

Current and Upcoming Evidence-Based Approach in CLI:

What is Best?

Mark W. Burket, MD

University of Toledo Medical Center

Toledo, OH



Disclosures

Bard Vascular: Research Support

Biotronik: Research Support, Consultant

Cook Medical: Research Support, Speaker

Mark W. Burket, MD

University of Toledo Medical Center

Toledo, Ohio



THE UNIVERSITY OF
TOLEDO
HEART AND VASCULAR CENTER

We're Short on Data...

The BASIL Trial

- Randomized 452 patients with critical limb ischemia
- Surgical bypass vs angioplasty
- Limitations:
 - Published 11 years ago
 - Simple angioplasty only (no long balloons)
 - Excluded dialysis patients



3 Year Results

A Prospective Multicenter Registry

- 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

- 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%



Predicting Major Amputation, Death

- Increasing age (HR 1.4)
- BMI \leq 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)

Randomized Trials

Currently Enrolling



US, Canada



England,
Scotland,

Northern Ireland

136 patients enrolled to date



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

ClinicalTrials.gov NCT02060630



Special thanks to Alik Farber, MD for slides

BEST-CLI Principal Investigators



Alik Farber, MD
Matthew Menard, MD
Kenneth Rosenfield, MD

Boston Medical Center
Brigham and Women's Hospital
Massachusetts General Hospital

Sponsor:

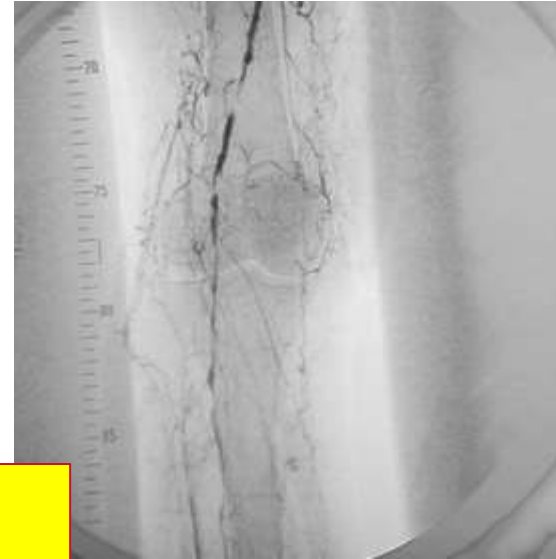
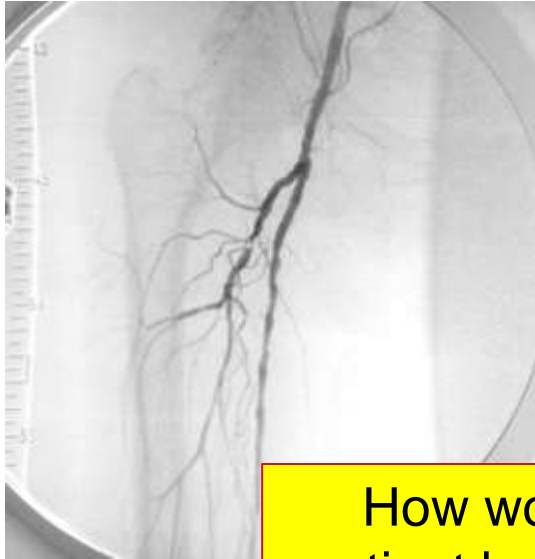
National Heart Lung and Blood Institute

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

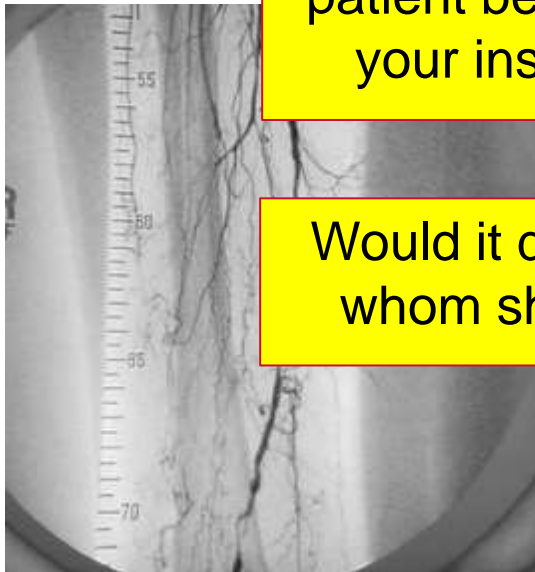
High Risk For:
Amputation
Death



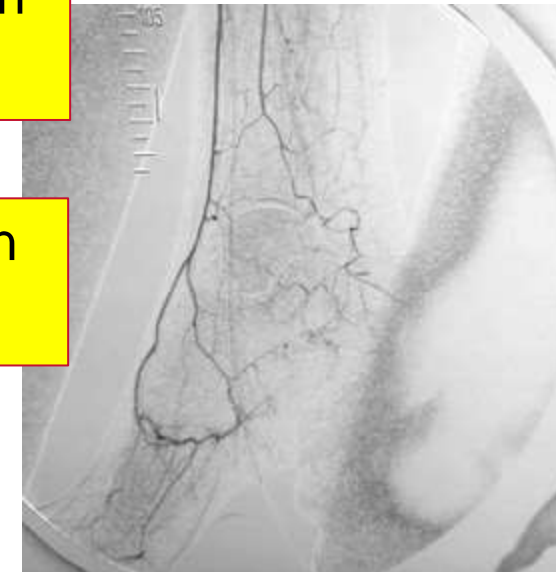
Angiogram: Femoropopliteal & Tibial Disease



How would this patient be treated in your institution?



Would it depend on whom she sees?



Revascularization Options in CLI

Bypass Surgery



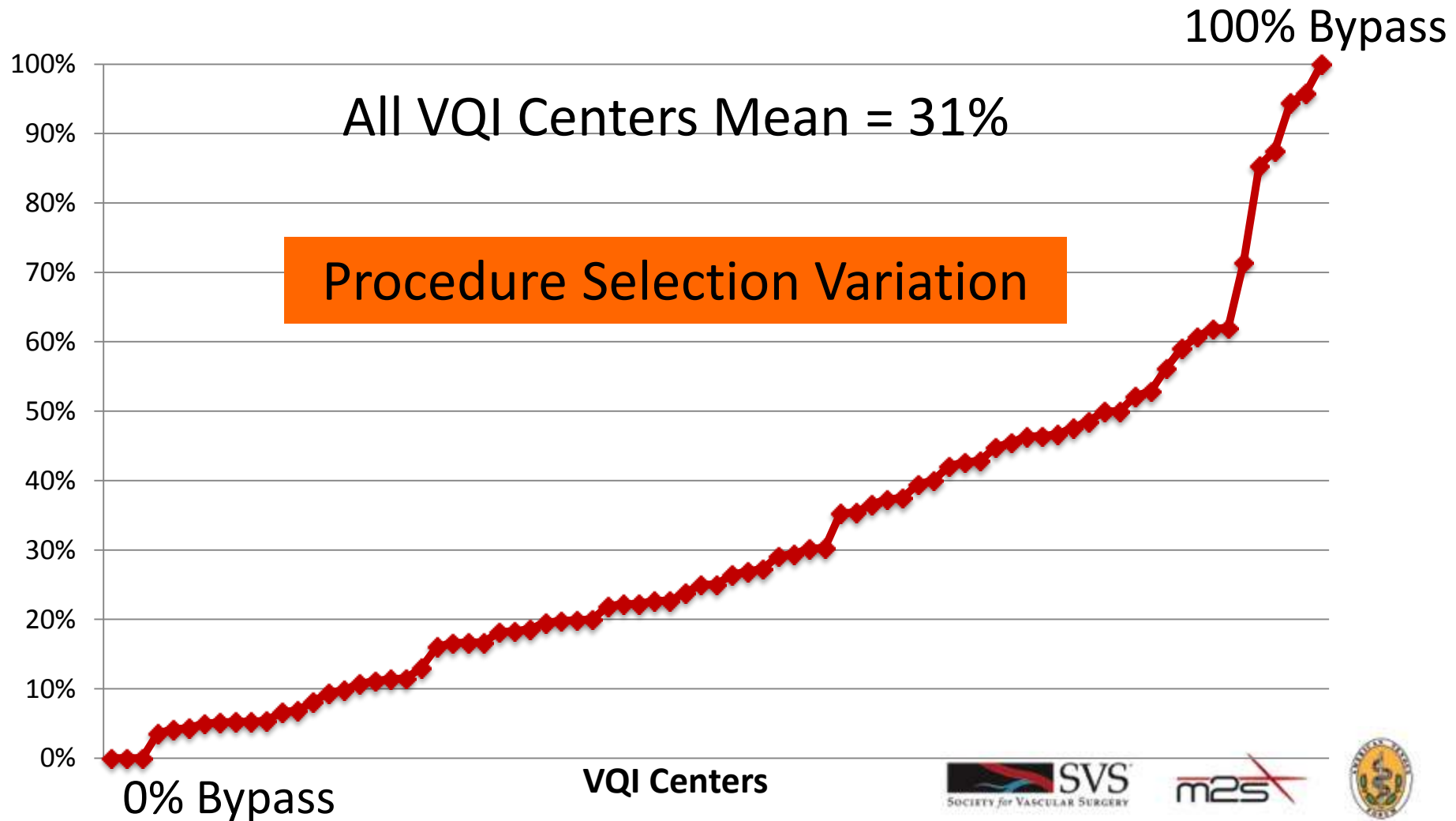
Endovascular Therapy



- Most physicians agree that there is equipoise 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)



We are starting with....

Multidisciplinary CLI Team

- Prospective, randomized, superiority trial
- **2,100** patients
- **140** clinical sites in United States and Canada
- **528** enrolled as of April 16, 2016
- At least 2 year follow-up (up to 4)

BEST-CLI Sites



- **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

Summary

- 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