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The VQI Varicose Vein Registry *First ten months results*

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No Disclosures

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Varicose Veins

Varicose Veins are a very common clinical problem, 10-15% of all men and 20-30% of all women afflicted with this chronic condition.

Varicose veins can cause a number of symptoms from pruritus, leg heaviness and aching to thrombophlebitis and occasionally eczema, lipodermatosclerosis, and even ulceration.

The annual incidence of development has been estimated 2% per year, associated with multiple pregnancies, obesity, family history, and increasing age.

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Chronic Venous Insufficiency

Prevalence of Venous Ulceration
0.06% - 2%

Estimates of the overall annual cost of chronic venous insufficiency of \$2.5 billion in the U.S.
(representing 1-2% of the total health care budget of European Countries)

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Outline

- **VVR VQI introduction**
- Compiled data all procedures
- Truncal reflux specific data
- Perforator specific data
- Cluster specific data
- Outcomes:
 - C score, VCSS and patient reported outcomes (PROs)

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VQI Varicose Vein Registry

- Purpose:
 - Analyze procedural and follow-up data
 - Benchmark outcomes regionally and nationally for continuous improvement
 - Improve outcomes by developing best practices
 - Help meet IAC certification requirements for Vein Centers

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VQI Varicose Vein Registry

- **Data collection:**
- Collecting procedural and follow-up data (90 days and 1 year)
- Data on ablation treatments includes:
 - Thermal Radiofrequency Ablation, including ClosureFast™
 - Thermal Laser Ablation
 - Mechanochemical Ablation
 - Chemical Ablation, including Varithena®
 - Embolic Adhesive Ablation, including VenaSeal®
 - Surgical Ablation, including high ligation, stripping, and phlebectomy

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VQI Varicose Vein Registry

Inclusion Criteria

- Percutaneous (closed) and/or cut-down (open) procedures to ablate or remove superficial truncal veins, perforating veins or varicose vein clusters in the lower extremity (C2 or greater venous disease).

Exclusion Criteria

- Any treatment of deep veins of lower extremity.
- Intervention done for trauma
- Treatment of C0 or C1 disease

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Objective

- To provide a “real world” view of trends in treatment and outcomes associated with varicose vein therapy.

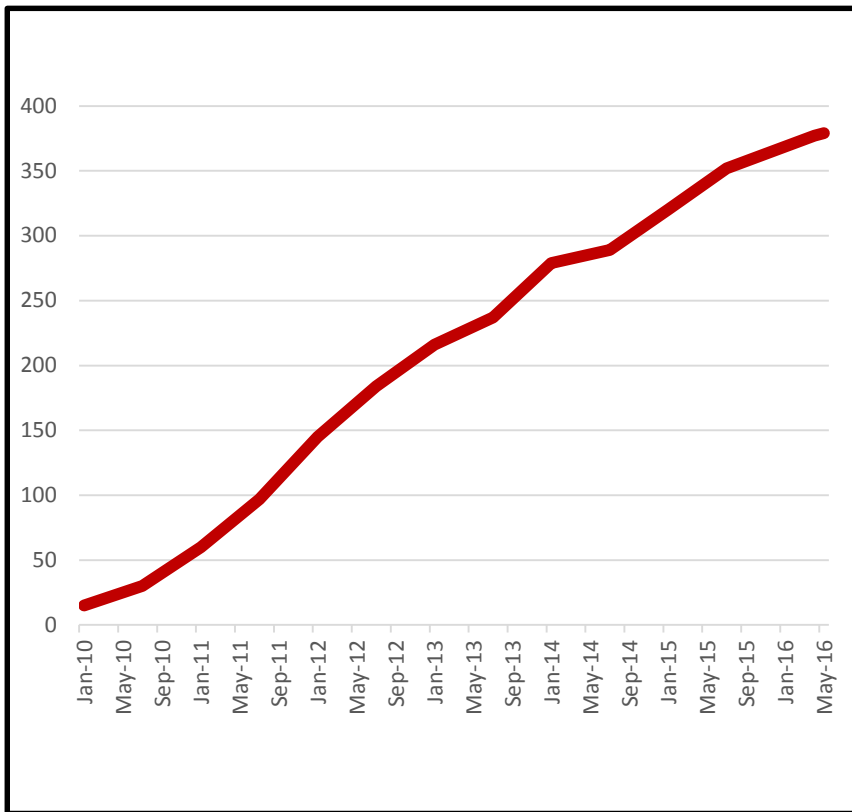
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Methods

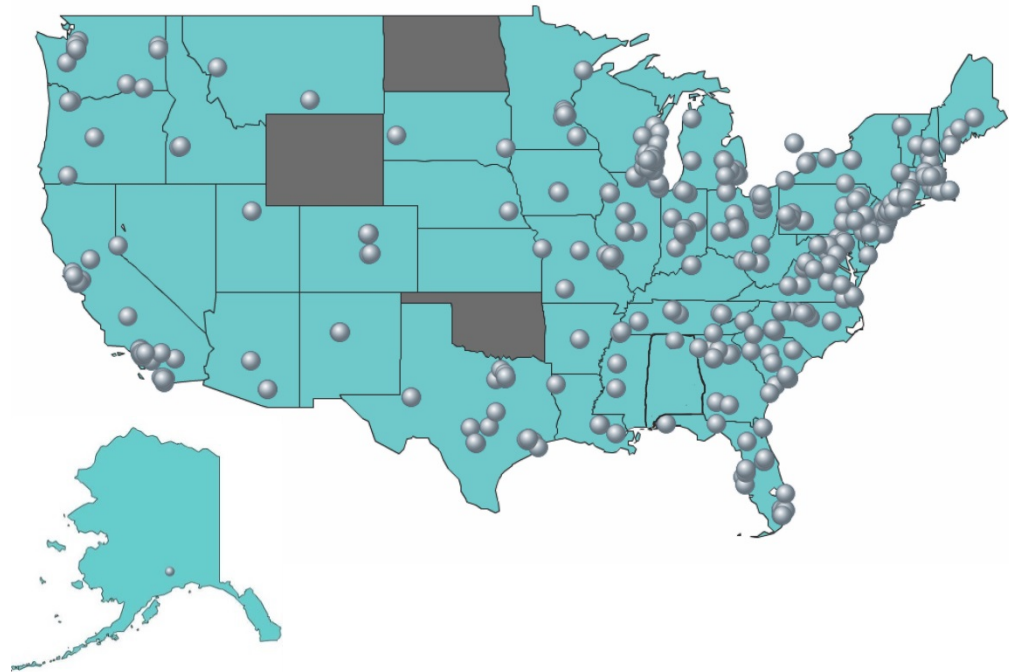
- Retrospective review of prospectively collected data from 1/2015-10/2015.
- Univariate statistical analysis performed by STATA.

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Participating Center Growth



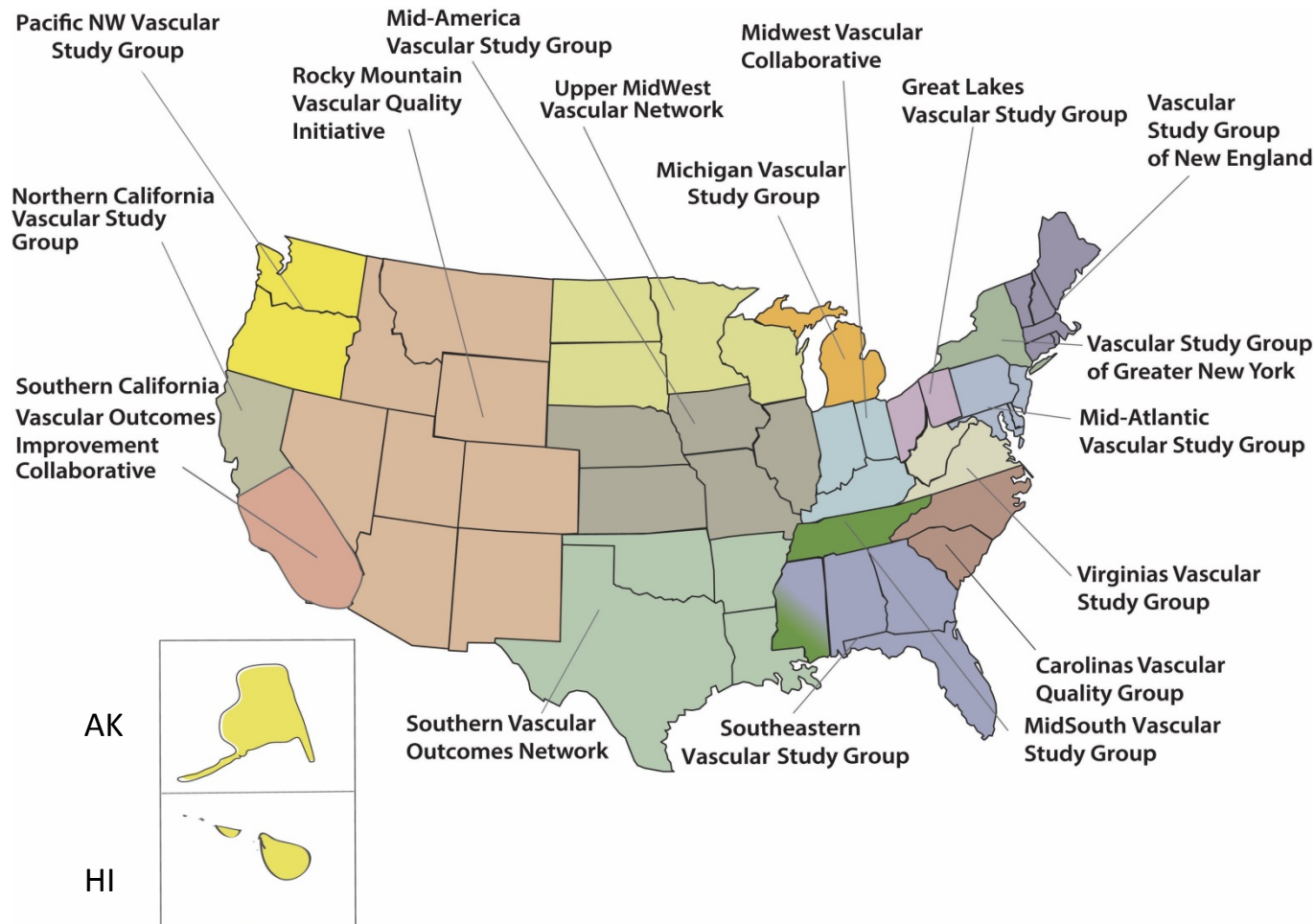
VQI Participating Centers



379 Centers, 46 States + Ontario

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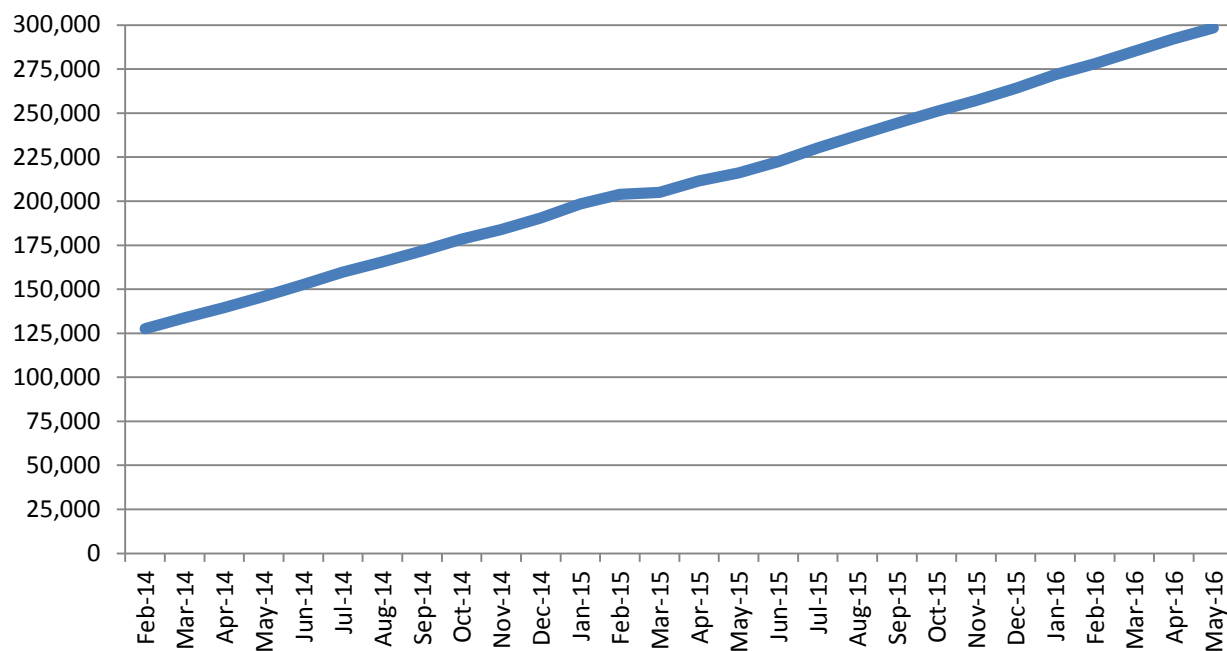
17 Regional Quality Groups



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Total Procedures Captured (as of 6/1/2016)	298,303
Peripheral Vascular Intervention	93,996
Carotid Endarterectomy	68,466
Infra-Inguinal Bypass	30,947
Endovascular AAA Repair	27,326
Hemodialysis Access	25,450
Carotid Artery Stent	11,183
Supra-Inguinal Bypass	10,508
Open AAA Repair	8,322
Thoracic and Complex EVAR	6,426
IVC Filter	5,541
Lower Extremity Amputations	5,399
Varicose Vein	4,739

VQI Total Procedure Volume



Society for
Vascular Surgery



Society for
Vascular Medicine

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Demographics

- Total individuals 1406
- Age 55 ± 14
- 71.5% female
- BMI 29 ± 7
- 78.3% Caucasian; 7% African American
- Previous varicose vein treatment: 31%
- History of DVT: 7%
- On anticoagulation: 8%

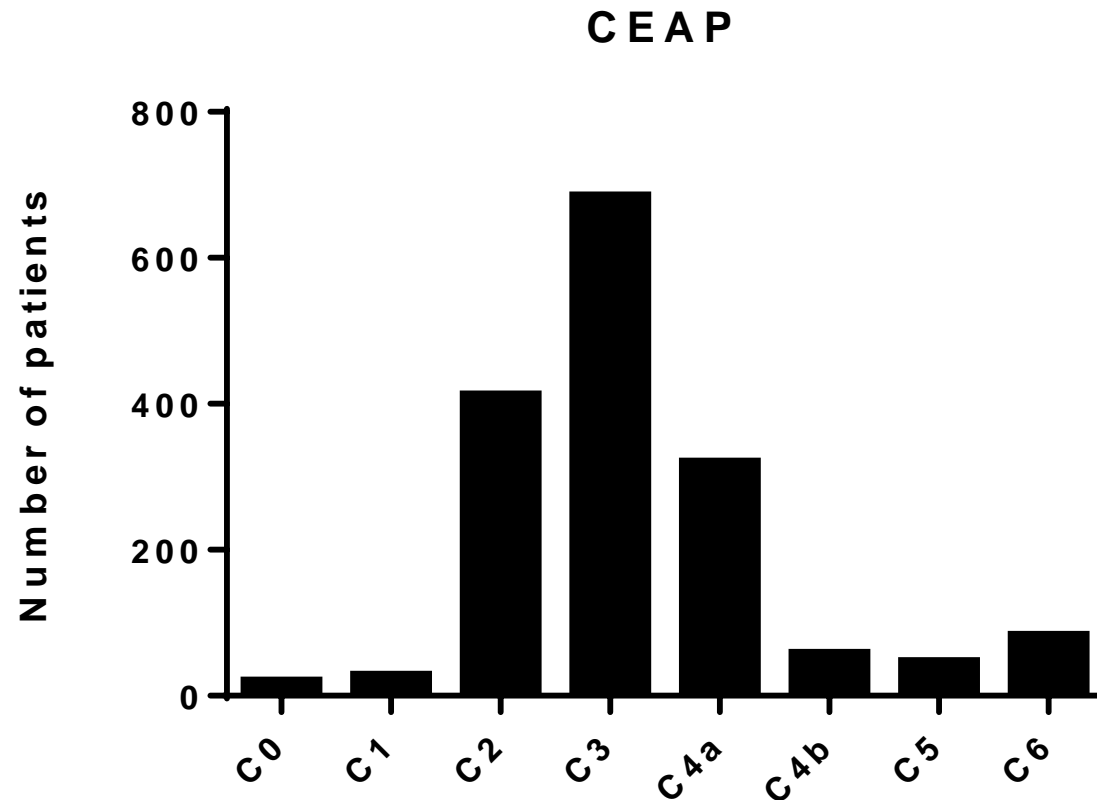
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Number treated

- 2661 veins were treated on 1803 limbs with 1751 procedures (either in office or operating room).
- Laterality:
 - 48% right
 - 49% left
 - 3% bilateral

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C classification



Preoperative, all available patients, n=1653

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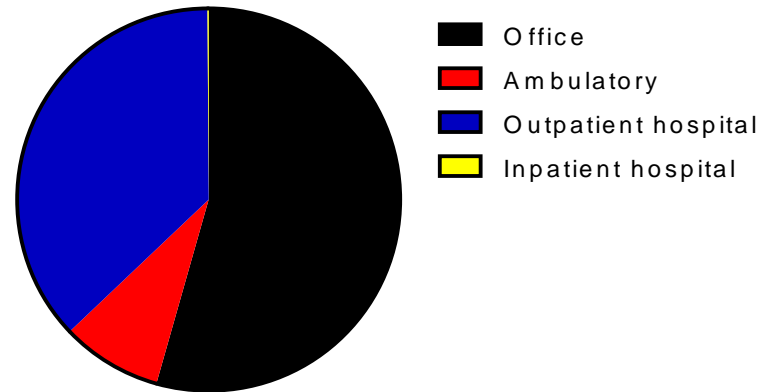
Anatomy of reflux

	Right n (percentage)	Left n (percentage)
GSV thigh	899 (74.7)	882 (74.0)
GSV calf	557 (46.3)	554 (46.5)
SSV	423 (35.2)	402 (33.7)
AASV	125 (10.4)	128 (10.7)
Deep veins	367 (30.5)	386 (32.4)

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Procedural details

- Anesthesia
 - 74% tumescent
 - 18% general
 - 61% local
 - 43% sedation
- Post procedure compression:
 - 46% stockings
 - 52% bandages
 - 2% none



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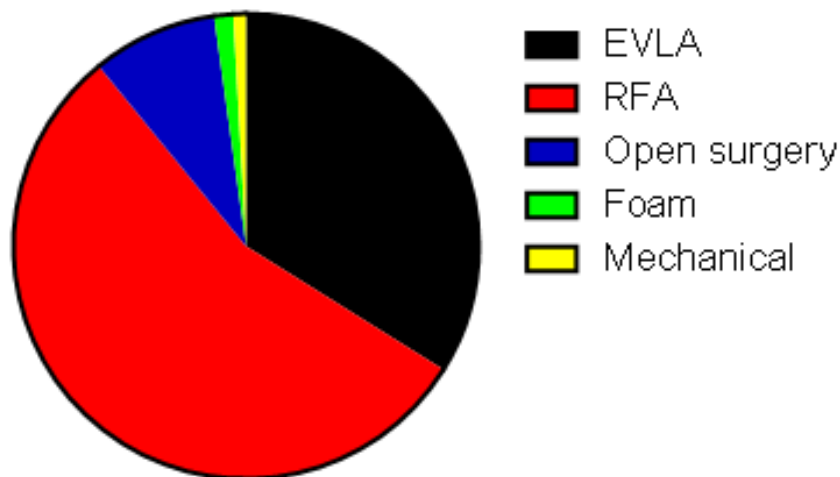
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Truncal reflux treatment

Location treated	Total	1561
	GSV thigh	871 (55.8)
	GSV calf	243 (15.5)
	SA GSV thigh	6 (0.4)
	AASV thigh	151 (9.7)
	AASV calf	2 (0.1)
	SSV thigh	9 (0.6)
	SSV calf	265 (17.0)
	Other	14 (0.9)
Largest vein diameter (mm)		7.74 ± 4.29
Length of vein treated (cm)		35.4 ± 16.7

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Truncal reflux treatment



55% RFA

34% EVLA

8% Open surgery

1% Foam

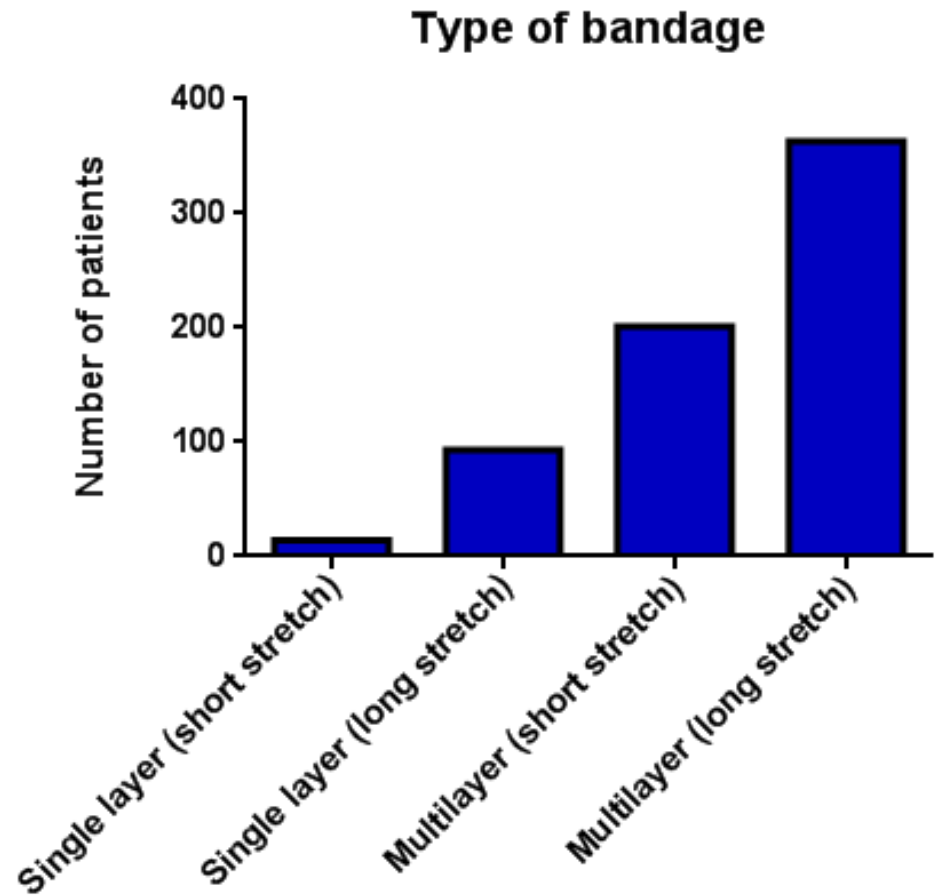
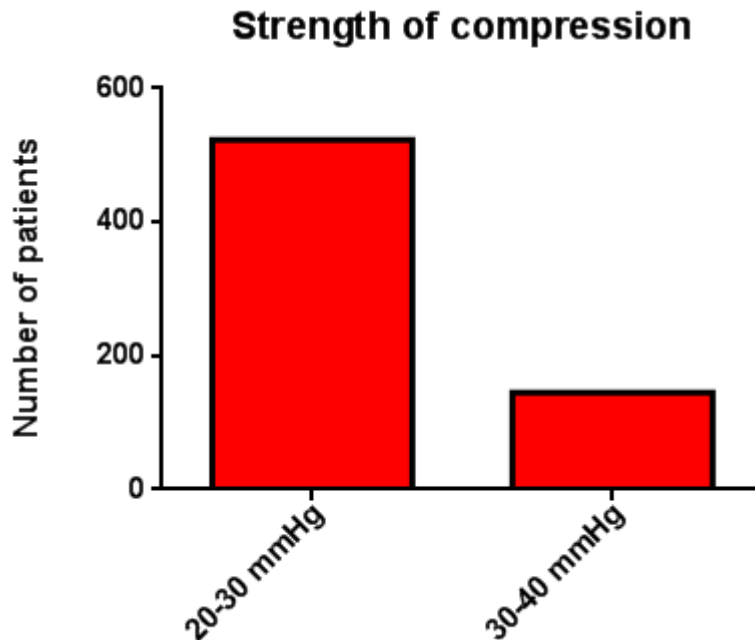
<1% mechanical

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Truncal reflux treatment

Postoperative
compression:

- 50% bandages
- 49% stockings



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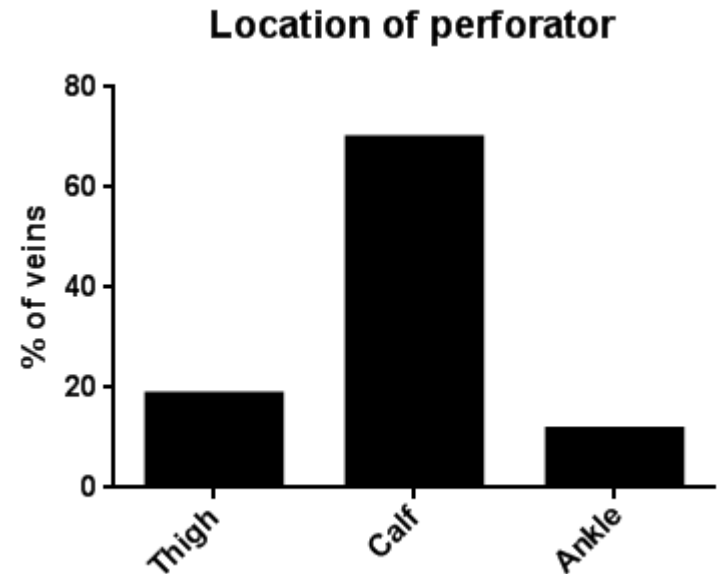
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Perforators

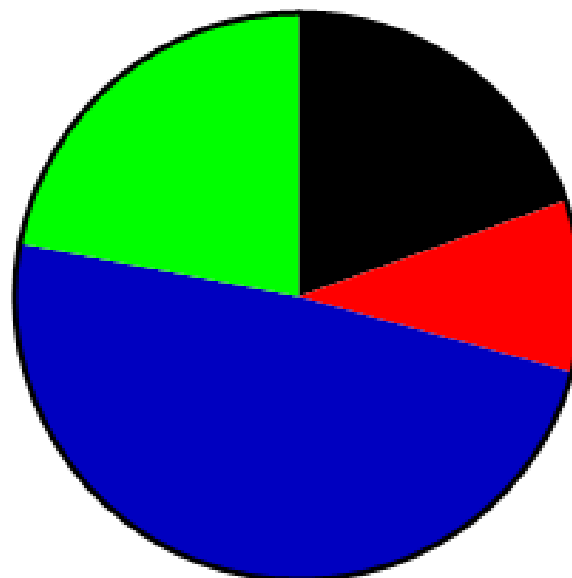
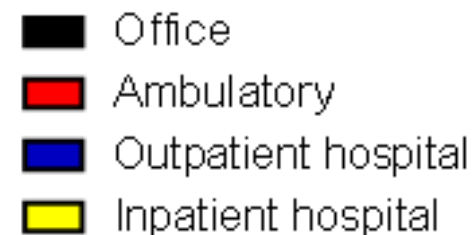
- N=43
- 28/43 were previously treated but reanalyzed.
- 70% located in the calf.
- Largest vein diameter $3.85\text{mm} \pm 1.20$
- All but 2 patients were treated with compression post-procedure



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Perforators

- Most treated in hospital outpatient center.
- Most common treatment was open ligation.



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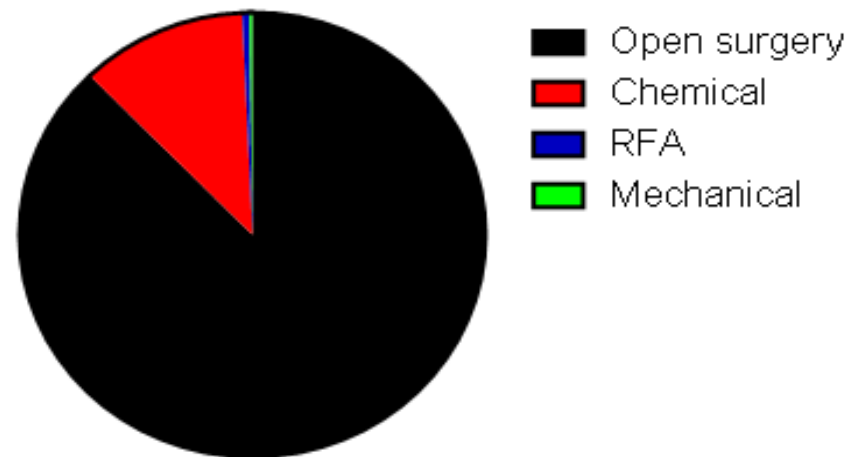
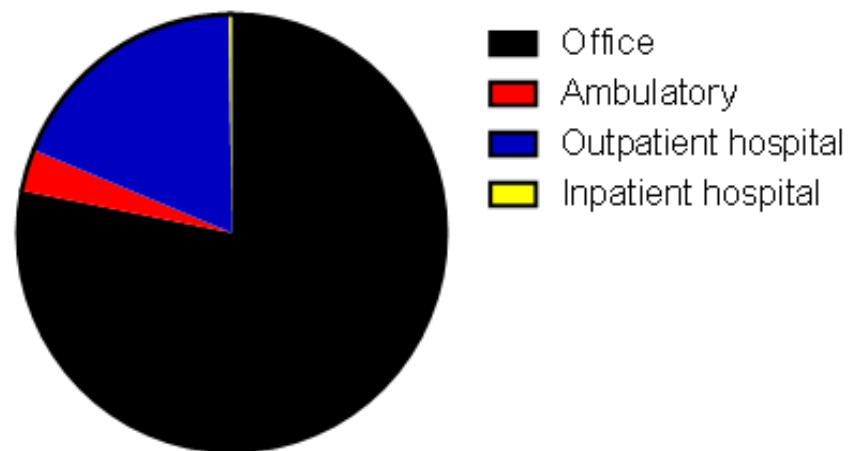
Clusters

- N=640
 - 66 thigh
 - 574 calf
- Largest vein diameter 4.54cm \pm 2.91
- Most common location of treatment was office (78%).

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Clusters

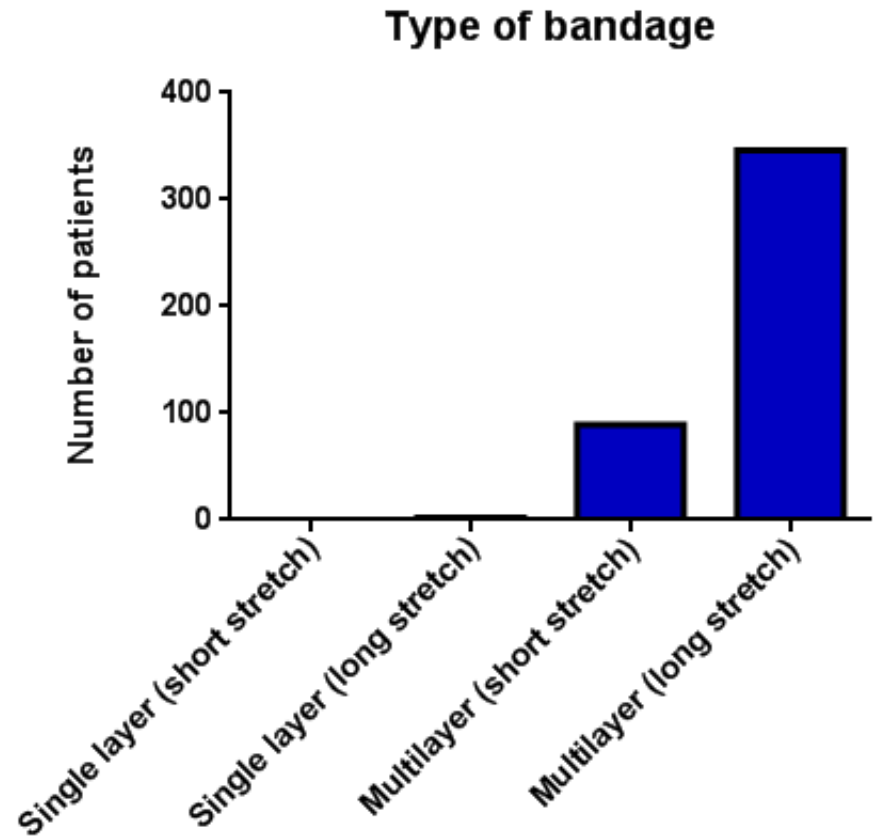
- Remainder performed in hospital outpatient (19%) or ambulatory surgery center (3%).
- Open surgery most common
 - 434 stabs
 - 78 trivex



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Clusters

- All patients except 3 underwent post procedure compression:
 - 439 bandages
 - 145 stockings



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Follow up

- Not applicable (yet): 53.7%
- Face to face: 44.3%
- Time to follow up: 44.6 days \pm 37.6
- Number of lost work days: 2.2 \pm 4.2

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Local complications

- N=714 limbs
- Pigmentation=1.3%
- Superficial phlebitis=1.0%
- Proximal thrombus extension=0.8%
- DVT=0.8%
- Wound infection=0.5%
- Skin blistering=0.5%

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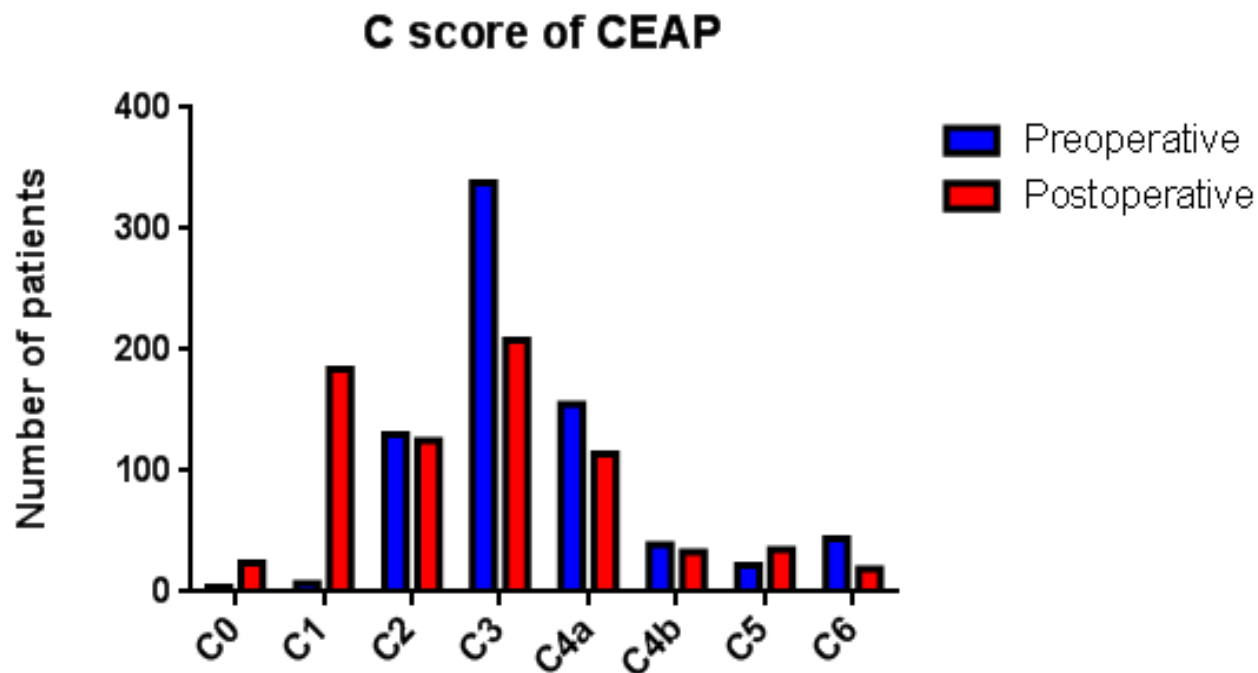
Systemic complications

- 3 unplanned admissions
- 2 mild allergic reactions
- 8 others (unspecified)

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C score change

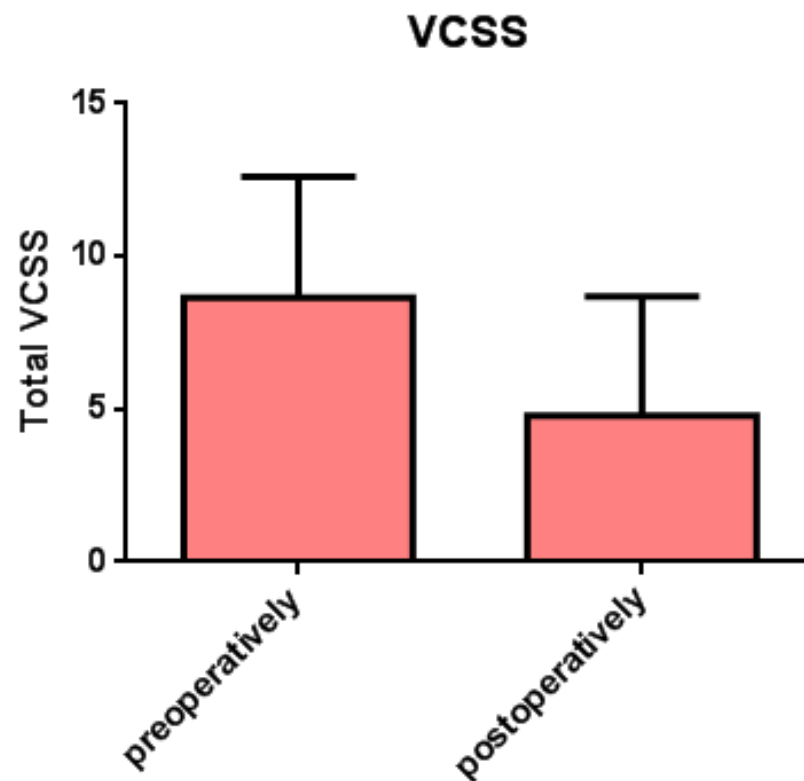
- N=739; Mean change of -0.71 ± 1.18 $p < 0.001$



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VCSS

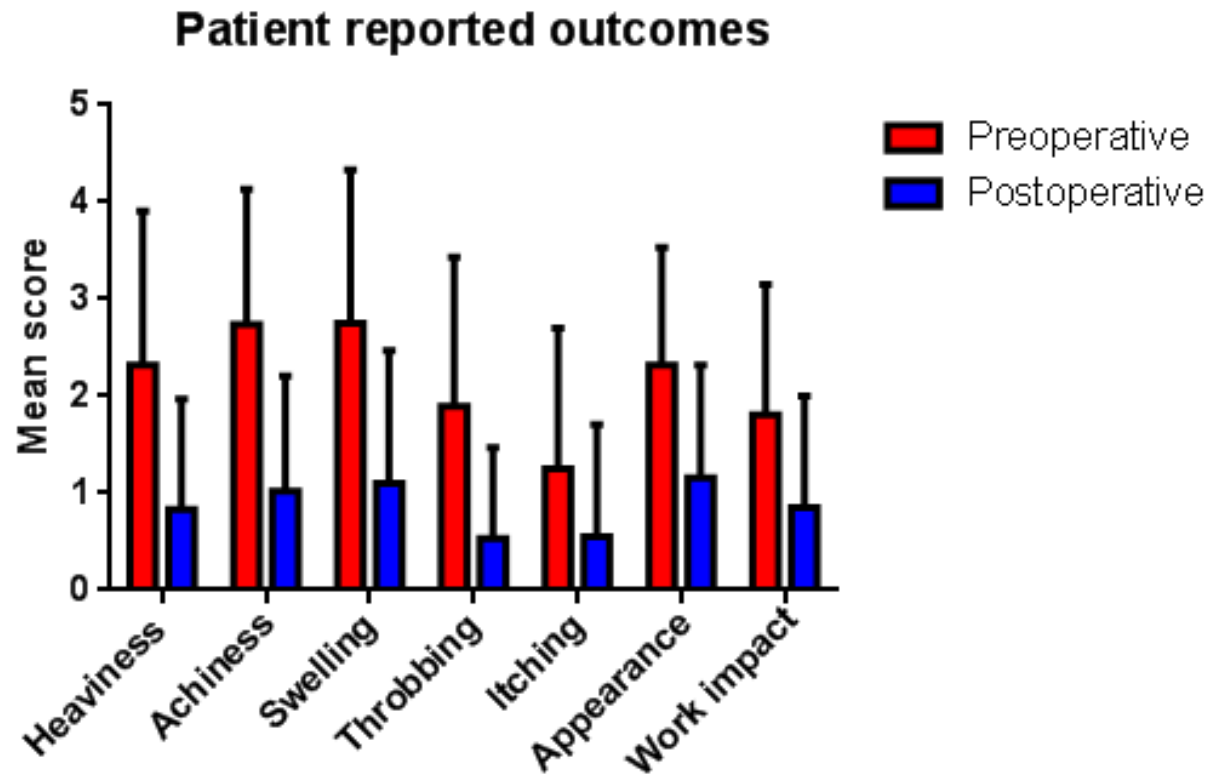
- N=714
- Change: -4.68 ± 3.35
- $P < 0.001$



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Patient reported outcomes

- Pre and post procedure data available for 607 patients
- Mean total change:
 -10.74 ± 6.94 ,
 $p < 0.001$



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Table I. Questions, responses, and method of scoring in the VVSymQ® questionnaire.

“Since waking up today, how often had you had the following problem in your leg to be treated?” This question was asked for each of the following five symptoms: heaviness, achiness, swelling, throbbing, and itching. Response to question:	
	Scoring
“None of the time”	0
“A little of the time”	1
“Some of the time”	2
“A good bit of the time”	3
“Most of the time”	4
“All of the time	5

“VVSymQ is the first PRO specifically designed in accordance with the FDA guidance for PROs, to evaluate varicose vein symptoms from the patient’s perspective in clinical trials”.

Paty J et al, *Phlebology* (Published on line), 2015

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Table 2. Patient demographics and screening/Baseline characteristics.

Parameter	Placebo (N = 112)	Pooled polidocanol endovenous microfoam ^a (N = 283)
Age		
Mean (SD), years	47.9 (11.05)	49.6 (10.43)
Sex, n (%)		
Male	27 (24.1)	78 (27.6)
Female	85 (75.9)	205 (72.4)
Race, n (%)		
White	105 (93.8)	264 (93.3)
Non-white	7 (6.3)	19 (6.7)
Black or African American	2 (1.8)	6 (2.1)
Native Hawaiian or Pacific Islander	0	2 (0.7)
Asian	1 (0.9)	1 (0.4)
American Indian or Alaska Native	3 (2.7)	1 (0.4)
Other	1 (0.9)	9 (3.2)
Weight		
Mean (SD), kg	82.3 (20.34)	83.1 (20.43)
BMI		
Mean (SD)	28.3 (5.87)	28.7 (5.95)

BMI: body mass index; SD: standard deviation.

^aIncludes polidocanol endovenous microfoam 0.5% + 1.0% + 2.0%.

Table 3. Change from Baseline to Week 8 in the 7-day average VVSymQ[®] daily diary overall score and individual component symptom scores.

VVSymQ [®] symptom		Baseline		Week 8		Change from Baseline		Cohen effect size ^c
	n ^b	Mean	(SD)	Mean	(SD)	Mean	(SD)	
VVSymQ [®] overall score								
Placebo	105	8.8	(4.93)	6.8	(5.12)	−2.0	(3.62)	−0.40
Pooled PEM ^a	265	9.0	(4.57)	3.5	(3.45)	−5.5	(4.35)	−1.21
Heaviness								
Placebo	105	1.9	1.17	1.5	1.27	−0.4	0.89	−0.36
Pooled PEM ^a	265	2.1	1.23	0.7	0.92	−1.3	1.12	−1.08
Achiness								
Placebo	105	2.0	1.17	1.6	1.22	−0.4	0.92	−0.36
Pooled PEM ^a	265	2.2	1.16	0.9	0.95	−1.2	1.08	−1.05
Swelling								
Placebo	105	2.0	1.44	1.7	1.46	−0.3	0.88	−0.24
Pooled PEM ^a	265	2.1	1.36	0.9	1.05	−1.3	1.25	−0.92
Throbbing								
Placebo	105	1.6	1.23	1.2	1.15	−0.5	0.91	−0.37
Pooled PEM ^a	265	1.7	1.24	0.6	0.84	−1.1	1.10	−0.89
Itching								
Placebo	105	1.2	1.13	0.9	1.08	−0.3	0.79	−0.29
Pooled PEM ^a	265	1.0	1.11	0.4	0.60	−0.6	1.00	−0.58

PEM: polidocanol endovenous microfoam; SD: standard deviation.

^aIncludes polidocanol endovenous microfoam 0.5% + 1.0% + 2.0% dose groups.

^bNumber of patients with both a Baseline value and a value at the subsequent visit.

^cEffect Size = Mean change from Baseline/Baseline SD.

Table 4. Change from baseline to Week 8 in VVSymQ[®] scores across various levels of PGIC.

PGIC level	Placebo (N = 105)		Pooled polidocanol endovenous microfoam (N = 265)	
	n (%)	Change in VVSymQ Score, mean (SD)	n (%)	Change in VVSymQ score, mean (SD)
Much improved	8 (7.6)	-6.2 (4.5)	136 (51.3)	-6.74 (4.54)
Moderately improved	6 (5.7)	-3.4 (5.5)	70 (26.4)	-4.61 (3.47)
A little improved	14 (13.3)	-4.0 (3.8)	45 (17.0)	-4.74 (4.04)
No change	52 (49.5)	-1.4 (2.7)	5 (1.9)	-1.10 (2.59)
A little worse	17 (16.2)	-0.4 (2.4)	6 (2.3)	-0.01 (3.08)
Moderately worse	7 (6.7)	0.3 (4.3)	2 (0.8)	-2.04 (2.17)
Much worse	1 (1.0)	-4.1 (-)	1 (0.4)	-4.00 (-)

PGIC: patient global impression of change; SD: standard deviation.

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Table 5. Pearson correlations between VVSymQ® score and other measures.

Assessment	VEINES-QOL ^a	PA-V ^{3b}	IPR-V ^{3b}	VCSS	Duplex response ^c
VVSymQ® Baseline	−0.72	0.06	0.05	0.20	
VVSymQ® Week 8	−0.75	0.39	0.21	0.42	−0.27

IPR-V³: Independent Photography Review – Visible Varicose Veins; PA-V³: Patient Self-Assessment of Varicose Veins; VCSS: Venous Clinical Severity Score; VEINES-QOL: Venous Insufficiency Epidemiological and Economic Study instrument-Quality of Life

^aHigher VEINES-QOL means better status (explaining negative correlation with VVSymQ® score).

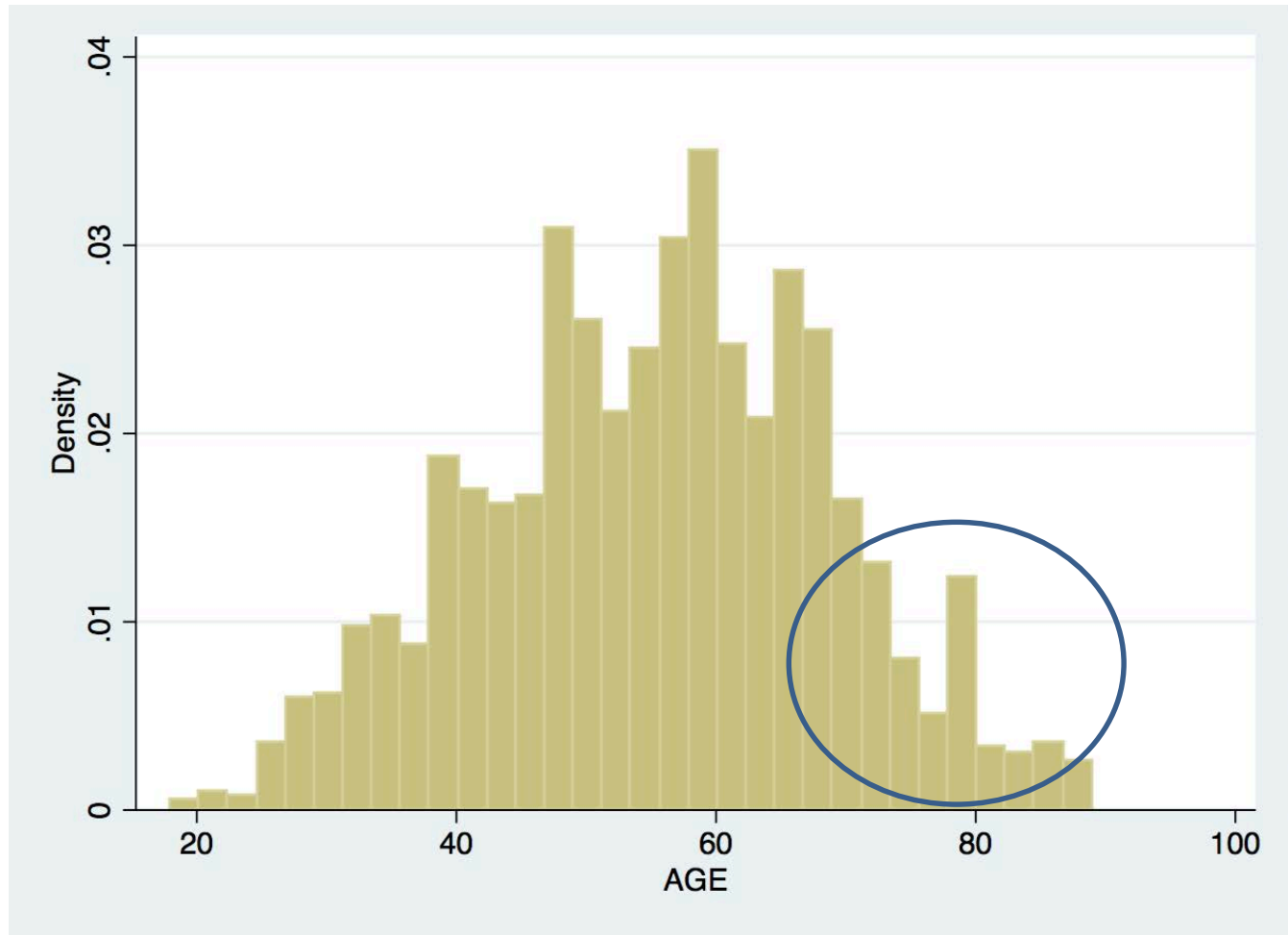
^bHigher scores on PA-V³ and IPR-V³ indicate worse appearance, (explaining positive correlation with VVSymQ® score).

^cDuplex responders have a value of 1, and non-responders a value of 0 (explaining negative correlation with VVSymQ® score).

This suggests that the PROs measure something different than what is usually determined by physician or provider-oriented measures and laboratory measures.

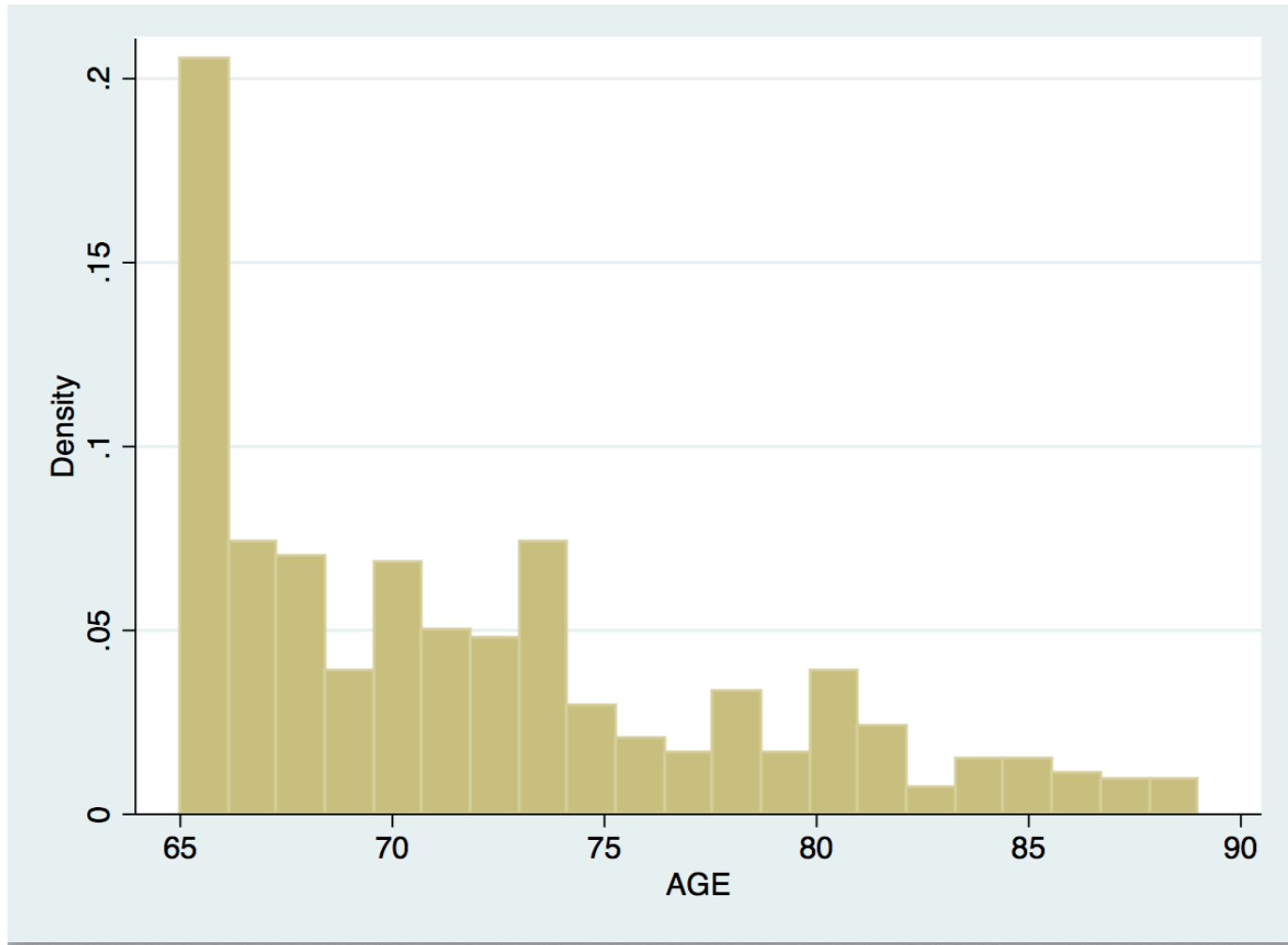
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Patients by age



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Patients by age



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Summary

- Modern day varicose vein treatment is characterized by:
 - Largely office-based and outpatient hospital based treatment.
 - Endovenous treatment of axial reflux.
 - Open surgery for perforators and clusters.
 - Nearly universal post operative compression.
 - Improvements in C score, VCSS and PROs.

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Conclusions

- VQI VVR provides complete assessment of varicose vein interventions.
- VQI VVR is particularly useful for monitoring changes after treatment.
- Future studies should utilize this database to identify best practices and continue to improve outcomes in varicose vein patients.

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Potential Questions the VVR could Answer

- The efficacy of combined procedures (ablation plus phlebectomy) vs. multiple single procedures
- The efficacy of tumescent-less (MOCA, glue) vs. thermal (RFA, EVLA) vs. foam sclerotherapy for saphenous vein ablations
- The role of perforator interruption in patients with C2-C4 disease
- The progression of C2 disease to higher levels of disease.
- The relationship of age to treatment outcomes including quality of life assessment
- Variation in indications being used for treatment of superficial venous disease across centers
- Modern day complication rates