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An Effect of *Siravyadhana* Therapy along with *Trishothadi Lepam* on Foot Ulcers

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ABSTRACT

BACKGROUND - *Siravyadhana* (Blood-letting), a popular Para-surgical procedure in *Ayurveda* system of surgery is time tested. It has been used for Pain relieving and for expulsion of victimized blood from the body; however mechanism of these effects has not been studied.

OBJECTIVES-To evaluate the effect of *Siravyadhan*therapy alone and in combination with *TrishothadiLepam* and also to establish the role of *Ayurveda*(Classical) technique in the management of Foot Ulcers to make them much more valid and evidence based.

STUDY DESIGN-A single controlled clinical study having sample size 20 patients, from OPD and IPD, Department of Shalya-Tantra at TTD's S.V. Ayurveda Hospital, Tirupati,(AP), were selected on the basis of Inclusion and Exclusion criteria. **GROUPING- Group-A-**

Siravyadhana, **Group-B-** *Siravyadhana* with *TrishothadiLepam***DURATION**- 42 days (6 weeks),weekly once with follow-up for 3 months.Oxygen saturation was measured with Pulse Oximetry before and after the procedure. **MAIN OUTCOME MEASURE**-Wound healing was found faster in this procedure. **RESULTS**- *Siravyadhana* is the most efficacious procedure found in this trial.The statistical evaluations of all the results were displayed in the form of tables and graphs. **CONCLUSION**-It is found effective in the management of foot ulcers. This procedure showed good effect on inflammatory markers and enhanced the proper circulation at the site of foot ulcer. Application of *TrishothadiLepam* though did not show any extra advantage but proved good effects on Wound Healing.

KEYWORDS

Siravyadhana Therapy, TrishothadiLepam, Blood-letting, Foot Ulcers



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INTRODUCTION

Ulcer is a break in continuity of the covering epithelium, either skin or mucous membrane due to molecular death. Foot ulcer rates have increased by 50% between 1980-1990 as per the data from National Hospital Discharge Survey^{1,2}.

Contemporary science prescribes a number of analgesics, anti-inflammatory and local applications followed by surgery for the treatment of foot ulcers but they do not render full care or satisfaction. Moreover these are costly and arise with many adverse effects. Thus an alternative *Siravyadhana*^{3,4}, parasurgical procedure is safe, cost effective and result oriented *Ayurveda* remedy was tried, expecting to fulfil the pitfall of contemporary science. Also, there is need to ensure the disease pathology according to present condition with proper parameters and measures. The techniques of *Siravyadhana* is widely found in management of foot ulcers across the classical texts in *Sushruta*, *Chakradatta*, *Vangasena*. The use of *Trishothadi Lepamas* a healing measure is also found in *SushrutaSamhita*. Thus the study was conducted with the objectives of screening and compiling the available literature on 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 efficacy of *Siravyadhana* alone and in combination with *TrishothadiLepam*.

MATERIALS AND METHODS

Details of study:-

Type of research work – Single clinical study

Sample size – 20 patients

Source of collection of data –Patients suffering from 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 at S.V. Ayurved College, Tirupati. No SVAC-IEC-2010-11-127

Inclusive criteria:-Both sex within the group of 17- 70 years.

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</i>
Group B	<i>Siravyadhanawith TrishothadiLepam</i>
Treatment plan	42 days (6 weeks), Weekly once <i>Siravyadhana</i> along with <i>TrishothadiLepam</i> and Follow up for 3 months (every 15 days).

METHODS

Purva Karma (Pre-operative measures)
Pradhana Karma (Principal procedure)
Paschata Karma (Post procedure measures)
*Trishothadi Lepam*³ (external application)

GROUP A (*Siravyadhana*)⁵

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

Pradhana Karma-*Siravyadhana karma*-The *uthapitasira* (vein) was punctured by the scalp vein set in surrounding area of ulcer (4 *angulas* from the ulcer) and blood was withdrawn with the help of a syringe and then measured.

Paschata Karma- Dressing was done. During the procedure, patient was carefully observed for any untoward complication and then advised for unwholesome diet.

GROUP B (*Siravyadhana* with *TrishothadiLepamas* external application)

Same procedures followed as mentioned in Group A. Freshly prepared *TrishothadiLepam* applied on the ulcer from 2nd day of *Siravyadhana* procedure daily for 42 days.

Study of Parameters: - Subjective parameters were Itching, Pain and Discharge. Objective parameters were Wagner’s Grade and Size of the ulcer Table 1,2 and 3.

SUBJECTIVE PARAMETERS

Table 1 Itching score criteria

S.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 2 Pain Score criteria

S.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 relieved by rest



5.	4	Unbearable pain
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Table 3 Discharge criteria

S.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

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 parameter 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.

OBSERVATION AND RESULTS

Cumulative percentage of benefits across all the groups was seen and it was found that, Group-A has shown highest

percentage with 71.60% followed by Group-B, 67.18%, therefore it is predictable that the *Siravyadhana* is more effective method for the treatment of foot ulcers. Also, it is observed in objective parameters that maximum percentage of benefit is found in Group-A [Table No. 4,5,6,7& 8]. [Graph No.1]

A. Subjective – Itching, Pain, Discharge

B. Objective –Wagner's gradation, Size of Ulcer

Table 4 Wagner's Grade Score criteria

S.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

RESULTS AND DISCUSSION

Subjective Parameters

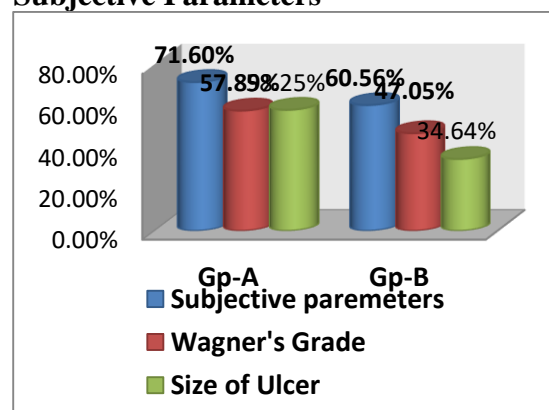


Fig 1 Accumulative % of Benefits



Table 5 Subjective Parameters of Group-A

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	

Table 6 Subjective Parameters of Group-B

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	

OBJECTIVE PARAMETERS

Table 7 Wagner's Gradation (Groupwise)

Sr.No.	Group-A		Group-B		Total	
	BT	AT	BT	AT	BT	AT
1	1	1	1	0	2	1
2	2	0	1	0	3	0
3	2	0	2	1	4	1
4	3	2	1	1	4	3



5	2	1	2	1	4	2
6	1	0	2	1	3	1
7	2	1	2	2	4	3
8	2	1	2	1	4	2
9	2	1	2	1	4	2
10	2	1	2	1	4	2
Total	19	8	17	9	36	17
Average	1.9	0.8	1.7	0.9	3.6	1.7
% of benefit	57.895		47.059		32.089	
SD	0.5676		0.4216		0.3174	
SE	0.1795		0.1333		0.1253	
t value	6.12**		6**		15.49**	
P value	<0.01		<0.01		<0.01	

Table 8 Size of Ulcer (Group wise in cm²)

Sr.No.	Group-A		Group-B		Total	
	BT	AT	BT	AT	BT	AT
1	2	0	1	0	3	0
2	16	0	0.5	0	16.5	0
3	3.75	0	15	8	18.75	8
4	30	20	1	0.25	31	20.25
5	1	0	0.25	0.01	1.25	0.01
6	1	0	15	12	16	12
7	4	0	4.5	4.5	8.5	4.5
8	4	2.25	12	10.5	16	12.75
9	12	8.75	4	1	16	9.75
10	1	0	16	9	17	9
Total	74.75	31	69.25	45.26	144	76.26
Average	7.47	3.1	6.92	4.52	15.01	7.62
% of benefit	58.5284		34.6425		49.4487	
SD	4.8908		2.6367		8.9956	
SE	1.5466		0.8338		2.8447	
t value	2.82*		2.87*		5.21*	
P value	<0.05		<0.05		<0.05	

DISCUSSION

The overall outcome was calculated in terms of percentage of benefits in reliving/improvement of subjective and objective parameters. *Siravyadhana* (Group-A Figure 1a, 1b) showed maximum percentage of benefit followed by Group-B (Figure 2a, 2b). The method of *Siravyadhana* without any specific *Lepamhas* shown remarkable significant



Fig 1a Group-A (*Siravyadhana*) Before Treatment



Fig 1b Group-A (Siravyadhana) After Treatment

improvement in the management of foot ulcers. *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.



Fig 2a Group-B (Siravyadhana with TrishothadiLepam) Before Treatment

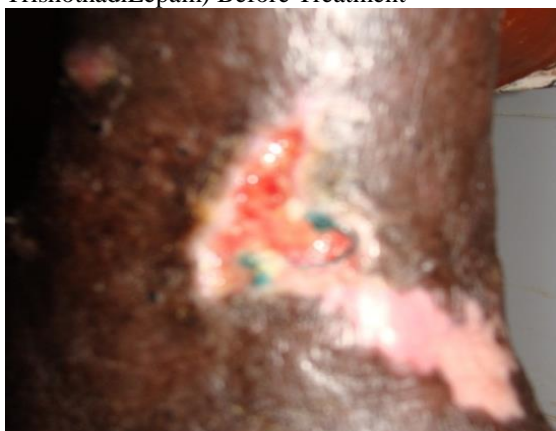


Fig 2a Group-B (Siravyadhana with TrishothadiLepam) After Treatment

Mode of action

TrishothadiLepam having *Prinana*, *Dhatuwardhana*, *Poshana* helped to reduce the **wound size** (Figure 3) by promoting healing and the rate of contraction. Also it's *Sthambhana*, *Shoshana Karma of Kashaya*, *Tikta Rasa and VishadaGuna with Kledahara*, *Raktasthambhana*, *Chhedana* activities followed by *Krimighna Karma* lead to prevention of any kind of discharge, slough and secretions. Tannins, Anthraquinone are known antioxidants, blood-purifiers with anti-inflammatory actions. As the oxidation process hampers the wound healing, antioxidants protect the tissue from the oxidative damage^{6,7}. *Siravyadhana* probably relieves vascular stasis, reduces venous congestion and helps in beginning of revascularization and other wound healing process.



Fig 3 TrishothadiLepam external application



CONCLUSION

After the overall assessment of the procedure for their efficacy on foot ulcers, *Siravyadhanah* 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. Hence this procedure was found to be very much safe, simple, cost-effective, easily administered in the patients of foot ulcers and also useful for prevention of amputation.



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