Endovascular Treatment vs Open Surgical Bypass: What is the BEST Revascularization Option in CLI?

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Disclosures

• BEST-CLI trial Co-Chair
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Critical Limb Ischemia (CLI)

- Presents with intractable foot pain at rest and/or tissue loss
- Affects 2-3% of patients with PAD
- Associated with impaired quality of life, high morbidity and mortality
- Costs > $4 billion/year

Hirsch AT et al. J Am Coll Cardiol 2006;47:1239-1312
Conte MS and Farber A. BJS 2015;102:1007-1009
Goals of CLI Treatment

• Improve limb perfusion
  – Relieve pain
  – Heal wounds
  – Preserve a functional limb
  – Maintain ambulatory status

– Perform above ankle amputation...if revascularization is futile

Hirsch AT et al. J Am Coll Cardiol 2006;47:1239-131
Conte MS and Farber A. BJS 2015;102:1007-1009
Revascularization Options

- Open Vascular Surgery
- Endovascular Therapy
- Hybrid Procedure

How do we choose what option is best?
Trends in PAD Therapy

Figure 2. Trends in Diagnostic Angiography, Therapeutic Endovascular Interventions, and Lower Extremity Bypass Surgery, 1996-2010

Goodney et al. JAMA Surg 2015;150(1):84-86
Open Vascular Surgery for CLI

Inflow Bypass

Endarterectomy

Infrainguinal Bypass

Diagram showing various vascular procedures including inflow bypass, endarterectomy, and infrainguinal bypass.
Open Vascular Surgery for CLI

- Traditional treatment
- Durable outcomes
- Long follow up periods available

- Invasive
- Is associated with
  - blood loss
  - morbidity
  - mortality
  - wound complications
Endovascular Therapy for CLI

- Minimally invasive
  - No incisions!
- No general anesthesia
- No hospitalization
  - Can be done in office setting!
- Reduced morbidity
- Reduced mortality
- Decreased durability
  - Low patency rates in some vascular beds
- Nephrotoxic contrast agents
- Expensive
- Driven by business interests
Revascularization Options in CLI

Which Treatment Strategy is Best?

Bypass Surgery

Endovascular Therapy
Current CLI Literature is not helpful!

- Retrospective
- Poorly controlled
- Poorly powered
- Suboptimal endpoints
  - Amputation free survival
  - Target lesion revascularization
  - Target vessel revascularization
- Sponsor bias
- Operator bias
- Inclusion of claudicants
- Short or incomplete follow up
Peripheral Vascular Disease

Comparative effectiveness of endovascular and surgical revascularization for patients with peripheral artery disease and critical limb ischemia: Systematic review of revascularization in critical limb ischemia

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Background  For patients with critical limb ischemia (CLI), the optimal treatment to enhance limb preservation, prevent death, and improve functional status is unknown. We performed a systematic review and meta-analysis to assess the comparative effectiveness of endovascular revascularization and surgical revascularization in patients with CLI.

Methods  We systematically searched PubMed, Embase, and the Cochrane Database of Systematic Reviews for relevant English-language studies published from January 1995 to August 2012. Two investigators screened each abstract and full-text article for inclusion, abstracted the data, and performed quality ratings and evidence grading. Random-effects models were used to compute summary estimates of effects, with endovascular treatment as the control group.

Results  We identified a total of 23 studies, including 1 randomized controlled trial, which reported no difference in amputation-free survival at 3 years (odds ratio [OR] 1.22, 95% CI 0.84-1.77) and all-cause mortality (OR 1.07, 0.73-1.56) between the 2 treatments. Meta-analysis of the observational studies showed a statistically nonsignificant reduction in all-cause mortality at 6 months (11 studies, OR 0.85, 0.57-1.27) and amputation-free survival at 1 year (2 studies, OR 0.76, 0.48-1.21) in patients treated with endovascular revascularization. There was no difference in overall death, amputation, or amputation-free survival at ≥2 years.

Conclusions  The currently available literature suggests that there is no difference in clinical outcomes for patients with CLI...
% of Patients with CLI and Infrainguinal PAD treated using Surgical Bypass (vs. Endovascular Therapy)

All VQI Centers Mean = 31%

Procedure Selection Variation

Vascular Quality Initiative®
Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

Sponsored by the National Heart Lung and Blood Institute
BEST-CLI Trial: Overview

- Prospective, randomized, multicenter, multispecialty, international, pragmatic open-label superiority trial
- 2100 patients at 160 clinical sites
- Funded by National Heart Lung and Blood Institute
- **Goal:** to assess outcomes, quality of life and cost in patients with CLI who are candidates for both open vascular and endovascular surgery
BASIL 2

Bypass vs. Angioplasty in Severe Ischaemia of the Leg-2

Pragmatic, superiority RCT comparing clinical and cost-effectiveness outcomes of a 'vein bypass first' with a 'best endovascular first' revascularisation strategy for SLI due to infra-popliteal (+/- femoro-popliteal) atherosclerotic disease
The Best Approach to CLI – Open vs. Endo?...

before Level I evidence becomes available!
In “Broad Strokes” ...

Old, frail, surgical high risk ➔ Endo

Young, healthy, good vein ➔ Open
Patient Factors

- Ambulatory Status
- Comorbidities
- Estimated life expectancy
- Prior vascular interventions
Limb Factors
Relevant Anatomical Factors

- Extent of occlusive disease
- Location of disease
- Lesion length
- Size of treated artery
- Degree of calcification
- Quality of runoff
- Quality of target
- Availability of good vein
Generalized CLI Treatment Strategy

• Ambulating patients with large wounds, few comorbidities, longer life expectancy, multilevel, diffuse occlusive disease and SSGSV → open vascular surgery

• Patients with smaller wounds, at high surgical risk, shorter life expectancy, less extensive occlusive disease, no SSGSV → endovascular therapy

• Patients with poor functional status, multiple comorbidities, short life expectancy, extensive tissue loss → primary amputation
Conclusions

• There is absence of good data to guide treatment of CLI

• BEST-CLI will provide a treasure trove of invaluable data on CLI and its management

• BASIL 2 will nicely complement BEST-CLI

• Patient, limb and anatomical factors are used to decide on CLI therapy in the current “data void”