

A prospective comparative evaluation of octenidine dihydrochloride and saline dressing in the management of diabetic foot ulcers

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Abstract

Aim: 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, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India for 18 months. A total of 100 patients, 50 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:** 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 100 subjects, 76(76%) were male and 24 (24%) were female. There was a male preponderance in both the groups (72% males in octenidine dihydrochloride group and 80% males in saline group). Mean age was 57.1 in octenidine dihydrochloride group and 56.3 in saline dressing group. About 52% in octenidine dihydrochloride group and 50% in saline group had a habit of smoking and 40% in octenidine dihydrochloride group and 36% 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 10.8 gm% and in saline group was 11.5 gm%. Mean duration of diabetes was 10.8 years in octenidine dihydrochloride group and 10.2 years in saline group. The comparison between the outcomes of octenidine dihydrochloride dressing group and saline dressing group in terms of surface area reduction of wounds were made. **Conclusion:** octenidine dihydrochloride dressing is more effective than saline dressing in achieving complete healing, reducing wound surface area, and decreasing morbidity in patients with DFU.

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

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Introduction

Foot ulcers are a common and disabling condition in people with diabetes, having a global prevalence of 6.3%. Men are more likely than women to develop a diabetic foot ulcer (DFU) and people with type 2 diabetes are at greater risk than those with type 1 diabetes.[1] DFUs have a negative impact on patients' quality of life, increase the risk of infection and amputation[2,3], 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

Biofilms and infection can also impact the rate of healing. The number of viable microorganisms present on a surface is known as the bio burden. Increased bio burden 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

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formation are diabetic neuropathy and vascular disease[6], which slow healing and increase the risk that wounds will become chronic.

days.[10] It can also be used to loosen encrusted dressings and cleanse hard-to-reach areas, such as small fissures and wound pockets.[11]

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 presence of ethylhexylglycerin therefore optimises the spread of octenilin® irrigation solution into all wound fissures. 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, Indira Gandhi Institute of Medical Sciences Patna, Bihar, India for 18 months, after taking the approval of the protocol review committee and institutional ethics committee.

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.

Methodology

The technique, risks, benefits, results and associated complications of the procedure were discussed with all patients. A total of 100

patients, 50 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

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 100 subjects, 76(76%) were male and 24 (24%) were female. There was a male preponderance in both the groups (72% males in octenidine dihydrochloride group and 80% males in saline group). Mean age was 57.1 in octenidine dihydrochloride group and 56.3 in saline dressing group. About 52% in octenidine dihydrochloride group and 50% in saline group had a habit of smoking and 40% in octenidine dihydrochloride group and 36% 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 10.8 gm% and in saline group was 11.5 gm%. Mean duration of diabetes was 10.8 years in octenidine dihydrochloride group and 10.2 years in saline group. Mean duration of existence of chronic wounds was 8 months in octenidine dihydrochloride group and 9 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: Comparing demographic parameters in both group

Parameter	Octenidine dihydrochloride dressing	Saline dressing
Age	57.1	56.3
Gender		
Male	36 (72%)	40(80%)
Female	14 (28%)	10 (40%)
Smoking	26 (52%)	25 (50%)
Alcohol	20(40%)	18 (36%)
Duration		
Diabetes (in years)	10.8	10.2
DFU (in months)	8	9
Hemoglobin	10.8	11.5

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- 10.8 sq.cm, 2nd week- 10.1 sq.cm, 4th week- 9.5 sq.cm, 6th week- 8.1 sq.cm; While in octenidine

dihydrochloride group was: baseline- 12.3 sq.cm, 2nd week- 10.1 sq.cm, 4th week- 7.2 sq.cm, 6th week- 5.3 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 $p < 0.05$.

Table 2: Comparison between outcomes of Octenidine dihydrochloride dressing group and saline dressing group in terms of reduction in surface area of wound

surface area reduction of wounds	Octenidine dihydrochloride dressing	Saline dressing
Baseline	12.3 sq.cm	10.8 sq.cm
2nd week	10.1 sq.cm	10.1sq.cm
4th week	7.2 sq.cm	9.5 sq.cm
6th week	5.3 sq.cm	8.1 sq.cm

Discussion

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.[12] It has no known microbial resistance and is well tolerated with no side effects.¹⁰ Eisenbeiss et al.[13] 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.[14] In our study the mean surface area of wound in saline group was: baseline- 10.8 sq.cm, 2nd week- 10.1 sq.cm, 4th week- 9.5 sq.cm, 6th week- 8.1 sq.cm; While in octenidine dihydrochloride group was: baseline- 12.3 sq.cm, 2nd week- 10.1 sq.cm, 4th week- 7.2 sq.cm, 6th week- 5.3 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.[15] DFUs have different characteristic in term of poly-microbial nature of infection, compromised tissue vascularity, loss of sensation and potentially deep-seated infection.[16] 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. Furthermore, Octenidine dihydrochloride dressing has broad spectrum anti-microbial activity which takes care of bio-film that forms frequently in patients with diabetes. Hence Octenidine dihydrochloride dressing is preferred over saline dressing in chronic DFU patients.

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