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Research Article

A randomised control clinical trial to evaluate the efficacy of Yashadamrita malahara in Shuddhavrana

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Abstract

Introduction: Every day many wound patients reach to the various hospitals and surgery is branch where wound is inevitable. Wound Healing is most important process for which the medical sciences are advancing from ancient time till today to provide the quality of the medicine and procedure which heals the wound fast without any complication. *Acharya Sushruta* described treatment of wound in detail and explained 60 *upakramas* which aid healing at various stages of wound. Many *Acharyas* have used *khanija* (minerals) and *aushada* (plant sources) for wound healing. In *Rasa Tarangini* one such medication explained is *Yashadamrita Malahara* (ointment) in *shuddha vrana* (non-contaminated wounds). Methods: A Randomized clinical, comparative study was undertaken. The samples were of age between 20 – 70 years, irrespective of gender, religion, occupation etc.fulfilling the inclusion criteria were selected. Total 30 patients randomly divided into two equal and identical clusters consisting of 15 patients each. The patients of Group A were dressed using *Yashadamrita Malahara* and patients of Group B were dressed with *Jatyadi taila* for 14 days. Assessment was done on the basis of *shuddha vrana lakshana* (Bates Jensen wound assessment tool). Results: The reduction in total score for Group A (mean = 9.60, S.D.= 1.55) and that in Group B (mean =8.67, S.D. =1.45) were not significantly different (*P*-value = 0.099) at 5% level of significance as observed by unpaired t test. Conclusion: *Yashadamrita malahara* shows equipotent effect with known standard drug in reducing *sadhyavrana.*

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Introduction

Vrana (wounds) refers to a disruption in the skin or tissue, which, even after healing, results in a scar that remains for lifetime (1). Worldwide prevalence of wounds is 1%, estimated that 1.5 million cases of wounds found every year (2). Factors that influence wound healing locally include infection, mechanical forces, the presence of foreign bodies, and the wound's size, location and type (3). When a wound fails to heal properly, it can lead to various complications (4). *Acharya Sushruta* defined *vrana as* "*vrana gatra vichurnane*" and"*vranayatiiti vranaha*" (5), which presents with symptoms such as *ruja* (pain) and *srava* (discharge). *Vranas* can be caused either by an imbalance in the body's *doshas* or by physical trauma (6). *Acharya Sushruta*, has outlined *shashti upakramas* (sixty procedure) for the treatment of *vrana* (chronic or infected wounds) (7). Many herbal preparations have been tried in the past research studies as *vranaropana* (8). "*Yashadamrita Malahara*" consists of 1 parts of *Sikta*, 6 parts of *Tila Taila* and 1 parts *Yashadha Bhasma*, which is subjected for preparation of *Yashamrita Mahalara,* and used locally for wounds (9, 10).

Objectives: To Study the efficacy of *Yashadamrita Malahara in shuddha vrana.*

Materials and methods

It was an open label comparative & Randomized Controlled Clinical Trial conducted on *shudhavrana* (non-contaminated wound) patients of either gender were selected from the OPD and IPD of *Shalya Tantra* Dept KLE's KAHER Hospital Belagavi. Total 30 samples were selected for the trial by using simple randomized method. 15 patients were recruited for the trial and

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15 were in control Group. Patients were given an explanation of the entire trial, and their signed written informed consent was obtained. Approval from the Institutional Ethics Committee (IEC) was obtained through letter no KLE/469/18, dated March 03, 2018. The Clinical Trials Registry- India also has this study registered under registration number CTRI/ 2018/07/014972.

Inclusion Criteria

Either sex between 20-70 years of age and Patients with the *lakshanas* of *shuddha vrana*

Exclusion Criteria

Patients suffering/diagnosed from wound(s) associated with systemic diseases like diabetes mellitus, tuberculosis, malignant wounds, HbsAg, HIV I& II.

Preparation of *Yashadamrita Malahara* (11): For the preparation of *Yashadamrita malahara*, *shodhita yashad* (purified Zinc) was taken 1 part (12). According to *Rasa Tarangini*, quantity required for preparation of *malahara* (13) is given as -*Yasad pushpa* 1 *tola* and *Sikta taila* (beeswax oil) (14,15)- 3 *karsha* by simple mixing the ingredients (Table 1). The final product was packed in 12 gm airtight containers and sent for analysis at Central research facility Belagavi and clinical study (Figure A-E). *Jatyadi oil* (16, 17) was procured from GMP certified pharmacy.

Table 1: Showing Method of preparation of trial drug.

Sl. No.	Drug	Quantity
1	*Yashada Pushpa*	1*Tola*
2	*Sikta Taila*	3 *Karsha*

Trial Interventions: After obtaining informed consent during the screening, general and systemic examinations were conducted. Thirty patients were selected who met the inclusion and exclusion criteria were registered for the study based on the baseline data and divided into 2 Groups: **Group A (Trial Group)** and **Group B (Standard Group).** Group A was subjected to *Yashadamrut Malahara* and Group B is treated with *Jatyadi taila* (18,19). Both the Groups were administered for duration of 14 days with the dosage as per wound size and wounds were assessed for the progression on 7th and 14th day according to BATES JENSEN CRITERIA (20) for wound assessment.

Follow Up Assessment: Patients were followed up visit for day 7th and 14th respectively. On follow up visit wound was assessed for size , discharge, margin & surface, colour, and granulation tissue. Throughout the study intervention and follow -up, the subjects did not get any further concurrent medications.

Statistical Analysis: For the qualitative nominal variable – discharge, efficacy of drug is tested using 'McNemar Chi-square test'. While to compare the improvement in patients between two Groups, 'Chi square test of proportion' was used. For the qualitative, ordinal assessment parameters efficacy of drug was tested using 'Friedman test' followed by pair wise Wilcoxon signed rank test as Post- Hoc test. To compare the improvement in patients between two Groups, 'Mann-Whitney U test' was used. For the quantitative assessment parameters, efficacy of drug is tested using 'paired t tests'. To compare improvement between two Groups, 'unpaired t tests' was used. Hypotheses are tested for each of the parameter and result was interpreted accordingly. Appropriate summary statistics – Means, Medians and S.D.s were provided where necessary. Observations and results are also supplemented with Tables. The level of significance was kept at 0.05.

Observations

It was observed that maximum number of patients i.e. 53% belongs age group of 20-29, followed by 27% belongs to from 40 – 49 years. Maximum 10 patients (67%) were male, while 5 patients (33%) were female in Group A. whereas, in group B, 12 patients (80%) were male while 3 patients (20%) were female patients. Most of the patients were housewives and students totaling to 8 patients (53.3%) followed by 3 businessmen (20%) in Group A, in group B, maximum numbers of i.e. 6 patients (40%) were worker, followed by 3 students (20%). In group A, in total 10 patients (67%) were having education less than or up to higher secondary level while 4 patients (27%) were graduate. In group B, in total 7 patients (47%) were having education less than or up to secondary level followed by 5 patients (33%) were graduate.

Results

Effect on Discharge: In Group A, all 15 patients were having discharge at 1st day while 14 of them were observed without discharge at 2nd week. While in Group B, all 15 patients were having discharge at 1st day while 12 of them were observed without discharge at 2nd week. This improvement is significant at 5% level of significance as observed by McNemar chi-square test in both the Groups (Table 2).

Table 2: Showing statistical analysis of wound Discharge

Groups	Discharge	1st Day	2nd Week	d.f.	McNemar chi-square statistic	P-value
Group A	Absent	0	14	1	14	<0.001
	Present	15	1			
Group B	Absent	0	12	1	12	<0.001
	Present	15	3			

Comparative Analysis: The proportion of improved patients was 0.933 for Group A, while 0.800 for Group B. There is no significant difference found in these proportions (*P* value = 0.283) at 5% level of significance. Hence, both treatments can be considered as equally efficacious with respect to discharge. (Table 2.1).

Table 2.1: Statistical analysis of Discharge (Mann-Whitney table with statistic)

Group	No. of patients		d.f.	Pearson chi-square statistic	P-value
	Cured	Total			
Group A	14	15	1	1.154	0.283
Group B	12	15			

Effect on Size of would: By using Friedman test, it was observed that, the reduction in size for Group A was significant (*P* value< 0.001) at 5% level of significance, while, Group B was significant (*P* value<0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in size over period '1st day – 1st week' (*P*-value<0.001) as well as '1st day – 2nd week' (*P* value < 0.001) were significant. Hence, there was significant reduction in size for Group A and Group B over study period (Table 3).

Table 3: Showing statistical Analysis of Size of wound

Group	Statistic	1st day	1st week	2nd week	d.f.	Friedman chi-squared	P–value
Group A	Median	3	2.000	1.000	2	30	<0.001
	Mean	3	1.800	0.733			
Group B	Median	3	2.000	1.000	2	30	<0.001
	Mean	3	1.733	0.733			

Comparative Analysis- The median reduction in size for Group A over study period '1st day – 2nd week' was 1 with of 1.2. Whereas, for Group B the median reduction was 1 and the mean reduction was 1.267. There was no significant difference observed between the reductions in two Group at 5% level of significance (*P* value = 0.692). Hence, both treatment A and treatment B can be considered as equally efficacious with size (Table 3.1).

Table 3.1: Showing Size of wound (Mann-Whitney table with statistic)

1stday – 2ndweek	n	Median	Mean	Mann Whitney U test	P value
Group A	15	2	2.267	112.5	1
Group B	15	2	2.267		

Effect on Margin & Surface: By using Friedman test, it was observed that, the reduction in margin &surface score for Group A was significant (*P* value<0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in margin & surface score over period '1st day – 1st week'*(P* value <0.001) as well as '1st day – 2nd week' (*P* value<0.001) were significant. Hence, there was significant improvement in margin & surface for Group A over study period.

By using Friedman test, it was observed that, the reduction in margin & surface score for Group B was significant (*P* value <0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in margin & surface score over period '1st day – 1st week' (*P* value = 0.001) as well as '1st day – 2nd week' (*P* value <0.001) were significant. Hence, there was significant improvement in margin & surface for Group B over study period (Table 4).

Table 4: Showing Margin and surface of wound

Group	Statistic	1st day	1st week	2nd week	d.f.	Friedman chi-squared	P–value
Group A	Median	3.0	1.000	1.000	2	28.429	<0.001
	Mean	2.8	1.267	0.533			
Group B	Median	2.0	1.000	1.000	2	28.182	<0.001
	Mean	2.4	1.267	0.600			

Comparative Analysis: The median reduction in margin & surface score for Group A over study period '1st day – 2nd week' was 2 with mean of 2.267. Whereas, for Group B the median reduction was 2 and the mean reduction was 1.8. The reductions in Group A were significantly higher (*P* value = 0.024) than that in Group B at 5% level of significance (*P* value = 0.692). Hence, treatment A can be considered as more efficacious in improving margin & surface (Table 4.1).

Table 4.1: showing Margin and surface of wound (Mann-Whitney table with statistics)

1stday – 2ndweek	n	Median	Mean	Mann Whitney U test	P value
Group A	15	2	2.267	157	0.024
Group B	15	2	1.800		

Effect on Colour: By using Friedman test, it was observed that, the reduction in colour score for Group A was significant (*P* value< 0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in colour score over period '1st day – 1st week' (*P* value = 0.001) as well as '1st day – 2nd week' (*P* value = 0.001) were significant. Hence, there was significant improvement in colour for Group A over study period.

By using Friedman test, it was observed that, the reduction in colour score for Group B was significant (*P* value<0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in colour score over period '1st day – 1st week' (*P* value = 0.001) as well as '1st day – 2nd week' (*P* value = 0.001) were significant. Hence, there was significant improvement in colour for Group B over study period (Table 5).

Table 5: Showing Colour of wound

Group	Statistic	1st day	1st week	2nd week	df	Friedman chi-squared	P–value
Group A	Median	3.000	1.0	1.000	2	26.235	<0.001
	Mean	2.600	1.2	0.600			
Group B	Median	3.000	1.0	1.000	2	25.2	<0.001
	Mean	2.467	1.0	0.733			

Comparative Analysis: The median reduction in colour score for Group A over study period '1st day – 2nd week' was 2 with mean of 2. Whereas, for Group B the median reduction was 2 and the mean reduction was 1.733. There was no significant difference observed between the reductions in two Group at 5% level of significance (*P* value = 0.244). Hence, both treatment A and treatment B can be considered as equally efficacious with colour (Table 5 .1).

Table 5.1: Showing Colour of wound (Mann-Whitney table with statistics)

1stday – 2ndweek	n	Median	Mean	Mann Whitney U test	P value
Group A	15	2	2.000	136.5	0.244
Group B	15	2	1.733		

Effect on Granulation Tissue: By using Friedman test, it was observed that, the reduction in granulation tissue score for Group A was significant (*P* value< 0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in granulation tissue score over period '1st day – 1st week' (*P* value = 0.001) as well as '1st day – 2nd week' (*P* value = 0.001) were significant. Hence, there was significant improvement in granulation tissue for Group A over study period.

By using Friedman test, it was observed that, the reduction in granulation tissue score for Group B was significant (*P* value < 0.001) at 5% level of significance. Further, post hoc analysis using pair wise Wilcoxon signed rank test shows that, the reduction in granulation tissue score over period '1st day – 1st week' (*P* value < 0.001) as well as '1st day – 2nd week' (*P* value= 0.001) were significant. Hence, there was significant improvement in granulation tissue for Group B over study period (Table 6).

Table 6: Showing Granulation tissue

Group	Statistic	1st day	1st week	2nd week	df	Friedman chi-squared	P–value
Group A	Median	2.000	1.000	0.000	2	29.103	<0.001
	Mean	2.267	0.933	0.067			
Group B	Median	2.000	1.000	0.000	2	29.103	<0.001
	Mean	2.267	1.067	0.133			

Comparative Analysis: The median reduction in granulation tissue score for Group A over study period '1st day – 2nd week' was 2 with mean of 2.2. Whereas, for Group B the median reduction was 2 and the mean reduction was 2.133. There was no significant difference observed between the reductions in two Group at 5% level of significance (*P* value = 0.808). Hence, both treatment A and treatment B can be considered as equally efficacious with granulation tissue. (Table 6.1)

Table 6.1 Showing Granulation tissue (Mann-Whitney table with statistics)

1st day – 2ndweek	n	Median	Mean	Mann Whitney U test	P value
Group A	15	2	2.200	118	0.808
Group B	15	2	2.133		

Total Score: For Group A, the mean reduction in total score over treatment period is 9.60 with S.D. of 1.55. This reduction is significant at 5% level of significance (*P* value <0.001) as per paired t test. Hence, treatments A can be considered as efficacious in reducing total score. For Group B, the mean reduction in total score over treatment period is 8.67 with S.D. of 1.45. This reduction is significant at 5% level of significance (*P* value < 0.001) as per paired t test. Hence, treatment B can be considered as efficacious in reducing total score (Table 7).

Table 7: Showing Total Score

Group	Mean			S.D. of diff.	Sample size	Paired t statistic	p-value
	BT	AT	Diff				
Group A	11.67	2.07	9.60	1.55	15	24.00	<0.001
Group B	11.13	2.47	8.67	1.45	15	23.19	<0.001

Comparative Analysis: The reduction in total score for Group A (mean = 9.60, S.D.= 1.55) and that in Group B (mean =8.67, S.D. =1.45) were not significantly different (*P* value = 0.099) at 5% level of significance as observed by unpaired t test. Hence, both treatment A and treatment B can be considered as equally efficacious in reducing total score (Table 7.1).

Table 7.1: Total Score (Mann-Whitney table with statistics)

Group	Mean diff (BT-AT)	S.D. of diff (BT-AT)	Sample size	Unpaired t statistic	P-value
Group A	9.60	1.55	15	1.70	0.099
Group B	8.67	1.45	15		

Discussion

Discussion on Clinical Trial

As zinc is Micronutrient which is essential during wound healing (21). All though in a probable action of *Yashadamrita Malahara* has been explained with classical and modern view. On Discharge - Due to *Kashaya*, *katu rasa* and *Kapha Pitta Shamaka* property of *Yashada (22),* it may help in reduction of secretion from the wound; it reduces the bacterial growth and exudates, decreases rate of deterioration of wound (23).

Sikta Taila has a property of *Madhura rasa, Snigdha* and *Picchila guna*, *Sandhanakara*, *Vranaropaka, Sheeta veerya* (23, 24, and 25) help in healing of wound. It also acts as barrier from evading of bacteria to the site of the wound (26). Research from as early as 1970 has demonstrated the significance of zinc concentrations for wound healing in patients who have experienced thermal damage or surgical stress (27).

Conclusion

This Study suggests that *Yashadamrita Malahara* is effective for wound healing in *Shuddha vrana* and the efficacy of *Yashadamrita Malahara* with *Jatyadi taila* in the management of *Shuddha Vrana* is comparable.

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Photos

Figure A Yashada	Figure B Shodhita Yashada	Figure C Powdered Yashad bhasma	Figure D Sikata taila	Figure E Final Yashadamrita Malahara.
				

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