Different techniques in radiofrequency ablation of varicose veins (traditional method and tumescentless method)

Mohamed H. Abdelmawla[a], Ayman Refaat[a], Abdulaziz Z. Algaby[a], Ahmed S. Abd El Basset[b]

Departments of [a]General Surgery, [b]Radiology, Beni Suef University, Beni Suef, Egypt

Correspondence to Mohamed Hassan Abdelmawla, MD, General Surgery Department, BeniSuef University, 62111, Egypt. Mob: 01001661653; fax: 0020822318605; e-mail: mohamedhasan8134@gmail.com

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Introduction
Treatment of refluxing chronic venous insufficiency nowadays has entered a new era. Now, models of venous ablation with minimally invasive surgery have replaced surgery. Performing venous ablation requires the use of tumescent anesthesia instilled locally deep to the saphenous fascia. This application of tumescent anesthetic made the procedure lengthy with some difficulty. It is supposed that application of ice cold saline topically on the skin leads to anesthetic effect and absorbs the heat generated to the surrounding area and adds ease to the procedure as well.

Patients and methods
A total of 40 patients with Doppler-confirmed great saphenous vein insufficiency underwent radiofrequency ablation between July 2017 and May 2019. Patients were divided into two groups according to anesthetic management. Group A consisted of 20 patients who received tumescent anesthesia before the ablation procedure, and group B consisted of 20 patients who received local hypothermia and compression technique, and no tumescent anesthesia was administered. The visual analog scale was used and recorded. Clinical examinations were performed at each visit, and Doppler ultrasonography was performed in the first and sixth month.

Results
Mean ablation time was significantly lower in group B compared with group A. The immediate occlusion rate was 100% for both groups. Visual analog scale was higher in group B. All patients returned to normal activity within 2 days. The primary closure rate of group A was 90% and group B was 100% at 6 months, and there was no significant difference between the groups ($P>0.05$) regarding primary closure, but there was a difference regarding the cost and length of procedure in favor of group B.

Conclusion
The topical application of ice cold saline during venous ablation led to less lengthy procedural time with effectiveness.

Keywords:
radiofrequency ablation, tumescent, tumescentless, varicose veins

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Introduction

The incidence of varicose veins ranges between 25 and 40% of the population [1]. In primary varicose vein, some pathological changes are observed within the wall and endothelium of the affected vein, such as change in the endothelium, in inflammatory molecules, and in the structure of the wall and valves, ending eventually to dilated tortuous veins. Varicose veins are predisposed to genetic and environmental factors [2]. Nowadays, the use of minimally invasive procedure has replaced the open surgical intervention for dealing with the affected vein [3]. The technology of radiofrequency (RF) depends on generating magnetic and electric waves through the affected venous wall. This leads to heat generation (95–120°C) with destruction of the endothelium, collagen denaturation, lumen obliteration, and shortening and thickening of the treated-segment venous wall [4]. The generated heat energy should be directed to the venous wall only with prevention of its dispersion to adjacent tissue. Application of tumescent anesthesia is mandatory to complete that action. It is composed of 450-ml normal saline, 20-ml lidocaine 1%, 10-ml sodium bicarbonate, and 1-mg epinephrine [5].

Nonthermal and nontumescent ablation techniques were introduced for treatment of varicose veins.

ClariVein was the first device introduced to perform mechanochemical ablation of saphenous veins, which has shown good results in the initial studies [6].

Another recently introduced nontumescent device is VenaSeal using cyanoacrylate for ablation of refluxing veins. After the initial safety studies in animal and then further studies in humans, short-term follow-up data regarding the efficacy, feasibility, and safety of this technique are available [7].

There are also studies in the literature that review the efficacy of cyanoacrylate, but none of these studies were designed to evaluate the cost-effectiveness of treatments of venous insufficiency. In a prospective randomized study comparing cyanoacrylate glue and LASER or radiofrequency ablation (RFA), cyanoacrylate was recommended as a safe, simple method that could be used as an effective endovenous ablation technique. This method is quick and does not involve tumescent anesthesia, compression stockings, paresthesia, burns, marks, or pigmentation [8].

A new device, the ClariVein mechanochemical ablation device (Vascular Insights, Madison, Connecticut, USA), has been introduced, which avoids the use of heat and tumescent infiltration. It combines an endovenous mechanical method using a rotating wire with simultaneous injection of liquid sclerosant. The wire rotates at 3500 rotations per minute, injuring the venous intima while the sclerosant is infused through an opening close to the catheter tip [9].

Patients and methods

This was a prospective randomized controlled study performed at the Vascular Surgery Unit in Beni Suef University Hospital from July 2017 to May 2019. A total of 40 patients were enrolled in the study. Informed consents were obtained.

Ethical considerations: The study was approved by the ethical committee of the Faculty of Medicine, BeniSuef University. An informed consent was approved, given the minimal risk to patients of the research conducted as it is an observational study with confirming confidentiality of the data.

Inclusion criteria were (a) symptomatic patients who have incompetent saphenofemoral junction and great saphenous vein (GSV) reflux, including (b) all ages and sexes.

Exclusion criteria were (a) patients with past history of deep venous thrombosis (DVT), (b) patients with recurrent varicose veins, (c) patients with connective tissue disorders, (d) patients with incompetent sapheno-popliteal junction, and (e) patients with very superficial position of GSV or tortuous course.

All patients underwent the following.

Preprocedural preparation included the following: (a) history taking, where full personal and medical history was taken; (b) clinical examination; (c) duplex mapping, to document the patency of the deep veins and to evaluate the extent and severity of the reflux in the superficial venous system (GSV, small saphenous vein, and perforators), and also the depth of GSV is assessed to determine the suitability for RFA; and (d) obtaining a written consent, after which the patients were randomized using a simple card numbering randomization method.

Radiofrequency ablation procedure

In both groups of patients, a catheter electrode was used to deliver a high-frequency alternating RF current that leads to venous spasm, collagen shrinkage, and physical contraction.

In group A, the procedure was done using local tumescent anesthetic in the operating theater. The local tumescent anesthetic is previously prepared by 20-ml xylocaine 1%, 20-ml 8.4% sodium bicarbonate and 1-ml adrenaline, in 500-ml saline kept at low temperature. The patient's leg is prepared with antiseptic solution and draped in a sterile fashion. With ultrasound guidance, the vein is cannulated percutaneously. The catheter used was the '7 F Closure FAST.' The catheter was then introduced through a 7-F sheath up to a point 2 cm before the saphenofemoral junction under ultrasound guidance. Then local tumescent anesthetic is then injected within the saphenous fascia around the target venous segment using a spinal anesthesia needle.

In group B, instead of local tumescent anesthesia, a local hypothermia technique was used (external compression with iced saline; +4°C) to prevent skin burn.

Postprocedural management

After RF treatment, patients were bandaged around limbs that had been treated to minimize bruising. Patients were discharged from hospital on the day of surgery. Two hours after the procedure, the patients were asked to indicate the intensity of current, best, and worst pain levels on 'The visual analog scale': a scale of

0 = no pain, 1–3 = mild, 4–6 = moderate, 7–9 = severe, and 10 = worst pain imaginable)

Patients were reviewed after 1 week to replace bandages with medical elastic stockings and to check for DVT by duplex ultrasound. Patients were reviewed postoperatively at 1, 3, and 6 months, to assess the outcome of these treatments.

Clinical results were assessed at the time of examination in hospital. Duplex ultrasonographic assessments were done at 1, 3, and 6 months postprocedurally.

Results

The current study was conducted at the Vascular Surgery Unit in Beni Suef University Hospital from July 2017 to May 2019 involving 40 patients presenting with GSV incompetence.

They were randomly grouped into two groups, with 20 patients in each group. Group A patients were treated with RFA and tumescent, and group B patients were treated with RFA without tumescent (Tables 1–4).

Figure 1 shows mean GSV diameter differences between both the groups.

Discussion

Till recently, the standard treatment for refluxing GSV was stripping. However, with the emergence of vein ablation aided by RF or laser, it became the preferred minimally invasive procedure of choice in those patients. Moreover, the early return to work with minimal postoperative pain is considered a great advantage [10]. In this study, we compared the nontumescent technique in RFA of GSV reflux with the standard tumescent technique. The mean age group for the tumescent group was 35.9±11.2 years, whereas the mean age group for the nontumescent group was 36.4±11.2 years, and of a total of 40 patients,

Table 1 Comparison between patients' characteristics in the two studied groups

Characteristics	Technique		*P* value
	Tumescent (20) (100%)	Nontumescent (20) (100%)	
Sex			
Males	10 (50)	12 (60)	0.999
Females	10 (50)	8 (40)	
Age			
Mean	35.9	36.4	
SD	11.2	11.2	
Minimum	20	24	0.921
Maximum	55	56	
Median	35.5	36	
BMI			
Mean	29.8	29.8	0.997
SD	2.48	3.36	
Minimum	26.7	24.8	
Maximum	32.9	37.6	
Median	29.8	29.9	

It shows no significant difference between both groups regarding patients' characteristics (age, sex, and BMI). *P* value more than 0.05 (nonsignificant).

Table 2 Comparison between the two studied groups regarding the main complaint and treated side

	Technique		*P* value
	Tumescent (20) (100%)	Nontumescent (20) (100%)	
Complaint			
Discomfort	14 (70)	16 (80)	0.606
Disfigurement	6 (30)	4 (20)	
Lower limb side			
Right	14 (70)	8 (40)	0.178
Left	6 (30)	12 (60)	
CEAP classification			
C2	6 (30)	4 (20)	0.606
C3	14 (70)	16 (80)	

It shows no significant difference between both groups regarding the main complaint, CEAP classification, and treated side. *P* value more than 0.05 (nonsignificant).

Table 3 Comparison between the two studied groups regarding the mean ablation time and number of cycles and visual analog score for pain

Characteristics	Technique		*P* value
	Tumescent (20) (100%)	Nontumescent (20) (100%)	
Time (min)			
Mean	45.6	23.3	
SD	18.7	3.4	<0.001*
Minimum	28	20	
Maximum	91	31	
Median	41.5	22.5	
Number of cycles			
Mean	10.3	7.8	
SD	3.5	1.6	0.055
Minimum	7	5	
Maximum	18	11	
Median	9.5	7.5	
Visual analog score			
Mean	4.2	6.5	
SD	1.6	1.56	0.0048*
Minimum	2	4	
Maximum	8	9	
Median	4	5	

It shows that the nontumescent technique took a significant shorter time (23.3±3.4 min) than the tumescent technique (45.6 ±18.7 min) ($P<0.001$). Regarding the number of cycles, there was no statistical significant difference between the two techniques ($P=0.055$). Visual analog scale score statistical analysis showed increased pain in group B more than group A ($P=0.0048$). *significance of shorter time in non tumescent group.

22 were males and 18 were females. In a multicenter study by Joseph *et al.* [11], males were the major proportion of patients with varicose vein (74.4), and the mean age was 46.7±14.5 years. Evans and colleagues, with the Edinburgh Vein Study 1999, concluded that chronic venous insufficiency is a disease of young adult and middle age. In males, it is usually with milder degree than females.

These results come in the same track as a study conducted by Korkmaz *et al.* [12] where 172 patients had RFA without tumescent (130 women and 42 men) and 172 had traditional tumescent technique (114 women and 58 men), with a median age of 46.1 (±10.6) and 44 (±10.2) years, respectively. Most patients of this study were classified as C2–C3 according to CEAP classification. Overall, 75% of cases were classified as C2, whereas 25% were classified as C3. The same is also seen in studies conducted by ElKaffas, Subramonia, and Korkmaz [12–14]. Regarding the patients' complaint, 75% came with the complaint of discomfort and 25% complained of disfigurement. Regarding the diameters of the GSV 2 cm from SFJ, there was a significant statistical difference (decrease in diameter after procedure) in the GSV diameters throughout the follow-up period of 1, 3, and 6 months, with a *P* value more than 0.05. In group A, the mean values of the GSV diameters decreased from 4.43 to 3.35 mm at 6-month follow-up. In group B, mean values of the GSV diameters decreased from 5.52 to 3.3 mm at 6-month follow up. Moreover, Korkmaz *et al.* [12] found no statistical significant difference between tumescent and nontumescent techniques regarding the GSV diameters.

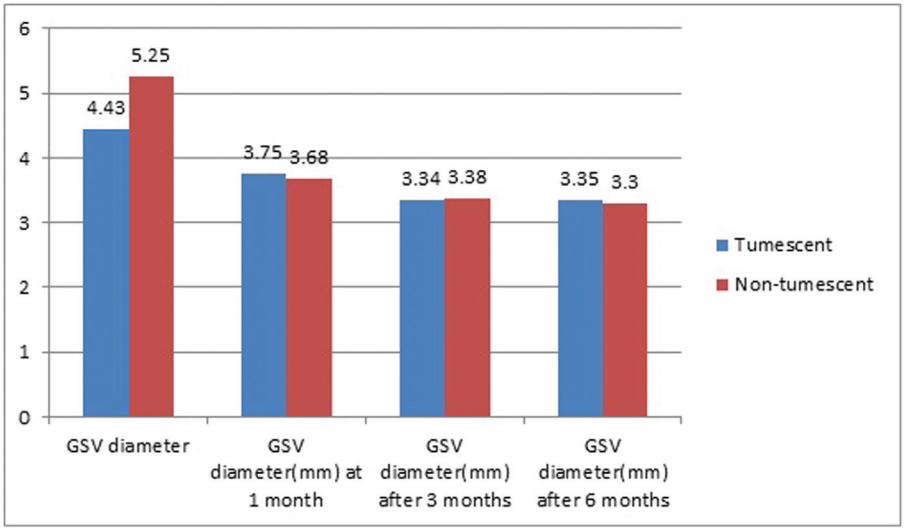
Table 4 Comparison between the two studied groups regarding the adverse postoperative sequelae

Sequelae	Technique		*P* value
	Tumescent (20) (100%)	Nontumescent (20) (100%)	
No complications	4 (20)	12 (60)	
Ecchymosis	8 (40)	2 (10)	
Thrombophlebitis	4 (20)	0 (0)	
Paresthesia	2 (10)	0 (0)	0.148
Hematoma	1 (5)	1 (5)	
Burn and ecchymosis	2 (10)	0 (0)	
Partial occlusion with reflux	1 (5)	1 (5)	

It shows no significant difference between both groups regarding postoperative sequelae and complication; however, complication rate was relatively more in group A. *P* value more than 0.05 (nonsignificant) regarding postoperative sequelae.

Regarding technique of nontumescent group B, local hypothermia and compression technique: external compression with Doppler probe for preventing extension of the thrombus to the deep venous system, and external compression with ice and dampening of the skin with saline (+4°C) to prevent skin burn. This was the same technique followed by other studies, such as Korkmaz *et al.* [12]. A total of 344 patients with Doppler-confirmed GSV insufficiency underwent RFA. Patients were divided into two groups according to anesthetic management. Group 1 consisted of 172 patients who received tumescent anesthesia before the ablation procedure, and group 2 contained 172 patients who received a local hypothermia and compression technique, and no tumescent anesthesia was administered.

Figure 1



Mean GSV diameters preoperatively and postoperatively. GSV, great saphenous vein.

Mean ablation time was significantly lower in group B (45.6±18.7 min) compared with group A (23.3 ±3.4 min). *P* value was less than 0.001. Korkmaz had the same result with shorter mean ablation time for both groups (7.2 min for the nontumescent group versus 18.9 min for the tumescent group). ElKaffas's results showed mean±SD time of 40±12 min to infiltrate tumescent and ablate the vein. Abd El-Mabood used spinal anesthesia in some and general anesthesia in other cases. He had a mean time of 62.5 ±5.4 min [12,13,15].

All patients went home on the same day and returned to daily activity within 1 week. One of our patients of the tumescent group had a complication of partial reflux with incidence 10%, whereas Korkmaz had a primary closure rate of 98% in the tumescent group and 98.8% in the nontumescent group, with no statistical significant difference between the groups [12]. Jin *et al*. [16] treated 183 limbs with GSV incompetence using RFA and reported an occlusion rate of 97.7% with detection of recanalization of the saphenous vein in 20 limbs at the 1-year follow-up. Another study was conducted by ElKaffas, where a total of 180 patients with saphenofemoral junction and great saphenous reflux detected on duplex were randomized to either ultrasound-guided RFA or standard surgical treatment; in six (6.6%) patients of RF group, the GSV was not occluded, and they required further intervention [13]. Hingorani *et al*. [17] and Puggioni *et al*. [18] showed 96% primary occlusion rate and 100% occlusion rate after RFA, respectively.

Burn is an unpleasant complication that occurred in two patients of the tumescent group with an incidence of 10%, whereas no burn occurred in the nontumescent group, with no statistical difference. Notably, this burn occurred at the site of puncture most probably during pull-out of the catheter, not attributed to the ablation procedure. Merchant and Pichot [19] reported an incidence of 1.8–0.5% of skin burn despite the use of tumescent anesthesia. Merchant stated that burn incidence was higher in previous studies up to 8%. Minor complications occurred in both groups. They occurred in the form of thrombophlebitis along the course of treated GSV (20% of group A and 0% of group B), paresthesia (10% of group A and 0% of group B), and hematoma, which spontaneously resolved during follow-up (5% of group A and 5% of group B). They did not show significant statistic difference, with *P* value of 0.148, but generally complication rate in group B was less than in group A. ElKaffas reported less incidence of complications in 90 patients: paresthesia (10%), pain (13.3%), thrombophlebitis (6.6%), and hematoma (3.3%). None developed cellulitis, edema, or skin burns. A meta-analysis that combined the results of three large trials by Nesbitt *et al*. [20] recorded an incidence of 8% of thrombophlebitis [13].

DVT or pulmonary embolism did not occur in any of our patients, although Marsh performed RFA on 2470 limbs and identified DVT in 17 (0.7%) limbs. Four were endovenous heat-induced thrombosis. Routine Doppler ultrasonography following RFA is essential to rule out DVT. Shepherd reported only one case (out of 131 cases) of pulmonary embolism following RFA but with no evidence of deep vein thrombosis [21,22].

Conclusion and recommendations

Patients presenting with refluxing GSV showed, over the whole 6-month follow-up period, an overall gradual improvement in the patients' symptoms with both tumescent and nontumescent techniques. Duplex documented recurrence in two, out of 40, patients in the short term (6 months). The nontumescent technique had significantly shortened procedural time compared with tumescent technique. Complications such as thrombophlebitis, paresthesia, and ecchymosis were higher in tumescent group in comparison with nontumescent group. Nontumescent technique is a new modified procedure in RF treatment of lower limb varicose vein that has the advantage of less time and complications in comparison with traditional tumescent method. It is similar to nontumescent nonthermal modalities of v.v. treatment such as ClariVein but these tools were expensive and not available at our unit in comparison with RFA. It appears to be safe and efficacious. Moreover, it shortens the operating time and prevents patient procedural discomfort.

However, further long-term follow-up (1–3 years or more) is required on a larger population.

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Conflicts of interest

There are no conflicts of interest.

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