Open procedures are needed in many CLTI patients. What is the percentage today and what will it be in 5 years?

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What factors impact outcome in CLTI patients and should influence choice of procedure:

- PATIENT risk and longevity: perioperative and 1-2 year mortality
- LIMB Stage at presentation: WIfI
- ANatomic Complexity: pattern and distribution of arterial occlusive disease
- Patency of revascularization (perhaps overrated, but important in select patients?)

I have no conflicts of interest related to this presentation.

What is the current landscape of open vs endo? Will future changes be shaped by data, teams or technology?

• There are islands, some quite large, of ENDO first for everything, but what is really being done on a wider scale?
• What are data for endo first for CLTI, especially for tibial disease, in broader populations than single center studies?

Endo versus Open for CLI:

• Faglia et al. 564 consecutive patients with DM and CLI (1999-2003); 554 followed until 2007 (mean f/u 5.93±1.28 years)
• Initial Therapy -
  - PTA 74.5%, BYPASS 20.6%, Neither 4.9%
• Restenosis or graft failure rate: 6.4-8.8%/year
  [94 pts clinical restenoses: 72 r-PTA, 9 BPG, 13 nil]
• Contralateral CLI: 14.76%/year
• Mortality: 12.53%/year
  - DIABETES CARE, VOLUME 32, NUMBER 5, MAY 2009
  - ESTIMATE: 25-30% eventually need open surgery

AHRQ data (2001-2010) 2.5 million inpatient DFUs
Only 8.5% underwent revascularization
OPEN 43.5%
ENDO: 51.1%
BOTH: 5.4%
Trend by 2010, 66% ENDO

Open bypass and endovascular procedures among diabetic foot ulcer cases in the United States from 2003 to 2010

Northern European Diabetic Foot Center of excellence: 2014
66% ENDO, 34% OPEN
What about current results?

- Long segment tibial angioplasty, although now more frequently technically successful, still has a very high early (<3 month) failure rate
- Selected patients don’t do well with early failures and repeat interventions, especially WIfI Stage 4

Old BASIL Trial: long-term results

- Bypass first group had better amputation free survival than angioplasty first group (RR .85)
- Bypass first arm had lower all cause mortality than angioplasty first (RR 0.65, p<0.009)
- Decreased survival associated with BMI, diabetes, age, serum creatinine level, and cigarette smoking
- But perhaps old Basil has lost its flavor?

What are results of long segment tibial angioplasty?

- 77 tibial angioplasties 62 limbs/58 CLI patients (26% Rutherford Class 4 and 74% Class 5); Lesions >8 cm
- AT 3 MONTHS (by angiography):
  - 31.2% patent without restenosis
  - 31.2% patent with >50% restenosis
  - 37.6% occluded
- Excellent limb salvage rate, but low grade CLI
- Contrast with results of pop-pedal bypass

FRESH BASIL!

A Comparison of Outcomes in Patients with Infrainguinal Disease Randomized to Venous Bypass or Main Reflow Angioplasty in the Bypass vs. Angioplasty in Severe Ischemia of the Leg (BASIL) Trial

What this paper adds

From the BASIL investigators: Patients randomized to venous bypass had similar rates of major adverse events (35.6% in both arms) and MACE. BASIL was designed to compare the initial and short-term outcomes of interprosthetic vein bypass with femoropopliteal angioplasty in patients treated for CLI.
Can WIfI help selection of Endo versus Open revascularization?

- WIfI stage is a significant predictor of amputation and wound healing time
- Stage 4 patients do worse regardless of revascularization approach, but data to date indicate bypass first may be better
- About 30-35% of patients undergoing revascularization are WIfI Stage 4

Risk of amputation versus SVS WIfI Stage: Compilation of published data

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<tr>
<th>Study (year)</th>
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Number of limbs at risk in each WIfI Stage with % amputation at 1 year to parentheses. Means in totals (in parentheses) are weighted

Is endo first a free shot?

NO!

BASIL:
Impact of treatment received on Amputation-Free Survival

Early and one-year results of infrapopliteal Bypass after failure of endovascular therapy

- Single referral center; 460 CLI pts over 4 year period underwent 273 endo, 307 open bypass revascularizations
- 159 pts had primary bypass; 114 bypass after failed endo
- Group 1 targets: 46% tibial/54% pedal
- Group 2 targets: 24% tibial/76% pedal
- Early (30 day) failures: 6% vs 24%
- One year patency (86% vs 71%) and AFS (78% vs 69%) both greater for Group 1

Prior failed ipsilateral percutaneous endovascular intervention in patients with critical limb ischemia predicts poor outcome after lower extremity bypass.

- VSGNE; N=1880 LEB for CLI
- Prior iPVI (134), iLEB (275)
- No diff in MAE or survival

Prior failed iPVI and iLEB imparted similar increased risk for amputation, graft failure, and MALE following LEB

Summary

- At least 1/3 of patients with CLTI and/or DFU currently undergoing revascularization get OPEN surgery
- Open first may be better for certain patient subsets (e.g. WIfI Stage 4 +/- Anatomic complexity)
- Unclear which of 3 WIfI factors most influences outcome, but unless restenosis rates can be reduced for tibial disease, this % not likely to change
- Choose 1st procedure carefully: failure isn’t free

Propensity score adjustment included approximately 20 patient-level, anatomic and surgical variables
The difference in outcomes is increasing with observation time
Key questions

• What is the patient’s overall medical condition?
• Does the patient have rest pain/minor tissue loss (toe) or major tissue loss (forefoot, midfoot, or heel gangrene)?
• What autogenous conduit is available?
• What is the proposed bypass target artery?
• Is the popliteal artery also involved?
• Is the lesion an occlusion or stenosis?
• Is the tibial lesion focal or diffuse?
• Is the lesion extensively calcified?

SVS WiFi: RE-STAGING

SVS WiFi: should be used to restage limbs after intervention (analogous to TNM)

One month scores correlate with amputation risk


SVS WiFi staging may help optimize revascularization strategy

Risk of amputation versus SVS WiFi Stage: Compilation of published data

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WIfI staging may help optimize revascularization strategy

Repetitive endovascular therapy versus WiFi stage


Repetitive endovascular therapy versus WiFi stage

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