INTERNAL COMPRESSION THERAPY FOR DEEP VENOUS İNSUFFICIENCY EARLY RESULTS IN PATIENTS

DERIN VENÖZ YETMEZLIĞI OLAN HASTALARDA İNTERNAL KOMPRESYON TEDAVISININ ERKEN DÖNEM SONUÇLARI

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ABSTRACT

Introduction: In the treatment of deep venous insufficiency (DVI), in addition to surgical interventions, internal compression therapy (ICT) using a paravalvular leak device, a percutaneous method, can also be employed. This study aims to present the early outcomes of ICT application in patients diagnosed with deep venous insufficiency exhibiting reflux at the saphenofemoral junction.

Methods: This study included 28 patients with deep venous insufficiency who underwent ICT. The patients were followed for 6 months. Clinical findings and venous Doppler ultrasound (USG) results were recorded. Our study was conducted with a retrospective method.

Results: There was a significant reduction in the mean reflux duration before the procedure and at 6 months post-procedure. Significant improvement was observed in the postoperative Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) scores in all patients ($p < 0.001$).

Conclusions: The aim of ICT is to narrow the vein diameter and achieve valve coaptation at the saphenofemoral junction. Consequently, we believe that ICT treatment significantly contributes to the improvement of deep venous insufficiency by preventing or reducing reflux in the venous system.

Keywords: deep venous surgery, venous reflux, deep venous insufficiency, venous insufficiency, internal compression therapy

ÖZET

Giriş: Derin venöz yetmezlik (DVY) tedavisinde cerrahi tedavilerin yanı sıra perkütan bir yöntem olan paravalvüler sızıntı cihazı ile internal kompresyon tedavisi (ICT) de kullanılabilmektedir. Bu çalışmada safenofemoral birleşkede reflü akımı olan derin venöz yetmezlik tanılı hastalarda ICT uygulamasının erken dönem sonuçlarını sunmayı amaçladık.

Yöntemler: Bu çalışmaya derin venöz yetmezliği olan ve ICT uygulanan 28 hasta dahil edildi. Hastalar 6 ay boyunca takip edildi. Klinik bulgular ve venöz Doppler USG sonuçları kaydedildi. Çalışmamız retrospektif yöntem ile yapılmıştır.

Bulgular: İşlem öncesi ve işlemden 6 ay sonra ortalama reflü süresinde anlamlı azalma görüldü. Ameliyat sonrası VCSS ve AVVQ skorlarında tüm hastalarda anlamlı iyileşme görüldü ($p < 0,001$)

Sonuç: ICT'nin amacı, safenofemoral birleşke bölgesinde ven çapını daraltmak ve kapak koarktasyonunu sağlamaktır. Sonuç olarak, ICT tedavisinin venöz sistemdeki reflüyü önleyerek veya azaltarak derin venöz yetmezliğin iyileşmesine önemli katkı sağladığına inanıyoruz.

Anahtar Kelimeler: Derin ven cerrahisi, venöz reflü, derin venöz yetmezlik, venöz yetmezlik, internal kompresyon tedavisi

INTRODUCTION

Chronic venous insufficiency (CVI) is a common disease affecting almost half of adult population. CVI can include various pathologies, ranging from insufficiency in superficial or deep vessels to their blockage. Studies show that 90% of CVI cases is superficial venous insufficiency, 30% is deep venous insufficiency and 20% is the perforating vein insufficiency (1). In addition, a wide range of clinical manifestations can be observed in patients, ranging from superficial varicose changes to chronic skin changes with ulceration. CVI can hamper people's daily activities and cause loss of work and time (2).

The presence of reflux in the deep venous system, such as the femoral vein, popliteal vein, is defined as deep venous insufficiency. Deep venous reflux (DVR) can be caused by a primary etiology such as valve absence or valve dysfunction, or it can also be a complication of proximal obstruction. In patients with DVR, symptoms are usually severe, and at least half of the symptomatic patients have DVR (3, 4).

Although there are various and effective treatment methods for the treatment of the superficial venous insufficiency, treatment for deep venous reflux and deep vein occlusions is limited to compression therapy in addition to medical treatment and wound care if there are ulcers (3).

Chronic venous insufficiency (CVI) has specific scoring methods to determine the clinical severity of the disease, with one of the most commonly used being VCSS. The scoring system consists of 10 parameters comprising clinical criteria determined by both the physician and the patient. Scoring is conducted by assigning scores ranging from 0 to 3 to the parameters to assess clinical severity (5).

The etiological causes of DVR are Es (post-thrombotic syndrome), Ep (primary deep valve insufficiency) and Ec (congenital valve malformation) according to the CEAP classification. In patients with post thrombotic syndrome (Es), serious damage to the valves occurs due to fibrosis and retraction, and valve repair might be unlikely. In primary deep valve insufficiency (Ep), there is an expansion of the valve ring due to elongation of the free edges of the valves and expansion in the commissures. This group is commonly found in the etiology of chronic venous insufficiency cases (6). In the treatment of these patients, methods such as valve reconstructions such as internal and external valvuloplasty, vein transplantation, and external tape have been reported in the literature. However, these invasive methods are technically difficult, wound complications are frequent, and success rates are low. Therefore, invasive approaches are not widely practiced today (2-7).

In the present study, therefore we applied a polymer consisting of a mixture of cyanoacrylate and hyaluronic acid between the deep vein and the muscle fascia in patients with CVI due to primary deep valve insufficiency. We aimed to evaluate the effectiveness and safety of this procedure.

MATERIALS AND METHODS

This study was initiated with the ethical approval numbered 26, dated 11.02.2021, obtained from the Ethics Committee of the Faculty of Medicine at Eskişehir Osmangazi University Hospital. Our study was conducted with a retrospective method.

A total of 28 patients admitted to our clinic with the diagnosis of primary femoral venous insufficiency between January of 2020 and June of 2021were treated with ICT. All the patients were diagnosed with femoral vein insufficiency through performing Doppler ultrasonography (DUS) by a radiologist. Although compression stockings were recommended to all of these patients, their compliances were low and all the patients were receiving medical treatment.

The patients with isolated deep vein insufficiency without concomitant superficial venous insufficiency were included in the present study. The patients with reflux of 2 sec and above in DUS were included. On the other hand, the patients with a diagnosis of postthrombotic syndrome and deep vein thrombosis, with congenital deep vein insufficiency, with valve anomalies, with superficial venous insufficiency or perforating vein insufficiency were excluded from the study.

The patients one day before and after the surgery; then one, three and six months after the surgery were checked to assess their clinical presentation and quality of life. The severity of the disease was assessed using the CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification and the Venous Clinical Severity Score (VCSS). The quality of life assessment of the patients was performed using the Aberdeen Varicose Vein Questionnaire (AVVQ) questionnaire. The results of DUS performed in the controls were compared. Success of the procedure was defined as no reflux in the deep vein valves in the early period and showing less than 1 second of reflux after six months.

All surgical procedures were performed under local anesthesia and under sterile conditions. The patients were placed on their backs and the position was given so that the lower limbs were slightly flexed. DUS was used to confirm the location of the deep vein valves and the severity of reflux. Vein diameter and reflux times were measured at the location of the valves in the femoral vein approximately 1 cm below the saphenofemoral junction.

Two 6F cannulas were inserted on the anterior and medial facets of the femoral vein in the space between the muscle fascia and the deep vein through the Seldinger method. A polymer (ICT) consisting of cyanoacrylate and hyaluronic acid (Invamed, Ankara, Turkey) was injected into the space till the gap between the valves filled. In this way, the vessel diameter was reduced. After it was confirmed that the reflux flow ended with DUS, the cannulas were withdrawn and the procedure was terminated.

Statistical analysis

While continuous data were expressed as Mean ± SE, categorical data were expressed as a percentage (%). Shapiro Wilk's test was used to investigate the conformity of the data to the normal distribution. The dependent sample t-test was used to compare the values at different measurement times with a normal distribution. IBM SPSS Statistics 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, N.Y.: IBM Corp.) was used. A value of $p < 0.05$ was accepted as the criterion for statistical signifiance.

RESULTS

A total of 28 patients were included in the present study. While 15 of them were female and 13 were male. The average age of the patients was 46 ± 11 (37 - 72). The right leg was operated in 16 patients and the left leg was operated in 12 patients. The mean duration of symptoms presented was 12 ± 8.8 years. According to the CEAP classification performed before the procedure, 11 of the patients were C4, 8 were C5 and 9 were C6 (Table 1).

Table 1: Demographic and Clinical Features

	mean ± SD	minimum	maximum
Age	46 ± 11	37	72
Average time for the symptoms (year)	12 ± 8,8		
	n	**%**	
Gender			
Male	13	46.42	
Female	15	53.58	
Operated side			
Right	16	57.14	
Left	12	42.86	
CEAP classification			
Clinic	**n**	**%**	
C4	11	39.28	
C5	8	28.57	
C6	9	32.15	

*CEAP scoring is used to determine the severity of postthrombotic syndrome. C (clinical), E (etiology), A (anatomy), P (pathology) C4: Skin Changes (Pigmentation or Lipodermatosclerosis), C5: Previously present but now healed venous ulcer, C6: Currently present active venous ulcer

The procedure was performed under local anesthesia on all 28 patients. The average amount of polymer applied was 2.8 ml (2.0 – 3.6). The mean duration of the procedure was 16.8 ± 14min, and the mean discharge time was 4.2 ± 2.5 hours. The mean distance between the end points of the valves was 3.8 mm (2.1-4.4). Dec After the procedure, cooptation was achieved on all valves.

The mean femoral vein diameter before the procedure was 12.5 ± 0.88 (10.5 - 14.8) mm but it determined to be 9.44 ± 0.76 (8.8 - 11.4) 6 months after the procedure (p < 0.001). On the other hand, while the mean reflux time before the procedure was 3.2 (2 - 8) sec it measured to be 0.2 sec (0 – 1) 6 months after the procedure (p < 0.001) (Table 2).

Table 2: Results Related to the Procedures

	(Mean ±SD)	(min - max)	p
Amount of the polymers applied (ml)	2.8	(2.0 – 3.6)	
Time for the procedure (minute)	16.8 ± 14	(12 - 25)	
Diameter of femoral vein (mm)			
Pre-operation	12.5 ± 0.88	10.5 – 14.8	
Postoperative 6th month	9.44 ± 0.76	8.8 – 11.4	**p<0.001**
Preoperative distance between the tips of the valves of the veins (mm)	3.8	2.1 – 4.4	
Reflux finding in CDUS (second)			
Pre-operation	3.2	(2 - 8)	
Postoperative 6th month	0.2	(0 - 1)	**p<0.001**

*CDUS : Color Doppler Ultrasonography

There was a significant improvement in postoperative VCSS and AVVQ scores in all patients. Before and 6 months after the procedure, VCSS scores were 9 (6 – 11.5) and 5 (4-8), respectively (p<0.001). Likewise, the AVVQ values before and 6 months after the procedure was 30 (28-35) and 19 (15-25), respectively (p<0.001). Complete recovery was observed in 6 of 9 patients with ulcers with an average duration of 8 weeks (66.6%) (Table 3).

Table 3: Complications Observed with the Patients

	n	%
Number of the patients with complications	3	10.7
Severe pain and sensitivity	2	7.1
Hematoma	0	0
Ecchymosis	1	3.5
Induration	1	3.5
Thrombophlebitis / Cellulite	0	0
Deep vein thrombosis / Pulmonary emboli	0	0

No significant morbidity or mortality related to the procedure was observed. No serious complications such as deep vein thrombosis, pulmonary embolism, phlebitis developed in any of the patients. Only two patients developed pain and sensitivity while one patient developed localized ecchymosis and induration (Table 4).

Table 4: Clinical Assessment

	Pre-operation n (min-max)	Post-operation 6 th month n (min-max)	**p**
VCSS	9 (6 – 11,5)	5 (4 – 8)	**P<0,001**
AVVQ	30 (28 - 35)	19 (15 - 25)	**P<0,001**

*Vcss: Venous Clinical Severity Score,
*AVVQ: Aberdeen Varicose Veins Questionnaire

DISCUSSION

In the present study, the short- and medium-term results of internal compression therapy (ICT) in primary deep valve insufficiency (Ep) were analyzed. The results showed that no serious side effects occurred during the 6-month follow-up. The results obtained have confirmed that the procedure was safe and feasible in the treatment of venous insufficiency.

Corrective surgery on the DVR is not often performed. Most surgens consider it risky and ineffective. In fact, this type of operation is not aggressive and the complication rate is low. However, surgical procedures are still controversial in terms of effectiveness, and there is no suitable treatment for deep venous insufficiency (8, 9).

Furthermore, CVI significantly reduces the quality of life of patients and causes significant economic burden as well as loss of productivity of the people. For these reasons, the treatment of these patients becomes even more important. Conventional treatment includes regular exercise, leg elevation, compression therapy such as compression stockings, and wound care. Although these treatment methods are very important, they usually fail due to low compliance rate of patients (8, 9).

Surgical repair or replacement of deep vein leafs was first described by Kistner in 1968 (10). Aftermath, external and internal valvuloplasty, valve transplantation and valve transposition from the saphenous vein or axillary vein, and many other open surgical procedures such as wrapping the dilated segment around the heads have been reported. These methods have not found widespread use due to the presence of wound complications and ulcer recurrence in a significant proportion of patients (8, 9). Makhatilov et al in their study in 2009 used an external endoscopic support system for the femoral valves and presented successful results. However, the number of patients treated in their study was limited to 24 (11).

Studies on the placement of prosthetic valves mounted in metal stents or similar structures by the endovascular method are mostly experimental practices. In 2021, Thodur Vasudevan et al. used a system with four integrated components, which they called the BlueLeaf system, and offered a treatment option by creating valves into the femoral and popliteal veins using an endovascular method (12). In their study, at least one monocuspid valve was successfully formed in 13 of 14 patients and no serious complications were noted. However, the number of patients in their study were few and long-term results were not available.

Moreover, ICT is a treatment method aimed at restoring venous valve functions. A polymer consisting of cyanoacrylate and hyaluronic acid is used and administered percutaneously around the vessel. Hyaluronic acid causes an increase in connective tissue, while cyanoacrylate takes

on the role of a skeleton that supports the vein environment by creating dense tissue. In this way, it is aimed to reduce the diameter of the vein and ensure the cooptation of the valves. In recent years, there are several studies available using this system (13,15). We aimed to investigate the effectiveness of ICT in the present study. All of our patients were patients with primary valve insufficiency (Ep). We excluded the patients with post-thrombotic insufficiency and valve aplasia since there is no treatment for etiologic deficiencies from the present study.

In their study in 2020, Yavuz et al. used ICT as a paravalvular leakage system in 286 patients with primary deep venous insufficiency and presented their mid-term clinical results (14). Furthermore, using the same method in 2021 Eroğlu et al. conducted a similar study and presented the clinical results of 18 months in 30 patients (13). Gultekin et al. A study of 27 patients reported a significant decrease in patients' postoperative VCSS scores (16). In all these studies, significant improvements in patients' VCSS scores were reported after the procedure and they emphasized that the ICT procedure was safe and effective. Our present study further supported their observations. In short, valve cooptation was achieved and reflux was eliminated through achieving adequate venous diameter narrowing in all our patients after ICT application. Besides, there was a significant decrease in VCSS and AVVQ values 6 months after the procedure compared to preoperative values and overall patient satisfaction was high. Finally, none our patients developed serious complications.

The most significant limitation of the current study is that it is a retrospective, single centered study and the data presented are based on records in patient files.

CONCLUSION

The vast majority of primary deep valve insufficiencies can be safely treated with ICT. Long-term results and randomized trials are needed to support the present results.

Ethics Committee Approval: The necessary permission to conduct the research was received from Eskişehir Osmangazi University Faculty of Medicine Ethics Committee (decision number 12.01.2021-26).

Informed Consent: Informed consent for the procedure was obtained from all patients, and they were informed that their data could be used in the study later.

Conflict of Interest: No conflict of interest was declared by the authors.

Authorship Contributions: Idea/Concept:CO,TT Design:ASK, TT Supervision:CO, Data Collection and Processing:ASK, TT, Analysis or Interpretation:ASK, TT Literature Search:ASK, Writing:TT, Critical Review:CO,ASK,TT, References and Fundings: ASK, TT, Materials: CO, ASK,TT.

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