

# MEDCAC : Lower Extremity Chronic Venous Disease –Evidence Gaps

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## Conflict of Interest for this presentation:

### Research Support:

VIVO iliac stent study (Cook, Inc) –  
Minor – less than \$10,000

### Venture Capital:

Percutaneous autogenous venous valve  
early development (InterVene, Inc) - Minor  
– less than \$10,000

# Standardization of Patient Classification and Measurement Tools of Treatment Success


- Confirms need for intervention and success
- VERY IMPORTANT FOR RESEARCH AND CLINICAL ARTICLES REGARDING VENOUS INTERVENTIONS TO ALLOW GENERALIZATION
  - CEAP classification: Precisely defines the patient
  - Measure effect of intervention:
    - Revised Venous Clinical Severity Score – MD view
    - Quality of Life - patient view
      - Generic: Overall Feeling of Health
        - 36-Item Short Form Health Survey (SF-36) (compare to other chronic diseases)
      - Venous Disease Specific:
        - VEINES-QOL/Symptoms (Insufficiency/Economic)
        - CIVIQ (Chronic Venous Insufficiency Questionnaire)
        - AVVQ (Aberdeen Varicose Vein Questionnaire)
        - CXVUQ (Charing Cross Venous Ulceration Questionnaire)
    - Procedural Outcomes: major and minor complications
      - Ulcer specific: Time to complete healing, rate of healing, recurrence

# Adoption of Venous Practice Guidelines to direct Venous Disease Care

- These guidelines do exist and efforts to encourage use clinically would help to standardize care & decrease variation
  - The care of patients with varicose veins and associated chronic venous disease: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. JVS 2011; (5 Supple) 53: 2S-48S
  - Clinical practice guidelines of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF): Management of venous leg ulcers. JVS 2014: (2 Suppl) 60; 3S-59S.

## Standardization of Venous Testing in CVD

- All venous studies should be performed in a standard fashion to allow comparison one patient to another, vascular laboratories involved in accreditation follow routine protocols. This should become a standard requirement for all venous studies to ensure reduced variability and improve patient care




Compression is essential to effective CVD treatment and should not be a financial burden to the patient who desires to be compliant

- Varicose veins and other early clinical stages
  - Evidence gap:
    - The precise level of compression required for disease class
- Advanced clinical stage disease including venous ulcer
  - Evidence gap:
    - The precise level of compression required per disease class
    - Optimal compression dressing method or device
    - Studies including precise tools for measuring success in the mid and long term

# The incidence and rate of early stage CVD which progresses to advanced disease

- Evidence Gap:
  - Longitudinal studies with appropriate imaging which defines the patients with a low/medium/high risk of disease progression
    - Studied by gender, race, age
    - Studied by initial clinical class
    - Studied by anatomic involvement
      - Occlusive verses reflux
      - Superficial vs deep vs perforator vs combination
  - Such studies would provide a clear basis for conservative verses an aggressive approach to prevent disease progression but would not change the need to treat based on symptom relief



A comprehensive understanding of venous physiology in terms of the vein (as conduit & valve function) as well as end organ response (skin/soft tissue) in the Medicare population

- This lack of basic knowledge limits the development of effective drugs to aid the treatment of symptomatic early disease & in healing/ preventing venous ulceration
  - Improving the venous system as conduit
  - Improving valve function to prevent reflux
  - Improving the calf pump function
    - Drug therapy, conditioning, exercise

# Well-designed long-term clinical trials which evaluate venous interventions used to treat advanced stages of CVD in Medicare patients

- Clinical trials or real life registries using standardized and validated tools to classify & determine treatment success to confirm mid and long-term success
  - Proximal deep venous occlusive disease
    - Long-term success in well defined patient cohorts
    - Best stent design, use of drug eluting agents
  - Deep venous reflux disease
    - Long term success in standard clinical practice
    - Percutaneous methods of valve repair
    - A well tolerated synthetic or autogenous implantable valve

# Well designed clinical studies of venous interventions (all types) focusing on quality for cost in the Medicare population

- Most venous intervention studies have not included cost analysis particularly in the Medicare population
  - When studied it has demonstrated improved cost benefit to definitive care but little data exists
    - Example: Michaels JA, Campbell WB, Brazier JE, et al. Randomized clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess 2006;10:1-196

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