

## Comparative evaluation of Super-oxidized Solution and Povidone Iodine solution in Management of Infected Diabetic Ulcers

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### Abstract

**Background:** Diabetic foot ulcer is a moving issue to each clinician in everyday practice. Super-oxidized Solution is a more up to date idea in the wound management. **Aim:** The current investigation was attempted to compare the effectiveness of super-oxidized preparations and povidone iodine in the management of infected diabetic ulcers. **Materials and methods:** This prospective study 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  $55.90 \pm 14.27$  years compared to  $51.50 \pm 13.18$  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  $3882 \pm 1890$  mm<sup>2</sup> compared to  $3992 \pm 2000$  mm<sup>2</sup> in group B. The mean final area in group A was significantly low ( $1607 \pm 862$  mm<sup>2</sup>) compared to group B ( $2351 \pm 1240$  mm<sup>2</sup>;  $p=0.009$ ) and the comparison of mean change in ulcer area was significantly high in group A compared to group B ( $2215 \pm 1060$  mm<sup>2</sup> vs  $1641 \pm 856$  mm<sup>2</sup>;  $p=0.024$ ). The mean percentage reduction in ulcer among patients with group A was significantly high ( $58.90 \pm 5.21$  percent vs  $40.90 \pm 8.76$  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.

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## Introduction

Each persistent illness carries with it fears, concerns, and individuals with diabetes face a particularly overwhelming chance; Infections that never mend, possibly finishing off with the loss of the appendage. One of the significant reasons for non-healing of ulcer in diabetes is disease brought about by an assortment of microbes, for example, *Staphylococcus aureus* and *Pseudomonas aeruginosa* which attack the wound and grow exponentially, delivering harmful poisonous substances, causing liquification of tissue and delay in wound mending [1]. The feasible management of diabetic foot ulcers requires offloading the injury by utilizing proper remedial footwear [2, 3], every day dressings to give a moist wound [4], debridement, anti-microbial treatment (if osteomyelitis or cellulitis is available) [4, 5], ideal control of blood glucose, and assessment and rectification of peripheral blood vessel inadequacy. The role of wound maintenance is essential in the management of diabetic ulcers. An ideal wound care item not withstanding controlling the disease ought to likewise secure the normal tissues and not meddle with ordinary wound healing [6]. As of now, contaminated ulcers are being treated by local dressing therapeutic materials like Povidone iodine, Eusol, Hydrogen peroxide, Acetic acid, locally applied antibiotics with each having their own impediments. Super-oxidized solution is latest concept in wound care and management with electrochemically prepared fluid preparation in neutral pH. They have demonstrated to be both harmless and effective as a wound care item that provides moisture, greasing, debrides and decreases the microbial heap of different kind of wounds [7]. It is altogether less harmful than sterile hydrogen peroxide and it doesn't incite genotoxicity or aggravated ageing [8].

Nonetheless, super-oxidized preparations, being latest concept, not many studies have evaluated the role of these dressings in the management of infected diabetic ulcers particularly in North Indian setting. Therefore, the current investigation was attempted to compare the effectiveness super-oxidized preparations and povidone iodine in the management of infected diabetic ulcers.

## Material and methods

### Study design

This was a single-center, prospective, randomized, non-blinded and comparative study. Patients with diabetic foot ulcer attending the Out Patient Department of Vardhman Institute of Medical Sciences, Pawapuri. The study was conducted over a

period of 18 months from February 2019 to August 2020. The study was approved by the Institutional Research Committee. An informed and written consent was obtained from all the participating subjects before the commencement of the study.

### Inclusion criteria

Patients with controlled diabetes

Age more than 20 years

Fasting blood glucose levels less than 126 mg/dL

Infected diabetic ulcers measuring more than 1 cm, with slough, foul smell and minimal granulation tissue, Patients with grade 1 and grade 2 of Wagner's classification

### Exclusion criteria

Wagner's classification Grade 3, 4, 5 patients

Patients with absent peripheral pulses

Other systemic disease

Non cooperative patients

### Randomization

The estimated sample size for the study was 60 patients. The patients who fulfilled the eligibility criteria were randomized into two treatment group.

Group A- Received dressing with topical super-oxidized solution.

Group B- Received dressing with povidone iodine.

### Patient assessment and data collection

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. 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.

### Statistical analysis

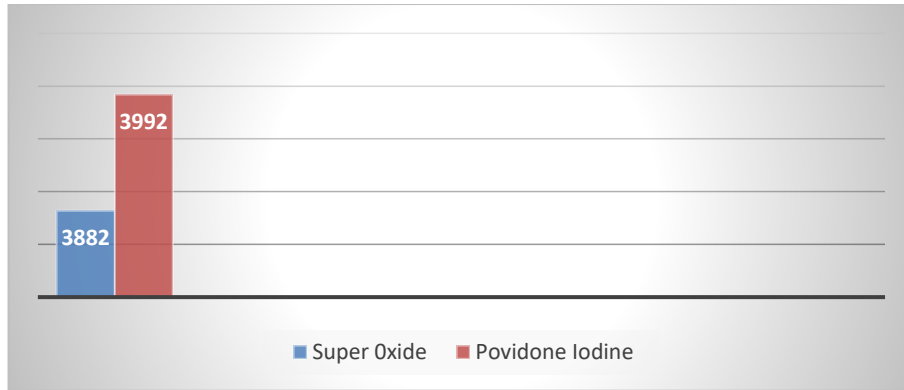
The categorical data was expressed as rates, ratios and percentages and comparison was done using Chi-square test and Fishers exact test. Continuous data was expressed as mean  $\pm$  standard deviation and the comparison was done using unpaired 't' test. A 'p'

value of less than or equal to 0.05 was considered as statistically significant.

**Results**

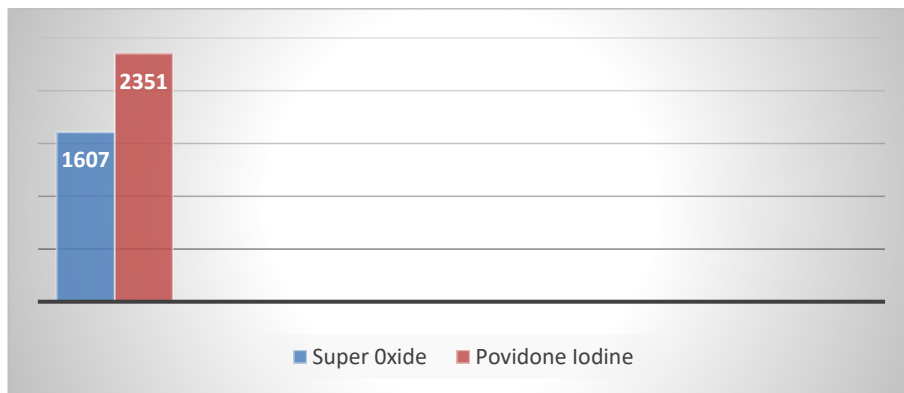
In this study, 76.67% of patients were males in group A and B compared to 23.33% of females. The male to female ratio was 3.2:1. Though there was male preponderance the sex distribution between group A and B was comparable (p=1.000). The mean age of group A was slightly high (55.90 ± 14.27 years)

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<sup>2</sup> compared to group B which was 3992 ± 2000 mm<sup>2</sup>, 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 (Fig 1).



**Fig 1:Mean initial ulcer area**

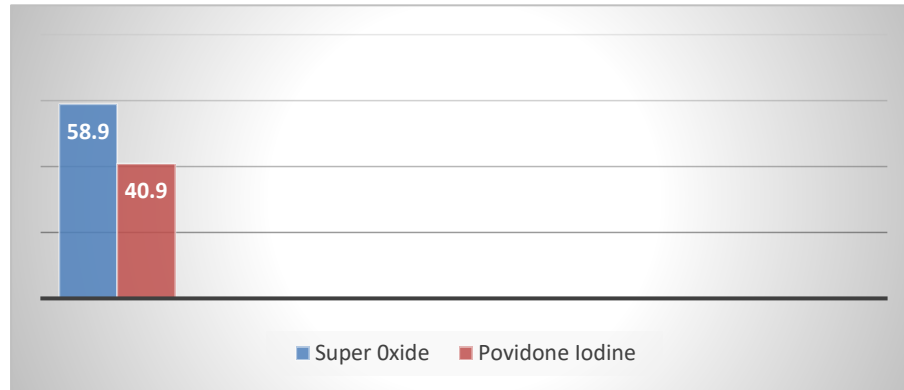
The final mean ulcer area in group A was found to be significantly low compared to group B (1607 ± 862 versus 2351 ± 1240 mm<sup>2</sup>; p=0.009) as per Fig 2



**Fig 2:Final mean ulcer area**

The comparison of mean change in ulcer area was also significantly high in group A that is, 2215 ± 1060 mm<sup>2</sup> compared to group B that is, 1641 ± 856 mm<sup>2</sup> (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 Fig 3.



**Fig 3: Mean 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 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
<b>Total</b>	<b>30</b>	<b>100.00</b>	<b>30</b>	<b>100.00</b>

### Discussion

Roughly 15% of all patients with diabetes will advance into a peripheral ulcer. A fifth of all patients with diabetes admitted to an emergency clinic will have a skin ulcer. The danger of limb forfeiture in a patient with diabetes is 15–40 times higher than that in a patient without diabetes. The presence of a ulcer in a diabetic patient profoundly affects the personal

satisfaction for the patient and on the conveyance of care. People with diabetes have up to a 40-overlay more serious danger of lower limb/part removal than their non-diabetic partners. The 5-year survival rate after removal of a diabetic appendage is under half. These inauspicious insights mirror an expanded pervasiveness of peripheral sores in diabetes, yet additionally postponed healing process [9].

Staphylococcus aureus and beta hemolytic streptococci quickly colonize the break in the skin. A high recurrence of anaerobic disease has likewise been accounted for [10]. The overwhelming advancements resulting to a infected ulcer that lead to the progress towards gangrene, necrotizing fasciitis and perilous circumstances like multi organ failure. In people with diabetes, contamination brings about miniature thrombi development in the more narrower vessels dissimilar to people without diabetes where it brings about vasodilatation. This debilitates blood flow in diabetes, changing over the small artery of the toes into end supply routes bringing about gangrene of the toes. High-impact Gram-positive cocci are the prevalent microorganisms that colonize and intensely infect breaks in the skin. Staph aureus and the hemolytic streptococci (bunches A, C, and G, yet particularly bunch B) are the most generally segregated microorganisms [11]. Chronic wound build up a more complex flora colony, including enterococci different Enterobacteriaceae, obligate anaerobes, Pseudomonas aeruginosa, and non-fermentative Gram-negative rods[12]. The way of wound care and management in diabetic ulcers is essential. Contamination of the diabetic ulcer can have serious outcomes. As of now, contaminated ulcers are being overseen by local dressing with agents like Povidone iodine, Eusol, Hydrogen peroxide, Acetic corrosive, topical antibiotics with each having their own constraints and there are no options referenced as best quality dressings material in the management of the ulcers. There has consistently been a quest for an ideal antiseptic that is quickly fatal to all types of microorganisms and their spores, fit for bactericidal property with no evil impact on tissues. Super-oxidized preparations may speak to be an option in contrast to the presently available antiseptic agents for the sterilization of skin and wounds. Super-oxidized Solutions have demonstrated to be both safe and effective as a wound care item that moistens, lubricates, debrides and lessens the microbial heap of different types of lesions [13, 14]. Super-oxidized solutions are electrochemically made fluid preparations made from unadulterated water and sodium chloride (NaCl). During the electrolysis cycle, water atoms are pulled separated, and responsive types of chlorine and oxygen are shaped. The standard of "Twisted Dressing with Super-Oxide Solution" was authoritatively begun in the year 2003 when it accomplished a status of "Disinfectant and Antiseptic" in its country Mexico [15, 16]. There have been isolated reports of its utilization in mending of

diabetic foot ulcers, canker holes, careful injuries and different kinds of ulcers [17]. Further, this preparation has been utilized in the treatment of chest wall infections and evidently decreased the hour of healing in a critical way [18]. A few studies have demonstrated the adequacy of the super-oxidized preparations and its wide scope of utilizations on a few sorts of wounds. A study of Kapur V, et al. [7] in Amritsar during 2008 to assess the impact and examination of Super-oxidized arrangement and Povidone Iodine in various kinds of wounds. Super-oxidized arrangement was protected and viable in a wide range of wounds. No systemic and local hypersensitive indications noted. Another examination by Abhyankar S, et al. [10] during 2009 in Mumbai on Efficacy and security of Super-oxidized arrangement in therapy of ongoing injuries has been inferred that the overly oxidized arrangement is novel innovation development in treatment of persistent injuries. In any case, anyway both oxum and povidone iodine treated populations demonstrated comparative outcomes concerning decline in edema, erythema and granulation. An investigation led by Hadi SF, et al. [19] in Islamabad in 2006 on treating contaminated diabetic injuries with Super oxidized water as germicide specialist. A primer experience uncovered that despite the fact that the underlying consequences of utilizing Super-oxidized water for the administration of contaminated diabetic wound are empowering, further multicenter clinical studies are justified before this antiseptic is suggested for general use.

## Conclusion

In general, effective super-oxidized preparations dressings quickened the healing cycle bringing about quicker healing through decrease in ulcer region in patients with infected diabetic ulcers contrasted with effective povidone iodine dressing and super-oxidized arrangement is successful and affordable option for better administration of diabetic foot ulcers. It is safe and can be utilized in different kinds of wounds like diabetic ulcers, venous ulcers, consumes and post-employable injuries.

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