2019 MID-ATLANTIC
CONFERENCE

9th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2019

Todd Gensler MD
May 3, 2019

Do We Undertreat or Overtreat Varicose Veins: What is the Natural History?

Disclosures

- None

Objectives

- Describe the natural history of varicose veins
- Describe methods for assessing outcome for intervention for varicose veins
- Answer the question

undertreat

overtreat

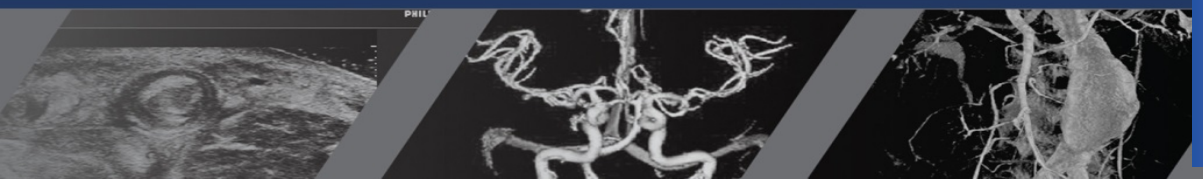
OBJECTIVE 1—NATURAL HISTORY

- Current knowledge about the natural progression of venous disease is lacking

Use of the Clinical, Etiologic, Anatomic, and Pathophysiologic classification and Venous Clinical Severity Score to establish a treatment plan for chronic venous disorders

October 2015 Volume 3, Issue 4, Pages 456–460

Jose I. Almeida, MD[a,*], Thomas Wakefield, MD[b], Lowell S. Kabnick, MD[c], Uchenna N. Onyeachom[d], Brajesh K. Lal, MD[e]



JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Revision of the CEAP classification for chronic venous disorders: Consensus statement

December 2004 Volume 40, Issue 6, Pages 1248–1252

Presented at the Sixteenth Annual Meeting of the American Venous Forum, Orlando, Fla, Feb 26-29, 2004

athophysiologic classification

Basic CEAP

Superficial veins			
	1. Telangiectase	12.	Deep femoral vein
	2. GSV above k	13.	Femoral vein
	3. GSV below k	14.	Popliteal vein
	4. Short saphen	15.	Crural veins: anterior tibial, posterior tibial, peroneal veins (all paired)
	5. Nonsaphenou	16.	Muscular veins: gastrocnemius, soleal, other
Deep veins			
	6. Inferior vena	Perforating veins	
	7. Common iliac	17.	Thigh perforator veins
	8. Internal iliac v	18.	Calf perforator veins
	9. External iliac vein		Great saphenous vein below knee
	10. Pelvic: gonadal, broad ligament veins, other		Small saphenous vein
	11. Common femoral vein		Nonsaphenous veins

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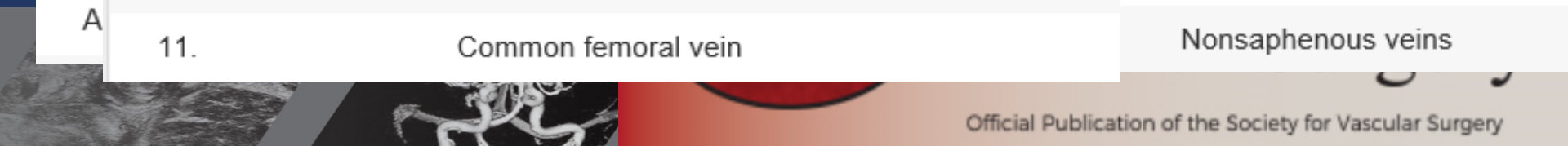

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C CLASS

Telangiectasia (≤1mm)
C1

Reticular Veins (>1mm--<3mm)
C1

Varicose Veins (≥3mm)
C2

Corona Phlebectatica (C3)

Venous Eczema/Stasis Dermatitis (C4a)

Pigmentation (C4a)

Atrophie Blanche (C4b)

Lipodermatosclerosis (C4b)

ULCERATION (C6)

EPIDEMIOLOGIC STUDIES

Study	Method	Sample size	Clinical class	Duplex ultrasound	Age range, years	Female, %
Edinburgh,[134] 1998	Cross-sectional	1566	Basle	Yes	18-64	55
French,[136] 2004	Cross-sectional	835	Anatomic	No	30-80	67
San Diego,[137] 2003	Cross-sectional	2211	CEAP	Yes	40-79	65
AVF screening,[139] 2008	Screening by invitation	2234	CEAP	Yes	17-93	77
Bonn,[138] 2008	Cross-sectional	3072	CEAP	Yes	18-79	56

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Report of the Society for Vascular Surgery and the American Venous Forum on the July 20, 2016 meeting of the Medicare Evidence Development and Coverage Advisory Committee panel on lower extremity chronic venous disease

Presented at the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting on Lower Extremity Venous Disease, Baltimore, Md, July 20, 2016.

Peter Gloviczki, MD[a,*], Michael C. Dalsing, MD[b], Peter Henke, MD[c], Brajesh K. Lal, MD[d], Thomas F. O'Donnell Jr., MD[e], Cynthia K. Shortell, MD[f], Ying Huang, MD, PhD[a], Jovan Markovic, MD[f], Thomas W. Wakefield, MD[c]

EPIDEMIOLOGIC STUDIES

- Bonn Vein Study
  - 3072 (1722 women, 1350 men) participants b/t 18 and 79 yrs
  - All participants answered a standardized questionnaire including the short-form health survey (36 items) (SF-36) quality of life questionnaire and standardized questions from the German health survey and were investigated clinically and by duplex sonography
  - The complete CEAP classification was used for classification of the findings

Bonn Vein Study

- 49.1% of the male and 62.1% of the female population had leg complaints related to the symptoms of venous diseases

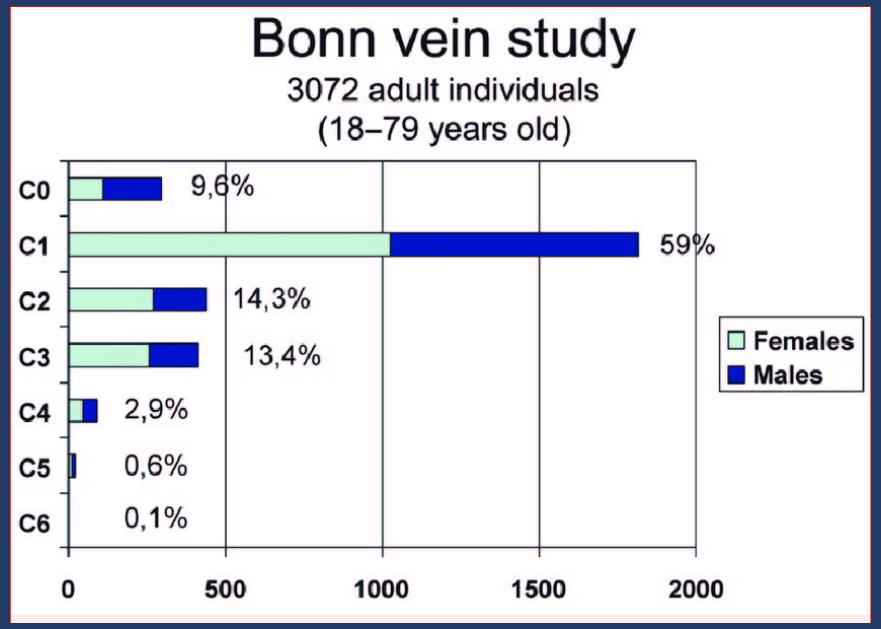
- 14.8% of the population, 7.9% of the men, and 20.2% of the women, had leg swelling in the last four weeks

Bonn Vein Study

- What have we learned from the Bonn Vein Study?

E. Rabe, F. Pannier – *Phlebolymphology* – 2006; 13 (4): 188

- 9.6% of the population (13.6% men, 6.4% women) showed no signs of venous disorders (C0)
- 59.1% (58.4% men, 59.5% women) showed only telangiectasias or reticular veins (C1)
- In 14.3% (12.4% men, 15.8% women), varicose veins were present without edema or skin changes (C2)
- 13.4% (11.6% men, 14.9% women) had pitting edema (C3)
- 2.9% (3.1% men, 2.7% women) C4 with skin changes like eczema, pigmentation, or dermatoliposclerosis
- 0.6%, showed healed venous ulceration (C5) and active venous ulcers, 0.1% (C6).



Bonn Vein Study

83.4% of C2 patients progressed

ears

veins
quivalent to

4.8% annually

- CEAP class C_2 increased to higher C classes in 19.8% (nonsaphenous varicose veins) and in 31.8% (saphenous varicose veins).

JVS Journal of Vascular Surgery
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Incidence of Varicose Veins, Chronic Venous Insufficiency, and Progression of the Disease in the Bonn Vein Studv II

March 2010 Volume 51, Issue 3, Page 791

E. Rabe[a], F. Pannier[b], A. Ko[a], G. Berboth[a], B. Hoffmann[c], S. Hertel[c]

EPIDEMIOLOGIC STUDIES

- Edinburg Vein Study (1994-96)
  - 1566 men and women
  - aged between 18 and 64 years, were asked to complete a standardized questionnaire and were investigated clinically and by duplex sonography
  - 40% of the male and 32% of the female population had saphenous varicose veins
  - More than 80% had telangiectasias or reticular veins
  - Chronic venous insufficiency was found in 9% of the male and 7% of the female population
  - significant increase in prevalence of chronic venous disease with age

Chronic venous insufficiency: Clinical and duplex correlations. The Edinburgh Vein Study of venous disorders in the general population

C. Vaughan Ruckley, ChM, Christine J. Evans, MFPHM, Paul L. Allan, FRCR, Amanda J. Lee, PhD, and F. Gerald R. Fowkes, FRCPE, *Edinburgh, Scotland*

Natural History—Edinburgh F/U

- 1566 adults at baseline, 880 f/u
- 334 had trunk varicose veins or CVI at baseline
- Mean follow-up was 13.4 (0.4) years
- Progression was found in 193 (57.8%), equivalent to 4.3% annually

JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Progression of varicose veins and chronic venous insufficiency in the general population in the Edinburgh Vein Study

January 2015 Volume 3, Issue 1, Pages 18–26

Amanda J. Lee, PhD[a], Lindsay A. Robertson, PhD[b], Sheila M. Boghossian, PhD[b], Paul L. Allan, FRCR[c], C. Vaughan Ruckley, FRCSE[d], F. Gerald R. Fowkes, FRCPE[b,*], Christine J. Evans, MD[e]

Natural History—Edinburgh F/U

- A definition of progression of CVD
  - increase in grade of varicose veins or CVI
  - development of CVI in those with varicose veins (or vice versa)
  - change from unilateral to bilateral disease
  - Presence of reflux was defined as retrograde flow ≥0.5 second

Journal of Vascular Surgery Venous and Lymphatic Disorders
JVS-VL

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193 PROGRESSORS

- In 95 progressors (49.2%), disease became worse only in one leg, equally affecting right (47 legs) and left (48 legs)
- 59 (30.6%), progression occurred in both legs
- 39 (20.2%), unilateral disease became bilateral without worsening in the leg affected at baseline
- IF both varicose veins and CVI were particularly prone to progression, with 54 of 55 subjects affected

Journal of Vascular Surgery Venous and Lymphatic Disorders
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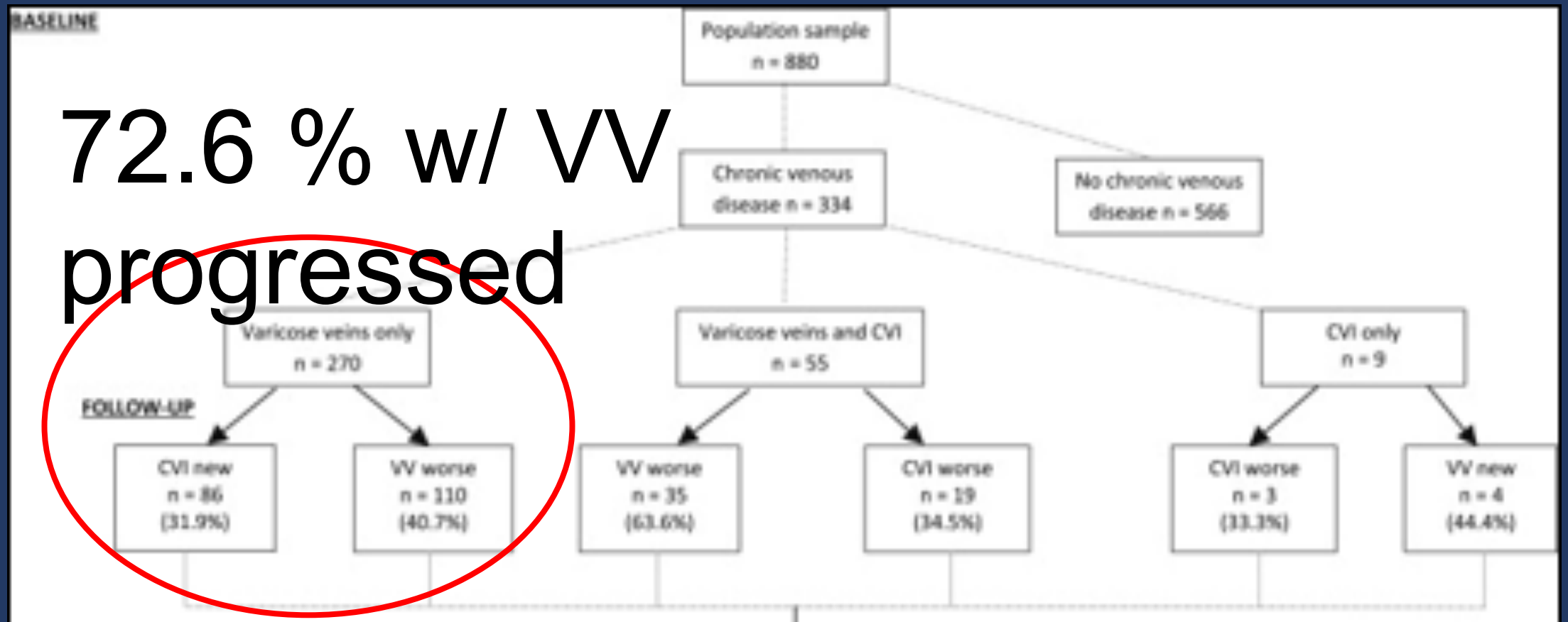
Natural History—Edinburgh F/U

72.6 % w/ VV progressed



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PROGRESSION: Varicose Veins vs CVI

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JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

- Among 270 baseline participants with only varicose veins, 86 (31.9%) developed CVI, of whom 67 were C3, 19 were C4, and none had ulceration (2.4% annually)
- In 64 w/ baseline CVI, the CVI deteriorated in 22 (34.4%)
    - 17 progressed from C3 to C4
    - 3 from C3 to C5
    - 2 from C4 to C5-6
    - In 9 subjects with CVI and no varicose veins at baseline
        - 4 (44.4%) developed varicose veins during follow-up
- The annual rate of progression of CVI was 2.6%

Natural History—Edinburgh F/U

- Overweight was assoc'd with ↑'d risk of CVI in those w/ VV (OR, 1.85; 95% CI, 1.10-3.12)
- Reflux in the superficial system ↑'d the likelihood of progression
  - esp in combo w/ deep reflux (OR 2.57;95% CI, 1.55-4.25)
  - When located in SSV (OR, 4.73;95% CI, 1.37-16.39)
- 22 subjects with deep axial reflux (defined as continuous reflux in the femoral and popliteal veins or in the common femoral, femoral, and popliteal veins), progression was 54.5% (OR, 4.48; 95% CI, 1.91-10.54)
- Reflux in only single deep venous segment did NOT increase risk of progression

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JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

Natural History—Edinburgh F/U

- 270 subjects w/ only varicose veins at baseline, 86 (31.9%) developed CVI, with the rate increasing consistently with age (*P* = .04)
- Almost all subjects (98%) with both varicose veins and CVI at baseline deteriorated
- Rate of Progression of chronic venous disease did NOT differ by gender or leg, BUT women more likely to progress
- FH of VV and hx of DVT increased risk

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JVS-VL Journal of Vascular Surgery Venous and Lymphatic Disorders

OBJECTIVE 2—OUTCOME ASSESSMENT

The goal of treatment in venous disease is primarily palliative and varies among physicians and their patients across the spectrum of conditions.

Venous Clinical Severity Score and quality-of-life assessment tools: application to vein practice

M A Vasquez and C E Munschauer
SUNY Buffalo Surgery, The Venous Institute of Buffalo, New York, USA

Phlebology 2008;**23**:259–275

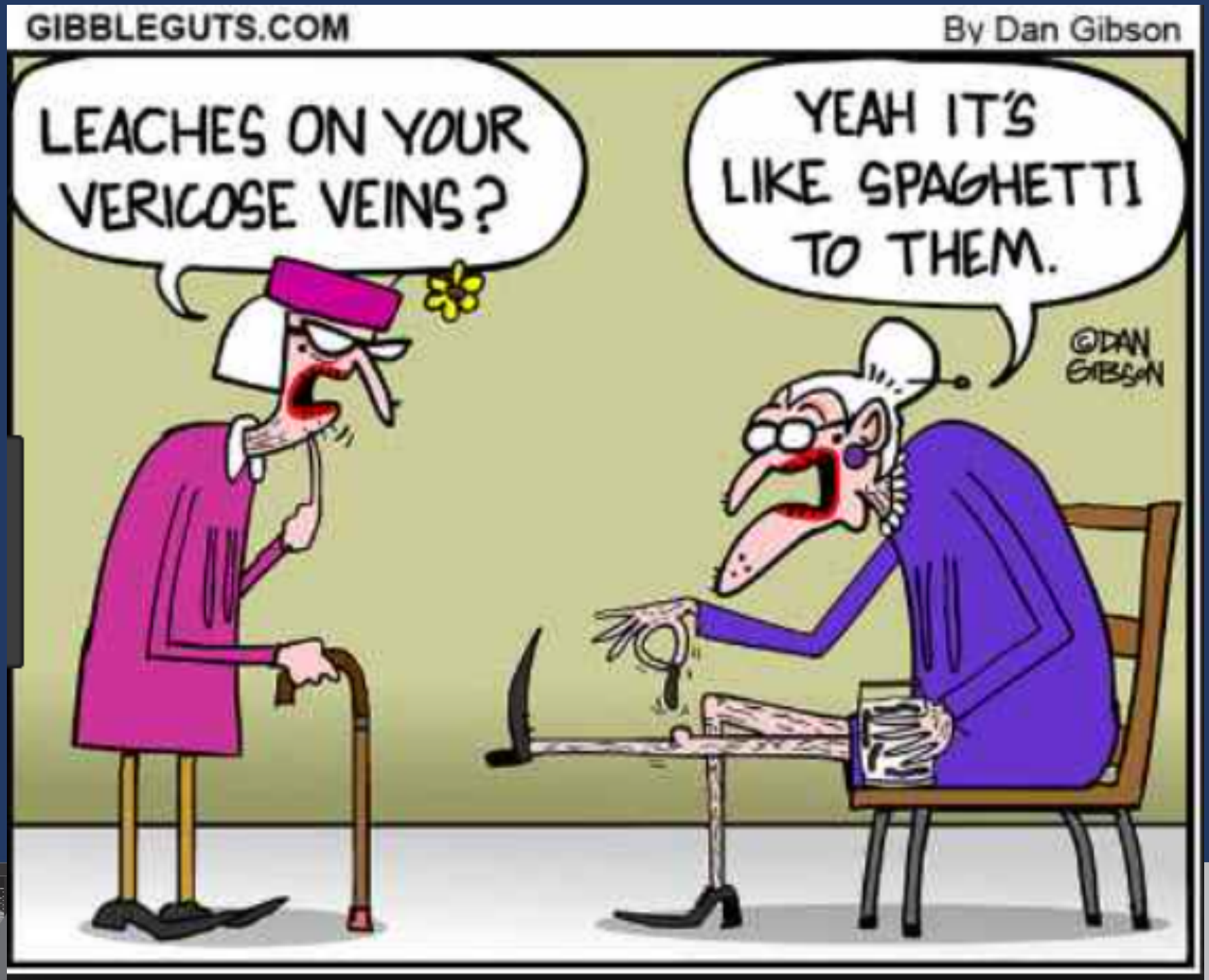
A systematic review of compression hosiery for uncomplicated varicose veins

Article *in* Phlebology · April 2009

DOI: 10.1258/phleb.2009.09s003 · Source: PubMed

COMPRESSION THERAPY ALONE

***Results*:** The search strategy identified 25 studies. Eleven were RCTs or systematic reviews, 12 non-randomized studies and two guidelines. No consensus was found regarding the class of compression needed for the effective management of varicose veins. Wearing compression improved symptom management, but could be confounded by the exclusion of high number of non-compliant patients within the trials. Wearing compression to slow the progression, or prevent the reoccurrence of varicose veins could not be supported by the current published evidence.


GIBBLEGUTS.COM
By Dan Gibson
LEACHES ON YOUR VERICOSE VEINS?
YEAH IT'S LIKE SPAGHETTI TO THEM.
©DAN GIBSON

Venous clinical severity score (VCSS)

Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily	Daily w/meds
Varicose veins	None	Few	Multiple	Extensive
Venous oedema	None	Evening only	Afternoon	Morning
Skin pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Mod cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No active ulcers	None	1	2	>2
Active ulcer size	None	<2 cm	2–6 cm	>6 cm
Ulcer duration	None	<3 months	3–12 months	>1 year
Compression therapy	None	Intermittent	Most days	Fully comply

Pain=2, VV=2, Oedema=2, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. Total VCSS =8

Max Score for VV =9

Improvement in CEAP/VCSS with treatment

C6V26 → C5V12

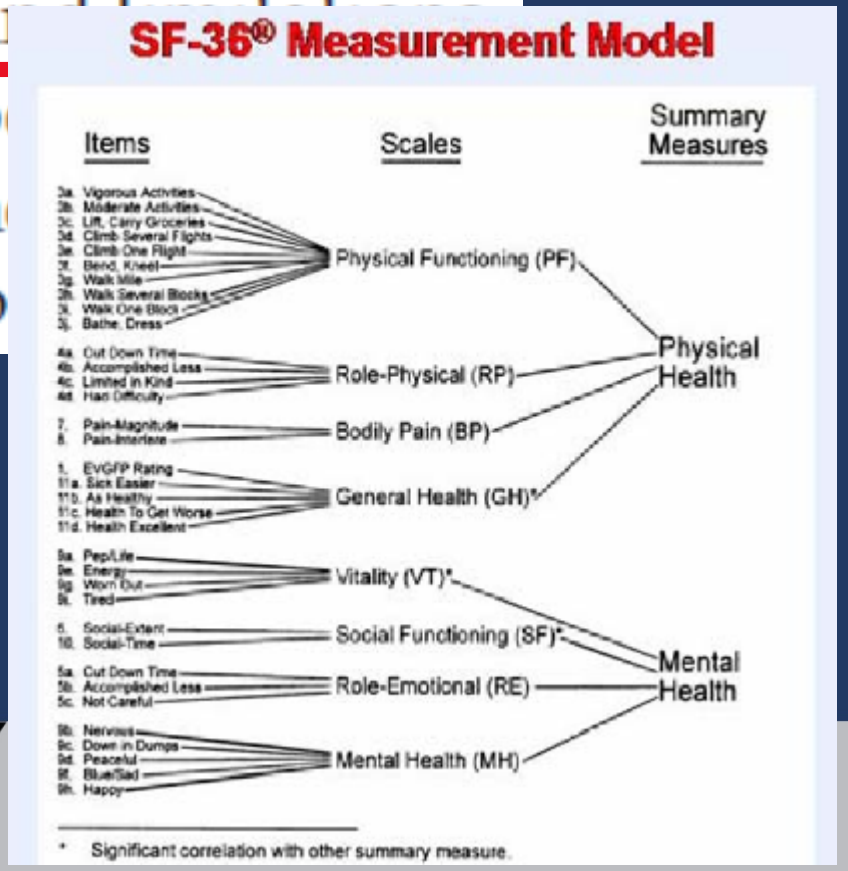
Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily	Daily w/meds
Varicose veins	None	Few	Multiple	Extensive
Venous oedema	None	Evening only	Afternoon	Morning
				er, recent
				re
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No active ulcers	None	1	2	>2
Active ulcer size	None	<2 cm	2–6 cm	>6 cm
Ulcer duration	None	<3 months	3–12 months	>1 year
Compression therapy	None	Intermittent	Most days	Fully comply

PATIENT REPORTED OUTCOMES (PRO)

- GENERIC
  - SF36, SF12, SF6D,EuroQOL 5D-5L
- VENOUS SPECIFIC
  - AAVQ
  - VEINES-QOL/SYM
  - CIVIQ 20
  - SQOR-V
  - VVSimQ

Kaplan RM, Criqui MH, Denenberg JO, Bergan J, Fronek A. Quality of life in patients with chronic venous disease: San Diego population study. *J Vasc Surg* 2003;37:1047–53

Kaplan *et al.*[14] studied 2404 patients for the presence of venous disease and application of the SF-36, finding that 'even modest venous disease translates into functional limitations a in daily activities. Venous disease do to affect emotional aspects of h quality of life'. Another large ep

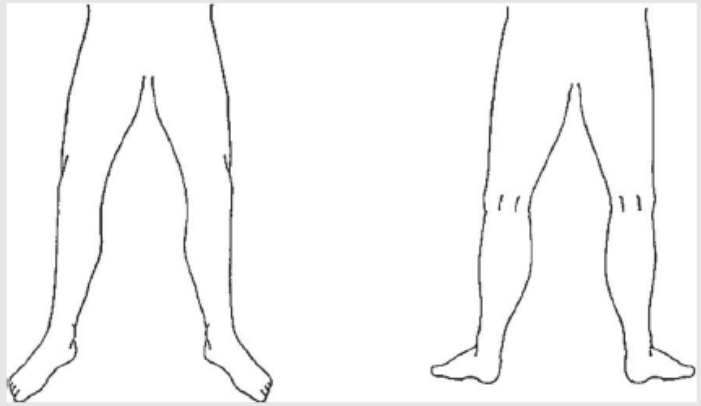


Aberdeen Varicose Vein Questionnaire (AVVQ)

Aberdeen Varicose Vein Questionnaire

1. Please draw in your varicose veins in the diagrams(s) below:

Legs viewed from front | **Legs viewed from back**



2. In the last two weeks, for how many days did your varicose veins cause you pain or ache? (Please tick one box for each leg)

	Right Leg	Left Leg
None at all		
Between 1 and 5 days		
Between 6 and 10 days		
For more than 10 days		

3. During the last two weeks, on how many days did you take painkilling tablets for your varicose veins? (Please tick one box)

None at all	
Between 1 and 5 days	
Between 6 and 10 days	
Fore more than 10 days	

4. In the last two weeks, how much ankle swelling have you had? (Please tick one box)

None at all	
Slight ankle swelling	
Moderate ankle swelling (eg. causing you to sit with your feet up whenever possible)	
Severe ankle swelling (eg. causing you difficulty putting on your shoes)	

5. In the last two weeks, have you worn support stockings or tights? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, those I bought myself without a doctor's prescription		
Yes, those my doctor prescribed for me which I wear occasionally		
Yes, those my doctor prescribed for me which I wear every day		

6. In the last two weeks, have you had any itching in association with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, but only above the knee		
Yes, but only below the knee		
Both above and below the knee		

7. Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes		

8. Do you have a rash or eczema in the area of your ankle? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes, but is does not require any treatment from a doctor or district nurse		
Yes, and it requires treatment from my doctor or district nurse		

9. Do you have a skin ulcer associated with your varicose veins? (Please tick one box for each leg)

	Right Leg	Left Leg
No		
Yes		

10. Does the appearance of your varicose veins cause you concern? (Please tick one box)

No	
Yes, their appearance causes me slight concern	
Yes, their appearance causes me moderate concern	
Yes, their appearance causes me a great deal of concern	

11. Does the appearance of your varicose veins influence your choice of clothing including tights? (Please tick one box)

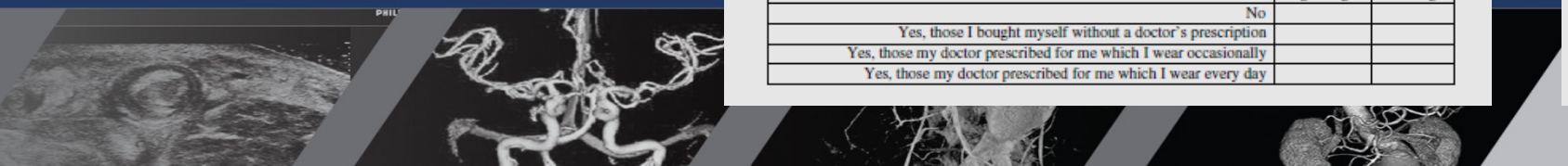
No	
Occasionally	
Often	
Always	

12. During the last two weeks, have your varicose veins interfered with your work/housework or other daily activities? (Please tick one box)

No	
I have been able to work but my work has suffered to a slight extent	
I have been able to work but my work has suffered to a moderate extent	
My veins have prevented me from working one day ore more	

13. During the last two weeks, have your varicose veins interfered with your leisure activities (including sport, hobbies and social life)? (Please tick one box)

No	
Yes, my enjoyment has suffered to a slight extent	
Yes, my enjoyment has suffered to a moderate extent	
Yes, my veins have prevented me taking part in any leisure activities	



VEINES-QOL/SYM QUESTIONNAIRE (Venous insufficiency epidemiological and economic study)

INSTRUCTIONS
HOW TO ANSWER:
Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

These questions are about your leg problem(s).

1. During the past 4 weeks, how often have you had any of the following leg problems?

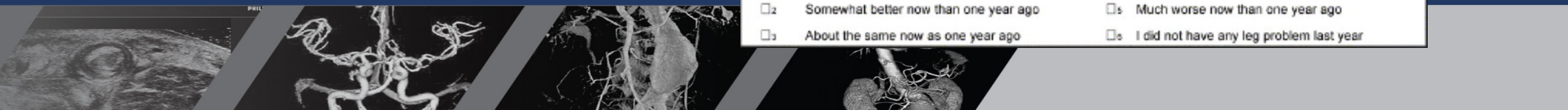
(check one box on each line)		**Every day**	**Several times a week**	**About once a week**	**Less than once a week**	**Never**
1.	Heavy legs	☐1	☐2	☐3	☐4	☐5
2.	Aching legs	☐1	☐2	☐3	☐4	☐5
3.	Swelling	☐1	☐2	☐3	☐4	☐5
4.	Night cramps	☐1	☐2	☐3	☐4	☐5
5.	Heat or burning sensation	☐1	☐2	☐3	☐4	☐5
6.	Restless legs	☐1	☐2	☐3	☐4	☐5
7.	Throbbing	☐1	☐2	☐3	☐4	☐5
8.	Itching	☐1	☐2	☐3	☐4	☐5
9.	Tingling sensation (e.g.pins and needles)	☐1	☐2	☐3	☐4	☐5

2. At what time of day is your **leg problem** most intense ? *(check one)*

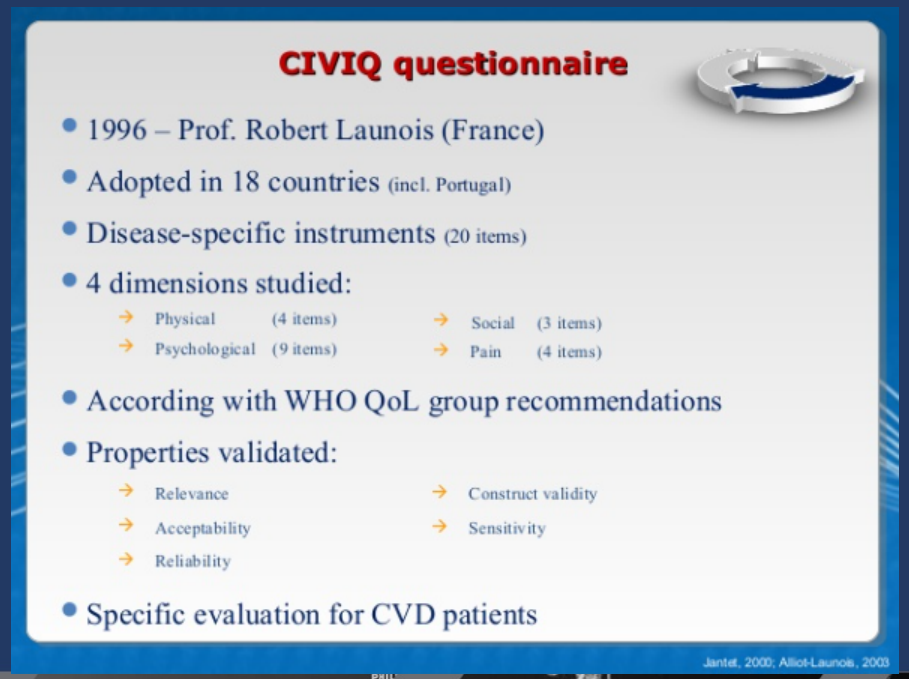
- ☐1 On waking
- ☐2 At mid-day
- ☐3 At the end of the day
- ☐4 During the night
- ☐5 At any time of day
- ☐6 Never

3. Compared to one year ago, how would you rate your **leg problem** in general now? *(check one)*

- ☐1 Much better now than one year ago
- ☐2 Somewhat better now than one year ago
- ☐3 About the same now as one year ago
- ☐4 Somewhat worse now than one year ago
- ☐5 Much worse now than one year ago
- ☐6 I did not have any leg problem last year



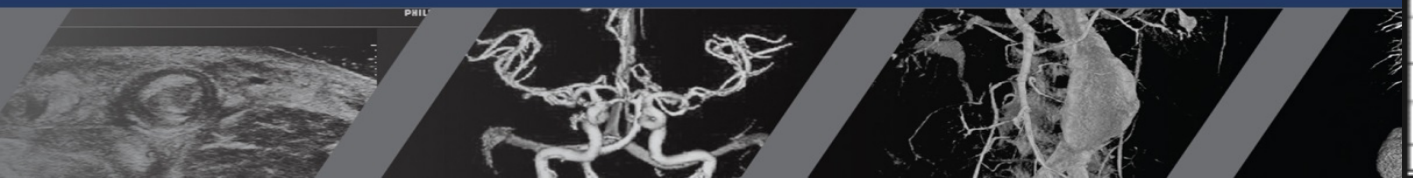
CIVIQ 20
(Chronic Venous Disease Quality of Life Questionnaire)



Dimension	Item
Pain	Pain in the legs
	Impairment at work
	Sleeping poorly
	Standing for long periods of time
Physical	Climbing several floors
	Squatting / kneeling
	Walking at a good pace
	Doing the housework
Psychological	Feeling nervous
	Having the impression of being a burden
	Being embarrassed to show legs
	Becoming irritable easily
	Having the impression of being disabled
	Having no desire to go out
	Having to take precautions
	Getting tired easily
	Difficulty in getting going
Social	Going to parties
	Performing athletic activity
	Traveling by car, plane, etc

SQOR-V

(specific quality of life and outcome response-venous)



Do your vein problems affect the overall appearance of both of your legs?

Left leg	Right leg
① no	no ①
② yes, slightly	yes, slightly ②
③ yes, moderately	yes, moderately ③
④ yes, severely	yes, severely ④
⑤ yes, extremely	yes, extremely ⑤

Do you choose your clothing based on your vein problems?
① never ② rarely ③ often ④ usually ⑤ always

Do you choose your activities based on your vein problems?
① never ② rarely ③ often ④ usually ⑤ always

To what extent do your vein problems affect your activities?
If any of these activities are not applicable to you, simply check the "does not apply to me" b

	Does not apply to me	No impact	Slight	Moderate	Severe	Extreme
Overall restriction	❑	①	②	③	④	⑤
at work	❑	①	②	③	④	⑤
at home	❑	①	②	③	④	⑤
sport or leisure activities	❑	①	②	③	④	⑤
prolonged standing	❑	①	②	③	④	⑤
prolonged sitting	❑	①	②	③	④	⑤
when walking	❑	①	②	③	④	⑤
when using stairs	❑	①	②	③	④	⑤
during sleep	❑	①	②	③	④	⑤
social activities	❑	①	②	③	④	⑤
intimate or sexual relations	❑	①	②	③	④	⑤

When do you experience the most discomfort or pain in your legs?

	No	Yes, slight	Yes, moderate	Yes, severe	Yes, extreme
Day and night	①	②	③	④	⑤
Morning	①	②	③	④	⑤
Middle of the day	①	②	③	④	⑤
Evening	①	②	③	④	⑤
At bedtime	①	②	③	④	⑤

VVSimQ
(Varicose Vein Symptom 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

Original Article

Phlebology

The VVSymQ® instrument: Use of a new patient-reported outcome measure for assessment of varicose vein symptoms

Jean Paty[1], Diane M Turner-Bowker[2], Celeste A Elash[3] and David Wright[4]

Abstract

Introduction: No existing patient-reported outcome instrument focuses solely on assessment of varicose veins symptoms that are bothersome to patients.

Methods: The VVSymQ® instrument is a five-item patient-reported outcome that assesses symptoms most important to patients with varicose veins (heaviness, achiness, swelling, throbbing and itching). This paper describes how the VVSymQ® instrument was incorporated into an electronic daily diary to monitor key outcomes over time and capture treatment benefit in two randomized, controlled, phase 3 clinical trials.

Results: Patients were highly compliant in completing the electronic daily diary, and the VVSymQ® instrument demonstrated ability to detect overall change and ability to detect change that is meaningful to patients.

Conclusion: The VVSymQ® instrument is a reliable, valid instrument responsive to measuring change in the patient experience of varicose vein symptoms pre- and post-intervention, and is uniquely focused on patient-reported symptoms compared with other widely used questionnaires completed by clinicians.

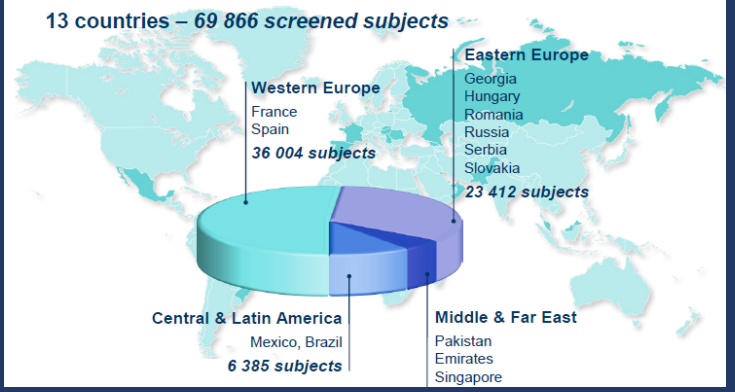
VEIN CONSULT Program

First results

70 000 subjects, 13 countries

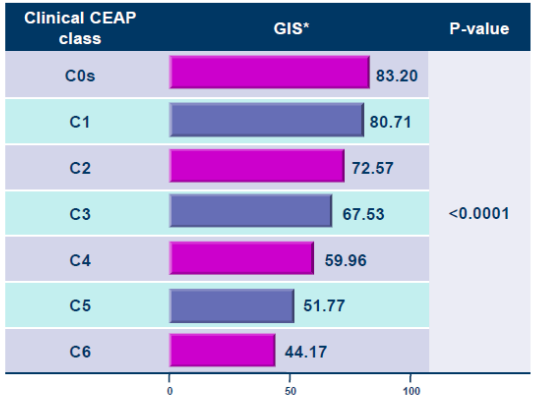
VEIN CONSULT Program in General Practice

Countries and number of screened subjects



Quality of Life According to CEAP Class

QOL decreases with increasing CEAP

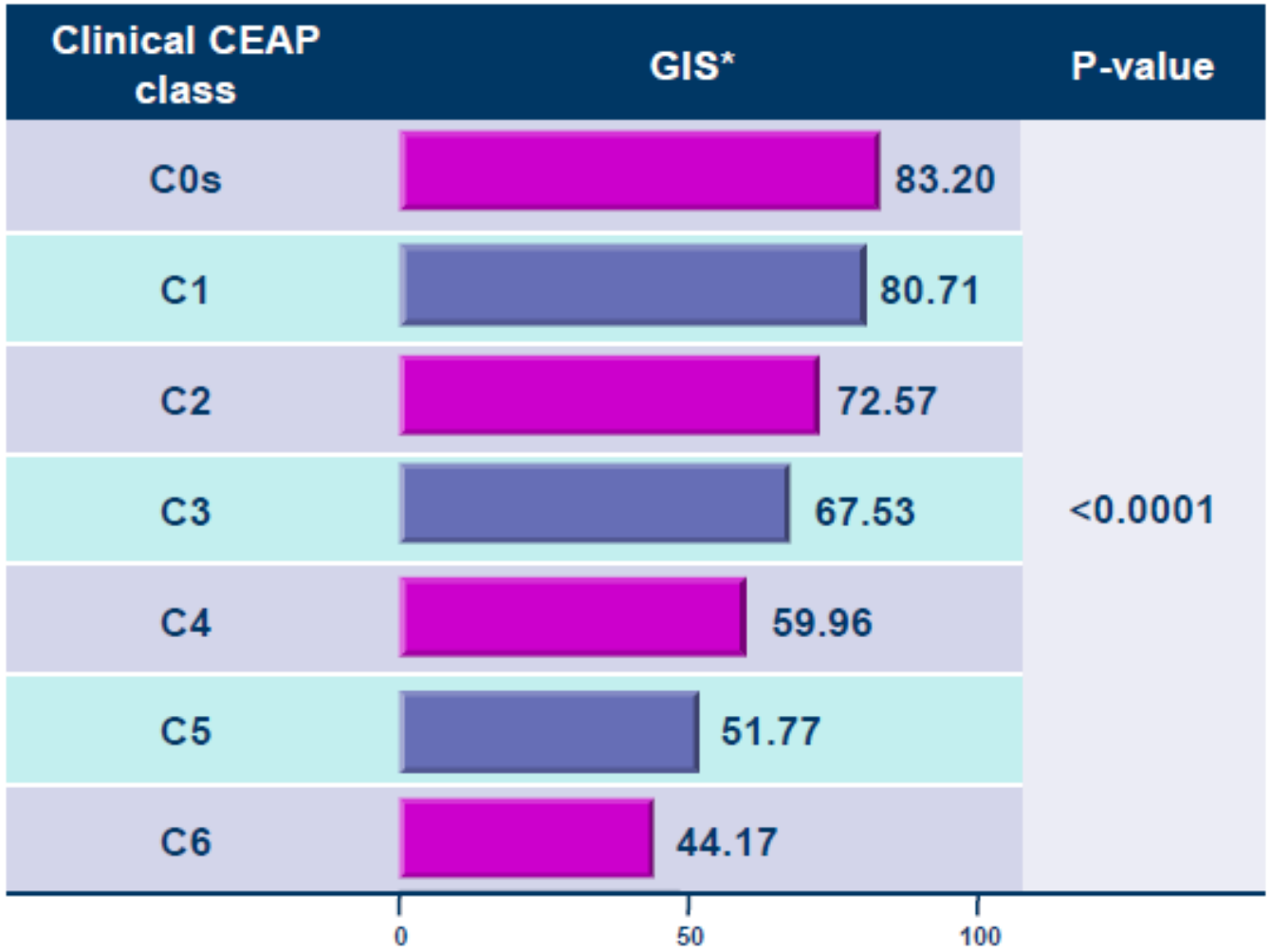


* GIS - Global Index Score

↑'d CEAP = ↓'d QOL

Quality of Life According to CEAP Class

QOL decreases with increasing CEAP



* GIS - Global Index Score

Guideline

SVS-

The care of p
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Surgery and

Peter Gloviczki, MD,* An
David L. Gillespie, MD,* Mc
Mark H. Meissner, MD,† M
Marc A. Passman, MD,† Jesc

**We recommend that the CEA
(GRADE 1A) and that the re
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Venous Guideline Committee
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weak (GRADE 2) if the benef
evaluation or treatment can b
these guidelines are: We reco
detailed physical examinatio
(GRADE 1A). We recommen
revised Venous Clinical Seve
therapy for patients with sym
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therapy as the primary treatm
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or laser) rather than high liga
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treatment of pathologic perfo
healed or active ulcers (CEAP
varices with coil embolization
2011;53:2S-48S.)

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IAC-Vein Center

1.1.1.1B A clinical evaluation of each patient being considered for treatment must be performed and documented in their medical record and must include, but is not limited to:

i. a history of the venous disorders;

ii. a review of past medical and family history, venous history, prior treatments, previous venous imaging studies, previous arterial perfusion studies, prior use of compression, medications and allergies;

iii. any changes in medical history, medications, allergies must be documented with each encounter;

iv. a directed physical exam and if indicated, a functional (reflux) ultrasound of the superficial, perforator and deep veins;

v. additional laboratory, imaging and/or consultations as indicated;

vi. use of clinical class score (CEAP) and Venous Clinical Severity Score (VCSS) at baseline, completion of treatment or as indicated.

STANDARD – Quality of Life Measurements

2.5C Quality of life measurement is encouraged.

2.5.1C Example of vein-specific quality of life instruments include CIVIQ, VEINES Sym/QoL, the Aberdeen Varicose Vein Score and the Specific Quality-of-life and Outcome Response-Venous [SQOR-V]) questionnaire.

IAC Standards for Vein Center Accreditation: Superficial Venous available at http://www.intersocietal.org

J Vasc Surg 2011; 53:2S-48S

Medicare DATA 2013-14

- Endovenous Ablations (EVA)
  - accounted for 160,000 procedures in 2013
  - 170,000 in 2014
  - represents 1/3 of the total endovenous procedures performed in the United States during those years
  - the volume of EVA procedures approaches the number of coronary artery bypass grafts (~200,000) performed during this same period
  - EVA is performed at 3x the rate of placement of either an IVCF or iliac stent, which both numbered approx 50,000/yr for 2013 and 2014

REACTIV TRIAL (2006)

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial)

JA Michaels,[1*] WB Campbell,[2] JE Brazier,[3] JB MacIntyre,[4] SJ Palfreyman,[1] J Ratcliffe[3] and K Rigby[1]

[1] Academic Vascular Unit, University of Sheffield, UK
[2] Royal Devon and Exeter Hospital and Peninsula Medical School, Exeter, UK
[3] School of Health and Related Research, University of Sheffield, UK
[4] Royal Devon and Exeter Hospital, Exeter, UK

* Corresponding author

Executive summary

Health Technology Assessment 2006; Vol. 10: No. 13

Health Technology Assessment
NHS R&D HTA Programme

- Ablation vs Conservative Rx
- Sx improvement at 1 y w/ ablation
- Anatomic extent of VV decreased
- 52% of conservative cohort changed over to surgery over 3 y

Prevalence/Cost of Venous Disease

- **Approximately 20 million C2 patients in the United States**
- ↑'s w/ age
- Venous ulcer (C5 or C6), affects 1% of the adult population and has a major impact on socioeconomics
- **Work disability from venous ulcers**
  - estimated loss of 2 million work days/year
  - is a cause of early retirement in >12% of workers
  - **$3 billion per year in the USA**
- **Health care system absorbs an estimated $2.5 billion expenditure on chronic wounds, of which venous ulcers represent the majority**

JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery

Report of the Society for Vascular Surgery and the American Venous Forum on the July 20, 2016 meeting of the Medicare Evidence Development and Coverage Advisory Committee panel on lower extremity chronic venous disease

Presented at the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting on Lower Extremity Venous Disease, Baltimore, Md, July 20, 2016.

Peter Gloviczki, MD[a,*], Michael C. Dalsing, MD[b], Peter Henke, MD[c], Brajesh K. Lal, MD[d], Thomas F. O'Donnell Jr., MD[e], Cynthia K. Shortell, MD[f], Ying Huang, MD, PhD[a], Jovan Markovic, MD[f], Thomas W. Wakefield, MD[c]

Cost

- American Venous Registry (2012)
  - country's first attempt to collect real-world data starting in 2012
  - Data on >7000 procedures were collected
    - >15% of patients with less than C2 disease were being treated with an ablation procedure
    - >30% of patients had undergone an ablation procedure without prior compression therapy
    - a large proportion of patients did not receive compression stockings after treatment

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COST

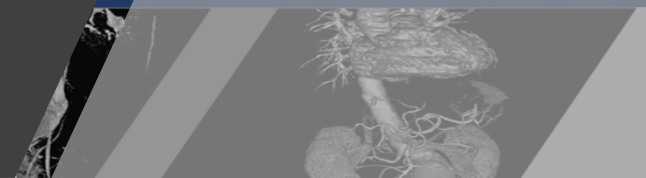
- Retrospective claims database study using data from the Truven Health MarketScan database
- Adults w/ newly dx'd varicose veins b/t January 2008-June 2010
- Divided into 6 cohorts—followed for 2 yrs
  - surveillance and compression therapy
  - Surgery
  - laser ablation
  - radiofrequency ablation
  - Sclerotherapy
  - multiple therapies

Treatment Patterns and Outcomes in Patients with Varicose Veins

Rajiv Mallick, PhD, Aditya Raju, MS, BPharm, Chelsey Campbell, PharmD, MBA, Rashad Carlton, PharmD, MSPH, David Wright, MD, Kimberly Boswell, MD, and Michael Eaddy, PharmD, PhD

AH&DB American Health & Drug Benefits

Am Health Drug Benefits. 2016 Nov; 9(8): 455–465. PMCID: PMC5394556



COST

- 144,098 patients met the study criteria
  - 100,072 (69.5%) surveillance and/or compression therapy
  - 14,007 (9.7%) received laser ablation
  - 9125 (6.3%) received radiofrequency ablation
  - 4778 (3.3%) received sclerotherapy
  - 4851 (3.4%) had surgery
  - 11,265 (7.8%) received multiple therapies.

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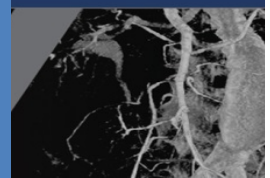

American Health & Drug Benefits

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COST

- 2-year follow-up period for the intervention grp
  - **54.7% of patients received add'l interventional treatment (DOES NOT ACCT FOR POSSIBILITY OF CONTRALAT PROCEDURE—45.6%)**
    - **same mode or a different mode from the initial treatment**
  - **30.1% had >1 postintervention claim for symptomatic varicose veins (not including additional procedures) at 8 weeks**
  - **44.2% had >1 postintervention claim for symptomatic varicose veins at 1 year after the initial interventional therapy**
  - **Costs associated with varicose veins greatly decreased in all the intervention cohorts in the second year posttreatment, suggesting a long-term benefit**

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TREATMENT C2

- Can present with a spectrum ranging from small asymptomatic varicose veins to very large painful varicosities
- Duplex ultrasound examination will help identify the source of reflux
- By adding the VCSS component, one can get a better sense of how severe the C2 disease is
  - VCSS ≥ 7 → TREATMENT
  - VCSS ≤ 6 → CONSERVATIVE Rx

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SUMMARY

- C2 DISEASE DOES PROGRESS IN 73-83% AT APPROXIMATELY 4% ANNUALLY
- OUR METHODS FOR ASSESSING INTERVENTION RESULTS SHOULD INCLUDE VENOUS CLINICAL SEVERITY SCORE AND PATIENT REPORTED OUTCOMES
- IF 20 MILLION PEOPLE W/ C2 DISEASE AND ROUGHLY 200,000 ABLATION PROCEDURES PER YEAR THEN 1% OF PATIENTS W/ VV ARE BEING TREATED ANNUALLY