Original research article

Superoxide solution (OXUM) vs povidone-iodine dressing in the management of diabetic foot ulcers: A prospective study

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Abstract

Aim: Diabetic foot ulcers (DFUs) are prevalent complication in diabetes, leading to significant morbidity and risk of lower limb amputation. Super-oxidized solutions (SOS) are emerging as a promising alternative to traditional antiseptics like povidone iodine due to their antimicrobial properties and reduced cytotoxicity. This study aimed to compare the effectiveness of super-oxidized solution dressings with povidone iodine dressings in the management of infected diabetic ulcers.

Materials and Methods: A prospective, randomized, non-blinded study conducted in a tertiary care center on 120 patients with diabetic ulcers, divided into two groups of 60 each. Group A received topical super-oxidized solution dressings, while Group B received topical povidone iodine dressings. Ulcer size, granulation, tissue quality, and discharge were assessed weekly for two weeks.

Results: The study included 73.33% males and 26.67% females, with mean ages of 54.90 ± 13.67 years in Group A and 50.50 ± 12.78 years in Group B. Type 2 diabetes prevalence was 93.33% in Group A and 90.00% in Group B. Initial ulcer areas were comparable. Group A demonstrated a significantly greater reduction in ulcer area ($1587 \pm 832 \text{ mm}^2 \text{ vs. } 2381 \pm 1200 \text{ mm}^2; \text{ p=0.008}$) and higher percentage of ulcer reduction ($59.90 \pm 5.11\%$ vs. $41.90 \pm 8.66\%$; p=0.021). Pseudomonas aeruginosa and Staphylococcus aureus were the most common organisms isolated in Groups A and B, respectively.

Conclusion: Super-oxidized solution dressings significantly improved healing outcomes in infected diabetic ulcers compared to povidone iodine dressings, making them a viable alternative for Diabetic Foot Ulcer management.

Keywords: Diabetic foot ulcer, super-oxidized solution, povidone iodine, wound management

Introduction

Diabetic foot ulcers (DFUs) are a significant complication of diabetes mellitus, affecting approximately 15% of all diabetic patients at some point in their lives ^[1]. These ulcers are often associated with high morbidity and mortality rates due to the complex pathophysiology involving neuropathy, peripheral arterial disease and infection ^[2]. Effective management of DFUs is crucial to prevent severe outcomes such as lower limb amputations, which occur at a rate 15-40 times higher in diabetic patients than in non-diabetic individuals ^[3].

Traditionally, DFUs are managed through a combination of offloading the affected limb, maintaining a moist wound environment, debridement, and appropriate antibiotic therapy ^[4, 5]. The choice of dressing is a critical component in the treatment regimen, as it impacts the healing process by maintaining moisture, reducing bioburden, and protecting the wound from further trauma ^[6].

Povidone iodine has been widely used as an antiseptic agent due to its broad-spectrum antimicrobial activity ^[7]. However, concerns about cytotoxicity and delayed wound healing have led to the exploration of alternative treatments ^[8]. Super-oxidized solutions (SOS) represent a newer approach in wound management. These solutions are electrochemically processed, producing a mixture of reactive oxygen

species with antimicrobial properties while being less toxic to tissues ^[9]. Studies have demonstrated that SOS can enhance wound healing by reducing microbial load and promoting granulation tissue formation ^[10]

Given the potential advantages of SOS over traditional antiseptics like povidone iodine, this study aims to compare the efficacy of super-oxidized solution dressings and povidone iodine dressings in managing infected diabetic ulcers.

Materials and Methods

This single-center, prospective, randomized, non-blinded comparative study was conducted over 18 months at a tertiary care center in Bengaluru. The study included 120 patients with controlled diabetes, aged over 20 years, and having infected diabetic ulcers larger than 1 cm with slough and minimal granulation tissue, classified as Wagner's Grade 1 and 2. Patients with Wagner's Grade 3, 4, or 5 ulcers, absent peripheral pulses, other systemic diseases, or non-cooperative behavior were excluded. Participants were randomly assigned into two groups of 60 each using computer-generated randomization. Group A received topical super-oxidized solution dressings, while Group B received topical povidone iodine dressings.

Demographic data such as age, sex, and ulcer characteristics were collected through patient interviews. Clinical examination findings were recorded on a predesigned proforma, and wound discharge samples were sent for culture and sensitivity testing. Patients received empirical antibiotics (Ciprofloxacin and Metronidazole), which were adjusted based on sensitivity reports. The culture was repeated after 10 days, and debridement was performed if necessary. Ulcer size was measured weekly by mapping the wound and recording the largest dimensions, and the ulcer was assessed for size reduction, granulation, tissue quality, and discharge. Statistical analysis involved comparing categorical data using Chi-square and Fisher's exact tests and continuous data using unpaired t-tests, with a p-value <0.05 considered statistically significant.

Results

The demographic data indicated that the gender distribution was similar between the two groups, with higher male prevalence (73.3% in-group A and 76.6% in-group B). The mean age was also comparable between the groups, showing no significant difference. Around 46% found to have hypertension in both groups showing no significant difference.

The initial ulcer area was similar between the groups, indicating that both groups started with comparable wound sizes. However, the final ulcer area was significantly smaller in Group A ($1587\pm832~\text{mm}^2$) compared to Group B ($2381\pm1200~\text{mm}^2$), with p value of 0.008 suggesting that the super-oxidized solution was more effective in reducing ulcer size.

The change in ulcer area and the percentage reduction in ulcer size were both significantly greater in Group A (59.9% reduction), reinforcing the efficacy of the super-oxidized solution in promoting wound healing.

Pseudomonas aeruginosa (30%) was the most commonly isolated organism in Group A, while Staphylococcus aureus was most common in Group B (33.3%). This suggests a variation in the microbial environment between the two treatment groups, which may influence the healing process and the choice of empirical antibiotics.

Results

Table 1: Baseline characteristics of the study participants in Group A and Group B (n=60 in each)

Characteristics	Group A (n=60)	Group B (n=60)	p-value
Mean age (years)	54.90 ± 13.67	50.50 ± 12.78	0.219*
Males (%)	44 (73.33%)	46 (76.67%)	0.785#
Females (%)	16 (26.67%)	14 (23.33%)	0.785"
Hypertension (%)	28 (46.67%)	27 (45.00%)	0.847#

^{*}Unpaired t test applied. # Chi square test. p value less than 0.05 considered as statistically significant.

Table 2: Organisms isolated in initial culture in Group A and Group B (n=60 in each)

Organisms isolated in initial culture	Group A (n=60)	Group B (n=60)	p-value
Pseudomonas aeruginosa	18 (30.00%)	10 (16.67%)	0.105
Staphylococcus aureus	6 (10.00%)	20 (33.33%)	0.003*
Escherichia coli	14 (23.33%)	12 (20.00%)	0.823
Streptococcus	4 (6.67%)	6 (10.00%)	0.739
Proteus	8 (13.33%)	6 (10.00%)	0.772
Klebsiella	4 (6.67%)	2 (3.33%)	0.678
Acinetobacter	6 (10.00%)	4 (6.67%)	0.745

Chi square test applied. *p value less than 0.05 considered as statistically significant.

Table 3: Ulcer Characteristics of the study participants in Group A and Group B (n=60 in each)

Ulcer Characteristics	Group A (n=60)	Group B (n=60)	p-value
Initial ulcer area (mm²)	3822 ± 1820	3952 ± 1950	0.716
Final ulcer area (mm²)	1587 ± 832	2381 ± 1200	*800.0
Change in ulcer area (mm²)	2235 ± 1040	1571 ± 826	0.022*
Percentage reduction in ulcer (%)	59.90 ± 5.11	41.90 ± 8.66	0.021*

Unpaired t test applied. *p value less than 0.05 considered as statistically significant.

Discussion

The findings from this study underscore the superior efficacy of super-oxidized solution (SOS) dressings compared to povidone iodine dressings in managing infected diabetic ulcers. The significantly greater reduction in ulcer size and higher percentage of ulcer reduction observed in Group A (super-oxidized solution) highlights the potential of SOS as a first-line treatment for diabetic foot ulcers (DFUs).

Diabetic foot ulcers are a major cause of morbidity in diabetic patients and are often complicated by infections that impede healing and increase the risk of lower limb amputation. Traditional treatments, including povidone iodine, have been effective to some extent but pose limitations due to cytotoxicity and potential delays in wound healing [1]. The use of SOS offers a promising alternative, providing antimicrobial properties without the associated cytotoxic effects, which is crucial for promoting faster and more effective healing [2].

The significantly smaller final ulcer area in the SOS group compared to the povidone iodine group aligns with previous studies that have demonstrated the effectiveness of SOS in enhancing wound healing. For instance, Kapur *et al.* ^[7] reported that SOS significantly reduced wound size and promoted granulation tissue formation in various types of wounds, including diabetic ulcers. Similarly, Abhyankar *et al.* ^[10] found that SOS was safe and effective for treating chronic wounds, with outcomes comparable to or better than traditional antiseptics.

Our study also identified Pseudomonas aeruginosa as the most commonly isolated organism in the SOS group, whereas Staphylococcus aureus was predominant in the povidone iodine group. This microbial profile is consistent with other studies on infected diabetic ulcers, which frequently isolate these pathogens ^[5]. The ability of SOS to effectively reduce the microbial load, including Pseudomonas and Staphylococcus species, contributes to its enhanced wound healing properties ^[6].

Comparative studies further support the advantages of SOS. In a study conducted by Mohanty *et al.* ^[11], SOS was found to significantly reduce wound size and accelerate healing in chronic wounds compared to traditional dressings. They concluded that SOS is a viable option for managing chronic wounds, including DFUs. Rajasekaran *et al.* ^[12] compared SOS and povidone iodine in postoperative wound care and found that SOS led to better wound healing and reduced infection rates, suggesting it as a superior alternative in postoperative settings.

Our findings are in agreement with Singh *et al.* ^[13], who assessed the effectiveness of SOS in treating diabetic foot ulcers and reported higher percentages of ulcer reduction and faster healing times compared to povidone iodine. They advocated for considering SOS as a first-line treatment for infected DFUs.

The broader implications of these findings are significant for clinical practice. The adoption of SOS dressings can lead to better patient outcomes by reducing healing times, minimizing infection rates, and potentially lowering the risk of amputations. Moreover, the reduced cytotoxicity of SOS compared to povidone iodine means that it can be safely used over extended periods, providing sustained antimicrobial action without damaging surrounding healthy tissues [14].

However, despite the promising results, this study has limitations. The sample size, while adequate, could be expanded in future studies to further validate these findings. Additionally, a longer follow-up period would help assess the long-term efficacy and safety of SOS in diabetic ulcer management.

In conclusion, this study demonstrates that super-oxidized solution dressings significantly improve healing outcomes in infected diabetic ulcers compared to povidone iodine dressings. The evidence supports the integration of SOS into routine clinical practice for managing DFUs, with the potential to significantly improve patient outcomes and reduce the burden of diabetic foot complications.

Conclusion

Super-oxidized solution dressings significantly improve healing outcomes in infected diabetic ulcers compared to povidone iodine. This study supports their use as a safe, effective, and affordable option for diabetic foot ulcer management. Given the positive results, further research involving larger sample sizes and longer follow-up periods warranted to confirm these findings and establish SOS as a standard treatment for infected diabetic ulcers.

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