MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.59218/makrjms.2023.12.209.213

OPEN ACCESS

Key Words
Cost effective treatment in diabetics, super oxidized solution, povidone-iodine, diabetic ulcer, wound healing

Corresponding Author
Amit Girme,
Department of Surgery, Dr. D.Y. Patil medical college and research Center Pimpri, India
dramit.girme@gmail.com

Author Designation
[1,2]Associate Professor

Received: 18 November 2023
Accepted: 29 November 2023
Published: 30 November 2023

Citation: Mahendra Wante and Amit Girme, 2023. Study of Cost Effective Solution for Healing in Diabetic Foot Ulcer. Res. J. Med. Sci., 17: 209-213, doi: 10.59218/makrjms.2023.12.209.213

Study of Cost Effective Solution for Healing in Diabetic Foot Ulcer

[1]Mahendra Wante and [2]Amit Girme
[1,2]Department of Surgery, Dr. D.Y. Patil medical college and research Center Pimpri, India

ABSTRACT
A non-communicable disease like diabetes appears to be a cause of morbidity and mortality. Diabetic foot is one of the many serious consequences of diabetes that has received little attention and awareness for many years leading to tissue loss and amputation. This causes an emotional and financial burden on patients. Between September 2020 and August 2022, this study was conducted at a tertiary care hospital in industrial area of pune to evaluate the cost effectiveness of the super oxidized solution (SOS) and povidone-iodine (PI) in treating diabetic foot ulcers of lower or middle working class. Sixty diabetes patients with lower limb ulcers took part in the study. Group A's treated with SOS, whereas Group B's treated with PI. The mean random BSL (blood glucose level) in groups A and B is 254.47 mg dL^{-1} and 254.96 mg dL^{-1} in both. HbA1c levels in group A were 8.30% and in B were 8.46%. The most frequent organisms isolated are Staphylococcus aureus and pseudomonas. Wound healing time was considerably shorter (37.45 days) for Group A than group B (46.37 days) and the average duration for achieving a nil growth culture in group A is 15.12 days, whereas 17.58 days in group B. The SOS treatment reduces the duration of hospital stay than the conventional PI treatment, according to the study, since it is less expensive for lower-and middle-class patients has moistening properties that promote quick healing and is non-irritating.

INTRODUCTION

A non-communicable disease like diabetes appears to be a cause of morbidity and mortality. Diabetic foot is one of the many serious consequences of diabetes that has received little attention and awareness for many years leading to tissue loss and amputation. This causes an emotional and financial burden on patients. Diabetes and Foot Care was declared the theme of World Diabetes Day 2005 by the WHO, recognizing the importance of raising public awareness about this global disease. The year's slogan was "Put Feet First Prevent Amputations". Every year on November 14th the WHO and the IDF commemorate World Diabetes Day, attracting the attention of people from all walks of life. The core message of the WHO's Diabetic Foot campaign is that lower-extremity amputations can be avoided by using low-cost options for treatment and an effective care plan, which is also the primary focus of this study.

Because the diabetic foot is a pivotal event in the life of an individual with diabetes this study emphasizes the significance of wound assessment, regular debridement and cleansing, infection recognition and management with suitable dressing choice to achieve optimal healing of the affected fe *et al.* ong with glycaemic management as a holistic approach. Unlike other chronic wounds, diabetic foot ulcers are generally caused by a wide range of diabetes-related complications such as neuropathy, vasculopathy, altered neutrophil function, limited tissue perfusion and deficient protein synthesis.

Such patient is capable of limited self care and confined to bed or chair adding to further cost of treatment and stay in hospital. Due to its location in an industrial region this institute primarily serves those in the lower middle class. The ultimate goal in this population continues to be the rapid healing of lower limb wounds and prevention of amputating in order to resume work as soon as possible. The neglect of wound is a common problem in lower middle class men.

SOS work at neutral pH to destroy organic material by undergoing chemical reactions with protein and molecules in microbes thus disturbing the cell walls of bacteria and other organisms by interfering with cellular processes leading to cell death. On the other hand, PI acts by releasing nascent oxygen as a small molecule to penetrate microorganisms to oxidize proteins, nucleotides and fatty acids in cell membranes leading to cell death but an irritant to the normal flora of the skin at the pH of[4]. The SOS treatment performs better than the conventional PI treatment, according to the study, since it is less expensive for lower and middle class patients, has moistening properties that promote quick healing and is non-irritating. This prospective study, which included 60 patients with diabetic lower limb ulcers, was carried out in consideration of the necessity of reducing cost of treatment for lower or middle working class patients. As a result, an integrated care strategy is adopted in this research. The study was conducted to compare effects of SOS to PI in management of a diabetic foot ulcer.

MATERIALS AND METHODS

Type of study: Interventional study.

Design of study: A Prospective comparative study.

Place of study: Dr. D.Y. Patil medical college, hospital and research centre, Pune. Dr. D.Y. Patil Vidyapeeth, Pune.

Period of study: September-August 2020-2022.

Period required for data collection: 2 years.

Sources: Super oxidized solution (available as brand name "oxum spray").

- Povidone-iodine solution
- Sterile wound swab test tube
- Culture and sensitivity report
- Doppler arterial study
- Laboratory investigations as per the check list given in patient performa

Method: Patients with diabetic ulcers admitted to the Dr. D.Y. Patil Medical College, Hospital and Research Centre's General Surgery department between September 2020 and August 2022 who met the inclusion and exclusion criteria were chosen and screened for this study. Sixty patients were randomly assigned to two groups of 30 each. After routine debridement and cleaning, Group A patients were dressed with super oxidized solution (SOS) and their outcomes were recorded. Following routine debridement and cleaning, Group B patients were dressed with povidone-iodine (PI). A team of diabetologists, general surgeons, orthopedic surgeons, radiologists, microbiologists and staff nurses cared for all patients.

Inclusion criteria:

- Age: 20-80 years
- Gender: both male and female
- Type I and II diabetes mellitus patient

Exclusion criteria:

- All ulcers other than diabetic ulcer
- Patients with deranged laboratory parameters (hypoalbuminemia/hyperbilirubinemia)

- Bleeding diasthesis
- Immuno compromised
- Diabetes with PVD
- Diabetes with varicose veins

RESULTS

This prospective study included 60 patients with diabetic lower limb ulcers, 30 of whom were assigned to group A and were dressed with super oxidized solution and the remaining 30 patients were assigned to group B and were dressed with povidone-iodine.

Group A's average age is 58.25 years, whereas Group B's average age is 55.34 years. Eighty four percent of the patients were men, while only 16% were women (SD- 10.9). The mean random BSL in groups A and B is 254.47 mg dL^{-1} and 254.96 mg dL^{-1} respectively. However, with a p-value of 0.973, there was no significant difference in mean random BSL (Table 1-2) and (Fig 1).

Fig. 1: Patient treated with superoxidized solution

Fig. 2: Patient treated with povidone iodine

Table 1: Age and gender wise distribution

Age (years) statistics	No
No	60
Mean	56.88
Std. error of mean	1.303
Std. deviation	10.09
Range	42
Minimum	34
Maximum	76

HbA1c levels in group A were 8.30% and in B were 8.46%. However, with a p-value of 0.595, there was no significant difference in mean HbA1c levels. The most frequent organisms isolated are staphylococcus aureus, pseudomonas and E coli. Before treatment the mean wound area was approximately comparable in super oxidized solution and povidone-iodine (37.69-37.40 cm^2, respectively) but on day 21 mean wound area decreased to 12.24 cm^2 in group A and 19.6 cm^2 in group B. With a p-value of 0.00, group A's wound healing time was significantly shorter (37.45 days) than group B's (46.37 days). The mean time observed for achieving a nil growth culture in group A was 15.12 days and 17.58 days in group B. However, there was no statistically significant difference (p>0.05) between the two (Table 3-6) and (Fig 2).

DISCUSSIONS

The conventional protocol and methods were used in this study to evaluate super oxidized solution with povidone-iodine solution for managing diabetic foot ulcers. The study assessed a potential method not only for treating diabetic ulcers but also for avoiding amputation.

Patients treated with super oxidized solution had a faster epithelialization process, better granulation tissue formation and a shorter healing time than patients treated with povidone-iodine in the current study. Moreover, there were no cases of allergy or irritation in the super oxidized solution-treated group. In this study the average age group was 58.25±10.9 years, with 84% of patients being male and 16% being female. However, there was no significant difference in mean random blood sugar levels or HbA1c levels between the two study groups. In one study, the male-to-female ratio was 3.2:1, with 76.67% of patients being males and 23.33% females[1]. Staphylococcus aureus was the most common organism isolated from wounds among the study subjects, with a frequency of 17, followed by pseudomonas and E coli, both with a frequency of 15. In addition, Klebsiella, MRSA, MSSA, streptococcus agalactiae, Bacteroides and acinetobacter were isolated. Staphylococcus aureus was the most common organism isolated on culture in studies based on other studies[2,3]. In a study conducted by[3] 52 diabetic foot ulcer and chronic leg ulcer patients with acute abscesses treated with SOS showed early granulation and epithelialization, as well as

Table 2: Random BSL and HbA1c values in both groups

Glucose	Group	No	Mean	SD	SEM	p-value
R-BSL	Superoxide solution	30	254.27	65.817	12.016	
(mg dL^{-1})	Povidone iodine	30	254.9	76.98	14.055	0.973
HbA1c (%)	Superoxide solution	30	8	1.33236	0.24325	
	Povidone iodine	30	8.2233	1.86209	0.33997	0.595

Table 3: Common organisms isolated in the study

Organism	Frequency
Bacteroides	1
E coli	15
Klebsiella	7
Acinetobacter	1
MRSA	2
MSSA	2
Pseudomonas	15
Staphylococcus aureus	17
Streptococcus agalactiae	2

Table 4:Comparison of efficacy of superoxide solution and povidone iodine

	Descriptive statistics			
Wound area	Group	No	Mean	Std. deviation
Day 1	Superoxide solution	29	37.6897	19.10704
	Povidone iodine	30	37.4	23.70159
	Total	59	37.5424	21.38104
Day 21	Superoxide solution	29	12.2414	7.60946
	Povidone iodine	30	19.6	15.0759
	Total	59	15.9831	12.46442

Table 5: Comparison between wound healing time among groups A and B

Variable	Group	No	Mean	SD	SEM	p-value
Healing time	Superoxide solution	28	37.11	6.338	1.198	0
	Povidone iodine	29	52.76	9.605	1.784	

Table 6: Comparison of time taken to achieve nil growth on culture between groups A and B

Variable	Group	No	Mean	SD	SEM	p-value
Time for nil growth culture	Superoxide solution	26	15.12	5.874	1.152	0.771
	Povidone iodine	26	15.58	5.478	1.074	

earlier clearance of periwound erythema and peri-wound edema at a mean, follow up of 21 days when compared to the PI group. The SOS group had a significantly larger reduction in wound size at day 21 than the PI group, according to their findings. On day 21 the mean wound area decreased to 12.24 cm^2 in the super oxidized solution treated group and 19.6 cm^2 in the PI group, indicating that SOS is more effective than PI, which is similar to the results of previous studies. With a p-value of 0.00, the mean wound healing time in group A was 37.45 days and 46.37 days in group B. From day 1-21 day both groups were compared on a number of wound outcome parameters the average reduction in wound size was statistically significant, with the SOS group showing a faster reduction in wound size than the PI group. The mean time for achieving a nil growth culture in this study was dependent on the organism isolated from the wound with a p>0.05. In contrast to our findings, Chittoria's study revealed a significant difference in wound disinfection in the SOS group versus the PI group[2-4]. The mean time for wound disinfection in the SOS group was 10±5 days, while the PI group took 25±5 days[4]. The neglect of wound is a common problem in lower middle class men.

SOS is a fairly new concept in wound dressing, got introduced in 2003. Previously, its antisepsis action was preferable to that of standard normal saline dressings, particularly in chronic wounds. The impressive antisepsis, faster wound healing and non-irritability results have promoted the use of SOS over the conventional use of PI to become more common all over the world, as evidenced by current literature.

According to[5] the efficacy of SOS is superior to other antiseptic agents such as PI. The findings of this study are consistent with previous research findings, proving how a SOS is a better solution than other antiseptic agents such as PI. SOS, according to Wolvos TA, could be used to treat a wide range of wounds, from simple to extremely complex[6]. It can be used as both a wound irrigation solution and to moisten the gauze used to cover the wound during basic dressing changes. SOS work at neutral pH to destroy organic material by undergoing chemical reactions with protein and molecules in microbes, thus disturbing the cell walls of bacteria and other organisms by interfering with cellular processes leading to cell death. On the other hand, PI acts by releasing nascent oxygen as a small molecule to penetrate microorganisms to oxidize proteins, nucleotides and fatty acids in cell membranes leading to cell death but an irritant to the normal flora of the skin at the pH of 4. The study stated that the moistening effects and low cytotoxicity in patients treated with the SOS made it a better alternative for

wound management due to non-antibiotic technology certainly providing a broader innovative approach to the treatment and prevention of acute and chronic wounds[7].

Chiara Goretti found that patients treated with SOS had a statistically significant shorter healing time and antibiotic therapy duration, as well as a better 6-month healing rate than those treated with PI ($p<0.01$)[8]. Recurrence of infection the need for debridement surgeries and the need for small amputations were significantly lower in the SOS treated patients than in PI treated patients ($p<0.05$). These preliminary findings suggest that using SOS as a wound dressing in conjunction with other local and systemic treatments may aid in the efficient healing of diabetic foot postsurgical lesions with minimal complications. In our current study, we discovered similar results.

Any technique that reduces treatment costs shortens hospital stays, quickly sterilizes infection loads and shortens healing time has an institutional benefit for patients. In diabetic foot ulcers the SOS was proven to be an effective option available to other standard antiseptics such as PI.

The SOS reduces the bacterial load at the wound site, is non-irritable, causes no tissue damage and promotes rapid wound healing, making it an excellent antiseptic. Because of the low cost of therapy and the fact that it is an economically beneficial alternative treatment to existing antiseptics, SOS is quickly gaining popularity, particularly in developing countries like India.

CONCLUSION

In this study the efficacy of SOS versus PI in the treatment of diabetic foot ulcers was compared where we found that SOS outperformed PI in the treatment. Patients who received super oxidized solution experienced the following outcomes. Early granulation and epithelialization. Shorter hospital stay and reduced cost of treatment. Relatively early wound disinfection. Rapid decrease in wound size. Minimizes the need for definite surgery. Therefore the SOS outperforms traditional treatment with PI due to its cost savings, moistening properties, ability to heal rapidly, non-irritability and lesser duration of hospital stay.

REFERENCES

1. Chaudhary, P., S. S. Kumari. and R. Singh, 2020. Comparative evaluation of Super-oxidized Solution and Povidone Iodine solution in Management of Infected Diabetic Ulcers. J. Health. Clin. Res., 3: 136-141.
2. Chittoria, R.K.M. Yootla, L.M. Sampatrao and S.V. Raman, 2007. The Role of SuperOxidized Solution in the Management of Diabetic Foot Ulcer: Our Experience. Nepal. Med. Coll. J., 9: 125-128.
3. Kapur, V. and A.K. Marwaha, 2011. Evaluation of effect and comparison of superoxidised solution (oxum) vs povidone iodine (betadine). Indian J. Surg., 73: 48-53.
4. Meera, D.S.S., P.N. Tamilselvan and D.P.S. kumar, 2016. A comparative study of efficacy of superoxidized solution against povidone iodine in the treatment of diabetic foot ulcers. IOSR J. Dent. Med. Sci., 15: 10-14.
5. Goretti, C., S. Mazzurco, L.A. Nobili, S. Macchiarini and A. Tedeschi *et al*., 2007. Clinical outcomes of wide postsurgical lesions in the infected diabetic foot managed with 2 different local treatment regimes compared using a quasi-experimental study design: A preliminary communication. Int. J. Lower Extremity Wounds, 6: 22-27.
6. Tom, W. A. 2007. A look at how combination therapy can optimize wound healing in clinical experience with a new and stable superoxidized water in wound treatment, advanced wound care with stable, superoxidized water. Supplement to January 2006 Wounds. Clinical. Res. Practice., 1: 11-13.
7. Landa-Solis, C., D. González-Espinosa, B. Guzmán-Soriano, M. Snyder, G. Reyes-Terán, K. Torres and A.A. Gutierrez, 2005. Microcyntm: A novel super-oxidized water with neutral pH and disinfectant activity., 10.1016/j.jhin.2005.04.021, http://dx.doi.org/10.1016/j.jhin.2005.04.021.
8. Goretti, C., S. Mazzurco, L.A. Nobili, S. Macchiarini and A. Tedeschi *et al*., 2007. Clinical outcomes of wide postsurgical lesions in the infected diabetic foot managed with 2 different local treatment regimes compared using a quasi-experimental study design: A preliminary communication. Int. J. Lower Extremity Wounds, 6: 22-27.