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A Comparative Study of Subfascial Endoscopic Perforator Surgery [SEPS] Versus Open Perforator Ligation [OSPL] in the Treatment of Great Saphenous Varicose Veins

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Abstract
The most common symptom is being aching or heaviness in the lower limbs especially increases in the evening after prolonged standing, and is relieved by Elevation or compression hosiery. Other symptoms include ankle swelling and itching. The presence of tortuous dilated subcutaneous veins which are confined to the greater saphenous system and lesser saphenous systems in approximately 60 and 20 per cent of cases, respectively. After consulting with the statistician the sample size was set as 50 patients in the study as per the following calculation. The required sample size is 12 patients per group by using formula. But after consideration the lost to follow up and to power the study, sample size will be 25 patients per group to test the mean difference between two groups for pain reduction (VAS score). The Master (2.0) software was used to calculate the sample size. This study has been done to assess the feasibility and safety of Subfacial Endoscopic Perforator Surgery in the management of Great Saphenous Varicose Veins and to compare it with Open Subfacial Perforator Ligation over a period of 18 months by enrolling a total of 50 patients and allocating 25 patients each group for intervention on alternate allocation method and the paramaters [operative time, number of perforators ligated/clipped, post op pain at day 1, post op pain at day 3, post op pain at day 7, day of discharge, day of return to work, scar size, post op venous Doppler] being observed and put on record in the preformed protocol and analysed Present study concludes that SEPS is feasible and cost effective technique. It is comparable with OSPL in terms of pre operative diagnosis, intra operative time, number of perforators clipped/ligated, post operative pain, day of discharge, day of return to work, scar size and post op missed perforators The operative time in SEPS technique is significantly low as compared to OSPL.

INTRODUCTION

The most common symptom is being aching or heaviness in the lower limbs especially increases in the evening after prolonged standing and is relieved by Elevation or compression hosiery. Other symptoms include ankle swelling and itching. The presence of tortuous dilated subcutaneous veins which are confined to the greater saphenous system and lesser saphenous systems in approximately 60 and 20 per cent of cases, respectively. The distribution of varicosities may indicate which superficial system is defective for example medial thigh and calf varicosities indicates great saphenous vein incompetence and posterolateral and calf varicosities are suggestive of short saphenous incompetence, anterolateral thigh and calf varicosities may suggest incompetence of the proximal anterolateral long saphenous tributary Percussion over the varices may elicit an impulse tap by the fingers placed over the dilated trunk[1-4]. Telangectasia-a confluence of dilated intradermal venules<1 mm in dm. Also called as spider veins, thread veins and hyphen webs. Reticular veins are dilated, sub dermal veins of 1-3 mm in dm. In saphena varix there is a large varicosity may be present in groin region. Appears when standing and disappearing on lying down position. Gentle palpation. Over the varix during coughing may elicit a thrill. Atrophie blanche is localized white atrophic skin which is frequently surrounded by dilated capillaries and hyper pigmentation and usually seen around the ankle. Corona phlebectasia are small intradermal veins usually on the medial or lateral aspects of the ankle or foot[5-7]. Also called as malleolar flare or ankle flares Pigmentation is usually a brownish discolouration due to haemosiderin deposition of the skin, mostly affecting the area around the ankle and may be associated with superficial thrombophlebitis and ulceration. Eczema it is an erythematous dermatitis which may leads to blistering, weeping or scaling of the skin, it should be differentiated with contact dermatitis. Dependent pitting oedema it is due to increase in volume of fluid in skin and subcutaneous tissue which increases throughout the day and is relieved by elevation of the limb and compression bandaging. Lipodermatosclerosis is a localised chronic inflammation and fibrosis of the skin and subcutaneous tissues of the leg. Ulceration is a breach in the continuity of the epithelium of the skin most commonly affecting the area around the ankle[8].

Aim and Objectives of the Study: To evaluate the feasibility and safety of Subfacial Endoscopic Perforator Surgery in the management of Great Saphenous Varicose Veins and to compare it with Open Subfacial Perforator Ligation in terms of Operating time. Number of perforators ligated. Pain in post operative period. Length of hospital stay. Return to work. Number of residual perforators. Cosmesis.

MATERIALS AND METHODS

After consulting with the statistician the sample size was set as 50 patients in the study as per the following calculation. The required sample size is 12 patients per group by using formula. But after consideration the lost to follow up and to power the study, sample size will be 25 patients per group to test the mean difference between two groups for pain reduction (VAS score). The nMaster (2.0) software was used to calculate the sample size. Inclsuion criteria are All consenting patients presenting with Great saphenous varicose veins and perforator incompetence, Age group between 18 and 65 years Exclusion criteria are Pregnancy, Morbid obesity, Uncontrolled medical conditions, History of previous varicose vein surgeries over the same leg, Patient unfit for anaesthesia. Statistical analysis was done using the statistical package for social sciences (SPSS). Different statistical methods were used as appropriate. Mean±SD was determined for quantitative data and frequency for categorical variables. The independent t-test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p-value<0.05 was considered significant.

RESULTS AND DISCUSSIONS

Table 1: Multiple Tourniquet Test

Study Group	SEPS		OSPL	
	N	%	N	%
Below Knee and Above Ankle	2	8.00	5	20.00
Below Knee and Mid Leg	1	4.00	5	20.00
Above Knee and Mid Leg	22	88.00	15	60.00
Total	25	100	25	100
Chi-square	5.28			
P-Value	0.07			
Significant	Not Significant			

By conventional criteria the association between the surgical treatment groups and the pre operative diagnosis of Site of perforator incompetence diagnosed clinically by performing Multiple tornique test is considered to be not statistically significant since p-value is >0.05.

Table 2: Fegan's Test

Study Group	SEPS		OSPL	
	N	%	N	%
Below Knee and Above Ankle	2	8.00	6	24.00
Below Knee and Mid Leg	1	4.00	4	16.00
Mid Leg and Above Ankle	22	88.00	15	60.00
Total	25	100	25	100
Chi-square	5.12			
P-Value	0.08			
Significant	Not Significant			

By conventional criteria the association between the surgical treatment groups and the pre operative diagnosis of Site of perforator incompetence diagnosed clinically by performing Fegans test is considered to be not statistically significant since p-value is >0.05

Table 3: Sapheno Femoral Incompetence

Study Group	SEPS		OSPL	
	N	%	N	%
Competent	9	36	4	16
Incompetent	16	64	21	84
Total	25	100	25	100
Chi-square	2.60			
P-Value	0.11			
Significant	Not Significant			

By conventional criteria the association between the surgical treatment groups and the pre operative diagnosis of Sapheno femoral incompetence is considered to be not statistically significant since p-value is >0.05.

Table 4: PRE OP Venous Doppler

Study Group	SEPS		OSPL	
	N	%	N	%
Above Knee, Below Knee and Above Ankle	0	0	4	16.00
Above Ankle and Mid Leg	19	76.00	12	48.00
Below Knee and Above Ankle	0	0	1	4.00
Below Knee and Mid Leg	2	8.00	3	12.00
Mid Leg and Above Ankle Incompetence	0	0	1	4.00
Mid Leg , Above Ankle & Below Knee	1	4.00	1	4.00
Mid-Thigh and Mid Leg	0	0	1	4.00
Mid Thigh, Mid Leg and Above Ankle	1	4.00	1	4.00
Mid Thigh, Below Knee, Mid leg and Above Angle	2	8.00	1	4.00
Total	25	100	25	100
Chi-square	9.11			
P-Value	0.33			
Significant	Not Significant			

By conventional criteria the association between the surgical treatment groups and the pre operative diagnosis of perforators by pre op Doppler is considered to be not statistically significant since p-value is >0.05.

Table 5: The Study Group and 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	

This study has been done to assess the feasibility and safety of Subfacial Endoscopic Perforator Surgery in the management of Great Saphenous Varicose Veins and to compare it with Open Subfacial Perforator Ligation over a period of 18 months by enrolling a total of 50 patients and allocating 25 patients each group for intervention on alternate allocation method and the paramaters [operative time, number of perforators ligated/clipped, post op pain at day 1, post op pain at day 3, post op pain at day 7, day of discharge, day of return to work, scar size, post op venous Doppler] being observed and put on record in the preformed protocol and analysed, indicated that SEPS was associated with lesser intra operative time and the number of perforators clipped was significantly higher as compared to OSPL. Significant difference were found in terms of post operative pain at day 1 and day 3 and day 7 that is patients underwent SEPS were found to have lesser post operative pain as compared to OSPL group. There is also significant difference were found in day of discharge and scar size. There is no significant difference in day of return to work and missed perforators assessed by venous Doppler at the end of 3 months.In the study group <30 years who underwent SEPS were 2 in number [8 percentage], whereas in OSPL it was 5 in number [20 percentage]. Age group between 31-40 who underwent SEPS were 8 in number [32 percentage] in OSPL it was also 8 in number. Age group between 41-50 years who underwent SEPS were 7 in number [28 percentage] in OSPL it was 4 in number [16 percentage]. Age group 51-60 years who underwent SEPS were 5 in number [20 percentage]. In OSPL it was 7 in number [28 percentage]. Age group more than 61 years who underwent SEPS were 3 in number [12 percentage] in OSPL it was 1 [4 percentage[9-12]]. Among the patients who underwent SEPS 84 percentage were males and 16 percentage were females, whereas who underwent OSPL 84 percentage were males and 16 percentage were females.Since age and gender are not statistically significant, it means that there is no difference between the groups. Also in simple terms the groups contain subjects with the same demographic characteristics. With this data it conveys that SEPS is comparable with OSPL. On analyzing the data , the time taken to complete the SEPS procedure <50 minutes in 11 patients [44 percentage], for another 11 patients procedure got completed in less than 60 minutes [44 percentage], only for 3 patients operative time exceeds 60 minutes [12 percentage] whereas in OSPL group for 16 patients the oprative time was more than 60 minutes [64 percentage] and for another 7 patients the operative time was between 50-60 minutes [28 percentage], only 3 for 3 patients the operative time was <50 minutes [12 percentage]. 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 Wieslaw Pesta, 1 Waldemar Kurpiewski ,1 Marek Kowalczyk, 1 Rafal Szynkarczuk, 1 Magdalena Luba, 1 Anna Zurada, 2 and Radoslaw Grabysa3 reported that intra operative time is less in seps due to proper visualisation of perforators after co2 insufflation[13]. Umber of perforators ligated/clipped

On analyzing 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 percentage], in 13 patients 4 perforators were clipped [52 percentage] and in 7 patients 3 and less perforators were endoclipped [28 percentage]. Whereas in OSPL group for 12 patients 3 perforators were ligated Subcutaneously [48 percentage] and for 5 patients only 2 perforators were ligated [20 percentage] ,only for 8 patients 4 perforators were ligated. Since the p value is <0.05 the difference between the groups for number of perforator ligation is statistically significant[14-16]. A Comparative study done by S Shivakumar, Gopi Tupkar, N Ravishankar and Divakar reported that the Total number of perforators ligated in SEPS group were more compared to open group. Similarly a study conducted by M.G. Vashist, Vijay Malik and Nitin Singhal reported that the number of perforator ligated in SEPS was more as compared to the open subfascial ligation group[17]. Possibly some perforators may be missed on Doppler localization and ligation, which may be a cause of future recurrence in varicose veins in the open ligation group.

CONCLUSION

Present study concludes that SEPS is feasible and cost effective technique. It is comparable with OSPL in terms of pre operative diagnosis, intra operative time, number of perforators clipped/ligated, post operative pain, day of discharge, day of return to work, scar size and post op missed perforators. 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 OSPL Post operative 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.

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