Radiofrequency ablation of the great saphenous vein in the treatment of varicose veins of the lower extremities

Ann. Ital. Chir., 2022 93, 2: 235-240
pii: S0003469X22034698

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OBJECTIVE: *The present study aims to investigate the therapeutic effect and safety of radiofrequency ablation (RFA) of the great saphenous vein in the treatment of varicose veins of the lower extremities.*
METHODS: *Sixty-nine affected limbs of 45 patients were treated with RFA of the great saphenous vein. All patients underwent retrograde puncture of the distal great saphenous vein under the guidance of B-ultrasound. An RFA catheter was introduced 1 cm below the junction of the great saphenous vein and the femoral vein. A tumescent solution was injected around the femoral vein, and the great saphenous vein was ablated section by section from the upper part to the lower part. Twelve months after RFA, color Doppler ultrasound was used to evaluate the closure of great saphenous vein, and changes in the clinical class, etiology, anatomy, pathology (CEAP) classification before and after treatment were compared. The visual analogue score (VAS) was used to evaluate the local pain on the first and third day after operation. The incidence of complications (e.g., phlebitis, thrombosis, infection) was also evaluated.*
RESULTS: *The ablation of the 69 affected limbs in all the 45 patients was successful. Instant B-ultrasound revealed occlusion of the great saphenous vein and the disappearance of blood flow immediately after ablation. There was no reoccurrence in all patients at the 12 month follow-up. The CEAP classification grade after treatment was significantly lower than that before the treatment, and the difference was statistically significant (χ^2 = 4.188, P<0.05). The VAS scores on the first and third days after operation were 1.85 ± 0.35 and 0.59 ± 0.21, respectively. Pain was mild, and only two patients required painkillers. No complications were noted, with the exception of five cases of local ecchymosis.*
CONCLUSION: *RFA of the great saphenous vein may represent an effective method for treating varicose veins of the lower extremities. RFA has the advantages of producing less trauma, fewer complications, and a lower incidence of recurrence.*

KEY WORDS: B-ultrasonography, Pain, Radiofrequency ablation, Varicose veins

Introduction

Varicose veins of the lower limbs are a common and frequently observed condition in clinical settings. The main etiologies of varicose veins are as follows:

1) venous valve dysfunction that results in a reduction in blood flow back to the heart and blood congestion in the veins, subsequently leading to circuitous expansion and deformation of the veins;
2) hereditary thinned and dilated venous walls;
3) pregnancy;
4) long-term standing [1-6].

The traditional surgical method for treating varicose veins involves high-level ligation and segmental stripping of the great saphenous vein. This surgery has the disadvantages of producing massive trauma, postoperative scarring, and a long length of hospital stay [7-10]. Bipolar radiofrequency ablation (RFA) is a new type of microinvasive treatment that can directly destroy the inner

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Pervenuto in Redazione Settembre 2020. Accettato per la pubblicazione Dicembre 2020
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walls of varicose veins and produce occlusion of the blood vessels. It has the advantages of a short operation time, less trauma, less pain, fewer complications, rapid recovery, and no postoperative scar formation.[5, 10-12] From January 2016 to December 2007, 45 patients (with 69 affected limbs) with varicose veins of the lower extremities were treated by RFA of the great saphenous vein at the Sixth Medical Center of the General Hospital of the Chinese PLA and achieved satisfactory results. These cases were retrospectively studied and are reported on in the present article.

Materials and Methods

Clinical Data

From January 2016 to December 2019, 45 patients with varicose veins of the lower extremities were treated with bipolar RFA (Olympus, Japan) at the Sixth Medical Center of the General Hospital of the Chinese PLA. Of these patients, 18 were male and 27 were female, and the average age was 57.5 years (37-75 years). The course of the disease ranged from eight to 20 years, with an average of 12.5 years. Nineteen cases were unilateral, and 25 were bilateral. A total of 69 affected limbs belonging to 45 patients were treated with RFA. According to the clinical class, anatomy, etiology, pathology (CAEP) classification standard of varicose veins, 12 affected limbs were grade 2 (varicose veins without skin changes), 20 were grade 3 (varicose veins with edema), 18 were grade 4 (with skin changes caused by venous diseases, such as pigmentation and eczema), 10 were grade 5 (with skin changes caused by venous diseases and healed ulcers), and nine were grade 6 (with skin changes caused by venous diseases and active ulcers). Before the operation, clinical examination and color Doppler ultrasound showed venous reflux caused by venous insufficiency of the lower extremities. Deep veins and superficial veins were unobstructed and were without thrombosis. The location and length of the ablated veins were determined before the operation. Routine blood examination was conducted, and coagulation function, blood glucose, hepatic function, and renal function were assessed. All patients provided signed informed consent.

Perioperative Nursing

Preoperative psychological nursing and preoperative preparation

RFA of the great saphenous vein represents a new method for treating varicose veins of the lower extremities. Some patients are nervous prior to operation because they are not familiar with what is involved in RFA. Responsible healthcare providers should educate patients and explain the operation process in easy-to-understand language. In the patients included in the present study, the great saphenous vein was punctured in the lower medial thigh, and the radiofrequency electrode was introduced through the 6F vascular sheath to close the reflux of the great saphenous vein. Patients were awake during the operation, which was completed under local anesthesia. The patients generally did not suffer from severe pain during the operation and were able to get out of bed immediately following the operation. Explaining the above trajectory of the operation to patients may be helpful in obtaining their cooperation, reducing fear and anxiety, thereby benefitting the performing of the operation itself.

Preoperative preparation

Prior to the operation, the patients were instructed to bathe and prepare the skin of the affected limb by removing body hair. When preparing the skin, care was taken to avoid skin injury. Attention was paid to the original ulcer site while making sure not to injure the skin. Patients with active ulcers had their dressing changed. Catheters were preset for patients with prostate hypertrophy and frequent urination.

Intraoperative cooperation and nursing

The patients were positioned in a supine position on the DSA operating table, and the surgical field was disinfected.

The affected limb was rotated outward, and the knee joint was bent 90 degrees to fully expose the puncture site.

The great saphenous vein was punctured retrogradely through the medial skin of the distal thigh under the guidance of ultrasound. The 6F vascular sheath was introduced into the saphenous vein, and the ablation electrode was inserted into the catheter 1cm below the junction of saphenous vein and femoral vein. To prepare the tumescent anesthetic solution, 50 mg procaine (or 5 ml 2% lidocaine) and 50 ml 5% sodium bicarbonate were added to 1000 ml normal saline (two bottles of 500 ml). The intraoperative dosage depended on the individual patient's specific circumstances.

To connect the tumescent solution injection pump, first, an 18G puncture needle and tumescent injection tube were opened on the operating table. The surgeon connected the injection tube to the puncture needle and handed the other end of the injection tube to the surgical nurse. The surgical nurse connected it to the outlet pipe of the injection pump, and the water inlet end was connected with the tumescent solution infusion device. The flow rate and pressure were adjusted until the surgeon was satisfied. Under the guidance of ultrasound,

tumescent anesthetic solution was injected around the great saphenous vein to separate the vein from the surrounding muscles, skin, nerves and other structures, which could avoid ablation damage to the surrounding tissues. Segmental ablation mode was used. Each ablation was 6-8 cm. The ablation started at 1 cm distal to the saphenofemoral junction. The ablation power was 18 watts, and the operator pumped the ablation electrode back and forth at the speed of 2-3 cm/s for 10-15 times. The increasing pushing resistance could be felt, which indicated that the blood was coagulated in the vein and the vein wall was adhesive to the catheter. The ablation process was completed when a high-key prompt sound the of ablation equipment appeared. Then the next ablation could be carried out. During the operation, a nurse communicated continually with the patients to monitor their feelings and comfort level in response to the puncture and location of the sheath, insertion of the catheter, injection of tumescent anesthesia, and the RFA procedure. If increased pain or other discomfort was noted during the ablation process, this was reported to the surgeon in a timely manner who would adapt the treatment to avoid complications such as burning the muscles, nerves, or skin.

After the operation, the puncture site was wrapped with accessories, and the patients were dressed in pre-prepared elastic socks. When wearing the elastic socks, care was taken to avoid skin abrasions on the lower leg due to healed or active ulcers. The distal toes were exposed from the elastic socks, and the dorsalis pedis artery was palpable. The elastic socks had a certain tension to fully compress the ablated great saphenous vein to avoid postoperative blood reflux into the great saphenous vein while walking.

After the operation, the patients were encouraged to walk around immediately and drink water to avoid deep vein thrombosis. Patients' postoperative pain was evaluated according to the visual analogue scale/score (VAS), and symptomatic treatment was adopted.

Data Analysis

The CEAP grades of each affected limb before and 12 months following treatment were evaluated and compared. Changes in the CEAP grade in 69 affected limbs of 45 patients were observed. A rank-sum test (Kruskal-Wallis test) was used to compare the change in the CEAP gradings before and after treatment. $P<0.05$ was considered statistically significant.

Results

Observation of the Puncture Site

No complications, such as phlebitis, thrombosis, and infection, were noted in any patients, and no hemorrhage and fluid leakage occurred at the puncture site. Five patients had skin ecchymosis due to tight elastic bandaging, though no complications related to RFA were observed.

Table I - *Comparison of the CEAP classification before and 12 months after the treatment.*

Group	CEAP classification (affected limb)					
	Grade 2	Grade 3	Grade 4	Grade 5	Grade 6	Sum
Before RFA	12	20	18	10	9	69
After RFA	19	21	19	9	1	69

Kruskal-Wallis test, $\chi 2=4.188$, $P<0.05$

Evaluation of Pain

The VAS scores on the first and third days after operation were 1.85 ± 0.35 and 0.59 ± 0.21, respectively. Oral nonsteroids were needed in only two patients, while 33 patients complained of mild pain that did not affect walking and sleeping.

Therapeutic Effect

The ablation of the 69 affected limbs in all 45 patients was successful. Instant B-ultrasound revealed occlusion of the great saphenous vein and the disappearance of blood flow immediately after ablation. All patients were discharged within 2-5 days of operation, and all patients' symptoms were significantly improved. All patients were followed-up for 12 months, and no reoccurrence was noted. In terms of clinical symptoms, all patients improved to varying degrees after operation. The CEAP grading 12 months after treatment was significantly lower than that before treatment. The difference was statistically significant according to the Kruskal-Wallis test ($\chi^2=4.188$, $P<0.05$; (Table I).

Discussion

RFA of the great saphenous vein represents an important method for treating varicose veins. A meta-analysis of randomized controlled trials of RFA and traditional high segment ligation (HSL) and stripping of the great saphenous vein in the treatment of chronic venous diseases of the lower extremities showed no significant difference in the operation time between HSL and RFA [13,14]. RFA was shown to be superior to HSL in terms of hematoma, inflammation, infection, and complications of phlebitis and thrombophlebitis after operation. RFA had a lower VAS pain score compared with HSL. Compared with HSL, patients who underwent RFA could resume normal

activity and return to work earlier. There was no statistical significance in the incidence of reoccurrence between the two treatments. Therefore, the short-term effects of RFA are preferable compared with HSL.

The heat energy produced by ion friction between the bipolar electrodes of RFA devices can destroy the endothelial cells of veins, causing transmural injury of veins that results in the shrinkage and collapse of the lumen, finally forming a fiber strip that blocks blood flow completely [15-19]. Heat conduction is limited from the venous cavity to the inner side of the venous wall, and injury to the surrounding muscle, nerves, and skin is minimal. Three factors should be considered in relation to the injection of the tumescent anesthetic solution into the soft tissue around the great saphenous vein before ablation: first, the veins should be isolated from the surrounding muscles, nerves, and skin to reduce heat conduction injury; second, the injection of the tumescent anesthetic solution compressed and thinned the venous cavity, meaning the bipolar ablation needle can directly contact the venous wall, which improves the ablation effect; third, after operation, the tumescent anesthetic solution between the tissues around the great saphenous vein continues to compress the great saphenous vein. Wearing elastic stockings prevents blood flow of the femoral vein to reflux to the great saphenous vein, even when the patients are in an upright position.

In the present study, good therapeutic effects were achieved in 69 affected limbs of 45 patients. The clinical symptoms improved to varying degrees, and the expected effect was achieved. No great saphenous vein reflux was noted in reexamination during the 12-month follow-up, and the CEAP classification was significantly reduced. Postoperative pain was mild; only five patients had subcutaneous ecchymosis, and no thrombosis, skin, or muscle burns, or other serious complications were observed. Therefore, RFA is worthy of further clinical application. Standardized perioperative nursing is of great importance for deepening the understanding of treatment methods, reducing patients' anxiety, improving the therapeutic effect, and avoiding complications. RFA or laser ablation of the great saphenous vein is gradually replacing traditional surgery and is becoming the main method for treating varicose veins of the lower limbs [20,21]. After RFA, the complete closure rate was 98.4%, and 99.6% of patients said they would recommended the treatment to other patients [21]. Some studies have shown that the success rate of RFA and endovenous laser ablation (EVLA) is similar, though patients with RFA experience less pain and fewer bruises during the postoperative period [22].

Riassunto

Questo studio si propone di indagare l'efficacia e la sicurezza dell'ablazione con radiofrequenza (RFA) della grande vena safena nel trattamento delle vene varicose degli arti inferiori.

Abbiamo trattato 45 pazienti, per un totale di 69 arti con RFA della grande vena safena. Tutti i pazienti sono stati sottoposti a puntura retrograda della grande vena safena distale sotto la guida dell'ecografia B, introducendo un catetere RFA 1 cm al di sotto della giunzione della grande vena safena con la vena femorale. Una soluzione anestetica è stata iniettata intorno alla vena femorale e la grande vena safena è stata asportata sezione per sezione dalla parte superiore a quella inferiore. Dodici mesi dopo la RFA, l'ecografia color Doppler è stata utilizzata per valutare la chiusura della grande vena safena e sono stati confrontati i cambiamenti nella classificazione della classe clinica, eziologia, anatomia e patologia (CEAP) prima e dopo il trattamento. Il punteggio analogico visivo (VAS) è stato utilizzato per valutare il dolore locale il primo e il terzo giorno dopo l'operazione. È stata valutata anche l'incidenza di complicanze (ad es. Flebite, trombosi, infezione).

L'intervento ha avuto successo in tutti 1 45 pazienti per complessivi 69 arti interessati.

L'ecografia B istantanea ha rivelato l'occlusione della grande vena safena e la scomparsa del flusso sanguigno immediatamente dopo l'ablazione. Non si sono verificate recidive in tutti i pazienti al follow-up di 12 mesi. Il grado di classificazione CEAP dopo il trattamento era significativamente inferiore a quello prima del trattamento e la differenza era statisticamente significativa ($\chi 2$ = 4,188, P <0,05). I punteggi VAS nel primo e nel terzo giorno dopo l'operazione erano rispettivamente 1,85 ± 0,35 e 0,59 ± 0,21. Il dolore era lieve e solo due pazienti necessitavano di antidolorifici. Non sono state osservate complicazioni, ad eccezione di cinque casi di ecchimosi locale.

In conclusione: la RFA della grande vena safena può rappresentare un metodo efficace per il trattamento delle vene varicose degli arti inferiori. La RFA ha il vantaggio di produrre meno traumi, meno complicazioni e una minore incidenza di recidive.

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Commento e Commentary

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La tecnica descritta è utilizzata da molto tempo ed i suoi vantaggi sono ben noti. Vengono riportati i risultati di un caso studio personale, per quanto non numeroso.
Le linee guida più aggiornate (anche Linee Guida Italiane SIF-SICVE) avrebbero dovuto essere inserite in bibliografia.
Gli autori, riferendosi alla chirurgia tradizionale, parlano di traumi massivi e di lunghe degenze ospedaliere, non considerando che la chirurgia ablativa tradizionale (oggi ancora necessaria in casi selezionati) può essere eseguita con approcci minimamente invasivi, in anestesia locale o loco-regionale, con il paziente essere scaricato al più tardi entro 24 ore.
Sarebbe utile riportare se i pazienti sono stati sottoposti ad una accurata valutazione ecocolordoppler emodinamica, la competenza o incompetenza delle principali valvole venose (valvola safeno-femorale terminale e pre-terminale, valvola femorale sopra-safena), lunghezza, ampiezza e durata del reflusso safeno. Tutte queste valutazioni consentono di classificare meglio i pazienti in base al loro pattern emodinamico, di adottare la corretta strategia terapeutica, oltre la classificazione CEAP.
In astratto gli autori fanno riferimento al posizionamento del catetere a 1 cm dall'SFJ, questo non è esattamente corretto; solitamente il catetere viene posizionato ad 1 cm sotto la confluenza della vena epigastrica superficiale e comunque sotto la confluenza dei collaterali SFJ superiori, in modo da consentire il lavaggio del moncone safeno.
Infine, gli autori segnalano una dimissione entro 2-5 giorni; uno dei vantaggi di RFA è la dimissione in giornata o al più tardi dopo un ricovero notturno, con pronta ripresa di ogni attività. Sarebbe utile nella discussione indagare e chiarire il motivo di questa dimissione tardiva dei pazienti.

* * *

The technique described has been used for a long time and whose advantages are well known. The results of a personal case study, however not numerous, are reported.
The most up-to-date guidelines (SIF-SICVE Italian Guidelines, too) should have been included in the bibliography.
The authors, referring to traditional surgery, speak about massive trauma and long hospital staying, not considering that traditional ablative surgery (today still necessary in selected cases) can be performed with minimally invasive approaches, under local or loco-regional anesthesia, with the patient being discharged within 24 hrs at the latest.
It would be useful to report if patients underwent an accurate hemodynamic echocolordoppler evaluation, the competence or incompetence of the main venous valves (terminal and pre-terminal saphenous-femoral valve, supra-saphenous femoral valve), length, amplitude and duration of saphenous reflux. All these evaluations allow to better classify the patients according to their hemodynamic pattern, to adopt the correct therapeutic strategy, beyond the CEAP classification.
In the abstract, the authors refer to the catheter positioning at 1 cm from SFJ, this is not exactly correct; usually, the catheter is positioned at 1 cm below the confluence of superficial epigastric vein and however below the confluence of the superior SFJ collaterals, in order to allow the saphenous stump washing.
Finally, the authors report a discharge within 2-5 days; one of the advantages of RFA is the discharge within the day or at the latest after one night hospitalization, with a prompt resumption of any activity. It would be useful in the discussion to investigate and clarify the reason for this late patients discharge.