



Effect of Trishothadi Lepam on Tropical foot ulcer – Case Report

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Abstract:

Siravyadhana and Trishothadi Lepam application was intended for healthy wound healing. Probably it will have an understanding of underlying mechanism of relieving vascular stasis, reducing venous congestion and beginning of re-vascularization and other wound healing process. The Group-B showing maximum percentage of benefit followed by Group-A. Hence it can be concluded that overall benefit is found maximum in Group-A where *Siravyadhana* with *Trishothadi Lepam* was administered. The drug *Trishothadi Lepam* might be shown the efficacy due to *Lekhana*, *Kledahara*, *Shoshana*, *Shotha* & *Dahahara*, *RaktaShodhaka* and *Twaka Prasadana* properties. this procedure is found to be very much safe, simple, cost-effective, easily administered in the patients of foot ulcers leading them for complete healing

avoiding the most unwanted outcome of amputation.

Key words: *Siravyadhana*, *Trishothadi Lepam*, congestion, amputation

Introduction:

Lower extremity complications have become an increasingly significant public health concern in both developed and developing world. These complications beginning with neuropathy and subsequent diabetic foot ulcers, frequently lead to infection and lower extremity amputation even in absence of critical limb ischemia ⁽¹⁾. One of the common lower extremity complications is ulceration.

In National Hospital Discharge Survey (NHDS) Data ⁽²⁾, foot ulcer rates increased by 50% between 1980-1990. The highest rates were observed in individual age between 45-64 years. A higher ulcer consistency rate was found in males than in

females. The present statistical data in India about the foot ulcer shows the incidence about 6 Lakhs new cases per year⁽³⁾.

Pathophysiological conditions such as non-healing nature of ulcer, infection, diabetes mellitus and local nutritional disorder etc. are the risk factors associated with development of foot ulcers. However, it is imperative to remember the fundamental basics in the healing of foot ulcers; adequate perfusion, debridement, infection control and pressure mitigation. Early recognition of the etiological factors along with prompt management of foot ulcers is essential for surgical outcome. A long term multidisciplinary care and integration of traditional new wound healing technologies are required for healthy healing.

Thus, this study with *Siravyadhana* and *Trishothadi Lepam* application was intended for healthy wound healing. Probably it will have an understanding of underlying mechanism of relieving vascular stasis, reducing venous congestion and beginning of re-vascularization and other wound healing process. These Blood-Letting procedures along with *Trishothadi Lepam* application probably work on the above said mechanism and establish a criteria of the wound healing mechanism & would become radical. The technique of *Siravyadhana* is widely found in management of Tropical Foot Ulcers across the classical texts in *Sushruta*, *Chakradatta*, *Vangasena*. The use of *Trishothadi Lepam* as a healing measure is also found in *Sushruta Samhita*.

Thus the study was conducted with the objectives of screening and compiling the available literature on Tropical Foot ulcer (*Vrana*), to diminish the detrimental

consequences associated with foot ulcers and to integrate traditional new wound healing technologies which are already mentioned in *Ayurveda* classics and to evaluate the effect of *Siravyadhana* alone and in combination with *Trishothadi Lepam*.

MATERIALS:

Details of study:-

Type of research work – Single blind comparative clinical study

Sample size – 20 patients

Source of collection of data –Patients suffering from Tropical foot ulcer, willing to participate in this clinical trial and fulfilling inclusive criteria were selected from OPD and IPD, Department of ShalyaTantra at TTD's Sri Venkateswara Ayurveda Hospital, Tirupati, Andhra Pradesh.

This study was conducted after taking written consent from the patient as per Helsinki declaration.

Ethical clearance was taken from Institutional Ethical Committee, Sri Venkateswara Ayurved College, Tirupati.

Inclusive criteria:-both sex within the group and 17- 70 years included for the study. **Exclusive criteria:**-Haemoglobin less than 10 gm%, Chronic systemic disorders, Renal failure, Heart ailments, AIDS, Tuberculosis and Hepatitis positive.

Investigations: – HB % level, Blood sugar level (FBS, PPBS), Bleeding time, Clotting time, Doppler study, Urine routine and microscopic, RFT, Others- X-rays, Biopsy to exclude concerned abnormality or Systemic disorders. A specific proforma was prepared and the patients of the present study.

Grouping :-

Group A	<i>Siravyadhana with Trishothadi Lepam</i>
Group B	<i>Siravyadhana</i>
Treatment plan	42 days (6 weeks), Weekly once <i>Siravyadhana</i> along with or without <i>Trishothadi Lepam</i> and Follow up for 3 months (every 15 days).

TREATMENT PROTOCOL:

2 groups had standard treatment protocol as mention below.

- Purva Karma* (Pre-operative measures) ^(4,5)
- Pradhana Karma* (Principle procedure) ^(4,5)
- Paschata Karma* (Post procedure measures) ^(4,5) ,
Trishothadi Lepam as external application) (5, Figure No.5)

GROUP A (*Siravyadhana with Trishothadi Lepam*)

Purva Karma ^(6,7)-Patients were subjected to *Abhyangam* and *Nadiswedanam* were done for 7 days. on 8 th day, preparation of *Uthapana* of *Sira* (prominence of vein) was done.

Pradhana Karma ^(6,7)-*Siravyadhana karma*-The *Uthapita sira* (vein) was punctured by

the scalp vein set in surrounding area of ulcer (4 *angulas* from the ulcer) and blood was withdrawn by syringe and amount of blood withdrawn was measured.

Paschata Karma ^(6,7)-.During the procedure, patient was carefully observed for any untoward complication. Dressing was done. Patient was advised to keep the foot end elevated, area dry, clean, avoid exertion, trauma and unwholesome diet. Freshly prepared *Trishothadi Lepam* applied on the ulcer from 2nd day of *Siravyadhana* procedure daily for 42 days.

GROUP B (*Siravyadhana*)

Siravyadhana procedure was followed as mentioned in Group A.

Study of Parameters: -Subjective parameters were Itching, Pain and Discharge (Table No. 1-3). Objective parameters were Wagner's Grade and Size of the ulcer (Table no.4).

Table No.1 Itching score criteria

Sr. No.	SCORING	CRITERIA
1.	0	No itching
2.	1	Often mild type of itching (1-2 times per day)
3.	2	Moderate itching episodes (1-2 times in a day)
4.	3	Moderate itching episodes (3 times and above)
5.	4	Severe itching episodes (continuous)

Table No.2 Pain Score criteria

Sr. No.	SCORING	CRITERIA
1.	0	No pain
2.	1	Localized feeling of pain during movement only but no feeling during rest
3.	2	Localized feeling of pain even during rest but not disturbing the sleep
4.	3	Localized continuous feeling of pain, radiating and not relived by rest
5.	4	Unbearable pain

Sr. No.	SCORING	CRITERIA
1.	0	No discharge
2.	1	Scanty and occasional discharge
3.	2	Frequent discharge with no bleeding on dressing
4.	3	Frequent discharge with bleeding on dressing
5.	4	Profuse, continuous discharge which needs frequent dressing

Sr. No.	SCORING	CRITERIA
1.	0	No ulcer in a high foot
2.	1	Superficial ulcer involving the full thickness but not underlying tissues
3.	2	Deep ulcer, penetrating down to ligaments and muscles, but no bone involvement or abscess formation
4.	3	Deep ulcer with cellulitis or abscess formation, often with Osteomyelitis
5.	4	Localized gangrene
6.	5	Extensive gangrene involving whole foot

Size of Ulcer-

The size of Ulcer of every patient was noted with the help of scale and assessed the area.

Follow up Study.

Follow up study was conducted for **3 months** after completion of the treatment (Every 15 days).

STATISTICAL ANALYSIS:

All information which were based on various parameters were gathered & Statistical analysis was carried out in terms of Mean (X), standard deviation (S.D.), Standard error (S.E.), paired test ('t') & finally result were incorporated term of Probability 'P' as-- $P < 0.050$ Insignificant, $P > 0.010$ Significant, $P > 0.001$ highly significant.

Observations- In this present trial, the causes of Tropical foot ulcer was found for

tobacco chewers in rural area farmers, having male female ratio was 34 and 06 respectively. Diabetic and Hypertensive patients were excluded in this trial. It is observed when all subjective parameters put together cumulative percentage of benefits across 2 groups, Group-B has shown highest percentage with 71.60% followed by Group-A (67.18%). Therefore it is predictable that the *Siravyadhana* is more effective method for the treatment of ulcers when used without specific *Lepam*. Also it is observed in objective parameters that maximum percentage of benefit is found in Group-B (*Siravyadhana*) which is followed by Group-A.

Results- Results was analysed based on Subjective and Objective parameters.

A. Effect of treatment on Subjective parameter – Itching, Pain, Discharge

Sr.No	Itching		Pain		Discharge		Total	
	BT	AT	BT	AT	BT	AT	BT	AT
1	1	0	2	0	1	0	4	0
2	2	1	1	0	2	1	5	2
3	4	3	3	1	2	0	9	4
4	4	3	4	2	1	0	9	5
5	2	0	2	0	1	0	5	0
6	3	0	2	0	3	1	8	1
7	1	0	1	0	2	1	4	1
8	4	3	3	1	4	3	11	7
9	3	2	2	0	3	2	8	4
10	3	2	2	0	3	2	8	4
Total	27	14	22	04	22	10	71	28
% of Benefit	48.14814		81.8181		54.5454		60.5633	
SD	0.6749		0.4216		0.4216		1.1595	
SE	0.2134		0.1333		0.1333		0.3667	
t value	6.0907**		13.5**		9**		11.72	
P value	<0.01		<0.01		<0.01		<0.01	

Effect of treatment on Objective parameter –Wagner’s Grade

Table No. 6 - Changes in Subjective Parameter in GROUP-B

S. No	Itching		Pain		Discharge		Total	
	BT	AT	BT	AT	BT	AT	BT	AT
1	3	2	1	0	2	1	6	3
2	3	1	3	1	2	0	8	2
3	3	0	3	1	3	1	9	2
4	4	3	3	0	4	2	11	5
5	3	1	2	0	3	1	8	2
6	2	1	1	0	2	1	5	2
7	3	1	3	0	4	2	10	3
8	3	1	3	0	3	1	9	2
9	3	1	3	0	4	1	10	2
10	1	0	2	0	2	0	5	0
Total	28	11	24	02	29	10	81	23
% of Benefit	60.7142		91.6666		65.5172		71.6049	
SD	0.6749		0.7888		0.5676		1.6865	
SE	0.2134		0.2494		0.1795		0.5333	
t value	7.9648**		8.8196**		10.5846**		10.87	
P value	<0.01		<0.01		<0.01		<0.01	

Sr.No.	Group-A		Group-B		Total	
	BT	AT	BT	AT	BT	AT
1	1	0	1	1	4	1
2	1	0	2	0	5	0
3	2	1	2	0	7	2
4	1	1	3	2	9	4
5	2	1	2	1	6	2
6	2	1	1	0	7	3
7	2	2	2	1	8	5
8	2	1	2	1	7	3
9	2	1	2	1	7	4
10	2	1	2	1	6	2
Total	17	09	19	08	67	26
Average	1.7	0.9	1.9	0.8	6.7	2.6
% of benefit	47.059		57.895		60.606	
SD	0.4216		0.5676		0.8162	
SE	0.1333		0.1795		0.2582	
t value	6**		6.12**		15.49**	
P value	<0.01		<0.01		<0.01	

Table no. 8- Effect of treatment on Objective Parameter on Size of Ulcer (Group wise in cm²)

Sr. No.	Group-A		Group-B		Total	
	BT	AT	BT	AT	BT	AT
1	1	0	2	0	13	0
2	0.5	0	16	0	19.5	0
3	15	8	3.75	0	42.75	8.29
4	1	0.25	30	20	71.25	48.25
5	0.25	0.01	1	0	4.25	0.1
6	15	12	1	0	28	21.3
7	4.5	4.5	4	0	34.5	19.5
8	12	10.5	4	2.25	21.5	13.5
9	4	1	12	8.75	46.5	31.75
10	16	9	1	0	19	9.09
Total	69.25	45.26	74.75	31	300.25	151.78
Average	6.92	4.52	7.47	3.1	30.02	15.17
% of benefit	34.6425		58.5284		49.4487	
SD	2.6367		4.8908		8.9956	
SE	0.8338		1.5466		2.8447	
t value	2.87*		2.82*		5.21*	
P value	<0.05		<0.05		<0.05	

Discussion-

The overall outcome is calculated in terms of percentage of benefits in reliving/improvement of subjective and objective parameters. The Group-B showing maximum percentage of benefit followed by Group-A. Hence it can be concluded that overall benefit is found maximum in Group-A where *Siravyadhana* with *Trishothadi Lepam* was administered. The drug *Trishothadi Lepam* might be shown the efficacy due to *Lekhana*, *Kledahara*, *Shoshana*, *Shotha* & *Dahahara*, *RaktaShodhaka* and *Twaka Prasadana* properties. *Siravyadhana* probably acted in healing of the wound due to its capability to

relieve the stasis of blood in the overloaded vessels which hampers the healing of wound and reduces venous congestion.

Mode of action of external application and procedures

Trishothadi Lepam ⁽⁸⁾ having *Prinana*, *Dhatuvardhana*, *Poshana* helped to reduce the **wound size** by promoting healing and the rate of contraction. Also it's *Sthambhana*, *Shoshana Karma* of *Kashaya*, *Tikta Rasa* and *Vishada Guna* with *Kledahara*, *Raktasthambhana*, *Chhedana* activities followed by *Krimighna Karma* leaded to prevention of any kind of

discharge, slough and secretions ^(9,10).

Tannins, Anthraquinone are known Anti-oxidants, Blood-purifiers with Anti-inflammatory actions ^(11,12). As the oxidation process hampers the wound healing, anti-oxidants protect the tissue from the oxidative damage ^(13,14). *Siravyadhana* probably relieves vascular stasis, reduces venous congestion and helps in beginning of revascularization.

Conclusion-

After the overall assessment of the procedure for their efficacy on Tropical foot ulcers, *Siravyadhana* has shown in edge for other methods. There were no complications and adverse reactions reported in the present trial validating the safety of methods. The status of completely healed ulcers was observed as healthy with light scar without spasm directs us to understand the 'Vaikrutapaham' method. Hence this procedure is found to be very much safe, simple, cost-effective, easily administered in the patients of foot ulcers leading them for complete healing avoiding the most unwanted outcome of amputation.

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