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 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*. 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. Acharya Sushruta has also mentioned *Haridra* for *Vrana Shodhana* and *Vrana Ropana*. The use of *Arka* preparations in *Vrana* is mentioned in classics. *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.

**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 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 highly statistically significant with P<0.001

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)
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 a highly statistically significant difference between the input groups (P = <0.001).

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 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).
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).

Table 1: Result summary of subjective and objective parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean score BT</th>
<th>Mean score AT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
</tr>
<tr>
<td>Itching</td>
<td>1.200</td>
<td>1.876</td>
</tr>
<tr>
<td>Smell</td>
<td>0.600</td>
<td>1.733</td>
</tr>
<tr>
<td>Size</td>
<td>1.733</td>
<td>2.733</td>
</tr>
</tbody>
</table>

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 against *Pseudomonas aeruginosa*

<table>
<thead>
<tr>
<th>Sample</th>
<th>Volume</th>
<th>Zone of inhibition- (Radius in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Haridra Arka</em></td>
<td>25µl</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 1: Summary of relief percentage of parameters

![Figure 1: Summary of relief percentage of parameters](image-url)
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 against Staphylococcus aureus

<table>
<thead>
<tr>
<th>Sample</th>
<th>Volume</th>
<th>Zone of inhibition - (Radius in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haridra Arka</td>
<td>25µl</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>50µl</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>75µl</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>100µl</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>125µl</td>
<td>0</td>
</tr>
<tr>
<td>Betadine</td>
<td>50µl</td>
<td>06</td>
</tr>
<tr>
<td>Std. (Gentamicin-240µl)</td>
<td>15µl</td>
<td>15</td>
</tr>
</tbody>
</table>

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

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 Virya. Its 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 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

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 anti-fungal 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.

REFERENCES

1. Acharya YT. Commentary Nibandha sangraha of Dalhanacharya on Sushrutha Samhitha, SutraSthana;
Ashna Ratheesh A.P. et al. Efficacy of Haridra Arka in the management of Dushta Vrana

ISSN: 2456-3110

January 2024


5. Noure SD, Dosoky, N Setzer W. Chemical Composition and Biological activities of Essential oils of Curcuma Species. Published online September 1, 2018.


How to cite this article: Ashna Ratheesh A.P., Gururaja D. 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. J Ayurveda Integr Med Sci 2024;1:15-22. http://dx.doi.org/10.21760/jaims.9.1.2

Source of Support: Nil, Conflict of Interest: None declared.