Comparative Study between Conventional Surgery and Radiofrequency Ablation in Treatment of Varicose Vein

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Background: Varicose veins are a very common problem all over the world. Surgery has been the gold standard treatment for many years, however now other less invasive options are available and sometimes more efficient.

Aim of the Work: To evaluate the RFA technique in treatment of GSV varicosities and to compare the results, clinical outcome, complications and recurrence rate after RFA and CS of GSV.

Patients and methods: This observational retrospective study included 41 patients with varicose veins recruited from general surgery department and vascular surgery unit at Ain Shams Hospitals and in Nasser Institute for Research and Treatment.

Results: Operative time was significantly less in CS compared to RFA. One , six and twelve months post intervention follow up using clinical examination and duplex imaging were used to asses outcome and detect complications and recurrence rate. No major complications were detected after both techniques; however minor post operative complications like paresthesia and ecchymosis were significantly less after RFA. Post operative pain, duration of analgesia use and time needed to return to normal activity were also significantly less in RFA group than CS group. Recanalization of GSV was not detected after radiofrequency maneuver nor CS. This study proved that radiofrequency ablation technique is safe and efficient in treating varicose veins however long-term results and cost effectiveness need further evaluation.

Conclusion: Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications. Duplex guided radiofrequency ablation is an efficient and a safe modality in the treatment of great saphenous vein varicosities. Of most importance is an adequate Duplex scan to identify accessory channels and double superficial systems.

Keywords: Radiofrequency ablation, varicose vein.

Introduction

Varicose veins, a common problem with effects on quality of life, account for a significant cost burden on the health care system. They are enlarged, tortuous, subcutaneous veins that commonly occur in the legs. Varicose veins are caused by faulty valves and decreased elasticity in the vein walls, which allow blood to backflow and pool. This is known as venous reflux. The affected veins enlarge and appear as green, dark blue or purple protrusions just below the skin's surface. The severity of symptoms associated with varicose veins varies and may include pain, heaviness, pruritis, ulceration, skin discoloration and edema. Severe symptoms include thrombophlebitis, bleeding and venous dermatitis, which often require intervention.[1]

A variety of therapies are available for treating varicose veins, including conservative therapies, surgical interventions and nonsurgical intervention. Conservative therapies are commonly recommended in asymptomatic patients or those with mild to moderate symptoms. Surgical interventions generally become necessary when symptoms of varicose veins significantly impinge on the patient's quality of life.[2]

Junction ligation with or without vein stripping is generally appropriate when the GSV and SSV have reflux or incompetence is demonstrated on duplex scanning. This intervention is generally performed as an inpatient procedure under general anesthetic. Junction ligation involves tying off the vessel at the SFJ or SPJ. Ligation alone usually leads to high rates of varicose vein recurrence; therefore, patients often require after-care treatment, such as sclerotherapy. In most cases, ligation is accompanied by GSV stripping and is generally regarded as the treatment of choice for varicose veins.[3]

Two endovenous modalities include radiofrequency ablation (RFA) and endovenous laser therapy (ELT). Both treatments involve inserting a heat-generating laser fiber or catheter into the incompetent

saphenous vein, positioned just below the SFJ or SPJ. Heat is generated through laser (ELT) or radiofrequency (RFA) energy, and as the fiber or catheter is slowly removed down the length of the vein, endothelial and venous wall damage occurs, causing contraction of the vein wall and ultimately destruction of the vessel.[4]

Aim of the Work

The aim of this work is to analyze the benefits and complications of radiofrequency ablation versus surgical stripping of great saphenous vein.

Patients and methods

This is an observational retrospective study that was carried out in the general surgery department and vascular surgery unit at Ain Shams Hospitals and in Nasser Institute for Research and Treatment. Sample size was calculated using PASS® version 11 program, setting the type-1 error (oe) at 0.05 with a width 0.1, and power at 80%. Result from previous studies showed that the average success rate for RFA 96.2% compared to 78% among surgical patients. Based on this the needed sample is 41 cases per each group (82 total).

Inclusion Criteria

1. Male and female patients.
2. Patients age (20-50) and fit for anesthesia.
3. Varicose veins affecting the GSV system.
4. Varicose veins confirmed on duplex ultrasound imaging.
5. Patients suitable for any of the treatment options.
6. Patients presenting with pigmentation, eczema, ulceration, varicosities, heaviness and pain.

Exclusion Criteria:

Patients with secondary varicose veins due to

1. Deep vein thrombosis.
2. Abdominal mass.
3. Pregnancy.

Preoperative assessment:

After informed written consent, patients were subjected to the following:

a. Clinical evaluation.
b. Duplex assessment.

Clinical evaluation was carried out for all patients according to the following scheme:

- Detailed history (disfigurement, pain, bleeding, deep venous thrombosis, anticoagulant therapy).
- Detailed general examinations.
- Lower limb examination to detect:
  1. Distribution of veins affected.
  2. Incompetent perforators.
  3. Shape (spider, serpentine or saccular)

Duplex was done as a routine to all patients to detect:

- Patency of the deep system.
- Sapheno-femoral or sapheno-popliteal reflux.
- Presence and number of perforators,
- Diameter of GSV.
- Exclusion of deep venous incompetence.

Operative procedures

Conventional surgery group

Under spinal or general anesthesia the patient's leg and groin were prepared with aqueous povidone iodine and draped with the entire leg exposed from above the groin to just above the ankle. Palpation of the femoral pulse and a transverse incision at the groin crease just medial to the femoral pulsations were done. After groin dissection, division of tributaries and flush ligation of the saphenofemoral junction (SFJ) then standard stripping of the GSV using a flexible intraluminal stripper fitted with an olive to strip the vein from groin to below the knee (down to just above the medial malleolus) by another incision were done. Associated varicosities if present were removed by multiple phlebectomies through small incisions. All legs were dressed postoperatively with cotton padding applied externally over the length of the GSV track which was secured using an elastic bandage.

Radiofrequency ablation group

Done mainly under local anesthesia (tumescent), only four patient required sedation (Deprivan) with the tumescent anesthesia.

Before skin preparation, the duplex scan was used to map the course of the GSV in the thigh and mark the vein access site at knee level. The leg was prepared and draped, and a superficial local anesthetic agent was used to anesthetize the site of cannulation. Needle puncture of the vessel was guided by duplex ultrasonography. The Seldinger technique was used to place a guide wire, which was removed.

The closure fast catheter (CLF) was introduced through the sheath and positioned in the GSV with its tip (1-2 cm) just below the saphenofemoral junction guided by duplex ultrasound.

Once the catheter has been positioned safely below the SFJ, tumescent anesthesia was introduced. Tumescent anesthesia, using generous volumes of buffered lidocaine 1% with sodium bicarbonate and epinephrine 1:100,000 diluted to 0.1% placed properly, resulted in pain free status. Care was taken to avoid lidocaine toxicity – dosage guideline was 7 mg/kg body weight, and no more than 500 mg was used at one setting.[5]

Then the catheter was connected to the EVRF

(endovenous radiofrequency) thermo coagulation. Then the EVRF was set to achieve an exact amount of joules, needed to coagulate any saphenous vein between 5 – 15mm.

The CLF catheter had a 7 cm–long coil (heating element) instead of previous bipolar electrodes and employed a segmental ablation technique. During energy delivery, the catheter remained stationary. The generator heated the catheter to 120uC for a period of 20 seconds. By conductive heat transfer, the vein wall segment in contact with the 7 cm catheter heating element reached a temperature of 100 to 110uC. The catheter was then moved distally in 6.5 cm increments, thus achieving a 0.5 cm treatment overlap zone at each treated segment. This segmental technique significantly increased the procedure speed.

Duplex ultrasound confirmed the occlusion of the GSV while retracting the RF catheter and also applied compression on ablated segments.

After complete ablation and removal of the catheter 2 compression bandage were applied over the whole limb.

Postoperative and follow up

Patients underwent radiofrequency ablation were discharged on the same day, while patients after surgery were discharged 24-48 hours after surgery. Both groups were followed up for period of 2 weeks to assess the early postoperative outcome.

All patients were prescribed 50 mg diclofenac twice daily as post-operative analgesia and were asked to record the consumption of this and other analgesia used post-operatively.

All patients were assessed on the 14-day post-operatively for thigh bruising, and asked about date of return to work and normal activity.

Patients in the radiofrequency group underwent duplex scan immediately post-operatively to assess the closure of GSV.

Patients were assessed for pain using 0-10 numeric pain intensity scale.

Follow up was done 1, 6, 12 months post operatively through examining the patients for recurrence of symptoms, neovascularization, recanalization of GSV, duplex study and patients were asked about their satisfaction from the maneuver and if they recommend it to other patients or not.

Statistical analysis

Data were analyzed using SPSS (Statistical Package for social sciences) version 15. Qualitative data was presented as number and percent. Comparison between groups was done by chi-square test. Quantitative data was presented as mean ±SD. Student t-test was used to compare between two groups. $P < 0.05$ was considered to be statistically significant.

Results

Table 1: Distribution of patients by gender

Sex	Conventional group (n=41)		Radiofrequency group (n=41)		P value
	No	%	No	%	
Male	18	43.9%	13	33.3	0.069
Female	23	56.1%	28	68.3%	

This table shows the sex distribution between the two groups.

Table 2: Distribution of patients by age

	Conventional group (n=41)	Radiofrequency group (n=41)	P value
Age (mean ± SD) range	33.17±10.58 20-50 y	33.23±9.22 20-50 y	0.979

This table shows the sex distribution between the two groups. There was no major difference between both groups, the mean age was 33.17 years in CS group and 33.23 years in RFA group.

Table 3: Classification of patients according to CEAP classification

CEAP	Conventional group (n=41)		Radiofrequency group (n=41)		P value
	No	%	No	%	
C2	31	75.6%	34	82.9%	0.785
C3	8	19.5%	5	12.2%	
C4-5	2	4.9%	2	4.9%	

This table show the distribution of both groups according to CEAP classification.

Table 4: Classification according to Venous Disability Score (VDS)

VDS	Conventional group (n=41)		Radiofrequency group (n=41)		P value
	No	%	No	%	
0	4	9.8%	3	7.3%	0.403
1	30	73.2%	36	87.8%	
2	7	17.0%	2	4.9%	

In this table all patients were subjected to classification according to venous disability score. Most of patients had score 1, (73.2%) in CS group and (87.8%) in RFA group.

Table 5: Operative procedure

	Conventional group (n=41)	Frequency group (n=41)	P value
Anesthesia General Regional	 4 (9.8%) Spinal 37 (90.2%)	 (Sedation) 5 (12.2%) Tumescent 36 (87.8%)	 0.688
Theatre time (min)	45.03 ± 5.05	61.47 ± 8.48	<0.001
Procedure time (min)	34.67 ± 4.66	49.43 ± 8.5	<0.001

General anesthesia were used for only 4 patients in CS group and in 5 patients in RFA group. While 37 patients underwent surgery under spinal anesthesia compared to 36 patients in RFA group done with local (tumescent) anesthesia.

Table 6: Adjunctive procedure

Adjunctive Procedures	Conventional group (n=41)	Radiofrequency group (n=41)	P value
None	5 (12.2%)	27 (65.9%)	< 0.001
Perforator interruption	7 (17.1%)	1 (2.4%)	0.023
Foam sclerotherapy	3 (7.3%)	11 (26.8%)	0.095
Phlebectomy	26 (63.4%)	2 (4.9%)	< 0.001

5 patients needed no adjunctive procedures in CS group compared to 27 patients in RFA group.

Table 7: Postoperative out come

Adjunctive Procedures	Conventional group (n=41)	Radiofrequency group (n=41)	P value
Pain score (VAS)	4.50 ± 0.94	2.06 ± 1.0	<0.001
Duration of analgesic (day)	7.33 ± 3.09	1.97 ± 1.47	<0.001
Hospital stay (hour)	31.20 ± 10.26	14.00 ± 10.05	<0.001
Return normal activity (day)	8.73 ± 2.68	4.27 ± 1.31	<0.001
Return to work (day)	14.10 ± 1.75	7.10 ± 1.83	<0.001

This table show the post-operative outcome, the table showed that outcome after RFA was better than CS regarding, pain, analgesia duration post operatively, duration of hospital stay, return to work, and normal activity after surgery.

Table 8: Postoperative complications

	Conventional group (n=41)		Radiofrequency group (n=41)		P value
	No	%	No	%	
Paresthesia	10	24.4	3	7.3	0.071
Ecchymosis	15	36.6	4	9.8	0.015
Thrombophlebitis	3	7.3	1	2.4	0.554
Hematoma	1	2.4	0	0	0.313
Wound infection	1	2.4	0	0	0.313
Thermal injury	0	0	0	0	-
DVT	0	0	0	0	-

The above table shows post-operative complication after the 2 procedures, there was no major difference between patients of both groups except for ecchymosis which complicate 15 (36.6%) patients in CS group and only 4(9.8%) patients in RFA group, and post-operative paresthesia which complicate 10 (24.4%) patients in CS group and only 3(7.3%) patients in RFA group.

Table 9: Ultrasonographic outcome

Adjunctive Procedures	Conventional group (n=41)	Radiofrequency group (n=41)	P value
1 month			
Recanalization	0 (0%)	0 (0%)	0.20
Neovascularization	0 (0%)	0 (0%)	
	No=28	No=29	
6 months	28	29	
Recanalization	0 (0%)	0 (0%)	0.20
Neovascularization	3 (10.3%)	1 (3.44%)	0.283
	No=24	No=25	
12 month			
Recanalization	0 (0%)	0 (0%)	0.20
Neovascularization	5 (20.8%)	2 (8.0%)	0.127

This table shows follow up by ultrasound examination (duplex). No new recanalised veins were detected among RFA nor CS group within first month. At 6 months follow up with 13 patients lost from CS group and 12 patients lost from RFA group, no new recanalised veins were detected in both groups, with 3 (10.7%) patients of CS group and 1 (3.44%) patient had developed neovascularization. At 12 months with added 4 patients lost from each group no new recanalised veins were detected in both groups while neovascularization complicated 5 (20.8%) patients of CS group compared to only 2 (8.0%) patients of RFA group.

Discussion

The ideal treatment for lower extremities primary varicose veins should be relatively noninvasive, repeatable if necessary, relatively safe and free from significant complications, effective in eliminating points of leakage, cost effective, cosmetically acceptable and obviate the necessity for extended periods of unemployment or absence from usual daily activities.[6]

Surgical treatment in the form of disconnection of the sapheno-femoral junction (SFJ) along with stripping of the great saphenous vein (GSV) and multiple phlebotomies is considered the standard treatment of varicose veins Excellent results are achieved as long as every source of reflux is eliminated. There are newer techniques available to destroy the GSV in the thigh, without physically removing the vein by stripping. The alternative techniques in common use are radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). There is now reasonable evidence that radiofrequency ablation is a slightly superior procedure especially for perioperative bruising and pain when compared with endovenous ablation.[7]

Eighty two patients were included in our study, 41 patients were randomized to conventional stripping, of which there were 18 male (46.3%) and 23 female (53.7%) and the other 41 were randomized to RFA, of which there were 13 male (31.7%) and 28 female (68.3%).

There was no difference between both groups of

patients considering age, mean age of patients in conventional group was (33.17±10.58 years) while in RFA group was (33.23±9.22 years).

All patients were symptomatic for their venous problems, with or without skin changes. The majority were in the C2 group of the CEAP classification (31 patients in conventional surgery group and 34 in RFA group, followed by C3 (8 patients in CS group and 5 patients in RFA group), and C4 (2 patients in CS group and 2 patients in RFA group).

In this study only 4 patients of CS group required general anesthesia (9.7%) compared to 5 patients in RFA group (12.2%), on their request, 37 patients in CS group (90.2%) were done under spinal anesthesia, compared to 36 patients in RFA group (87.8%) were done under local anesthesia (tumescent anesthesia).

Radiofrequency ablation took significantly longer time to perform compared to CS. This was due to tumescent infiltration and detailed duplex scanning before and after treatment. However, the procedure time was still considerably quicker than the duration of RFA from an earlier trial.[8]

In Subramonia and Lees,[9] the mean of total theatre time (between entry into and exit from the theatre suite) was 82 min for RFA and 60 min for CS. The total procedure time between marketing the course of the GSV under duplex guidance in RFA or antiseptic preparation of the operative field in CS to application of compression bandage in both instances was 76 min for RFA and 48 min for CS, indicating that the observed time difference was not due to extraneous factors.

In (2002) Rautio et al.[8] time operation was 75 min as a mean for RFA and 57 min for CS.

In our studies there was no major difference from other studies regarding operative time, RFA group took longer time during maneuver with mean (49.43 min±8.53) while CS group had mean (34.67 min ±4.66).

In a study from one center in Oulu, Finland Significant advantages of the RFA were shown regarding less pain, early return to activities, fewer sick leaves from work and better quality of life scores. When these findings included time lost from work, the authors found RFA to be cost effective despite initial high hospital cost.[8]

Post-operative pain and analgesic requirements were considerably less following RFA. Pain scores beyond the first week similarly favored RFA. 7 patients experienced no pain after ablation (recorded 0 on pain VAS) and ten did not require any analgesia. In contrast, all patients experienced pain after CS and all except one required post-operative analgesia. Patients returned to their full level of normal house hold activity, to driving and to work significantly more quickly following RFA than after CS.[9]

In our study 3 patients experienced no pain after RFA while all patients had pain with different degrees with the mean pain score for RFA group was (2.06±1.07), while all patients of CS group had more degrees of pain with a mean (4.50±0.94) by VAS scale ($p<0001$), also there were great difference in the analgesic requirement in favor to RFA ($p<0.001$).

Patients after radiofrequency ablation returned to their work much earlier (mean 7.10±1.83 days) than CS patients whom mean time was (14.10±1.75 days).

Nerve damage is one of the most common causes of litigation after varicose vein surgery.[10] Paresthesia or numbness may arise following RFA and Cs, but in most cases improves over the course of few weeks.[11]

Nerve injury associated with RFA is seen as areas of hypoesthesia noted on follow up examination in the first week post operatively. The majority of these occurred in the early cases before the routine instillation of tumescent anesthesia. To avoid injury following early clinical experience, the procedure was recommended to be limited to above knee GSV treatments.[12]

The saphenous nerve is actually adherent to the GSV in the distal leg and injury to this nerve is usually un avoidable when GSV is attempted much below the knee.[13]

Andrien O. Tonev et al.,[14] also recorded saphenous paraesthesia in (10%) of patients after conventional stripping and only (2%) after RFA in his study which included 50 patients in each group.

Ten (24.4%) in our study experienced saphenous paraesthesia after CS compared to only 3 patients (7.3%) patients after RFA. All patients had recovery and disappear of symptoms in a period between 3 to 6 weeks.

The drawbacks of stripping of the GSV in the thigh are blood loss, bruising, wound infection and post-operative pain,[15] and the occurrence of strip tract hematoma, which is considered as a major adverse side effect. This causes the patient post-operative pain and discomfort. It may also be responsible for recurrence when revascularization occurs in the hematoma.[16]

Phlebitis can occur with the RFA procedure as in

any treatment of varicose veins, and it is usually the result of residual blood trapped within vein segments. Some degree of phlebitis is inherent in the whole process since the obliteration occurs as a result of injury to the vein by heating process. It is occasionally seen as a tender, erythematous or ecchymotic band over the treated vein in distal thigh. It resolves over several weeks without any specific treatment other than foe symptomatic relief, the use of nonsteroidal anti-inflammatory drugs, heat, and compression hosiery.[17]

Skin burns, initially seen in a minority of early RFA ablation cases, essentially have vanished since the institution of tumescent anesthesia (merchant et al., 2002). Ablation in the thin or skinny leg should prompt careful attention to detail to minimize thermal injures to the overlying skin due to excessive external compression, which can arise from the duplex ultrasound probe during intraoperative monitoring.[18]

DVT can develop in the deep veins of the calf, or a thrombus can circulate from the treated superficial veins following RFA and stripping. DVT after endovenous ablation is extremely rare and most case series and trials show no evidence of it.[19]

There was no major differences in post-operative complications in this study except for ecchymosis which complicate 15 patients (36.6%) after CS and only a patients (9.8%) after RFA (p=0.015), all patients received antibiotics, advised to apply hot fomentations and apply continuous compression. All ecchymotic areas resolved within 2-3 weeks.

Other complications included thrombophlebitis which appeared in just one patient after RFA and 3 patients after CS, one patient only had had post-operative hematoma and also only one patient developed wound infection, both were after CS.

In our study there was no recorded thermal burn or post-operative DVT in both groups.

The pathophysiology of varicose vein recurrence has been considered in several studies based on investigations using ultrasonography, varicography, clinical and pathological evidence, leading to the proposal that a neovascularization mechanism is responsible. Nyameke described neovascularization as serpentine neovascular veins between a thigh varicosity and the common femoral vein resulting in a 68% recurrence at the previously ligated SFJs. However, several issues concerning the definition, incidence, pathophysiology, diagnostic evaluation and progression of this cause of recurrence remain controversial.[20]

Leopardi et al.,[3] showed a high early success rate with a very low subsequent recurrence rate up to 10 years after treatment. Early and mid-range results are comparable to those obtained with other endovenous ablation techniques. The overall experience has been a 90% success rate, with rare patients requiring a repeat procedure in 6-12 months. Overall efficacy and lower morbidity have resulted in endovenous ablations replacing surgical stripping.

Data on over 1000 limbs treated without high ligation have been collected in an ongoing Registry of the VNUS Closure® treatment Study Group comprising 35 centers in the US, Europe, and Australia. Early results from this registry at various follow up periods through January 2002, show successful ablation ranging from 93% at one week to 85% at two years, with absence of vein reflux (defined as absence of reversed flow at or near the SFJ or in any segment of the treated vein) of 90% at two years, and patient satisfaction of 95% at two years follow up. In addition, 111 of 142 limbs with 2 year DUS examination were also scanned at 1 year to DUS evidence of reflux at 2 years.[21]

Duplex examination after 1, 6, 12 months for patients in our study showed no new recanalization among patients after radiofrequency or surgery. After 6 months follow up with 12 patients lost from RFA group (no=29) and 13 patients from CS group (no=28) there was only 1 patient (3.44%) who exhibits superficial varicosities outside the course of the GSV (neovascularization) compared with 3 patients from the other group (10.7%).

After one year of treatment with another lost 4 patients from RFA group (no=25) and 4 patients from CS group (no=24) another 1 patient from RFA group (3.5%) had developed new superficial varicosities but with no symptoms, while 2 new patients (8.3%) in CS group had neovascularization.

Conclusion

Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications. Duplex guided radiofrequency ablation is an efficient and a safe modality in the treatment of great saphenous vein varicosities. Of most importance is an adequate Duplex scan to identify accessory channels and double superficial systems.

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