Factors Influencing the Decision for Direct/Open Surgical Revascularization for Chronic Limb Ischemia & Anticipated Outcomes for These Interventions

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Disclosure

I have no relevant financial relationships with proprietary entities producing health care goods or services related to the content of this presentation.

Content may not reflect position of US Government.
Outcome Assessment

Surgeon Perspective

- Patency most important
- Variables
  - Location of bypass
  - Type of conduit
  - Quality of inflow/outflow
  - Patient’s other comorbidities
- Limb salvage
- Return to acceptable QOL
Outcome Assessment

Patient Perspective

- Return to acceptable QOL
- Limb salvage
- Duration of incapacitation
- Patency irrelevant
Management Paradigm for PAD

Pre 1990

- Claudication
  - Conservative management
- Exercise
- Limited pharmacotherapy
- Risk factor control
- PTA for treatment failures
- Bypass rarely justified
Management Paradigm for PAD

Pre 1990

- **Chronic CLI**
  - Intervention based therapy
  - Surgical bypass for limb salvage
  - Pharmacotherapy limited value
  - Endovascular intervention used occasionally
    - Primarily PTA – often hybrid procedure component
Management Paradigm for PAD

1990 - Present

• **Claudication**
  • Endovascular intervention increasingly more common as first line treatment
  • Exercise, pharmacotherapy not considered first line therapy in “most” vascular practices
  • Better risk factor control
  • Bypass still rarely justified
Management Paradigm for PAD

1990 - Present

- CLI
  - Endovascular intervention primary therapy
  - Bypass for limb salvage after EVI failure
  - Pharmacotherapy rarely used
  - Patients prospect for survival & functional status not routinely considered in decision for therapy
Direct Surgical Therapy for Lower Extremity Revascularization

• **Pros**
  - **Durable**
  - **Results generally predictable**
  - **Time tested procedures with evidence based outcomes**

• **Criticisms**
  - **Significant morbidity & mortality**
  - **Expensive - related to need for longer hospitalization than EVI and wound issues**
Aorto-femoral Bypass

- Best & most durable arterial reconstruction
- 3% per year failure rate
- 75% 10-year patency
- 3-5% mortality
- 10-15% major morbidity risk
- 50% of patients deceased 5 years from other comorbidities
- DM – mild increase in M/M
Above-Knee Femoral-Popliteal Bypass

- Claudication
  - Rarely justified unless symptoms truly disabling
  - Status of profunda femoris perfusion – key determinate

- Critical Limb Ischemia
  - Bypass of SFA lesions usually required to heal ischemic lesions on foot / toes

Above-Knee Femoral-Popliteal Bypass

- **Autogenous vein – best conduit**
  - 5 yr patency – 60% - 76%
- **Heparin bonded PTFE & Dacron**
  - Equivalent patency
  - 5 yr patency – 40% - 45%

Klinkert, et al 2003
Johnson, et al 2000
Femoral-popliteal Bypass
Below Knee

- Used for long segment femoral-popliteal occlusions or multiple segmental stenoses & occlusions
- May be necessary for relief of disabling claudication
- Necessary to heal ischemic foot/toe lesions
- Autogenous vein, reversed or in-situ, is best conduit
Femoral-tibial or Popliteal-tibial Bypass Procedures

• Autogenous vein best conduit except for femoral-anterior tibial grafts where prosthetics may be equivalent
• Use of adjunctive outflow AV fistula maximizes flow through grafts & can be useful when a prosthetic conduit is all that is available
• Patency
  • Autogenous vein: 70% 5-year
  • Prosthetic: variable, 50-70% 2 year; should be used for limb salvage only
  • 15-20% decreased patency with DM
Segmental Endarterectomy

- Reserved for very localized segmental disease
- Requires relatively large artery
- Frequently mandates use of patch closure of vessel
- Patency generally less than for vein bypass procedures but is more durable than prosthetic bypass grafting
- Rarely possible in diabetic patients
Surgeons: 
*What We Gloss Over*

- Chronic kidney disease, nutritional status & DM predictors of poor long term outcome for bypass
- Wound healing problems in 10 – 35% of saphenous vein harvest sites
- CLI patients
  - 25% 1 year mortality
  - ~ 50% 2 year mortality
Outcomes of Lower Extremity Revascularization Meta-Analysis

- Medline and Embase (English language)
- 1980 – June 2010
- Sub-group of patients with diabetes reported separately (30 pubs)
- Ulceration/gangrene/tissue loss reported (80% of pubs)
- PAD: any flow limiting atherosclerotic lesion of the arteries below the inguinal ligament
- No medical, topical or local therapies considered
- Outcomes: Ulcer healing, limb salvage, major amputation, survival
Meta-Analysis

- 8,290 patients
- 49 studies
- No randomized trials
- 3 studies with a control group
- 46 case series
Why is PAD difficult to treat in patients with diabetes?

- Multilevel disease
- Extensive calcification
- Long occlusions
- Predilection for crural vessel disease
- Technically challenging
Mortality

- Perioperative
  - Reported in 30 studies
  - 1.4% (0.8 - 3.7%) open surgery (n=20)
  - 0.5% (0 - 4.3%) endovascular (n=10)

- 30-day - 0% - 9%
- 1 year - 13.5% (11.3 – 31.8%)
- 5 years - 46.5% (36-52.3%)
- Rates varied widely
- Paucity of data on endovascular
Limb Salvage and Wound Healing

Lack of clear definitions

- Most studies reported on limb salvage
- 1-year 85% (80 – 90%) open surgery
- 1-year 76% (72 – 78.5%) endovascular
- Wound healing poorly reported
- > 60% at 1-year in all studies
Amputation

- Rates of minor amputation varied considerably (12 – 92%)
- Major amputation within 2 years
  - 17.3% (12.8 – 22.8%) open surgery
  - 8.9% (5.4 - 12.5%) endovascular
Chronic Kidney Disease

- 6 pubs
- Definitions of chronic kidney disease varied
- Appeared to have significantly worse outcomes
  - 1-year mortality 38% (25.5 – 41.5%)
  - 1-year limb salvage rates 70% (65 – 75%)
Pedal Bypass Grafts

- 10 pubs
- Severity of PAD and foot lesion poorly described
- Limb salvage
  - 86% (85-98%) at 1-year
  - 82.3% (81.3 – 88.5%) at 3-years
  - 78% (78 – 82.3%) at 5-years
- Numbers low at 3 and 5 year follow-up
Discussion

Evidence of effectiveness of revascularization

• Limb salvage rate 54% at 1-year with NO revascularization (Lepantalo)
• 78 – 85% 1-year limb salvage with revascularization – open or endo
Discussion

- Increasing numbers of studies reporting patients with PAD and diabetes / ulcer
- Study quality generally poor (selection / publication bias)
- Insufficient evidence to recommend PTA over bypass surgery
- Optimize medical therapy (high mortality)
- Need standard reporting / standard management
## Cost

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost</th>
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<tbody>
<tr>
<td>Angioplasty Balloon</td>
<td>$500 - $1600</td>
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<tr>
<td>Balloon Expand Stent</td>
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<td>Self Expand Stent</td>
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<td>SilverHawk</td>
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<td>Laser Catheter</td>
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<td>Open</td>
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<tr>
<td>Endo</td>
<td>$15,454.83</td>
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P < 0.001
Baylor Scott & White Lower Extremity Revascularization Experience 2005 - 2012

- 400 patients
  - 242 male
  - 158 female
  - 439 total limbs
- Type of vascular intervention
  - 267 endovascular
  - 172 open
- No significant difference in age & co-morbidities
- All prospectively followed – mean follow-up 5 years
Outcomes

- Patients receiving open bypass have an increase incidence of CAD, CVD, COPD, and worse TASC score
- Amputation rate is higher in open group
- Open operations are more cost effective in the OR, but lose their benefit in cost due to length of stay
Improving Outcomes

• Risk factor reduction
  • Statins LDL < 70
  • Ace/ARB
  • Hgb A1C < 7.0
  • Stop Smoking!
• Earlier treatment of disease?
• More aggressive treatment of disease
• Will there be a better technique?
  • Increased use of hybrid operations
  • Angioplasty, stenting, atherectomy, drug coatings to balloons or stents
Thank You