A PROSPECTIVE COMPARATIVE STUDY OF RADIOFREQUENCY ABLATION VERSUS SUBFASCIAL ENDOSCOPIC PERFORATOR SURGERY FOR THE TREATMENT OF VARICOSITIES IN VARICOSE VEINS PATIENTS.

Dr. Rana Parth Harajivandas¹, Dr. Firdaus A Dekhaiya², Dr. Smit Mehta³

¹3rd year Resident, ²Associate Professor, ³Assistant Professor

^{1,2,3} Department of General Surgery, Government Medical College, Sir T. Hospital, Bhavnagar, Gujarat.

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Corresponding author: Dr. Rana Parth Harajivandas

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Abstract

Introduction: Dilated & tortuous subcutaneous veins 3mm or more in diameter are known as varicose veins. When perforating veins become incompetent, it causes chronic venous insufficiency. Majority cases are managed conservatively. Cases with significant skin changes and ulcers, requires surgical procedures.

Methods: A prospective comparative study of 30 patients of varicosities, divided into two groups, A and B according to CEAP classification were assessed for VCSS preoperatively. They underwent radiofrequency ablation (RFA) and subfascial endoscopic perforator surgery (SEPS) respectively and postoperative VCSS was calculated at follow up at 4 weeks. Collected data was assessed for the change in clinical severity of the disease and compared for the complications of both surgical methods.

Results: The mean difference of pre op and post op VCSS in patient treated by RFA is 6.0 and the mean difference of pre op and post op VCSS in patient treated by SEPS is 5.4. Post RFA complications include pain (20%) and ecchymosis (13.3%). Paraesthesia and DVT was not noted. Post SEPS complications include pain (40%), ecchymosis (40%) and paresthesia (13.33%). DVT was not noted post SEPS. Only 1 case (6.66%) treated by SEPS developed recurrence post operatively.

Conclusion: RFA and SEPS are two different approaches for varicosities, RFA being truncal therapy and SEPS for perforators, both are almost equally effective in context of postoperative hospital stay and improvement of VCSS; safe in terms of post op complications.

Keywords: Radiofrequency ablation (RFA), Subfascial endoscopic perforator surgery (SEPS), venous clinical severity score (VCSS), varicose veins

Introduction

Varicosity is the penalty for verticality against gravity.[1] Dilated, tortuous and elongated veins are called varicose veins most commonly found over lower extremities. It is in the developed countries, patients turn up for treatment of cosmetic reasons. In Indian scenario patients consult doctors when complications arise. That is why, although being a common problem, varicose veins remain as an iceberg phenomenon. In spite of vast research, aetiology of commonly occurring varicose is still inadequately understood. Increase incidence of varicose veins has been found associated with aging and various other risk factors like long standing, parity, obesity and family history.[2,3] Valvular insufficiency and venous dilation are among the prominent aetiological factors of varicose veins.[4-5] In the present study, we have compared both Radiofrequency ablation RFA and Subfascial endoscopic perforator surgery SEPS with each other using Venous clinical severity score VCSS score to be measured preoperatively and postoperatively both and comparing the change in clinical severity of the disease and also comparing the rate of complications involved in both the procedures. RFA involves the use of high frequency alternating current delivered via a bipolar catheter, placed intraluminally under

duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating resulting in venous spasm and irreversible denaturation of collagen with intimal destruction. This produces a fibrotic luminal seal with minimal thrombus formation. Radio frequency ablation procedure offer advantages over the conventional stripping operation in terms of reduced post operative pain, shorter sick leaves and faster return to normal activities. [6,7] Because the procedure is associated with shorter convalescence, this new method may potentially replace conventional varicose vein surgery. SEPS is a minimal access option to open surgery in patients with chronic venous insufficiency due to perforator incompetence. Two endoscopic ports introduced in the subfascial plane in the calf away from ulceration. A space-maker balloon creates the initial space, which is then maintained by carbon dioxide. Under direct vision, the incompetent perforators are clipped and divided or dealt with by harmonic scalpel or vessel sealer. Advantage of SEPS is that since the incision is remote and in a healthy skin wound complications are minimized. Healing rates and maintenance of healing for stasis ulceration after 5 years is 90% in normal functioning deep vein and 80% in patients with deep venous insufficiency.[8,9] Aim of this study was to compare the radiofrequency ablation (RFA) versus subfascial

endoscopic perforator surgery (SEPS) in the treatment of varicose veins.

Material and Methods:

This study is a prospective comparative interventional study conducted from November 2019 – October 2020 in Department of General surgery, Govt. Medical College & Sir T Hospital, Bhavnagar. Patients were selected for study by inclusion and exclusion criteria.

Inclusion criteria:

- Age: Above 18 years
- Patients having both truncal varicosities and perforator incompetencies

Exclusion criteria:

- Patients with deep vein thrombosis
- Patients not willing for the surgery
- Patients unfit for the surgery
- Patients with deep venous reflux.

Data collection and Sample size – It was a fixed duration study in which no. of patients admitted for varicosities from 14/11/19 to 31/07/2020 became the sample size of the study which was 30 patients. Patients history was taken, Clinical examination of the patients was done according to

Clinical- Etiology - Anatomy - Pathological, CEAP classification. The truncal and perforator incompetencies were confirmed. All routine investigations were done. Patients were assessed by venous duplex study and the site of incompetent perforators as well as truncal varicosities was marked. Diagnosis was confirmed and patients were divided into two groups by random allocation of numbers to the patients i.e. Group A and Group B where group A was treated by RFA and group B was treated by SEPS. Pre op VCSS was done and then actual plan of treatment will be employed. After 4 weeks of surgery, patients were followed up with Post op VCSS to compare the change in the clinical severity of the disease and post op venous doppler done at 4 weeks to check for any recurrences. Appropriate statistical test was applied to obtain the results in Microsoft excel.

VCSS (Venous Clinical Severity Score) The VCSS system includes 10 clinical descriptors (pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, number of active ulcers, duration of active ulceration, size of ulcer, and compressive therapy use), scored from 0 to 3 (total possible score, 30) that may be used to assess changes in response to therapy.³² The strength of the VCSS lies in its ability to identify subtle intra subject changes after intervention over time. The components of the VCSS provide outcome analysis on many levels, including technical, patient reported, and clinical.

Total Venous Clinical Severity Score (VCSS)

Clinical descriptor	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily not limiting	Daily limiting
Varicose veins	None	Few	Calf or thigh	Calf and thigh
Venous oedema	None	Foot and ankle	Below knee	Knee and above
Skin pigmentation	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Inflammation	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Induration	None	Limited perimalleolar	Diffuse lower 1/3 calf	Wider above lower 1/3 calf
Number of active ulcers	None	1	2	≥ 3
Ulcer duration	None	< 3 month	3-12 month	> 1 year
Active ulcer size	None	< 2 cm	2-6 cm	> 6 cm
Compression therapy	None	Intermittent	Most days	Fully comply

Radiofrequency ablation of varicose veins (RFA):

The radiofrequency endovenous ablation system works by thermal destruction of the venous tissue using electrical energy passing through tissues in the form of high-frequency alternating current. This current was converted into heat, which causes irreversible localized tissue damage.

Figure 1: Before and After RFA

Subfascial endoscopic perforator surgery (SEPS)

SEPS is a minimal access option to open surgery in patients with chronic venous insufficiency due to perforator incompetence. Two endoscopic ports introduced in the subfascial plane in the calf away from ulceration. A space-maker balloon creates the initial space, which is then maintained by carbon dioxide. Under direct vision, the incompetent perforators are clipped and divided or dealt with by harmonic scalpel or vessel sealer.

Figure 2: Port creation.

Figure 3: Creation of subfascial space

Figure 4: Clipping of perforator

Figure 5: After clipping of perforator

Results:

1) Age wise distribution:

In this study, age varies from 18 to 75 yrs. 1 cases was in the age range of 18– 20 years, 6 (20%) were in between the age ages of 21 to 40 yrs, 15(49.99%) were found to be in the age group of 41 – 60 yrs and 8 (26.66%) cases were aged more than 61 yrs. □ In our study, more than half (17 pts.) of the study population (56.67%) were in the age group between 30 to 60 years.

2) Sex Distribution:

In this study, out of 30 cases, 21 (70%) were males and 9 were (30%) females.

3) Distribution according to CEAP classification:

Table 1: Distribution according to CEAP Classification.

Sr. no.	CEAP Classification	No. of Case	% of Case
1	C1	0	0
2	C2	7	23.33
3	C3	9	30
4	C4	8	26.66
5	C5	4	13.33
6	C6	2	6.66

Out of 30 cases, 16 of the cases presenting with perforator incompetence were in the CEAP classification of C class 2 and 3 (53.33%), 8 cases were in class 4(26.66%) and 6 cases were class 5 and 6 category (19.99%) with ulcer.

4) Mean Pre op and post op VCSS difference

In the present study, the mean VCSS difference of pre op VCSS and post op VCSS in patient who underwent RFA is 6.0 and the mean VCSS difference of pre op VCSS and post op VCSS in patient who underwent SEPS is 5.4.

Bar chart 1: Showing Mean pre op and post op VCSS difference

Post Op Complications

In the present study, post RFA complications include pain in 3 patients (20%), ecchymosis in 2 patients (13.3%).None of the patient has developed paraesthesia and DVT. Post SEPS complications include pain in 6 patients (40%), ecchymosis in 6 patients (40%) and paraesthesia in 2 patients (13.33%). No patient has developed DVT post SEPS.

Table 2: Showing Post op complications.

Sr. No	Complications	RFA	SEPS
1	Pain	3(20%)	6(40%)
2	Ecchymosis	2(13.3%)	6(40%)
3	Paraesthesia	0(0%)	2(13.33%)
4	DVT	0(0%)	0(0%)

5) Mean post procedure hospital stay:

In the present study, the mean post procedure hospital stay of patient who underwent RFA is 2.0 and the mean post procedure hospital stay of patient who underwent SEPS is

2.13.

6) Recurrence:

In the present study, no recurrence was found in patients who underwent RFA. From all those patients who underwent SEPS, 1 patient has developed recurrence found on post op Doppler which is due to new incompetent perforator.

Table 3: Statistical comparison of two surgical methods on basis of mean VCSS:

In the present study, on the basis of mean VCSS, the two surgical procedures used showed no significant difference (P-value >0.05).

Group	Therapy	Mean	SD	P value	Significance
A	RFA	6.0	0.98	>0.05 (2.048)	Not significant
B	SEPS	5.4	0.96		

Discussion:

This is a prospective, unbiased randomized interventional comparative study of RFA versus SEPS in the treatment of varicose veins cases. The outcomes are measured by assessing the change in clinical severity of the disease using Venous Clinical Severity Score (VCSS) and postoperative hospital stay was also compared. The complications of both RFA and SEPS are also studied. Post op venous duplex scan was done for confirmation of absence or presence of reflux in the trunk. In the present study, out of 30 cases, 15 cases were grouped in group A (operated by RFA) and other 15 cases in Group B (operated by SEPS). The randomization was done by odd-even method. The mean VCSS difference of pre op VCSS and post op VCSS in patient who underwent RFA is 6.0. The mean VCSS difference of pre op VCSS and post op VCSS in patient who underwent SEPS is 5.4. In a study done in 2015-17 on efficacy and safety of radiofrequency ablation for lower limb varicose veins by Dr. Anushtup De, Dr. Prabal Roy, Dr. Sunil Kumar [10], the mean pre op VCSS of 58 cases was 7.98 and the mean post op VCSS of 58 cases was 2.24. In a Study of clinical outcomes of subfascial endoscopic perforator surgery in perforator incompetence done by Dr Usha H in 2016 [11], the pre op VCSS of 30 cases was 6.66 and the post op VCSS of 30 cases was 4.2. In the present study, post RFA complications include pain in 3 patients (20%), ecchymosis in 2 patients (13.3%). None of the patient has developed paresthesia and DVT. Post SEPS complications include pain in 6 patients (40%), ecchymosis in 6 patients (40%) and paresthesia in 2 patients (13.33%). No patient has developed DVT post SEPS. In a study done in 2015-17 on efficacy and safety of radiofrequency ablation for lower limb varicose veins by Dr. Anushtup De, Dr. Prabal Roy, Dr. Sunil Kumar, out of 58 total cases, 6 cases (10.34%) had post op pain, 2 cases (3.44%) had paresthesia, 17 cases (29.31%) Ecchymosis and 1 case (1.72%) had deep vein thrombosis. Jugenheimer and Junginger et al [12] reported “dysesthesia in 9.7% (n=103limbs) with severe subfascial infection in 2(1.9%) patients”. Witten et al [13] reported ‘severe subfascial

infection necessitating surgical intervention on both sides’. Synbrandy et al reported “wound infection in 10% of patients”. Baron et al reported no wound complications in his study. Tenbrook et al [14] reported “9% haematoma formation”. In the present study, the mean post procedure hospital stay of patient who underwent RFA is 2.0 and the mean post procedure hospital stay of patient who underwent SEPS is 2.13. Both are minimally invasive procedures hence mostly the postoperative stay is not more than 1 or 2 days. Many centers carry out RFA as a day care procedure, in which tumescent anesthesia is being used. There is a protocol at our center to carry out the procedure under spinal anesthesia, often unilateral, and for that we admit patients 2-3 days prior to the procedure for pre-anesthetic and physical fitness and optimization of co-morbid conditions. SEPS is a very good procedure in hands of those who are very well versed with laparo/endoscopies. The learning curve is very long and Instrument manipulation is difficult for untrained surgeons. Also, it requires a skilled assistant who can rotate the camera according to needs to facilitate the dissection. On the basis of mean VCSS, the two surgical procedures used, showed no significant difference (P-value >0.05). However there is a gross improvement of venous symptoms showing their efficacy. In the present study, post RFA complications include pain in 3 patients (20%), ecchymosis in 2 patients (13.3%). None of the patient has developed paresthesia and DVT. Post SEPS complications include pain in 6 patients (40%), ecchymosis in 6 patients (40%) and paresthesia in 2 patients (13.33%). No patient has developed DVT post SEPS. Recurrence was seen in one case operated by SEPS.

Conclusion:

Based on observations we can conclude that, RFA and SEPS are two different approaches for symptomatic varicose veins, RFA being truncal therapy and SEPS for perforators, both are more or less similarly effective in context of postoperative hospital stay and improvement of VCSS (Venous Clinical Severity Score); safe in terms of post operative complications.

However, none is a single comprehensive therapy for complete cure of the venous reflux and need to be combined with other procedures very often. Hence it can be stated that whatever therapy available at a particular center can be offered to the patients with equal results.

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