



Management of Sirajanya Dusta Vrana W.S.R to Varicose Ulcer.

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ABSTRACT: Varicose Ulcers are wounds which occur due to improper functioning of venous valves, usually of the lower limbs. It is one of the most serious chronic venous insufficiency complications, occurring in 70% to 90% of chronic wound cases. If this ulcer is not treated properly, it may get infected leading to cellulitis or gangrene and eventually may need amputation of the limb.

If the conservative management like compression stocking, foot elevation, antibiotics, regular dressing of wound fails, then surgical treatment like skin grafting, sclerotherapy, laser ablation or surgical correction of superficial venous reflux is done. However, recurrence of venous ulcers is common, ranging from 54 to 78% by the fifth year after healing.

In Ayurveda, varicose ulcers can be correlated with “*sira jayna dusta vrana*”. In Sushrut Samhita, where we get the most scientific description of wounds and its management. So these kind of wounds can be managed with the specific ayurvedic adjuvant therapies.

Considering all these, the present study was taken up with the objective of evaluating efficacy of *shanshamni vati* (internally) and *jatyadi taila* (local application) in the management of varicose ulcer. The symptoms like pain, oedema, hyper pigmentation, size of ulcer, granulation tissue were assessed during the treatment. The trial drug proved statistically significant in relieving the above symptoms. The results revealed that the estimated treatment showed significant improvement ($p < 0.01$) in all cardinal signs and symptoms. Adjuvant treatment with *jatyadi taila* (local application) and *shanshamni vati* (orally) statistically proved to be much potent and effective in management of varicose ulcer, hence study concludes ancient management is safe, easily available devoid of complication and has better acceptability.

Key words: *shanshamni vati*, *jatyadi taila*, Varicose ulcer management, *vrana upakarma*, *sira janya dusta vrana*.

INTRODUCTION:

Varicose vein are the part of penalty we pay for the adoption of erect posture. The overall incident rate is 0.76% in men and 1.42% in women.^{1} They are also known as stasis ulcer or venous ulcers and are most commonly seen in the female population. Most common aetiological factors include increased intra venous pressure secondary to DVT, chronic constipation, long standing occupation. Chronic long standing cases of

varicose veins renders valves incompetent resulting in venous hypertension allowing blood proteins fibrinogen leakage causing varicose ulcer. Deficiency in fibrinolysis causes fibrin to build up around vessels preventing oxygen and nutrients from reaching cells, these fibrin plugs causes ischemia resulting in delayed healing of wounds.^[2]

Venous hypertension damages capillaries of skin and subcutaneous tissues make them 'glomerulus like'(convoluted) resulting in fibroid process called lipodermatosclerosis from capillaries proliferation and inflammation which if uncontrolled progresses into venous ulceration.^[3]

Conservatively disease can be managed with compression stockings, foot elevation, antibiotics, and daily dressing of ulcer. Surgical management consist of ultrasound guided foam sclerotherapy, ELVA(Endo Venous Laser Ablation), RFA(Radio Frequency Ablation), Saphenofemoral ligation and Long saphenous vein stripping, skin grafting etc.^[4]

In Ayurveda, the comprehensive management of all *vranas*(wounds) is exclusively described by Acharya Sushruta under *shashthi upakarma* (sixty procedures).^[5] He has described wound from its different aspects right from the definition, causes, types and their management in detail. While describing the types of *vranas*, he mentioned the term *Dushtavrana* which is having clinical features which resembles to the non-healing type of wound according to present medical science. Acharya Sushruta has also explained about *vranas* (wounds) which is located in lower exrtemities eliminate (pus etc) from below in upper direction (anti gravity drainage) are difficult to cure. There are lot of drugs in different formulations, described for *vrana ropan* (wound healing) according to its site, types, chronicity but the management of *vranas*, particularly *dustavranas* (non healing ulcers) is still a challenge for surgeons.

Jatyadi taila have *vrana ropaka* (wound healing) and *vrana shodhana* (wound cleansing) properties which promote wound healing. *Sira* and *snayu* are bi product (*upadhatu*) of *rakta*(blood) and '*Shanshamni Vati*' (*guduchi- tinospora cordifolia*)^[6,7] have *raktaprasadniya* and *shodhak*(blood purification), *rakta vardhak*(improves haematopoiesis) and *shothhar*(anti inflammatory) characters, *guduchi* works as immune modulator. Hence it facilitates formation of healthy newer tissues which promote the wound healing. It also strengthens the blood vessels, thus venous valvular dysfunction. .

AIM OF STUDY: To clinically evaluate the efficacy of *Sanshamni Vati* (internally) and *Jatyadi Taila* (local application) in the management of varicose ulcer.

OBJECTIVES OF STUDY:

To evaluate the role of *sanshamni vati* in management of varicose ulcer.

To evaluate the role of *jatyadi taila* local application in the management of varicose ulcer.

To evaluate the role of *shanshamni vati* and *jatyadi taila* adjuvantly in management on the parameters of varicose ulcer, i.e. pain, size of ulcer, hyper pigmentation, granulation tissue, oedema.

TYPE OF STUDY: Open Non Comparative Clinical Study.

MATERIALS & METHODS:

SOURCE OF DATA: A open clinical study had taken up on the management of varicose ulcer. The sample size was 50 in total. The Patients were collected from inpatient & outpatient department of Shalyatantra of D.Y Patil Ayurvedic hospital by simple random sampling procedure, fulfilling the selection criteria.

DRUG AND DOSAGE:

Local application of *jatyadi taila* once daily.

shanshamni vati 250mg 2BD orally.

Duration - 8 weeks

Clinical features were recorded before the treatment that is on zero day. Changes with the treatment were observed from 1st week till 8th week, as per the Case Record Form of the case sheet, prepared for the study.

Follow up: Patients were advised to come to the hospital for daily regular dressing upto 6 weeks and further follow up after 2 weeks. Clinical observations were recorded systematically and thoroughly.

Advice: Above knee stockings, protein rich diet, two pillows leg elevation, avoid dressing soakage, avoid bare foot walking.

All the raw materials were collected from the local market. Its identification & authentication was done from Mithibai college botany department. The drugs were prepared according to textual reference in Rasa Shastra Bhaishajya Kalpana Department of D.Y. Patil school of Ayurveda. Standardization was done from Anchrom Lab. Mulund (east), Mumbai.

Ethical Clearance for the study was taken from Institutional Ethical Committee DYP AYU. PG/2014-15/20-9-2015.

Methodology:

Method of preparation:

Jatyadi taila:

Jatyadi taila was prepared by *snehpak vidhi* (medicated oil preparation methodology) according to sushrut samhita.^[8]

1part- *kalka dravya*; 4parts-*sneha dravya* (tila taila); 16parts- *drava dravya* (water).

1part each of *Manjistha* (*Rubia cordifolia*), *Haridra* (*Curcuma longa*), *Jati Patra* (*Myristica fragrans*), *Nimba patra* (*Azadirachta indica*), *Patola patra* (*Trichosanthes dioica roxb*), *Haritaki* (*Terminalia chebula*), *Karanja* (*Pongamia pinnata*), *Yasti* (*Glycyrrhiza glabra*), *Padamka* (*Prunus cyrasoidus*), *Katuka* (*Picrorrhiza kurrora*), *Kutaja* (*Holarrhena antidysentrica*), *Lodhra* (*symplocos racemosa*), *Kamala* (*Nelumbo nucifer*), *Daru haridra* (*Berberis aristata*), *Sariva* (*Hemidesmus indicus*), *Tuttha* (*CuSO₄*), beewax were taken. Thickly pulverized all these materials and triturated them on a stone slab along with water to obtain *kalka* (paste) out of it. Combine with tila taila (4parts) and water (16parts). Cooked the mix methodologically to obtain the medicated *jatyadi taila*.^[9]

Shanshamni vati:

Raw material (fresh thick bark) of *Guduchi* drug were cut in small pieces. Crushed the *guduchi* pieces then boiled it with 4 times water till left ¼th of it. Then this *guduchi kwatha* was boiled over *mandagni* (low heat) till it reached the thick consistency. Then contents were collected into the tray. The paste obtained was converted into *varti*. These *varti*'s were subjected into tablet cutting machine. Each tablet is of 250mg. Finally dried in dryer to reduce the moisture contents of it.^[10]

SELECTION CRITERIA:

INCLUSIVE CRITERIA:

Patients diagnosed with varicose ulcer.

Patients irrespective of sex, religion, occupation & economic status.

Patients in between the age group of 18 to 60 years.

Patients not enrolled in any other clinical trials.

EXCLUSIVE CRITERIA:

Patients having embolism, bleeding disorder, arterial occlusion disease other infective skin disorders etc.

Patients with immune-compromised diseases like HIV, HbsAg, Cancer etc.

Patient with Diabetes and Hypertension.

Patient with DVT and venous pump failure disease.

Patients with history of previous surgeries for varicose ulcer.

GRADATION OF PARAMETER:

The improvement in the patient was assessed mainly on the basis of relief in the cardinal signs & symptoms of the disease. To assess the effect of therapy, all the signs and symptoms were given scoring depending upon their severity as below:

Subjective and Objective Assessment-

Table -1 Showing the gradation of parameters for assesment.

	Parameter	Gradation
1.	Pain	Grade
	No pain	0
	Mild pain	1
	Moderate pain	2
	Severe pain	3
	Worst pain	4
	VAS Scale used for pain gradation-0=0, 1-3=1, 4-6=2, 7-9=3, 10=4	
2.	Size of ulcer	Grade
	absent	0
	25%	1
	50%	2
	Base line	3
3.	Hyper Pigmentation	Grade
	None	0
	Slight	1
	Medium	2
	Heavy	3
4.	Granulation Tissue	Grade
	100%	0
	75%	1
	Island	2
	No granulation	3
5.	Oedema (in cm)- at calf, ankle and foot	Grade
	Absent	0
	25%	1
	50%	2
	100%	3

Assessment criteria-Relief-

- Cured - 100 % relief (100% Improvement)
- Markedly Improved - 51 – 75 % relief (Marked Improvement)
- Improved - 26 – 50% relief (Moderate Improvement)
- No Change - Below 25% relief (No Improvement)

LABORATICAL INVESTIGATIONS:

- 1.CBC and ESR
2. Blood Sugar 1) Fasting 2) Post Prandial
3. BT, CT, PT
4. Venous Doppler study of lower limb.
5. Urine tests - Sugar, Albumin
6. HIV I & II,HBsAg

OBSERVATIONS& RESULT:

The observed data is grouped under two headings- Demographic analysis and clinical efficacy of treatment during study.

Demographic analysis-

The age wise distributions of 50 patients showed that maximum number of patients i.e. 46% belonged to age group of 45-54 years, followed by 34% patients to 55-64years and 16% patients to 35-44 years. Lastly 4% patients belonged to age Group of 25-34 years.

According to Gender - Among 50 patients, 62% i.e.31were males, 38% i.e.19 were females.

According to Occupation - Among 50 patients, 42% i.e.21 patients were businessmen, 22% i.e.11 patients were housewives, 22% i.e.11 patients were retired, 10% that is 5 patients were servicemen, 4% i.e.2 patients were waiters.

While observing the Nature of diet- it was found that mixed diet patients were majority in number 70% i.e. 35 patients and 30% i.e.15 patients were of vegetarian diet.

While observing Religion– out of 50 patients 86% i.e.43 patients are Hindus and remaining 14% i.e.7 patients are Muslims.

According to *Prakruti*– out of 50 patients 32% i.e.16 patients were of *Pitta-Kapha*, 32% i.e.16 patients were of *Vata-Kapha*, 26% i.e.13 patients were of *Vata-Pitta* and 10% i.e. 5 patients were of *Kapha-Pitta*.

While observing Socio-Economic status- out of 50 patients 62% i.e.31 patients were of upper and upper middle class, 26% i.e. 13 patients were of lower middle class and 12% i.e.6 patients were of lower class.

While observing family history- 70% i.e. 35 patients have no family history, while 18% i.e.9 patients had paternal family history, 12% i.e. 6 patients had maternal family history.

While observing Duration – out of 50 patients 30% i.e. 15 patients had history of varicose ulcer <12 months, 24% i.e.12 patients had history since 12 months, 14% i.e.7 patients had history since 24 months, 26% i.e. 13 patients had history since 36months, 6% i.e. 3patients had history since 48months.

Assessment of Results-

This combination of *jatyadi taila* local application and *shanahmni vati* orally have provenstatistically significant in the management of varicose ulcer, as the ‘p’ value <0.001.

For obtaining observations and results on gradation parameter Wilcoxon’s signed rank test and Paired Z test were used.

Table – 2: Gradation parameter Analysis of Patients (Before and After Treatment).

Assessment parameters	Gradation	Before Treatment		After Treatment	
		N	%	N	%
Hyper Pigmentation	None	0	0.0	20	40.0
	Slight	0	0.0	27	54.0
	Medium	3	6.0	3	6.0
	Heavy	47	94.0	0	0.0

Oedema Calf	Absent	0	0.0	31	62.0
	25%	0	0.0	19	38.0
	50%	3	6.0	0	0.0
	100%	47	94.0	0	0.0
Oedema Ankle	Absent	0	0.0	37	74.0
	25%	0	0.0	13	26.0
	50%	3	6.0	0	0.0
	100%	47	94.0	0	0.0
Oedema Foot	Absent	0	0.0	37	74.0
	25%	0	0.0	11	22.0
	50%	2	4.0	2	4.0
	100%	48	96.0	0	0.0
Granulation Tissue	100%	0	0.0	34	68.0
	75%	0	0.0	16	32.0
	Island	13	26.0	0	0.0
	No Granulation	37	74.0	0	0.0
Pain	No pain	0	0.0	32	64.0
	Mild	12	24.0	18	36.0
	Moderate	25	50.0	0	0.0
	Severe	13	26.0	0	0.0
	Worst	0	0.0	0	0.0
Size of Ulcer	Absent	0	0.0	37	74.0
	25%	0	0.0	13	26.0
	50%	2	4.0	0	0.0
	Base line	48	96.0	0	0.0

.All the parameters like Hyper pigmentation, Oedema calf, Oedema ankle, Oedema foot, Granulation tissue, Pain and size of ulcer are significantly changed after treatment of Patients. All the given parameters are statistically highly significant at 0.01% level i.e. $P < 0.001$.

Table – 3 show the statistical analysis of parameters of patients before and after treatment.

Parameter (Before Vs After)	Wilcoxon Signed rank Test	P-value	Significant at 5% level
Hyper pigmentation	6.327	<0.001	Yes
Oedema Calf	6.358	<0.001	Yes
Oedema Ankle	6.446	<0.001	Yes
Oedema Foot	6.486	<0.001	Yes
Granulation Tissue	6.306	<0.001	Yes
Pain	6.295	<0.001	Yes
Size of Ulcer	6.450	<0.001	Yes

Other Findings-

After assessing haematological investigations before and after treatment Hb, RBC, BT, CT are not statistically significant at 5% level i.e. $P > 0.05$ but WBC, ESR are statistically significant at 0.01% i.e. $P < 0.001$.

Table -4 showing the statistical analysis of investigations (before and after treatment).

Investigation	Treatment	N	Mean	Stdev.	Z – test	P value	Significant at 5% level
Hb	Before	50	12.3560	1.5508	-0.802	0.427	No
	After	50	12.4180	1.5834			
RBC	Before	50	4.3200	0.4607	1.248	0.218	No
	After	50	4.2760	0.5723			
WBC	Before	50	7624.00	1623.75	3.707	0.001	Yes
	After	50	6672.00	1162.87			
ESR	Before	50	28.1600	15.7199	5.872	0.000	Yes
	After	50	15.5800	12.0138			
BT	Before	50	1.7656	0.3610	-1.817	0.075	No
	After	50	1.8176	0.4659			
CT	Before	50	1.7656	0.3610	-1.817	0.075	No
	After	50	1.8176	0.4659			

RESULT:

Over all Effects of Treatment - 10% i.e. 5 patients are fully cured where as 54% i.e. 27 patients are relieved and remaining 36% i.e. 18 patients are markedly improved. But overall patients improvement are significantly visible. None of patient showed no improvement in size of ulcer and none of the patient showed worsened condition by this adjuvant treatment.

Table -5 Showing the overall result of *jatyadi taila* and *shanshamni vati* on 50 patients after treatment.

Result	No. of Patients	Percentage
Cured	5	10.0%
Relieved	27	54.0%
Markedly Improved	18	36.0%
No Improvement	0	0.0%
Worsened	0	0.0%
Total	50	100.0%

This study was based on clinical features like pain, hyper pigmentation, granulation tissue, size of ulcer, oedema and calf, ankle foot. Demographic analysis on Independent variables like Age, Gender, Economic status, Religion, Occupation, Diet, *Prakruti* and duration were assessed but not considered in drawing conclusion.

DISCUSSION:

Varicose ulcer and its complication are a common recurring problem. The management scheme for venous ulcer oedema, hyper pigmentation have been evolving through years, with the primary goal of reducing venous congestion and enhancing tissue perfusion and wound healing.

Typically conservative management with a regime of double elastic stockings, leg elevation at rest and calf muscle exercise, requires good and prolonged patient compliance and has its own problem.

According to Acharya Shushruta symptoms of *siragat vata janya dusta vrana* can be co-related to varicose ulcer and treatment regime for these kind of *vrana* has been explained in sixty measures of wound management.

The present study was carried out to establish potent *ayurvedic* adjuvant treatment for healing of varicose ulcer and reducing oedema, hyperpigmentation by getting rid of venous stasis. On the basis of this study we can conclude that ayurveda can give a ray of hope in treatment of varicose ulcer.

PROBABLE MODE OF ACTION-

Shanshamni vati have *guduchi* which comes in traditional rejuvenator Ayurvedic plant category. It supports in the functioning of the immune system by maintaining sufficient levels of WBC (white blood cells) such as macrophages. So it enhances immune system by expelling toxins from the body and rejuvenating the body. Hence it works as immune modulator. ^[11]

‘*Sira*’ and ‘*Snayu*’ are the bi product (*updhatu*) of *rakta* (blood) and ‘*shanshamni vati*’ has ‘*Raktaprasadniya*’ character. Hence, it facilitates formation of Healthy Newer tissues and also strengthens the blood vessels, thus corrects venous valvular dysfunction As per Ayurvedic texts, *guduchi* purifies the *Raktadhatu* due to its *Raktaprasadniya* character. Further, once *Rakta* is purified, its bi product (*updhatu*) i.e. *Sira* (veins) and its kinematics also gets pacified, thus may corrects venous valvular dysfunction when used internally along with the adjuvant treatment.

Tikta-kasaya rasa; madhura vipaka; usnavirya; tridosashmaka; dipaniya, and dahanashamak are its properties. The chloroform and benzene extracts of *guduchi* were found to possess significant antibacterial activity as compared with the standard. *Guduchi* leaf extract is useful in infections due to *Proteus vulgaris*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Bacillus subtilis*, and *Escherichia coli*.^[12]

Guduchi also includes tinosporal, clombin tinosporal, tinosporic acid and palmarin, the drug possesses 1/5th of the analgesic sodium salicylate effect, that is used commonly as an analgesic medicine. ^[13]

Jatyadi taila is good *shodhna* (cleansing) and *ropana* (healing) drug. Most of the ingredients used in *jatyadi taila* are *shothahara* (anti inflammatory), *vedanasthapana* (analgesic) and *ropaka* (wound healing), which are important requirements of healing of a wound and relieves pain too. The ingredients like *nimba patra* (*Azadirachta indica*) and *daruharidra* (*Berberiaristata DC*) are antibacterial and promote wound healing. ^[14]

CONCLUSION:

In this present work on varicose ulcer 50 patients were selected according to the criteria and *jatyadi taila* (daily dressing) was done and *shanshamni vati* (orally) were given for 6 weeks.

While observing Result 10% i.e. 5 patients are fully cured where as 54% i.e. 27 patients are relieved and remaining 36% i.e. 18 patients are markedly improved. But overall patients improvement are significantly visible. None of patient showed no improvement in size of ulcer and none of the patient showed worsened condition by this adjuvant treatment.

Jatyadi taila and *shanshamni vati* statistically also showed significantly decrease in venous congestion and resulting into reducing of edema and hyper pigmentation and increase granulation and result into wound healing.

These drugs do not affect the Hb, RBC, BT, CT but it help in decrease in WBC and ESR count.

The complication with such therapy are wound infection, hypersensitivity and bleeding. None of the complication was observed in this study. In view of no any adverse effects and affordable economically by all, it can be recommended in combination for adjuvant treatment of varicose ulcer.

FUTURE SCOPE AND LIMITATIONS:

Multi centric trial can be carried out with larger sample size.

In future it can be used as an alternative option to avoid modern treatment and surgery.

Histopathology study to prove the mechanism of healing of varicose ulcer with *jatyadi taila* can be done.

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