Mechano-Chemical Endovenous Ablation of Great Saphenous Vein Insufficiency: Two-Year Results

Büyük Safen Ven Yetmezliklerinin Mekano-Kimyasal Endovenöz Ablasyonu: İki Yıllık Sonuçlar

Yücel ÖZEN,[a]
Davut ÇEKMECELİOĞLU,[a]
Sabit SARIKAYA,[a]
Murat Bülent RABUŞ,[a]
Ebuzer AYDIN,[a]
Mehmet DEDEMOĞLU,[a]
Kaan KIRALİ[a]

[a]Clinic of Cardiovascular Surgery, Kartal Koşuyolu Heart Training and Research Hospital, İstanbul

Geliş Tarihi/*Received:* 05.09.2014
Kabul Tarihi/*Accepted:* 28.10.2014

Yazışma Adresi/*Correspondence:*
Yücel ÖZEN
Kartal Koşuyolu Heart Training and Research Hospital,
Clinic of Cardiovascular Surgery,
İstanbul,
TÜRKİYE/TURKEY
yucelozen74@yahoo.com.tr

ABSTRACT Objective: The objective of this study is to evaluate the reliability and 2-year results of ClariVein® device used in mechanochemical endovenous ablation of great saphenous vein (GSV). **Material and Methods:** In our clinic, 63 patients with GSV insufficiency had been treated using ClariVein® device and polidocanol for 2 years. Both legs were treated in 10 of these patients. The anatomical and clinic success were assessed by Doppler ultrasonography 6 months, 1 year, and 2 years later. **Results:** The implementation success rate of the technique was 98%. The anatomical success was found as 94% at the end of 6 months, 95% at the end of 1 year, and 95% at the end of 2 years. The venous clinic severity score was found as 3.2 (interquartile range: IQR: 2-6) after 6 months, 1.2 (IQR: 1-3, p<0.001) after 1 year, and 1.1 (IQR: 1-2, p<0.001) after 2 years. No complications developed in any of the patients. **Conclusion:** ClariVein® is a simple, reliable, and efficient treatment method for GSV insufficiency. In 2-year follow-up, the anatomical success rate was found as 95%, and no major complications were observed.

Key Words: Saphenous vein; varicose vein treatment; polidocanol

ÖZET Amaç: Bu çalışmanın amacı mekanokimyasal endovenöz ablasyonda kullandığımız ClariVein® cihazının büyük safen vende (BSV) güvenilirliğini ve iki yıllık sonuçlarını değerlendirmektir. **Gereç ve Yöntemler:** Kliniğimizde iki yıl içinde 63 hasta BSV yetmezliği nedeniyle ClariVein® cihazı ve polidokanol kullanılarak tedavi edildi. Bu hastaların 10 tanesinin iki bacağına da işlem uygulandı. Anatomik ve klinik başarı 6 ay, 1 yıl ve 2 yıl sonunda yapılan Doppler ultrasonografilerle değerlendirildi. **Bulgular:** Tekniğin uygulama başarısı %98 idi. Anatomik başarı Doppler ölçümlerinde 6. ayda %94, 1. yılda %95, 2. yılda %95 bulundu. Venöz klinik şiddet skoru (VCSS) tedavi öncesine göre 3,2 (interquartile range: IQR: 2-6) 6. ayda 1,2 (IQR: 1-3, p<0,001) 1. yılda 1,1 (IQR: 1-2, p<0,001) belirgin olarak az bulundu. Hiçbir hastada komplikasyon görülmedi. **Sonuç:** ClariVein® BSV yetmezliği tedavisinde basit, güvenilir ve etkili bir tedavi metodudur. İki yıllık hasta takibinde anatomik başarı %95 bulunmuş ve major komplikasyona rastlanmamıştır.

Anahtar Kelimeler: Safen ven; variköz ven tedavisi; polidokanol

Damar Cer Derg 2014;23(3):176-9

Venous insufficiency is a venous disease widely seen throughout the population (20-60%).[1] The development of minimally invasive procedures for the treatment of varicose veins has been led by a desire to reduce operative trauma and bruising associated with standard surgical techniques.[2] Currently, there are two major thermal endovenous treatments available: Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA). The risk of nerve injury is a major concern in endovenous ther-

doi: 10.9739/uvcd.2014-41766

mal ablation of the GSV.[3] For this reason, mechanochemical endovenous ablation techniques which do not radiate heat and do not require the tumescence have been started to be used in recent years. Recently introduced mechanochemical endovenous ablation technique using the ClariVein® catheter (Vascular Insights, Madison, CT, USA) is unique: mechanical injury to the venous endothelium is combined with simultaneous catheter-guided infusion of a liquid sclerosant. No heat is generated and, therefore, tumescent is not required. Recent studies have proven that mechanochemical endovenous ablation is a feasible and safe treatment for GSV insufficiency.[4,5] We aimed to evaluate the initial results and 2-year follow-up of mechanochemical endovenous ablation using the ClariVein® catheter in combination with polidocanol in GSV insufficiency.

MATERIAL AND METHODS

The ClariVein® was used on 73 legs of 63 patients between May 2012 and June 2014. Before the treatment, the patients were assessed in terms of Clinical severity, Etiology, Anatomy, Pathophysiology (CEAP) classification and venous clinic severity score (VCSS). In order to evaluate deep and surficial veins, Doppler ultrasonongraphy (USG) was performed in all the patients before the operation. The ClariVein® was not used in patients with history of allergy. In patients with a great saphenous vein diameter larger than 4.5 mm and Grade-4 reflux in sephanofemoral junction, ClariVein® was used. It was not used on patients with a deep venous thrombosis history or deep venous insufficiency on Doppler USG, and in the patients with peripheral artery disease. The patients who had ClariVein® implementation were called for follow up with colored Doppler USG after 6 months, 1 year, and 2 years.

OPERATION TECHNIQUE

All interventions were performed with the ClariVein® device, combined with polidocanol (Aethoxysklerol®, Kreussler Pharma, Wiesbaden, Germany) by a caridovascular surgeon in the operation room. General or spinal anesthesia was not used. The operations were performed under local anesthesia. ClariVein® device consists of 2 single-use parts. These are a 2.6 F single-lumen catheter used for injecting the liquid sclerosant, and the motor unit controlled by hand (Figure 1). By rotating at 3000 rpm speed, the catheter of this device creates damage and spasm in saphenous vein intima by means of the curved bun at its tip. Moreover, it fills the saphenous vein by foaming the sclerosant matter. Aethoxysklerol®40 mg (2%) was used as the sclerosant material. Phlebectomy was performed if patients had varicose packers. The legs of patients were kept in bandage for 48 hours.

STATISTICAL ANALYSIS

Variables are presented as mean with standard deviation (SD) or range for parametric continuous variables, as median with interquartile range (IQR) for non-parametric continuous variables and as frequencies and percentages for categoric variables. Anatomical success estimates were calculated by using Kaplan Meier analyses. Change in VCSS was analyzed with Wilcoxon signed rank test. Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) 19.0 software (SPSS Inc, Chicago, IL, USA). $p<0.05$ was considered significant.

RESULTS

The study included 73 legs of 63 patients. Of the patients, 43 were females and 20 were males. The mean age was 45.3 ±12.9 years (26-72). The demographic characteristics of the patients are given in Table 1. The technical success of the operation was found as 98% (72 of 73) in USG control after Clar-

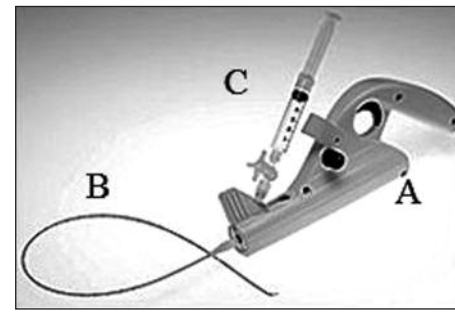

FIGURE 1: ClariVein® device consists of motor handle unit **(A)**, infusion catheter **(B)** and injector **(C)**.

TABLE 1: Patient demographics and treatment characteristics.

	n	%	Mean±SD
Total patient	63	100	
Total legs	73	100	
Bilateral operation	10	16	
Age (years)			45.3±12.9 (26-72)
Male	20	32	
Female	43	68	
GSV diameter (mm)			6 (4.7-7.8)
GSV length (cm)			42.1 (36-52)
Weight (kg)			67 (45-115)
Total polidocanol dose (mg)			124±9.2
Total polidocanol volume (ml)			6.5±1.5
Phlebectomy	21	29	
C2 (varicose vein)	46	63	
C3 (edema)	15	20	
C4 (skin change)	6	6	
C5 (ulcer scar)	4	8	
C6 (active ulcer)	2	3	

GSV: Great saphenous vein.

TABLE 2: Anatomical success.

	n	Occluded	%
6th month	72	68	94
12th month	64	61	95
24th month	42	40	95

iVein® implementation. In 10 of the patients, both of the legs were operated. Phlebectomy was performed in same session in 21 legs. Colored Doppler USG control performed after 6, 12, and 24 months. After 6 months, closure of the saphenous vein was seen in 68 of 72 legs, and the anatomical success rate was found as 94%. Similarly, the anatomical success was found as 95% (61 of 64) at the end of 1st year, and 95% (40 of 42) at the end of 2nd year (Table 2). When compared to preoperative values, the VCSS was found to be less by 3.2 (IQR 2-6) at 6th month, by 1.2 (IQR 1-3, $p<0.001$) at 1st year, and 1.1 (IQR 1-2, $p< 0.001$) at 2nd year. No major complications such as nerve damage, deep venous thrombosis or infection were observed. Local ecchymosis developed in 6 legs (8%), hardening and pain developed at injection point in 13 legs (18%), and surficial thrombophlebitis developed in 10 legs (13%).

DISCUSSION

The treatment of superficial venous insufficiency has changed dramatically in the last decade. Ligation, with or without surgical stripping of insufficient saphenous veins has mostly been replaced by thermal endovenous catheter therapies, due to their superior efficacy and less invasive character.[6] Besides them, ultrasound-guided sclerotherapy is used in treatment of varicose veins. However, the anatomical success rate was found low in saphenous vein insufficiency.[7-9] Mechanical damage of the endothelial vein wall is a crucial component of ClariVein®. Treatment of GSV insufficiency with only a liquid sclerosant results in a disappointing outcome. In a meta-analysis, anatomic success of liquid sclerotherapy was 39.5% vs 76.8% for ultrasound guided sclerotherapy.[9] An ex vivo histologic study evaluated the effect of mechanical damage of the ClariVein® system.[10] Elias and Raines showed an excellent success rate at 6 months of 96.7 % (29 of 30) in the first human study.[5] In another study, Van Eekeren et al. found the occlusion rate as 97% after 6 weeks in GSV by using polidocanol and ClariVein® together, and no major complications were seen.[11]

In our study, the occlusion rate was 94% after 6 months. Serious complications, such as pulmonary embolism, deep venous thrombosis, nerve injury, and skin burns, are uncommon with all endovenous treatment modalities for varicose veins, although different techniques can cause specific complications.[12] Endothermal techniques use heat to obliterate the vein and require tumescence anesthesia. Segmental RFA causes venous closure by venous wall denaturation at 120 ºC, whereas EVLA causes thrombotic occlusion with temperatures of 1200 ºC to 1400 ºC at the tip.[13,14] Perforation of veins and heating of surrounding tissue are thought to be associated with hematoma and prolonged post-procedural pain. Ecchymoses and pain are frequently reported side effects of EVLA. Device-related complications are rare, but serious. Lun et al. reported laser fiber migration into the pelvic cavity.[15] Significantly less postprocedural pain was

reported after ClariVein® when compared to RFA and EVLA.[16] Patients go to work early due to absence of pain after operation and early mobilization. They can be discharged from hospital on the day of surgery.

Nesbitt et al. compared foam sclerotherapy and surgery, and stated that recurrence rates were similar, and there were no differences between the groups for symptomatic recurrence (odds ratio 1.74, 95% confidence interval 0.97 to 3.12; p=0.06, and odds ratio 1.28, 95% confidence interval 0.66 to 2.49, respectively).[17]

CONCLUSION

The ablation made by using ClariVein®, which is a first generation mechano-chemical endovenous ablation device, is a reliable and efficient method in treatment of GSV insufficiency. By means of absence of pain after operation and the early mobilization, the patients can be discharged earlier, and the quality of life increases.

Conflict of Interest

Authors declared no conflict of interest or financial support.

REFERENCES

1. Callam MJ. Epidemiology of varicose veins. Br J Surg 1994;81(2):167-73.
2. Stirling M, Shortell CK. Endovascular treatment of varicose veins. Semin Vascular Surg 2006;19(2):109-15.
3. Van Den Bos RR, Neumann M, De Roos KP, Nijsten T. Endovenous laser ablation-induced complications: review of literature and new cases. Dermatol Surg 2009;35(8):1206-14.
4. van Eekeren RR, Boersma D, Elias S, Holewijn S, Werson DA, de Vries JP, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011;18(3):328-34
5. Elias S, Raines JK. Mechanochemical tumescentless endovenousablation: final results of the initial clinical trial. Phlebology 2012;27(2): 67-72.
6. Tellings SS, Ceulen RP, Sommer A. Surgery and endovenous techniques for the treatment of small saphenous varicose veins: a review of the literature. Phlebology 2011;26(5):179-84.
7. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomised clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg 2011;98(8):1079-87.
8. Smith PC. Chronic venous disease treated by ultrasound guided foam sclerotherapy. Eur J Vasc Endovasc Surg 2006;32(5):577-83.
9. Hamel-Desnos C, Allaert FA. Liquid versus foam sclerotherapy. Phlebology 2009;24(6): 240-6.
10. Kendler M, Averbeck M, Simon JC, Ziemer M. Histology of saphenous veins after treatment with the ClariVein devicedan ex-vivo experiment. J Dtsch Dermatol Ges 2013;11(4):348-52.
11. van Eekeren RR, Boersma D, Elias S, Holewijn S, Werson DA, de Vries JP, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011;18(3):328-34.
12. Van Den Bos RR, Neumann M, De Roos KP, Nijsten T. Endovenous laser ablation-induced complications: review of the literature and new cases. Dermatol Surg 2009;35(8):1206-14.
13. Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, Rother W, Bethge S, et al. Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. J Vasc Surg 2002;35(4):729-36.
14. Schmedt CG, Sroka R, Steckmeier S, Meissner OA, Babaryka G, Hunger K, et al. Investigation on radiofrequency and laser (980 nm) effects after endoluminal treatment of saphenous vein insufficiency in an ex-vivo model. Eur J Vasc Endovasc Surg 2006;32(3):318-25.
15. Lun Y, Shen S, Wu X, Jiang H, Xin S, Zhang J. Laser fiber migration into the pelvic cavity: A rare complication of endovenous laser ablation. Phlebology. 2014 Jun 25. pii: 0268355514541982. [Epub ahead of print]
16. van Eekeren RR, Boersma D, Konijn V, de Vries JP, Reijnen MM. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. J Vasc Surg 2013;57(2):445-50.
17. Nesbitt C, Bedenis R, Bhattacharya V, Stansby G. Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices. Cochrane Database Syst Rev 2014;7:CD005624.