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Original Research Article

Clinical study in management of infected diabetic foot ulcers: superoxidised solution versus povidine iodine solution

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ABSTRACT

Background: Diabetic foot ulcer is a one of the major challenging problem to every surgeon in day to day practice. Superoxidised solution is an effective concept in the wound management. The present study was aimed to compare the efficacy of dressings with superoxidised solution versus povidine iodine in the management of infected diabetic ulcers.
Methods: This is a randomized controlled study conducted over a period of one year. In our study, total of 60 patients presenting with infected diabetic ulcers are included. Patients were randomly divided into two groups of 30 each, group A (Topical superoxidised solution dressing) and group B (Topical povidine iodine dressing). Wound was observed for decrease in size of the ulcer, granulation, tissue quality and discharge from the wound at the end of each week for two weeks.
Results: In the present study, 76.67% of patients in group A and B were males and the male to female ratio was 3.2:1. The mean age in group A was 55.90±14.27 years compared to 51.50±13.18 years in group B. The mean initial ulcer area in group A was 3882±1890 mm^2 compared to 3992±2000 mm^2 in group B. The mean post treatment final area in group A was significantly low (1607±862 mm^2) compared to group B (2351±1240 mm^2; p=0.009) and the comparison of mean change in ulcer area was significantly high in group A compared to group B (2215±1060 mm^2 vs 1641±856 mm^2; p=0.024). The mean percentage reduction in ulcer area among patients with group A was significantly high (58.90±5.21 percent vs. 40.90±8.76 percent; p=0.024). The commonest organism isolated in group A was *Escherichia coli* (26.67%) and in group B, it was staphylococcus. The culture was positive in 26% of the patients in group A compared to 50% in group B (p=0.063).
Conclusions: Overall, topical superoxidised solution dressing for diabetic foot ulcer accelerated the healing process resulting in faster recovery through reduction in ulcer area compared to topical povidine iodine dressing.

Keywords: Diabetic foot ulcer, Superoxidised solution dressings, Topical povidine iodine

INTRODUCTION

Diabetes mellitus is most common noncommunicable chronic disease in India affecting about 7% of adult population. Non-healing foot ulcers one among the many complications that increase the morbidity of the patients. This will increase fear and concerns for the patients and more daunting task for the surgeons and physicians. Super added infections can further increase duration of healing or may potentially ending in the loss of the limb. One of the major causes of non-healing of ulcer in diabetes is infection caused by a variety of micro-organism such as *Staphylococcus aureus* and *Pseudomonas aeruginosa* which invade the wound and multiply, producing harmful toxic substances, causing destruction of tissue and disturbance in wound healing.[1] The most effective steps in management of diabetic foot ulcers include offloading the wound by using appropriate

therapeutic footwear, daily dressings to provide a moist wound environment, debridement, parenteral antibiotic therapy (if osteomyelitis or cellulitis is present), glycemic control, and evaluation and correction of peripheral arterial insufficiency.[2-5] The major role of surgeon comes in wound care in the management of diabetic ulcers. An ideal wound care product in addition to controlling the infection should also protect the normal tissues and not interfere with normal wound healing.[6]

Many topical agents are being used for infected ulcers for local dressing like, Povidine iodine, EUSOL, Hydrogen peroxide, Acetic acid, local antibiotics with each having their own limitations. Superoxidised solution is a new concept in wound management with electrochemically processed aqueous solution and neutral ph. They have shown to be both safe and efficient as a wound care product that moistens, lubricates, debrides and reduces the microbial load of various type of wounds.[7] It is significantly less toxic than antiseptic hydrogen peroxide concentrations and it does not induce genotoxicity or accelerated ageing.[8]

However, superoxidised solution, being a new concept, very few studies assessed the role of these dressings in the management of infected diabetic ulcers especially in rural Indian context. Hence the present study was undertaken to compare the efficacy of dressings with superoxidised solution versus povidine iodine (mot commonly used topical agent in many rural part of south India) in the management of infected diabetic ulcers.

METHODS

The study was a randomized control trial. Diabetic patients of age more than 30 years, type 2 DM, patients with controlled diabetes with fasting blood glucose levels less than 126 mg/dL, patients having infected diabetic ulcers measuring more than 1cms, with slough, foul smell and minimal granulation tissue, patients with grade1 and grade 2 of Wagner's classification were included in this study, whereas type1 DM patients, foot ulcers of Grade 3, 4 and 5 Wagner's classification and patients with absent peripheral pulses were excluded. The approval from the ethical and research committee board was obtained before the commencement of the study. The written informed consent was taken from all the subjects.

A total of 60 patients were divided into two groups of 30 each by computer generated random numbers. The patients in group A are managed with dressing using topical superoxidised solution, whereas those in group B received dressing with povidine iodine.

Predesigned proforma used for all subjects to collect detailed data such as age, sex, duration and type of diabetes, diabetic treatment, ulcer site, discharge was noted. Further these patients were subjected to clinical examination and the findings were noted. Wound discharge was sent for culture and sensitivity. Empirical antibiotics– Ciprofloxacin and Metronidazole were started and changed to sensitive antibiotics after sensitivity report.

Surgical debridement was done whenever necessary. Foot ulcer of each subjects was thoroughly washed with normal saline and then topically used superoxidised solution (group A subjects) and povidine iodine (group B subjects). The culture was repeated after 10 days of the dressing.

Ulcer size was assessed at the end of every week. Ulcer mapping was made and the size recorded by superimposing a gauze over the ulcer and thus assessing the largest dimensions of the ulcer. Size was measured twice and the mean of the both measurements was considered as the size of the wound. Wound was observed for decrease in size of the ulcer, type of granulation, tissue quality and discharge from the wound at the end of each week for two weeks (Figure 1 A and 1 B).

Figure 1: A) Ulcer before dressing; B) Decrease in ulcer size after dressing with superoxidised solution.

The categorical data was expressed as rates, ratios and percentages and comparison was done using Chi-square test and Fishers exact test. Continuous data was expressed as mean±standard deviation and the comparison was done using unpaired 't' test. The 'p' value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

In this study, 76.67% of patients were males in group A and B compared to 23.33% of females (Figure 2). The male to female ratio was 3.2:1.

Though there was male preponderance the sex distribution between group A and B was comparable (p=1.000). The mean age of group A was slightly high (55.90±14.27 years) compared to group B (51.50±13.18

years) but the difference was statistically not significant (p=0.227) (Figure 3).

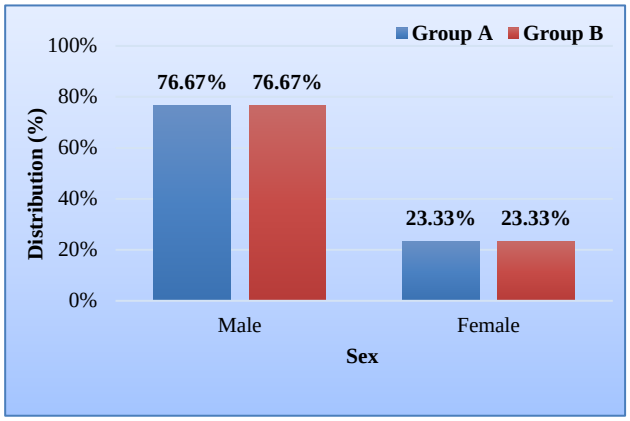

Figure 2: Sex distribution.

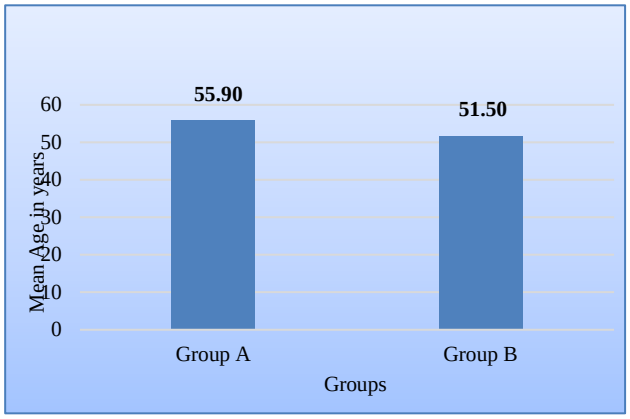

Figure 3: Comparison of mean age.

The mean initial ulcer area in group A was 3882±1890 mm^2 compared to group B which was 3992±2000 mm^2, however the difference was statistically not significant (p=0.736) (Figure 4). The above findings on age, sex, diabetic history including type, duration, and treatment and the ulcer characteristics were comparable in both the groups.

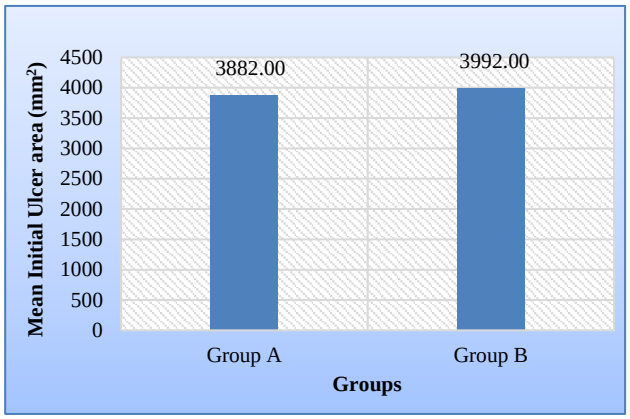

Figure 4: Comparison of initial ulcer area.

The final mean ulcer area in group A was found to be significantly low compared to group B (1607±862 versus 2351±1240 mm^2; p=0.009) (Figure 5).

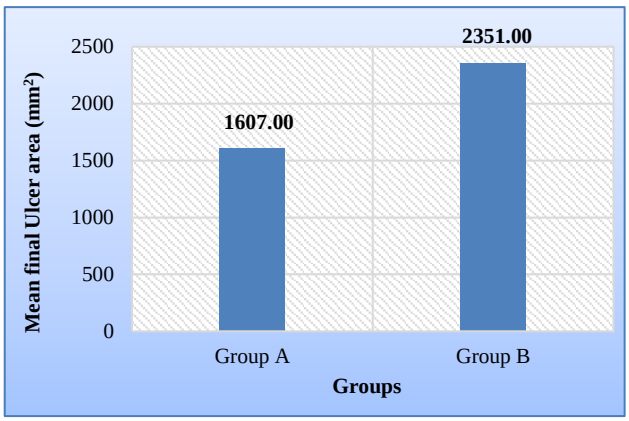

Figure 5: Comparison of final ulcer area.

The comparison of mean change in ulcer area was also significantly high in group A that is, 2215±1060 mm^2 compared to group B that is, 1641±856 mm^2 (p=0.024). Similarly, the mean percentage reduction in ulcer area in group A was significantly high that is, 58.90±5.21 percent compared to 40.90±8.76 percent in group B (p=0.024) (Figure 6).

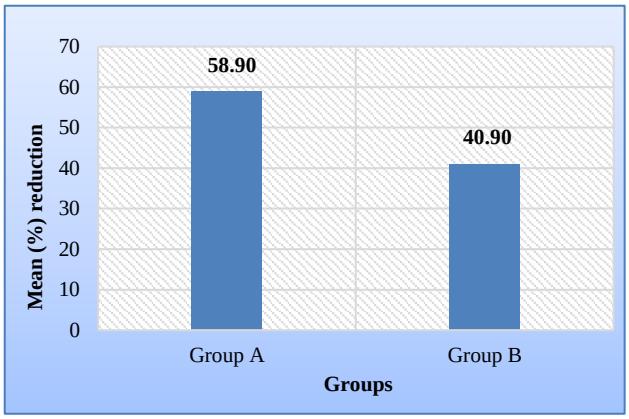

Figure 6: Percentage reduction in ulcer area.

In this study, *Escherichia coli* and pseudomonas were the commonest organisms isolated in patients with group A (26.67% each) followed by Streptococcus, Proteus and Acinobacter (10% each), Klebsiella (6.67%), Staphylococcus, Acinobacter with *Escherichia coli* and *Escherichia coli* with Proteus (3.33% each).

In group B, staphylococcus (30%) was the commonest organism isolated while and Escherichia coli, Pseudomonas, Streptococcus and Proteus were seen in 20%, 16.67%, 6.67% and 16.67% of the patients respectively. The other organisms in group B included Staphylococcus with pseudomonas and Klebsiella with Escherichia coli (3.33% each) (Table 1).

Table 1: Organisms isolated in initial culture.

Organism	Group A (n=30)		Group B (n=30)	
	No.	%	No.	%
E. coli	8	26.67	6	20.00
Staphylococcus	1	3.33	9	30.00
Proteus	3	10.00	5	16.67
Pseudomonas	8	26.67	5	16.67
Klebsiella	2	6.67	0	0.00
Streptococcus	3	10.00	2	6.67
Klebsiella+*E. coli*	0	0.00	2	6.67
Staphylococcus + pseudomonas	0	0.00	1	3.33
Acinobacter	3	10.00	0	0.00
Acinobacter+*E. coli*	1	3.33	0	0.00
E. coli = proteus	1	3.33	0	0.00
Total	30	100.00	30	100.00

DISCUSSION

Foot ulcer is seen in approximately 15% of all patients with Diabetes Meletus. Approximately 20% of all patients with diabetes admitted to a hospital will have a skin ulcer. The risk of amputation in a patient with diabetes is 15-40 times higher than that in a patient without diabetes.

The quality of life of diabetic patients is affected profoundly by the presence of nonhealing infected foot ulcer for the patient and on the delivery of care. Diabetic patients will have 40 times higher risk of lower extremity amputation than their non-diabetic counterparts.

There were approximately 86,000 hospital discharges for diabetes-related non-traumatic amputations in the United States in 1996. The 5-year survival rate after amputation of a diabetic limb is less than 50%. These grim statistics reflect an increased prevalence of peripheral lesions in diabetes, but also delayed healing.[9]

Staphylococcus aureus and beta hemolytic streptococci rapidly colonize the break in the skin. A high frequency of anaerobic infection has also been reported.[10] This may cause subsequently devastating complications to an infected ulcer that can lead to the development of cellulitis, necrotizing fasciitis, gangrene and life-threatening situations like multi organ failure.

In persons with diabetes, infection results in micro-thrombi formation in the smaller vessels this impairs blood flow, and this when affects the digital end arteries of the toes causes gangrene of the toes. Aerobic Gram-positive cocci are the predominant bacteria that colonize and acutely infect breaks in the skin.

Staph aureus and the hemolytic streptococci (groups A, C, and G, but especially group B) are the most commonly isolated pathogens.[11] Chronic wounds develop a more complex colonizing flora, including enterococci various Enterobacteriaceae, obligate anaerobes, *Pseudomonas aeruginosa*, and non-fermentative Gram-negative rods.[12]

The approach to management of infected diabetic ulcers in our study is represented in (Figure 7). The role of topical wound care management in case of diabetic ulcers is crucial. Infection of the diabetic ulcer can have serious consequences. Presently, infected ulcers are being managed by local dressing with agents like Hydrogen peroxide, Povidine iodine, EUSOL, Acetic acid, local antibiotics with each having their own limitations and interestingly none of these dressings are gold standard in the management of the ulcers. There has always been a search for an ideal antiseptic that is rapidly lethal to all forms of bacteria and their spores, capable of bactericidal property for a prolonged period with no ill effect on host tissues. Superoxidised solutions may represent an alternative to the currently available antiseptics for the disinfection of skin and wounds. Superoxidised Solutions have shown to be both safe and efficient as a wound care product that moistens, lubricates debrides and reduces the microbial load of various types of lesions.[13,14]

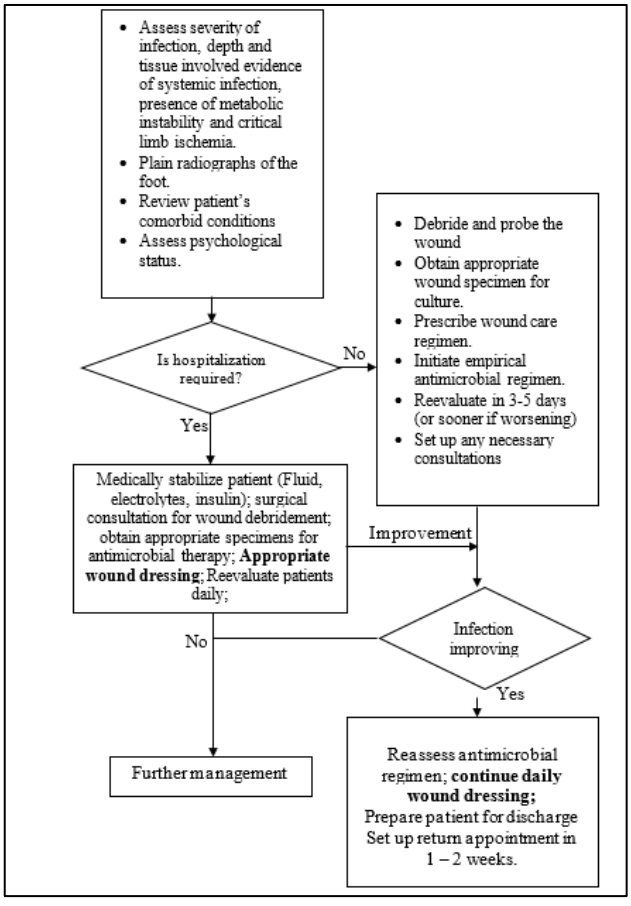

Figure 7: Approach to the management of infected diabetic foot.

Superoxidised solutions are electrochemically processed aqueous solutions manufactured from pure water and sodium chloride (NaCl). During the electrolysis process,

water molecules are pulled apart, and reactive species of chlorine and oxygen are formed. The principle of "Wound Dressing with Super-Oxide Solution "was officially started in the year 2003 when it achieved a status of "Disinfectant and Antiseptic" in its homeland Mexico.[15,16] There have been isolated reports of its use in healing of diabetic foot ulcers, abscess cavities, surgical wounds and various other types of ulcers.[17] Further, this solution has been used in management of chest wall infections and reportedly reduced the time of healing in a significant manner.[18]

Several studies have shown the efficacy of the superoxidised solutions and its wide range of applications on several types of wounds. A study done by Kapur V et al in Amritsar during 2008 to evaluate the effect and comparison of Superoxidised solution and Povidine Iodine in different types of wounds.[7] Superoxidised solution was safe and effective in all types of wounds. No systemic and local allergic manifestations were noted. Another study by Abhyankar S et al in Mumbai on Efficacy and safety of Superoxidised solution in treatment of chronic wounds has been concluded that the super oxidized solution is novel technology innovation in therapy of chronic wounds.[10] A study conducted by Hadi SF et al in Islamabad in 2006 on treating infected diabetic wounds with Super oxidized water as antiseptic agent: A preliminary Experience revealed that although the initial results of employing Superoxidised water for the management of infected diabetic wounds are encouraging, further multicenter clinical trials are warranted before this antiseptic is recommended for general use.[19]

CONCLUSION

Overall, topical superoxidised solution dressings accelerated the healing process resulting in faster recovery through reduction in ulcer area in patients with infected diabetic ulcers compared to topical povidine iodine dressing. Superoxidised solution is effective and economical alternative for better management of diabetic foot ulcers. It is safe and can be used in various types of wounds like diabetic ulcers, venous ulcers, burns and post-operative wounds.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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