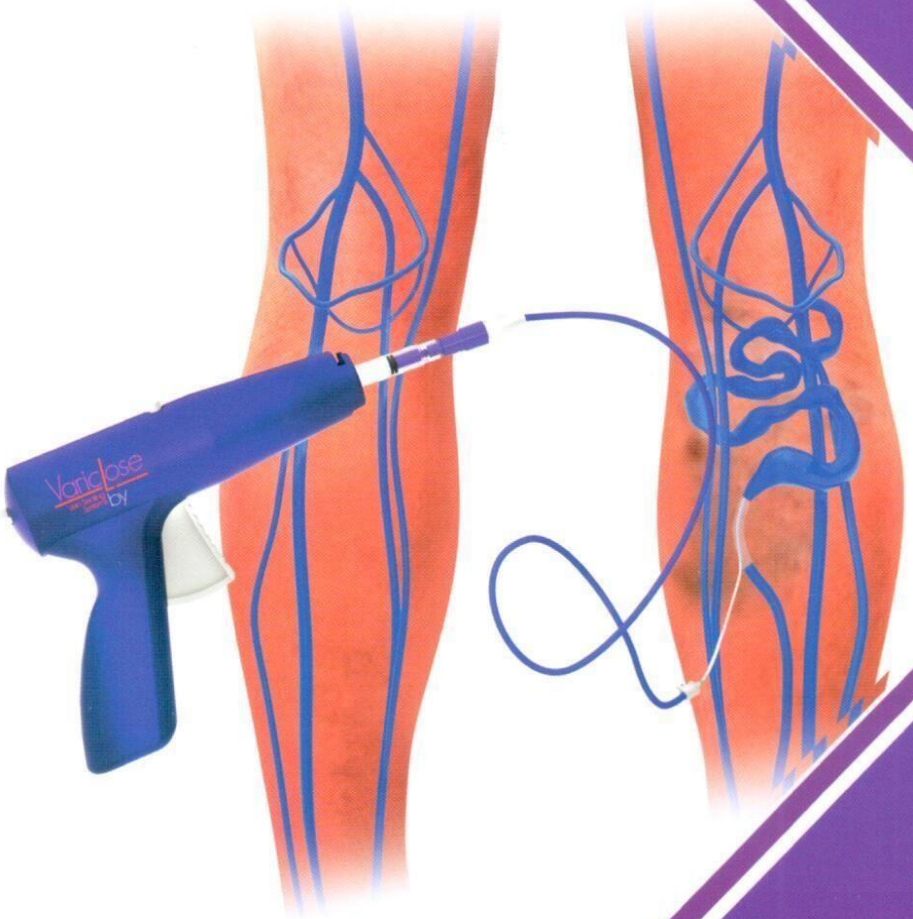
VariClose

Vein Sealing Systems by biolas®



VariClose

Yeni nesil
varis tedavisi ile tanışın

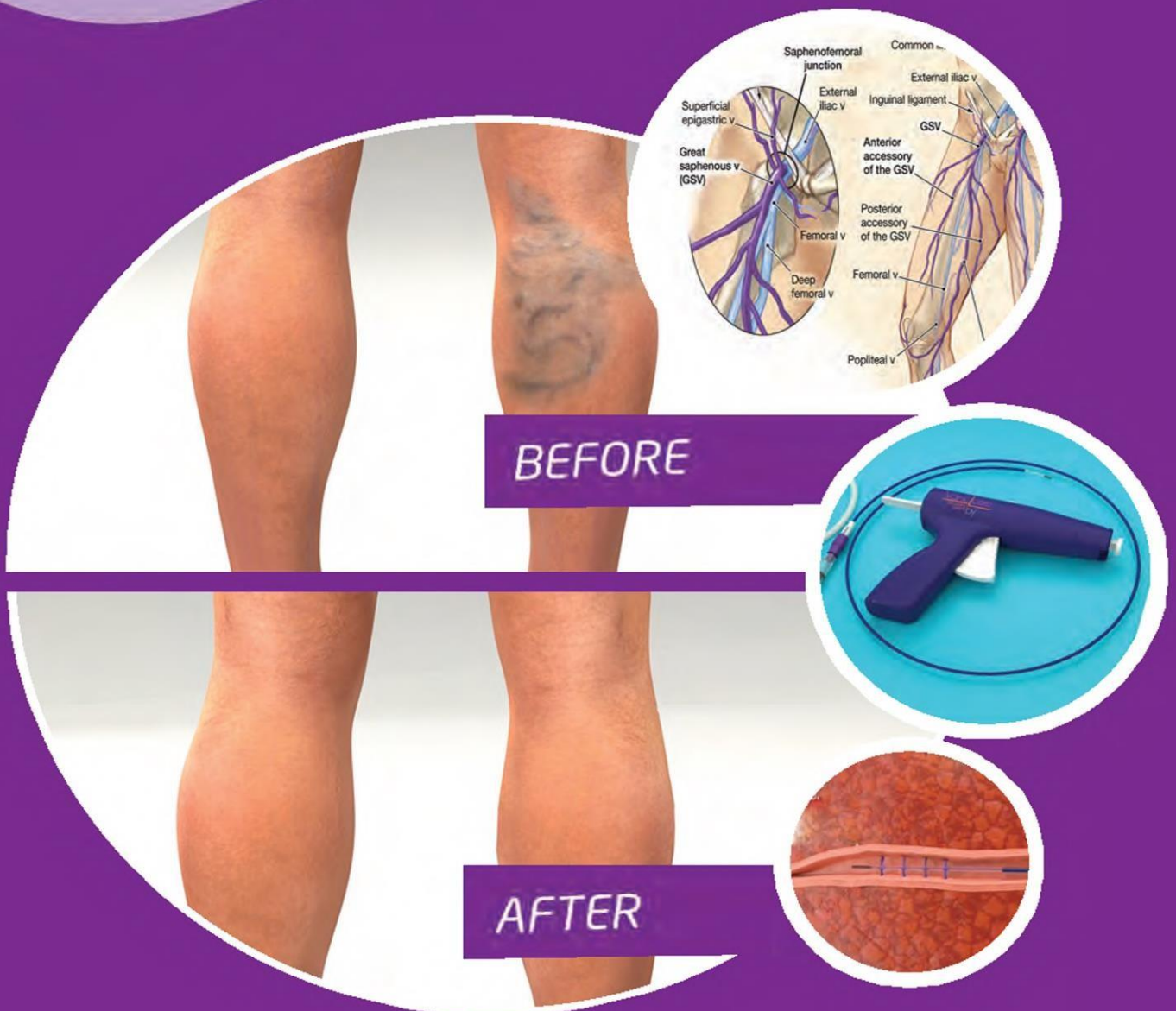
biolas®
www.biolas.net

FG GRUP
www.fggrup.com

VariClose

Vein Sealing Systems by biolas

biolas® HEALTH INC.



Discover the Future With VariClose

VariClose ile geleceği keşfedin...

FG GRUP

www.fggrup.com

Phlebology

A prospective comparison of a new cyanoacrylate glue and laser ablation for the treatment of venous insufficiency

Ahmet Kürşat Bozkurt[1] and Muhammet Fatih Yılmaz[2]

Phlebology
2016, Vol. 31(1S) 106–113

DOI: 10.1177/0268355516632652
phl.sagepub.com
SAGE

Abstract

Introduction: Cyanoacrylate ablation is the newest nonthermal vein ablation technique. The one-year results of a prospective comparative study of a new cyanoacrylate glue versus endovenous laser ablation for the treatment of venous insufficiency is presented.

Material and methods: A total of 310 adult subjects were treated with cyanoacrylate ablation or endovenous laser ablation. The primary endpoint of this study was complete occlusion of the great saphenous vein. Secondary endpoints were procedure time, procedural pain, ecchymosis at day 3, adverse events, changes from baseline in Venous Clinical Severity Score, and Aberdeen Varicose Vein Questionnaire.

Results: Operative time was shorter (15 ± 2.5 versus 33.2 ± 5.7, <0.001), and periprocedural pain was less (3.1 ± 1.6 versus 6.5 ± 2.3, <0.001) in cyanoacrylate ablation group compared to the endovenous laser ablation group. Ecchymosis at the third day was also significantly less in cyanoacrylate ablation group (<0.001). Temporary or permanent paresthesia developed in seven patients in endovenous laser ablation group and none in cyanoacrylate ablation group ($p = 0.015$). One, three, and 12 months closure rates were 87.1, 91.7, and 92.2% for endovenous laser ablation and 96.7, 96.6, and 95.8% for cyanoacrylate ablation groups. Closure rate at first month was significantly better in cyanoacrylate ablation group (<0.001). Although there is a trend of better closure rates in cyanoacrylate ablation patients, this difference did not reach to the statistical difference at sixth and 12th month ($p = 0.127$ and 0.138, respectively). Both groups had significant improvement in Venous Clinical Severity Score and Aberdeen Varicose Vein Questionnaire postoperatively (<0.001), but there was no significant difference in Venous Clinical Severity Score and Aberdeen Varicose Vein Questionnaire scores between the groups at first, sixth, and 12 months. Only a slightly better well-being trend was noted in cyanoacrylate ablation group in terms of Aberdeen Varicose Vein Questionnaire scores ($p = 0.062$).

Conclusions: The efficacy and safety analysis shows that cyanoacrylate ablation is a safe, simple method which can be recommended as an effective endovenous ablation technique. The follow-up data more than one year will clarify the future role of cyanoacrylate ablation for the treatment incompetent great saphenous veins.

Keywords

Cyanoacrylate ablation, nontumescent endovenous ablation, varicose veins, chronic venous insufficiency

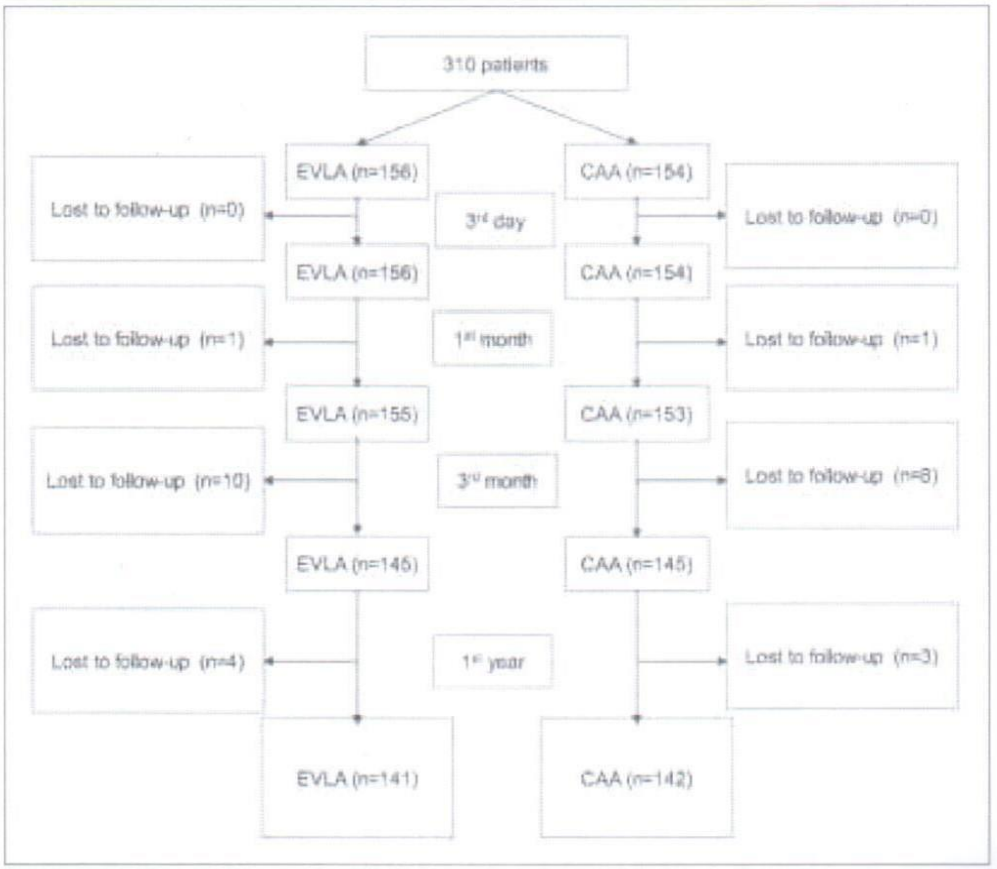


Figure 1. Flow chart. CAA: cyanoacrylate ablation; EVLA: endovenous laser ablation.

Table 2. Procedure characteristics and adverse events.

	EVLA (n = 156)		CAA (n = 154)		
	Mean±SD (n)	n (%)	Mean ± SD (n)	n (%)	P value
Length of treated segment (cm)	29.7 ± 8.1		29.8 ± 5.4		0.176
Procedure duration (min)	33.2 ± 5.7		15 ± 2.5		<0.001
Pain during procedure	6.5 ± 2.3		3.1 ± 1.6		<0.001
Phlebitis		12 (7.7)		7 (4.5)	0.248
Ecchymosis					<0.001
None		83 (53.2)		132 (85.7)	
<25%		47 (30.1)		19 (12.3)	
25–50%		20 (12.8)		2 (1.3)	
50–75%		5 (3.2)		1 (0.6)	
>75%		1 (0.6)		0 (0)	
Skin pigmentation		3 (1.9)		2 (1.3)	1
Paresthesia					
Total		7 (4.5)		0 (0)	0.015
Temporary		5 (3.2)		0 (0)	0.061
Permanent		2 (1.3)		0 (0)	0.498
Miniphlebectomy or foam[a]		33 (21.2)		37 (24)	0.545

CAA: cyanoacrylate ablation; EVLA: endovenous laser ablation; SD: standard deviation.
[a]Residual side branch treatment after three months.

Table 3. Closure rates.

	EVLA (n = 156)	CAA (n = 154)	
	Mean ± SD (n) n (%)	Mean ± SD (n) n (%)	P value
Closure—third day			0.184
Total	152 (97.4)	154 (100)	
Partial	1 (0.6)	0 (0)	
Recanalization	3 (1.9)	0 (0)	
Closure—first month			0.001
Total	135 (87.1)	148 (96.7)	
Partial	4 (2.6)	3 (2)	
Recanalization	16 (10.3)	2 (1.3)	
Closure—sixth month			0.127
Total	133 (91.7)	141 (96.6)	
Partial	4 (2.8)	3 (2.1)	
Recanalization	8 (5.5)	2 (1.4)	
Closure—12th month			0.318
Total	130 (92.2)	136 (95.8)	
Partial	4 (2.8)	3 (2.1)	
Recanalization	7 (5)	3 (2.1)	

CAA: cyanoacrylate ablation; EVLA: endovenous laser ablation; SD: standard deviation.

Table 4. Post procedure clinical assessment.

	EVLA (n = 156)	CAA (n = 154)	
	Mean ± SD (n) n (%)	Mean ± SD (n) n (%)	P value
VCSS			0.997*
Preintervention	5.7 ± 1.2 (156)	5.7 ± 2.3 (154)	
First month	2.2 ± 0.7 (155)	2.4 ± 0.9 (153)	
Sixth month	1.2 ± 0.6 (145)	1.3 ± 0.9 (145)	
First year	0.7 ± 0.5 (141)	0.6 ± 0.7 (142)	
AVVQ			0.062*
Preintervention	18.8 ± 4.6 (156)	18.1 ± 5 (154)	
First month	7.9 ± 2 (155)	7.5 ± 2.1 (153)	
Sixth month	4.9 ± 1.3 (145)	4.6 ± 1.4 (145)	
First year	4.9 ± 1.3 (141)	4.6 ± 1.4 (142)	

AVVQ: Aberdeen Varicose Vein Questionnaire; CAA: cyanoacrylate ablation; EVLA: endovenous laser ablation; SD: standard deviation; VCSS: Venous Clinical Severity Score.
*p value of repeated measures analysis of variance.

Conclusions

These initial results showed that this novel cyanoacrylate glue appears to be safe and efficacious out to one year. The technique eliminates the need for tumescent anesthesia, improves patient discomfort, shortens the physician learning curve, shortens procedure time and obviates compression stockings. The great majority of incompetent GSVs can be treated with this technique.

Original communication

N-butyl cyanoacrylate in the treatment of venous insufficiency – the effect of embolisation with ablative polymerisation

Eyüp Serhat Çalık[1], Ümit Arslan[1], Fırat Ayaz[2], Mehmet Tort[1], Ziya Yıldız[1], Volkan Aksu[3], Oruç Alper Onk[4], Hüsnü Kamil Limandal[1], Evren Ekingen[5], Özgür Dağ[1], Mehmet Ali Kaygın[1], and Bilgehan Erkut[1]

[1] Erzurum Training and Research Hospital, Erzurum, Turkey
[2] Diyarbakır Gazi Yaşargil Training and Research Hospital, Turkey
[3] Ardahan State Hospital, Turkey
[4] Erzincan University Medical Faculty, Turkey
[5] Batman Region State Hospital, Turkey

Summary: *Background:* The primary objective of this multicentre prospective observational study was to evaluate the early results of a new non-thermal embolisation method using N-butyl cyanoacrylate in venous insufficiency. *Patients and methods:* A total of 181 patients with a varicose vein diagnosis were treated with the VariClose: Vein Sealing Systems at four different centres. The protocol included physical and colour Doppler ultrasonography examination, venous clinical severity score and quality of life assessment before and after the procedure on days 1 and 7 and at months 1, 3 and 6. Clinical recovery was evaluated by comparing the venous clinical severity score and the quality of life assessment before and after the procedure. *Results:* In total, 215 embolisation procedures were successfully completed on 181 patients (110 female) with a mean age of 37.6 ± 13.2 years (range 18 – 72 years). The 215 procedures consisted of 25 bilateral applications on 206 great saphenous veins and 9 small saphenous veins. The average pre-interventional diameter of great saphenous veins was 6.5 ± 1.4 mm (4.3 – 14 mm), and the mean diameter of small saphenous veins was 5.2 ± 1.3 mm (3.8 – 8.6 mm). The average length of the sealed vein segments was 31.6 ± 6.1 cm (23 – 70 cm), and the average N-butyl cyanoacrylate usage for the patient was 0.9 ml (0.7 – 2.1 ml). The procedural occlusion rate was 100 %. Post-operative pain was observed in 11 patients (6.1 %), and thrombophlebitis was observed in 1 patient (0.5 %). No total recanalisation was observed. Five (2.7 %) partial recanalisations were observed at the 6 month follow-up. The 6 month total occlusion rate was 97.2 %. *Conclusions:* This new tumescent-free non-thermal embolisation method can be applied safely with high success rates.

Key words: Chronic venous insufficiency, varicose veins, treatment, embolisation, cyanoacrylate

Table I. Inclusion and exclusion criteria

Inclusion criteria
Patients between the ages of 18-75 with symptomatic varicose veins, CEAP classification between C2-C5, GSV insufficiency 0.5 sec, and who were over-determined by CDUS, could come to follow up examinations and were mentally healthy to approve the operation.
Exclusion criteria
Saphenous vein duplication or accessory saphenous vein with venous insufficiency
Advanced tortuous GSV
Saphenous vein under 3 mm and over 15-mm diameter
DVT history
Active thrombophlebitis in deep or superficial veins
Arterial insufficiency history or ankle-brachial index under 0.9
Significant femoral or popliteal vein insufficiency
History of intervention (surgical, thermal or chemical ablation) with saphenous vein to be treated
Hypersensitivity to the NBCA or reaction history with the past surgeries
Cancer
Life expectancy under two years

Abbr.: CEAP: clinical, aetiological, anatomical and pathophysiological classification, GSV: great saphenous vein, CDUS: colour Doppler ultrasonography, DVT: deep vein thrombosis, NBCA: N-butyl cyanoacrylate

Procedure technique

GSV or SSV embolisations were performed with VariClose®, which contains a 7F introducer set, a 0.035" guidewire, two or more of 1 ml VariClose NBCA, a 2-ml syringe, a 5F long introducer sheath, and a VariClose delivery system (VDS) consisting of a 4F delivery catheter, a dispensing gun and an adaptor. The VDS is designed to deliver 0.3 cc NBCA in 5 s for 10 cm of vein. Holding the trigger for 5 s provides 0.3 cc of NBCA. A pulling back rate of 2 cm/sec relates to 0.03 cc of NBCA applied to each cm of the vein. VariClose® is a specially developed formulation of NBCA that creates rapid polymerisation upon interaction with the endothelium. The NBCA was developed specifically for long vein segment sealing. It has lower viscosity with reinforced adhesive properties. Therefore, it leads to fast polymerisation, and the difference in the method used results from this property of VariClose®.

The GSV was accessed percutaneously with a 7F sheath under ultrasound guidance at the level of the knee or ankle. For SSV treatment, access was performed at the outer malleoli level. A 0.035" guidewire was inserted through the short sheath of the introducer kit and was advanced into the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ). The tip of the guidewire at the junction was confirmed using ultrasonography (USG). A 5F long introducer was advanced over the wire to the junction. After the tip of the catheter was confirmed to be at the beginning of the junction by USG, a long introducer sheath was pulled back 6 cm distal to the junction. The access sheath was removed due to the fast pull back procedure. A delivery catheter was inserted into the long introducer sheath and then advanced through and secured using a spin lock mechanism. The tip of the delivery catheter was confirmed to be 3 cm distal to the SFJ or SPJ by USG.

The VDS was prepared using the gun, adapter and injector after filling the injector with 2 cc NBCA. The VDS was attached to the delivery catheter using a spin lock mechanism. SFJ or SPJ compression by USG and closure of the junction was confirmed. Before injecting NBCA into the vein lumen, the catheter was primed by pulling the trigger for 1 s. After priming, the trigger was pulled again and pressed for 5 s. While the trigger was being pulled, the delivery catheter was pulled back 2 cm per second. The pullback rate was observed using the markers over the long introducer sheath. After injecting NBCA for the first 10 cm in 5 s, the trigger was pulled and pressed for 5 s again. Simultaneously, after the first 10 cm of NBCA injection, pressure was applied over the GSV or the SSV by USG probe (transducer) at the pull-back rate of 2 cm/s, while the compression over the SFJ continued. This injection/retraction process was repeated until the whole vein segment was sealed. After the whole vein segment was injected with NBCA, pressure was applied with a towel over the whole vein segment for 30 s. Then, venous closure was confirmed by USG, and a small elastic bandage with approximately 20–30 mmHg pressure was applied to the treated vein segment for one day.

The protocol included a physical and CDUS examination and QOL assessment before and after the operation on days 1 and 7 and at months 1, 3, 6, 12 and 24. Follow-ups were completed on days 1 and 7 and at months 1, 3 and 6. The success of the operation was defined as the total occlusion of the treated vein segment, or in any segment opening or recanalisation below 5 cm [20]. The evaluation of clinic recovery was performed by comparing VCSSs and QOL assessments before and after the procedure.

Conclusions

We believe that our success rate was highly dependent on the polymerisation rate and viscosity. Therefore, our procedure technique differs from previous methods. A continuous technique that offers fast application without leaving any open segments in the vein should be considered significant. Consequently, this new tumescent-free, non-thermal embolisation method can be applied safely with high success rates. These results should be further supported by our long-term results and new alternative studies. Low procedure times, early recovery times and the immediate return to a daily routine without compression stockings are all significant advantages of this technique.

Results

Overall, 215 embolisation procedures were successfully completed. Procedures were performed by 8 different specialists in the 4 different clinics. The 215 procedures consisted of 25 bilateral applications on 206 GSVs and 9 SSVs.

The average pre-interventional diameter of the GSVs was 6.5±1.4 mm (4.3–14 mm). The mean diameter of the SSVs was 5.2±1.3 mm (3.8–8.6 mm). The average length of the sealed vein segments was 31.6±6.1 cm (23–70 cm). For all patients with GSV insufficiency, the segment above the knee was occluded. In 18 patients, the segment below the knee was also occluded, and, in three patients, the entire GSV was treated. The SSVs were completely occluded in 9 patients. The average NBCA usage for the patients was 0.9 ml (0.7–2.1 ml), and the average procedure time was 5.4±2.5 min (3–14 min). Mini phlebectomy was performed on 3 legs with very large varicosities during the operations, and adjunctive foam sclerotherapy was performed on 5 legs with large varicosities during the follow-up with a slight deviation in the protocol.

Efficacy

The 1-, 3- and 6-month follow-up visits were completed in 163 (90%) patients. The average follow-up time was 7.5 months (range 6–11 months). Clinical, CDUS and QOL evaluations of the patients were performed during the follow-up visits. The procedural 1-day, 7-day and 1-month occlusion rates were 100%. No total recanalisation was observed in any patients, and 5 (2.7%) partial recanalisations were observed during the follow-up. Two of them were at the SFJ level at 8- and 10-cm in length, at three months. The other three recanalisations were in the middle of the thigh at 6-, 4-, and 4-cm in length, at six months. Based on the life-table analysis (*ESM 1*), the 6 month total occlusion rate was 97.2%, and the 6 month success rate was 98.3%. The patients with recanalisation were not clinically symptomatic. Importantly, recanalisations occurred around the aneurysmal segments and junctions of large varicosities.

Clinical success

All baseline and follow-up VCSS values were recorded and compared (*ESM 2*). At the 6 month follow-up, VCSSs declined from 4.9±1.2 to 1.4±0.8 (P<.0001). During follow-up, patients free from leg oedema, pain and varicosities are shown at *ESM 3*.

Quality of life assessment

QOL measurements have provided valuable information about the success of treatment. Measurements in five categories were acquired before the procedure and at each follow-up visit. QOL scores demonstrated meaningful improvement during the follow-up (*ESM 4*). CIVIQ scores improved significantly for all categories. Therefore, the global CIVIQ score improved significantly from a baseline value of 42.9±18.6 to 17.4±3.8 at 6 months (P<0.0001).

Phlebology OnlineFirst, published on March 27, 2016 as doi:10.1177/0268355516638577
Original Article

Phlebology

A new non-tumescent endovenous ablation method for varicose vein treatment: Early results of N-butyl cyanoacrylate (VariClose®)

Phlebology
0(0) 1–6

DOI: 10.1177/0268355516638577
phl.sagepub.com
SAGE

Alptekin Yasim[1], Erdinc Eroglu[1], Orhan Bozoglan[1], Bulent Mese[1], Mehmet Acipayam[1] and Hakan Kara[2]

Abstract

Objective: This report aims to present the early results of a retrospective study of the use of N-butyl cyanoacrylate (VariClose®)-based non-tumescent endovenous ablation for the treatment of patients with varicose veins.

Method: One hundred and eighty patients with varicose veins due to incompetent saphenous veins were treated with the VariClose® endovenous ablation method between May 2014 and November 2014. The patient sample consisted of 86 men and 94 women, with a mean age of 47.7 ± 11.7 years. The patients had a great saphenous vein diameter greater than 5.5 mm and a small saphenous vein diameter greater than 4 mm in conjunction with reflux for more than 0.5 s. Patients with varicose veins were evaluated with venous duplex examination, Clinical, Etiological, Anatomical and Pathophysiological classification (CEAP), and their Venous Clinical Severity Scores were recorded.

Results: The median CEAP score of patients was three, and the saphenous vein diameters were between 5.5 and 14 mm (mean of 7.7 ± 2.1 mm). A percutaneous entry was made under local anesthesia to the great saphenous vein in 169 patients and to the small saphenous vein in 11 patients. Duplex examination immediately after the procedure showed closure of the treated vein in 100% of the treated segment. No complications were observed. The mean follow-up time was 5.5 months (ranging from three to seven months). Recanalization was not observed in any of the patients during follow-up. The average Venous Clinical Severity Scores was 10.2 before the procedure and decreased to 3.9 after three months ($p < 0.001$).

Conclusion: The application of N-butyl cyanoacrylate (VariClose®) is an effective method for treating varicose veins; it yielded a high endovenous closure rate, with no need for tumescent anesthesia. However, long-term results are currently unknown.

Keywords

Varicose vein, N-butyl cyanoacrylate, endovenous ablation

Table 1. Exclusion criteria.

1. Patients under the age of 18
2. Patients with obstruction in the deep venous system
3. Patients who have previously used another invasive treatment method (thermal and chemical ablation, surgery)
4. Patients with cardiac and renal failure
5. Immobile patients
6. Patients with secondary varicose vein
7. Hypercoagulability status
8. Local or systemic infection
9. Obesity (body mass index > 35)

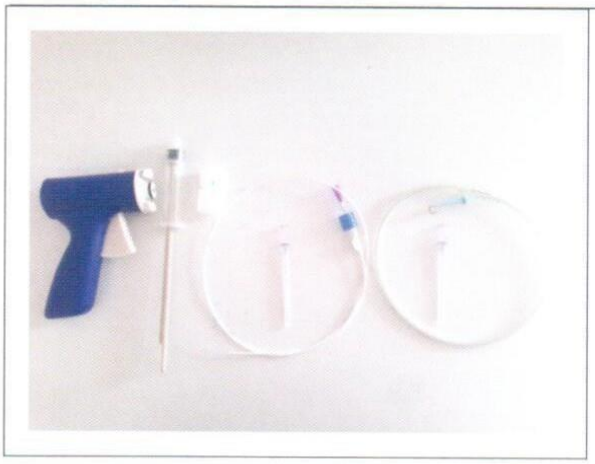


Figure 1. The content of VariClose Vein Sealing System.

Methods

Patients

One hundred and eighty patients were admitted to our unit with symptoms of venous insufficiency between May 2014 and November 2014. Patients with incompetent great and/or small saphenous veins diagnosed using colored Doppler ultrasonography (USG) were included in the study. The inclusion criteria were as follows: a great saphenous vein diameter greater than 5.5 mm and a small saphenous vein diameter greater than 4 mm in conjunction with reflux for more than 0.5 s. The exclusion criteria are given in Table 1. A maximum vein size was not imposed during patient selection. The patients were assessed again with colored Doppler USG immediately before the procedure. This assessment was conducted with a Mindray model M7 USG (Shenzen, China) by the surgeon who performed the cases. The patients were informed and their consent was obtained, and they were then taken to the operating room. The study protocol was approved by our local ethics committee.

After the ablation procedure, the ablation of the vein was immediately verified by the surgeon with duplex ultrasound to assess the success of the procedure. Elastic stockings were applied to the patients, and they were asked to return for a follow-up visit two days after the procedure. Additional follow-up visits were conducted at one month, three months, and six

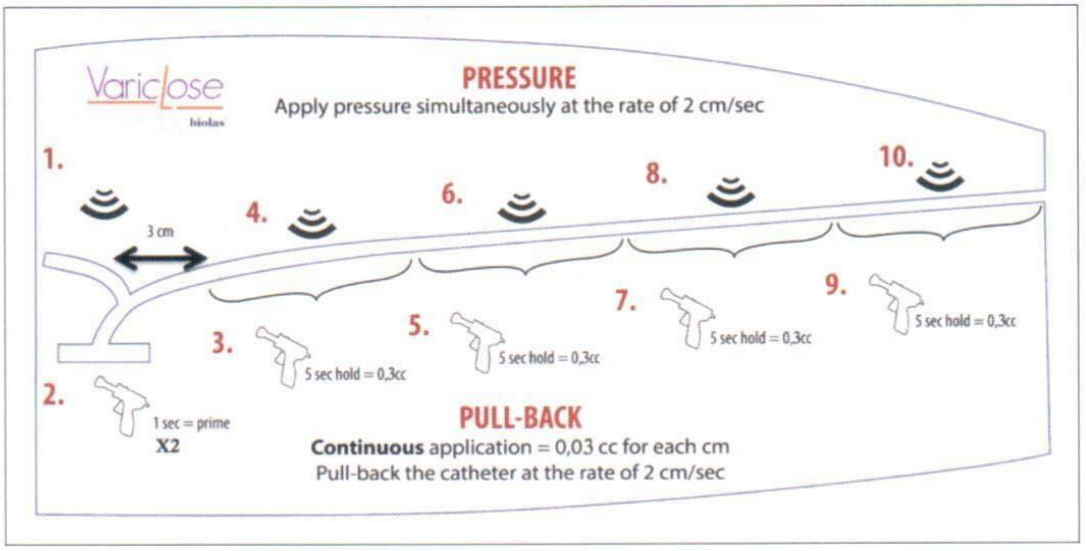


Figure 2. The application of VariClose® Vein Sealing System.

Table 2. Patient characteristics.

Age	47.7 ± 11.7
Gender (M/F)	86/94
Targeted vein	Large saphenous vein: 169 patients (90 right, 79 left) Small saphenous vein: 11 patients (5 right, 6 left)
CEAP classification (min-med-max)	2-3-5
Diameter of saphenous vein	7.7 ± 2.1 mm (5.5–14 mm)
Distance of vein to skin at the point of intervention	15.7 ± 6.6 mm (3–40 mm)
Length of saphenous vein targeted for ablation	Was 26.2 ± 6.5 cm (9–43 cm)
Duration of procedure	15.2 ± 2.6 minutes (10–25 minutes)
VCSS (Pre-procedure)	10.2 ± 1.5 (7–15)
VCSS (Post-procedure)	3.9 ± 1.6 (2–9)

VCSS: Venous Clinical Severity Score.

Conclusions

In conclusion, VariClose® seems to be an effective technique for managing varicose veins based on this observational study in the short-term period. Data on the effectiveness of VariClose® during the long-time period are currently lacking. However, similar results can also be expected for the late period given the high success rates in the short-time period. This agent has several advantages, such as short procedure duration, no need for tumescent anesthesia, improved patient comfort, and ease of application. Therefore, this agent may be preferable to laser and radiofrequency treatment.

Ablation of the great saphenous vein with nontumescent *n*-butyl cyanoacrylate versus endovenous laser therapy

İsmail Koramaz, MD,[a] Helin El Kılıç, MD,[a] Fatih Gökalp, MD,[a] Macit Bitargil, MD,[a] Nilüfer Bektaş, MD,[a] Ersoy Engin, MD,[a] Mehmet Taşkın Egici, MD,[b] *and* Ahmet Kürşat Bozkurt, MD,[c] *Istanbul, Turkey*

ABSTRACT

Objective: The endovenous application of *n*-butyl cyanoacrylate (NBCA) is a new nontumescent ablation technique for the treatment of venous insufficiency. The aim of this study was to retrospectively compare an NBCA-based ablation method with endovenous laser ablation (EVLA) for the management of incompetent great saphenous veins.

Methods: Between May 2013 and August 2014, there were 339 patients with incompetent varicose veins who were treated with either the endovenous application of NBCA (VariClose Vein Sealing System [VVSS]; Biolas, Ankara, Turkey) or EVLA. The preprocedural, intraprocedural, postprocedural, and follow-up data of the patients were collected and retrospectively compared.

Results: The mean age was 45.09 ± 12 years in the VVSS group and 47.08 ± 11 years in the EVLA group ($P = .113$). The average ablated vein length was 31.97 ± 6.83 cm in the VVSS group and 31.65 ± 6.25 cm in the EVLA group ($P = .97$). The average tumescent anesthesia use was 300 mL (range, 60-600 mL) in the EVLA group. The average procedure time was 7 minutes (range, 4-11 minutes) in the VVSS group and 18 minutes (range, 14-25 minutes) in the EVLA group ($P < .01$). On the basis of ultrasound examinations performed at the end of the procedure, all procedures in both groups were successful, and the target vein segments were fully occluded. The 12-month total occlusion rates in the VVSS and EVLA groups were 98.6% and 97.3%, respectively ($P = .65$). In both the VVSS and EVLA groups, the Venous Clinical Severity Score declined significantly with no difference between groups. There were fewer adverse events after VVSS treatment compared with EVLA treatment (pigmentation, $P \leq .002$; phlebitis, $P \leq .015$). There was no need for tumescent anesthesia in the VVSS group.

Conclusions: The NBCA-based vein sealing system is a fast and effective treatment option for the management of incompetent saphenous veins that does not involve tumescent anesthesia, compression stockings, paresthesia, burn marks, or pigmentation. Further large-scale studies with long-term outcomes are required to identify the optimal treatment modalities for patients with saphenous vein insufficiency. (J Vasc Surg: Venous and Lym Dis 2017;5:210-5.)

ARTICLE HIGHLIGHTS

- **Significance:** Saphenous ablation using *n*-butyl cyanoacrylate (NBCA) is a new, minimally invasive intervention that does not require use of tumescent anesthesia or compression.
- **Type of Research:** Retrospective nonrandomized analytical study of 339 patients treated for varicose veins.
- **Take Home Message:** Great saphenous vein ablation using NBCA was as effective as endovenous laser therapy at achieving vein closure and improving clinical outcome at 12 months.
- **Recommendation:** The authors suggest that saphenous ablation with NBCA, without tumescent anesthesia, is as effective as endovenous laser ablation at 1 year after intervention.
- **Strength of Recommendation:** 2. Weak.
- **Level of Evidence:** B. Low or very low.

Table I. Study eligibility criteria

Inclusion criteria	
1.	Age ≥20 years and ≤70 years
2.	Vein diameter at the GSV ≥5.5 mm and ≤15 mm
3.	Reflux in GSV >0.5 second
4.	CEAP classification between C2 and C5
5.	Patients attended the follow-up examinations
6.	Patients were sufficiently mentally healthy to consent to the operation
Exclusion criteria	
1.	Tortuous GSV
2.	Symptomatic peripheral arterial disease history or an ABI <0.9
3.	History of DVT or PE
4.	Life expectancy <2 years
5.	Active thrombophlebitis in the deep or superficial veins
6.	Significant femoral or popliteal venous insufficiency and perforator vein insufficiency
7.	Known sensitivity to cyanoacrylate adhesives
8.	Aneurysm >15 mm in the target vein
9.	Previously treated GSV
10.	Existence of malignant disease
11.	Pregnancy
12.	Immobilization

ABI, Ankle-brachial index; *CEAP*, Clinical, Etiology, Anatomy, and Pathophysiology classification; *DVT*, deep venous thrombosis; *GSV*, great saphenous vein; *PE*, pulmonary embolism.

Table II. Demographics and baseline characteristics

	Group		
	VVSS (n = 150)	EVLA (n = 189)	*P*
Sex			
Male	74 (49.3)	95 (50.3)	.865[a]
Female	76 (50.7)	94 (49.7)	
CEAP class (preprocedural)			
C2	20 (13.3)	22 (11.6)	.788[a]
C3	66 (44.0)	93 (49.2)	
C4	54 (36.0)	64 (33.9)	
C5	10 (6.7)	10 (5.3)	
Age, years	45.09 ± 12 (43 [20-70])	47.08 ± 11 (46 [20-86])	.113[b]
VCSS	7.53 ± 1.03 (7 [7-13])	7.73 ± 1.58 (7 [7-13])	.493[b]
GSV diameter, mm	6.88 ± 1.80 (range, 15-5.5) (6.05 [4.6-16.0])	7.15 ± 1.77 (range, 14-5.5) (6.70 [4.5-14.0])	.065[b]

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology classification; *EVLA*, endovenous laser ablation; *GSV*, great saphenous vein; *VCSS*, Venous Clinical Severity Score; *VVSS*, VariClose Vein Sealing System.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation (median [minimum-maximum]).
[a]χ^2 test.
[b]Mann-Whitney *U* test.

Table IV. Adverse events

	Group		
	VVSS (n = 150)	EVLA (n = 189)	*P*
Pain (first week)	7 (4.7)	17 (9.0)	.123[a]
Burns	—	4 (2.1)	.133[b]
Pigmentation	—	11 (5.9)	.002[b]
Bruising	—	5 (2.6)	.069[b]
Paresthesia	—	3 (1.6)	.258[b]
Phlebitis	3 (2.1)	15 (7.9)	.015[b]
DVT	—	3 (1.6)	.258[b]

DVT, Deep venous thrombosis; *EVLA*, endovenous laser ablation; *VVSS*, VariClose Vein Sealing System.
Values are reported as number (%).
[a]χ^2 test.
[b]Fisher exact test.

Table III. Procedure characteristics

	VVSS	EVLA	*P*
GSV diameter, mm	6.88 ± 1.80 (range, 15-5.5) (6.05 [4.6-16.0])	7.15 ± 1.77 (range, 14-5.5) (6.70 [4.5-14.0])	.065
Length of the ablated GVS, cm	31.97 ± 6.84 (30 [23-70])	31.64 ± 6.26 (30 [23-70])	.974
Amount of tumescent anesthesia, mL	—	300 (range, 60-600)	
Procedure duration, minutes	7 (range, 4-11)	18 (range, 14-25)	<.001
Occlusion rate	148 (98.6)	184 (97.3)	.659
Pretreatment VCSS	7.53 ± 1.03 (7 [7-13])	7.73 ± 1.58 (7 [7-13])	.493
Post-treatment VCSS	2.79 ± 1.05 (2 [1-6])	2.83 ± 1.21 (2 [2-6])	.882
P[b]	<.001	<.001	

EVLA, Endovenous laser ablation; *GSV*, great saphenous vein; *VCSS*, Venous Clinical Severity Score; *VVSS*, VariClose Vein Sealing System.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation (median [minimum-maximum]) unless otherwise indicated.
[a]Mann-Whitney *U* test.
[b]Wilcoxon signed rank test.

CONCLUSIONS

Current minimally invasive methods of ablating the saphenous vein involve the use of thermal energy and require the use of tumescent anesthesia and postoperative compression stockings. The NBCA-based vein-sealing system has been suggested to be a viable alternative method that does not involve the use of tumescent anesthesia or require the postoperative use of compression stockings and has a shorter procedure time. Vein ablation rates and complication rates are comparable to those of EVLA.

The Heart Surgery Forum #2016-1496
19 (3), 2016 [Epub June 2016]
doi: 10.1532/hsf.1496

Online address: http://journal.hsforum.com

Early-Term Outcomes for Treatment of Saphenous Vein Insufficiency with N-Butyl Cyanoacrylate: A Novel, Non-Thermal, and Non-Tumescent Percutaneous Embolization Technique

Mustafa Tok,MD,[1] Oktay Tuydes MD,[2] Ahmet Yuksel MD,[2] Sefa Senol MD,[3] Serkan Akarsu MD[4]

[1]Department of Cardiovascular Surgery, Uludag University Faculty of Medicine, Bursa; [2]Department of Cardiovascular Surgery, Bingol State Hospital, Bingol; [3]Department of Cardiovascular Surgery, Education and Research Hospital, Elazig; [4]Department of Cardiovascular Surgery, Medical Art Izmir Hospital, Izmir, Turkey

ABSTRACT

Background: The purpose of this study was to present early-term outcomes of VariClose® Vein Sealing System, which is a novel, non-thermal, and non-tumescent percutaneous embolization technique for treatment of saphenous vein insufficiency.

Methods: Between March 2014 and July 2015, 189 saphenous veins in 141 patients were treated with Variclose Vein Sealing System containing n-butyl cyanoacrylate. Pre-, intra-, post-procedural, and follow-up data of patients were collected and retrospectively reviewed.

Results: Mean age of patients was 42.5 ± 14.0 years, of which 53% were female. Technical success rate of intervention was 98.9%. Mean procedure time was 14.3 ± 7.5 minutes. Eighty-nine percent of patients (n = 126/141) were available at mean follow-up time of 6.7 months. Mean Venous Clinical Severity Score was significantly improved from 8.3 ± 2.2 at pre-procedure period to 3.3 ± 1.8 at follow-up. No complete recanalization was observed, but 2 patients were presented with partial recanalization during follow-up. The complete occlusion rate was 98.4%. No serious adverse event related to procedure was observed.

Conclusion: Variclose Vein Sealing System appears to be safe and effective in treatment of saphenous vein insufficiency. Further randomized studies with long-term outcomes are required for determining optimal treatment modality in patients with saphenous vein insufficiency.

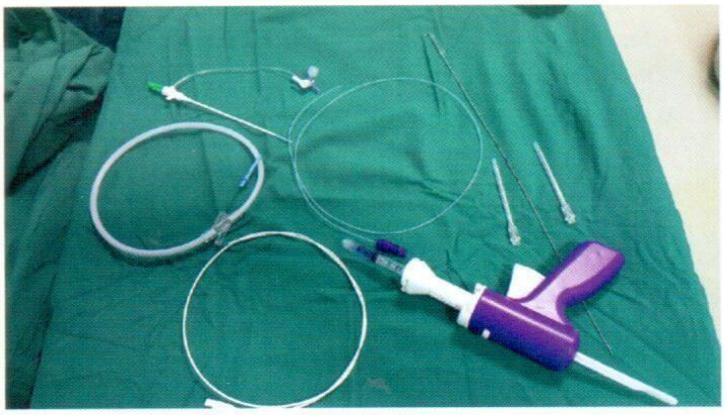


Figure 1. The components of the Variclose Vein Sealing System.

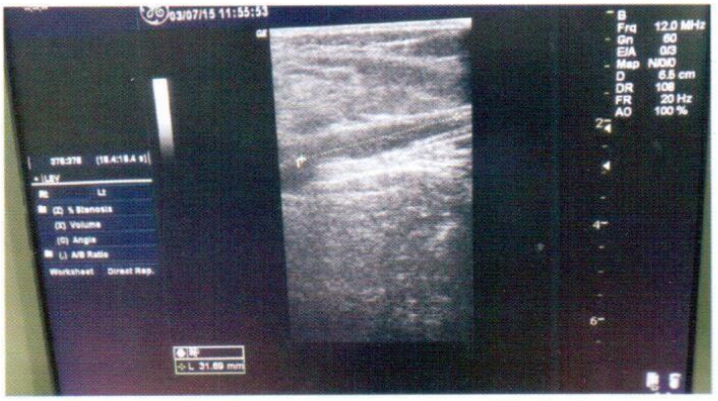


Figure 2. The distance between catheter tip and saphenofemoral junction (3 cm) is shown ultrasonographically.

Table 1. Study Eligibility Criteria

Inclusion Criteria
1. Age ≥ 18 years and ≤ 80 years
2. Vein diameter at the GSV ≥ 5.5 mm and ≤ 15 mm & at the SSV ≥ 4 mm and ≤ 15 mm
3. Reflux time ≥ 2 second
4. CEAP classification between C1-C6
5. Patients who were sufficiently mentally healthy to consent to the intervention
Exclusion Criteria
1. Tortuous GSV or SSV
2. Symptomatic peripheral arterial disease history or an ABI index < 0.9
3. History of DVT or PE
4. Life expectancy < 2 years
5. Active thrombophlebitis in the deep or superficial veins
6. Significant femoral or popliteal venous insufficiency
7. Known sensitivity to cyanoacrylate adhesives
8. Aneurysm > 15 mm in the target vein
9. Previously treated GSV or SSV
10.Existence of malignancy
11. Pregnancy
12. Immobilization

GSV: Great saphenous vein, SSV: Small saphenous vein, DVT: Deep venous thrombosis, PE: Pulmonary embolism

RESULTS

Mean age of patients was 42.5 ± 14.0 years (range: 20-79), and 53% (n = 75) of them were female. The CEAP classification was C1 (6%, n = 8), C2 (22%, n = 32), C3 (43%, n = 62), C4 (21%, n = 30), C5 (6%, n = 9) and C6 (1%, n = 2). Mean preprocedure VCSS was 8.3 ± 2.2 (range: 5-19). Mean GSV diameter at the saphenofemoral junction was 7.6 ± 2.1 mm (range: 5.5-15), and mean SSV diameter at the saphenopopliteal junction was 7.0 ± 1.8 mm (range: 4.2-11). Most of the saphenous veins (79%) had continued reflux flow; the others had 2-6 second reflux with valsalva maneuver before the procedure.

A total of 191 interventions (158 to GSV and 33 to SSV) were planned; however, two interventions were unsuccessful due to shortening of vein diameter and vasospasm at the time of vein puncture. The technical success rate of intervention was 98.9%. Mean GSV and SSV treatment lengths were 30.2 ± 4.1 and 19.5 ± 3.8 cm, respectively. Mean delivered amount of n-BCA to GSV and SSV were 0.91 ± 0.12 and 0.58 ± 0.11 mL, respectively. Mean procedure time was 14.3 ± 7.5 minutes (range: 4-37). In the early post-procedural period, thrombophlebitis was observed in 6 (3%) patients, who were treated with oral non-steroidal anti-inflammatory drugs and/or antibiotics (two patients were treated with oral antibiotics, and one patient with parenteral antibiotics). Ecchymosis at the puncture area, with a size no greater than 10 cm, was observed in 4 (2%) patients. No hematoma, paresthesia, DVT, or PE were observed in any of the patients.

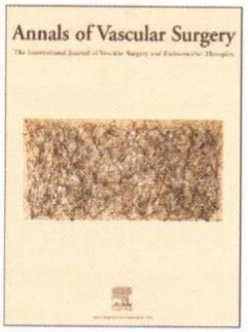
Follow-up was completed for 128 of the patients, but 15 patients were lost to follow-up. Additionally, two patients who underwent unsuccessful interventions were not considered for follow-up examination (reintervention was suggested for these patients, but they refused reintervention and were treated medically); in total, the results of a total of 126 patients were examined during follow-up. Mean follow-up time was 6.7 ± 4.1 months (range: 1-15). Post-procedure VCSS did not improve in only three patients; the rest were clinically better according to VCSS. Mean VCSS was significantly improved from 8.3 ± 2.2 at baseline to 3.3 ± 1.8 (range: 1-11) at follow-up. In DUS assessments, no complete recanalization was observed, but 2 patients presented with partial recanalization during follow-up. The complete occlusion rate was 98.4%. No adjunctive treatment of the target vein was required during follow-up period.

Conclusions

To the best of our knowledge, this report is the first published clinical analysis of Variclose Vein Sealing System for treatment of SVI. Use of the Variclose Vein Sealing System enables treatment without either tumescent or general anesthesia. Moreover, wearing of compression stockings is not necessary after treatment. This means that patients may quickly return to work and operate vehicles. They may drive directly to work after the procedure and resume their general daily activities. They may also participate in sports more quickly. Furthermore, adverse events related to the procedure were acceptable, and no serious adverse event was observed in our series.

The major limitation of this study was the retrospective nature of the data collection of nonrandomized patients.

In conclusion, this study shows that Variclose Vein Sealing System is a novel, non-thermal, and non-tumescent endovenous embolization method that is safe and effective. Further randomized studies with long-term outcomes are required to determine the optimal treatment modality in patients with SVI.



Non Thermal, Non Tumescent Endovenous Treatment of Varicose Veins

Ali İhsan Tekin, MD, Osman Nuri Tuncer, MD, Mehmet Erdem Mehmetoğlu, MD, Ümit Arslan, MD, Ahmet Öztekin, MA, Bayram Yağmur, MD, Mahmut Biçer, MD, Rıfat Özmen, MD

PII: S0890-5096(16)30467-8

DOI: 10.1016/j.avsg.2016.03.005

Reference: AVSG 2864

Absract

METHODS: This is a single center prospective study of treatment of great saphenous vein incompatence in 62 patients with vein sealing system (Biolas VariClose® FG Group TURKEY) All cases were implemented under local anesthesia.Tumescent anesthesia was not required. Patients were not given any non-steroidal anti-inflammatory drug postoperatively only adviced to wear elastic bandages for one day and compression stockings was not offered.

RESULTS: Treatment success was defined as complate occlussion of treated vein or recanalized segment shorter than 5 cm. Subtotal recanalization was defined as great saphenous vein flow containing 5-10 cm segment of treated vein. A recanalized great saphenous vein or treatment failure was defined as an open part of the treated vein segment more than 10 cm in length.

At the one week and one month control duplex scans showed total occlusion for all the patients(100%).,total occlusion for 58 patients(93.5%) and subtotal occlusion for 4 patients(6,5%) at thirth month control.

At the end of 6 month total occlusion 56 patients(90.3%) and subtotal occlusion for 2 patients(3.2%).For the 4 (6.5%) patients no occlusion was observed,the diameter was greater than 11 mm.

DISCUSSION: Embolization of great saphenous vein with cyanoacrylate has been performed since beginning of this decade .Combined chemical and physical mechanism of action results permanent vein closure. In a recently published study a 24 month occlusion rate of 92% was demonstrated. The most commonly reported complications of cyanoacrylate use for the treatment of varicose vein disease, so far, include ecchymosis and phlebitis. Almeida et al reportad that phlebits is the most frequent side effect as a rate of 16%. In our study phlebitis rate was not as high as reported. It may cause due to shorter time of follow up in hospital.

CONCLUSSION:Endovenous ablation of incompetent great saphenous vein with a cyanoacrylate based glue is feasible. Operation time is short, tumescent anesthesia is unnecessary as postprocedure compression stockings. Lack of significant side-effects and an aerly success rate of 100% are benefits of the system

RESULTS:

Between January 2014 and July 2014 vein sealing system (Biolas VariClose®) examination was performed to 62 patients at Kayseri Research and Training Hospital in Kayseri/TURKEY ,who had documented GSV insufficiency after a duplex venous examination . There were 38 male(%62) and 24 female(%38)patient. The following premorbid conditions were present in these patients: hypertension %8 and diabetes mellitus %3.The patients mean age was 44.5+/-11.1(range 29-72). Table 1 shows the patient demographics.

The lengths of the GSV's that were treated in the present study ranged from 20 to 40 cm(median 28 cm).The mean operating time was 17 minutes(range 9-37 min).The median follow-up period was 8 months(range 0-13 months). The mean diameter of GSV's was 7.5+/-1.5mm(range 5.5-13mm).

Treatment success was defined as complate occlussion of treated vein or recanalized segment shorter than 5 cm. Subtotal recanalization was defined as GSV flow containing 5-10 cm segment of treated vein. A recanalized GSV or treatment failure was defined as an open part of the treated vein segment more than 10 cm in length

The CEAP scores were recorded at baseline and at all follow-up visits by the same physician according to the corresponding guideline. The mean CEAP score decreased from 3 to 0.8 at the end of sixth month.

All 62 patients were avaible for follow-up . At the one week and one month control duplex scans showed total occlusion for all the patients(100%).

Duplex scans showed total occlusion of the GSV's for 58 patients(93.5%) and subtotal occlusion for 4 patients(6,5%) at thirth month control.

At the end of 6 month follow up period,post-procedural duplex scans showed total occlusion of the treated GSV's for 56 patients(90.3%) and subtotal occlusion for 2 patients(3.2%).For the 4 (6.5%) GSV's where no occlusion was observed,the diameter was greater than 11 mm.

There was no mortality in our study . The complications of vein sealing system that were experienced by our patients were thrombophlebitis in 2 patients(%3.2) and hematoma in 1 patient(%1.6). No patient underwent a secondary surgical procedure,and none of the patients developed a deep vein thrombosis or pulmonary embolism.

CONCLUSSION:

Endovenous ablation of incompetent GSVs with a cyanoacrylate based glue is feasible. Operation time is short, tumescent anesthesia is unnecessary as postprocedure compression stockings. Lack of significant side-effects and an aerly success rate of 100% are benefits of the system. Further studies of the system are neccesarry especially in large diameter of GSV.

Yeni Nesil Varis Tedavisi İle Tanışın

VariClose ven kapama sistemi son derece kolay bası tekniği ile embolizasyonu birleştirerek problemli ven segmentini güvenli ve etkili bir şekilde kapatır.

Hekim sadece ultrason ile birlikte ameliyathane koşullarına ihtiyaç duymadan klinikte dahi dakikalar içerisinde işlemi gerçekleştirebilir.

Hastalar günlük rutinlerini bozmadan tedavi olup yaşantılarına geri dönebilirler.

Meet With The New Varicose Vein Treatment Generation

VariClose vein sealing system combines a simple pressure technique with embolization to safely and efficiently seal diseased vein segment.

Phsycian only needs an ultrasound to perform the procedure without the need of surgery room in clinic within several minutes.

Patients can get the treatment and return to their lives without interrupting their daily routines.

Avantajları

- Tümescent anestezi olarak ifade edilen laser ve radyofrekansta kullanılma zorunluluğu olan koruyucu sıvı enjeksiyonuna ihtiyaç duyulmaz
- Genel yada spinal anestezi gerektirmez
- Teknik olarak laser ve radyofrekanstan daha kolay uygulanır
- Laser ve radyofrekansta oluşan ısıya bağlı deri, sinir hasarı ve uyuşma riskini tamamen ortadan kaldırır
- Varis tedavisinde mükemmel sonuçlar sağlar
- Hasta aynı gün işine ve günlük hayatına geri dönebilir
- Hastane yada ameliyathaneye ihtiyaç olmadan uygulanabilir
- Tedavi sonrası deride leke yada iz bırakmaz.

Advantages

- No need for tumescent anesthesia which is have to be used in laser and radiofrequency ablations as an protective liquid injection
- No need for general or spinal anesthesia
- Easy to use compared to laser and radiofrequency ablations
- Eliminates numbness, skin and nerve damage risks that caused by heat in the laser and radiofrequency ablations
- Provides perfect results in the varicose vein treatment
- Patients can return work and daily routines same day
- No need for hospital or surgery room to perform procedure
- No skin lesions or burn marks after treatment.

Variclose
Vein Sealing Systems by biolas

REFERANS KODLARI/ REFERENCE CODES	MODEL FARKLILIKLARI / MODEL DIFFERENCES
CA0001	3 cc, 90 cm kateter, 93cm kateter/3 cc, 90 cm catheter, 93cm catheter
CA0002	2 cc, 90 cm kateter, 93cm kateter/2 cc, 90 cm catheter, 93cm catheter
CA0003	1 cc+1 cc+1 cc, 90 cm kateter, 93cm kateter/1 cc+1 cc+1 cc, 90 cm catheter, 93cm catheter
CA0004	2 cc+2 cc, 90 cm kateter,93cm kateter/2 cc+2 cc, 90 cm catheter, 93cm catheter
CA0005	3 cc+ 2 cc, 2 adet 90 cm kateter, 2 adet 93cm kateter/3 cc+ 2 cc, 2 x 90 cm catheters, 2 x 93cm catheter
CA0006	3 cc+3 cc, 2 adet 90 cm kateter, 2 adet 93cm kateter/3 cc+3 cc, 2 x 90 cm catheters, 2 x 93cm catheter
CA0141	1 cc, 65 cm Uyumlu Kateter/1 cc, 65 cm Compatible Catheter
CA0142	1 cc, 70 cm Uyumlu Kateter/1 cc, 70 cm Compatible Catheter
CA0143	1 cc, 75 cm Uyumlu Kateter/1 cc, 75 cm Compatible Catheter
CA0144	1 cc, 80 cm Uyumlu Kateter/1 cc, 80 cm Compatible Catheter
CA0145	1 cc, 85 cm Uyumlu Kateter/1 cc, 85 cm Compatible Catheter
CA0146	1 cc, 90 cm Uyumlu Kateter/1 cc, 90 cm Compatible Catheter
CA0147	1 cc, 65 cm Uyumlu Kateter/1 cc, 65 cm Compatible Catheter
CA0148	1 cc, 70 cm Uyumlu Kateter/1 cc, 70 cm Compatible Catheter
CA0149	1 cc, 75 cm Uyumlu Kateter/1 cc, 75 cm Compatible Catheter
CA0150	1 cc, 80 cm Uyumlu Kateter/1 cc, 80 cm Compatible Catheter
CA0151	1 cc, 85 cm Uyumlu Kateter/1 cc, 85 cm Compatible Catheter
CA0152	1 cc, 90 cm Uyumlu Kateter/1 cc, 90 cm Compatible Catheter
CA0153	70 cm kateter/70 cm catheter
CA0154	75 cm kateter/75 cm catheter
CA0155	80 cm kateter/80 cm catheter
CA0156	85 cm kateter/85 cm catheter
CA0157	90 cm kateter/90 cm catheter
CA0158	95 cm kateter/95 cm catheter
CA0159	70 cm Uyumlu Kateter/70 cm Compatible Catheter
CA0160	75 cm Uyumlu Kateter/75 cm Compatible Catheter
CA0161	80 cm Uyumlu Kateter/80 cm Compatible Catheter
CA0162	85 cm Uyumlu Kateter/85 cm Compatible Catheter
CA0163	90 cm Uyumlu Kateter/90 cm Compatible Catheter
CA0164	95 cm Uyumlu Kateter/95 cm Compatible Catheter
CA0165	100 cm Uyumlu Kateter/100 cm Compatible Catheter
CA0166	80 cm kateter/80 cm catheter
CA0167	85 cm kateter/85 cm catheter
CA0168	90 cm kateter/90 cm catheter
CA0169	95 cm kateter/95 cm catheter
CA0170	100 cm kateter/100 cm catheter

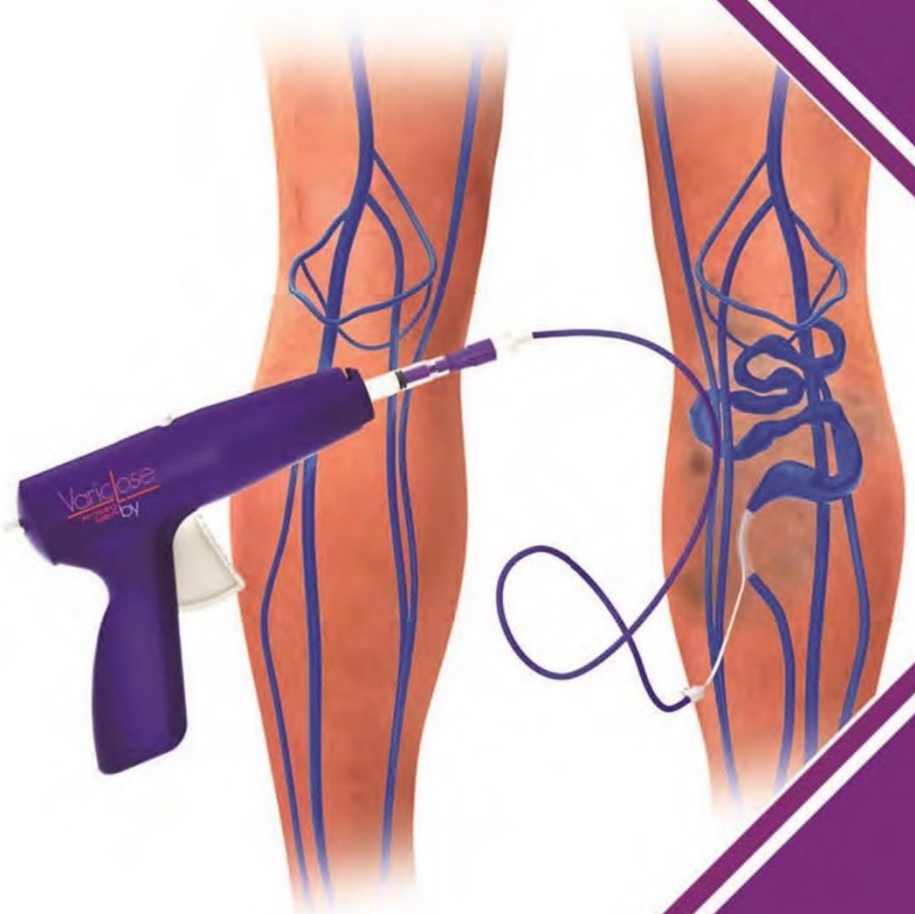
biolas®
HEALTH INC.
www.biolas.net

Üretici / Manufacturer
FG GRUP
www.fggrup.com

Üretici Firma/Manufacturer
FG Grup Sağlık İnş. Har. Mim. Müh. Elektronik San. Ve Tic. A. Ş.
Malıköy Başkent OSB Mah.
Teknokent Blv. NO: 39 Sincan/ANKARA
Tel: +90 312 472 11 18/25
Fax: +90 312 472 11 26
info@fggrup.com.tr/ www.fggrup.com

VariClose

Vein Sealing Systems by biolas®



VariClose

Yeni nesil
varis tedavisi ile tanışın

biolas®
www.biolas.net

FG GRUP
www.fggrup.com