Radiofrequency Ablation (RFA) for Patients with Great Saphenous Vein Incompetence

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Abstract

Introduction: **The broad spectrum of chronic venous disease encompasses varicose veins, edema, hyperpigmentation and venous ulcers. Radiofrequency thermal ablation is indicated for the treatment of superficial venous reflux of the lower limb. Our research aims to identify the efficacy and safety of Endo-Venous Radio-Frequency Thermal Ablation in Patients with Great Saphenous Vein Incompetence in managing chronic venous insufficiency of the lower limbs.**
Methods: **Patients admitted to vascular unit, general surgery department, Suez Canal University Hospitals' in Ismailia, Egypt, from March 2021 to March 2023 with the clinical diagnosis of varicose veins of the lower limbs, treated by thermal ablation with radiofrequency.**
Results: **The mean GSV diameter for RF ablation was 7.12 ± 1.271. By the 12th month of Follow-up visits, two patients experienced recanalization of short segment (below 5 cm) occlusion, two experienced recanalization of long-segment occlusion, and two experienced recurrent varicose veins. GSV diameter dropped dramatically after surgery, reaching a mean of 0.82 ± 0.252 after 6 months of follow-up. In terms of complications, paresthesia, transient ecchymosis and bruising, and permanent pigmentation noted. No patients developed deep vein thrombosis (DVT).**
Conclusions: **RF ablation demonstrated effectiveness in treating lower leg varicose veins. However, recanalization and recurrence were noticed among patients.**

Keywords: Laser, Radio Frequency, Thermal Ablation, Saphenous Vein Incompetence.

Introduction

The dorsal venous arch in the foot continues into the great saphenous vein (GSV). It ascends in the superficial fascia along the medial portion of the lower extremities, passes in front of the medial malleolus, and empties into the deep system at the saphenofemoral junction. [1]. Although these veins may fulfil the diagnostic criteria for venous incompetence, these perforators might restore their competence following the successful treatment of an incompetent GSV, suggesting that their dilatation is a consequence of reflux rather than the fundamental aetiology. Likewise, elevated deep venous pressure is conveyed to superficial veins via the perforating veins, resulting in superficial varicosities, stasis dermatitis, and venous ulcers [2].

Historically, refluxes have been addressed with surgical ligation and stripping under general anaesthesia; however, recent focus has shifted towards minimally invasive methods performed under local anaesthesia. Minimally invasive treatments such as ultrasound-guided foam sclerotherapy (USGFS) have transformed management [3].

Both endogenous laser ablation and ultrasound-guided sclerotherapy have proven to be successful treatments [4].

Various techniques for the treatment of saphenous reflux have been established over time, including high ligation of the

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saphenous vein, saphenous vein stripping, and ultrasound-guided sclerotherapy, along with different combinations of these methods. Endogenous thermal ablation has recently been recognized as a viable treatment option for patients experiencing saphenous reflux [5].
Radiofrequency ablation (RFA) is a minimally invasive technique that effectively treats venous reflux with minimum discomfort and reduced recovery time for patients. A principal advantage of RFA is that the operation can be conducted in an outpatient office environment utilizing local tumescent anaesthesia [6]. This study aimed to evaluate the impact of targeted endogenous radiofrequency ablation on the therapy of Saphenous Vein Incompetence.

Material and Methods

This prospective study was conducted randomly on 19 patients of both sexes, aged 18 to 70, with incompetent SFJ and GSV at the vascular unit, general surgery department, Suez Canal University Hospitals in Ismailia, Egypt, from March 2021 to March 2023. The patients provided their signed, informed consent.
Exclusion criteria were patients with DVT, pregnancy, breastfeeding, severe illness, recurring cases, and those with secondary varicose veins were excluded.
All patients underwent comprehensive history taking, clinical examination, laboratory tests including CBC, FBS, glycated haemoglobin, HbA1c, prothrombin time, PTT, international normalized ratio, and serum creatinine, as well as radiological tests such as duplex ultrasound, ultrasound, color-flow Doppler, and gray-scale B-mode.

Operative technique
RFA was performed in the operating room following US protocols, utilizing spinal or tumescent anaesthesia. Tumescent anaesthesia consists of 20 ml of 2 percent lignocaine with 1:100,000 adrenaline, combined with 480 ml of normal saline, and includes the addition of 10 ml of sodium bicarbonate to mitigate irritation caused by the acidic lignocaine. The specified entry point is the knee joint or the area directly beneath it. Access was initiated with a micro-access set comprising a 20-gauge needle and a 7F sheath in the RFA group. The diameter of the long saphenous vein is assessed using ultrasound to ascertain the energy output of the laser generator. The generator is subsequently adjusted to target the necessary energy output.

Postoperative care and follow-up examination
The clinical evaluation was conducted based on specific criteria: one week post-surgery, the patient was assessed for pain, skin condition, and GSV diameter through duplex ultrasonography. One month after therapy, the patient was assessed in the outpatient clinic for paraesthesia, discomfort, ongoing symptoms, and ecchymosis. Three months post-surgery, participants underwent duplex ultrasonography screening to assess the degree of venous obstruction. Occlusions lasting less than the entire treatment duration were classified as partially occluded, according to the criteria of having a brief segment that was fully open and measuring less than 5 cm. A lengthy object has been extended to a total length of approximately 5 cm. No surgical procedures were performed, and the patients were discharged on the same day.

Statistical analysis

SPSS v26 was used for statistical analysis (IBM Inc., Chicago, IL, USA). The mean

and standard deviation (SD) of the quantitative variables were shown. Chi-square or Fisher's exact test was used to analyse the qualitative variables, which were shown as frequency and percentage (%). Statistical significance was defined as a two-tailed P value < 0.05.

Results

The average age was 36.4 ±6.17, 28 patients (100%) had a standing employment, 11 patients (57.89%) were married, and 10 cases (52.26%) were female. Eight patients (21.1%) had discomfort and leg heaviness, four patients (10.5%) experienced ulcers, and 2 patients (68.4%) experienced disfigurement. 19 (100%) had SPJ that was competent. Table 1

Table 1: Demographic data, complaint, SFJ and SPJ competence of the studied patients

		N=19
Age (years)		36.4±6.17
Sex	Male	9 (47.36%)
	Female	10(52.26%)
Marital status	Married	11 (57.89%)
	Single	8(42.1%)
Job		19(100%)
Complain Disfigurement Ulcer pin		12 (63.15%) 2(10.5%) 4(21.1%)
SFJ competence		0(0.0%)
SPJ competence		19(100%)

Data are presented as mean ± SD or frequency (%). SFJ: sapheno-femoral junction, SPJ: sapheno-popliteal junction.

The mean GSV diameter for RF ablation was 7.12 ± 1.271. By the 12th month of follow-up Visits, two patients experienced recanalization of short segment (below 5 cm) occlusion, two experienced recanalization of long-segment occlusion, and two experienced recurrent varicose veins. Table 2.

Table 2: Pre-operative diameter of GSV and evaluation of treatment failure

	Group I (n=19)
GSV diameter (4.50 – 9.50 mm)	--
GSV diameter (5. 50 – 10.0 mm)	7.12±1.271
Evaluation of treatment failure	
Recanalization of short segment (below 5 cm) occlusion	2(10.526%)
Recanalization of long segment (above 5 cm) occlusion	2(10.526%)
Recurrent varicose veins by 12th month	2(10.526%)

Data are presented as mean ± SD or frequency (%). GSV: great saphenous vein.

GSV diameter dropped dramatically after surgery, reaching a mean of 0.82 ± 0.252 after 6 months of follow-up. Table 3.

Table 3: Evaluation of GSV diameter preoperatively and postoperatively

	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
After RFA ablation					
GSV diameter	7.12±1.271	5.31±1.273	3.50±1.070	2.28±0.731	0.82±0.252

Data are presented as mean ± SD. GSV: great saphenous vein, EVLA: endovenous laser ablation, RFA: radio-frequency ablation

After the surgical procedure, patients experienced various postoperative outcomes. Notably, postoperative pain was reported as a common occurrence. In terms of complications, 1 patient (5.26%) experienced paraesthesia, while transient ecchymosis and bruising affected 5 patients (26.32%). There was also 1 case (5.26%) of permanent pigmentation noted. Fortunately, no patients (0.0%) developed deep vein thrombosis (DVT). Recanalization occurred in 2 patients (10.53%), and there were also 2 instances (10.53%) of recurrence. Table 4

Table 4: Complications in study group

	Group I (n=19)
Postoperative pain	19
Paresthesia	1(5.26%)
Transient ecchymosis and bruising	5(26.32%)
Permanent pigmentation	1(5.26%)
DVT	0(0.0%)
Recanalization	Total 4(21.06) Short segment 2(10.53%)
Recurrence	2(10.53%)

Data are presented as frequency (%). DVT: deep venous thrombosis

Discussion

The emergence and development of varicose veins are influenced by multiple factors, predominantly the contemporary lifestyle marked by sedentary behaviour, insufficient physical activity, and obesity. Surgery has long been regarded as the gold standard for treating varicose veins, with high ligation at the saphenofemoral junction and stripping of the great saphenous vein being the preferred methods for managing affected veins. SSV reflux was also addressed surgically through the ligation of the SPJ and stripping [7].

Minimally invasive procedures are therapeutic for lower extremity varicose veins and can be employed for the prevention and treatment of recurrent cases following conventional high ligation, offering advantages such as safety, efficacy, ease of manipulation, and minimal invasiveness, resulting in no scarring. [8].

The targeted use of therapeutic radiofrequency catheter ablation (RFA) enhances the prevention and management of adverse outcomes associated with conventional surgery, improves quality of life, reduces pain, and elevates patient satisfaction rates, without significant complications such as thrombophlebitis, hematoma, or recanalization [9].

This study highlights a significant female preponderance, accounting for around 57.9% of patients, with the female gender identified as a risk factor for varicose veins. This finding aligns with our research, despite the lack of unanimity on the definition of varicose veins [9-11]. However, the Andercou study indicated a women-to-men ratio of 1.79:1 [7], While this ratio cannot be used to extrapolate the incidence of varicose veins in the general population, it does reflect the gender disparity associated with this vascular pathology [12, 13]. In the Robertson study, a prospective cohort analysis involving 1456 patients over a 13-year duration, no statistically significant

difference was observed in the incidence of lower limb varicose veins between male (15.2%) and female patients (17.4%) (p = 0.97) [14].

The mean age of the participants in this study was 36.4 years old, which is equivalent to the average age of 58.2 years old that was observed in a study that was carried out in 2018 on the Romanian population by Feodor et al. [15]. In a 2002 study conducted by Criqui et al., more than 75% of the patients were over the age of 50 [16]. There is no clear cause for the variation between studies, but it can be explained. by raising public knowledge of the symptoms and signs of varicose veins, which encourages patients to have them scanned.

The mean GSV diameter for RF ablation was determined to be 7.12 ± 1.271 in this study. At

The 12-month follow-up, recanalization was observed in two cases of short segment recanalization (less than 5 cm), while two cases exhibited recanalization of long-segment occlusion. Additionally, two cases presented with recurrent varicose veins. The GSV diameter significantly decreased post-surgery, averaging 0.82 ± 0.252 at the 6-month follow-up.

Recent studies indicate no significant difference in the results depending on the pre-operative diameter of the great saphenous vein (GSV).

In our study, the diameter ranged from 4.50 to 9.50 mm, with a mean of 7.12 ± 1.271 mm. while, Orhan Bozoglan et al. reported a mean diameter of 10.3 ± 2.8 mm in the RFA group with no significant difference in the results.[19]

We found that this procedure was effective because the study group experienced relief from symptoms after the operation, particularly leg soreness and heaviness. In accord, He et al. reached the same results on this Cohort [18].

Impaired superficial sensation resulting from saphenous nerve injury is a prevalent complication following great saphenous vein stripping; it has been documented to occur in 23–40% of individuals receiving complete saphenectomy and 7–19% of those undergoing partial saphenectomy (above the knee). Our findings indicated that saphenous nerve neuralgia exhibited similarities in radiofrequency ablation (RFA). By the third month, only one patient in the RFA group experienced saphenous nerve neuralgia. Notwithstanding the utilization of a distinct sample size, Ewida et al. achieved a same result [19].

In relation to skin pigmentation and post-operative ecchymosis, our findings indicate that within the RFA group, only five patients experienced transient skin ecchymosis and bruising by the first week, while one patient developed persistent skin hyperpigmentation. Our study indicates that RFA is superior to EVLA in terms of skin bruising and ecchymosis, with complete resolution by the second week without any residual effects. Shepherd et al. reported that skin ecchymosis, bruising, and pigmentation were the most prevalent findings [20].

There were no recorded cases complicated with persistent saphenous nerve damage in our study. Mohammadi et al. [21] reported the same results as our study [22].

In this study, the GSV diameter significantly decreased after surgery, with a mean value of 0.82 ± 0.252 in the RFA group. Shepherd et al. found a significant GSV width reduction and no difference over time.[20] Two patients in the RFA group exhibited recanalization of short-segment occlusions (less Than 5

cm), two patients demonstrated recanalization of long-segment occlusions, and two patients presented with recurrent varicose veins.

Ewida et al. reported findings analogous to those of our study regarding the recanalization of the long segment [19]. With the exception of one patient who experienced saphenous nerve neuralgia after the RFA procedure, which resolved without incident three months later. According to Dermody et al., patients who received RFA had the same favorable outcomes [23].

Additionally, several studies have shown that RFA method had good satisfaction rates and the same quality of life after surgery. According to several meta-analysis studies, such as the one by Luebke et al. [24]

The surgical treatment yielded a total complication rate of 61.5%, comprising 34.6% local inflammation, 23.1% cellulitis, 7.7% paraesthesia, 11.5% pain, and 19.2% hematoma or haemorrhage, as reported in the Andercou study [7].

Proebstle et al. reported a low complication rate after 6 months of the clinical trial, including bruising (6.4%), paraesthesia (3.2%), hyperpigmentation (2%), hematoma (1.6%), erythema (1.6%), and phlebitis (0.8%) [25, 26].

In a 2006 study, Mekako et al. did not observe any skin lesions or deep vein thrombosis [27]. Elshafei, et al. (2023) reported that the adverse effects associated with the use of RFA were as follows: postoperative pain (18%), bruises and ecchymosis (68%), swelling (18%), phlebitis (9%), paraesthesia along the distribution of sural nerve (9%), and no patients had experienced deep vein thrombosis (DVT). However, no patients had experienced DVT [10]. Skin discoloration (pigmentation) was observed in three (10%) extremities at the 3- to 6-month postoperative Follow-up, as reported by Abd El-Mabood et al. (2017) Recurrence was observed in only one (3.3%). The paraesthesia was significantly reduced and observed in one patient (3.3%) [28].

Conclusions

Radiofrequency ablation (RFA) is a safe and less invasive treatment for great saphenous vein incompetence that reduces vein diameter while easing symptoms. Despite modest adverse effects such as paraesthesia and skin discoloration, there have been no reports of deep vein thrombosis. RFA's low recanalization and recurrence rates, fewer post-procedural problems, and shorter recovery time make it a promising alternative to standard surgical treatments.

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