A Comparative Study between Superoxidised Water Dressings Versus Conventional Dressings In Management Of Non Diabetic Wounds

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Abstract
Background
Wounds and their management are fundamental in the practice of surgery. Superoxidised solution is a new concept in wound management, and it is an electrochemically processed aqueous solution with neutral pH. Very few studies conducted to compare the efficacy of superoxidised solution and povidone-iodine. Hence, this study is conducted as wounds are a great burden on the Healthcare system.
OBJECTIVES: To compare the efficacy of Superoxidised solution versus povidone-iodine in the management of nondiabetic wounds and to observe a decrease in wound size, the appearance of granulation tissue wound disinfection, and duration of hospital stay in both groups.
MATERIALS AND METHODS:A prospective study of patients with nondiabetic wounds randomized into two groups; Group A with Superoxidised solution, Group B with povidone-iodine with 50 patients in each group, and wound assessment is done at regular intervals like day 3,7,14,21, and various wound outcome variables are compared using statistical analysis of data.
RESULTS:In a study of 100 patients, there was a 40% decrease in wound size in Group A compared to 27% in Group B at day 21, early appearance of granulation tissue, decrease in wound size, disinfection, and less duration of hospital stay achieved in Group A.
CONCLUSION:This study shows more favorable results for Group A -Superoxidised solution as compared to Group B povidone-iodine in the healing of nondiabetic wounds, which are statistically significant.Superoxidised solution has a faster response in wound healing and has better efficacy compared to the traditional povidone-iodine solution in Nondiabetic wound care management.
Keywords: *non diabetic wound,superoxidised solution*

I.   Introduction

Wounds and their management are basic fundamentals in the practice of surgery. With the prevalence of (1% - 2%) approximately and is slightly higher in the adult population. [1]very much summarize leg ulcer management, ulcers on the leg form a very extensive and important burden, the treatment of such cases is generally looked upon as an inferior branch of practice an unpleasant and inglorious task where much labor must be bestowed, and little honor gained. [2]

Lower limbs are a very common sight involving in any surgical ward, and the scarcity of epidemiological studies on the incidence of leg ulcers probably reflects a general lack of interest in a chronic, nonfatal condition that mainly affects the elderly. Their origin is multifactorial, and hence the proper diagnosis of arterial, venous, and neuropathic ulcers is essential, Ulcers may appear similar, but upon closer inspection, it becomes apparent that they are completely different entities.

Lower limb ulcers have different etiologies and specific anatomic locations, which by itself gives rise to special problems in their management.

The past three decades gained a piece of considerable knowledge regarding physiology, anatomy, pathology, and management of lower limb ulcers.

Also, with the advent of new and precise diagnostic techniques like duplex scanning, angiographic and venographic studies, and modern surgical techniques, there is a resurgence of interest in lower limb ulcer management.

Various treatment modalities are discovered over the years in forms of different types of wound dressings - creams, ointments, solutions. Other classes of wound dressings are occlusive dressing, nonocclusive dressing, absorptive dressing, skin substitutes, and negative suction vacuum dressing.

An ideal wound care product, in addition to controlling the infection, should also protect the normal host tissues and not interfere with the normal wound healing.

Povidone-iodine is the most commonly used topical conventional wound care product in clinical practice and has been efficiently used over the years in the treatment of lower limb ulcers.

The superoxidised solution is a new concept in wound management, and it is an electrochemically processed aqueous solution with neutral pH, nontoxic, non-irritant dermal wound irrigant used in humans for wound care treatment including postoperative wound care.

Both are affordable solutions for the patient population of this study. Very few studies are conducted to compare the efficacy of superoxidised solution and povidone-iodine.

Leg ulcers are reported to have an impact on virtually every aspect of daily life, pain is a common symptom, sleep is often impaired, mobility and work capacity tend to be restricted, and personal finances are often adversely affected.

It is known that social activities are restricted due to fear of injury and negative body image. Chronic leg ulcers are usually associated with significant morbidity, high cost of healthcare, loss of productivity, and reduced quality of life. [3]

II. Material and methods

- **Subjects** : 100
- **Study Duration** : 2018 -2019.
- **Study Place** : Department of general surgery
SVRRGGH, Tirupati.
- **Study Design** : Prospective study.
- **Ethical considerations:** The ethical committee of at S.V medical college and hospital approved this study. The cases were taken up for study on admission and after obtaining written consent.
- **Inclusion criteria:**
➢ All non-diabetic wounds with patients age more than 18 years.
- **Exclusion criteria:**
• wounds with osteomyelitis
• patients who had not given consent
• wounds with poor vascularity determined by peripheral pulses
• other comorbid conditions like
o renal failure,
o metabolic disorders,
o liver failure,
o diabetes mellitus,
o and factors which adversely affect wound healing.

Methodology

Patients with Lower Limb Ulcers admitted at SVRRGGH General Surgery Department UNIT 3 were screened and selected for this study. 100 patients were randomized into 2 groups with 50 patients in each group.Group A being Superoxidised Solution (SOS) ,Group B being Povidone-Iodine (PI).

Procedure for Randomization: Randomization was done using minimization procedure. This was done using a software program called minim developed by Stephan Evans. Age in years with two categories, sex with two categories (male/female) and wound size with two categories was factored and weighed into the minimization program. Wound size and age is given a weight score of 5 and sex was given a weight score of 2. On receipt of screening checklist, the random allocation to groups was done at SVRRGGH using this simulation program. This method has advantages over stratified and blocked randomization methods as it ensures equal allocation of subjects in both groups controlling of confounding factors.

Various Assessment Tools were used to compare wound healing between SOS and PI groups based on:
• Day of wound disinfection.
• Organisms Isolated/Growth on Culture sensitivity procedures done
• (debridement/Fasciotomy/no procedure)
• appearance of Granulation tissue
• duration of hospitalization
Antibiotic coverage was given for all patients, in some patient's intravenous antibiotics was followed by oral antibiotics. Wound Size Assessment Wound size was measured at baseline-Day 1 for all patients and subsequent Assessments were done on days 3,7,14 and 21.

The change in wound size was calculated from baseline (Day1) and last day measurement, i.e.; Day 21 and in some patients, who underwent Split skin grafting (SSG) before 21 days, it was calculated one day prior to SSG. The largest diameter of wound size was considered for analysis.

Data Analysis Data were transcribed onto excel file and epi info version 7.2.2.6 for windows was used to perform both descriptive and inferential analysis. Frequencies were reported for distribution of categorical variables and Chi square test was performed for any differences among Superoxidised Solution (SOS) and Povidone Iodine (PI) group. Data were normally distributed, and parametric independent samples t test was used to detect group differences for all outcome measures. Bivariate Relationships were determined using Pearson's correlation analysis.

III. Results

Group A people underwent superoxidised solution dressings and results are categorized according to-
* Age relation
* Sex
* Procedure
* Wound disinfection
* Appearance of granulation
* Decrease in the wound size
* Duration of hospital stay.

SUPEROXIDISED GROUP

Table 1: Age Distribution

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	2	4.0	4.0	4.0
	2	12	24.0	24.0	28.0
Valid	3	34	68.0	68.0	96.0
	4	2	4.0	4.0	100.0
	Total	50	100.0	100.0	

Group 1 – 18-30 years
Group 2 - 31-50 years
Group 3 - 51-70 years
Group 4 -> 70 years
Most of the patients are between 30 – 60 decades.

Table 2: Sex Distribution

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	29	58.0	58.0	58.0
Valid	2	21	42.0	42.0	100.0
	Total	50	100.0	100.0	

Group 1- male
Group 2- female
In group A superoxidised solution dressings most of them are males

Table 3: PROCEDURE

		Frequency	Percent	Valid Percent	Cumulative Percent
		25	50.0	50.0	50.0
Valid	DEB	17	34.0	34.0	84.0
	FSCTMY	8	16.0	16.0	100.0

	Total	50	100.0	100.0	

In group A superoxidised solution
25 people underwent procedures on consecutive days before dressing
Among them 17 patients underwent debridement and 8 patients underwent fasciotomy.

Table 4: Wound Disinfection

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	46	92.0	92.0	92.0
	3	4	8.0	8.0	100.0
	Total	50	100.0	100.0	

Wound disinfection days are categorized into 4 groups
Group 1- days 3-7
Group 2- days 8-11
Group 3- days 12 -14
Group 4- days >14 .Wound disinfection was achieved early in Group A people who underwent super oxidized solution dressings i.e. 3-7 days.

Table 5: Appearance of Granulation tissue

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	35	70.0	70.0	70.0
	2	12	24.0	24.0	94.0
	3	3	6.0	6.0	100.0
	Total	50	100.0	100.0	

Group 1- days 3-5
Group 2- days 6-7
Group 3- days >8
Patients in Group A who underwent superoxidised solution dressings the granulation tissue appeared early between days 3 to 5.

Table 6: Duration of Hospital-Stay

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	28	56.0	56.0	56.0
	2	18	36.0	36.0	90.0
	3	4	8.0	8.0	98.0
	Total	50	100.0	100.0	

Duration of hospital stay for super oxidized solution dressings were categorized into
Group 1- days 8- 14
Groups 2 - days 15- 21
Group 3- days > 21
Most of the patients was discharged and planned for skin grafting at days between 8 to 14.

Group B

underwent povidone-iodine dressings and results are categorized according to-

- Age relation
- Sex
- Procedure
- Wound disinfection
- Appearance of granulation
- Decrease in the wound size
- Duration of hospital stay.

Table 7: Age Distribution

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	4	8.0	8.0	8.0
	2	17	34.0	34.0	42.0
Valid	3	29	58.0	58.0	100.0
	Total	50	100.0	100.0	

Group 1- 18-30 years
Group 2- 31-50 years
Group 3- 51-70 years
Group 4- >70 years
Most of the patients are in between age group of 30 to 70 years.

Table 8: Sex Distribution

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	34	68.0	68.0	68.0
Valid	2	16	32.0	32.0	100.0
	Total	50	100.0	100.0	

Group 1 – males
Group 2- females
Among them most of them are males.

Table 9: Procedure

		Frequency	Percent	Valid Percent	Cumulative Percent
		19	38.0	38.0	38.0
	DEB	27	54.0	54.0	92.0
Valid	FSCTMY	4	8.0	8.0	100.0
	Total	50	100.0	100.0	

In group B povidone-iodine solution ,31 patients underwent procedures on consecutive days before dressing Among them 27patients underwent debridement and 4 patients underwent fasciotomy.

Table 10: Days of Wound Disinfection

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	35	70.0	70.0	70.0
Valid	3	15	30.0	30.0	100.0
	Total	50	100.0	100.0	

Wound disinfection days are categorized into 4 groups
Group 1- days 3-7
Group 2- days 8-11
Group 3- days 12 -14
Group 4- days >14
Wound disinfection was achieved in Group B people who underwent povidone-iodine solution dressings i.e. 3-7 days.

Table 11: Appearance of Granulation

	GROUP		Frequency	Percent	Valid Percent	Cumulative Percent
B	Valid	1.00	5	10.0	10.0	10.0
		2.00	27	54.0	54.0	64.0
		3.00	18	36.0	36.0	100.0
		Total	50	100.0	100.0	

Group 1- days 3-5
Group 2- days 6-7
Group 3- days >8
Patients in Group B who underwent Povidone-iodine solution dressings the granulation tissue appeared maximum between days 6 to 7.

Table 12: Duration of Hospital Stay

		Frequency	Percent	Valid Percent	Cumulative Percent
	1	3	6.0	6.0	6.0
Valid	2	20	40.0	40.0	46.0
	3	27	54.0	54.0	100.0
	Total	50	100.0	100.0	

Duration of hospital stay for super oxidized solution dressings are categorized into
Group 1- days 8- 14
Groups 2 - days 15- 21
Group 3- days > 21
Most of the patients was discharged and planned for skin grafting at days between >21.

Decrease in the wound size
Insuperoxidisedsolution group (group A) and povidone-iodine (group B),Decreased in the wound size were assessed in following days and results are produced and tabulatedInitial assessment was done at day 1 at time of admission and post procedure,Later size was assessed on following days,Day 3,Day7,Day 14,Day 21.

Table 13: Descriptive Statistics (Wound Size)

	GROUP	N	Mean	Std. Deviation
A	Percentage	50	40.1311%	12.12796%
	Valid N (listwise)	50		

B	Percentage	50	27.3868%	6.52845%
	Valid N (listwise)	50		

Organisms isolated in both group a and group b:
The commonest organism on Culture sensitivity taken on day 1 for all patients was Staphylococcus aureus – 37 patients, whereaspseudomonas in 20 patients, no growth noted in 5 patients

Figure - group a patient day 1

Figure - group a patient day 3

Figure -group a patient day 7

Figure -group a patient day 14

Figure -group b patient day1

Figure - group b patient day 3

Figure -group b patient day 7

Figure - group b patient day 14

IV. Discussion

In the present study, the effect of superoxidised solution versus povidone iodine in the management of lower limb ulcers in a group of 100 non-diabetic patients was studied.The age of patients in the study was maximum in between 30 to 70 years of which most of the patients were male.Most of them are having traumatic etiology.,All of them were nondiabetic.Various wound outcome variables were compared between both groups.**Wound disinfection:**

Group *wound disinfection crosstabulation

Count

		DAYS DISINFECTION		Total
		1	3	
GROUP	1	46	4	50
	2	35	15	50
Total		81	19	100

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	7.862[a]	1	.005		
Continuity Correction	6.498	1	.011		
Likelihood Ratio	8.281	1	.004		
Fisher's Exact Test				.009	.005
Linear-by-Linear Association	7.784	1	.005		
N of Valid Cases	100				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 9.50.

b. Computed only for a 2x2 table

In current study 90% patients achieved wound disinfection in Group A(1) SOS by 5 ± 2 days. In Group B(2) PI 70% patients achieved wound disinfection by 5 ± 2 days.In a study conducted by Chittoria RK54 et al for role of SOS in the management of diabetic foot ulcers in Andhra Pradesh on 20 patients, 19 out of 20 cases were negative for infection after 5 days.In current study Pearson Chi-Square value is 7.862[a] with difference of 1 and p value < 0.005.Which is statistically significant in the study with use of superoxidised solution in nondiabetic wounds.

Appearance of granulation tissue:

Group * appearance of granulation crosstabulation

			DAY				
			3	4	5	6	7
GROUP	A	Count	6	12	17	7	5
		% within GROUP	12.0%	24.0%	34.0%	14.0%	10.0%
	B	Count	0	0	5	15	12
		% within GROUP	0.0%	0.0%	10.0%	30.0%	24.0%
Total		Count	6	12	22	22	17
		% within GROUP	6.0%	12.0%	22.0%	22.0%	17.0%

Group *appearance of granulation crosstabulation

			DAY		Total
			8	9	
GROUP	A	Count	3	0	50
		% within GROUP	6.0%	0.0%	100.0%
	B	Count	8	10	50
		% within GROUP	16.0%	20.0%	100.0%
Total		Count	11	10	100
		% within GROUP	11.0%	10.0%	100.0%

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	42.610a	6	.000

In current study in Group A SOS 70% of patients developed early granulation tissue in 4 ± 1 days.In Group B PI only 54% of patients developed granulation tissue in 6 ± 1 days.So, among both group Pearson Chi-Square value is 42.610a with difference of 6,With p value < 0.001 which is statistically significant.Best results are achieved in SOS Group using Superoxidised solution there was early appearance of granulation tissue.
Ashok Anand, comparedefficacy of SOS versus PI in post
C-section wounds, showed that 88% had granulation by day 5 in SOS group compared to 80% in PI group and by day 10 there was granulation in all patients. By day 5, 4% in SOS group had erythema at surgical wound compared to 12% in PI group. The results are similar in our study although done on lower limb ulcers.

Duration of hospital stay :

Group * duration of hospital stay crosstabulation

Count

		DAYS HOSPITAL STAY			Total
		1	2	3	
GROUP	1	28	18	4	50
	2	3	20	27	50
Total		31	38	31	100

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	38.469[a]	3	.000
Likelihood Ratio	44.026	3	.000
Linear-by-Linear Association	8.879	1	.003
N of Valid Cases	100		

a.   2 cells (25.0%) have expected count less than 5. The minimum expected count is .50.

In current study Group A(1) SOS 56% of patients were discharged, and some are posted for split skin graft in 11 ± 3 days.In Group B(2) PI it was > 21 days.
Pearson Chi-Square value is 38.469[a]   with difference of 3 and p value is <0.001Which is statistically significant.Best results wereachievedin Group A, there was early discharge and early intervention, compared to Group B.

Decrease in the wound size :
T-Test-:

Group Statistics

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
Percentage	A	50	40.1311%	12.12796%	1.71515%
	B	50	27.3868%	6.52845%	0.92326%

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means	
		F	Sig.	T	df
Percentage	Equal variances assumed	14.930	.000	**6.543**	98
	Equal variances not assumed			6.543	75.197

Independent Samples Test

		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
Percentage	Equal variances assumed	**.000**	**12.74431%**	1.94786%
	Equal variances not assumed	.000	12.74431%	1.94786%

In current study by use of superoxidised solution there wasmean 40% decrease in wound size with standard deviation of 12%compared with Group B by use of povidone-iodine there was 27% decrease in wound size with standard deviation of 6%independent t test was applied, and results are produced having t value 6.543 with difference of 98 with p value <0.001which is statistically significant.so, use of superoxidised solution there was significant decrease in wound size compared to povidone – iodine group.

Chiara Goretti in his study stated that Povidone iodine has been shown to be an effective antimicrobial agent for the treatment of various conditions and is routinely used for the management of chronic wounds. The significantly faster healing time and shorter duration of required antibiotic therapy in patients treated with SOS indicates that SOS has superior antimicrobial activity than povidone iodine. In current study too, there was earlier wound disinfection in SOS group compared to PI group.

The global efficacy evaluation also confirms the superiority of Superoxidised solution over Povidone-iodine as good to excellent efficacy response was recorded in relatively a greater number of patients in SOS treated group as compared to povidone-iodine treated group.

Hence, in the current study there was faster healing rate of ulcers treated with superoxidised solution compared to Povidone-iodine, proving superoxidised solution to be safe, efficient and superior as a wound care product compared to povidone-iodine in the management of non-diabetic lower limb ulcers.

V. Conclusion

The Efficacy of Superoxidised solution with Povidone-iodine in the management of nondiabetic lower limb ulcers is compared in this study. This study shows more favorable results for Superoxidised solution as compared to Povidone Iodine in the healing of lower limb ulcers, which are highly statistically significant.

In patients treated with Superoxidised solution, comparatively we found that there was: Earlier appearance of granulation, Early wound disinfection, Rapid decrease in wound size, Shorter duration of

hospitalization On correlation of the wound outcome variables, This study confirms that Superoxidised 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 in management of lower limb ulcers. Hence it is an excellent choice for the management of non-diabetic lower limb ulcers.

VI. Summary

Wounds and their management are fundamental in the practice of surgery. This study was done forcomparisonof Efficacy between Superoxidised solution versus Povidone-Iodine in the Management of nondiabetic wounds. 100 patients were randomized into 2 groups for SOS and PI with 50 patients in each group. Wound assessments are done at regular intervals, and various wound outcome variables were compared.

In a study of 100 patients, most patients were in the age group of 30-60years, and 63% were males. There was a rapid decrease in wound size in the SOS group compared to the PI group at final dayand earlier appearance of granulation in the SOS group. There was a shorter duration of hospital stay, earlier wound disinfection, and a greater number of patients who underwent skin grafting were in the SOS group. The results were statistically significant and in favor of SOS. Superoxidised solution has a faster response in wound healing. It gives better efficacy as compared to the traditional Povidone-Iodine solution for use in wound care in the Management of non-diabetic lower limb wounds.

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