Quality Of Life Surveys In Patients Undergoing Intervention For Chronic Venous Disease:

Current state
- More than 20 different instruments
- 8 QoL instruments are commonly used for venous pathology:
  - Villalta, SF-12/36(v2), EQ-5D-5L, AVVQ, CIVIQ-14/20, VEINES-QOL/Sym
  - C/EAP and VCSS are common for clinical scoring
- Increasing demand for QoL data:
  - healthcare insurance companies and governments
  - Research outcome

Limitations
- No consensus on overall QoL instrument
- Makes comparing outcomes difficult
- Selective applicability: only varicose veins, C1-C4 or PTS
- Cumbersome for patients: 50+ questions is common
- High administrative load for physicians
  - Assisting in filling in the questionnaires
  - Making sure QoL is completed for every patient
- High administrative load for researchers
  - Combining clinical with QoL scores
  - Digitalizing paper questionnaires
  - Difficult to decipher syntaxes and scoring algorithms

Limitations
- Statistical significance vs clinical relevance
  - What difference is clinically relevant?
    - 10 points>20 points? (100 point VAS scale)
    - 0.8 points on 30 point VCSS scale with p=0.001
    - NOT clinically relevant!
  - How to define clinical relevance?
    - Tool specifications (norm)
    - Based on patient reported outcome (subjective)
    - Based on clinical outcome (objective)
    - Mathematically (statistically-defined; p-value)
Limitations

- Clinical relevance (basic rule):
  - Minimally ½ standard deviation change!!
- Broad consensus in literature:
  - Norman et al (Med Care 2003 May; 41(5):582-92, “Remarkable universality”)

Future

- QoL should be combined with clinical scores and technical outcomes
  - That way you get:
    - In theory objective measures of:
      - Quality
      - Success
      - Indication for treatment outcome
      - Predictive value for treatment outcome
      - Cost effectiveness

- Applicable to the whole venous spectrum
  - Varicose veins to PTS and ulcers
  - Items based on venous symptoms:
    - Venous claudication, varicose veins, PCS, recurrent thrombosis, discoloration, restrictions in ADL
  - Not solely symptom, clinical outcome or QoL items but also:
    - Age, sex, anatomical information, comorbidity
  - All play a role in the impact and burden of disease, the effectiveness and outcome of treatment and cost-effectiveness.

- Multiple perspectives:
  - Patient-reported and clinician-reported: QoL scores + clinical scores, with the addition of imaging, comorbidity, age, sex, etc
  - Maximum of 20 items
  - Based on Health Believe Model (HBM)
  - Each Item should be multiple choice
  - Same amount of answers for each question: scored on a Likert scale
  - Comply with COSMIN criteria
  - Proof of methodological correctness
  - Items need to be specific for venous disease
  - No generic “pain”, “limitations” etc items without context

- We need this new uniform venous questionair, which measures, QoL, treatment outcome and cost effectiveness
- International cooperation (AVF, ACP, ESVS, ECoP, EVF, UIP)
  - World wide registry for venous disease
  - Incorporation of QoL and clinical scores
- Guidelines
  - Promote the usage of one uniform instrument
  - Make it obligatory
- Make use of the digital world
  - Data collection directly from patient records
  - Use eHealth initiatives (smartphones, apps, etc.)