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Original article

The Impact of Targeted Endovenous Radiofrequency Ablation versus Excluded Saphenous Vein Surgery in Management of Incompetent Giacomini Vein

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Abstract:

Background: Insufficiency in the Giacomini vein can present in isolation but is mostly seen together with a GSV insufficiency. It has been shown to be effectively treated either with endogenous laser ablation or by ultrasound guided sclerotherapy. The aim of this work was to compare the effect of targeted endogenous radiofrequency ablation versus excluded saphenous vein surgery in management of incompetent Giacomini vein. **Methods:** The current prospective study was conducted on 64 patients with incompetent Giacomini vein. Patients were divided equally into 2 groups, group (A) n= (32) who were treated with radiofrequency ablation and group (B) n= (32) who were treated with surgery. Follow up was planned 6 months for (Pigmentation, Ecchymosis, Paraesthesia and Recurrence). **Results:** The mean age of the included patient was (36.87 ± 9.34) and (37.70 ± 9.37) in group A&B respectively. There was no statistically significant difference between the two groups regarding the postoperative complications at 1, 3 and 6 months (pigmentation, ecchymosis, paraesthesia, and recurrence). The VCSS (After treatment) was statistically significantly lower in the RFA group. Both groups showed improvement of VCSS after treatment. **Conclusions:** Targeted endogenous radiofrequency ablation was associated with better outcomes during the management of incompetent Giacomini vein. Vein, with lower duration of the procedure, VAS score, hospital stay duration, the recovery time and duration to return to work, additionally higher satisfaction compared to traditional surgery.

Keywords: Targeted Endogenous Radiofrequency Ablation; Excluded Saphenous Vein Surgery; Incompetent Giacomini Vein; Great Saphenous Vein; Sclerotherapy

Introduction

The great saphenous vein (GSV) is a continuation of the dorsal venous arch in the foot. It travels anterior to the medial malleolus and ascends in the superficial fascia along the medial aspect of the lower extremity and drains into the deep system via the saphenofemoral junction [1]. While these veins may meet diagnostic criteria for venous incompetence, these perforators can regain their competence after successful treatment of an incompetent GSV, indicating that their dilation is secondary to reflux rather than the primary cause. Similarly, it is through the perforating veins that high deep venous pressure is transmitted to superficial veins, causing superficial varicosities, stasis dermatitis and venous ulcers [2]. Traditionally, refluxes have been treated with surgical ligation and stripping under general anaesthesia, but, lately, minimally invasive techniques under local anaesthesia have become areas of growing interest. Minimally invasive techniques like ultrasound-guided foam sclerotherapy (USGFS) have revolutionized the management [3].

The Giacomini vein is a communicant vein between the great saphenous vein (GSV) and the small saphenous vein (SSV). The Giacomini vein courses the posterior thigh as either a trunk projection, or tributary of the SSV. In one study it was found in over two-thirds of limbs [4]. It can be part of a draining variant of the SSV which continues on to reach the GSV at the proximal third of the thigh instead of draining into the popliteal vein. The direction of its flow is usually anterograde, but it can be retrograde when this vein acts as a bypass from an insufficient GSV to SSV to call on this last one to collaborate in draining [5]. Insufficiency in the Giacomini vein can present in isolation but is mostly seen together with a GSV insufficiency. It has been shown to be effectively treated either with endogenous laser ablation or by ultrasound guided sclerotherapy [6].

Multiple techniques for treating saphenous reflux have been developed over the years, including high ligation of the saphenous vein, saphenous vein stripping, and ultrasound-guided sclerotherapy, as well as various combinations of these procedures. Most recently, endogenous thermal ablation has also been identified as a viable treatment option for patients with saphenous reflux [7].

Radiofrequency ablation (RFA) is a minimally invasive technology that provides efficacious treatment of venous reflux with minimal discomfort and “downtime” for patients. One of the primary advantages of RFA is that the current procedure can be performed in an outpatient office setting with use of local tumescent anaesthesia [8]. Sclerotherapy represents a well-established treatment for the management of venous reflux. The sclerosing agent must contact the vein wall in order to cause endothelial damage, and this occurs with some variability [9]. Mechano-chemical ablation is a new minimally invasive closure, non-thermal, non-tumescent technique. It works by the mechanism of endothelial mechanical damage and chemical injury with a foam sclerosant infusion. Tumesce anaesthesia is not required and no risks of heat-related injury to the surrounding tissue and structures [10].

The aim of this work was to compare the effect of targeted endogenous radiofrequency ablation versus excluded saphenous vein surgery in management of incompetent Giacomini vein.

Patients and Methods

Study design

The current prospective study was randomized conducted on 64 patients with incompetent Giacomini vein at the vascular unit, general surgery department Benha University, throughout the period from December 2022 till May 2023. The study was conducted the ethical prospective Helsinki consideration which ethical approved from ethical of research committee (Approval code: Ms-9-12-22)

Inclusion criteria were both males and females with age >18 years old, patients with primary GSV incompetence & reflux,

incompetent Giacomini vein and with bilateral varicosities.

Exclusion criteria were patients with allergic to sclerosant, with history of deep venous thrombosis, peripheral arterial disease (ABPI < 0.8), patients, receiving anticoagulation with warfarin, unfit for surgery, with recurrent after surgery, with Lipodermosclerosis, vein diameter < 3mm or > 15mm.

Randomization

It was done using specific software (Random Allocation Software 1.0, 2011). This block randomization was done by an independent investigator.

The patients were subdivided into two equal group, group (A) who were treated with radiofrequency ablation and group (B) who were treated with surgery.

Surgical technique:

Radiofrequency ablation:

In group A, Giacomini vein was identified and marked before operation. Local tumescent anaesthesia or spinal anaesthesia was performed. All patients were positioned supine with leg slightly flexed abducted and externally rotated leg to make the GSV more accessible, then all patient were positioned prone to make Giacomini vein more accessible. The RFA procedure involved using a catheter electrode to deliver a high-frequency alternating radiofrequency current that leads to venous spasm, collagen shrinkage and physical contraction. The patient's leg was prepped with antiseptic solution and draped in a sterile fashion. With ultrasound guidance, 2-cm away from S.F.J. the vein was cannulated, and local tumescent aesthetic was then injected around the target venous segment. The catheter was then introduced through a sheath. The radiofrequency current was then delivered, resulting in circular homogeneous denaturation of the venous collagen matrix and endothelial destruction at a temperature of 110–120° C. Venous segments 3–7cm in length were treated in 20-second cycles. The same manner ablation for Giacomini vein, was done. Patients were instructed to wear 20–30 mm Hg graduated elastic compression stockings for at least 14 days (Figure 1 – Figure 4) [22]

Figure 1: Device of radiofrequency

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Figure 2: A,B: Giacomini vein,

C: Giacomini vein ablation

Figure 3: A: Us guided needle insertion, B: Sheath insertion, C: Us guided needle insertion, D: Mickey mouse appearance show common femoral art, common femoral vein and great saphenous vein, E: Withdrawal of wire

Figure 4: A: Patient before treated by radiofrequency, B: Patient after treated by radiofrequency

Surgery (ligation & stripping):

In group B, a technique called ligation and stripping involved tying off the vein in the affected leg and then removing it was performed. Then, Giacomini vein was identified and marked before operation. After that, Local tumescent anaesthesia or spinal anaesthesia was performed. All patients were positioned supine with leg slightly flexed abducted and externally rotated leg to make the GSV more accessible. Then, all patients were positioned prone to make Giacomini vein more accessible, then sterilization and disinfection. 2 small incisions were made; the first was made near the groin at the top of the varicose vein and is approximately 5cm in diameter and the second was a smaller cut that was made further down your leg, usually around knee. The top of the vein (near the groin) was tied up and sealed. A thin, flexible wire was passed through the bottom of the Giacomini vein and then carefully pulled out and removed through the lower cut in leg. The blood flow in legs was not affected by the surgery. This was because the veins deep within the legs were taken over the role of the damaged veins. Ligation and stripping can cause pain, bruising and bleeding. More serious complications are rare, but could include nerve damage or deep vein thrombosis, where a blood clot forms in one of the deep veins of the body.

All patients were followed for operative time, hospitalization, recovery time, quick return to work, patient satisfaction, complication as post intervention pain, pigmentation, itching, ulcers, DVT or Superficial thrombophlebitis, residual or recurrence and ecchymosis (Figure 5). [23].

Figure 5: Stripping technique

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Outcomes:

Primary outcome was the efficacy of targeted endogenous radiofrequency ablation of incompetent Giacomini vein useful modality with minimal postoperative complication. Secondary outcomes were decreasing incidence of recurrence after 6 months .and follow up was designed for at least 3 months postoperative.

Sample size:

Assuming; Mean ±SD of duration of post-operative recurrence was (7.3 ± 3,4) and confidence level is 95% with power of study 80%. Sample size calculated using Open Epi, is 64 patients, divided to 32 patients for each group.

Statistical analysis:

Statistical analysis was done by SPSS v28 (IBM©, Armonk, NY, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analysed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were analysed by Mann Whitney-test. Qualitative variables were presented as frequency and percentage (%) and analysed using the Chi-square test or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

Results

The mean age of the included patient was (36.87 ± 9.34) and (37.70 ± 9.37) in group A&B respectively

Table 1 shows that there was no statistically significant difference between the two groups regarding the sociodemographic data (age, sex, and BMI), comorbidities (diabetes mellitus, hypertension and smoking) and the clinical classification and VCSS (before treatment).

There was no statistically significant difference between the two groups regarding the anaesthesia and length of treated vein. The duration of the procedure, VAS score, hospital stay duration, the recovery time and duration to return to work were statistically significantly lower in the RFA group. Table 2

Table 1: Analysis of the sociodemographic, comorbidities and demographic and history data in the two study groups

		Group A (RFA) (N= 32)		Group B (Surgery) (N= 32)		Test of significance
Age (years)		36.87 ± 9.34		37.70 ± 9.37		t = - 0.345, P= 0.731
Gender	**Females**	22	68.8 %	24	75 %	χ^2 = 0.238, P = 0.626
	Males	10	31.2 %	8	25 %	
BMI (Kg/m^2)		29.19 ± 2.84		28.23 ± 2.77		t = 1.330, P= 0.189
Comorbidities	**Diabetes mellitus**	4	12.5%	4	12.5%	FET = 0, P = 1
	Hypertension	3	9.4 %	4	12.5%	FET = 0.162, P = 0.688
	Smoking	8	25 %	12	37.5 %	χ^2 = 1.200, P = 0.277
Clinical classification	**C2**	5	15.6 %	6	18.8 %	MC = 1.161, P = 0.762
	C3	10	31.3 %	12	37.5 %	
	C4	14	43.8 %	10	31.3 %	
	C5	3	9.4 %	4	12.5 %	
VCSS (Before treatment)		15 (11 – 19)		14 (10 – 19)		z = - 0.701, P = 0.483

Data presented as mean ± SD or frequency (%), t: independent samples t-test, FET: Fisher's exact test, P: probability, Categorical data expressed as Number (%)

Table 2: Analysis of the operative and early and late postoperative follow up in the two study groups

		Group A (RFA) (N= 32)		Group B (Surgery) (N= 32)		Test of significance
Anesthesia	**General anesthesia**	2	6.2 %	3	9.4 %	MC = 0.388, P = 0.824
	Spinal anesthesia	15	46.9 %	16	50 %	
	Epidural anesthesia	15	46.9 %	13	40.6 %	
Length of treated vein (cm)		40.5 (16 – 55)		10 (8 – 13)		z = - 0.326, P = 0.745
Duration of the procedure (min)		33.80 ± 7.73		43.57 ± 10.44		t = - 4.118, **P < 0.001***
VAS score (For pain)		3 (2 -5)		6 (4 -8)		z = - 5.778, **P < 0.001***
Hospital stay (Days)		1 (1 -3)		2 (1 -4)		z = - 5.778, **P < 0.001***
Return to daily activities (Days)		0 (0 – 3)		1 (0 -5)		z = - 2.307, **P = 0.021***
Return to work (Days)		9 (4 – 12)		10 (6 – 15)		z = - 2.242, **P = 0.025***

Data presented as mean ± SD or frequency (%), VAS: Visual Analogue Scale, t: independent samples t-test, MC = Monte-Carlo test, t: Independent samples t-test, z: Mann-Whitney U-test, *: Statistically significant (P < 0.05),

There was no statistically significant difference between the two groups regarding the postoperative complications at 1, 3 and 6 months (pigmentation, ecchymosis, paraesthesia, and recurrence). However, the incidence of complications was higher in surgery group. Table 3.

The VCSS (After treatment) was statistically significantly lower in the RFA group. Both groups showed improvement of VCSS after treatment. Table 4

Table 5 shows that there was no statistically significant difference between the two groups regarding patient satisfaction.

Table 3: Analysis of postoperative complications at 1, 3, 6 months in the two study groups

		Group A (RFA) (N= 32)		Group B (Surgery) (N= 32)		Test of significance
At 1 months	**Pigmentation**	2	6.2 %	5	15.6 %	FET = 1.456, P = 0.228
	Ecchymosis	2	6.2 %	4	12.5 %	FET = 1.218, P = 0.334
	Paresthesia	3	9.4 %	4	12.5 %	FET = 0.162, P = 0.688
	Recurrence	1	3.1 %	2	6.2 %	FET= 0.351, P = 0.554
At 3 months	**Pigmentation**	1	3.1 %	3	9.4 %	FET = 1.071, P = 0.301
	Ecchymosis	2	6.2 %	4	12.5 %	FET = 1.218, P = 0.334
	Paresthesia	2	6.2 %	2	6.2 %	FET = 0, P = 1
	Recurrence	1	3.1 %	3	9.4 %	FET = 1.071, P = 0.301
At 6 months	**Pigmentation**	1	3.1 %	3	9.4 %	FET = 1.071, P = 0.301
	Ecchymosis	0	0 %	0	0 %	FET = 0, P = 1
	Paresthesia	0	0 %	1	3.1 %	FET = 0.351, P = 0.554
	Recurrence	0	0 %	2	6.2 %	FET = 2.069, P = 0.150

Data presented as frequency (%), FET: Fischer's exact test, P: probability

Table 4: Analysis of the VCSS before and after treatment in the two study groups

	Group A (RFA) (N= 32)	Group B (Surgery) (N= 32)	Test of significance
VCSS (Before treatment)	15 (11 – 19)	14 (10 – 19)	z = - 0.701, P = 0.483
VCSS (After treatment)	7 (3 – 11)	9 (5 – 14)	z = - 3.805, P = **0.001***
Wilcoxon signed Rank test	**< 0.001***	**< 0.001***	

Data presented as median (IQR), z: Mann-Whitney U-test, *: Statistically significant (P < 0.05), P: probability

Table 5: Analysis of patient satisfaction in the two study groups

	Group A (RFA) (N= 32)		Group B (Surgery) (N= 32)		Test of significance
Highly satisfied	11	34.4 %	8	25 %	
Satisfied	9	28.1 %	6	18.8 %	
Neutral	10	31.3 %	11	34.4 %	MC = 3.416, P = 0.172
Dissatisfied	2	6.3 %	6	18.8 %	
Highly Dissatisfied	0	0 %	1	3.1 %	

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Discussion

Different management modalities are used for the treatment of varicose veins based on its clinical management &presence of complication. The major shift towards less invasive procedures in medicine also included varicose vein treatments, including but not limited to techniques such as radiofrequency ablation (RFA), EVLA, and foam sclerotherapy [11].

In the current study, there was a statistically significant improvement in the VCSS after treatment as compared to before treatment ($p < 0.001$), however, the degree of improvement was statistically significantly higher in the endogenous radiofrequency ablation group.

This was in agreement with study by Atasoy et al., [12] who retrospectively screened 335 patients with varicose disease who underwent endogenous laser ablation and determined 17 patients who underwent Giacomini vein ablation. The results showed that in the cases with Giacomini vein at six months, the median CEAP classification score decreased from 3 (range, 2–5) before the procedure to 1 (0–4), while median rVCSS decreased from 7 (range, 2–12) before the procedure to 1 (range, 0–7). Clinical outcomes measured by CEAP and rVCSS showed significant improvement compared with the pre-treatment scores ($P < 0.001$).

In a case series by Elshafei et al., [13] that used radiofrequency ablation to treat 34 patients suffered from leg varicosity (either primary or recurrent) attended to outpatient clinic and were referred for duplex scan to ensure SSV incompetency. They reported that the median VCSS reduced from 13.5 (IQR 12) pre-operatively to 3 (IQR 6) 1-month post-operatively [$Z < 0.001$]. Technical success was reached by total occlusion of the SSV at the end of the procedure confirmed by the duplex US which occurred in 100% of the cases.

In other cases, with varicose veins, the advantage of endogenous ligation was also reported. [21] in their study examining 682 limbs treated with RFA, the overall mean baseline for VCSS was 8.8 and 3.6 at the last follow-up visit [14].

In the study published in 2011 by Proebstle, et al., [15] it was reported that the average VCSS score to be 1.5 ± 1.8 at 6 months compared with 3.9 ± 2.1 preoperatively. While in 2019 Sincos , et al.,[16] reported the average VCSS score to be 4.00 (2.91–5.09) at 1 year compared with 7.58 (6.37–8.79) preoperatively for the RFA group, while the average VCSS score was 4.35 (3.56–5.13) at 1 year compared with 7.78 (6.52–9.04) preoperatively for the surgical group.

In 2020[17], it was reported that the average VCSS score to be 1 (1–3) at 1 year compared with 5 (1–9) preoperatively. Study by [18] showed that VCSS improved from 5.31 ± 0.60 (at the baseline) to 1.10 ± 0.13, 0.39 ± 0.09, 0.14 ± 0.06, and 0.06 ± 0.03 at 1, 3, 6, and 12 months, respectively.

The results of the current study showed that VAS score and Hospital stay duration were statistically significantly lower in the RFA group. Also, the recovery time and duration to return to work were statistically significantly lower in the RFA group.

This came in accordance with others [19] who included a total of 54 individuals were randomly divided into two groups (using a computerized random number generator), with nine patients having bilateral lower-limb disease (total 63 legs). The first group (29 patients − 33 legs) underwent CS in the form of ligation of the SFJ with short stripping of GSV to just below the knee. The results showed that the second group showed significantly lesser pain scores associated with less need for analgesic intake. Also, we found that there was a decrease in the time to return to normal activities in the second group (3.00 ± 1.323) compared with the first group (7.21 ± 1.634).

Within the same line, researchers [20] conducted a prospective randomized controlled study was conducted on 26 patients (31 limbs) with primary VV; all patients were treated with RFA using VNUS closure under tumescent anesthesia. Patients were randomly allocated into two groups according to the performed RFA technique:

group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs]. Follow-up period was 6 months. They reported that on using a VAS, patients in both groups experienced significantly less PO pain on first 2 days (VAS: 2.09±0.3 vs. 3.05±0.01; P=0.001) and seventh day (VAS: 0.9±1.1 vs. 1.51±0.9; P=0.001). The mean time to return to work in group A was 9.2±1.7 days and in group B was 14.1±1.6 days. Group B had slightly longer duration till return to work.

In the current study, there was no statistically significant difference between the two groups regarding the postoperative complications (Pigmentation, Ecchymosis, Paraesthesia and Recurrence) at 1 month, 3 months and 6 months after treatment, in the RFA group, at 1 month after treatment.

In 2023, Elshafei, et al., [13] study, the adverse effects reported with the use of RFA were in the form of post-operative pain 18%, bruises and ecchymosis in 68%, swelling in 18%, phlebitis in 9%, paraesthesia along the distribution of sural nerve in 9%, and none of the patients had suffered from deep vein thrombosis (DVT).

According to Abd El-Mabood, et al., [20], at 3–6-month postoperative follow-up, skin discoloration (pigmentation) was noticed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Residual varicosities was noticed only in two (6.6%) limbs in group B and treated by FS. Recurrence was noticed only in one (3.3%) limb in group A. Paraesthesia was markedly declined and observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. The overall complications were less in group A [14, 93.3%) limbs].

A one- and two-year follow-up of the multicentre study conducted by Lurie et al., [21] showed that 41% of obliterated GSVs became ultrasonically undetectable, and another 51% remained visible, but occlusion rat exhibited progressive diameter shrinkage. Vein remnants that remained visible by DUS were larger at the time of RF ablation than those that became invisible. Clinical status of limbs that underwent RF ablation was at least equal to the status of limbs that received vein stripping. The cumulative rate of recurrence of varicose veins was 14.3% in the RF group compared with 20.9% in the stripping group. Using the CEAP classification system, 33% of RF patients and 28% of stripping patients had no signs of venous disease at two years. Quality of life questionnaires were administered at all follow-up visits. While the observed superiority of the RF group over the stripping group diminished by four months, it re-emerged at both the one- and two-year intervals.

Conclusions:

Targeted endogenous radiofrequency ablation was associated with better outcomes during the management of incompetent Giacomini vein. Vein, with lower duration of the procedure, VAS score, hospital stay duration, the recovery time and duration to return to work, additionally higher satisfaction compared to traditional surgery.

Conflict of interest:

None of the contributors declared any conflict of interest.

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