

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 *Haridraditaila* is selected for chronic ulcer management. The trial drug '*HaridradiTaila*' i.e. medicated oil consisted of *Haridra* (*Curcuma longa*), *Manjistha* (*Rubiacordifolia*), *Nimbapatra* (*Azadirachta indica*), *Yastimadhu* (*Glycyrrhizaglabra*), *Neelkamal* (*Nelumbonucifera*) & Sesame oil (*Sesamum indicum*). 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 *Haridraditaila* 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 *Haridraditaila* possess sufficient efficacy in wound healing without producing any deleterious effects.

Keywords: *DushtaVrana*, Chronic Ulcer, *Haridraditaila*, 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.¹

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.²

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.³ For the management of *dushtavrana* (chronic ulcer), *Sushruta* incorporated number of drugs broadly classified into *vrnashodhana* and *vrnaropana*. The process of *shodhana* and *ropana* have been therapeutically grouped under seven heading i.e. *kashaya*, *varti*, *kalka*, *sarpi*, *taila*, *rasakriya* and *avachurna*.⁴

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* (*Rubiaccordifolia*), *Nimbapatra* (*Azadirachtaindica*), *Yastimadhu* (*Glycyrrhizaglabra*), *Neelkamal* (*Nelumbonucifera*) have been selected from text book of *dravyaguna*.⁵ These drugs were processed in Sesame oil (*Sesamumindicum*) and prepared in the form of *taila*.⁶ 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 H₂O₂(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 1months.

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

- 2- Less granulation tissue
- 3- No evidence of 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:

Parameters	Mean Score		M.D.	±SD	±SE	T	P
	BT	AT					
Shoola (Pain)	2.67	0.83	1.83	0.41	0.17	11.00	<0.001
Daha (Burning sensation)	2.50	1.00	1.50	0.58	0.29	7.20	<0.001
Kandu (Itching)	2.33	0.67	1.67	0.56	0.32	8.18	<0.001
Strava (Discharge)	2.50	0.75	1.33	0.58	0.33	7.13	<0.001
Gandha (Odour)	2.40	0.80	1.60	0.55	0.24	6.53	<0.001

Table 2: Statistical analysis on objective parameters:

Parameters	Mean Score		MD	±SD	±SE	t	P
	BT	AT					
Size and Shape:							
Length	4.56	0.68	3.76	1.56	0.45	13.32	<0.001
Breadth	3.07	0.24	2.82	1.08	0.31	13.86	<0.001
Hight	0.94	0.08	0.86	0.50	0.13	9.09	<0.001
Tenderness	2.80	1.00	1.80	1.22	0.55	7.31	<0.001
Colour	2.60	0.40	2.20	0.45	0.20	11.00	<0.001
Granulation tissue	2.17	0.33	1.83	0.75	0.31	8.42	<0.001
Inflammation	2.20	0.60	1.60	0.89	0.40	10.19	<0.001

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.⁷ *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 (*Sesamum indicum*). 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* is as 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.⁸ *Manjistha* has wound healing property; it soothes, reduces the pain and heals the wound.⁹ *Nimbapatra* has anti-bacterial and antifungal activity also it act as a *krimighna*.¹⁰ *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 *Kashayarasa* which helped to reduce the inflammation and thus relieved the pain and tenderness.¹¹ *Neelkamal* has *kashaya* rasa which help

to keep wound clean and formation of granulation tissue.¹²

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.¹³

CONCLUSION

Trial drug *HaridradiTaila* found efficacious in wound healing. The *taila* removes slough and necrotic tissue and its act for smooth healing of *Dhustavrana* (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.

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Figures: Before and after treatment of *HaridradiTaila*

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