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Mid-term results of endovenous radiofrequency ablation therapy on small saphenous vein

Küçük safen vene uygulanan endovenöz radyofrekans ablasyon tedavisinin orta dönem sonuçları

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ABSTRACT

Objectives: In the present study, we aimed to investigate the feasibility, effectiveness, and safety of radiofrequency ablation (RFA) of the small saphenous vein (SSV) and to report our mid-term follow-up results.

Patients and methods: A total of 52 patients (32 males, 20 females; mean age 44.5±11.8 years; range, 31 to 71) who underwent RFA for incompetency of SSV between January 2015 and January 2017 and who were followed for maximum 33 months were included in our study. Postoperative clinical results and risk factors for SSV sural neuritis were analyzed.

Results: Most of the patients were in Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) clinical Class 3 (n=41, 78.8%). The mean Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ2) score was 26.8±3.8. The mean diameter of the SSV was 6.6±1.5 mm (range 4.5 to 11 mm). The immediate occlusion rate was 100%. All patients returned to normal activity within two days. The CIVIQ2 scores improved significantly postoperatively from 26.8±3.8 to 12.0±4.2 (p=0.01). Post-ablation sural neuritis was diagnosed in two patients (3.8%). At six months, Doppler ultrasound showed partial recanalization in the proximal segment of the SSV in one patient (1.92%).

Conclusion: Our study results suggest that RFA offers many potential advantages over conventional surgery for incompetent SSVs and SSV reflux. However, post-ablation sural nerve injury is a common complication after RFA of SSV, although it is usually temporary. In addition, preoperative CEAP score seems to be a potential risk factor for sural neuritis.

Keywords: Chronic venous insufficiency; endovenous radiofrequency ablation; small saphenous vein.

ÖZ

Amaç: Bu çalışmada küçük safen vene (KSV) radyofrekans ablasyonun (RFA) uygulanabilirliği, etkinliği ve güvenilirliği araştırıldı ve orta dönem takip sonuçlarımız sunuldu.

Hastalar ve Yöntemler: Bu çalışmaya Ocak 2015 - Ocak 2017 tarihleri arasında KSV yetmezliği nedeniyle RFA yapılan ve maksimum 33 ay takip edilen toplam 52 hasta (32 erkek, 20 kadın; ort. yaş 44.5±11.8 yıl; dağılım 31-71 yıl) alındı. Ameliyat sonrası klinik sonuçlar ve KSV süral nörit risk faktörleri incelendi.

Bulgular: Hastaların birçoğu Klinik, Etiyoloji, Anatomi ve Patofizyoloji (CEAP) klinik sınıfı 3 olan hastalar idi (n=41, %78.8). Ortalama Kronik Venöz Yetmezlik Yaşam Kalitesi Anketi (CIVIQ2) skoru 26.8±3.8 idi. Ortalama KSV çapı 6.6±1.5 mm (dağılım 4.5-11 mm) idi. İşlem anındaki kapanma oranı %100 idi. Hastaların tümü iki gün içinde normal aktivitelerine döndü. Ameliyat sonrası CIVIQ2 skorları 26.8±3.8'den 12.0±4.2'ye anlamlı düzeyde düzeldi (p=0.01). İki hastaya (%3.8) ablasyon sonrası süral nörit tanısı kondu. Altıncı ayda, bir hastada (%1.92) Doppler ultrasonda KSV'nin proksimal segmentinde parsiyel rekanalizasyon izlendi.

Sonuç: Çalışma bulgularımız, RFA'nın KSV yetmezliğinde ve reflüsünde konvansiyonel cerrahiye kıyasla muhtemel avantajları olduğunu göstermektedir. Ancak, ablasyon sonrası süral nörit SSV'ye RFA'nın sık görülen bir komplikasyonu olmakla birlikte, genellikle geçicidir. Bununla birlikte, ameliyat öncesi yüksek CEAP skorları, süral nöritin muhtemel bir risk faktörü olarak görünmektedir.

Anahtar sözcükler: Kronik venöz yetmezlik; endovenöz radyofrekans ablasyon; küçük safen ven.

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Varicose veins are a common problem and epidemiologic studies show an overall prevalence between 20 and 60%.[1] In general, superficial venous disease has been associated with great saphenous vein (GSV) incompetence, although recent findings have demonstrated that small saphenous vein (SSV) reflux is responsible for nearly 15% of all varicose vein diseases.[2]

The standard treatment for varicose veins associated with saphenopopliteal and SSV incompetence is ligation of the saphenopopliteal junction (SPJ) with or without stripping of the SSV. However, SSV surgery is more challenging and higher recurrence and complication rates has been reported.[3-7] The anatomical location of the sural nerve (SN) is close to SSV which increases the risk of injury during the operation. Furthermore, nearly in 22% of patients the proximal SSV/SPJ cannot be identified even under preoperative ultrasound (US) localization due to the anatomical variations,[8] and this fact results in the extension of the incision during the operation which increases the risk of wound healing problems and infection in nearly 20% of cases.[9,10]

Technological development in minimally invasive endovenous ablation techniques totally revolutionized the management of varicose veins, and open surgery and stripping are no longer wise alternatives with recurrence rates of 30 to 50%[11,12] and a high incidence of SN damage being reported.[11,13,14] Excellent results proving the success of endovenous radiofrequency ablation (RFA) of the GSV has been published in several studies;[15-17] however, less is known about the safety and effectiveness of RFA of the SSV. Radiofrequency ablation is based on heating of the vein wall which causes collagen contraction and destruction of endothelium, which stimulates vein wall thickening leading to luminal contraction and vein fibrosis. Radiofrequency ablation often requires the instillation of tumescent anesthesia, although there are several studies which published excellent results of tumescentless ablation of the GSV.[18]

In the present study, we aimed to investigate the feasibility, effectiveness, and safety of RFA of the SSV and to report our mid-term follow-up results.

PATIENTS AND METHODS

A total of 52 patients (32 males, 20 females; mean age 44.5±11.8 years; range, 31 to 71) who underwent RFA for incompetency of SSV at Ankara Numune Training and Research Hospital, Turkey between January 2015 and January 2017 and who were followed for maximum 33 months were included in our study. All treated patients were symptomatic including pain, itching, cramps, restless leg and limb heaviness. Preoperatively, the clinical severity was assessed using the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification as assessed by a vascular surgeon. The study protocol was approved by the Ankara Numune Training and Research Hospital Ethics Committee and a written consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Doppler venous imaging was performed in all patients to document the extent and the severity of the reflux in SSV and deep venous system with Aloka Prosound Alpha 7 (Hitachi Aloka Medical Ltd., Tokyo, Japan) using 5- and 7-mHz linear probes. Pathological venous reflux was defined as a reverse flow persisted over 0.5 sec in response to the release calf or thigh compression with the patient standing, and after a Valsalva maneuver in the supine position. Several variables (SSV diameter at the SPJ, peak reflux velocity, and presence of the adjacent deep vein or muscle vein reflux) on Duplex scan were recorded. The quality of life (QoL) score was calculated according to the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ2) pre- and postoperatively. Only patients with documented SSV reflux and in CEAP Class 3 or above were included in this study. Patients who had impalpable pedal pulses, cardiovascular disease, inability to ambulate, deep vein thrombosis, general poor health, pregnancy, nursing or plan to become pregnant during the study, and extremely tortuous SSVs which would not allow endovenous catheterization and passage were excluded.

Intervention

Duplex US was performed in standing position to map the sources of venous reflux and we marked the skin overlying the incompetent portion of the SSV starting at the SPJ. We also assessed the presence of flow from the deep to superficial venous system in perforating veins in the thigh and calf. All operations were performed under spinal anesthesia. Two milliliter hyperbaric bupivacaine 0.5% (Marcaine Spinal Heavy, Astra-Zeneca, Lund, Sweden) was administered through L3-L4 or L4-L5 intervertebral

space for spinal anesthesia. After adequate anesthesia was maintained, all patients were placed in the prone position. The patients were draped in the usual sterile fashion from posterior mid-thigh to ankle. A linear 5- or 7-mHz probe was inserted into a sterile cover and under US guidance, and the SSV was cannulated at the mid-calf or distal third of the SSV. Following the introduction of a 0.025-inch guidewire into the SSV, a 6-Fr introducer sheath was advanced over it. The RFA catheter (ClosureFast Endovenous Radiofrequency Ablation Catheter, Covidien IIc, MA, USA) was, then, inserted into the SSV lumen and advanced to the popliteal fossa. The correct position of the RFA catheter tip was confirmed by US imaging and always positioned approximately 2 to 3 cm below the SPJ. If the proximal thigh extension of the SSV or Giacomini vein was observed, the tip was, then, placed at the knee crease. In all patients, tumescent anesthesia (500 mL normal saline, 15 mL 2% lidocaine, 20 mL 8.4% sodium bicarbonate, and 0.5 mL epinephrine [1:1000]) was administered with a 21-gauge needle. Tumescent anesthesia was infiltrated in the perivenous tissue under Duplex US to create a heat sink barrier and to separate and isolate the SSV from SN and surrounding tissue for at least 1 cm. The volume of 5 to 10 mL/cm of tumescent anesthesia was adequate to cover the ablated vein segment. The ablation procedure was performed under US guidance to ensure protection and to apply compression on SSV for aiding obliteration. Compression and local hypothermia was also supported by external compression with ice and dampening the skin with saline (+4°C). We maintained a temperature of 120°C for 20 sec for ablation of the SSV, according to the manufacturer's instructions. Intermittent 2:1 cycles of energy (40W) were delivered along the ablatable SSV with 3-cm catheter withdrawal per cycle. We also performed varicose vein excision and perforant vein ligation in most of our patients. Following procedure, the patients were discharged at same day and a Class 2 (30-40 mmHg) full-thigh graduated support stocking was worn for one month during the day. All of patients were prescribed a non-steroidal anti-inflammatory drug for three days to reduce inflammatory changes in the SSV, an antibiotic and a venoactive drug for three months. They encouraged resuming their daily activities as soon as possible.

Follow-up examinations

The patients were evaluated functionally and clinically in the third hour, first week, and first and sixth month after the procedure. After the procedure, the patients were assessed using QoL scores (CIVIQ2) and Doppler US. Patients underwent Duplex scanning at first and sixth month to assess the closure rate. Treatment-related side effects and complications, including the presence of ecchymosis, palpable induration, phlebitic reaction and neurogenic pain were recorded. At the postoperative first month, electromyographic (EMG) study of the SN was made to evaluate the SN function and latency, amplitude and conducting velocity of the nerve was measured. If a damage in SN was observed, the damage was confirmed with Doppler imaging study. The duration of all symptoms was also recorded.

Statistical analysis

Statistical analysis was performed using the PASW version 18.0 software (SPSS Inc., Chicago, IL, USA). The Mann-Whitney U-test and Spearman correlation test were used for the statistical analyses. A p value of <0.05 (two-sided) was considered statistically significant.

RESULTS

Of a total of 52 patients with incompetency of SSV were treated with endovenous RFA. Twelve patients (33.1%) were previously operated due to incompetency of GSV (6 bilateral (11.5%), 5 unilateral left (9.6%), and 1 unilateral right (1.9%)). The most of the patients was in the CEAP clinical Class 3 (41 patients, 78.8%). The mean CIVIQ2 score was 26.8±3.8. The mean diameter of the SSV of the patients was 6.6±1.5 mm (range 4.5 to 11 mm). The demographic variables are shown in Table 1, and preoperative and operative grey-scale measurements are listed in Table 2.

Tumescent anesthesia was used in all of the patients. Consistent with the preoperative mapping, all varicose veins were removed by phlebectomy in all patients (5.8±2.4 incision/patient). In 33 patients (63.5%), 3.4±1.2 perforating veins were found and ligated surgically through additional incisions.

An immediate occlusion rate was 100%. All patients returned to normal activity within two days. There were no cases of endovenous heat-induced thrombosis or deep venous thrombosis. The CIVIQ2 score was calculated pre- and postoperatively and improved significantly from 26.8±3.8 to 12.0±4.2 (p=0.01). All patients reached the six-month follow-up point. The CEAP score was also estimated in all patients and

Table 1. Demographic data of the patients

Variable	Frequency	Percentage
	n	%
Gender		
Female	20	38.5
Male	32	61.5
Prior great saphenous vein surgery		
None	40	76.9
Unilateral right	1	1.9
Unilateral left	5	9.6
Bilateral	6	11.5
CEAP class		
3	41	78.8
4a and/or above	11	21.2
Side		
Right	31	59.6
Left	21	40.4

was found to improve significantly from 3.4±0.7 to 1.6±0.5 at the sixth month follow-up ($p<0.01$). At the first month Doppler US follow-up, no recanalization was occurred. In one patient (1.9%), a superficial phlebitis in distal GSV was observed. Post-ablation sural neuritis was diagnosed in two patients (3.8%). At the sixth month Doppler US follow-up, partial recanalization in the proximal segment of the SSV was observed in one patient (1.92%).

DISCUSSION

Surgery for SSVs is more challenging, with more complications and higher recurrence rates than for GSVs. Ultrasound-guided foam sclerotherapy, endovenous ablation by laser, radiofrequency, or bipolar diathermy is the minimally invasive alternatives for obliterating the incompetent SSV with an expectations of less invasiveness and fewer postoperative complications. There is abundant literature on the treatment of GSV insufficiency; however, large comparative trials for the treatment of SSV are lacking. According to the American Venous Forum Guidelines recommend using RFA as an effective and safe treatment option for incompetence of the GSV, with a high level of recommendation;[19] however, we were able to only find three randomized control trials randomizing between different treatment modalities and the analysis of these trials showed that endovenous laser ablation (EVLA) and RFA techniques to treat SSV insufficiency had higher anatomical success rates, compared to surgery and/or UGFS.[20-22] A few reports supported the efficacy and safety of RFA for incompetent SSVs.[23,24] Park et al.[22] reported that the SSV obliteration rate was

Table 2. Preoperative and operative grey-scale and Doppler measurements

Measurement	Value	
	Mean±SD	Min-Max
Diameter of the small saphenous vein	6.6±1.5	4.5-11
Total length of ablation	23±4.9	14-36
Small saphenous vein-skin distance	3.2±1.1	1.8-6.1
Peak reflux velocity (cm/s)	45.4±14.1	

SD: Standard deviation; Min: Minimum; Max: Maximum.

93.4% at one year and 89.1% at two years after RFA.[25] Follow-up can be considered the major drawback in evaluating reliable success rate in the treatment of SSV, since most of the studies in the literature had substantial loss to follow-up or failed to report on loss to follow-up.[26] Our study had a follow-up time for six months and all patients included in our study reached to the follow-up point. Our obliteration rate was 98.1% at six months and partial recanalization in the proximal segment of the SSV was observed in one patient. A possible cause of recanalization was the high preprocedural diameter of SSV at the SPJ (11 mm) and high- preoperative peak reflux velocity which was measured as 55 cm/s.

The SN is an axial nerve formed by sensory branches of the tibial and peroneal nerves and it is distant from the SSV in the upper part of the calf and remains very close to the SSV from the apex of the calf down to the ankle.[27] The risk of neurological damage is clinically important in the surgical treatment and thermal ablation. In addition to more complex anatomy and anatomical variations of the proximal SSV and SPJ, positioning difficulties and technical challenges and its close proximity to SN makes the surgical or minimally invasive management of SSV more challenging. The high risk of failure and SN injury has deterred many vascular surgeons from traditional ligation and stripping technique. Sural neuritis after endovenous treatment of SSV incompetency has been reported variously as 1.6 to 40%.[29-31] The incidence of neurological complications may be underreported in the literature due to mild or transient complaints, lack of performing routine neurological examination, and in most studies reporting the neurological complications only subjective evaluation of the symptoms. We performed EMG study of the SN to evaluate the SN function and latency, amplitude and conducting velocity at the postoperative first month to all study group. Furthermore, if a damage in SN was observed, the damage was confirmed with Doppler imaging

study. Preoperative mapping of the SN and showing its anatomical course and relationship with SSV is important. Also, delivering the adequate amount of tumescent anesthesia to the truly mapped perivenous area and displacing the SN away from SN is very crucial in avoiding neural injury.[32] Moreover, tumescent reduces the diameter of the SSV by wrapping around the vessel and gives an opportunity to perform a better ablation. The patients whom sural neuritis was diagnosed were both males, the CEAP clinical Class 4b and they were given anti-inflammatory and antibiotic drugs before the procedure. They had more than four excised varicosities and according to the preoperative mapping they had approximately four perforant vein ligation per patient. C score of CEAP greater than 4a, the number of excised varicosities and resulting ecchymosis/hematoma and preoperative inflammatory/infectious state of the ablated limb can be the risk factors for sural neuritis, although the number of the patients in the study group was inadequate to make a statistically significant difference. The symptoms were self-limited and resolved within four weeks with anti-inflammatory medication and physical treatment. In terms of safety, no postoperative endovenous heat-induced thrombosis or deep venous thrombosis were observed. In one patient, a superficial phlebitis in distal GSV was observed. The patient was male, CEAP Class 5 and medically treated.

Another main concern associated with RFA of the SSV is postoperative recanalization and possible recurrent varicosities. Although introduction of tumescent anesthesia eliminated the vein diameter to be a factor that affects the recanalization rate,[33] preoperative peak reflux velocity, the diameter of the SSV at SPJ, presence of adjacent reflux-deep vein or calf perforator reflux and the number of excised varicosities were put forward as risk factors for recanalization.[24,34-36] In our study, at the sixth month Doppler US follow-up, partial recanalization in the proximal segment of the SSV was observed in one patient (1.92%). Possible cause of recanalization was the high pre-procedural diameter of SSV at the SPJ (11 mm) and high preoperative peak reflux velocity which was measured as 55 cm/s. This is an acceptable result and similar to results reported previously.[37,38]

The treatment of SSV incompetency with RFA is a minimally invasive procedure and do not always require general anesthesia.[39] Intravenous sedation and analgesia with opiates and benzodiazepines or propofol; it may prolong post-procedural recovery time,[40] but these are day-case procedures and a quicker return to normal activities is essential. In many centers, only tumescent anesthesia has been routinely used. Pain is a problem of tumescent application, due partly to multiple injections, and partly to the volume induced increase of subcutaneous tension. In our study group, the number of phlebectomies and incisions for perforating vein ligation was high, so only use of local tumescent anesthesia would not be able to provide adequate anesthesia and analgesia. In addition, to create a statistically homogenous group, we performed the operations under spinal anesthesia with hyperbaric bupivacaine. Hyperbaric bupivacaine allows an effective analgesia and the risk of side effect is low. Therefore, we preferred spinal anesthesia during RFA.

On the other hand, this study has some limitations, it is retrospective in nature, not randomized or blinded, and includes a small number of patients, potentially limiting the statistical power of the results. Therefore, further, large-scale studies are needed to confirm these findings.

In conclusion, RFA offers many potential advantages over conventional surgery for incompetent SSVs and SSV reflux: this treatment modality is performed with on-table US imaging. It is a safe and reliable option and has a high patient satisfaction. Post-ablation SN injury is a common complication after RFA of SSV, although it is usually temporary, and surgeons should not afraid of it. There is no doubt that there would be a lot of debate about the optimal treatment choice for SSV reflux in forthcoming years. Our study demonstrates that preoperative CEAP score is a potential risk factor for sural neuritis, although further studies are indicated to confirm these findings.

Declaration of conflicting interests

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