MAK HILL Publications Research Journal of Pharmacology

Research Article
doi: 10.36478/makrjp.2025.1.7.11

A Study of Efficacy of Topical Super Oxidized Solution in Comparison with Povidone Iodine for the Management of Lower Limb Diabetic Ulcers

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OPEN ACCESS

Key Words
Povidone iodine, diabetic ulcers, wound erythema, super oxidized solution

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Received: 28 November 2024
Accepted: 31 December 2024
Published: 25 January 2025

Citation: Seelam Paparao and K. Harikrishna Redd, 2025. A Study of Efficacy of Topical Super Oxidized Solution in Comparison with Povidone Iodine for the Management of Lower Limb Diabetic Ulcers. Res. J. Pharm., 19: 7-11, doi: 10.36478/makrjp.2025.1.7.11

ABSTRACT

Wounds and their management are fundamental in the practice of surgery. This Prospective cohort study was done to compare the efficacy of super oxidized solution versus Povidone Iodine in the management of lower limb diabetic ulcers. 100 patients were randomized into 2 groups for SOS and PI with 50 patients in each group. Wound assessments done at regular intervals on day 1, 9, 15 and 21 days and various wound outcome variables were compared. In a study of 100 patients, most patients were in the age group of 51-60 years and 68% were male. There was rapid decrease in wound size in SOS group compared to PI group at day 21 and earlier appearance of granulation tissue in SOS group. Resolution of peri wound erythema and peri wound 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. The results were statistically significant and in favour of SOS. Thus Super oxidized 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 Diabetic ulcers. On correlation of the wound outcome variables, we also noticed that the duration for formation of granulation day (r value=0.303, p value=0.002), peri wound erythema resolution day (r value=0.417, p value=0.000), peri wound Oedema resolution day (r value=0.403, p value=0.000), Disinfection day (r value=0.262, p value=0.010) and Hospital stay (r value=0.232, p value=0.02) are having significantly positive correlation with wound size for 21 days in both groups.

INTRODUCTION

Diabetes mellitus is a chronic disorder and affects large segments of population. The worldwide prevalence of diabetes now exceeds 200 million and is predicted to rise to more than 300 million in the next 20 years[1]. Diabetic foot ulcer affects 10-15% of patients with diabetes during their life time and may be the cause of morbidity, hospitalization and there by affecting the quality of life of person suffering from the condition. Infected, non-healing ulcer is the major cause of non-traumatic lower limb amputation. It is estimated to be 40 times greater than those in the non-diabetics. Over 1 million amputations for diabetes related complications occur every year[1]. It has increased the cost of treatment, hospitalization and its management involves a multidisciplinary approach[2]. The peculiarity of a chronic wound is that in spite of daily dressing with expensive local applications, the wound does not heal. This problem is especially seen in diabetic ulcers, venous ulcers and pressure ulcers. Thus to treat these is a constant challenge for the surgeon. The risk of amputation in a patient with diabetes is 15-40 times higher than that in a patient without diabetes. The prevention of diabetic foot is crucial, considering the negative impact on a patient's quality of life and the associated economic burden on the healthcare system[3]. Wound healing has a multi factorial etiology. Various treatment modalities have been discovered over the years in forms of different types of wound dressings. An ideal wound care product in addition to controlling the infection should also protect the normal tissues and not interfere with the normal wound healing[4]. Some commonly used dressing agents are povidone iodine, collagen, gentian violet, benzoyl peroxide, EUSOL, acetic acid, silver sulfadiazine etc. Povidone iodine is the most commonly used topical wound care product in practice and has been efficiently used over the years in the treatment of lower limb diabetic ulcers and other wounds[5]. The Super oxidized solution (SOS) is a new concept of wound management. It has anti inflammatory effect and produce an environment with an unbalanced osmolarity that damage single cell organism not multicellular organism, therefore host tissues are spared[5]. The present study was conducted to assess the efficacy of topical application of Super oxidized solution (SOS) as compared to Povidone iodine in healing process in lower limb diabetic ulcers and prove that topical application of Super oxidized solution can be used as much better alternative option in the management of lower limb diabetic ulcers.

Aims and Objectives of the Study: To study the efficacy of topical Super oxidized solution in comparison with Povidone iodine in the management of lower limb Diabetic ulcers to observed.

- Wound size.
- Time taken for the appearance of healthy granulation tissue after starting treatment.
- Wound disinfection.
- Duration of hospital stay.

MATERIALS AND METHODS

This is a prospective, comparative and single centered study done on 100 cases making them in to two groups for comparison between topical super oxidized solution and Povidone iodine in the management of lower limb diabetic ulcers admitted in the department of General surgery, satisfying all the inclusion criteria.

Inclusion Criteria:

- Both males and females.
- Patients age between 15-75 years.
- Patients with chronic Lower limb ulcers with diabetic mellitus type 1 or 2, infected, non healing, non weight bearing area ulcers of the dorsum of foot, toes, leg, thigh and wound size <5% TBSA.
- Patients with diabetic foot ulcers of grade I, II, III of Wagner's classification.
- Patients giving informed written consent for topical therapy of super oxidized solution and Povidone iodine.

Exclusion Criteria:

- Age group <15 and >75years.
- Chronic ulcers with other than Diabetic aetiology like venous ulcers, decubitus ulcers, malignant ulcers and specific ulcers (TB, syphilis, Leprosy).
- Other comorbid conditions like chronic renal failure, generalized debility and other factors, adversely affecting wound healing.

Method of Data Collection: The included patients were subjected to:

- Detailed clinical history.
- General Physical examination and local ulcer examination.

Investigations:

- Routine blood investigations-Complete blood count, renal function tests, blood sugars FBS, PPBS, RBS and HBA1c.
- Radiological-X ray of underlying bone wherever indicated.
- Swab Culture sensitivity(C/S) of ulcer on Day 1 in all patients and subsequent C/S on variable days.
- Informed Written Consent for SOS and PI topical therapy.
- Blood sugar was controlled by insulin and/or oral hypoglycemia drugs.
- Endocrinologist opinion was taken for all cases.

- Antibiotic coverage was given for all patients swab for culture and antibiotic sensitivity was taken every patient and appropriate antibiotics used.
- An assessment of the wound was done on day 1,3,5,7,9,12,15,18,21.

Application of Dressing: After admission of the patient swab was taken for culture sensitivity from wound for all the patients was sent in the study group and control group. In study group the lower limb diabetic ulcers were irrigated daily with Super Oxidized Solution and covered with gauze soaked in Super Oxidized Solution and in control group dressing was done with 5% Povidone iodine solution. Before applying both dressing daily wound is cleaned with normal saline. The ulcer dimensions as well as the surface area assessed using vernier callipers, before both types of dressings were applied. At the end of 21 days the wound in both the groups were observed and compare for healing. Assessment of the healing of wound is done under the following parameters:

- Percentage of decreased Wound size.
- Mean duration for appearance of Granulation tissue.
- Mean duration for resolution of Peri wound Erythema.
- Mean duration for resolution of Peri wound Edema.
- Organisms isolated/Growth on Culture (as reported by microbiology dept).
- Procedures done (no procedure/skin grafting/ Debridement/Fasciotomy).
- Day of wound disinfection.
- Mean duration of hospitalization.

Wound Size Assessment: Wound size was measured in Cm^2 at Day 1 for all patients and subsequent assessments were done on days 9, 15 and 21. The change in wound size was calculated from baseline (Day1) and last day 21 measurement and in some patients who underwent Split skin grafting before 21 days, it was calculated one day prior to SSG. In this study few patients underwent SSG after Day 9 and Day 15. Hence Day 9, 15 and Day 21 have been considered as the last day for measuring the change in wound size. The wound surface area was calculated by multiplication of largest diameter of length and width in Cm^2 considered for analysis[6].

Statistical Analysis: Data has been entered in to MS-Excel and statistical analysis was done by using IBM SPSS for windows version 20.0. For categorical variables, the data values are represented as number and percentages, to test the association between the groups, chi-square test was used. For continuous variables, the data values are represented as mean and standard deviation, to test the mean difference between the groups., student's t-test (Independent and or paired sample t test) was used. Bi-variate relationships were determined using Pearson's correlation analysis.

RESULTS AND DISCUSSIONS

The mean age of patients in both groups was 53.64±13.33, of Group A was 52.36±14.48 and in Group B-54.92±12.18. The age of the patients in the study varied from 15-75 years. The maximum number of patients were in the age group of 51-60 years in both Group A and Group B (36 patients). In Group A, the youngest patient was 19 years and oldest patient was 72 years of age. In Group B, the youngest patient was 23 years and oldest patient was 74 years of age. In Group A, there are 38 male and 12 female patients. In Group B there are 30 male, 20 female patients, with overall 68% male and 32% female patients in both groups. The difference was not statistically significant. In Group A, Right lower limb was affected in 27%, Left lower limb in 22% and Bilateral involvement in 1%. In Group B, Right lower limb was affected in 25%, Left lower limb in 24% and Bilateral involvement in 1%. The difference in both groups was not statistically significant. In both Group A and Group B, ulcers most commonly involved the dorsum of the foot and either alone or together with other sites. Diabetic foot ulcer was graded according to Meggit Wagner classification and only grades I, II, III are included in the study. 52 Patients had Grade I ulcers, 29 Patients had Grade II Ulcers and 19 patients had Grade III Ulcer. The Wound size was measured in cm^2. The mean wound size assessment was done on day 1,9,15, 21. The mean wound size at day 1 in group A was 14.05±5.6 cm^2 and group B was 15.78±3.75 cm^2 and this difference was statistically not significant (p-0.076). The average percentage of decrease in wound size from day 1 to day 21 was 70.95% with SOS group compared to 54.29% in Povidone Iodine group and this was statistically significant (P<0.0001). In Group A (SOS), the mean duration for the appearance of granulation tissue was 5.04±1.59 days. In Group B (PI), the mean duration for appearance of granulation tissue was 6.78±2.23 days. There was significant difference between Group A (SOS) and Group B (P) in the appearance of granulation tissue, P<0.001. In Group A (SOS), the mean duration for Peri wound Edema Resolution was 7.98±2.31 days. In Group B (PI), the mean duration for Peri wound Edema Resolution was 12.26±2.51 days. There was significant difference between Group A (SOS) and Group B (P) for Peri wound oedema resolution, with P<0.001. In Group A (SOS), the mean duration of hospitalization was 12.54±2.88

days. In Group B (PI), the mean duration of hospitalization was 16.12±3.57days. There was significant difference between Group A (SOS) and Group B (PI) on Duration of hospital stay, P<0.001. Among both Groups, wound healed without surgical intervention was in 60 cases (Group A 33, Group B 27) and additional surgical intervention was done in 40 cases in both Groups. 16 cases underwent Debridement, 2 cases in Group A and 14 cases in Group B. 7 cases underwent Fasciotomy, 2 cases in Group A and 5 cases in Group B. 13 cases underwent Split Skin Grafting in Group A and 4 cases in Group B. In Group A (SOS), 13 cases underwent SSG before 21 days and in Group B (PI), 4 cases underwent SSG before 21 days, hence, χ2=5.74 and p=0.017. Granulation day (rvalue=0.303, p value=0.002), peri wound erythema resolution day (r value=0.417, p value=0.000), peri wound Oedema resolution day (r value=0.403, p value=0.000), Disinfection day (r value=0.262, p value=0.010) and Hospital stay, (r value=0.232, p value=0.02) are having significantly positive correlation with wound size for 21 days.

Table 1: Mean Duration of Peri Wound Erythema Resolution

		Day of Resolution of Periwound Erythema (days)
Group A	Mean±S.D.	4.72±1.51
	N	50
Group B	Mean±S.D.	7.90±2.01
	N	50

Table 2: Mean Duration of Peri Wound Odema Resolution

		Day of Resolution of Peri wound Edema (days)
Group A	Mean±S.D.	7.98±2.31
	N	50
Group B	Mean±S.D.	12.26±2.51
	N	50

Table 3: Organism on Culture Sensitivity

Organism on Culture sensitivity	Group A	Group B	Total
Staph aureus	14	11	25
Enterococci	5	7	12
Pseudomonas	7	5	12
Klebsiella	4	7	11
E.coli	4	6	10
Citrobacter	5	3	8
Streptococcus	5	3	8
Proteus	4	3	7
Acinetobacter	1	3	4
No growth	1	2	3

Table 4: Number of Patients with Split Skin Grafting (n=100)

Split skin grafting	Group A	Group B
Yes	13 (26.00%)	4 (8.00%)
No	37 (74.00%)	46 (92.00%)
Total	50	50

Wound dressings have evolved from the status of providing physical protection to the raw surface, absorbing exudates and controlling local infections by local medications to the level of providing adequate environment which promote wound healing. This has been achieved by modern wound dressing equines promoting granulation tissue formation. The concept of moist wound dressings which came into vogue in 1960 revolutionized wound care. This led to further research in this direction leading to influx of many products. This study was done as a prospective randomized controlled comparative study to compare the effect of topical application of super oxidized solution versus Povidone iodine in the management of lower limb diabetic ulcers in 100 patients with 50 patients in each group. The observations and results were subjected to statistical analysis. The present study reveals that age of the patients varied from 15-75 years and most of the patients belong to middle age group. The maximum numbers of cases belong to the age group of 51-60 years. The mean age of patients in both groups was 53.64 years and in Group A was 52.36 years and in Group B was 54.92 years and the difference was statistically not significant and predominant sex in both study and control group are more of males 68% in comparison with females 32%. Our study reports that in both study and control groups right lower limb is more involved (52%) compared to left lower limb (46%) and bilateral involvement was seen in 2% of cases. Diabetic ulcers were graded according to Meggit-Wagner classification[6] and grade I, II, III were included in the study. In both study and control groups more number of patients had Grade I ulcers followed by grade II and grade III ulcers. In the present study mean wound size was assessed in cm2 at day 1 and day 9, day 15 and on day 21. The average percentage of decrease in wound size from day 1 to day 9 was 18.56% with SOS group compared to 15.22% in Povidone Iodine group, which was statistically significant (P<0.004). In our study, granulation tissue appeared earlier in SOS group (5.04±1.59 days) when compared to control PI Group (6.78±2.23days). There was significant difference between the groups in the appearance of granulation tissue, P<0.001. In the current 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 significant difference between Group A (SOS) and Group B (P), P<0.001. In our study there was 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. There was significant difference between Group A (SOS) and Group B (P), P<0.001. In our study, patients in both groups were assessed for the effect of topical SOS in comparison with povidone iodine on reduction in bacterial load as shown by negative culture and sensitivity. The mean duration for day of wound disinfection (Culture negative) was earlier in Group A (SOS) 9.13±2.53 days as compared to Group B (PI) 12.63±3.15 days. There was significant difference between SOS Group and PI Group, P<0.001. In present study both groups showed that Staphylococcus aureus in 25 patients, Enterococci in 12

patients, no growth in 3 patients on Culture sensitivity taken on day 1. Some patients had growth of 2 or more organisms on culture and sensitivity. The quality of life of the patient in both the groups was determined by the assessment of total hospital stay as number of days of admission in the hospital. The mean duration of hospitalization was 12.54±2.88 days in Group A (SOS) which included Skin grafting in 13 cases as compared to 16.12±3.57 days in Group B (PI), showing shorter hospital stay in patients treated with SOS. There was significant difference between two Groups, P<0.001. In Dr. Miranda Altamirano[7] study on superficial partial, deep partial and full thickness burns hospital stay was reduced by 50% in oxum group v/s control group. In current study out of 100 cases, 60 cases (Group A 33, Group B 27 cases) were healed by SOS and PI, rest of 40 cases in both groups are healed byadditional Surgical intervention like debridement, Fasciotomy and Split Skin Grafting (SSG). Out of 40 cases, 13 cases were fit for SSG in SOS group only 4 cases were fit for PI group at the end of 21 days, which is statistically significant.(p=0.017). Hence, in the current study there was faster healing rate of ulcers treated with super oxidized solution compared to Povidone iodine, proving SOS to be safe, efficient and superior as a wound care product compared to povidone iodine in the management of lower limb diabetic ulcers.

CONCLUSION

In patients treated with super oxidized solution, comparatively we found that there was:

- Earlier appearance of granulation tissue.
- Earlier resolution of peri wound erythema.
- Earlier resolution of peri wound edema.
- Rapid decrease in wound size.
- Patients are taken for SSG early.
- Shorter duration of hospitalization

This study confirms that Super oxidized solution with its moistening effects and cost effectiveness is safe, has faster response in wound healing and gives better efficacy as compared to the traditional Povidone Iodine solution for use as a topical/irrigant solution in wound care and in management of lower limb diabetic ulcers. Hence it is a good choice for management of lower limb diabetic ulcers.

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