

Original Research Article

Role of Neutral pH Super Oxidised Solution in Diabetic Foot Ulcers

Vinod Ingale¹, Hemanth S Ghalige², Mahanth HM³, Satyanarayan V⁴, Shabana J Thaha⁵,
Dhananjya BM⁶

¹Junior Resident, Department of General Surgery, ESIC MC & PGIMSR, Rajajinagar, Karnataka, India

²Faculty, Department of General Surgery, ESIC MC & PGIMSR, Rajajinagar, Karnataka, India

³Assistant Professor, Department of General Surgery, Raja Rajeshwari Medical College, Bengaluru

⁴Professor, Department of General Surgery, ESIC MC & PGIMSR, Rajajinagar, Karnataka, India

⁵Junior Resident, Department of General Surgery, ESIC MC & PGIMSR, Rajajinagar, Karnataka, India

⁶Faculty, Department of General Surgery, Raja Rajeshwari Medical College, Bengaluru, India

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Abstract

Background: Chronic wounds in the background of infection require long term treatment with various dressing. The study was done to evaluate role of commonly used topical solutions in the management of Diabetic foot ulcers. **Aims and Objectives:** To compare the efficacy of neutral pH super oxidised solution (SOS) versus Povidone Iodine (PI) in the management of diabetic foot ulcers. **Methods:** Prospective study of patients with Diabetic Foot ulcers admitted in ESIC MC and PGIMSR Rajajinagar, Bengaluru between Jan 2019 to June 2020, satisfying the inclusion criteria were randomized into 2 groups. Super Oxidised Solution group and Povidone Iodine group had 100 patients each. Wound assessments done at regular intervals and various wound outcome variables compared. Statistical analysis of data done using chi square test, independent student t test, 1-way ANOVA, post hoc Bonferroni correction and Pearsons correlation. **Results:** In a study of 200 patients, most patients were in the age group of 51-60 years, and 75.5% were males. There was 35% decrease in wound size in SOS group compared to 20% in PI group at day 21, and earlier appearance of granulation and epithelialization in SOS group. Resolution of periwound erythema and periwound edema was earlier in SOS group compared to PI Group. There was shorter duration of hospital stay, earlier wound disinfection and more number of patients who underwent skin grafting before 21 days in SOS group compared to PI group. **Conclusion:** Super oxidised solution has faster response in wound healing and gives better efficacy as compared to the traditional Povidone Iodine solution for use in wound care in management of lower limb ulcers.

Keywords: Super Oxidised Solution, Povidone Iodine, Debridement.

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Introduction

Diabetic foot is defined as the presence of infection, ulceration and/or destruction of deep tissues associated with neurologic abnormalities and various degrees of peripheral arterial disease (PAD) in the lower limb in patients with diabetes [1,2]. The prevalence of diabetic foot ulceration in the diabetic patients is 4–10%; and it is more frequent in older patients [3,4]. An ideal wound management involves control of infection and prevention of tissue damage and promoting normal wound healing. Hence, we conducted a comparative study between, most used wound care product in practice i.e. Povidone Iodine and Neutral pH super oxidised solution. Superoxidised solution [5] is an aqueous solution of sodium hypochlorite, modified with sodium bicarbonate, used as a solution to mechanically cleanse and debride open wounds. The sodium hypochlorite concentration is 0.0125% weight / volume. Super oxidized solutions are electrochemically processed aqueous solutions manufactured from pure solutions which is rich in reactive oxygen species with neutral pH and longer half-life (>12 months). It is FDA approved. SOS contains Oxidized solution (H₂O), sodium hypochlorite 35.7mg/L (NaOCl), Hypochlorous Acid 25.2mg/L (HOCl), Hydrogen peroxide (H₂O₂), Ozone (O₃), Chlorine dioxide (ClO₂), Sodium

hydroxide (NaOH), Sodium Carbonate (Na₂CO₃) and Sodium chloride 110.6mg/L (NaCl).

osmolarity - 13 mOsm /kg

ORP >800mV

super-oxidised water (999.8%)

pH 6.2-7.8

Hypotonic solution

Sodium hypochlorite is a solution preservative.

Materials and Methods

Patients admitted in Department of Surgery at ESIC MC AND PGIMSR Rajajinagar between Jan 2019 TO June 2020, 200 patients with Meggit Wagner Grade I and Grade II DFU were included, 100 in each group were selected randomly assigned to either SOS group or PI group. All patient gave informed written consent and Institutional Ethical Committee approval obtained for the study. DFU patients of Wagner grade I and II with ulcer dimension <100cm² were included. Patients with vasculopathy, chronic venous insufficiency, CKD were excluded. Off-loading of pressure from the affected area and adequate control of infection was maintained in both the groups. If culture grows organism, both control and study group cases would be treated with antibiotics as per culture sensitivity report. The initial wound area was recorded after sharp debridement by Measuring length x width (ulcer should be less than 10x10 cm). The outcome, that is the area of the target ulcer was measured by Planimetry using a

*Correspondence

Dr. Hemanth S Ghalige

Department of General Surgery, ESIC MC & PGIMSR, Rajajinagar, India

E-mail: hemu.gskims@gmail.com

transparent graph sheet. Results were calculated by using student 't' test. Assessments were done on day 1,3,5,7,9,12,15,18,21.

Various Assessment Tools were used to compare wound healing between SOS and PI groups based on:

- Decrease in Wound size
- Appearance of Granulation tissue
- Duration of hospitalization
- Day of wound disinfection.

Antibiotic coverage was given for all patients, in some patients intravenous antibiotics was followed by oral antibiotics.

SPSS 22.0 version was used for data analysis. Frequencies were reported for distribution of categorical variables and Chi square test was performed for any differences among Superoxidised Solution (SOS) and Povidone Iodine (PI) group. Data were normally distributed and parametric independent sample t test was used to

detect group differences for all outcome measures. One way ANOVA with post hoc Bonferroni correction was used to compare wound outcomes between different wound procedures with 95% Confidence Interval and $p=0.01$.

Results

Decrease in wound size:Wound size was measured at baseline-Day 1 for all patients. The change in wound size was calculated from baseline (Day 1) and last day of measurement, i.e.; Day 21. The largest diameter of wound size was considered for analysis. The change in wound size from baseline (Day 1) was assessed and at day 9, day 12 and day 21. There was no significant change in wound size between Group A (SOS) and Group B (PI) groups at day 1-9 ($t=0.96$, $p=0.35$) and day 1-12 ($t=1.85$, $p=0.09$) but significance was seen with greater decrease in wound size at day 21 in Group A (SOS) compared to Group B (PI) ($t=10.87$, $p<0.001$).

Table 1: Distribution of Patients w.r.t Wound size

Intervention Group	Wound size day 1 (in cms)	Wound size day 9 (in cms)	Wound size change D1-D9(in cms)	Wound size day 12 (in cms)	Wound size change D1-D12 (in cms)	Wound size day 21 (in cms)	Wound size change D1-D21 (in cms)
Group B (PI) Mean±SD	16.78±5.26	11.95±3.9	1.85±0.35	9.53±2.14	2.20±0.49	13.50±4.16	3.73± 1.36
N	100	2		7		91	
Group A (SOS) Mean± SD	15.43±5.43	7.39±2.02	2.35±0.71	8.32±2.67	3.30±1.49	10.17±3.2	6.67± 2.15***
N	100	14		10		76	

*** $P<0.001$ between Group A and Group B using independent samples t test.

In Group A (SOS), the average percentage decrease in wound size at Day 21 was 34% compared to 19.5% in Group B (PI). There was significant difference between Group A (SOS) and Group B (PI) on ANOVA for mean duration of hospitalisation. ($F(2,158)=11.28$, $p<0.001$), Confidence Interval (CI) was 3.47 – 2.39.

Appearance of granulation tissue:In Group A (SOS), the mean duration for Day of appearance of Granulation tissue was 4.78 ± 1.60

days where as the mean duration for day of appearance of Granulation tissue was 6.79 ± 2.06 days in Group B. ANOVA test was used to analyse the outcomes. There was significant difference between Group A (SOS) and Group B (PI) on ANOVA for day of appearance of granulation tissue. ($F(2,159)=17.9$, $p<0.001$), Confidence Interval (CI) was 1.49 – 2.5.

Table 2: Appearance of Granulation tissue

Group	Mean ± SD	Appearance of Granulation tissue (days)
Group A (SOS)		$4.78^{***} \pm 1.60$
	N	100
Group B (PI)		6.79 ± 2.06
	N	100

*** $P<0.001$ between groups using independent samples t test

Duration of hospital stay:In Group A (SOS), the mean duration of hospitalisation was 12.58 ± 2.87 days. In Group B (PI), the mean duration of hospitalisation was 15.77 ± 3.58 days.

There was significant difference between Group A (SOS) and Group B (PI) on ANOVA for mean duration of hospitalisation. ($F(2,159)=22.32$, $p<0.001$), Confidence Interval (CI) was 2.28 – 4.09.

Table 3: Duration of Hospitalisation

Group	Mean ± SD	Appearance of Granulation tissue (days)
Group A (SOS)		$12.58^{***} \pm 2.87$
	N	100
Group B (PI)		15.77 ± 3.58
	N	100

*** $P<0.001$ between groups using independent samples t test

Day Of Wound Dysinfection

In Group A (SOS), the mean duration for day of Wound Disinfection (Culture negative) was 8.52 ± 2.57 days.

In Group B (PI), the mean duration for day of Wound Disinfection (Culture negative) was 12.33 ± 3.12 days.

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 4: Wound Disinfection

Group	Mean ± SD	Appearance of Granulation tissue (days)
Group A (SOS)		$8.52^{***} \pm 2.57$
	N	100
Group B (PI)		12.33 ± 3.12
	N	100

***P<0.001 between groups using independent samples t test

Discussion

In the present study, the effect of superoxidised solution versus povidone iodine in the management of Diabetic Foot ulcers in a group of 100 patients each was studied. The mean age of patients in the study was 56.52 ± 13.6 years, 75% of patients were male. Various wound outcome variables were compared between both groups. The average reduction in wound size from day 1 to day 21 was statistically significant, with the Superoxidised solution group showing more rapid reduction in wound size compared to Povidone Iodine group. In the present study, there was earlier resolution of periwound erythema in Group A (SOS) - 4.7 ± 1.5 days as compared to Group B (PI) - 7.23 ± 1.76 days. There was also earlier resolution of periwound edema in Group A (SOS) - 7.8 ± 2.01 days as compared to Group B (PI) - 11.3 ± 2.3 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 [6]. 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 [7]. 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 periwound edema when compared to PI group at a mean follow up of 21 days [8]. 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 [9]. 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 8.52 ± 2.5 days compared to 12.3 ± 3.1 days. In a study conducted by Chittoria R Ket al for role of SOS in the management of diabetic foot ulcers in Andhra Pradesh on 20 patients, 19 out of 20 cases were negative for infection after 5 days [10]. Most commonly cultured organisms were Staphylococcus aureus 51(25.5%), Enterococci - 30(15%), pseudomonas- 25 (12.5%) and E.coli - 20(10%). Staph aureus was the commonest organism on culture in studies conducted by V.Kapur et al and Chittoria RK et al [8,10]. Wolvos TA opined that Superoxidized solution had wide usage of patterns ranging from simple to extremely complex wounds [6].

Conclusion

Neutral pH super oxidised solution is safe, efficient as a wound care product in terms of early disinfection, early granulation tissue formation and faster healing in management of DFU.



Fig 1: Photograph showing Diabetic Foot Ulcer Treated with SOS on day 1 and day 21

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