

Factors Associated With Recanalization And Reintervention Following Below Knee Polidocanol Endovenous Microfoam (PEM)®


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No disclosures

Most Popular Non-Surgical Saphenous Veins Tx




1999 • RFA (+ VenClose® 2017)

2001 • EVLT

2008 • Clarivein®

2014 • Varithena®

2015 • Venaseal®



NTNT Ablations Complications

- SVT
- DVT
- Sclerothrombus retention
- Hyperpigmentation
- Embolization
- Hypersensitivity
- Migraines
- Failure to obliterate target



Pre-procedure Venous Assessment


Clinical + Imaging

2020 Appropriate Use Criteria		Chronic Venous Disease	
American Venous Forum	SVS Society for Vein Care	Multi-Society Document	International Union of Phlebology
Great Saphenous Vein (GSV) ablation		Perforating vein ablation	
CEAP 4 ⁰	Appropriate	CEAP 4 ⁰ , with high outflow and large diameter directed toward affected area	Appropriate
Below knee in CEAP 4 ⁰	Appropriate	CEAP 4 ⁰ , with high outflow and large diameter directed toward affected area	Appropriate
Small Saphenous Vein (SSV) ablation	Appropriate	CEAP 4 ⁰ in symptomatic patient	Appropriate
CEAP 3 ⁰ when reflux is directed to affected area	Appropriate		
CEAP 4 ⁰ when reflux is GSV or thigh veins	Appropriate		
Accessory Saphenous Vein (ASV) ablation	Appropriate	Thigh Vein of Martin-Veins (TV) ablation	Appropriate
CEAP 4 ⁰ when reflux is directed to affected area	Appropriate	CEAP 4 ⁰ for obstructive disease without superficial thrombophlebitis	Appropriate
Ablation of any vein	Appropriate	CEAP 3 (obstructive) for obstructive disease with or without superficial thrombophlebitis	Appropriate
CEAP 3 to compressive disease and saphenous	Appropriate	In asymptomatic patient for fibrous compression such as May-Thurner compression. Found an incidental finding by imaging, with or without telangiectasis (CEAP 3)	Appropriate
NO reflux	Appropriate	In asymptomatic patients	Appropriate


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LE Venous Mapping Protocol

- Patency / thrombosis of deep veins (femoral-popliteal)
- Previously treated veins (obliterated, removed)
- Superficial veins (thigh + calf) size and depth, reflux, tortuosity, acute and chronic thrombi
 - GSV thigh, leg, duplicate
 - SSV
 - AASV
 - Visible symptomatic tributaries
- Perforating veins (size, flow direction / reflux)





LE Venous Mapping Documentation, TVC



- Simple, easy to read
- Has all necessary components
- IAC Accreditation Compliant
- Justifies planned procedures
- Assures approval by insurance
- Determines preliminary feasibility
 - Thermal vs NTNT saphenous ablations
 - Foam ablations
 - Surgical vein Tx


Varithena® (1% PEM) experience (6 years)

- USA FDA Approved 2014 for GSV (off-label SSV)
- > 3100 cases
 - GSV leg – 1390 cases
 - Tributaries – 1000 cases
 - SSV – 537 cases
 - GSV thigh – 130 cases
 - AASV– 63 cases
 - Perforators – 15 cases
- Symptomatic >3 mm, any depth, length, tortuosity, thrombi
- Caution with GSV and SSV (deep venous washout)
- Larger veins > 5 mm?

Methods

- Treatment Protocol Data analyzed:
 - Indication (CEAP), PEM volume administered, success, days to documented duplex after treatment, incidence of adverse VTEs, time to recanalization on duplex
- Surveillance duplexes were performed:
 - At the end of procedure and ≤7 days after
 - Repeated every 3-6 months for 1 year, PRN



Results

Characteristics of the study cohort per ablation

Characteristic	All Ablations (n=597)	Ablation Outcome		p
		Closed (n=533)	Recanalized (n=63)	
Age, Mean (SD), y	68 (14)	68 (14)	68 (12)	0.90
Sex				0.015
Male, n (%)	246 (41.3)	211 (35.4)	28 (4.7)	
Female, n (%)	350 (58.7)	322 (54)	35 (5.9)	
BMI, Median (IQR)	31 (8.4)	32.3 (8.2)	32.8 (10)	0.59
Treated Laterality				0.14
Right, n (%)	297 (49.6)	260 (43.6)	37 (6.2)	
Left, n (%)	299 (50.4)	273 (45.8)	26 (4.4)	

Results

Characteristics of the study cohort per ablation

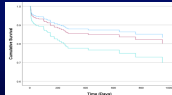
Characteristic	All Ablations (n=597)	Ablation Outcome		p
		Closed (n=533)	Recanalized (n=63)	
Clinical Severity Score				0.79
2, n (%)	18 (3)	12 (2.5)	3 (0.5)	
3, n (%)	257 (44.5)	235 (39.5)	30 (5)	
4, n (%)	196 (33.4)	181 (30.4)	18 (3)	
5, n (%)	3 (0.5)	3 (0.5)	0 (0)	
6, n (%)	99 (18.6)	99 (16.6)	12 (2)	
Vein Diameter, Mean (SD), mm	4.3 (1.2)	4.3 (1.2)	4.9 (1.3)	0.001
Tribunal Vein Type				0.06
GSV, n (%)	554 (93)	499 (83.7)	55 (9.2)	
SSV, n (%)	42 (7)	34 (5.7)	8 (1.3)	
Microfoam Volume, Mean (SD), cc	4.3 (1.1)	4.3 (1.1)	4.6 (1.4)	0.24
Antithrombotic Medication				
None, n (%)	287 (48.2)	265 (44.4)	22 (3.7)	
Anticoagulation, n (%)	95 (15.9)	79 (13.3)	16 (2.7)	0.03
Antiplatelet, n (%)	214 (35.9)	189 (31.7)	25 (4.2)	0.51

* Range: 3.5 mm – 10.2 mm

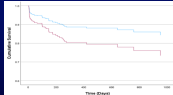
Results

Name	Coefficient	Std. Error	z	p	Exp(O)	Lower 95% CI	Upper 95% CI
Male Sex	0.59	0.23	2.3	.022	1.81	1.09	3.01
Vein Size	0.25	0.09	2.78	.005	1.28	1.08	1.53
Antiglobulin Use	0.19	0.3	0.65	.514	1.21	0.68	2.16
Anticoagulation Use	0.67	0.33	2.04	.041	1.96	1.03	3.74

ANTITHROMBOSIS AND RECANALIZATION



PATIENT SEX AND RECANALIZATION



Initial failure vs later recanalization with lower PEM volume
4cc, IQR=1.5cc vs 5cc, IQR=2 p=0.025

Quest to improve PEM use experience

- Procedures variety, time, comfort
- Veins size (too large?)
- PEM volume (cost)
- Obliteration rate
- VTE incidence

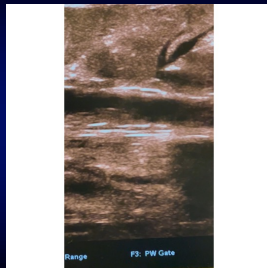


Proximal Tumescence Use

- 186 patients (66 M / 120 F) - 12 months
- 294 cases / 248 LE by 2 Operators (EA and NM)
 - 200 BK GSV
 - 71 SSV
 - 23 AK GSV
- Outcomes Examined
 - Use of Proximal Tumescence (as binary variable and volume)
 - Closure rate, Incidence of VTE, PEM Volume (cc)



Proximal Tumescence SSV



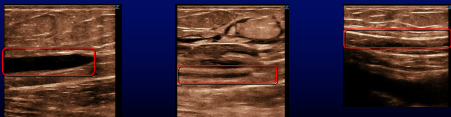
Proximal Tumescence Results

Characteristic	Ablation Type		p	
	All Ablations (n=294)	Non-Tumescence (n=175)		Tumescence (n=119)
Age, Mean (SD), y	68.3 (14)	67.7 (13.2)	69.1 (15.2)	0.39
Sex				
Male, n (%)	103 (35)	54 (30.9)	49 (41.2)	
Female, n (%)	191 (65)	121 (69.1)	70 (58.8)	0.28
Treated Limb(s)				
Right, n (%)	132 (44.9)	74 (10.3)	58 (48.7)	
Left, n (%)	162 (55.1)	101 (57.7)	61 (51.3)	0.34
Clinical Severity Score				
2, n (%)	7 (2.4)	6 (3.4)	1 (0.9)	
3, n (%)	69 (23.3)	56 (32)	33 (27.7)	
4, n (%)	134 (45.6)	80 (45.7)	54 (45.4)	
5, n (%)	8 (2.7)	5 (2.9)	3 (2.5)	
6, n (%)	54 (18)	28 (16)	25 (21)	
Vein Diameter, Mean (SD), mm	4.3 (1.1)	4 (0.87)	4.8 (1.3)	<0.001
PEM Volume, Mean (SD), cc	2.8 (0.6)	2.8 (0.6)	2.9 (0.7)	0.09
Incidence of VTE, n (%)	14 (4.8)	9 (5.1)	6 (5)	0.07
Vein Closed, n (%)	271 (92.2)	164 (93.7)	107 (89.9)	0.23

Tumescence volume 6cc ± 2.4 (3 - 16 cc)

Varithena foam volume vs vein diameter

	P 1 (597)	P 2 (119)	P
Vein diameter	4.3 ± 1.2	4.8 ± 1.3	<0.001
PEM volume	4.3 ± 1.1	2.9 ± 0.7	<0.001



Conclusion

- PEM ablation failures for saphenous veins are associated with ↑ vein D, male, AC, ↓ PEM volume
- Proximal vein compression with tumescence helps improve results for larger veins while using lower PEM volume

