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A randomized controlled clinical study to evaluate the efficacy of Haridra Arka in the management of Dushta Vrana vis-à-vis Chronic Non-Healing Ulcer

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ABSTRACT

Introduction: A chronic wound is a wound that does not heal in an orderly set of stages and in a predictable amount of time. Any wound after 7 days is to be considered as Dushta Vrana. The use of Arka preparations in Vrana is mentioned in classics. **Objective:** To evaluate the efficacy of Haridra Arka in the management of Dushta Vrana and to study the anti-microbial property of Haridra Arka. Methodology: A single blind clinical study with pre-test and post-test design. The 30 patients with diagnostic criteria of Dushta Vrana were selected from Muniyal Institute of Ayurveda Medical Sciences, Manipal. In Group A, the wound is cleaned and dressed with Haridra Arka. In the control group, Betadine was used for dressing. Wound management done once in a day. Duration of the study for 30 days or till the formation of granulation tissue. Follow-up done once in 7 days for 1 month. The data were graded based on the assessment criteria and were analysed statistically. Results: The outcome of the treatment after 30 days showed high statistical significance in parameters like depth, edge and exudates amount, and other parameters like pain, itching, smell, undermining, necrotic tissue type, necrotic tissue amount, exudates type, skin colour surrounding the wound and granulation tissue showed statistical significance. Conclusion: Both these treatments showed reduction in symptoms but Group B in which Betadine was used showed better results. It can be concluded that Haridra in the form of Arka is not very effective in the management of Dushta Vrana when compared to Betadine.

Key words: Dushta Vrana, Haridra Arka, Betadine, Chronic Non-Healing Ulcer, Ayurveda.

INTRODUCTION

Vrana is one of the important diseases mentioned by Acharya Sushrutha. While describing the definition of Shalya tantra, Dushta Vrana has been highlighted.^[1] Dushta Vrana is a major health problem worldwide and has great impact at personal, professional and social levels with high cost in terms of human and material sources. In practise, Dushta Vrana is commonly

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encountered by medical practitioners, wound healing is the major problem in surgical practise even though wound healing is a natural phenomenon and continues in sequential manner until formation as a healthy scar, usually nature takes complete care during healing. A chronic wound is a wound that does not heal in an orderly set of stages and in a predictable amount of time. There are Indian studies on the epidemiology of chronic wounds; one study estimated the prevalence as 4.5 per 1000 population. It has been reported that ulcer related to venous insufficiency constitute 70%, arterial disease 10% and ulcer of mixed aetiology 15% of leg ulcers. The remaining 5% of the ulcers result from less common pathophysiological causes and this later group comprise considerable challenges in diagnosis, assessment and management.^[2] Acharya Sushrutha described management of Vrana in the form of Shashti Upakramas (60 procedures for Vrana management).^[3] Herbal treatments have been used to heal wound infections since ancient times. The active component of the therapeutic herbs, however, is now the subject

of investigation. One of the most investigated substances with pleiotropic effects in treating skin disorders is curcumin, the active ingredient of the medicinal plant *Curcuma longa*.^[4] The curcumin found in turmeric can help wound heal by decreasing inflammation and oxidation. It can also positively affect tissue and collagen as well. *Haridra* is also having antibacterial properties, anti-fungal properties, promotes blood circulation and removes blood stasis.^[5] Acharya Sushrutha has also mentioned Haridra for Vrana Shodhana^[6] and Vrana Ropana.^[7]

The use of *Arka* preparations in *Vrana* is mentioned in classics.^[8] *Arka* is the preparation which is obtained by distillation of liquid or drug soaked in water and extracted by *Arkayantra*. Due to its increased potency, decreased dose, better shelf life, easy absorption, fast action, patient compliance- *Arka Kalpana* is the 1st choice in growing demand among current population.^[9]

MATERIALS AND METHODS

Source of data

The patients suffering from Chronic non-healing ulcers were selected from OPD and IPD of Muniyal Institute of Ayurveda Science, Hospital, Manipal. All the drugs were identified and collected from local and other areas and *Arka* was prepared as mentioned in *Arkaprakasha* from R&D department of Muniyal Institute of Ayurveda Science, Hospital, Manipal.

Method of collection of data

The subjects suffering from chronic non-healing ulcers were screened under strict diagnostic, inclusion and exclusion criteria and were selected for the study. Eligible subjects were invited to participate in the study after signing a detailed informed consent and registered for this clinical trial. A randomised controlled clinical study in comparison with a control group will be done on 30 patients suffering from chronic non-healing ulcers selected as per the criteria mentioned in assessment criteria. The patients enrolled in the study will be divided into two groups- a) Study group; b) Control group, each comprising of 15 patients each. The signs and symptoms and other

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parameters, as per the assessment criteria mentioned will be observed before and after the treatment and the results of the two groups will be compared, analysed statistically and discussed.

Design of the study: An Open labelled, randomized, comparative, interventional clinical study

Inclusion Criteria

- Patient having the Lakshanas of Dushta Vrana occurring only in lower extremities.
- Venous ulcers, diabetic ulcers, neurogenic ulcers of any duration.
- Patients of either sex will be taken.
- Patient aged between 20-70 years.
- Diabetic patients with controlled blood sugar levels (RBS<200mg/dl).

Exclusion Criteria

- Patients with pre-diagnosed disorders like Malignancy, Leprosy, Osteomyelitis, Syphilitic ulcer, Tubercular ulcer.
- Ulcers with signs of gangrene, cellulitis and active infections.
- Immunocompromised patients with pre-diagnosed HIV and HBsAg positive.

Investigations

The following Investigation is undertaken to estimate the patient's general health condition and also will assist in determining the severity of infection.

Laboratory tests: HB%, RBC, TC, DC, ESR, RBS, HbA₁C, HIV, HBsAg. Any other investigations (if necessary).

Assessment Criteria

Subjective Parameters

- Pain
- Itching
- Smell

Objective Parameters

Bates-Jensen Wound Assessment Tool^[10]

Intervention

Study Group

The wound was examined, exudates, debris, slough was removed, the surrounding area was cleaned. *Pariseka* with *Haridra Arka* was done over the wound for 5 minutes. A gauze soaked in *Haridra Arka* was placed and wound dressing was done once in a day. The patient was educated to do the same for 30 days. The duration of study was 30 days or till wound healing whichever is earlier.

Control Group

The wound was examined, exudates, debris, slough was removed, the surrounding area was cleaned with betadine, a gauze soaked in betadine was placed and wound dressing was done once in a day. The patient was educated to do the same for 30 days. The duration of study was 30 days or till the wound heals whichever is earlier.

Duration of the study

Wound management was done once in a day and duration of study was 30 days or till the wound heals whichever is earlier.

Follow-up

The patient was followed up on the 7th, 14th, 21st, 29th days during the course of treatment and after that follow-up was done on the 45th day.

Statistical analysis

Statistical analysis was done on Sigma Plot software version 14.0. In this study Wilcoxon Signed Rank test was taken in place of paired t test when data is ordinal, where distribution is not normal or sample size is small. For the analysis in between group, Mann Whitney test is used for ordinal data, when distribution is not normal or small sample size.

OBSERVATIONS AND RESULTS

Effects of Haridra Arka and Betadine on Itching

Effect on Group A: The mean score of itching which was 1.200 has been reduced to 0.733 after treatment. The improvement recorded was statistically significant with P=0.016

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Effect on Group B: The mean score of itching which was 1.867 has been reduced to 0.867 after treatment. The improvement recorded was highly statistically significant with P<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to exclude the possibility that the difference is due to random sampling variability; there is a statistically significant difference (P = 0.013).

Effects of Haridra Arka and Betadine on Smell

Effect on Group A: The mean score of smell which was 0.600 has been reduced to 0.200 after treatment. The improvement recorded was statistically significant with P=0.031

Effect on Group B: The mean score of smell which was 1.733 has been reduced to 0.600 after treatment. The improvement recorded was highly statistically significant with P<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to exclude the possibility that the difference is due to random sampling variability; there is a statistically significant difference (P = 0.004).

Effects of Haridra Arka and Betadine on Size

Effect on Group A: The mean score of size which was 1.733 has been reduced to 1.600 after treatment. The improvement recorded was not statistically significant with P = 0.500

Effect on Group B: The mean score of size which was 2.733 has been reduced to 1.60 after treatment. The improvement recorded was highly statistically significant with P = <0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to reject the possibility that the difference is due to random sampling variability. There is a highly statistically significant difference between the input groups (P < 0.001)

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Effects of *Haridra Arka* and Betadine on Necrotic tissue amount

Effect on Group A: The mean score of necrotic tissue amount which was 2.267 has been reduced to 1.733 after treatment. The improvement recorded was statistically significant with P = 0.008.

Effect on Group B: The mean score of necrotic tissue amount which was 3.267 has been reduced to 2.267 after treatment. The improvement recorded was highly statistically significant with P=<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to reject the possibility that the difference is due to random sampling variability. There is a statistically significant difference between the input groups (P = 0.003).

Effects of *Haridra Arka* and Betadine on Exudate amount

Effect on Group A: The mean score of exudate amount which was 2.733 has been reduced to 1.867 after treatment. The improvement recorded was highly statistically significant with P = <0.001.

Effect on Group B: The mean score of exudate amount which was 3.267 has been reduced to 2.067 after treatment. The improvement recorded was highly statistically significant with P=<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to reject the possibility that the difference is due to random sampling variability. There is not a statistically significant difference between the input groups (P = 0.064).

Effects of *Haridra Arka* and Betadine on skin colour surrounding wound

Effect on Group A: The mean score of skin colour surrounding wound which was 2.60 has been reduced to 1.933 after treatment. The improvement recorded was statistically significant with P = 0.031.

Effect on Group B: The mean score of skin colour surrounding wound which was 2.733 has been reduced to 1.667 after treatment. The improvement recorded was highly statistically significant with P=<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to reject the possibility that the difference is due to random sampling variability. There is no statistically significant difference between the input groups (P = 0.121).

Effects of *Haridra Arka* and Betadine on peripheral tissue oedema

Effect on Group A: The mean score of peripheral tissue oedema which was 2.0 has been reduced to 1.733 after treatment. The improvement recorded was not statistically significant with P =0.125

Effect on Group B: The mean score of peripheral tissue oedema which was 3.0 has been reduced to 2.0 after treatment. The improvement recorded was highly statistically significant with P=<0.001

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great enough to reject the possibility that the difference is due to random sampling variability. There is a highly statistically significant difference between the input groups (P = <0.001).

Effects of *Haridra Arka* and Betadine on granulation tissue

Effect on Group A: The mean score of granulation tissue which was 2.40 has been reduced to 1.867 after treatment. The improvement recorded was statistically significant with P = 0.031.

Effect on Group B: The mean score of granulation tissue which was 3.0 has been reduced to 2.0 after treatment. The improvement recorded was highly statistically significant with P=<0.001.

Comparing the effect of treatments between the groups: Statistical analysis in between two groups with respect to difference in the median values is not great

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enough to reject the possibility that the difference is due to random sampling variability. There is a statistically significant difference between the input groups (P = 0.011).



Photo 2: Wound on 30th day

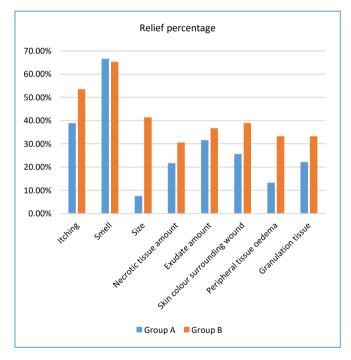


Table 1: Result summary of subjective and objectiveparameters

Parameters	Mean score BT		Mean score AT			
	Group A	Group B	Group A	%	Group B	%
Itching	1.200	1.876	0.733	38. 9%	0.876	53. 5%
Smell	0.600	1.733	0.200	66. 6%	0.600	65. 3%
Size	1.733	2.733	1.600	7.6 %	1.600	41. 4%

Necrotic tissue amount	2.267	3.267	1.733	21. 7%	2.267	30. 6%
Exudate amount	2.733	3.267	1.867	31. 6%	2.067	36. 7%
Skin colour surrounding wound	2.600	2.733	1.933	25. 6%	1.667	39. 0%
Peripheral tissue oedema	2.000	3.000	1.733	13. 3%	2.000	33. 3%
Granulation tissue	2.400	3.000	1.876	22. 2%	2.000	33. 3%





Result of Experimental Study

Haridra Arka did not show anti-bacterial activity in different volumes used against Pseudomonas aeruginosa (gram negative bacteria).

Table 2: In vitro anti-bacterial activity againstPseudomonas aeruginosa

Sample	Volume	Zone of inhibition- (Radius in mm)	
Haridra Arka	25µl	0	0

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	50µl	0	0
	75µl	0	0
	100µl	0	0
	125µl	0	0
Betadine	50µl	06	06
Std. (Gentamicin- 240μl)	15µl	15	16

Haridra Arka did not show anti-bacterial activity in different volumes used against Staphylococcus aureus (gram positive bacteria).

Table 3: In vitro anti-bacterial activity againstStaphylococcus aureus

Sample	Volume	Zone of inhibition- (Rac	lius in mm)
Haridra Arka	25µl	0	0
	50µl	0	0
	75µl	0	0
	100µl	0	0
	125µl	0	0
Betadine	50µl	09	09
Std. (Ampicillin) 1mg/ml	25µl	15	15

*Haridra Arka d*id not show anti-fungal activity in different volumes used against Candida albicans.

Table 4: In vitro anti-fungal activity against Candidaalbicans

Sample	Volume	Zone of inhibition- (Radius in mm)	
Haridra Arka	25µl	0	0
	50µl	0	0
	75µl	0	0
	100µl	0	0
	125µl	0	0

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Betadine	50µl	07	07
Std. (Clotrimazole)	10µl	09	09

DISCUSSION

Discussion on Haridra

Turmeric has been used in Indian folk medicine for reducing pain, swelling, wound healing and inflammation. Haridra has Katu-Tikta Rasa, Laghu Guna and Ushna Virva. lts Krimighna, Dahaprashamana property is due to Tikta Rasa. Vranahara property is due to Katu Rasa. Vedana Shamaka property is due to Ushna Virya. Tikta Rasa checks inflammation, Pitta-Kapha Dosha is corrected, also squeezes out toxins and necrotic tissue thus checks excess exudation (Kleda-Puya-Sleshma Shoshana), and thus facilitates wound healing (Vrana Ropana). Tikta and Katu Rasa have Kushtaghna property and this facilitates granulation tissue formation. Laghu-Ruksha property helps in prevention of slough formation, in turn cleanses the wound and reduces smell.

Effect on Itching

Reduction in itching was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **38.9%** in Group-A and **53.5%** in Group-B. When the effects of both the treatments are compared, the patients in Group B showed better response in reduction of itching.

Effect on Smell

Reduction in smell was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **66.6%** in Group-A and **65.3%** in Group-B. When the effects of both the treatments are compared, the patients in Group A and Group B showed comparable response in reduction of smell.

Effect on Size

Reduction in size was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **7.6%** in Group-A and **41.4%** in Group-B. When the effects of both the

treatments are compared, the patients in Group B showed better response in reduction of size.

Effect on Necrotic Tissue Amount

Reduction in necrotic tissue amount was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **21.7%** in Group-A and **30.6%** in Group-B. When the effects of both the treatments are compared, the patients in Group B showed better response in reduction of necrotic tissue amount.

Effect on Exudates Amount

Reduction in exudates amount was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **31.6%** in Group-A and **36.7%** in Group-B. When the effect of both the treatments is compared, the patients in Group A and Group B showed comparable response in reduction of exudates amount.

Effect on Skin Colour Surrounding Wound

Improvement in skin colour surrounding wound was observed in both the groups of patients of chronic ulcer. As observed, there is an improvement in the percentage by **25.6%** in Group-A and **39%** in Group-B. When the effects of both the treatments are compared, the patients in Group B showed better response in improvement of skin colour surrounding wound.

Effect on Peripheral Tissue Oedema

Reduction in peripheral tissue oedema was observed in both the groups of patients of chronic ulcer. As observed, there is a reduction in the percentage by **13.6%** in Group-A and **33.3%** in Group-B. When the effects of both the treatments are compared, the patients in Group B showed b better response in reduction of peripheral tissue oedema.

Effect on Granulation Tissue

Improvement in granulation tissue was observed in both the groups of patients of chronic ulcer. As observed, there is an improvement in the percentage by **22.2%** in Group-A and **33.3%** in Group-B. When the effects of both the treatments are compared, the patients in Group B showed better response in improvement of granulation tissue.

Discussion on Assessment Tool

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Reduction in severity of wound was observed in both the groups of patients of chronic ulcer. In Group A, 4 patients had moderately severe wound and after treatment, it has reduced to 2 patients. 11 patients had mildly severe wound and after treatment it has reduced to 7 patients and 6 patients had minimally severe wound. In Group B, 15 patients were under moderately severe wound. After the treatment, 13 patients had mildly severe wound and 2 patients had minimally severe wound.

Discussion on Anti-Microbial Study

Haridra Arka did not show any anti-bacterial and antifungal activity. According to classical texts, Haridra have Krimighna property. The terpinoids, alkaloids, flavonoids etc. present in Haridra gives the Krimighna action. Most of chemical constituents present in Haridra are insoluble in water and they work well in fat soluble medium. This can be the reason for negative anti-microbial result of Haridra Arka.

CONCLUSION

Both these treatments showed reduction in symptoms but Group B in which Betadine was used showed better results. Betadine was having good results in reducing pain, itching, size, depth, necrotic tissue amount, peripheral tissue oedema and peripheral induration. Group B also showed improvement in necrotic tissue type, exudate type and skin colour surrounding the wound. Both the groups had equal and comparable effect in reduction of smell, edge, undermining and exudate amount. It can be concluded that *Haridra* in the form of *Arka* is not very effective in the management of *Dushta Vrana* when compared to Betadine. Other factor that may improve outcome is by making use of *Haridra* in other *Kalpanas* like *Taila*, *Ghritha* etc.

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