Extensive (TASC D) Femoropopliteal Disease in the Claudicant: Do the Results Justify Intervention?

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Disclosures

I have nothing to disclose

Logical Fallacies
- Attacking the Person
- Appeal to Authority
- Appeal to Popular Opinion
- Association Fallacy
- Begging the Question
- Circular Argument
- Relationship Implies Causation Fallacy
- False Dilemma/Dichotomy

Definitions
- Extensive (TASC D) Femoropopliteal Disease in the Claudicant: Do the Results Justify Intervention?

Interventions
- Revascularization
  - Endovascular
  - Surgical
- Medical therapies
  - Supervised Exercise
Natural History of Claudication

- 1508 patients with claudication seen from 1947 – 1953
- Most diagnosed with angiography
- Seen every 3 months with treadmill walking test
- No patients treated surgically
- Diabetes in 4%

**Bloor K. Natural History of Arteriosclerosis of the Lower Extremities.**

Interventions for Claudication

- Goal of functional improvement in the limb
  - Quality of life
- Interventions should exceed the natural history of disease
- Primum non nocere

**Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: Management of asymptomatic disease and claudication**

- “We suggest that a minimal effectiveness threshold for invasive therapy in IC be a >50% likelihood of sustained clinical improvement for at least 2 years. Freedom from hemodynamically significant restenosis in the treated limb is considered a pre-requisite for this goal.”
PTA + Stent for TASC D

Endovascular interventions for TASC II D femoropopliteal lesions

- Failed attempts not included
- 6.3% complications
- Mean follow up just 10.7 months
- 38% restenosis
- 11% occluded
- 37% re-interventions
- 11% multiple re-interventions

Pharmacotherapy for Functional Improvement

- Registry Data of 48 limbs

Drug Eluting Stents

Treatment of TASC C and D Femoropopliteal Lesions with Paclitaxel eluting Stents: 12 month Results of the STELLA-PTX Registry

- Registry Data of 48 limbs

Drug Eluting Stents

Endovascular interventions for TASC II D femoropopliteal lesions

- Zilver PTX post market registry for long lesions

- Zilver PTX HCT
- Zilver PTX SAS
- Zilver PTX SAS LL

<table>
<thead>
<tr>
<th></th>
<th>Zilver PTX HCT</th>
<th>Zilver PTX SAS</th>
<th>Zilver PTX SAS LL</th>
<th>Zilver PTX Longer Lesions</th>
<th>Durability 2000</th>
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<tbody>
<tr>
<td>Patients</td>
<td>235</td>
<td>787</td>
<td>134</td>
<td>45</td>
<td>100</td>
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<tr>
<td>Lesions</td>
<td>247</td>
<td>900</td>
<td>139</td>
<td>45</td>
<td>100</td>
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<tr>
<td>Lesion length (mm)</td>
<td>66 ± 30</td>
<td>100 ± 82</td>
<td>126 ± 44</td>
<td>189 ± 91</td>
<td>242</td>
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<tr>
<td>Diameter stenosis (%)</td>
<td>82 ± 17%</td>
<td>85 ± 16%</td>
<td>97 ± 9%</td>
<td>99 ± 12%</td>
<td>N/A</td>
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<tr>
<td>Total occlusions</td>
<td>30%</td>
<td>38%</td>
<td>84%</td>
<td>82.2%</td>
<td>N/A</td>
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<tr>
<td>1-year Primary Patency</td>
<td>82.7%</td>
<td>86.2%</td>
<td>77.6%</td>
<td>89.1%</td>
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<tr>
<td>1-year Freedom from TLR</td>
<td>90.8%</td>
<td>89.3%</td>
<td>85.4%</td>
<td>86.1%</td>
<td>68.2%</td>
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<tr>
<td>1-year Fracture Rate</td>
<td>0.9%</td>
<td>1.3%</td>
<td>2.1%</td>
<td>0.0%</td>
<td>6.0%</td>
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</tbody>
</table>

*Authorship note: J. Queret et al. for HCT and longer lesions (Zilver PTX)*
Randomized trial of 148 TASC C + D lesions
• Viabahn vs BMS

Covered Stent Trials

30% @ 3 yrs

Single arm study of 71 patients

Covered Stent Trials

67% @ 1 yr

Popliteal Lesions

246 lesions
• 30% CTO
• 80% claudicants

Interventions for Claudication


“We suggest that a minimal effectiveness threshold for invasive therapy in IC be a >50% likelihood of sustained clinical improvement for at least 2 years. Freedom from hemodynamically significant restenosis in the treated limb is considered a pre-requisite for this goal.”
Above Knee Bypass

- Weighted mean primary patency rates for all randomized controlled trials comparing vein with PTFE grafts for above knee femoropopliteal bypass

PREVENT III data: CLI patients only

Vein Bypass

- Major complications: 18.7%
- 7.4% graft thrombosis
- 9.4% wound infections
- MI: 2.37%
- Dialysis: 2.52%

Surgical Morbidity

Significant perioperative morbidity accompanies contemporary infrainguinal bypass surgery: An NSQIP report

Femorotibial bypass for claudication: Do results justify an aggressive approach?

Michael S. Contor, MD,* Michael Retkin, MD, Magruder C. Donaldson, MD, Patricia Baum, BSN, John A. Mannick, MD, and Anthony D. Whittenmore, MD, Boston, Mass.
**Pharmacotherapy for Functional Improvement**

- Goal of functional improvement in the limb
- FDA approved with indication for PAD
  - Cilostazol
  - Pentoxifylline
- Available in Europe
  - Naftidrofuryl

**Pharmacotherapy Trials**

- Randomized, double blind, placebo controlled trial of pentoxifylline vs cilostazol in claudication
- 698 patients randomized
- Treadmill testing up to 6 months

**Exercise Therapy**

- Mechanism of action likely biochemical and biomechanical
  - Enlargement of existing collateral vessels
  - Exercise induced angiogenesis
  - Enhanced nitric oxide (NO) endothelium-dependent vasodilatation of the microcirculation
  - Improved bioenergetics of skeletal muscle
  - Improved hemorrhology
- Improvement in biomechanical measures even without improvement in resting ABI

**Exercise Program Components**

- Walking is the best modality
  - Superior to cycling, stair climbing, tiptoe raises, dancing, and static or dynamic leg exercises
  - Neither strength training nor upper extremity aerobic exercise appear to augment responses to walking
  - Low intensity = High intensity
- Walking session must be > 30 min and > 3x per week
- Duration of program > 26 weeks
- Can expect improvement in walking ability of 50% - 200% with improvements maintained for up to 2 years
OMT, Exercise and Interventional Rx

9 randomized controlled trials comparing supervised exercise program vs. revascularization for claudication

- Aortoiliac and femoropopliteal disease
- Varying degrees of optimal medical therapy
- Balloon angioplasty +/- stent
- Hemodynamic and functional testing

Greater short-term benefit from PTA than exercise therapy but this was not sustained after 1 – 2 years

Some trials showed longer walking distances in non-interventional arm at 2 years


Supervised Exercise Versus Primary Stenting for Claudication Resulting From Aortoiliac Peripheral Artery Disease
Six-Month Outcomes From the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) Study

- CLEVER study
- Randomized 111 patients with aortoiliac disease to:
  - Optimal medical therapy (OMT)
  - OMT + supervised exercise
  - OMT + stent revascularization

Primary endpoint was peak walking time by treadmill test

Secondary endpoints was community podometer, QOL

Summary of Recommendations for Claudication

- Supervised exercise program is 1st line treatment of claudication
  - > 30 min per session at least 3x/week
  - Duration of treatment > 12 weeks

Revascularization for IC reserved for active patients with favorable risk benefit profile and who have failed non-invasive treatment

Revascularization only if a reasonable likelihood of sustained benefit (>50% likelihood of clinical efficacy for at least 2 years)
Thank You