Original Research Article

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Outcomes of subfascial endoscopic perforator ligation surgery versus open subfascial ligation surgery of incompetent perforator veins in the treatment of varicose veins

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ABSTRACT

Background: Varicose veins are common and are present in at least 10% of the general population. There are several techniques available in surgeon's armamentarium for varicose veins treatment such as, ultrasound guided foam sclerotherapy, endovenous laser ablation, radiofrequency ablation, open perforator ligation, endoscopic perforator ligation.

Methods: It was prospective randomized study. Test group underwent subfascial endoscopic perforator surgery (SEPS) by the two-port method. Control group underwent open subfascial ligation of perforators.

Results: Study included 25 patients in each group. Perforator incompetence was seen in bilateral limbs in 8% in both the groups. Post op stay in open group is 7.3±0.6 days and 5.2±0.9 days in SEPS group. Post-operative day 7 VAS scoring was 1.0±0.4 in open group and 0.4±0.5 in SEPS group which is statistically significant. Post operatively wound site hematoma was seen in 9 patients in open group on post-operative day 1, which disappeared in 8 patients by day 5 and in 1 patient evacuation was done and 3 patients developed wound site hematoma in SEPS group, which resolved by day 5. Ulcer recurrence was not seen in both groups at 1 year follow up.

Conclusions: This study shows the superiority of SEPS over open technique because of shorter hospital stay, lesser post-operative complications like pain, hematoma formation, wound infection, total number of perforators ligated, early recovery. Though longer follow up is needed to comment about the true superiority of SEPS versus open subfascial ligation of perforators in treatment of varicose veins.

Keywords: SEPS, Varicose veins, Perforator ligation, Sub-fascial endoscopic surgery

INTRODUCTION

Varicose veins are elongated, dilated and tortuous veins. They are defined as dilated palpable subcutaneous veins, generally larger than 4mm in the upright position.¹ The word 'varicose' is derived from the Latin word 'varix', which means twisted. The adoption of the erect position by humans is thought to have greatly influenced the development of venous diseases of the lower limbs.

Reflux may occur in venous tributaries in the absence of axial reflux in the truncal, deep or perforator veins.² Impairment of return of venous blood to the heart against gravity as a result of the erect position, results in the

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development of acute venous thrombosis, varicose veins, and chronic venous insufficiency.

Subfascial endoscopic perforator surgery (SEPS) is a new, minimally invasive technique performed in patients with advanced chronic venous insufficiency.

SEPS enables surgeons to address perforator vein incompetence less invasively, with small upper calf incisions remote from severely diseased skin in the distal leg. SEPS is performed in many centres as a component of a comprehensive treatment program for venous insufficiency, but few studies have compared SEPS with the open subfascial perforator ligation.³

In the only randomized trial, Pierik et al found similar ulcer healing and recurrence rates and lower surgical complication rates with SEPS, but the study was too small to enable definitive conclusions about the efficacy of SEPS.⁴ The rest of the studies incorporating SEPS, have had an observational study design, often without comparison treatment groups, so the usefulness of SEPS in patients with venous disease remains uncertain.

The current study is undertaken to compare the outcomes of open perforator ligation and endoscopic perforator ligation in terms of surgical outcomes and complications in order to determine the better technique for the treatment of perforator incompetence in lower limb varicose veins patients.

METHODS

The patients for this study are diagnosed varicose veins of lower limbs with perforator incompetence who presented in the Department of General Surgery at Vydehi Institute of Medical Sciences and Research Centre over the period from January 2016 to June 2018 with minimum follow-up of 3 months to maximum of 18 months. 25 patients in each study group subjects will be randomized into 2 groups by sealed envelope method group A and group B.

Data was collected using a case recording performa, all the relevant investigation required pre-operatively was done, all patients underwent, bilateral venous doppler with perforator marking and ultrasound abdomen with pelvis.

Inclusion criteria

Inclusion criteria was all patients with primary varicose veins of lower limbs with perforator venous incompetence from C0-C6 under CEAP (clinical-etiology-anatomy-pathophysiology) classification.

Exclusion criteria

Exclusion criteria were patients below 18 years of age, pregnant women, patients with contraindication to study

like DVT, secondary varicose veins, varicose veins in other body parts. Subjects were randomized into 2 groups by sealed envelope method group A and group B. Group A patients (test group) underwent subfascial endoscopic perforator surgery by the two-port method.

All the visualized big perforators were ligated endoscopically by clips, and small perforators were coagulated with electro cautery. Group B patients (control group) underwent open subfascial ligation of perforators at the sites marked by colour doppler. Blomgren et al showed that the use of preoperative duplex scan resulted in changes to the planned surgery, and more importantly, resulted in less residual and recurrent varices at 2 years.⁵

Both the groups were studied for incidence of postoperative complications like hematoma, pain, wound infection, and saphenous nerve injury. Other parameters like duration of surgery, duration of hospital stay. At 3 months follow up, relief of symptoms and cosmoses were assessed and incidence of residual incompetent perforators were assessed by doing colour doppler. Before starting of the study, a written/informed consent was obtained in local vernacular for each patient.

Statistical analysis

Data from the two different groups was analyzed using SPSS (statistical presentation system software). The difference between the two groups are analysed using student 't' test and qualitative variables are analyzed using chi-square test with a p value <0.05 which is considered statistically significant.

RESULTS

In this prospective comparative study, 50 patients had undergone surgical treatment for incompetent leg perforators for varicose veins, of which 25 had undergone SEPS (group A/1) and the other 25 patients had under gone open subfascial perforator ligation surgery (group B/2).

In the present study age distribution among the open group (n=25) maximum age was 61 years and minimum age was 26 years with mean age of 44.40. 8.9 SD, and among the SEPS group (n=25) maximum age was 62 years and minimum age was 27 years with mean age of 43.32±10.2 SD (Figure 1). There was no statistically significant difference found between groups in relation to age of presentation.

Our study included 8 female patients and 17 male patients in SEPS group. 5 female patients and 20 male patients in open group. There was no statistically significant difference found between gender of the patient.

In our study perforator incompetence was seen in bilateral limbs in 2 patients (8%) in both the groups, left side involvement in 11 patients (44%) and 14 patients (56%), right side involvement in 12 patients (48%) and in 9 patients (36%) in SEPS and open group respectively, there was no statistically difference in sides (Table 1).

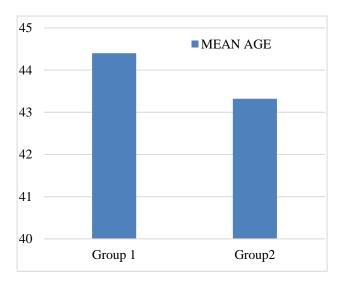


Figure 1: Comparison of mean age between the groups.

Table 1: Distribution of subjects according to side and groups.

| Side | Group | | Total | P |
|-----------|--------|--------|--------|-------|
| | 1 | 2 | Total | value |
| Bilateral | 2 | 2 | 4 | |
| | 8.0% | 8.0% | 8.0% | |
| Left | 11 | 14 | 25 | |
| | 44.0% | 56.0% | 50.0% | 0.674 |
| Right | 12 | 9 | 21 | |
| | 48.0% | 36.0% | 42.0% | |
| Total | 25 | 25 | 50 | _ |
| | 100.0% | 100.0% | 100.0% | |

In the present study perforators identified intraoperatively among the open group, 1 incompetent perforators was identified and ligated in 1 patients (4%), 2 perforators in 5 patients (20%), 3 perforators in 9 patients (36%), 5 perforators in 3 patients (12), 7 perforators in 4 (28%) and in SEPS group 2 incompetent perforators were identified and ligated in 1 patients (4%), 3 incompetent perforators were ligated in 1 patients (4%), 4 perforator in 9 patients (36%), 5 perforators in 5 patients (20%), 6 perforator in 8 patients (32%), 7 perforators in 1 patient (4%) which was statistically significant with p value 0.003.

In the present study post operatively wound site hematoma was seen in 9 (36%) patients in open group on post-operative day 1 which disappeared in 8 patients after post-operative day 5 and in 1 patient evacuation was done and 3 (12%) patient developed wound site hematoma in SEPS group, which resolved by day 5. There was a statistically significant difference found in the incidence of haematoma between the groups.

In our study 4 patients (16%) had post-operative saphenous nerve injury in open group and 1 patient (4%) in SEPS group. There was no statistically significant difference found about saphenous nerve injury between the groups (Table 2).

Table 2: Distribution of subjects according to saphenous nerve injury and groups.

| Saphenous | Group | | | P | |
|-----------------|--------|--------|--------|-------|--|
| nerve injury | 1 | 2 | Total | value | |
| No | 24 | 21 | 45 | 0.157 | |
| NO | 96.0% | 84.0% | 90.0% | | |
| Voc | 1 | 4 | 5 | | |
| Yes | 4.0% | 16.0% | 10.0% | | |
| Total | 25 | 25 | 50 | | |
| Total | 100.0% | 100.0% | 100.0% | | |

In the present study post-operative wound site infection was noted in 3 patients (12%) in open group, none in SEPS group. There was no statistically significant difference found in the incidence of wound infection among the groups.

In our study preoperative ulcer size in open group was $8.18\pm5.36~\text{cm}^2$, on post-operatively 2 weeks ulcer size decreased to $5.06\pm1.12~\text{cm}^2$, and on postoperatively 1 month ulcer size decreased to $2.28\pm0.1~\text{cm}^2$ and complete ulcer healing was observed by post operatively 3 months, in SEPS group, preoperative ulcer size was $7.75\pm5.52~\text{cm}^2$, on post-operatively 2 weeks, ulcer size decreased to $4.45\pm1.29~\text{cm}^2$, on post operatively 1 month ulcer size was $3.86\pm0.30~\text{cm}^2$, and complete ulcer healing was observed by postoperatively 3 months, however this observation was not significant statistically.

In our study, 10 patients had ulcers in open surgery group, among them 2 patient had complete ulcer healing by 2 weeks post-operatively, 6 patients had complete ulcer healing by 1 month post operatively, 2 patient had complete ulcer healing by 3 months post operatively and 4 patients had ulcers in SEPS group, 3 patients had complete ulcer healing by 1 month post-operatively, and 1 patient had complete ulcer by 3 months post-operatively.

In our study post-operative doppler scanning at 6 months in open group showed 1 residual perforators in 5 patients (20%). 2 perforators in 7 patients (28%), 3 perforators in 1 patient (4%), 4 perforators in 1 patient (4%). In SEPS group I residual perforator in 1 patient (4%) and 2 perforators in 1 patient (4%). There was a statistically

significant difference found about residual perforators between groups (Table 3).

Table 3: Distribution of subjects according to residual perforators and groups.

| Residual | Group | — Total | |
|-------------|--------|---------|--------|
| perforators | 1 2 | | Total |
| 0 | 23 | 11 | 34 |
| U | 92.0% | 44.0% | 68.0% |
| 1 | 1 | 5 | 6 |
| 1 | 4.0% | 20.0% | 12.0% |
| 2 | 1 | 7 | 8 |
| | 4.0% | 28.0% | 16.0% |
| 3 | 0 | 1 | 1 |
| 3 | 0.0% | 4.0% | 2.0% |
| 4 | 0 | 1 | 1 |
| 4 | 0.0% | 4.0% | 2.0% |
| Total | 25 | 25 | 50 |
| 10tai | 100.0% | 100.0% | 100.0% |

P value=0.009.

DISCUSSION

This was a prospective comparative study, comparing 50 patients who had undergone surgical treatment for incompetent leg perforators for varicose veins, of which 25 had undergone SEPS (group A/1) and the other 25 patients had under gone open subfascial perforator ligation surgery (group B/2).

In our study age distribution among the open group (n=25) maximum age was 61 years and minimum age was 26 years with mean age of 44.40. 8.9 SD, and among the SEPS group (n=25) maximum age was 62 years and minimum age was 27 years with mean age of 43.32±10.2 SD.

In our study, perforator incompetence was seen in bilateral limbs in 2 patients (8%) in both the groups, left side involvement in 11 patients (44%) and 14 patients (56%), right side involvement in 12 patients (48%) and in 9 patients (36%) in SEPS and open group respectively, there was no statistically difference in sides.

In the present study, perforators identified intraoperatively among the open group, 1 incompetent perforators identified and ligated in 1 patients (4%), 2 perforators in 5 patients (20%), 3 perforators in 9 patients (36%), 5 perforators in 3 patients (12), perforators in 4 (28%) and in SEPS group 2 incompetent perforators were identified and ligated in 1 patients (4%), 3 incompetent perforators were ligated in 1 patients (4%), 4 perforator in 9 patients (36%), 5 perforator in 5 patients (20%), 6 perforator in 8 patients (32%), 7 perforators in 1 patient (4%) which was statistically significant with p value 0.003. Jugenheimer et al have reported a total of 456 perforators with a range of 2-11 perforators, averaging 4 perforators per limb.⁶ Pierik et al have reported a total of 54 perforators with a range of 1-6 perforators, averaging 2.9 perforators per limb.⁴

In the present study mean duration of stay in hospital in open group is 7.3±0.6 days and 5.2±0.9 days in SEPS group which is statistically significant with p value <0.0001, similarly study conducted by Pierik et al conducted randomized trial on endoscopic versus open subfascial division of incompetent perforating veins in the treatment of venous leg ulceration, where patients in the open group needed longer hospital stays (mean, 7 days; range, 3 to 39 days) than patients in the endoscopic group (mean, 4 days; range, 2 to 6 days; p=0.001).⁴

In the present study, comparison of pain postoperatively was done using VAS scale, VAS scoring was 3 ± 0.7 on postoperative day 1 in open group and 2 in SEPS group which was statistically significant with p value <0.0001, on postoperative day 3 VAS scoring was 2.2 ± 0.5 in open group and 1.2 ± 0.4 in SEPS group which was statistically significant with p value <0.0001 and on postoperative day 7 VAS scoring was 1.0 ± 0.4 in open group and 0.4 ± 0.5 in SEPS group which was statistically significant with p value <0.0001.

In the present study postoperatively wound site hematoma was seen in 9 (36%) patients in open group on postoperative day 1 which disappeared in 8 patients after postoperative day 5 and in 1 patient evacuation was done and 3 (12%) patient developed wound site hematoma in SEPS group, which resolved by day 5. Study conducted by Kulbaski et al have done a prospective study on subfascial endoscopic perforator surgery where 20 cases of subfascial endoscopic perforator surgery (SEPS) was done in 19 patients, one patient required re-exploration for a subfascial hematoma.⁷

In the present study, postoperative wound site infection was noted in 3 patients (12%) in open group, none in SEPS group in contrast study similar conducted by Nelzen et al on prospective study of safety, patient satisfaction and leg ulcer healing following saphenous and subfascial endoscopic perforator surgery, 107 patients underwent the procedure, in which wound site infection was found in 7% of the patients. Luebke and Brunkwall have also reported significant lower rate of wound infection with SEPS and concluded that it benefits most patients of chronic venous insufficiency. Kurdal et al could also achieve sustainable wound healing with SEPS. 10

In the present study, no patients in both groups had ulcer recurrence over a period of follow up of 1 year, similarly study conducted by Pierik, et al have done a randomized trial on Endoscopic versus open subfascial division of incompetent perforating veins in the treatment of venous leg ulceration, no recurrences were noticed in either group, for follow up period of 21 months.⁴

In our study 4 patients (16%) had postoperative saphenous nerve injury in open group and 1 patient (4%)

in SEPS group, in contrast study conducted by Gloviczki et al a retrospective study on safety, feasibility, and early efficacy of subfascial endoscopic perforator surgery has observed that saphenous neuralgia in 10 patients, out of 155 SEPS procedures done.¹¹

In our study, preoperative ulcer size in open group was 8.18 ± 5.36 cm², on postoperatively 2 weeks ulcer size decreased to 5.06 ± 1.12 cm², and on postoperatively 1 month ulcer size decreased to 2.28 ± 0.1 cm² and complete ulcer healing was observed by post operatively 3 months, in SEPS group, preoperative ulcer size was 7.75 ± 5.52 cm², on post-operatively 2 weeks, ulcer size decreased to 4.45 ± 1.29 cm², on post-operatively 1 month ulcer size was 3.86 ± 0.30 cm², and complete ulcer healing was observed by postoperatively 3 months, however this observation was not significant statistically.

In our study, 10 patients had ulcers in open surgery group, among them 2 patient had complete ulcer healing by 2 weeks postoperatively, 6 patients had complete ulcer healing by 1 month post-operatively, 2 patient had complete ulcer healing by 3 months postoperatively and 4 patients had ulcers in SEPS group, 3 patients had complete ulcer healing by 1 month post-operatively, and 1 patient had complete ulcer by 3 months post-operatively. 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. 12

In our study, postoperative doppler scanning at 6 months in open group showed 1 residual perforators in 5 patients (20%). 2 perforators in 7 patients (28%), 3 perforators in 1 patient (4%), 4 perforators in 1 patient (4%). In SEPS group I residual perforator in 1 patient (4%) and 2 perforators in 1 patient (4%). Sybrandy et al reported persistent perforators in 20% of patients in the SEPS group also. ¹³

CONCLUSION

Our study has shown that SEPS is definitely superior to open technique because of shorter mean hospital stay, lesser postoperative complications like pain, haematoma formation and wound infection, in terms of number of perforators ligated. Recurrence of varicose veins/varicose ulcer at one year follow up was none, though longer follow up is needed to comment about the true superiority of SEPS versus open subfascial ligation of perforators in treatment of varicose veins.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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