Comparative Evaluation of Conventional Surgery with Radio Frequency Ablation in the Treatment of Varicose Veins

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Abstract: The standard treatment for a varicose vein is the elimination of the reflux and the abnormal superficial venous system. Conventional surgery involves venous ligation with the stripping of great or short saphenous veins and hence plenty of tissue injuries. Minimal invasive procedures, like Radio Frequency Ablation or sclerotherapy, ablates the superficial venous system without causing significant tissue injuries, hence, an increase in the acceptability of the procedure. Thus, a randomized study was conducted to evaluate endovenous procedures against the gold standard conventional surgery for its potential benefits. <u>Methodology</u>: A randomized controlled study was conducted in the department of general surgery at a tertiary care military hospital on 60 patients between 18-60 years of age suffering from varicose veins from the period of January 2016 to March 2019. The patients were categorized into two groups. Group A underwent Radio Frequency Ablation, while Group B underwent Ligation and Stripping. All the patients were reviewed at 1, 6 and 12 months to assess the presence of residual or a recurrent varicose vein (PREVAIT). Data were processed and analyzed using SPSS 24.0. Data were presented as frequencies with percentages (for categorical data), proportions, graphs, mean with standard deviation, Chi-Square test and univariate analysis. A p-value <0.05 was considered statistically significant. <u>Results</u>: Postoperative pains was considerably less in the RFA group compared to the Stripping group and the mean Visual Analogue Scores at 72 hours and at 7 days were significantly lower in the RFA group. A significantly more minor post complication were seen in the Stripping group. <u>Conclusion</u>: Both Conventional open surgery with micro phlebectomy and RFA with foam sclerotherapy are effective methods of tackling varicose veins. The immediate post-operative results and acceptance of the procedure are more encouraging with the minimally invasive procedures.

Keywords: Radio frequency Ablation, Sclerotherapy, Varicose veins, Conventional surgery

1. Background

A varicose vein is a twisted, enlarged vein that occurs due to prolonged standing in an erect posture, existing in nearly 10% of the general population. [1] Despite being benign, it has a considerable clinical and socio-economic impact. [2] It is usually associated with varied clinical symptoms ranging from cosmetic concerns to Lipodermatosclerosis and nonhealing venous ulcers, thus impairing quality of life. [3] The most common cause of varicose veins is the insufficiency and reflux of the blood in the superficial venous system, i.e., the great saphenous vein, the short saphenous vein and the perforators communicating the superficial and deep venous systems. [4] The standard treatment is the elimination of the reflux and the abnormal superficial venous system. [5] Conventional surgery involves ligation the of saphenofemoral or saphenopopliteal junction with the stripping of great or short saphenous veins and multiple phlebectomies. [6] The surgery involves blind avulsion of long segments of superficial veins and hence plenty of tissue bruising, cutaneous nerve injuries, wound infection leading to a delayed return to work, a sense of dissatisfaction and inhibition towards the surgical treatment. [7]

Minimal invasive endovenous procedures, like Radio Frequency Ablation or chemical sclerotherapy, ablates the superficial venous system without causing significant tissue injuries as caused by conventional stripping⁸. Thus there are fewer post-operative complications enabling an early return to work. As a result, there may be an increase in the acceptability of the procedure. Regardless of the claims, it is important to evaluate these endovenous procedures against the gold standard conventional surgery for its potential benefits.

A randomized study was conducted in a selected population of serving soldiers, ex-serviceman and their families at a tertiary care military hospital for a comparative analysis between the conventional open surgery for the peripheral varicosities and the radiofrequency ablation of saphenous vein and foam sclerotherapy for the peripheral varicosities.

2. Methodology

After seeking due approval from the ethical committee of the institution, we conducted a prospective randomized study in the department of general surgery at a tertiary care military hospital on a selected group of patients consisting of mainly the serving soldiers and their dependents suffering from varicose veins from the period of January 2016 to March 2019.

Patients between 18-60 yrs of age with C1-C5 (Clinical-Etiology-Anatomy-Pathophysiology: CEAP classification) disease, saphenofemoral (SF) or saphenopopliteal (SP) junction incompetence on duplex imaging and requiring surgery, patients fit for anaesthesia (ASA grade I or II), patients with a physical condition allowing ambulation after the procedure, and belonging to Army health care system, i.e. serving personnel, ex-serviceman and their dependents were included in the study. While varicose veins with competent SF or SP junction and patients with old/ fresh deep or superficial venous thrombosis on duplex imaging, patients with varicosity in pregnancy, patients with previous peripheral arterial disease, patients with CEAP C6 disease and those who refused to follow up and did not give consent to be a part of the study were excluded from the study.

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A total of 73 varicose veins patients were seen from January 2016 to March 2019. Out of 73 patients, nine patients declined randomization, and four patients revealed an anterior accessory saphenous vein incompetence, which was defined as an exclusion criterion. Finally, 60 patients were found suitable to be enrolled in this study group. Once a patient was registered for the study, they were randomized into either of the two groups using the **balloting method**, i.e., all patients prior to surgery were asked to pick one of 60 sealed envelopes containing a folded paper on which one of two treatments modality was written. The envelope, once taken out, was discarded after noting the type of operative procedure.

After randomization, group A (N=30) consisted of patients who were offered radiofrequency ablation (RFA) for the incompetent great saphenous vein (GSV) or short saphenous vein (SSV) accompanied with foam sclerotherapy for the peripheral varicosities. Group B (N=30) consisted of patients who were offered conventional surgery that is flush ligation of SF junction followed by stripping of the GSV just below the knee joint or the flush ligation of SP junction followed by stripping of SSV up to lower calf accompanied with microplebectomies for the peripheral varicosities.

3. Intervention

A day prior to the surgery, venous mapping was done in the patients of both groups. All the patients were given a prophylactic dose of antibiotic at the time of induction of anaesthesia. The surgeries were performed by the same team of surgeons in both groups. A note of duration, starting from the time of incision to dressing of the leg, was maintained in all patients.

Group A (RFA group): All procedures were done under Femoral block accompanied with tumescent anaesthesia made by adding 50 ml of 2% lignocaine, 50 ml 8.4% sodium bicarbonate in 500 ml of 0.9% normal saline. We used Olympus Celon lab Precision (RFA generator) for all the cases of this group (Figure 1). The saphenous vein was cannulated percutaneously under ultrasound guidance below the knee site in case of GSV (Figure 2) and lower calf region in case of SSV using a 7 F sheath. The bipolar catheter was advanced up to 2cms distal to the SF or the SP junction. Tumescent anaesthesia was infiltrated under ultrasound guidance to prevent the lateral damage because of heat and to get a good compression of the vein over the bipolar catheter. Thermal energy (temperatures of 200º-210º by using a power of 18-20W) was applied continuously using a continuous pull-back technique at a rate of 2 cms/min under ultrasound guidance. A duplex scan was performed on completion of the procedure; if any inadequately ablated vein segment was found, retreatment was performed immediately. Following this, the peripheral varicosities were dealt with by cannulating the vein with a 25 gauge butterfly infusion set under ultrasound guidance and injecting them with 1-3 ml of freshly prepared foam, depending on the length and diameter of the varicose vein. The sclerosant foam was prepared using the double syringe technique (Tessari technique) with STS 3% (sodium tetradecyl sulphate) to air ratio of 1:4.



Figure 1: Celeron RFA generator



Figure 2: Cannulation of GSV

Group B (Ligation and Stripping group): All the surgeries in this group were performed under spinal anaesthesia. The Surgical procedure was done through a skin crease groin incision, starting just medial to the femoral pulsations. The SF junction was dissected out; all the tributaries were ligated and cut. The GSV was flushed and ligated at SF Junction and divided. A pin stripper is passed in the distal cut end of the GSV up to just below the knee joint, where a small incision is given on the skin to retrieve the stripper from this incision. The cut end of the GSV is secured with the upper end of the stripper. Then the stripper is pulled out of the below knee incision along with the GSV hence stripping the long segment of the vein. The groin wound is sutured in two layers after ensuring hemostasis.

For the SP Junction ligation, the junction was preoperatively identified and marked using Doppler a day prior to the surgery. The incision was given over the mark, and the SP Junction was dissected out. SSV was flush ligated at the SP junction and divided. A stripper is passed at the distal cut end of the SSV up to the lower calf, and the lower end of the stripper is retrieved through a small incision. The upper part of the stripper is secured with the cut end of the SSV. Now the stripper is pulled out of the lower calf incision along with the SSV hence stripping the long segment of SSV.

All the peripheral varicosities were removed by giving small multiple stab incisions over the previously marked dilated veins and then avulsing them out of these stab wounds. The incisions were closed using sterile strips.

Post procedure, the leg was wrapped in a sterile cohesive compression bandage for 48 hours. Patients were instructed to lie down with their legs elevated. After removal of bandages, patients were instructed to use 20-30 mmHg compression stocking for four weeks. Injectable / oral Diclofenac was used for analgesia in the post-operative period as and when required in both groups.

The outcome compared were the time taken to complete the two procedures, post-operative pain, return to normal activity, early return to work, complications, if any, PREVAIT [**PRE**sence of **VA**rices (residual or recurrent) after Interventional Treatment] score and the difference in clinical venous severity score before and after the procedure.

4. Follow Up

Because most of the patients were serving soldiers in both groups, hence all these patients were mandatorily kept in the ward for observation post-operatively for one week. Here the patients were asked to document the pain using Visual analogue scores (VAS) at 72 hours and then at one week, a record of their normal activities in the ward was documented. All these patients were motivated for early ambulation and going for a walk around the hospital premises during the hospitalization period. After one week, the patients were re-assessed for the pain on VAS and the presence of any early complications was noted. The patients with VAS scores of 5 and more were sent on sick leave for convalescence, and those patients with VAS scores less than 5 were returned to unit/work with few excuses from duty like prolonged standing and strenuous exercise. All the patients were reviewed at 1, 6 and 12 months and a venous doppler was repeated for a) assessment of the GSVtechnically, success was defined as the presence of a sclerosed GSV in group A and an absent GSV in group B, b) presence of residual or a recurrent varicose vein (PREVAIT). If any PREVAIT was noted during the followup, these were tackled with ultrasound-guided foam sclerotherapy (UGFS) as a daycare procedure, and the individuals were sent back to their respective workplaces.

5. Data Processing and Analysis:

Data were processed and analyzed using SPSS 24.0. Descriptive statistics were presented as frequencies with percentages (for categorical data), proportions, and graphs. Continuous variables were presented as the mean with standard deviations Association between categorical variables was tested using the Chi-Square test and univariate analysis; A minimum 95% confidence interval or p-value <0.05 was considered statistically significant.

6. Results & Observation

A total of 73 patients with varicose veins were assessed between January 2016 to March 2019; after meeting the selection criteria, 60 patients were randomized into two treatment groups. Group A (n=30) was treated with Radiofrequency ablation for the incompetent GSV and Ultrasound-guided Foam Sclerotherapy for the perforators and peripheral varicose veins (UGFS); Group B (n=30) was treated with flush ligation and stripping of GSV with micro phlebectomy for the peripheral varicosities;

Table 1: Distribution of pat	tients based on their clinico-social	characteristics (N=60)
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Parameters		Total, N=60	Group A: RFA (n=30)	Group B: Stripping (n=30)	P value	
		n (%)	n (%)	n (%)		
Age	Mean Age	38±12.88	41.57±12.92	34.63±12.83	0.04	
Gender	Male	54 (90.0)	26 (86.7)	28 (93.33)	0.03	
	Female	6 (10.0)	04 (12.33)	02 (6.7)		
Profession	Soldier	41 (68.3)	20 (66.7)	21 (70.0)		
	Homemaker	6 (10.0)	04 (13.3)	02 (6.7)		
	Student	3 (5.0)	01 (3.3)	02 (6.7)	0.0	
	Farmer (ex-ser)	5 (8.3)	02 (6.7)	03 (10.0)	0.9	
	Mechanic (ex-ser)	2 (3.3)	01 (3.3)	01 (3.3)		
	Security guard (ex-ser)	3 (3.3)	02 (6.7)	01 (3.3)		

The mean age of the patients in the study group was 38 ± 12.88 , it was comparatively lower in group B (34.63 ± 12.83 years) than in group A (41.57 ± 12.92 years). Overall there were 41 (68.33%) serving personnel and 19 (31.66%) ex-servicemen and dependents. The male to female ratio was 9:1 in the entire study group. [Table 1]

Table 2: Distribution of patients ba	sed on their clinical profile (N=60)
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Parameters		Total N=60 n (%)	Group A: RFA (n=30) n (%)	Group B: Stripping (n=30) n (%)	P value
Side of the leg	Right	31 (51.7)	14 (46.7)	17 (56.7)	0.4
	Left	29 (48.3)	16 (53.3)	13 (43.3)	0.4
Color Doppler	SFJ Incompetence	50 (83.3)	24 (80.0)	26 (86.7)	
	SPJ Incompetence	10 (16.7)	06 (20.0)	04 (13.3)	
Operative time (in minutes)	30-45	3 (5.0)	3 (10.0)	0 (0.0)	
	46-60	21 (35.0)	11 (36.7)	10 (33.3)	
	61-75	21 (35.0)	7 (23.3)	14 (46.7)	0.078
	76-90	8 (13.3)	5 (16.7)	3 (10.0)	0.078
	91-105	3 (5.0)	3 (10.0)	0 (0.0)	
	106-120	4 (6.7)	1 (3.3)	3 (10.0)	
VAS score (72 hrs)	4.0	5 (8.3)	5 (16.7)	0 (0.0)	
	5.0	7 (11.7)	7 (23.3)	0 (0.0)	< 0.0001
	6.0	6 (10.0)	6 (20.0)	0 (0.0)]

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	7.0	15 (25.0)	6 (20.0)	9 (30.0)	7
	8.0	17 (28.3)	5 (16.7)	12 (20.0)	
	9.0	9 (15.0)	1 (3.3)	8 (13.3)	
	10.0	1 (1.7)	0 (0.0)	1 (3.3)	
Complications	DVT	1 (1.7)	1 (3.3)	0 (0.0)	
	Thrombophlebitis	2 (3.3)	2 (6.7)	0 (0.0)	
	SSI	2 (3.3)	0 (0.0)	2 (6.7)	0.008
	Hematoma/ ecchymosis	3 (5.0)	0 (0.0)	3 (10.0)	0.008
	Sensory loss/ Parasthesia	6 (10.0)	0 (0.0)	6 (20.0)	
	None	46 (76.7)	27 (90.0)	19 (63.3)	

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Right leg: Left leg involvement of varicose veins in group B (57:43) was higher than in group A (47:53). The colour doppler of the venous system of the lower limb revealed that in group A, 24 (80%) patients had SF junction incompetence and whereas in group B,26 (86.7%) individuals had SF junction incompetence which was comparable in either of the groups.

The operative time ranged between 30 minutes to 120 minutes for the study group. Although statistically there was no difference (p value= 0.078) in the operating time in either of the groups, however, it was observed that in 3 (10%) patients the operative time was between 106—120 minutes in group B compared to group A, where only in 1 (3.3%) patient the operative time was 106-120 minutes.

Postoperative pain was considerably less in the group A (RFA) patients compared to the Stripping group and hence the analgesics requirement. The mean Visual Analogue Scores at 72 hours (P Value :< 0.0001) and at 7 days were significantly lower in the RFA group.

A significantly higher number (36.7%) of minor post complications were seen in the Stripping group, with 6 patients (20%) developing cutaneous sensory loss and tingling, 3 patients (10%) had hematoma or deep ecchymosis and two patients had SSI at the inguinal incision. In The RFA group, there were not many complications, 2 patients (6.7%) developed thrombophlebitis of GSV post-operatively however one patient developed a major complication in the form of DVT in the Posterior Tibial vein, six days following the foam sclerotherapy.

 Table 3: Presence of Varicose veins After Interventional Treatment (PREVAIT).

Follow up		Group A RFA	Group B Stripping	p-	
		(n=30)	(n=30)	value	
At Month 1	No Varicose	26 (86.7)	29 (96.7)		
	PREVAIT	3 (10.0)	1 (3.3)	0.07	
	Missing	1 (3.3)	0 (0.0)		
At Month 12	No Varicose	25 (83.3)	27 (90.0)		
	PREVAIT	3 (10.0)	1 (3.3)	0.2	
	Missing	2 (6.7)	2 (6.7)		

In this randomized study, the number of patients with PREVAIT (Presence of varicose vein after interventional treatment) was found to be higher in the RFA with foam sclerotherapy group at 1 month (3patients, 10%). Colour doppler did not show any re-canalized or presence of GSV, however on an average 2-3 peripheral varicose veins with reflux were seen in them, which were managed with USG guided foam (UGFS) as a daycare procedure. At 1 year, 2 patients in either group did not report for the follow-up.

Three patients (10%) in the RFA group had the presence of 1-2 peripheral varicosities as compared to the Stripping group (1 patient, 3.3%). In spite of these peripheral varicosities, none of them was symptomatic with any pain or swelling of the limbs. These individuals were again managed with UGFS on a daycare basis and sent back to the place of duty. The average venous clinical severity score in either of the group improved when compared to pre-treatment with 1 and 12 months follow up and there was no significant difference in either group.

7. Discussion

The goal of treatment when dealing with the varicose veins is to get rid of the dilated tortuous veins. Endovenous ablation provides a comfortable and durable alternative to occlude the affected vein hence preventing the reflux. [8] The potential short term benefits of radiofrequency ablation over conventional flush ligation and stripping were confirmed in this single-centre based randomized comparative study. The study revealed that RFA can be completed under regional blocks (femoral combined with tumescent anaesthesia) whereas it is difficult to perform the surgery in the conventional group. [9]

n this study, the average time taken to perform the RFA and Foam Sclerotherapy was more as compared to the stripping and microphlebectomy group. Similar findings were observed by Subramonia S et al, [10] where the time taken to perform RFA was longer (84 minutes) than that of conventional surgery (56 minutes). Elian WA et al. [11] and Mohamed MI et al. [12] also revealed a longer operative time to perform RFA compared to conventional surgery. However, Latchu et al. [13] in their study, reported shorter time duration to perform RFA (1.93 hours) compared to conventional surgery (2.71 hours). Mohamed et al. [14] reported comparatively shorter time duration to perform RFA (35-50 minutes) compared to conventional surgery (40-70 minutes). The longer time duration to perform RFA, as well as sclerotherapy, may be attributed to the fact that it is performed under USG guidance which requires identification and localization of the probe in the vein, also the instillation of tumescence anaesthesia which also requires precision under USG guidance and is timeconsuming.

The pain experienced by the patient in the post-op period was remarkably less in the RFA group compared to the conventional open surgery, and so was the analgesics requirement by the 3 and 7 days post-surgery. Patients were managed with injection Heparin and subsequently with oral Acitrom. At 1 year follow up, patients had mildly increased girth at the calf level (approx 1 cm as compared to the counterpart leg) with few secondary varicose veins and the colour doppler revealed partial recanalized vein. Four patients in the RFA group had clotted blood in the ablated vein which clinically gave a cord-like appearance to the vein. These clots were evacuated by giving a small venotomy incision on the affected vein segment. Besides this patient, no complications in either of the groups were noted at the 1, 6 and 12 months follow up period. The studies by Subramonia S et al., [10] Elian WA et al., [11] and Latchu et al. [12] also revealed that the pain was significantly less in the RFA group compared to conventional surgery.

Similarly, the return to normal activities recorded in the wards at 72 hours and at the end of one week was significantly better in the RFA group. Nearly all the patients who underwent RFA surgery could easily walk a 1.2kilometre circle by the end of 7 days whereas only 20% of patients could do so in the conventional surgery group. Similar findings were observed by Latchu et al. [12] wherein the RFA group patients returned to their normal activities in 4.73 days compared to conventional surgery (6.96 days). Subramonia S et al., [10] Elian WA et al., [11] Mohamed et al. [13] and Naithani V et al. [16] also reported a significantly quicker return to the normal activities in the patients who underwent RFA compared to conventional surgery. This is definitely attributable to the extensive dissection done for both the stripping and phlebectomy causing more tissue trauma.

Helmy EK et al. [15] observed a comparatively higher complication rate in the conventional surgery group. However, in this study, the increased incidence of postoperative complications like hematoma, cutaneous nerve injuries and surgical site infection was more frequently observed in the RFA group compared to the conventional surgery. Similar to the present study, Elian WA et al. [11] and Naithani V et al. [16] reported significantly fewer postoperative complications (paresthesia and ecchymosis) after RFA. Various studies revealed that conventional surgery, even in the absence of complications, may cause comparatively early morbidity and prolong recovery. For this study, the presence of complications cancelled out the perceived benefit of improved satisfaction, confidence and cosmesis hence, the QoL index in the early days after surgery gradually became the same for both the groups after a month and subsequently during the follow up for the next one year.

In this study, the incidence of PREVAIT score for recurrence was significantly higher in the RFA with foam sclerotherapy group when compared to the stripping and microphlebectomy group both at 1 month and 1 year. Similar findings were observed in various studies where recurrence rates of varicose veins were higher among the patients who underwent RFA treatment compared to the conventional surgery [12], [17], [18] The reason could be neo-vascularisation or early recanalization after foam sclerotherapy. However, Elian WA et al. [11] did not report recanalization while comparing conventional surgery and RFA in the treatment of varicose veins.

8. Conclusion

Both Conventional open surgery with micro phlebectomy and RFA with foam sclerotherapy are effective methods of tackling the varicose veins. The immediate post-operative results and acceptance of the procedure are more encouraging with the minimally invasive endovenous RFA. In this study, the PREVAIT was comparable in both the groups, but keeping in view the limitation of the short follow up period of year duration, the actual incidence of recurrence is difficult to comment upon.

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