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# Radiofrequency Ablation of the Varicosed Long Saphenous Vein, Results After 6 Months Follow Up.

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## Abstract

***Background:*** **Since 1990s, the techniques of endovenous ablation, as a treatment for varicose veins, have emerged such as radiofrequency ablation (RFA) and laser treatment. RFA was superior to Laser ablation as measured by a comprehensive array of post-procedural recovery and quality of life parameters.** ***Aim:*** **This study aimed to assess the efficacy of RFA in the treatment of varicose veins and the postoperative outcomes for improving the quality of life of patients.** ***Materials and Methods:*** **This is a prospective, interventional, quasi-experimental study that includes 20 participants presenting with lower limb varicose veins in the outpatient clinic of the Suez Canal University Hospital.** ***Results:*** **Twenty patients were eligible for RFA of varicosed great saphenous vein (GSV) in our study. The overall pre-operative venous clinical severity score (VCSS) mean was 4.4 ± 0.68. On 6 months follow up, patency of the ablated vein was assessed by using duplex ultrasound, 16 patients (80%) had completely occluded GSV, only 4 patients (20%) had intermittent patent segments with average length of <5 cm showing no residual refluxing. No patients had patent segments of >5 cm in length. The overall post-operative VCSS mean was 2.1 ± 0.3. There were 4 participants (20%) having post-operative ecchymosis, one patient (5%) had skin burn, 4 patients (20%) had induration. Only 2 patients (10%) experienced post-ablation hyperpigmentation.** ***Conclusion:*** **RFA is an effective feasible modality in the management of GSV incompetence and reflux. The clinical parameters showed significant improvement after RFA including VCSS. Post-operative complications after RFA are mild and self-limiting.**

**Keywords:** Varicose veins, Thermal ablation

## Introduction:

Varicose veins, a sign of chronic venous disease, affects around 25-40 % of the adult population worldwide. [1] People are more susceptible to develop varicose veins as they age, because wear and tear on their veins allow their walls to weaken, leading to enlargement of the veins. [2] The sheer prevalence of varicose veins and the substantial cost of managing late complications such as chronic venous ulcers contribute to an increased burden on health care resources. [3] Since the 1990s, the techniques of endovenous thermal ablation have emerged, as radiofrequency ablation and laser treatment. In comparison between these two endovenous ablation techniques for closure of GSV, RFA was significantly superior to endovenous laser ablation as measured by a comprehensive array of

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post-procedural recovery and quality of life (QOL) parameters [4] with alleged immediate occlusion rate reaching 100 percent either with or without tumescent anaesthesia and primary closure rate ranges between 90-100 percent at 6 months. All patients could return to normal activity within 2 days. [5] In comparison with conventional open surgery,

RFA can be done in the outpatient setting without the need for hospital admission or general anaesthesia. On the other hand, the procedure is not feasible in tortuous or very small or huge veins, and it might be less cost-effective than conventional open surgery due to the catheter cost.[6]

## Materials and methods

This study is a prospective interventional quasi-experimental study, started on 1st July 2020, took place in the vascular surgery unit, surgery department, Suez Canal University Hospital in Ismailia, Egypt, targeting patients presenting with symptoms suggesting lower limb varicose veins to the outpatient clinic. The study population was the patients proved to have varicose veins with the following inclusion criteria: patients over 18 years old, of any gender, with SFJ diameter >7 mm or GSV diameter > 5 mm by duplex scanning on standing, or with SFJ incompetence on duplex scanning with a reflux > 1 second. The exclusion criteria were patients who refused to be included in the study, patients with elevated bleeding profile, secondary varicose veins, previous venous surgery, pregnant women, thrombosed varicose veins, varicosed short saphenous vein, bilateral varicose veins and patients with anterior accessory saphenous vein reflux. This study aimed to assess the clinical outcomes of RFA of varicosed GSV without doing high ligation of the SFJ over 6 months follow up duration. The main outcome measures were status of occlusion of the treated vein segments, the presence of varicose veins and reflux in the treated veins, clinical symptoms scores and post-operative adverse events.

**Sample size**

The sample size was calculated using the following formula [7]:

$$n = [(Z_{/2} + Z_{} )/(P_1 - P_2 )]^2 (p_1 q_1 + p_2 q_2)$$

Where:

n = sample size

$Z_{/2}$ = 2.576 (The critical value that divides the central 99% of the Z distribution from the 1% in the tail)

$Z_{}$ = 1.24 (The critical value that separates the lower 10% of the Z distribution from the upper 90%)

$P_1$ = Prevalence/proportion of treatment failure = 22.2% [8]

$P_2$ = Prevalence/proportion of treatment success = 77.8% [8]

So, by calculation, the sample size is equal to 20 subjects, after the addition of a drop-out proportion of 10%.

**Pre-operative assessment**

All patients were assessed clinically by a questionnaire including personal data, clinical presentation and medical history. Full clinical examination, laboratory investigations and duplex ultrasound assessment were done. Patients were classified by CEAP Classification and VCSS according to the clinical and radiological data. The VCSS is calculated according to 10 parameters [9] which are: pain, varicose veins, venous oedema, skin pigmentations, inflammation, induration, use of compression therapy, active ulcers number, duration and size. Each

parameter should be classified either none, mild, moderate or severe. It is considered a tool of follow up and monitoring of treatment outcomes.

**Technique of Radiofrequency Ablation**

The catheter used in this study was ClosureFast™ Endovenous Radiofrequency Ablation Catheter that heats a 7 cm segment of the vein in one 20-seconds interval. The heat provided by the catheter shrinks and collapses the treated vein, creating a fibrotic seal and closing the vessel. The generator used was the ClosureRFG generator that delivers radiofrequency energy to the ClosureFast™ catheter. The feedback mechanism controls intravascular heat parameters in real time to automatically regulate therapeutic power.

**Anaesthesia**

Tumescent anaesthesia was administered along the target vein guided by ultrasound. The anaesthetic solution for tumescent anaesthesia includes 500 ml normal saline, 50 ml 2% lidocaine, 10 ml 8.4% sodium bicarbonate and 1/100,000 ml adrenaline. [10]

**Procedure**

The patient was positioned in the recumbent reverse Trendelenburg position. The limb was optimally placed (hip was abducted to approximately 30° and knee is gently flexed). Access to the target vein was done by the vascular surgeon at the knee level, by Seldinger cannulation using ultrasound guidance, then the introduction of a 7F endoluminal introducer sheath was done. The ablation catheter was introduced and advanced, guided by ultrasound, to the target SFJ, placement of the tip of the catheter 2 cm below the SFJ was adopted, to decrease the risk of endovenous heat-induced thrombosis (EHIT). Then the tumescent anesthetic solution is delivered effectively around the catheter inside the saphenous fascia. 10 ml volume per 1 cm of vein was the minimal volume advised for good effect. RFA proceeded near the target SFJ in a caudal direction downwards towards the site of venous access. External pressure was applied using the ultrasound probe held in longitudinal axis with the catheter electrode. After treatment completion, an occlusive dressing or pad was applied over the puncture site with application of compression bandaging to the treated limb. Compression was recommended for at least 2 weeks following the procedure. Participants were instructed to ambulate immediately and frequently after the procedure. [11]

**Postoperative Care and Follow-Up**

The patients were discharged on the next day with instructions to apply the elastic stocking for 2 weeks. Post-operative pain was assessed according to Numeric Rating Scale (NRS-11) for pain assessment. Clinically, evaluation was done on the 1st, 3rd and 6th postoperative months and consist of a questionnaire, physical examination and duplex ultrasound. The questionnaire included the presence or absence of varicose veins symptoms as pain & limb oedema. The physical examination was done to assess the presence of apparent varicosities and post-operative adverse effects as ecchymosis, hematoma, oedema or thrombophlebitis. Duplex ultrasound was used to assess the patency of the ablated vein, the presence of non-occluded segments, the length and diameter of those segments if present and the presence of reflux in the vein. The patients were categorized into three groups according to Merchant et al.

closure pattern: complete occlusion group (CO), near-complete occlusion group (NCO) and failure group. [12] Failure of vein obliteration was considered when there was a patent segment in the ablated vein > 5 cm in length and shows reflux with duplex ultrasound examination or with symptoms of varicose veins persist. Recurrence was considered when primary closure occurred followed by recanalization of a segment of the ablated vein > 5 cm in length during the follow up period.

## Results

The study included 20 participants of mean age 33.1 ± 2.61 years old, the minimum age was 30 years old, and the maximum age was 38 years old, none of them had previous surgical or endovenous interventions. The ratio between males and females was 1:1.

**Pre-operative clinical characteristics**

Regarding the clinical presentation of the participants, 12 patients (60%) presented with right-sided affected lower limb and 8 patients (40%) presented with left-sided affected limbs. All participants reported symptoms described as achy or heavy feeling in the leg that starts soon after performing daily activities, worsening after standing for a period, associated with gradually increasing visible small veins along the leg where itching around them occurred in some times. While only 8 participants (40%) reported the presence of swelling in the distal leg and around the ankle after standing for long periods of time. No patients reported the presence of skin manifestations such as skin eczema or lipodermatosclerosis, also no patients had any healed or active ulcers along the course of the disease. According to CEAP classification at presentation, clinically 12 patients (60%) presented with only visible varicose veins, classified as (C2), while 8 patients (40%) presented with visible varicose veins associated with oedema, classified as (C3), all of them presented with primary varicosities because of refluxing superficial venous system classified as (Ep, As & Pr). On the other hand, according to the VCSS, all the participants reported daily pain with moderate score, only 2 participants (10%) had few varicose veins with mild score and 2 participants (10%) had extensive varicose veins with severe score, while most of the participants accordingly 16 of them (80%) had multiple varicose veins with moderate score. When we come to oedema of the limb, 8 participants (40%) reported oedema at the evening only with mild score, while the rest of the sample accordingly 12 patients (60%) had no oedema at all. All the participants had no evidence of more advanced symptoms according to VCSS, no pigmentations, no inflammation, no induration, no active or healed ulcers and no need for compression therapy along the course of the disease. The overall pre-operative VCSS mean of all participants was 4.4 ± 0.68 with minimum score of 4 and maximum score of 6.

**Pre-operative duplex ultrasound assessment**

All patients had patent competent deep venous system, with dilated incompetent SFJ and GSV, the sapheno-popliteal junction (SPJ) and short saphenous vein (SSV) of all participants were competent with a diameter within normal range. The SFJ mean diameter was 9.9 ± 2.97 mm with minimum diameter of 7 mm and maximum diameter of 16 mm, the mean

reflux time of the SFJ was 3 ± 1.13 seconds. While the GSV mean diameter was 8.8 ± 4.38 mm with minimum diameter of 5 mm and maximum diameter of 18 mm, the mean reflux time of the GSV was 3 ± 1.03 seconds.

**Operative details**

Puncture of the GSV was done at the lowest predefined incompetent point at knee level via ultrasound guidance in 19 patients (95%), while failure of cannulation at knee level occurred in one patient (5%) where cannulation at ankle level with venesection technique took place. Before ablation, the catheter was introduced to 2 cm away from the SFJ in all patients, the first 7 cm had 2 cycles of ablation each for 20 seconds in 18 patients (90%) and 3 cycles each for 20 seconds in only 2 patients (10%). Additional treatments performed at the time of the study procedure, adjuvant phlebectomy of superficial varicosities in the same session with RFA was done in 12 patients (60%), while 8 patients (40%) requested adjuvant sclerotherapy of the residual reticular and spider varicosities during follow up period for more satisfying results.

**Post-operative outcomes**

On 6 months follow up, patency of the ablated vein was assessed by using duplex ultrasound, 16 patients (80%) had completely occluded GSV with no patent intermittent segments (Complete occlusion - CO group), only 4 patients (20%) had intermittent patent segment with average length of <5 cm showing no residual refluxing (Near complete occlusion - NCO group). No patients had patent segments of >5 cm in length (Failure group) (Table 1). According to the VCSS after 6 months, all patients reported occasional mild pain not interfering with daily activities, 18 patients (90%) had few residual varicose veins with mild score while only 2 patients (10%) had multiple residual varicosities with moderate score. No patients experienced lower limb oedema and all the participants had no evidence of more advanced symptoms according to VCSS at 6 months follow up, no pigmentations, no inflammation, no induration, no active or healed ulcers and no need for compression therapy after 2 weeks post- operatively. The overall post-operative venous clinical severity score mean of all participants was 2.1 ± 0.3 with minimum score of 2 and maximum score of 3.

**Table 1. Closure rate and details of patent segments**

| | | Number of cases | Percentage | Average length of patent segment after ablation | Refluxing patent segment after ablation | |
|---|---|---|---|---|---|---|
| | | | | | No reflux | Reflux |
| Vein closure after ablation | CO group | 16 cases | 80% | ----- | ----- | ----- |
| | NCO group | 4 cases | 20% | ≤ 5 cm | 4 cases | 0 cases |
| | Failure group | 0 cases | 0 % | 5 cm > | 0 cases | 0 cases |

**Post-operative adverse effects**

Immediate post-operative adverse effects of RFA were assessed within the first week post-operative, according to the Numeric Rating Scale (NRS-11) for pain assessment, all patients faced mild pain interfering little with activities of daily living with average pain score 2.2 ± 0.89. There were 4 participants (20%) having post-operative ecchymosis at the anatomical distribution of the ablated vein disappeared gradually within few days, one patient (5%) had skin burn at the site of cannulation, 4 patients (20%) had areas of induration at the site of the ablated vein that were relieved soon after applying warm fomentations. No patients had post-operative thrombophlebitis of the ablated vein or any of its tributaries immediately after the operation. No reported cases of endovenous heat-induced thrombosis (EHIT) within the first week post-operative. When we come to late complications, only 2 patients (10%) experienced post-ablation hyperpigmentation of the distal part of great saphenous vein. No patients showed symptoms of nerve injury such as numbness or paraesthesia over 6 months.

**Relation between pre-operative GSV diameter and closure rate after ablation**

The pre-operative GSV diameter in the studied population ranged from 5 mm to 18 mm with mean of 8.8 ± 4.38 mm, complete closure (CO) occurred after ablation in 16 patients (80%) having veins with diameter less than 16 mm with average vein diameter 6.8 ± 1.37 mm, while there were intermittent patent segments (NCO) in 4 cases (20%) where GSV diameter is equal to or greater than 16 mm with average vein diameter 17 ± 1.15 mm. Therefore, the mean pre-operative GSV diameter has a statistically significant relation with the closure rate after RFA (P-value < 0.01).

**Relation between pre-operative GSV reflux time and closure rate after ablation**

According to the parameter of pre-operative GSV reflux time in the studied population its mean was 3 ± 1.03 seconds, in complete occlusion (CO) group which were 16 patients (80%) having veins with mean pre-operative GSV reflux time 2.9 ± 1.09 seconds, while in near complete occlusion group (NCO) which were 4 cases (20%) with mean pre-operative GSV reflux time 3.5 ± 0.5 seconds. However, the mean pre-operative GSV reflux time has no statistically significant relation with the closure rate after RFA (P-value = 0.023).

**Relation between pre-operative SFJ diameter and closure rate after ablation**

The pre-operative SFJ diameter in the studied population ranged from 7 mm to 16 mm with mean of 9.9 ± 2.97 mm, in complete occlusion (CO) group which were 16 patients (80%) having veins with SFJ diameter average 9.1 ± 2.83 mm, while in near complete occlusion group (NCO) which were 4 cases (20%) where SFJ diameter average 13 mm. Accordingly, the mean pre-operative SFJ diameter has a statistically significant relation with the closure rate after RFA (P-value < 0.01).

**Relation between pre-operative SFJ reflux time and closure rate after ablation**

The mean pre-operative SFJ reflux time in the studied population was 3.03 ± 1.13 seconds, in complete occlusion (CO) group which were 16 patients (80%) having veins with mean SFJ reflux time of 2.9 ± 1.21 seconds, while in near complete occlusion group (NCO) which were 4 cases (20%) with mean saphenofemoral junction reflux time 3.5 ± 0.57 seconds. But the mean pre-operative saphenofemoral junction reflux time has no statistically significant relation with the closure rate after RFA (P-value = 0.017).

**Relation between vein closure and symptoms of varicose veins assessed by VCSS**

In complete occlusion (CO) group which were 16 patients (80%), the mean pre-operative VCSS was 4.5 ± 0.7 while the mean post-operative VCSS was 2.1 ± 0.3 showing a significant decrease in the overall symptoms of varicose veins. In near complete occlusion group (NCO) which were 4 cases (20%), the mean pre-operative VCSS was 4 while the mean post-operative VCSS was 2 showing also a significant decrease in the overall symptoms of varicose veins. Accordingly, no statistically significant difference between the two groups in the pre-operative VCSS when compared with each other or the post-operative VCSS as well (P-value = 0.75 and 0.83 respectively). Therefore, our sample was homogenous with no bias. However, the difference between VCSS pre-operatively and post-operatively in complete occlusion (CO) group is seen statistically significant (P-value < 0.01). Also, the difference between VCSS pre-operatively and post-operatively in near complete occlusion (NCO) group is seen statistically significant as well (P-value < 0.01) (Table 2).

**Table 2. Relation between vein closure and VCSS**

| | | Near complete occlusion | Complete occlusion | P-value |
|---|---|---|---|---|
| Pre-op. VCSS | Mean | 4 | 4.5 | 0.75* |
| | St. deviation | 0 | 0.7 | |
| Post-op. VCSS | Mean | 2 | 2.1 | 0.83* |
| | St. deviation | 0 | 0.3 | |
| P-value | | < 0.01* | < 0.01* | |

*Statistically significant < 0.05*

## Discussion

### Occlusion rate

There are several reports assessing the closure rate of great saphenous vein after RFA. Merchant et al. classified the closure pattern into three types: veins with no evidence of flow were defined as Complete occlusion type (CO) veins. Near complete occlusion type (NCO) was defined as less than or equal to 5 cm segment of flow inside otherwise closed vein. On the other hand, greater than 5 cm of flow in any treated vein segment was defined as recanalization. In Merchant et al. report, at 6 months follow up 192 of 223 treated limbs (86.1%) with follow-up were CO, 17 of 223 (7.6%) were categorized as NCO, and 14 of 223

(6.3%) were recanalized. However, in this study the first generation of RFA catheters was used. Other authors reported higher rates of occlusion after different follow up periods. [12] Proebstle et al. in a study described as first clinical experience occlusion rates were 99.6% at 3 months and 6 months follow-up dates according to life-table analysis. [13] Proebstle et al. in another prospective multicentre trial showed the probability of occlusion was 92.6% at 36 months in a total of 256 of 295 treated GSVs. [14] Helmy et al. assessed the closure rate in a total of 90 patients up to 24 months after RFA. The primary closure rate was 94.5%. [15] In a study carried out by Jung Hyun Choi et al. in a total of 53 of 56 treated GSV, 94.6% were CO, 2.7% were NCO, and 2.7% were recanalized at a mean of 13.9 months follow up. [16] In our study, 16 of 20 patients showed complete truncal occlusion (CO) with an occlusion rate of 80% at 6 months follow up, 4 of 20 patients (20%) showed near complete occlusion (NCO) of the ablated GSV and none of the treated veins showed recanalization according to Merchant et al. classification of occlusion pattern.

**Post-operative adverse events**

According to Proebstle et al. in the first clinical experience, the rate of post-operative ecchymosis was 6.4% of the study population. [13] In the three-years follow up prospective multicentre trial, ecchymosis was reported in 5.8% of patients at 1 week duration. [14] In our study, 4 of 20 patients (20%) had post-operative ecchymosis mostly due to difficult canulation or tumescent infiltration.

Skin burn is a relatively rare adverse effect of thermal ablation, caused by exposure to high temperature. It may be related to the tumescent anaesthesia improperly administered. Wozˊniak et al. reported a single case (1.8%) of skin burn in the RFA group, it was third-degree burn needed surgical debridement with removal of necrotic tissue. [8] In our study, also skin burn was seen in a single case (5%), similarly it was third-degree burn but occupying a small area requiring no surgical debridement.

Skin hyperpigmentation is an unsatisfying cosmetic adverse event that was reported after endovenous thermal ablation. According to Wozˊniak et al., transient skin hyperpigmentation was reported in 2 patients (3.7%) having RFA along the GSV within the lower one-third of the thigh and/or the upper one-third of the leg resolved completely and spontaneously within 6 months of the procedure, while persistent skin hyperpigmentation was reported in 3 patients (5.6%) of the RFA group, 2 of them had local combined intense pulse light and radio frequency (IPL-RF) therapy, they had 6 sessions after which the hyperpigmented skin either completely resolved or significantly improved. The remaining case of persistent skin hyperpigmentation did not receive any treatment, and her skin hyperpigmentation did not resolve over the follow-up period. [8] In our study, persistent skin hyperpigmentation was reported in 2 of 20 patients (10%), it appeared along the GSV within the lower one-third of the thigh and did not resolve spontaneously or change within the 6 months follow up duration. Dysesthesia (impaired sensation) was reported in many studies of RFA follow up, Helmy et al. reported 9 of 90 patients (10%) of the RFA group having focal paraesthesia. [15]

Woz´niak et al. reported a total of 3.7% having post- operative saphenous nerve neuropathy either transient or permanent, all of which had access point at the level of the ankle. [8] In our study, no patients developed either transient or permanent paraesthesia along the course of follow up, even the case having access at the ankle level due to difficulty access near the knee.

Endovenous heat-induced thrombosis (EHIT) is a potential serious adverse effect that may accompany endovenous thermal ablation. According to a case reports study by Mozes et al., the cumulative incidence of deep vein thrombosis after the VNUS Closure procedure is 2.1%. [17] However, experts report lower incidences: in a cumulative series from Merchant et al. there were 5 attacks of DVT among 1150 cases (0.4%). [18] Many authors reported no DVT in their follow up studies of RFA treated patients, however, in many series of RFA, the post-operative duplex ultrasound follow-up scanning is incomplete; so, the exact incidence of asymptomatic deep vein thrombosis is not known. Shepherd et al. reported 1 patient with pulmonary embolism after intervention although no evidence of deep vein thrombosis or clot propagation in the leg veins was found on duplex scanning. [19] Fortunately, we did not report any cases with deep venous thrombosis among the study sample.

**Conclusion**

RFA is an effective feasible modality in the treatment of great saphenous vein incompetence and refluxing. The clinical parameters including CEAP classification and VCSS showed significant improvement after RFA. Post-operative adverse effects after RFA are mild and self-limiting.

**Data management**

Data was collected from the patients in the outpatient clinic, processed by SPSS v.23 computer package and presented in the form of tables and figures using Microsoft Office computer package

**Conflicts of interest**

There are no conflicts of interest.

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