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A new application of external valvuloplasty using interventional injection of N-butyl cyanoacrylate for malfunctioning venous valves

Venöz kapak yetmezliği için N-butil siyanoakrilatın girişimsel enjeksiyonunu kullanan yeni bir harici valvüloplasti uygulaması

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Ethics Committee Approval: The ethic approval of the present the study was obtained from Ethical Committee of Gaziantep University, School of Medicine (Approval number: 2020/288 Date: 9/23/2020). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.
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Abstract

Aim: Chronic venous insufficiency (CVI) is a common disorder that occurs when the venous valves are not working sufficiently. The treatment strategies depend on ameliorating the function of the valves. The aim of this study was to evaluate the external application of N-Butyl Cyanoacrylate to improve venous valves' functions.

Methods: Thirty patients with CVI who were admitted to the cardiovascular surgery clinic with CVI complaints and underwent extravenous N-Butyl Cyanoacrylate application (extravenous application to the area surrounding the malfunctioning venous valves) between January 2020 and June 2020 were included in this retrospective cohort study. Preoperative and postoperative (third and sixth month) venous Doppler ultrasound findings and complaints were noted, and the results were compared.

Results: The diameter of the great saphenous vein was found to have decreased during the postoperative period (9.27 (1.95 mm) vs. 6.27 (2.16), *P*=0.001). Decremental saphenofemoral reflux durations were detected in postoperative ultrasound evaluations when compared with preoperative data (0.77(0.87) vs. 4.77(0.97) seconds). CVI complaints, including oedema, pigmentation and restless leg syndrome, improved within months after the operation.

Conclusion: The external application of N-Butyl Cyanoacrylate gel seems effective for recovering venous valve function in the medium term.

Keywords: Chronic venous insufficiency, Incompetent venous valve, Treatment, External gel application

Öz

Amaç: Kronik venöz yetmezlik (CVI), venöz kapaklar yeterince çalışmadığında ortaya çıkan yaygın bir hastalıktır. Bu nedenle tedavi stratejileri, kapakların fonksiyonlarının iyileştirilmesine dayanır. Bu çalışmada, venöz kapak fonksiyonlarını iyileştirmek için N-Butil Siyanoakrilat'ın harici uygulamasını değerlendirmeyi amaçladık.

Yöntemler: Ocak 2020-Haziran 2020 tarihleri arasında kardiyovasküler cerrahi kliniğine CVI şikayetleri ile başvuran hastalar geriye dönük olarak kayıt altına alındı. Ekstravenöz N-Butil Siyanoakrilat uygulaması yapılan 30 hasta (fonksiyonu bozulmuş venöz kapak çevresini sarma olarak ekstravenöz uygulama) çalışmaya dahil edildi. Preoperatif ve postoperatif (3. ve 6. ay) venöz Doppler ultrason bulguları ve şikayetleri not edildi ve sonuçlar karşılaştırıldı.

Bulgular: Büyük safen ven çapı postoperatif dönemde geriledi (9,27 (1,95 mm) ve. 6,27 (2,16), *P*=0,001). Preoperatif verilerle karşılaştırıldığında, postoperatif ultrason değerlendirmelerinde azalan safenofemoral reflü süreleri saptandı (0,77 (0,87) ve 4,77 (0,97) saniye). Operasyondan aylar sonra ödem, pigmentasyon, bacakta huzursuzluk vb. şikayetler geriledi.

Sonuç: Sonuçlarımız, N-Butil Siyanoakrilat jelin harici uygulamasının orta vadede venöz kapak fonksiyonlarının iyileştirilmesinde etkili olduğunu gösterdi.

Anahtar kelimeler: Kronik venöz yetmezlik, Venöz kapak yetersizliği, Tedavi, Harici jel uygulaması

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Introduction

Chronic venous insufficiency (CVI) is a worldwide problem that affects quality of life and can result in high treatment costs for health care systems. It is responsible for almost 70% of all lower extremity vascular ulcers, which lead to prolonged hospital stays and wound care protocols [1,2]. Other CVI symptoms, such as restless leg syndrome, edema and pigmentation, result in further social and psychological problems [1,3].

Most treatment strategies consist of conservative methods, such as compression stockings, food care, exercises and venoactive drugs. However, in patients with advanced failure, these treatments cannot provide sufficient or long-term protection [4,5]. In such cases, microsurgical strategies on venous valves can be used, but they are highly invasive and controversial [5–7]. Recently, some minimally invasive treatment strategies, albeit controversial, have been reported. Banding or wrapping of the incompetent venous valve is one example of these suggested strategies [6]. External valvular stenting is another option for the treatment of venous valve incompetence in patients with CVI [7,8]. Better long-term outcomes were reported in external valvular stenting patients when compared with conventional surgical stripping. However, that also requires surgical incision [8].

Less invasive methods might be superior to surgical external valvular venous applications. Therefore, this study aimed to investigate the outcome of ultrasound-guided external N-Butyl Cyanoacrylate application to incompetent venous valves.

Materials and methods

The retrospective data of 30 CVI patients who underwent ultrasound-guided external venous valvuloplasty with percutaneous N-Butyl Cyanoacrylate gel application were examined. Ethics Approval was obtained from the local ethics committee of Gaziantep University, School of Medicine (Approval number: 2020/01). Power analysis of the study was calculated as follows: A sample size including 30 patients for the extra venous application was enough to detect a clinical significance with a type one error rate (α) of 5% and a (β) power of 0.9644. Patients who had post-phlebitic syndrome or recurrent deep venous thrombosis history were not included in the study. The demographic findings, clinical classification [according to the CEAP classification as described in previous reports [9]] and preoperative and postoperative Doppler ultrasound findings were noted.

Preoperative venous insufficiency and postoperative ultrasound follow-ups were recorded by the same radiologist with the same ultrasound device (Mindray® DP-20 Vet, Shenzhen, China). The evaluation of venous reflux with Doppler ultrasound is shown in Figure 1.

The external application of N-Butyl Cyanoacrylate gel was made with a special medical device (Viniera X™, Noegenix, Ankara, Turkey). This method depends on percutaneous puncture of the inguinal area and ultrasound-guided interventional injection of N-Butyl Cyanoacrylate in the surroundings of the incompetent venous valve (Figure 2). After detection of the saphenofemoral junction (SFJ) and incompetent venous valves with Doppler ultrasound, a 6 F sheath was placed using the Seldinger technique [10]. Thereafter, the surrounding tissue of the SFJ was dissected with a polytetrafluoroethylene catheter. N-Butyl Cyanoacrylate gel was diffusely infused just external to the surroundings of the malfunctioning venous valves of the great saphenous vein (GSV) and deep femoral vein using the Viniera X™ device (Figure 3 A, B).

Statistical analysis

The obtained data were statically analyzed using the SPSS software program (ver. 15.0, Chicago, Illinois, USA). Mean (standard deviation (SD)) was used for continuous variables, and categorical values were expressed as percentages. The preoperative and postoperative values were analyzed with the Mann-Whitney U test. The paired samples t-test was used to evaluate the significance of the difference between two variables. $P<0.05$ was considered statistically significant.

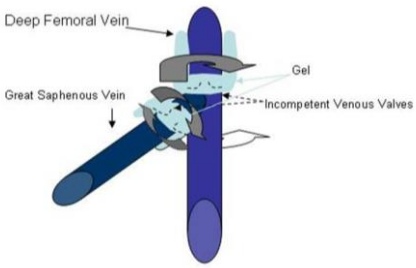

Figure 1: Illustration of N-Butyl Cyanoacrylate gel application on the surrounding area of the incompetent venous valves

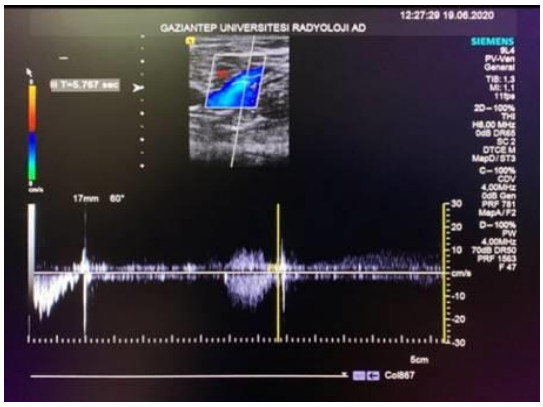

Figure 2: Colored Doppler ultrasound evaluation of venous reflux

Figure 3: A: The Viniera X™ device and contents of package (Seldinger needle, guide-wire, catheters) B: Ultrasound-guided application of Viniera X™ device in the operating room for treatment of venous reflux

Results

There were 19 (63%) male patients and 11 (37%) female patients. The mean age of all patients was 44.1 years (7.6, range 32–58 years). The accompanying conditions included hypertension (n=12, 40%), hyperlipidemia (n=5, 17%) and smoking (n=21, 70%). There were seven patients (23%) with CEAP 3 class, 11 patients (37%) with CEAP 4 class, nine patients (30%) with CEAP 5 class and three patients (10%) with CEAP 6 class. All patients were discharged uneventfully at the eighth hour of operation.

The preoperatively calculated mean GSV diameter at the level of the SFJ was 9.27mm (1.95, range 6.00–13.20 mm). Postoperatively decremental GSV diameters [6.27 (2.16) mm: range 4.20–9.40 mm] were obtained when compared with preoperative values (P=0.001). The reflux at the SFJ reduced significantly after the operation to 0.77 (0.87) seconds (range 0.15–5.22 seconds) from the preoperative value of 4.77 (0.97) seconds (range 3.12–6.43 seconds) (P<0.001). The preoperative and postoperative values are presented in Table 1. The preoperative and postoperative ultrasonographic examination (three months later) of reflux at the SFJ level is demonstrated in Figure 4.

Table 1: The comparison of preoperative and postoperative values

	Preoperative Mean (SD)	Postoperative Mean (SD)	*P*-value
GSV* diameter, mm	9.27 (1.95)	6.27 (2.16)	0.001
Reflux at SFJ**, sec	0.77 (0.87)	4.77 (0.97)	<0.001

SD: Standard deviation, GSV: Great saphenous vein, SFJ: Saphenofemoral junction

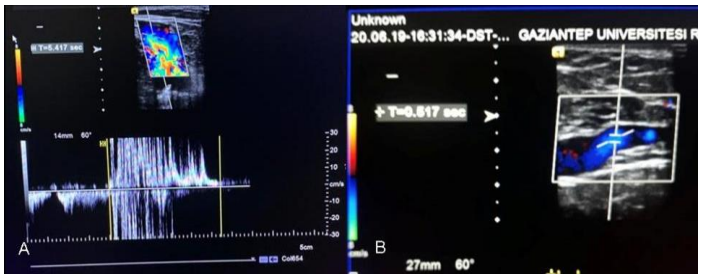

Figure 4: Preoperative and postoperative ultrasonographic examination of reflux at the SFJ level; A: Preoperative reflux; B: Postoperative reduced reflux

Discussion

Interventional treatment of venous valve incompetency seems an effective method with reduced postoperative reflux duration and decreased venous diameter. Moreover, all procedures were completed with local anesthesia, and the treatment was performed without a surgical incision. The results show that the Viniera X™ extravalvular gel application device resulted in short hospital stays and improved medium-term outcomes.

CVI is a progressive disease that can result in disrupted quality of life and socioeconomic problems. It can be easily managed and treated in its early phases; however, it can lead to chronic non-healing wounds and severe limb edema if neglected [9,11]. Conventional treatment modalities involve vasoactive drugs and compression stockings. Wound care and palliative strategies can be applied for recurrent ulcers. However, these strategies are generally directed towards the symptoms and not curative. The more precise treatment strategies consist of surgical methods for remission of complaints and recovery of venous function as much as possible [11]. Direct venous valve repair or venous valve replacement strategies are more invasive and require an experienced center [12]. There is insufficient evidence to recommend these strategies, and the exact methodology is still controversial [12,13]. Therefore, minimally invasive strategies that can be applied with less trauma have been developed. The most common strategies depend on surgically externally banding or wrapping strategies of incompetent venous valves. The long-term data present beneficial outcomes with these strategies [14]. Technically, the vein can be tightened to the desired diameter until competence is achieved, but the result should be confirmed with ultrasonographic evaluation. Valve incompetence is not sufficiently treated if not properly tightened, or venous stenosis, thrombosis or thrombophlebitis can occur [14–16]. Interventional methods without surgical incision allow simultaneous Doppler examination for evaluation of incompetent venous valves during application. External venous shaping utilizing perivenous fluids is a more recently reported technique that offers promising results. However, there is insufficient data to obtain precise evidence regarding long-term results. The ultrasound-guided application of injectable fluids can cover incompetent venous valves and improve valve function via reshaping the enlarged venous structure [17]. N-Butyl Cyanoacrylate was used in this study as an injectable fluid for ultrasound-guided vein shaping. The diameter of the saphenous veins reduced, and reflux durations shortened after the application of N-Butyl Cyanoacrylate with the newly developed medical device Viniera X™. Patient complaints regressed after application, and no operational complications were observed.

Limitations

The main limitations of this study are its small sample size and its single-center design. The findings should be confirmed with larger cohort studies.

Conclusions

Viniera X™ seems a minimally invasive and feasible method to eliminate venous reflux in patients with CVI. The ultrasound-guided application provides simultaneous confirmation of sufficient and anatomically precise injection of perivenous N-Butyl Cyanoacrylate for adequate covering of the enlarged vessels.

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