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A Comparative Study of efficacy of Superoxidized solution against Povidone Iodine in the treatment of Diabetic Foot Ulcers

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Abstract: *Diabetes is a common, non-communicable endocrine disorder which is a major culprit of morbidity and mortality of mankind at present. Of all known complications of Diabetes, Diabetic foot ranks first in decapitating the affecter's day today activities. According to WHO, 'Somewhere in the World, for every 30 seconds, a lower limb amputation is done due to Diabetes', in which the pathetic concern is that nearly 50% of all these diabetic leg amputations could have been prevented with basic medical care and awareness. Considering the burden of wound care on health system, this study is undertaken comparing the efficacy of Superoxide against Povidone Iodine in the treatment of Grade II and III Diabetic foot ulcers in our Medical College hospital. Out of 100 patients studied, superoxide was proved to be superior over Povidone Iodine in terms of time taken for the lesion to heal and disinfection of wound. Early detection, prompt debridement and wound care with Superoxide along with proper glycaemic control as a holistic approach definitely prevents morbid amputations.*

Keywords: *Diabetic foot, Superoxidized water, Povidone Iodine*

I. Introduction

"It is unacceptable that so much disability and death are caused by leg amputations, when the solutions are clear and affordable"
Dr. Catherine Le Gales – Camus
Assistant Director-General, WHO.

Diabetes is a common, non-communicable endocrine disorder which is a major culprit of morbidity and mortality of mankind at present. WHO projects that Diabetes mellitus will be the 7th leading cause of death in 2030. The global burden of the disease can be understood with WHO fact sheet that 347 million people worldwide suffer from Diabetes. Of all known complications of Diabetes, Diabetic foot ranks first in decapitating the affecter's day today activities. According to WHO, 'Somewhere in the World, for every 30 seconds, a lower limb amputation is done due to Diabetes', in which the pathetic concern is that nearly 50% of all these diabetic leg amputations could have been prevented with basic medical care and awareness. Considering the burden of wound care on health system, this study is undertaken comparing the efficacy of Superoxide against Povidone Iodine in the treatment of Grade II and III Diabetic foot ulcers in our Medical College hospital.

II. Aims And Objectives

- To compare the efficacy of Superoxide aqueous solution against Povidone Iodine on infected Diabetic foot ulcerations in terms of wound healing and disinfection.
- To compare the graded percentage decrease in ulcer size, peri-ulcer oedema and erythema, pus discharge and graded percentage increase in granulation tissue and epithelialisation.

III. Materials And Methods

III.1. Study type: Interventional
III.2. Study Design: Prospective Randomized Comparative study.
III.3. Study group: Over two years, 100 patients suffering from Grade 2 and 3 diaabetic ulcer foot (according to University of TEXAS classification), who had either Type I or Type II Diabetes mellitus attending the General Surgery department of GMK medical college hospital, Salem were considered as data source. Individuals who fulfilled the inclusive and exclusive criteria were enrolled in the study and randomized to enter the study protocol. Out of 100 cases, 50 cases were randomized into Group A and 50 were randomized into

Group B. In group A patients the ulcers were cleaned with Superoxidised solution and in Group B patients with Povidone Iodine after routine debridement.

Iii.4. Inclusion Criteria

1. Age : 20 to 70 years
2. Sex : both male and female
3. Both Type I and II Diabetic patients
4. Grade 2 and 3 Foot ulcers

Iii.5. Exclusion Criteria

1. Grade 1.4 and 5
2. Wound swab negative ulcers
3. Not willing to give consent
4. Vascular occlusion
5. Osteomyelitis in affected foot.

Iii.6. Study Method Instituted:

All patients were treated as Outpatients/ Inpatients by the foot care team comprising of General Surgeon, Diabetologist, Orthopaedician, Radiologist, Plastic Surgeon, Microbiologist and Staff nurse. Screening was done by Medical history, clinical examination and laboratory investigations. Clinical assessment was performed at the beginning of the treatment and at each dressing for each group. Detailed examinations were recorded every week. The necrotic tissues were removed by debridement with sterile precautions on each dressing. Area of each wound was calculated at weekly intervals by multiplying longest vertical and horizontal dimensions of Diabetic foot ulcers. Foot wear, offloading of ulcer and compliance were inspected at every visit and corrections were made when required. Cultures from the depth of the wounds were obtained at the beginning of the study and subsequently at end of every week and antibiotics were prescribed according to sensitivity. Bony involvement was excluded with the help of Radiographs and Orthopaedici surgeon's opinion. Vascular compromise was excluded by Doppler Arterial Study of affected limb. Glycaemic management was appropriately taken over by the physician. Both groups were treated until complete healing of the wound or until the wound becomes fit for skin grafting without any evidence of infection. Wound bed fitness for skin grafting was obtained from plastic surgeon. Statistical analysis of data from the Superoxidised solution treated Group (A) and Povidone Iodine treated Group (B) was done and results tabulated. Students T test (Paired samples t-test) was used as the statistical test to analyse the data obtained in this study.

Follow up: Regular Ulcer survey was made on days 1, 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 78, 85, 90 respectively.

IV. Results

The present study of 100 patients prospectively randomized into A group (Superoxidised solution group) and B group (Povidone Iodine group) of 50 patients each, was conducted with inclusion of same graded wounds in both groups. Every time, measurement of ulcer in square centimeters, measurement of granulation tissue in square centimeters, concomitant therapy and assessment of adverse effects were carried out and tabulated.

TABLE 1: Ulcer size assessment

DAY	**PERCENTAGE DECREASE IN ULCER SIZE**	
	SUPER OXIDE TREATED GROUP	**POVIDONE IODINE TREATED GROUP**
1	BASELINE	BASELINE
8	19	15
15	30	20
22	70	50
29	80	65
P = 20.27318 Students t test		

TABLE 2: Statistical comparative depict of Ulcer size assessment

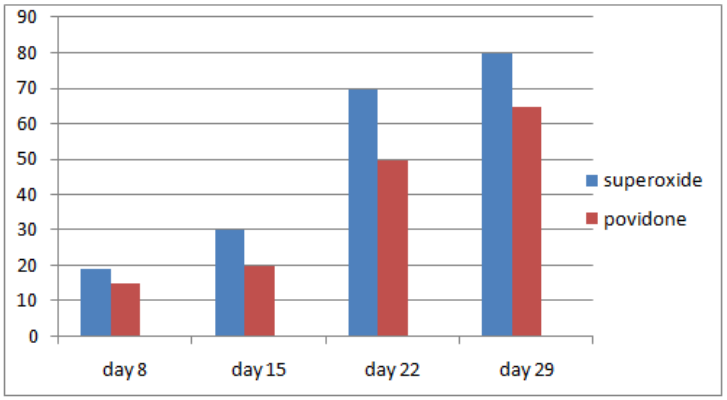
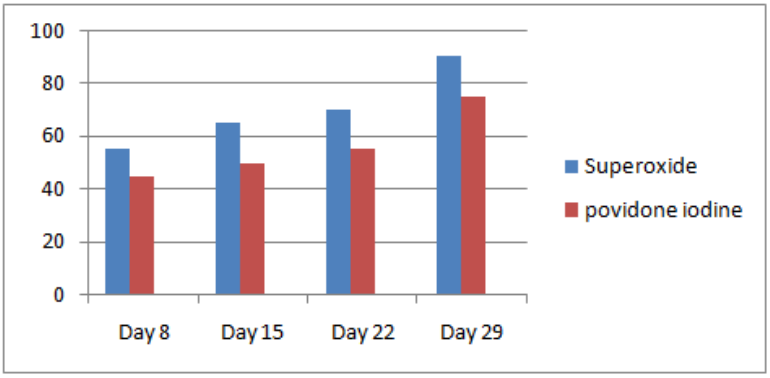


TABLE 3: Peri-Ulcer edema and erythema assessment

DAY	PERCENTAGE DECREASE IN PERI-ULCER EDEMA AND ERYTHEMA	
	SUPER OXIDE TREATED GROUP	POVIDONE TREATED GROUP
1	BASELINE	BASELINE
8	55	45
15	65	50
22	70	55
29	90	75
P+0,21297 students t test		

TABLE 4: Statistical comparative depict of Decrease in peri-ulcer edema and erythema



Superoxidised group developed healthy granulation tissue earlier than Povidone group. But, Povidone Iodine appeared granulo-toxic in healing ulcers thus delaying fitness for skin grafting.

Fig 1: Superoxide Treated Group

TABLE 5: Time to lesion healing

MEAN HEALING TIME	
SUPER OXIDE TREATED GROUP	**POVIDONE TREATED GROUP**
40+_14 days	55+_14 days

TABLE 6: Microbial culture and their outcome

TIME TAKEN FOR NIL GROWTH IN CULTURE	
SUPEROXIDE TREATED GROUP	**POVIDONE TREATED GROUP**
10+_-5 days	25+-5 days

Gram negative bacilli especially Klebsiella formed the major culprit of the isolated wound specimens as depicted in Fig 2.

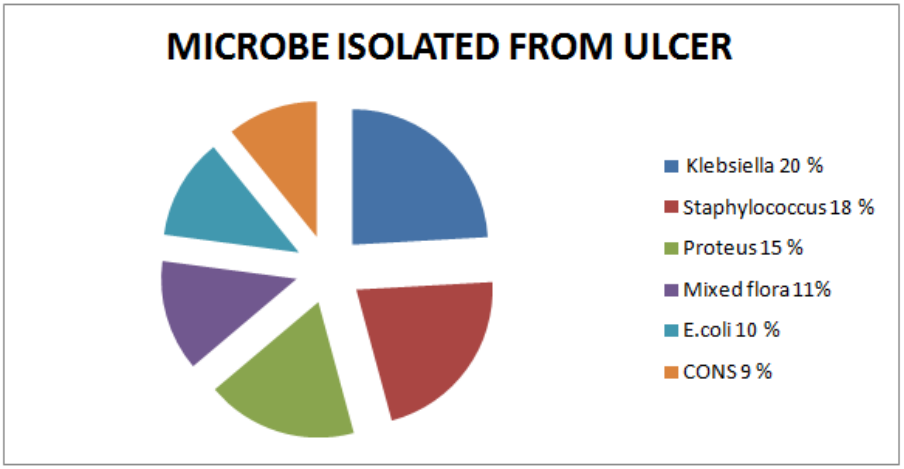


Fig 2: Microbial burden of Diabetic foot Ulcer

In the present study, based on our results, it is concluded that the Superoxidised solution is superior than Povidone Iodine in terms of quick elimination of bacterial load of the ulcer, early wound healing, no tissue irritation and lower economical burden for the patient.

V. Discussion

In this current study, the comparison of Superoxidized solution with Povidone Iodine for treating the diabetic foot ulcer was done with the standard protocol and methods. The study has revealed a promising gateway in not only treating the diabetic foot ulcer and also in avoidance of amputations.

In this current study, patients treated with Superoxidised solution have shown early epithelialisation process and speedy granulation tissue formation, less time to lesion healing, earlier asepsis than the Povidone iodine treated group of patients. Also, there were no reported cases of allergy or irritation in Superoxidised solution treated group. As concluded by Pandey et al 2011, the efficacy of Superoxidised solution is superior over other antiseptic agents [4]. Many researchers have studied the effect of Povidone Iodine on not only diabetic foot ulcers but also many chronic wounds. But comparatively, the literature available on Superoxidised solution is minimal. Superoxide solution is relatively a new concept in wound dressing and started after 2003 only. The promising effects on antisepsis, faster wound healing and non-irritable nature of Superoxide solution's have prompted more people to use this solution for dressing diabetic foot ulcers than Povidone Iodine across the globe and a large scale of recognition is evident through the literatures [1,3].

In developing countries, Superoxide solution gains rapid importance due to its low cost and it is an economically feasible alternative over existing antiseptics. Superoxide solution is a pH neutral solution with a longer shelf life (>12 months) which acts by the difference in osmolarity of the solution and the pathogen's cell wall, resulting in lysis of the pathogen [5]. It has proved its antimicrobial activity against bacteria, viruses, fungi and bacterial spores. Superoxide solutions are electro-chemically processed aqueous solutions manufactured from pure water and USP grade sodium chloride. USP grade sodium chloride is a granular, white crystalline sodium chloride manufactured in United States of America under stringent process-control procedures, and is intended for pharmaceutical applications such as preparation of saline solutions for injection and dialysis [2]. The concept of electrolysis is very simple: tap water is purified through reverse osmosis (RO) and USP grade sodium chloride is added and then submitted to an electric field. During the process of electrolysis, molecules are pulled apart in a chamber with positive and negative poles and finally hypochlorite / hypochlorous species and free radicals are formed. The final result is a blend of high reactive species of chloride and oxygen as depicted in Fig. 3

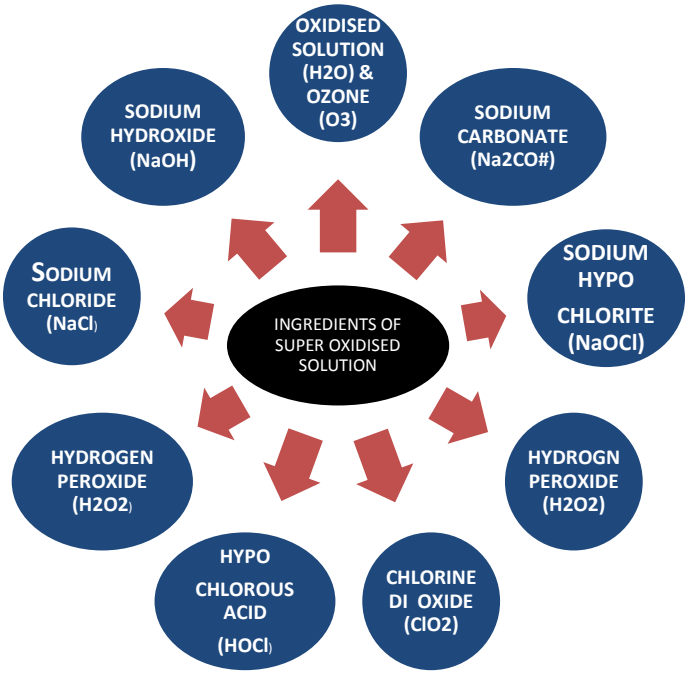


Fig 3: Ingredients of Superoxidized Solution

These ions and free radicals rapidly react and denature proteins of bacterial cell wall. They also have anti-inflammatory effect and produce an environment with an unbalanced osmolarity that damages single cell organism. The damage is due to direct result of the osmolarity difference between the concentrations of the ions in superoxidised solution versus the concentration of the same ions in the cell. Multicellular organisms are not prone to such osmolarity changes, therefore host tissues are spared only the single cell organisms are damaged and henceforth, it is host friendly [4].

VI. Conclusion

Superoxidized solution is superior than the Povidone Iodine in the management of **D**iabetic **F**oot **U**lcers (**DFU**) in terms of Quick elimination of bacterial load in **DFU,** Early wound healing, non irritation of patient tissue and lower economical burden to the community.

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