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Original Article

The comparison of pain intensity in the patients undergoing thermal and non-thermal ablation of lower extremity veins for chronic venous insufficiency with visual analogue scale

Kronik venöz yetmezlik nedeniyle alt ekstremite venlerine termal ve termal olmayan ablasyon uygulanan hastalarda ağrı şiddetinin görsel analog skala ile karşılaştırılması

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Abstract

Aim: To compare the procedural pain intensity measured with VAS in patients undergoing thermal or non-thermal ablation of lower extremity veins for chronic venous insufficiency (CVI).

Material and Method: Patients who underwent a venous procedure, either thermal or non-thermal, in our clinic between June 2022 and December 2022 evaluated for inclusion to this retrospective study. The patients with available complete medical records in the database of the health center were included. Patients who had a history of deep venous thrombosis, thrombophlebitis, a venous intervention or who underwent open surgical venous procedure were excluded. Patients were asked to draw a line representing the intensity of the procedural pain on visual analogue scale (VAS).

Results: A total of 183 patients were evaluated and 60 (100%) patients whom complete medical records were available were included. The non-thermal ablation group included 30 (50%), the thermal ablation group included 30 (50%) patients. There were 14 (46.67%) males in non-thermal ablation group, 12 (40.00%) in thermal ablation group (P=0.602). The mean age in the non-thermal ablation group was 47.10 ± 9.84 years, 44.70 ± 8.84 years in the thermal ablation group (P=0.324). The procedure duration was significantly longer in thermal ablation group (22.70 ± 4.45 min in non-thermal ablation group vs 33.10 ± 3.64 min in thermal ablation group, P<0.001). VAS score was significantly higher in thermal ablation group (46.63 ± 15.76 in non-thermal ablation group vs 61.13 ± 10.65 thermal ablation group, P=0.001).

Conclusion: The endovenous non-thermal ablation of vena saphena magna (VSM) with cyanoacrylate is a more comfortable and less painful alternative for the thermal ablation technique for the patients with CVI.

Keywords: Chronic venous insufficiency; cyanoacrylate; radiofrequency; vena saphena magna; thermal ablation.

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Öz

Amaç: Kronik venöz yetmezlik için alt ekstremite venlerine termal veya termal olmayan ablasyon uygulanan hastalarda VAS ile ölçülen işlemsel ağrı yoğunluğunu karşılaştırmak

Gereç ve Yöntemler: Haziran 2022 ile Aralık 2022 tarihleri arasında kliniğimizde termal veya termal olmayan venöz girişim uygulanan hastalar bu retrospektif çalışmaya dahil edilmek üzere değerlendirildi. Sağlık merkezi veri tabanında tıbbi kayıtları tam olan hastalar dahil edildi. Derin ven trombozu, tromboflebit, venöz girişim öyküsü olan veya açık cerrahi venöz girişim uygulanan hastalar çalışma dışı bırakıldı. Hastalardan görsel analog skala (VAS) üzerinde işlem sırasındaki ağrının şiddetini temsil eden bir çizgi çizmeleri istendi.

Sonuçlar: Toplam 183 hasta değerlendirildi ve tıbbi kayıtları eksiksiz olan 60 (%100) hasta dahil edildi. Termal olmayan ablasyon grubu 30 (%50), termal ablasyon grubu 30 (%50) hastayı içeriyordu. Termal olmayan grupta 14 (%46,67), termal ablasyon grubunda 12 (%40,00) erkek vardı (P=0,602). Ortalama yaş termal ablasyon uygulanmayan grupta 47,10 ± 9,84, termal ablasyon uygulanan grupta 44,70 ± 8,84 idi (P=0,324). İşlem süresi termal ablasyon grubunda anlamlı olarak daha uzundu (termal olmayan grupta 22.70 ± 4.45 dk ve termal ablasyon grubunda 33.10 ± 3.64 dk, P<0.001). VAS skoru termal ablasyon grubunda anlamlı olarak yüksekti (termal ablasyon olmayan grupta 46,63 ± 15,76 ve termal ablasyon grubunda 61,13 ± 10,65, P=0,001).

Tartışma: Kronik venöz yetmezlikli hastalarda vena safena magna'nın (VSM) siyanoakrilat ile endovenöz termal olmayan ablasyonu, termal ablasyon tekniğine göre daha konforlu ve daha az ağrılı bir alternatiftir.

Anahtar Kelimeler: Kronik venöz yetmezlik, siyanoakrilat, radyofrekans, vena safena magna, termal ablasyon

Introduction

Varicose veins are the enlarged subcutaneous veins mostly seen in the lower extremity and mainly caused by the chronic venous insufficiency (CVI). The prevalence of varicose veins of the lower extremity is about 25.1%, chronic venous insufficiency is about 16% and it is slightly higher in women (1,2). Clinical manifestations and symptoms vary from eczema, hyperpigmentation, leg heaviness, pedal swelling, pain and chronic ulcers which significantly diminish the quality of life of patients (3,4).

There are thermal and non-thermal treatment options for CVI. Non-thermal treatment modalities include venoactive drugs such as flavonoids, calcium dobesilate, etc., sclerotherapy, glue ablation (cyanoacrylate), compression stockings and vein stripping (5–7). Thermal treatment options include ablation of the vein with the heat energy of radiofrequency, laser, and steam (8,9). A tumescent anesthesia is generally needed for thermal modalities and non-thermal interventions are usually performed under local anesthesia (6,9–11).

Visual analogue scale (VAS) is a psychometric response measurement tool to evaluate subjective characteristics or attitudes such as pain or symptom severity in medicine. It has been used in several medical studies to evaluate the pain before or after a procedure or during the course of a disease (12–14).

Herein, we aimed to compare the procedural pain intensity measured with VAS in patients undergoing thermal or non-thermal ablation of lower extremity veins for chronic venous insufficiency.

Material and Methods

Patients who underwent a venous procedure, either thermal or non-thermal, in our clinic between June 2022 and December 2022 evaluated for inclusion to this retrospective study. The patients with available complete medical records in the database of the health center were included in this study. Patients who had a history of deep venous thrombosis, thrombophlebitis, a venous intervention or who underwent open surgical venous procedure were excluded. Preprocedural informed consent was taken from all of the patients. Local ethical committee approval was taken to conduct the study.

Patients were asked to express the intensity of pain they felt during the procedures by drawing a line starting from point 0 to point 100 on a VAS. It was explained to the patients that the longer the line, the more intense the pain.

The procedure length was measured starting from the first vein puncture until completion of the vein ablation and recorded. The length of the treated vein segment was measured with a sterile ruler in the procedure. All patients were checked for the presence of a non-diagnosed venous thrombosis and the diameter of the target veins were measured to check the indication for intervention in the beginning of the procedures.

The procedures

All procedures were done in the operating room. Non-thermal ablation procedures were performed under local anesthesia. Thermal ablation procedures were performed under spinal anesthesia or femoral nerve block of the target extremity and radiofrequency-powered catheters were used in all of them.

In non-thermal ablation procedures, after proper cleaning and covering the surgical site with surgical cloths, the vena saphena magna (VSM) was accessed with a micro puncture introducer set. A 0.035-inch J guidewire was inserted with the guidance of ultrasonography probe into the vein. Then a 5F introducer sheath was advanced over the J guidewire followed by introduction of the 4F delivery catheter. The delivery catheter was filled with cyanoacrylate and attached to the injection gun of the system. The system injected 0.3 cc cyanoacrylate in every pressing of the trigger for 5 seconds. The catheter was pulled back 2 cm per second while pressing the trigger of the delivery gun. In this method, 0.03 cc cyanoacrylate was delivered in every centimeter of the vein. Extrinsic pressure was applied over the vein for proper adhesion of the vessel wall. The following products were used in the non-thermal venous ablation procedures Venex (Vesta Medical Devices, Ankara, Turkey), VariClose Vein Sealing System (Biolas, Ankara, Turkey) and Musyan (Neogenix, Ankara, Turkey).

In the thermal ablation procedures, tumescent anesthesia was also applied in addition to the spinal anesthesia or femoral nerve block to prevent skin thermal injury. A solution of 35 mg lidocaine in a 500 ml saline was used for the tumescent anesthesia and it was injected around the target vein under ultrasonography guidance. In these procedures, the VSM was cannulated near the most distal point of the venous reflux and the catheter tip was placed 1.5 to 2 cm distal to the saphenofemoral junction under ultrasonography guidance. All the thermal procedures were done with 7 cm radiofrequency-powered heat generating coils (ClosureFast, Medtronic, Minneapolis, USA and FCare, Berchem, Belgium). The radiofrequency (RF) catheter was passed through the vein with the application of the thermal energy in every 7 cm long segments with an overlap of 0.5 cm and the energy was applied for 20 seconds in every segment. Extrinsic pressure was applied over the vein during the procedures.

All the patients were transferred to the inpatient ward and discharged in the same day. All procedures were resulted with technical success.

Statistical analysis

The Statistical Package for The Social Sciences (SPSS version 16.0 Inc., Chicago, IL, USA) software was used to statistical analyzation of the data. Categorical data were expressed as numbers and percentages. Continuous data were presented as mean ± standard deviation (SD). The Kolmogorov-Smirnov test was used to test the normality of data distribution. Categorical data were tested with Chi-square and Fisher's Exact tests and continuous data were tested with independent samples t-test. The non-parametric continuous data were tested with Mann-Whitney U test. P values <0.05 was accepted as statistically significant.

Results

A total of 183 patients were evaluated. The complete medical records of 60 (100%) patients were available and they were included in this study. The first group (non-thermal ablation) consisted of the patients (n=30) who underwent non-thermal venous ablation procedures and the second group (thermal ablation) consisted of the patients (n=30) who underwent thermal venous ablation procedures. There were 14 (46.67%) males in the first group and 12 (40.00%) males in the second group (P=0.602). The mean age in the first group was 47.10 ± 9.84 years and 44.70 ± 8.84 years in the second group (P=0.324). There were no statistically significant differences between the groups in regard to the preoperative variables. The preoperative data were presented in Table 1.

The number of patients who received local anesthesia were significantly higher in non-thermal ablation group (26 (86.67%) patients in non-thermal ablation group vs 1 (3.33) patient in thermal ablation group, P<0.001). The numbers of patients who received spinal anesthesia or femoral nerve block were significantly higher in thermal ablation group (3 (10.00%) patients in non-thermal ablation group vs 12 (40.00%) patients in thermal ablation group and 1 (3.33%) patient in non-thermal ablation group vs 17 (56.67%) patients in thermal ablation group respectively, P<0.001). The procedure duration was significantly longer in thermal ablation group (22.70 ± 4.45 min in non-thermal ablation group vs 33.10 ± 3.64 min in thermal ablation group, P<0.001). VAS score was significantly higher in thermal ablation group (46.63 ± 15.76 in non-thermal ablation group vs 61.13 ± 10.65 thermal ablation group, P=0.001). The postoperative data were presented in Table 2.

Table 1. Preoperative data			
	Non-Thermal ablation (n=30)	Thermal ablation (n=30)	P value
Male n (%)	14 (46.67)	12 (40.00)	0.602
Age years mean ± SD	47.10 ± 9.84	44.70 ± 8.84	0.324
Diabetes mellitus n (%)	7 (23.33)	6 (20.00)	0.754
Hypertension n (%)	5 (16.67)	3 (10.00)	0.445
Smoking n (%)	7 (23.33)	12 (40.00)	0.165
COPD n (%)	2 (6.67)	1 (3.33)	0.550
Bilateral venous insufficiency n (%)	12 (40.00)	9 (30.00)	0.417
CAD n (%)	11 (36.67)	23.33)	0.260
Urea mg/dl mean ± SD	30.64 ± 9.39	29.62 ± 10.01	0.684
Creatinine mg/dl mean ± SD	0.81 ± 0.32	0.75 ± 0.14	0.345
Glucose mg/dl mean ± SD	106.87 ± 31.67	96.77 ± 22.84	0.162
Venous reflux duration sec mean ± SD	5.47 ± 3.40	4.97 ± 4.97	0.585
Reflux duration other extremity mean ± SD	4.67 ± 2.64	6.56 ± 3.50	0.174
VSM diameter mm mean ± SD	5.99 ± 1.12	6.45 ± 1.35	0.159
VSM diameter other extremity mm mean ± SD	6.15 ± 1.01	6.23 ± 1.91	0.888
CEAP Classification n (%) C2	22 (73.33)	20 (66.67)	0.769
C3	5 (16.67)	8 (26.67)	
C4a	2 (6.67))	1 (3.33)	
s C4b	1 (3.33)	1 (3.33)	

COPD: Chronic obstructive pulmonary disease; CAD: Coronary artery disease; SD: Standard deviation; VSM: Vena saphena magna;

Table 2. Postoperative data				
		Non-Thermal ablation (n=30)	Thermal ablation (n=30)	P value
Treatment extremity n (%)	Right	9 (30.00)	13 (43.33)	0.105
	Left	21 (70.00)	15 (50.00)	
	Bilateral	0	2 (6.67)	
Anesthesia type n(%)	Local	26 (86.67)	1 (3.33)	<0.001
	Spinal	3 (10.00)	12 (40.00)	
		1 (3.33)	17 (56.67)	
Procedure duration mins mean ± SD		22.70 ± 4.45	33.10 ± 3.64	<0.001
Length of treated segment cm mean ± SD		31.17 ± 6.60	30.97 ± 5.75	0.784
VAS score mm mean ± SD		46.63 ± 15.76	61.13 ± 10.65	0.001

SD: Standard deviation; VAS: Visual analogue scale.

Discussion

According to the results of this study, non-thermal ablation of the lower extremity varicose veins was less painful and could be done in a shorter time when compared to the thermal ablation technique. The length of the vein to be treated had no effect on the pain perception or the duration of the procedures in this study.

Endovenous ablation of the saphenous vein (both thermal and non-thermal) for the treatment of chronic venous reflux is a widely used method and it is recommended as the first treatment choice for lower extremity chronic venous insufficiency (CVI) in the guidelines of the Society for Vascular Surgery, American Venous Forum, and European Society for Vascular Surgery (8,15). There are many advantages of the endovenous treatment methods of CVI reported in the literature over the open surgery such as higher patient comfort, lower postprocedural pain, lower rates of complications and faster recovery of the patients to the daily life (16–19).

Thermal and non-thermal venous ablation techniques have their advantages and disadvantages. Thermal ablation needs tumescent anesthesia which prolongs the procedural time, causes patient discomfort, hematoma and ecchymosis but it has lower risk of postablation thrombus extension to saphenofemoral junction (20). Non-thermal ablation technique is based on the polymerization of cyanoacrylate after its contact with plasma and blood and causes the closure of the target

vein (21). It is more comfortable for the patients because there is no thermal energy involved in its mechanism and there is no significant postprocedural side effects or complications reported in the literature (7). But Proebstle et al reported in 8 (21%) of the 38 patients undergoing non-thermal ablation of the saphenous veins postprocedural thrombus extension through the saphenofemoral junction (22). Both methods are used in our clinic in routine venous ablation procedures and it is the operating surgeon's call which method will be used.

In a randomized trial including 222 patients, the efficacy, procedural comfort and postprocedural complications after radiofrequency ablation (RF) and cyanoacrylate embolization (CAE) for symptomatic GSV incompetence were compared. After three months, the closure rates were 99% in CAE and 94% in RFA. The intensity of the pain during the procedures were similar in both groups. But there was less ecchymosis in the treated region after CAE in comparison to RFA (P<0.01) (23).

There are some studies comparing another thermal energy based endovenous ablation technique, the endovenous lase ablation (EVLA), with the RFA technique in terms of procedural pain, ecchymosis and tenderness. Almeida et al (24) treated 87 veins in 69 patients with either ClosureFast or 980-nm EVLA for CVI in their randomized study. They reported significantly lower scores related with pain, ecchymosis and tenderness in ClosureFast group at 46 hours, 1 week and 2 weeks. They also reported more prevalent minor complications in EVLA group (P=0.210). Sheperd et al (25) treated 131 CVI patients randomly either with EVLA or RFA. They reported lower postprocedural pain scores over 3 days in RFA group (26.4 ± 22.1 mm for RFA vs 36.8 ± 22.5 mm for EVLA, P=0.010). The most common choice of thermal ablation technique in our center is also the RFA technique.

In their study Morrison et al (23) reported lesser mean procedure time in CAE group than RFA group (24 vs 19 minutes, P<0.01). On the contrary, Bozkurt et al (20) compared 156 CVI patients treated with EVLA and 154 CVI patients treated with CAE and reported lower mean procedure time in CAE group (33.2 ± 5.7 minutes in EVLA group vs 15 ± 2.5 minutes in CAE group, P<0.001). The mean procedure time was significantly lower in non-thermal ablation (CAE) group in our study.

In thermal endovenous ablations, a mean local anesthesia volume of 10 – 12 ml/cm administration to the perivenous space is recommended for the tumescent anesthesia in the literature (26). Another anesthesia technique is the combination of general anesthesia with supraglottic device and tumescent anesthesia in EVLA procedures to reduce patients' discomfort and pain (27). In their study Lafçı and Budak (28), compared the patients undergoing RFA for CVI under general anesthesia or spinal anesthesia. They reported significantly lower pain scores at 1 hour in spinal anesthesia group (0.1 cm vs 1.7 cm, P<0.001). Also duration in the operating room and surgery times were significantly lower in spinal anesthesia group (45.2 ± 0.2 minutes versus 43.9 ± 0.4 minutes, P<0.01; and 28.1 ± 0.2 minutes versus 26.5 ± 0.3 minutes, P<0.001, respectively). The anesthesia types used in the groups were significantly different in our study. The non-thermal ablations (CAE) were performed in local anesthesia because there was no thermal energy application in the procedure and the main source of pain in the procedure was the vein puncture for vascular access. The thermal ablations were performed either under spinal anesthesia or femoral nerve block because the thermal energy application was a painful procedure. Also perivascular tumescent anesthesia was also administered in addition to spinal anesthesia or femoral vein block to prevent skin burns and reduce postprocedural discomfort.

Limitations of the study

The main limitations of this study was its retrospective nature and it was a single center study. Also only one type of thermal ablation was used in this study. We did not measure the total tumescent anesthetic agent volume administered in the patients.

Conclusion

The endovenous non-thermal ablation of GSV with cyanoacrylate is a more comfortable and less painful alternative for the thermal ablation technique for the patients with CVI. We think that more prospective randomized studies should be conducted including larger patient populations on this subject.

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