BEST - CLI TRIAL UPDATE

Michigan Vascular Study Group and BMC2

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Michigan Vascular Center

50th Anniversary 1963-2013

Since 1963

BEST-CLI

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

BWH

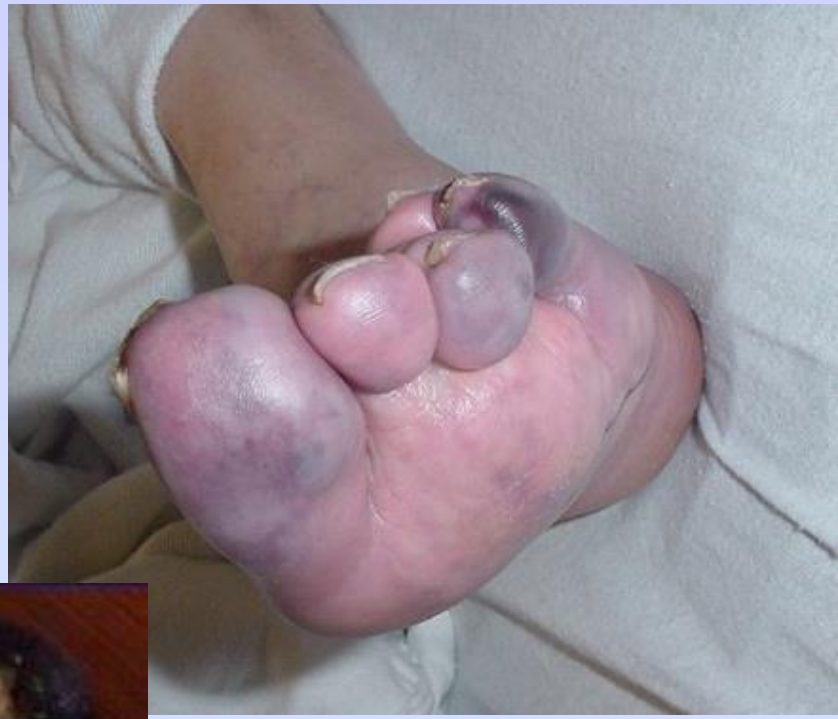
BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

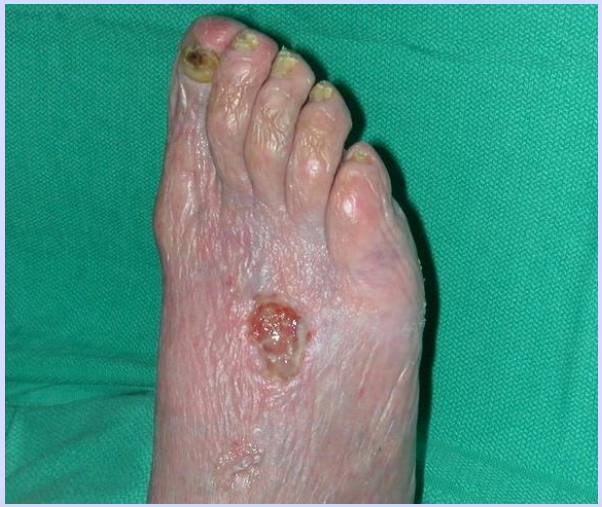
MGH 1811

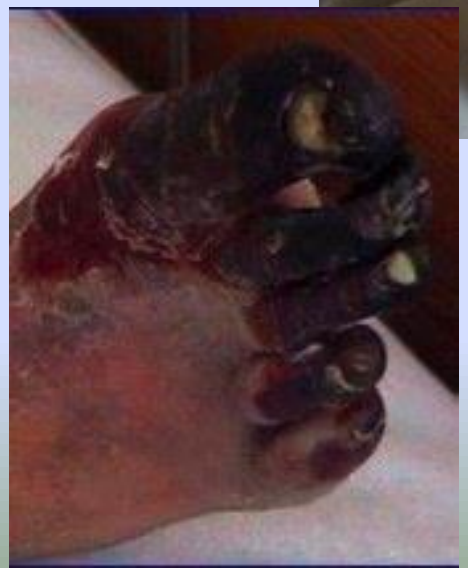
neri
New England Research Institutes

Chronic Limb Ischemia - CLI

- Pain at rest
  - Forefoot, leg/ calf
- Ulcers, gangrene







Critical Limb Ischemia (CLI) - Impact

- CLI is treated with measures to improve limb perfusion
- In the absence of revascularization, limb amputation rate in patients with CLI approaches 40%

Hirsch AT et al. J Am Coll Cardiol 2006;47:1239-1312

Trial Overview

- Prospective, randomized, multicenter, open label superiority trial
- **2,100** patients at **120** clinical sites in United States and Canada
- 4-year trial with each patient having minimum of 2 year follow-up
- Funded by National Heart Lung and Blood Institute at level of $24,990,000

Trial Overview

- Inclusion Criteria
  - Male or Female age 18 or older
  - Infrainguinal PAOD
  - CLI defined as arterial insufficiency with gangrene, ulceration or rest pain consistent with Rutherford categories 4-6
  - Candidate for both endovascular and open infrainguinal revascularization
  - Adequate aortoiliac inflow
  - Popliteal, tibial or pedal revascularization target which can support a distal anastomosis of a surgical bypass
  - Willingness to comply with protocol and follow up.

Trial Overview

- Exclusion Criteria
  - Popliteal aneurysm > 2cm in index limb
  - Life expectancy less than 2 years
  - Excessive risk for surgical bypass
  - Planned above-ankle amputation within 4 weeks of index procedure
  - Active vasculitis, Buerger's disease, or acute limb-threatening disease
  - Any prior index limb infrainguinal stenting or stent grafting associated with significant restenosis within 1 cm of the stent or stent-graft, unless the occlusion/restenosis site is outside of the treatment zone
  - Any of the following procedures performed on the index limb within 3 months: pta, atherectomy, stent, bypass with either vein or prosthetic

Trial Overview

- Exclusion Criteria continued:
  - Open surgical inflow procedure within 6 weeks prior to enrollment
  - Current chemotherapy or radiation
  - Absolute contra-indication to iodinated contrast
  - Pregnancy or lactation
  - Administration of an investigational drug for PAOD within 30 days
  - Participation in a clinical trial within 30 days
  - Prior enrollment or randomization into BEST-CLI

Trial Objective

BEST Trial Aim

To compare **treatment efficacy**, **functional outcomes** and **cost** in patients with CLI and infrainguinal PAD undergoing best **open surgical** or best **endovascular** revascularization

Patient Population

Patients with CLI and infrainguinal PAD who are candidates for ***both*** open surgical infrainguinal revascularization ***and*** endovascular treatment, in the eyes of the ~~individual investigator~~ CLI team

Map of BEST-CLI Sites

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Enrollment Update

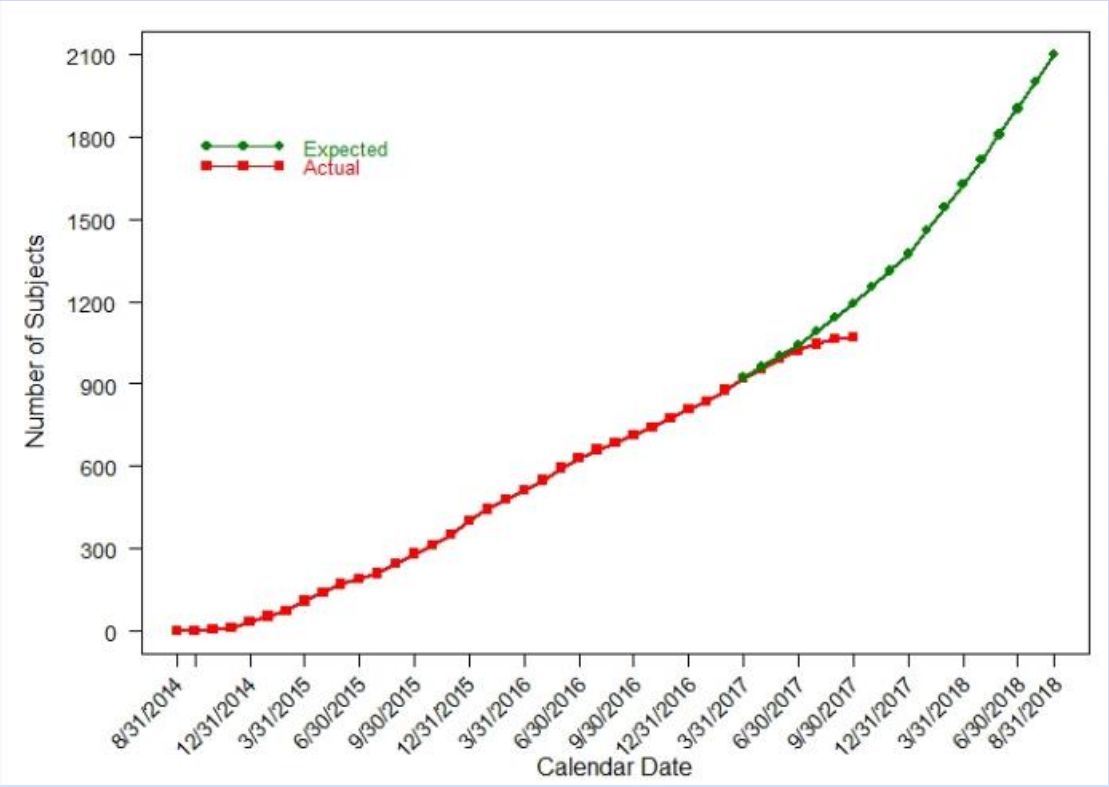
To date (9/14/17)

- First patient randomized 8/28/14
- 158 of 171 sites activated
- 1072 subjects randomized

Top 5 enrolling sites:

#1160 Keck Medical Center of USC - 52 subjects
#1258 Boston Medical Center - 50 subjects
#1238 Univ. of Massachusetts – 31 subjects
#1273 Univ. Florida (Gainesville) – 23 subjects
#1309 Iowa Heart – 22 subjects

Enrollment Goals



Milestones:

1,188 Subjects by 9/30/17

2,100 Subjects by 8/31/18

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Top 10 Reasons for Screen Failures

- 909 = Excessive risk for surgical bypass
- 591= Pt doesn't want to be part of research
- 568= Pt doesn't want surgical procedure
- 523= Inadequate aortoiliac inflow
- 509= Disallowed index limb proc in prior 6mo
- 470= Inadequate revascularization target
- 390= Occlusive disease on imaging not severe enough
- 371=Procedure performed on index limb within 3 months prior to enrollment
- 348= Significant restenosis of prior stent/graft
- 316= Other Reasons

Obstacles to enrollment

- Convincing partners to review and enroll their patients
- Introducing study to patients is difficult given that both open and endo are available as standard of care.
- Personal bias
- Lack of site specific plan for screening process and patient flow