A CLINICAL STUDY TO EVALUATE THE EFFICACY OF HARIDRADITAILA IN THE MANAGEMENT OF DUSHTAVRANA W.S.R. TO CHRONIC ULCER

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ABSTRACT

DushtaVrana (chronic ulcer) is the type of wound which breaks integrity or continuity of skin or mucous membrane. Wound healing is a natural restorative response to tissue injury. Healing is the interaction of a complex cascade of cellular events that generates resurfacing, reconstitution, and restoration of the tensile strength of injured skin or membrane. It is difficult to management of wound with a single drug. In the present study Haridradita taila is selected for chronic ulcer management. The trial drug ‘HaridradiTaila’ i.e. medicated oil consisted of Haridra (Curcuma longa), Manjistha (Rubiacordifolia), Nimbatapatra (Azadiractaindica), Yastimadhu (Glycyrhizaglabra), Neelkamal ( Nelumbonucifera) & Sesame oil (Sesamumindicum). These drugs possess VranaShodhana (wound cleaning) and VranaRopana (wound healing) properties. The present study was carried out on all types of Dushtavrana (chronic ulcer). Total 30 patients were selected and the study was single blind clinical study to evaluate the efficacy of HaridradiTaila by the subjective and objective criteria. The Haridradita taila was applied topically twice a daily for 30 days or till healing of wound whichever is earlier. This study shown that, there are significant results found in DushtaVrana (chronic ulcer) by anti-infective, analgesic and anti-inflammatory property which reduces pain, discharge, inflammation, tenderness, burning sensation and itching which contribute healthy granulation tissue formation, thus Haridradita taila possess sufficient efficacy in wound healing without producing any deleterious effects.

Keywords: DushtaVrana, Chronic Ulcer, Haridradita taila, wound healing

INTRODUCTION
The wound healing process is not only complex but also fragile, and it is susceptible to interruption or failure leading to the formation of non-healing chronic ulcer. Factors that contribute to non-healing chronic wounds are diabetes, infection, and metabolic disorder of old age.

Chronic ulcers may be painful. Most patients complain of constant pain at night and during the day. Chronic ulcer symptoms usually include increasing pain, friable granulation tissue, foul odour, and wound breakdown instead of healing.

Wound care encourages and speeds wound healing via cleaning and protection from re-injury or infection. Healing is a systematic process, traditionally explained in terms of 4 overlapping classic phases: haemostasis, inflammation, proliferation, and maturation. While platelets play a crucial role in clot formation during haemostasis, inflammatory cells debride injured tissue during the inflammatory phase. Epithelialization, fibroplasia, and angiogenesis occur during the proliferative phase. Meanwhile, granulation tissue forms and the wound begin to contract. Finally, during the maturation phase, collagen forms tight cross-links to other collagen and with protein molecules, increasing the tensile strength of the scar.

After injury, healing is a natural phenomenon and continues in sequential manner till the formation as the healthy scar. Certain general factors such as age, obesity, malnutrition, vitamin deficiency, anaemia, malignancy, diabetes and immunosuppressive disease, infection, poor blood supply, recurrent trauma etc. which either alone or in combination of influence the normal wound healing.

In Ayurveda particularly Acharya Sushruta has mentioned various types of wound and their management. He explain Vranashodhana (wound cleaning) and later Vranaropana (wound healing) includes six different strategies i.e. Shashtiupakrama for different condition of Vrana (wound) in the management of wound. For the management of dushtavrana (chronic ulcer), Sushruta incorporated number of drugs broadly classified into vranashodhana and vranaropana. The process of shodhana and ropana have been therapeutically grouped under seven heading i.e. kashaya, varti, kalka, sarpi, taila, rasakriya and avachurna.

It is important to find out effective formulation that possesses both Vranashodhana and Vranaropana properties. For this study five drugs viz. Haridra (Curcuma longa), Manjistha (Rubiacordifolia), Nimbatpatra (Azadirachtaindica), Yastimadhu (Glycyrrhizaaglabra), Neelkamal (Nelumbonucifera) have been selected from text book of dravyaguna. These drugs were processed in Sesame oil (Sesamumindicum) and prepared in the form of taila. An effort is made to know the efficacy of these drugs combination in the management of Dushtavrana (Chronic ulcer).

**AIMS AND OBJECTIVE:**
- To evaluate the efficacy of Haridraditaila application in the management of Dushtavrana (Chronic ulcer).
- To see whether any significant relief obtain by these drugs in the wound healing.

**MATERIALS & METHODS:**
This is a single blind clinical study on 30 patients suffering from Dushtavrana. Patients
were randomly selected from our Shalyatantra department OPD of KGMP Hospital. *Dushtavrana* cleaned with H$_2$O$_2$ (Hydrogen peroxide), dead tissue, debridement removed, *Haridraditaila* applied locally over the wound and banding done in two times a day (morning & evening).

Trail Duration: Total 30 days or till wound healing whichever is earlier.

**Inclusion Criteria:**

- Patient age between 18-60 years.
- Patient of either sex were taken.
- Patients with all types of *Dushtavrana* with maximum history of 1 months.

**Exclusion Criteria:**

- Patients with uncontrolled DM, sign of gangrene, HIV and Hepatitis.
- Patients suffering from degenerative diseases and diabetic foot.
- Patients suffering from lesions like tuberculosis, syphilis, malignant ulcer etc.
- Pregnant women, child below age 18 yr.
- *Dushtavrana* on movable and highly movable joints.

**Assessment criteria:**

All sign and symptoms were recorded before treatment, during each follow-up and after treatment by subjective and objective criteria.

**Subjective Criteria:**

1. *Shoola* (Pain)
2. *Daha* (Burning sensation)
3. *Kandu* (Itching)
4. *Strava* (Discharge)
5. *Gandha* (Odour)

**Objective criteria:**

1. Size and Shape

2. Tenderness
3. Colour
4. Granulation tissue
5. Inflammation

All subjective & Objective criteria were recorded on the basis of score adopted with grading (0, 1, 2 & 3)

**Scoring pattern:**

*Shoola* (Pain):

0- No pain
1- Mild (localized feeling of pain during movement but tolerable.
2- Moderate (Localized feeling of pain not disturbing sleep)
3- Sever (Continuous localized feeling of pain which disturbs sleep)

*Daha* (Burning sensation):

0- No *Daha* (Burning sensation)
1- Mild (Intermittent burning sensation)
2- Moderate (Continuous burning sensation not disturbing sleep)
3- Sever (Continuous burning sensation disturbing sleep)

*Kandu* (Itching):

0- No *Kandu* (Itching)
1- Mild (Slight localized itching sensation)
2- Moderate (More localized itching sensation but not disturbing sleep)
3- Severe (Continuous itching disturbing sleep)

*Strava* (Discharge):

0- No *Strava* (Discharge)
1- Mild (Scanty occasionally discharge and little wet gauze)
2- Moderate (Often discharge and with blood on dressing)
3- Severe (Profuse continuous discharge which needs frequent dressing)

*Gandha* (Odour):

0- No *Gandha* (Odour)
1- Mild (Unpleasant smell)
2- Moderate (Foul smell but tolerable)
3- Severe (Foul smell which is intolerable)

**Size and Shape:**

Dimension were measured using a disposable centimetre ruler by recording Length & Breadth as the longest dimensions and the depth was measured with help of a sterile probes.

**Tenderness:**

0- No tenderness
1- Tenderness palpating with finger
2- Tenderness after palpating with pressure
3- Tenderness on touch with soft object.

**Colour:**

0- Equivalent to skin colour
1- Pink
2- Reddish
3- Yellow

**Granulation tissue:**

0- Healthy granulation tissue
1- Pale granulation tissue

**Inflammation:**

0- No inflammation
1- Mild inflammation
2- Moderate inflammation
3- Severe inflammation

**OBSERVATION AND RESULTS:**

Total 30 patients were registered from OPD & IPD of Department of Shalyatantra in this study. Each patient was observed thoroughly and noted neatly.

Table no 1 & 2 shows that the effect of therapy on different signs and symptoms in patients of Dushtavrana (Chronic ulcer). Haridraditaila shows significant results in the assessment criteria of both subjective and objective. Thus Haridraditaila is showing better result in the management of Dushtavrana (Chronic ulcer).

### Table 1: Statistical analysis on subjective parameters:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean Score</th>
<th>M.D.</th>
<th>±SD</th>
<th>±SE</th>
<th>T</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoola (Pain)</td>
<td>2.67</td>
<td>0.83</td>
<td>1.83</td>
<td>0.17</td>
<td>11.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Daha (Burning sensation)</td>
<td>2.50</td>
<td>1.00</td>
<td>1.50</td>
<td>0.29</td>
<td>7.20</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kanda (Itching)</td>
<td>2.33</td>
<td>0.67</td>
<td>1.67</td>
<td>0.32</td>
<td>8.18</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Strava (Discharge)</td>
<td>2.50</td>
<td>0.75</td>
<td>1.33</td>
<td>0.33</td>
<td>7.13</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gandha (Odour)</td>
<td>2.40</td>
<td>0.80</td>
<td>1.60</td>
<td>0.24</td>
<td>6.53</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Table 2: Statistical analysis on objective parameters:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean Score</th>
<th>MD</th>
<th>±SD</th>
<th>±SE</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size and Shape:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>4.56</td>
<td>0.68</td>
<td>3.76</td>
<td>0.45</td>
<td>13.32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Breadth</td>
<td>3.07</td>
<td>0.24</td>
<td>2.82</td>
<td>0.31</td>
<td>13.86</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hight</td>
<td>0.94</td>
<td>0.08</td>
<td>0.86</td>
<td>0.13</td>
<td>9.09</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tenderness</td>
<td>2.80</td>
<td>1.00</td>
<td>1.80</td>
<td>0.55</td>
<td>7.31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Colour</td>
<td>2.60</td>
<td>0.40</td>
<td>2.20</td>
<td>0.20</td>
<td>11.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Granulation tissue</td>
<td>2.17</td>
<td>0.33</td>
<td>1.83</td>
<td>0.31</td>
<td>8.42</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Inflammation</td>
<td>2.20</td>
<td>0.60</td>
<td>1.60</td>
<td>0.40</td>
<td>10.19</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
DISCUSSION

Wound healing is a complex and dynamic process of replacing devitalized and missing cellular structures and tissue layers. In human wound healing process can be divided into 4 distinct phases. These are inflammatory, proliferation, remodelling and haemostasis phase. Ropana (healing) is always associated with Shodhana (Cleaning) because a wound cannot be healed if it is not shuddha (Clean). Taila application is one which could be adopted when vranas have raised granulation, little unctuous and discharge.

HaridradiTaila contains Haridra, Manjistha, Nimbapatra, Yastimadhu, Neelkamal & Sesame oil (Sesamumindicum). All the mentioned drugs in HaridradiTaila possessed Vranashodhana and Vranaropana property. These all drugs have Katu, Tikta, Kashayarasa. They absorbed kleda from Dushitavrana and restored Vranashodhana property. Probable mode of action of contents of HaridradiTaila on Dushtavrana as is follows, Haridra has analgesic and anti-inflammatory property locally, it used in contused wound and chronic ulcer. It has wound cleaning and wound healing property. Manjistha has wound healing property; it soothes, reduces the pain and heals the wound. Nimbapatra has anti-bacterial and antifungal activity also it act as a krimighna. Yastimadhu has Madhurrasa and it helps to contract the wound size by promoting fibrosis and epithelialization. Vatahara due to Snigdha and Guruguna, Shothahara and Dahashamana (anti-inflammatory) effects was observed due to Sheetaguna and Kasha- yarasa which helped to reduce the inflammation and thus relieved the pain and tenderness. Neelkamal has kashaya rasa which help to keep wound clean and formation of granulation tissue.

The dressing of HaridradiTaila provides moist environment that enhance epithelialization prevent scab formation and can be easily remove from wound surface without causing pain or damage to the new growing tissue.

The wounded person should not sleep during day, should remain inside a house devoid of breeze and under the control of the physician gets cured of the wound quickly. Swelling of the wound occurs due to exertion, redness due to keeping awake a night; these two and also pain occur due to sleeping at day time and death due to copulation. The wounded man who adheres to this regimen obtains happiness (health) and long life.

CONCLUSION

Trial drug HaridradiTaila found efficacious in wound healing. The taila removes slough and necrotic tissue and its act for smooth healing of Dushtavrana (chronic ulcer). Local application of HaridradiTaila has analgesic effect, reduces pain, burning sensation and itching, also reduce discharge. The clinical study on efficacy of HaridradiTaila in the management of Dushtavrana (Chronic ulcer) has significant remarkable result with Vranashodhana and Vranaropana properties without any adverse effect.

REFERENCES
Figures: Before and after treatment of *HaridradhiTaila*

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