

A Comparative Study Between Trendelenburg Procedure Versus Radiofrequency Ablation for Varicose Vein Surgery in a Tertiary Care Teaching Hospital - A Single Institute Study

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Abstract

Background: Chronic Venous Insufficiency leading to varicose veins is one problem faced by adults. We compare two treatment modalities Classic Trendelenburg procedure vs. Radio Frequency Ablation in the treatment of varicose veins using physical, clinical and radiologic imaging.

Methods: In present study, it was reported that 200 patients in total were assessed in the study, out of which, 110 were non-randomized, and 110 underwent the intervention as a daily procedure. 55 patients underwent RFA and 55 patients had conventional surgery. Group R consisted of 35 males; 20 were females; Group C consisted of 25 males and 30 were females.

In CEAP classification,

In C2 class, there were 40 in group R, 39 in group C;

In C3 class, there were 8 in group R, 11 in group C;

In the C4-6 class, 7 were in group R and 5 were in group C.

The key outcomes for great saphenous varicose veins after RFA and traditional surgery are compared. Theatrical time was in Group R for 45 minutes, group C for 72 minutes, group R for 35 minutes, group C for 60 minutes, group R for pain first week for group R for 3.5 minutes for group C for analgesic time for Group R for 1 day, group C 10 days in Group C for two days and group R patients for two days and C for 15 days. After 1 week of follow-up on numbness/reduced sensation, 8 patients and 16 patients showed engorgement/reduced feeling after 1 week in Group R and Group C.

Conclusion: The study concluded that RFA took a shorter time to perform than conventional surgery. It also gave better results and significantly reduced recovery time and morbidity in patients with minimal complications in the varicose veins.

Introduction

Chronic venous insufficiency is a condition where veins cannot pump enough deoxygenated blood to the heart, resulting in stasis due to an impaired musculo-venous pump.

Dilated, elongated, tortuous and palpable superficial veins are defined as varicose veins resulting from venous hypertension. It's more common in India, particularly in the male population [1, 2]. A varicose vein is due to a vessel wall pathology or valvular pathology. It usually affects the people who work by standing for a long time. Venous pathology develops when the venous pressure increases and the return of blood is impaired, including valvular incompetence, perforator incompetence, and venous obstruction.

Most of the patients usually present with swelling and leg pain, severe limitations in normal daily activities due to superficial venous insufficiency and a poor quality of life, because it can progress to cause complications of venous hypertension including skin ulceration. For proper diagnosis, classification of severity and management of varicose veins is essential to do a physical examination and venous study [10, 14].

Most of the patients who seek surgery for either cosmetic purposes or pain not controlled by compression hose are relatively young and desire rapid returns to work or daily activities. Surgery for varicose vein surgery is one of the routine and commonest procedures and is important for training surgeons. Principles have been increasingly challenged since the advent of new minimally invasive techniques, such as ultrasound-guided foam Sclerotherapy (UGFS), endovenous laser therapy (EVLT), and radiofrequency ablation (RFA), have been introduced in the last decade [3], when compared to classical Trendelenburg operation which is juxta femoral flush ligation of saphenous veins and stripping of veins up to below the knee, followed by multiple (phlebotomy) for the below knee dilated veins [7, 8, 15].

Radiofrequency ablation is a minimally invasive procedure and has replaced the Trendelenburg technique and getting popular because of fewer complications. It works by the thermal destruction of vein tissues through the tissue by electrical energy in the form of high-frequency alternating current 16-18]. Thus the need for study is to compare the Trendelenburg and radiofrequency in terms of complication, early recovery period and postoperative pain in the selected group.

Aims

Compare efficacy of RFA vs. Classical surgery in cases of varicose veins.

Duration

June 2021-23.

Center

Shree Balaji Medical College & Hospital, Chrompet, Tamil Nadu, India.

Methods

This is a single-centre, non-randomized, non-blinded prospective study in which we compared the outcomes of endovenous radiofrequency ablation and traditional surgery in patients with primary venous insufficiency in the lower extremity. This study was conducted in the Department of General Surgery in Shree Balaji Medical College & Hospital, Chrompet, Tamil Nadu, India from the period July 2021 and June 2023.

Inclusion and exclusion criteria are summarized in below Table 1 and 2.

Inclusion criteria	Age between 18 and 60 years	Primary bilateral GSV insufficiency requiring surgery and confirmed by duplex scan (insufficiency with reverse venous flow was regarded significant if persisting more than 0.5 seconds in a standing position)
	Clinical, etiological, anatomical, pathophysiological (CEAP): clinical grades 2 to 6(C2-6), primary (Ep), superficial (As), and reflux only (Pr)	Patients able to give informed consent
	Suitability for radiofrequency ablation confirmed by duplex scan (see exclusion criteria)	

Table 1: Inclusion Criteria.

Exclusion criteria	Varicose veins without GSV insufficiency on duplex scan	Thrombus in the GSV	Patients with high blood pressure not controlled by medication
	Previous varicose vein surgery	Patients with a pacemaker or internal defibrillator	Patients with known thrombophilia, cancer or lupus
	Associated small saphenous vein reflux, duplication of the GSV at the SFJ, deep venous insufficiency, or previous deep vein thrombosis on duplex scan	Concomitant peripheral arterial disease (ankle-brachial pressure index of ≤ 0.9)	Pregnancy
	GSV diameter <3 mm or >12 mm in the supine position	Patients on oral anticoagulants	

Table 2: Exclusion criteria.

The patients were split into two groups, each with 55 patients. In cases of GSV disease, high ligation of the sapheno-femoral junction with short stripping to just below the knee, or ligation of the sapheno-popliteal junction in cases of SSV disease, the first party, or group-C, underwent traditional surgery. Phlebectomy of varicose veins and triple ligation of incompetent perforators by miniincisions are included as adjunctive procedures at the time of care [6, 10, 12].

Under duplex scan guidance, the second party, known as group-R, underwent endovenous radiofrequency ablation with the ® radiofrequency generator and the closure fast® catheter. Foam Sclerotherapy of incompetent perforators and superficial varicosities is an adjunctive technique done at the time of treatment [3-5].

A radiologist analyzed pre-operative duplex scans using duplex ultrasonography. Patients in each category were paired using the same inclusion and exclusion criteria. After the procedure, a crepe bandage was applied, followed by compression stockings for 4-6 weeks. Both operations are ambulatory, and patients are not limited in their physical activity. Patients were given non-steroidal anti-inflammatory drugs and analgesics as needed [5, 6].

The esmarch bandage was removed and the sheath was extracted to treat the lowest section of the vein, which was bound from the knee to the groin with the leg elevated and the patient in a Trendelenburg position. A duplex scan was conducted after the procedure was completed. An accomplished surgeon performed traditional surgery in the Trendelenburg. The GSV's tributaries were ligated and separated by a groin incision in the skin crease, revealing the SFJ.

The skin was incised at this stage to retrieve a perforated invagination stripper that had been passed down through the open distal end of the vein to emerge at knee level. The vein was stripped by pulling the stripper down to the knee level and out of the exit wound. Bupivacaine was used to infiltrate the wound, which was then secured with absorbable sutures. After the intervention, the patients were followed up on at the end of the first week and the end of the sixth week. A duplex scan was performed at the first follow-up appointment.

Procedure

The *OLYMPUS Radiofrequency Generator* was used to perform radiofrequency ablation. The patient is put in a reverse Trendelenburg position under GA or SA while the procedure is being performed. A 7-F venous catheter sheath was cannulated in the GSV trunk just above the ankle under ultrasound guidance over a 0.18 guide wire. The tip of a radiofrequency catheter was located 3 cm distal to the SFJ after it was inserted through the sheath. Perivenous tumescent fluid was injected under USG guidelines to minimize treatment-related pain and vein diameter, as well as to protect Perivenous tissues from heat damage, in the case of GA.

With continuous pull-down until the knee, the heating element was enabled with radio-frequency energy to 120°C. With a persistent pull down until the ankle, the energy supply below the knee is reduced to 60-70°C. Manual compression was used to achieve external compression during treatment. A sterile adhesive dressing was used. Following the operation, a crepe bandage was applied from the foot to the groin.

Foam Sclerotherapy was used to treat below-knee varicosities in both treatment groups in the same sitting, including varicosities caused by incompetent perforators (usually above the ankle) [1-5].

Trendelenburg operation: After ligating designated (superficial circumflex, superficial external pudendal, superficial epigastric vein), a juxta femoral flush ligation of the long saphenous vein (i.e. flush with femoral vein) is performed. Tributaries should be ligated to avoid recurrence.

Vein stripping: The vein is stripped using Myer's stripper. It is physically easier to strip from the bottom up. The use of a crepe bandage as soon as possible reduces the risk of bleeding and the development of a hematoma. Injury to the saphenous nerve may result in saphenous neuralgia.

The veins in the lower part of the leg are not normally stripped.

It is more effective to strip the vein. The vein should be firmly attached to the stripper's end and pushed out to allow the vein to invert. Short saphenous vein stripping is more effective than ligation at the sapheno popliteal junction. To prevent damage to the sural nerve, it is performed from the top down with a rigid stripper [6-9, 20].

Results

Out of a total of 200 patients evaluated in the study, 110 met the inclusion and exclusion criteria, and the patients were not randomized; 110 received the intervention based on their needs. RFA was performed on 55 patients, while traditional surgery was performed on the other 55.

Demographic Distribution in The Study

Sex	Males	Females
GROUP R	35	20
GROUP C	25	30

Distribution based on clinical etiologic anatomic pathophysiologic (CEAP)

CEAP	GROUP R	GROUP C
C2	40	39
C3	8	11
C4-6	7	5

Distribution based on venous disability score (VDS)

VDS	GROUP R	GROUP C
0	5	3
1	18	26
2	25	21
3	7	5

Main outcomes after RFA and conventional surgery for great saphenous varicose veins

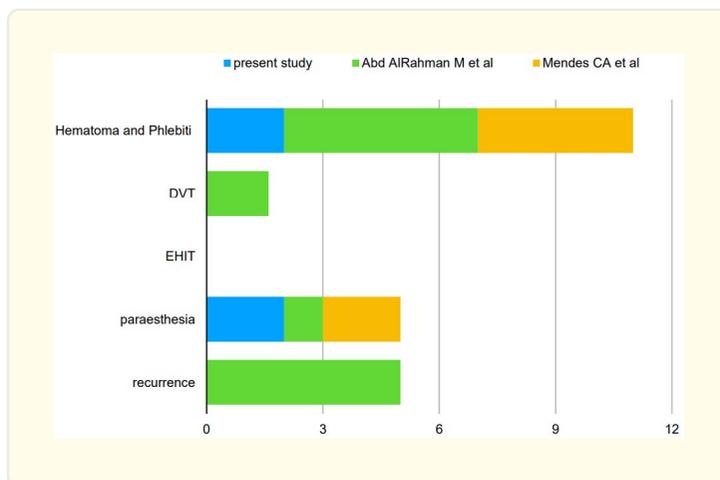
OUTCOME	GROUP R	GROUP C
Theatre time (minutes)	90 minutes	130 minutes
Procedure Time (minutes)	60 minutes	90 minutes
Pain in first week (VAS score)	1	3.0
Duration of analgesia (days)	1 days	5 days
Return to normal activity (days)	2 days	14 days
Return to work (days)	6 days	20 days

Complications

Comparison of completion form different study in RFA

COMPLICATION	GROUP R	GROUP C
Perforation of the vein	nil	2
Failure of closure	nil	nil
Hematomas and Bruises	2	4
Phlebitis	1	2
Deep vein thrombosis (DVT)	nil	2
Endothermal Heat Induced Thrombosis (EHIT)	nil	nil
Skin burns & pigmentation	1	nil
Paraesthesia	2	2
Recurrence	nil	1

Comparison of completion form different study in conventional



Discussion

Removing the refluxing saphenous vein from the sapheno-femoral junction at the knee or up the leg, with individual ligation of the named saphenous branches at the groin, is the normal treatment for patients with symptomatic incompetent superficial veins. Endovascular obliteration of the vein with radiofrequency probes inserted inside the vein through a percutaneous puncture or a cut down in the upper leg is a newer technique.

The goal of our study was to compare the efficacy of endovenous therapy versus standard open therapy (high ligation and stripping) for treating superficial venous incompetence and symptom relief. The study was designed as a prospective study with the goal of assessing operative adverse events, post-operative sequelae, and patient recovery over a one-year period.

A total of 200 patients were enrolled in this study, out of which 110 were fit in to the criteria and the rest were non randomized, of which 55 men and 50 women. The average age of presentation in our sample was 40.18 years, with a male preponderance. Though there appears to be no clear reason for this finding, it is possible that the majority of patients with the disease were involved in strenuous labor or required to stand or walk for long periods of time in their line of work, since more males are involved in hard work. Females often seek help later and are more likely to rely on males for medical care in a hospital, particularly if they are from a low socioeconomic background [8, 12, 13, 19].

The study sample was well matched with the other randomized studies.

Clinical classification of the varicose veins were done based on CEAP classification and among those who underwent treatment 71.82 % (n=79) belonged to C2, 17.27 % (n=19) belonged to C3, 10.91 % (n=12) belonged to C4-6.

In this study, Conventional group and endovenous thermal ablation were found to be equally efficient in eliminating the incompetent saphenous vein as demonstrated by duplex examination within 72 hours of procedure with the success rate of 100%. The similar success rate have been shown in various studies; randomized trial comparing endovenous laser ablation of GSV with Conventional group in patients with varicose veins: short term results from the American Venous Forum (100%) [19], Abd AlRahman M et al, Mendes CA et al was observed.

The occurrence of adverse events was minimum and not different among the groups. Like hematoma and bruising, which was statistically more in the Conventional group (7.27%) compared to RFA (3.64%), the bruising event was low in our study compared to other studies which showed around 14%-20%.

In our sample, the incidence of parasthesia was 3.64 % in both groups, while other studies from the literature reported a higher incidence in RFA (23.3%) and conventional (13.9%) [8, 19].

Although DVT has been reported in up to 5.6% of laser patients and up to 16% in RFA patients [1, 2, 7], our study had two incidences of DVT (3.64%) in conventional group which was managed successfully with anticoagulation.

In all 55 patients who underwent traditional surgery, postoperative pain in the leg was higher than after endovenous operations, as shown by statistically significant discrepancies in pain score and the presence of tenderness ($P < 0.0001$). The discomfort was almost always localized to the surgical site, which was treated with analgesics. The tumescent fluid placed within the saphenous canal under ultra sound guidance may have probably reduced the immediate post-operative pain in the endovenous group as there was no significant difference in pain score in the subsequent follow up visits in both the groups.

Also the average duration of hospital stay was considerably less in the endovenous group averaging 2 days compared to 5 days in the conventional group with return to normal activities in less than 2 days in endovenous group and averaging 5 days in conventional group. The same was observed in other studies where the return to normal activities 0 to 3 days in RFA Vs. 3 to 15 days in conventional groups.

For the treatment of GSV incompetency, modern minimally invasive approaches such as radiofrequency ablation, endovenous laser ablation, and foam Sclerotherapy have emerged in the last decade as an alternative to traditional high ligation and stripping. In the literature, there are a variety of randomized controlled trials using these new approaches.

When compared to traditional stripping, the four RCTs comparing radio frequency ablation to high ligation and stripping revealed that radio frequency ablation has major advantages, including quicker recovery, less operative discomfort, less adverse events, and better quality of life ratings [8, 9, 20, 21].

The final conclusions of the Society for Vascular Surgery/American Venous Forum guidelines for the treatment of varicose veins were published in the May 2011 issue of JVS. Endovenous thermal ablation is to be recommended as the first line of treatment for varicose veins associated with axial reflux over open surgery due to its minimally invasive nature and equivalent or better early term and midterm outcomes [13].

Conclusion

RFA took less time to perform than traditional surgery, but it produced better results and significantly reduced recovery time and morbidity in patients with varicose veins with minimal complications, according to this study.

For a long time, traditional surgery has been used to treat varicose veins, with varying degrees of success. Endovenous Varicose Vein RFA has been proven to be a viable and effective alternative to traditional surgery.

In patients with varicose veins, RFA took less time to perform, but it resulted in a better outcome and significantly reduced recovery time and morbidity.

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