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## Octenidine dihydrochloride dressing versus saline dressing in diabetic foot ulcers: a prospective comparative study

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### Abstract

**Background:** Diabetic foot ulcers (DFU) are commonly encountered during clinical practice and are often difficult to treat. The aim of this study was to evaluate the effectiveness of octenidine dihydrochloride dressing and saline dressing in healing diabetic foot ulcers.

**Methods:** A total of 50 patients (25 patients in each group of octenidine dihydrochloride and saline dressing group) with complaints of chronic diabetic foot ulcer attending surgery outpatient department of Sri Ramakrishna Hospital were included in this prospective comparative study from September 2018 to November 2019. Dressings were done on daily basis for a period of 6 weeks, and the results were compared on 2nd, 4th and 6th week, using reduction in surface area of the wound as parameter of healing process. Other parameters such as age, gender, associated co morbidities were assessed.

**Results:** The mean surface area of wound in saline group was: baseline- 10.2 sq.cm, 2nd week- 9.8 sq.cm, 4th week- 8.6 sq.cm, 6th week- 7.5 sq.cm; While in octenidine dihydrochloride group was: baseline- 11.8 sq.cm, 2nd week- 9.6 sq.cm, 4th week- 6.8 sq.cm, 6th week- 5.2 sq.cm. 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:** 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

### Introduction

Diabetic foot ulcers (DFU) are the most common complication encountered in diabetics during the course of the disease. India being the diabetic capital of the world, DFU are more frequently encountered by clinical practitioners in day to day life. They have a global prevalence of 6.3%. Each year, an estimated 2–2.5% of people with diabetes develop a DFU [1]. Men are more likely to be affected with diabetic foot ulcers than women. Studies suggest that patients with type 2 diabetes are at greater risk of developing foot ulcers than those with type 1 diabetes [2]. The management of DFU is often challenging to surgeons due to varied reasons, especially their chronicity. Most of the time DFUs have a delayed wound healing because of their propensity to form a biofilm over the wound. This will have an increased rate of wound infection and eventually land up in amputation of limb, severely affecting the quality of life of diabetic patients. The number of viable microorganisms present on the wound surface is known as the bio-burden, which is an important factor in deciding the rate of healing. Adequate debridement, proper dressings with topical agents and use of appropriate systemic antibiotics will collectively help in faster healing and better prognosis in such patients. Octenidine dihydrochloride is an antimicrobial with broad-spectrum efficacy and no known microbial resistance [3]. This study focuses on the use of octenidine, which contains a broad-spectrum antimicrobial, in the treatment of DFUs to address bio-burden, prevent infection and progress wound healing.

### Material and methods

This was a prospective comparative study with duration from September 2018 to November 2019. A total of 50 patients, 25 patients in each arm of Octenidine dihydrochloride dressing group and Saline dressing group, with complaints of chronic DFU, attending Surgery Outpatient

Department of Sri Ramakrishna Hospital were included in this study. Study was undertaken after the approval from the Hospital Ethics Committee. Informed written consent was taken from all the patients after explaining to them, the procedure and purpose of 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 (Figure1-4).



Fig 1



Fig 2



Fig 3



Fig 4

Fig 1 to 4: showing the decrease in wound surface area after the use of octenidine dihydrochloride dressing.

#### 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.
- Those who refuse to be a part of the study.

#### Statistical analysis

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

#### Results

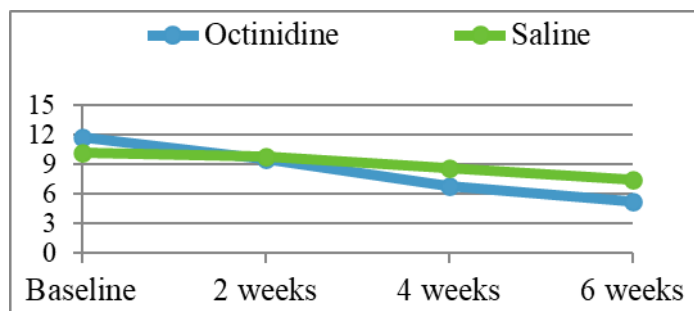
A total of 50 subjects with 25 in each group of octenidine

dihydrochloride group and saline group completed the follow-up period. Among the total of 50 subjects, 35 (75%) were male and 15 (25%) were female. There was a male preponderance in both the groups (68% males in octenidine dihydrochloride group and 72% males in saline group). Mean age was 56.4 in octenidine dihydrochloride group and 55.8 in saline dressing group. About 48% in octenidine dihydrochloride group and 44% in saline group had a habit of smoking and 36% in octenidine dihydrochloride group and 40% 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 10.6 gm% and in saline group was 11.2 gm%. Mean duration of diabetes was 11.5 years in octenidine dihydrochloride group and 10 years in saline group. Mean duration of existence of chronic wounds was 7 months in octenidine dihydrochloride group and 8 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 various parameters in both group

Parameter	Octenidine dihydrochloride dressing	Saline dressing
Age	56.4	55.8
Gender		
Male	17 (68%)	18 (72%)
Female	8 (32%)	7 (28%)
Smoking	12 (48%)	11 (44%)
Alcohol	9 (36%)	10 (40%)
Duration		
Diabetes (in years)	11.5	10
DFU (in months)	7	8
Hemoglobin	10.6	11.2

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- 10.2 sq.cm, 2nd week- 9.8 sq.cm, 4th week- 8.6 sq.cm, 6th week- 7.5 sq.cm; While in octenidine dihydrochloride group was: baseline- 11.8 sq.cm, 2nd week- 9.6 sq.cm, 4th week- 6.8 sq.cm, 6th week- 5.2 sq.cm. (Graph 1). 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  $p < 0.05$ .



**Graph 1:** Comparison between outcomes of Octenidine dihydrochloride dressing group and saline dressing group in terms of reduction in surface area of wound

### 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 [3]. It has no known microbial resistance and is well tolerated with no side effects [4]. Eisenbeiss *et al.* [5], 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 [6]. Many different types of dressings for DFU have been studied by many authors [7]. DFUs have different characteristic in term of poly-microbial nature of infection, compromised tissue vascularity, loss of sensation and potentially deep-seated infection [8]. 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

It is evident from the study 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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