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Research Article

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF *YASTIMADHU GHRITA* AND *TILA KALKA MADHU GHRITA* IN THE MANAGEMENT OF *SADHYO VRANA*

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ABSTRACT

Sadhyo Vrana (acute wounds) is a common clinical condition that requires prompt and effective management to promote faster healing and prevent complications. Ayurveda offers various formulations for wound healing, among which *Yastimadhu Ghrita* and *Tila Kalka Madhu Ghrita* are known for their *Vrana Ropana* (wound-healing) properties. **Objective:** This study aims to compare the efficacy of *Yastimadhu Ghrita* and *Tila Kalka Madhu Ghrita* in the management of *Sadhyo Vrana* based on clinical parameters such as pain, inflammation, wound contraction, and epithelialization time. **Methodology:** A randomized comparative clinical trial was conducted on patients presenting with *Sadhyo Vrana*. Participants were divided into two groups: Group A received *Yastimadhu Ghrita*, and Group B received *Tila Kalka Madhu Ghrita* as local applications. The progress of wound healing was assessed using standard parameters, including pain reduction, exudate control, granulation tissue formation, and complete wound closure. **Results:** Both formulations showed significant improvement in wound healing. *Yastimadhu Ghrita* was more effective in reducing pain and inflammation due to its *Shothahara* (anti-inflammatory) and *Vata-Pitta Shamaka* properties. *Tila Kalka Madhu Ghrita*, with its *Ropana* and *Vrana Shodhana* (wound cleansing) effects, demonstrated faster granulation tissue formation and wound contraction. **Conclusion:** Both *Yastimadhu Ghrita* and *Tila Kalka Madhu Ghrita* are effective in the management of *Sadhyo Vrana*. However, *Yastimadhu Ghrita* is preferable for pain and inflammation, while *Tila Kalka Madhu Ghrita* promotes faster wound healing. Further studies with larger sample sizes are recommended.

INTRODUCTION

Ayurved, the fountainhead of Indian medicine was conceived as a science and preached in this country some 3000 years ago, long before the other countries could not dream of systematizing the concept of remedies for human ailments. It is a universally accepted truth that the origin of human life and *Vrana*[1] have come up side by side simultaneously.

There is so much evidence that prehistoric man was familiar with Vrana[2] (Wound). The study of Ayurvedic classics reveals that the most common disease entity in surgery is only *Vrana*[3].

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Further in day-to-day routine and during wartime this clinical discontinuity of *Dhatu, Updhatu* including *Marma sthana* is observed maximum by practitioners.

A wound is defined as disrupting the integrity and function of tissues in the body. Wounds are described by many defining characteristics, including location, size (length, width, and depth), per wound descriptors (colour, integrity, temperature, and texture), colour, odor, moisture, drainage, and base material (e.g. granulation tissue, scar, slough, subcutaneous tissue, muscle, bone, and tendon)[4].

The overall treatment depends on the types, causes, and depth of the wound and whether other structures beyond the skin (dermis) are involved. Treatment of recent lacerations involves examining, cleaning, and closing the wound.

Usually requires no active treatment except keeping the area clean, initially with soap and water. Cleaning can be accomplished using several different

solutions, including tap water and sterile saline solution. Acharya Sushrut described the following characteristics of *Vrana*.[5]

- **तत्रायतो विशालः समः सुविभक्तो निराश्रय इति व्रणगुणाः ||सू.सू.५/८**
- *Aayat* (rectangular/ long)
- *Vishal* (expanded/huge)
- *Sam (*straight)
- *Suvibhakta* (cut of cleanly)
- *Niraashray* (destitute)

As the above-described characteristics of wound and *Vrana* are similar, the two can be correlated accordingly and described comparatively. Acharya Sushrut talked about various types of wounds due to wars and other reasons.

Wounds indeed represent a significant aspect of physical disabilities, as they involve a disturbed state of tissue caused by various factors such as physical trauma, chemical exposure, microbial infections, or immunological reactions. The Wound Healing Society defines wounds as physical injuries leading to an opening or break in the skin, disrupting the normal anatomy and function of the skin.

Wound healing is a dynamic process that involves the regeneration or repair of damaged tissue. Researchers have dedicated considerable efforts to developing improved healing agents to enhance the recovery process. The speed of wound healing is influenced by various factors, and one crucial aspect is the contraction that initiates a few days after the injury and continues for several weeks.

In addition to trauma, millions of surgical wounds are created annually during routine medical care in the United States and Europe [6]. Facilitating the healing of these unintended and deliberate injuries minimizing the aesthetic impact on the patient and maximal restoration of tissue function remains a central concern of clinical care. Although minor injuries in healthy individuals generally heal well, larger injuries or the presence of a variety of physiological or common disease states including age, infection, diabetes/vascular disease, and cancer can negatively affect the healing process in ways that are currently poorly understood.

Advances in this field contribute to better management of wounds, minimizing the impact of physical disabilities resulting from these injuries.

swelling, alleviate pain, remove damaged tissue, treat infections, mask unpleasant Odors, and promote healing.

AIMS AND OBJECTIVES

1. Contemporary and comprehensive study of the related problem.
2. To establish the efficacy of *Yashtimadhu Ghrita* and *Tila Kalka Madhu Ghrita* in the formation of wound beds for the management of wounds.

MATERIAL AND METHODS

A research study should always be well strategic so that a proper design is taken up well to avoid imprecision. The present study was carried out with the following approach.

Research Design

The study was planned as open clinical trial patients were chosen using a simple randomized sampling methodology clinical study to compare the efficacy of *Yashtimadhu Ghrita* versus *Tila Kalka Madhu Ghrita* in patients with *Sadhyo Vrana*.

Ethical Clearance

The topic of the study, together with the case proforma was submitted to the Institutional Ethical Committee of the university. The significance, aims and objectives, methodology, and probable outcome of the study were clarified to the committee and ethical clearance was obtained for the conduction of the study. The trial has been registered in CTRI with the reference CTRI/2023/08/056678.

Diagnostic criteria

Investigations

- CBC
- BT
- CT
- ESR
- Blood sugar-FBS -PPBS
- Pus Culture

Trial period: 60

Follow up period: 7 days

Plan of Clinical Study

- Consent with knowledge.
- Patients were registered using a research proforma created specifically for the study.
- During the treatment, patients were told to stay away from all other medications.
- Every 7th day, a clinical exam or assessment was scheduled.
- In the event of any other disease, patients were instructed to notify the P.G. scholar as soon as possible.

Selection Criteria of the Patient

Inclusion criteria

- The patient gave written informed consent.
- Age group 20 – 60 years.
- Patients with classical signs and symptoms of ulcer were included in the trial.

Exclusion criteria

- Patient suffering from any malignancy.
- Patient suffering from tuberculosis.
- Patient suffering from HIV & Hepatitis B.
- Patient suffering from any major systemic disorder- HTN, T2DM etc.

Method of The Study

It is an open clinical trial in which patients were chosen using a simple randomized sampling methodology after being clinically and A detailed history was taken from the informant and the patient, the thorough general and systemic examination was done as per the particular research proforma prepared for the study (added in annexure) incorporating all the specifics of the wound including both Ayurvedic and Modern parameters. The disease has been thoroughly studied conceptually, and the production of "*Yahtimadhu ghrita*" [7] and "*Tila kalka madhu ghrita*"[8] as well as dose and route of administration procedures, have been incorporated as per the texts.

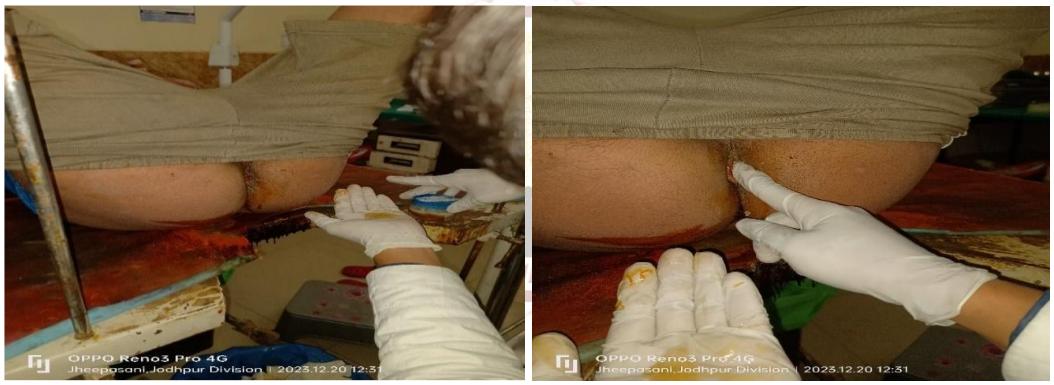
Method of preparation of *Yashtimadhu ghrita* and *Tila kalka madhu ghrita*

S.No	Name of drug	Botanical name	Part used	Properties of drugs	Quantity
1	*Yashtimadhu*	Glycyrrhiza glabra	Root	*Vedanasthapana, Shotha hara, Dahashamaka*	1
2	*Tila*	Sesamum indicum	Seed	*Vatahara, Tvacya, Balya, Keśya, Šukrala*	1

Preparation of the Formulation

Under the guidance of the Head of Pharmacy (University College of Ayurveda, Rasa Shastra and Bhaishajya Kalpana department, Jodhpur), raw drugs were collected and preparation of *Yashtimadhu ghrita* and *Tila kalka madhu ghrita* was done. Method of collection of data.

***Yastimadhu Ghrita* Use on Patient**



***Yashtimadhu ghrita* using on patient**

Figure 1: 0th day

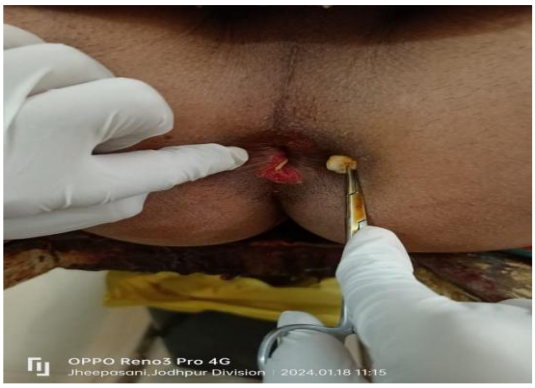


Figure 2: 1st day

Figure 3: After 7 days

Figure 4: After 14 days

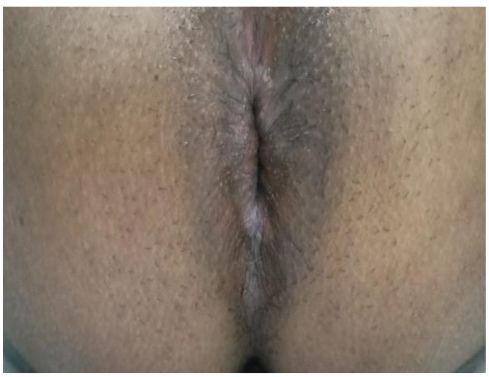


Figure 5: After 21 days

Tila Kalka Madhu

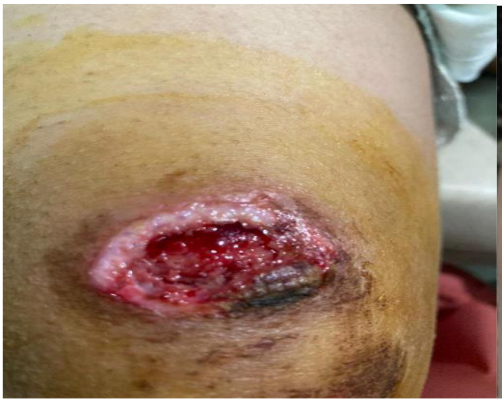


Figure 1: 0 days

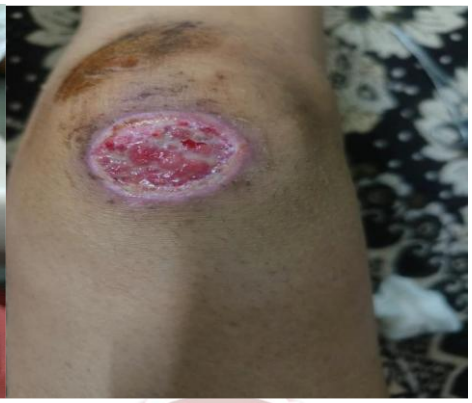


Figure 2: 1 days

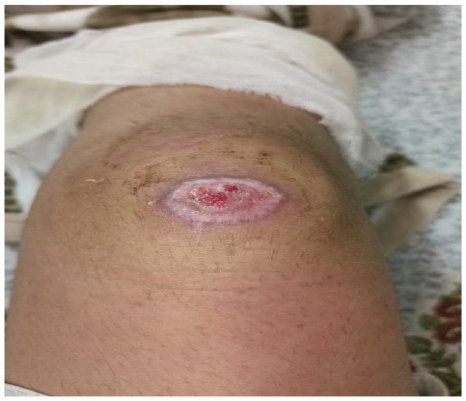


Figure 3: After 7 days

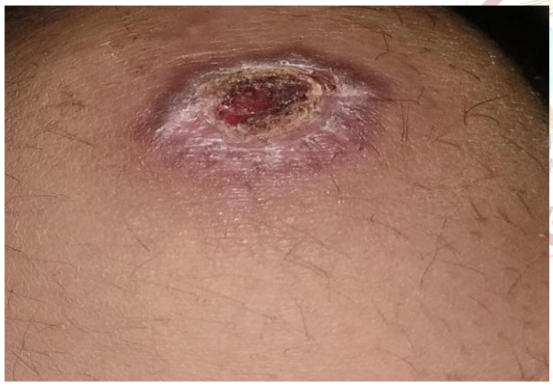


Figure 4: After 14 days

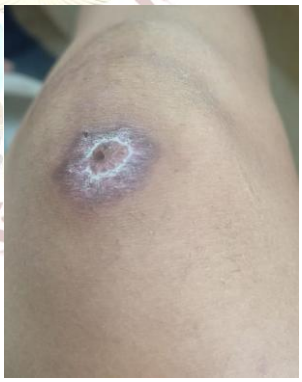
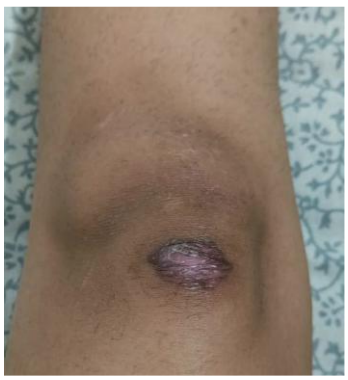


Figure 5: After 21 days



Figer 6: After 28 days

Assessment criteria

Subjective Parameters

- Redness
- Heat
- Pain
- Loss of function
- Swelling

Objective Parameters

- Tenderness
- Colour
- Site
- Discharge

Subjective Parameters

Gradation of wound

It is based on feeling pf patients. So researcher has to depend on his patient for assessment. It known as simple verbal scale. In this particular research work, subjective criteria are as follows.

Pain

Grade	Explanations
0	No pain
1-3	Mild pain
4-6	Moderate pain

7-8	Severe pain
9-10	Very severe/excruciating pain

Heat

Grade	Explanations
0	(No heat) normal temperature
1	(Mild warmth) slight temperature increase, localized
2	(Moderate warmth) easily noticeable, may spread over a larger area
3	(Severe warmth) hot to the touch, covers a larger or deeper area, often accompanied by redness and swelling

Redness

Grade	Explanations
0	(No Redness): Skin appears normal, with no visible erythema
1	(Mild Redness): Slight redness is visible, but it is faint and localized
2	(Moderate Redness): Redness is easily noticeable and more widespread; covers a larger area
3	(Severe Redness): Intense, deep redness, may extend over a large area, often associated with swelling

Loss of Function

Grade	Explanations
0	(No Loss of Function): No impairment; normal range of motion and function
1	(Mild Loss of Function): Slight difficulty with movement or function, but still able to perform daily tasks
2	(Moderate Loss of Function): Significant limitation in movement or function; impacts daily activities
3	(Severe Loss of Function): Almost complete loss of function; unable to perform normal activities or movement

Swelling

Grade	Explanations
0	(No Swelling): No visible swelling or puffiness
1	(Mild Swelling): Slight puffiness, may be localized to a small area
2	(Moderate Swelling): Noticeable swelling, covering a larger area; skin may feel tight or stretched
3	(Severe Swelling): Pronounced swelling, skin may appear shiny or tight, possibly with pitting (indentation when pressed)

Objective Parameters

Tenderness

Grade	Explanations
0	(No Tenderness): No discomfort or pain upon touch or pressure
1	(Mild Tenderness): Slight discomfort when touched, but tolerable. Doesn't cause the patient to pull away
2	(Moderate Tenderness): Noticeable pain upon touch, causes withdrawal or flinching, but the pain is bearable
3	(Severe Tenderness): Extreme pain even with light touch, causing significant discomfort or strong reaction (e.g., flinching or withdrawal)

Colour

Grade	Explanations
0	(Normal Colour): Skin is normal in color for the patient, no signs of discoloration, redness, or other abnormal hues
1	(Mild Change in Colour): Slight redness or change in colour, often localized. May indicate mild inflammation or irritation
2	(Moderate Change in Colour): Noticeable redness, bruising, or paleness. May be a sign of moderate inflammation, injury, or poor circulation
3	(Severe Colour Change): Deep red, blue/purple (bruising or cyanosis), or black (necrosis). Indicates significant inflammation, poor blood flow, or tissue damage

Site

Grade	Explanations
0	(No Symptoms): No visible or palpable signs of abnormality at the site
1	(Localized, Superficial): Symptoms are confined to a small, localized area on the skin's surface
2	Localized, Deeper Tissue Involvement): Symptoms affect a specific site but extend into deeper tissues (muscle, tendons, etc.)
3	(Diffuse or Widespread): Symptoms spread over a larger area or involve multiple regions, affecting deeper tissues or organs

Discharge

Grade	Explanations
0	(No Discharge): Wound is clean and dry, indicating proper healing or no infection
1	(Mild Discharge - Serous): Clear, watery fluid, possibly indicating early healing or mild irritation
2	(Moderate Discharge - Sanguineous or Serosanguinous): Blood-tinged or pinkish fluid, indicating some bleeding or active healing process
3	(Severe Discharge - Purulent or Foul-Smelling): Thick, yellow or green pus-like discharge, often foul-smelling, indicating infection or severe tissue damage

Criteria for Assessment

The impact of the therapy was tested in two phases, for both groups, observations were made on the 0th day before treatment, the 7th,14th, 21st, 28th, 35th, and 60th days after treatment.

Group – A. After the completion of the topical dosage of the *Yashtimadhu ghrita* schedule.

Group-B. After the completion of the topical dosage of the *Tila kalka madhu ghrita* schedule.

Statistical Analysis

The obtained data was analyzed statistically. Wilcoxon Signed Rank Test and Paired t-test were used to test the hypothesis of the study. P value of < 0.05 was considered as statistically significant and p value < 0.01 and < 0.001 were considered as highly significant. The level of significance was noted and interpreted accordingly.

Assessment of Result

The assessment of progress was done after 7 days, i.e., after completion of the course of treatment. An assessment scale shall be framed to assess the rate of improvement. At the end of treatment, the percentage of relief was calculated and classified under the following headings:

1. Maximum improvement: More than 75% improvement of the clinical signs and symptoms
2. Moderate improvement: 50–75% improvement of the above-mentioned clinical signs and symptoms
3. Mild Improvement: 25–50% improvement of the above-mentioned clinical signs and symptoms.
4. No Improvement: 0–25% improvement of the above-mentioned clinical signs and symptoms.

Overall Assessment

Overall assessment of the therapy was assessed based upon the significance of Student's Paired t-Test and Wilcoxon Signed Rank Test values in both subjective and objective parameters and mean of all subjective.

RESULTS

Follow up		Total symptoms score results			P value
		Mean ±SD	Mean difference	% of improvement	
Yashtimadhu Ghrita	Baseline treatment	30.66+1.11	-	-	-
	1st week	20.66+1.11	10.00	32.62	<0.0001*
	2nd week	11.66+1.17	19.00	61.97	<0.0001
	3rd week	4.13+2.66	26.53	86.53	<0.0001*
	4th week	1.33+1.17	29.33	95.66	<0.0001*
Tila kalka madhu ghrita	Baseline treatment	32.13+1.18	-	-	-
	1st week	21.86+1.30	10.26	31.93	<0.0001
	2nd Week	12.33+2.49	19.80	61.62	<0.0001
	3rd week	9.8+1.08	22.33	69.50	<0.0001
	4th week	5.06+3.53	27.06	84.22	<0.0001

***Paired t test, Wilcoxon sign rank test**

Yashtimadhu Ghrita

Starting with a baseline mean symptom score of 30.66, participants showed marked improvement throughout the study. By the end of the first week, the mean score decreased to 20.66, reflecting a 32.62% improvement. The most significant reduction occurred by the fourth week, where the mean score dropped to 1.33, corresponding to a remarkable 95.66% improvement. All changes were statistically significant (P<0.0001), indicating a strong effect of this treatment.

Tila kalka madhu ghrita

Similarly, *Tila kalka madhu ghrita* began with a slightly higher baseline mean of 32.13. The treatment led to a 31.93% improvement in the first week (mean score of 21.86) and continued to show progressive benefits. By the fourth week, the mean score reached 5.06, resulting in an 84.22% overall improvement. Like *Yashtimadhu Ghrita*, all results were statistically significant (P < 0.0001).

Comparative Insights

While both treatments demonstrated significant efficacy in symptom reduction, *Yashtimadhu Ghrita* achieved a higher percentage of improvement by the end of the study compared to *Tila kalka madhu ghrita*. This suggests that *Yashtimadhu Ghrita* may be a more effective option for alleviating symptoms in the studied population.

Overall, these findings highlight the potential of both herbal treatments in providing relief, with *Yashtimadhu Ghrita* showing particularly strong results over the four-week duration.

DISCUSSION

Comparative Analysis

A direct comparison of the two treatments reveals that *Yashtimadhu Ghrita* was more effective in pain reduction, discharge control, and overall wound healing than *Tila Kalka Madhu Ghrita*. The statistical analysis shows that the pain reduction was significant (P<0.05) in both groups, but *Yashtimadhu Ghrita* had a faster and more pronounced effect. Similarly, while both treatments effectively reduced swelling and discharge, *Yashtimadhu Ghrita* had a slight edge in terms of the speed and extent of improvement.

This suggests that while both formulations are effective in wound management, *Yashtimadhu Ghrita* may be more suitable for cases where faster relief from pain and inflammation is required.

On the other hand, *Tila Kalka Madhu Ghrita*, with its balanced effects, can still be considered a viable alternative, particularly for patients who may have specific contraindications to the ingredients in *Yashtimadhu*.

CONCLUSION

The comparative clinical study evaluating the efficacy of *Yashtimadhu Ghrita* and *Tila Kalka Madhu Ghrita* in the management of *Sadhyo Vrana* (acute wound) provides valuable insights into the potential of these two traditional Ayurvedic formulations in wound healing. Both groups demonstrated notable improvements in wound healing parameters, but the overall efficacy varied between the two treatments.

Pain Management: Both *Yashtimadhu Ghrita* and *Tila Kalka Madhu Ghrita* showed significant improvements in reducing pain, with *Yashtimadhu Ghrita* demonstrating a faster and more substantial reduction in pain levels over the course of the treatment. By the fourth week, patients treated with *Yashtimadhu Ghrita* experienced a 96.1% improvement in pain, compared

to an 89.38% improvement in the *Tila Kalka Madhu Ghrita* group.

Wound Characteristics: Across all parameters, including swelling, redness, tenderness, and discharge, both groups exhibited progressive improvement. However, *Yashtimadhu Ghrita* showed faster healing in terms of wound discharge and swelling, with nearly complete healing achieved by the fourth week in the majority of cases.

Inflammation: Reduction in inflammatory signs, such as heat and redness, was observed in both groups. Although the *Tila Kalka Madhu Ghrita* group initially showed slightly better results in reducing redness and heat, the difference was not statistically significant.

Tissue Recovery: *Yashtimadhu Ghrita* was particularly effective in improving tissue recovery, as indicated by significant improvements in loss of function and site parameters. The overall improvement in these aspects was faster and more substantial in this group compared to the *Tila Kalka Madhu Ghrita* group.

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