ORIGINAL RESEARCH

To evaluate the Role of Neutral pH Super Oxidised Solution in the Treatment of Diabetic Foot Ulcers

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ABSTRACT

Aim: To evaluate the Role of Neutral pH Super Oxidised Solution in the Treatment of Diabetic Foot Ulcers.

Materials and Methods: A total of 220 patients diagnosed with Meggit Wagner Grade I and Grade II diabetic foot ulcers (DFU) were included in the study. The patients were divided into two groups, with 110 patients randomly allocated to either the SOS group or PI group. Patients diagnosed with diabetic foot ulcers (DFUs) of Wagner grade I and II, with ulcer dimensions less than 100cm2, were included in the study. The measurement of the target ulcer's area, specifically the result, was conducted by the use of Plannimetry, using a clear graph sheet. The results were computed using a student's t-test. The assessments were conducted on days 1,7, 14, and 21.

Results: The alteration in wound dimensions from the first measurement (Day 1) was evaluated at day 7, day 14, and day 21. There was no notable difference in wound size between Group A (SOS) and Group B (PI) at day 1-7 ($t=0.89$, $p=0.22$) and day 1-14 ($t=2.05$, $p=0.07$). However, a significant difference was seen at day 21, with Group A (SOS) showing a larger reduction in wound size compared to Group B (PI) ($t=12.44$, $p<0.001$).The average percentage reduction in wound size at Day 21 was 36.36% in Group A (SOS) and 20% in Group B (PI). A notable disparity was seen between Group A (SOS) and Group B (PI) in the ANOVA analysis regarding the average length of hospital stay. In Group A (SOS), the average length for the appearance of Granulation tissue on the Day was 5.17±0.62 days, while in Group B, the average duration for the appearance of Granulation tissue on the Day was 7.08 ± 0.96 days. The average length of hospital stay in Group A (SOS) was 13.25 ± 1.88 days. The average length of hospital stay in Group B (PI) was 16.37 ± 2.06 days.

Conclusion: The neutral pH super oxidised solution is a safe and efficient wound care medication that effectively disinfects wounds, promotes the production of granulation tissue, and accelerates the healing process in the treatment of diabetic foot ulcers (DFU).

Keywords: Super Oxidised Solution, Diabetic Foot Ulcers, Wound

INTRODUCTION

Diabetes mellitus is the prevailing noncommunicable chronic illness in India, with a prevalence rate of around 7% among the adult population. Non-healing foot ulcers are among the several problems that contribute to the increased morbidity of patients. This phenomenon is likely to amplify apprehension and anxieties among patients, while simultaneously imposing additional challenges for surgeons and clinicians. The occurrence of further infections might exacerbate the length of the healing process or even result in limb amputation. The non-healing of ulcers in individuals with diabetes can be attributed to infection resulting from a diverse range of microorganisms, including Staphylococcus aureus and Pseudomonas aeruginosa. These microorganisms infiltrate the wound site and proliferate, generating detrimental toxins that lead to tissue damage and disruption in the process of wound healing [1]. The management of diabetic foot ulcers is optimised through a series of effective steps. These steps encompass offloading the wound by utilising suitable therapeutic footwear, conducting daily dressings to maintain a moist wound environment, performing debridement, administering parenteral antibiotic therapy in cases of osteomyelitis or cellulitis, ensuring glycemic control, and assessing and addressing peripheral arterial insufficiency [2-5]. The primary responsibility of a surgeon is in the provision of wound care for the effective treatment of diabetic ulcers. In addition to effectively managing infection, an optimal wound care solution should also possess the ability to safeguard the integrity of normal tissues and refrain from impeding the natural process of

wound healing [6]. Various topical compounds are used for the treatment of infected ulcers as local dressings. These agents include Povidine iodine, EUSOL, Hydrogen peroxide, Acetic acid, and local antibiotics. Each of these medicines has its own set of restrictions. The use of a superoxidized solution in wound therapy is a novel approach, involving the utilisation of an electrochemically treated aqueous solution with a neutral pH. The aforementioned product has been shown to possess both safety and efficacy in the context of wound care. It effectively provides moisture, lubrication, debridement, and reduction of microbial load in diverse types of wounds [7]. The toxicity of this substance is much lower compared to quantities of antimicrobial hydrogen peroxide, and it does not cause genotoxicity or accelerated ageing, as shown by previous studies [8,9]. The content of sodium hypochlorite is 0.0125% w/v. Super oxidised solutions are aqueous solutions that undergo electrochemical processing. These solutions are derived from pure solutions that have a high concentration of reactive oxygen species. They possess a neutral pH and exhibit a prolonged half-life, lasting for more than 12 months. The product has received approval from the Food and Drug Administration (FDA).The SOS solution has many components, including an oxidised solution of water (H2O), sodium hypochlorite (Na OCI) at a concentration of 35.7mg/L, hypochlorous acid (HOCI) at a concentration of 25.2mg/L, hydrogen peroxide (H2O2), ozone (O3), chlorine dioxide (ClO2), sodium hydroxide (NaOH), sodium carbonate (Na2CO3), and sodium chloride (Na Cl) at a concentration of 110.6mg/L. The osmolarity of the solution is measured at 13 milliosmoles per kilogramme, while the oxidation-reduction potential (ORP) exceeds 800 millivolts. The composition of the super-oxidized water is 99.98%, with a pH range of 6.2 to 7.8. The hypotonic solution and sodium hypochlorite serve as solutions for preservation purposes.

MATERIALS AND METHODS

The present investigation was conducted inside the department of general surgery. A total of 220 patients diagnosed with Meggit Wagner Grade I and Grade II diabetic foot ulcers (DFU) were included in the study. The patients were divided into two groups, with 110 patients randomly allocated to either the SOS group or PI group. Informed written agreement was acquired from all patients, and the research received clearance from the Institutional Ethical Committee. Patients diagnosed with diabetic foot ulcers (DFUs) of Wagner grade I and II, with ulcer dimensions less than 100cm2, were included in the study. Patients diagnosed with vasculopathy, chronic venous insufficiency, and chronic kidney disease (CKD) were not included in the study. Both groups in the study used strategies to alleviate pressure on the afflicted region and effectively manage infection. In the event that culture is found to grow organisms, it is customary to provide antibiotics to both the control and research groups based on the results of the culture sensitivity report. The measurement of the original wound area was obtained after the implementation of sharp debridement, using the technique of measuring the length and breadth of the ulcer, with the stipulation that the ulcer should not exceed dimensions of 10x10 cm. The measurement of the target ulcer's area, specifically the result, was conducted by the use of Plannimetry, using a clear graph sheet. The results were computed using a student's t-test. The assessments were conducted on days 1,7, 14, and 21. Several assessment tools were used to conduct a comparative analysis of wound healing between the SOS and PI groups. These tools included evaluating the reduction in wound size, the presence of granulation tissue, the length of hospital stay, and the timing of wound cleaning. All patients received antibiotic treatment, with some individuals transitioning from IV to oral medications.

DATA ANALYSIS

The data analysis was conducted using SPSS version 25.0. The distribution of categorical variables was analysed, and frequencies were reported. A Chi-square test was used to see whether there were any significant differences between the Superoxidised Solution (SOS) and Povidone Iodine (PI) groups. The data had a normal distribution and were analysed using a parametric independent sample approach. The t-test was used to identify any disparities between groups in relation to any outcome indicators. The study used a one-way analysis of variance (ANOVA) with a post hoc Bonferroni correction to assess and compare wound outcomes across various wound procedures. The analysis was conducted at a 95% confidence interval, and the obtained p-value was 0.01.

RESULTS

The size of the wound was measured on the first day for all patients. The alteration in wound size was determined by comparing the measurements taken on the first day (baseline) with the last day of assessment, namely Day 21. The investigation focused on the wound size's maximum diameter. The alteration in wound dimensions from the first measurement (Day 1) was evaluated at day 7, day 14, and day 21. There was no notable difference in wound size between Group A (SOS) and Group B (PI) at day 1-7 ($t=0.89$, $p=0.22$) and day 1-14 ($t=2.05$, $p=0.07$). However, a significant difference was seen at day 21, with Group A (SOS) showing a larger reduction in wound size compared to Group B (PI) ($t=12.44$, $p<0.001$).

Table: 1 Gender and age distribution of the patients

Gender	Number	Percentage
Male	177	80.45
Female	43	19.55
Age		
30-40	18	8.18
40-50	64	29.09
50-60	109	49.55
Above 60	29	13.18
Mean Age	51.25±5.52	

Table: 2 Wound size of the patients

Intervention Group	Wound size day 1 (in cms)	Wound size day 7 (in cms)	Wound size change D1-D7(in cms)	Wound size day 14 (in cms)	Wound size change D1-D14 (in cms)	Wound size day 21 (in cms)	Wound size change D1-D21 (in cms)
Group B (PI) Mean±SD	17.11±2.25	12.58±1.16	2.03±0.56	10.06±1.63	2.39±0.36	14.06±1.08	4.11± 0.58
Group A (SOS) Mean± SD	16.24±2.74	8.44±1.19	2.44±0.36	9.01±1.06	3.57±0.74	11.06±1.09	6.98± 0.88

The average percentage reduction in wound size at Day 21 was 36.36% in Group A (SOS) and 20% in Group B (PI). A notable disparity was seen between Group A (SOS) and Group B (PI) in the ANOVA analysis regarding the average length of hospital stay. The statistical test yielded a significant result ($F = 10.63$, $p < 0.001$), and the Confidence Interval (CI) ranged from 4.15 to 3.08. In Group A (SOS), the average length for the appearance of Granulation tissue on the Day was 5.17±0.62 days, while in Group B, the average duration for the appearance of Granulation tissue on the Day was 7.08 ± 0.96 days. The results were analysed using an ANOVA test. A notable disparity was observed between Group A (SOS) and Group B (PI) in the ANOVA analysis regarding the day of granulation tissue formation. The statistical test yielded a significant result ($F = 15.85$, $p < 0.001$), and the Confidence Interval (CI) ranged from 1.58 to 3.24.

Table 3: Appearance of Granulation tissue

Group	Appearance of Granulation tissue (days)	P value
Group A (SOS)	5.17±0.62	<0.001
Group B (PI)	7.08 ± 0.96	

The average length of hospital stay in Group A (SOS) was 13.25 ± 1.88 days. The average length of hospital stay in Group B (PI) was 16.37 ± 2.06 days. A notable disparity was seen between Group A (SOS) and Group B (PI) in the ANOVA analysis for the average length of hospitalisation. The statistical analysis yielded a significant result ($F = 19.98$, $p < 0.001$), and the Confidence Interval (CI) ranged from 2.11 to 3.99.

Table 4: Duration of Hospitalisation

Group	Duration of Hospitalisation	P value
Group A (SOS)	13.25 ± 1.88	0.001
Group B (PI)	16.37 ± 2.06	

In Group A (SOS), the mean duration for day of Wound Disinfection (Culture negative) was 9.04 ± 1.08days. In Group B (PI), the mean duration for day of Wound Disinfection (Culture negative) was 13.05± 1.58days. There was significant difference between Group A (SOS) and Group B (PI)on ANOVA for day of Wound Disinfection (Culture negative). (Table 10)($F(2,157) = 26.86$, $p<0.001$), Confidence Interval (CI) was 2.98 – 4.63.

Table 5: Wound Disinfection

Group	Wound Disinfection	P value
Group A (SOS)	9.04 ± 1.08	0.001
Group B (PI)	13.05± 1.58	

DISCUSSION

A prevalence rate of roughly 15% has been seen for foot ulcers among individuals diagnosed with Diabetes Mellitus. It has been observed that about 20% of individuals diagnosed with diabetes who are hospitalised to a healthcare facility would present with a skin ulcer. The incidence of amputation in those

diagnosed with diabetes is significantly elevated, ranging from 15 to 40 times greater compared to those without diabetes. The existence of a nonhealing infected foot ulcer has a significant impact on both the quality of life experienced by diabetes patients and the provision of healthcare services. Individuals diagnosed with diabetes are at a significantly elevated risk, about 40 times greater, of experiencing lower extremity amputations compared to those without diabetes. In 1996, the United States saw an estimated 86,000 instances of hospital discharges specifically attributed to non-traumatic amputations connected to diabetes. The survival percentage for those who have amputation of a limb due to diabetes is below 50% during a span of five years. The aforementioned figures indicate a heightened occurrence of peripheral lesions in individuals with diabetes, as well as a prolonged healing process [10].The current research aimed to investigate the comparative impact of superoxidised solution and povidone iodine on the treatment of Diabetic Foot ulcers. A total of 110 patients were included in each group for analysis. The research found that the average age of patients was 51.25 years with a standard deviation of 5.52 years. Additionally, it was observed that 80.45% of the patients were male. A comparison was made between the two groups in terms of several wound outcome characteristics. There was a statistically significant average decrease in wound size seen from day 1 to day 21. The group treated with the Superoxidised solution exhibited a more quicker reduction in wound size compared to the group treated with Povidone Iodine. In the current investigation, it was observed that Group A (SOS) had a shorter duration of periwound erythema resolution, with an average of 5.09 ± 0.88 days, in comparison to Group B (PI), which had an average of 8.06 ± 0.79 days. Group A (SOS) had a shorter duration of periwound edoema resolution, with an average of 8.26 ± 1.06 days, in comparison to Group B (PI), which had an average resolution time of 12.25 ± 1.87 days. The mean healing time was (45±14) days in SOS group and (58±20) days in PI group in a study conducted on 218 patients suffering from chronic diabetic foot ulcers by Dr. Luca Dalla Pao [11]. Chiara Goretti in his study stated that Povidone iodine has been shown to be an effective antimicrobial agent for the treatment of various conditions and is routinely used for the management of chronic wounds [12]. The significantly faster healing time and shorter duration of required antibiotic therapy in patients treated with SOS indicates that SOS has superior antimicrobial activity than povidone iodine. In our study too, there was earlier wound disinfection in SOS group compared to PI group. Same has been noted in present study.In a study conducted by V. Kapur et al 52 diabetic foot ulcer and chronic leg ulcers patients and acute abscesses treated with SOS also showed early granulation and epithelisation and earlier resolution of periwound erythema and periwoundedema when compared to PI group at a mean follow up of 21 days [13]. Their study also showed that average reduction in wound size at day 21 was greater in SOS group as compared to PI group. These results are comparable and similar to the results of present study. Ashok Anand et al, compared efficacy of SOS versus PI in post C-section wounds, showed that 88% had granulation by day 5 in SOS group compared to 80% in PI group and by day 10 there was granulation in all patients [14]. By day 5, 4% in SOS group had erythema at surgical wound compared to 12% in PI group. The results are similar in our study although done on lower limb ulcers. In Group A (SOS) the average duration for wound disinfection was 9.04 ± 1.08 days compared to 13.05± 1.58days. A research done by Chittoria R Ket al examined the function of SOS in managing diabetic foot ulcers in Andhra Pradesh. The study included 20 patients, and after 5 days, 19 out of 20 instances showed no signs of infection [15]. The most frequently cultivated organisms were Staphylococcus aureus, accounting for 27.27% (60 cases), followed by Enterococci with 15.91% (35 cases), pseudomonas with 13.64% (30 cases), and E.coli with 11.36% (25 cases). Staphylococcus aureus was the most prevalent microorganism found in cultures according to investigations done by V. Kapur et al and Chittoria RK et al [13,15].

CONCLUSION

The neutral pH super oxidised solution is a safe and efficient wound care medication that effectively disinfects wounds, promotes the production of granulation tissue, and accelerates the healing process in the treatment of diabetic foot ulcers (DFU).

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