



COMPARISON BETWEEN TRENDLENBURG WITH STRIPPING AND RADIOFREQUENCY ABLATION OF THE GREAT SAPHENOUS VEIN FOR THE MANAGEMENT OF PRIMARY VARICOSE VEINS

Surgery

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ABSTRACT

Introduction : Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Besides cosmetic problems, varicose veins often itch and are painful, especially when standing or walking. Though varicose veins rarely present with an acute emergency or life threatening complication, symptoms like dragging sensation, heaviness, pain, bleeding, ulceration or lipodermatosclerosis require an active intervention to get relief from the disease. A new approach to management of saphenous vein reflux is endovascular obliteration of the vein with a radiofrequency generated heating probe placed through a percutaneous puncture or mini incision in the calf. The procedure is less invasive and may, therefore result in shorter convalescence and ability to resume work sooner, thus reducing the costs of the productivity. Any alternative technique to high ligation and stripping must ideally have the same or better outcome but without the associated morbidity.

Aims And Objectives: To assess and compare the efficacy of Trendelenburg and Stripping with RFA of GSV for the management of primary varicose veins in Indian setup.

Materials And Methods: Patients divided into two- Ligation-Stripping(LS) group (n=30) and; Radiofrequency Ablation(RFA) group (n=30). Patients were given a questionnaire (Likert's questionnaire) consisting of six questions to fill on postoperative day 3, 7, 28 and at 90 days.

Conclusion: Radiofrequency ablation of GSV for the treatment of varicose veins, is as effective as High ligation and stripping. The two procedures are comparable in terms of quality of life indicators, postoperatively, but the cost of RFA procedure is almost 3 times higher than the LS procedure of GSV.

KEYWORDS

Ligation-Stripping (LS); Radiofrequency Ablation (RFA); GSV; Trendelenburg; Saphenous Vein; Varicose Vein.

INTRODUCTION

Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Besides cosmetic problems, varicose veins often itch and are painful, especially when standing or walking. Though varicose veins rarely present with an acute emergency or life threatening complication, symptoms like dragging sensation, heaviness, pain, bleeding, ulceration or lipodermatosclerosis require an active intervention to get relief from the disease¹.

Non-surgical treatments include, compression elastic stockings, elevating the legs, and exercise. The traditional surgical treatment has been vein stripping to remove the affected veins. Because most of the blood in the legs is returned by the deep veins, the superficial veins, which return only about 10 per cent of the total blood of the legs, can usually be removed or ablated without serious harm^{2,3}. Conventional surgery (stripping of the veins) has been the time tested modality of treatment for varicose veins.

The treatment of varicose veins has undergone vast research and modification in its course. The three main categories of primary venous insufficiency are: telangiectasias, reticular varicosities, and varicose veins, all being physiologically similar, differing only in the caliber. The unifying end result is dilated, tortuous, elongated veins with dysfunctional or non-functional valves. Operations on varicose veins are amongst the most common surgical procedures. In the conventional management of the Incompetent saphenous vein in patients with symptomatic varicose veins, it is generally believed that the best treatment is removal of the great saphenous vein (GSV) from the sapheno-femoral junction to the level of knee or below, along with individual ligation of the saphenous tributaries in the groin. The stripping operation is a relatively inexpensive day surgery procedure that needs no special instrumentation. Varicose vein surgery though regarded as a safe and minor procedure; is nevertheless associated with significant surgical morbidity and dissatisfaction. Flush ligation and stripping of the GSV is standard treatment for varicose veins with highest rate of initial success and lower rates of recurrence. But recurrence rates as high as 10% at 5 years have been reported, and

approximately 5% of varicose veins operations are done for recurrence, most common cause of recurrence being neovascularisation at the saphenofemoral junction.

But newer modalities have arisen which are less invasive. Newer, less invasive treatments, such as ultrasound-guided foam sclerotherapy, radiofrequency ablation and endovenous laser treatment, are slowly replacing traditional surgical treatments. Further experience with these procedures will help to determine which one will become method of choice for treating this complex disease process.

Increasingly well informed patients who pressure the treating surgeon for cosmetically acceptable results in conjunction with expansion of minimally invasive techniques have made the treatment of superficial venous reflux and varicose veins a rapidly evolving field. It is very likely that some of these procedures like RFA will replace the procedures that we currently use today⁴. In our study we will focus on the various aspects of conventional surgery and radiofrequency ablation and make a comparison between the two modalities.

A new approach to management of saphenous vein reflux is endovascular obliteration of the vein with a radiofrequency generated heating probe placed through a percutaneous puncture or mini incision in the calf. The procedure is less invasive and may, therefore result in shorter convalescence and ability to resume work sooner, thus reducing the costs of the productivity.

Any alternative technique to high ligation and stripping must ideally have the same or better outcome but without the associated morbidity.

AIMS AND OBJECTIVES

To assess and compare the efficacy of Trendelenburg and Stripping with Radiofrequency Ablation of Great Saphenous veins for the management of primary varicose veins in Indian setup.

MATERIALS AND METHODS

This is a prospective randomized study conducted in the Department of General Surgery, and Department of Radio diagnosis at GMCH,

Udaipur from August 2017 to August 2019. Total 60 patients with varicose veins without any co-morbid condition were inducted in the study. The patients were divided into two groups namely:

- I. Ligation-Stripping (LS) group (n=30) and;
- II. Radiofrequency Ablation (RFA) group (n=30)

Inclusion Criteria :

- All male and female patients 18 years and above with lower limb varicosities and having ASA grade I/II.

Exclusion Criteria:

- Patients below 18 years of age and/or having DVT.
- Patients with coagulopathy.
- Patient of varicose vein with venous ulcer.

All patients admitted to male and female surgical wards were considered as data source using clinical performa.

Group 1: Ligation–Stripping (LS).

Group 2: Radio-Frequency Ablation (RFA).

All patients were assessed clinically to identify symptoms and signs related to vein diseases both before treatment and after treatment. Changes in symptoms and signs together with treatment related complications and presence of residual or recurrent varicosities were assessed. Study group were compared for the reduction in the symptoms and signs together with treatment related complications and presence of residual or recurrent varicosities.

- Blood- CBC, FBS, PPBS, RBS, HbA1c, Blood urea, Sr. Creatinine, HIV, HBsAg, lipid profile.
- Urine routine & microscopy - for albumin, sugar, ketone bodies & for epithelial cells, pus cells.
- ECG – to know any ischemic changes in heart.
- Ultrasonography – Doppler study - arterial and venous system of the affected limb.

1. LS Procedure:-

This procedure was first suggested by Homans, and not Trendelenburg. This flush ligation of the saphenous vein with the femoral vein in the groin, prevents the reflux of blood into the origin of long saphenous vein and any of four or five tributaries that join near its termination. An oblique incision is made just below the crease of groin centered over the sapheno-femoral junction, which is 4 cm lateral and below the pubic tubercle. The subcutaneous tissue and fascia is dissected and the dissection is continued along the GSV until the junction with femoral is seen. There are six named tributaries that join the GSV at or near its termination, but they are variable in their number and position. These are postero-medial, antero-lateral veins of the thigh, the superficial inferior epigastric, the superficial circumflex iliac and the superficial external pudendal, and lastly the deep external pudendal vein which might join the femoral vein directly from medial side. Once all the tributaries have been clearly displayed, they can be doubly clipped, ligated in continuity and divided. The long saphenous vein itself can then be ligated, in continuity, with absorbable ligatures and divided.

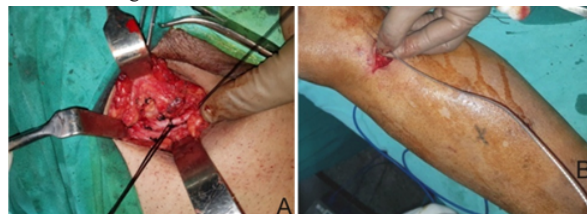
For stripping of the upper half of the long saphenous vein, it is advised that sapheno-femoral ligation should first be carried out at the groin, i.e. the vein is exposed and all tributaries entering its upper segment are divided as described above. The vein is then transfixed and ligated at its junction with the femoral and is divided below the ligature. The distal end is temporarily controlled with a loosely tied ligature held in a haemostat. The long saphenous vein is now exposed through a small skin crease incision three finger breadths below the knee joint; the stripper is introduced and is passed upwards until it emerges through the upper end of the vein in the groin incision. A small acorn is attached and the vein tied on to the stripper. The stripper is drawn a short distance upwards so that the acorn-head is drawn in through the incision. The vein is then divided below the ligature and the lower cut end is tied off. The vein is not stripped out at this stage. It will usually be necessary for further incisions to be made in the leg for ligations of perforators which were marked by Doppler ultrasound preoperatively. The groin and knee wounds are closed with absorbable subcuticular sutures. In the groin incision the suture along-side the stripper is left untied, the loose ends being controlled by haemostats.

The remaining part of the operation - multiple phlebectomy is now performed - after which wounds are closed with skin strips, dressed

and the leg elevated and bandaged with cohesive bandage as the stripper is withdrawn through the groin incision and the last suture is tied, the whole diseased GSV is stripped out. Sterility being maintained by using the haemostats to tie the knot.



Groin incision given SFJ identified



A. GSV and all tributaries ligated and divided;
B. Below knee incision given, GSV identified



Stripper inserted and acorn head attached to the stripper



Incision site closed and GSV stripped out

Rf Procedure:-

GSV is percutaneously punctured at the knee joint or mid-leg. 7 Fr sheath is placed, RF-catheter is advanced in the GSV upto 3 cm distal to SFJ. Under USG guidance peri-venous tumescent anesthesia is given and then segmental ablation of the vein is performed via

withdrawing the catheter 7 cm at a time. Percutaneous foam sclerotherapy of varicose vein is performed 50% STDS form without opacifying the deep system. The procedure was done by Consultant Interventional Radiologist. Efficacy outcome was assessed on the following parameters at baselines, 3 days, 7 days, 28 days, 3 months. Adverse events/complications were recorded along a checklist prepared for this study (intraoperative, postoperative day 3, 7, 28, 90). Patients were given a questionnaire (Likert's questionnaire) consisting of six questions to fill on postoperative day 3, 7, 28 and at 90 days. The patients marked their response as 100- definitely true; 50- can't say, 25 mostly false, 0 definitely false. The response was assessed with median and percentage.

Questionnaire

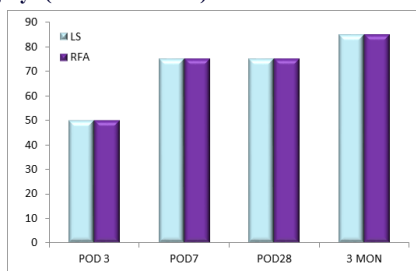
1. Was helped as much as I thought I will be post surgery.
2. My problem/ problems were reduced as much as I expected them to after surgery.
3. The benefit of my care outweigh the setback it caused me.
4. Overall I am happy with the care I am receiving for my legs.
5. All things considered, I would have the surgery again for the same reason.

RESULTS

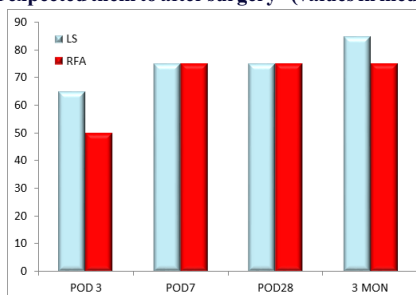
Table 1: Distribution of Patients According to Presenting Signs and Symptoms to Type of Skin Involvement to Limb Involvement

Factors	Stripping & flush ligation group (n=30)	Radio-frequency Ablation group (n=30)	P-value
Ulceration	None	None	-
Pain	13	9	NS
Itching	None	None	-
Skin involvement	12 (40%)	10 (33.33%)	NS
Left	25 (83.3%)	25 (83.3%)	NS
Right	5 (16.67%)	5 (16.67%)	
No. of incompetent perforators	15 (0-3)	15 (0-3)	NS

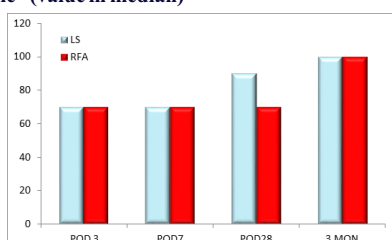
Graph 1: Response to "I was helped as much as I thought I will be post surgery" (values in median)



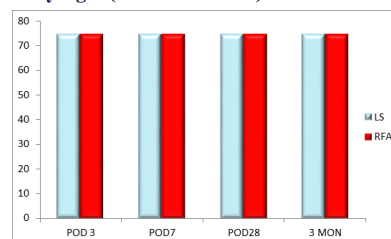
Graph 2: Response to "My problem/problems were reduced as much as I expected them to after surgery" (values in median)



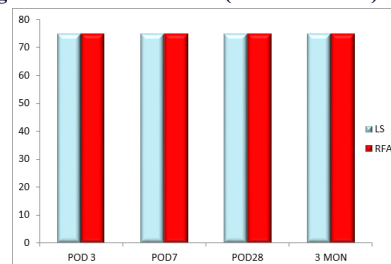
Graph 3: Response to "the benefit of my care outweigh the setback it caused me" (value in median)



Graph 4: Response to "Overall I am happy with the care I am receiving for my legs" (value in median)



Graph 5: Response to "All things considered, I would have the surgery again for the same reason" (value in median)



DISCUSSION

Treatment of varicose veins has been a topic of research and the search for adequate and ideal treatment of this common condition has seen various stages of evolution, ranging from conservative compression stocking to the most recent endovenous laser application. However, surgery in the form of high/flush ligation of SFJ and stripping of GSV has been traditionally described as the gold standard. Beale and colleagues in 2005, did a review of the various treatment options being used in the treatment of this disease'.

Operative treatment strategies can be minimally invasive ones, like RFA and EVLA, or conventional techniques like flush ligation with stripping of GSV with its modifications. In RFA, the vein is cannulated at knee level using a 5-8Fr diode catheter and advanced to SFJ under USG control and then withdrawn slowly. Application of heat result in endothelial denudation, collagen denaturation and the actual vein contraction. The technique is suitable for veins upto 12mm diameter, thus not being applicable to all the patients.

Complications associated with this technique, apart from recanalisation, include thermal burns, saphenous neuritis, and DVT. Other minimally invasive endovenous technique is laser ablation. In this, the vein does not immediately shrink, but does so over a period of 6 weeks, then it eventually disappears. Main complications are bruising and thrombophlebitis, with less evidence of burns, paraesthesia and DVT. Complications associated with formal surgery include nerve injury, hematoma, wound infection, thromboembolism and recurrence.

Over the years, with the advancement of technology and the advent of radiofrequency and laser, and their application in surgical practice, has made these minimally invasive techniques lucrative treatment options. Proponents of these procedures claim to overcome the morbidity and complications associated with LS of GSV, but these techniques are not flawless and have their own complications.

In our study we compared the two procedures and assessed the outcomes in terms of occlusion rates, the complication rates and QOL measures. We found that we could achieve 100% occlusion rates in both the procedures, we did not find any statistically significant difference in the complication rates and the patients did not show any predilection towards any one specific mode of treatment. The cost of radio frequency ablation procedure is almost three times higher than the trendenbun and stripping procedure of GSV. We found that the two procedures were comparable to each other, in terms of the incidence of complications and recurrence of disease in our duration of study.

The clinical stage of disease, showed an improvement in all the treated patients regardless of the procedure they underwent. Deep vein thrombosis was not seen in any of the patient. We measured QOL indicators using direct questions and used a questionnaire which was based on Likert's scale. The responses did not show any significant

difference in outcomes, when compared in the two groups.

There have been multiple trials evaluating the efficacy of RFA as a treatment strategy for varicose veins. In one such study, conducted in 2002, as a multi-centre trial by Merchant et al⁴, the difference in the clinical outcomes in patients treated with RFA were assessed as a function of technical outcomes.

Our results of 100% occlusion rates in RFA at 3 months follow up, are better than the reported results in other studies with a similar follow up period. Hingorani⁵ reported an occlusion rate of 96% at 1 month. Ogawa⁶ reported an occlusion rate of 100% at 1 month follow up. In 2006, Dunn⁷ reported an occlusion rate of 90% at 6 months follow up. Our results are comparable with these studies. As noted by Merchant⁴ RFA deals mainly with the truncal varicosity. We however feel that a longer follow up will help us realize the actual incidence of recanalisation and neo-reflux and the implications of the modification in the procedure.

Quality of life measures have been reported to be better with minimally invasive techniques. The issues which we assessed were postoperative pain and analgesic requirement, time taken to return to normal activity and patient satisfaction, as indicated by a questionnaire. The patient profile amongst our patients and the ones in other studies was similar.

They were comparable within both the groups and with other studies. The clinical stage of our patients was also comparable to the patients in other studies. We did not exclude patients in advanced stage of venous disease if the condition was found to be direct progression of reflux disease and no evidence of deep vein insufficiency was detected. This however, has no significant impact on the result as the response to surgery was favourable in both the groups. Patients in both the groups reported that they were generally satisfied with the care of the limb that they received, and were willing to undergo similar procedure given the need in future for the other limb. We did not find any significant statistically difference in QOL scores during the analysis of our results. The wound infection rates were slightly worse for the RFA group than the ligation stripping group, but the difference was not significant statistically. The difference in QOL scores get diluted over longer follow-up periods and thus the conclusions that both RFA and Stripping and ligation are associated with better short term outcomes, with earlier recovery and return to work and normal activity. In our study, we used spinal anesthesia, for stripping and ligation group and tumescent anesthesia during the RFA procedure.

The authors could identify a non-GSV reflux site in as many as 25% of limbs with recurrence. In 37% of recurrence cases, an inadequately ligated, incompetent stump and with one or more intact tributary was identified during re-exploration.

The result of our study indicated no major differences in the outcome parameters when compared b/w the two group of treated patients. However, the study is not without limitations.

CONCLUSION

Radiofrequency ablation of GSV for the treatment of varicose veins, is as effective as High ligation and stripping. The two procedures are comparable in terms of quality of life indicators, postoperatively. The clinical improvement in patients of varicose veins was similar in both the groups. The cost of RFA procedure is almost 3 times higher than the LS procedure of GSV.

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