



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

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# Disclosures

- **BEST-CLI trial Co-Chair**
  - Supported by NHLBI: 1U01HL107407-01A1

# 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

Norgren L et al. TASC II. J Vasc Surg 2007;45:S5-67.

Biancari F. J Cardiovasc Surg (Torino) 2013;54:663-9.

Fowkes FG et al. Lancet 2013;382:1329-40.

Sachs T et al. J Vasc Surg 2011;54:1021-1031.

# Goals of CLI Treatment

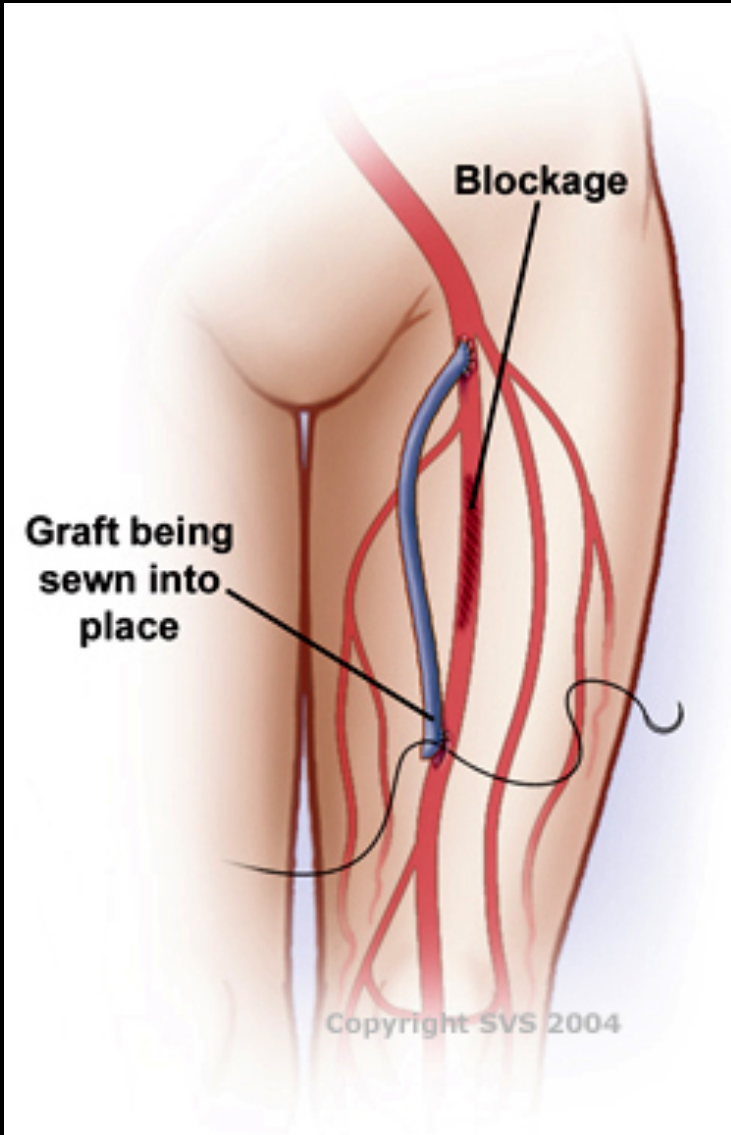
- **Improve limb perfusion**
  - Relieve pain
  - Heal wounds
  - Preserve a functional limb
  - Maintain ambulatory status
- **Perform above ankle amputation...if revascularization is futile**

# Revascularization Options

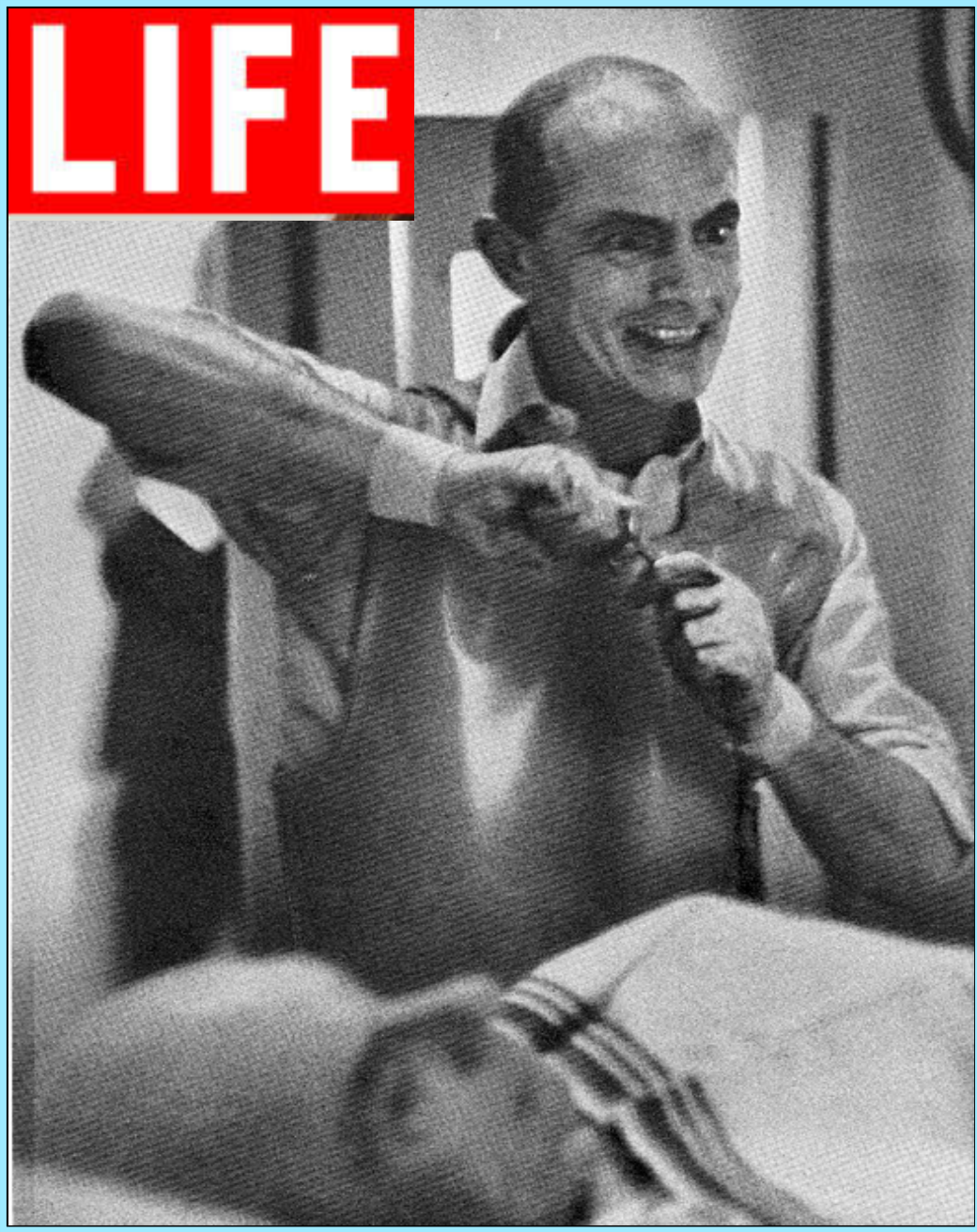
- **Open Vascular Surgery**
- **Endovascular Therapy**
- **Hybrid Procedure**

**How do we choose what option  
is best?**

# Surgical Bypass



1948- 1<sup>st</sup> successful femoral popliteal bypass using rGSV in a patient with PAD  
(Kunlin J. Rev Chir Paris 70:206-236, 1951)



1964

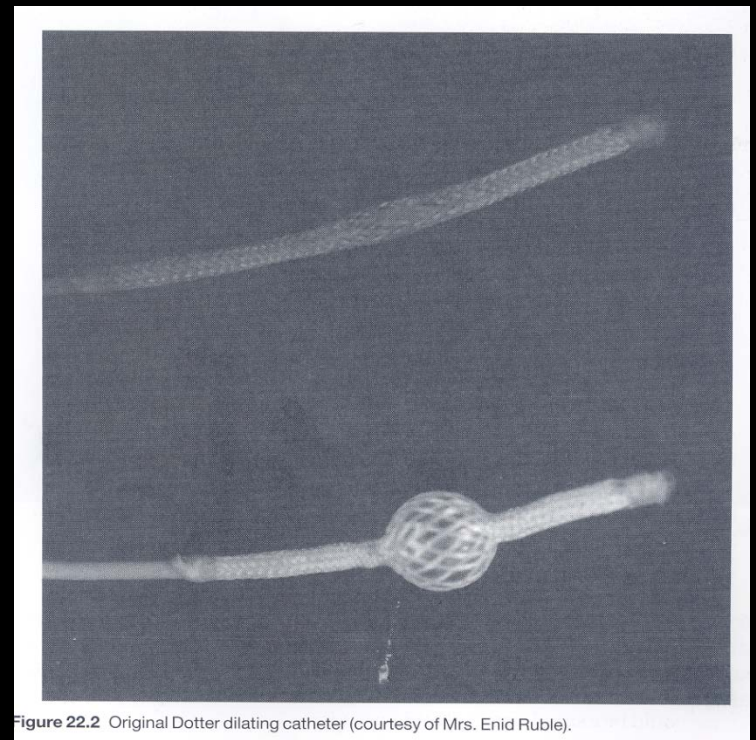
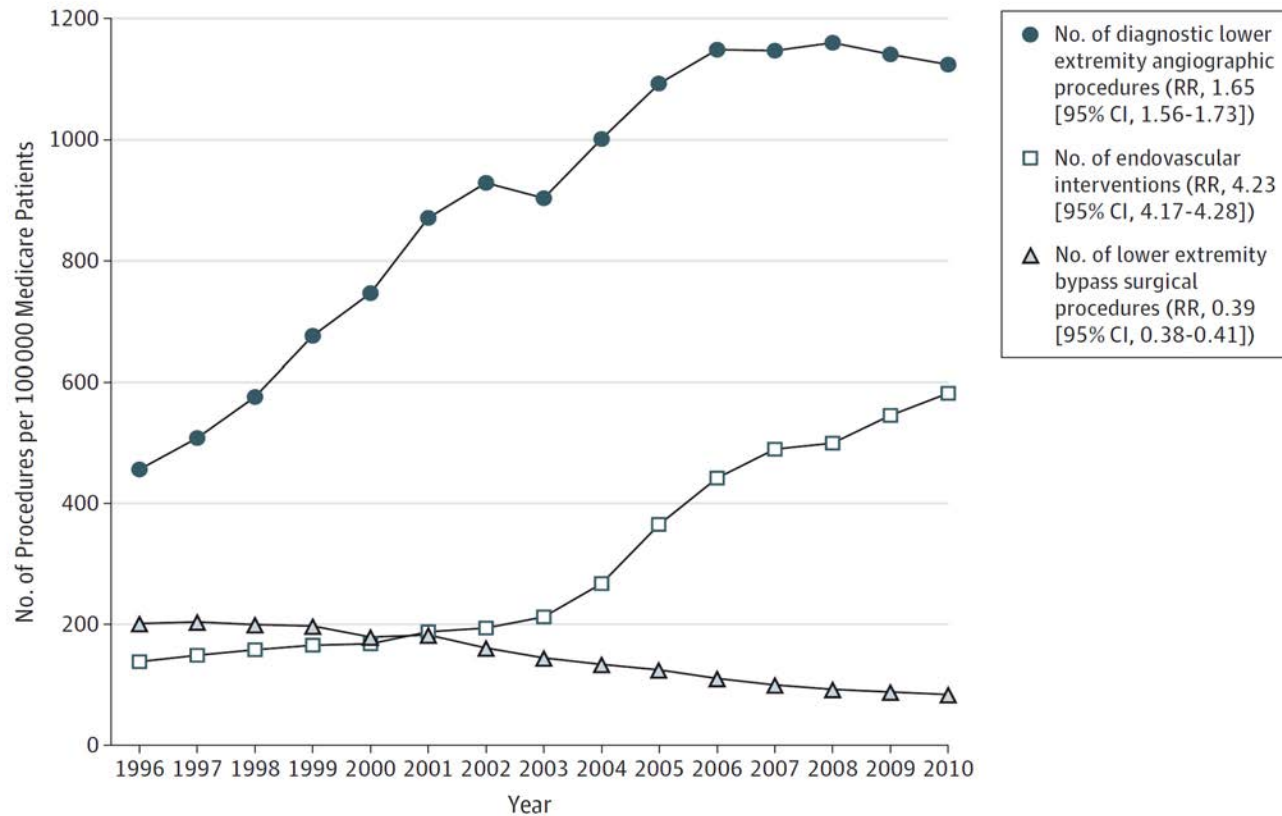


Figure 22.2 Original Dotter dilating catheter (courtesy of Mrs. Enid Ruble).

# Trends in PAD Therapy

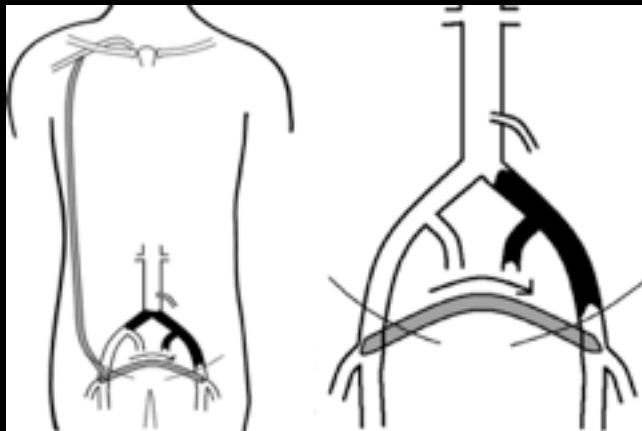
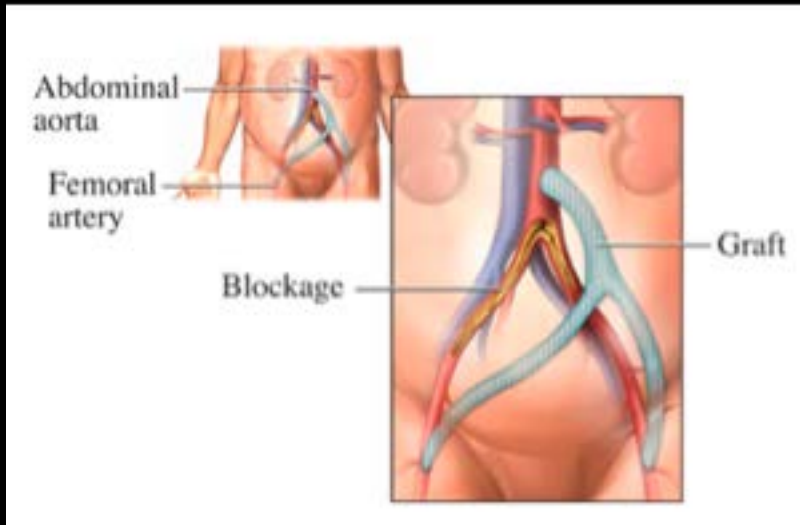
Figure 2. Trends in Diagnostic Angiography, Therapeutic Endovascular Interventions, and Lower Extremity Bypass Surgery, 1996-2010



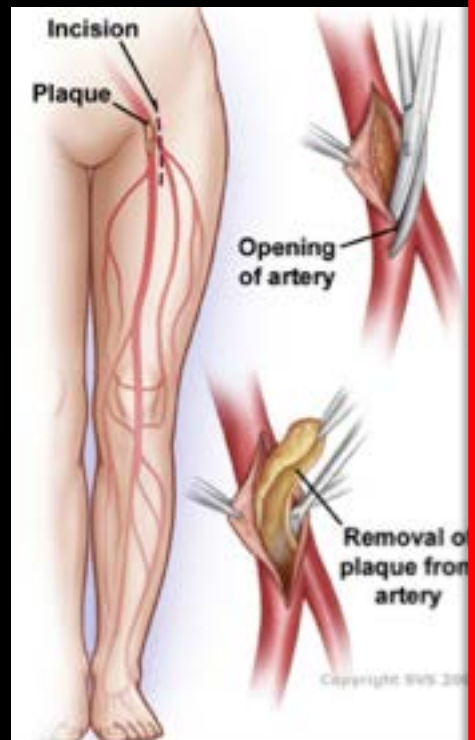


# Open Vascular Surgery for CLI

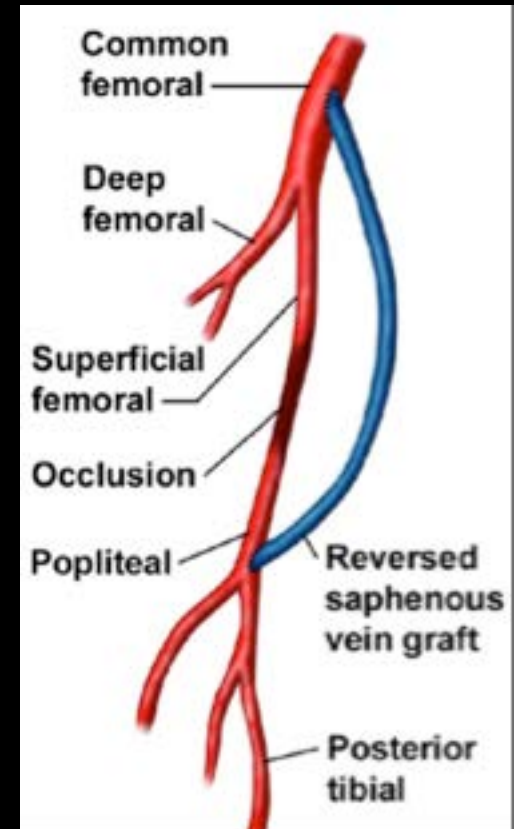
## Inflow Bypass



## Endarterectomy



## Infrainguinal Bypass

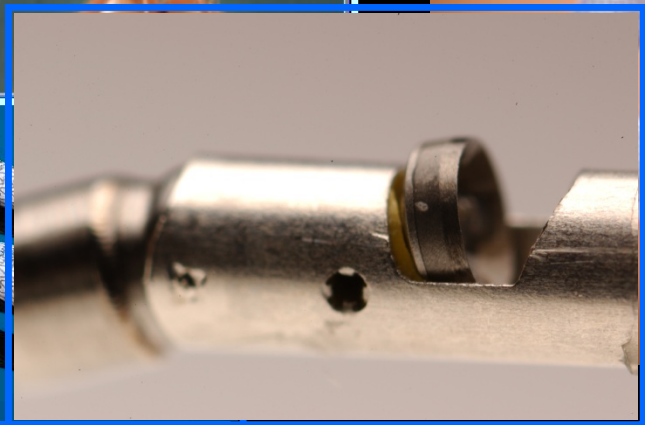
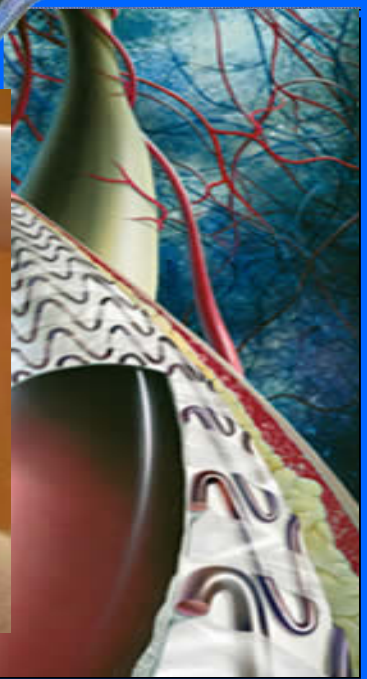
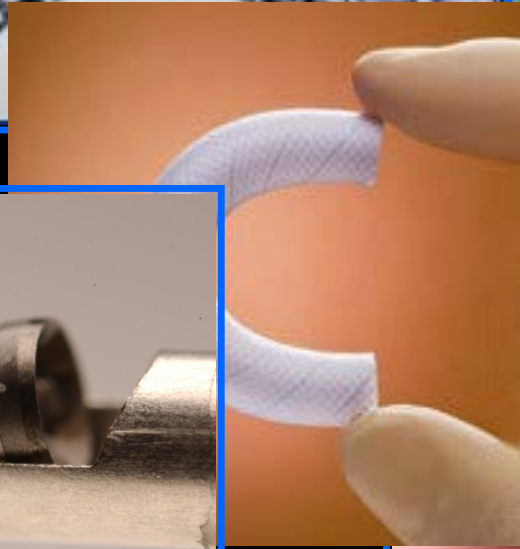
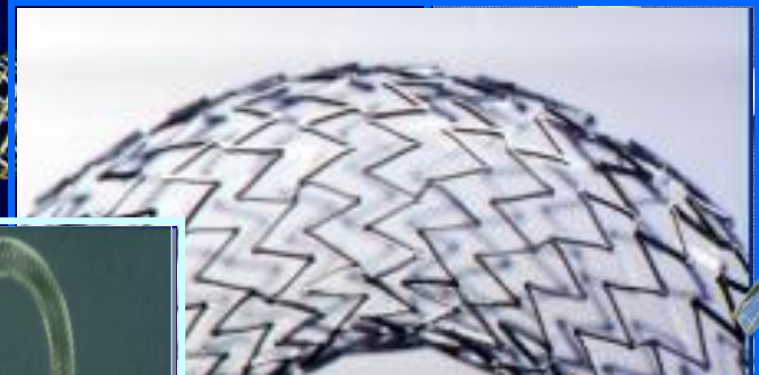
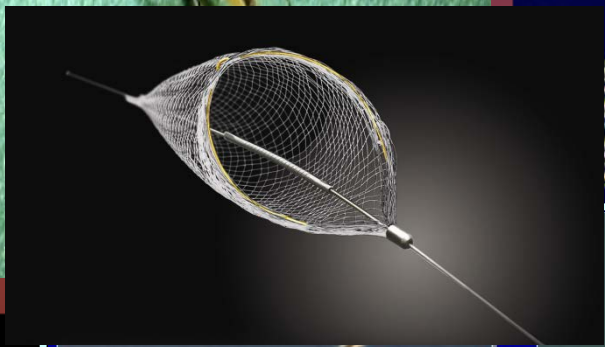
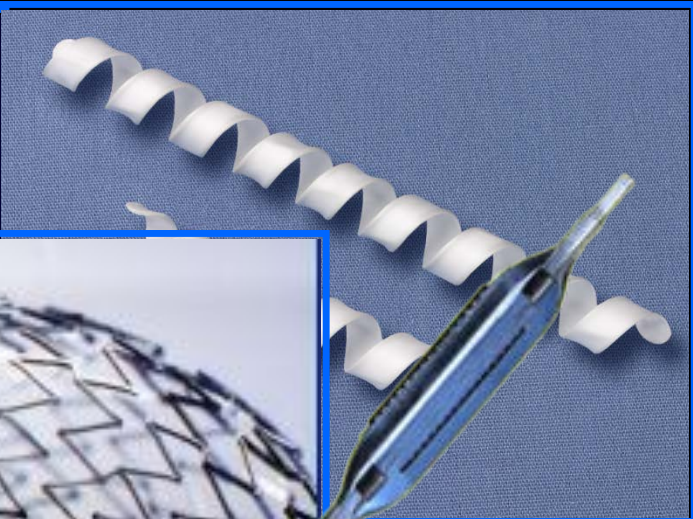
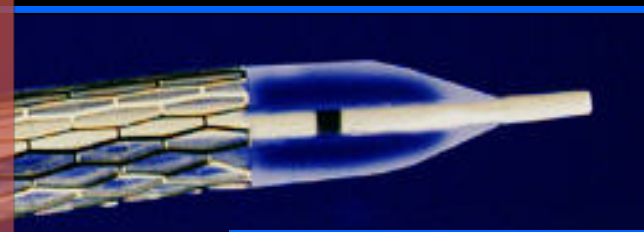
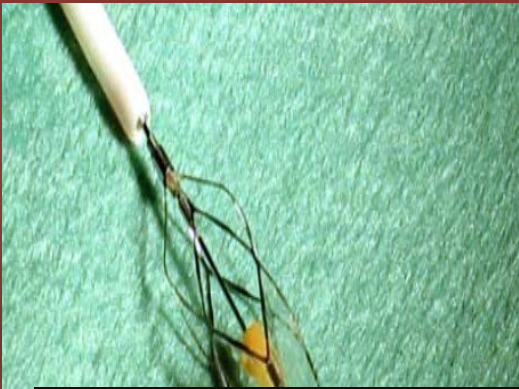


# Open Vascular Surgery for CLI

- Traditional treatment
- Durable outcomes
- Long follow up periods available
- Invasive
- Is associated with
  - blood loss
  - morbidity
  - mortality
  - wound complications



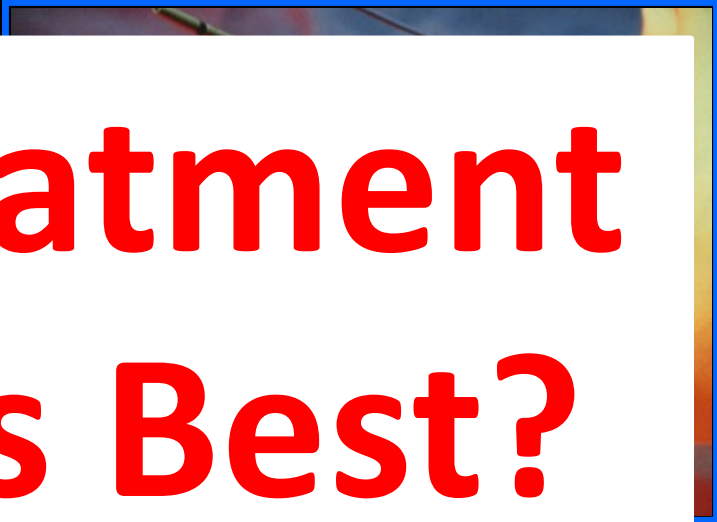
# Endovascular Modalities



# 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

## 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

W. Schuyler Jones, MD,<sup>a,b</sup> Rowena J. Dolor, MD,<sup>a,c</sup> Vic Hasselblad, PhD,<sup>a</sup> Sreekanth Vemulapalli, MD,<sup>a,b</sup> Sumeet Subherwal, MD,<sup>a</sup> Kristine Schmit, MD,<sup>a,c</sup> Brooke Heidenfelder, PhD,<sup>a,c</sup> and Manesh R. Patel, MD<sup>a,b</sup>  
*Durham, NC*

**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  $\geq 2$  years.

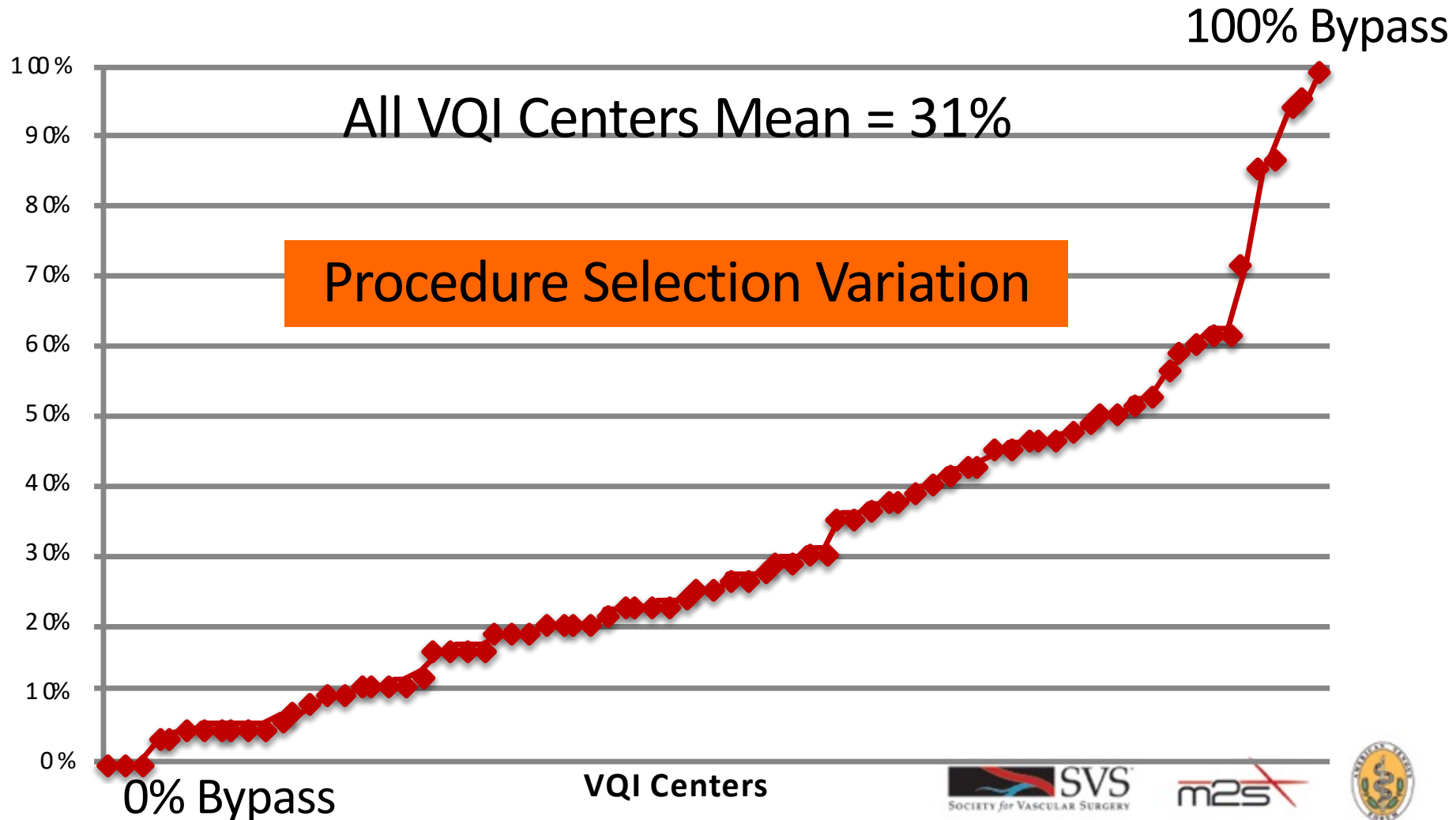
**Conclusions** The currently available literature suggests that there is no difference in clinical outcomes for patients with CLI

...There is paucity of high-quality data available to guide clinical decision making....



# Vascular Quality Initiative<sup>®</sup>

**% of Patients with CLI and Infrainguinal PAD treated using Surgical Bypass (vs. Endovascular Therapy)**







Best **E**ndovascular vs. Best **S**urgical **T**herapy in Patients with **C**ritical **L**imb **I**schemia

*Sponsored by the National Heart Lung and Blood Institute*

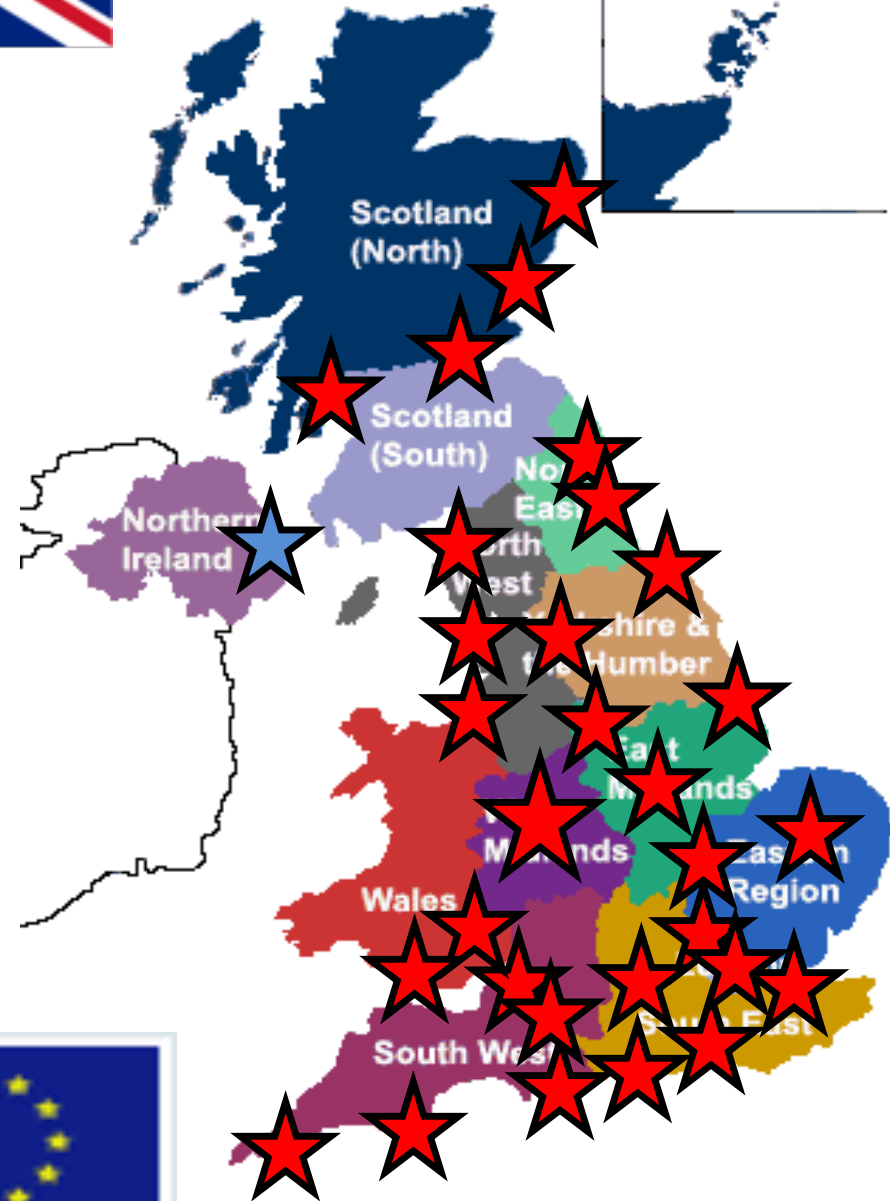


# BEST-CLI Trial: Overview

- 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***



The outer  
Islands



# 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



UNIVERSITY OF  
BIRMINGHAM

Heart of England 

NHS Foundation Trust



# **The Best Approach to CLI – Open vs. Endo?...**

**before Level I evidence becomes  
available!**

# In “Broad Strokes” ...

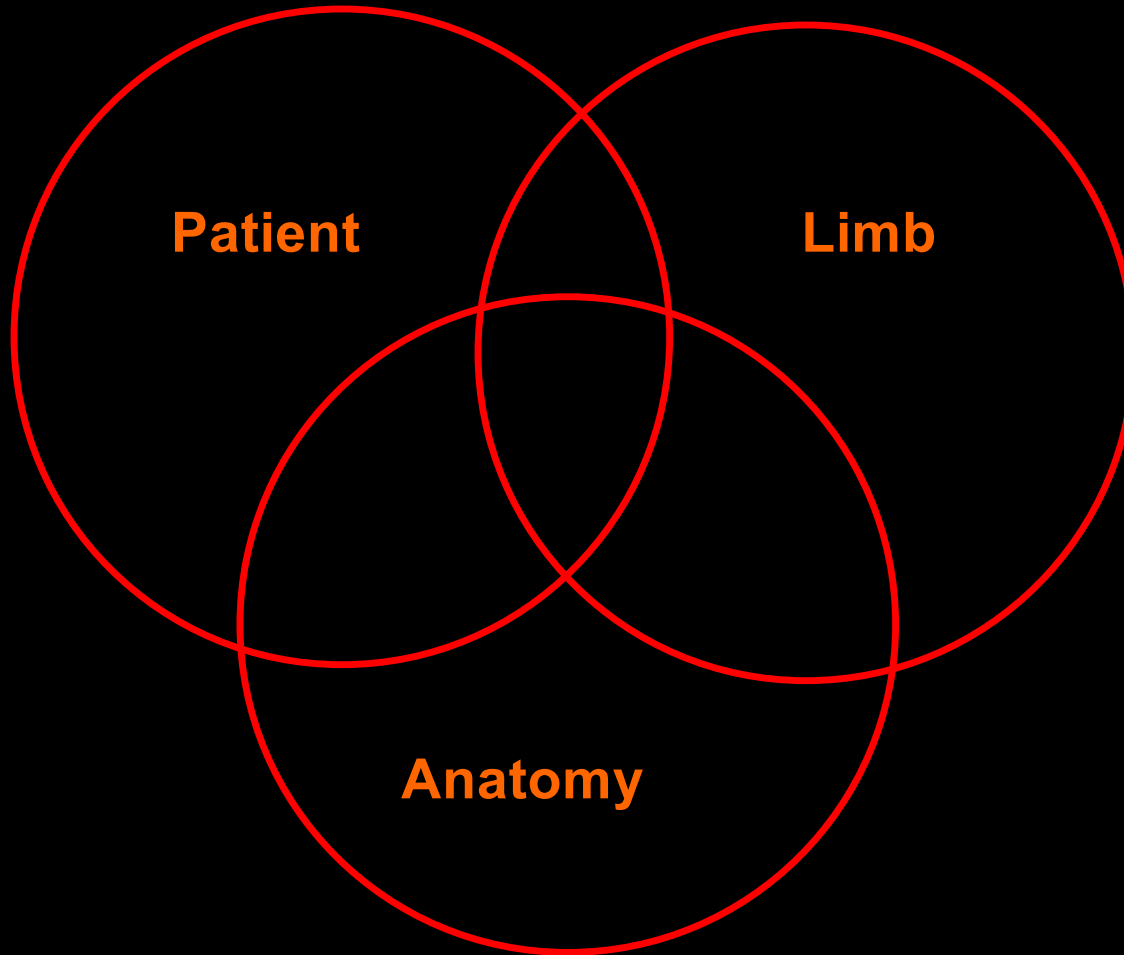
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Old, frail, surgical high risk → Endo

Young, healthy, good vein → Open



# Relevant Domains



# 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”**

