

## A Comparatative Study of Conventional Surgery versus Endovenous Radiofrequency Ablation with Sclerotherapy for the Management of Varicose Veins

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### Abstract

*Background:* Lower limb varicose veins are the commonest of all vascular disorders. It is one of the important vascular conditions that affect 25 million people in western civilizations. The most important underlying cause for primary varicose veins is incompetence of the great saphenous venous system, most commonly due to reflux at the sapheno-femoral junctional valve. These varicose veins can be treated by either open surgery or new modalities like endovascular surgeries. Conventional surgery (open surgery) involves sapheno-femoral disconnection at the sapheno-femoral junction and stripping of the great saphenous vein above the knee, which may be accompanied by phlebectomies of minor varicosities. *Aim:* To compare the short term outcome between open surgery versus endovenous radiofrequency ablation with sclerotherapy for great saphenous varicose veins in terms of post operative pain, duration of surgery, duration of hospital stay, early return to activities, complications such as hematoma, wound infection, and patient satisfaction. *Methods:* A comparative study was carried out among 60 subjects attending Department of Surgery, K.R. Hospital, Mysuru over a period of 12 months. Patients with symptomatic varicose veins who belong to CEAP classification 2-6 due to great saphenous vein incompetence with perforator incompetence were included in the study. Descriptive statistics reported using mean and standard deviation for continuous variable, numbers and percentage for the categorical variable and chi-square test or fisher's exact test and

for continuous variable Independent t-test or Mann Whitney u-test were used to analyse the results. *Results:* Endovenous radiofrequency ablation is a better option in terms of less morbidity, less postoperative pain, requirement of analgesia, and it resulted in lesser hospital stay, and early return to normal activities than conventional surgery. *Conclusion:* Endovenous radiofrequency ablation performed quicker and safer and resulted in a significantly better early outcome than conventional surgery.

**Keywords:** Sapheno-Femoral Junction; Incompetence; Conventional Surgery; Endovenous Radiofrequency Ablation; Sclerotherapy.

### Introduction

Lower limb varicose veins are the commonest of all vascular disorders. It is one of the important vascular conditions that affect 25 million people in western civilizations [1]. They can impair the quality of life [2].

The most important underlying cause for primary varicose veins is incompetence of the great saphenous venous system, most commonly due to reflux at the sapheno-femoral junctional valve. These varicose veins can be treated by either open surgery or new modalities like endovascular surgeries [3]. Conventional surgery (open surgery) involves sapheno femoral disconnection at the saphenofemoral junction and stripping of the great saphenous vein above the knee, which may be accompanied by phlebectomies of minor varicosities [4]. The difficulty encountered in stripping is that it is difficult to make assessment as to whether the stripper has passed down the great saphenous veins or to its tributaries [5]. Studies has shown that stripping is

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associated with increased morbidity in terms of bruising, hematomas, pain, wound infection, delay recovery and return to work [6].

Risk factors for development of varicose veins include age older than 50 years, female sex hormones, heredity, gravitational hydrostatic force, and hydrodynamic force due to muscular contraction [7].

Localized symptoms include pain, burning, or itching, whereas generalized symptoms consist of leg aching, fatigue, or swelling. Women are more prone to these symptoms due to hormonal influences. Men will often develop symptoms consists after the varicosities have enlarged to sufficient size to increase pressure on the somatic nerves [8].

Symptoms are often worse at the end of the day, especially after episodes of prolonged standing. There does not appear to be a correlation with the severity of the varicose veins and the severity of symptoms. Varicose veins and reflux involving the superficial venous system can lead to venous ulceration. Of patients with venous ulceration, only 17% will have isolated superficial venous reflux as the etiology. Large varicose veins may lead to skin changes and eventual ulceration [9].

The primary objective of treatment of primary varicose veins should be ablation of the hydrostatic forces of axial reflex, and in severe forms it may be accompanied by removal of the hydrodynamic forces of perforator vein outward flow. Studies have shown that saphenous vein ligation with stripping achieved excellent results in terms of decreased recurrence rate [10].

The rationale behind both radiofrequency ablation and vein stripping is to remove the incompetent vein from the venous circulation to reduce the venous hypertension. The advantages of radiofrequency ablation (Figure 1-5) over vein stripping are demonstrated by different randomized comparative studies [11].

Rautio and colleagues [12], reported significantly less post operative pain in the radiofrequency ablation group than in the stripping group at rest, on standing, and on walking. The analgesics needed in the radiofrequency ablation group were statistically less compared to the stripping group. Sick leaves were also significantly shorter in the radiofrequency ablation patients and physical functions were restored faster in the radiofrequency ablation patients. However, both surgeries were successful and the complications were similar between the two groups. These patients were followed up at 3 years and found that none of the radiofrequency ablation occluded great saphenous veins were reanalyzed. Varicose vein

recurrence rate was documented in 5 of 15 limbs (33%) in the radiofrequency ablation group and 3 of 13 limbs (23%) in the stripping group, and the difference was not statistically significant.

Stotter and colleagues [13], in their randomized trial in Germany, reported a significantly lower pain score in the radiofrequency ablation group versus the stripping group within 6 weeks following procedure.

In a comparatative study, Elkaffas KH et al [14], found that Radiofrequency had fewer complications and shorter hospital stay with similar occlusion rates (94.5 per cent vs. 100 per cent for surgery), but was more expensive. Recurrence rates were similar after 24 months in his study.

Perala J et al [15], in their comparatative study showed radiofrequency endovenous obliteration versus stripping of the long saphenous vein in the management of primary varicose veins; 3 year outcome of a randomized study reported, out of 28 patients 5 had recurrent varicose veins after radiofrequency ablation compared with 3 after stripping in a three year study period.

In his study Subramonia S, Lees T et al [16], concluded that radiofrequency ablation was more expensive, but people who were employed returned to work on average one week sooner. Overall outcomes for radiofrequency ablation at 2 years were at least equivalent to those of conventional surgery.

Subramonia and T. Lees [16] in their Randomized clinical trial of radiofrequency ablation or conventional high ligation and stripping for great saphenous varicose veins found that radio frequency ablation took longer to perform but resulted in a significantly better early outcome than conventional surgery in suitable patients with great saphenous varicose veins.

## Materials and Methods

After obtaining Institutional ethical committee approval, a prospective, open label, randomized, single centered study was conducted among 60 subjects attending General Surgery OPD, K.R. Hospital, Mysuru meeting the inclusion and exclusion criteria over a period of 12 months (November 2016 - October 2017) after obtaining a written informed consent using a purposive sampling technique.

Patients between 18 and 70 years, either sex, symptomatic GSV reflux (primary or recurrent) confirmed by duplex imaging, duplex scan confirmed

suitability for radio frequency ablation were included in the study.

Varicose veins without GSV incompetence on duplex imaging, associated small saphenous vein reflux and deep venous incompetence on duplex imaging, tortuous GSV above the knee felt to be unsuitable for catheterization, great saphenous veins diameter less than 3 mm or more than 12 mm in supine position, thrombus in the great saphenous veins, patients with a pacemaker or internal defibrillator, concomitant peripheral arterial disease and pregnant patients were excluded from the study.

Descriptive statistics reported using mean and standard deviation for continuous variable, numbers and percentage for the categorical variable and chi-square test or fisher's exact test and for continuous variable Independent t-test or Mann-Whitney u- test were done to test the association between the open surgery and radiofrequency ablation with clinical and satisfactory variables. These are the analysis that were done and  $P < 0.05$  is considered as significant.

## Results

During the twelve months study period, 30 patients underwent conventional surgery (Group-A) and 30 patients underwent radiofrequency ablation with sclerotherapy (Group-B). The mean age group of the study subjects was 46.37 (range 32-68) years in group-A and 49.66 (range 36-64 years) in group-B. The gender distribution showed 13 females (43.33%) as compared to 17 males (56.67%) in group-A and 7 females (23.33%) as compared to 23 males (14%) in group-B.

There were no significant differences between the groups in terms of anesthetic induction or recovery. Conventional surgery took average of 1 hour 43 minutes and radiofrequency ablation took an average of 1 hour 12 minutes to perform. Procedural difficulties encountered in radiofrequency ablation were difficulty to cannulate the vein leading to venous spasm and poor visualization on the duplex scan. Skin burns were not encountered in the study. All patients achieved planned first follow-up at one week time. Duplex imaging after radiofrequency ablation revealed successful ablation in all patients.

Postoperative pain and analgesic requirements were considerably less following radiofrequency ablation. 8 (26.67%) patients experienced mild pain after radiofrequency ablation and none of them had severe pain and 22 (73.33%) required only oral analgesia. In contrast, 21 (70%) patients experienced

moderate pain and 3(10%) had severe pain after conventional surgery and majority required postoperative intravenous analgesia. The mean duration of hospital stay in conventional surgery group was 4.76 days, and in radiofrequency ablation group patients were discharged within 3.12 days. Minor problems encountered after conventional surgery included wound infection in 3(10%) patients, haematoma in 1(3.33%) at the site of introduction of the stripper around the knee and edema of the foot in 5(16.67%) all of which resolved spontaneously. Clinically evident haematomas in the thigh and leg were seen only after conventional surgery and not after radiofrequency ablation. Thrombophlebitis encountered in both groups but not statistically significant.

Patients returned to their full level of normal household activities, and to work significantly more quickly following radiofrequency ablation than after conventional surgery. Patient satisfaction was significantly better after radiofrequency ablation. 16 (53.33%) patients were completely satisfied compared with 6 (20%) in conventional surgery group ( $P = < 0.001$ ). Significantly, more patients in the



Fig. 1: Vein mapping using ultrasound in endovenous Radiofrequency ablation



Fig. 2: Insertion of guide wire by seldinger technique



Fig. 3: FAST catheter in-situ.



Fig. 4: Injection of tumescence anesthesia



Fig. 5: Compression applied during endovenous Radiofrequency ablation

radiofrequency ablation group were willing to recommend the operation to others.

### Discussion

Endovenous Radiofrequency ablation is a

minimally invasive procedure. This study also confirms that Endovenous Radiofrequency Ablation is a much faster and easy to perform in experienced hands and in this procedure patients experienced less pain and they recovered more quickly, which was reflected in better patient satisfaction. Surgeons with sufficient experience performed all the procedure.

Being a percutaneous procedure, radiofrequency ablation involves considerably less tissue trauma. Patients who had radiofrequency ablation experienced considerably less pain, required less analgesia and were able to return to their activities more quickly, at least a week earlier than those who had conventional surgery.

Recent randomized trials have demonstrated significant early benefits after radiofrequency ablation in suitable patients with varicose veins. S. Subramonia and T. Lees et al [16], in their randomized study reported better short term results of radiofrequency ablation in terms of reduced hospital stay, less post operative pain, early return to normal activities, and better patient satisfaction, which corresponds to the findings in this study. However, they reported that radiofrequency ablation took longer time to perform than open surgery.

This is in contrast to the findings in our study where mean duration of radiofrequency ablation and open surgery were 1 hour 12 minutes and 1 hour 43 minutes respectively, which was statistically significant. Similarly, patients who underwent radiofrequency ablation returned to work at least a week earlier than those who had conventional surgery which correlates well with the study done by S. Subramonia and T. Lees et al [16].

### Conclusion

Endovenous Radiofrequency ablation is a better option in terms of less morbidity, less post operative pain requirement of analgesia, and it resulted in lesser hospital stay, and early return to normal activities. It can be performed quicker, and safer in experienced hands. It resulted in a significantly better early outcome than Conventional surgery in suitable patients with great saphenous varicose veins.

### Funding

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### Conflict of Interest:

None.

### *Ethical Approval*

The study was approved by institutional ethical committee.

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