

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF TILABHAYAADI LEPAM IN THE MANAGEMENT OF DUSHTA VRANA (VENOUS ULCER)

Dr. Ediga Sukanya*¹ and Dr. T. Srinivasa Rao²

¹Final Year PG Scholar, Department of Shalya Tantra, Sri Venkateswara Ayurvedic College
and Hospital T.T.D, Tirupati.

²Senior Lecturer, Department of Shalya Tantra, Sri Venkateswara Ayurvedic College and
Hospital T.T.D, Tirupati.

Article Received on
11 November 2024,
Revised on 01 Dec. 2024,
Accepted on 21 Dec. 2024
DOI: 10.20959/wjpr20251-34678



*Corresponding Author

Dr. Ediga Sukanya

Final Year PG Scholar,
Department of Shalya
Tantra, Sri Venkateswara
Ayurvedic College and
Hospital T.T.D, Tirupati.

ABSTRACT

Vrana (Ulcer) – in ayurveda is defined as structural deformity in the skin and deeper structures(gaatra vichurnana)^[1] associated with ruja(pain), srava(discharge), vikruti(deformity) etc caused either by vitiation of doshas or due to any trauma. Vrana is basically 2 types – Dushta vrana^[2], Shuddha vrana.^[3] Shuddha vrana (Acute ulcer) is easily treatable. Dushta vrana(Chronic ulcer) is unresponsive to any treatment. Acharya Sushruta mentioned 60 methods(Sashti upakramas) to treat such ulcers. Alepana (plastering) is one among them. TILABHAYAADI LEPAM, explained in Chakradatta 46th chapter Bhagandhara Chikitsa Adhyaaya has been taken as the drug of choice in the treatment of Dustha vrana. It is also expounded that when Kalka applied as Lepa on vrana acts as Mamsaraktha Prasadana, Doshasamana, Ruja Kandu nivaranam, and even does the Shodhana and Ropana of the vrana.

KEYWORDS: Dushta Vrana, Tilabhayaadi Lepam, Shodana and Ropana of Vrana.

INTRODUCTION

Surgery is an ever-progressive, continuously changing facet of medicine. Art of surgery revolves around the ulcer and its essence is uncomplicated healing. Better wound healing with minimal scar formation and controlling the pain effectively are the prime motto of every surgeon.

Certain factors are primely responsible for changing a simple ulcer into a chronic or non-healing ulcer. These factors are low vitality, smoking, alcohol addiction, malnutrition, old age, constant irritation to the ulcer, certain debilitating diseases like diabetes, tuberculosis, leprosy, hepatitis, poor surgical technique that leave devitalized tissue, foreign material of any kind including drain, sutures etc.

Dushta vrana (complicated ulcers) are a frequently encountered problem in present era produced commonly as a complication of trauma or pathologic insult. Vrana chikitsa (wound/ulcer treatment) is integral part of Shalya tantra (Surgery in Ayurveda).

Lakshanas of Dusthavrana^[4]

Acharya Susrutha explained vrana with lakshanas like Athisamvrutho (Slightly exposed), Athivivrutho (Broad), Atikathina (Very hard), Athimrudu (Very soft), Athisheetha (Very cold), Atyushna (Very hot), Utsanna (Elevated), Avasanna (Depressed), and different colours like Krishna (Black), Rakta (Red), Peetha (Yellow), Shukla (White), filled with pus in Mamsa (Muscle tissue), Sira (Veins), Snayu (Ligaments), Unmargi (Moving Abnormally), Utsangi (Wound raised up), Amanognadarshana (Having Unpleasant look), Gandhoatyartha (Foul smell), Vedana (Severe pain), Daha (Sensation), Raaga (Redness), Paaka (Suppuration), Kandu (Itching), Shopha (Swelling), Pitika (Eruptions), Upadrutoatyartha (With complications), Dustha Shonithasrava (Exuding vitiated blood), Deerghakalanubandhi (Persisting for Long time).

ULCER^[5]

An ulcer is the discontinuity of the skin or mucous membrane which occurs due to microscopic death of the tissues. The most common types of ulcers are venous stasis ulcers^[6], arterial ulcers (ischaemic ulcers)^[7] and neurotropic ulcers.^[8]

Venous ulcers are wounds occurring due to improper functioning of venous valves, usually of the legs. Damaged venous valves prevent the backflow of blood and cause pressure in the veins. Hence an arterial pressure reduces significantly than venous and therefore, blood is not pumped as effectively into the area.

Various terms are being used e.g., Varicose ulcers, Static ulcers, Post thrombotic ulcer, Gravitational ulcer etc. The loss of skin surface in the drainage area of a varicose vein, usually in the leg resulting from stasis and infection. (Also known as Stasis ulcer) It is the

commonest ulcer of the leg. The basic cause of Venous ulcer is abnormal Venous hypertension in the lower third of the leg, ankle, and dorsum of the foot.

AIM OF THE STUDY

Aim of this particular study is to diminish the detrimental consequences associated with Chronic ulcers by using certain drugs of Ayurveda and secondly to integrate traditional and new wound healing technologies required for healthy healing of an ulcer. Tilabhayaadi lepam is selected as drug to this present study to fulfill the aim of the study.

OBJECTIVES OF THE STUDY

To evaluate the efficacy of Tilabhayaadi lepa in the Dustha vrana w.s.r to venous ulcer.

MATERIALS AND METHODS

Type of research work: Single blind Clinical study.

Sample size: 20.

Source of collection of data: Screening, Selection and Registration of 20 cases randomly from OPD/IPD, of S. V. Ayurveda Hospital, Tirupati in SHALYA TANTRA unit based on Inclusive and Exclusive Criteria.

INCLUSION CRITERIA

- Patients diagnosed with Venous ulcer for more than 2 months.
- Patients irrespective of Sex, Religion, Occupation, Economic status.
- Patients between the age of 20-60 years.
- Patients not enrolled in any Clinical trials.
- History of varicose veins.

EXCLUSIVE CRITERIA

- Patients having Embolism, Bleeding Disorders, Arterial Occlusion Diseases, other Infective Disorders.
- Patients who are under anticoagulant therapy.
- Patients with Immunocompromised Diseases like HIV, HbsAg, etc.
- Patients with Diabetes mellitus, Hypertension, Tuberculosis, Liver failure, Renal failure, Osteomyelitis, and any Malignancies.
- Patients with previous surgery for Varicose veins.

Alepana with Tilabhayaadi lepam^[9]

Equal quantity of Tila^[10] seeds, Fruit rind of Haritaki^[11] fruit, Lodhra^[12] leaves, Neem^[13] leaves, Haridra^[14], Rhizome of Vacha^[15], Kushta^[16] roots are mixed with equal amounts of Madhu^[17] and Ghritha^[18] and made into fine paste. Due to healing properties of above drugs in Tilabhayadi lepa, it has been selected for present study.

STUDY PLAN

Procedure is carried out in aseptic conditions wearing gloves. Clinical study is carried out in three phases.

Purva Karma

- Routine investigations done.
- Ulcer is exposed properly and area is cleaned with Normal Saline.
- Slough is removed and area is to be dried by a cotton plug using artery forceps.

Pradhana Karma

- After cleaning the ulcer, Tilabhayadi lepa is applied over the ulcer with thickness of 0.25cms.

Pascat Karma

- A dry sterile pad is placed over the ulcer and bandaging is done.
- If the bandage becomes wet completely within 24 hours re-bandaging is done.

INVESTIGATIONS

Hb%, Bleeding time and clotting time, HbsAg, HIV, CBC, Doppler study.

ASSESSMENT CRITERIA

Table No. 1: Showing Parameters of Study.

SUBJECTIVE PARAMETERS	OBJECTIVE PARAMETERS
Pain	Size of the ulcer
Burning sensation	Colour of the ulcer
Itching	Discharge

Parameters with grading**a) Subjective Parameters****Grade****1. VEDANA (PAIN)**

- i. No Pain - 0
- ii. Mild (Localized feeling of pain during movement, no pain at rest) - 1
- iii. Moderate (Localized pain at rest, sleep not disturbed) - 2
- iv. Severe (continuous localized pain that disturbs sleeps) – 3

2. DAHA (BURNING SENSATION)

- i. No Burning sensation - 0
- ii. Mild (Intermittent burning sensation) - 1
- iii. Moderate (Continuous Burning sensation, sleep not disturbed) - 2
- iv. Severe (continuous Burning sensation that disturbs sleeps) - 3

3. KANDU (ITCHING SENSATION)

- i. No Itching - 0
- ii. Mild (Slight Localized itching) - 1
- iii. Moderate (More Localized itching, sleep not disturbed) - 2
- iv. Severe (continuous Itching disturbs sleep) - 3

b) Objective parameters**1. SIZE OF THE ULCER**

- i. Completely healed with acceptable scars - 0
- ii. 3/4 th of initial size is reduced - 1
- iii. 1/2 nd of initial size is reduced - 2
- iv. 1/4 th of initial size is reduced – 3

2. COLOR OF THE ULCER

- i. Equivalent to skin color - 0
- ii. Pink - 1
- iii. Reddish - 2
- iv. Yellow – 3

3. SRAVA (Discharge)

- i. No Discharge - 0
- ii. Mild (Scanty, Occasional discharge) - 1
- iii. Moderate (Often discharge with blood on dressing) - 2
- iv. Severe (Profuse continuous discharge) - 3

SUBJECTIVE PARAMETERS OF THE STUDY**Table NO. 2: Showing Subjective parameters.**

PATIENT CODE NO.	PAIN		BURNING SENSATION		ITCHING	
	BT	AT	BT	AT	BT	AT
GAU1	2	1	2	0	2	1
GAU2	3	1	2	1	2	0
GAU3	3	1	3	1	2	0
GAU4	2	0	1	0	1	0
GAU5	2	1	1	0	1	0
GAU6	1	0	1	0	1	0
GAU7	3	1	2	0	1	0
GAU8	3	1	1	1	1	1
GAU9	2	1	1	0	1	1
GAU10	2	0	2	0	2	1
GAU11	3	1	3	1	2	0
GAU12	2	0	1	0	1	0
GAU13	2	0	1	0	1	0
GAU14	3	2	2	0	2	1
GAU15	2	0	1	0	1	0
GAU16	1	0	1	0	1	0
GAU17	1	0	1	0	1	0
GAU18	2	1	2	1	2	1
GAU19	3	1	1	0	1	0
GAU20	2	0	1	0	1	0
TOTAL	44	12	30	5	27	6
MEAN VALUE	2.21	0.63	11.5	0.25	1.35	0.30

OBJECTIVE PARAMETERS OF THE STUDY**Table No. 3: Showing Objective parameters.**

PATIENT CODE NO.	SIZE OF THE ULCER		COLOUR		DISCHARGE	
	BT	AT	BT	AT	BT	AT
GAU1	3	1	3	1	3	1
GAU2	3	1	3	1	3	2
GAU3	2	0	2	1	2	1
GAU4	1	0	2	0	2	1

GAU5	3	1	3	1	3	1
GAU6	3	1	3	1	2	1
GAU7	3	2	3	1	2	0
GAU8	2	1	2	1	1	0
GAU9	2	1	3	1	2	0
GAU10	2	1	3	1	2	1
GAU11	2	0	2	1	1	0
GAU12	1	0	2	0	1	0
GAU13	2	1	1	1	1	0
GAU14	1	1	1	0	1	0
GAU15	1	1	2	1	1	1
GAU16	2	1	1	0	1	1
GAU17	2	1	2	1	1	1
GAU18	3	2	3	1	2	1
GAU19	2	1	2	1	1	0
GAU20	2	1	1	0	1	0
TOTAL	42	18	44	15	33	12
MEAN	2.8	1.2	2.933	1	2.2	0.8

Table No. 2: showing the statistical data of subjective parameters and Objective parameters of Tilabhayaadi lepam efficacy.

Parameters	N	BT Mean	AT Mean	M.D	Relief %	S. D BT	S.D AT	S. E	't'	Df	P value
PAIN	20	2.21	0.63	1.58	72.72	0.71	0.60	0.116	13.568	18	<0.0001
BURNING SENSATION	20	1.5	0.25	1.25	83.33	0.69	0.44	0.123	10.16	19	<0.0001
ITCHING	20	1.35	0.3	1.05	77.77	0.49	0.47	0.114	9.199	19	<0.0001
SIZEOF ULCER	20	2.1	0.9	1.2	57.14	0.72	0.55	0.138	8.717	19	<0.0001
COLOUR	20	2.2	0.75	1.45	65.90	0.77	0.44	0.135	10.72	19	<0.0001
DISCHARGE	20	1.65	0.6	1.05	63.63	0.75	0.60	0.135	7.764	19	<0.0001

Table showing all the parameters results with its relief percentage which has been mentioned that all the 6 parameters are highly significant at 95% of confidence interval.

OVERALL RESULT OF THE THERAPY ON THE BASIS OF STATISTICAL EVALUATION

The overall result is calculated in terms of percentage on the basis of improvement in Subjective and Objective parameters of the study. On a final note, based on the results from paired 't' test it is proved that Group A with the treatment modality of *Tilabhayaadi lepam* has shown maximum relief in both Subjective parameters and Objective parameters.

DISCUSSION

It is observed that from the present study, on clinical examination of patients Pain, burning sensation, Itching, Size of the ulcer, Colour and Discharge are seen as major signs and

symptoms. All the six symptoms have been taken as parameters for the study. Besides hyperpigmentation of the surrounding skin and swelling were also noted in patients but this study is confined only to the parameters which has been taken.

Pain is seen in 100% of patients in the study.

EFFECT ON PAIN

It is observed that when compared with the relief percentage of subjective parameter before and after treatment, study *has* shown a high significant of relief of Pain by 72.72%.

BURNING SENSATION

The percentage of relief in Subjective parameters of Burning sensation, study has shown 83.33% of relief.

EFFECT OF ITCHING

The percentage of relief in Subjective parameters of Itching, study has shown 77.77% of relief.

EFFECT ON SIZE OF ULCER

When statistically evaluating the objective parameters effect on Size of ulcer by the clinical trial study has shown significant results by showing the percentage relief by 57.14%.

EFFECT ON COLOUR

The percentage relief of Colour is 65.9%.

EFFECT ON DISCHARGE

The percentage of relief in objective parameters of Discharge, study has shown 63.63% of relief.

PROBABLE MODE OF ACTION OF TILABHAYAADI LEPAM IN DUSHTA VRANA

Tilabhayaadilepam is an external application in this study. The ingredients are Tila, Haritaki, Lodhra, Vacha, Kushta, Haridhra, Nimba, Madhu & ghritam. All these ingredients are made into paste at the time of application on the *vrana*.

- In this study, the prepared drug i.e., Tilabhayaadilepa contains different types of phytochemicals which help in cleansing(sodhana) and healing(ropana) of the wound.
- The aqueous and ethanolic extracts of lodhra have anti-ulcer properties. Methanolic

extract of lodhra leaves have anti-inflammatory activity.

- Polyphenols in nimba twak are powerful anti-oxidants helpful in healing and have anti-inflammatory properties. Alkaloids of neem possess anti-microbial property and maintain healing process by reducing bacterial growth. Nimbidin reduces Oedema and shows anti-microbial activity.
- Krimighna, Vishagna, Kustagna, Vranaghna property of Nimba helped in reducing the formation of unhealthy granulation tissue & vishagna property promotes the lysis of local bacteria and local tissue lysis and also by enhancing the macrophage development.
- Curcumin, active constituent of haridra is a powerful anti-oxidant. It inhibits various type of cancerous cells (Lekhania), anti-inflammatory (Sothahara), wound healing (vranaropana), anti-parasitic, anti-bacterial, anti-fungal.
- Curcumin helps faster wound closure by re-epithelialization of epidermis and increased migration of various cells including my fibroblasts, fibroblasts and macrophages in wound bed.
- Chemical constituents of Kushta like sesquiterpene, glycosides etc help in anti-allergic activity. Terpinoids help in proliferative phase of wound healing. Glycosides have angiogenic effect. Acetone and costunolide of Kushta has anti-ulcer property.
- Madhura rasa to reduce the Size of the wound by its Dharana property, and by promoting healthy healing & increase the rate of contraction of the wound.
- Kaphapitta hara property reduces the discharge from ulcer which helps in pacifying the inflammatory process thus relieved pain and tenderness of the wound.
- Madhu helps in removing the debris and reduces discharge due to its Lekhaniya and samgrahi properties.
- Ghrutha and tila imparts snigdhatta, which alleviates the aggravated vatadosha and helps to minimise the inflammation as well as increases the moisture to protect the healing surface. Madhu is a best yogavahi substance without changing its properties, it carries the effects of the drugs added to it by imbibing the properties of the added drug.
- Vrana ropana and shodhana karma of madhu helped in healing the ulcer and purifying the ulcer without any further recurrence of the ulcer.
- Madhura & kashaya rasa will reduce the size of the ulcer.
- Phytosterols are known to be good emulsifiers. It promotes healing and thus getting reduction in the size of ulcer in clinical feature.
- Thus, it is inferred that the Tilabhayaadi lepam used in the trial has got all the around wound healing properties which has promoted faster healing.

CONCLUSION

The present study entitled with “A CLINICAL SYUDY TO EVALUATE THE EFFICACY OF TILABHAYAADI LEPAM IN THE MANAGEMENT OF DUSTHA VRANA (VENOUS ULCER)” was carried out with 20 patients Application of *Tilabhayaadi lepam* is done for 30 days daily on the ulcer. This reference has been taken from Chakradatta chapter 46 Bhagandhara Chikitsa Adhyaya. This treatment protocol was conducted for 30 days with one month of follow up. At the end of the clinical trial the following Conclusions are drawn.

- Application of *Tilabhayaadi lepam* is a very easy procedure with minimal expenditure and does not even require any hospital stay.
- It is easy to prepare, apply and has become a handy and effective remedy to patients suffering from venous ulcer.
- After overall assessment of the procedure for the efficacy on *Dushta vrana* w.s.r to Venous ulcers the application of *Tilabhayaadi lepam* is more beneficial and economically feasible for the patients suffering from long standing non- healing ulcers.
- There were no complications that occurred during the study and any other adverse reactions reported in the study due to the procedure applied in the clinical trial.
- Hence both the trials conducted in the study has shown very significant variation in the symptoms and is simple, cost effective, easily administered and very much safe for patients. Hence, *Tilabhayaadi lepam* is more effective in the management of *Dushta vrana*.

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