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Original Research Article

Varicose vein surgery stripping method compared to radio frequency ablation

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ABSTRACT

Background: This randomised study was conducted to evaluate clinical, patient based outcomes after RFA and conventional surgery in a selected population.
Methods: This study was conducted in the Meenakshi Medical College Hospital and Research Institute, Enathur, Kanchipuram, Tamil Nadu, India.
Results: In present study, it was reported that 150 patients in total were assessed in the study, out of which, 110 were randomised, 100 underwent the intervention as a daily procedure. 50 patients underwent RFA and 50 patients had conventional surgery. In group R, males were 15, females were 35; in group C, males were 17 and females were 33. 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, 6 in group C; in C4-6 class, 2 were in group R and 5 were in group C. The highest total clinical severity score was 1 i.e. 30 in group R and 32 in group C. Highest venous disability score was in 1 i.e. 46 in group R, 42 in group C. Main outcomes after RFA and conventional surgery for great saphenous varicose veins. Theatre time was 80 mins in group R, 52 mins in group C, procedure time was 74 mins in group R, 46 mins in group C, pain in first week (VAS score) was 1.5 in group R, 3.5 in group C, duration of analgesia was 3 days in group R, 11 days in group C, in 4 days group R patients returned to normal activity, in 13 days group C patients returned to normal activity. Numbness/reduced sensation was followed up after 1 week and 6 week, in group R, 8 patients and in group C, 16 patients have shown numbness/reduced sensation after 1 week; 6 patients in group R and 14 patients in group C have shown numbness/reduced sensation after 6 weeks.
Conclusions: 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.

Keywords: RFA, Varicose vein, Endovenous laser ablation

INTRODUCTION

Of all the vascular disorders, lower limb varicose veins are the most common problem which impairs quality of life. It approximately affects 15% of men and 25% of women globally. When compared to other symptomatic vascular diseases like coronary artery disease or stroke, varicose veins have the maximum prevelance. Majority of varicose vein problem are asymptomatic, they usually have heaviness of legs, aching, itching, oedema and ulceration and sometimes cosmetic reasons.[1] There are a number of treatment options. It depends how bad your varicose veins are. These tests may help decide the proper treatment; Venous Blood Flow Study is a test that checks for blockages in your deep veins.

Duplex Scan test also checks your veins and valves. It may show blockages or faulty valves. Venography test

also checks your valves and for blockages in the veins.[2] Based on the results of your tests, your doctor will give you treatment choices. These include both non-surgery treatments and surgery. The goal of treatment is to relieve pain in your legs, prevent bleeding from varicose veins and improve the look of your legs.[3]

Treatment choices are; leg elevation, use of support hose or ace bandages, exercise, weight loss, avoiding prolonged standing, sclerotherapy (varicose veins are injected with chemicals to make them disappear), Endovenous laser ablation (heat from laser makes the vein collapse and disappear), Radiofrequency ablation (radiofrequency energy makes the vein collapse and disappear) and Vein ligation surgery.[4] The traditional way for treating varicose vein is vein ligation or stripping of the involved vein. In this procedure, when the veins are removed in surgery, the upper end of the damaged vein is tied off and removed. This will not affect blood flow in your legs because the blood will then flow through the deep veins back to the heart.[5] Both vein ligation surgery and RFA will likely be done as an outpatient in the operating room. Radiofrequency ablation (RFA) is also a minimally-invasive treatment for varicose veins. The doctor uses radiofrequency energy (instead of laser energy) to damage the varicose vein. This forms scar tissue which closes off the varicose vein. In this procedure, catheter is introduced in the dilated veins with an electrode extending from the tip.

The vein wall is heated to 85-120ºC by a generator which delivers radiofrequency energy. The catheter keeps the temperature at a set target by using a feedback mechanism which evaluates the vein wall impedance and adjusts the energy delivered which causes collagen denaturation, shrinkage and complete obliteration of vessel wall. This randomised study was conducted to evaluate clinical, patient based outcomes after RFA and conventional surgery in a selected population.

METHODS

This study was conducted in the vascular unit of Meenakshi Medical College Hospital and Research Institute, Enathur, Kanchipuram, Tamil Nadu, India.

Inclusion Criteria was patients who were aged between 18 and 70 years, either sex who were electively admitted. Patients who were undergoing GSV reflux on duplex imaging and requiring surgery.

Patients who were confirmed for duplex scan were suitable for RFA, patients fit for general anaesthesia, patients physical condition allowing ambulation after the procedure, patients who were able to give informed consent, patients who were willing for all follow up visits. Exclusion Criteria was varicose veins without GSV incompetence, associated small saphenous or deep venous incompetence on duplex imaging, for catheterisation, tortuous GSV above the knee felt unsuitable, thrombus in GSV, GSV diameter <3 mm or > 12 mm in the supine position, patients with a pacemaker or internal defibrillator, peripheral arterial disease, pregnant patients were excluded. The study was approved by intuitional ethical committee. By using a randomised method, the patients were divided into two groups, Group R who underwent RFA and Group C who underwent conventional surgery. In both groups, all operations were performed under general anaesthesia. For simultaneous avulsion of varicosities that had been marked before operation, phlebectomy hooks were used. Radiofrequency ablation was performed by surgeons with sufficient experience.

To map the course of GSV in the thigh and to mark the vein access site at knee level before skin preparation, the duplex scan was used. The intravascular catheter with bipolar electrodes was introduced in the GSV with its tip just below the entry of the superficial epigastric vein. Using saline, the tissues overlying the GSV were infiltrated under duplex guidance to achieve vein compression. The catheter position of the tip was confirmed and its proximal end was connected to radiofrequency generator. The wall contact was tested by measuring the impedance by unsheathing the electrodes. The temperature was set to 85ºC. The catheter was pulled backwards at the rate of 1.5-2 cm per min for the first 3 cm and 2-3 cm for remainder of the procedure and the ablation was done just distal to the entry of superficial epigastric vein. To prevent thrombus formation on the electrodes, the saline was infused through the central lumen of the catheter.

The esmarch bandage which was tied from the knee to groin with the leg elevated and the patient was placed in trendelenburg position, it was removed and the sheath was withdrawn to treat the lowest segment of the vein. On completion of procedure, a duplex scan was performed. In trendelenburg position, conventional surgery was performed by an experienced surgeon.The tributaries of the GSV were ligated and divided, through the skin crease groin incision exposing the SFJ.

A perforated invagination stripper was passed down through open distal end of the vein to emerge at knee level and the skin incised at this point to retrieve the stripper. This stripper was pulled down to the knee level and out of the exit wound thus stripping the vein. The wound was infiltrated with bupivacaine and closed by absorbable sutures. The patients were followed up for the end of the first week and end of the sixth week after intervention. At the first follow up, a duplex scan was carried out.

RESULTS

150 patients in total were assessed in the study, out of which, 110 were randomised, 100 underwent the

intervention as a daily procedure. 50 patients underwent RFA and 50 patients had conventional surgery.

Table 1: Demographic distribution in the study.

Sex distribution	Males	Females
Group R	15	35
Group C	17	33

Table 1 shows that in group R, males were 15, females were 35; in group C, males were 17 and females were 33.

Table 2: Distribution based on clinical etiologic anatomic pathophysiologic (CEAP).

CEAP	Group R (n=50)	Group C (n=50)
C2	40	39
C3	8	6
C4-6	2	5

Table 2 shows that in C2 class, there were 40 in group R, 39 in group C; in C3 class, there were 8 in group R, 6 in group C; in C4-6 class, 2 were in group R and 5 were in group C.

Table 3: Distribution based on total clinical severity score (TCSS).

TCSS	Group R (n=50)	Group C (n=50)
0	6	6
1	30	32
2	10	8
3	3	3
≥4	1	1

Table 3 shows that the highest total clinical severity score was 1 i.e. 30 in group R and 32 in group C.

Table 4: Distribution based on venous disability score (VDS).

VDS	Group R (n=50)	Group C (n=50)
0	3	3
1	46	42
2	1	5

Table 4 shows that highest venous disability score was in 1 i.e. 46 in group R, 42 in group C.

Table 5 shows main outcomes after RFA and conventional surgery for great saphenous varicose veins.

Theatre time was 80 mins in group R, 52 mins in group C, procedure time was 74 mins in group R, 46 mins in group C, pain in first week (VAS score) was 1.5 in group R, 3.5 in group C, duration of analgesia was 3 days in group R, 11 days in group C, in 4 days group R patients returned to normal activity, in 13 days group C patients returned to normal activity.

Table 5: Main outcomes after RFA and conventional surgery for great saphenous varicose veins.

Outcomes	Group R (n=50)	Group C (n=50)
Theatre time (mins)	80	52
Procedure Time (mins)	74	46
Pain in first week (VAS score)	1.5	3.5
Duration of analgesia (days)	3	11
Return to normal activity (days)	4	13
Return to work (days)	11	19

Table 6 shows that numbness/reduced sensation was followed up after 1 week and 6 week, in group R, 8 patients and in group C, 16 patients after 1 week; 6 patients in group R and 14 patients in group C after 6 weeks.

Table 6: Sensory abnormalities after treatment.

Abnormalities	Group R (n=50)	Group C (n=50)
Numbness/reduced sensation		
1 week follow up	8	16
6 week follow up	6	14
Paraesthesia		
1 week follow up	3	10
6 week follow up	5	4

DISCUSSION

In present study, it was reported that 150 patients in total were assessed in the study, out of which, 110 were randomised, 100 underwent the intervention as a daily procedure. 50 patients underwent RFA and 50 patients had conventional surgery. In group R, males were 15, females were 35; in group C, males were 17 and females were 33. 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, 6 in group C; in C4-6 class, 2 were in group R and 5 were in group C. The highest total clinical severity score was 1 i.e. 30 in group R and 32 in group C. Highest venous disability score was in 1 i.e. 46 in group R, 42 in group C. Main outcomes after RFA and conventional surgery for great saphenous varicose veins.

Theatre time was 80 mins in group R, 52 mins in group C, procedure time was 74 mins in group R, 46 mins in group C, pain in first week (VAS score) was 1.5 in group R, 3.5 in group C, duration of analgesia was 3 days in group R, 11 days in group C, in 4 days group R patients returned to normal activity, in 13 days group C patients returned to normal activity. Numbness/reduced sensation

was followed up after 1 week and 6 week, in group R, 8 patients and in group C, 16 patients have shown numbness/reduced sensation after 1 week; 6 patients in group R and 14 patients in group C have shown numbness/reduced sensation after 6 weeks. Subramonia S et al; 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 47 patients. 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).

Postoperative 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. Haridas KP et al; have conducted a study in which symtomatic 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.[7] 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. Toregeani JF et al; 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 analog 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). Mendes CA et al; 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 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 ultrasonographer were not made aware of the treatment done in each case. Among the clinical variables analyzed, 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. Venermo M et al; conducted a study which included 214 patients: 65 had surgery, 73 had EVLA and 76 had UGFS.[10] At 1 year, the GSV was occluded or absent in 59 (97 per cent) of 61 patients after surgery, 71 (97 per cent) of 73 after EVLA and 37 (51 per cent) of 72 after UGFS (P <0·001). The AVVSS improved significantly in comparison with preoperative values in all groups, with no significant differences between them. Perioperative pain was significantly reduced and sick leave shorter after UGFS (mean 1 day) than after EVLA (8 days) and surgery (12 days).

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.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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