What role does bypass play in the treatment of claudication

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What drives revascularization of claudication patients

- Limits of medical therapy
  - Lack of reimbursement for exercise programs
- Aorto-iliac intervention technical success, clinical effectiveness and durability
  - **Endovascular first strategy for nearly all aorto-iliac lesions except**
    - Infra-renal occlusions
    - Significant aneurysmal disease
    - Severe calcification
- Infra-inguinal interventional tools showing continuous improvement in effectiveness and durability
  - **Endovascular first strategy for a majority of fem-pop disease**
    - Drug-coated balloon angioplasty
    - Drug-eluting stents
    - Interwoven nitinol stents

Kaiser Study:
Periph Vasc Intervention (PVI) vs Lower Ext Bypass (LEB)

- Kaiser Permanente Colorado or Kaiser Permanente Northern California
- January 1, 2005, and December 31, 2011
- 2161 patient charts identified by coding data for arterial reconstructions:
  - 265 concomitant surgical and endovascular procedures excluded
  - 29 patients who had <6 months enrollment before the identified procedure
  - 9 patients without dx of claudication or CLI excluded
- 1858 patients in final cohort:
  - 975 with open surgery and 883 endovascular procedures
  - 51% Claudication
  - 49% CLI
  - 3.2 years Median FU

Kaiser Study: PVI vs LEB

- **TLR rates in claudication patients at 1 and 3 years:**
  - LEB: 5.2% and 8.3%
  - PVI: 12.3% and 19.0%  \( p<0.001 \)
- **TLR rates in CLI patients at 1 and 3 years:**
  - LEB: 10.8% and 16.0%
  - PVI: 19.1% and 31.6%  \( p<0.001 \)
- **30 day overall complications rates:**
  - LEB: 37.1%
  - PVI: 11.9%  \( p<0.001 \)
- No difference in amputation rates with PVI vs LEB
- No data on symptomatic status or patency


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

- **5.16.** We recommend endovascular procedures over open surgery for focal occlusive disease of the SFA artery not involving the origin at the femoral bifurcation
  - Grade 1, level of evidence C.
- **5.17.** For focal lesions (<5 cm) in the SFA that have unsatisfactory technical results with balloon angioplasty, we suggest selective stenting
  - Grade 2, level of evidence C.
- **5.18.** For intermediate-length lesions (5-15 cm) in the SFA, we recommend the adjunctive use of self-expanding nitinol stents (with or without paclitaxel) to improve the midterm patency of angioplasty.
  - Grade 1, level of evidence B


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

- **5.21.** We recommend surgical bypass as an initial revascularization strategy for patients with diffuse FP disease, small caliber (<5 mm), or extensive calcification of the SFA, if they have favorable anatomy for bypass (popliteal artery target, good runoff) and have average or low operative risk
  - Grade 1, Level of evidence B
- **The primary reference cited as the data source for these recommendations on the clinical question of surgery vs endo for femoral popliteal treatment of claudication states in it's conclusion:**
  - "High-level evidence demonstrating the superiority of one method over the other is lacking."
Meta-analysis of endo vs bypass in fem pop revascularization

• Below studies all show relative equivalence of endo and bypass
  • No difference PTFE stent vs bypass in 25 cm long lesions
  • Better outcomes for PTA/stenting but lesions less severe than bypass patients
  • TASC C better with endo, TASC D better bypass
  – Sultan S, J Endovasc Ther 16(3): 270-83, 2009
  • Trend for higher clinical patency with angioplasty/stenting but no sig difference compared to bypass for TASC C & D lesions
  – BASIL trial last updated 2010
  • CLI trial with amputation rates equivalent
  • All of above studies with data from cases done prior to 2008


The treatment of disabling intermittent claudication in patients with superficial femoral artery occlusive disease - Decision analysis

• A Markov-state transition model of clinical decision making used to predict outcomes in femoral-popliteal revascularization
• Conclusion: 65 year old with a TASC 1, C lesion would benefit from PTA/stenting as first line therapy if there was a 32% primary patency rate for PTA/stenting at 5 years


Meta-analysis of endo vs bypass in fem pop revascularization

• Studies showing superiority of bypass
  • Propensity matched analysis, 5 years endo vs bypass - patency of 74% vs 88%
  • Randomized trial, 1 year stent graft vs bypass - patency 48% vs 94%
  • Observational study, 1-year PTA vs bypass - patency 43% vs 82%
  – Ah Chong AK, et al
  • Retrospective study with 1 yr PTA vs bypass - patency 48% vs 60%
  • Observational study with 2 year PTA vs bypass - patency 18% vs 68%
• Only one of these studies showed >50% 1 year patency for endovascular treated femoral/popliteal vessels


DES in long lesions

• Zilver PTX single arm registry
  – 135 patients
  • Mean lesion length 22.6 cm
  • 1 yr primary patency 77.6%
  • 1 yr freedom from TLR 85.4%


Interwoven nitinol in long lesions

• Supera 500 registry
  – 492 limbs
  – Mean lesion length 12.6 cm
  – 1 yr primary patency 83.3%
  – 2 yr primary patency 72.8%
• SUPERB trial long lesion subset
  – 87 pts in top tercile length
  • Mean lesion length 12.6 cm
  • 1 yr primary patency 88%
  • 1 yr freedom from TLR


DCB vs DES in long lesions
Propensity based analysis to define similar cohorts in a real world experience

<table>
<thead>
<tr>
<th></th>
<th>DES N=97</th>
<th>DCB N=131</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>19.5 +/- 6.5 cm</td>
<td>19.4 +/- 8.6 cm</td>
</tr>
<tr>
<td>Re-stenotic lesions</td>
<td>44%</td>
<td>52%</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>63%</td>
<td>53%</td>
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<tr>
<td>TLR (12 mo)</td>
<td>16%</td>
<td>19%</td>
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Saint Louis University experience with interwoven nitinol stents

- Retrospective review of patients treated with Supera nitinol stents between April 2010 and December 2011
- 54 limbs in 48 patients
- Mean follow up of 27.5 ± 12.3 months
- Median follow up of 30 months
- Clinical follow up: clinical interview, ABIs, and duplex US
  - Clinical primary patency: clinical resolution of symptoms and freedom from secondary interventions
  - Primary assisted patency: requiring a secondary intervention due to in-stent restenosis
  - Secondary patency: requiring a secondary intervention to restore patency after occlusion of the stent

Primary patency 85.6% at 12 months 83.1% at 24 months 76.7% at 36 months
Secondary patency 93.8% at 12 months 91.8% at 24 months 89.3% at 36 months

Conclusion

- Bypass has a diminishing role in the treatment of claudication due to the increasing success of a wide range of endovascular interventions
- Role for bypass may remain for the most complex disease and for recurrence after endovascular intervention
- In my own practice endo first for the vast majority including TASC D lesions