

Evaluation of stab avulsion versus subfascial endoscopic perforator surgery in the management of chronic venous insufficiency resulting from incompetent leg perforators in primary varicose veins

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Abstract

Chronic venous insufficiency (CVI) resulting from incompetent perforators due to varicose veins is a common surgical condition present in at least 10% of the general population. This study was planned to evaluate stab avulsion vs subfascial endoscopic perforator surgery in the management of incompetent perforators resulting in CVI. Forty patients of CVI resulting from primary varicose veins, falling into class 4 to 6 as per the clinical part of CEAP classification, along with Duplex assessment with proven incompetent perforators of lower extremity, irrespective of the status of saphenous-femoral or saphenous-popliteal junction status, were included in the study. All the patients were randomized into two groups, A and B, by a computer-generated draw. Group A patients underwent stab avulsion, and group B patients underwent SEPS for incompetent perforators. The following parameters were evaluated: (i) pain score using a visual analog scale at 1 hour, 12 hours and 24 hours after surgery, (ii) ulcer healing 1 month and 3 months after surgery, (iii) reversal of skin changes after 1 month and 3 months of surgery during follow-up, and (iv) wound-related complications. Early relief of symptoms in terms of ulcer healing, reversal of skin changes, and decreased incidence of wound complications was found to be better in the subfascial endoscopic perforators surgery (SEPS) group.

Introduction

Chronic venous insufficiency (CVI) resulting from incompetent perforators and varicose veins is a common surgical condition present in at least 10% of the general population. The options available for surgical treatment of varicose veins are based upon: ablation of saphenous vein reflux, greater or smaller, incompetent perforator interruptions, and elimination of residual varicosities. Incompetent perforators interruptions can be performed through the following methods: subfascial endoscopic perforators surgery (SEPS), stab avulsion technique, subfascial ligation of the medial communicating veins (Linton's procedure), extra-fascial ligation of perforators (Cockett's procedure), posterior approach (Rob's procedure). Stab avulsion and SEPS are two commonly used methods which are utilized in the treatment of incompetent perforators. Stab avulsion permits the removal of incompetent veins below the saphenofemoral and sapheno-popliteal junction. SEPS is a minimally invasive subfascial endoscopic perforator surgery in patients with incompetent perforator veins. The present study evaluated the role of SEPS vs stab avulsion in the management of CVI resulting from primary varicose veins in terms of post-operative pain, ulcer healing and effect on skin changes.

Materials and methods

This was a prospective randomized control trial study conducted in the Department of Surgery, Maulana Azad Medical College, and Lok Nayak Hospital, New Delhi, India.

Inclusion criteria

Patients with CVI (class 4-6) resulting from incompetent perforators in primary lower limb varicose veins were included in the study. All these patients had a failure of conservative therapy, like graded elastic compression therapy. Failure of compression therapy was defined when the ulcer size did not reduce by at least 50%, or there was no appreciable reversal of skin changes as per the photographic record.

Exclusion criteria

(i) Patients with a history of deep vein thrombosis; (ii) patients with recurrent varicose veins; (iii) patients with secondary varicose veins; (iv) patients with class 1-3 CVI. Forty consecutive patients attending the surgery outpatient department for the treatment of CVI who met the above criteria were taken up for the study; the sample size was chosen based on the convenience of the

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Contributions: SJ: concept and design of the study; MJ: patient study, coordination, compilation; VS: prepared first draft of manuscript, statistical analysis and interpretation; RS: patient study and compilation
Conflict of interest: None.

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Ethics approval and consent to participate: Ethical Committee clearance was taken from the institution's ethics committee, and all patients had a right to exit the study at any point in time without compromising their treatment. Written informed consent was taken from all the patients to participate in the study.

Availability of data and materials: All data generated or analyzed during this study are included in this published article.

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institute as for workload. Patients were randomized into two groups, A and B, by a computer-generated number. These numbers were kept in a sealed envelope and were opened only at the time of surgery by an anesthesiologist who was not part of this

study. All patients were operated by the first author, SJ, who is well-experienced in performing this surgery. Group A patients underwent stab avulsion and group B patients underwent SEPS (Figure 1). Both groups of patients were operated under spinal anesthesia.

Post-operation follow-up was carried out by the second and third authors, who were not part of the operating team. All patients underwent photography of skin changes and ulceration. The size of the ulcer was measured by Vernier caliper on follow-up visits.

Methodology

Ethical Committee clearance was taken from the institution's ethics committee, and all patients had a right to exit the study at any point in time without compromising their treatment. Written informed consent was taken from all the patients to participate in the study.

All patients were assessed with a Duplex scan for the following findings: (i) The site of incompetent perforators. Perforators were identified as veins running in the subfascial plane and piercing deep fascia to join the superficial system; incompetent perforators were identified by the presence of bidirectional flow or reversed flow from deep to superficial system; (ii) the competence of saphenofemoral or saphenous-popliteal junction; (iii) the patency of deep veins; (iv) the site of incompetent perforators was marked in each case. However, it was noted during the performance of SEPS there were many more perforators were detected during the procedure than those detected by the Duplex scan. Probably these were unnamed indirect perforators connecting superficial veins to muscular venous sinuses; (v) the incompetence of valves in superficial dilated veins was determined by Schwartz test clinically and confirmed on Duplex examination.

The stripping of the long saphenous vein up to the knee joint with ligation of saphenofemoral junction (SFJ) was performed in patients having incompetent SFJ, while ligation of saphenous-popliteal junction (SPJ) was done in patients having incompetent SPJ. The stripping of the great saphenous vein (GSV) / ligation of SPJ was carried out at the same time while performing perforator surgery. We chose to perform stripping of GSV/ligation of SPJ at the same sitting, because it is our experience that the recurrence rate of ulcers is very high due to consistently raised venous pressure if varicose surgery is left for a future date.

Technique of stab avulsion

Stab avulsion was carried out under spinal anesthesia. Small 2-4 mm incisions were made along the previously marked perforators and the dilated veins were pulled out of the wound with the help of a vein hook then dissected, divided and carefully resected in both proximal and distal directions. Skin incisions were closed and a pressure bandage was applied from the foot to the thigh at the end of the surgery (Figure 2). The pressure bandage was removed after 24 hours to look for any hematoma. Patients were made ambulatory after 24 hours and discharged. No incision was given in the pathological area; even when the incompetent perforator was located nearby, with a little bit of dissection we were able to identify the perforator and ligate it

Technique of subfascial endoscopic perforator surgery (SEPS)

All patients underwent SEPS under spinal anesthesia by the two-port laparoscopic technique with 30 mm pressure. No tourniquet was used in the thigh for the exsanguination of blood in the lower limb. One 10-mm port was introduced beneath the deep fascia, 8-10 cm below the plateau of tibia, 2 cm medial to the anterior border, which was used as camera port and for insufflation of carbon dioxide gas. A zero-degree 10-mm telescope was used. Subfascial dissection was carried out by the tip of the telescope. A second 5-mm port was introduced, 6-8 cm posterior and inferior to the first port as the working port. Only the harmonic ace dissector, set at a frequency of 55.5 kHz was used for the dissection of subfascial space and for the transection and coagulation of the perforators (Figure 1). All the vertical venous structures running vertically in subfascial skin incisions were closed with 3-0 nylon sutures without any drain. Pressure bandages were applied from the foot to the thigh.

Follow-up

The pain score was analyzed in all the patients by using a visual analog scale at 1 hour, 12 hours and 24 hours after surgery. Patients were discharged 24 hours after surgery. Follow-up was done one and three months after surgery. During follow-up visits, the following things were noted: (i) ulcer healing, and (ii) skin changes. Ulcer healing was defined as completely healed, or more than 50% healed ulcer. The effect on skin changes was defined as improving, same as pre-operative or deteriorating. At follow-up, clinical photographs were taken, the ulcer was examined and its size measured

Statistical analysis

Quantitative data: Wilcoxon Mann Whitney Rank Sum test. Qualitative data: Chi-Square/Fischer Exact test. Data was analyzed using SPSS version 17.0 statistical software

Results

Likelihood ratios were calculated and a p-value of <0.05 was considered to be significant. The observations and results of this study are as follows:

Age and sex distribution

The median age of the patients in the SEPS group was 33.5 years (25-54), and in the stab avulsion group was 33.5 years (18-60) without any statistically significant difference. The age distribution of the patients in each group is shown in (Table 1).

Distribution of side of limbs in each group

Out of 40 patients, 18 had right lower limb varicose veins (10 in the stab avulsion



Figure 1. SEPS - perforator seen.



Figure 2. Stab avulsion of perforator.

Table 1. Age and limb distribution of the patients.

1. Age distribution in the two groups	Age group	SEPS	Stab avulsion	p-value=0.50	
	18-30	8	8		
	31-50	10	6		
	51-70	2	6		
	Total	20	20		
2. Showing side distribution	Limb	SEPS	Stab avulsion	Total	p-value=0.50
	Right limb	8	10	18	
	Left limb	12	10	22	
	Total	20	20	40	
3. CEAP stage distribution	Stage	SEPS	Stab avulsion	Total	p-value=0.090
	Stage 4	4	6	10	
	Stage 5	2	2	4	
	Stage 6	14	16	26	
	Total	20	20	40	
4. Showing only PVI or SFJ and PVI distribution		SEPS	Stab avulsion	Total	p-value=0.50
	PVI	18	4	22	
	SF and PVI	2	16	18	
	Total	20	20	40	
5. Distribution of SFJ in competence	SFI	SEPS	Stab avulsion	Total	p-value=0.064
	Clinical assessment	0	2	2	
	On Duplex assessment	2	14	16	
	Total	2	16	18	
6. Distribution of ulcer as preoperative finding amongst two groups	Preoperative ulcer	SEPS	Stab avulsion	Total	p-value=0.064
	No	6	8	14	
	Yes	14	12	26	
	Total	20	20	40	
7. Distribution of skin changes as preoperative finding	Preoperative skin changes	SEPS	Stab avulsion	Total	p-value=0.50
	No	2	0	2	
	Yes	18	20	38	
	Total	20	20	40	
8. Comparison of pain score at 1 hour after surgery	Pain at 1 hour	N	Mean rank	Sum of ranks	p-value=0.374
	(VAS) SEPS	20	23.40	468.00	
	Stab avulsion	20	18.6	372.00	
	Total	40			
9. Statistics of pain score at 12 hours	Mann-Whitney U	38.000			
	Asymp. Sig. (2-tailed)	0.314			
10. Comparison of pain score at 12 hours after surgery	Pain at 12 hours	N	Mean Rank	Sum of Ranks	
	(VAS) SEPS	20	20.50	410.00	
	Stab avulsion	20	20.50	410.00	
	Total	40			
11. Ulcer healing at one month amongst the two groups (n=13)	Ulcer at 1 month	SEPS	Stab avulsion	Total	p-value=0.302
	Not healed / <50% healed	0	4	4	
	Partial healed / >50% healed	4	2	6	
	Complete healed	10	6	16	
	Total	14	12	26	
12. Ulcer healing at one month amongst the two groups (n=13)	Ulcer at 1 month	SEPS	Stab avulsion	Total	p-value=0.302
	Not healed / <50% healed	0	4	4	
	Partially healed / >50% healed	4	2	6	
	Completely healed	10	6	16	
	Total	14	12	26	
13. Improvement in skin changes at one month amongst the two groups (n=19)	Skin changes at 1 month	SEPS	Stab avulsion	Total	p-value=0.345
	Same as preoperative	12	18	30	
	Partial improvement	6	2	8	
	Total	18	20	38	
14. Ulcer healing at three months amongst the two groups (n=13)	Ulcer at 3 months	SEPS	Stab avulsion	Total	p-value=0.264
	Partial healed / >50% healed	0	2	2	
	Complete healed	14	10	24	
	Total	14	12	26	
15. Improvement in skin changes at three months (n=19)	Skin changes at 1 month	SEPS	Stab avulsion	Total	p-value=0.386
	Same as preoperative	4	12	16	
	Partial improvement	14	8	22	
	Total	18	20	38	
16. Comparison of post-operative infection between the two surgical groups	Post op Infections	SEPS	Stab avulsion	Total	p-value=0.50
	No	20	18	38	
	Yes	0	2	2	
	Total	20	20	40	

group and 8 in the SEPS group) and 22 had left lower limb varicose veins (10 in the stab avulsion group and 12 in the SEPS group). The limb distribution is shown in (Table 1).

CEAP Class distribution as per the procedure done

In both surgical groups, patients' distribution as per CEAP classification was comparable and belonged to C4-6, and there was no statistically significant difference.

The presence of perforator vein incompetence (PVI)

In the two groups was assessed by a venous Doppler study. Perforators were marked by indelible ink on the morning of surgery.

The presence of a preoperative ulcer

A total of 26 patients of both groups had ulceration at the time of presentation, and the distribution was statistically insignificant.

The presence of preoperative skin changes

In the form of hyperpigmentation was statistically insignificant (Figure 3) at the time of presentation.

A comparison of pain score at 1 hour, 12 hours and 24 hours between the two surgical groups

Was done using the visual analog score (VAS) between the two groups is shown in Table I.

Ulcer and reversal of skin changes comparison between 2 groups

(i) Ulcer healing at 1 month, 3 months and 12 months of follow-up was done. It was graded as not healed, if not at all or less than 50% healed, partially healed, if more than 50% healed but not completely healed; (ii) reversal of skin changes at 1 month and 3 months of follow-up was present in almost all patients. Skin changes during follow-up were graded as not improved, partially improved, completely improved or deteriorated (Figure 4). Although there was no difference in the reversal of skin changes or ulcer healing rate we decided to follow up with patients at six months and one year, and found out that the SEPS group showed much better healing rate and reversal of skin changes

A comparison of postoperative infection between the two surgical groups

Was done.

Discussion

The present study was done to compare the efficacy of SEPS vs stab avulsion in the management of primary varicose veins. Most patients in the present study were in the age group of 18–50 years (80%), with a mean age of 33.5 years. This age group requires maximum long-standing activities for earning for their families. In literature, the age distribution of varicose veins in most studies varies from 30 to 40 years.¹

In the present study, all patients were male, however, female predominance has been quoted in Western literature;² as per the literature, females are affected more commonly as compared to males.³

The present study revealed that the left lower limb is more involved than the right lower limb. Primary varicose veins can be due to reflux in superficial venous system, deep venous system or perforators. In this study, SFJ incompetence and long saphenous vein involvement were present in 45% of patients. In other studies, SFJ incompetence and long saphenous vein involvement were found in 55%,⁴ 89%,⁵ 84% of the patients.⁶ Involvement of long saphenous system occurs in 2/3 of cases. Ting *et al.* have reported SFJ incompetence in 87%, and SPJ incompetence in 13% of patients in their study. In a significant number of patients, isolated perforator incompetence is the cause of symptoms as in the present study, indicating the significance of perforators in the pathogenesis of varicose veins.⁷

In this study, 40 patients of primary varicose veins with CEAP stage C4-C6 were involved. Active ulceration was seen in 26 (65%) patients in this study. Fourteen patients in the SEPS group and 12 patients in the stab avulsion group had ulceration. Out of 14, 4 patients in the SEPS group had ulceration on the lateral aspect of the leg, which is a unique finding and can be explained by the presence of unnamed perforators present on the posterior aspect of the leg which were not picked up by Doppler but picked up in SEPS during surgery. In the SEPS group, 14 patients had an active ulcer. After 1 month, 4 (28.5%) patients had partial healing of the ulcer and 10 (71.4%) had complete healing of the ulcer; however, all the patients had complete ulcer healing after 3 months, with no recurrence. In a prospective study by O. Nelzen *et al.*, SEPS was the only operation performed in 16% of limbs with leg ulcers, all of which healed.⁸ In the stab avulsion group 12 patients had an active ulcer. After 1 month, 4 (33.33%) patients had a non-healing ulcer, 2 (16.67%) had a partially healing ulcer and 6 (50%) patients' ulcers

completely healed. After 3 months, 10 (83.33%) patients' ulcers completely healed, and 2 (16.67%) patients had a partially healing ulcer.

In the present study, we created a wide space between the anterior to posterior midline, with high pressure of 30 mmHg, to pick up all the perforators. We did not rely only on Doppler findings while performing SEPS; and transected all the perforators crossing the fascia during SEPS. Ulcer healing ranged from 66 to 100% in various studies reported in the literature, while it was 100% in SEPS. Sybrandy *et al.*, have reported comparable healing rates in the groups, 95% in the SEPS and 100% in the open subfascial ligation group.⁹ Tenbrook *et al.*, reported the median time of ulcer healing as 30–60 days.¹⁰ Table I compares the results of various studies on SEPS in patients with advanced chronic venous disease. In the present study, ulcer healing was quicker in the SEPS group compared to the stab avulsion group, with 71.4% of limbs in the SEPS group showing complete ulcer healing at 1 month, 28.5% limbs showing partial ulcer healing, 0% had not healed ulcer in the SEPS group in comparison to 50% completely healed, 17% partial healed



Figure 3. Patient n°14 - SEPS group ulcer and skin changes at the time of presentation.



Figure 4. Patient n° 14 - SEPS group ulcer after 3 months completely healed and skin changes partial improvement.

ulcer and 33% not healed ulcer in the stab avulsion group. In the SEPS group, after 1 month, ulcer healing was faster than in the stab avulsion group; the finding was in accordance with a study done in India.⁷ However, all the ulcers in SEPS groups and 83% of ulcers in the stab avulsion group healed by 3 months.

In the present study, there was no paraesthesia in the SEPS group or in the stab avulsion group. In the literature, paraesthesia has been reported in 0–11% of cases in open ligation of perforators, and in 0–7% of cases in the SEPS group.^{9–11} The possible reason for paraesthesia in the open ligation group is the incidental ligation of nerves along with veins. In the present study, we had no incidence of hematoma formation in the SEPS group, while Tenbrook *et al.*, reported hematoma in 9% cases.¹⁰ Wound infection was seen in 2 (10%) cases in the stab avulsion group, as compared to the 0% observed in the SEPS group. However, there was no statistically significant difference in the two groups in regard to post-operative wound infection. A similar finding was observed by Lee *et al.*, in which they used ultrasonic harmonic.^{2,12,13} The high incidence of wound infection in the open group is because of an incision in already compromised skin, which causes delayed wound healing and increases the chances of infection. In the present study, there was no redness, ecchymosis, and pain at the site of incisions in both groups, as reported in the literature.^{9,11} The wound complications in most series of the SEPS group were significantly low ranging from 0 to 6.1%, and are comparable to our study.

In this study, 38 patients (95%) had skin changes. In the literature, the incidence of skin changes in varicose vein patients is quoted as 90%.⁵ All the patients of the stab avulsion group had skin changes and 18 patients of the SEPS group had skin changes. In our study, in the SEPS group, 33% of patients had a partial reversal of skin changes after 1 month, and 77.77% patients had partial reversal of skin changes after 3 months. In the stab avulsion group, partial reversal of skin changes was found in 10% of patients after 1 month, and 40% of patients after 3 months. None of the patient's skin changes deteriorated after 1 month or 3 months. In this study, there was no difference in the reversal of skin changes in the two groups statistically, however, this could be because of type I error and the small sample size.

None of the patients in the two groups had recurrence after 3 months; this was in accordance with the study. In both groups, there was no statistically significant differ-

ence in pain score at 1 hour, 12 hours and 24 hours after surgery. At 12 months of follow-up, the ulcer healing rate was much higher and the recurrence of skin changes was much less. This can probably be explained by the fact the average number of perforators ligated in SEPS was much higher (around 8–10) in comparison to 3–4 in stab avulsion. In SEPS, we were able to ligate all unnamed perforators, which are not normally detected on Duplex study.

SEPS can be performed by using an ultrasonic scalpel,^{2,12,14,15} metal clips,⁷ electrocautery.⁷ The use of metal clips is time-consuming and may act as a nidus for infection, and also there is a risk of a migration of the clips. The use of electrocautery in a limited space increases the risk of damage to the surrounding tissues, such as nerve and muscle by the electric current. Moreover, the smoke produced by the electric current obscures the operative field and makes surgery difficult. The use of an ultrasonic scalpel in SEPS can obviate all these problems to a great extent. In this method, the electrical energy is converted into ultrasonic vibrations, which can simultaneously transect and coagulate the soft tissue with minimal damage to the surrounding tissues. It causes the denaturation of tissue proteins, and a coagulum is formed, which seals off the vessel. Moreover, it is less time-consuming when there are multiple perforators. This instrument, which works in a smoke and blood-free space, is now widely used in a number of laparoscopic procedures.¹⁶

SEPS can be performed by using routine endoscopic urology or gastrointestinal surgery instruments^{2,7,12,14,17,18} or specialized instruments designed for SEPS, but these ports increase the cost of surgery.^{12,15} In our study, we did not use any specially designed instruments, but we used routine laparoscopic instruments. In most of the study, the author used two ports to perform SEPS,^{5,7,14} but, in a few instances, single endoscopic ports were used.^{5,19}

To enlarge subfascial space, carbon dioxide insufflation,^{5,7,14,20} or balloon expanders can be used.⁵ Carbon-dioxide gas insufflation into subfascial space was used to improve visualization in our study.

We did not use any thigh tourniquet, as it is said to be associated with pressure necrosis, and the risk of proximal embolism is very minimal.^{5,7} Interruption of incompetent perforators using an ultrasonic scalpel eliminated the necessity for tourniquets.¹⁵ For SEPS, pressure can be maintained from 10 mmHg to 30 mmHg to create subfascial space.^{7,14,15,20} For SEPS, we kept a 30 mmHg pressure to create a wider space, which helped us to tackle more incompetent perforators and better vision. High pressure

creates wide subfascial space, which improves visualization and access to the perforators,¹⁴ but such high pressure can aggravate surgical trauma.²¹

Limitations of the study

Type I error and small sample size.

Conclusions

The present study of 40 patients with primary varicose veins was designed to evaluate SEPS vs stab avulsion in the management of primary varicose veins. The following conclusions were drawn: (i) all the patients in the present study were males; (ii) the left lower limb was more commonly involved than the right lower limb; (iii) the great saphenous system was affected in two third of the cases; (iv) both SEPS and stab avulsion were found to be equally effective in terms of ulcer healing and reversal of skin changes at 3 months of follow-up, but there was a complete regression of skin changes at one year of follow-up in the SEPS group, and recurrence in the stab avulsion group; (v) ulcer healing rate was much better in patients operated by SEPS at 1 month, leading to early recovery and less loss of manpower work; (vi) SEPS can be effectively performed by commonly available laparoscopic ports and there is no need for specially designed ports; (vii) an ultrasonic scalpel is an effective tool in the interruption of incompetent perforators while performing SEPS.

SEPS improves the outcome by leaving no residual incompetent perforators. SEPS together with complementary methods is a recommendable way of treating lower leg varicose veins to reduce long-term recurrences and better immediate wound healing.

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