Section: General Surgery

Original Research Article

COMPARATIVE STUDY OF RADIO FREQUENCY ABLATION AND TRENDELENBERG PROCEDURE DURING A ONE YEAR FOLLOW UP IN A TERTIARY CARE HOSPITAL

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Abstract

Background: This retrospective study was conducted to evaluate clinical, patient based outcomes after RFA and conventional surgery in a selected population. **Materials and Methods:** This study was conducted in the Kanyakumari Government Medical College Hospital during a period of 12 months from January 2022 to December 2022. **Result:** In present study, it was reported that 66 patients in total were assessed in the study, out of which, 32 underwent RFA and 34 underwent trendelenberg procedure. In RFA group, males were 15, females were 17; in trendelenberg group, males were 14 and females were 20. In CEAP classification, in C2 class, there were 25 in RFA group, 26 in trendelenberg group; in C3 class, there were 5 in group RFA, 6 in trendelenberg group; in C4-5 class, 2 were in group RFA and 2 were in trendelenberg group. Main outcomes after RFA and conventional surgery for great saphenous varicose veins were, theatre time was 84 mins in RFA group, 52 mins in trendelenberg group, procedure time was 78 mins in RFA group, 50 mins in trendelenberg group, pain in first week (VAS score) was 3 in RFA group, 6 in trendelenberg group, duration of analgesia was 4 days in RFA group, 6 days in trendelenberg group. Complications like infection, haematoma, skin colour changes and nerve injury were less in RFA group when compared to conventional group and none in both groups developed DVT post operatively. **Conclusion:** This study concluded that compared to conventional surgery, RFA took longer time to perform but it gave better and significantly early outcome in patients with varicose veins.

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.[1] 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 Non-surgical treatments include, compression elastic stockings, elevating the legs, and exercise.[2] 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. 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.[3]

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 inpatients 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

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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 regards 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 neovascularization 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.[4] 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 today.[5] 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

The aim of our study is to compare the efficacy of Radio frequency ablation over conventional Trendelenburg surgery on a shorter follow-up period of one year.

Objectives

The Objectives of our study are comparing RFA vs Trendelenburg surgery in terms of

- Complications
- Duration of surgery
- Requirement of analgesia
- Duration of hospital stay
- Return to daily activities

MATERIALS AND METHODS

Inclusion Criteria

Patient age group was 25 – 65 years with varicose veins diagnosed using Doppler study and having a C2-C5 in CEAP classification.

Exclusion Criteria

Patients with

- Recurrent varicosities
- Active venous ulcers
- Associated DVT
- Patients with coagulopathy

This retrospective Study was done by analysing the in-patient records during the period from January 2022 to December 2022 over a period of twelve months in Kanyakumari Government Medical College Asaripallam, Nagercoil. A total of 32 patients who underwent Radio frequency ablation and 34 patients underwent Trendelenburg procedure.

Group 1: Trendelenberg Procedure. Group 2: Radio-Frequency Ablation.

All patients were assessed clinically and ultrasonographically. Study group were compared for the treatment related complications duration of hospital stay and return to daily activities along with demographic data.

1. Trendelenburg 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 centred over the sapheno-femoral junction, which is 4 cm lateral and below the public tubercle. The subcutaneous tissue and fascia are dissected and the dissection is continue 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 no 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 medical 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

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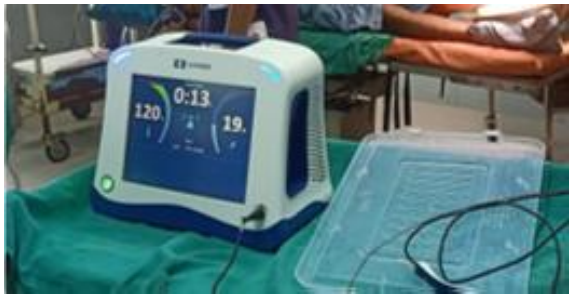
through a small skin crease incision three finger breadths below the knee joint; the stripper is introduced and is passed upwards until it emerges through the upper end of the vein in the groin incision. A small acorn is attached and the vein tied on to the stripper. The stripper is drawn a short distance 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 and ligation of perforators were done.

2. RFA:

GSV is percutaneously punctured at the knee joint or mid-leg. 7 Fr sheath is placed, RF-catheter is advanced in the GSV up to 3 cm distal to SFJ. Under USG guidance peri-venous tumescent anaesthesia is given and then segmental ablation of the vein is performed via withdrawing the catheter 7 cm at a time while compression and usg confirmation of obliteration of vein is being confirmed.



RESULTS

Demographic Data

In our study of the total 32 persons who participated in the RFA group 15 were males and 17 were females and in trendelenberg group 14 were male and 20 were females.

Sex Distribution	Males	Females
RFA	15	17
Trendelenberg	14	20

CEAP Distribution:

CEAP	RFA	Trendelenberg
C2	25	26
C3	5	6
C4-5	2	2

Main Outcomes:

Outcomes	RFA	Trendelenberg
Theater time(mins)	84	52
Procedure time(mins)	68	40
Pain in first week (VAS)	3	6
Duration of analgesia(days)	4	6

Complications:

Complications	RFA	Trendelenberg
Infection	2	4
Haematoma	1	3
DVT	0	0
Skin colour changes	1	2
Nerve injury	0	1

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Duration of Hospital Stay

Duration	<D5	D6-D10	D10-D15
RFA	24	7	1
Trendelenberg	5	29	0

Patients Needing Intravenous/ Intramuscular Anaelgesia

Days	D1	D1-D3
RFA	31	1
Trendelenberg	32	12

Return To Daily Activities

Days	<D10	D10-15	D15-20
RFA	11	20	1
Trendelenberg	1	10	23

DISCUSSION

In our study of the total of 66 patients who were studied 32 were performed with Radio frequency ablation and 34 underwent trendelenberg procedure.
In trendelenberg group males were 14 and females were 20 and in RFA group males were 15 and females were 17.
In CEAP classification in C2, 25 underwent RFA and 26 underwent trendelenberg, Of the total 11 in C3, 5 were in RFA group and 6 were in trendelenberg group. Remaining people belong to either C4 or C5 of them both group had 2 each.

Main Outcomes

In our study the theatre time was on a mean of 84 mins for trendelenberg operation and 52 mins for RFA. Procedure time for the same were 68 mins and 40 mins for RFA and trendelenberg respectively which is in accordance with Subramonia S et al,[6] conducted a randomized clinical trial which compared early outcomes after radiofrequency ablation (RFA) and conventional surgery for varicose veins.[6] RFA resulted in successful obliteration of the GSV in all 47patients. Complete above-knee stripping was unsuccessful in seven of 41 patients. RFA took longer than conventional surgery: median interquartile range 76(67-84) versus 48 (39-54) min; P <0.001. Patients returned to their normal activities significantly earlier after RFA (median 3 (2-5) versus 12.5 (4-21) days; P<0.001). Post operative pain was significantly less after RFA (median score on visual analogue scale 1.70 (0.50-4.30) versus 4.0 (2.35-6.05); P = 0.001). Patient satisfaction, quality of life improvement and analgesic requirements significantly favoured RFA.
In our study the mean pain in Visual analogue score in first week was 3 for RFA and 6 for trendelenberg. The mean duration for analgesia requirement in days for RFA is 4 and for trendelenberg procedure is 6. Patients requiring additional intravenous or intramuscular analgesia ranged from on D1 31 people required IV analgesia when compared to 32 of the patients who underwent trendelenberg procedure. While on Day 1-3 only one in RFA group required additional analgesia whereas 12 in trendelenberg required additional analgesia which is in accordance with Toregeani JF et al,[7] conducted a study from May 2012 to April 2013 146 varicose veins patients with saphenous insufficiency, 90 of whom were treated with conventional surgery (G1) and 56 with RF ablation (G2), were evaluated prospectively.[8] In G1, 88.61% of patients complained of postoperative pain and needed to take analgesics, compared with 28.85% in G2 (p<0.05). Mean pain rating on an analogue scale from 0 to 10 was 3.91±2.13 points for G1 and 1.76±3.01 points for G2 (p<0.05). Recovery periods ranged from 26.63±13.3 days to 18.26±19.37 days, for G1 and G2 respectively. Mean time taken to become totally asymptomatic was 66.78±60.9 days for G1 and 38.38±46.8 days for G2 (p<0.05).
When comparing duration of Hospital stay in our study 24 of the people who underwent RFA had only a hospital stay of within 5 days while 29 of trendelenberg patients had a stay of 6 to 10 days.

Complications

Haridas KP et al,[8] have conducted a study in which symptomatic varicose vein patients presenting to surgery OPD, who met the Doppler ultrasonography (USG) criteria for suitability for RFA, were offered RFA instead of open surgery. Radiofrequency ablation of varicose vein was done using the radiofrequency generator and segmental ablation catheter, under USG guidance. Patients who underwent RFA were followed up by check Doppler at 21 days and at 90 days. Out of a total of 1288 RFAs, technical success at 90 days was 99%. Factors affecting technical success were highlighted. Complications were minor and negligible. Modification of the technique to prevent some of the complications were carried out.
Mendes CA et al,[9] conducted a randomized controlled trial that included 18 patients and was carried out between November 2013 and May 2015.9 Each of the lower limbs of each patient was randomly assigned to undergo either radiofrequency ablation or conventional surgery. Clinical features (hyperpigmentation, hematoma, aesthetics, pain, skin burn, nerve injury, and thrombophlebitis) were evaluated at one week, one month, and six months

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postoperatively. Hemodynamic assessments (presence of resection or occlusion of the great saphenous vein and recurrent reflux in the sapheno-femoral junction and in the great saphenous vein) were performed at one month, six months, and 12 months postoperatively. The independent observer (a physician not involved in the original operation), patient, and duplex ultra sonographer were not made aware of the treatment done in each case. Among the clinical variables analysed, only the aesthetic evaluation by the physicians was significant, with radiofrequency ablation being considered better than conventional surgery (average, 0.91 points higher: standard deviation: 0.31; 95% confidence interval: -1.51, -0.30; p=0.003). However, in present study, authors observed primary success rates of 80% for radiofrequency ablation and 100% for conventional surgery.

In our study of the total 32 who underwent RFA only 2 had infection which was localised while patients undergoing trendelenberg 4 had localised infection, 3 of the trendelenberg group has haematoma/seroma formation only one had a haematoma formation in RFA group. One in RFA and 3 in trendelenberg has skin colour changes and one in trendelenberg group had a nerve injury. Hingorani et al,[10] had suggested there is apossibility of developing DVT post RFA none of our patients developed DVT post operatively.

Limitations

Due to shorter duration of study long term complications like recurrence could not be studied.

CONCLUSION

This study concluded that compared to conventional surgery, RFA took longer time to perform but it gave better and significantly early outcome in patients with varicose veins.

REFERENCES

1. Varicose Veins.2010-07-06.http.//www.web citation.org/5r1PRrJul. Mount Sinai Hospital, New York.
2. Merck Manual Home Edition 2nd Edition 2004; 48(4):839-46.
3. Teruya TH Ballared JL New approaches for the treatment of varicose veins. Surg Clin N Am 2004; 84:1397-417.
4. Merchant RF, DePalma RG, Kabnick LS. Endovascular obliteration of saphenous reflux: a multicenter study. J Vase Surg 2002; 35:1190-6.
5. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O et al. Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVeS): two-year follow-up. Eur J Vasc Endovasc Surg.2005;29:67-73.
6. Subramonia S, Lees T. Randomized clinical trial ofradiofrequency ablation or conventional highligation and stripping for great saphenous varicoseveins. Br J Surg. 2010;97:328-36.
7. Toregeani JF, Rocha AS, Kimura CJ, Araújo RA,Kawai AK, Rotta LS et al. Radiofrequency thermalablation versus conventional saphenectomy. J Vasc Brasileiro. 2015 Mar;14(1):4-9.
8. Haridas KP, Prasad V. Radiofrequency ablation of varicose veins large series from a single centre; J Evid Based Med Healthcare. 2015 Jan 1;2(9):1148-54.
9. Mendes CD, Martins AD, Fukuda JM, Parente JB, Munia MA, Fioranelli A et al. Randomized trial of radiofrequency ablation versus conventional surgery for superficial venous insufficiency. Clinics. 2016;71(11):650-6. 10. Venermo M, Saarinen J, Eskelinen E, Vähäaho S, Saarinen E, Railo M et al. Randomized clinical trial comparing surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy for the treatment of great saphenous varicose veins. BJS. 2016;103:1438-44.
10. Hingorani AP, Ascher E, Markevich N, et al. Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: a word of caution. J Vasc Surg. 2004;40:500–504.

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