

## Original Research

### To compare the Octenidine dihydrochloride dressing versus saline dressing in diabetic foot ulcers

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#### ABSTRACT:

**Aim:** The purpose of this research was to determine whether or not a dressing containing octenidine dihydrochloride or a dressing containing saline is more successful in treating diabetic foot ulcers. **Material and methods:** The Department of General Surgery was the location of this prospective comparative study that was carried out. This research comprised a total of 200 patients, with persistent DFU symptoms; 100 patients were assigned to each of the two treatment arms (saline dressing group and octenidine dihydrochloride dressing group), for a total of 200 patients. In one group, regular wound dressings were done using octenidine dihydrochloride topical ointment, while in the other group, regular wound dressings were done with saline. Over the course of the trial, the wounds were evaluated on a regular basis to see how well they were healing. **Results:** The octenidine dihydrochloride group had a mean age of  $56.96 \pm 4.59$  years, whereas the saline dressing group had a mean age of  $57.99 \pm 5.63$  years. Approximately 39% of people in the octenidine dihydrochloride group and 35% of people in the saline group had a habit of drinking alcohol. About 51% of people in the saline group smoked cigarettes, whereas only 49% of people in the octenidine dihydrochloride group did so. In addition to the blood tests that were performed, the concentration of haemoglobin (Hb) was taken into account for the statistical analysis. In the saline group, the mean surface area of the wound at baseline was 10.9 square centimeters; in the octenidine dihydrochloride group, the mean surface area of the wound at baseline was 12.4 square centimeters; in the 2nd week, it was 10.2 square centimeters; in the 4th week, it was 9.6 square centimeters; and in the 6th week, it was 8.2 square centimeters. **Conclusions:** We came to the conclusion that the dressing containing octenidine dihydrochloride is more efficient than the dressing containing saline when it comes to attaining quick wound healing, avoiding infections, and reducing morbidity in patients who have chronic DFU. In addition, octenidine dihydrochloride dressing has wide range anti-microbial action, which eliminates the biofilm that usually develops in diabetic patients. Because of this, octenidine dihydrochloride dressing is recommended for patients with chronic DFU rather than saline dressing.

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

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#### INTRODUCTION

Diabetic foot ulcers are a frequent and debilitating ailment, with a worldwide frequency of 6.3%. These ulcers may occur anywhere on the foot. Those who have type 2 diabetes are at a larger risk of developing diabetic foot ulcers (DFU) than those who have type 1 diabetes, and males are more likely to acquire diabetic foot ulcers than women are.<sup>1</sup> DFUs have a detrimental effect on the patients' quality of life, raise the risk of infection and amputation<sup>2,3</sup>, and place a significant financial burden on the healthcare providers.<sup>4</sup> An estimated 2–2.5% of diabetics may develop a diabetic foot ulcer each and every year. One billion pounds was reported to have been spent on

foot ulceration and amputation in England in the fiscal year 2014–2015, and it is anticipated that this sum would increase in the years to come.<sup>5,6</sup> Thus, it is very necessary to rapidly diagnose and treat DFUs in order to improve outcomes for patients and lessen the financial demands placed on healthcare providers. Diabetic neuropathy and vascular disease are two of the most prevalent risk factors for diabetic foot ulcer development. Both of these conditions impede the healing process and increase the likelihood that wounds will become chronic. The pace at which a wound heals may also be affected by biofilms and infections. The amount of living microorganisms that may be found on a surface is referred to as the

bioburden of that surface. It has been suggested that increased bioburden is a significant factor that plays a role in poor healing results.<sup>7</sup> After going through the processes of attachment, development, and division, microorganisms (including bacteria, fungus, and protists) are able to transform from their single-celled, free-moving forms into a structured community of cells known as a biofilm. Antibiotics, antiseptics, and disinfectants all have a tough time removing mature biofilms because they are encased in a protective matrix and are surrounded on all sides by it. A biofilm is present in at least sixty percent of all chronic wounds.<sup>8,9</sup> Because of their existence, wound healing is slowed down, and if they are not successfully treated, they might serve as a gateway for infection.<sup>8,9</sup> Octenidine dihydrochloride is an antibiotic that is effective against a wide variety of bacteria and has not been shown to be resistant to any microbes. It is an agent that is both safe and effective in preventing the development of germs.<sup>10</sup> It is well tolerated, it does not have any adverse effects, and it is not absorbed throughout the body. Moreover, octenidine has the ability to eliminate unpleasant odors, may become active in as little as sixty seconds, and maintains its biocidal action for at least forty-eight hours. Octenilin® wound irrigation solution (Schuke) is an odorless, alcohol-free solution that contains octenidine. Its purpose is to wash and moisturize chronic wounds and burns. Octenilin® wound irrigation solution (Schuke) has no color. It has been shown that treatment with octenilin® may prevent the production of biofilm material for up to three days.<sup>10</sup> In addition to this, it may be used to dislodge crusted dressings and clean difficult-to-access regions, such as minor fissures and wound pockets.<sup>11</sup> octenilin® irrigation solution has ethylhexylglycerin, which is a compound that can act as a surfactant, an emollient, improve the condition of the skin, and fight microorganisms. Ethylhexylglycerin has the ability to lower the surface tension of aqueous solutions, which in turn improves the wetting behavior of those solutions.<sup>10</sup> Because of this, the presence of ethylhexylglycerin ensures that the octenilin® irrigation solution is distributed evenly throughout all of the wound fissures. This research was conducted with the intention of determining whether or not a dressing containing octenidine dihydrochloride or a dressing containing saline is more effective in healing diabetic foot ulcers.

## MATERIAL AND METHODS

After receiving clearance from the protocol review committee and the institutional ethics committee, this research was a prospective comparison that was carried out within the Department of General Surgery. The patient's background was thoroughly questioned after receiving their informed permission first. Every patient was given an explanation of the operation, as well as its method, risks, advantages, and outcomes, as well as any related problems. This research

comprised a total of 200 patients, with persistent DFU symptoms; 100 patients were assigned to each of the two treatment arms (saline dressing group and octenidine dihydrochloride dressing group), for a total of 200 patients. In one group, regular wound dressings were done using octenidine dihydrochloride topical ointment, while in the other group, regular wound dressings were done with saline. Over the course of the trial, the wounds were evaluated on a regular basis to see how well they were healing.

## INCLUSION CRITERIA

Individuals who had diabetic foot ulcers that had been present for more than six weeks before to the start of the trial and who were willing to take part in it. Throughout the research, we only included wounds that were completely free of any symptoms of acute inflammation and clinically clean.

## EXCLUSION CRITERIA

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

## STATISTICAL ANALYSIS

The data from the study were analyzed to determine whether or not applying octenidine dihydrochloride topical ointment dressing was more effective than applying saline dressing. In order to conduct this analysis, both the SPSS software and the Microsoft Excel software are utilized. The significance of the findings is determined with a Chi-square test, and a value of  $p$  less than 0.05 is required for acceptance.

## RESULTS

The follow-up period was successful for a total of 200 people, with 100 participants in each of the two groups (octenidine dihydrochloride group and saline group). 150 of the total 200 participants were male, which is 75% of the total, and 50 of the total were female, which is 25%. There was a significant gender disparity between the two study groups, with 71% of participants in the octenidine dihydrochloride group being male and 79% of participants in the saline group being male. The octenidine dihydrochloride group had a mean age of  $56.96 \pm 4.59$  years, whereas the saline dressing group had a mean age of  $57.99 \pm 5.63$  years. Approximately 39% of people in the octenidine dihydrochloride group and 35% of people in the saline group had a habit of drinking alcohol. About 51% of people in the saline group smoked cigarettes, whereas only 49% of people in the octenidine dihydrochloride group did so. In addition to the blood tests that were performed, the concentration of haemoglobin (Hb) was taken into account for the statistical analysis. The octenidine dihydrochloride group had a mean hemoglobin level of 10.70 gm%, whereas the saline group had a mean Hb level of 11.60 gm%. The octenidine dihydrochloride group had a mean duration

of diabetes of 11.11 years, whereas the saline group had a mean duration of diabetes of 10.22 years. The average length of time that chronic wounds lasted was 7.5 months in the group that received octenidine dihydrochloride and 8.5 months in the group that

received saline. Both groups were similar in terms of demographics, behaviors, laboratory examinations, length of time with diabetes, and length of time with chronic diabetic foot ulcers (Table 1).

**Table 1: Comparing demographic parameters in both group**

Parameter	Octenidine dihydrochloride dressing	Saline dressing
Age	56.96±4.59	57.99±5.63
Gender		
Male	71	79
Female	29	21
Smoking	51	49
Alcohol	39	35
Duration		
Diabetes (in years)	11.11	10.22
DFU (in months)	7.5	8.5
Hemoglobin	10.70	11.60

In this study, the results of the octenidine dihydrochloride dressing group and the saline dressing group were compared with regard to the amount of surface area decrease experienced by the wounds. In the saline group, the mean surface area of the wound at baseline was 10.9 square centimeters; in the octenidine dihydrochloride group, the mean surface area of the wound at baseline was 12.4 square

centimeters; in the 2nd week, it was 10.2 square centimeters; in the 4th week, it was 9.6 square centimeters; and in the 6th week, it was 8.2 square centimeters (table 2). At six weeks, the findings are statistically significant at the  $p < 0.05$  level if the mean decrease in surface area of the wound is greater in the octenidine dihydrochloride dressing group compared to the saline dressing group.

**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	12.4 sq.cm	10.9 sq.cm
2nd week	10.2 sq.cm	10.2sq.cm
4th week	7.3 sq.cm	9.6 sq.cm
6th week	5.4 sq.cm	8.2 sq.cm

## DISCUSSION

Since its discovery more than two decades ago, octenidine dihydrochloride has been considered a new bispyridine chemical. It is efficient against both gram-positive and gram-negative bacteria, and it is also safe to use.<sup>12</sup> It is well tolerated and there are no known adverse effects or microbial resistance associated with it.<sup>10</sup> In a prospective randomized trial conducted by Eisenbeiss et al.<sup>13</sup> on 61 patients with superficial skin graft donor site wounds, the researchers found that it dramatically reduced microbial colonization in comparison to the placebo. The purpose of applying a wound dressing is to ensure that the wound is reasonably clean, has a low bacterial count, and is in an ideal environment for the healing process.<sup>14</sup> In our research, the mean surface area of wounds in the saline group was: 10.9 sq.cm at the beginning of the study, 10.2 sq.cm after two weeks, 9.6 sq.cm after four weeks, and 8.2 sq.cm after six weeks. The mean surface area of wounds in the octenidine dihydrochloride group was: 12.4 sq.cm at the beginning of the study, 10.2 sq.cm after two weeks, 7.3 sq. (table 2). At six weeks, the findings are

statistically significant at the  $p < 0.05$  level if the mean decrease in surface area of the wound is greater in the octenidine dihydrochloride dressing group compared to the saline dressing group. Several writers have conducted research on a wide variety of various kinds of dressings for DFU. There are distinct types of DFUs, each of which exhibits a unique feature in terms of the polymicrobial nature of the infection, reduced tissue vascularity, loss of feeling, and the possibility of a deep-seated infection.<sup>15,16</sup> When octenidine dihydrochloride is used as part of biofilm-based wound care in combination with debridement and systemic antibiotics, it is capable of controlling bio-burden in chronic wounds and assists in the process of speedy healing.

## CONCLUSION

We came to the conclusion that the dressing containing octenidine dihydrochloride is more efficient than the dressing containing saline when it comes to attaining quick wound healing, avoiding infections, and reducing morbidity in patients who have chronic DFU. In addition, octenidine

dihydrochloride dressing has wide range antimicrobial action, which eliminates the biofilm that usually develops in diabetic patients. Because of this, octenidine dihydrochloride dressing is recommended for patients with chronic DFU rather than saline dressing.

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