2024 MID-ATLANTIC CONFERENCE

12th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2024

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 18-20

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April 19, 2024

Open Versus Endovascular Therapy for PAD: An Ongoing Debate

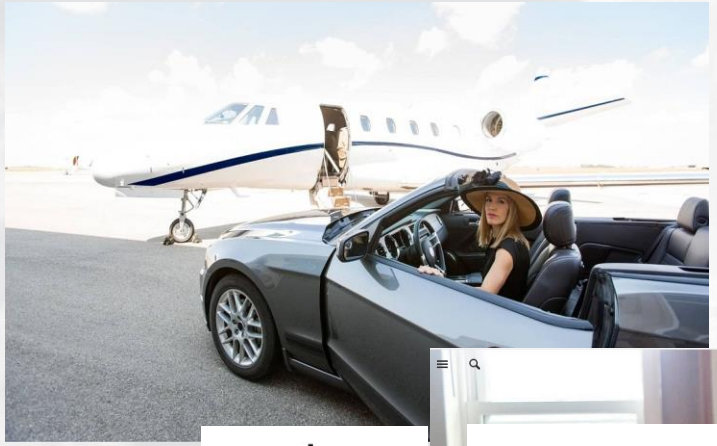
Justin Milligan MD FACS

Sentara Vascular Specialists

Disclosures

- None

Sentara



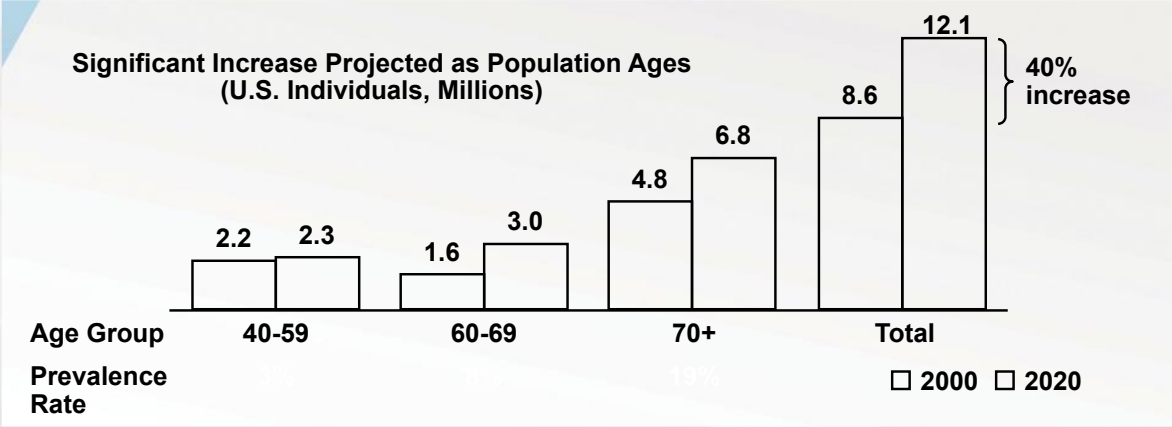
PROPUBLICA

In the "Wild West" of Outpatient Vascular Care, Doctors Can Reap Huge Payments as Patients Risk Life and Limb

The New York Times

Sentara

Why is PAD a serious healthcare issue?



- Longer lifespans/Rising incidence of diabetes

- Early detection and intervention can help prevent disease progression, leg ischemia and ultimately amputation along with reducing overall cardiovascular risk of Stroke/MI

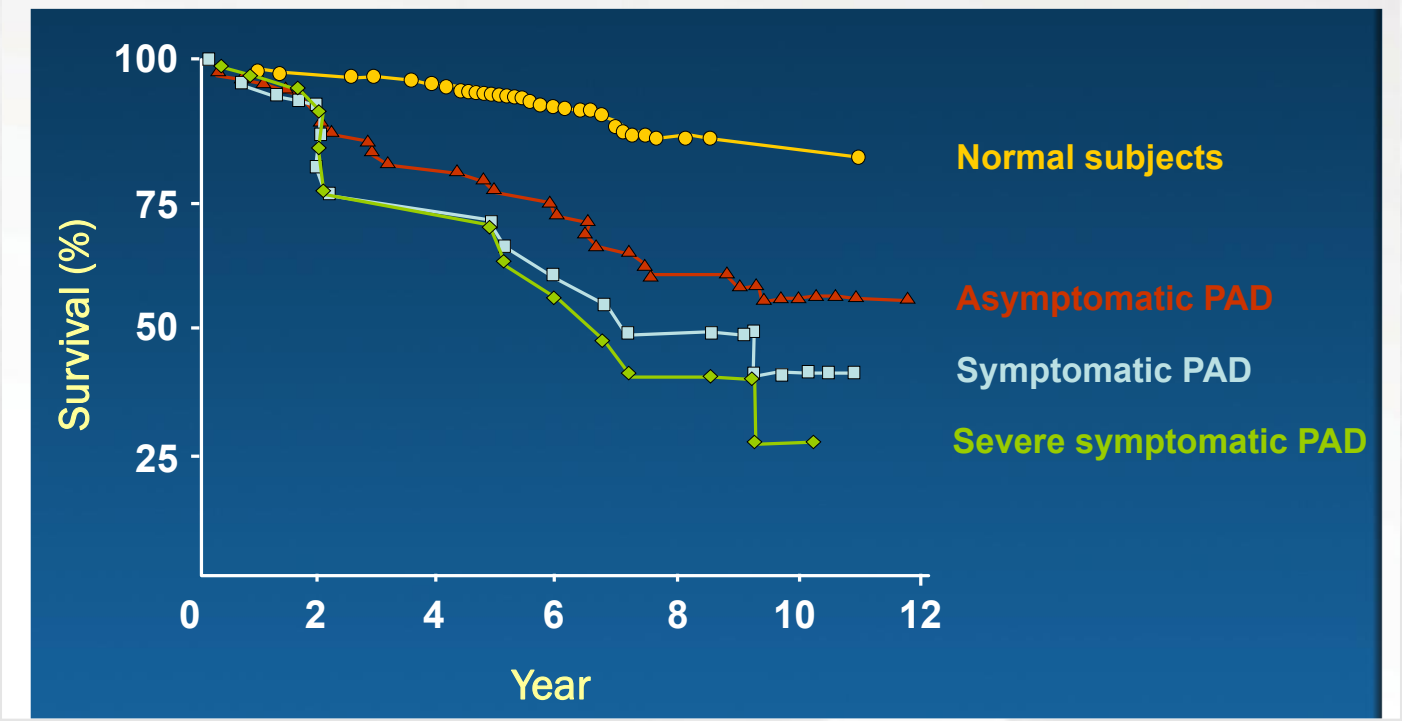
CORONARY ARTERY DISEASE

Cerebrovascular Disease

PAD

Proportion of PAD patients with CAD and/or CBVD = 61%

Long-Term Survival in Patients With PAD



Criqui MH et al. *N Engl J Med*. 1992;326:381-386. Copyright © 1992 Massachusetts Medical Society. All rights reserved.

Common Symptoms

Asymptomatic	• Nearly everyone who has PAD suffers from an inability to walk as fast, or as far, as they could before PAD.
Classic claudication	• Lower extremity symptoms confined to the muscles with a reproducible onset with exercise and relief with rest.
“Atypical” leg pain	• Lower extremity discomfort during exertion but does not always resolve with rest, limiting exercises at similar distances
Critical limb ischemia	• Ischemic rest pain, nonhealing wound, or gangrene.
Acute limb ischemia	• 3Ps→Pain, Pulselessness, Pallor, Paresthesias, Paralysis. Poikilothermia

Source: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001215/

GOALS OF TREATMENT

CLTI vs. PAD

- **CLTI** → **Limb salvage**

- **PAD** →
  - CV risk reduction
  - Symptom management
  - Preserve functional status
  - Improve QOL

Chronic Limb Threatening Ischemia

- Rest pain
- Ulceration
- Gangrene
- 200 million PAD patients worldwide
  - 11% (22 million) w/ CLTI

Global vascular guidelines on the management of chronic limb-threatening ischemia

Michael S. Conte, MD • Andrew W. Bradbury, MD • Philippe Kolh, MD • ... Kalkunte R. Suresh, MD • M. Hassan Murad, MD, MPH • the GVG Writing Group * • Show all authors • Show footnotes

JVS Journal of Vascular Surgery SVS Society for Vascular Surgery

VOLUME 69, ISSUE 6,

SENTARA®

5 Year Mortality Rates

Pancreatic	92%
Lung	81%
Ovarian Ca	53%
Myeloma	49%
Leukemia	39%
Colorectal Ca	36%
Renal	26%
Breast Ca	10.3%
Prostate	1.2%

- CLTI 54% → 5 year mortality
- Major amputation 79% → 5 year mortality

Mean Age
77

22%
Over Age 85

90%
Present with Tissue Loss

1-Year Survival
75%

2005 – 2007 MEDICARE CLTI PATIENTS

My Algorithm For CLTI

Get to know each patient

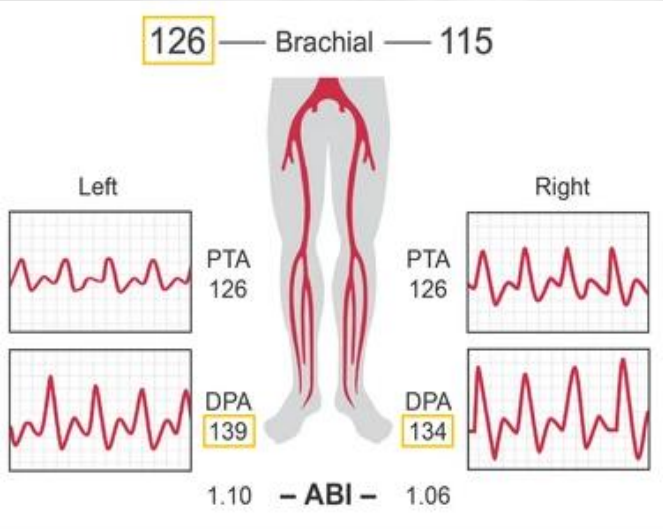
Sentara

My Algorithm For CLTI

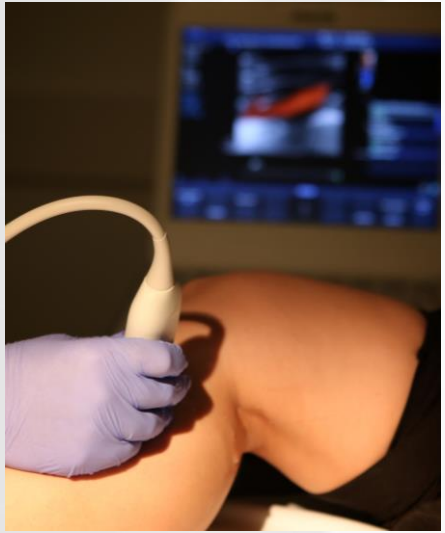
Get to know each patient

Non-invasive vascular testing

Key Non-Invasive Vascular Testing



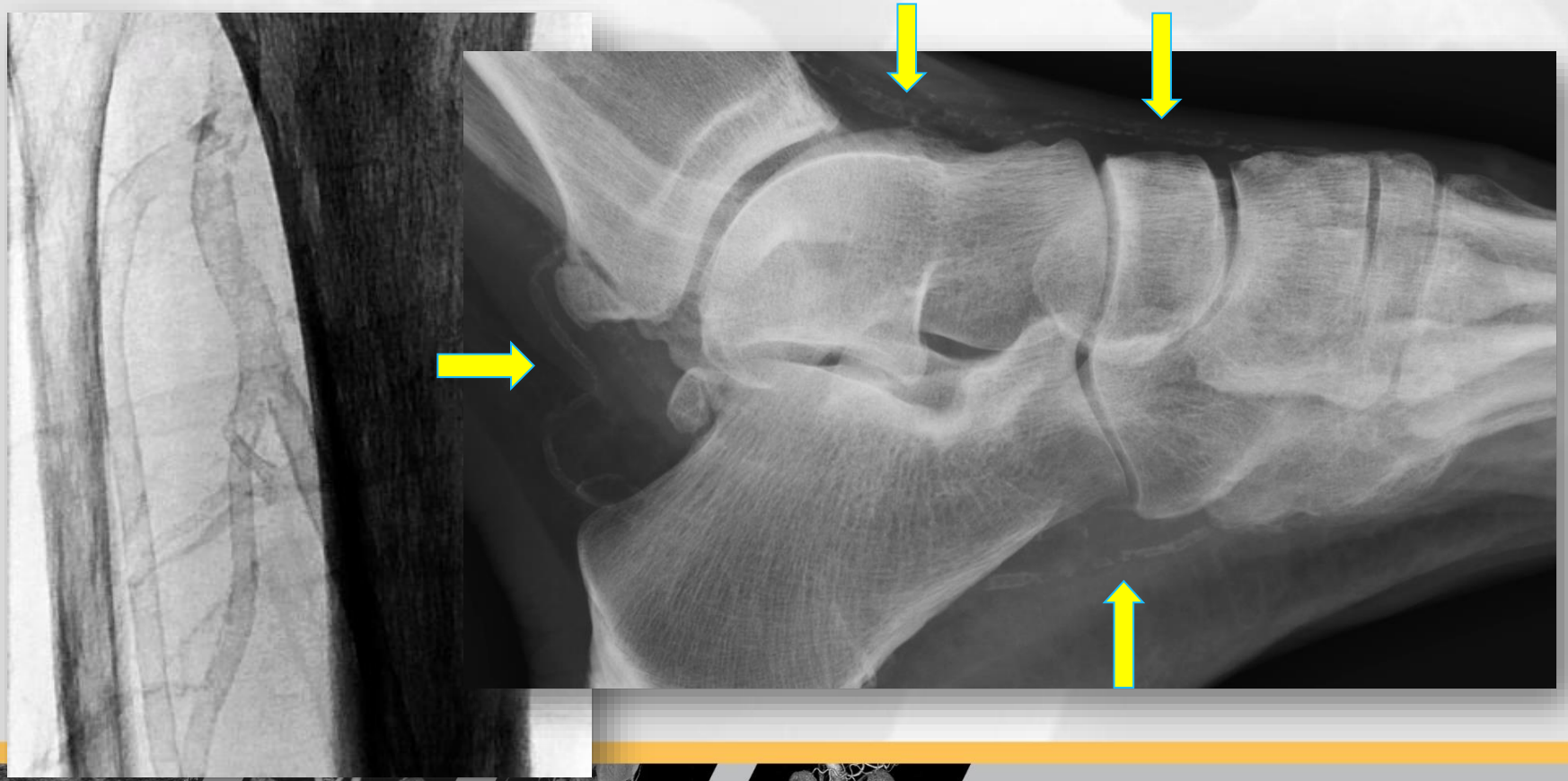
DOPPLER/ABI



DUPLEX US

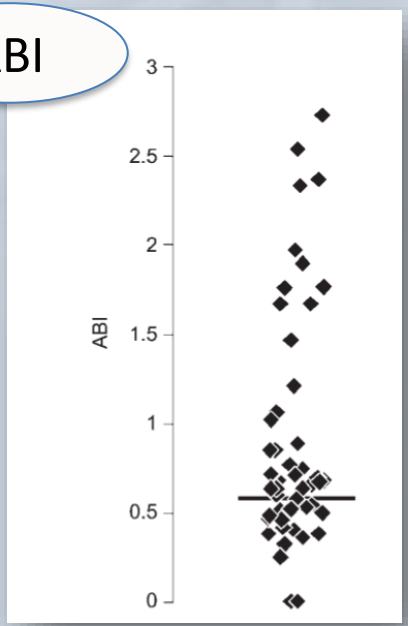
CT ANGIOGRAPHY

Medial Calcification Can Falsely Elevate ABI



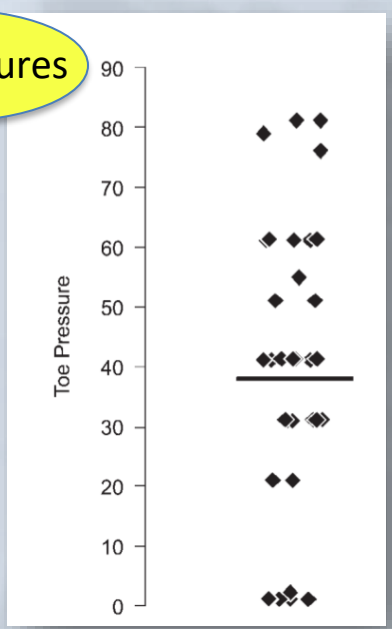
Toe Pressures Can Be Inaccurate in CLTI

ABI



Review of 50 Consecutive VA Patients Presenting with CLI

Toe Pressures



Shah AP et al. Cath Cardiovasc Interv 74:11-19; 2009

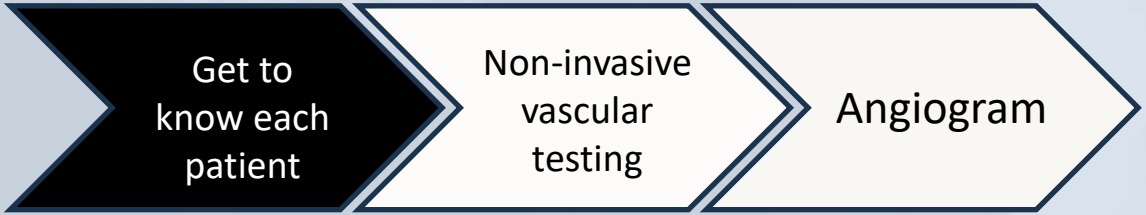
Each of These Patients Has a **NORMAL** ABI…

ANTERIOR TIBIAL

PERONEAL

POSTERIOR TIBIAL

My Algorithm For CLTI



ORIGINAL ARTICLE

Impact of Intensity of Vascular Care Preceding Major Amputation Among Patients With Chronic Limb-Threatening Ischemia

Eric A. Secemsky, MD, MSc; Lee Kirksey, MD, MBA; Elina Quiroga, MD, MPH; Claire M. King, PharmD, MSPS; Melissa Martinson, PhD, MS; James T. Hasegawa, MPH, MBA; Nick E.J. West, MA, MD; Rishi K. Wadhera, MD, MPP, MPhil

BACKGROUND: Lower-limb amputation rates in patients with chronic limb-threatening ischemia vary across the United States, with marked disparities in amputation rates by gender, race, and income status. We evaluated the association of patient, hospital, and geographic characteristics with the intensity of vascular care received the year before a major lower-limb amputation and how intensity of care associates with outcomes after amputation.

METHODS: Using Medicare claims data (2016–2019), beneficiaries diagnosed with chronic limb-threatening ischemia who underwent a major lower-limb amputation were identified. We examined patient, hospital, and geographic characteristics associated with the intensity of vascular care received the year before amputation. Secondary objectives evaluated all-cause mortality and adverse events following amputation.

RESULTS: Of 33 036 total Medicare beneficiaries undergoing major amputation, 7885 (23.9%) were due to chronic limb-threatening ischemia; of these, 4988 (63.3%) received low-intensity and 2897 (36.7%) received high-intensity vascular care. Mean age, 76.6 years; women, 38.9%; Black adults, 24.5%; and of low income, 35.2%. After multivariable adjustment, those of low income (odds ratio, 0.65 [95% CI, 0.58–0.72]; $P<0.001$), and to a lesser extent, men (odds ratio, 0.89 [95% CI, 0.81–0.98]; $P=0.019$), and those who received care at a safety-net hospital (odds ratio, 0.87 [95% CI, 0.78–0.97]; $P=0.012$) were most likely to receive low intensity of care before amputation. High-intensity care was associated with a lower risk of all-cause mortality 2 years following amputation (hazard ratio, 0.79 [95% CI, 0.74–0.85]; $P<0.001$).

CONCLUSIONS: Patients who were of low-income status, and to a lesser extent, men, or those cared for at safety-net hospitals were most likely to receive low-intensity vascular care. Low-intensity care was associated with worse long-term event-free survival. These data emphasize the continued disparities that exist in contemporary vascular practice.

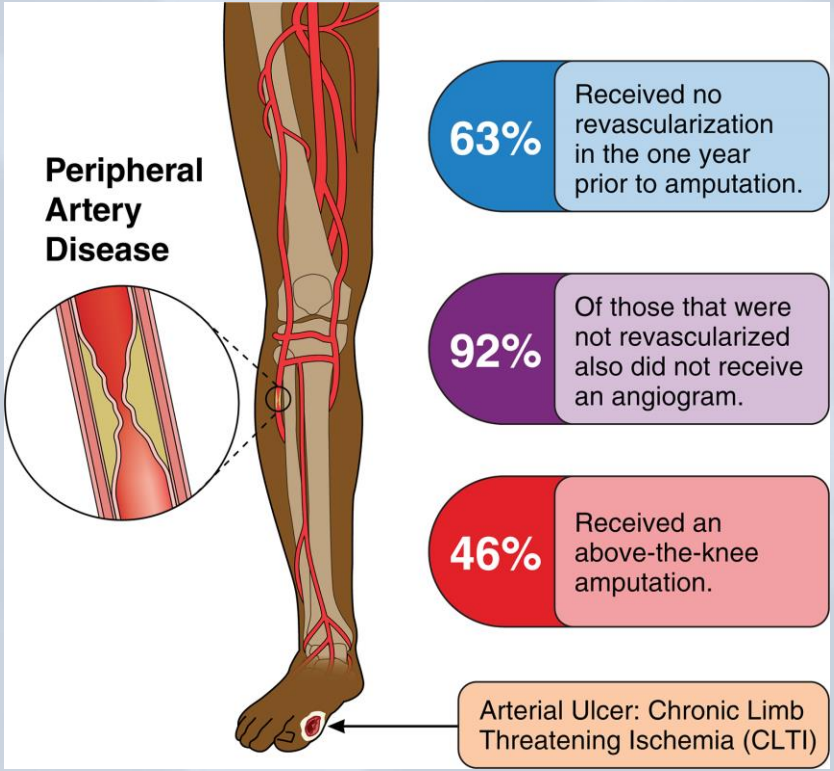
GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: chronic limb-threatening ischemia ■ ethnicity ■ peripheral artery disease

- 2016-2019 survey of all Medicare pts undergoing major amputation
- 33,036 total amputations
- 7885 pts with CLTI studied
- Pts divided into 2 groups
  - Low-intensity care (no angiogram)
  - High-intensity care (angiogram ± revascularization)

Secemsky, EA et al. Circ Interventions 2024;17:e01279

Nearly 2/3 of patients with CLTI **DID NOT** receive an angiogram prior to major amputation



Secemsky, EA et al. Circ Interventions 2024;17:e01279

Why Don't We Do More Angiograms?

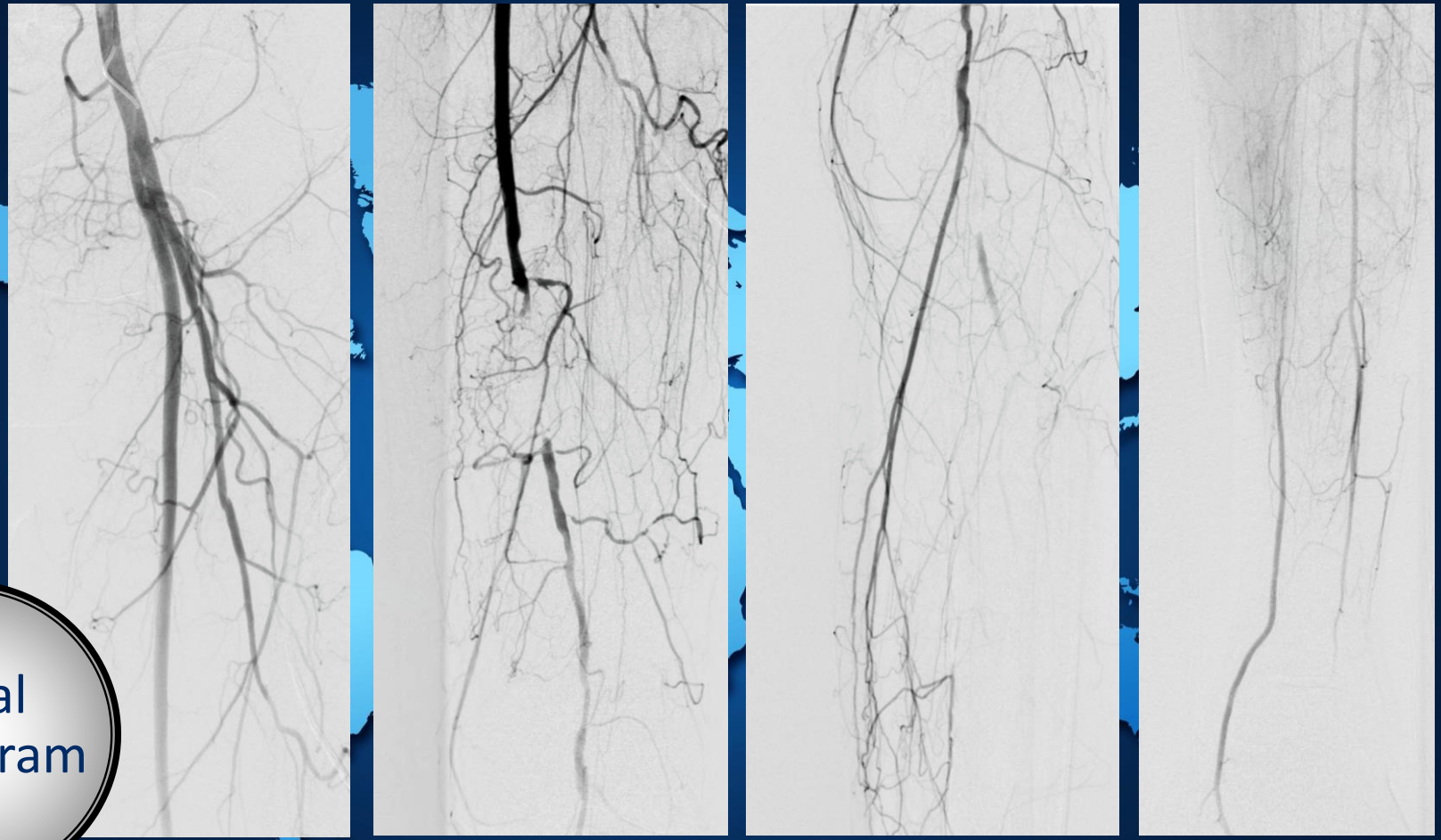
"The ABI is >0.7"

"The wound is small. Let's give it more time"

"I can feel her DP pulse"

"His doppler signals are good"

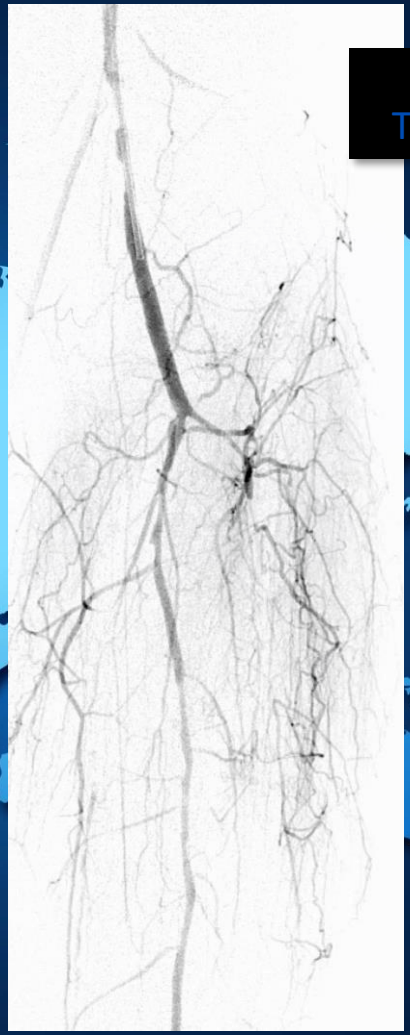
"I'll do an angiogram if the amputation doesn't heal"



Initial Angiogram

Distal SFA, Popliteal

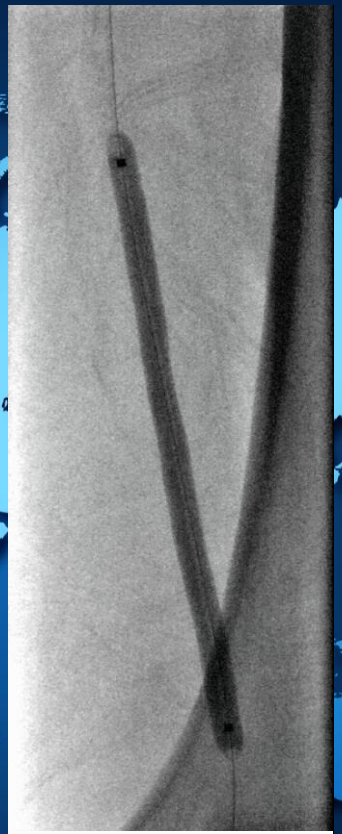
Popliteal, Trifurcation



18 hours later

Distal SFA

ATHERECTOMY



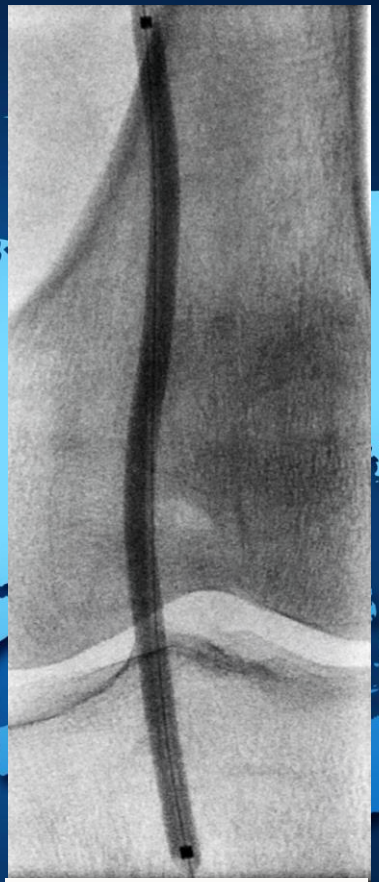
DCB

Final

Mid Popliteal

Initial Lesion

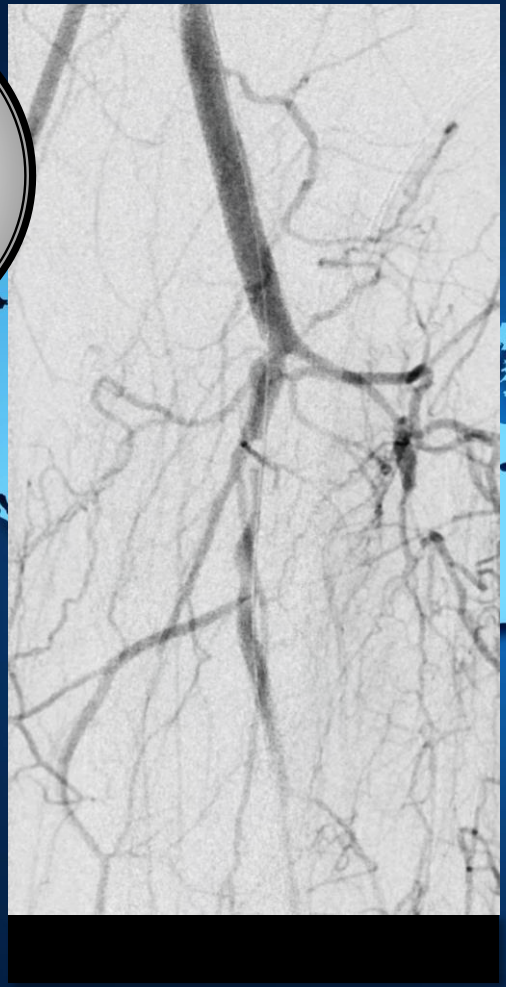
ATHERECTOMY



DCB

Final

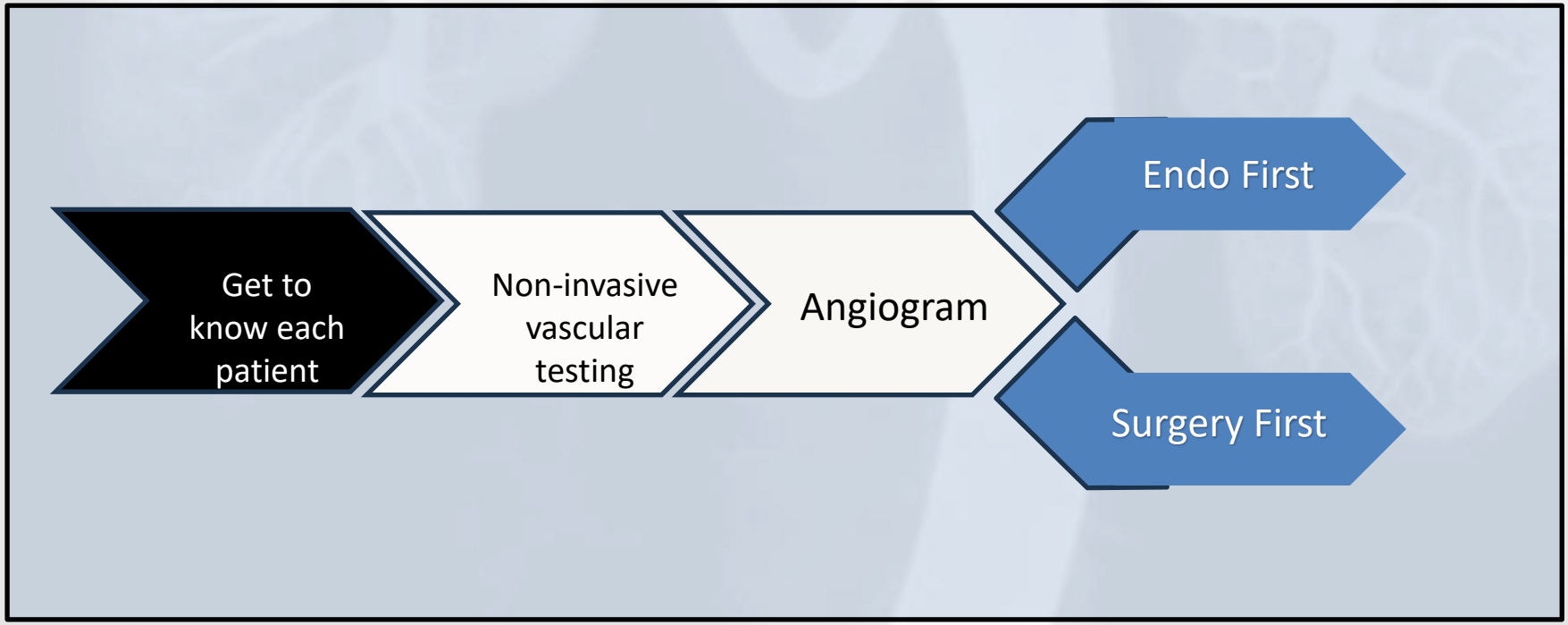
TP Trunk, Peroneal Artery



ATHERECTOMY/PTA

Final

My Algorithm For CLTI



3 REASONS WHY I CHOOSE **ENDO** FIRST

1 LESS **MORBITY & MORTALITY** THAN OPEN SURGERY

Results of PREVENT III: A multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery

Michael S. Conte, MD,[a] Dennis F. Bandyk, MD,[b] Alexander W. Clowes, MD,[c] Gregory L. Moneta, MD,[d] Lynn Seely, MD,[e] Todd J. Lorenz, MD,[e] Hamid Namini, PhD,[e] Allen D. Hamdan, MD,[f] Sean P. Roddy, MD,[g] Michael Belkin, MD,[a] Scott A. Berceli, MD,[h] Richard J. DeMasi, MD,[i] Russell H. Samson, MD,[j] and Scott S. Berman, MD,[k] for the PREVENT III Investigators, *Boston, Mass; Tampa, Gainesville, and Sarasota, Fla; Seattle, Wash; Portland, Ore; South San Francisco, Calif; Albany, NY; Norfolk, Va; and Tucson, Ariz*

Objective: The PREVENT III study was a prospective, randomized, double-blinded, multicenter phase III trial of a novel molecular therapy (edifoligide; E2F decoy) for the prevention of vein graft failure in patients undergoing infrainguinal revascularization for critical limb ischemia (CLI).
Methods: From November 2001 through October 2003, 1404 patients with CLI were randomized to a single intraoperative ex vivo vein graft treatment with edifoligide or placebo. After surgery, patients underwent graft surveillance by duplex ultrasonography and were followed up for index graft and limb end points to 1 year. A blinded Clinical Events Classification committee reviewed all index graft end points. The primary study end point was the time to nontechnical index graft reintervention or major amputation due to index graft failure. Secondary end points included all-cause graft failure, clinically significant graft stenosis (>70% by angiography or severe stenosis by ultrasonography), amputation/reintervention-free survival, and nontechnical primary graft patency. Event rates were based on Kaplan-Meier estimates. Time-to-event end points were compared by using the log-rank test.
Results: Demographics, comorbidities, and procedural details reflected a population with CLI and diffuse atherosclerosis. Tissue loss was the presenting symptom in 75% of patients. High-risk conduits were used in 24% of cases, including an alternative vein in 20% (15% spliced vein and 5% non–great saphenous vein) and 6% less than 3 mm in diameter; 14% of the cases were reoperative bypass grafts. Most (65%) grafts were placed to infrapopliteal targets. Perioperative (30-day) mortality occurred in 2.7% of patients. Major morbidity included myocardial infarction in 4.7% and early graft occlusion in 5.2% of patients. Ex vivo treatment with edifoligide was well tolerated. There was no significant difference between the treatment groups in the primary or secondary trial end points, primary graft patency, or limb salvage. A statistically significant improvement was observed in secondary graft patency (estimated Kaplan-Meier rates were 83% edifoligide and 78% placebo; $P = .016$) within 1 year. The reduction in secondary patency events was manifest within 30 days of surgery (the relative risk for a 30-day event for edifoligide was 0.45; 95% confidence interval, 0.27-0.76; $P = .005$). For the overall cohort at 1 year, the estimated Kaplan-Meier rate for survival was 84%, that for primary patency was 61%, that for primary assisted patency was 77%, that for secondary patency was 80%, and that for limb salvage was 88%.
Conclusions: In this prospective, randomized, placebo-controlled clinical trial, ex vivo treatment of lower extremity vein grafts with edifoligide did not confer protection from reintervention for graft failure. (J Vasc Surg 2006;43:742-51.)

- 1404 CLI patients treated with vein bypass at 83 N American sites (2001-2003)
- Tissue loss present in 75% of patients
- Multiple 30-day and 1-year endpoints

1 LESS **MORBITY & MORTALITY** THAN OPEN SURGERY

BASIL (2005)

- MORTALITY—5.5%
- MI—7%
- STROKE—1.5%
- WND CMPLX—22%

30-DAY MORBIDITY & MORTALITY

Myocardial infarction	4.7%
Cardiac or resp arrest	1.5%
Pneumonia	1.6%
Major wound comp	4.8%
Graft occlusion	5.2%
Major amputation	1.8%
Stroke / TIA	1.4%
Death	2.7%

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Conclusions: In this prospective, randomized, placebo-controlled clinical trial, ex vivo treatment of lower extremity vein grafts with edifoligide did not confer protection from reintervention for graft failure. (J Vasc Surg 2006;43:742-51.)

1-YEAR MAJOR ADVERSE LIMB EVENTS + MORTALITY

Graft replacement, thrombectomy, or thrombolysis	**12%**
Major amputation	**8.8%**
Mortality	**16%**

2

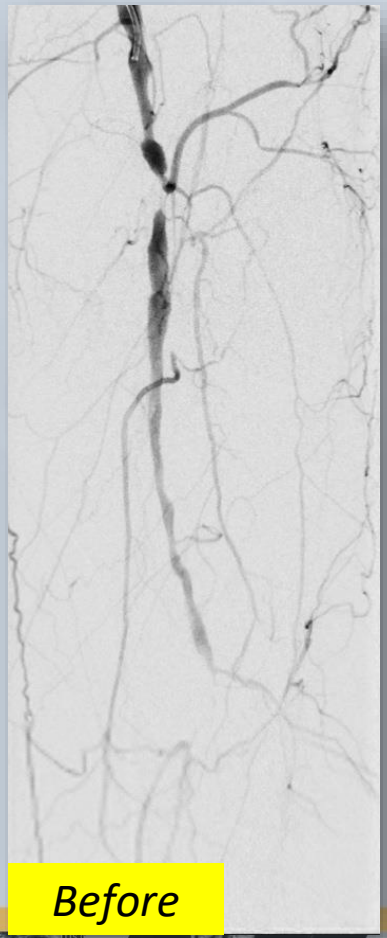
MORE TREATMENT OPTIONS

ENDOVASCULAR

- Treat more than one tibial vessel
- Create pedal outflow if necessary
- Variety of arterial accesses

BYPASS SURGERY

- Must choose one target outflow vessel
- Poor pedal outflow may compromise bypass
- Surgical incisions dictated by location of patent vessels



Before

- FEMORAL ACCESS
- PEDAL ACCESS
- MULTIPLE VESSELS TREATED

After

Before

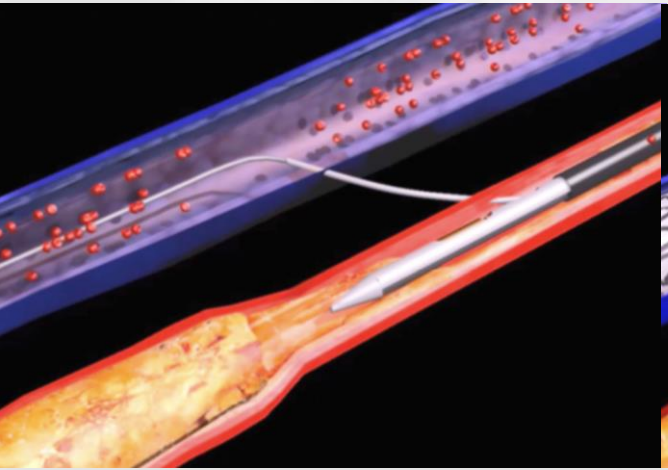
- FEMORAL ACCESS
- MULTIPLE VESSELS TREATED
- RESTORATION OF OPTIMAL PEDAL PERFUSION FOR HEALING

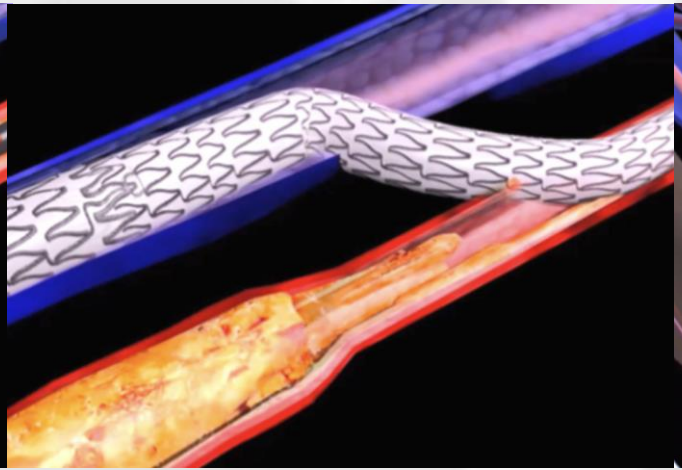
After

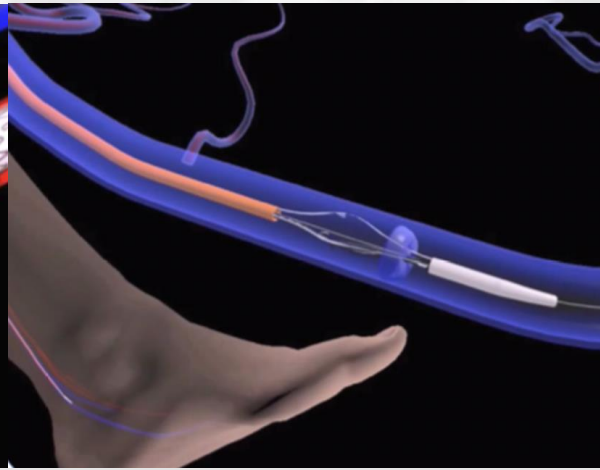
Deep Venous Arterialization

For when there is
NO REVASCULARIZATION OPTION

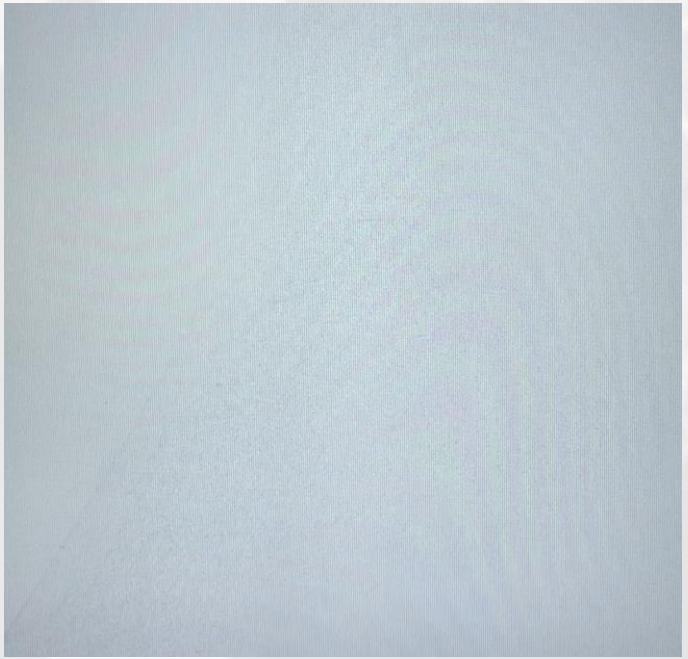
Deep Venous Arterialization







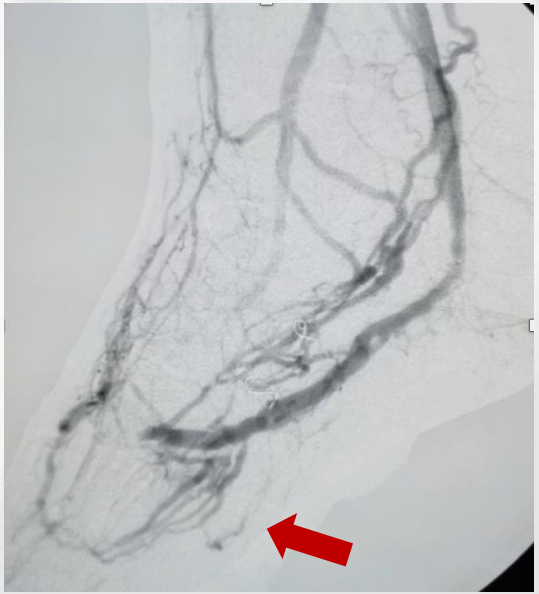
Deep Venous Arterialization



Deep Venous Arterialization

Initial Angiogram

1 Month Later



3 Months Later

Open TMA

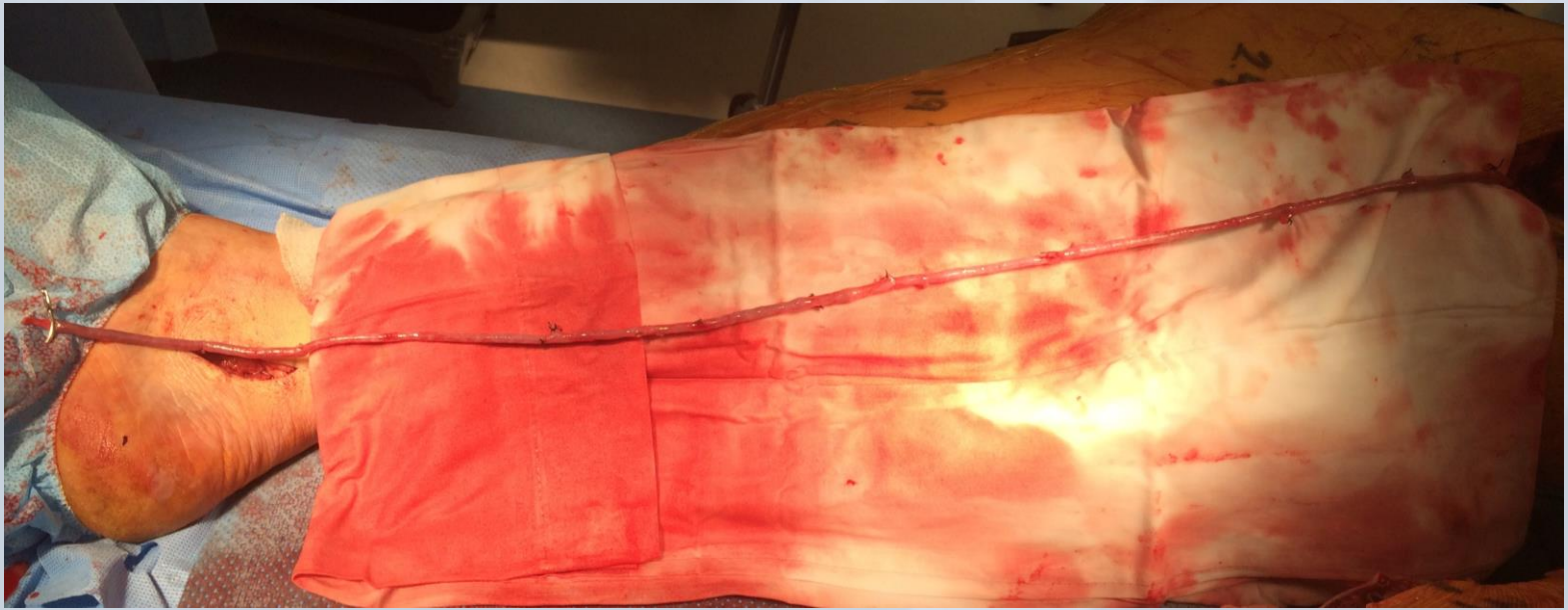
2 Months Later

4 Months Later

3

PATIENTS PREFER IT

When do I BYPASS?



When do I **BYPASS?**

1) **Heavily calcified, long SFA CTOs**

2) **Long CTOs from CFA to tibials**

3) **For repeated endo failures**

Landmark Trials

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

A. Farber, M.T. Menard, M.S. Conte, J.A. Kaufman, R.J. Powell, N.K. Choudhry, T.H. Hamza, S.F. Assmann, † M.A. Creager, M.J. Cziraky, M.D. Dake, M.R. Jaff, D. Reid, F.S. Siami, G. Sopko, C.J. White, M. van Over, M.B. Strong, M.F. Villarreal, M. McKean, E. Azene, A. Azarbal, A. Barleben, D.K. Chew, L.C. Clavijo, Y. Douville, L. Findeiss, N. Garg, W. Gasper, K.A. Giles, P.P. Goodney, B.M. Hawkins, C.R. Herman, J.A. Kalish, M.C. Koopmann, I.A. Laskowski, C. Mena-Hurtado, R. Motaganahalli, V.L. Rowe, A. Schanzer, P.A. Schneider, J.J. Siracuse, M. Venermo, and K. Rosenfield, for the BEST-CLI Investigators†

ABSTRACT

BACKGROUND

Patients with chronic limb-threatening ischemia (CLTI) require revascularization to improve limb perfusion and thereby limit the risk of amputation. It is uncertain whether an initial strategy of endovascular therapy or surgical revascularization for CLTI is superior for improving limb outcomes.

METHODS

In this international, randomized trial, we enrolled 1830 patients with CLTI and infrainguinal peripheral artery disease in two parallel-cohort trials. Patients who had a single segment of great saphenous vein that could be used for surgery were assigned to cohort 1. Patients who needed an alternative bypass conduit were assigned to cohort 2. The primary outcome was a composite of a major adverse limb event — which was defined as amputation above the ankle or a major limb reintervention (a new bypass graft or graft revision, thrombectomy, or thrombolysis) — or death from any cause.

RESULTS

In cohort 1, after a median follow-up of 2.7 years, a primary-outcome event occurred in 302 of 709 patients (42.6%) in the surgical group and in 408 of 711 patients (57.4%) in the endovascular group (hazard ratio, 0.68; 95% confidence interval [CI], 0.59 to 0.79; P<0.001). In cohort 2, a primary-outcome event occurred in 83 of 194 patients (42.8%) in the surgical group and in 95 of 199 patients (47.7%) in the endovascular group (hazard ratio, 0.79; 95% CI, 0.58 to 1.06; P=0.12) after a median follow-up of 1.6 years. The incidence of adverse events was similar in the two groups in the two cohorts.

CONCLUSIONS

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Drs. Farber and Menard contributed equally to this article.

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Articles

A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial

OA

Andrew W Bradbury, Catherine A Moakes, Matthew Popplewell, Louis Meecham, Gareth E Bate, Lisa Kelly, Ian Chetter, Athanasios Diamantopoulos, Asraf Gaunchan, Jack Hall, Simon Hobbs, Ken Haydock, Hugh Jarrett, Suzanne Lockyer, Jonas Mahmoudi, Jai V Patel, Snehal Patel, S Jouquier Rashid, Athanasios Sanders, Gemma Shaw, D Julian A Scott, Harry Zayed, Jonathan Deeks, on behalf of the BASIL-2 Investigators

Summary

Background Chronic limb-threatening ischaemia is the severest manifestation of peripheral arterial disease and presents with ischaemic pain at rest or tissue loss (ulceration, gangrene, or both), or both. We compared the effectiveness of a vein bypass first with a best endovascular treatment first revascularisation strategy in terms of preventing major amputation and death in patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion.

Methods In the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-2 was an open-label, pragmatic, multicentre, phase 3, randomised trial done at 41 vascular surgery units in the UK (n=39), Sweden (n=1), and Denmark (n=1). Eligible patients were those who presented to hospital-based vascular surgery units with chronic limb-threatening ischaemia due to atherosclerotic disease and who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion. Participants were randomly assigned (1:1) to receive either vein bypass (vein bypass group) or best endovascular treatment first endovascular treatment group) as their first revascularisation procedure through a secure online randomisation system. Participants were excluded if they had ischaemic pain or tissue loss considered not to be primarily due to atherosclerotic peripheral artery disease. Most vein bypasses used the great saphenous vein and originated from the common or superficial femoral arteries. Most endovascular interventions comprised plain balloon angioplasty with selective use of plain or drug eluting stents. Participants were followed up for a minimum of 2 years. Data were collected locally at participating centres. In England, Wales, and Sweden, centralised databases were used to collect information on amputations and deaths. Data were analysed centrally at the Birmingham Clinical Trials Unit. The primary outcome was amputation-free survival defined as time to first major (above the ankle) amputation or death from any cause measured in the intention-to-treat population. Safety was assessed by monitoring serious adverse events up to 30 days after first revascularisation. The trial is registered with the ISRCTN registry, ISRCTN27728689.

Findings Between July 22, 2014, and Nov 30, 2020, 345 participants (65 [19%] women and 280 [81%] men; median age 72·5 years [62·7–79·7]) with chronic limb-threatening ischaemia were enrolled in the trial and randomly assigned: 172 (50%) to the vein bypass group and 173 (50%) to the best endovascular treatment group. Major amputation or death occurred in 108 (63%) of 172 patients in the vein bypass group and 92 (53%) of 173 patients in the best endovascular treatment group (adjusted hazard ratio [HR] 1·35 [95% CI 1·02–1·80]; p=0·037). 91 (53%) of 172 patients in the vein bypass group and 77 (45%) of 173 patients in the best endovascular treatment group died (adjusted HR 1·37 [95% CI 1·00–1·87]). In both groups the most common causes of morbidity and death, including that occurring within 30 days of their first revascularisation, were cardiovascular (61 deaths in the vein bypass group and 53 in the best endovascular treatment group) and respiratory events (25 deaths in the vein bypass group and 48 in the best endovascular treatment group; number of cardiovascular and respiratory deaths were not mutually exclusive).

Interpretation In the BASIL-2 trial, a best endovascular treatment first revascularisation strategy was associated with a better amputation-free survival, which was largely driven by fewer deaths in the best endovascular treatment group. These data suggest that more patients with chronic limb-threatening ischaemia who required an infra-popliteal, with

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THE LANCET

BEST-CLI

BASIL-2

Who Exactly Was Studied?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

A. Farber, M.T. Menard, M.S. Conte, J.A. Kaufman, R.J. Powell, N.K. Choudhry, T.H. Hamza, S.F. Assmann,* M.A. Creager, M.J. Cziraky, M.D. Dake, M.R. Jaff, D. Reid, F.S. Siami, G. Sopko, C.J. White, M. van Over, M.B. Strong, M.F. Villarreal, M. McKean, E. Azene, A. Azarbal, A. Barleben, D.K. Chew, L.C. Clavijo, Y. Douville, L. Findeiss, N. Garg, W. Gasper, K.A. Giles, P.P. Goodney, B.M. Hawkins, C.R. Herman, J.A. Kalish, M.C. Koopmann, I.A. Laskowski, C. Mena-Hurtado, R. Motaganahalli, V.L. Rowe, A. Schanzer, P.A. Schneider, J.J. Siracuse, M. Venermo, and K. Rosenfield, for the BEST-CLI Investigators†

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In this international, randomized trial, we enrolled 1830 patients with CLTI and infrainguinal peripheral artery disease in two parallel-cohort trials. Patients who had a single segment of great saphenous vein that could be used for surgery were assigned to cohort 1. Patients who needed an alternative bypass conduit were assigned to cohort 2. The primary outcome was a composite of a major adverse limb event — which was defined as amputation above the ankle or a major limb reintervention (a new bypass graft or graft revision, thrombectomy, or thrombolysis) — or death from any cause.

RESULTS
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The NEW ENGLAND JOURNAL of MEDICINE

BEST-CLI

THE LANCET

BASIL-2

How Generalizable Are BEST Results?

Potential Patients Screened

150 sites
~100 pts/yr
5 yr

75,000 patients

Enrollment Rate for BEST-CLI

2.4%

Actually Enrolled

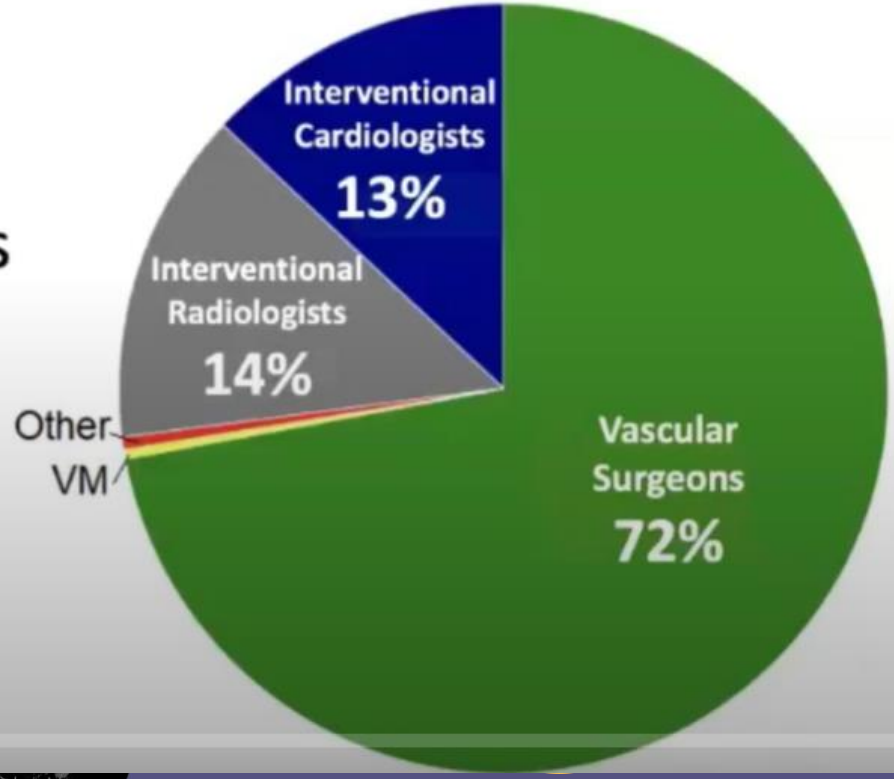
1830 pts

BEST-CLI Investigators by Specialty

BEST-CLI

1,096 Investigators

786 Vascular Surgeons
145 Interventional Cardiologists
156 Interventional Radiologists
4 Vascular Medicine
5 Other



BEST - CLI

- International, prospective, randomized trial of CLTI patients with infrainguinal PAD
- Patients enrolled if 2 operators (1 with expertise in bypass / 1 with expertise in endovascular therapy) both agreed patient could be equally treated by either modality
- 1:1 randomization between surgical bypass and any available endovascular therapy

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- **Two cohorts studied**
  - Adequate GSV
  - Alternative conduit
- **Follow-up q6mo up to 7 years**
- **Primary endpoint – MALE and death**
- **MALE- Major Adverse Limb Event**
  - Major amputation
  - Bypass revision
  - Thrombectomy
  - Thrombolysis
  - New Bypass?

Patients Treated in BEST-CLI

1830

Patients with CLTI & Equally Treated By Bypass OR Endovascular Therapy

1436 pts

Adequate GSV
(Cohort 1)

Bypass (n=718)

Endo Tx (n=716)

Alternative Conduit
(Cohort 2)

396 pts

Bypass (n=197)

Endo Tx (n=199)

Farber et al., N Engl J Med 2022; 387:2305-16

Patients Treated in BEST-CLI

1830

Patients with CLTI & Equally Treated By Bypass OR Endovascular Therapy

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Endo Tx (n=716)

Alternative Conduit
(Cohort 2)

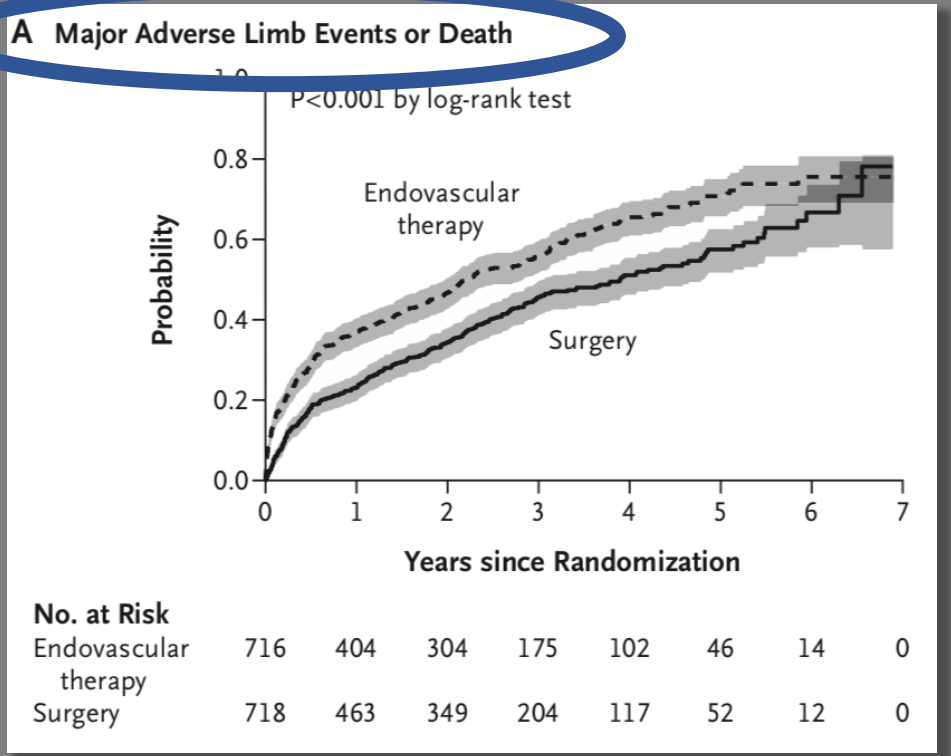
396 pts

Bypass (n=197)
Endo Tx (n=199)

2.7 yrs **MEAN FOLLOW-UP** 1.6 yrs

Farber et al., N Engl J Med 2022; 387:2305-16

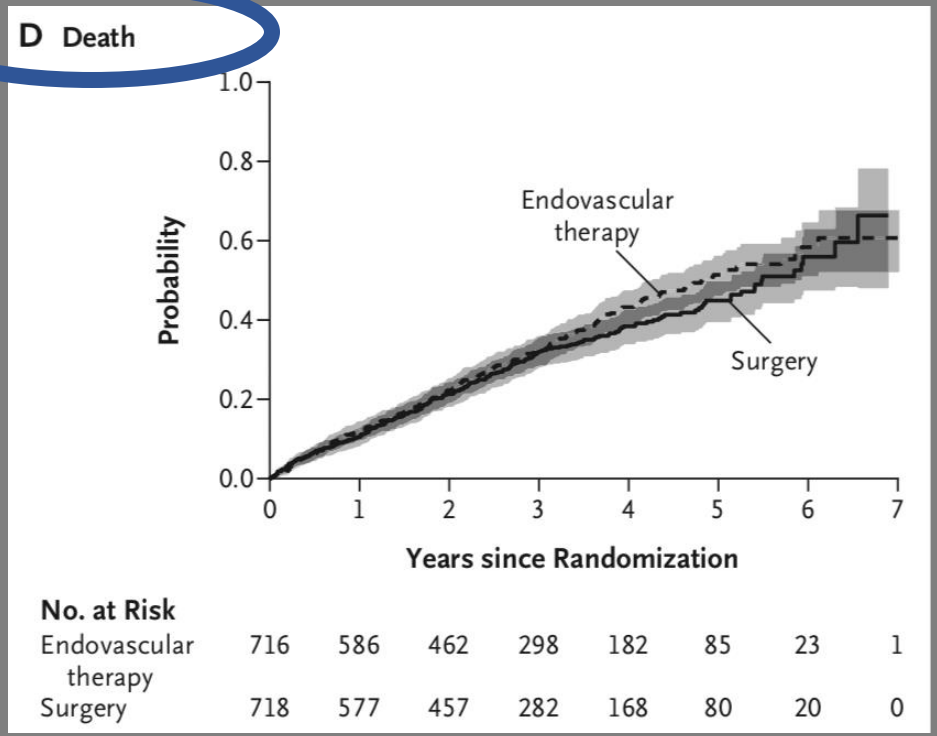
Primary Outcomes (Cohort 1)



Farber et al., N Engl J Med 2022; 387:2305-16

Primary Outcomes (Cohort 1)

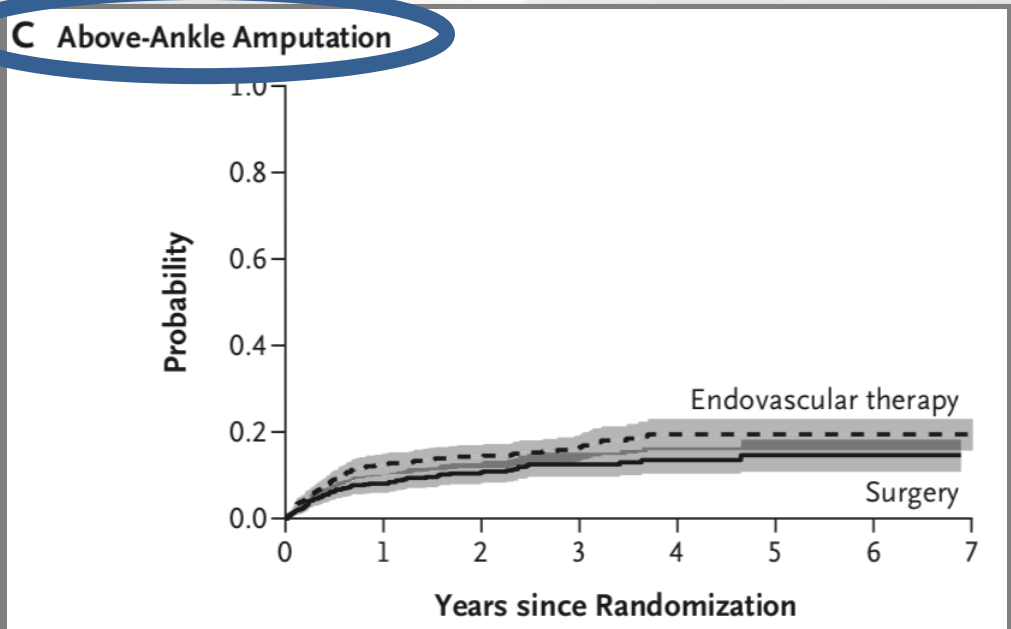
No difference in mortality



Farber et al., N Engl J Med 2022; 387:2305-16

Primary Outcomes (Cohort 1)

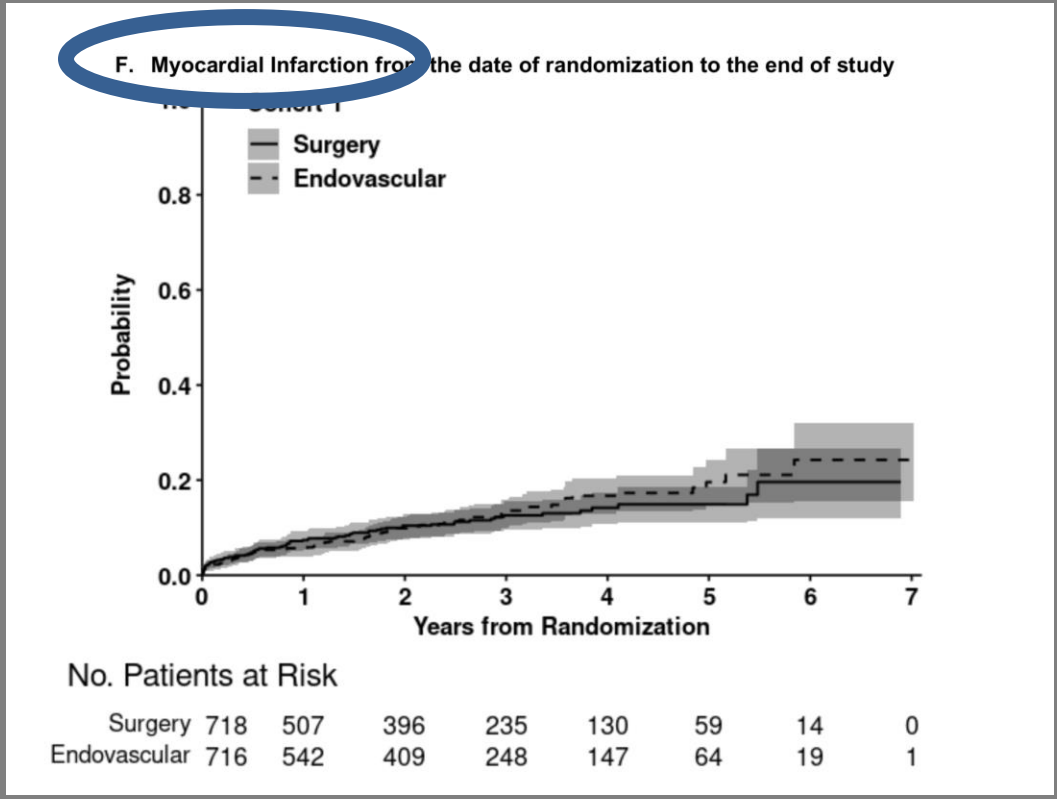
No difference in amputation



Farber et al., N Engl J Med 2022; 387:2305-16

Primary Outcomes (Cohort 1)

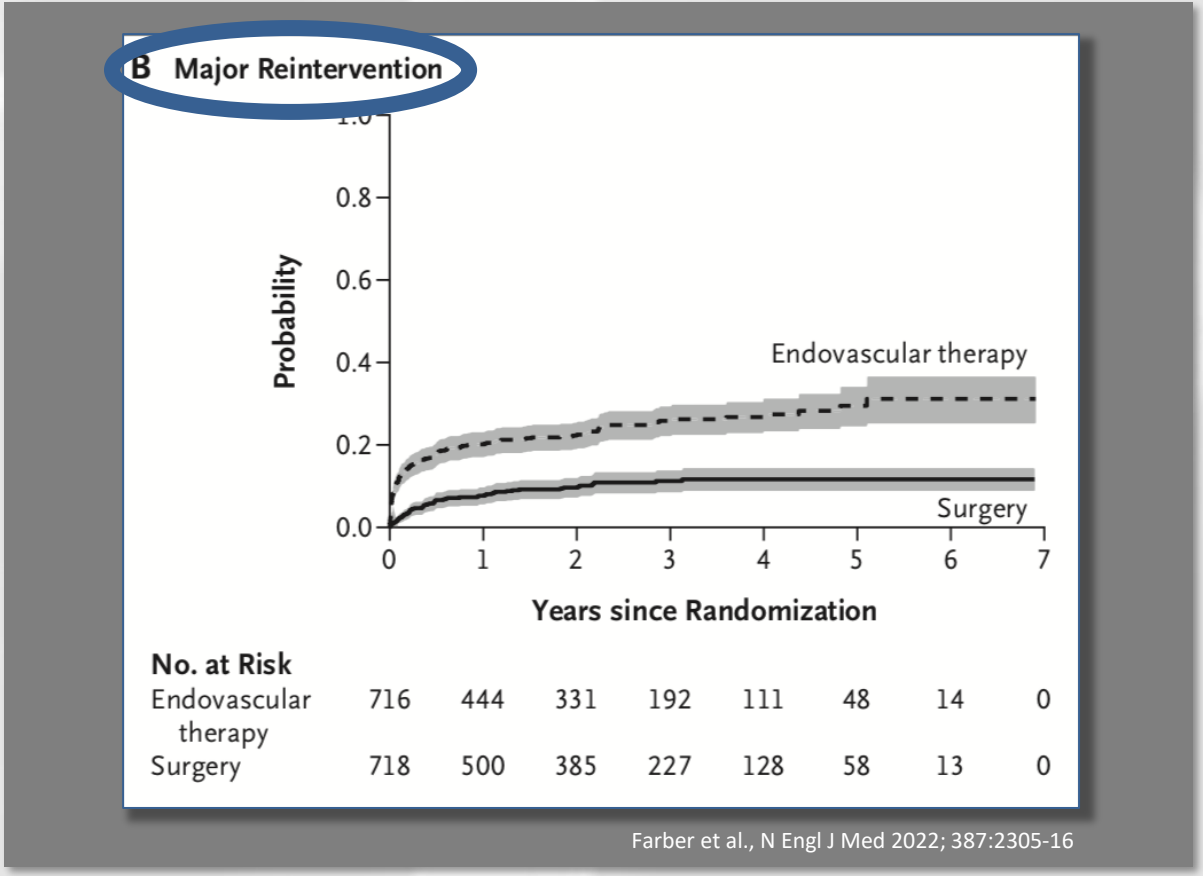
No difference in rate of MI



Farber et al., N Engl J Med 2022; 387:2305-16

Primary Outcomes (Cohort 1)

Difference in primary endpoint driven by <u>increased major reintervention</u>



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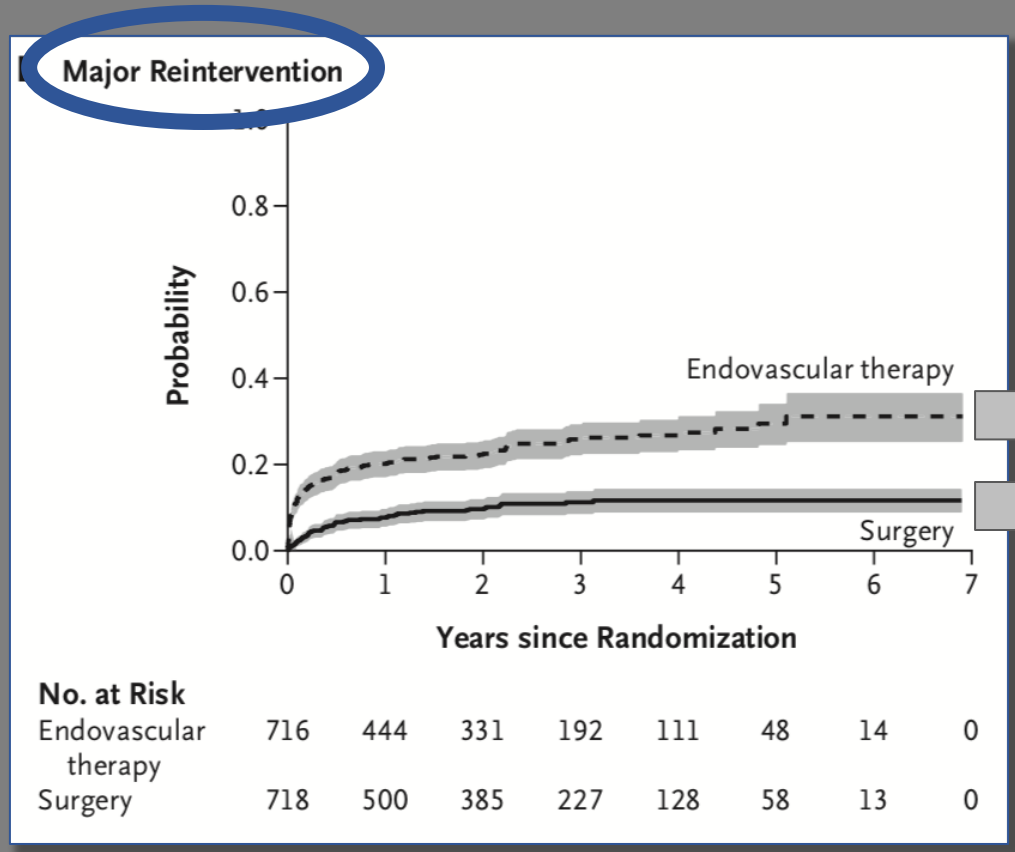


Technical Success

80.6% **(1 in 5 patients**

100%

BYPASS

Farber et al., N Engl J Med 2022; 387:2305-16

Technical Success

ENDO 80.6%

BYPASS 100%

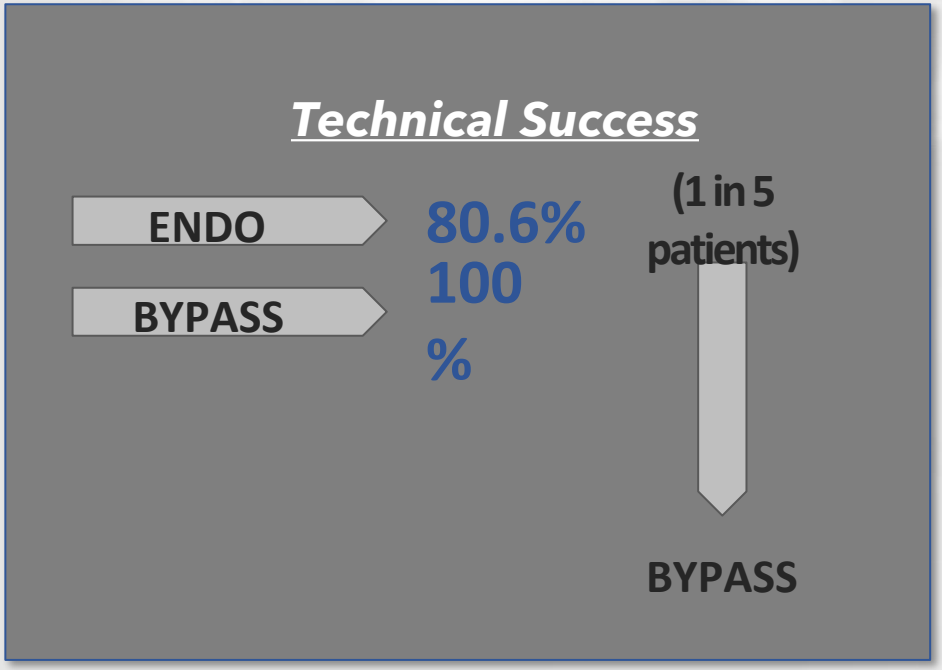
(1 in 5 patients)

BYPASS

Conclusions?

Bypass after a failed endovascular attempt is a MALE?

Farber et al., N Engl J Med 2022; 387:2305-16



Conclusions?

Bypass in the endovascular arm = MALE

Bypass in the surgery arm = primary therapy

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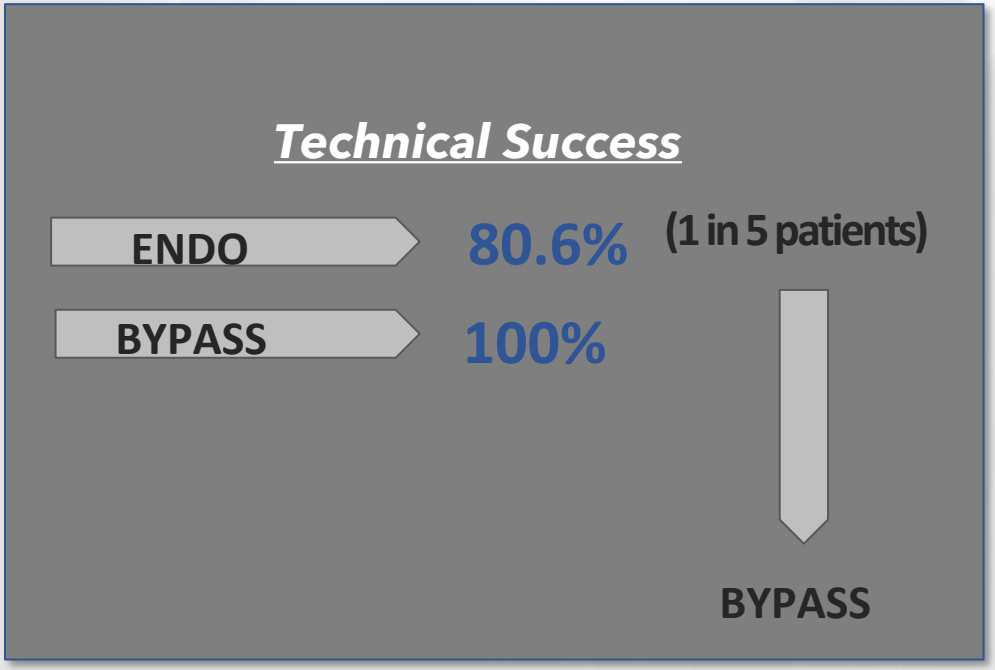
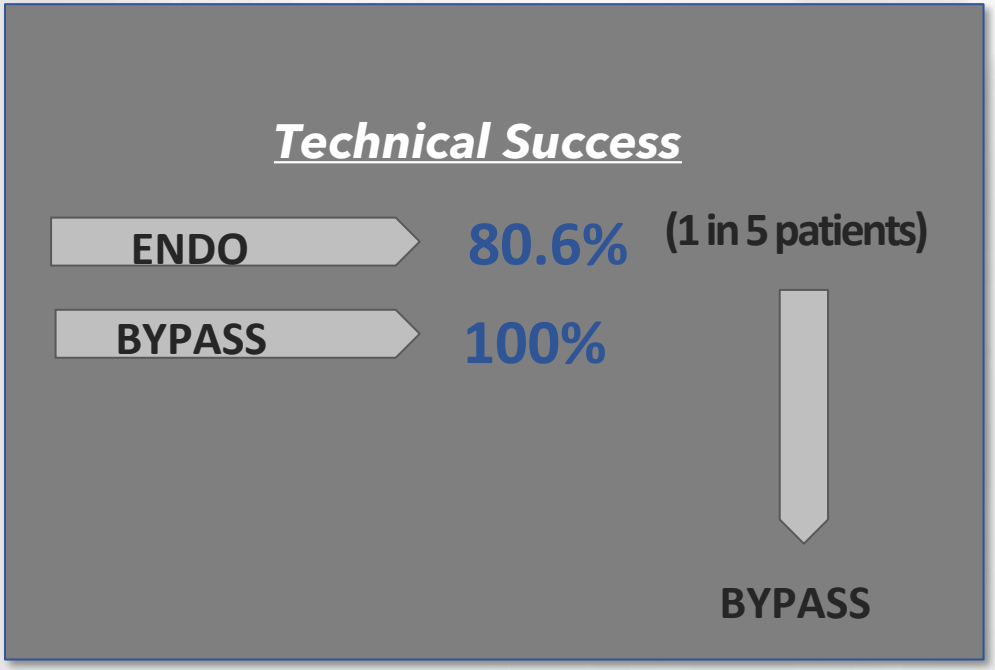


Conclusions?

1 in 5 patients needed bypass in the endo arm, so EVERYONE should have bypass?

Farber et al., N Engl J Med 2022; 387:2305-16



Conclusions?

"Fewer secondary interventions"

5 PTS ENDO First

→ 5 angiograms + 1 bypass

5 PTS BYPASS First

→ 5 diagnostic angiograms + 5 bypasses

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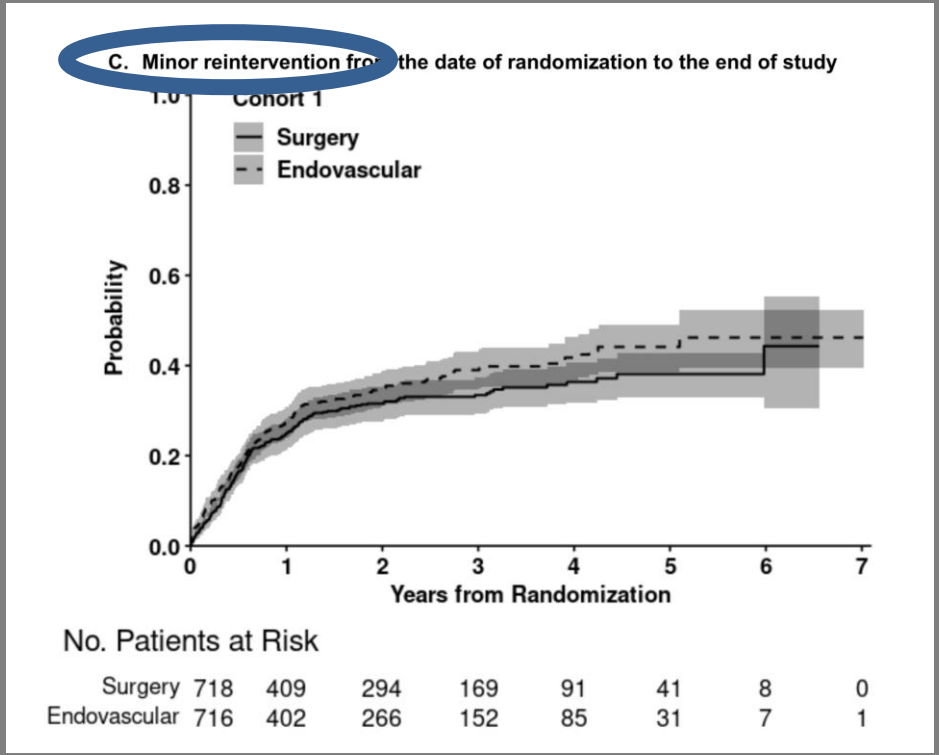
Primary Outcomes (Cohort 1)

No difference in minor reinterventions



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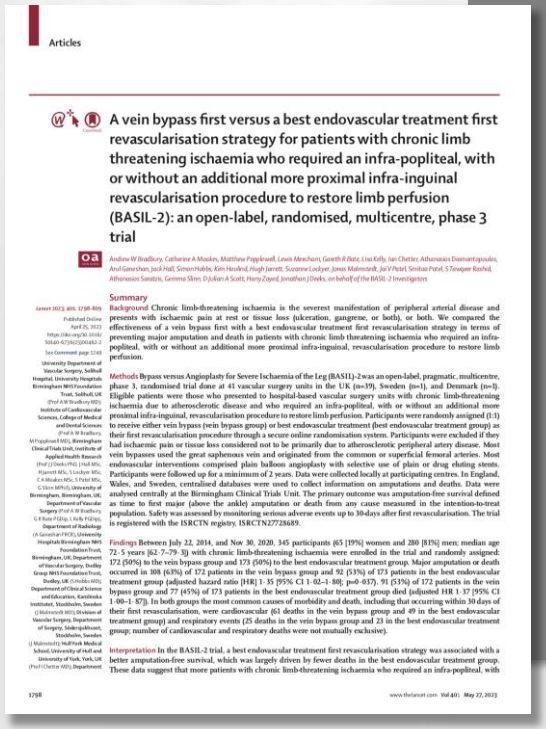
BASIL - 2



Articles

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Background Chronic limb-threatening ischaemia is the severest manifestation of peripheral arterial disease and presents with ischaemic pain at rest or tissue loss (ulceration, gangrene, or both), or both. We compared the effectiveness of a vein bypass first with a best endovascular treatment first revascularisation strategy in terms of preventing major amputation and death in patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion.

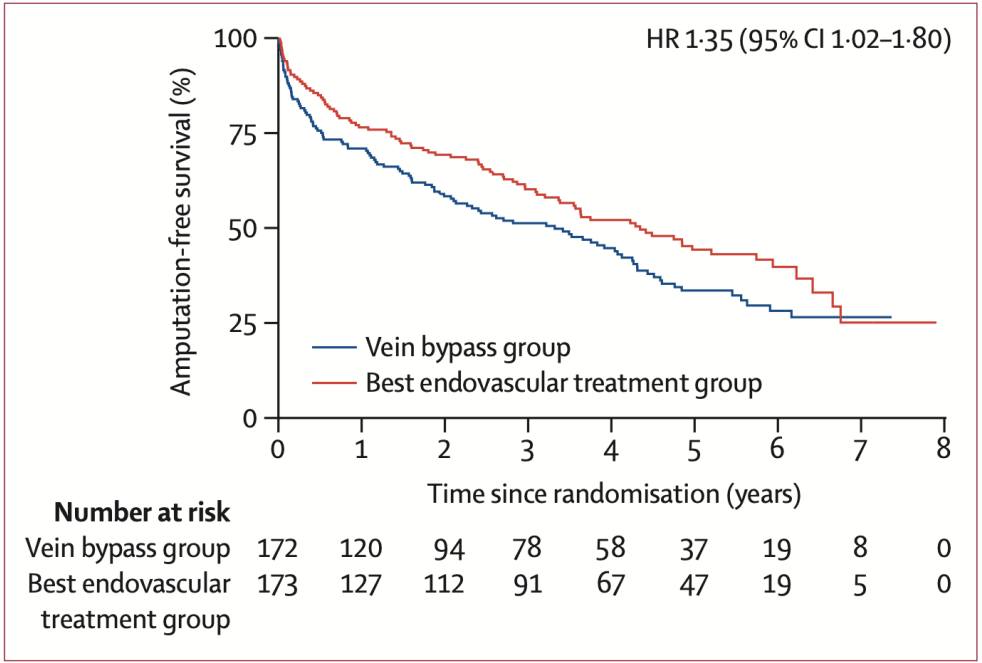
Methods Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL)-2 was an open-label, pragmatic, multicentre, phase 3, randomised trial done at 41 vascular surgery units in the UK (n=39), Sweden (n=1), and Denmark (n=1). Eligible patients were those who presented to hospital-based vascular surgery units with chronic limb-threatening ischaemia due to atherosclerotic disease and who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion. Participants were randomly assigned (1:1) to receive either vein bypass (vein bypass group) or best endovascular treatment (best endovascular treatment group) as their first revascularisation procedure through a secure online randomisation system. Participants were excluded if they had ischaemic pain or tissue loss considered not to be primarily due to atherosclerotic peripheral artery disease. Most vein bypasses used the great saphenous vein and originated from the common or superficial femoral arteries. Most endovascular interventions comprised plain balloon angioplasty with selective use of plain or drug eluting stents. Participants were followed up for a minimum of 2 years. Data were collected locally at participating centres. In England, Wales, and Sweden, centralised databases were used to collect information on amputations and deaths. Data were analysed centrally at the Birmingham Clinical Trials Unit. The primary outcome was amputation-free survival defined as time to first major (above the ankle) amputation or death from any cause measured in the intention-to-treat population. Safety was assessed by monitoring serious adverse events up to 30 days after first revascularisation. The trial is registered with the ISRCTN registry, ISRCTN27728689.

Findings Between July 22, 2014, and Nov 30, 2020, 345 participants (65 [19%] women and 280 [81%] men; median age 72·5 years [62·7–79·3]) with chronic limb-threatening ischaemia were enrolled in the trial and randomly assigned: 172 (50%) to the vein bypass group and 173 (50%) to the best endovascular treatment group. Major amputation or death occurred in 108 (63%) of 172 patients in the vein bypass group and 92 (53%) of 173 patients in the best endovascular treatment group (adjusted hazard ratio [HR] 1·35 [95% CI 1·02–1·80]; p=0·037). 91 (53%) of 172 patients in the vein bypass group and 77 (45%) of 173 patients in the best endovascular treatment group died (adjusted HR 1·37 [95% CI 1·00–1·87]). In both groups the most common causes of morbidity and death, including that occurring within 30 days of their first revascularisation, were cardiovascular (61 deaths in the vein bypass group and 49 in the best endovascular treatment group) and respiratory events (25 deaths in the vein bypass group and 23 in the best endovascular treatment group; number of cardiovascular and respiratory deaths were not mutually exclusive).

Interpretation In the BASIL-2 trial, a best endovascular treatment first revascularisation strategy was associated with a better amputation-free survival, which was largely driven by fewer deaths in the best endovascular treatment group. These data suggest that more patients with chronic limb-threatening ischaemia who required an infra-popliteal, with

- Randomized trial of 345 pts with CLTI and requiring infra-popliteal intervention
- Randomized to best endovascular tx or vein bypass
- Primary endpoint – amputation–free survival
- Median follow-up 40 months

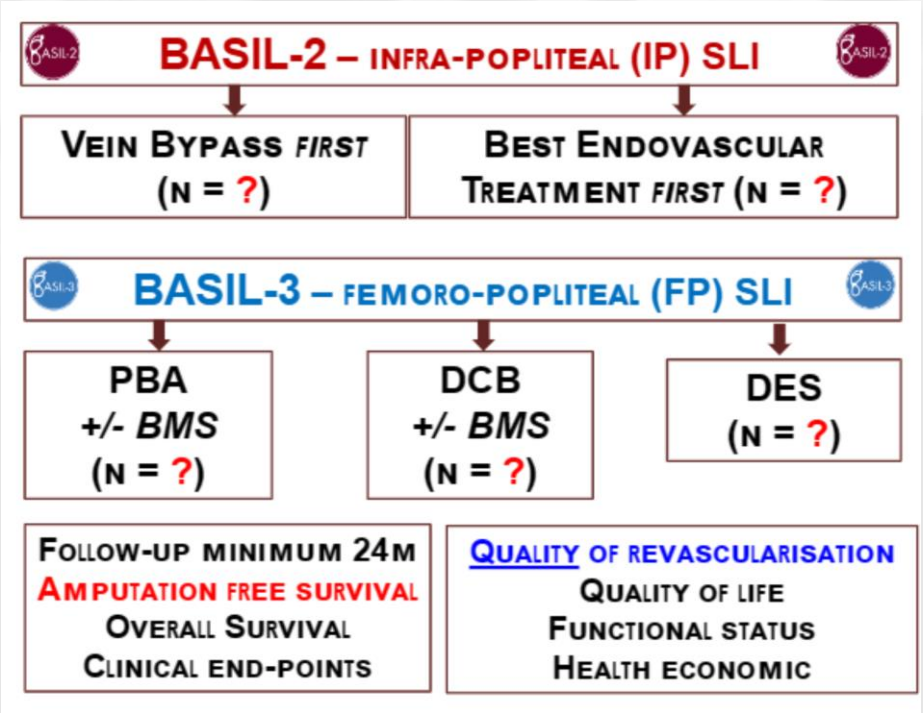
Amputation-Free Survival



BASIL TRIAL

- Randomized trial, published in 2005, found that endovascular therapy **equaled** the results with surgery based on amputation-free survival at 6 months. Endovascular therapy was a less morbid procedure with equivalent quality of life outcomes and was significantly less costly than surgery.

BASIL-3?


BASIL-2 – INFRA-POPLITEAL (IP) SLI
VEIN BYPASS FIRST (N = ?)
BEST ENDOVASCULAR TREATMENT FIRST (N = ?)
BASIL-3 – FEMORO-POPLITEAL (FP) SLI
PBA +/- BMS (N = ?)
DCB +/- BMS (N = ?)
DES (N = ?)
FOLLOW-UP MINIMUM 24M
AMPUTATION FREE SURVIVAL
OVERALL SURVIVAL
CLINICAL END-POINTS
QUALITY OF REVASCULARISATION
QUALITY OF LIFE
FUNCTIONAL STATUS
HEALTH ECONOMIC

CLTI Treatment Strategies

Surgery

- Byass & endarterectomy
- Femoral, popliteal, tibial, pedal exposures
- Facile use of vein, PTFE, cryopreserved conduits

Endovascular

- US-guided access (femoral, popliteal, pedal)
- Contrast & CO2 angiography
- Angioplasty, stent deployment, proficiency with multiple atherectomy devices, and balloon lithoplasty
- CTO crossing skills
- Embolization management
- Deep venous arterialization

OPTIMAL MANAGEMENT OF CLI REQUIRES BOTH SURGICAL AND ENDOVASCULAR SKILL SETS

AVAILABLE DATA DO NOT ESTABLISH SUPERIORITY OF SURGICAL VS ENDOVASCULAR APPROACH

EACH OPERATORS' ALGORITHM SHOULD BE DERIVED FROM HONEST ASSESSMENT OF SKILL SETS