CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Cyanoacrylate vs laser ablation. Turkish experience

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University of Istanbul

Disclosure

Speaker name: A. Kursat Bozkurt

- I have the following potential conflicts of interest to report:

Abdi Ibrahim – Travel support
Bayer – Speaker bureau
Biolas – Travel support
Boehringer Ingelheim - Speaker bureau
Pfizer - Speaker bureau
Santa Farma – Travel support
Servier - Speaker bureau

Endovenous ablation in Turkey and Personel experience

- Endovenous ablation program – March 2005
- Full reimbursement in the last 7 years
- Full reimbursement for glue in the last 2 years
- Initially 980 lazer
- 2008-2014 RF
- Since 2014 RF and Glue
- Over 4000 patients and 4500 legs
- Satisfactory closing rates with over 92%

Why we need another one when we are using EVTA?

- Results are good with current techniques ✓

HOWEVER:

- **New!!!! (Patient preference)**
- **Tumescent anesthesia for thermal ablation**
- **Substantial post interventional discomfort (stockings!)**
- **Thermal injury**

Cyanoacrylate

- Cyanoacrylates include methyl 2-cyanoacrylate, ethyl-2-cyanoacrylate ("Super Glue" and ”Crazy Glue")
- **n-butyl cyanoacrylate and 2-octyl cyanoacrylate** used in medical, veterinary applications for 40 years

Medical Application Areas

- AVM
- Bleeding from vascular structures
- Gastric, esophageal, duodenal and colonic varices

VenaSeal data

- Feasibility study, 3 year data
- Escope, 2 year data
- VeClose, 1 year data

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Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose)

Nick Morrison, MD, Kathleen Gibson, MD, Scott McEnroe, MD, et al.

Journal of Vascular Surgery

Volume 61, Issue 4, Pages 985-994 (April 2015)

- 222 patients with symptomatic GSV incompetence
- CAE (n = 108) with the VenaSeal Closure System or RFA (n = 114)
- Primary end point: Closure of the target vein at month 3 as assessed by duplex ultrasound

Results

- 3-month closure rates were 99% for CAE and 96% for RFA
- Pain scores was mild and similar between treatment groups (2.2 for CAE and 2.4 for RFA
- At day 3, less ecchymosis in the treated region was present after CAE compared with RFA ($P < .01$).

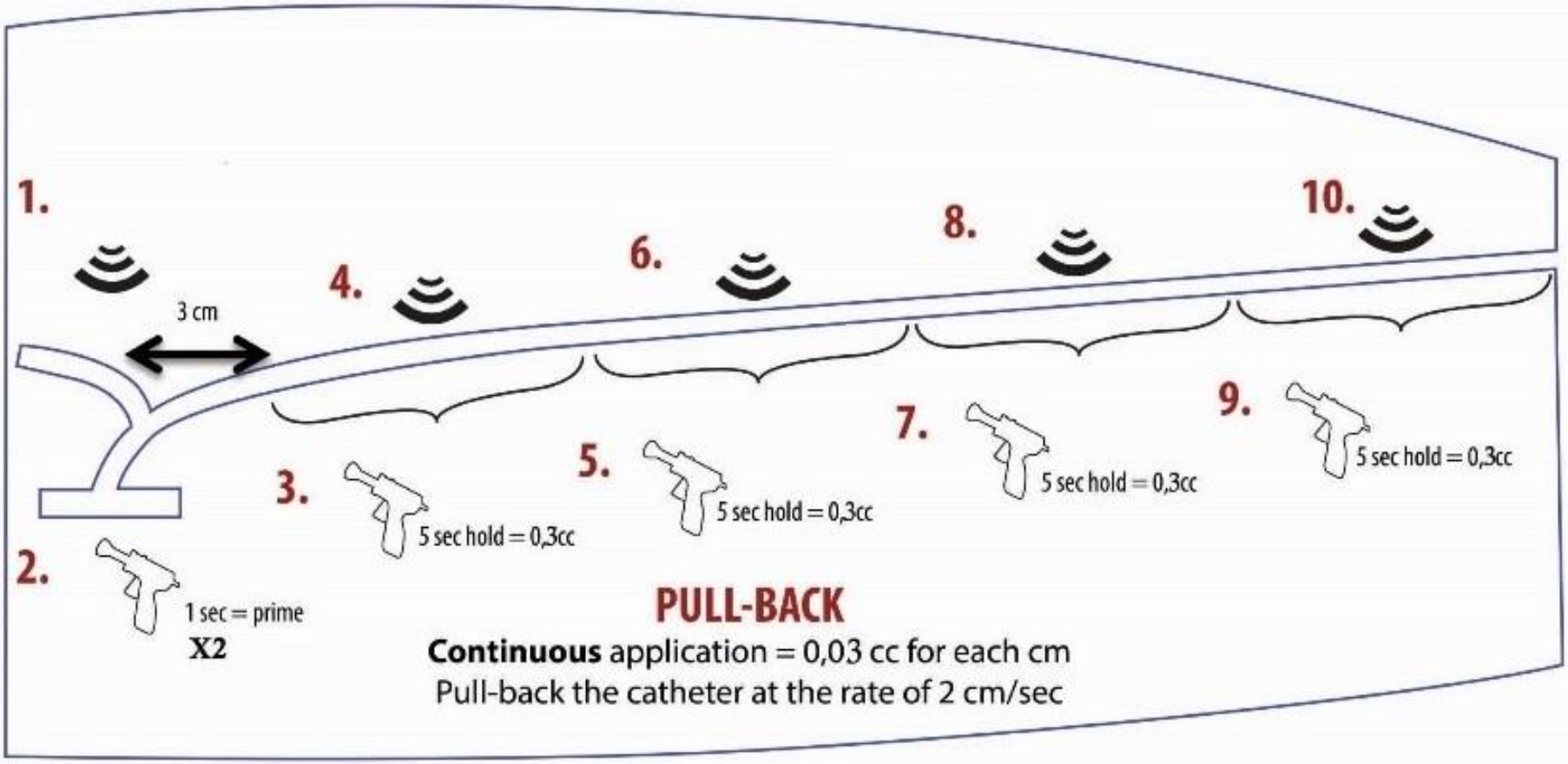
Are all glues equal?

Turkish Glue

- **Like water**
- **Quick polimerisation**
- **Continuous application**
- **Distance to SFJ: 3 cm**
- **Moderate strong data**
- **Less phlebitis?**
- **Shorter procedure time (15 min)**

VenaSeal

- **Like honey**
- **Longer polimerisation**
- **Segmental application**
- **Distance to SFJ: 5 cm**
- **Stronger data**
- **More phlebitis?**
- **Longer procedure time (24 min)**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1 sec = prime
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5 sec hold = 0,3cc
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6.
7.
5 sec hold = 0,3cc
8.
9.
5 sec hold = 0,3cc
10.
PULL-BACK
Continuous application = 0,03 cc for each cm
Pull-back the catheter at the rate of 2 cm/sec

Original Article

Phlebology

Phlebology
2016, Vol. 31(1S) 106–113

DOI: 10.1177/0268355516632652
phl.sagepub.com
SAGE

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]

Table 1. Demographic and baseline data of the study subjects.

	EVLA (n = 156)	CAA (n = 154)	
	Mean ± SD (n) n (%)	Mean ± SD (n) n (%)	P value
Age (years)	40.2 ± 11.2	42.5 ± 13.1	0.099
Female gender	79 (50.6)	79 (51.3)	0.908
Target leg			
Left	72 (46.2)	83 (53.9)	0.173
Right	84 (53.8)	71 (46.1)	0.173
GSV diameter (cm)	7.1 ± 1.6	7.2 ± 1.8	0.978
CEAP category			0.108
C2	119 (76.3)	104 (67.5)	
C3	33 (21.2)	38 (24.7)	
C4a	2 (1.3)	9 (5.8)	
C4b	2 (1.3)	3 (1.9)	

CAA: cyanoacrylate ablation; CEAP: clinical, etiology, anatomy and pathophysiology classification; EVLA: endovenous laser ablation; GSV: great saphenous vein; SD: standard deviation.

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.

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 2016;■:1-6.)

Table III. Procedure characteristics

	VVSS	EVLA	P[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
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.

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.

Did you mean: ***varicose*** (20632 items)

1. Nonthermal, Nontumescent Endovenous Treatment of Varicose Veins.
   Tekin Aİ, Tuncer ON, Memetoğlu ME, Arslan Ü, Öztekin A, Yağmur B, Biçer M, Özmen R.
   Ann Vasc Surg. 2016 Oct;36:231-235. doi: 10.1016/j.avsg.2016.03.005.
   PMID: 27421205
   Similar articles

2. Early-Term Outcomes for Treatment of Saphenous Vein Insufficiency with N-Butyl Cyanoacrylate: A Novel, Non-Thermal, and Non-Tumescent Percutaneous Embolization Technique.
   Tok M, Tüydeş O, Yüksel A, Şenol S, Akarsu S.
   Heart Surg Forum. 2016 Jun 20;19(3):E118-22. doi: 10.1532/hsf.1496.
   PMID: 27355146
   Similar articles

3. N-butyl cyanoacrylate in the treatment of venous insufficiency--the effect of embolisation with ablative polymerisation.
   Çalık ES, Arslan Ü, Ayaz F, Tort M, Yıldız Z, Aksu V, Onk OA, Limandal HK, Ekingen E, Dağ Ö, Kaygın MA, Erkut B.
   Vasa. 2016;45(3):241-6. doi: 10.1024/0301-1526/a000531.
   PMID: 27129070
   Similar articles

4. A new non-tumescent endovenous ablation method for varicose vein treatment: Early results of N-butyl cyanoacrylate (**VariClose®**).
   Yasim A, Eroglu E, Bozoglan O, Mese B, Acipayam M, Kara H.
   Phlebology. 2016 Mar 27. pii: 0268355516638577. [Epub ahead of print]
   PMID: 27022011
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Advantages of glue ablation

- No need for Tumescent Anesthesia
- Easy to use compared to EVTA
- Eliminates nerve damage caused by thermal ablation
- No need for compression stockings
- No skin lesions or burn marks after treatment
- No need for operating room conditions
- Patients can return work and daily routines immediately

- Overall experience in Turkey is around 32000 cases
- Initial experience is good (2 years)
- Long term data is necessary

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VEITH 2016, New York

Perforating Vein Closure With Turkish Cyanoacrylate Adhesive: Interim Results of 50 Patients

Prof. Dr. A. Kursat Bozkurt

Istanbul University
Cerrahpaşa Medical Faculty


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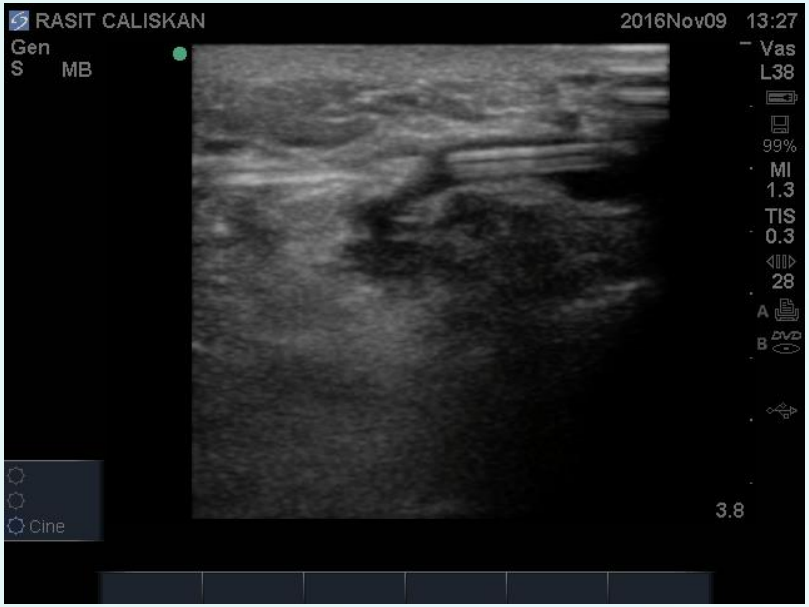
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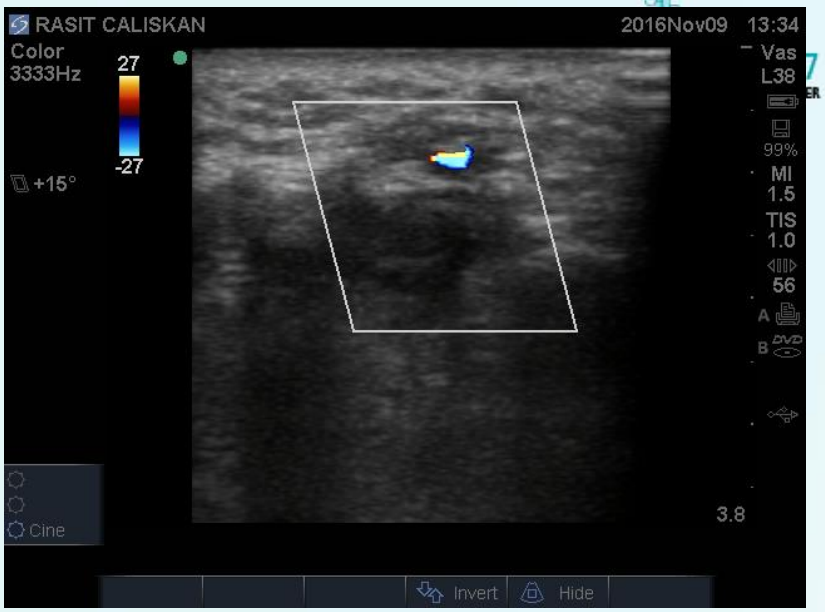
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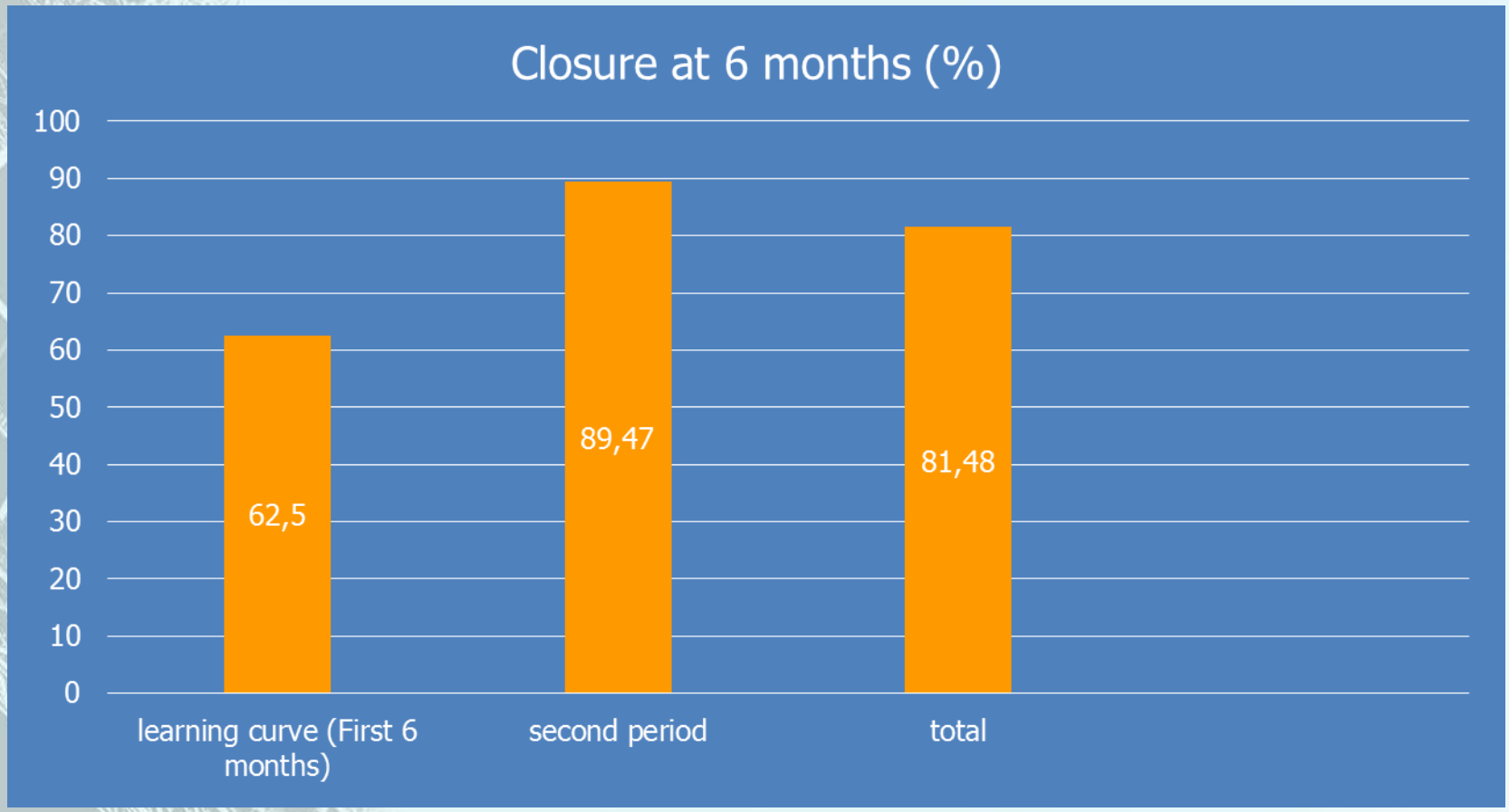
Closure at 6 months (%)
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learning curve (First 6 months)
second period
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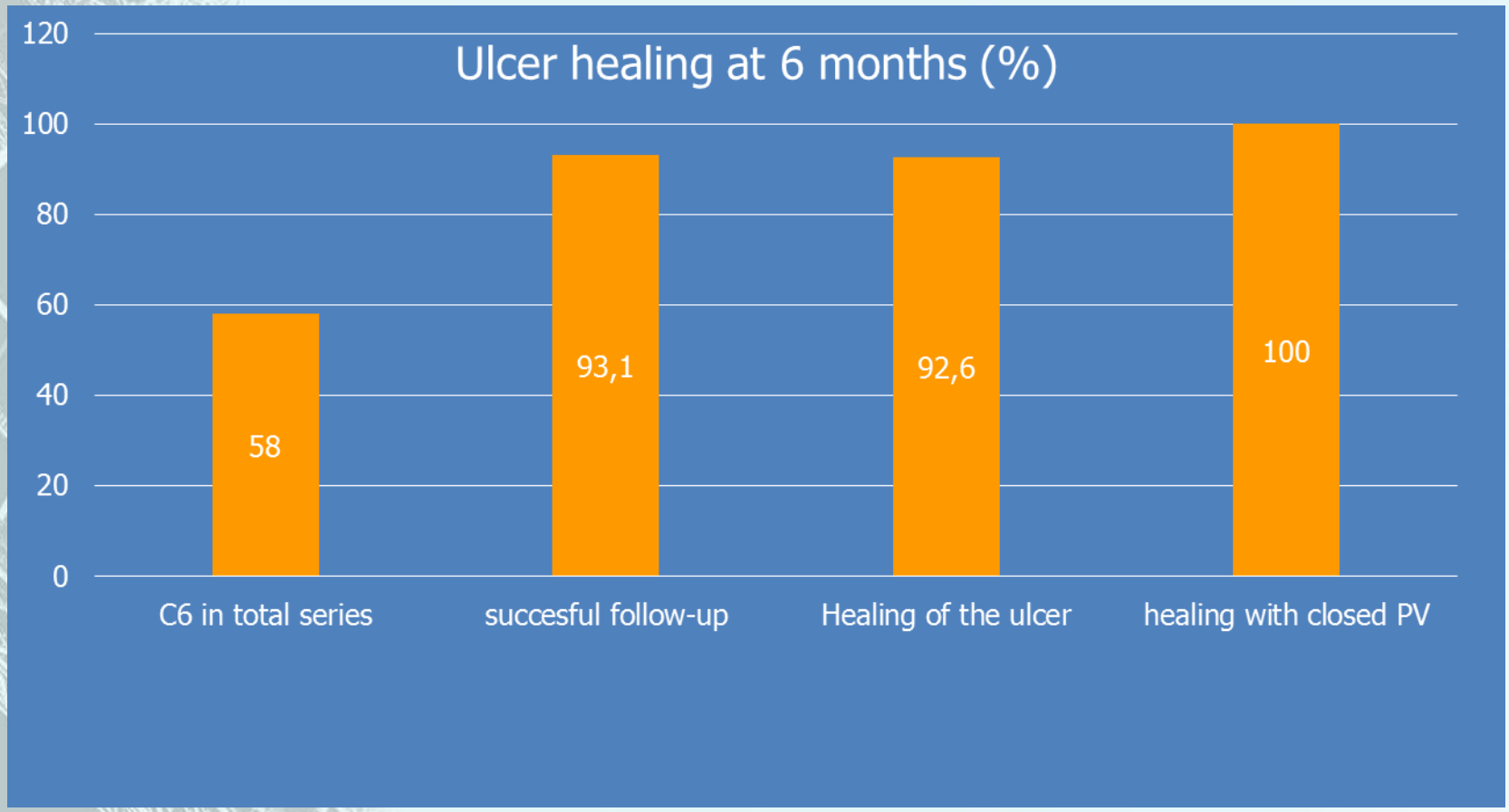
Ulcer healing at 6 months (%)
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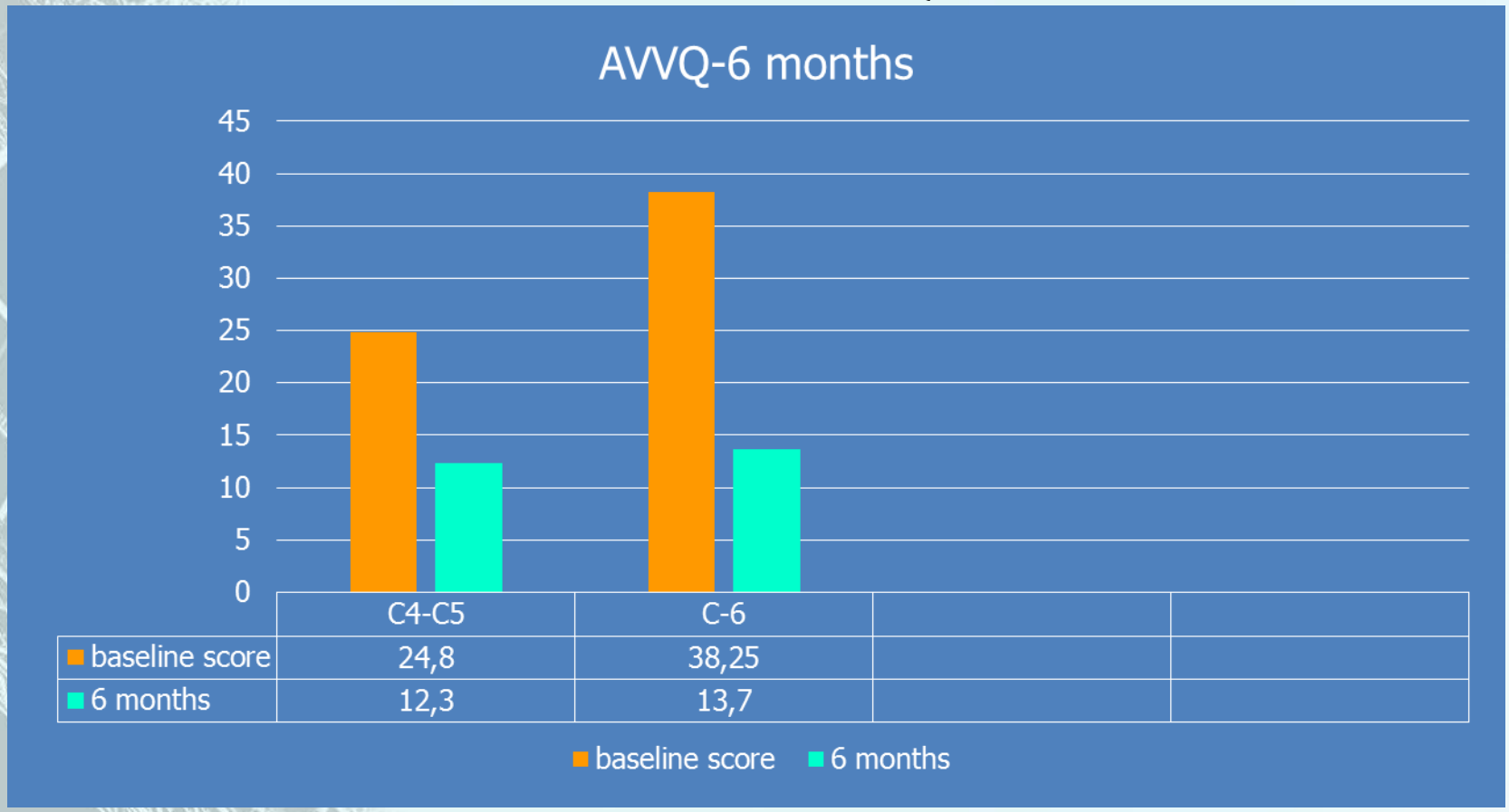
Healing of the ulcer
healing with closed PV

AVVQ


AVVQ-6 months
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13,7
baseline score
6 months

CrossMark

Journal of Vascular Surgery
Venous and Lymphatic Disorders™

Current state of the treatment of perforating veins

Ellen D. Dillavou, MD,[a] Michael Harlander-Locke, MPH,[b] Nicos Labropoulos, MD,[c] Steven Elias, MD,[d] and Kathleen J. Ozsvath, MD,[e] *Pittsburgh, Pa; Los Angeles, Calif; and Stony Brook, New York, and Albany, NY*

Table II. Technical success of radiofrequency ablation (*RFA*), endovenous laser ablation (*EVLA*), and ultrasound-guided foam sclerotherapy (*UGFS*)

Primary author (year)	*Perforator treatment modality*	*No. of patients/ procedures*	*Mean follow-up, months*	*Method and timing of evaluating procedure success*	*Overall success rate, %*
Rueda[10] (2013)	RFA and SEPS	64	37	DUS, 1 week	100
Kiguchi[13] (2014)	UGFS	62	30	DUS, 2 weeks	54
Harlander-Locke[14] (2012)	RFA	20/28	25	DUS, 48-72 hours	96
Harlander-Locke[15] (2012)	RFA	88/140	12	DUS, 48-72 hours	82
Dumantepe[16] (2012)	EVLA	13/23	14	DUS, 12 months	87
Köroglu[17] (2011)	EVLA + UGFS	24	6	DUS, 24 hours	75
Lawrence[18] (2011)	RFA	45/51	13	DUS, 48-72 hours	71
Corcos[19] (2011)	EVLA	303/534	28	DUS; mean, 28 months	72
Nelzén[11] (2011)	SEPS	37	12	DUS, 6-9 months	87
Hissink[20] (2010)	EVLA	28/33	3	DUS, 3 months	78
Marrocco[21] (2010)	RFA	241	5	DUS, 1-7 days	100
Marsh[22] (2010)	RFA	53	14	DUS; mean, 14 months	82
van den Bos[23] (2009)	RFA	12/14	3	DUS, 3 months	64
Hingorani[24] (2009)	RFA	38/48	2	DUS, 3-7 days	88
Bacon[25] (2009)	RFA	37	60	DUS, 5 years	81

THANK YOU

Definition of Phlebitis!

- The inflammation after glue is not a real usual thrombophlebitis with trapped thrombus (no cord is felt!)
- In some cases the inflammation with mild tenderness may be present
- It resolves over several days in comparison with thromboflebitis that can last several weeks.
- Some patients have no symptoms, but mostly only the visual appearance. It looks more a temporary foreign body reaction.

Table VI. Adverse events

	VenaSeal, No. (%)	*RFA, No. (%)*	P *value*[a]
No. of adverse events per subject			
0	74 (69)	85 (75)	.37
1	28 (26)	22 (19)	
2	6 (6)	6 (5)	
3	0 (0.0)	0 (0.0)	
4	0 (0.0)	1 (1)	
Event severity			
Mild	26 (24)	30 (26)	.35[c]
Moderate	12 (11)	7 (6)	
Severe	2 (2)	1 (1)	
Procedure-related adverse events[b]	27 (25)	31 (27)	.76
Device-related adverse events[b]	13 (12)	7 (6)	.16
Reported adverse events			
Phlebitis, any zone	22 (20)	16 (14)	.36
Phlebitis in treatment zone	11 (10)	10 (9)	.82
Phlebitis not in treatment zone	8 (7)	4 (4)	.24
Phlebitis in both treatment zone and nontreatment zone	1 (1)	1 (1)	1.0
Paresthesia in treatment zone	3 (3)	3 (3)	1.0
Stocking irritation	2 (2)	3 (3)	1.0

VenaSeal™ closure treatment of saphenous v aricosis Indication, technique, initial results J. Alm Gefaessabteilung am Dermatologikum Hamburg, Germany - www.phlebologieonline.de on 2014-09-21 | IP: 109.128.171.87 Phlebologie 5/2014 © Schattauer 2014 243 J. Alm:

- Follow-up data on 227 great saphenous veins, and 24 small saphenous veins following glue ablation
- Minor complications after treatment of the great saphenous vein were inflammatory reactions in 44 legs and phlebitis in 32 legs (14% vs 4.5% in the current series)

How can we explain this?

- Definition of phlebitis?
- The composition of NBCA?
- Continuous delivery method and fast polymerization enables to give cyanoacrylate to each cm of the vein (0.03 cc per cm)
- We believe, in this technique development rate of thrombophlebitis might be lower, as there is no empty space filled without glue and no residual blood inside the vessel.