Treatment of Claudication: Perspectives of the Patient, the Provider and the Health Care System

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PAD IS A MAJOR GLOBAL HEALTH PROBLEM

REACH Registry: One Year Costs Associated with Hospitalizations for Vascular Reasons

PAD TREATMENT MORE COSTLY THAN CAD!

10-Year Natural History in Patients With Intermittent Claudication
Trends in the national outcomes and costs for claudication and limb threatening ischemia: Angioplasty vs bypass graft

Do the results justify the utilization? Are we spending too much on treatments that provided limited benefit for a benign condition??

IF YOU WERE A PAD PATIENT:
What is the minimum efficacy threshold you would accept for an invasive treatment for life-style limiting claudication?

A. >50% likelihood of improvement for at least one year
B. >50% likelihood of improvement for at least two years
C. >50% likelihood of improvement for at least three years

IF YOU WERE THE DECISION-MAKER FOR A MAJOR PAYOR:
What is the minimum efficacy threshold you would expect to justify the costs of an invasive treatment for life-style limiting claudication?

A. >50% likelihood of improvement for at least one year
B. >50% likelihood of improvement for at least two years
C. >50% likelihood of improvement for at least three years
### Treatment Goals in IC

- Reduce secondary CV events
- Prevent/reduce likelihood of disease progression to CLI and potential amputation (overall low risk)
- Reduce IC-related disability
  - Improved walking ability in daily life
  - Improve self-perceived QoL
  - Maximize symptom-free survival
  - Maintain independent function
- Minimize interventions (frequency and severity), morbidity, hospitalizations, and overall costs
- “Right patient, right time, right procedure”

### Disability in IC: Not So Benign

- Historical data suggests that “clinical deterioration” occurs in 20-30% of pts with IC
- More recent evidence using objective testing suggests that ambulatory function significantly worsens over time in PAD, with increasing levels of disability during follow-up
  - McDermott et al WALCS Trial (N=460)
  - Multiple measures of functional performance, 5 years of f/u
  - Adjusted HR 2.29 for inability to complete a six-minute walk at 5 year f/u visit
  - Greater declines associated with older age, higher BMI, lower baseline ABI, less daily physical activity, pulmonary disease, spine disease, diabetes
- Paucity of functional data using validated assessment tools

### IC Treatment “Paradigm Shifts”

#### Old paradigm
- Stop Smoking and Exercise
- Surgery or Intervention for Selected Patients
  - Low comorbidities/risk assessment paramount
  - Favorable lesion anatomy for treatment
  - Durability a key measure of success

#### New paradigm
- “Let’s do some imaging and take a look”
- Endovascular interventions have lowered the entry bar
  - Broadly disseminated
  - Generally low procedural risk, but costly
  - Technical success high; overestimates clinical success
  - Limited durability but may be repeated
  - Unclear effects on clinical/anatomic disease progression, or on the outcomes of subsequent revascularization
  - Potential risk of “Treatment Trap”

### IC Therapy: Comparative Effectiveness

- Few studies have compared the impact of revascularization, medical therapy, or exercise on functional and QoL outcomes
- Supervised exercise, endovascular and open revascularization all appear superior to medical therapy
- Revascularization has greater effects on blood flow; surgical treatments have higher morbidity but greater durability
- Spronk et al randomized 151 pts to PTA first or SE
  - PTA pts had reduced ipsilateral symptoms at 6 months but no difference in clinical, functional capacity or QoL at 6,12 months
- MIMIC Trial- PTA associated with improved walking parameters vs SE at 24 months
- Recent Cochrane reviews:
  - Gains for both exercise and PTA appear short term
  - Inadequate number of high quality studies
  - Value of surgical bypass also questioned

**Claudication: Exercise Vs Endoluminal Revascularization (CLEVER) Trial**
“Stop Smoking and Start Walking!!”

Effects of Exercise Training on Claudication

Efficacy of Supervised Exercise: Results of a Meta-Analysis

- Predictors of improvement
  - Moderate claudication pain
  - Walking exercise
  - >6 months’ exercise training
  - Supervised exercise

Multicenter RCT comparing Optimal Medical Therapy (OMT), OMT plus Supervised Exercise (SE), and OMT plus Stenting (ST) for the treatment of Intermittent Claudication secondary to Aorto-iliac Occlusive Disease

N=119 subjects

Both SE and ST were both superior to OMT for measures of walking performance, QoL

Peak walking time (treadmill) was greater for SE than ST

QoL measures showed greater improvement for ST than SE


Options for TASC C/D SFA Disease

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Estimated 2-yr Patency (%)</th>
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<tr>
<td>POBA</td>
<td>20-30</td>
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<td>CLAUDICATION MATH for Bilateral SFA Disease:</td>
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<tr>
<td>Patency 1\textsuperscript{st} limb at 2 years= 0.6</td>
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<tr>
<td>Patency 2\textsuperscript{nd} limb at 2 years= 0.6</td>
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Likelihood of Clinical Success at 2 years:
-- if you assume you need anatomic success in two legs= 0.36 !!

Vein (AK or BK) 70-80
Prosthetic (AK) 65-80
Prosthetic (BK) 40-60
What Does the Patient Want?

- Reassurance they are not likely to lose their limb
- Better understanding of the underlying disease and how they can exert some control over its progression
- Improved limb function and associated QoL
- Avoid/minimize invasive procedures, hospitals, and physician visits
- Avoidance of other atherosclerotic CV complications

What Does the Provider Want?

- A happy, compliant patient
- A good outcome
- Significant, durable gains for patients with the greatest disability
- Enhanced reputation and associated referrals
- ADDRESS EDUCATION, LIFESTYLE, MEDICAL THERAPY AND EXERCISE PRIMARILY
- CAREFULLY SELECT PTS FOR REVASCULARIZATION AND INFORM THEM PROPERLY OF THE LIMITATIONS, RISKS AND BENEFITS

What Does the “Health System” Want?

- A happy, compliant patient
- A good outcome at low cost
- Significant, durable gains for patients with the greatest disability
- Enhanced reputation of the health plan
- PROVIDE RESOURCES FOR EDUCATION, LIFESTYLE, MEDICAL THERAPY AND EXERCISE
- INCENTIVIZE APPROPRIATE SELECTION OF PTS FOR REVASCULARIZATION
Treatment of IC: Current State

- Emphasis on optimal medical therapy, smoking cessation and regular exercise for the majority of patients
- Engage the patient in measuring performance, and reassure them on low risk of limb loss
- Reserve revascularization for severe disability, failure to improve after adequate trial of conservative measures
- Patient comorbidities/risk, anatomic pattern of disease, prior interventions, and conduit availability influence treatment choice and expected outcomes
- Strategy for intervention should be based on a reasonable estimate of clinical durability, e.g., at least 50% likelihood of sustained success for 2 or more years. Anatomic patency necessary though not sufficient.
- Shared decision making requires adequate pt education re trade-offs
- Evidence-based practice hampered by scarcity of high quality RCTs and comparative effectiveness studies, particularly with patient-centered outcomes assessment