Comparative Evaluation of Rifampicin Powder Dressing versus Betadine Dressing in Lower Limb Ulcers Using the Bates-Jensen Wound Assessment Tool (BWAT): A Prospective Randomized Controlled Study

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ABSTRACT

Introduction: Ulcer is defined as breech in epithelium or mucosa. Lower limb ulcers are most commonly due to venous, arterial or neuropathic causes. Most commonly in India the lower ulcers are due to a venous pathology whereas in JSS hospital the most common cause of lower ulcers was found to be diabetes mellitus.

Objectives: To assess wound healing of lower limb ulcers in patients treated with local application of rifampicin powder dressing using BATES-JENSEN Wound Assessment Tool (BWAT) at 3, 5.

Methodology: This study is a prospective interventional randomized control study which was conducted over a period of 18 months, with 100 patients participating in the study amongst which 50 patients underwent betadine dressing (Group A) and 50 patients underwent rifampicin dressing (Group B). After patient have been selected the ulcer will be scored according to BWAT score and that will be considered the baseline score of the ulcer. Under sterile precautions the ulcer will be cleaned and thorough debridement will be done. Rifampicin 150mg capsules containing rifampicin powder will be used for the local application over the ulcer.

Results: The study showed significant decrease in size of the ulcer, decrease in exudate amount, peripheral tissue edema and induration in patients treated with rifampicin dressing when compared with ulcers treated with betadine dressing. There was also significant increase in granulation tissue for the ulcers treated with rifampicin dressing. 52% patients who underwent rifampicin dressing were found have no growth in the pus culture implying reduction in bacterial load of the ulcer.

Conclusion: Rifampicin is a cheap drug which is easily available all over India. Local application of rifampicin is an easy method of local antibiotic application to treat the lower limb ulcers to hasten the process of wound healing and decrease the need for debridement and prepare the ulcers earlier for SSG.

Keywords: Lower limb ulcers, rifampicin powder dressing, Betadine dressing, Wound healing, Bates-Jensen Wound Assessment Tool (BWAT).

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Introduction

Ulcer is defined as breech in epithelium or mucosa. Prevalence of ulcers is 1 % in the adult population and 3-5 % in the population above 65 years of age.[1] It has been reported that lower limb ulcers related to venous insufficiency constitutes 70% of cases, arterial disease 10%, ulcer of mixed aetiology 15% and 5% of lower limb ulcers occur due to lesser-known pathophysiological causes.[2] In JSS hospital though the most common cause of lower limb ulcers has been found to be diabetes mellitus. Various factors are involved in healing of an ulcer such as nutrition, co-morbidities, presence of foreign body, location of the ulcer, status of ulcer, etc.

Wound healing is a multistep procedure which involves various inflammatory cells and eventually leads to wound contraction in case of favourable environment.[3] Appropriate treatment and wound care accelerate the healing process and prevention of infection and chronicity of the wound. Management of ulcer requires a multisystem approach which includes nervous, vascular, skeletal and immune system. Various techniques for wound dressing have been established till date such as betadine dressings, muprocin dressings, oxum dressings, autolyse dressing, etc. Chronic wounds are always colonized by bacteria and infection can be

present with various clinical signs. Treatment with topical antibiotics should be considered for wounds which are not healing despite good quality regular dressing and IV antibiotics. Local application of antibiotic help in achieving higher concentration of the antibiotic at the ulcer site for faster action against the bacteria.[4]

Rifampicin, generally used in treatment of Tuberculosis is an oral antibiotic agent. Its mechanism of action is by inhibiting **bacterial DNA-dependent RNA polymerase. [2,3]** Rifampicin acts locally against the bacteria of the ulcer. Rifampicin being broad spectral antibiotics helps in reducing the bacterial load of the ulcer and acts against mainly staphylococcus aureus, pseudomonas, gram negative bacteria as well. Thus, Rifampicin powder can be used as local application for ulcers to fasten the healing by reducing bacterial load of the ulcer.

Materials and Methodology

It was a Prospective interventional study conducted for a period of 18 months through Purposive sampling technique.

Sample size was calculated using the following formula :$S = Z^2pq/d^2$

Where z is the standard deviation which is 1.96 at 95% confidence interval.

p is the prevalence of the lower limb ulcers in JSS hospital, which was found to be 7% as per a pilot study through Hospital statistics.

q is (1-p)

d is clinically expected variation of 5%.

$S= (1.96)^2$ X 0.07 X $0.93/(0.05)^2 = 100$. Hence sample size will be 50 individuals in each group of the study.

a comparative study which included 100 individuals based upon the inclusion and exclusion criteria and then divided into 2 groups using the lottery method.

The 2 groups include: A. Rifampicin local application dressing

B. Betadine dressing

Individuals will then be treated with the specific types of dressing daily after due consent and wound healing will assessed using BWAT scoring system at 3, 5 and 8th day.

STUDY CONDUCT:

This shall be a Prospective interventional study with Purposive sampling.
100 individuals selected according to inclusion and exclusion criteria

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Consent for study will be taken

↓

Lottery method used to divide them into 2 groups

↙ ↘

Group A (Rifampicin dressing) | Group B (betadine dressing)

↓ ↓

Detailed clinical history and physical examination is done:
1.Personal Details: name, age, sex, address
2. Chief complaints and brief history of presenting illness
3. Past history of co morbidities or surgery in past.
4. General physical examination
5. Local examination of ulcer in detail.

↓ ↓

Wounds will then be scored using the BWAT score – Baseline score | Wounds will then be scored using the BWAT score – Baseline score

↓ ↓

Wounds will be treated with rifampicin local application dressing daily and wound healing will be assessed at 3, 5 and 8th day using BWAT. | Wounds will be treated with betadine dressing daily and wound healing will be assessed at 3, 5 and 8th day using BWAT

↓ ↓

Culture swab taken on 8th day | Culture swab taken on 8th day

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The BWAT score will be compared between Group A and Group B at 3, 5 and 8th day.

Percentage of patients with negative culture reports taken on Day 8 in Group A and Group B will be compared.

Study Treatment:

Rifampicin capsule 150mg shall be used in the study which contains rifampicin powder. After thorough debridement rifampicin powder is applied on the ulcer to cover the whole of surface of the ulcer. And then sterile dressing is done.

a. Inclusion Criteria

1. Individuals with lower limb ulcers
2. Size of the ulcer should be more than 1x1cm
3. One or more ulcers without evidence of osteomyelitis
4. Post op SSG cases with ulcers between the skin grafting sites.

b. Exclusion Criteria

1. Ischemic lower limb ulcers (ankle brachial index less than 0.7)
2. Healing lower limb ulcers with culture showing no growth in 48 hours.
3. Pregnant females
4. Malignant ulcers proven by biopsy
5. Known case of liver disease or patient with deranged LFT

Results

Table 1- Demographic details of the study:

			Group		Total
			Betadine dressing	Rifampicin dressing	
Ages	<40	Count	1	5	6
		% within group	2.0%	10.0%	6.0%
	41-50	Count	11	6	17
		% within group	22.0%	12.0%	17.0%
	51-60	Count	20	15	35
		% within group	40.0%	30.0%	35.0%
	61-70	Count	13	19	32
		% within group	26.0%	38.0%	32.0%
	70+	Count	5	5	10
		% within group	10.0%	10.0%	10.0%
Total		Count	50	50	100
		% within group	100.0%	100.0%	100.0%

Amongst the controls mean age was 57 years whereas among the cases the mean age was 58 years which was comparable. In controls youngest patient was of 37years and oldest of 77 years. In cases youngest was 23 years and oldest 85 years. In the study population there were 25% females and 75% males amongst which 24% female and 76% males were in rifampicin dressing group and 26% females and 74% males in betadine dressing group.

Table 2- Reduction in ulcer size score amongst cases and controls:

	Group	Mean	Std. Deviation	N
Size score on day 1	Controls	2.74	1.084	50
	Case	3.14	1.088	50
	Total	2.94	1.099	100
Size score on day 3	Controls	2.74	1.084	50
	Case	3.16	1.037	50
	Total	2.95	1.077	100
Size score on day 5	Controls	2.70	1.055	50
	Case	3.12	1.062	50
	Total	2.91	1.074	100
Size score on day 8	Controls	2.42	.992	50
	Case	3.04	1.106	50

	Total	2.73	1.090	100

The reduction in change in size score amongst cases was found significant (p=0.004).

Table 3- Reduction in depth score for study population:

	Group	Mean	Std. Deviation	N
Depth score on day 1	Controls	2.78	.737	50
	Case	2.70	.647	50
	Total	2.74	.691	100
Depth score on day 3	Controls	2.72	.701	50
	Case	2.62	.602	50
	Total	2.67	.652	100
Depth score on day 5	Controls	2.58	.609	50
	Case	2.36	.485	50
	Total	2.47	.559	100
Depth score on day 8	Controls	2.26	.527	50
	Case	2.10	.303	50
	Total	2.18	.435	100

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
CHANGE	18.890	3	6.297	59.126	0.001
CHANGE * group	0.300	3	0.100	0.939	0.422
Error (CHANGE)	31.310	294	0.106		

Reduction in depth change score in total study population was significant whereas reduction in depth change score was not found significant(p=0.422) when compared between the 2 groups.

Table 4- Reduction in edges score in the study population:

	Group	Mean	Std. Deviation	N
Edges score on day 1	Controls	2.88	.799	50
	Case	2.58	.575	50
	Total	2.73	.709	100
Edges score on day 3	Controls	2.80	.756	50
	Case	2.48	.544	50
	Total	2.64	.674	100
Edges score on day 5	Controls	2.58	.642	50
	Case	2.12	.558	50
	Total	2.35	.642	100
Edges score on day 8	Controls	2.06	.586	50
	Case	1.70	.544	50

	Total	1.88	.591	100

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
CHANGE	43.940	3	14.647	138.105	0.001
CHANGE * group	.380	3	0.127	1.194	0.312
Error (CHANGE)	31.180	294	0.106		

Reduction in edge change score in total study population was significant whereas reduction in edge change score was not found significant(p=0.312) when compared between the 2 groups.

Table 5- Reduction in undermining score for the ulcer amongst the study population:

	Group	Mean	Std. Deviation	N
Undermining score on day 1	Controls	2.26	1.084	50
	Case	2.18	1.155	50
	Total	2.22	1.115	100
Undermining `score on day 3	Controls	2.16	.997	50
	Case	2.04	1.009	50
	Total	2.10	1.000	100
Undermining score on day 5	Controls	1.96	.903	50
	Case	1.60	.756	50
	Total	1.78	.848	100
Undermining score on day 8	Controls	1.68	.794	50
	Case	1.34	.557	50
	Total	1.51	.703	100

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
CHANGE	30.888	3	10.296	70.765	0.001
CHANGE * group	1.588	3	0.529	3.637	0.013
Error (CHANGE)	42.775	294	0.145		

Undermining score reduction was found significant(p=0.013) amongst the cases and controls.

Table 6- Reduction in type of necrotic tissue score for the ulcer amongst the study population:

	Group	Mean	Std. Deviation	N
Necrotic tissue type on day 1	Controls	3.08	.665	50
	Case	3.28	.671	50
	Total	3.18	.672	100
Necroti	Controls	2.92	.528	50

c tissue type on day 3	Case	3.00	.670	50
	Total	2.96	.602	100
Necrotic tissue type on day 5	Controls	2.78	.507	50
	Case	2.48	.707	50
	Total	2.63	.630	100
Necrotic tissue type on day 8	Controls	2.22	.790	50
	Case	1.90	.647	50
	Total	2.06	.736	100

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
CHANGE	71.227	3	23.742	150.844	0.001
CHANGE * group	5.248	3	1.749	11.113	0.001
Error (CHANGE)	46.275	294	0.157		

Necrotic tissue type score reduction was significant(p=0.001) amongst the cases and controls in the study population reduction in necrotic tissue amount change score was not found significant(p=0.465) when compared between the 2 groups.

Table 7- Reduction in total BWAT score:

	Group	Mean	Std. Deviation	N
Total BWAT score on day 1	Controls	40.9400	6.59749	50
	Cases	39.9800	7.76568	50
	Total	40.4600	7.18503	100
Total BWAT score on day 3	Controls	39.5000	5.92900	50
	Cases	37.8800	4.74939	50
	Total	38.6900	5.40612	100
Total BWAT score on day 5	Controls	36.6800	5.44898	50
	Cases	32.7200	4.68624	50
	Total	34.7000	5.43371	100
Total BWAT score on day 8	Controls	31.7600	6.40013	50
	Cases	27.2200	5.04385	50
	Total	29.4900	6.17014	100

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
CHANGE	7108.890	3	2369.630	257.224	0.001
CHANGE * group	228.690	3	76.230	8.275	0.001
Error (CHANGE)	2708.420	294	9.212		

The reduction in total BWAT score was found significant (p=0.001) amongst the 2 groups in the study population i.e wound healing was found better in case of rifampicin dressing group patients.

Table 8- Comparison between the 2 groups of patients who required debridement within 3 months:

		Group		Total
		Controls	Cases	
Yes	% within group	88.0%	88.0%	88.0%
	Count	6	6	12
	% within group	12.0%	12.0%	12.0%

Total	Count	50	50	100
	% within group	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	.000	1	1.000	
Fisher's Exact Test				1.000

Table 9- Comparison between the 2 groups of patients who underwent SSG within 3 months:

			Group		Total
			Controls	Cases	
Patients who underwent SSG	No	Count	38	26	64
		% within group	76.0%	52.0%	64.0%
	Yes	Count	12	24	36
		% within group	24.0%	48.0%	36.0%
Total		Count	50	50	100
		% within group	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	6.250	1	0.012	
Fisher's Exact Test				0.021

48% of patients treated with rifampicin dressings underwent SSG whereas only 24% of patients treated with betadine dressing underwent SSG.

Discussion

Patients with lower limb ulcers in India suffer from significant morbidity and mortality. Most commonly the cause of these lower limb ulcers includes diabetes mellitus, varicose veins, peripheral vascular disease and trauma.[5] India being diabetes mellitus capital significantly contribute to lower limb ulcers. The main cause of chronicity of ulcers includes persistent infection of the ulcers. Due the persistence of infection the ulcers require surgical debridement procedure or amputations[6]. Various methods have been tried for treatment for the same and this study too aims in reducing the bacterial load of the ulcers and thus hasten the wound healing. Local application of antibiotic help in achieving higher concentration of the antibiotic at the ulcer site for faster action against the bacteria. Various antibiotics have been used for local application over the ulcers such as gentamicin, amikacin, metronidazole, muprocin, neomycin, Fucidin. [7,8]

This study focused on use of Rifampicin powder as local applicant over the ulcer for 8 days and assess the wound healing using Bates- Jensen Wound assessment tool. This study was performed over a period of 18 months with 100 patients included in the study who were randomly grouped into 2 groups of betadine dressing and rifampicin dressing which is comparable to studies done by other authors [8,9,10]

The study concluded that lower limb ulcers are more common in middle age population with mean age of 57 years amongst controls and mean age of 58 years amongst cases with male predominance in both groups. Among the controls 98% and among cases 72% were diabetic patients.

BWAT used 13 parameters to assess the wound healing and the reduction of score represented healing of ulcers. Hence reduction in scores in both groups were compared and found to have significant reduction in score in rifampicin dressing patients implying faster healing process.

The study showed significant decrease in BWAT score in the patients who underwent rifampicin dressing implying faster wound healing with reduction in size of ulcer, exudate amount and peripheral tissue edema with induration which is similar to results achieved by other studies [11,12]

52% patients who underwent rifampicin dressing were found have no growth in the pus culture implying reduction in bacterial load of the ulcer. Also 24 patients

(48%) underwent split skin grafting within 1 month of rifampicin dressing as the wounds were found healing.

Thus, Rifampicin powder can be used as local application agent in case of wounds found non healing or infected to help the wound healing process by killing the bacteria locally. Thus, patients can undergo SSG earlier.

No side effects of local application of rifampicin powder were reported. Hence rifampicin can be safely used in patients with lower limb ulcers with normal liver function tests and with no vascular compromise.

Our study has few limitations:

A sample size of 100 with 50 cases and 50 controls is a small sample size and may not be adequate to represent the entire population.

The use of rifampicin causes orange discoloration of the floor of the ulcer and assessment of factors involved in wound healing requires thorough saline wash. Hence if inadequate wash is given, orange discoloration of the floor of the ulcer may hinder in wound healing assessment.

This study does not analyze the various other factors that hinder wound healing such as nutrition, anemia, co-morbidities, immunosuppression.

This study does not include patients with osteomyelitis and with peripheral vascular disease, hence further research is required in those fields

Conclusion

Lower limb ulcers can be treated in various ways which include surgical debridement, regular dressing, antibiotics, etc to promote wound healing. This study concluded that use of rifampicin powder for local application over the ulcer help in reduction of size of the ulcer, undermining of the ulcer, exudate amount, surrounding induration, peripheral tissue edema. The study also concluded that rifampicin dressing helps to increase the granulation tissue of the ulcer, promotes epithelialisation, changes the type of necrotic tissue thus promoting wound healing. The study showed significant decrease in positive pus culture reports in patients treated with rifampicin dressing. Due to faster wound healing and decrease in bacterial load of the ulcer, 48% of the patients who underwent rifampicin dressing could undergo SSG within 1 month. Rifampicin is a cheap drug which is easily available all over India. Local application of rifampicin is an easy method of local antibiotics application to treat the lower limb ulcers.

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