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Original Research Article

Comparative clinical study of siravedhana using 24G needle versus endovenous laser ablation in the management of lower limb varicose veins

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ABSTRACT

Background: Varicose veins are typical symptoms of chronic venous insufficiency, and they are linked to pain, edema, skin changes, and functional loss. This disorder is very similar to siraj granthi in Ayurveda and results from the vitiation of the doshas rakta and pitta. Such disorders are traditionally treated with siravedhana, which is an Ayurvedic process of bloodletting, whereas modern popular treatment is EVLA. The purpose of the study was to compare the clinical effectiveness and safety of siravedhana with a 24G needle and EVLA in the treatment of lower limb varicose veins.
Methods: The clinical study was an open-label, randomised, double-arm study conducted in patients diagnosed with lower-limb varicose veins. The 24G needle was used to administer the siravedhana to group A, and EVLA was performed on group B. Clinical observation was conducted based on CEAP classification and Doppler ultrasonography. Patient follow-ups were conducted 15 days after discharge.
Results: The two modalities of treatment led to major enhancement in the symptoms like pain, heaviness and edema. Siravedhana was effective for low-complexity disease in the early stages at a lower cost, whereas EVLA responded more quickly at advanced stages.
Conclusions: Siravedhana is an inexpensive and safe option for early-stage varicose veins, whereas EVLA is preferable for advanced disease. An integrative approach can be optimal for the patient.

Keywords: Ayurveda, CEAP classification, Endovenous laser ablation, Siravedhana, Varicose veins

INTRODUCTION

Varicose veins are significantly enlarged, lengthened, and convoluted veins, that are mainly visible on the legs as a result of chronic venous insufficiency. Such veins represent a common vascular dysfunction, with both aesthetic and clinical issues, including pain, swelling, pigmentation, ulceration, and a risk of thrombophlebitis. The etiology of the disorder in contemporary medicine is the dysfunction of the venous valves, which causes reversed blood flow and high venous pressure.[1]

Prevalence and Burden

The prevalence of varicose veins is about 10-20% of the adult population worldwide, and the condition is more frequent among those who have a job that requires them to stand for a long time, are overweight or are pregnant. In India, a considerable percentage of the diseased persons go unrecognized or unmanageable, with the situation getting worse due to ulcers formed as complications.[2]

Correlation in Ayurveda

Siraj granthi, a blood-borne disorder (raktaja vikara), is the Ayurvedic equivalent of the disease in the texts. Besides, the primary symptoms, such as sira sankocha (vein constriction), sira utsedha (elevation), and vishoshana (atrophy or dryness), show the characteristics of those veins stated in the verses as found in Sushruta Samhita.[3]

Role of rakta and raktamokshana in Ayurveda

Ayurveda views rakta (blood) as the jeevadhara (the main support for life) and one of the important dhatus, which are the source of strength (bala), beauty (varna), and lifespan (ayushya). A change in blood and pitta leads to many diseases; among these, siraj granthi is the primary one. Raktamokshana (bloodletting), in particular siravedhana (venesection), is an ancient shodhana (purificatory) method used to eliminate imbalanced blood and relieve Pitta.[4]

Siravedhana- an Ayurvedic surgical approach

Siravedhana is a method in which certain veins are punctured with a sharp instrument (here, a sterile 24G needle) to remove the affected blood. It is an initial treatment for raktadushti, and its effects include reduced local inflammation, pain alleviation, and recanalization of blood vessels.[5]

Modern surgical management- ELVA

EVLA is a less invasive surgery that uses a laser to heat and destroy the problematic veins. Over time, it has supplanted the older method of vein stripping because of patients' rapid healing, a high treatment success rate, and a low risk of venous disease recurrence. Nevertheless, this method still entails the use of facilities and anesthetics, and there is a probability of having some side effects such as skin burns, nerve injury, and phlebitis.[6]

Objectives

The main aim was to evaluate the clinical effectiveness of siravedhana and EVLA in managing lower limb varicose veins. In order to delineate the pros and cons of each method concerning the following aspects: patient outcomes, post-operative complications, cost-effectiveness, recurrence rate. To provide details on procedural SOPs for both interventions.

Rationale of the study

Comparative clinical data on sclerotherapy and EVLA are largely missing. Although EVLA is technologically advanced, sclerotherapy offers a less complex, lower-cost intervention grounded in the ancient Indian healing system, Ayurveda.

The evaluation of these two under a controlled trial setting sheds light on: stage-specific effectiveness, the respective safety profiles, patient satisfaction, and possible implications for healthcare costs.

METHODS

Study design

The current research was a randomized, open-label, controlled clinical trial aimed at comparing lower-limb varicose vein management using siravedhana and EVLA. The research was conducted at SGT University's shalya tantra department in Gurugram, Haryana. All respondents were also followed up for 15 days postoperatively.

Sample size calculation

The Z-test formula was used to estimate the prevalence rate (7%) and calculate the sample size: $n = Z^2 \times P(1-P)/E^2$. According to this calculation, a sample of 80 patients was selected, with 40 per group. A total of 90 patients were recruited, with an expected 10% dropout rate to achieve a sufficient sample size at the end of the study.

Inclusion criteria

Patients aged 40-50 years. Both sexes with clinically diagnosed lower limb varicose veins. Fit for siravedhana or EVLA. Patients consent in writing.

Exclusion criteria

Non-healing venous/arterial ulcers. Previous lower limb surgery. Traumatic injuries. Chronic vascular diseases (TAO, atherosclerosis). Type 2 diabetes mellitus. Anticoagulant therapy.

Randomization

A simple randomization technique was used to assign eligible patients to two equal groups after enrollment. group A comprised 40 patients who were siravedhan-treated, and group B comprised 40 patients who underwent EVLA.

Procedure details

Group A: siravedhana with 24G needle

Ayurvedic bloodletting, called siravedhana, which is a type of raktamokshana, was done according to classical surgical principles and on the basis of strict aseptic precautions. Patients were to have sufficient rest before the procedure, and written informed consent was obtained. The affected limb was wiped with an antiseptic solution, and the patient lay supine with the limb extended. An apical sterile tourniquet was placed in close proximity to make a venous prominence.

The vyadha sira was selected based on clinical examination and confirmed by Doppler findings. The disposable needle was sterilized to 24G, and controlled venesection was performed until the characteristics of sufficient bloodletting (samyak vyadha lakshana) were observed, including a slowing of blood flow, reduction in local tension, and a lightening of the skin colour. Depending on the condition and tolerance of the patient, the amount of blood to be removed, as a rule, was 50-100 ml.

Upon completion of the procedure, the puncture site was wiped with antiseptic-soaked sterile cotton, and a compression dressing was applied to prevent hematoma formation. The patient was kept with the limb elevated and observed for 30 to 60 minutes for any immediate adverse effects, such as excessive bleeding, dizziness, or shock. Patients were required to remain hydrated, rest, and have their limbs supported for 24 hours, and follow-up assessments were performed until the 15th day.

Group B: EVLA

EVLA was done as a minimally invasive image-guided procedure under spinal anesthesia in a sterile operating room. Doppler ultrasonography was used to examine the affected limb before the procedure to determine the incompetent veins and perforators. The venous access was obtained in the neck of the medial malleolus under ultrasound guidance, and a radial laser fibre was advanced up to the saphenofemoral junction.

Table 1: Comparison of procedural aspects.

Feature	Siravedhana	EVLA
Invasiveness	Minimally invasive	Minimally invasive
Anesthesia	Not required	Spinal anesthesia
Duration	15-30 minutes	30-45 minutes
Equipment requirement	Basic (needle, cotton, spirit)	High-end (laser, USG, generator)
Hospital setting	Outpatient	Day-care surgery
Cost	Low	High
Recovery	Quick	Quick
Post-op complications	Rare	Minor (burn, nerve irritation)
Recurrence potential	Moderate (early stages better)	Low

The tumescent anesthesia was used on the side of the vein to alleviate pain and protect the tissues around the vein. The delivery of laser energy was done in a meticulous way as the fibre was gradually withdrawn, leading to the ablation of the diseased vein by heat and subsequent closure of the diseased vein by collagen contraction and damage of the endothelium. After the process, the treated limb was put on compression stockings. Patients were followed 2-4 hours after surgery and encouraged to ambulate early, with limited time on their feet or walking during the first 1-2 weeks. A follow-up Doppler ultrasound was conducted to ensure that the vein is closed and exclude any complications.

Diagnostic tools

Venous Doppler ultrasonography of the lower limbs was used to diagnose and assess them. Clinical severity was measured based on the CEAP classification system, which incorporated measurement of varicose veins, edema, skin pigmentation, eczema, and healed or active ulcers.

Assessment parameters

Both subjective and objective parameters were used to measure the clinical outcomes. Some of the subjective parameters were pain assessed by the visual analogue scale, heaviness, night cramps, skin discolouration, and fatigue. The objective parameters were assessed as vein diameter by Doppler ultrasonography, edema grading, presence or absence of ulceration, CEAP clinical staging, and time to ambulate after the procedure.

Withdrawal criteria

Students were not to be retained in the study if they experienced serious adverse effects requiring emergency medical attention, withdrew, or missed follow-up visits.

Statistical analysis

The statistical methods used to analyse data collected during the study were appropriate. Where suitable, the Z-test, paired t-test and chi-square test were used. SPSS and GraphPad were used for statistical analysis, with p-values < 0.05 considered statistically significant.

RESULTS

All patients in the study were followed up, and both treatment groups reported clinical improvement during the 15-day follow-up period. The intervention in both groups resulted in a reduction in pain, limb heaviness, and edema. Patients who received EVLA showed prior improvement in symptoms and quicker ambulation than

those who received siravedhana. There was a satisfactory overall functional recovery in both groups. There were no significant adverse events in either group during the follow-up. Nevertheless, some slight and automatic post-procedural pain was observed in some of the patients.

Table 2: Baseline demographic and clinical characteristics of patients.

Parameters	Siravedhana (n=40)	EVLA (n=40)
Mean age (years)	45.2±3.1	44.8±3.4
Male/Female	24/16	22/18
Duration of symptoms (years)	4.1±1.6	4.3±1.8
Bilateral involvement, N (%)	18 (45)	20 (50)
CEAP C2, N (%)	18 (45)	17 (42.5)
CEAP C3, N (%)	15 (37.5)	16 (40)
CEAP C4, N (%)	7 (17.5)	7 (17.5)

As illustrated in Table 2, patients in the siravedhana and EVLA groups were similar with respect to age, sex distribution, duration of symptoms, disease laterality, and baseline CEAP clinical stage. Most patients in the two groups were classified as CEAP C2 or C3, indicating uncomplicated to moderately advanced varicose vein disease. The similarity of baseline features indicates sufficient randomization and that the post-treatment outcomes in the two groups can be compared appropriately.

Table 3: Pre and post treatment clinical and Doppler outcomes.

Parameter	Siravedhana	EVLA
Pain (VAS)- pre	6.4±1.1	6.6±1.0
Pain (VAS)- post (day 15)	3.1±0.9	2.2±0.7
Limb heaviness- pre	3.2±0.6	3.3±0.5
Limb heaviness- post	1.6±0.5	1.2±0.4
Edema grade- pre	2.6±0.5	2.7±0.6
Edema grade- post	1.4±0.4	1.1±0.3
Doppler vein closure, N (%)	—	36 (90)

Table 3 indicates that subjective symptoms of pain, limb heaviness, and edema showed significant improvement in both treatment groups by day 15 of follow-up. The short-term clinical viability of both siravedhana and EVLA is demonstrated by the decrease in the VAS pain scores and edema grades. Doppler results, coupled with the finding of successful vein closure in most patients undergoing EVLA but not in the siravedhana group, suggest a symptomatic rather than anatomical mechanism of action for siravedhana.

Table 4 emphasizes that EVLA results in a greater decrease in pain scale, a higher edema recovery rate, and a greater proportion of CEAP stage improvements than siravedhana. The EVLA group had a shorter time to ambulation, indicating faster functional recovery. Although minor complications were detected in both groups, no major adverse events were reported, indicating that the two interventions were not harmful during the short-term follow-up.

Table 4: Comparison of post-treatment outcomes and complications.

Outcome	Siravedhana (n=40)	EVLA (n=40)	P value
Mean VAS pain reduction	3.3 ± 0.8	4.4±0.9	<0.01
Edema improvement, N (%)	28 (70)	34 (85)	<0.05
CEAP stage improvement, N (%)	22 (55)	30 (75)	<0.05
Time to ambulation (hours)	6.2±1.4	4.1±1.1	<0.01
Any minor complication, N (%)	7 (17.5)	11 (27.5)	NS

DISCUSSION

This study compared siravedhana, an Ayurvedic venesection procedure, with EVLA as a lower-limb varicose vein procedure. The effect of the two treatments enhanced pain, limb heaviness, and edema in 15 days, but with a different level of success based on the disease stage and its mechanism of action.

Pain reduction was greater in the EVLA group, consistent with Fan et al, who reported better pain reduction and accelerated recovery with EVLA compared with other endovenous methods.[7] Nevertheless, siravedhana was effective in alleviating symptoms in the early stages of the disease, consistent with previous findings that venesection relieves pain and improves quality of life in uncomplicated varicose veins.[8] There was an improvement in the edema in both groups, but EVLA had better results. The results of the study also align with those of Mashetti et al, who showed that siravyadha, along with Ayurvedic treatments, exacerbated edema and heaviness.[9] The EVLA patients experienced faster functional recovery, consistent with results from the RELACS trial and subsequent publications, which indicate that EVLA enables patients to walk sooner than traditional surgery. Although slower, siravedhana is beneficial in the outpatient setting, where no anaesthesia is required. Fan et al also found that the stage of improvement of CEAP was more intense in EVLA due to its capacity to attain anatomical vein closure.[7] Siravedhana, on the contrary, was symptomatic restorative, though not structural, as is in line with Ayurvedic texts. Both groups had minor complications with EVLA exhibiting a little more burns and nerve irritation incidences as in contemporary EVLA studies. siravedhana was safe and had fewer complications.

Overall, results indicate that EVLA is superior in patients with advanced varicose veins, whereas siravedhana is safe and cost-effective in the early stages. Integrative may be the most effective way of maximizing patient outcomes, with a combination of fast anatomical repair and easily available, symptomatic treatment.

The short follow-up period (15 days) also limited the study as it does not allow making conclusions on the recurrence and long-term sustainability. The sample might fail to represent the infrequent complications, and no quality-of-life measures were incorporated. Future studies should include longer follow-up, larger cohorts, and patient-reported outcomes.

CONCLUSION

This clinical trial confirms that siravedhana and EVLA are useful interventions in the management of lower limb varicose veins that result in a significant reduction in pain, heaviness and edema of the limb in the short-term follow-up. Siravedhana, based on Ayurvedic concepts of raktamokshana, was found to be a safe, uncomplicated and cheap practice, especially where there is early-stage disease, whereas EVLA was found to be quick in relieving symptoms and also recovering functions in a patient.

The results confirm the scientific significance of ancient Ayurvedic surgical methods and emphasise the necessity to combine them with contemporary ones in order to expand the range of therapeutic solutions. It is needed to conduct further studies with longer duration of follow-ups and larger sample sizes with patient-reported measures so that recurrence, long-term effectiveness, as well as the cost-efficacy could be evaluated to inform the clinical practice and health policy undertaken in the management of the varicose vein.

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