An Evidence-Based Approach to CLI: Endovascular vs. Surgery (OLIVE 2 Year and BEST CLI Trial) What is Best?

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We're Short on Data... The BASIL Trial

- Randomized 452 patients with critical limb ischemia
- Surgical bypass vs angioplasty
- Limitations:
 - Published 12 years ago
 - Simple angioplasty only (no long balloons)
 - Excluded dialysis patients





A Prospective Multicenter Registry

Study Design



• 314 Japanese patients with CLI (Rutherford 4-6)

- 71% with diabetes
- 52% on dialysis
- Infrainguinal endovascular therapy
 - Angioplasty, bare nitinol stents
 - In-line flow to foot achieved in 93%
- Primary outcome: amputation-free survival

Study Design



- Secondary outcomes:
 - Freedom from major adverse limb events (MALE)
 - Wound-free survival
 - Wound recurrence rate
- Exclusions
 - Unsalvageable limb
 - Iliac disease

MALE: above ankle amputation, revascularization surgery, treatment of thrombotic occlusion



3 Year Results

- 95% completion of follow-up
- Amputation-free survival: 55%
- Freedom from MALE: 84%
- Wound-free survival: 50%

MALE: above ankle amputation, revascularization surgery, treatment of thrombotic occlusion



Bad Things

- Death: 37%
- Major amputation: 12%
- Wound recurrence: 44%
 - (4 times more likely with isolated BTK disease)
- Reintervention: 43%

Major amputation: above ankle



Predicting Major Amputation, Death

- Increasing age (HR 1.4)
- BMI < 18.5 (HR 2.2)
- Dialysis (HR 2.9)
- Rutherford 6 (HR 1.6)



Predicting MALE

- Statin use (HR 0.3)
- Straight-line flow to foot (HR 0.3)
- Heart failure (HR 2.0)
- Rutherford 6 (HR 2.4)

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Randomized Trials Currently Enrolling



US, Canada



England, Scotland, Northern Ireland 150 patients enrolled to date





Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

Sponsored by the National Heart Lung and Blood Institute

ClinicalTrials.gov NCT02060630









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BEST-CLI Principal Investigators



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Sponsor:

National Heart Lung and Blood Institute



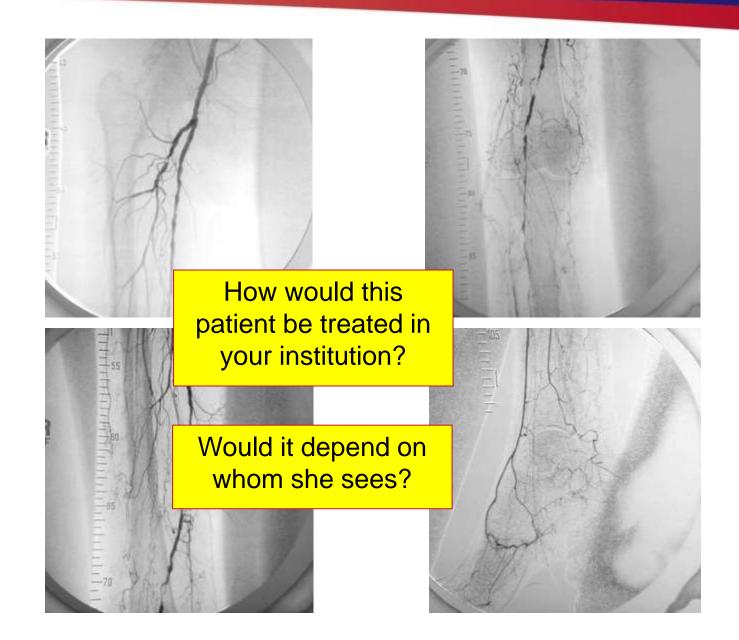
- 75 year old diabetic woman with right toe gangrene
- Absent distal pulses
- R ABI: 0.3



High Risk For: Amputation Death

Angiogram: Femoropopliteal & Tibial Disease





Revascularization Options in CLI



Bypass Surgery



Endovascular Therapy

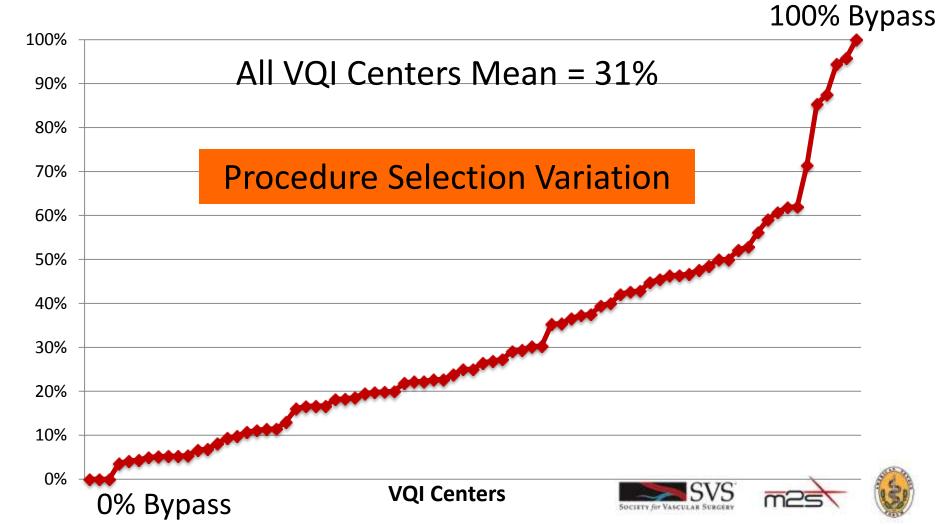




- Most physicians agree that there is <u>equipoise</u> as to what treatment is best for CLI patients
- Little scientific data exist to support the choice of therapy
- Same patient would often be offered different treatment if seen by another specialist

Vascular Quality Initiative®

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





- Prospective, randomized, superiority trial
- **2,100** patients
- 140 clinical sites in United States and Canada
- 900 patients enrolled
- At least 2 year follow-up (up to 4)

BEST-CLI Sites

Hopplulu

HAWAII





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Cohort #1 Patients with adequate single segment great saphenous vein (SSGSV) N=1620

Open surgery vs. Any commercially available endovascular treatment

Cohort #2 Patients without adequate SSGSV (arm vein, short saphenous vein, composite vein, cryopreserved vein, and prosthetic conduit) N=480

Open surgery vs. Any commercially available endovascular treatment



Major Adverse Limb Event (MALE) – free survival

MALE defined as:

Above ankle amputation

Major re-intervention

- new bypass graft
- jump/interposition graft revision
- thrombectomy/thrombolysis

Multiple Secondary Endpoints



All financial costs of care

- Hospital care (index admission and all f/u)
- Outpatient care
- Rehabilitation

Functional status / quality of life measures

• EQ5D as main measure; also SF-12



- All that we know *for sure* about CLI patients is that they do poorly
- Registry data are helpful in predicting outcomes
- BEST-CLI promises to define an evidence-based standard of care