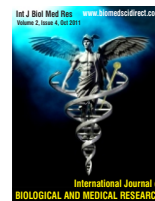


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### Original Article

# Outcomes of superoxide solution dressings in surgical wounds: a randomized case control trial

P K Pandey<sup>a</sup>, M Koushariya<sup>b</sup>, S Shukla<sup>a</sup>, S Das<sup>c</sup>

<sup>a</sup> Flat no. 404, Ratan sadan, Premises number 137, Tollygunge circular road, Kolkata – 700053, India

<sup>b</sup> Department of General Surgery, Gandhi Medical College & Hamidia Hospital, Bhopal, Madhya Pradesh – 462001, India

<sup>c</sup> Department of Microbiology, Peerless hospital, Panchasayar, Kolkata – 700094, India

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#### ABSTRACT

**Aims:** This study was undertaken to evaluate the role of super-oxide solution in wound healing. At the same time an effort was made to compare the efficacy and outcomes of super-oxide solution dressings and those with povidone iodine solution. **Methods:** 100 Patients in age group of 6 to 65 yrs with different types of wounds were randomized in two different groups of 50 each. Patients of group A were treated by dressing with super-oxide solution whereas those belonging to group B with povidone-iodine solution. The prospective analysis of results was done and compared in each group. **Results:** Decrease in surface area of wounds at the ends of 1st, 2nd, 3rd and 4th weeks was more in group A when compared to group B and this was statistically significant ( p values 0.005, 0.002, < 0.001 and 0.001 respectively ). No report of discontinuation in either of the groups was reported. Allergic reactions were found in one patient of group A and 2 patients in group B. The occurrence of infection in primarily sterile cases was lesser (15%) in group A than in group B (36%). Persisting infection at the end of 1st, 2nd, 3rd and 4th weeks of dressings was lower in patients of group A in comparison to group B patients. **Conclusion:** The outcome of this study supports the concept of wound healing with super oxide solution, a novel and effective mode of treatment. The efficacy of super-oxide solution in different types of wounds was found to be superior than the conventional method of treatment with povidone iodine.

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### 1. Introduction

The science of wound healing has advanced in leaps and bounds, particularly as a result of new therapeutic approaches such as growth factors, skin substitutes, gene and stem cell therapy [1]. Super-oxidized waters (SOWs) have been investigated as disinfectants for instruments and hard inanimate surfaces in hospitals and some literatures have been described the use of SOWs in humans for various indications including the treatment of infectious skin defects or ulcers. SOWs have been recommended for hand washing of medical personnel. In vitro, various SOWs exert distinct microbicidal activity against a large number of bacteria and *Candida* species. In contrast to other common disinfectants (e.g. ethanol), SOWs can even kill spores of *Bacillus atrophaeus* and *B.cereus* [2].

However, there are marked differences between various SOWs tested to date (i.e. acidic, neutral or alkaline). The various properties of electrolysed water including pH, concentration of chlorine and oxidation–reduction potential (ORP), determine the germicide activity, shelf life and corrosion potential of each SOW. In order to maintain microbicidal activity and to increase tissue compatibility and shelf life, the production of neutral-pH SOWs has been attempted [3].

Keeping in mind these facts, an attempt has been made to study the effect of super oxide solution dressings on wounds of patients who received treatment in Department of General Surgery, Hamidia Hospital, Bhopal - one of the eminent medical Institution in central India which serves patients mainly from low socio-economic status.

\* Corresponding Author : P K Pandey

Flat no. 404, Ratan sadan,  
Premises number 137, Tollygunge circular road,  
Kolkata – 700053, India  
E mail – drpandeypraveen@gmail.com

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## 2. Material and Methods

The present study was carried out in the Department of Surgery, Gandhi Medical College and Hamidia Hospital, Bhopal, India from April 2006 to March 2007. The patients gave an informed consent approved by the institutional Ethical committee.

100 Patients in age group of 6 to 65 yrs with different types of wounds were included in this study and were randomized in two different groups [ Table 1].

Group A included those who were treated by meticulous surgical debridement followed by dressing with super-oxide solution whereas group B patients were treated by dressing with povidone-iodine solution. The super-oxide solution used in the study is marketed in India by Alkem Laboratories Ltd. by the brand name of "OXUM" whereas the povidone iodine solution used was 5% weight/volume in concentration. All patients received broad spectrum antibiotics which were changed as per the pus culture sensitivity results.

Criteria for inclusion in the study consisted of any wounds in patients irrespective of its etiology, anatomic site, and size. However, exclusion criteria were age more than 65 yrs or less than 6 yrs of age, patients with hemoglobin less than 8 gm/dl, having signs of septicemia and immunodeficiency disorders.

Spectrum of wound type varied from gross Necrotizing fasciitis, gangrene due to infections, diabetic foot ulcer, immobility (spinal cord injuries or operative) trophic ulcers, post operative abdominal wound dehiscence and post operative (incision and drainage or release incisions) wounds.

Clinical assessments of wounds were performed at beginning of treatment and at each dressing change for each group. The examinations were recorded on weekly basis. The necrotic tissue was removed by meticulous debridement using sterile technique on each dressing. On first day of treatment, by multiplying longest vertical and horizontal dimensions of wound, area of each wound was calculated and this was repeated also at the ends of every subsequent weeks. The presence or absence of any allergic reaction and signs of systemic toxicity were ascertained within 48 hours of first dressing in both the groups.

Pus cultures from wound were obtained at beginning of study and at every subsequent week. Treatment continued until total closure of wound took place or wound was ready for skin grafting full of granulation tissue with out evidence of residual infection. Preventive measures such as minimizing immobility, ensuring adequate nutrition and hydration were used in both groups.

Statistical comparison of data from super oxide solution (group A) and povidone iodine (group B) groups was performed using appropriate tests.

## 3. Results

In this study, the maximum number of patients belonged to 26 – 35 yrs of age group [ Table 1 ]. The mean age was 38 years in group A and 39.2 years in group B. The M : F sex ratio was 3:1. It was noticed that males suffer more, probably because of more chances of injuries and exposure to infections.

**Table No. 1. Age Groups**

Age Group	Group A		Group B		Total	
	No.	%	No.	%	No.	%
6 – 15	2	4	2	4	4	4
16 – 25	7	14	12	24	19	19
26 – 35	10	20	11	22	21	21
36 – 45	16	32	3	6	19	19
46 – 55	10	20	7	14	17	17
56 – 65	5	10	15	30	20	20

Number of cases due Necrotizing fasciitis, trauma, decubitus ulcers, diabetic foot wound, fourniers' gangrene, after incision and drainage and post operative abdominal wound dehiscence were 21,3,7, 6, 4 , 5, 4 in group A and 23, 2,8, 6, 1, 6, 4 in group B respectively.

Within 48 hours of application of dressings, moderate degree of pain was observed in total of 4 patients, 2 each from both the groups using Visual Analogue Scale. Allergic reactions in form of itching, eruptions and stinging sensation was found in one patient in group A and two of group B. However, erythema was noticed in two patients in group A and 8 of group B.

Number of patients having wounds over left upper limb, left lower limb, right upper limb, right lower limb, trunk and over perineum were 2, 13, 2 , 15, 12 , 6 in group A and 2, 13, 4 , 12, 16, 3 in group B respectively.

Presence of complicating factors in terms of diabetes mellitus, tuberculosis, malignancy, cachexia , recurrent infections, claudication and immobilisation were present in 6, 5, 1, 11, 18, 3, 6 patients in group A and 6, 4, 1, 13, 18, 2 , 6 patients in group B respectively [ Table 2 ]. Persisting infection at the end of 1st, 2nd, 3rd and 4th week in percentage was 49, 38, 31, 27 in group A and 51, 43, 38, 34 in group B respectively [Table 3].

**Table No. 2. Complicating Factors**

History	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Diabetes	6	12	6	12	12	12
Tuberculosis	5	10	4	8	9	9
Malignancy	1	2	1	2	2	2
Cachexia	11	22	13	26	24	24
Recurrent Infections	18	36	18	36	36	36
Claudication	3	6	2	4	5	5
Immobilisation	6	12	6	12	12	12

**Table No. 3. Incidence of Infection**

Group	1 <sup>st</sup> week		2 <sup>nd</sup> week		3 <sup>rd</sup> week		4 <sup>th</sup> week	
	No.	%	No.	%	No.	%	No.	%
A	37	49	29	38	24	31	21	27
B	39	51	33	43	29	38	26	34

The incidence of infection in primarily sterile cases was 15% in group A and 36% in group B respectively [Table 4]. The most common infecting organism isolated in the study was *Pseudomonas aeruginosa* followed by *Staphylococcus aureus* and *Klebsiella* spp.

Healing for cases in terms of decrease in surface area of wounds after 1 week of dressing was 20.17% in group A whereas 13.83% in group B. The student t-test showed that the healing rate of wounds in group A is highly significant as compared to group B (p value=0.005). After 2 weeks, decrease in surface area noticed was 45.9% in group A and 36.3% in group B. The t test showed healing rate in group A to be highly significant in comparison to group B (p value=0.002). After 3 weeks, the decrease in surface area noticed was 71.3% for group A and 59.1% for group B. After 3 weeks of wound dressing, better healing rate was noticed in group A wounds in comparison to group B and was statistically highly significant (p value<0.001). After 4 weeks, fall in surface area after dressings was 88.7% for group A and 77.8% for group B. The t-test showed that the healing rate in group A was still better and the difference of healing in both groups was highly significant (p value=0.001).

**Table No. 4 Secondary Infection**

Group	Primary Sterile Culture	Secondary Positive Culture	Incidence Of Secondary Infection( % )
A	13	2	15.00
B	11	4	16.00

#### 4. Discussion

Life is a constant battle against entropy (i.e., disorder). The skin provides the primary barrier between the human body and the entropy of the external environment. Breach in this primary barrier predisposes the individual to development of wounds.

Wounds are classified as either acute or chronic. The healing spectrum of wounds is broad. Wounds with delayed healing are characterized by decreased wound healing strength in comparison to wounds that heal at a normal rate [4]. However, they eventually achieve the same integrity and strength as wounds that heal normally. Normal healing is affected by both systemic and local factors. Debridement of infected wounds with local dressing and systemic antibiotics are the commonest and conventional mode of treatment of wounds [5, 6].

The main purpose of wound dressings is to provide the ideal environment for healing. Although the ideal dressing is still not a clinical reality, but novel advances are on their way for the achievement of the same [7].

The principle of “Wound Dressing with Super-Oxide Solution” was officially started in the year 2003 when it achieved a status of “Disinfectant and Antiseptic” in its homeland Mexico [8]. Dressing with super-oxide solution is not a very old topic of discussion and lately a good number of efforts have been made to evaluate the effectiveness of this approach in wound healing. There have been isolated reports of its use in healing of diabetic foot ulcers, abscess cavities, surgical wounds and various other types of ulcers [9]. The use of super oxidized aqueous solution for jet lavage debridement has been found to be as safe and effective as saline [10].

Healing rates have been reported to be significantly shorter in cases dressed with super oxide solution. Also duration for cultures to become negative and of antibiotic therapy were also reported to be shorter. Super oxide solution has been found to be safe and effective in the management of wide postsurgical lesions in the infected diabetic foot [11]. Reports have also been published indicating a better response to this solution in management of acne as compared to benzoyl peroxide. At the same time no systemic effects were observed [12]. Further, this solution has been used in management of chest wall infections and reportedly reduced the time of healing in a significant manner [13].

In this study, the results indicated that the application of super-oxide solution is helpful in healing of wounds. In order to evaluate the role of super-oxide solution in dressing of various types of wounds, results were compared with conventional method. Thus this study also establishes the replacement of conventional method by treatment with super-oxide solution if possible.

Our study revealed less indurations in wound margins when super-oxide solution is used. This finding appears to be consistent with the previously quoted fact that this solution does not damage cellular elements or restrict microcirculation of wound. Thus it ensures well being of surrounding healthy tissue. The study also revealed early reduction in discharge from wound dressed with SOS as compared to povidone iodine solution. Granulation tissue formation was also earlier in group A (cases) as compared to group B (controls) and more as per surface area as compared to controls. The findings are also comparable with earlier work of Allie et al [14] in which they have noticed that topical application of SOS enhances healing including reduction of indurations & discharge. At the same time, a significant elimination of bacterial strains in group A was found as compared to group B. The rate of secondary infection in primary sterile wounds in group A was significantly less than in group B.

A limited number of studies have been done with super-oxide solution. Results in some of them are similar to our experience. A report by Bryant cited an unpublished study where super oxide solution was used, found that it reduced the average hospital stay for patients with second and third degree burns from 28 days to 14 days, and reduced the need of antibiotics.

In a conference presentation Allie et al [14] described comparison in patients with lower extremity ulcer treated with super-oxide solution with matched historical group who received traditional wound care. They found no local complications and the ulcers healed in 98% patients of SOS group compared with 92% of traditional wound care group. In 300 neuropathic diabetic patients only a very few experienced pain with super- oxide solution.

Reports indicate that super oxidized solution has helped in complete healing of wounds, and prepared wounds for definite cover in diabetic foot patients with minimal side effects[15]. Same was our experience with this solution in patients with diabetic foot as pain or reactions observed were not significant enough leading to discontinuation of its use. Although, literature has also been suggestive of discontinuation of dressings due to intolerance to this solution [16], we have not found so in the present study.

## 5. Conclusions

In conclusion, this study further strengthens the concept of wound healing with this novel but effective mode of treatment, concerning the efficacy of super-oxide solution in different types of wounds which were previously managed with conventional method of treatment.

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