2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 20-22

2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

Critical Limb Ischemia
Gangrene and Tissue Loss
End-of-the-road PAD

Fem-Pop, Fem-Flop, Chop-Chop

Peripheral Arterial Disease

- Chronic, progressive, multisystem disease
  - Claudication = Exertional pain, “claudico” Latin: to limp
    - Amputation at 5 years: 1-3%
    - Death at 5 years: 20-30%
  - Rutherford 1-3
  - ABI >0.5

Peripheral Arterial Disease

- Chronic, progressive, multisystem disease
  - Claudication
    - Amputation at 5 years: 1-3%
    - Death at 5 years: 20-30%
- **Critical limb ischemia:** PAD in combination with rest pain, gangrene, or ulceration > 2 weeks rest pain, tissue loss, gangrene
  - Rutherford 4-6
  - ABI <0.5
- At 1 year: 45% alive both limbs, 30% major amputation, 25% death
- At 5 years: >60% death

Table 1. Comparison of 5-Year Mortality Rates Across Disease Processes

Disease	5-Year Mortality Rate
CLTI without amputation	55%–65%[32]
Female breast cancer	10%[58]
Bladder cancer	23%[58]
Colon cancer	35%[58]
Myeloma	50%[58]
Lung and bronchus cancer	82%[58]
Pancreatic cancer	92%[58]

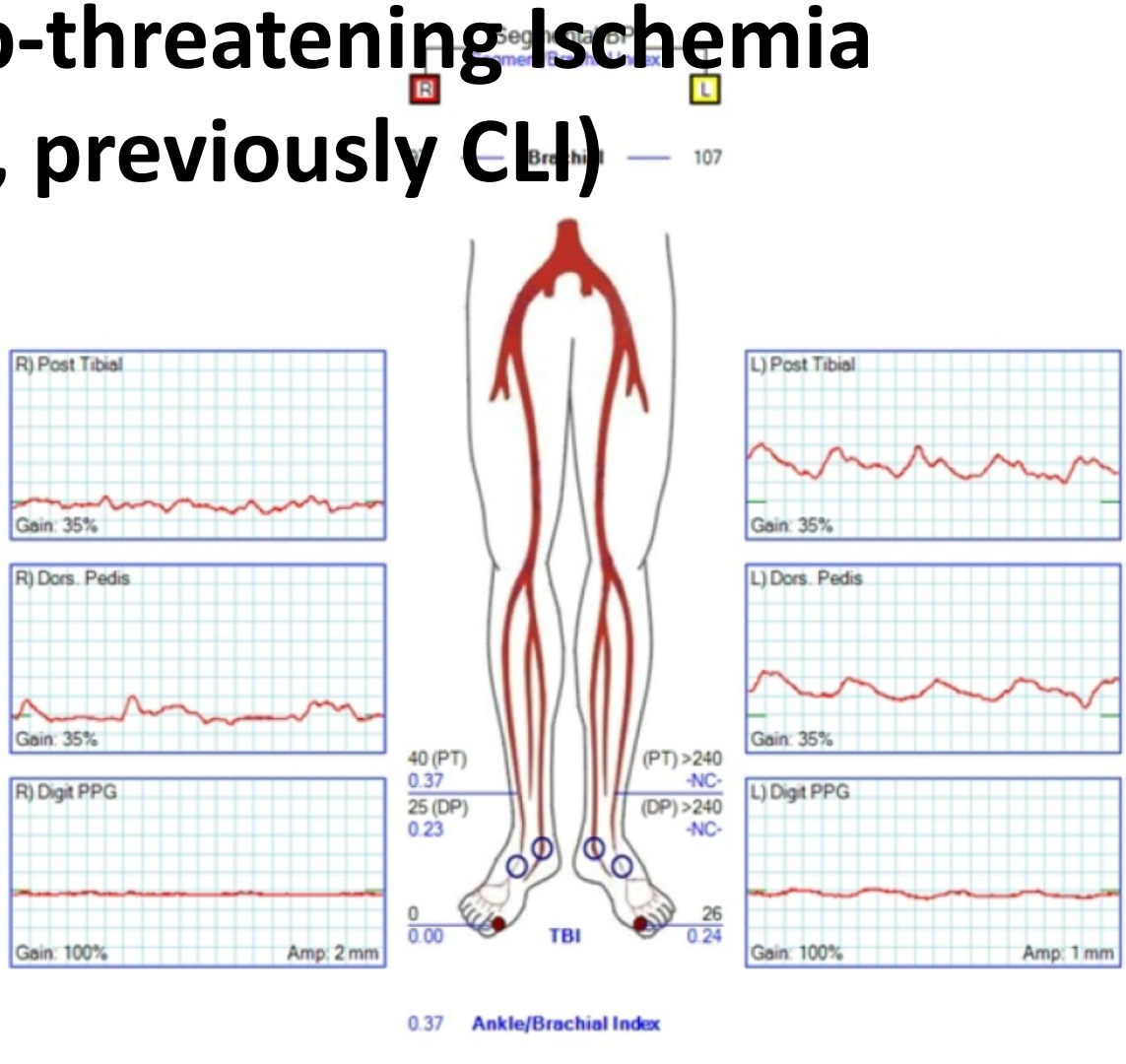
32. Duff S, Mafilios MS, Bhounsule P, Hasegawa JT. The burden of critical limb ischemia: a review of recent literature. **Vasc Health Risk Manag**. 2019; 15:187–208.
58. American Cancer Society. Cancer Facts & Statistics. American Cancer Society

Critical Limb-threatening Ischemia (CLTI, previously CLI)

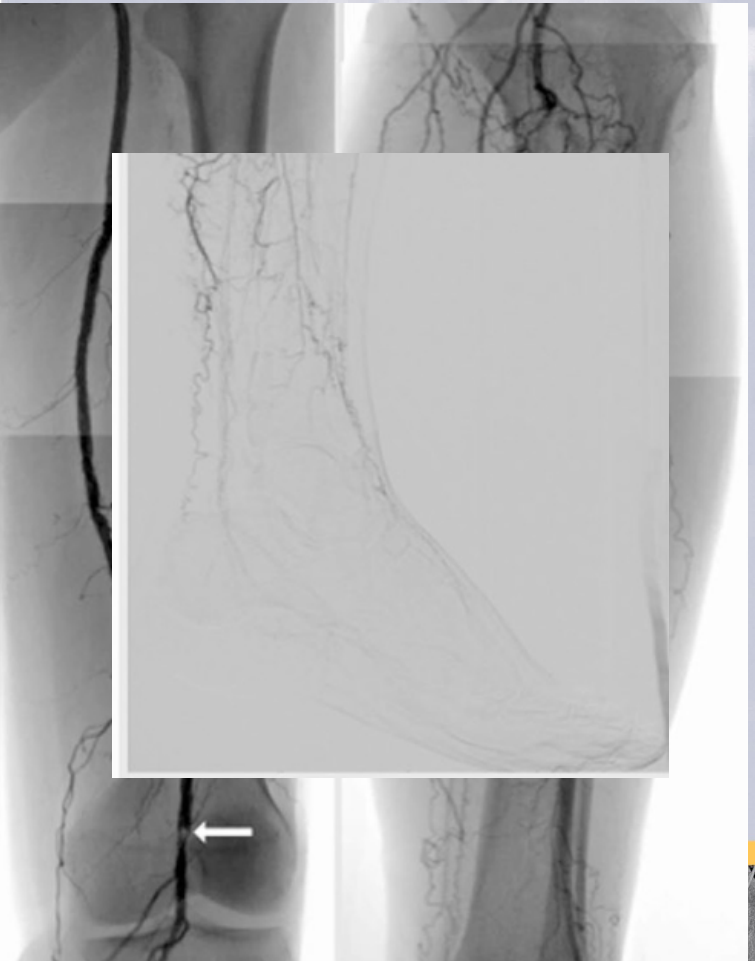
- Two-year life expectancy (2YLE)
- Independent prognostic factors
  - Age 65 to 79 years (odds ratio [OR]: 1.9), 80 years of age or older (OR: 3.7)
  - Body mass index (BMI in kg/m(2)) 18.0 to 19.9 (OR: 1.5), BMI <18.0 (OR: 2.9)
  - Nonambulatory status (OR: 2.4)
  - Hemodialysis (OR: 2.1),
  - Cerebrovascular disease (OR: 1.6),
  - Left ventricular ejection fraction (LVEF) of 40% to 49% (OR: 1.8), LVEF <40% (OR: 2.6),
  - Tissue Loss: Rutherford class 5 (OR: 1.9), and Rutherford class 6 (OR: 3.4).
- Calculate based on each OR (full score: 15 points).
- **A 2YLE score of ≥8 points indicates a <50% probability of 2-year survival.**

Critical Limb-threatening Ischemia (CLTI, previously CLI)

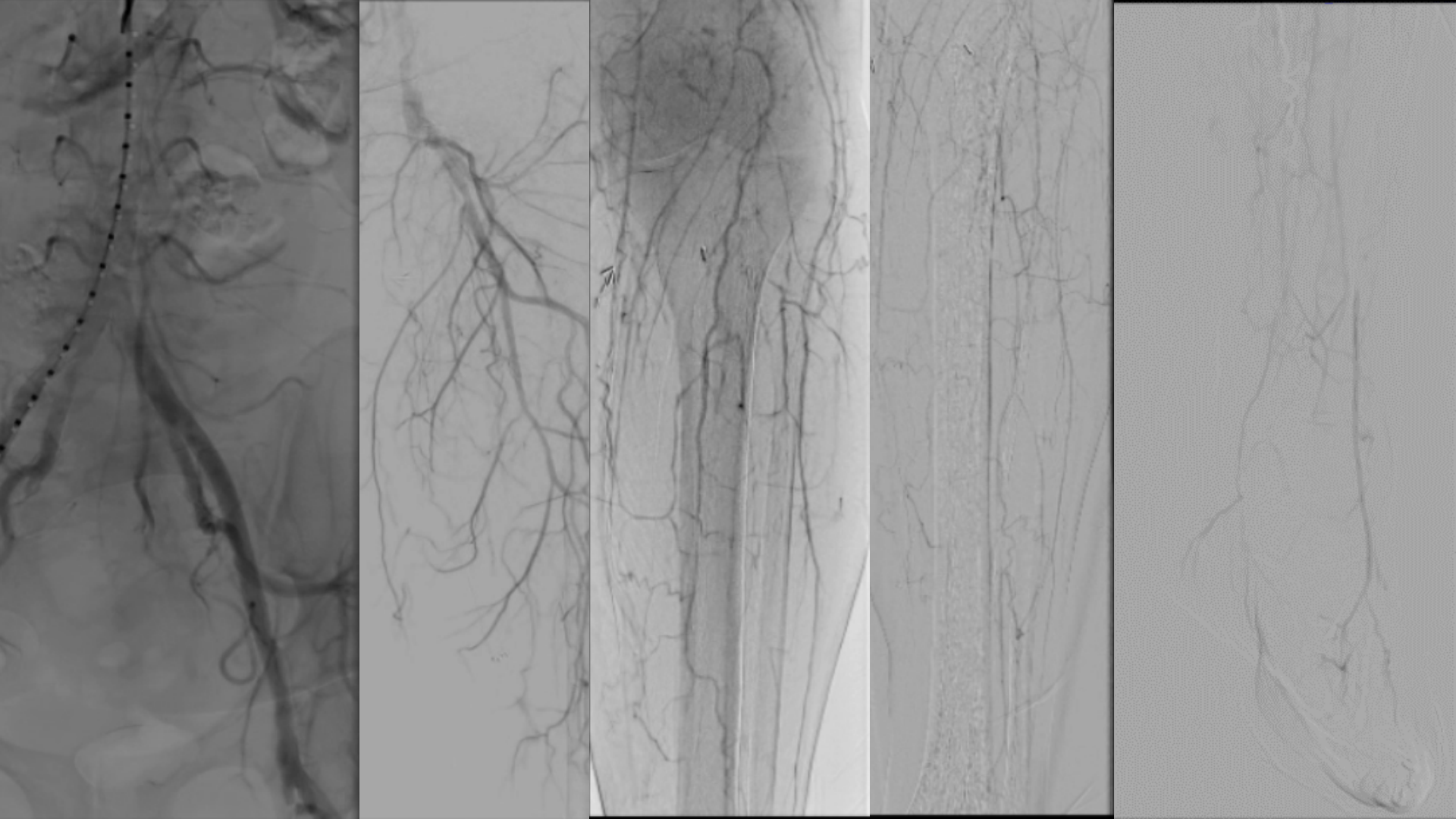
- ABI <0.5
  - **Severe [0.35-0.5]**
    Ischemic [<0.35]
- Toe pressures predictive of successful wound healing
  - 30 non-DM
  - 55 DM



Critical Limb-threatening Ischemia (CLTI, previously CLI)

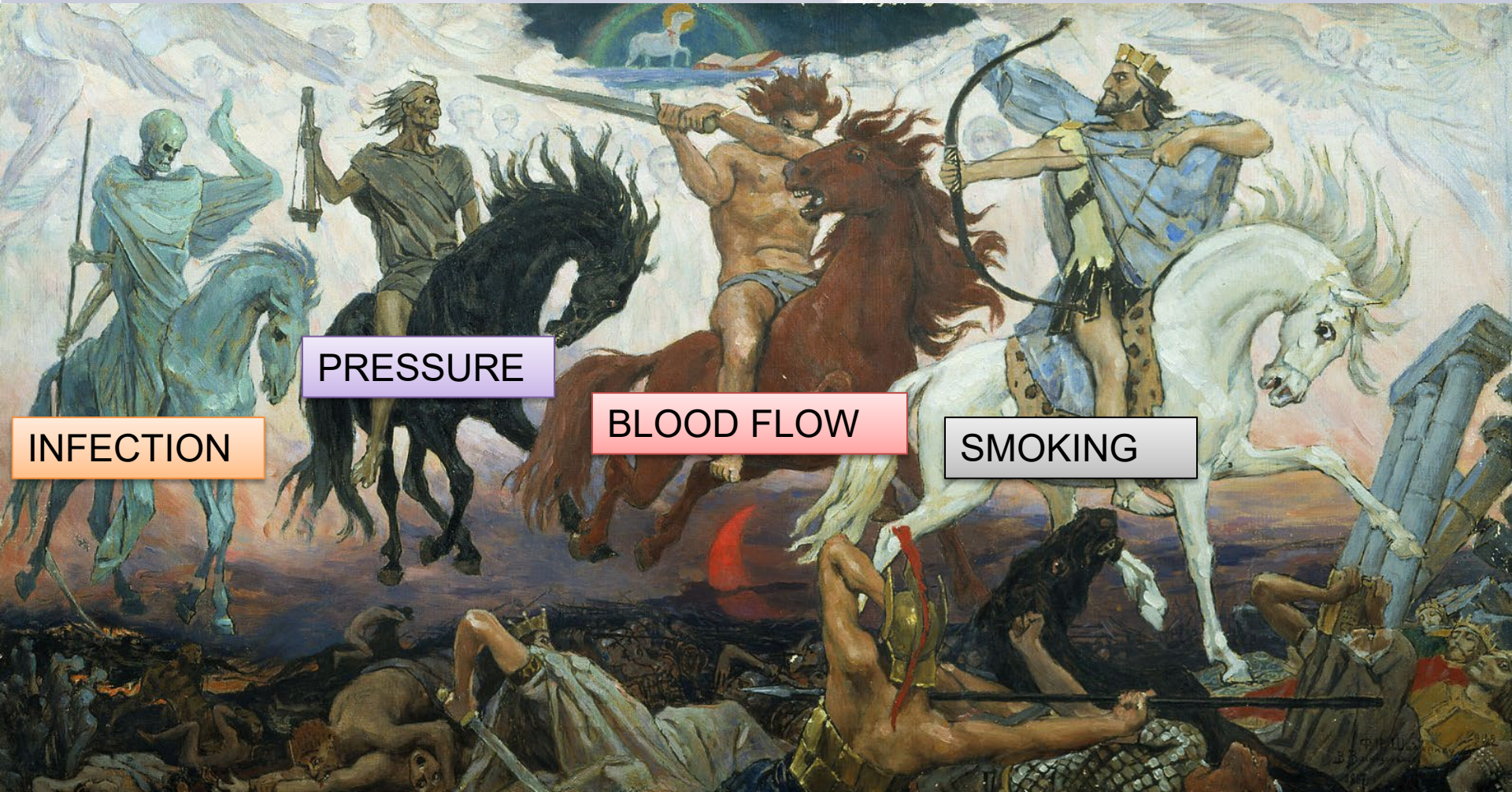


- CLI = rest pain, ulceration, and gangrene
- Threatened limbs = multi-level disease
  - Inflow
  - Outflow



Basic Principles

- Conservative treatment is indicated
  patients who might not tolerate



Four Horsemen of the Apocalypse, an 1887 painting by Viktor Vasnetsov. From left to right are Death, Famine, War, and Conquest

CLI is most often a surgical issue

- Endovascular or open revascularization

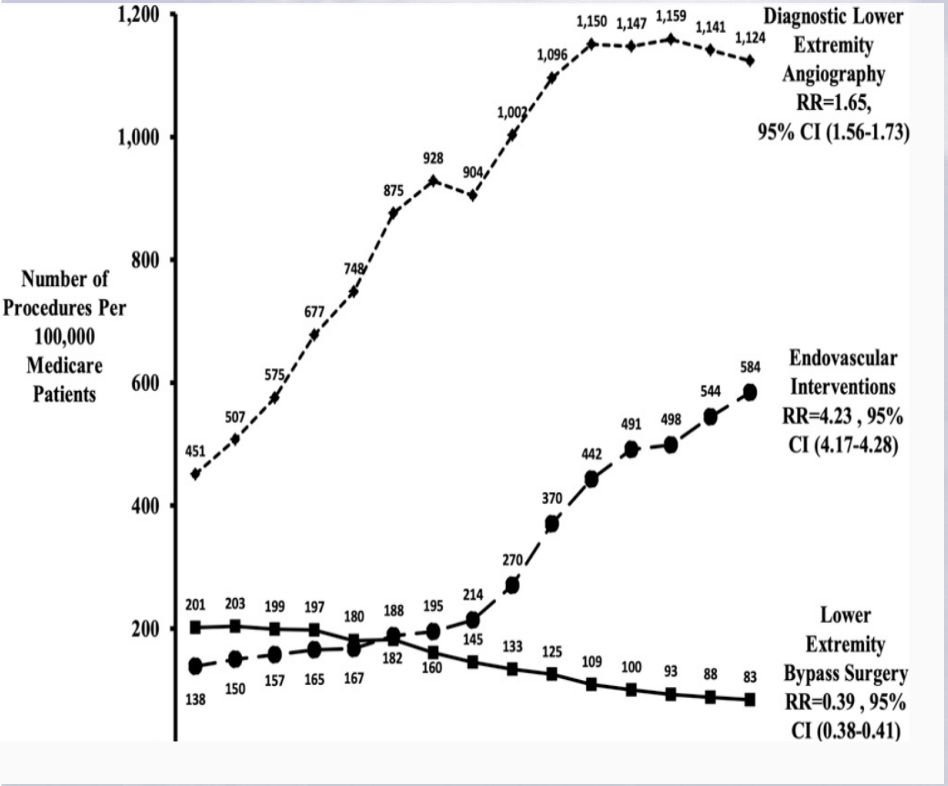
– BASIL (Bypass versus angioplasty in severe ischaemia of the leg, Nov 2005, Lancet)

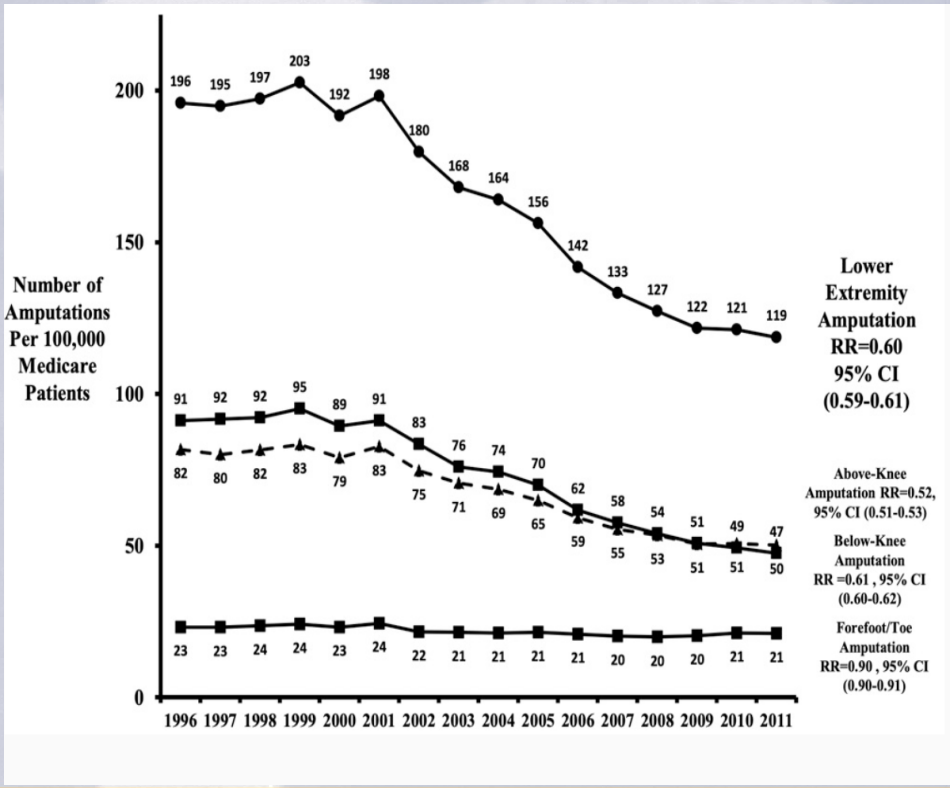
  – In patients presenting with severe limb ischaemia due to infra-inguinal disease and who are suitable for surgery and angioplasty, a bypass-surgery-first and a balloon-angioplasty-first strategy are associated with broadly similar outcomes in terms of amputation-free survival.

– BEST – CLI (Best Endovascular Versus Best Surgical Therapy in Patients With CLTI, Nov 2022)

  - In patients with CLTI in whom both surgical and endovascular interventions were feasible, surgical revascularization with a single-segment GSV conduit was superior to endovascular intervention in reducing major adverse limb events or death, primarily driven by a reduction in MALE.
  - When a GSV conduit was not available, outcomes were similar between surgery and endovascular therapies. Baseline health-related QOL was quite poor in these patients, with greater improvements among patients undergoing endovascular intervention compared with surgery.

CLI is most often a surgical issue





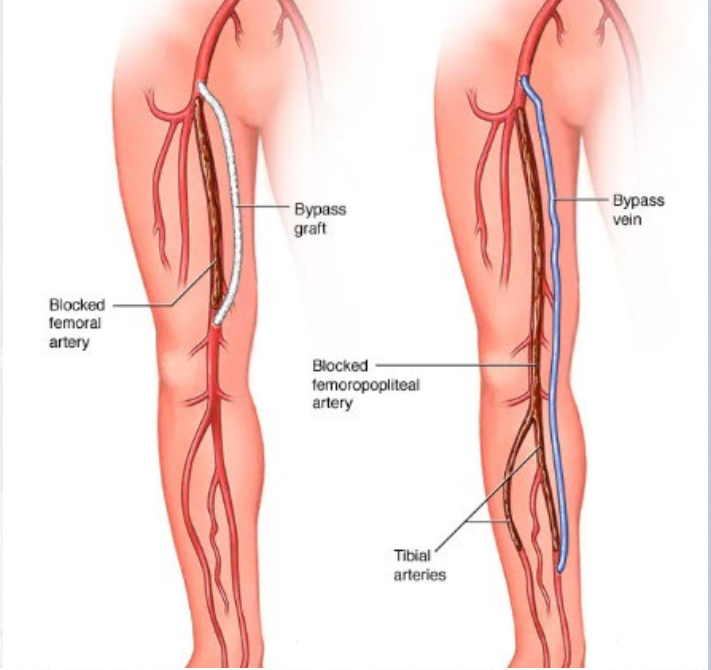
BEST - CLI

- BEST-CLI is the largest head-to-head comparison of endovascular therapy and surgery in people eligible for either treatment, having enrolled 1,830 patients from 150 centers in the United States, Canada, Italy, Finland, and New Zealand. Farber presented the results today in a late-breaking session at the American Heart Association 2022 Scientific Sessions, and they were simultaneously published in the *New England Journal of Medicine*.
    - Patients with chronic limb-threatening ischemia (CLTI) and suitable anatomy, surgery results in fewer major adverse limb events (MALE), major limb interventions, and amputations than endovascular therapy, according to data from the BEST-CLI trial.
    - Quality-of-life (QoL) data from the trial showed trends favoring endovascular therapy, but similar overall improvement for patients who underwent either type of revascularization.
- Farber and colleagues found that in patients who had an adequate single segment great saphenous vein (SSGSV) that could be used for bypass surgery, 42.6% of those treated with surgery and 57.4% treated with endovascular intervention had a primary outcome event ($P < 0.001$), which was a composite of MALE or all-cause death at a median follow-up of 2.7 years.
- In patients who did not have an SSGSV but had an alternative conduit, 42.8% of those treated with surgery had a primary outcome event compared with 47.7% of those in the endovascular group ($P = 0.12$), a nonsignificant difference at a median follow-up of 1.6 years. Those who underwent surgery had 32% fewer major medical events related to CLTI, driven by a 65% reduction in major reinterventions and a 27% reduction in above-ankle amputations. The differences emerged within the first 6 months in favor of surgery, with 42.5% of first reintervention events occurring within 30 days.
- Rates of MACE also were similar between surgical and endovascular groups at 30 days and over the trial's full follow-up

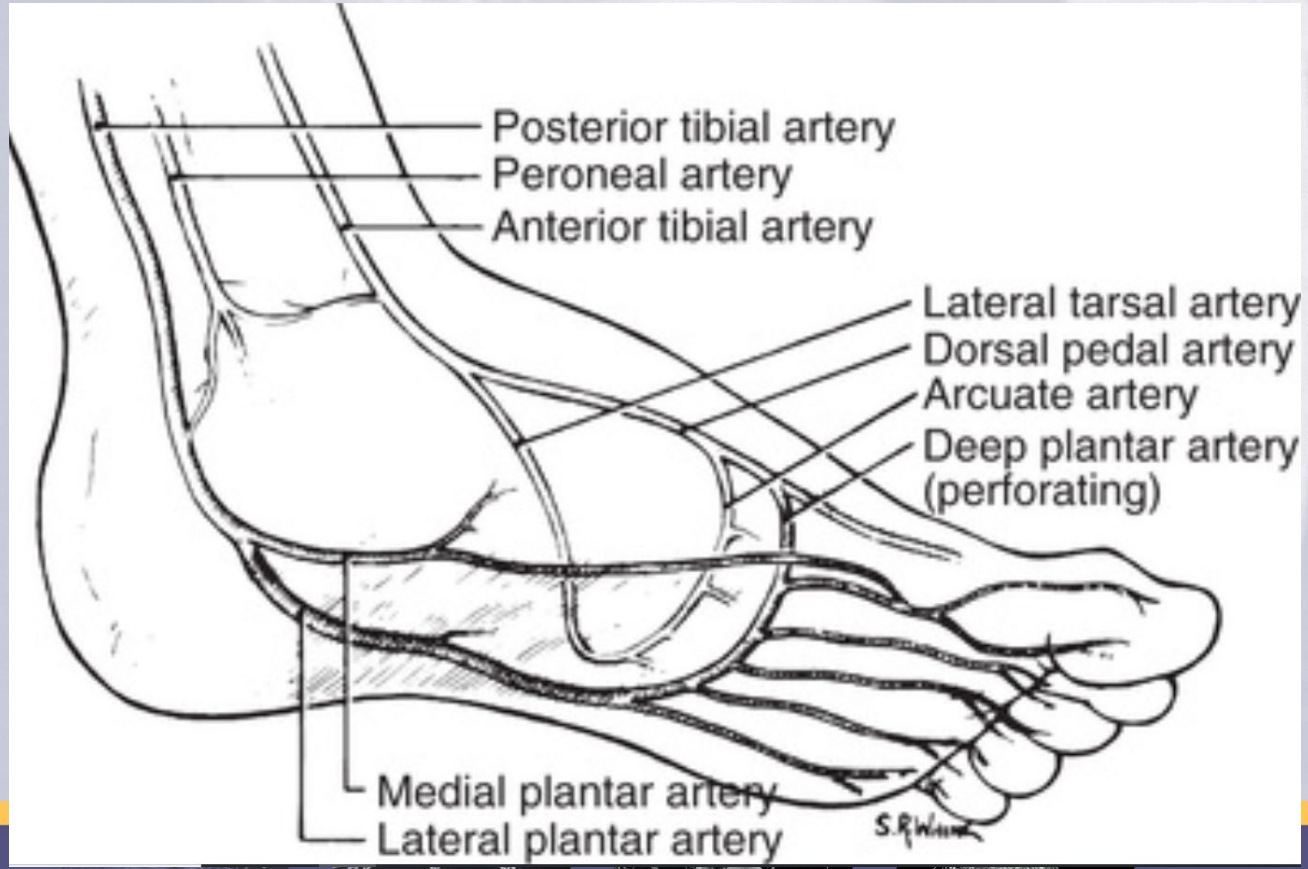
SENTARA®

….. Fem-Pop …..

- Femoral artery to popliteal artery bypass
  - Above knee
  - Below knee
- Femoral artery to tibial/peroneal artery (Fem-distal)
- Patency at 1 and 5 years:
  - Above (SVG) 85-90%, 75-80%
  - Above (PTFE) 80-90%, 50-70%
  - Below (SVG) 86-92%, 70-80%
  - Below (PTFE) 50-75%, 45%
  - Distal (SVG) 82-88%, 60-70%
  - Distal (PTFE) 60-65%, 20-30%

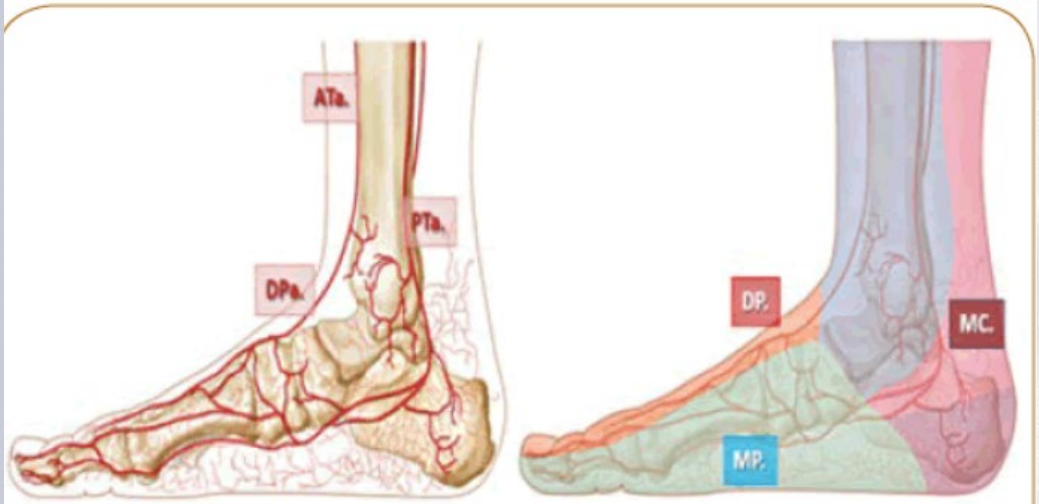


Pedal bypasses (Fem-Far away)



- Diagram showing important pedal arteries. All these named arteries can be used for limb salvage revascularizations.
- (From Ascer E, Veith FJ, Gupta SK: Bypasses to plantar arteries and other tibial branches: an extended approach to limb salvage. J Vasc Surg 8:434–441, 1988.)

Angiosomes



Abbreviations: ATa: Anterior Tibial artery; PTA: Posterior Tibial artery; DPa: Dorsalis Pedis artery; DP: Dorsalis Pedis angiosome (from the Anterior Tibial artery); MP: Medial Plantar angiosome (from the Posterior Tibial artery); MC: Medial Calcaneal angiosome (from the Posterior Tibial artery)

Figure 2 Schematic clinical representation (Medial view) of the main foot arterial trunks (left side), and appended Angiosome territories (right side).

- Bypasses to non-target angiosomes will likely not heal a wound in a different angiosome

Patency/Longevity

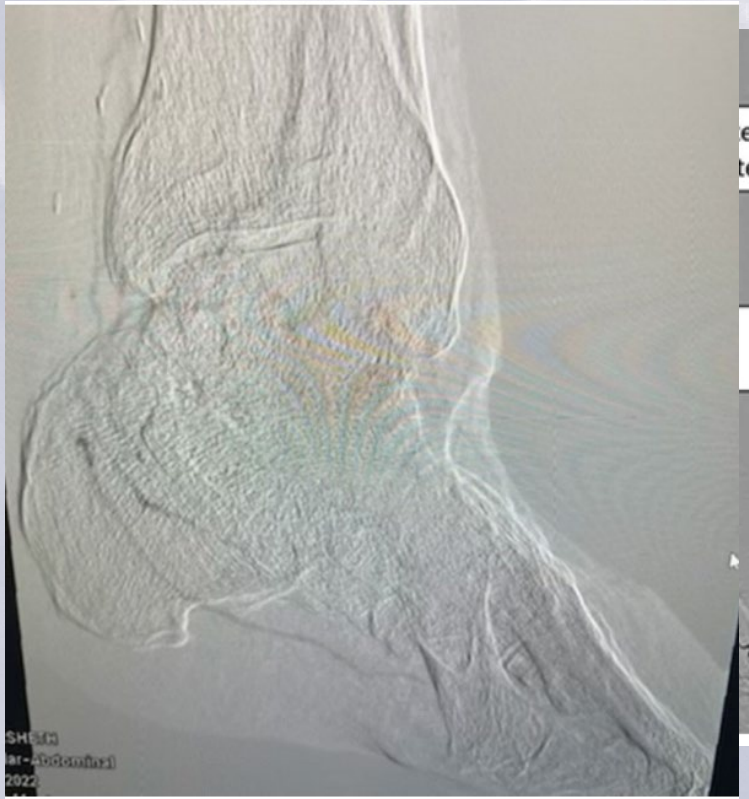
- Inflow → Outflow → Conduit
- Fem-Pop (AK vs BK)
  - AK vein = prosthetic
  - BK vein > prosthetic
- Fem-Distal (tibial/pedal)
  - Longer bypasses, worse patency
- Cryo vein: 30% 1 year patency, HOWEVER limb salvage achieved 70% at 1 year

Multiple Redo Procedures

- Some patients are subject to repetitive failure of lower extremity revascularization procedures, including bypasses.
  - Lipsitz and colleagues43 have recently demonstrated the value of repetitive redo bypasses, performed over several years, in preserving the limb of these patients. They observed that the duration of patency following more than three bypasses was substantial and resulted in more than 3 years of extended limb salvage in more than 50% of the patients who would otherwise have required an amputation.43
  - Repetitive bypasses should be performed only when the patient would otherwise require an immediate major amputation.
- Some believe that patients who have failure of two or more bypasses in the same lower extremity should, if they redevelop critical ischemia, undergo a major amputation.

Desert Foot

- End-stage PAD
  - Diabetic and Renal patients
- “No-Option CLI”
- If there is no distal target, bypass is not technically feasible
- If there is no runoff into the limb trying to be salvaged, revascularization is not feasible
- Deep venous arterialization
  - Mixed results



Fem-Pop……

- What happens next?
- When the limb is no longer FUNCTIONAL
  - Advanced ischemia
  - Gangrene, severe sepsis
  - Non-weight bearing status
  - Severe, intractable pain
  - If the patient is not ambulatory to begin with the first operation should be amputation. Very little value in revascularization.
- It is amputation time.

Conclusion

- All surgical treatment efforts should be used to salvage the threatened foot in elderly, high-risk patients who will not walk well after one major amputation and certainly will not after bilateral amputations.
- Although the surgical methods to save limbs and maintain limb salvage may be time consuming and technically demanding, and although they require a continuing commitment on the part of the vascular surgeon, they are gratifying to those who perform them.
- Reward: Patient is able to maintain an ambulatory life style in the presence of advanced atherosclerosis.
- **Goal: Functional limb**

Summary

- Progressive, life-threatening disease
- If you're going to save that leg, Remember the 4 Horsemen
- In most cases, CLI is a surgical problem
- BEST-CLI: surgical is better than endovascular revascularization in certain circumstances
- Use the vein
- Revascularize the right angiosome to heal the wound
- Goal for the patient is a functional limb
- End-stage PAD, prepare the patient for amputation

References

- Sidawy AN, Perler BA. **Rutherford's vascular surgery and endovascular therapy**. Philadelphia, PA: Elsevier; 2019.
- Farber A, Menard MT, Conte MS, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. *N Engl J Med*. 2022
- Wolfle KD Bruijnen H Loeprecht H et al. Graft patency and clinical outcome of femorodistal arterial reconstruction in diabetic and non-diabetic patients: results of a multi-centre comparative analysis.
- Eur J Vasc Endovasc Surg. 2003; 25: 229-234
- Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45(suppl S):S5–S67.
- Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45(suppl S):S5–S67.
- Lipsitz EC, Veith FJ, Cayne NS, et al. Repetitive bypass and revisions with extensions for limb salvage after multiple previous failures. Vascular. 2013;21:63–68
- Veith FJ, Gupta SK, Wengerter KR, et al. Changing arteriosclerotic disease patterns and management strategies in lower limb threatening ischemia. Ann Surg. 1990;212:402–414.

SENTARA®

- Bypasses to arteries below the popliteal artery should be performed for limb salvage with PTFE grafts in which of the following circumstances?
  - a. When no acceptable autologous vein is present in the involved lower extremity
  - *b. Only when no autologous vein is available in any of the patient's four extremities
  - c. In no circumstances
  - d. Only to the posterior tibial artery
- Which bypass has the best patency?
  - A. femoral to tibial artery with single-segment vein
  - B. femoral to below-knee popliteal artery with graft
  - **C. femoral to above-knee popliteal artery with single-segment vein
  - D. femoral to below-knee popliteal artery with spliced-vein