

Comparative study to evaluate the wound healing property of *Khanduchakka ghrita* (*Ehertia laevis* Roxb.) in the management of *Dushtavrana*: A study Protocol

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Abstract

Background: The healing of wound or an ulcer is the natural response of the body. Naturally wound will heal in one week if there is no secondary infection. The *vrana* (Wound) lasting for more than a week and which fails to heal for a long period, resulting into chronic wound is called *dushta vrana*, *Ghruta* application is the best line of management for *dushtavrana* as told by *Sushruta* in 60 *upakramas* for the treatment of *vrana*.

Aims and Objectives: The present work is further step in the field of *Shalyatantra* entitled “Comparative study of *Jati* (*Jasminum Grandiflorum* L.) *ghrita* and Traditional *Khanduchakka* (*Ehertia laevis* Roxb.) *ghrita* on *Dushtavrana*” with following aims and objectives.

- Assessment of efficacy of *Khanduchakka ghrita* (*Ehertia laevis* Roxb.) and *Jati ghrita* (*Jasminum grandiflorum* L.) in management of *Dushtavrana*.
- To evaluate the effective measures for management of *Dushtavrana*.
- To compare the duration period for *Ropana* (healing) of *Khanduchakka ghrita* with *Jati ghrita* on *Dushtavrana*.

Methodology: Thirty patients of *Dushtavrana* are divided into two groups Group- A & Group- B each having fifteen patients irrespective of age, and gender. *Khanduchakka ghrita* as group-A and *Jatighrita* as group-B.

Conclusions: Conclusions will be pointed out after data analysis.

Keywords: *Ehertia laevis* Roxb, *Jasminum grandiflorum* L, *Dushtavrana*

1. Introduction

The perfect health is one of the prime goals of man who is superior among the most of all species. All the researches have been directed by the eminent scholars to achieve the same, from Vedic era up to this modern era. *Ayurveda* the indigenous system of medicine is an integral part of Indian culture. The management of chronic wounds is still a challenge for the clinician. *Acharya Sushruta* was also responsive towards the importance of wound management and has described *Shashthi Upakramas* (sixty measures) for *Vrana Ropana* (wound healing) ^[1]

The ancient *Acharyas* from centuries had used polyherbal and herbo-mineral formulations for prevention and treatment of various ailments ^[2]. It deals with conservation of health rather than treatment. Only the absence of illness is not defined as health. Today it is defined as comprehensive state of well-being which refers to physical, mental, spiritual and social well-being of an individual (W.H.O.’s definition of health), which is very similar to definition of *Swastha* (healthy person given by *Acharya Sushruta*).

Shalya Tantra is one of the important branch of *Ayurveda* in which surgical and para surgical techniques are described for management of various diseases. *Vrana* is one of them which have been managed by human being from starting of civilization. Under the circumstances the first thing which the man came across was the injury from different sources which caused him the *Vrana* (wound). *Vrana* is seen as

debilitating and scaring disorder usually seen affecting the human being irrespective of age. *Vrana* is the most important and widely described chapter of *Shalya Tantra*. According to *Acharya Sushruta* among the 60 measures of wound treatment local application of medicine is a measure indicated for non-healing wounds located in muscle and having slough. The herbal medicine performs both functions of “*Shodhana*” (cleaning) and “*Ropana*” (healing) in *Dushta Vrana* ^[3]

The prevalence of wounds in the Indian population studied (n = 6917) was 15.03 per 1000. The prevalence of acute and chronic wounds was 10.55 and 4.48 per 1000 of the population respectively ^[4]. Chronic wound prevalence has been estimated to be between 0.18% and 1.3% in the adult population ^[5]. Prevalence of foot infection is higher among rural than urban patients, Amputation rates are also higher among rural than urban patients. Recurrence of foot infection is higher among rural than urban patients. Surgical intervention is also more frequent among rural than urban patients ^[6].

Ehertia laevis (*Khanduchakka*) is a medicinal plant mainly used for wound healing, joint pain and minor fractures by local people of Wardha district of Maharashtra which shows potential result. *Thakre Rushikesh et al.* (2016) studied on ethano botanical properties of an unexplored plant *khandu chakka* (*Ehertia laevis* roxb.), used for wound healing. Therefore, in this present research study *Ehertia laevis* roxb

ghrita is projected to evaluate the efficacy of *khandu chakka* (*Ehretia laevis roxb*) *ghrita* in *dushtavrana*.

2. Purpose of Study

In ancient *Ayurvedic* literature different *Acharyas* have explained many herbal preparations which act as *Vranaropana* [7]. In India, many indigenous drugs have been mentioned in our old precious literature to heal the wounds. A vast scope of research exists in the field of *Ayurveda* for the benefit of the science as well as humanity at large. It is true that many scientists & medicine experts are working on various preparations which may help in achieving wound healing. There are so many compound drugs given in our texts which are needed to be evaluated and re-established with scientific manner.

In a country like India, where maximum of the population resides in rural areas under poor hygienic and undernutritional conditions, so the incidence of wound infection and delayed wound healing is more. Often due to their poverty and unhygienic living conditions even simple wounds get infected to cause a great sufferance to them. Therefore, the present study is planned to evaluate the effect of *Khanduchakka ghrita* application in *Dushtavrana* in comparison to *Jati ghrita* application.

3. Aims and Objectives

The present work is further step in the field of *Shalyatantra* entitled "Comparative study of *Jati* (*Jasminum Grandiflorum* L.) *ghrita* and Traditional *Khanduchakka* (*Ehertia laevis* Roxb.) *ghrita* on *Dushtavrana*" with following aims and objectives.

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- To evaluate the effective measures for management of *Dushtavrana*.
- To compare the duration period for *Ropana* (healing) of *Khanduchakka ghrita* with *Jati ghrita* in *Dushtavrana*.

4. Research Question: Whether local application of *Khanduchakka ghrita* (*Ehertia laevis* Roxb.) is more effective than *Jati-ghrit* (*Jasminum Grandiflorum* L.) in *Dushtavrana*?

5. Hypothesis: Local application of *Khanduchakka ghrita* (*Ehertia laevis* Roxb.) is effective in the management of *Dushtavrana*

6. Null Hypothesis: Local application of *Khanduchakka ghrita* (*Ehertia laevis* Roxb.) is less effective than *Jati-ghrit* (*Jasminum Grandiflorum* L.) In *Dushtavrana*

7. Study Type: Randomized comparative clinical trial

8. Material and methods

▪ Methodology

The study was initiated after seeking approval from institutional ethical committee

Study at a glance

- **Place of study:** Mahatma Gandhi Ayurved College, Hospital & Research Center. Salod (H), Wardha, MS
- **Duration of study:** - 30 days.
- **Sample size:** - 30 patients

▪ Grouping

30 patients of *Dushtavrana* are equally divided into two groups. Group- A and Group- B irrespective of age, and gender. *Khanduchakka ghrita* as group- A and *Jatighrita* as group- B.

9. Dignostic criteria

Diagnosis was made on the basis of *lakshanas* (symptoms) of *Dushtavrana* (infected wound) like

- *Deerghakaleena* (Long duration)
- *Pootipuya* (Pus discharge)
- *Ateevavedana* (Pain)
- *Daha* (Burning)
- *Kandu* (Itching)
- *shopha* (Inflammation)
- *Shonitasrava* (Blood Discharge)

Patients of non-healing wound more than 7 days without any co-morbidity were selected from OPD & IPD irrespective of gender & age subjective with *Dushtavrana* on lower extremities only.

Patients fulfilling above criteria were selected and enrolled in the study upon their consent and based on inclusion and exclusion criteria.

10. Inclusion criteria

Chronic ulcers (more than 30days)

Diabetic patients with control measures.

Patients of all age group

11. Exclusion criteria

Patient suffering from major illness like

- Cirrhosis liver
- Ascites
- Renal failure
- Tuberculosis
- HIV/Hepatitis
- Malignant ulcers
- Bleeding disorders
- Varicose ulcers
- Arterial ulcers
- Leprosy ulcers
- Gonorrheal ulcers
- Syphilitic ulcers
- Burn ulcers
- Cellulites

At the beginning base line data was recorded which includes Random Blood Sugar and Complete Blood Count.

The wound was examined, recorded, measured and was cleaned in aseptic condition.

Khanduchakka ghrita and *Jati ghrita* in sufficient quantity was applied and the wound was closed properly.

12. Assessment criteria

Assessment of pain

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 the sleep.
3. Localized continuous feeling of pain, radiating & not relieved by rest.

Assessment of colour

0 – Normal pigmentation & of skin,

1. Slight red.
2. Reddish black.
3. Pale yellow/ Blackish / Bluish

Assessment of discharge

0 - No discharge / dry dressing,

1. Scanty occasional discharge & little wet dressing.
2. Often discharge & with blood on dressing
3. Profuse, continuous discharge which needs frequent dressing.

Assessment of granulation tissue

0 - Healthy granulation tissue,

1. Smooth, less & irregular granulation base covered with slight discharge.
2. Little healthier granulation tissue & discharge which needs dressing.
3. Rich unhealthy granulation tissue with profuse discharge, & needs frequent dressing.

Assessment of size:

0 - No discontinuity of skin/mucous membrane,

1. Within 1-4 cm (length x width)
2. Within 5-8 cm (length x width)
3. Within 9-12 cm (length x width)

Assessment criteria**Table 1**

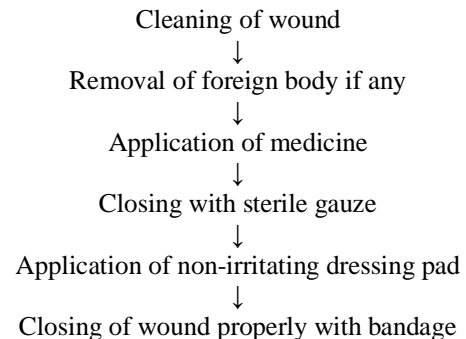
Sr.no.	parameter	Grading
1	Vedana (pain)	3
		2
		1
		0
		3
2	Varna (colour)	3
		2
		1
		0
		3
3	Srava (discharge)	3
		2
		1
		0
		3
4	Granulation tissue	3
		2
		1
		0
		3
5	Size of wound	3
		2
		1
		0

13. Method of Preparation of Khanduchakka and Jati Ghrita

Both the *ghruta* used in this research are prepared in government approved Ayurved pharmacy (Rasashala) as per standard method of preparation according to Ayurveda science.

For preparation of *Khanduchakka and Jati Ghrita*, 1 part of *Kalka Dravya* (paste of leaves) of *Khanduchakka and Jati*, 4 parts of cow ghee and 16 parts of *Drava* (liquid) are to be mixed together & heated by *Mandagani*. When foam disappears and *Ghrita* emerges colour, smell, taste of the

drug, free from water, not producing any crackling sound on fire, it is filtered and stored. *Agni* used for *Snehapak: Mridu* and *Madhyamagni* only. Vessel used for *Snehapak*: Copper or iron pan or earthen vessel is taken. Usually wide mouthed and less depth having tin coated, copper vessel is used.

Method of dressing of wound

The wound was opened next day and dressing was done with changes if any distinguished

This procedure will continue till the complete healing of wound.

14. Criteria for Discontinuing or Modifying Allocated Interventions

Subject will be pulled back from the study if any troublesome charge, highlights of medication affectability or some other difficulty or issue emerges, the subject will be offered free treatment till the issue dies down.

15. Methods

Literature review search, plan of work, blue print in the form of flow chart, raw materials collection, preparation of medicine, data collection, treatment and its effect will be observed and statistically analyzed.

Data Collections Methods: Randomized sampling

Data Management: The data coding will be done by principle investigator

Statistical Analysis: Data will be analyzed on the basis of appropriate statistics unpaired t-test and ANOVA by using SPSS software.

Consent or Assent: Patient will be given detail information regarding intervention in his own language. Then written consent will be taken from patients before starting the study. During study the confidentiality of each patient will be maintained.

Dissemination Policy: The data will be disseminated in the form of paper publication and Monograph. Authorship eligibility guidelines and any intended use of professional writers.

Informed consent material- patient will be given all consent material in the form of hard copy, and other related documents.

Strengths: *Ehertia laevis* will be very effective on wound healing. If proposed study results in positive outcomes then it will be established as new approach in the management of wound.

Limitation: Specific geographical area, convincing the patients for research.

Primary Outcomes

In this research work we will scrutinize the impact of *Ehertia laevis* and *Jasminum Grandiflorum* on wound healing; Information will be communicated as ordinary mistake of mean at 5 % level of distinction. It is hypothesized that *Ehertia laevis* will be more effective and will compare with *Jasminum Grandiflorum*

Secondary Outcomes

We will distinguish the effect of *Ehertia laevis* on all standard parameters of wound assessment.

16. Discussion

Ehertia laevis plant is effective in wound healing irrespective of infected and non-infected wound status. The microbiological study done on *Ehertia laevis* confirmed the antimicrobial potentials of the plant, supporting its folklore application as a preventive remedy for various microbial diseases^[8]

According to pharmacology *Jasminum Grandiflorum* mainly contains tannins which have the capacity to combine with tissue protein and precipitate them Salicylic acid present in *Jasminum Grandiflorum* is antibacterial, antifungal, antiviral, and anti-inflammatory properties^[9] reviewed study for discussion.

17. Conclusion

Conclusion will be drawn from the calculated and analyzed data.

18. References

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