

## Comparing Outcomes of Endoscopic Versus Duplex-Guided Open Subfascial Interruption of Incompetent Perforators in Management of Varicose Veins: A Randomized Control Trial

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### Abstract

*Introduction:* This randomized controlled study was conducted to compare outcomes of both subfascial endoscopic perforators surgery (SEPS) by using conventional laparoscopic instruments and duplex-guided open subfascial interruption of perforators. *Methods:* Patients with clinical lower limb varicosities were allocated randomly to open subfascial interruption of perforator or SEPS. After completion of SEPS if patients had incompetent SFJ, flush ligation and stripping of GSV from SFJ to level of the first port was done concurrently (Trendelenberg's procedure). *Results:* Eighteen patients were allocated to SEPS and 17 to the open surgery group. Two patients in the SEPS group were excluded (lost to follow up). Mean operative time (statistically insignificant) and mean number of perforators (statistically significant) were slightly higher in SEPS. Wound complications and mean hospital stay time was significantly reduced in SEPS. SEPS also resulted in faster ulcer healing with zero event rates of paresthesia, DVT and recurrence. *Conclusion:* SEPS warrants an early return to home and minimizes wound complications. DVT and recurrence were not noted in SEPS group. SEPS is easy, safe and feasible by conventional laparoscopic instruments. It is an attractive option of treatment for incompetent perforators in a developing country where endovenous ablation facilities are not widely available.

**Keywords:** Subfascial Endoscopic Perforator Surgery; Open Perforator Ligation; Varicose Veins;

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Perforator Incompetence.

### Introduction

Varicose veins are a common pathology affecting between 25-35% of the population [1,2]. This is characterized by dilated, elongated and tortuous veins of lower leg most commonly arising at the main interconnection between superficial and deep venous system i.e. saphenofemoral junction (SFJ), saphenopopliteal junction (SPJ) and perforators [3]. Objectified assessments of clinical severity of lower limb venous disease allows for delivery of treatment pathways and enables health care workers to generalize the findings of research units from different countries. The CEAP (Clinical, Etiological, Anatomical and Pathophysiological) classification is commonly used for uniform treatment and comparison [4]. Three percent of patients of varicose veins have venous ulcer and incompetent perforators have major role in etiopathology of venous ulcer. Since the introduction of Linton's operation in 1938 and modified Linton's procedure (Cockett and Dodd procedure) for incompetent perforating veins in which incisions are given on unhealthy skin and causing significant wound related complications [5,6,7].

Endovenous closure techniques have now been established as the choice of treatment for varicose veins [8]. Endovenous thermal ablation is the preferred procedure for truncal varicose veins and even for perforators [9,10]. Surgery is still the most feasible and economical treatment at places where endovenous thermal ablation is not available. Subfascial endoscopic perforator vein surgery (SEPS) avoids incision on unhealthy skin and has shown to be safe with high rates of ulcer healing, favorable

clinical outcome, and wound complications rates in long term follow up [11].

Hence, the aim of this randomized trial was to compare outcomes of both subfascial endoscopic perforators surgery (SEPS) by using conventional laparoscopic instruments and duplex-guided subfascial interruption of perforators by giving small incision at marked incompetent sites.

## Materials & Methods

Post ethical approval from institutional ethics committee, a randomized controlled study was conducted at Department of General Surgery, King George Medical University UP India for a period of 12 months (August 2014 to July 2015).

Patients irrespective of gender with age 18 years and above with medial aspect of below knee incompetent perforating veins documented by color doppler of lower limb were included in study after proper informed and written consent. All patients were detailed out research outline of the research study. Patients with concomitant peripheral arterial disease or deep venous thrombosis (DVT), significant cardiovascular disease, on anticoagulant therapy and secondary varicose veins were excluded.

A standard proforma was completed for each patient; this included clinical findings, etiology, anatomical findings and pathophysiology (CEAP) classification for each leg, duration of symptoms and duplex ultrasound scan before surgery, at 6 weeks, 2 months and 6 months after surgery.

### Outcome Assessment

Following parameters were compared - duration of surgery, ulcer healing time, mean hospital stay, total number of perforators ligated and complications of surgery (event rates of hemorrhage, surgical site infection, paresthesia, recurrence and deep vein thrombosis).

### Assessment of Flow in the Calf Perforating Veins

To evaluate the competency of the perforators, patients were examined by duplex ultrasound (Sonosite USA) in the standing position with distal compression maneuvers. If the flow was bi-directional, with duration of reflux longer than 0.5 s, the vein was considered incompetent.

### Operative Procedure

Patients were randomly allocated to either

endoscopic or open surgery by opening sealed envelopes (Figure 1).

### Group A - Subfascial Endoscopic Perforator Surgery (SEPS)

Endoscopic subfascial exploration was performed by use of conventional laparoscopic instruments via 2 ports.

### Position of Patient

Patient was placed in Trendelenberg's position. Knee of diseased side was flexed and slightly elevated by placement of a sand bag/pillow. Surgeon stood on the diseased side of the leg. Assistant stood on the same side or the opposite side.

### Placement of First Port (5mm)

A transverse incision was made five to six cm posteromedial to tibial tuberosity. After cutting deep fascia subfascial space was created by balloon inflation (finger gloves were tied on tip of endoscopic suction cannula and inflated in subfascial space by 100 ml normal saline). The port (5mm) was then inserted beneath the fascia and CO<sub>2</sub> gas was used for insufflation (15-18 mm Hg). This port was used for the working channel.

### Placement of Second Port (5mm or 10mm)

A second transverse incision was made 6-8 cm postero-inferior from the first one, and the second 5 or 10 mm port was inserted under visual control or guided by first port. This port was used for the telescope (Figure 2A).

### Subfascial Dissection

Under videoscopic control, all connective tissues bridging between the muscles and fascia were dissected with Maryland dissecting forceps and endoscopic scissors.

### Perforators' Interruption

Perforating veins bridging the subfascial space were visualized easily (Figure 2B). Perforators were isolated and interrupted by ultrasonic (harmonic) scalpel or by bipolar diathermy. If the size was bigger than 5mm then they were clipped (300 size clips) and divided (Figure 2C). Complete visualization of all perforating veins down upto the medial malleolus, posteriorly to the midline of leg and anteriorly to the tibial edge was performed.

*Wound Closure*

The wound was sutured with 2/0 absorbable sutures for the subcutaneous tissues and 3/0 non-absorbable sutures for the skin.

*Stripping of Great Saphenous Vein(GSV)*

After completion of SEPS if patients had incompetent SFJ, flush ligation and stripping of GSV from SFJ to level of the first port was done concurrently (Trendelenberg’s procedure).

*Group B - Duplex Guided open Subfascial Ligation*

Incompetent perforators were marked by doppler-guided USG. Small incision was given at the marked sites and perforators were ligated in subfascial space. After completing perforators division, if patients had an incompetent SFJ, flush ligation and stripping of GSV at level of just below knee was done concurrently.

The time taken for each operation were documented as the time between the first incision and skin closure and it excluded time taken for Trendelenberg’s procedure.

*Postoperative Management*

All patients had bandages applied to their legs (cotton crepe bandage BP), which remained in place until the 1-week follow-up. Early ambulation was encouraged and 30-degree elevation of operated for specially for first 24 hours was done. Patients were discharged as soon as they were comfortably walking and were pain-free. Patients were seen for removal of skin sutures in the outpatients department at a later date.

*Follow up*

Each patient was followed regularly for 3 postoperative visits at 6 weeks, 2 and 6 months. A repeat duplex scanning was done to document any missed incompetent perforator during follow up period. Post operative complications like wound

infection, paresthesia, subfascial haematoma, deep vein thrombosis etc were documented.

*Statistical Analysis*

Fischer exact test was used to calculate the statistical significance in respect to the different variables among the two groups. For all analyses, P < 0.05 in a two-sided test was considered to be significant. Data were analyzed in SPSS version 23 (SPSS, Chicago, Illinois, USA).

**Results**

A total of 40 patients with diagnosis of varicose veins were admitted. Five patients were excluded from the study due to secondary varicose veins and refusal for participation. N=35 (age 18-46 years; M:F = 27:6) patients were finally randomized into two groups; Group A n=18 underwent SEPS and Group B n=17 underwent open doppler USG guided perforator ligation surgery. Two patients in Group A were lost to follow up and were not analyzed.

*Patient Characteristics*

Right leg was more commonly involved (52%) than the left side (41%), and bilateral involvement was observed in 7% of the cases. In patients having bilateral varicose veins, procedure was performed on the more diseased side. Patients having incompetent perforators with saphenofemoral junction (SFJ) incompetency was found in 20 patients (60.6%) and saphenopopliteal junction (SPJ) was found incompetent in 8 patients (24.2%). Five patients (15.15%) had isolated perforator incompetence as a sole cause of their varicose veins. Two patients had venous ulcer (C<sub>6</sub>) in each group. Average size of venous ulcer was 3.2 cm x2.4 cm. Clinical characteristics of patients have been described in Table 1.

*Surgery*

There was no significant difference between the groups in time taken to perform SEPS and open

**Table 1:** Clinical characteristics of patients in both groups

Patients characteristics	SEPS (Group A)n=16	Open ligation (Group B)n=17	Total
Varicose vein only (C <sub>2</sub> )	6	7	13
Venous edema (C <sub>3</sub> )	5	6	11
Having skin changes (C <sub>4</sub> )	3	2	5
Having healed ulcer (C <sub>5</sub> )	0	0	0
Having open ulcer (C <sub>6</sub> )	2	2	4

perforator ligation. There was a significant difference in number of phlebectomies performed and the mean hospital stay between the two groups.

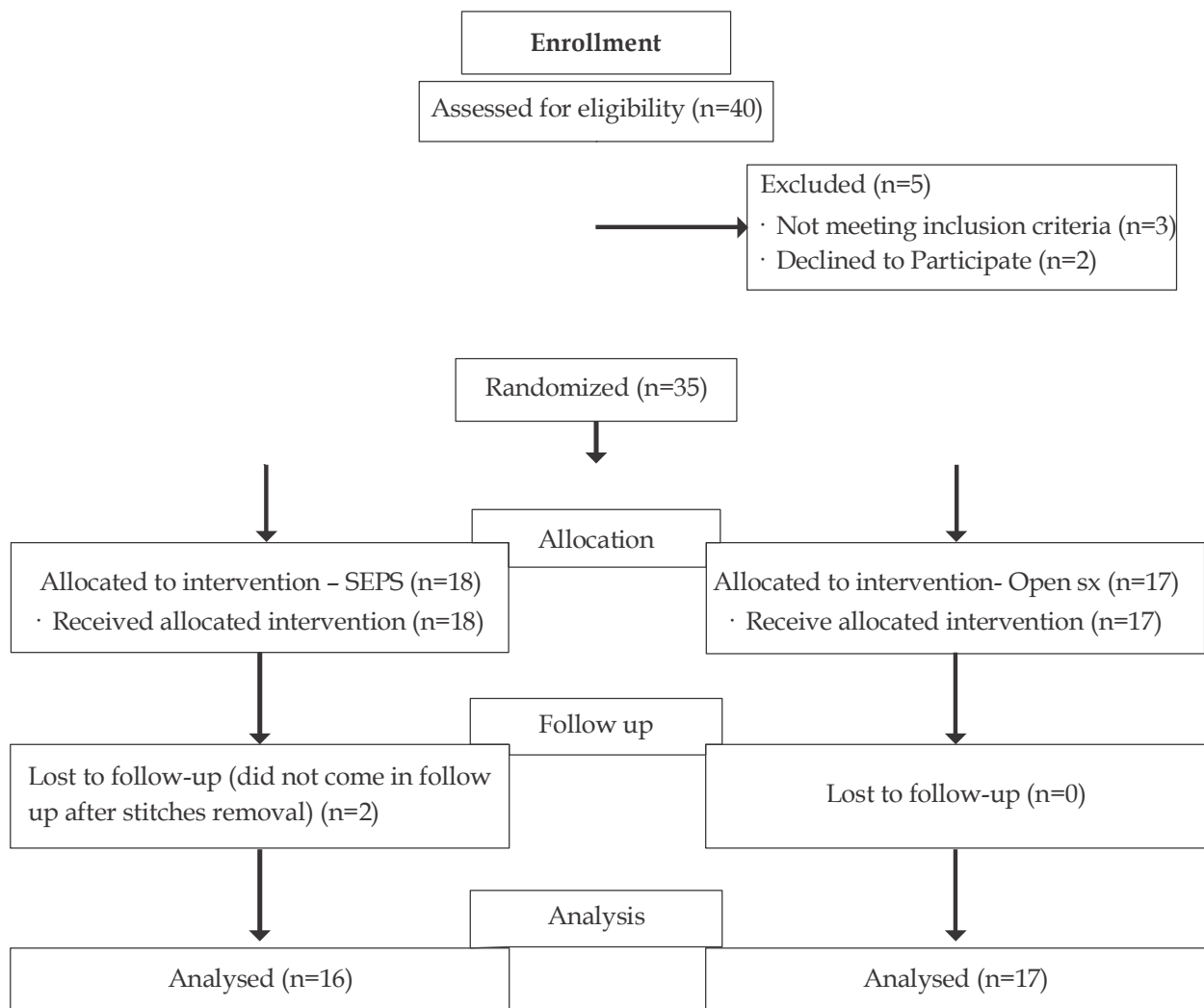
#### Postoperative Complications in follow up

Event rates of wound infections, subfascial hematomas, paresthesia and deep vein thrombosis

were more reported in open surgery group compared to endoscopic surgery group. Patients with SEPS reported no recurrence during 6 months follow up period with also less ulcer healing time with a decrease of 4 weeks. Recurrence was detected on repeated duplex scanning during follow up in open surgery group and was due to new incompetent perforators.

**Table 2:** Results comparing both groups(at end of 6 month follow up period)

	Group A (SEPS) n=16	Group B (Open perforator ligation)n=17	P value
Mean operative time (minutes)	38.4	32.7	0.123
Mean number of perforators	5.06 (2-12)	3.64 (2-5)	0.036
Mean hospital stay time (in days)	1.7 (1-4)	2.6 (1-5)	0.023
Wound infection	2 (13%)	10 (59%)	0.004
Subfascial hematoma	1 (6.3%)	3 (18%)	0.103
Paresthesia	0 (0%)	2 (12%)	0.227
DVT	0 (0%)	1 (6.3%)	0.485
Recurrence of incompetent perforators	0 (0%)	3 (18%)	0.103
Mean ulcer healing time	8 weeks	12 weeks	



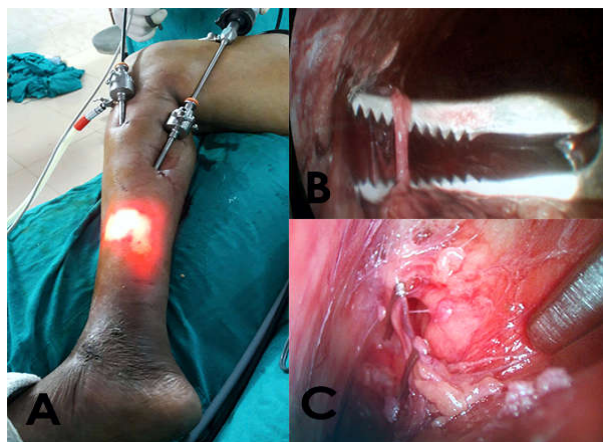


Fig. 2:

### Discussion

Surgical treatment of incompetent perforating veins has been reported to give good results in the healing of chronic venous insufficiency. In 1938 Linton described a technique for perforator management by a long incision through the medial skin from knee to the medial malleolus. Perforators could then be identified below the fascia and divided. However, wound-related complications such as surgical site infections, flap necrosis, and delayed healing occurred in about one fifth of patients and caused the procedure to fall into disfavor [5]. Ever since several modifications of the Linton's procedure have been developed to minimize wound morbidity such as the posterior stocking seam and parallel oblique incisions [6,7]. With the advent of duplex scanning (combining ultra-sonology with doppler), ligation of perforators began to be done by giving small subfascial incisions. This recently too started fallen out of favor because it required incisions on the unhealthy skin despite Basbug HS et al reported color doppler USG guided incompetent perforators ligation by giving small incision with no severe wound complication, DVT episodes and paresthesia [12]. Subfascial endoscopic perforator surgery was first introduced by Hauer & Fischer in 1985 [13] which started the era of use of minimally invasive surgery in treatment of varicose veins. O'Donnell [14] employed saline infusion in the subfascial space to create an adequate optical space to avoid hypothesized risk of CO<sub>2</sub> thromboembolism. Gloviczki [15] employed CO<sub>2</sub> insufflation and this lead to a renewed interest due to the increase in technical ease, associated with CO<sub>2</sub> insufflation [16].

However, SEPS has not been widely adopted because of its less ergonomic design. In Japan, the two-port system utilizing screw-type ports (EndoTIP®, Karl Storz, Tuttlingen, Germany) was

introduced by Haruta in the beginning of the 21st century, which made the performance of SEPS simpler and easier [17]. Subsequently Kusagawah et al and Hirokawa et al also have performed SEPS using screw type ports and soft trocars respectively [18,19]. We have performed SEPS by using conventional laparoscopic instruments. Since the cost involved in acquiring specialized instruments for SEPS is a major concern in a developing country, using conventional instruments for the same may prove to be a viable and novel option. Moreover although reported in a theoretical model, SEPS was more cost-effective in healing venous ulcers due to incompetent perforators compared with compression bandaging [20].

Comparing complication rates, subfascial-hematoma was present in 3 patients (18%) of open ligation group. Tenbrook et al. reported hematoma in 9% cases with SEPS whereas it was 6.3% in the present study [21]. In our study wound infection was present in 59% of patients in open subfascial ligation group and 13% of patients of SEPS group. In literature same has also been reported in high percentage of patients in open subfascial ligation of perforators – in 32.4% cases by Stuart et al. and 53% cases by Sybrandy et al. while it was 10% and 0% in the SEPS group respectively [11,22]. The high incidence of wound infection in the open group is because of incision in already compromised skin which causes delayed wound healing and increases chances of infection. In the present study, there was no redness, ecchymosis, and pain at the site of incisions in both the groups as reported in literature. <sup>11,22</sup>The wound complications in most series of the SEPS group were significantly low ranging from 0 to 6.1%. Tenbrook et al. in reported wound infection in 6% cases following SEPS procedure in their study [21]. Baron et al. reported no hematoma, wound infection, paraesthesia, redness, ecchymosis, and pain in patients undergoing SEPS procedure in their study [23]. However, Nelzen [24] reported a wound complication rate of 16% in his study of 37 patients, which is comparable to our data. In a recent meta analysis by Luebke and Brunkwall [25] including two RCTs and one retrospective comparative study have reported that compared with open perforating vein surgery, SEPS was significantly associated with a reduction in wound infections, recurrent ulcers and a reduction in hospital stay. However it was found that there were no statistically significant differences in the rate of mortality, deep vein thrombosis, hospital readmission and ulcer healing at four months between the two groups. The high incidence of wound infection in the open group is because of incision in already compromised skin which causes delayed wound healing and increases the chances of infection.

Kurdal et al. could also achieve sustainable wound healing with SEPS [26]. Baron et al. noted decrease in edema, regression of changes, and subjective improvement in physical performance in all the patients in their study. Out of 53 limbs with ulceration, primary healing occurred in 41 within 12 weeks following the SEPS procedure. In the remaining 12 cases, healing took longer time, but none exceeded 6 months [23]. Ulcer healing has ranged from 66 to 100 % in various studies reported in the literature. It was 100 % in our cases with faster healing in SEPS group (by 4 weeks). Sybrandy et al. have reported comparable healing rates in both the groups, 95 % in the SEPS and 100 % in the open subfascial ligation group. The ulceration healed within 4 months (16 weeks) after surgery in 17 of 20 patients [11]. The healing rate reported by them was also comparable for both the groups, but they reported slightly faster healing in the open subfascial group than in the SEPS group. Tenbrook et al. reported median time of ulcer healing as 30–60 days [21]. Gloviczki et al. analyzed and reported the contribution of operative experience with SEPS and reported that ulcer healing was longer in centers with fewer than 10 operations [27].

Commenting about other complications paresthesia was present in 12% of patients with open ligation but was absent from the SEPS group. In the literature paresthesia has been reported in 0–11 % cases in open ligation of perforators and in 0–7 % cases in the SEPS group. The possible reason for paresthesia in the open ligation group is attributed to the incidental ligation of nerves along with veins.<sup>11,21,22</sup> We did not find in our study incompetent perforators on the lateral aspect of legs. In a study where SEPS was performed for lateral side of perforators in 13 patients, postoperative duplex scans showed persistent insufficient perforating veins in about 25 % of patients [28].

In a study with mean follow-up of 3.7 years recurrence of 22 incompetent perforating veins was observed in 20 (21.7%) of 92 limbs, and recurrent leg ulcers were observed in 2 (9.5%) of 21 limbs [29]. In our study recurrence after 6 weeks was 18% in open ligation and none with SEPS. These missed perforators may be a possible cause of future recurrence of varicose veins on long-term follow-up. In our study there was no perforator reflux after SEPS confirmed by repeat duplex scanning in follow up period. Sybrandy et al. reported persistent perforators in 20% of patients in the SEPS group also [11]. A possible explanation could be their subfascial course in the septum intermuscularis, which sometimes obscures incompetent perforators. Another explanation could be an erroneously placed or dislodged clip [30]. The

difference in results may attain more significance on long-term follow-up, as the missed perforators in the open ligation group may be a cause of future recurrence. Cosmetic results were good in both the groups in the present study.

## Conclusion

Subfascial endoscopic perforator vein surgery using conventional laparoscopic surgery instruments is a safe and effective method for treating incompetent perforating veins especially in a developing country with a limited access to higher technology. SEPS has the advantage of exploration of the entire subfascial space so that majority of the perforators can be identified and ligated with less complication rates, faster ulcer healing time and reduced hospital stay.

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