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# Efficacy of *Dhataki ghrīt* Tulle in Comparison with Framycetine Sulphate Tulle in Management of *Dusta Vrana*

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## Abstract

**Background:** Since life, humans have been susceptible to injury caused by wound healing deficiency. Modalities are needed to treat wounds from very early developmental stages. Ayurveda has various treatment modalities mentioned in texts for treatment of *vrana*. Modalities have been described in the form of local application, oral medication as per the stages and *sadhyasadyata* of disease. Local use of *ghrita* with herbal formation is best practice for acharyas from ancient times until now. **Aims and Objectives:** Efficacy of *Dhataki ghrīt* tulle in the management of *Dusta vrana* in comparison with Framycetine sulphate tulle. And to study the effect of *dhataki ghrīt*, plain *ghrita* and framycitene sulphate on *dusta vrana*. **Methodology:** in this study total 210 patient will be divided randomly into 3 groups (70 each).

In group A ( Experimental) *Dhataki Grita* tulle will be applied on wound locally in group B(Control) Plain *Go ghrita* will be applied and in group C(control) Framycetine sulphate tulle will be applied . Assessment will be recorded as per criteria. **Results:** Changes will be observed in objective outcomes. **Conclusion:** *Dhataki ghrīt* tulle may be the best and cheap modality used as dressing material. Will be drawn as per suitable data.

**Keywords:** *Dhataki*, *Wound*, *Vrana*, *Wound healing*, *Framycitene sulphate*, *Sofratulles*

## Background

Wound healing plays an significant role in Ayurvedic literature. The earliest medical literature mention wound care thoroughly, wound treatment is undoubtedly the first medical issue faced by humans. In reality, the nonhealing existence of ulcer often times poses a challenge. *Vrana* healing is a natural process but it becomes *dusta* and normal healing process delayed due to interference of vitiated doshas . Chronic wound is long standing ailment with profuse discharge and slough where more importance should be given in removing the debris and enabling the proliferation of healthy tissue. The prevalence of wounds in the surveyed population (n=6917) was 15.03 for every 1000. The prevalence of acute and chronic wounds in the population was 10.55 and 4.48 per 1000, respectively. The lower extremity

was the most common site for both acute and chronic wounds. Unlike Western studies, an untreated, acute, traumatic wound was the most common etiology for a chronic lower extremity wound. This in effect underlines the need for community-based wound-care teams in India<sup>[1]</sup>

*Acharya sushruta* mentioned *Dusta vrana* in its definition of *shalya tantra* with other significant factors<sup>[2]</sup>. He further defines 60 therapeutic steps known as *shasti-upakrama* for the management of *vrana*<sup>[3]</sup>.

For the *Shodhan* and *Ropana* seven *kriyakalpas* are mentioned that are *kashaya*, *varti*, *avachurnana*, *taila* and *sarpi*. Mode of *kriyakalpas* is according to the combination of drugs used. Among these *Sarpi* is the one in which *ghrita* is used along with different *kalpas*

and different ways<sup>[4]</sup>. *Dhataki (Woodfordia fruticosa)* plays important role in *vranaropana*<sup>[5]</sup>.

Debridement consists of three surgical, chemical, and mechanical forms. Removing dosha from dead and vitiated by surgical means damages healthy tissue. For chemical debridement various chemicals like povidone ointment, eosol, hydrogen peroxide, Framycetine sulphate etc in the form of ointment, liquids and tulle are being used. Povidone ointment should not be used in case of sensitive participants. Flushing or hydrotherapy is used in mechanical debridement since chemical materials used for dressing have their own setbacks in this study. *Dhataki ghrīt* will be used in the form of tulle.

**Rationale of the study-** Sofra tulle (Framycetine sulphate) has been used from several years which is tropical antibiotic. Framycetine sulphate is very useful for wound healing but cost of one tulle is very high as for dressing of any type of wound there is need of many tulle for daily dressing, hence it cost high to patient. Similarly overuse of any antibiotic can cause resistant to specific bacteria or specific component. The main purpose of this study is to improve the care of the participants and to reduce the costs associated with *Dusta vrana* (chronic non-healing ulcers) also by using this study we can reduce the use of antibiotics.

*Dhataki* due to its *vranaropak* activity heals *vrana* by reducing pain, itching and discharge<sup>[5]</sup>. *Dhataki* is available freely hence it is economically viable and it become easy to prepare with *Goghrit* which is also easily available. This research is therefore being suggested to evaluate the efficacy of *Dhataki ghrīt* tulle as comparison to Framycetine sulphate.

### Aim and Objectives

**Aim:** Efficacy of *Dhataki ghrīt* tulle in the management of *Dusta vrana* in comparison with Framycetine sulphate tulle.

#### Objectives:

- To study the effect of *Dhataki ghrīt* tulle on healing of *Dusta vrana*

- To study the effect of Framycetine sulphate tulle on healing of *Dusta vrana*

- To study the effect of Plain *Goghrit* tulle on healing of *Dusta vrana*

- To compare effect of *Dhataki ghrīt* tulle, Framycetine sulphate tulle and plain *Goghrit* tulle on healing of *Dusta vrana*.

### Case definition

#### *Dusta Vrana-*

Participants of *vrana* on extremities with following Clinical features:-

*Samruta* (Narrow mounted), *Kathina* (Hard),

*Avasanna-* depressed, *Vedonarvn-* (severe pain),

*Vivrutta* (Wide mounted), *Ushna* (Hot),

*Daha* (burning sensation at the site), *Paka* (suppuration),

*Raga* (Redness), *Puyastrava* (Discharging pus), *Manojnadarshana* (with ugly site),

*Kandu* (Itching), *shopha* (swelling), *Pidaka* (with boils), *Mrudu* (soft),

*Bhairava* (Frightful), *Putimamsasirasnayu* (full of pus muscles, vessels, ligaments)<sup>[6]</sup>

*Dusta Vrana* (Chronic non healing wound) which is difficult to heal. *Dusta* is one in which there is localization of *doshas vata pitta* and *kapha*. *Vrana* which has a bad smell, has abnormal color with profuse discharge, intense pain and it takes long period to heal.<sup>[7]</sup>

### Research Question:

Is *Dhataki ghrīt* tulle effective as that of Framycetine sulfate tulle in management of *Dusta vrana*. **Hypothesis:**

*Dhataki ghrīt* tulle may be effective in management of *dustavrana* than Framycetine sulphate tulle due to its *vranaropak* activity.

### Null Hypothesis:

*Dhataki ghrī* tulle may not be effective than Framycetine sulphate tulle in management of *Dustavrana*.

**Trial design:** Randomized Standard controlled Study called Double Arm Open. Interventional study with ratio of 1:1:1 on 3 parallel group. This is an experimental analysis.

### Methodology

**Study setting :** The study will be conducted in academic hospital MGACH & RC, Salod (H), Wardha.

### Inclusion criteria

- Participants will be selected irrespective of sex, age, religion, occupation, economic and educational status.
- Participants between the age group of 18-55 years will be selected.
- Participants of *vranā* presenting with minimum 4 signs and symptoms of *Dusta vranā* which are mentioned in case definition and willing to participate in study will be recruited.

### Exclusion criteria

1. Participant with
  - Known case of Malignancy,
  - Known case of Tuberculosis ,
  - Known case of Leprosy and
  - HIV and HbSAg positive will be excluded from this study

### Criteria for discontinuing or modifying allocated interventions:

The subject will be withdrawn from the study if any incidence, drug sensitivity characteristics or any other disease or problem arises the subject will be offered free treatment until the problem subsides.

**Follow up:** 0 and 30<sup>th</sup> day

**Primary outcomes** – we will see the effect of interventional drug on the basis of assessment criteria on pain, itching, discharge. The data will be expressed as a standard error of 5 % significance, it is hypothesized that Dhataki pushpa tulle in the form of dressing material would be more effective in wound healing.

**Secondary Outcome** – we will see the changes of wound within its bacteriological phenomenon . It is hypothesized that dhataki pushpa tulle will be also effective in controlling bacteriological growth.

### Discussion

Many research studies regarding *Dusta vranā* ( Chronic wound healing ) are carried out in modern medicine as well as in *Ayurveda*.

Modern drugs and dressing materials used in management of chronic wound are very limited and preparations like sofratulle are much costly for general population also there are many setbacks with the overuse of tropical antibiotics and antimicrobial drugs<sup>[8,9]</sup>, hence there is need of study to prove efficacy and safety in management of *Dusta vranā*(Chronic Non healing Ulcer). So, this study is being undertaken to prove the effectiveness of Dhataki ghrī tulle in *Dusta vranā* management compared to Framycetine Sphate tulle.

Dhataki cures *vranā* because of its *vranaropak* activity by reducing pain, itching and discharge. Dhataki is freely available, which makes it economically viable and easy to prepare with easily available Goghrit.

### Analysis plan (Statistical test):

The statistical analysis will be carried out using descriptive and inferential statistics using Chi square test, Dunnett D test, One way ANOVA and the software used in the study will be SPSS 22.0 and Graphpad prism 7.0 and EPI-INFO 7.0 edition.

**Intervention period:** 30 days

**Follow up period on–** 60 day

**Time schedule of enrolment, Intervention period:** 30 days

**Recruitment:** 210 Participants (70 in each group) will be selected using simple random sampling Lottery process, and PI will assign and enroll the patient.

**Methods:** Data collection, enrolment then management, and analysis

**Data collection methods:**

Assesement criteria

Objective parameters-

**Size** (Blotting paper Technique) **Bacteriological test** (Conventional Method)

**Data management:** The data entry coding will be done by PI

**Statistical methods:** Paired and Unpaired ‘t’ Check objective criteria.

**Ethics and dissemination:**

**Research ethics approval;** approval from research ethics committee has taken. No-Ref.No.DMIMS (DU)/ IEC/2018-19/7598

**Consent or assent:** The written consent will be taken from the participant prior to start the study.

The confidentiality of the individual participants will be protected throughout the study.

**Dissemination policy:** The data will be disseminated on paper.

Eligibility requirements for authorship and any planned use by qualified authors

**Informed consent materials:** With all the information model, the participants will be given consent form and other relevant documentation.

**Strengths:** If Dhataki Improves wound healing it will be a very effective and versatile dressing device. Unless the proposed study results in a positive outcome then the best parallel modality for wound management will be given.

**Limitations:** Single drug therapy is used to determine the efficacy of dhataki ghril tulle in Dustavrana (Chronic Non Healing Wounds) treatment. Additional drugs may be added for better outcomes and combined formulation may be prepared.

**Gantt chart (in Quarterly based)**

Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Enrollment of Volunteer								
Data collection								
Writing the thesis parts up to methods								
Data analysis								
Writing the thesis parts up to results and Conclusions								
Submission								

### Conclusion

Conclusion is drawn by careful examination of the results.

**Conflict of Interest:** None

**Funding:** None

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