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Original Article

Efficacy of Superoxide Solution (Oxum) as Compared to Povidone-iodine in Healing of Chronic Ulcers

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Abstract

Background: Wound healing is a dynamic and complex process. The main purpose of wound dressings is to provide the suitable environment for healing. Various treatment modalities have been discovered over the years in the form of different types of wound dressings. As wounds are great burdens on the health-care system contributing to substantial mortality, morbidity and costs hence the need for study.

Materials and Methods: The present study is a single-center, prospective, clinical trial comparing oxum (superoxidized water) and betadine as a topical treatment of chronic wounds conducted in 100 Indian patients, with 50 patients in each group. All patients underwent daily dressing, debridement when needed and appropriate antibiotics. Clinical findings were recorded on day 1, 5, 7, 12, and 21 and compared.

Results: Reduction in wound size in oxum group was more as compared to betadine, however, it was not significant on day 5, 7, and 12 but results were significant for day 21. Rate of secondary infection for Group A was 22.22% and Group B was 38.44%. Appearance of granulation tissue and epithelization was earlier in Group A as compared to Group B. At day 12 in Group A, 96% of patients developed granulation, and in Group B, 56% of patients had granulation. At day 12 in Group A, 68% of patients had epithelization, and in Group B, 36% of patients had epithelization. Average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129. No adverse reaction was seen in either group.

Conclusion: In the management of lower limb ulcer, a superoxide solution (SOS) debrides necrotic tissue, reduces microbial load, promotes granulation, and decreases the healing time, without damaging the normal tissue or complications. Those patients, who have small superficial ulcers or not fit for definite surgery, can be managed conservatively with SOS only. Hence, SOS is safe, more effective, and efficacious as compared to povidone-iodine for ulcer management.

Key words: Chronic, Healing, Ulcers

INTRODUCTION

The management of wounds is fundamental in the practice of surgery. There has always been a search for an ideal antiseptic that is rapidly lethal to all forms of bacteria and their spores, capable of bactericidal property for a prolonged period with no ill effect on host tissues. Superoxidized solution (SOS) is an electrochemically processed aqueous solutions manufactured from pure water and sodium chloride. Oxum is a solution with neutral pH, longer half-life (>12 months), non-toxic, non-irrigating, no rinse dermal wound irrigant used in humans for wound care treatment including post-operative (post-surgical) wound care.[1] It is FDA approved. SOS is bactericidal, fungicidal, virucidal, and sporicidal. Ions and free radicals of Oxum rapidly react and denature proteins of bacterial cell wall, have anti-inflammatory effect, and produce an environment with an unbalanced osmolarity that damages single-cell organism. Multicellular organisms are not prone to such osmolarity changes, therefore, host tissues are

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spared. As wounds are a great burden on the health-care system, keeping in mind, these factors an attempt have been made to study the effect of SOS dressings as compared to povidone-iodine on lower limb ulcers patients who received treatment in IMCHRC, Indore.

Aim

This study aims to study the role of SOS in wound healing and compare the efficacy and outcomes of SOS dressings and those with povidone-iodine solution in various aspects of wound healing.

MATERIALS AND METHODS

The study was conducted at IMCH and RC, Indore, from August 2014 to March 2017. A total of 100 patients with lower limb ulcers were studied. The patients underwent dressings after obtaining informed consent. The patients were randomized to be divided into two different groups. Group A patients were offered SOS dressing while in Group B patients, 5% povidone dressing was done.

Antibiotics were given as per culture and sensitivity reports. Treatment continued until the wound size reduced to <10 cm^2 to reduce the duration of hospital stay and further follow-up was done on outpatient basis. SSG was performed for ulcers whose size was more than 30 cm^2 and bed was ready for skin grafting full of granulation tissue without evidence of residual infection after the initial 21 days of treatment.

Preventive protocols such as minimizing immobility, ensuring adequate nutrition, and hydration were used for both groups. Assessments were done on day 1, 5, 9, 12, and 21 and efficacy was compared in basis decrease in wound size, appearance of granulation tissue, epithelialization, control of infection, and duration of hospital stay.

RESULTS

In Group A, mean wound size at the time of presentation was 47.80 ± 27.81. In Group B, mean wound size at the time of presentation was 49.96 ± 26.82.

At day 5, in Group A, mean wound size was 42.08 ± 25.04, and in Group B, it was 47.84 ± 26.19. Both the results were compared and no significant difference was found between the two ($P > 0.05$). At day 9, in Group A, mean wound size was 37.48 ± 23.44 and in Group B was 42.28 ± 24.174. At day 21, mean wound size for Group A was 12.74 ± 10.81 and for Group B was 21.20 ± 13.84 with $P < 0.05$ which is statistically significant.

Granulation Tissue

In Group A, granulation was initially present in 3 (6%) chronic ulcers which increased to 19 (38%), 31 (62%), 48 (96%), and 50 (100%) on day 5, 9, 12, and 21, respectively.

In Group B, granulation was present initially in 5 (10%) ulcers which increased to 13 (26%), 21 (42%), 28 (56%), and 47 (94%) on day 5, 9, 12, and 21, respectively.

Epithelization

In Group A, epithelization on day 9 was seen in 11 (22%) patients, on day 12 was seen in 34 (68%) patients, and on day 21 was seen in 50 (100%) patients. In Group B, epithelization was noted in 6 (12%), 18 (36%), and 38 (76%) patients on 9, 12, and 21 days, respectively.

Incidence of Infection

Cultures were performed on ulcers on day of presentation, that is, day 1, day 9, and day 21 and following results were found.

In Group A, cultures from 9 out of 50 patients of Group A were found to be negative (primary sterile), out of which two became positive on next culture on day 9 with secondary infection rate of 22.22%.

In remaining 41 (52.56%) primarily infected cases from Group A, cultures of 30 patients were found to be negative on the 9th day culture with infection rate of 38.46%. On culture of the 21st day, number of positive cases reduced to 15 with an infection rate of 19.23%.

In Group B, cultures from 13 out of 50 patients of Group A were found to be negative (primary sterile), out of which five became positive on next culture on day 9 with secondary infection rate of 38.46%. In remaining 37 (47.44%) primarily infected cases from Group B, cultures of 32 patients were found to be negative on the 9th day with infection rate of 41.02%. On culture of the 21st day, number of positive cases reduced to 25 with an infection rate of 32.05%. Most common bacteria isolated from initial culture was *Staphylococcus aureus* in 35 cultures (44.87%).

Outcome

In Group A, SSG was performed in 8 (16%) cases and remaining 42 (84%) patients healed by their own. In Group B, 13 (26%) patients undergone SSG while 37 (74%) patients did not undergo any surgical procedure.

Duration of Hospital Stay

In the current study, average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129 [Tables 1-4].

DISCUSSION

The main purpose of wound dressings is to provide the ideal environment for healing. Although the ideal dressing is still not a clinical reality, novel advances are on their way for the achievement of the same.[1-3] The principle of "Wound Dressing with Superoxide Solution" was officially started in the year 2003 when it achieved a status of "Disinfectant and Antiseptic" in its homeland Mexico.[4]

Healing rates have been reported to be significantly shorter in cases dressed with SOS. Furthermore, duration for cultures to become negative and of antibiotic therapy was also reported to be shorter. SOS has been found to be safe and effective in the management of wide post-surgical lesions in the infected diabetic foot.[5] Hadi *et al.*[6] in Islamabad in 2006 on treating infected diabetic wounds with superoxidized water as antiseptic agent. A preliminary experience revealed that although the initial results of employing superoxidized water for the management of infected diabetic wounds are encouraging, further multicenter clinical trials are warranted before this antiseptic is recommended for general use. In the present study, a total of 100 patients were studied. Patients with lower limb ulcers were selected and randomly divided into two groups. Neither age, sex, nor underlying disease were considered in selection process.

In Group A, mean wound size was 42.08 ± 25.04 cm and for Group B 47.84 ± 26.19 cm. After 21 days of dressing with oxum, wound size reduces to 12.74 ± 10.81 cm while wound size in povidone-iodine group was found to be 21.20 ± 17.84 cm ($P < 0.05$). Dressing with SOS is found to be better in relation to decrease in wound surface area in comparison to povidone-iodine.

In a study conducted by Prabhakar *et al.*, SOS was found to be better with 58.90% ± 5.21% reduction in surface area as compared to 40.90% ± 8.76% in povidone-iodine group.[7]

In a study conducted by Kapur and Marwaha, after the mean follow-up of 21 days, average reduction in wound size in oxum group was 70% as compared to 50% in betadine group.[8]

Healing in Terms of Granulation Tissue, Epithelization

Initially, none of the ulcer had granulation tissue. On day 5, 38% of the cases show early granulation tissue in Group A as compared to 26% of patients in Group B. On day 9, 62% of patients from Group A had granulation tissue while in 42% of patients shown healthy granulation tissue. About 96% wounds from Group A had healthy granulation tissue as compared to 56% in Group B at day 12. At 21 days, 100% of patients of Group A and 94% of patients had healthy granulation tissue in Group B.

Epithelization was noticed earlier in Group A as compared to Group B. At day 12, 68% of patients started epithelization in Group A while it was present in 36% of cases of Group B. At day 21, maximum patients showed epithelization while in Group A, while in Group B, 86% of patients had epithelization. In the study conducted by Kapur and Marwaha, diabetic foot ulcer and chronic leg ulcers patients treated with oxum show early granulation and rapid epithelization when compared to betadine group.[8]

Incidence of Infection

Out of 100 patients, 22 cultures were found negative on day 1, that is, at the time of presentation. Out of which nine patients were from Group A while cultures from 13 patients of Group B were negative.

Out of nine primary sterile cultures from Group A, two cultures became positive with secondary infection rate of 22.22%. While secondary infection rate in Group B was found to be 38.46% in Group B which is higher as compared to SOS group.

Out of 41 positive cultures in Group A, incidence of infection was found to be 38.46% and 19.23% on cultures of the 9th and 21st day, respectively. In Group B, incidence of infection was found to be 41.02% and 32.04% for day 9 and day 21. These data are suggestive of SOS being more efficient in reduction of infection as compared to povidone-iodine. Most common organism isolated on culture was found to be *S. aureus*.

In a study conducted by Pandey *et al.*, rate of secondary infection was found to be 15% and 16%, respectively, and most common organism isolated was coagulase positive *S. aureus*.

Duration of Hospital Stay

In the current study, average duration of hospital stay for Group A was 19.84 days with SD of 16.041 while average hospital stay time for Group B was 25.31 with ±6.129. On the basis of these data, this can be concluded that rate of wound healing for SOS is better than povidone-iodine and hence duration of hospital stay is less for SOS.

In a study conducted by Paola on 218 patients suffering from chronic diabetic foot ulcers, 110 patients were treated with SOS (oxum) and 108 patients with povidone-iodine. The mean healing time was lower in the oxum group (45 ± 14) days versus (58 ± 20) days in betadine group.[9]

In a study conducted by Satish Kumar *et al.*, average duration of hospital stay was found to be 16.4 days and it was less than that of povidone-iodine.[10]

Table 1: Wound size (in cm^2) after day 1, 5, 9, 12, and 21 of dressing

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
A	47.80	27.81	42.08	25.04	37.48	23.44	31.94	21.08	12.74	10.81
B	49.96	26.82	47.84	26.196	42.28	24.174	38.02	22.63	21.20	13.84

Table 2: Appearance of granulation tissue

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	No	%	No	%	No	%	No	%	No	%
A	3	6	19	38	31	62	48	96	50	100
B	5	10	13	26	21	42	28	56	47	94

Table 3: Appearance of epithelization

Group	Day 1		Day 5		Day 9		Day 12		Day 21	
	No.	%	No.	%	No.	%	No.	%	No.	%
A	0	0	0	0	11	22	34	68	50	100
B	0	0	0	0	6	12	18	36	38	76

Table 4: Incidence of infection

Group	Day 1		Day 9		Day 21	
	No	%	No	%	No	%
A	41	52.56	30	38.46	15	19.23
B	37	47.44	32	41.02	25	32.05

CONCLUSION

The main purpose of wound dressings is to provide the ideal environment for healing. Although the ideal dressing is still not a clinical reality, novel advances are on their way for the achievement of the same. In the management of lower limb ulcer, a SOS debrides necrotic tissue, reduces microbial load, promotes granulation, and decreases the healing time, without damaging the normal tissue or complications. Those patients, who have small superficial ulcers or not fit for definite surgery, can be managed conservatively with SOS only. The results of our study favor the effective role of SOS in wound healing, and we found it to give better efficacy as compared to conventional topical agent (povidone-iodine). It promotes rapid healing without damaging the normal tissue.

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