ADVANTAGE OF SUBFASCIAL ENDOSCOPIC PERFORATOR SURGERY [SEPS] OVER OPEN PERFORATOR LIGATION [OSPL] IN TREATMENT OF GREAT SAPHENOUS VARICOSE VEINS-A COMPARITIVE STUDY

Surgery

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ABSTRACT

This comparative study was conducted at ESIC MEDICAL COLLEGE & PGIMSR, K.K.NAGAR, CHENNAI -78 for a total of 50 patients who were diagnosed with Great saphenous varicose veins with perforator incompetence for a period of 18 months from April 2018. Patients underwent open subfascial perforator ligation or subfascial endoscopic perforator ligation in a 1:1 ratio by alternate allocation method. Odd numbered patients were treated by subfascial endoscopic perforator surgery and even numbered patients were treated by open subfascial perforator ligation. The observation and inference is noted in this presentation.

KEYWORDS

Varicose veins, sub facial endoscopic perforator surgery, open sub facial perforator ligation, Variables.

INTRODUCTION

Varicose vein is defined as dilated, tortuous, superficial vein more than 3 mm in diameter which is measured in the upright position with demonstrable reflux.

The prevalence rate of varicose veins is higher in women than men. It is 25–30 per cent in women and 15 percent in men¹. Prevalence of varicose veins increases with age, increased body mass index and height². Pregnancy appears to increase the risk. There is evidence regarding increased prevalence of varicose veins in smokers and in occupations involving prolonged standing like bus conductors etc.

The CEAP classification [clinical – aetiology–anatomy–pathophysiology] is followed in classifying varicose veins.³

Treatment options are Compression hosiery,⁴ Ultrasound-guided foam sclerotherapy, Endo-Venous Laser Ablation (EVLA) and Radiofrequency ablation.

Surgeries done are Sapheno femoral junction ligation,⁵ Great Saphenous Vein Stripping and Sub facial Endoscopic Perforator

Ligation [SEPS].⁶

AIM AND OBJECTIVE

To study the advantage of Sub facial Endoscopic Perforator Surgery in the management of Great Saphenous Varicose Veins and to compare it with Open sub facial Perforator Ligation in terms of certain variables such as intra operative and postoperative variables.

METHODOLOGY:

The study sample size was 50 patients as per the following calculation

Sample size calculation:

Standard deviation in group	0.4
Standard deviation in group	0.5
Mean difference in pain reduction (VAS score)	0.6
Effect size	1.3
Alpha error (%)	5
Power (1 – beta) %	90
1 or 2 sided	2

Required sample size per Group	12
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Inclusion criteria

All consenting patients in the age group of 18 and 65 years, with Great saphenous varicose vein and perforator incompetence.

Exclusion criteria

Morbid obesity, Pregnancy, Previous varicose surgery, uncontrolled medical condition, unfit for anaesthesia.

SEPS PROCEDURE

SEPS is done by two port method, Knee is flexed to 90 degree and hip joint flexed and abducted. 10mm port is put over the medial aspect of the calf, posterior to the medial border of Tibia 5 to 7 cm distal to Tibial tuberosity under direct vision by incising the fascia. Subfascial space will be created by inflation of CO₂ at 25 to 30 mmHg and direct dissection with the tip of telescope. 2nd 10mm trocar will be placed postero-medially and slightly inferior to the first port. The Subfascial space will be explored and all the perforators will be clipped using endoclip application. By rotating the ports the whole of the leg will be explored and all the Perforators clipped.

Fig[a] perforators visualised in saphenous Fig [b] showing trocar incision in SEPS technique

OSPL PROCEDURE:

Skin and fascial incision will be at the point of the marked incompetent perforator. Subfascial plane is to be created and perforator is identified. The perforator is then transfixied using 2-0 vicryl. Closure done. Sterile dressing, Elasto Crepe Bandage application and limb elevation is given.

Fig [c] clipping of perforator using endoclip.

STUDY VARIABLES:

For every patient the following variables were recorded in the preformed protocol

I. Intra operative variables

1. Operative time
2. Numbers of perforators clipped/ligated.

II. Post-operative variables

1. Postoperative pain at day 1 and day 3 and day 7
2. Day of discharge
3. Day of return to work
4. Scar size
5. Post Op venous Doppler

The observation at the end of the study is tabulated as given below:

I. INTRA OPERATIVE VARIABLE

1: operative time

Operative Time	STUDY GROUP			
	SEPS		OSPL	
	N	%	N	%
< 50 Mints	11	44.00	2	8.00
50 – 60 Mints	11	44.00	7	28.00
> 60 Mints	3	12.00	16	64.00
TOTAL	25	100	25	100
Chi-square	16.01			
P-Value	0.001			
Significant	Significant			

Statistical significance

Significant since p-value is < 0.05. The operative time in OSPL group is predominantly more when compared to SEPS. A p value of 0.001 is not a chance occurrence.

Clinical significance

Out of 25 cases performed by OSPL technique it required more than 60 minutes in 16 cases, Whereas in SEPS technique more than 60 minutes was required only in 3 cases.

Variable No: 2 NO. OF PERFORATORS LIGATED/CLIPPED

	SEPS	OSPL
Mean	3.88	3.16
Sd	0.97	0.75
t-value	2.94	
Df	48	
P-value	0.01	
Significant	Significant	

Statistical significance:

The number of perforators ligated in OSPL group is low in number as compared to SEPS. It is statistically significant with a p value of 0.01 and has not occurred by chance.

Clinical significance:

Number of perforators ligated in SEPS group is significantly higher as compared to OSPL group i.e the mean in SEPS group is 3.88 whereas in OSPL group is 3.16.

POST OP VARIABLES **VARIABLE 1 – POST OP PAIN AT DAY 1**

	SEPS	OSPL
Mean	5.48	6.28
Sd	0.59	0.68
t-value	4.46	
Df	48	
P-value	0.001	
Significant	Significant	

POST OP PAIN AT DAY 3

	SEPS	OSPL
Mean	3.24	3.92
Sd	0.66	0.57
t-value	3.88	
Df	48	

P-value	0.001
Significant	Significant

POST OP PAIN ON FOLLOW UP DAY 7

	SEPS	OSPL
Mean	1.28	1.68
Sd	0.46	0.56
t-value	2.77	
Df	48	
P-value	0.01	
Significant	Significant

Statistical significance:

Statistically significant since p-value is < 0.05 . In other words postoperative pain is low at day 1, Day 3 and in Day 7 in SEPS group as compared to OSPL group. This difference is true and significant.

Clinical significance:

Postoperative pain which was assessed in patients who undergone perforator ligation by SEPS technique by visual analogue scale at the post op day 1, Day 3 and Day 7 was significantly low.

In OSPL group postoperative pain assessed by visual analogue scale was high. This difference is true and significant.

VARIABLE 2-DAY OF DISCHARGE:

POST OP DAY	STUDY GROUP			
	SEPS		OSPL	
	N	%	N	%
2nd Post OP Day	2	8.00	0	0
3rd Post OP Day	15	60.00	1	4.00
4th Post OP Day	8	32.00	11	44.00
5th Post OP Day	0	0	12	48.00
6th Post OP Day	0	0	1	4.00
TOTAL	25	100	25	100
Chi-square	27.72			
P-Value	0.001			
Significant	Significant			

Statistically significant since the p-value is 0.001.

VARIABLE 3 - DAY OF RETURN TO WORK:

Day of Return to Work	STUDY GROUP	
	SEPS	OSPL

	N	%	N	%
2nd Week	2	8.00	0	0
3rd Week	20	80.00	18	72.00
4th Week	3	12.00	7	28.00
TOTAL	25	100	25	100
Chi-square	3.71			
P-Value	0.16			
Significant	Not Significant

Not statistically significant since p-value is > 0.05

VARIABLE 4 - SCAR SIZE:

SCAR SIZE (Cm)	STUDY GROUP			
	SEPS		OSPL	
	N	%	N	%
< 2 cm	5	20.00	1	4.00
2- 3 cm	4	16.00	12	48.00
> 3 cm	16	64.00	12	48.00
TOTAL	25	100	25	100
Chi-square	7.24			
P-Value	0.03			
Significant	Significant			

Statistically significant since p-value is < 0.05 . It is statistically significant with a p value of 0.03 according to chi-square test. This difference is true and significant.

VARIABLE 5 - POST OPDOPPLER MISSED PERFORATORS:

	STUDY GROUP			
	SEPS		OSPL	
	N	%	N	%
Present	1	4.00	3	12.00
Absent	24	96.00	22	88.00
TOTAL	25	100	25	100
Chi-square	0.09			
P-Value	0.30			
Significant	Not Significant			

Not statistically significant since p-value is 0.30.

DISCUSSION:

This study was done to assess the effects of Subfascial Endoscopic Perforator Surgery in the management of Great Saphenous Varicose Veins and to compare it with Open Subfascial Perforator Ligation over a period of 18 months from April 2018 by studying a total of 50 patients. The analysis indicated that SEPS was associated many advantages as compared to OSPL.

There was NO significant difference in day of return to work and missed perforators assessed by venous Doppler at the end of 3 months.

INTRAOPERATIVE TIME

The time taken to complete the SEPS procedure less than 50 minutes in 11 patients [44 %], for another 11 patients procedure got completed in less than 60 minutes [44 %], only for 3 patients operative time exceeds 60 minutes [12%] whereas in OSPL group for 16 patients the operative time was more than 60 minutes [64 %] and for another 7 patients the operative time was between 50–60 minutes [28 %], only 3 for 3 patients the operative time was less than 50 minutes [12%] since p value is <0.05.

The difference between the groups were statistically significant. In simple words OSPL technique requires more time than SEPS for perforator ligation reported that intra operative time is less in SEPS due to proper visualisation of perforators after CO₂ insufflation.

NUMBER OF PERFORATORS LIGATED /CLIPPED

On analysing the study it is found to be that in SEPS group the average number of perforators clipped was 3.88. In 5 patients 5 and more perforators were clipped by using endoclip [20 %], in 13 patients 4 perforators were clipped. [52 %], and in 7 patients 3 and less perforators were endoclipped [28 %].

Whereas in OSPL group for 12 patients 3 perforators were ligated Subcutaneously [48 %] and for 5 patients only 2 perforators were ligated [20 %], only for 8 patients 4 perforators were ligated. Since the p value is <0.05, it is statistically significant.

POST OPERATIVE PAIN AT DAY 1:

Pain assessed by Visual Analogue Score (VAS) depicts that in SEPS group 10 patients experienced score 6 [56 %] and 14 patients experienced VAS 5 [20 %] and 1 patient experienced VAS 7 [4 %]. In OSPL group 10 patients experienced pain of VAS 7 [40 %], 3 patients experienced VAS 5 [12 %] and 12 patients experienced VAS 6 [48 %]. Since the p value is <0.05 the pain difference between both the groups is statistically significant.

In simple words the patients who underwent SEPS experienced less pain as compared to the OSPL group.

POST OPERATIVE PAIN AT DAY 3:

Pain assessed by VAS showed that in SEPS group 13 patients experienced VAS 3 [52 %], 9 patients experienced VAS 4 [36 %] and 3 patients experienced VAS 2 [12 %] whereas in OSPL group 20 patients experienced VAS 4 [80 %] and 2 patients experienced VAS 2 [8 %] and 2 patients experienced VAS 3 [8 %] and 1 patient experienced VAS 2 [4 %] since the p value is <0.05 the pain difference between both the groups is statistically significant. In simple words the patients who underwent SEPS experienced less pain as compared to the OSPL group at post op day 3.

POST OP PAIN AT DAY 7:

Pain assessed by VAS shows that in SEPS group 18 patients experienced VAS 1 [72 %], 7 patients experienced VAS 2 [28 %] whereas in OSPL group 15 patients experienced VAS 2 [60 %] and 1 patient experienced VAS 3 [4 %] and 1 patient experienced VAS 1 [36 %]. Since the p value is <0.05 the pain difference between both the groups is statistically significant. In simple words the patients who underwent SEPS experienced less pain as compared to the OSPL group at post op day 7.

VARIABLE 2 - DAY OF DISCHARGE:

All the patients were discharged post operatively once they were symptomatically free.

On analysis the data indicated that among the patients who underwent OSPL, 10 patients were discharged at 4th post op day [40 %], 12 patients were discharged at 5th post op day [48 %], 2 patients were discharged at 3rd post op day [8 %] and 1 patient got discharged at 6th post op day [4 %].

Whereas in SEPS group 14 patients got discharged at 3rd post op day [56 %], and 8 patients got discharged at 4th post op day [32 %], and 3 patients got discharged at 2nd post op day [12 %].

This data is statistically significant since p value is less than 0.05. In simple words patients underwent SEPS got discharged earlier than OSPL group.

VARIABLE 3 - DAY OF RETURN TO WORK:

The data of patient return to work depicted that 21 patients [84 %] who underwent SEPS returned to their work on the 3rd week. And 2 patients returned to their work on the 2nd week [8 %], and another 2 patients returned to their work on the 4th week [8 %]. Whereas in OSPL group 18 patients went to their work on the 3rd week [72 %], and another 7 patients went to their work on the 4th week [28 %]. Since the p value is 0.05 it is statistically not significant. Therefore the two procedures SEPS and OSPL don't differ with respect to patients return to work post op.

VARIABLE 4 - SCAR SIZE:

In 10 patients who underwent OSPL the scar size at 3 months is >3cm [40 %], remaining 15 patients scar size is less than 3cm [60 %]. Whereas patients underwent SEPS only 2 cases the scar size is >3cm at 3 months [8 %], remaining 23 patients [92 %] scar size is <3cm. Since the p value is <0.05 the difference between the groups regarding scar size at three months is statistically significant.

VARIABLE 5 - POST OP VENOUS DOPPLER AT 3RD MONTH

At the end of 3 months in both the groups post op Doppler was done to find out the missed perforators. It is found to be that 3 cases who undergone OSPL were found to have missed perforators [12 %]. And similarly 1 patient underwent SEPS was found to have missed perforator [4 %]. Since p value is <0.05 it is statistically not significant.

SUMMARY

This Randomized controlled study was conducted at ESIC MEDICAL COLLEGE & PGIMS, K.K. NAGAR, CHENNAI - 78 for 1 and half years, total 50 patients diagnosed as Great saphenous varicose veins with perforator incompetence. In the present study mean age in subfascial endoscopic perforator surgery was 45 and open subfascial perforator surgery was 42. By conventional criteria the association between the surgical treatment groups (i.e. SEPS and OSPL) were that OSPL technique requires more time than SEPS for perforator ligation, the number of perforators clipped in SEPS was more as compared to OSPL. Post op pain was low in SEPS as compared to OSPL, day of discharge in SEPS group was low as compared to OSPL, but there is no significant difference in day of return to work and missed perforators numbers as assessed by post op venous Doppler. SEPS is cosmetically better as compared to OSPL.

CONCLUSION

This study indicates that SEPS is a feasible and cost effective method⁷. It is advantageous over OSPL in terms of preoperative diagnosis, intra operative time, number of perforators clipped/ligated, postoperative pain, day of discharge, day of return to work, scar size and post op missed perforators⁸.

The operative time in SEPS technique is significantly low as compared to OSPL. The number of perforators clipped in SEPS is significantly higher as compared to number of perforators ligated in OSPL⁹. Postoperative pain at day 1, day 3, day 7 is significantly lower in SEPS as compared to OSPL. Day of return to work and number of missed perforators assessed post operatively by Doppler study shows that there is no significant difference. SEPS has cosmetic benefits over OSPL, both statistically and clinically.¹⁰

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