Original Research Article

Comparison of Super-oxidized Solution versus Povidone Iodine in Management of Infected Diabetic Ulcers: Our Experience

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Abstract

Background: Diabetic foot ulcer is a challenging problem to every clinician in day to day practice. Super-oxidized Solution is a newer concept in the wound management. The present study was aimed to compare the efficacy of dressings with super-oxidized solution versus povidone iodine in the management of infected diabetic ulcers.

Materials and methods: This one year randomized controlled trial was conducted on a total of 60 patients presenting with infected diabetic ulcers. Patients were divided into two groups of 30 each based on computer generated randomization that is, group A (Topical super-oxidized solution dressing) and group B (Topical povidone 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 group A was 55.90 ± 14.27 years compared to 51.50 ± 13.18 years in group B. Type 2 diabetes was present in 96.67% and 93.33% of patients in group A and B. The mean initial ulcer area in group A was 3882 ± 1890 mm^2compared to 3992 ± 2000 mm^2in group B. The mean 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^2vs 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).

Conclusion : Overall, topical super-oxidized solution dressings accelerated the healing process resulting in faster recovery through reduction in ulcer area in patients infected with diabetic ulcers compared to topical povidone iodine dressing.

Key words

Diabetic foot ulcer, Super-oxidized solution dressings, Topical povidone iodine.

Introduction

Every chronic disease brings with it fears, concerns, and people with diabetes face an especially daunting possibility; Infections that never heal, 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 effective management of diabetic foot ulcers requires offloading the wound by using appropriate therapeutic footwear [2, 3], daily dressings to provide a moist wound environment [4], debridement, antibiotic therapy (if osteomyelitis or cellulitis is present) [4, 5], optimal control of blood glucose, and evaluation and correction of peripheral arterial insufficiency. The role of wound care is crucial 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].

Presently, infected ulcers are being managed by local dressing with agents like Povidone iodine, Eusol, Hydrogen peroxide, Acetic acid, local antibiotics with each having their own limitations. Super-oxidized 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, super-oxidized solution, being a new concept, very few studies assessed the role of these dressings in the management of infected diabetic ulcers especially in Indian context. Hence the present study was undertaken to compare the efficacy of dressings with super-oxidized solution versus povidone iodine in the management of infected diabetic ulcers.

Materials and methods

The study was a randomized control trial. Diabetic patients of age more than 20 years, Patients with controlled diabetes with fasting blood glucose levels less than 126 mg/dL, Patients having infected diabetic ulcers measuring more than 1 cm, with slough, foul smell and minimal granulation tissue, Patients with grade1 and grade 2 of Wagner's classification were included in the study, whereas Grade 3, 4, 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 received dressing with topical super-oxidized solution (**Photo – 1**), whereas those in group B received dressing with povidone iodine. Demographic data such as age, sex and ulcer details were obtained through an interview. Details such as duration and type of diabetes, diabetic treatment,

ulcer site, discharge were noted. Further these patients were subjected to clinical examination and the findings were noted on a predesigned proforma. Wound discharge was sent for culture and sensitivity. Empirical antibiotics – Ciprofloxacin and Metronidazole were started and changed to sensitive antibiotics after sensitivity report. The culture was repeated after 10 days of the dressing and Debridement was done if necessary.

Photo - 1: Ulcer before dressing and decrease in ulcer size after dressing with super-oxidized solution.

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**.**

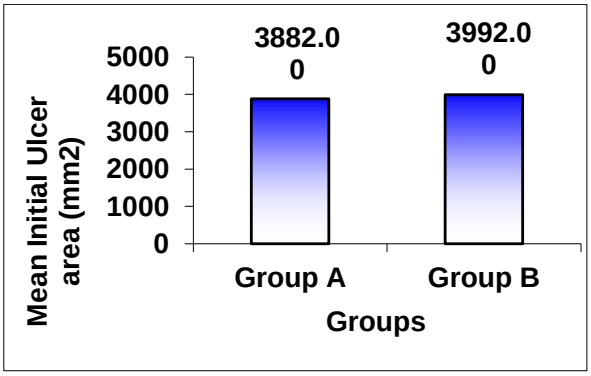
The categorical data was expressed as rates, ratios and percentages and comparison was done using Chi-square test and Fishers exact test. Continuous data was expressed as mean ± standard deviation and the comparison was done using unpaired't' test. A 'p' value of less than or equal to 0.05 was considered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

Results

In this study, 76.67% of patients were males in group A and B compared to 23.33% of females. 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).

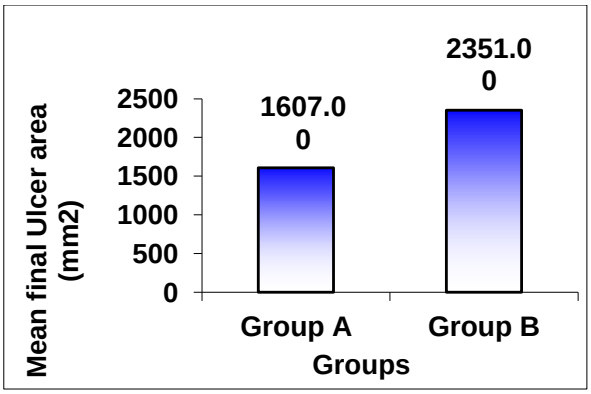
The mean initial ulcer area in group A was 3882 ± 1890 mm^2 compared to group B which was 3992 ± 2000 mm^2, however the difference was statistically not significant (p=0.736)**.** The above findings on age, sex, diabetic history including type, duration, and treatment and the ulcer characteristics were comparable in both the groups (**Graph – 1**).

Graph - 1: Comparison of initial ulcer area.



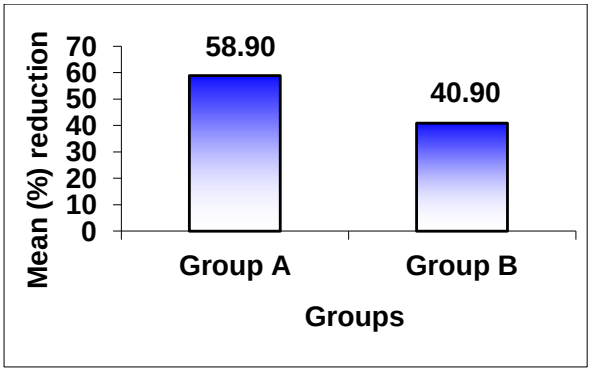
The final mean ulcer area in group A was found to be significantly low compared to group B (1607 ± 862 versus 2351 ± 1240 mm^2; p=0.009) as per **Graph – 2**.

Graph - 2: 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) as per **Graph – 3**.

Graph - 3: 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) as per **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

Approximately 15% of all patients with diabetes will develop a peripheral ulcer. Twenty percent 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 presence of an ulcer in a diabetic patient has a profound impact on the quality of life for the patient and on the delivery of care. Persons with diabetes have up to a 40-fold greater 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

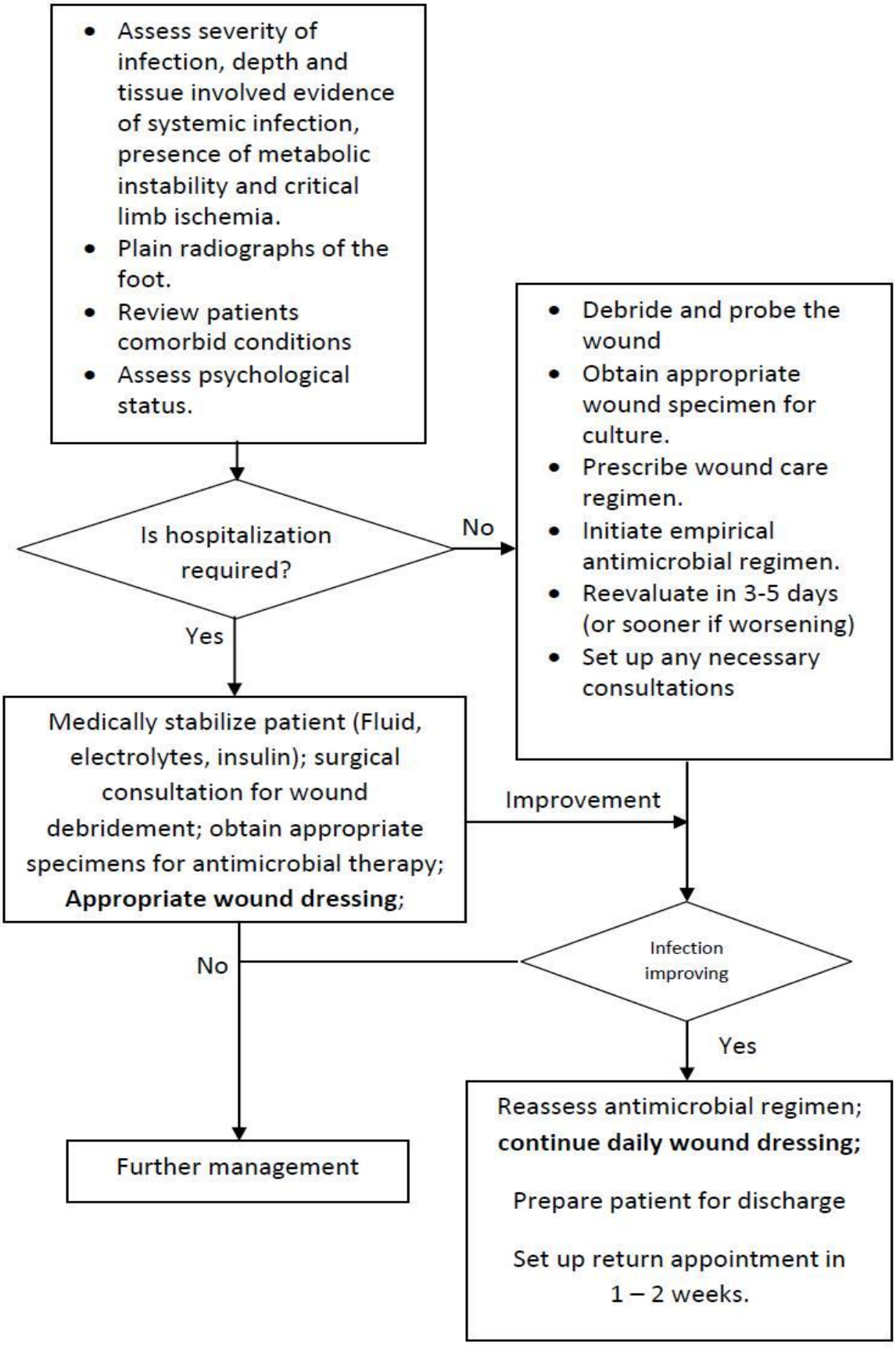
also delayed healing [9]. Staphylococcus aureus and beta hemolytic streptococci rapidly colonize the break in the skin. A high frequency of anaerobic infection has also been reported [10]. The devastating developments subsequent to an infected ulcer that lead to the development of gangrene, necrotizing fasciitis and life threatening situations like multi organ failure. In persons with diabetes, infection results in micro-thrombi formation in the smaller vessels unlike persons without diabetes where it results in vasodilatation. This impairs blood flow in diabetes, converting the small arteries of the toes into end arteries resulting in 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 is represented in **Figure – 1**. The role of 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 Povidone iodine, Eusol, Hydrogen peroxide, Acetic acid, local antibiotics with each having their own limitations and none of the above mentioned 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. Super-oxidized solutions may represent an alternative to the currently available antiseptics for the disinfection of skin and wounds. Super-oxidized 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].

Super-oxidized 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 super-oxidized solutions and its wide range of applications on several types of wounds. A study done by Kapur V, et al. [7] in Amritsar during 2008 to evaluate the effect and comparison of Super-oxidized solution and Povidone Iodine in different types of wounds. Super-oxidized solution was safe and effective in all types of wounds .No systemic and local allergic manifestations noted. Another study by Abhyankar S, et al. [10] during 2009 in Mumbai on Efficacy and safety of Super-oxidized solution in treatment of chronic wounds has been concluded that the super oxidized solution is novel technology innovation in therapy of chronic wounds. But however both oxum and povidone iodine treated groups showed similar results with regards to decrease in edema, erythema and granulation. A study conducted by Hadi SF, et al. [19] 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 Super-oxidized water for the management of infected diabetic wounds are encouraging, further multicenter clinical trials are warranted before this antiseptic is recommended for general use.

Figure - 1: Approach to the management of infected diabetic foot [13].



Conclusion

Overall, topical super-oxidized solution dressings accelerated the healing process resulting in faster recovery through reduction in ulcer area in patients with infected diabetic ulcers compared to topical povidone iodine dressing and super-oxidized 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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