

Original Article

To evaluate the effectiveness of octenidine dihydrochloride dressing and saline dressing in healing diabetic foot ulcers

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ABSTRACT:

Aim: The aim of this study was to evaluate the effectiveness of octenidine dihydrochloride dressing and saline dressing in healing diabetic foot ulcers. **Methods:** This was a prospective comparative study conducted among 120 patients, 60 patients in each arm of Octenidine dihydrochloride dressing group and Saline dressing group, with complaints of chronic DFU, were included in this study. Regular wound dressings were done with octenidine dihydrochloride topical ointment in one group and with saline in other group and the wounds were assessed regularly for healing progress during the study period. **Results:** The comparison between the outcomes of octenidine dihydrochloride dressing group and saline dressing group in terms of surface area reduction of wounds were made. The mean surface area of wound in saline group was: baseline- 11.1 sq.cm, 2nd week- 10.3 sq.cm, 4th week- 9.7 sq.cm, 6th week- 7.9 sq.cm; While in octenidine dihydrochloride group was: baseline- 11.9 sq.cm, 2nd week- 9.9 sq.cm, 4th week- 7.3 sq.cm, 6th week- 5.4 sq.cm. (table 2). After 6 weeks, the mean reduction in surface area of wound is more in the octenidine dihydrochloride dressing group compared with the saline dressing group and the results are statistically significant at a $p < 0.05$. **Conclusions:** We concluded that the Octenidine dihydrochloride dressing is more effective when compared to saline dressing in achieving rapid wound healing, preventing infections and decreasing morbidity in patients with chronic DFU.

Keywords: Diabetic foot ulcer, octenidine dihydrochloride, saline dressing, management

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INTRODUCTION

Diabetic foot ulcer (DFU) is the most costly and devastating complication of diabetes mellitus, which affect 15% of diabetic patients during their lifetime.¹ It is estimated that approximately 20% of hospital admissions among patients with DM are the result of DFU.² DFUs have a negative impact on patients' quality of life, increase the risk of infection and amputation³, and constitute a considerable economic burden for healthcare providers.⁴ Each year, an estimated 2–2.5% of people with diabetes develop a DFU. In England in 2014–15, the estimated cost of foot ulceration and amputation was £1 billion, and this figure is expected to rise in the future.⁵ It is, therefore, essential to identify and treat DFUs promptly to patient improve outcomes and reduce financial pressures on healthcare providers. The most common

risk factors for DFU formation are diabetic neuropathy and vascular disease⁶, which slow healing and increase the risk that wounds will become chronic. Biofilms and infection can also impact the rate of healing. The number of viable microorganisms present on a surface is known as the bioburden. Increased bioburden has been proposed as an important predictor of poor healing outcomes.⁷ Microorganisms (bacteria, fungi and protists) can change from single-celled free-moving forms to a structured community of cells known as a biofilm following attachment, growth and division phases. Mature biofilms are surrounded by a protective matrix, which makes them difficult to remove with antibiotics, antiseptics and disinfectants. At least 60% of chronic wounds have a biofilm.^{8,9} Their presence delays wound healing and they can act as a precursor

to infection if not managed effectively.^{8,9} Octenidine dihydrochloride is an antimicrobial with broad-spectrum efficacy and no known microbial resistance. It is a safe and effective agent that prevents bacterial growth.¹⁰ It is well tolerated, has no side effects and is not absorbed systemically. Octenidine also has deodorising properties, is active in as little as 60 seconds, and its biocidal activity lasts at least 48 hours. octenilin® wound irrigation solution (schülke) is a colourless, alcohol-free solution containing octenidine, which has been designed to cleanse and moisturise chronic wounds and burns. octenilin® has been shown to inhibit the formation of biofilm material for up to 3 days.¹⁰ It can also be used to loosen encrusted dressings and cleanse hard-to-reach areas, such as small fissures and wound pockets. octenilin® irrigation solution contains ethylhexylglycerin, which has surfactant, emollient, skin-conditioning and antimicrobial properties. Ethylhexylglycerin reduces the surface tension of aqueous solutions, enhancing its wetting behaviour.¹⁰ The aim of this study was to evaluate the effectiveness of octenidine dihydrochloride dressing and saline dressing in healing diabetic foot ulcers.

MATERIAL AND METHODS

This was a prospective comparative study conducted in the Department of General Surgery after taking the approval of the protocol review committee and institutional ethics committee. After taking informed consent detailed history was taken from the patient. The technique, risks, benefits, results and associated complications of the procedure were discussed with all patients. A total of 120 patients, 60 patients in each arm of Octenidine dihydrochloride dressing group and Saline dressing group, with complaints of chronic DFU, were included in this study. Regular wound dressings were done with octenidine dihydrochloride topical ointment in one group and with saline in other group and the wounds were assessed regularly for healing progress during the study period.

INCLUSION CRITERIA

All Patients with diabetic foot ulcers of greater than 6 weeks duration, who were willing to be a part of the

study. Only clinically clean wounds without any signs of acute inflammation were included in the study.

EXCLUSION CRITERIA

- Patients with cellulitis
- active wound infection,
- venous insufficiency and venous ulcers.
- Patient with previous history of autoimmune disease.

STATISTICAL ANALYSIS

The study data was analysed to evaluate the effect of octenidine dihydrochloride topical ointment dressing over saline dressing. SPSS 21.0 were used in this analysis. Chi-square test is used to evaluate the results and $p < 0.05$ is considered to be significant.

RESULTS

A total of 100 subjects with 50 in each group of octenidine dihydrochloride group and saline group completed the follow-up period. Among the total of 120 subjects, 93(77.5%) were male and 27 (22.5%) were female. There was a male preponderance in both the groups (73.33% males in octenidine dihydrochloride group and 81.67% males in saline group). Mean age was 56.87 in octenidine dihydrochloride group and 55.63 in saline dressing group. About 58.33% in octenidine dihydrochloride group and 55% in saline group had a habit of smoking and 41.67% in octenidine dihydrochloride group and 35% in saline group had a habit of alcohol consumption. Among the blood investigations done, haemoglobin (Hb) was taken into consideration for statistical analysis. Mean Hb in octenidine dihydrochloride group was 10.7 gm% and in saline group was 11.4 gm%. Mean duration of diabetes was 11.3 years in octenidine dihydrochloride group and 11.1 years in saline group. Mean duration of existence of chronic wounds was 7.5 months in octenidine dihydrochloride group and 8.5 months in saline group. Both the groups were comparable in terms of demographic characteristics, habits, lab investigations, duration of diabetes and duration of chronic diabetic foot ulcer. (Table 1).

Table 1: Demographic Profile in both group

Parameter	Octenidine dihydrochloride dressing	Saline dressing
Age	56.87	55.63
Gender		
Male	44 (73.33%)	49(81.67%)
Female	16 (26.67%)	11 (18.33%)
Smoking	35 (58.33%)	33 (55%)
Alcohol	25(41.67%)	21(35%)
Duration		
Diabetes (in years)	11.3	11.1
DFU (in months)	7.5	8.8
Hemoglobin	10.7	11.4

Table 2. Reduction in surface area of wound

Surface area reduction of wounds	Octenidine dihydrochloride dressing	Saline dressing
Baseline	11.9 sq.cm	11.1 sq.cm
2nd week	9.9 sq.cm	10.3sq.cm
4th week	7.3 sq.cm	9.7 sq.cm
6th week	5.4 sq.cm	7.9 sq.cm

The comparison between the outcomes of octenidine dihydrochloride dressing group and saline dressing group in terms of surface area reduction of wounds were made. The mean surface area of wound in saline group was: baseline- 11.1 sq.cm, 2nd week- 10.3 sq.cm, 4th week- 9.7 sq.cm, 6th week- 7.9 sq.cm; While in octenidine dihydrochloride group was: baseline- 11.9 sq.cm, 2nd week- 9.9 sq.cm, 4th week- 7.3 sq.cm, 6th week- 5.4 sq.cm. (table 2). After 6 weeks, the mean reduction in surface area of wound is more in the octenidine dihydrochloride dressing group compared with the saline dressing group and the results are statistically significant at a $p < 0.05$.

DISCUSSION

The aim of wound dressing is to provide a relatively clean wound with low bacteria count that provides optimal environment for healing.¹¹ The role of saline as a dressing material has been studied by many authors.¹²⁻¹⁴ Most of the studies involving saline dressing were conducted on different types of diabetic wounds show similar results as that of ours. DFUs have different characteristic in term of polymicrobial nature of infection, compromised tissue vascularity, loss of sensation and potentially deep seated infection.¹⁵ Octenidine dihydrochloride is a novel bispyridine compound and was introduced more than 20 years ago. It is a safe and effective against gram-positive and gram-negative bacteria.¹⁶ It has no known microbial resistance and is well tolerated with no side effects.¹⁰ Eisenbeiss et al.¹⁷ in his prospective randomised study of 61 patients with superficial skin graft donor site wounds, it significantly lowered microbial colonisation compared to placebo. The aim of wound dressing is to provide a relatively clean wound with low bacteria count that provides optimal environment for healing.¹⁸ In our study the The mean surface area of wound in saline group was: baseline- 11.1 sq.cm, 2nd week- 10.3 sq.cm, 4th week- 9.7 sq.cm, 6th week- 7.9 sq.cm; While in octenidine dihydrochloride group was: baseline- 11.9 sq.cm, 2nd week- 9.9 sq.cm, 4th week- 7.3 sq.cm, 6th week- 5.4 sq.cm. (table 2). After 6 weeks, the mean reduction in surface area of wound is more in the octenidine dihydrochloride dressing group compared with the saline dressing group and the results are statistically significant at a $p < 0.05$.

Many different types of dressings for DFU have been studied by many authors.¹⁹ DFUs have different characteristic in term of poly-microbial nature of infection, compromised tissue vascularity, loss of sensation and potentially deep-seated infection.²⁰ When Octenidine dihydrochloride is used in

conjunction with debridement and systemic antibiotics as part of biofilm-based wound care, it is capable of managing bio-burden in chronic wounds and helps in rapid healing.

CONCLUSION

We concluded that the Octenidine dihydrochloride dressing is more effective when compared to saline dressing in achieving rapid wound healing, preventing infections and decreasing morbidity in patients with chronic DFU.

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