

The different venous disease quality of life questionnaires and scores useful : are they useful and relevant?

Pr François-André Allaert Medical evaluation chair ESC Dijon & cenbiotech

www.cacvs.org



### Disclosure

Speaker name:

Allaert

- □ I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
  - X I do not have any potential conflict of interest with this paper

What are the required quality



 For a quality-of-life instrument or a severity score to be a valuable measure of what is intended, it must be reliable and valid.



• For it to gain popularity among researchers and clinicians, it must also be practical.

M A Vasquez and C E Munschauer Venous Clinical Severity Score and quality-of-lif assessment tools: application to vein practice Phlebology 2008;23:259–275

www.cacvs.org



- Reliability evaluates the consistency of provided answers across the spectrum of patients using it. Patients with similar conditions should answer questions in a similar way.
- Validity evaluates the ability of a question to measure the object variable and examines the consistency of responses to questions over time.
- M A Vasquez and C E Munschauer Venous Clinical Severity Score and quality-of-lif assessment tools: application to vein practice Phlebology 2008;23:259–275





- Practicality is a function of the study at hand and the information that can reasonably be expected to be collected by study personnel to provide the necessary data
- Is it usable in daily practice?



## Quality of Life (QOL)

- Generic instruments usually assess global states of well-being, provide and are appropriate for use across a wide spectrum of disease states.
- The 36-Item Short Form Health Survey or it reduced version SF12
- Nottingham Health Profile
- The EuroQol-5D

## The best today ? The EQ-5D



- QUALITE DE VIE QOL-5
- Entourez pour chaque catégorie la réponse qui correspond le plus à votre situation :
- •

#### Mobilité

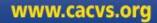
- 1. Je n'ai aucun problème pour me déplacer à pied.
- 2. J'ai des problèmes pour me déplacer à pied.
- 3. Je suis obligé(e) de rester alité(e).
- •

### Autonomie de la personne

- 1. Je n'ai aucun problème pour prendre soin de moi.
- 2. J'ai des problèmes pour me laver ou m'habiller tout(e) seul(e).
- 3. Je suis incapable de me laver ou de m'habiller tout(e) seul(e).
- •

#### Activités courantes

- 1. Je n'ai aucun problème pour accomplir mes activités courantes (e.g. travail, études, travaux domestiques, activités familiales ou loisirs).
- 2. J'ai des problèmes pour accomplir mes activités courantes.
- 3. Je suis incapable d'accomplir mes activités courantes.
- •
- Douleurs/gêne
- 1. Je n'ai ni douleurs ni gêne.
- 2. J'ai des douleurs ou une gêne modérée(s).
- 3. J'ai des douleurs ou une gêne extrême(s).
- •
- Anxiété/Dépression
- 1. Je ne suis ni anxieux(se) ni déprimé(e).
- 2. Je suis modérément anxieux(se) ou déprimé(e).
- 3. Je suis extrêmement anxieux(se) ou déprimé(e)



### **Disease-specific instruments**



- Disease-specific surveys focus on elements associated with particular disease processes and treatment effects. This increases the sensitivity to trends and outcomes of the condition being studied.
- Chronic Venous Insufficiency Questionnaire (CIVIQ)
- Venous Insufficiency Epidemiological and Economic Study (VEINES)
- Aberdeen Varicose Vein Questionnaire (AVVQ)

## **Disease-specific instruments**



• Use the CIVIQ or rather the CIVIQ 20 with only 20 questions

- Use the sub part i.e. The VEINES quality-of-life questionnaire (VEINES-QOL) which comprises 25 items that estimate the effect of disease on QoL
- Aberdeen Varicose Vein Questionnaire (AVVQ) is a 13-question survey addressing all elements of varicose vein disease. Physical symptoms and social issues, and the effect of varicose veins on daily activities, are examined in addition to the effect of varicose veins from a cosmesis standpoint.
- What about the patients' satisfaction ?

### Severity score



- CEAP classification
- It is not a scoring but a classification system for the pupose of standardized description
- Venous Severity Scoring

The American Venous Forum in 2000 derived the Venous Severity Scoring (VSS) system from elements of the CEAP classification.

Venous Disability Score :The total score represents the degree of disability caused by the venous disease but too much focused on work rather on activity

Venous Segmental Disease Score: Despite the use of ultrasonography, the VSDS has been reported to be arbitrary and difficult to grade

Venous Clinical Severity Score : on item concern compression with

higher scores representing greater compliance which is a strange mix of symptoms and therapy

## **Venous Clinical Severity Score**



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, severe limiting activities or requiring regular use of analgesics
Varicose veins <sup>a</sup>	None	Few, scattered: branch VVs	Multiple: GS varicose veins confined to calf or thigh	Extensive: Thigh and calf or GS and LS distribution
Venous edema <sup>b</sup>	None	Evening ankle edema only	Afternoon edema, above ankle	Morning edema above ankle and requiring activity change, elevation
Skin pigmentation <sup>e</sup>	None or focal, low intensity (tan)	Diffuse, but limited in area and old (brown)	Diffuse over most of gaiter distribution (lower 1/3) or recent pigmentation (purple)	Wider distribution (above lower 1/3) and recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involves most of gaiter area (lower 1/3)	Severe cellulitis (lower 1/3 and above) or significant venous eczema
Induration	None	Focal, circummalleolar (<5 cm)	Medial or lateral, less than lower third of leg	Entire lower third of leg or more
No. of active ulcers	0	1	2	> 2
Active ulceration, duration	None	<3 mo	>3 mo, <1 y	Not healed >1 y
Active ulcer, size <sup>d</sup>	None	<2-cm diameter	2- to 6-cm diameter	>6-cm diameter
Compressive therapy <sup>e</sup>	Not used or not compliant	Intermittent use of stockings	Wears elastic stockings most days	Full compliance: stockings + elevation

#### Table III. Original Venous Clinical Severity Score

<sup>au</sup>Varicose" veins must be >4-mm diameter to qualify so that differentiation is ensured between C1 and C2 venous pathology.

<sup>b</sup>Presumes venous origin by characteristics (eg, brawny [not pitting or spongy] edema), with significant effect of standing/limb elevation and/or other clinical evidence of venous etiology (ie, varicose veins, history of DVT). Edema must be regular finding (eg, daily occurrence). Occasional or mild edema does not qualify.

'Focal pigmentation over varicose veins does not qualify.

<sup>d</sup>Largest dimension/diameter of largest ulcer.

eSliding scale to adjust for background differences in use of compression therapy.

### www.cacvs.org

## Reasons for such a problem?



- The score were developped by great experts but not according the good rule for developing questionnaires contrary to what has been done in QOL questionnaire
- They are more adapted to severe venous disease that daily venous disease seen in daily practice
- They do not take into account the what the patients are expecting (satisfaction)
- Derive the severity score from the CEAP is perhaps a deadlock

# What we need ?



- We need a severity score developed according the good practice ie:
- Conduct interviews with patient and not only with experts
- Extract information
- Build a first version of the questionnaire
- Chech if it is readible and comprehensible
- Analyse the rate of answer, its stucture, its internal consistency and reduce its item number using ACP methods and verimed varimax rotation
- test it reliability (test-retest)
- Test it internal coherence
- Test it external validity
- Test its sensibility of change
- And the propose it.....

## Conclusion



- We have good Quality of life questionnaire
- We have poor severity scores
- The same work has to be conducted on severity score that was conducted on quality of life using an adequate methodology
- Something simple conducted according good practice and more focused on patients' opinion