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Research Protocol

Ayurveda Section

Efficacy of *Thumari* (*Securinega leucopyrus*) Ointment and Betadine Ointment in Managing *Shastrakruta Vrana*: A Randomised Controlled Trial Research Protocol

DEVESH HETRAM NAGPURE[1], SHEETAL GAJANAN ASUTKAR[2]

ABSTRACT

Introduction: Acharya Sushruta highlighted the enduring significance of wounds in surgery, addressing various types caused by trauma and imbalances in *Vata, Pitta*, and *Kapha* (the fundamental energies governing physiological and psychological functions). *Thumari*, or *Katupila* (*Securinega leucopyrus*), a traditional remedy from India and Sri Lanka, is renowned for its exceptional wound-healing properties, including purification, healing, and skin restoration.

Need of the study: Surgical site infections are a significant concern in India (23-38% incidence), and Betadine ointment's potential side effects (skin irritation, redness, itching) underscore the need for improved wound healing options. *Thumari*-based products (gel, oil, *kalka*) have demonstrated effective wound healing, anti-inflammatory, analgesic, antibacterial, and antifungal properties, attributed to their tannin and flavonoid content. While small-scale studies show positive results, larger comparative trials are needed to confirm *Thumari's* efficacy.

Aim: To evaluate the comparative efficacy of *Thumari* ointment and Betadine ointment in managing *Shastrakruta Vrana* (surgical wounds).

Materials and Methods: This randomised controlled trial (CTRI/2023/02/049990) will be conducted at Mahatma Gandhi Ayurveda College, Hospital and Research Centre (MGACHRC), Salod Hirapur, Maharashtra, India (March 2023-October 2024). Seventy patients (aged 18-60 years) will receive either Betadine or *Thumari* ointment for local application on their surgical wounds. Assessment parameters include pain, tenderness, colour, margin, discharge, inflammation, and healing time. Data analysis will use Mann-Whitney U test, Chi-square test, and Independent t-test (SPSS 27.0; $p<0.05$ for significance).

Keywords: *Katupila*, Ointment, Surgical wound infection, Sushruta, Wound healing

INTRODUCTION

Acharya Sushruta emphasised the lasting impact of wounds (Vrana), even after complete healing [1]. His detailed wound management (*Shashti Upakrama*) highlights its surgical significance [2].

Ayurveda attributes wound types to Vata, Pitta, Kapha imbalances or external trauma (cut, perforated, punctured, lacerated, contusion, abrasion wounds) [3].

Wounds disrupt skin/tissue integrity, causing structural and functional damage (physical, chemical, thermal, microbial, or immunological factors) [4]. The Rank and Wakefield system provides a comprehensive wound classification framework [4], considering nature, depth, structural involvement, and duration. Operative wounds are categorised by infection risk (clean <2%, clean-contaminated ~10%, contaminated 15-30%, dirty-infected 40-70%) [5].

Betadine (povidone-iodine) is widely used due to its broad-spectrum antimicrobial properties [6], preventing and managing wound infections. However, its cytotoxicity and potential to impair wound healing by damaging fibroblasts and keratinocytes are debated [7].

Thumari (Katupila in Sri Lanka) is a traditional remedy from the Saurashtra region, possessing purification, healing, and skin restoration properties [8,9]. *Raj Nighantu* and *Nighantu Ratnakar* describe its cooling (*Sheeta Gunatmaka*), analgesic (*Vedanashamak*) properties in dysuria and urinary retention [10]. It is also known as *Patli, Pandurfali, Dhusara, Vruttabijaka, Bhurifali*, and *Pandufali* [10]. This study aims to compare the efficacy of *Thumari* and Betadine ointments in managing *Shastrakruta Vrana* (surgical wounds).

Primary Objectives:

1. To study *Thumari* ointment's efficacy in managing *Shastrakruta Vrana*.
2. To study Betadine ointment's efficacy in managing *Shastrakruta Vrana*.

Secondary Objectives:

1. To compare the efficacy of *Thumari* and Betadine ointments in managing *Shastrakruta Vrana*.

Hypothesis:

Null hypothesis (H0): *Thumari* ointment is not as effective as Betadine ointment.

Alternative hypothesis (H1): *Thumari* ointment is more efficacious than Betadine ointment.

REVIEW OF LITERATURE

Ajmeer AS et al., showed *Katupila's* topical effectiveness in treating *Dushta Vrana* (chronic wounds) [11] and diabetic wounds [12,13], promoting wound healing and fine scarring. Studies on povidone-iodine highlight its role in accelerating wound healing through infection prevention and sterilisation [6,14].

MATERIALS AND METHODS

This study will be a randomised, standard-controlled superiority trial conducted at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha. The trial will be carried out from March 2023 to October 2024 with patients selected from the Shalya Tantra OPD and IPD. Informed consent will be obtained from all participants before their inclusion in the study. The trial will be registered with the Clinical Trials Registry-India (CTRI) under the number CTRI/2023/02/049990, and ethical clearance has been received from the Institutional Ethics Committee (IEC) with the approval number MGACHRC/IEC/July-2022/569.

This randomised, standard-controlled superiority trial will include 70 patient (35 in each group) patients aged 18 to 60 years with *Shastrakruta Vrana* (surgical wounds) who meet the inclusion criteria. Exclusion criteria include surgical malignancy, severely infected wounds, and unwillingness to participate.

Inclusion criteria:

1. Postoperative patients (18-60 years).
2. Patients with surgical wounds (irrespective of sex, religion, socio-economic class).
3. HIV-positive patients.
4. Tuberculosis-positive patients.
5. Controlled diabetes mellitus patients.
6. Post operative cases (hernia, hydrocele, lipoma, sebaceous cyst, dermoid cyst).
7. Patients providing written informed consent.

Exclusion criteria:

1. Cases involving surgical treatment of malignancies.
2. Severely infected wounds (extensive tissue damage, systemic infection signs, pus production, deep tissue involvement, gangrene, necrosis).
3. Unwillingness to participate.

Sample size calculation: To calculate the sample size for your study comparing *Thumari* Ointment and Betadine Ointment for surgical wound management, Considering proportion wound healing (normal) as the primary variable.

To calculate the sample size for a study comparing two groups, we use the following formula.

The proportions in this case are P1=71.6% and P2=96.6%.

Sample size formula for comparing two proportions (P1 and P2) is:

$$n=\{(Z\alpha/2+Z\beta)^2 * (P1\ (1-P1)+P2\ (1-P2))\}/(P1-P2)^2$$

Where:

- n=required sample size per group
- $Z\alpha/2$=Z-score corresponding to the desired significance level (e.g., 1.96 for 5% significance level)
- $Z\beta$=Z-score corresponding to the desired power (e.g., 0.84 for 80% power)
- P1=proportion in the Povidone-iodine group (71.6% or 0.716) as per the reference article [15].
- P2=proportion in the trial group (96.6% or 0.966) considering 30% superiority estimated

Using the values:

$Z\alpha/2=1.96$, $Z\beta=0.84$

P1=0.716, P2=0.966

$(1.96+0.84)^2 *(0.716*(1-0.716)+0.966*(1-0.966))/(0.716-0.966)^2$

Sample Size per group (n)=33 per group.

Considering 7 percent dropout=2

Total sample size required=33+2=35 per group.

Total sample size required for 2 groups (n)=70.

The parameters to be assessed will include wound pain, tenderness, colour, margin, and discharge.

Two groups, each with 35 patients, will receive different ointments for wound care. Group-A will apply Betadine ointment on 0, 3rd, 7th, 10th, and 14th day, and Group-B will use *Thumari* ointment during dressing changes on the 0, 3rd, 7th, 10th, and 14th day once daily, with approximately thickness of 1 to 5 mm of thickness over the surgical wound. The ointments will be applied in amounts sufficient to cover the wound area. The treatment duration for both groups is 14 days, with follow-up assessments on the 21st and 28th days.

Collection of betadine ointment: Betadine ointment contains povidone iodine. Its 5% formulation will be used and will be procured from MGACH and RC, pharmacy. Betadine ointment in India, primarily manufactured by Win-Medicare, contains povidone-iodine (5% to 10%) as its active ingredient, known for its broad-spectrum antimicrobial action effective against bacteria, fungi, viruses, and protozoa [16,17]. Available in tubes of varying sizes (such as 5 g, 10 g, and 20 g), it is intended for external use only to prevent infections in minor cuts, burns, and abrasions by gradually releasing iodine to reduce microbial activity [18]. The ointment is produced under Good Manufacturing Practices (GMP) as mandated by Indian regulatory standards, ensuring quality and efficacy [19,20]. It should be stored below 25°C with a typical shelf life of about two years under recommended storage conditions [20].

Preparation of Thumari ointment: *Thumari* was procured from Authentic seller from Gujarat and it was authenticated from *Dravyagun* Department of MGACH&RC, Salod, Hirapur, Wardha. *Thumari* ointment will be prepared in two steps. Firstly, *Thumari* oil will be prepared by guideline of *Sneha-Kalpana* given by Ayurvedic Formulary of India (AFI) [20]. *Thumari Kalka* (1 part), *Til-Taila* (4 part), *Thumari Kwath* (16 part) will be used *as Drava-Dravya* while preparing. *Thumari* Oil continuous heated and when *Siddhi Lakshan* of Sneha free from water, no cracking sound on fire, froth appearance, desired colour, odour of drug were observed then the *Thumari* Oil will be collected. Secondly, *Thumari* oil (6 part), stearic acid (1 part), Bee wax (1 part), White paraffin (1 part) and Cetostearyl alcohol (1 part) will be mixed thoroughly [21]. *Thumari* Ointment will be prepared in Rasa Shala of MGACH&RC under supervision of subject expert [Table/Fig-1].

[Table/Fig-1]: *Thumari* ointment.

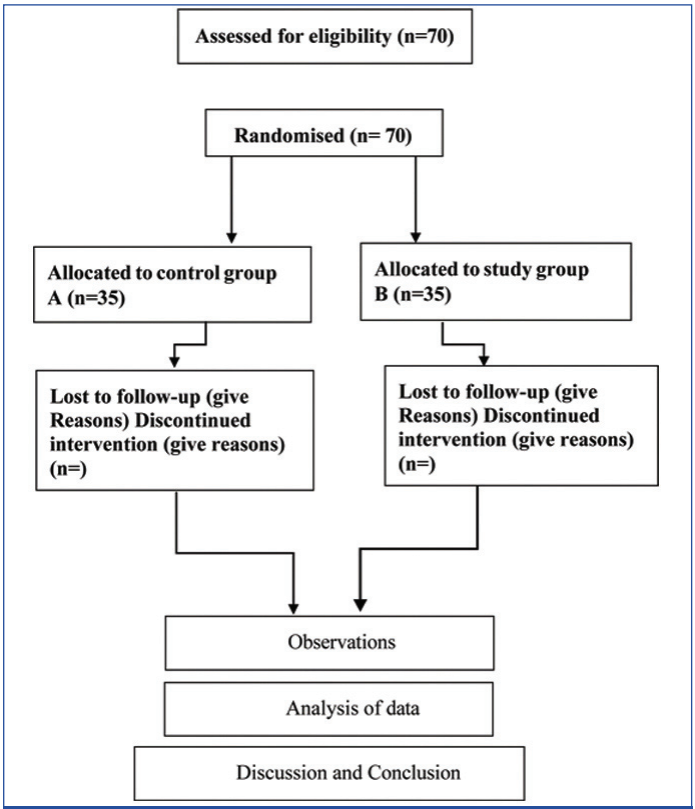
Allocation of the subjects and intervention in each group is explained in [Table/Fig-2].

The study procedure is explained in [Table/Fig-3].

Groups	Sample size	Intervention	Frequency	Dose	Duration	Follow-up
Group-A	35	Betadine ointment	Local application once while Dressing (0, 3rd, 7th, 10th and 14th day)	Quantity sufficient	14 days	21st and 28th day

Group-B	35	*Thumari* ointment	Local application once while Dressing (0, 3rd, 7th, 10th and 14th day)	Quantity sufficient	14 days	21st and 28th day

[Table/Fig-2]: Application of Betadine Ointment and *Thumari* Ointment: Patient will either apply Betadine ointment or *Thumari* ointment on the surgical wound locally.



[Table/Fig-3]: CONSORT flow diagram.

Assessment Criteria [22] [Table/Fig-4-9]:

The following are the criteria for subjectively evaluating pain, tenderness, colour, margin, and discharge of a condition:

Pain is graded on a scale of 0 to 3, where:

S. No.	Observation	Score
1	No pain.	0
2	Localised pain that occurs only during movement and not at rest.	1
3	Localised pain that persists at rest without radiating to other areas.	2
4	Continuous, radiating pain that is not alleviated by rest.	3

[Table/Fig-4]: Pain gradation.

Tenderness is evaluated using the same scale, where:

S. No.	Observation	Score
1	Tolerance to pressure.	0
2	Slight reaction to sudden pressure.	1
3	Wincing of the face upon superficial touch.	2
4	Resistance to touch accompanied by rigidity.	3

[Table/Fig-5]: Evaluation tenderness.

Colour is assessed on a scale from 0 to 3, with:

S. No.	Observation	Score
1	Normal pigmentation.	0
2	A slight red colour.	1
3	A reddish-black hue.	2
4	Pale yellow, blackish, or bluish discolouration.	3

[Table/Fig-6]: Assessment of colour.

The assessment of margins follows a similar scale:

S. No.	Observation	Score
1	Adhering margins.	0
2	Smooth, even, and regular margins.	1
3	Rough, regular, and inflamed margins.	2
4	Rough, irregular margins with an unattractive appearance.	3

[Table/Fig-7]: Assessment of margins.

Discharge is evaluated on a scale of 0 to 3, where:

S. No.	Observation	Score
1	No discharge with a dry dressing.	0
2	Scanty, occasional discharge with a slightly wet dressing.	1
3	Frequent discharge requiring daily dressing changes.	2
4	To profuse, continuous discharge needing frequent dressing changes.	3

[Table/Fig-8]: Evaluation of discharge.

Inflammation is evaluated on a scale of 0 to 3, where:

S. No.	Observation	Score
1	No inflammation.	0
2	Slight inflammation with a slight red colour.	1
3	More inflammation with a dark red colour.	2
4	High inflammation, with resistance to touch and a reddish, angry appearance.	3

[Table/Fig-9]: Evaluation of inflammation.

Criteria for discontinuing or modifying allocated interventions: If any adverse events, signs of drug hypersensitivity, or issues arise during the intervention, patients will be removed from the treatment and provided with free care until the wound has healed and any local symptoms have subsided.

STATISTICAL ANALYSIS

The study will employ several statistical tests to analyse the data. The Mann-Whitney U test will be used to compare the efficacy of Thumari and Betadine ointments on ordinal scales like pain, tenderness, colour, margin, and discharge, given the potential non-normal distribution of these variables. The Chi-square test will compare categorical outcomes, such as the presence or absence of side-effects between the two groups. Additionally, the Independent t-test will assess differences in continuous variables, such as overall wound healing time, between the groups. Statistical significance will be determined using p-values, with a threshold of 0.05 to identify significant differences. All analyses will be conducted using appropriate statistical software SPSS 27.0 version.

Outcomes:

Primary Outcomes:

1. **Pain relief:** The study will measure the reduction in pain associated with surgical wounds, using a standardised pain scale (0-3) as detailed in the assessment criteria.
2. **Reduction in tenderness:** The effectiveness of *Thumari* and Betadine ointments will be evaluated based on the reduction of tenderness in the wound area.
3. **Side-effects and adverse reactions:** Any side-effects or adverse reactions to *Thumari* and Betadine ointments, such as skin irritation, allergic reactions, or other unexpected symptoms, will be documented and analysed.

Secondary outcomes:

1. **Rate and quality of wound healing:** The study will assess the speed and overall quality of wound healing in patients using *Thumari* versus Betadine ointment. This will be determined by

evaluating factors such as wound colour, margin adherence, and the presence and amount of discharge.

2. **Comparison of efficacy between *Thumari* and Betadine ointments:** The study will compare the overall effectiveness of *Thumari* ointment to Betadine ointment in managing surgical wounds. This will include analysing differences in pain relief, tenderness reduction, wound healing rate, and any side-effects.
3. Patient satisfaction: Patient satisfaction with the treatment, including comfort and ease of use of the ointment, will be assessed and compared between the two groups.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Scholar, Department of Shalyatantra, Mahatma Gandhi Ayurvedic College, Hospital and Research Centre, Salod (H), Sawangi (Meghe), Wardha, Maharashtra, India.
2. Professor and Head, Department of Shalyatantra, Mahatma Gandhi Ayurvedic College, Hospital and Research Centre, Salod (H), Sawangi (Meghe), Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Devesh Hetram Nagpure,
Postgraduate Scholar, Department of Shalyatantra, Mahatma Gandhi Ayurvedic College, Hospital and Research Centre, Salod (H), Sawangi (Meghe), Wardha, Maharashtra, India.
E-mail: deveshbmw@gmail.com

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