

CLINICAL EVALUATION OF THE SHODHANA EFFECT OF HARIDRA TAILA AND ROPANA EFFECT OF MADHU IN DUSHTA VRANA

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ABSTRACT

The presence of *Dushta Vrana* (non-healing ulcer) worsens the quality of life of the patient with various complications and may prove fatal. Although *Vrana* is the oldest known ailment and its healing is still a matter of concern. When it refuses to heal despite of best efforts or due to improper treatment of *Chikitsachatushpada* (four parts necessary for treatment) it turns to *DushtaVrana*. Chronic wounds of mixed aetiologies showed a pooled prevalence of 2.21 per 1000 population. Its high prevalence worldwide, chronicity and expensive treatment is still a matter of concern. Every research done has a cause. The aim of present research work to provide an economical treatment with least side-effects and in comparatively less time. A clinical trial was conducted in this study group of 30 patients diagnosed with Non-Healing Ulcer (*DushtaVrana*). Patients were selected randomly irrespective of their age, sex, religion, race, occupation etc. Their *Vrana* were dressed in *Hraidra Taila* and *Madhu* daily till the *Vrana* heals or for three months maximum and monitored at every 15 days interval during the study period. Symptoms like pain and signs likesize, tenderness, discharge, depth of ulcer, granulation tissue floor were used as parameters to assess the effect of the treatment on *Dushta Vrana*. Analysis of result showed improvement in *DushtaVrana* (non-healing ulcer). On the basis of clinical observations, it can be concluded that in the present

clinical study result of *Shodhana* (cleansing) effect of *Haridra Taila* and *Ropana* (healing) effect of *Madhu* is very effective.

Keywords *Dushta Vrana, Haridra Taila, Madhu.*

INTRODUCTION

To heal is nature's response. *Acharya Sushruta* has dedicated various chapters of *Sutrasthana* (1st part of *Sushruta Samhita*) and few of *Chikitsasthana* (fourth part of *Sushruta Samhita*) for the study of whole science of the wound. He has talked about *Sadyovrana* (fresh wound) and its healing in *chikistasthana*¹. When a wound fails to heal even after the best efforts of *chikitsachatushpada*² (*Vaidya* (doctor), *Aushadh* (medicine), *Paricharak* (attendant) and *Rogi* (Patient)) either due to some underlying pathology or improper treatment is known as *DushtaVrana*. It is not easy to eradicate wound. Every surgery begins with a wound. Accidents and wars since very ancient times were the causes of wounds. Recently road traffic accidents have increased the incidence of wound many times. In *Sushruta Samhita* lot of description is available regarding the wound and its management under the heading of *Vrana*. In *Chikitsa Sthana* he has described about *Shasti Upkrama*³ (60 treatment modalities for the treatment of ulcer) where he has mentioned about use of different oil for application for *shodhana*⁴ and *Madhu*⁵ for *Ropana*. *Haridra* is mentioned as *vrana-paha* (eradicates wound) by *Acharya Bhavprakash*⁶. *Katu* and *Tikta Rasa, Ushna Veerya, Katu Vipak, Aampachan Guna, Raktshodhaka Guna* of *Haridra*⁷ helps in *Shodhana* of *Dushtavrana*. *Madhu* is kept in *Sandhaneya Gana* by *Acharya Sushruta*. These two *Dravyas* (article) has been used since long for wound healing.

Dushta Vrana is major point of concern for health. Since the ancient time there are continuous and vigorous attempts made for better wound healing over past two thousand years. With the various advancement in molecular and cellular biology research, objective assessment of tissue repair has become more and more sophisticated. India being a country with larger population and a still developing nation the poverty does not allow every patient to reach a sophisticated and

expensive treatment. Keeping above facts in mind the present clinical study "Clinical evaluation of the *Shodhana* effect of *Haridra Taila* and *Ropana* effect of *Madhu* in *DushtaVrana*" has been done.

Aim & Objectives:

"Clinical evaluation of the *Shodhana* effect of *Haridra Taila* and *Ropana* effect of *Madhu* in *Dushta Vrana*"

To cure the disease in less time.

To give complication free therapy.

To explore literature about *DushtaVrana* in Modern as well as *Ayurved*.

Materials & Methods: The present study is entitled with "The *Shodhana* effect of *Haridra Taila* and *Ropana* effect of *Madhu* in *Dushta Vrana*".

Materials

1. Patients suffering from *Dushta Vrana*. *Haidra Taila* and *Madhu*

A. Selection of The Patients: 30 Patients of non-healing wound were selected from the O.P.D./I.P.D. of Patanjali Ayurved Hospital, Haridwar. Most of the cases were registered as OPD patients. The cases were recorded with the help of special proforma prepared for this study. The patients were treated with *Haridra Tail* for *Shodhana* and *Madhu* for *Ropana* of *DushtaVrana*.

B. Selection of Drug: CO₂ extracted *Haridra Taila* for *Shodhana* and *Madhu* for *Ropana*

C. Duration of Study -90 days

D. Type of Study- Open and Prospective Study

E. Selection of Patients

Inclusion Criteria:

Patient aged between 18-70 years

Patient willing to undergo trial and ready to give informed and written consent.

• Patient irrespective of age, sex, religion, socio-economic status and occupation will be taken.

- Patient with the clinical features of *Dushta Vrana*.
- Traumatic ulcers
- Arterial ulcers
- Venous ulcers
- Neurogenic ulcers
- Diabetes ulcers (DM under control)

Exclusion Criteria:

- Patient not willing to undergo trial or not ready to give informed and written consent.
- HIV or Hepatitis B or Hepatitis C positive patients.
- Patients with evidence of malignancy and malignant ulcer
- Tubercular ulcer
- Syphilitic ulcer
- Soft chancre sores (Ducrey's)
- Diabetes mellitus (uncontrolled)
- Patients suffering from chronic renal disease.

Investigations

- Routine blood examination
- Routine urine examination
- Blood sugar fasting and post prandial
- LFT
- KFT
- X-Ray of the part to look for osteomyelitis (if required)
- Culture and sensitivity of the pus (if required)
- VDRL (if required)
- Any other necessary investigations

Drugs selected for Study: CO₂ extracted *Haridra Taila* and *Madhu*

Procedure of preparation of supercritical CO₂ extracted *Haridra Taila*⁸: It consists mainly of a high – pressure pump, a SCO₂ generator vessel, two 1000 mL Extractors (each of 42 cm height and 5.5 cm inside diameter) and two low pressure 1000mL. Separators, and a low temperature CO₂ storage and a Control Unit to view and change the system setting.

Operational Procedure: The operational procedure used in this SFE module was described in detail by S.Roy et al . Initially a particular type of feed shell was filled in full of comminute turmeric samples and placed inside the extractor vessel to carry the runs.

Pressurized solvent CO₂ from the pump was allowed to enter the extractor vessel through SCO₂ generation vessel to attain the desired extraction pressure. Once the extractor pressure was stabilized, the extract laden SCO₂ was expanded to reduce the pressure and recover the essential oil through two successive separators. In the procedure extraction was continued for a period of 240 minutes and the samples were collected and weighed at intervals of 15, 30, 45, 60, 90, 120, 150, 180, 210 and 240 minutes using separate sampling bottles and recorded to construct over all construction curve. This SFE unit was equipped with a solvent CO₂ recovery system and the recovered solvent was returned back to the low temperature CO₂ storage vessel for reuse. After extraction total yield was centrifuged and the pure essential oil part was separated and stored in refrigerator unit.

Mode of Application

- Local application of *Haridra Taila* for dressing once daily.
- After appearance of healthy granulation tissue application of *Madhu* on ulcer daily.

Methodology: It is an open and prospective clinical trial. Thorough history and the complaints of the patients were taken in the chronological order. Each and every patient was carefully examined clinically for general and systemic examination. Full explanation about the trial was given to the patients and their attendants and informed consent of each and every patient was taken before the commencement of the treatment after. Total 30 patients were selected for the present clinical trial on the basis of clinical diagnosis.

Study Design: It is an Open and Prospective study

Duration of Study - 90 days

Criteria for Assessment: Assessment was done on the basis of improvement in following signs and symptoms of Non-Healing Wound

Subjective Parameters: Pain

Objective Parameters:

- Size (by using sterile blotting paper)
- Tenderness
- Discharge
- Depth of ulcer
- Granulation tissue floor

Subjective parameters:

1. Pain

Grading	Criteria
0	No Pain
1	Localized feeling of pain during movement only but no feeling during rest.
2	Localized feeling of pain even during rest but not disturbing sleep.
3	Localized continuous feeling of pain, radiating and not relieved by rest.

Objective parameters:

1. Size

Grading	Criteria
0	No ulcer
1	Less than 5 cm
2	Within 5-10 cm

It was recorded by using a sterile blotting paper which was placed over the ulcer and pressed with uniform pressure. The impression was measured directly.

2. Tenderness

Grading	Criteria
0	Tolerance to pressure
1	Little response to pressure
2	Winching effect on super slight touch
3	Resist to touch and rigidity

3. Discharge

Grading	Criteria
0	No discharge /dry dressing
1	Scanty occasional discharge and little wet dressing
2	Often discharge and with blood on dressing
3	Profuse, continuous discharge

4. Depth of ulcer - The depth was measured with the help of sterile probe.

Grading	Criteria
0	Healed
1	Less than 0.5 cm
2	Within 0.5-1.5 cm
3	>1.5 cm

5. Floor and granulation tissue

Grading	Criteria
0	Red granulation tissue
1	Pale and smooth granulation tissue
2	Patchy granulation tissue
3	Slough

Assessment of Results: The treatment effect was assessed every 15 days on the basis of the relief of signs and symptoms of the disease on scoring pattern by a specially designed proforma.

Sr. No.	Result	Criteria
1.	Healed	100% relief in signs and symptoms.
2.	Markedly healed	76-99% relief in signs and symptoms.
3.	Moderately healed	51-75% relief in signs and symptoms.
4.	Mild improvement	26-50% relief in signs and symptoms.
5	No improvement	<25% relief in signs and symptoms.

Assessment of the effect of treatment was done on the basis of above given assessment criteria before and after treatment schedule.

Statistical Analysis: The information regarding demographic data was given in percentage. The data obtained in clinical study is subjected to statistical tests and analyzed as in terms of Mean (X), standard deviation (S.D.), standard error (S.E.), Friedman’s test & Wilcoxon sign rank test finally result were incorporated in term of probability ‘P’ as-

- P>0.050 Not significant
- P<0.010 Significant
- P<=0.001 Highly significant

Observations

- ❖ The demographic profile shows that maximum number of patients i.e. 30% were in between 45-60 years.
- ❖ There were more of male patients (76%) in the study.
- ❖ The number of Hindu patients (97%) were more.
- ❖ Maximum number of patients were graduate

- (46.6%).
- ❖ Maximum number of the patients (20%) belong to service class.
- ❖ Maximum number of the patients 76.66% were married.
- ❖ Majority of patients (90%) belonged to medium socioeconomic status.
- ❖ Majority of patients (80%) are dwelling in urban area.
- ❖ On analysis of *Prakriti* greater part (50%) of the patients were *Vata-Paittik* in *Prakriti*.
- ❖ 20% of patients were addicted to smoking.
- ❖ 63.34% of patients were on mixed diet.
- ❖ 76.66% of patients were married.
- ❖ Maximum number of patients 83.33% suffered *Vrana* at lower limb
- ❖ Maximum number of *Dushta Vrana* are *Adhishtit* on *Mamsa Dhatu* (66.67%).
- ❖ 46.66% of patients had no addiction probably due to unacceptance.

Table 1: Distribution of patient according to symptom and signs-

Sr. no	Symptom	Number of patients	Percentage
1	Pain	27	90%
2	Size	30	100%
3	Discharge	30	100%
4	Tenderness	29	96.66%
5	Depth	30	100%
6	Floor	30	100%

Table no.1 shows the percentage of most commonly seen features in *Dushta Vrana* in all patients. In the present clinical study total 90% patient were found suffering with pain. Size was observed in 100% pa-

tients. Discharge was observed in 100% patients. Tenderness was found in 96.66% patients. Depth was observed in 100% patients. Patients with floor with unhealthy granulation tissue were 100%.

Result: The Data gathered and compiled from this clinical trial was sorted out and processed further by subjection to varied statistical methods and presented

in the following sequence. Result of *therapy* was statistically analysed by Friedman’s test and Wilcoxon sign rank Test. The results are:

Table 2: Summarised results after completion (90 days) of treatment:

Parameters	Wilcoxon signed rank W	P value	% effect	Result
Pain	-4.631	=<0.001	83.63%	Highly Significant
Size	-4.878	= 0.03	75%	Significant
Tenderness	-4.779	=<0.001	90.5%	Highly Significant
Discharge	-4.787	=<0.001	92.6%	Highly Significant
Depth of ulcer	-4.730	=<0.02	79.8%	Significant
Granulation tissue floor	-4.968	=<0.001	95%	Highly Significant

Table no 2 shows the percentage of relief. The observations made here are on ordinal scale (gradation) scale. Hence in this study we have used Wilcoxon Signed Rank test to test efficacy of the drug. From the above table we can find out that the P value for pain,

tenderness, discharge and granulation tissue floor parameters is less than 0.001 whereas P value for size and depth of ulcer is between .001 and .05. Therefore, we can conclude that effect observed is significant.

Overall effect of the therapy

Table 3: Overall Result of the Study

Sr.no	Result	No. of patients	Percentage
1	Healed	18	60%
2	Markedly heal	4	3.33%
3	Moderately healed	6	20%
4	Mildly healed	2	6.66%
5	No improvement	0	0

On the basis of the specific scoring pattern adopted, the total effect of therapy had been assessed. Out of 30 patients 18 patients i.e. 60% were completely healed. 4 patients i.e. 3.33% were markedly heal, 6 patients i.e. (20%) were moderately healed and 2 patients i.e. 6.66% were mildly healed after the completion of the course as well as follow up period.

DISCUSSION

Dushta Vrana is a commonly found ailment with a lower rate of recovery. Surgical intervention also does not cure the disease completely and the recurrence rate is also high. To avoid these hard times for a patient this study was conducted on *Haridra Taila* and *Madhu* to reduce the healing time and recurrence.

Probable Mode of Action

The probable mode of action of *Haridra Taila* and

Madhu on the *Dushta Vrana* is as follows-

Removal of local “Dhatu Dushti”:

Severity of wounds depends on the local *Dhatu Dushti* with derangement of *Sihanik Twaka* (skin) and *Mamsa Dhatu* (muscle) with the involvement of *Rakta Dhatu* (blood). *Haridra Taila* possess the property of *Tikta, Katu*

Rasa, Rooksha Guna, Ushnavirya, Katuvipaka which are driving agents in actions like *Chedana* (removal, destruction), *Lekhana, Shodhana, Kapha-Pitta Nashana* (pacification), *Vishanashana* (antitoxic medication), *Vedanashamana* (analgesic), *Twak-doshahara* action. These properties of *Haridra Taila* enable it to remove or clean *Dhatu Dushti*. The drug also carries debridement action by the virtue of *Lekhana Guna* at the site of *Dushta Vrana* (wound /ulcer) and helped in the *Shodhana* of *Dushta Vrana*.

Effect on Clinical features:

Earlier mentioned *Rasa, Guna (s) & Karma (s)* of the trial drug helps to check out its effect on clinical features of the *Vrana* as follows-

1. *Vatahara (Ushna Guna), Shothahara*, anti-inflammatory properties reduce the inflammation and thus helps to relieve the **pain and tenderness**. *Shothahara* property helped to reduce the **swelling** in the *Vrana*.
2. *Shoshana karma* of *Tikta rasa* and *Rakta Shodhana* and *Krimighna karma* helped to minimize the infection and *Chedana* and *Lekhana Karma* removed previous slough and prevents the formation of any new **discharge, slough and secretions**.
3. **Unhealthy granulation tissue-** *Lekhana, Chedana, Raktashodhana Karma* and *Kaphapitta Shamakguna* played an important role in removing out the **debris** and **slough**.
4. *Rakta Shodhana (Tikta Rasa) Pittashamak, Varnya, Raktaprasadak* actions improved the **wound colour** by improving the local circulation.
5. **Infection-** was prevented by the *Krimighna, Vishaghna* and *Rakshoghna* properties of the drug.

Probable mode of action of Madhu

Application of *Madhu* is mentioned as 57th treatment modality in *Shasti Upkarama* given by *Acharya Sushruta*. Clinical observation made during study has shown its effectiveness in treatment of *DushtaVrana*. It has got properties like *Shodhana, Lekhana, Sandhana, Ropana* and *Tridoshaghna*. Honey is recommended as a traditional remedy in India from ancient years to treat skin conditions like eczema and skin infections.

The *Vrana* here was in *Shudha Awastha* for application of *Madhu*. *Ropana Guna* helps in healing of the *Vrana* and *Lekhana, Shodhana* and *Tridoshaghana guna* helps to alleviate the any *Dosha* imbalance later. Once the healthy granulation tissue appears application of *Madhu* which has *Vranaropaka* and *Prasadana Guna*, due to its *Sukshma Guna*, it gets readily absorbed. Thus, it is absorbed by the *Vrana* at cellular level and thus helps in faster growth of granulation

tissue and henceforth healing. Due to its low water content microorganism does not grow in *Madhu*. Pure undiluted *Madhu* is hyperosmolar which is antibacterial in activity. Honey is acidic in nature with a pH 3.2-4.5. It prevents colonization and bacterial growth in wound tissue due to their acidic nature and thus keeps infection in control.

Honey contains glucose oxides an enzyme which produces Hydrogen Peroxide (H₂O₂), a known antiseptic. The amount produced is very less and thus acts like an antiseptic without producing any damaging effect of the Hydrogen peroxide used otherwise. Honey has been proved to be effective against organism esp. *Staphylococcus aureus*. Honey is especially useful against the multidrug resistant strain of organisms. By virtue of the above said properties, wound healing with least of the scar tissue i.e. less fibrosis, colour almost similar to normal skin pigmentation, smooth, regular even surface was observed. *Varnya, Twakaprasadana, Raktaprasadana* actions of the *Haridra Taila* and *Madhu* lead to colour similar to the skin pigmentation.

CONCLUSION

In present clinical study *Shodhana* effect of *Haridra Taila* and *Ropana* effect of *Madhu* was evaluated against *Dushta Vrana*. Regarding signs and symptoms of *DushtaVrana, Haridrataila* and *Madhu* showed significant relief in pain, size, discharge, tenderness, depth of the ulcer and granulation tissue floor. It indicates effectiveness of above-mentioned drugs in improving the signs and symptoms of *Vrana* due to *Shodhana* effect of *Haridra Taila* and *Ropana* effect of *Madhu*.

This formulation is cost effective and provides complication free therapy.

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