

## **Perforator Ligation versus Open Ligation of Perforators – A Comparative Study in Management of Perforator Incompetence in Varicose Vein**

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### **Abstract**

**Introduction:** Varicose veins are dilated tortuous and thickened veins. Chronic venous insufficiency have varied spectrum of clinical features and global prevalence rates of are variable. All of these ultimately lead to prolonged morbidity and decreased quality of life. The only way to tackle this pathway is by performing direct perforator vein division preferably by subfascial endoscopic perforator ligation surgery for perforator incompetence.

**Objectives:** To assess the benefits of subfascial endoscopic perforator surgery (SEPS) for the treatment of venous leg ulcers in terms of alleviation of symptoms, ulcer healing and recurrence v/s the conventional open method of perforator ligation

**Materials and Methods:** A total of 30 adult patients of either sex with primary varicose vein and perforator incompetence with or without secondary skin changes admitted in our hospital during January 2017 to June 2019 were taken into the study. All patients underwent surgical management with multiple open perforator ligation or subfascial endoscopic perforator ligation. Patients were

followed up for a minimum period of 3 months with serial clinical & radiological assessment.

**Results:** The right side was involved in 28 patients and the left side was involved in 22 patients. Bilateral involvement was observed in 10 patients. In case of bilateral involvement, surgery was done on the more affected side (the right side in 4 patients, and the left side in 6 patients). Dilated and tortuous veins were the commonest presenting complaints. They were present in all the patients. With intervention the number of perforators ligated in SEPS was more and also SEPS has fewer incidences of wound complications which were considerably high in the open ligation group.

**Conclusion:** Subfascial endoscopic perforator vein surgery is a safe and effective method for treating incompetent perforating veins. Hence, SEPS should be added to varicose vein surgery for the management of incompetent perforators to reduce long-term recurrences and better immediate wound healing.

**Keywords:** Chronic venous insufficiency, minimally invasive, multiple open perforator ligation, SEPS, wound healing, complications, recurrence.

## **Introduction**

Varicose veins are dilated tortuous and thickened veins. Although less commonly perceived, many aspect of venous diseases are more complicated and then the associated arterial diseases with chronic venous insufficiency(CVI) having varied spectrum of clinical features ranging from being asymptomatic, telengectasia, heaviness of limb to oedema, lipodermatosclerosis and ulcerations usually over the medial aspect of leg. Hence it is a cause of significant morbidity. But just like in arterial system, the maintenance of regular and effective flow within the veins depend on effective interaction of muscular pumps and functional conduit where the perforating veins perform a normal function in transporting superficial venous blood inward to deep veins for further transmission into the heart.

Global prevalence rates of CVI are variable. It has been estimated that approximately 1-2% of the adult population presents with lower-limb ulceration, from which 70-90% of these ulcers are attributed to CVI<sup>[1]</sup>. In addition, for each patient with frank ulceration, there are up to 30 patients with lipodermatosclerosis<sup>[2]</sup>. Between sex, the prevalence may be as high as 40% among females and 17% among males<sup>[3]</sup>.

The traditional treatment of venous ulceration is conservative. This includes extremity elevation, graded compression, wound care, and patient education. Due to prolongation of symptoms, some form of surgical intervention is necessary as the patients with chronic venous insufficiency usually do not stick to conservative management which can be both cumbersome and an economic burden to the person and the health care system. The incompetent perforators which are sometimes very big in size, have a definite role in the pathophysiology of chronic venous insufficiency, and they need ligation either

by open surgery or by subfascial endoscopic perforator surgery (SEPS).

Primary valvular incompetence leading to cutaneous venous hypertension in 60% of the patients results in a series of cutaneous manifestation which in its severe form presents as ulcers over the medial malleolus. The deep venous system communicates with the superficial system by the perforators with inward flow. Perforator incompetence is one of the leading cause for chronic venous insufficiency in lower limbs Many studies have demonstrated that most patients with venous or varicose ulcers or long standing venous insufficiency have a large number of incompetent perforators compared to patients with uncomplicated varicose veins.

The rationale for ligating incompetent perforators lies in preventing abnormal pressure transmission from the deep to the superficial veins, thereby decreasing ambulatory venous hypertension. Although described nearly 70 years ago<sup>[4]</sup>, the role of such operations in the treatment of venous ulcers remains controversial. The classic papers of Linton<sup>[4,5]</sup> and Cockett and Jones<sup>[6]</sup> and Dodd and Cockett<sup>[7]</sup> reported open perforator ligation to be beneficial. However wound complication rates were high with associated delayed ulcer healing and increased incidence of recurrence on prolonged follow up were noted.

The only way to tackle this pathway is by performing direct perforator vein division preferably by subfascial endoscopic perforator ligation surgery for perforator incompetence.

**Objectives** To assess the benefits of subfascial endoscopic perforator surgery (SEPS) for the treatment of venous leg ulcers in terms of alleviation of symptoms, ulcer healing and recurrence v/s the conventional open method of perforator ligation.

## **Materials and Methods**

It was a single centre prospective study. And the study was conducted in Dept. Of General Surgery, ESIC MC PGIMSR, Rajajinagar, Bangalore. Ethical clearance from the institute was obtained prior to commencement of the study.

**Sample Size:** 30 patients in each group were selected by systematic sampling method.

**Study Period:** January 2018 – Jun 2019

### **Inclusion Criteria**

All patients 18yrs and above who have given written consent to be part of the study group who were diagnosed with primary varicose veins involving the lower limb with multiple incompetent perforators ± secondary skin changes or venous ulceration.

### **Exclusion Criteria**

1. Deep venous occlusion
2. Arterial occlusive disease
3. Infected ulcers
4. Recurrent varicose vein
5. Previously operated limb
6. Pregnancy
7. Those not willing to participate in the study

### **Methods**

After taking history with clinical examination, demographic data recorded, preop work up done with colour Doppler and perforators were marked. Data collected and recorded on printed proforma. Superficial venous incompetence was treated with flush saphenofemoral ligation. Patient divided into two groups' one undergoing open ligation and other into SEPS group.

### **Preoperative Preparation**

Pre-operative evaluation included duplex scanning of the affected limb and the incompetence in superficial, deep and perforator levels were documented. The incompetent perforator vein on the skin was marked accurately using

a skin marker on the day of surgery using doppler which helps the surgeon during surgery. All patients received a single dose prophylactic antibiotic just before induction of anaesthesia for patient with active ulcers.



Fig. 1: Doppler guided perforator marking

### **Steps Procedure**

- The leg is then positioned with the knee and ankle elevated on padded stands so that the lower leg is elevated and parallel to the table
- Two incisions are placed in the upper calf outside the limit of lipodermatosclerosis.
- The first incision is placed 2 cm from the edge of the tibia and at least 10 cm distal to the tibial tuberosity.
- Small retractors are used to directly visualize the fascia, which is then incised.
- A 10 mm port is then placed in the initial incision, and the subfascial tunnel is expanded and maintained with CO<sub>2</sub> insufflation to 15 mm Hg.
- A 0° scope of 10 mm introduced which aids in blunt dissection and visualization.
- A 5 mm port is then placed approximately 5 cm lateral and distal to the first incision

- Connective tissue bridging the subfascial plane is taken down by blunt dissection
- After interruption of all perforating veins, the tourniquet is released and the ports are removed. The incisions are closed and the leg wrapped with an ace bandage.



Fig. 2: Exploration of Subfascial space

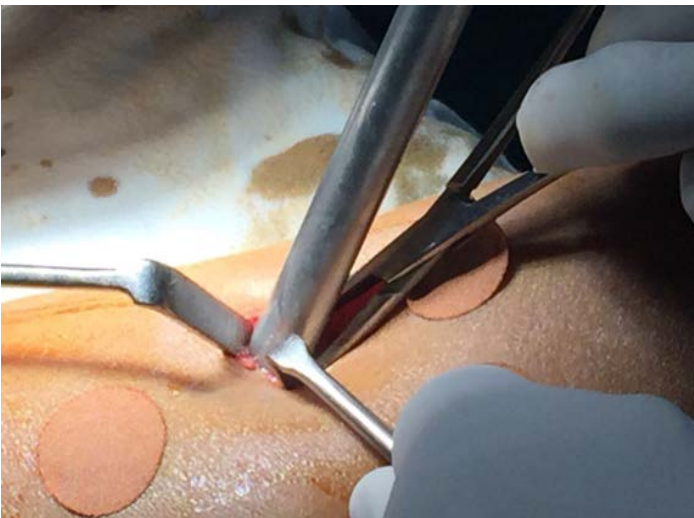


Fig. 3: insertion of 10mm scope



Fig 4- Course of GSV on illumination

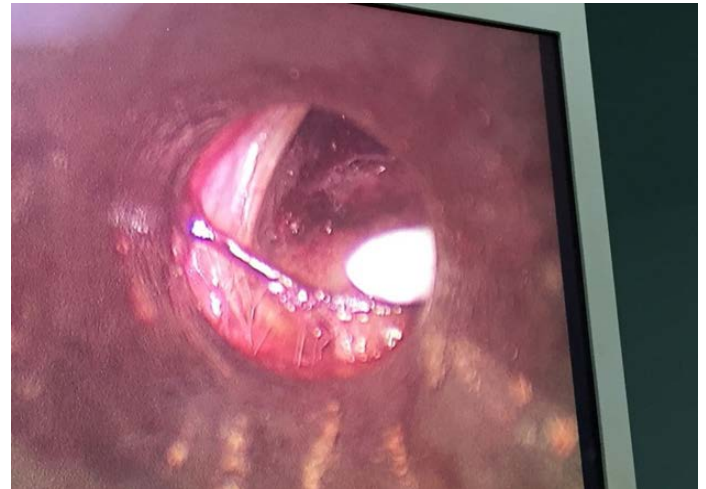


Fig. 5: Incompetent perforator vein

#### Open Perforator Ligation Procedure

- Multiple small transverse incisions are made on the previously marked perforator site
- Skin opened and subcutaneous tissue separated
- T junction visualised by tracing the superficial dilated vein
- Perforators are ligated deep to deep fascia using vicryl 2-0
- On completion of the procedure carbon dioxide is expressed out manually. Wound closed primarily. Limb elevated and wrapped in an elastic bandage.

#### Post-operative assessment

Once the spinal anaesthesia wears off, the patients were encouraged to ambulate on the same day as surgery and all patients received antibiotics for 48 hours post-surgery. Patients were discharged in 3-6 days with post-operative instructions on ambulation, limb elevation and maintaining the elasto-crepe compression bandage regularly. Ulcer dressings were done regularly and skin sutures removed on follow up with assessment of clinical symptom reduction and ulcer size reduction at 1, 2 and 3rd week post-surgery.

All patients were also treated with ambulatory compression therapy for the duration of at-least 3 months

**Follow up**

Included routine visits at POD 2, 1week, 2 weeks, 6 weeks and 3 months. Physical examination and duplex scan were used to detect residual perforating veins.

**Results**

Our present study consisted total of 60 cases of varicose veins diagnosed with primary varicose veins of lower limb with incompetent saphenofemoral junction and multiple medial and posterior leg perforator incompetence with or without secondary skin changes and venous ulcers. Of these all 60 cases underwent saphenofemoral flush ligation by trendelenburg procedure and the perforators were addressed either with open perforator ligation or subfascial endoscopic perforator ligation surgery. Our study included patients with 30 cases who underwent multiple open perforator ligation and other 30 cases who underwent subfascial endoscopic perforator surgery. This study was conducted from January 2018 – June 2019.

The following observations were made in our study.

Table 1 shows the age wise distribution of the study participants in both Subfascial Endoscopic Perforator Ligation and Open Ligation of Perforators group. Among variants of Sub facial Endoscopic Perforator Ligation group, about 60% were under age 40 years and 40.0% were ≥40 years. Similarly, among Open Ligation of Perforators group, about 63.3% were under age 40 years and 36.7% were ≥40 years. Chi square test was applied to analyse the homogeneity of the age distribution among both the groups related to the strata of age groups. Analysis shows, there is no statistically significant difference related to age distribution between both the groups. (p=0.26). Independent t test shows, there was no significant difference related to mean age between both the groups. (p=0.13).

Table 1: Distribution of Age among the study participants

AGE (YEARS)	SEPS	OPEN LIGATION	TOTAL	P VALUE
<40	18(60.0)	19(63.3)	37(61.7)	0.26
≥40	12 (40.0)	11(36.7)	23 (38.3)	
Total	30(100.0)	30(100.0)	60(100.0)	
Mean age	39.2±8.0	38.4±7.0	-	0.13

Chi square test, Independent t test, sig. 2 tailed, p<0.05

Table 2 shows the gender wise distribution of the study participants in both Subfascial Endoscopic Perforator Ligation and Open Ligation of Perforators group. Among variants of Sub facial Endoscopic Perforator Ligation group, about 30.0% were females and 70.0% were males. Among the Open Ligation of Perforators group, about 10.0% were females and 80.0% were males. Chi square test was applied to analyse the homogeneity of the gender distribution among both the groups. Analysis shows, there is no statistically significant difference related to gender distribution between both the groups. (p=0.745).

Table 2: Distribution of Gender among the study participants

	SEPS	Open Ligation	Total	Chi Square	P- value
Male	21(70.0)	27(90.0)	48 (80.0)	1.475	0.745
Female	9 (30.0)	3 (10.0)	12 (20.0)		
Total	30 (100.0)	30 (100.0)	60 (100.0)		

Chi square test, sig. 2 tailed, p<0.05

Table 3 shows distribution of comorbidities among the study participants in in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group. About 13.3% had co morbidities in both Sub facial Endoscopic Perforator Ligation and Open Ligation of Perforators group.

There was no significant difference between both the groups. (p=1.00).

Table 3: Distribution of comorbidities among the study participants

		SEPS	Open ligation	Total	Chi Square	P- value
Comorbidities	No	26(86.7)	26(86.7)	52(86.7)	0.00	1.00
	Yes	4(13.3)	4(13.3)	8(13.3)		
Total		30(100.0)	30(100.0)	60(100.0)		

Table 4: Distribution of lipodermatosclerosis among the study participants

		SEPS	Open ligation	Total	Chi Square	P- value
lipodermatosclerosis	No	26(86.7)	19(63.3)	45(75.0)	4.492	0.032
	Yes	4(13.3)	11(36.7)	15(25.0)		
Total		30(100.0)	30(100.0)	60(100.0)		

Chi square test, sig. 2 tailed,  $p < 0.05$

Table 4 shows distribution of lipodermatosclerosis among the study participants in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group.

About 13.3% had lipodermatosclerosis in Open Ligation of Perforators group and 36.7% had lipodermatosclerosis in

Sub facial Endoscopic Perforator Ligation. There was significant difference between both the groups. ( $p=0.032$ ).

**Table 5:** Distribution of ulcer presence among the study participants

		SEPS	Open ligation	Total	Chi Square	P- value
ulcer presence	No	28(93.4)	25(83.3)	53(88.3)	1.451	0.42
	Yes	2(6.6)	5(16.7)	7(11.6)		
Total		30(100.0)	30(100.0)	60(100.0)		

Chi square test, sig. 2 tailed,  $p < 0.05$

Table 5 shows distribution of ulcer presence among the study participants in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group. About 6.6% had ulcer in Open Ligation of

Perforators group and 16.7% had ulcer in Sub facial Endoscopic Perforator Ligation. There was no significant difference between both the groups. ( $p=0.42$ ).

Table 6: Distribution of Recurrence among the study participants.

Table 6 shows distribution of Recurrence among the study participants in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group. About 20% had recurrence in Open Ligation of Perforators group and 13.3% had ulcer in Sub facial Endoscopic Perforator Ligation. There was no significant difference between both the groups. ( $p=0.474$ )

		SEPS	Open ligation	Total	Chi Square	P- value
Recurrence	No	24(80.0)	26(86.7)	50(83.4)	0.784	0.474
	Yes	6(20.0)	4(13.3)	10(16.6)		
Total		30(100.0)	30(100.0)	60(100.0)		

Chi square test, sig. 2 tailed,  $p < 0.05$

Table 7: Distribution of Hematoma among the study participants

		SEPS	Open ligation	Total	Chi Square	P- value
Hematoma	No	26(86.7)	30(100.0)	56(93.3)	4.258	0.031
	Yes	4(13.3)	0(0.00)	4(6.7)		
Total		30(100.0)	30(100.0)	60(100.0)		

Chi square test, sig. 2 tailed,  $p < 0.05$

Table 7 shows distribution of Hematoma among the study participants in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group. About 13.3% had hematoma in Open Ligation of Perforators group and none of the subjects had hematoma in Sub facial Endoscopic Perforator Ligation. There was significant difference between both the groups. ( $p=0.031$ ).

Table 8: Distribution of Surgical site infection among the study participants.

		SEPS	Open ligation	Total	Chi Square	P- value
SS infection	No	25 (83.3)	30 (100.0)	55 (91.6)	5.224	0.012
	Yes	5 (6.6)	0 (0.0)	5 (8.4)		
Total		30(100.0)	30 (100.0)	60 (100.0)		

Chi square test, sig. 2 tailed,  $p < 0.05$

Table 8 shows distribution of Surgical site Infection among the study participants in both Sub-facial Endoscopic Perforator Ligation and Open Ligation of Perforators group. About 6.6% had surgical site infection in Open Ligation of Perforators group and none of the subjects had surgical site infection in Sub facial Endoscopic Perforator Ligation. There was significant difference between both the groups. ( $p=0.012$ )

Table 9: Mean difference between the study participants

	group	Mean	Std. Deviation	Std. Error Mean	T test	P value
Ulcer size	open	.050	.2013	.0368	2.006	0.005
	SEPS	1.500	3.9545	.7220		
Healing time	open	.93	3.552	.648	12.74	0.012
	SEPS	3.73	8.956	1.635		
Hospital stay	open	3.10	.803	.147	1.74	0.414
	SEPS	3.80	.805	.147		
Return to normal activity	open	6.13	2.529	.462	4.74	0.041
	SEPS	6.53	2.897	.529		

Table 9: Hospital stay between all the post op cases dint show any difference. Even though the average ulcer size was greater in the case of Sub-facial Endoscopic Perforator Ligation group. Average Healing time and time return to normal activity was higher for the Sub-facial Endoscopic Perforator Ligation group with significant data between the two.

## Discussion

Ours was a prospective longitudinal study with clinical outcomes of subfascial endoscopic perforator surgery comparing it with multiple open perforator ligation – addressing the incompetent perforators in leg, after flush ligation of saphenofemoral junction, with a study population of 30 patients. Duplex scan was used to confirm the perforator vein incompetence of whom majority of the population belonged to CEAP classification of 4, 5 and 6. Mean age of patients presented in our study were in the range of 37.5 years with 70% males and 30% females included in our study with right side more commonly involved then left side. A study conducted by M.G.Vashist and Nitin Singhal in Indian journal of surgery in 2014 also showed similar figures[6]. Another study reported by Synbrandy et al showed reported 31% males and 69% females [7]. Tenbroocket al[8] have compared data from 20 studies and an overall average sex distribution was 51% females and 49% males. The reason for male predominance in our study could be because more number of males working in ESI corporation majority belonging to working class with long hours of standing. Our study also showed that majority of our patient were in the age group of <40 years(63%) and rest were above the age of 40years(36.7%). A study published in 2014 in Indian journal of surgery also observed that 58 out of 100 patients were in the age group of 16-35 with a mean of 33.6 years, which was like our study. The diagnosis of varicose vein associated Comorbidities in our study group was negligent with hypertension being the most common. About 25% of our study group had secondary skin changes but only 11% had overlying ulcer. Majority of these patients underwent SEPS. Most patients in our study had a perforator incompetence in the right lower limb (60%) and left side in (25%) and bilateral disease (15%). In case of bilateral disease in the limbs with advanced CEAP and VCSS score

were operated. Gloviczki et al[9] reported right sided involvement in 49% patients and left in 46% of patients and bilateral in 5% of patients under study. Hauer et al 26 reported 19% right sided chronic venous insufficiency and 35% on the left side In our study the mean number of perforators ligated were 4.2. In a study published in Indian journal of surgery by M.G. Vashisht and Nitin singhal 53 a total of 314 perforators were ligated in 100 limbs. Pierik et al[10] divided 54 perforators with the range of 1-6 averaging 2.9 perforators. Jugenheimer et al[11] reported “a total of 456 perforator ligation with arrange of 2-11 with an average of 4 per limb” In our study the most common group of perforators ligated were the Cockett group which were clinically tested to be incompetent were the most accessible group with this procedure. Anatomical studies have revealed that only about 60% of perforators are accessible through this region. All patients reported symptomatic relief post procedure in our study. Similar study results were observed in 2014 by M.G. Vashisht and Nitin Singhal reported that “patients with complaints of pain during walking could walk without feeling discomfort at 14 days after SEPS”. Uncu et al[12] in his series of 28 patients observed “improvement in symptom by clinical improvement index after 3 months of SEPS from 8.14 v/s 2.54 which was statistically significant”. Baron et al reported “decrease in oedema and regression of symptoms with subjective improvement in physical performance in all patients”. Post procedure follow up complications like paresthesia, heaviness of limb, emphysema were not seen in any of the patients after undergoing SEPS for perforator incompetence. Whereas those who underwent open perforator ligation had hematoma and surgical site infection in 13.3% and 6.6% respectively which were managed conservatively. These complications were not seen among SEPS group. Jugenheimer and Junginger et al reported

“dysesthesia in 9.7% (n=103 limbs) with severe subfascial infection in 2(1.9%) patients”. Witten et al reported ‘severe subfascial infection necessitating surgical intervention on both sides’. Synbrandy et al reported “wound infection in 10% of patients”. Baron et al reported no wound complications in his study. Tenbrook et al reported “9% haematoma formation “In our study we noted the rate of average healing time of active venous ulcer after 3 weeks post SEPS was significantly better when compared to those among open perforator ligation surgery. 0.04). Synbrandy et al reported “a ulcer healing rate of 95% after SEPS”. Tenbrook et al 35 reported “a median time as 30-60 days for complete healing after SEPS”. Baron et al reported “primary healing following SEPS in 41 out of 53 patients in 12 weeks and in the remaining 12 it took longer time but none exceeded 6 months”. In a study done Anjay kumar included 21 patients of varicose veins with the perforating vein incompetence underwent SEPS using harmonic scalpel showed “ulcer healing in 8 weeks with no recurrences in 11.9 month of follow up”. Negus and freugood 25 reported “84% ulcer healing rate”.

Table 10: Comparison between studies

	Sato et al <sup>[40]</sup> (1999)		Synbrandy et al <sup>[34]</sup> (2001)		M G Vashisht et al <sup>[37]</sup> (2014)		Our Study	
	(Open)	(SEPS)	(Open)	(SEPS)	(Open)	(SEPS)	(Open)	(SEPS)
Wound infection	45%	7%	53%	0	16%	0	6.6%	0
Nerve Injury	0	0	11%	0	4%	0	0	0
Healing	100%	90%	100%	95%	-	100%	70%	100%
Recurrence	68%	28%	22%	12%	8%	0	20%	13%

**CONCLUSION** On day to day basis in the outpatient department we come across a lot of patients diagnosed with varicose veins with or without skin changes and associated chronic venous ulcers both newly diagnosed and the ones on a long term follow up. After the initial diagnosis the first preference is usually conservative line of management. Though the venous ulcers can be managed



by bed rest and limb elevation which lead to its healing, but due to either patient factor or disease course by itself leads to lack of adherence to the compression stockings or long term ingestion of venotonic medications, causing significant morbidity and decreased quality of life for the patients. The open technique of exploration of the sub-facial plane for ligation of incompetent perforating veins leads to delayed wound healing, wound infection and recurrence. Hence a less invasive approach like the endoscopic technique should be preferred over the classical operation as these have an advantage of minimal post-operative pain with early active mobilization. Sub-facial endoscopic perforator vein surgery is a safe and effective method for treating incompetent perforating veins. In a tertiary care centre this procedure of sub-facial endoscopic perforator ligation surgery can be performed with available laparoscopic instruments and apparatus. Endoscopic procedures not only reduce the post-operative sequelae but also require small skin incisions for port placement. These endoscopic explorations of subfascial area in patients with venous ulcers results in fewer incidences of wound complications and healing of wound. The number of perforators ligated in SEPS was more as compared to the open subfascial ligation group. This technique can also be utilized to perform ligation of the incompetent perforating veins in patients with lipodermatosclerosis and active ulcers to identify and legate the perforators beneath the ulcer site which thus helps in ulcer healing and prevent ulcer recurrences Hence, SEPS should be added to varicose vein surgery for the management of incompetent perforators to reduce long-term recurrences and better immediate wound healing. Limitation of our study is that it is not a Randomised control study, sample size is small, and shorter follow up period.

#### List of Abbreviations Used

CVI	Chronic Venous Ischemia
GSV	Great Saphenous Vein
PAV	Posterior Arch Vein
PI	Perforator Incompetence
SEPS	Subfascial Endoscopic Perforator Surgery
SFJ	Saphenofemoral Junction
SPC	Superficial Posterior Compartement
SSV	Short Saphenous Vein
CBC	Complete Blood Count
RBS	Random Blood Sugar
RFT	Renal function Test
LFT	Liver function Test
SE	Serum electrolytes
HIV	Human Immunodeficiency Virus
HCV	Hepatitis C Virus
HBsAg	Hepatitis B surface antigen
ECG	Electrocardiogram

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