effectiveness is lacking. Thus, this study was conducted to evaluate and compare clinical effectiveness of cadexomer iodine and nanocrystalline silver dressings on healing of chronic infected leg ulcers with respect to wound healing rate (% change in wound surface area) and the number of healed wounds (100% closure) ; over a 12-week period.

MATERIALS AND METHODS

After approval from institutional ethical committee, a parallel-group, open label, study design was used to study the patients who were recruited from those visiting Plastic surgery OPD, BHU from January 1, 2019 to February 28, 2019. Following recruitment, patients were randomly allocated to each treatment group. Patients were eligible for the study if they had following:

1. had a lower leg ulcer of duration more than 4 weeks
2. the wound was 15 cm or less in diameter
3. were aged 18 years or older
4. had not been on a course of topical antiseptic treatment in the 1 week before recruitment.
5. were not using any antibiotics 48 hours before recruitment
6. were not using systemic steroids.
7. did not have a diagnosis of a malignancy related to the leg ulcer.
8. were not receiving palliative care and in addition, had at least one ofthe following clinical signs of infection[5] :

a. cellulitis (pain, heat, erythema and swelling of surrounding tissues);
b. suppuration (purulence or the presence of pus);
c. lymphangitis;
d. sepsis (requiring confirmation by blood test);
e. bacteremia;
f. changes in granulation tissue (change in the color of granulation tissue, which may appear dusky, darker or bright red, hypergranulation tissue, friable or fragile granulation tissue that is prone to bleeding);
g. increased or malodorous exudate;
h. new areas of slough or wound breakdown;

9. impaired or delayed wound healing (epidermis fails to migrate across the wound bed, static, rolled or undermined wound edges or bridging segments of epithelial closure and breakdown in the tissues);
10. increased or new pain.

Data collection and measures

Wound size was measured using tracing sheet and graph paper. Wound area was traced on a tracing sheet. The tracing was superimposed over a graph paper. Number of grids included in the area were measured to obtain the wound size in cm^2.

Measurements were taken at recruitment (baseline) and at two weekly intervals for 12 weeks or less if the patient healed. Antibiotics were administered according to culture - sensitivity reports.

The Statistical Package for the SocialSciences (SPSS) was used to analyze these data. Linear mixed models (LMM) and analysis of covariance (ANCOVA) were used to test the significance of data.

RESULTS

Overall 68.75% patients healed over the 12 week period (complete epithelization). Within each treatment group, a comparable number of patients healed; 70% from the silver group and 67.5% from the iodine group. Mean surface area reduction was noted to be 69.78% in silver group and 65.87% in iodine group. LMM and ANCOVA found no significant difference between the treatment groups in the overall wound healing rate, with the exception of the first 2 weeks.

For the first 2 weeks, the healing rate for the silver group was significantly higher than for the iodine group. Additional significant difference between the antimicrobials was detected for wounds that did not heal during the observation period. For this segment, the wounds were healing at a significantly quicker rate when treated with nanocrystalline silver compared with cadexomer iodine. No adverse reactions were noted.

Table 1 : pre trial clinical details of the patients

Clinical measure	Dressed with cadexomer iodine	Dressed with nanocrystalline silver
Number of patients	40	40
Males	28	23
Females	12	17

Age mean +/- SD (years)	63.5 +/- 1.8	64.8 +/- 2.8
Duration of ulceration mean +/- SD (months)	15 +/- 3.1	19.1 +/- 4.3
Area of ulceration mean +/- SD (cm2)	135.2 +/- 18.1	127.5 +/- 27.0

Table 2 : Time for ulcer healing in both groups

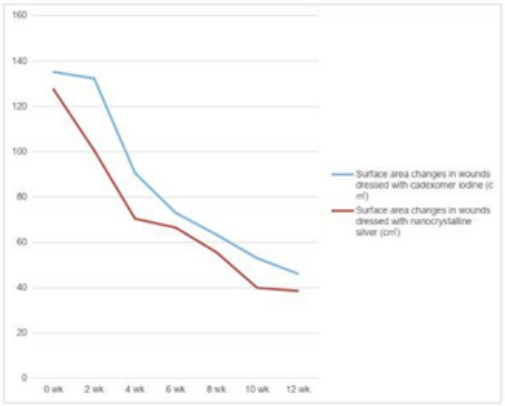
Week of observation	Patients who healed completely in cadexomer iodine group	Patients who healed completely in nanocrystalline silver group	Total number of patients
2	2 (5 %)	3 (7.5 %)	5 (6.25 %)
4	9 (22.5 %)	7 (17.5 %)	16 (20 %)
6	5 (12.5 %)	6 (15 %)	11 (13.75 %)
8	5 (12.5 %)	5 (12.5 %)	10 (12.5 %)
10	3 (7.5 %)	3 (7.5 %)	6 (7.5 %)
12	3 (7.5 %)	4 (10 %)	7 (8.75 %)
> 12	13 (32.5 %)	12 (30 %)	25 (31.25 %)
Total	40 (100 %)	40 (100 %)	80 (100 %)

Table 3 : Reduction in mean surface area of wounds in both treatment groups

Time in weeks	Mean surface area of wounds dressed with cadexomer iodine (cm2)	Mean surface area of wounds dressed with nanocrystalline silver (cm2)
0	135.2	127.5
2	132.23	100.47
4	90.58	70.43
6	73.01	66.46
8	63.37	55.62
10	52.98	39.93
12	46.14	38.53

Image 1: Ages of wound dressed with nanocrystalline silver at recruitment, 2 weeks and 4 weeks.

Chart 1 : Reduction in mean surface area of wounds in both treatment groups



Discussion

Effective healing of skin wounds implies the regeneration of normal skin by resurfacing with new epithelium. A number of silver and iodine compounds with antimicrobials activity are used for dressings. A gap in the evidence exists with regards to the effectiveness of cadexomer iodine when compared with nanocrystalline silver dressings.

While silver produces a quicker reduction in wound size, the lack of difference in overall clinical effectiveness of the treatment indicates that iodine operates in a different, although ultimately as effective manner. Iodine's noted inflammatory mechanism[6], which contrasts to silver's anti-inflammatory action[7] ,may explain the absence of an immediate wound size reduction observed in the iodine treatment group.

Wound healing trajectories[8] (healing time curves) have been reported to be effective outcome measures for leg ulcers and provide more information about the healing process while allowing for dynamic comparison at meaningful intervals. It was because of this approach, these nuances in the clinical effectiveness of the antimicrobial treatments could be identified in this study.

Summary

Although both antimicrobials were ultimately comparable over a 12-week period, our findings suggest that when wanting to achieve an immediate reduction in wound size and when attending clients with large and chronic leg ulcers or a history of protracted healing, a silver antimicrobial can be considered for the first choice.

Conflicts of interest

Nil.

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