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"Comparative Study of Subfascial Endoscopic Perforator Surgery & Open Subfascial Ligation of Perforators in Cases of Perforator Incompetence – A Prospective Study"

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I. Introduction

In this modern era, Varicose veins have become a common social problem and needs surgical interventions in order to improve the quality of life. Varicose veins are identified as dilated tortuous, thickened or widened veins which are the branches of great saphenous vein and small saphenous vein .[1] The epidemiological data states that the prevalence of varicose veins and chronic venous insufficiency affects 10-30% of general population.[2] Based on the CEAP Classification, the severity of this condition ranges from telangiectatic veins to venous ulceration.[3]

Considering the anatomical aspects, perforator veins perform a normal function in transporting superficial venous blood inward to the deep veins for further transit to the heart. If perforator veins become incompetent and transmit outward flow leads to chronic venous insufficiency which plays major role in pathophysiology of chronic venous insufficiency. In the era of management of varicose veins, Trendelenberg was the one introducing surgery as an option for the management of varicose veins which serves as the base for the beginning of modern vascular surgery.[4]

There are vast varieties of surgical treatment approaches available in the management of varicose veins which includes high ligation, open surgery, Sub-fascial endoscopic perforator surgery (SEPS) ,stripping, minimally invasive procedures like catheter directed sclerotherapy, ablation techniques such as radiofrequency ablation, endothermal ablation, laser ablations, non endothermal/non-tumescent ablations and excision/ligation of veins.[5] In the recent times, different techniques of ligation are in practice among which open surgery or Sub-fascial endoscopic perforator surgery (SEPS) is utilized in this study in the management of perforators incompetence in varicose veins.

Open surgery or Linton method is a ligation technique and utilized as a primary treatment of a reflexing superficial axis.[6] This technique has the greater advantage that all perforators can be seen clearly during surgery which facilitates proper ligation with appreciable long-term results compared to minimally invasive procedures. Sub facial Endoscopic Perforator Surgery (SEPS) is a minimally invasive technique which utilizes endoscopic instruments to aid interruption of incompetent perforators using small incisions in the areas of ulceration.[7] The main advantage of this technique is the patient can be discharged after a few hours of observation post surgery and also hastens wound healing process in already compromised skin and evidently the results are comparable to the classic Linton's procedure or open method. This prospective study aims to compare the subfascial endoscopic perforator surgery & open subfascial ligation of perforators in cases of perforator incompetence.

II. Aims and Objectives

AIM:

To compare the efficacy of Sub fascial Endoscopic Perforator Surgery (SEPS) and open surgery in the subfascial ligation of perforators in varicose veins.

OBJECTIVE:

1. The primary objective is to evaluate and analyze the clinical effectiveness of SEPS and open surgery in perforator veins incompetence.
2. The secondary objective is to estimate the difference in post -surgical outcomes in terms of quality of life between SEPS and Open surgery after one-year post treatment.

III. Materials and Methods

This study was designed as a Prospective study conducted in the surgical clinic in Theni government medical college and hospital. The purpose of this study was to evaluate and compare the efficacy of SEPS and open surgery in the subfascial ligation of perforators in varicose veins. This study was conducted from May 2018 to Jan 2021.

ETHICAL COMMITTEE APPROVAL:

This study proposal was placed before the Institutional Ethical Committee and prior approval were procured before the commencement of the study (REFERENCE NO: 884/MElll/19). All the patients participating in the study were explained about the nature of the disease related defects, the surgical procedure and their possible complications, following which a written informed consent was obtained before initiation of treatment.

Sample size for the study was calculated based on the study done by Vashist et al in 2014.[49] A total of 138 patients who full-filled the inclusion criteria and exclusion criteria were allocated into the study where 82 patients underwent open surgical procedures and 56 patients underwent SEPS. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019) was used.

RECRUITMENT OF PATIENTS:

The recruitment of patients was done followed by the evaluations such as General examinations, systemic examinations, investigations such as complete hemogram, liver function test, renal function test, USG abdomen, Color doppler lower limb, ESR, CXR. Along with these evaluations, patients who satisfies the inclusion criteria were included in the study.

SUBJECT SELECTION CRITERIA: INCLUSION CRITERIA:

1. Patients aged between 18-60 years
2. Patients with Perforator vein incompetence

EXCLUSION CRITERIA:

1. Patients aged above 60 yrs
2. Patients with systemic complications
3. Patients with Deep Vein Thrombosis

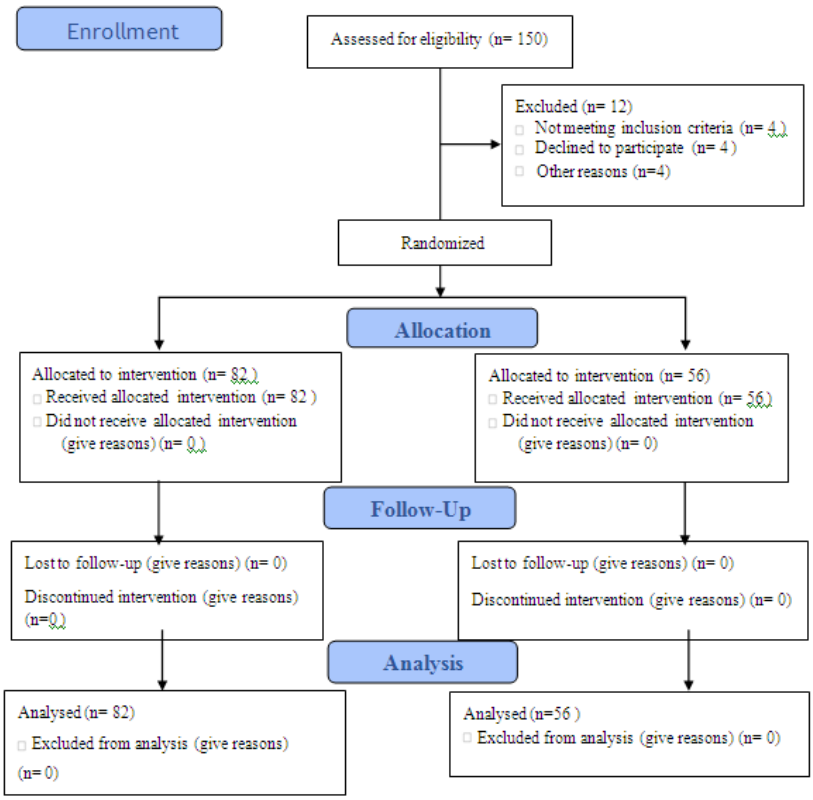


FIGURE 1: Enrolment flow chart

RANDOMISATION:
The cases were randomized into two groups as Group A and Group B

GROUP A : Patients 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 electrocautery.
GROUP B : Patients were subjected to open subfascial ligation of perforators at the sites marked.
Both the groups were studied for incidence of hematoma, pain, wound infection, and saphenous nerve injury.
SURGICAL PROCEDURES:
Trendelenburg procedure was done for all patients in both groups with saphenofemoral incompetence.

TRENDELENBURG PROCEDURE:

Under strict aseptic precautions and under sub arachnoid block, patient was laid in supine position with leg abducted and externally rotated, parts painted and draped. Low inguinal skin crease (2-3cm) incision made with femoral artery as lateral extent. Sub cutaneous tissue incised. Great saphenous vein identified, dissected. Three named tributaries (superficial external pudendal, superficial epigastric, superficial circumflex iliac) were identified and ligated. Great saphenous vein flush ligation done at the saphenofemoral junction. Great saphenous vein stripping done using mayo strippers. After attaining complete haemostasis, wound closed in layers, sterile dressing applied. Deep vein thrombosis prophylaxis given. Elastic crepe bandage applied.[4]

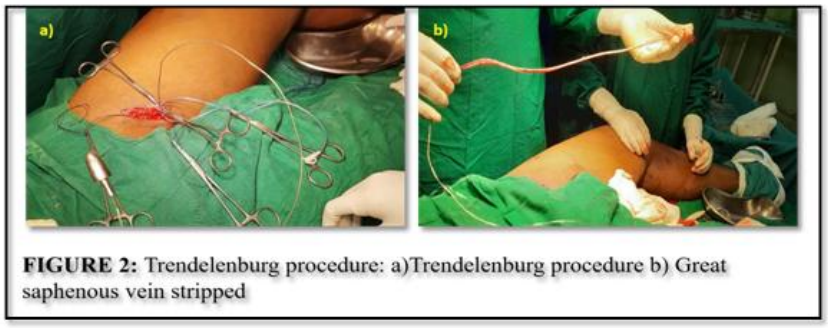


FIGURE 2: Trendelenburg procedure: a)Trendelenburg procedure b) Great saphenous vein stripped

OPEN SURGERY PROCEDURE:

1. Stab avulsion procedure: Perforator sites were marked preoperatively. After finishing Trendelenburg procedure, incision made over the perforator site, stab avulsion and ligation of the perforators done. After attaining complete hemostasis, wound closed in layers, sterile dressing applied, elastic crepe bandage applied.
2. Linton's procedure: Long, longitudinal incision made in the medial aspect of leg, sub cutaneous tissue incised, deep fascia incised. All perforators identified, ligated, cut. After attaining complete hemostasis, wound closed in layers.

FIGURE 3: Surgical procedure for open surgery group: a) Pre-operative image b)Stab avulsion procedure c) Open perforators ligation d) Post stab avulsion of perforators e)Lintons open incision f) Lintons sub facial ligation of perforators g) Post operative stab avulsion h) Post operative healing image

SUB FASCIAL ENDOSCOPIC PERFORATOR LIGATION SURGERY (SEPS):

Under the same sub arachnoid block for Trendelenburg procedure, one 10mm endoscopic port inserted in the sub facial plane and inflated with CO_2, camera inserted. Another 5mm working port inserted, all perforators identified. All the perforators were electrocauterized using bipolar cautery. Complete hemostasis attained, wound closed in layers, sterile dressing applied. Elastic crepe bandage applied.[7]

FIGURE 4: Surgical procedure of Subfascial Endoscopic Perforator Surgery: a) Pre-operative image b)Inserting camera port trocar c) Inserting working port trocar d) Endoscopic view of perforators e) Post operative image f) Post operative image after 12 months

POST OPERATIVE FOLLOWUP AND INSTRUCTIONS:

In post operative ward, after anesthesia effect weaned, all patients were scored by pain scale. Followed by analgesics were given. Patients were made mobilize with elastic crepe bandage in situ. Limb elevation during night and limb active exercise were advised. Wound opened after 48 hours and checked for collection, infection and bleeding. Daily cleaning and dressing done. Patients were discharged based on individual patients' condition. Sutures were removed on 10^{th} day. Patients were kept under regular follow-up.

SCREENING PROCEDURES AND FOLLOWUPS:

- Patients were reviewed immediately post – surgery and the surreal parameters were recorded.
- Pain assessment were done six hours post - surgery followed by once in 1 day, 1 week, 1 month, 3 months, 6 months, 9 months and 12 months using Visual Analogue Scale in order to measure the intensity of the pain.
- Ambulation assessment were done six hours post - surgery followed by once in 1 day and after suture removal along with pain and discomfort evaluation.
- The total number of days of hospital stay of the patient is also recorded post - surgery.

EVALUATION AFTER 1 YEAR POST OPERATIVELY:

The parameters evaluated after 1 year of post -surgery includes

- Pain in leg
- Pigmentation
- Cosmetic appearance of the skin
- Swelling of leg
- Healing of ulcer
- Bleeding
- Resumed day to day activities
- Resumed routine work
- Ability to do work
- Recurrence
- Overall opinion about surgery

IV. Results

The purpose of the study was to evaluate and analyze the clinical effectiveness of SEPS and open surgery in perforator vein incompetence. A total of 138 patients who full-filled the inclusion criteria and exclusion criteria were allocated into the study where 82 patients underwent open surgical procedures and 56 patients underwent SEPS. To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk,

NY: IBM Corp. Released 2019) was used. Significance level was fixed as 5% ($\alpha = 0.05$).

The Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests results reveal that variables (Age, Hospital stay, and Resumed day-to-day activity) follow Normal distribution and pains scores at different time points do not follow Normal distribution. Therefore, to analyse the data both parametric and non-parametric methods were applied. For parameters which follow Normal distribution, to compare the mean values between treatment groups independent samples t-test was applied. For non-Normal variates (pain scores) to compare pain scores between treatment groups Mann Whitney test was applied. To compare proportions between treatment groups Chi-Square test was applied, if any expected cell frequency is less than five then Fisher's exact test was used.

TABLE 1: AGE DISTRIBUTION

Variable	Treatment	N	Mean ± SD	p-value
Age	Open surgery	82	48.24±13.327	<0.001
	SEPS	56	56.80±13.493	

TABLE 2: GENDER DISTRIBUTION

Gender	Treatment			
	Open		SEPS	
	N	%	N	%
Male	70	86.4%	49	87.5%
Female	12	13.6%	7	12.5%
Total	82	100.0%	56	100.0%

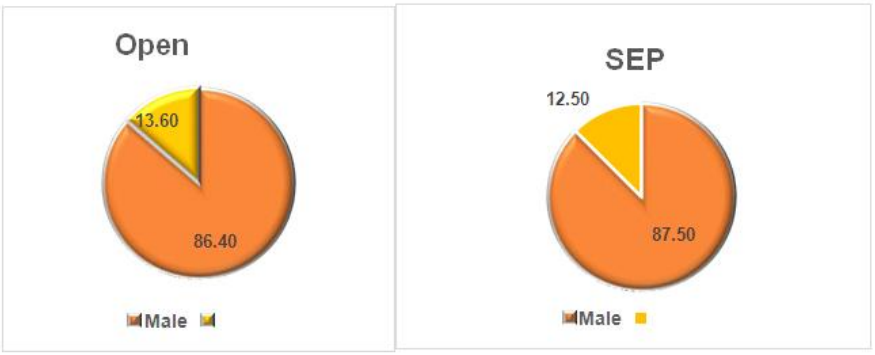


TABLE 3: SURGICAL SITE IN LOWER LIMB

Surgical site lower limb	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Left	43	52.4%	33	58.9%	76	55.1%	0.516*
Right	37	45.1%	23	41.1%	60	43.5%	
Both	2	2.4%	0	0.0%	2	1.4%	
Total	82	100.0%	56	100.0%	138	100.0%	

TABLE 4: HOSPITAL STAY

Variable	Treatment	N	Mean	Std Dev	p-value
Hospital stay (days)	Open	82	6.95	.915	<0.001
	SEPS	56	3.73	.863	

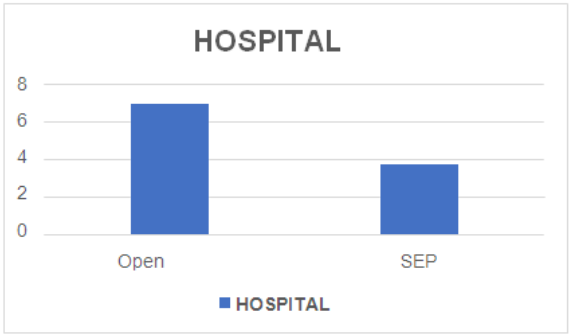


TABLE 5: PAIN EVALUATION BETWEEN TEST AND CONTROL GROUP POST TREATMENT:

Parameters **(Post surgical Pain -VAS)**	**Open surgery (Mean ± S.D)**	**SEPS (Mean ± S.D)**	**P-Value**
6 hrs	4.1 ± 0.31	2.1 ± 0.33	<0.001
1 day	3.0 ± 0.42	1.1 ± 0.31	<0.001
1 week	0.8 ± 0.39	0.1 ± 0.23	<0.001
1 month	0.0 ± 0.19	0.0 ± 0.00	0.149
3 months	0.0 ± 0.00	0.0 ± 0.00	-
6 months	0.0 ± 0.00	0.0 ± 0.00	-
9 months	0.0 ± 0.00	0.0 ± 0.00	-
12 months	0.0 ± 0.00	0.0 ± 0.00	-

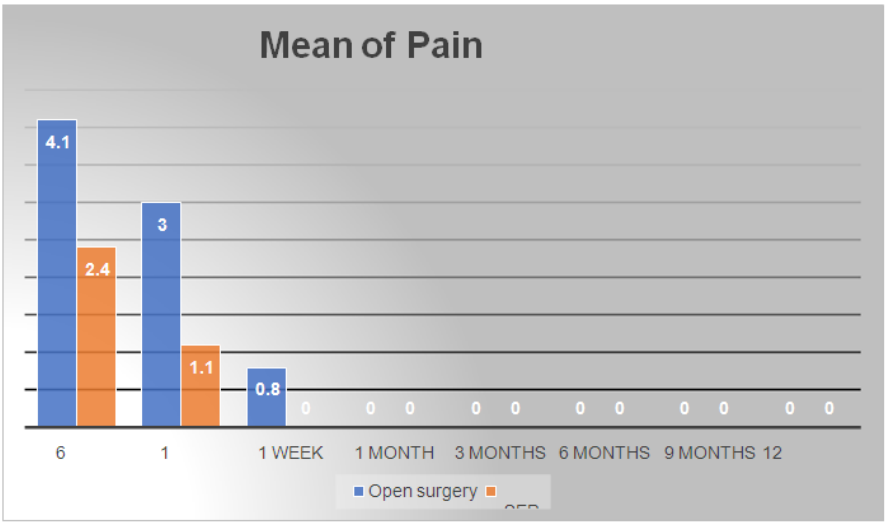
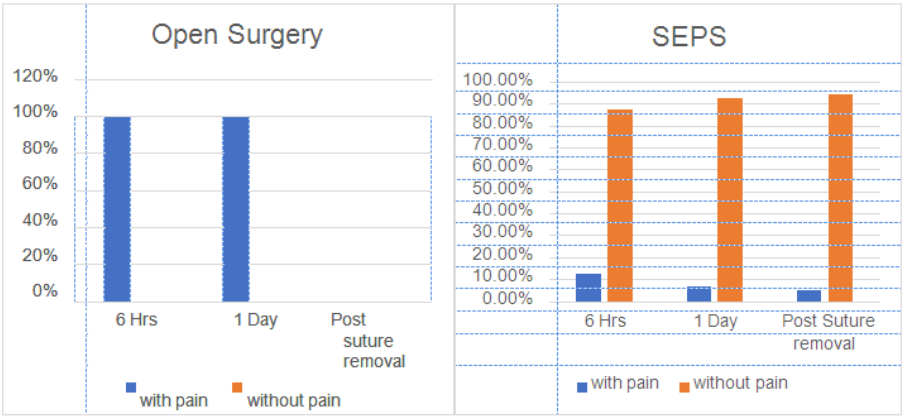


TABLE 6: AMBULATION EVALUATION BETWEEN TEST AND CONTROL GROUP POST TREATMENT:

Post-surgical ambulation		**Open surgery**		**SEPS**	
		N	**%**	**N**	**%**
6 hrs	With pain	82	100%	7	12.5%
	Without pain	0	0%	49	87.5%
1 day	With pain	82	100%	4	7.1%
	Without pain	0	0%	52	92.9%
Post suture removal	With comfort	67	81.7%	53	94.6%
	Without comfort	15	18.3%	3	5.4%



EVALUATION AFTER 1 YEAR OF TREATMENT:

TABLE 7: EVALUATION OF PAIN IN LEG 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Pain in leg	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Much better	70	85.4%	5	8.9%	75	54.3%	
Cured	12	14.6%	51	91.1%	63	45.7%	
Total	82	100.0%	56	100.0%	138	100.0%	<0.001

TABLE 8: EVALUATION OF PIGMENTATION IN SURGICAL SITE 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Pigmentation	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Same	57	69.5%	18	32.1%	75	54.3%	
Much better	18	22.0%	19	33.9%	37	26.8%	
Cured	7	8.5%	19	33.9%	26	18.8%	<0.001
Total	82	100.0%	56	100.0%	138	100.0%	

TABLE 9: EVALUATION OF COSMETIC APPEARANCE OF SKIN 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Cosmetic appearance of skin	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Bad	33	40.2%	0	0.0%	33	23.9%	
Good	47	57.3%	31	55.4%	78	56.5%	
Very good	2	2.4%	25	44.6%	27	19.6%	<0.001
Total	82	100.0%	56	100.0%	138	100.0%	

TABLE 10: EVALUATION OF SWELLING OF LEG 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Swelling of leg	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Much better	8	9.8%	9	16.1%	17	12.3%	
Cured	9	11.0%	7	12.5%	16	11.6%	
NA	65	79.3%	40	71.4%	105	76.1%	0.493
Total	82	100.0%	56	100.0%	138	100.0%	

TABLE 11: EVALUATION OF HEALING OF ULCER 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Healing of ulcer	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Much better	10	12.2%	6	10.7%	16	11.6%	
Cured	6	7.3%	8	14.3%	14	10.1%	
NA	66	80.5%	42	75.0%	108	78.3%	0.410
Total	82	100.0%	56	100.0%	138	100.0%	

TABLE 12: EVALUATION OF BLEEDING IN THE SURGICAL SITE 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Bleeding	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Much better	1	1.2%	0	0.0%	1	0.7%	
Cured	4	4.9%	4	7.1%	8	5.8%	
NA	77	93.9%	52	92.9%	129	93.5%	0.831*
Total	82	100.0%	56	100.0%	138	100.0%	

* Fisher's exact p-value

TABLE 13: EVALUATION OF RESUMED ROUTINE WORK 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Resumed routine work	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
2 weeks	8	9.8%	47	83.9%	55	39.9%	<0.001*
1 month	70	85.4%	9	16.1%	79	57.2%	
2 months	4	4.9%	0	0.0%	4	2.9%	
Total	82	100.0%	56	100.0%	138	100.0%	

* Fisher's exact p-value

TABLE 14: EVALUATION OF ABILITY TO DO WORK 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Ability to do work	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Same	5	6.1%	4	7.1%	9	6.5%	0.146*
Good	74	90.2%	45	80.4%	119	86.2%	
Excellent	3	3.7%	7	12.5%	10	7.2%	
Total	82	100.0%	56	100.0%	138	100.0%	

* Fisher's exact p-value

TABLE 15: EVALUATION OF RECURRENCE RATE AFTER 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Recurrence	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Yes	7	8.5%	0	0.0%	7	5.1%	0.041*
No	75	91.5%	56	100.0%	131	94.9%	
Total	82	100.0%	56	100.0%	138	100.0%	

* Fisher's exact p-value

TABLE 16: EVALUATION OF OVER ALL OPINION OF SURGERY 1 YEAR POST OPERATIVELY IN BOTH THE GROUPS

Overall opinion of surgery	Treatment						p-value
	Open		SEPS		Total		
	N	%	N	%	N	%	
Not satisfied	7	8.5%	0	0.0%	7	5.1%	0.004*
Satisfied	72	87.8%	47	83.9%	119	86.2%	
Excellent	3	3.7%	9	16.1%	12	8.7%	
Total	82	100.0%	56	100.0%	138	100.0%	

* Fisher's exact p-value

V. Discussion

The present study was designed as a prospective study in which we compared the clinical effectiveness between open surgery and SEPS in the sub facial ligation of perforators in varicose vein. In the present study, multiple surrogate markers were analysed with the time duration of immediate and 1 year post surgery in order to compare the clinical effectiveness more appropriately. In relevance with the allocation of subjects, age factor plays a predominant role. In our study, there was statistical significance in the age distribution between open surgery and SEPS, which pays a way of quite more appropriate outcome of the study. In accordance with the gender distribution, 80% males and 20% were included in the study. But based on the literature findings, females were most common victim for the pathophysiology of varicose vein than males. Sybraundy et al stated that females (69%) are more prone to get chronic venous sufficiency than males(31%).[50] In the current study there was a male predominance that might be because of psychological aspect that males were easily turned up for the surgical treatment than the females. Regarding with the surgical site in the lower limb (i.e) right and left side, there was a statistical significance between the two groups which aids in the appropriate results of the study.

Considering the hospital stay, in case of patients treated with open surgery , the mean hospital stay duration was 6.95 and in case of seps, the mean hospital stay was 3.73. This vast difference is due to the minimally invasive surgical access in SEPS group of patients which promotes the healing faster and thus decreases the duration of hospital stay.

The most important surrogate marker in the analyzation of clinical effectiveness of surgical procedures between group is pain. In the current study, the pain was recorded with the help of visual analogue scale in

regular intervals post-surgically once in 6 hours, 1 day, 1 week, 1 month, 3 months, 6 months, 9 months and 12 months. There was a high statistical significance between both the groups in 6 hours, 1 day and 1 week duration. But there was a statistical insignificance noted between groups in the duration of 1 month with increased standard duration in open surgery group. The less invasive surgical technique promoted the primary wound healing faster and thus reduced the pain in the surgical site in comparison with the open surgical technique with more invasive procedures.

In addition to pain, the next most important surrogate marker is the effective ambulation post surgery. The ambulation was recorded post- surgery once in 6 hrs, 1 day and after suture removal. Statistically, the increased mean percentage of ambulation with pain is recorded in open surgery group in 6 hours (100%), 1 day (100%) and post suture removal (81.7%). In case of SEPS group, in 6 hours (12.5%), 1 day (7.1%) and post suture removal (5.4%). In SEPS group, there was increased patience convenience.

Along with the evaluation of these important parameters, certain other parameters were evaluated after 1 year of post-surgery in order to evaluate and compare the clinical effectiveness between open surgical technique and SEPS in long term. The parameters in relevant to the skin changes such as pigmentation and cosmetic appearance in relation to the surgical site was reported much better and good in cases of SEPS than the open surgery group. The parameters such as pain in leg, swelling of leg, bleeding and healing of ulcer were similar in both the groups with not much appreciable variation. Luebke and Brunkwall reported lower rate of infections and promoted healing response in SEPS group in the management of chronic venous insufficiency.[51]

The most crucial parameter in the management of varicose vein is the recurrence rate. There was no recurrence reported in the SEPS group with 8.5% recurrence reported in the open surgery group at 12 months post-surgery.

Baron et al in his study noted decrease in edema and subjective improvement in healing within six months where SEPS showed greater healing within 6 weeks of treatment.[52] In the current study, the resumed ability to do work and ability to do work were statistically significant in both the groups at 12 months post operatively. The over all opinion about both the surgical techniques were satisfactory. Hence, both the techniques showed preferably appreciable results in the management of varicose veins. But in the frame of time duration of healing protocol SEPS group showed faster healing with minimal scars and improved the quality of living.

VI. Conclusion:

In the comparison of the clinical efficacy of Sub fascial Endoscopic Perforator Surgery (SEPS) and open surgery in the subfascial ligation of perforators in varicose veins showed that there is statistically significant improvement in the analysed parameters in both the groups after 1 year of post-operative management. But in the frame of time duration of healing protocol SEPS group showed faster healing with minimal scars, comparatively decreased pigmentation and improved the quality of living.

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