



## “EFFICACY OF SUPEROXIDIZED SOLUTION VERSUS POVIDONE- IODINE IN HEALING DIABETIC FOOT ULCERS”

### General Surgery

|                                |                                                                                                                                                  |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Dr. Sunil Kumar Maurya*</b> | Junior Resident- 3, Department of General Surgery, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh. *Corresponding Author |
| <b>Dr. Silvi Beniwal</b>       | Junior Resident- 3, Department of General Surgery, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh.                       |
| <b>Dr. Mohsin Ali</b>          | Associate Professor, Department of Medicine, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh.                             |
| <b>Dr Raza Farooqui</b>        | Professor, Department of General Surgery, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh.                                |
| <b>Dr Ayush Teotia</b>         | Junior Resident- 3, Department of General Surgery, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh.                       |
| <b>Dr Gaurav Kumar Nirwal</b>  | Assistant Professor, Department of General Surgery, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh.                      |

### ABSTRACT

**Background:** Diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus, leading to significant morbidity, infection, and risk of limb amputation. Effective local wound management is crucial to improve healing outcomes. This study aimed to compare the efficacy of Superoxidized Solution with Povidone-Iodine in the treatment of infected diabetic foot ulcers. **Aim & Objectives:** To compare the efficacy of Superoxidized Solution versus Povidone- Iodine in promoting wound healing in infected diabetic foot ulcers. **Material & Methods:** A hospital-based analytical study was conducted at Muzaffarnagar Medical College involving 100 patients with diabetic foot ulcers. Patients were randomly assigned to two groups: Group A received dressings with Superoxidized Solution, and Group B with Povidone-Iodine. Wound healing parameters, including ulcer size reduction, granulation tissue formation, epithelialization, peri- ulcer edema, erythema, pus discharge, and healing time, were assessed over two weeks. Statistical analysis was performed using SPSS version 20, with a significance threshold of  $p < 0.05$ . **Results:** Group A (Superoxidized Solution) showed a significantly greater mean percentage reduction in ulcer size (47% vs. 39%), higher granulation tissue formation (57% vs. 43%), and faster epithelialization (67% vs. 49%) compared to Group B ( $p < 0.0001$  for all). Although peri-ulcer edema, erythema, and pus discharge were slightly lower in Group A, the differences were not statistically significant. Healing was significantly faster in Group A, with 62% of patients healing within 45 days, while all patients in Group B took longer than 45 days. The mean healing time was  $42.78 \pm 9.81$  days in Group A versus  $72.9 \pm 20.83$  days in Group B ( $p < 0.0001$ ). **Conclusion:** Superoxidized Solution proved to be more effective than Povidone-Iodine in promoting wound healing and reducing healing time in diabetic foot ulcers. Its use may offer a superior alternative in the management of DFUs.

### KEYWORDS

Diabetic Foot Ulcer, Superoxidized Solution, Povidone- Iodine, Wound Healing, Granulation Tissue, Epithelialization.

### INTRODUCTION:

Diabetes mellitus is a complex, chronic metabolic disorder characterized by persistent hyperglycemia, requiring continuous medical care and multifactorial risk reduction strategies beyond glycemic control. Its prevalence is steadily increasing worldwide, particularly in developing countries like India, where approximately 77 million people were estimated to have diabetes in 2020, with projections reaching nearly 134 million by 2045.<sup>[1]</sup> Among its many complications, diabetic foot disease represents a major cause of morbidity, significantly affecting patients' quality of life, burdening healthcare systems, and often leading to lower limb amputations.<sup>[2]</sup> The pathogenesis of diabetic foot ulcers (DFUs) involves a triad of peripheral neuropathy, peripheral vascular disease, and increased susceptibility to infection.<sup>[3]</sup> Neuropathy, through sensory loss, autonomic dysfunction, and motor impairment, predisposes patients to repeated, unnoticed trauma and subsequent ulcer formation.<sup>[4,5]</sup> Approximately 60–80% of foot ulcers heal within 6–18 months, but 10–15% remain active, and 5–24% eventually lead to limb amputation.<sup>[6]</sup> Identifying the "foot at risk" through clinical examination, vascular assessments, and neuropathy screening is crucial in preventing ulcer formation and progression.<sup>[3]</sup>

Management of DFUs involves a combination of wound debridement, infection control, pressure offloading, glycemic optimization, and the use of appropriate wound dressings.<sup>[3,7,8]</sup> Antimicrobial dressings have been commonly used to control infection and promote wound healing. Povidone-iodine, a well-established topical antiseptic, has long been utilized in the management of infected wounds, including DFUs, due to its broad-spectrum antimicrobial activity.<sup>[9]</sup> However, concerns over its potential cytotoxicity and delayed wound healing have prompted the exploration of alternative agents. Superoxidized solutions (SOS), produced by electrolysis of saline, have emerged as promising wound care agents, offering antimicrobial, anti-inflammatory, and wound

healing-promoting properties with minimal cytotoxicity.<sup>[10,11,12]</sup> These solutions possess sporicidal, fungicidal, viricidal, and bactericidal effects while maintaining a neutral pH, making them safe for use on healing tissues.<sup>[13,14,15]</sup>

Previous studies have highlighted the potential benefits of superoxidized solutions in diabetic foot management. Chittoria RK et al.<sup>[16]</sup> reported total healing in 8 out of 20 cases and significant infection control in others using SOS. Kapur V et al.<sup>[17]</sup> demonstrated faster wound healing and reduced inflammation with SOS compared to povidone-iodine. Similarly, Bakhshi GD et al.<sup>[18]</sup> found earlier granulation tissue formation and disinfection with SOS dressings. However, while evidence is encouraging, further comparative studies are needed to firmly establish the clinical superiority of superoxidized solutions over traditional agents like povidone-iodine. Against this background, the present study was undertaken to comparatively evaluate the efficacy of Superoxidized Solution versus Povidone-Iodine in the treatment of infected diabetic foot ulcers.

### AIM & OBJECTIVES

1. To compare the efficacy of Superoxidized Solution and Povidone-Iodine in healing infected diabetic foot ulcers.
2. To assess differences in wound healing parameters, including ulcer size reduction, granulation, epithelialization, peri-ulcer inflammation, and pus discharge.

### MATERIAL AND METHODS:

This hospital-based analytical study was conducted in the Department of General Surgery, Muzaffarnagar Medical College, Muzaffarnagar. The study included 100 diabetic patients aged between 25 and 70 years, presenting with foot ulcers, selected from both inpatient and outpatient services over a period of 18 months (12 months of data

collection and 6 months for data compilation). Inclusion criteria were diabetic patients with foot ulcers, blood glucose levels greater than 126 mg/dL, and willingness to provide informed consent. Patients who did not consent or were lost to follow-up were excluded from the study. Simple random sampling was employed for participant selection.

After obtaining written informed consent and Institutional Ethical Committee approval, patients were enrolled. Detailed clinical histories were recorded, and thorough physical examinations were conducted. Preliminary investigations included routine blood tests and culture and sensitivity swabs from the ulcer site. Following necessary surgical debridement and cleansing with normal saline, patients were randomly assigned into two groups: Group A received dressings with Superoxidized Solution, while Group B received dressings with Povidone-Iodine. Antibiotic therapy was initiated and adjusted according to culture and sensitivity results.

Wound healing was evaluated based on multiple parameters, including percentage decrease in ulcer size, percentage increase in granulation tissue and epithelialization, presence or absence of peri-ulcer edema, erythema, pus discharge, and the total time taken for complete healing. Patients were monitored and assessed weekly for changes in these parameters. Data were compiled and analysed using SPSS version 20 and StatCalc2 software. Statistical significance was determined using appropriate tests, and a p-value <0.05 was considered significant. Ethical clearance for the study was obtained from the Institutional Ethics Committee of Muzaffarnagar Medical College, Muzaffarnagar, and all participants provided informed written consent prior to enrollment.

## RESULTS:

A total of 100 patients with diabetic foot ulcers were enrolled in the study, with 50 patients each in Group A (Superoxidized Solution) and Group B (Povidone-Iodine). The baseline characteristics of the study participants in both groups were comparable. The two groups were comparable at baseline. The average age was similar—44.34 years in the Superoxidized Solution group and 43.48 years in the Povidone-Iodine group. There was a slight male predominance in both groups. More patients in Group A had diabetes for less than 5 years, while shorter ulcer duration (under 3 months) was more common in Group B. Ulcer sizes between 50–100 mm were the most frequent in both groups. Overall, these baseline differences were not large enough to affect the comparison of outcomes. (Table 1).

At two weeks, patients in the Superoxidized Solution group showed significantly better healing, with greater ulcer size reduction, more granulation tissue, and faster epithelialization compared to the Povidone-Iodine group. (Table 2).

At the end of two weeks, both groups showed similar levels of peri-ulcer inflammation and infection. Mild reductions in edema, erythema, and pus discharge were seen in the Superoxidized Solution group, but the differences were not statistically significant compared to the Povidone-Iodine group. (Table 3)

Patients treated with Superoxidized Solution healed significantly faster than those in the Povidone-Iodine group. While 62% of Group A patients healed within 45 days, all patients in Group B required more than 45 days. The mean healing time was notably shorter in Group A ( $42.78 \pm 9.81$  days) compared to Group B ( $72.9 \pm 20.83$  days), and this difference was statistically significant ( $p < 0.0001$ ) as shown in Table 4.

Figure 1 further illustrates the distribution of patients according to the time taken for complete wound healing, highlighting the faster recovery associated with the use of Superoxidized Solution.

**Table 1: Baseline Characteristics Of Study Participants**

| S. No. | Characteristic                   | Group A (Superoxidized Solution) (n=50) | Group B (Povidone-Iodine) (n=50) |
|--------|----------------------------------|-----------------------------------------|----------------------------------|
| 1      | Mean Age (years)                 | 44.34                                   | 43.48                            |
| 2      | Gender: Male                     | 29                                      | 33                               |
|        | Female                           | 21                                      | 17                               |
| 3      | Duration of Diabetes (0-5 years) | 52%                                     | 30%                              |

|   |                                |     |     |
|---|--------------------------------|-----|-----|
| 4 | Duration of Ulcer (0-3 months) | 32% | 66% |
| 5 | Ulcer Size (50-100mm)          | 42% | 50% |

**Table 2: Comparison Of Ulcer Healing Parameters Between Groups**

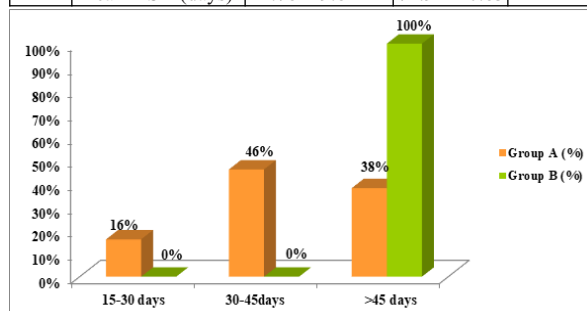
| S. No. | Parameter                             | Group A (Superoxidized Solution) | Group B (Povidone-Iodine) | p-value |
|--------|---------------------------------------|----------------------------------|---------------------------|---------|
| 1      | Mean % Decrease in Ulcer Size         | $47 \pm 0.02$                    | $39 \pm 0.01$             | <0.0001 |
| 2      | Mean % Increase in Granulation Tissue | $57 \pm 0.02$                    | $43 \pm 0.01$             | <0.0001 |
| 3      | Mean % Increase in Epithelialization  | $67 \pm 0.03$                    | $49 \pm 0.01$             | <0.0001 |

**Table 3: Comparison Of Inflammatory And Infection Parameters Between The Two Groups At Two Weeks**

| S. No. | Parameter                | Group A (Superoxidized Solution) | Group B (Povidone-Iodine) | p-value |
|--------|--------------------------|----------------------------------|---------------------------|---------|
| 1      | Peri-ulcer Edema (%)     | 39 (78%)                         | 43 (86%)                  | 0.43    |
| 2      | Peri-ulcer Erythema (%)  | 40 (80%)                         | 43 (86%)                  | 0.59    |
| 3      | Pus Discharge (%)        | 42 (84%)                         | 43 (86%)                  | 0.78    |
|        | Positive Pus Culture (%) | 40 (80%)                         | 43 (86%)                  | 0.42    |

**Table 4: Comparison Of Time Taken For Complete Healing Between The Two Groups**

| S. No. | Time to Healing      | Group A (Superoxidized Solution) | Group B (Povidone-Iodine) | p-value |
|--------|----------------------|----------------------------------|---------------------------|---------|
| 1      | 15–30 days           | 8 (16%)                          | 0 (0%)                    | <0.0001 |
| 2      | 30–45 days           | 23 (46%)                         | 0 (0%)                    |         |
| 3      | >45 days             | 19 (38%)                         | 50 (100%)                 |         |
| 4      | Mean $\pm$ SD (days) | $42.78 \pm 9.81$                 | $72.9 \pm 20.83$          |         |



**Figure 1:** Figure Showing Participants According To Time Taken In Healing

## DISCUSSION:

In the present study, Superoxidized Solution demonstrated significantly better wound healing outcomes compared to Povidone-Iodine in the management of diabetic foot ulcers. Patients treated with Superoxidized Solution showed greater ulcer size reduction, faster granulation tissue formation, higher epithelialization rates, earlier resolution of peri-ulcer edema and erythema, and shorter healing times.

These findings are consistent with previous studies that have highlighted the superior efficacy of superoxidized solutions in promoting wound healing. Chittoria RK et al.<sup>[16]</sup> reported that Superoxidized Solution led to total healing in 40% of cases and significantly improved wound bed preparation for definitive surgical closure in the remaining patients. Similarly, Kapur V et al.<sup>[17]</sup> observed that wounds treated with Superoxidized Solution exhibited earlier reduction in inflammation and faster healing compared to those treated with Povidone-Iodine.

The enhanced granulation tissue formation seen in our study mirrors the findings of Bakhshi GD et al.<sup>[18]</sup>, who noted that wounds treated with Superoxidized Solution showed earlier appearance of healthy granulation tissue and lower complication rates. This is attributed to the ability of superoxidized solutions to not only reduce microbial load but also create an optimal wound environment that promotes tissue regeneration<sup>[14,15,16]</sup>.

After two weeks of treatment, both groups continued to show signs of peri-ulcer inflammation and infection, though the Superoxidized Solution group showed slightly better outcomes. These findings are somewhat in contrast to earlier studies that reported more pronounced infection control with Superoxidized Solution. For instance, **Meera SS et al.**<sup>[19]</sup> and **Chittoria RK et al.**<sup>[16]</sup> found faster resolution of local infection and inflammation with Superoxidized Solution compared to Povidone-Iodine. The relatively modest difference in this study may be due to the short follow-up duration of two weeks or the underlying severity of infections at presentation. Though not statistically significant, the slightly better infection control in the Superoxidized group may still hold clinical value when considering long-term outcomes in diabetic foot care.

The time taken for complete wound healing was significantly shorter in the Superoxidized Solution group compared to the Povidone-Iodine group. While over 60% of patients in Group A healed within 45 days, none in Group B achieved similar outcomes in that timeframe. These results are consistent with previous studies such as those by **Chittoria RK et al.**<sup>[16]</sup> and **Kapur V et al.**<sup>[17]</sup>, which reported faster healing and shorter hospital stays with Superoxidized Solution dressings. The superior healing rate in Group A may be attributed to its balanced antimicrobial action and minimal cytotoxicity, which allows for active tissue repair without compromising the wound bed<sup>[10,11,12]</sup>. In contrast, the prolonged healing time in the Povidone-Iodine group reflects its known limitations, including delayed epithelialization due to tissue irritation and toxicity<sup>[20]</sup>. These findings underscore the potential of Superoxidized Solution as an effective agent for accelerating recovery in patients with diabetic foot ulcers.

Overall, the findings of the present study reinforce the growing body of evidence that supports the use of Superoxidized Solution as an effective and safe agent for the management of diabetic foot ulcers. Its ability to enhance wound healing outcomes without causing additional tissue toxicity offers a significant advantage, particularly in a population vulnerable to delayed healing and infections.

## CONCLUSION:

The present study demonstrated that Superoxidized Solution is significantly more effective than Povidone-Iodine in the management of infected diabetic foot ulcers. Patients treated with Superoxidized Solution exhibited greater ulcer size reduction, enhanced granulation tissue and epithelialization, faster resolution of peri-ulcer inflammation, and significantly shorter healing times. These findings, supported by comparable studies, suggest that Superoxidized Solution offers a safer, faster, and more effective alternative to traditional antiseptics. Incorporating Superoxidized Solution into diabetic foot ulcer care protocols may contribute to improved patient outcomes and reduced healthcare burdens.

## REFERENCES:

- Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. *Indian Journal of Ophthalmology*. 2021 Nov;69(11):2932.
- Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ, Lipsky BA; IWGDF Editorial Board. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). *Diabetes Metab Res Rev*. 2020 Mar;36 Suppl 1:e3266. doi: 10.1002/dmrr.3266. PMID: 32176447.
- Alexiadou K, Doupis J. Management of diabetic foot ulcers. *Diabetes Ther*. 2012 Nov;3(1):4. doi: 10.1007/s13300-012-0004-9. Epub 2012 Apr 20. PMID: 22529027; PMCID: PMC3508111.
- Brem H, Sheehan P, Boulton AJ. Protocol for treatment of diabetic foot ulcers. *Am J Surg*. 2004;187:1S–10S.
- Bowering CK. Diabetic foot ulcers. Pathophysiology, assessment, and therapy. *Can Fam Physician*. 2001;47:1007–16.
- Katsilambros N, Dounis E, Makrilakis K, Tentolouris N, Tsapogas P. *Atlas of the diabetic foot*. 2nd ed. Oxford: Wiley-Blackwell; 2010.
- Larsson J, Apelqvist J, Agardh CD, Stenstro'm A. Decreasing incidence of major amputation in diabetic patients: a consequence a multidisciplinary foot care team approach? *Diabet Med*. 1995;12:770–6.
- Lavery LA, Wunderlich RP, Tredwell JL. Disease management for the diabetic foot: effectiveness of a diabetic foot prevention program to reduce amputations and hospitalizations. *Diabetes Res Clin Pract*. 2005;70:31–7.
- Boulton AJM. The diabetic foot. In: Feingold KR, Anawalt B, Boyce A, et al, editors. *Endotext* [online]. South Dartmouth, MA: MD text.com, 2016.
- Eming SA, Smola-Hess S, Kurschat P, Hirche D, Krieg T, Smola H. A novel property of povidone iodine: inhibition of excessive protease levels in chronic non-healing wounds. *J Invest Dermatol*. 2006;126(12):2731–3.
- Clement JL, Jarrett PS. Antibacterial silver. *Met Based Drugs*. 1994;1(5–6):467–82.
- Lok CN, Ho CM, Chen R, He QY, Yu WY, Sun H, et al. Proteomic analysis of the mode of antibacterial action of silver nanoparticles. *J Proteome Res*. 2006;5(4):916–24.
- Abhyankar S, Venkatesh V, Karnad S, et al. Efficacy and safety of oxum in treatment of chronic wounds. *Journal of Indian Medical Association* 2009;107(12):904–6.
- Anand A. Comparative efficacy and tolerability of oxum against povidone iodine topical application in the post - caesarean section wound management. *Indian Med Gazette* 2007; p. 498–505.
- Gutiérrez AA. The science behind stable, superoxidized water. Exploring the various applications of super oxidized solutions. *Wounds* 2006;18(Suppl 1):7–10.
- Chittoria RK, Pandey A, Upreti L, Bihari I. The role of super oxidized solution in the management of diabetic foot ulcer: our experience. *Diabet Foot Ankle*. 2007 Jul; 23(2): 123–127. doi:10.1016/j.diabres.2007.07.004.
- Kapur V, Marwaha AK. Evaluation of effect and comparison of superoxidised solution (Oxum) v/s povidone iodine (Betadine). *Indian J Surg*. 2011 Jan-Feb; 73(1): 48–53.
- Bakhshi GD, Joshi G, Bakhshi RG. A Comparative Study of Efficacy of Superoxidized Solution against Povidone Iodine in the Treatment of Diabetic Ulcers. *International Journal of Science and Research*. ISSN: 2319-7064. ResearchGate Impact Factor (2018): 0.28 | SJIF (2019) 7.583
- Meera SS, Tamilselvan N, Satheeshkumar P. A Comparative Study of efficacy of Superoxidized solution against Povidone Iodine in the treatment of Diabetic Foot Ulcers. *IOSR Journal of Dental and Medical Sciences*. 2016 Aug; 15(8): 10-14. e-ISSN: 2279-0853, p-ISSN: 2279-0861. Available from: www.iosrjournals.org.
- Naidu AL, Vinda NM, Ragumani P. Prospective study to compare the efficacy of super oxidized solution vs povidone iodine in diabetic foot ulcer. *Afr J Biol Sci*. 2024;6(13):1457-1481. doi: 10.33472/afjbs.6.13.2024.1457-1481.