Araştırma Makalesi (Research Article)

Yüzeyel Venöz Yetmezlik Tedavisinde Yeni Bir Yöntem Olarak; Ven Restorasyon Tedavisi (Vrt)

As a New Method for Treatment of Venous Insuffciency; Vein Restoration Treatment (Vrt)

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Özet

Amaç: Primer safen ven yetersizliğin tedavisinde yeni bir yöntem olan ve perkütan uygulanan Ven restorasyon Tedavisinin (VRT) 1 aylık klinik sonuçlarını sunmak.

Gereç ve Yöntemler: Kasım 2019 - Aralık 2019 tarihleri arasında izole primer safen ven yetersizliği tanısı konulan 12 hasta çalışmaya dahil edildi. Hastaların işlem öncesi safen ven bileşke ve dizüstü çapları ve reflü süreleri ölçüldü. CEAP (klinik etiyoloji, anatomi, patofizyoloji) klasifikasyonu ve Venöz klinik şiddet skorları (VCSS) kaydedildi. Ayrıca venöz hayat kalite skorları (VQOL) da kaydedildi. Ardından hastaların safen venlerinin anterior ve posterioruna perkütan olarak VRT uygulanarak safen ven çapları daraltıldı ve kapak koaptasyonu sağlandı. İşlem sonrası tekrar ven çapları ve reflü süreleri ölçüldü. Hastalar 1. ayda kontrole çağrılarak bütün parametreler tekrar değerlendirildi..

Bulgular: 12 hastanın 8'i kadın, 4'ü erkekti. Ortalama işlem süresi 15.1±2.9 dakika idi. Hastaların işlem öncesi safen ven çapları safenofemoral bileşke düzeyinde ortalama 7.6 mm, diz üstünde 6.7 mm iken, hemen işlem sonrası bileşke düzeyinde 5.2 mm, diz üstünde ortalama 6.6 mm, 1 ay sonra da yine bileşke düzeyinde ortalama 5.1 mm ve diz üstünde ortalama 4.9 mm olarak ölçüldü ($p<0.001$). İşlem öncesi reflü süresi 4-6 saniye arasında değişirken işlem sonrası hemen ve 1. ayda hiçbir hastada reflü izlenmedi ($p<0.001$). VCSS skoru işlem öncesi ortalama 10 iken; 1. ayda ayda 6 bulundu ($p<0.001$). Venöz hayat kalite skoru ise işlem öncesi 28 iken; 1. ayda 22 olarak tespit edildi ($p<0.001$).

Sonuç: Primer safen ven yetersizliğinin tedavisinde VRT uygulaması 1 aylık takip sonuçları oldukça başarılı ve tatmin edici olup uzun dönem sonuçları için daha fazla hasta sayılı randomize kontrollü klinik çalışmalara ihtiyaç vardır.

Anahtar kelimeler: Safen ven yetmezliği, perkütan tedavi, ven restorasyon

Abstract

Aim: Presenting the one-month clinical results of percutaneous Vein Restoration Therapy (VRT), a new method for the treatment of primary saphenous venous insufficiency.

Material and Methods: The study included 12 patients diagnosed with isolated primary saphenous vein insufficiency between November 2019 and December 2019. Saphenous vein junction, above knee diameters and reflux times of patients were measured prior to the procedure. CEAP (clinical etiology, anatomy, pathophysiology) Classification and Venous Clinical Severity Scores (VCSS) were recorded. Venous Quality of Life scores (VQoL) were also recorded. Saphenous vein diameters were narrowed and valve coaptation was achieved by percutaneous VRT applied to the anterior and posterior of the saphenous veins of the patients. Vein diameters and reflux times were measured after the procedure. Patients were called to check in at month 1 and all parameters were re-evaluated.

Results: Of the 12 patients, 8 were female, and 4 were male. The mean procedure time was 15.1±2.9 minutes. The saphenous vein diameters of the patients were measured as 7.6 mm at the saphenofemoral junction level and 6.7 mm at the above knee level, while 5.2 mm at the junction level and 6.6 mm at the above knee level were measured immediately after the procedure. After one month, it was again measured as 5.1 mm on the compound level and 4.9 mm on the above knee level ($p<0.001$). The reflux time before the procedure ranged from 4-6 seconds, while no reflux was observed immediately after the procedure and in the first month ($p<0.001$). The VCSS score was 6 in the first month, while the pre-procedure average was 10 ($p<0.001$). The mean Venous Quality of Life (VQoL) Score was 22 in the first month compared to 28 before the procedure ($p<0.001$).

Conclusion: The first-month follow-up results of VRT Procedure for the treatment of Primary Saphenous Venous Insufficiency are very successful and satisfactory, and more randomized controlled clinical trials including more patients are needed for long-term results.

Key words: Saphenous vein insuffiency, percutaneous treatment, vein restoration

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INTRODUCTION

Chronic venous disease occurs due to any or combination of superficial venous insufficiency, deep venous insufficiency, or peripheral venous insufficiency. Usually the cause is superficial vein insufficiency. The treatment of this condition is done adequately today with endovenous ablation methods. The saphenous vein is obliterated in all these treatment methods (1). There is no effective treatment that can be done by preserving the saphenous vein. However, about 10% of patients with venous insufficiency have non-saphenous venous reflux. It is called deep venous insufficiency only in the femoral or popliteal veins.

Primary superficial venous insufficiency is a condition that affects the quality of life and comfort of patients at least as much as other forms of venous disease. Procedures such as stripping and ligation have been used in surgical treatment of this disease (2,3). The objective of these procedures is to remove reflux by cutting or linking the saphenous vein. Nevertheless, in any of these procedures, the saphenous vein is not preserved. It is important to preserve the saphenous vein because this vein is the most widely used grafting in coronary bypass surgery. In addition, the grafting that has the best long-term opening in peripheral bypass surgery is the saphenous vein. In the case of superficial venous insufficiency, it is obvious that the procedures that preserve the saphenous vein and prevent insufficiency will be the most widely used treatment method in the future.

For this purpose a new system, inspired by compression socks (varsity socks) and developed by preserving the integrity of the vessel without obliterating the vessel, was called Venous Restoration Therapy (VRT). (FG Group, Ankara, Turkey) VRT is an innovative and promising procedure for treating superficial venous insufficiency as minimally invasive surgical intervention.

MATERIAL AND METHODS

Study Design/Model:

The study was carried out in accordance with the 1975 Helsinki Declaration at the Kahramanmaras Sutçu Imam University (KSU) Medical Faculty Cardiovascular Surgery Clinic between November 2019 - December 2019 after the approval of Kahramanmaras Sutçu Imam University (KSU) local ethics committee. 12 patients who were diagnosed with primary saphenous vein insufficiency were included in the study. The patients were all receiving medical treatment. Patients with post-thrombotic or congenital superficial venous insufficiency were not included in the study. Patients with perforating vein insufficiency were also excluded.

Saphenous Venous Insufficiency was diagnosed by Duplex Ultrasonography (DUS) performed by the radiologist. Patients with reflux time for 4 seconds or more at DUS were included in the study. Patients were informed about the application and received written consent. The severity of the disease was evaluated with CEAP (Clinical Etiology-Anatomy-Pathophysiology) classification and Venous Clinical Severity Score (VCSS). Pre-operative CEAP, VCSS, and Venous Quality of Life (VQoL) values were recorded. The patients were then re-examined by the vascular surgeon who performed the procedure in the operation room. Vein diameters and reflux times were measured and recorded.

Procedure:

VRT (Vein Restoration Treatment, FG Group, Ankara, Turkey) was applied to 12 patients between November 2019 and December 2019. The region to be treated was wiped with antiseptic solution and then covered with sterile cloth. The saphenous vein was re-evaluated at the DUS valve level after local anesthesia was applied to the region to be treated. It was then inserted into the anterior and posterior saphenous veins percutaneously with 19 G needles under DUS guidance. The needles were drawn by passing the 0.035 inch guide wire through the needle. The 6F application catheter (VRT, FG Group, Ankara, Turkey) developed by the manufacturer via wire was placed between the femoral vein and the fascia or between the saphenous vein and the fascia. Both catheters were connected to a single line. The embolization agent (with the barcode numbers 8680400437020,8680400437013 and 8680400437037, VRT, FG Group, Ankara, Turkey) in 2 separate bottles was then mixed into a single injector and injected simultaneously until the valves in the saphenous vein were coapted by the composed polymer ultrasound. After it was seen that adequate coaptation had been achieved, the process was terminated and the catheters were pulled-over.

After the procedure, the patient's vein diameters and reflux times were re-evaluated. Patients were called to examination after 3 days and clinical evaluation was performed for complications. Patients were called back for a check-up at first month, clinical and ultrasonographic examinations were performed. The CEAP, VCSS, and VQoL values were recorded again.

Statistical Method:

In the evaluation of the data, the suitability of the variables for normal distribution was examined by the Shapiro-Wilk test. The difference between repeated measurements in normal distributed variables was examined by ANOVA (variance analysis in repeated measurements). It was performed with Bonferroni from multiple comparison (post-hoc) tests. The difference between measurements in non-normal variables was examined by the Friedman test. Dunn-sidak was used from Post-hoc tests. Statistical parameters were expressed with mean standard deviation, median (minimum-maximum). Statistical significance as $p<0.05$ was accepted. The data was evaluated with IBM SPSS version 22 (IBM SPSS for Windows version 22, IBM Corporation, Armonk, New York, United States).

RESULTS

8 of the patients were female and 4 were male. The mean age was 40.1 ± 8 (34-49). 9 patients underwent right leg surgical intervention and 3 patients underwent left leg surgical intervention. The average procedure time was 15 minutes. The amount of polymer given was 1.5 cc on average **(Table 1)**.

The saphenous vein diameters performed before the procedure were 7.6 mm in the saphenofemoral junction and 6.7 mm in the above knee level, while the average saphenous vein diameter immediately after the procedure was 6.6 in the above knee level and 5.2 mm in the saphenofemoral junction. In postoperative first month, saphenous vein was measured as 5.1 mm in saphenofemoral junction and 4.9 mm in above knee level. The post-operative diameter was statistically significant compared to the pre-operative values (p<0.001). The values are presented in **Table 2**.

The reflux time before the procedure ranged from 4 seconds to continuous reflux in the saphenous veins, while the reflux time of less than 1 second in the saphenous vein was observed in one patient immediately after the procedure. No reflux has been found in other patients. It was observed in the first month that the reflux in the saphenous vein was lost in the patient. Reflux has not been found again in other patients.

Whereas the CEAP classification of patients was 3 (3-4) before to the procedure 2 (1-4) was found in the first post-operative month. Whereas VCSS values were 10 (9-12) before to the procedure 6 (4-7) were found in the first post-operative month. Once more VQoL values were 28 (25-31) before the procedure and 22 (18-25) in the first post-operative month. Post-procedure values in all 3 parameters were statistically significantly lower than pre-procedure values. The values are presented in **Table 3**.

After the procedure, none of the patients had deep vein thrombosis, phlebitis, ecchymosis or pigmentation. Clinical improvement has been observed in all patients who have undergone the procedure.

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Table 1. Descriptive data of the patients

Gender (F/M)	8/4
Age (year)	40
Treated leg (right/left)	9 - 3
Duration of the procedure (minute)	15
Amount of polymer supplied (ml)	1.5

Table 2. Vein diameters in the perioperative and postoperative periods

	Preop Junction Saphenous Vein	Preop above knee Saphenous Vein	Postoperative 1st month Junction Saphenous Vein	Postop 1st month above knee Saphenous Vein	p
Vein Diameter (mm)	17.6	6.7	5.1	4.9	<0.001*

*p <0.05, statistically difference

Table 3. Perioperative and postoperative CEAP, VCSS and VQOL values

	Preop	Postop 1st month	p
	Mean	Mean	
CEAP	3(3-4)	2(1-4)	<0.001*
VCSS	10(9-12)	6(4-7)	<0.001*
VQOL	28(25-31)	22(18-25)	<0.001*

Abbreviatios: CEAP: Clinical, etiologic, anatomic and pathopysiologic classificatio
VCSS: Venous clinical severity score; VQQL: Venous Quality of Life. *p <0.05, statistically difference

DISCUSSION

Today, saphenous venous insufficiency is treated in a short time with highly practical treatment methods for vascular surgeons. Methods used in treatment are usually performed with small surgical incisions or by percutaneous methods without surgery. Nevertheless, in all of these procedures the saphenous vein is either removed by surgery or blocked by ablation with percutaneous methods.

Vein Restoration Treatment is a treatment that corrects the function of a venous valve. By injecting a percutaneous polymer around the vein, the diameter of the vein is narrowed so that the valves can be coapted. It's just like the effect it has on compression socks (varsity socks), but it's much more effective than them, because it's directly targeted. The cyanoacrylates used in this product are non-toxic products.

In this study, a sufficient contraction in saphenous vein diameters was obtained after the procedure and valve coaptation was achieved and reflux was eliminated. While reflux continued in one patient immediately after the procedure, no patients were detected in the measurements in the first month. VCSS values of these patients decreased from 10 to 8 at the end of the first month and VQoL values decreased from 28 to 22. These results also show that patients are clinically relieved.

When we look at the literature, it is reported that different results were obtained in the attempts made to patients with primary saphenous vein insufficiency. In the study of Saraç et al., symptomatic improvement was detected in 51 patients (61.4%) in the 2-year results of surgical external valvuloplasty (EVP) on 83 patients with isolated saphenous vein insufficiency, but no improvement was observed in the remaining 32 patients and additional procedures were performed (7). Makhatilov and et al. found that 91.6% of the valves were competent in the femoral veins where they endoscopically applied external support (8). However, they also said that the severity of symptoms decreased in their patients, although they did not objectively show this. Among the surgical techniques performed to prevent saphenous vein reflux, Joh et al. reported (9) positive results in 101 extremity external banding valvuloplasty studies. They followed saphenous vein diameter and saphenous vein reflux with venous DUS similar to our study. The mean value of preoperative 6.4±1.4 mm in saphenous vein diameter was reported as 4.8±1.7 in postoperative period. Statistically significant difference was found for this parameter (p<0.01). This finding parallels our study. Our preoperative mean value for saphenous vein diameter at junction level was 7.6 mm and 5.1 mm was measured in the first month of our follow-up studies.

Budak et al. in their studies of 52 patients with saphenous vein ablation with radiofrequency, were determined that a progressive decrease in VQoL score from 26.8 to 12.0 at the end of 6 months follow-up (10). Similarly, in our study, a progressive decrease in VQoL score from 28 to 22 was observed in the first month. In a study in which 200 patients underwent saphenous vein laser ablation, Karaslan et al. found that VCSS decreased from pre-operative 8.3 to 2.2 in the 6th month (11). Similarly in our study, VCSS decreased from pre-operative 10 to 6 in the first month.

All of the methods used in all these studies are operations done by closing the saphenous vein. In our study, this method is applied percutanically in order to narrow the diameter of the saphenous vein by the expansion of the saphenous vein at the valve level. This method does not directly interfere with the vein and the polymer is injected between the vein

and the muscular fascia. Thus, the possibility of a possible venous damage is eliminated. After the procedure, the patient is not hospitalized and discharged immediately.

As a result, in this preliminary study, VRT method in the treatment of primary saphenous vein insufficiency, VRT application one-month follow-up results were very successful and satisfactory. However, since this is a preliminary study, the number of patients is very small and short-term results are presented. Randomized controlled clinical trials involving more patients are needed for long-term results.

Compliance with ethical standards

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Conflict of interests

The authors have no conflict of interests to declare.

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