Combined radiofrequency ablation and truncal foam sclerotherapy for greater saphenous vein incompetence can reduce recurrence and complications of radiofrequency ablation

Abdelrahman M. Gameel, Mohamed E. Elsherbeni, A. Elboushi, Ayman M. Samir, Waleed A. Sorour, Ahmed M. Tawfik, Ayman Salem

Department of Vascular Surgery, Zagazig University, Zagazig, Egypt

Correspondence to Abdelrahman M. Gameel, MD, Department of Vascular Surgery, Zagazig University, Zagazig, Egypt
Tel: + +20 122 406 1496; fax: 0552366211;
e-mail: abdlgm2611@gmail.com

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Objective
Although radiofrequency ablation (RFA) has been established as an effective method for the treatment of lower limb varicose veins with a good outcome, in all interventions, there were complications and recurrence, because of which in this study we are modifying our technique to reduce the rate of complications and recurrence that we faced in our previous work.
Patients and methods
A total of 74 patients (86 lower limbs) with greater saphenous vein (GSV) incompetence were randomized to two treatment groups; the first group was treated by RFA with duplex guided perforator injection and the second group was treated by RFA with duplex guided perforator injection plus below knee truncal sclerotherapy of incompetent GSV. Groups were followed up for 12 months and compared demographically; venous clinical severity scores (VCSS), need for sclerotherapy during follow-up and postintervention complications including recanalization and recurrence were determined.
Results
There was no statistically significant difference between both groups as regards demographic criteria, VCSS preoperatively, paresthesia around the medial malleolus and recurrence of varicose veins during the follow-up period. There was significant difference between both groups as regards GSV recanalization with a *P* value of 0.046; also there were significant difference between four different time periods of VCSS (preintervention, 3, 6 and 12 months postintervention) by pairwise comparison of the two groups. A significant difference was found between the two groups in the need for postintervention sclerotherapy all over 12 months with a *P* value of 0.038.
Conclusion
The addition of below knee truncal sclerotherapy to the above knee RFA of GSV can reduce the rate of recanalization, recurrence of varicose veins, and decrease the need for postintervention sclerotherapy without risk of increase in the total number of complications.

Keywords:
radiofrequency, sclerotherapy, varicose veins

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Introduction

Lower limb varicose veins management has changed rapidly in the recent years, with replacement of the conventional surgery by newer endovenous methods [1].

Durability of any vascular procedure, especially if it costs too much and how to make it live longer is a vital issue and important goal [2].

The natural history and the fate of untreated below knee greater saphenous vein (GSV) is important in understanding the ongoing chronic venous disease [3].

There is a close association between saphenous nerve and GSV throughout its course particularly several centimeters below the knee to the medial malleolus. Several branches of the nerve cross directly over the vein and are liable for injuries during any manipulation over the vein [4].

Paresthesia and numbness around the medial malleolus due to nerve damage following below

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knee radiofrequency ablation (RFA) and other varicose vein surgery are the most common causes of legal dispute and litigation [5].

Patients and methods

The study was conducted in Zagazig University Hospitals and at a private center during the period from August 2014 to August 2016 on 74 patients with GSV incompetence; patients were randomly divided into two groups; the first group was treated by RFA with duplex guided perforator injection (DGPI) and the second group by RFA with DGPI plus below knee truncal sclerotherapy (BKTS) of incompetent GSV. Patients with any of the following criteria were excluded: acute deep vein thrombosis, arterial disease of the lower limbs, lesser saphenous vein incompetence, superficial thrombophlebitis, thrombophilia, pregnancy, or are allergic to polidocanol.

The degree of venous insufficiency and severity of the disease was assessed by clinical examination, duplex ultrasound, and venous clinical severity score (VCSS).

All steps of the intervention, including type of anesthesia and possible complications which might be acquired were discussed carefully with all patients and written consents were obtained from all patients which were approved by the Institutional Review Board.

Under spinal anesthesia, GSV puncture above the medial malleolus under duplex guidance was made, using guidewire then 7 or 5 French sheath was inserted into the GSV. Normal saline injection inside the sheath with duplex ultrasound observation of its flow inside the vein was done for confirmation of the site of the sheath inside the vein. The ClosureFast (VNUS Medical Technologies Inc., San Jose, California, USA) was advanced through the sheath to 1.5 cm below SFJ. Under duplex guidance tumescent fluid (500 ml normal saline plus 1 ml adrenaline) was injected into the saphenous compartment in a subfascial location using spinal needle by multiple punctures along the course of the vein, in order to compress GSV and to decrease the incidence of local complications. In Trendelenburg position the catheter ablates a 7 cm segment of the GSV vein for 20 s per cycle. Two cycles were applied to the first segment, whereas the last segment was that just above the knee confirmed by the position of the tip of the catheter under duplex guidance, then the catheter was removed and polidocanol foam was injected from the sheath into the below segment of GSV in the second group followed by duplex guided foam injection of incompetent perforators in both groups.

The polidocanol foam was produced by the Tessari method [6] (double-syringe system) which involves the mixing of polidocanol 3% with room air in a ratio of 1 : 4 in two syringes linked through a three-way connector. A completion duplex ultrasound was done in both groups from SFJ downward to assess vein closure and fullness of below knee segment by foam in the second group and to measure immediate technical success rates. Follow-up duplex ultrasound at 3, 6, 12 months postintervention was conducted with reporting all cases of recanalization with return of venous flow in a previously obliterated venous segment or whole GSV recanalization and recurrence of varicosities related to previously treated venous segment.

Statistical analysis

Statistical package for the social sciences software (SPSS for Windows, version 17.0; SPSS Inc., Chicago, Illinois, USA) was used for data analysis.

Patients with bilateral lower limbs were treated as one for data analyzed by subject, but were included in the SPSS data analysis by one limb for each side separately. *P* values less than 0.5 were considered statistically significant.

Results

A total of 74 patients with 86 limbs, the first group included 38 patients and the second group included 36 patients with 43 limbs in each group; the first group included 25 (65.7%) women and was treated by RFA with DGPI and the second group included 22 (61.1%) women and was treated similarly as the first one plus BKTS of incompetent GSV. There was no statistically significant difference between both groups as regards demographic criteria as noticed in Table 1.

VCSS scores in both groups before the procedure (VCSS0), at 3 months (VCSS3), 6 months (VCSS6), and 12 months (VCSS12) after the procedure are shown in Table 2, whereas the comparison between both groups in the mean VCSS at the different time periods was shown in Fig. 1, for example, VCSS0 was 5.09±1.65 for the first group and 5.30±1.87 for the second group with a *P* value of 0.408.

As regards the different VCSS values in both groups during follow-up, there was no statistically significant

Table 1 Demographic criteria of all treated limbs in both groups

	First group [*n* (%)]	Second group [*n* (%)]	*P* value
Age (mean±SD) (years)	32.76±8.5	33.06±8.5	0.891[a]
Sex			
Female	27 (63)	28 (65)	0.018[b]
Male	16 (37)	15 (35)	0.032[b]
Side			
Unilateral	38 (88.3)	36 (83.7)	0.054[b]
Bilateral	5 (11.7)	7 (16.3)	0.333[b]
GSV diameter (mean±SD) (mm)	8.80±1.70	8.68±1.63	0.128[a]
Height (mean±SD) (cm)	168±6.6	171±5.9	0.917[a]
Weight (mean±SD) (kg)	76.16±6.7	78.43±7.6	0.474[a]
BMI (mean±SD)	26.64±2.02	26.44±2.18	0.832[a]
Diabetes mellitus	4 (9.3)	7 (16.2)	0.260[c]
Smoking	5 (11.6)	4 (9.3)	0.500[c]
Hypertension	6 (13.9)	8 (18.6)	0.386[c]
IHD	3 (6.9)	1 (2.3)	0.308[c]
Venous ulcer	9 (20.9)	7 (16.2)	0.400[c]

IHD, ischemic heart disease; GSV, greater saphenous vein; [a]Independent sample *t*-test; [b]χ^2-test; [c]Fisher's exact test.

difference between RFA group and RFA plus BKTS group as noticed in Table 3.

The significance was between the four different time periods of VCSS, so a pairwise comparison was made to identify what period of VCSS caused this difference, which is clearly shown in Table 4, that VCSS0 causes the difference between the four follow-up time periods; also there was a statistically significant difference between VCSS3 and VCSS12, which means there is significant improvement in patient symptoms over the follow-up periods.

There were 12 (27.9%) patients from the first group and five (11.6%) patients from the second group who required sclerotherapy over the 12 months period of follow-up for treatment of residual varicosities postintervention showing statistically significant difference between both the groups with a *P* value of 0.038 as shown in Fig. 2.

Primary GSV closure was achieved in all patients of both study groups. During the follow-up period, there were 11 (25.5%) cases of recanalization in the first group and four (9.3%) cases in the second group with a *P* value of 0.046 as described in Fig. 3) But as regards recurrence there were seven (16.2%) cases in the first group and three (6.9%) cases in the second group with a *P* value of 0.163 by the Kaplan–Meier test as described in Fig. 4. Recanalization was not associated with recurrent varicose veins in four cases of RFA group and one case in RFA plus BKTS group. Mean and median

Table 2 Venous clinical severity score in both groups before radiofrequency ablation, at 3, 6, and 12 months follow-up time

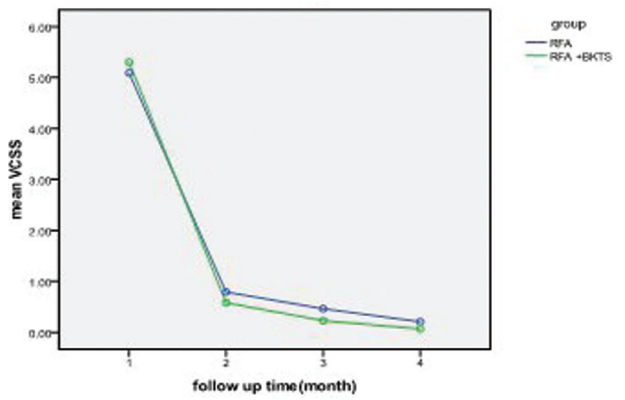
	Before radiofrequency						At 3 months follow-up						At 6 months follow-up						At 12 months follow-up					
	Mild		Moderate		Sever		Mild		Moderate		Sever		Mild		Moderate		Sever		Mild		Moderate		Sever	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
Pain	13	14	2019	15	10	14	6	7	4	2	–	–	5	3	2	1	–	–	3	1	–	–	–	–
Varicose veins	24	27	–	16	–	–	10	11	3	1	–	–	6	3	–	–	–	–	5	2	–	–	–	–
Venous edema	17	26	3	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Pigmentations	15	13	–	2	–	–	8	7	1	–	–	–	5	2	–	–	–	–	1	–	–	–	–	–
Inflammation	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Induration	–	–	2	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
No of active ulcers	7	5	–	2	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Ulcer duration	9	7	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Ulcer size	9	7	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
Compression	4	1		–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

A, RFA and DGPI groups; B, RFA and DGPI+BKTS groups; BKTS, below knee truncal sclerotherapy; DGPI, duplex guided perforator injection; RFA, radiofrequency ablation.

for recanalization and recurrence are discussed in Tables 5 and 6.

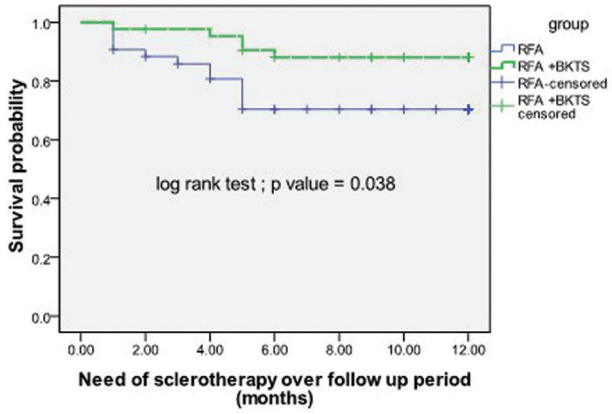
The pattern of recanalization in the first group was two (4.6%) cases with opened stump into the femoral vein due to tributary vein insertion, four (9.3%) cases with recanalization in the middle segment of the GSV, and five (11.6%) cases of whole GSV recanalization, whereas the pattern of recanalization in the second group was one (2.3%) case of groin recanalization due to undiagnosed anterior accessory saphenous vein and three (6.9%) cases with recanalization in the middle segment of GSV due to attachment to incompetent perforators and no cases of below knee or whole GSV recanalization.

Figure 1



Comparison between both groups in the mean VCSS at the different time periods.

Figure 2



Comparison between both groups in the need of sclerotherapy over follow up periods.

Table 3 Testing the relation between different values of venous clinical severity score together and the difference between the two study groups

Sources	Time	Type III sum of squares	df	Mean square	*F*	Significance	Partial η^2
Time	Linear	1034.626	1	1034.626	596.718	0.000	0.877
	Quadratic	397.965	1	397.965	306.329	0.000	0.785
	Cubic	70.409	1	70.409	75.819	0.000	0.474
Time×group	Linear	1.230	1	1.230	0.710	0.402	0.008
	Quadratic	1.407	1	1.407	1.083	0.301	0.013
	Cubic	0.084	1	0.084	0.090	0.765	0.001
Error (time)	Linear	145.644	84	1.734			
	Quadratic	109.128	84	1.299			
	Cubic	78.007	84	0.929			

Time: four VCSS values (VCSS0, VCSS3, VCSS6, and VCSS12); Groups: RFA and RFA plus BKTS; BKTS, below knee truncal sclerotherapy; RFA, radiofrequency ablation; VCSS, venous clinical severity score.

Table 4 Pairwise comparison between four different venous clinical severity score values represented by time

Time (I)	Time (J)	Mean difference (I–J)	SE	Significance[a]	95% confidence interval for difference	
					Lower bound	Upper bound
1	2	4.512	0.220	0.000	3.917	5.106
	3	4.849	0.218	0.000	4.258	5.439
	4	5.058	0.200	0.000	4.517	5.600
2	1	4.512	0.220	0.000	5.106	3.917
	3	0.337	0.148	0.149	0.061	0.736
	4	0.547	0.130	0.000	0.196	0.897
3	1	4.849	0.218	0.000	5.439	4.258
	2	0.337	0.148	0.149	0.736	0.061
	4	0.209	0.097	0.203	0.053	0.472
4	1	5.058	0.200	0.000	5.600	4.517
	2	0.547	0.130	0.000	0.897	0.196
	3	0.209	0.097	0.203	0.472	0.053

Time 1: VCSS0; time 2: VCSS3; time 3: VCSS6; time 4: VCSS12; VCSS, venous clinical severity score.

Paresthesia around the medial malleolus due to saphenous nerve damage was observed in two (4.6%) patients in the first group and in five (11.6%) patients in the second group with a *P* value 0.433 by Fisher's exact test. This paresthesia was temporary in the two patients of the first group and four patients of the second group and was permanent after 6 months in only one patient of the second group.

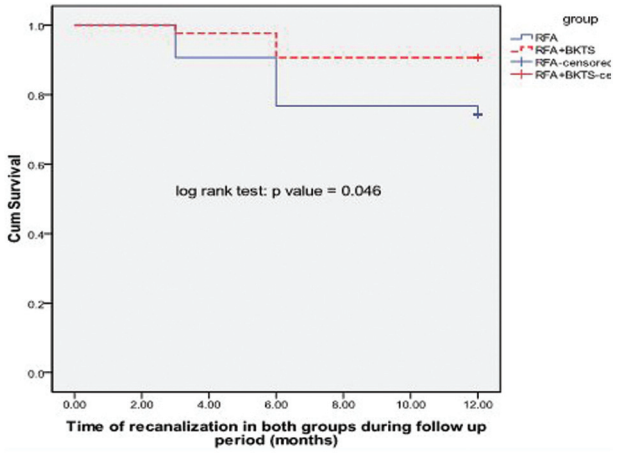
Discussion

To solve the problem of the durability of any varicose veins procedure as regards recurrence after a short time in our community so we were aiming to perform below knee GSV sclerotherapy not to achieve thrombosis of the vein *per se*, which may recanalize, but with almost transformation of the vein into a fibrous cord.

We discussed before in our previous work [7] that 15 (12.8%) cases had postoperative phlebitis which dropped to four (9.3%) cases among the first group plus three (6.9%) cases among the second group with a total number (7/86=8.1%) in the present study. As regards paresthesia, it was permanently affecting four (3.4%) cases in our previous study, dropped to only one case in the radiofrequency (RF) and truncal sclerotherapy group in the present study.

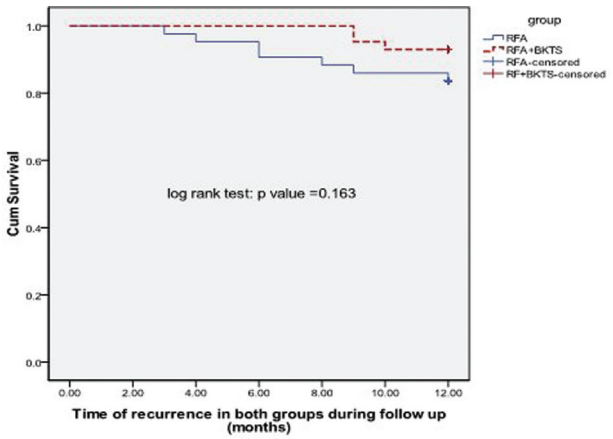
Shoab *et al.* [8] have stated that retreatment was required in below the knee branches in 46% of patients requiring additional treatment after initial endovenous laser ablation which meant that the reason for offering reintervention in those patients was reflux in residual below the knee segment of GSV with the potential risk for continued venous hypertension and recurrence of symptoms. So when we are facing a whole segment below the knee and although all incompetent perforators related were duplex guided injected, soon it may provide new

Figure 3



Recanalization in both groups during follow up periods.

Figure 4



Recurrence in both groups during follow up periods.

Table 5 Mean and median of recanalization in both groups

Groups	Mean[a]				Median			
			95% confidence interval				95% confidence interval	
	Estimate	SE	Lower bound	Upper bound	Estimate	SE	Lower bound	Upper bound
RF	10.326	0.500	9.346	11.305	–	–	–	–
RF+truncal sclerotherapy	11.372	0.305	10.774	11.970	–	–	–	–
Overall	10.849	0.298	10.264	11.434	–	–	–	–

RF, radiofrequency; [a]Estimation is limited to the largest survival time if it is censored.

Table 6 Mean and median for recurrence in both groups

Groups	Mean[a]				Median			
			95% confidence interval				95% confidence interval	
	Estimate	SE	Lower bound	Upper bound	Estimate	SE	Lower bound	Upper bound
RF	11.163	0.366	10.446	11.879	–	–	–	–
RF+truncal sclerotherapy	11.814	0.105	11.608	12.020	–	–	–	–
Overall	11.488	0.190	11.115	11.862	–	–	–	–

RF, radiofrequency; [a]Estimation is limited to the largest survival time if it is censored.

varicosities with increase in the venous pressure after a period of time or it may be itself a source of patient dissatisfaction after RF and incompetent perforators injection.

Chan *et al.* [9] reported that, 22 of 54 (40.7%) patients in the endovenous laser group required sclerotherapy within 6 months of the original surgery for the management of residual varicosities, which represents a higher rate of postendovenous intervention need for sclerotherapy than encountered in our study.

The statistically significant difference among both groups in freedom from postintervention sclerotherapy with a *P* value 0.038 in favor of RFA plus BKTS group reflects the lower rate of recanalization and although there was no statistically significant difference between both groups over 12-month follow-up as regards the recurrent cases, the number of recurrent cases may be increased over the longer follow-up periods than in our study timeframe especially with significant increased rate of recanalization in RFA with the DGPI group than the second group.

Although the number of patients affected by paresthesia in our study was higher in RFA plus BKTS group which may be attributed to the proximity to saphenous nerve during injection and the use of 7 French sheath in the early cases which was replaced by 5 French sheath, yet there was no statistically significant difference between both the groups.

Jin *et al.* [10] have stated that although there was occlusion failure or recanalization in a segment or whole GSV, there was significant reduction of the saphenous vein diameter and absence of venous reflux was noticed, which may explain symptomatic improvements in some cases

Not all cases of recanalization were associated with recurrence in our study; there were four (9.3%) in the RFA group and one (2.3%) case in the RFA plus BKTS group without recurrence of varicose veins or venous ulceration, which means that there were great benefits from ablation and sclerotherapy with elimination of annoying symptoms in all patients. Even those with recurrence had no ulcers and were managed by single sessions of duplex guided sclerotherapy.

Although there was no statistically significant difference between both groups as regards recurrence along 12 months follow-up, the total number of recurrent cases was lower in RF and in the truncal sclerotherapy group with no cases of below knee recurrence.

Cases of groin recurrence in both groups represent disease progression which may be due to increased venous pressure with recent reflux along the anterior or posterior accessory saphenous veins. Cases with recurrence in the thigh and who had recanalization in the GSV segment might had primarily thrombotic occlusion and subjected to enhanced recanalization caused by recent perforator incompetence not injected before.

As regards a series of complications which were reported by other studies [11,12], life-threatening pulmonary embolism, deep venous thrombosis, transient visual disturbance, anaphylactic shock were not encountered in our study

Conclusion

This study although has some limitations as regards the small sample size, relatively short period of follow-up, still give promising results of reduced recurrence rates and increased sclerotherapy survival-free periods without increase in the total number of complications.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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