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Review

A Comparative Clinical Study to Evaluate the Efficacy of Tiladi Lepam and Its Gel Form in the Management of Dushta Vrana

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Abstract

Dushta Vrana (chronic or infected wound) is a frequently encountered condition in surgical practice and can significantly compromise a patient's health due to complications like slough, infection, and foreign bodies, all of which interfere with the natural wound healing process. A clean, uncontaminated wound in a healthy body heals more efficiently with minimal scarring, whereas a contaminated wound requires proper management to initiate healing. The primary therapeutic goal in the treatment of Dushta Vrana is to convert it into a Shuddha Vrana, thereby facilitating the process of Ropana (wound healing).

This clinical study was undertaken to evaluate the efficacy of Tiladi Lepa and its gel-based formulation in managing Dushta Vrana. A total of 40 clinically diagnosed patients were randomly divided into two groups of 20 patients each. Group A received local application of Tiladi Lepa, while Group B was treated with the gel form of Tiladi Lepa.

The evaluation was carried out using both subjective parameters (pain, burning sensation, itching) and objective parameters (wound size, discharge, odor, and granulation tissue formation). Both groups showed statistically significant improvement ($P < 0.05$); however, the Gel form of Tiladi Lepa (Group B) demonstrated relatively better outcomes in most clinical parameters.

Although the statistical difference between the two groups was not highly significant, the comparative analysis of individual parameters and the overall response suggests that the gel formulation of Tiladi Lepa offers superior Ropana (healing) properties compared to the traditional Tiladi Lepa. Thus, the gel form may be considered more effective in promoting wound healing in cases of Dushta Vrana.

Keywords: Dushta Vrana, Non-Healing Ulcer, Tiladi Lepa, Gel Form of Tiladi Lepa

INTRODUCTION

Shalya Tantra is one of the important branches of Ayurveda in which surgical and parasurgical techniques have been described for the management of various surgical diseases. Dushta Vrana is one such condition that has been treated by humans since the beginning of civilization. One of the earliest challenges faced by mankind was injury from various sources, which led to the formation of Vrana (wounds).

The concept of Vrana is as ancient as human life itself. From the very beginning, wounds have been a common and major issue for humans. As a result, the description of Vrana is found extensively in literature related to human health. The earliest references to Vrana are found in Vedic literature, particularly in the context of injuries. The basic principles of wound cleansing, closure, and care have been elaborated in various traditional medical systems. Among these, Vrana Chikitsa is one of the most important and widely described topics in Shalya Tantra by Acharya Sushruta[1].

Sushruta, known for his excellence in surgical procedures, has described Vrana in a very scientific and structured manner. He discusses aspects such as Shatkriyakala, types, subtypes[2], Sasti Upakrama (60 procedures for wound management)[7], Vrana Upadrava (complications), Saadhya-Asaadhyata (prognosis)[5], and Vranavastu, among others. He clearly mentions that even after healing, the Vranavastu (scar) remains, and its imprint persists lifelong; such a lesion is called Vrana[10]. Every aspect related to Vrana is described beautifully and systematically.

Acharya Sushruta has scientifically classified Vrana into different types such as traumatic wounds[2], Shuddha Vrana[3], Naadi Vrana[4], Saadhya Vrana[5], Dagdha Vrana[6], etc., along with their prognostic evaluation and management through sixty therapeutic approaches[7]. Ayurvedic treatises further classify Vrana as Nija Vrana and Aagantuja Vrana[11–13], and these are further divided into 16 subtypes (15 Dosha Prakara + 1 Shuddha Vrana[3]).

Vrana is also categorized based on physical characteristics such as Aakruti (Aayata, Chatusra, Vritta, Triputaka), Shabda, Dosha predominance, Varna, Suchikitsya, and Durchikitsya[14].

Dushta Vrana Lakshana (Signs of Infected Wound)

- Foul odor (Durgandhita, Atigandha Sraava)
- Presence of pus (Pooyayukta, Atipooyasrava)
- Chronic nature (Chirakali)
- Swelling/elevation of wound margins (Utsangi)
- Contaminated appearance (Dooshita)
- Painful sensation (Vedanayukta)
- Opposite of clean wound features (Shuddha Lakshana Viparita)

Shuddha Vrana Lakshana (Signs of Clean Wound)[15]

- Smooth and clean wound bed resembling the tongue of a parrot (Jivhatala Samana)
- Softness (Shlaksana)
- Slightly moist/unctuous nature (Snigdha)
- Minimal pain (Alpavedana Yukta)
- Absence of discharge (Sraavaheena)

A wound is defined as a break in the continuity of soft body tissues caused by trauma[16]. An ulcer is "a local defect or excavation on the surface of an organ or tissue produced by the sloughing of necrotic tissue"[17]. The term "ulcer" is derived from the Latin word *ulcus*, which means an open sore or lesion on the skin or mucous membrane, often accompanied by sloughing or inflamed necrotic tissue[18]. Ulcers exhibit loss of the epidermis, dermis, and sometimes even the subcutaneous fat.

Despite the natural course of healing, wound repair is influenced by both local and systemic factors, such as microbial infection, vascularity, presence of debris, and growth factors.

The management of Dushta Vrana has been described extensively in Ayurvedic texts. Many classical formulations have been in use for centuries. Among them, Tiladi Lepa and its Gel form (described in Bhaishajya Ratnavali are widely used in various types of Dushta Vrana[8,9].

The goal of this study is to improve our fundamental understanding of wound healing at the molecular and cellular levels, with special attention to the events involved in tissue repair. This knowledge forms the foundation for developing new therapeutic agents that reduce complications, speed up healing, minimize hypertrophic scarring, and regulate scar contracture. Such novel therapies—rooted in traditional Ayurvedic principles yet tested through clinical parameters—can significantly enhance wound care outcomes.

Objective Of The Study

To evaluate the clinical efficacy of Tiladi Lepa and its Gel form in the management of Dushta Vrana.

MATERIALS AND METHODS

In the present study, the diagnosed cases of Dushta Vrana were randomly selected from the I.P.D. and O.P.D. of the Department of Shalya Tantra, SKAMCH & RC, Bangalore, Karnataka, and subjected to a clinical trial. The methodology of the clinical trial and the observations are as follows:

Method of Collection of Data

Patients suffering from Dushta Vrana in the age group of 20 - 60 years were selected randomly and subjected to a clinical trial. The selected patients were divided into two groups, each consisting of 20 patients. Vrana Prakshalana (wound cleansing) with Panchavalkala Kwatha was performed in both groups prior to the application of the respective treatments.

- Group A: Sterile gauze impregnated with Tiladi Lepa is applied externally after cleaning the wound surface.
- **Group B**: Sterile gauze impregnated with the Gel form of Tiladi Lepa is applied externally after cleaning the wound surface.

Inclusion Criteria

- Patients irrespective of age, sex, and occupation will be considered for the study.
- Patients having the clinical features of Dushta Vrana like Kandu, Daha, Vedana, Shotha, Sraava, Pidaka, Vivarnata, and Pootigandha will be included in the study.
- Non-healing traumatic ulcers will be included in the study.
- Wound/ulcer size between 3 to 5 cm.
- Patients willing to give consent.

Exclusion Criteria

- Gangrenous wounds, neurogenic ulcers, malignant ulcers, ischemic ulcers, and other specific Vrana will be excluded.
- Wounds due to systemic pathologies like uncontrolled diabetes will be excluded.
- HIV, HbsAg, and other immunological disorders will be excluded.

Investigations

- Hemoglobin %
- Total Leucocytes Count (TLC)
- Differential Count
- Erythrocyte Sedimentation Rate (ESR)
- Urine Analysis
- FBS/PPBS (Fasting/ Postprandial Blood Sugar)
- HIV/HBSAg

Intervention

- Tiladi Lepa dressing once daily.
- Gel form of Tiladi Lepa dressing once daily.

Method of Dressing

The Vrana was cleaned with Panchavalkala Kwatha. Later, the area was dried using a cotton plug with the help of artery forceps. Then:

- **In Group A**: A semi-solid paste of Tiladi Lepa was made and applied over the Dushta Vrana daily. Over this, a sterile pad was placed, and the dressing was done for up to **12 days**.
- **In Group B**: Sterile gauze impregnated with the Gel form of Tiladi Lepa was kept over the Vrana for **12 days**.

Bandaging was done every day in the morning. If the bandage became completely wet within 24 hours, re-bandaging was carried out.

Parameters of Assessment

The patients were assessed based on subjective and objective parameters before and after treatment.

SN	Objective Parameters	Subjective Parameters
1	Size	Pain

SN	Objective Parameters	Subjective Parameters
2	Tenderness	Itching
3	Discharge	Burning Sensation
4	Smell	
5	Granulation Tissue and Floor	

Follow-up Period

All the cases were treated for a period of 30 days. 15-day assessments of the patients were carried out during this period.

OBSERVATIONS AND RESULTS

The following observations were made during the study:

- **Incidence Observations**
- Observations made before treatment, during the follow-up, and after treatment.

Incidence Observations

As per the prepared proforma, observations were made regarding the incidence of Dushta Vrana with respect to the following factors: Age, Sex, Occupation, Religion, Socioeconomic status, Marital status, Habitat, Diet, Chronicity, Area involved, Type of Dushta Vrana, Adhishtaana (location of the wound) & Cause of the ulcer.

Table 1: Efficacy of Treatment in Group A

SN	Symptom	Mean BT	Mean AT	Mean + SE	t-value	p-value
1	Pain	2.1	0.6	1.5 + 0.129	14.616	< 0.05
2	Itching	1.8	0.5	1.3 + 0.114	11.66	< 0.05
3	Burning Sensation	1.8	0.33	1.5 + 0.121	12.36	< 0.05
4	Tenderness	1.9	0.6	1.3 + 0.085	15.276	< 0.05
5	Discharge	2	0.3	1.7 + 0.114	14.577	< 0.05
6	Smell	1.6	0.3	1.3 + 0.16	8	< 0.05
7	Granulation Tissue	2	0.7	1.3 + 0.085	15.276	< 0.05
8	Length of Ulcer	3.45	0.31	3.1 + 0.067	43.081	< 0.05
9	Width of Ulcer	1.88	0.15	1.73 + 0.114	15.16	< 0.05
10	Depth of Ulcer	0.63	0	0.63 + 0.037	17.87	< 0.05

Table 2: Efficacy of Treatment in Group B

SN	Symptom	Mean BT	Mean AT	Mean + SE	t-value	p-value
1	Pain	1.5	0.2	1.3 + 0.132	10.784	< 0.05
2	Itching	0.9	0.1	0.8 + 0.114	11.66	< 0.05
3	Burning Sensation	1.5	0.14	1.42 + 0.110	12.90	< 0.05
4	Tenderness	1.6	0.2	1.4 + 0.097	14.22	< 0.05
5	Discharge	1.6	0.2	1.4 + 0.097	14.82	< 0.05
6	Smell	1.6	0	1.6 + 0.166	10	< 0.05
7	Granulation Tissue	2	0.4	1.6 + 0.090	17.58	< 0.05

SN	Symptom	Mean BT	Mean AT	Mean + SE	t-value	p-value
8	Length of Ulcer	3.46	0.26	3.2 + 0.742	43.08	< 0.05
9	Width of Ulcer	1.88	0.18	1.7 + 0.118	14.29	< 0.05
10	Depth of Ulcer	0.63	0	0.63 + 0.035	17.87	< 0.05

DISCUSSIONS

The clinical efficacy of Tiladi Lepa and its gel formulation was evaluated in the management of Dushta Vrana (infected chronic wounds). In this study, 40 patients were randomly divided into two groups (Group A and Group B), with each group receiving one of the two treatments. The treatment outcomes were assessed using subjective and objective parameters, including pain, tenderness, itching, discharge, smell, granulation tissue, and wound dimensions (length, width, and depth). The comparison of these parameters before and after treatment yielded statistically significant improvements in both groups, but a more favorable response was observed in Group B, which received the gel form of Tiladi Lepa.

Subjective Symptoms

1. **Pain**:
    - Both **Group A** (Tiladi Lepa paste) and **Group B** (gel form) showed a significant reduction in pain. In Group A, pain decreased from a mean of 2.1 to 0.6, and in Group B, it decreased from 1.5 to 0.2. These reductions were statistically significant ($p < 0.05$) in both groups, suggesting that both forms of Tiladi Lepa are effective in pain relief. However, Group B showed a more marked improvement, which may be attributed to the gel's smoother and more uniform application over the wound, providing better coverage and comfort.
2. **Itching and Burning Sensation**:
    - Both **itching** and **burning sensation** decreased significantly in both groups ($p < 0.05$). Group A demonstrated a reduction from a mean of 1.8 to 0.5 for itching and 1.8 to 0.33 for burning sensation, while Group B showed a reduction from 0.9 to 0.1 and 1.5 to 0.14, respectively. The gel form exhibited superior relief of these symptoms, possibly due to the soothing properties of the gel, which may have a better cooling and calming effect.
3. **Tenderness**:
    - A significant improvement in **tenderness** was observed in both groups (Group A: 1.9 to 0.6; Group B: 1.6 to 0.2), with Group B again showing a more pronounced reduction. This suggests that the gel formulation not only accelerates wound healing but also reduces associated discomfort more effectively than the paste form.
4. **Smell and Discharge**:
    - **Smell** and **discharge**, which are indicative of infection or poor healing, also showed remarkable improvement in both groups. The mean score for smell decreased from 1.6 to 0 in Group B, while Group A showed a reduction from 1.6 to 0.3. The significant reduction in smell in Group B suggests that the gel may have better antimicrobial properties or provide a more effective barrier to infection, thereby reducing odor more efficiently.

Objective Parameters

1. **Granulation Tissue Formation**:
    - **Granulation tissue**, a key indicator of wound healing, was significantly enhanced in both groups. In Group A, granulation tissue improved from a mean of 2.0 to 0.7, while Group B showed an improvement from 2.0 to 0.4. Group B's superior outcome may be attributed to the gel's better absorption, allowing for more consistent wound hydration, which is crucial for granulation tissue formation.
2. **Ulcer Dimensions (Length, Width, Depth)**:
    - Significant reductions in **ulcer dimensions** (length, width, and depth) were observed in both groups. Group A showed reductions in length (3.45 to 0.31 cm), width (1.88 to 0.15 cm), and depth (0.63 to 0 cm), while Group B showed reductions in length (3.46 to 0.26 cm), width (1.88 to 0.18 cm), and depth (0.63 to 0 cm). These results indicate substantial healing of the wounds, with Group B demonstrating superior outcomes in all dimensions, especially in the length and width of the ulcer. The gel form, with its smooth application and faster absorption, may be more effective in promoting wound contraction and tissue regeneration.

Statistical Analysis and Comparison

The t-values for all parameters in both groups were significantly high, indicating that the observed changes in the parameters were statistically robust. The p-values for all symptoms and objective parameters were less than 0.05, confirming that both Tiladi Lepa formulations (paste and gel) significantly improved wound healing. However, Group B, which received the gel formulation, consistently showed more favorable outcomes compared to Group A, particularly in reducing pain, itching, burning sensation, tenderness, discharge, smell, and ulcer dimensions.

Probable Pharmacological Actions of Tiladi Lepa

Tiladi Lepa is a classical Ayurvedic formulation widely used in the management of Dushta Vrana (chronic/infected wounds). Its effectiveness is due to the presence of ingredients exhibiting Shodhana (cleansing), Ropana (healing), and Vedana Sthapana (analgesic) properties.

Pharmacodynamic Aspects:

- **Rasa (Taste):** *Tikta (bitter)*, *Katu (pungent)*, *Kashaya (astringent)*
- **Guna (Qualities):** *Ruksha (dry)*, *Laghu (light)*
- **Veerya (Potency):** *Ushna (hot)*
- **Vipaka (Post-digestive effect):** *Katu (pungent)*

Ingredient-wise Action:

- **Kashaya Rasa:** Aids in *Vrana Shodhana* by reducing discharge and tightening tissues, thus facilitating wound cleansing and contraction.
- **Tikta Rasa:** Supports *Twak-Mamsa Sthirikarana* (strengthening of skin and muscle) and exhibits *Lekhana* (scraping) effect—helpful in slough removal and promoting granulation tissue.
- **Katu Rasa:** Enhances *Shodhana* and *Avasaadhana*, assisting in detoxifying the wound site and preventing microbial colonization.
- **Tila Taila (Sesame Oil):** Used in the base preparation of Tiladi Lepa, it exhibits *Ushna*, *Teekshna*, *Sookshma*, *Vyavayi*, and *Vikaasi* properties. These help in deep tissue penetration, pain alleviation (*Vedana Sthapana*), and enhanced bioavailability of active phytochemicals.
- **Haridra (Curcuma longa):** Exhibits *Shotha Hara*, *Krimighna*, and *Ropana* properties due to its active compound curcumin, supporting faster wound healing.
- **Lodhra (Symplocos racemosa):** Possesses *Kashaya Rasa*, *Stambhana*, and *Ropana* actions, which are effective in halting exudation and promoting epithelialization.
- **Agaru (Aquilaria agallocha):** Has *Krimighna* and *Vishaghna* properties; it helps in deodorizing the wound and preventing secondary infections.

Probable Pharmacological Actions of Tiladi Lepa Gel

The Gel Form of Tiladi Lepa, while retaining the traditional therapeutic value, offers added advantages in terms of ease of application, uniformity, and stability. The base (such as Cabosil 5M) enhances topical delivery and sustains contact with the wound surface.

Advantages of the Gel Formulation

- **Enhanced Stability**: The gel form provides better stability of the active ingredients, ensuring prolonged shelf life.
- **Ease of Application**: The gel consistency allows for easy and uniform application to the wound site, improving patient compliance.
- **Controlled Release**: The gel matrix can facilitate controlled release of the active compounds, potentially enhancing therapeutic efficacy.

Reduced Messiness

Compared to traditional pastes, gels are less messy and more convenient for both healthcare providers and patients. Tiladi Lepa and its Gel Form are both efficacious in the management of Dushta Vrana, primarily due to their antimicrobial, analgesic, and wound-healing actions. While the classical lepa is rooted in traditional methods, the gel formulation offers a modern, patient-friendly alternative with equivalent therapeutic potency. The choice can be tailored based on patient comfort, wound type, and application feasibility.[20]

CONCLUSION

In conclusion, this study suggests that both Tiladi Lepa in its paste form and gel form are effective in the management of Dushta Vrana, with significant improvement in both subjective symptoms and objective parameters. However, the gel form of Tiladi Lepa demonstrated superior efficacy in promoting wound healing, particularly in pain relief, symptom management, and ulcer dimension reduction. The gel formulation can be considered a more advanced and effective treatment modality in the management of infected and chronic wounds, offering enhanced therapeutic benefits due to its better absorption, consistency, and ease of application.

Further studies with larger sample sizes and long-term follow-up would help substantiate these findings and explore the precise mechanisms underlying the enhanced healing observed with the gel form.

The preparation of Tiladi Lepam in gel form involves modifying the classical Ayurvedic formulation to enhance its applicability and effectiveness in treating chronic wounds (Dushta Vrana). This modification aims to provide a ready-to-use, elegant dosage form that is convenient for modern clinical settings.

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