

A collection of medical instruments is laid out on a light-colored surface. At the top center is a white Omron M4-1 digital blood pressure monitor with a green LCD screen showing '0'. To its left is a beige Doppler ultrasound device with a speaker and a probe. Below the Doppler is a manual sphygmomanometer with a black cuff and a circular gauge. To the right of the sphygmomanometer is a long, thin metal ruler. Further right is a vernier caliper with a circular dial. The background is a plain, light-colored surface with a blue border on the left and a yellow-green rectangle in the top right corner.

# Measuring venous symptoms

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# Disclosures of interests

- ▶ Panelist in SymVein consensus document. (unrestricted research grant, Servier International)



Nos seules vérités, hommes, sont nos douleurs.

*Alphonse de LAMARTINE*



Signs can be observed



Symptoms can only be told



# Consequences of venous disorders:

- ▶ **Signs**, that can be observed by the physician (and the patient too):
  - ▶ Dilated veins, skin changes, edema, lipodermatosclerosis, ulcers ...
- ▶ **Symptoms**, which are solely felt and described by the patient, not the physician
  - ▶ aches and pains, throbbing, discomfort, heaviness, swelling, etc ...
- ▶ **Aesthetic consequences**, which can be observed by the physician and diversely considered/contemplated by the patient
- ▶ Disability
- ▶ Impairment of quality of life
- ▶ Complications
- ▶ Expenses
- ▶ Death

# Why do we need to measure Venous symptoms ?

- ▶ To evaluate the severity of the disease at all stages of its evolution
- ▶ To describe the effects of interventions : success or failure
- ▶ To validate the choice of interventions (including socio-economic value)
- ▶ Because the sole evaluation of signs is not sufficient
- ▶ Because symptoms are important to the patient !

Remember : whatever the reason, if the patient is not satisfied after the intervention(s) it is a failure.

*Intervention can be any action undertaken (e.g. compression, sclero, drugs, surgery, rehab, etc...)*

# Why is it a difficult problem

- ▶ There is no robust subrogate marker for venous disorders' severity at grades CEAP 1-2-3 which are the most frequent (skin changes are better measured but only at CEAP 4-5-6 levels)
- ▶ So called venous symptoms may have another aetiology (spinal, muscular, metabolic, etc ...)
- ▶ Symptoms are the patient's own (not perceived by the physician), and can be the patient's main concern / or not
- ▶ **Measuring symptoms is an empirical process using imperfect tools to appraise fuzzy feelings**



# Available approaches

- ▶ Reporting patient's complaints after interrogation/examination
    - ▶ Physician generated outcomes = the paternalistic old time approach, e.g. : typically the VCSS (Venous Clinical Severity Score)
  - ▶ Measuring symptoms directly by means of **VAS(Visual Analog Scales)**
  - ▶ Evaluating Quality of Life or any other item through **self administered auto questionnaires** (generic or specific)
    - ▶ Patient Reported Outcome Measures = **PROMs**
- The patient is the final referee !

# Is the CEAP classification of any help here ?

- ▶ CEAP does not take into account symptoms much
- ▶ Only one descriptor in « C »: e.g.:
  - ▶ C1s, Ep, As, Pr for heavy legs with telangiectasias
  - ▶ C2346s, Es, Adp, Pro for a severe and painful post thrombotic ulcer
- ▶ But CEAP only classifies and does not measure

# VCSS and physician assessed outcomes

- ▶ VCSS takes symptoms into account for a limited fraction of its total value:
  - ▶ **Pain or other discomfort (ie, aching, heaviness, fatigue, soreness, burning)**
  - ▶ **From None = 0 to severe = 3**
  - ▶ **Out of 10 items = 3/30 points = 10% of the total**
- ▶ VCSS value is evaluated and computed by the physician, it is under the influence of the Observer Expectancy Effect
- ▶ However, VCSS is somehow correlated to PROMs

# VCSS 10 Items

# Graded 0 to 3

**Table 63.1** Venous Clinical Severity Score (from Rutherford *et al.*<sup>6)</sup>)

Attribute	Absent = 0	Mild = 1	Moderate = 2	Severe = 3
Pain	None	Occasional, not restricting activity or requiring analgesics	Daily, moderate activity limitation, occasional analgesics	Daily, severely limits activities, regular use of analgesics
Varicose veins*	None	Few, scattered: branch varicose veins with competent great saphenous/small saphenous	Multiple: single-segment great saphenous/small saphenous reflux	Extensive: multisegment great saphenous/small saphenous reflux
Venous edema	None	Evening ankle edema only	Afternoon edema above ankle	Morning edema above ankle requiring activity change, elevation
Skin pigmentation	None or focal, low intensity (tan)	Diffuse, but limited in area and old (brown)	Diffuse over gaiter distribution (lower third) or recent pigmentation (purple)	Wider distribution (above lower third) and recent pigmentation
Inflammation	None	Mild cellulitis, limited or marginal area around ulcer	Moderate cellulitis, involves most of gaiter area	Severe cellulitis (lower third or above) or venous eczema
Induration	None	Focal, circummalleolar (< 5 cm)	Medial or lateral, less than lower third	Entire lower third or more
Total no. ulcers†	0	1	2–4	> 4
Active ulceration, duration	None	< 3 months	> 3 months, < 1 year	Not healed > 1 year
Active ulcer, size	None	< 2 cm diameter	2–4 cm diameter	> 4 cm diameter
Compressive therapy‡	Not used or not compliant	Intermittent use of stockings	Wears elastic stockings most days	Full compliance stockings + elevation

\*To assure differentiation between C1 and C2, "varicose" veins must be > 4 mm diameter to qualify for C2. Occasional or mild edema and focal pigmentation over varicose veins does not qualify for C3 or C4.

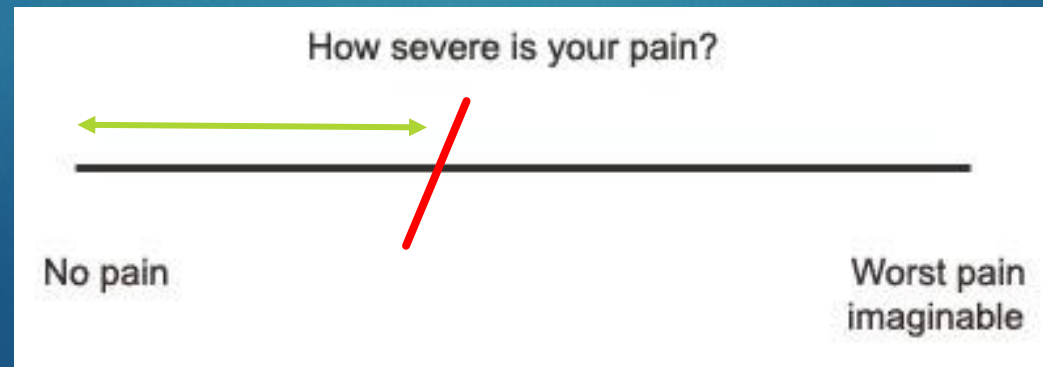
†Presumes venous origin by characteristics, e.g., brawny (not pitting or spongy) edema, with significant effect of standing/limb elevation and/or other clinical evidence of venous etiology, i.e., varicose veins, history of deep vein thrombosis. Edema must be a regular finding, e.g., daily occurrence.

‡Total number equals active and healed.

¶Sliding scale to adjust for background differences in use of compressive therapy.

# Direct measurement of symptoms

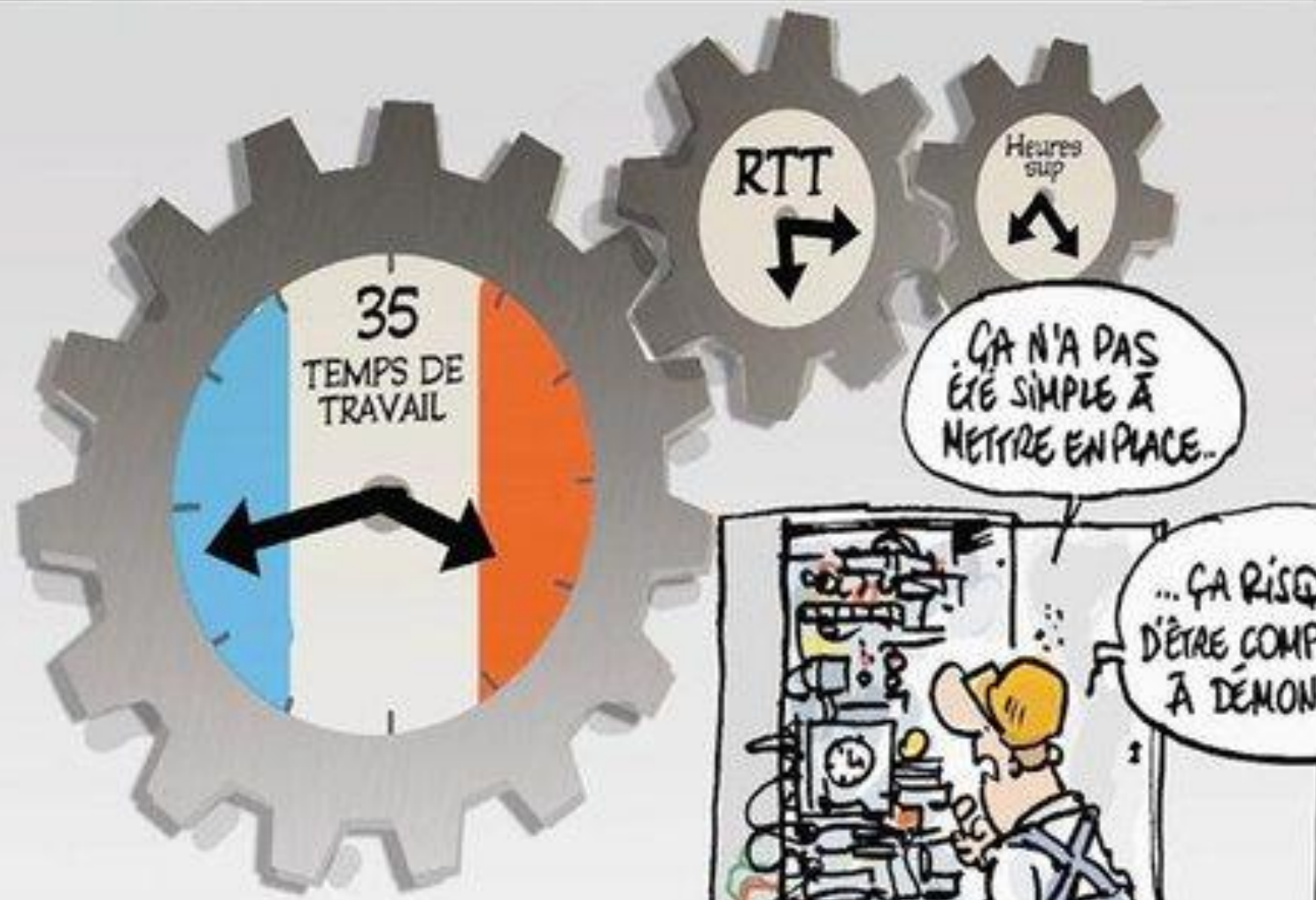
- ▶ By the physician: it underestimates actual pain (*Tait, Chibnal. 1997*)
- ▶ By means of painkiller intake count: it does not prove satisfactory (*Moquet, ANAES 1999*)
- ▶ Is usually done by the patient himself with Visual Analog Scale. Although 15% of patients are unable to use them (*Jensen 1996*)
- ▶ A VAS is constituted of a 100 mm line with one extremity indicating NO PAIN, the other WORST IMAGINABLE PAIN, the patient draws a mark on the line, the value is measured in mm from No pain



# When to measure

- ▶ In similar conditions of time, temperature, occupation





ÇA N'A PAS ÉTÉ SIMPLE À METTRE EN PLACE..

... ÇA RISQUE D'ÊTRE COMPLIQUÉ À DÉMONTER!

Made in France

DELIANT

# Relevance

- ▶ Necessary to the construction of a protocol
- ▶ Not too many in the same RCT
- ▶ But VAS can be used for very specific items such as procedural pain, post-op pain, etc ...



# Symptoms scoring in QoL

- ▶ Both generic and specific QoL self administered questionnaires take symptoms into account.
- ▶ Generic QoL still in use is Euroqol EQ 5D-5L, since it allows direct computation of QALYS for socio economic purposes.
- ▶ Frequently used Specific QoL questionnaires are:
  - ▶ CIVIQ, AVVQ, VEINES-QOL, SQOR-V

## Your own health state today

By placing a tick in one box in each group below, please indicate which statement best describes your own health state today.

Do not tick more than one box in each group.

### Mobility

- I have no problems in walking about  
 I have some problems in walking about  
 I am confined to bed


### Self-care

- I have no problems with self-care  
 I have some problems washing and dressing myself  
 I am unable to wash and dress myself


### Usual activities (eg. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities  
 I have some problems with performing my usual activities  
 I am unable to perform my usual activities


### Pain/discomfort

- I have no pain or discomfort  
 I have moderate pain or discomfort  
 I have extreme pain or discomfort


### Anxiety/depression

- I am not anxious or depressed  
 I am moderately anxious or depressed  
 I am extremely anxious or depressed


## Your own health state today

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is.

Your own  
health state  
today

Best  
imaginable  
health state

100

90

80

70

60

50

40

30

20

10

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

0

Worst  
imaginable  
health state

Madame, Monsieur,

Nous cherchons à mieux connaître les conséquences de vos problèmes de jambes sur votre vie familiale ou professionnelle.

Vous trouverez ci-après un certain nombre de situations, de symptômes, de sensations ou de gênes que vous pouvez ou non éprouver, et qui peuvent rendre votre vie quotidienne plus ou moins difficile. Pour chaque situation, symptôme, sensation ou gêne énoncée, nous vous demandons de répondre à la question posée. Pour chaque question posée, 5 possibilités de réponses vous sont proposées. Nous vous remercions de répondre le plus spontanément possible.

Sexe :  masculin  féminin

Année de naissance

Activité professionnelle  oui  non

si oui station debout

oui  non

Concernant vos problèmes de jambes, pouvez-vous classer du plus préoccupant (1) au moins

préoccupant (5) les 5 items suivants : Inconfort /gêne / douleurs

Apparence / Aspect esthétique

Risque/menace pour votre santé

Restriction des mouvements / des activités

Problèmes émotionnels

Pour chacune de vos jambes et pour chaque symptôme, veuillez évaluer l'intensité ressentie :

① si le symptôme n'est aucunement ressenti

④ si le symptôme est fortement ressenti

② si le symptôme n'est que faiblement ressenti

⑤ si le symptôme est ressenti de façon extrême

③ si le symptôme est moyennement ressenti

jambe gauche	symptôme à évaluer	jambe droite
① ② ③ ④ ⑤	Gêne globale	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Douleur	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Pesanteur ou lourdeur	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Démangeaisons	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Crampes nocturnes	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Gonflement	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Sensation de chaleur ou de brûlure	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Picotements	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Elancements ou sensation de lancements	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Jambes sans repos ou impatiences	① ② ③ ④ ⑤
① ② ③ ④ ⑤	Aggravation avec la chaleur (Amélioration avec le froid)	① ② ③ ④ ⑤

SQOR-V (GUEX ET AL 2009)

Pour chacune de vos jambes, leur apparence globale est elle affectée par vos problèmes veineux ?

Jambe gauche

① non

② oui un peu

③ oui moyennement

④ oui beaucoup

⑤ oui extrêmement

Jambe droite

non ①

oui un peu ②

oui moyennement ③

oui beaucoup ④

oui extrêmement ⑤

Vos problèmes veineux conditionnent-ils le choix de vos vêtements ?

① jamais ② rarement ③ souvent ④ habituellement ⑤ toujours

Vos problèmes veineux conditionnent-ils le choix de vos activités ?

① jamais ② rarement ③ souvent ④ habituellement ⑤ toujours

Dans quelle mesure vos problèmes veineux ont-ils une influence sur vos activités ?

Si une des activités ne vous concerne pas, il vous suffit de cocher la case « ne me concerne pas »

	Ne me concerne pas	Aucune influence	Faiblement	Moyennement ou modérément	Beaucoup ou fortement	Extrêmement
...Restriction globale	<input type="checkbox"/>	①	②	③	④	⑤
au travail ou activité professionnelle	<input type="checkbox"/>	①	②	③	④	⑤
... à la maison	<input type="checkbox"/>	①	②	③	④	⑤
... sportives ou activités de loisirs	<input type="checkbox"/>	①	②	③	④	⑤
... station debout prolongée	<input type="checkbox"/>	①	②	③	④	⑤
... position assise prolongée	<input type="checkbox"/>	①	②	③	④	⑤
... lors de la marche	<input type="checkbox"/>	①	②	③	④	⑤
... utilisation des escaliers	<input type="checkbox"/>	①	②	③	④	⑤
... au cours du sommeil	<input type="checkbox"/>	①	②	③	④	⑤
... activités sociales	<input type="checkbox"/>	①	②	③	④	⑤
...relations intimes ou sexuelles	<input type="checkbox"/>	①	②	③	④	⑤

A quel moment vos problèmes de jambes sont-ils les plus gênants, les plus pénibles ?

	Non	Oui un peu	Oui moyennement	Oui beaucoup	Oui extrêmement
Jour et nuit	①	②	③	④	⑤
Matin	①	②	③	④	⑤
Milieu de journée	①	②	③	④	⑤
Soir	①	②	③	④	⑤
Au coucher	①	②	③	④	⑤

Pour chacune de vos jambes, vos problèmes ont-ils évolué depuis l'année dernière ?

Jambe gauche

- ① aggravation importante
- ② aggravation modérée
- ③ ni aggravation ni amélioration
- ④ amélioration modérée
- ⑤ amélioration importante

Jambe droite

- ① aggravation importante
- ② aggravation modérée
- ③ ni aggravation ni amélioration
- ④ amélioration modérée
- ⑤ amélioration importante

Évaluez les conséquences émotionnelles liées à votre problème veineux :

	Non	Oui un peu	Oui moyennement	Oui beaucoup	Oui extrêmement
Conséquences émotionnelles globales	①	②	③	④	⑤
"A cause de mon problème veineux, je suis à cran"	①	②	③	④	⑤
"A cause de mon problème veineux, je suis irritable"	①	②	③	④	⑤
"A cause de mon problème veineux, j'ai l'impression d'être un fardeau pour les autres"	①	②	③	④	⑤

De façon globale, vos problèmes veineux vous inquiètent-ils ?

- ① non    ② oui un peu    ③ oui moyennement    ④ oui beaucoup    ⑤ oui extrêmement

La possible aggravation de votre maladie veineuse vous inquiète-t-elle ?

- ① non    ② oui un peu    ③ oui moyennement    ④ oui beaucoup    ⑤ oui extrêmement

La possible complication de votre maladie veineuse vous inquiète-t-elle ?

- ① non    ② oui un peu    ③ oui moyennement    ④ oui beaucoup    ⑤ oui extrêmement

Le fait qu'un de vos proches souffre de maladie veineuse vous inquiète-t-il ?

- ① non    ② oui un peu    ③ oui moyennement    ④ oui beaucoup    ⑤ oui extrêmement

# Conclusion

- ▶ Measuring symptoms is mandatory when evaluation of CVD is needed
- ▶ It must be done by patients themselves: PROMs
- ▶ PROMs are the ultimate outcome for health care interventions (Revicki 2007)

Whether we like it or not, the reign of the almighty doctor is over, patients decide if they are happy with the outcome or not.

