Surgery is and Remains the Gold Standard for Limb-Threatening Ischemia

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Disclosure

- **None**

What you will do with That ?

?

Definition of Critical Limb Ischemia Rutherford 5

- "Inadequate blood flow to accommodate resting metabolic needs"
- Will result in limb loss unless perfusion is improved
- Includes ischemic rest pain, non-healing ischemic, and gangrene

Introduction

- Peripheral Artery Disease (PAD) is estimated to affect 8 to 10 million Americans
- Critical limb ischemia (CLI) is the most advanced form of PAD, it is associated with a high risk of cardiovascular events, including major limb loss, myocardial infarction, stroke, and death
- The likelihood of death has been reported to be as high as 20% within 6 months of CLI diagnosis and surpasses 50% at 5 years post diagnosis

- *Criqui MH, Langer RD, Fronek A, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med. 1992;326:381–386.*
- *Hirsch AT, Hartman L, Town RJ, Virnig BA. National health care costs of peripheral arterial disease in the Medicare population. Vasc Med. 2008;13:209–215. doi: 10.1177/1358863X08089277.*

Economic Impact

- A study analyzing Medicare data for 2001 $4.37 billion was spent on PAD-related treatment

- In total, PAD-related treatment accounted for approximately 13% of all Medicare Part A and B expenditures for the PAD-treated cohort, and 2.3% of all Medicare Part A and B annual spending
- *Total Medicare expenditure in 2011 was 549.1 B*

- *Hirsch AT, Hartman L, Town RJ, Virnig BA. National health care costs of peripheral arterial disease in the Medicare population. Vasc Med. 2008;13:209–215. doi: 10.1177/1358863X08089277.*

Chronic Lower Extremity Ischemia Classification

Rutherford Category	Clinical Description
0	Asymptomatic
1	Mild claudication
2	Moderate claudication
3	Severe claudication
4	Rest pain
5	Minor tissue loss/non-healing ulcer/focal gangrene
6	Major tissue loss or gangrene, extending above the transmetatarsal level

(Adapted from Rutherford RB, Flanigan DP, et al. Suggested standards for reports dealing with lower extremity ischemia. J Vasc Surg 1986; 4:80–94.)

SVS
Lower Extremity Threatened Limb Classification
WIFI Index

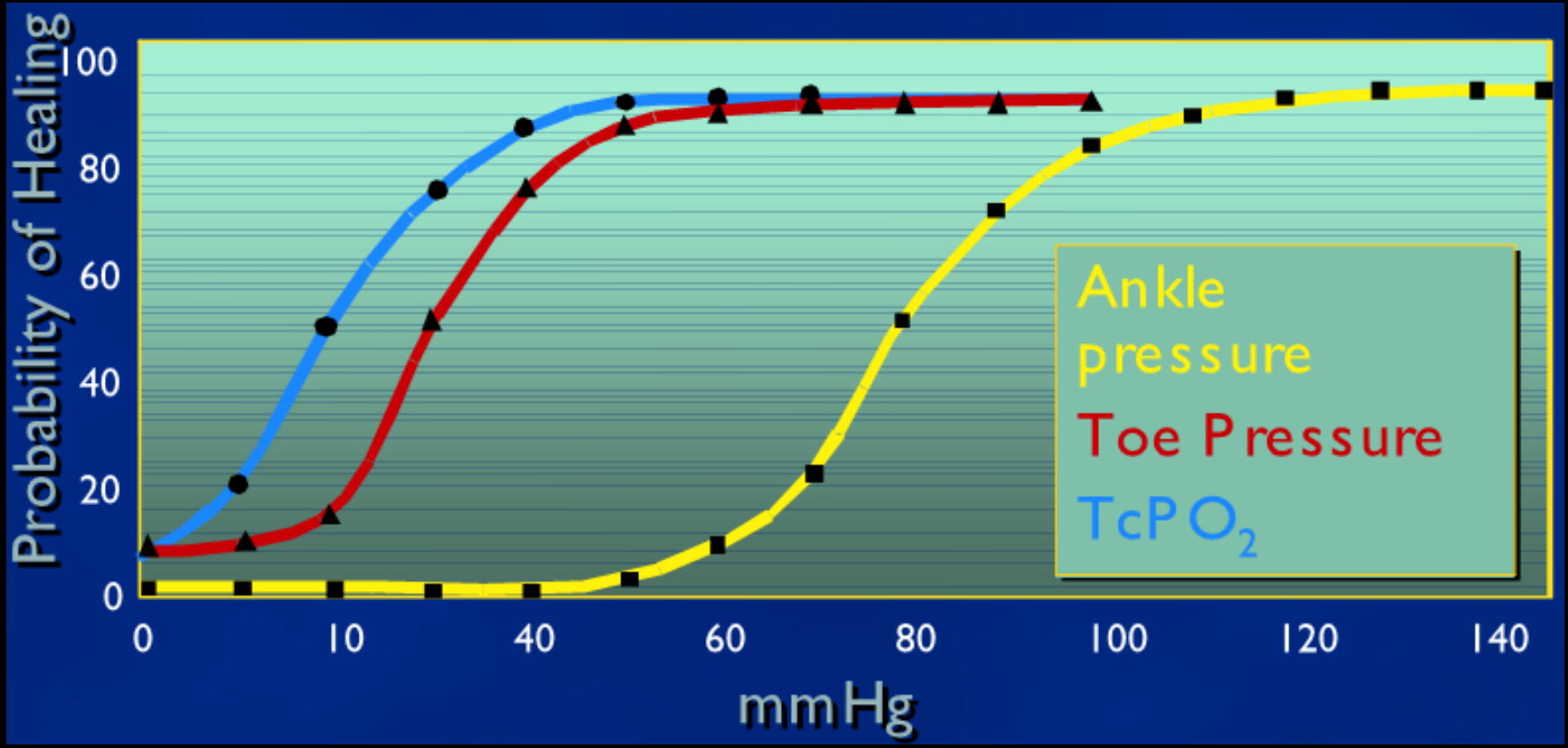
- Wound: extent and depth
- Ischemia: perfusion/flow
- Foot Infection: presence and extent

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

Joseph L. Mills, Sr, MD,[a] Michael S. Conte, MD,[b] David G. Armstrong, DPM, MD, PhD,[a] Frank B. Pomposelli, MD,[c] Andres Schanzer, MD,[d] Anton N. Sidawy, MD, MPH,[e] and George Andros, MD,[f] on behalf of the Society for Vascular Surgery Lower Extremity Guidelines Committee, *Tucson, Ariz; San Francisco and Van Nuys, Calif; Brighton and Worcester, Mass; and Washington, D.C.*

Critical limb ischemia, first defined in 1982, was intended to delineate a subgroup of patients with a threatened lower extremity primarily because of chronic ischemia. It was the intent of the original authors that patients with diabetes be excluded or analyzed separately. The Fontaine and Rutherford Systems have been used to classify risk of amputation and likelihood of benefit from revascularization by subcategorizing patients into two groups: ischemic rest pain and tissue loss. Due to demographic shifts over the last 40 years, especially a dramatic rise in the incidence of diabetes mellitus and rapidly expanding techniques of revascularization, it has become increasingly difficult to perform meaningful outcomes analysis for patients with threatened limbs using these existing classification systems. Particularly in patients with diabetes, limb threat is part of a broad disease spectrum. Perfusion is only one determinant of outcome; wound extent and the presence and severity of infection also greatly impact the threat to a limb. Therefore, the Society for Vascular Surgery Lower Extremity Guidelines Committee undertook the task of creating a new classification of the threatened lower extremity that reflects these important considerations. We term this new framework, the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System. Risk stratification is based on three major factors that impact amputation risk and clinical management: Wound, Ischemia, and foot Infection (WIfI). The implementation of this classification system is intended to permit more meaningful analysis of outcomes for various forms of therapy in this challenging, but heterogeneous population. (J Vasc Surg 2014;59:220-34.)

Hemodynamics and Probability of Healing of a Diabetic Foot Ulcer- No Threshold



Healing unlikely if toe pressure < 55 mmHg, Mills, JVS 2014

Options for Revascularization in CLI

- Endovascular
  - Angioplasty
  - Stent
  - Atherectomy
  - Lysis
- Open surgery
  - Bypass with vein/artery
  - Bypass with prosthetic graft
  - Endarterectomy
- Non-operative
  - Hyperbaric Rx
  - Arterial compression
  - SCS
  - Optimal wound care

Gold Standard & Literature

- The BASIL (Bypass Versus Angioplasty in Severe Ischaemia of the Leg) trial, sponsored by the UK National Institute of Health Research Health Technology Assessment program, is the only randomized controlled trial (RCT) comparing open surgical bypass with endovascular therapy in patients with CLI due to infrainguinal disease

- **Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005;366:1925–1934. doi: 10.1016/S0140-6736(05)67704-5. [PubMed] [Cross Ref]**

BASIL Trial

- Study started in 1999 randomly assigned *452* patients from *27* centers reported an no difference in overall survival or amputation-free survival by intention-to-treat analysis between surgical bypass and endovascular therapy, with surgery being more expensive in the short term .
- However, post hoc analysis demonstrated that beyond 2 years, patients initially assigned to open bypass surgery had a significantly improved amputation-free survival (adjusted HR, 0.37; 95% CI, 0.17–0.77; P = 0.008) and reduced all-cause mortality (adjusted HR, 0.34; 95% CI, 0.17–0.71; P = 0.004) relative to angioplasty [6].

Take Home Point !

Patients presenting with severe limb ischemia 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, and in the short-term, surgery is more expensive than angioplasty

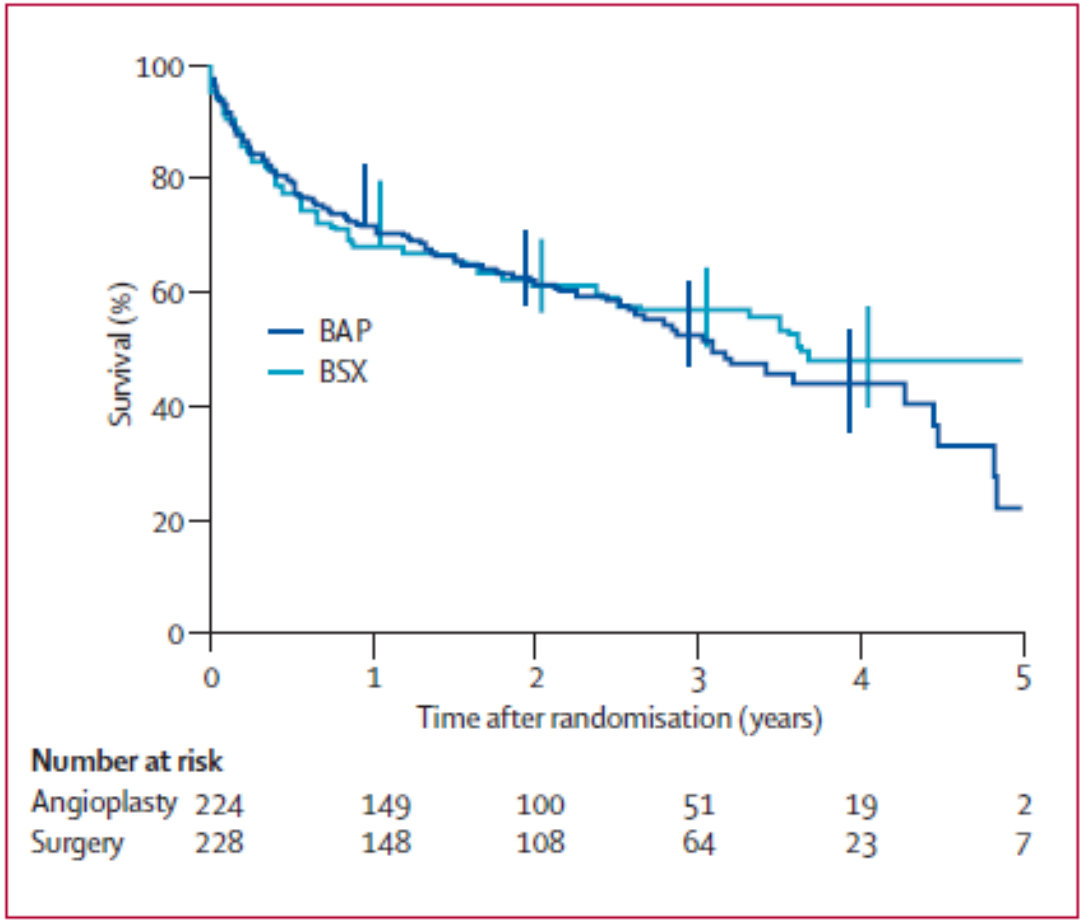


Figure 2: **Amputation-free survival after bypass surgery and balloon angioplasty**
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

Lancet 2005; 366:1925-34

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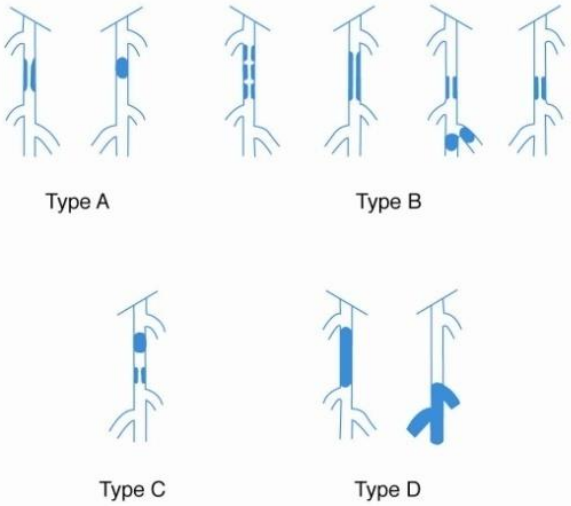
TASC II Guidelines (Only Anatomic!)

- Evidence based
- Stratifies Rx of arterial occlusive disease, based on location (iliac and femoral) and extent of disease
- Increasingly ignored by Cardiologists, IR, and Vascular Surgeons

Journal of Vascular Surgery January 2007



Lesion type	Description
A	Single stenosis ≤10 cm in length *Single occlusion ≤5 cm in length*
B	Multiple lesions (stenoses or occlusions), each ≤5 cm *Single stenosis or occlusion ≤15 cm not involving the infrageniculate popliteal artery* Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass *Heavily calcified occlusion ≤5 cm in length* Single popliteal stenosis
C	Multiple stenoses or occlusions totaling >15 cm with or without heavy calcification *Recurrent stenoses or occlusions that need treatment after two endovascular interventions*
D	Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery) *Chronic total occlusion of popliteal artery and proximal trifurcation vessels*

Debate at 2009 SVS VAM

Should endovascular or open surgery be the initial therapy for TASC D disease of the infrapopliteal arteries?

- Strong arguments made by Meier supporting endovascular first approach, and Conte, supporting open first approach

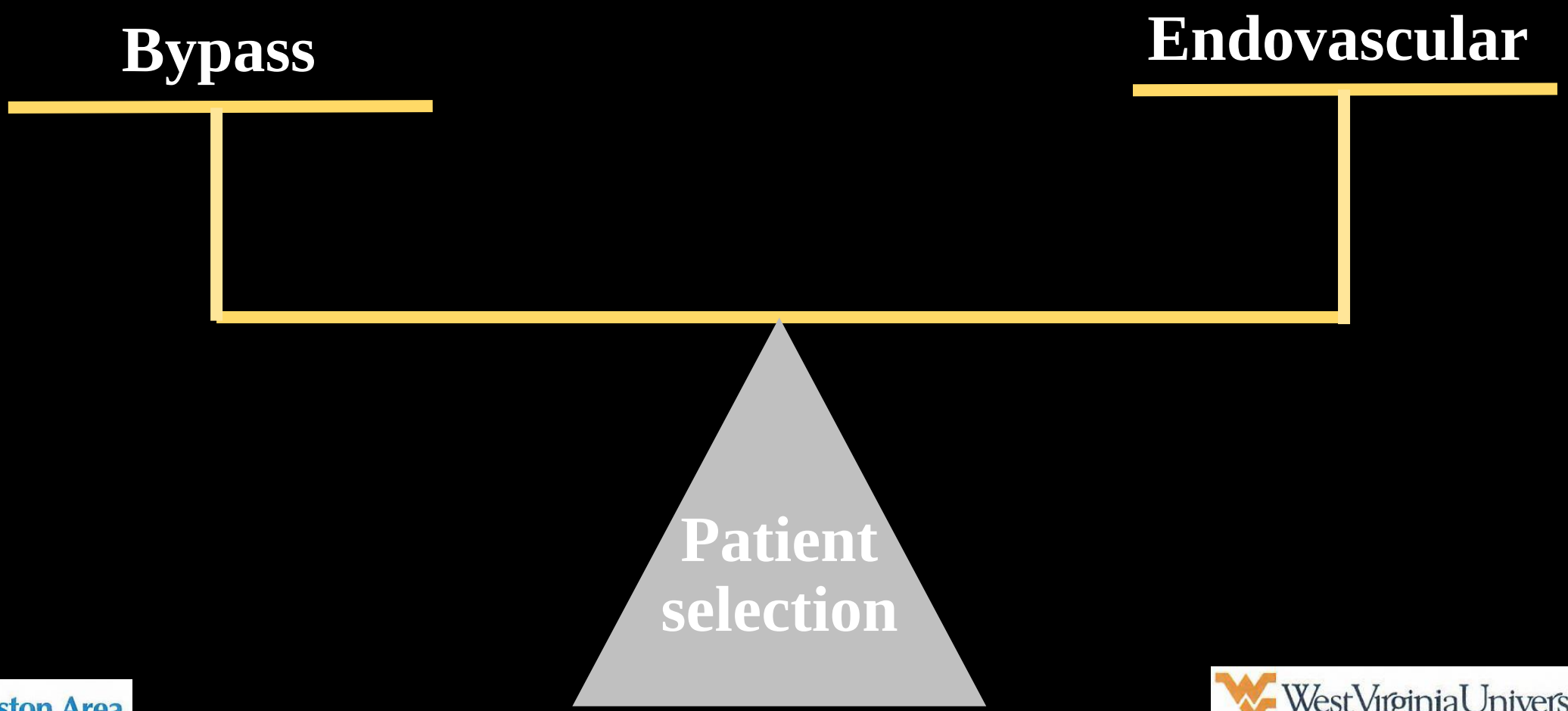
Arguments For "Endo First" Procedures for CLI

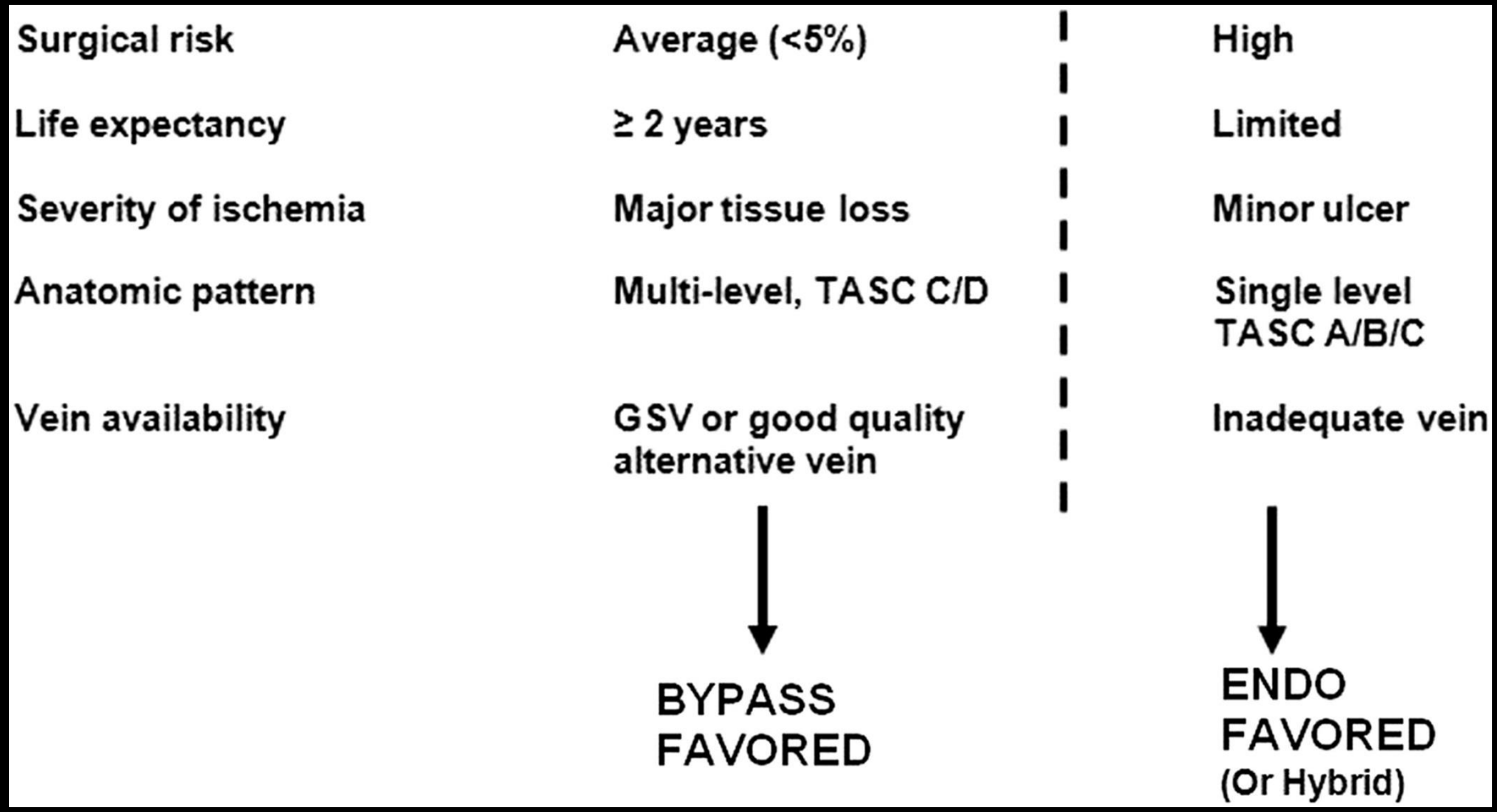
- Better patient acceptance
- Lower initial morbidly and mortality with endo procedures
- Fewer wound complications
- More rapid return to activity in most patients
- "Adequate" improvement in perfusion with endo approach
- Limited life expectancy
- Better reimbursement per hour of work

Arguments for "Open First" Procedure for CLI

- Immediate complete revascularization
  - Greater increase in blood flow to the limb
- More durable than endovascular
- "Minimally invasive" open techniques are no more invasive than endovascular
- Cost is less than with repeated endo procedures
- Long-term survival is the same

When Should Surgery Be Initial Therapy for CLI?

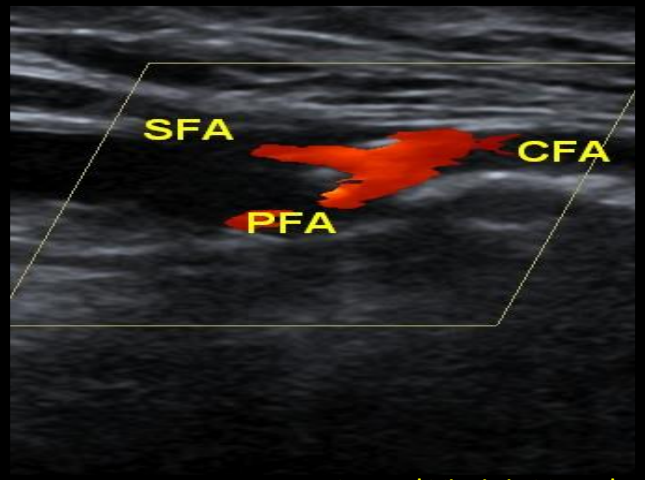


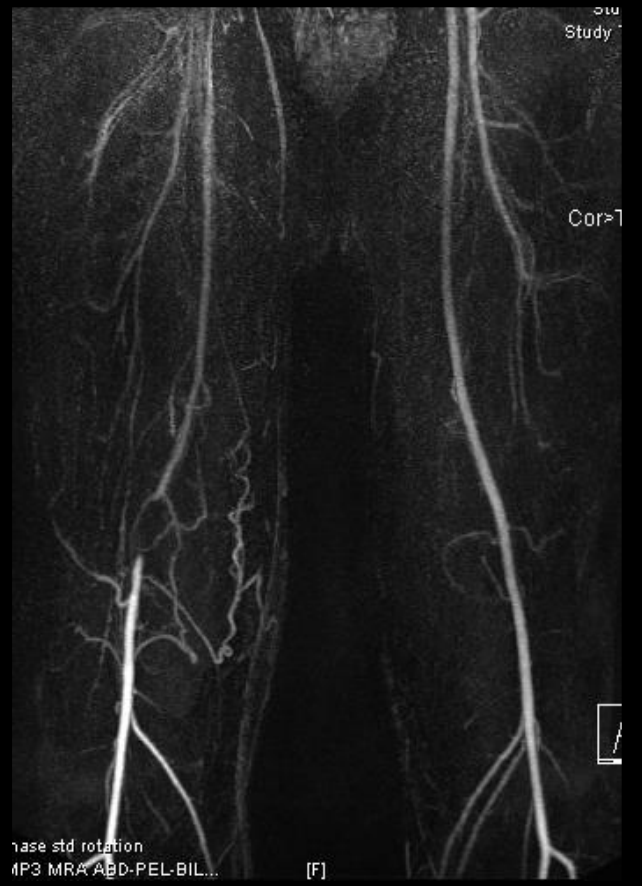


Journal of Vascular Surgery 2013 57, 8S-13SDOI: (10.1016/j.jvs.2012.05.114)

Imaging
Key to Decision Making in CLI

- Duplex arterial ultrasound
  - Localizes disease
  - Requires technical expertise
  - Does not give complete physiologic information
- CT angiogram
- MR angiogram
- Catheter angiogram



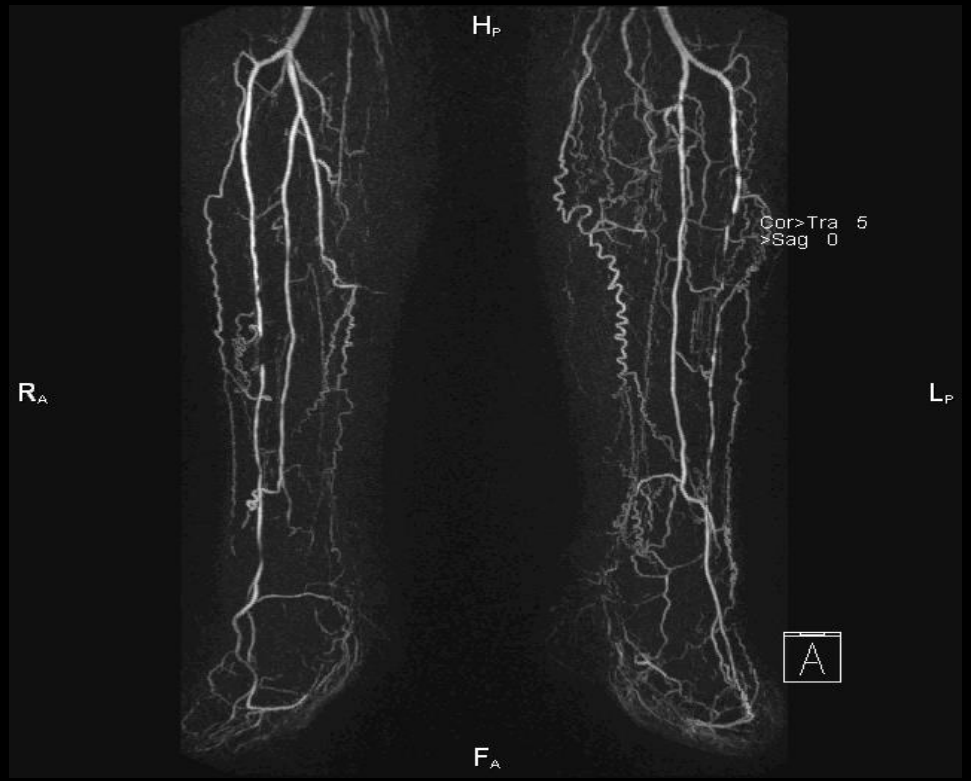


0.3 mmol/kg

0.1 mmol /k

0.2 mmol /kg

Severe Calf disease: 7 ml Gd

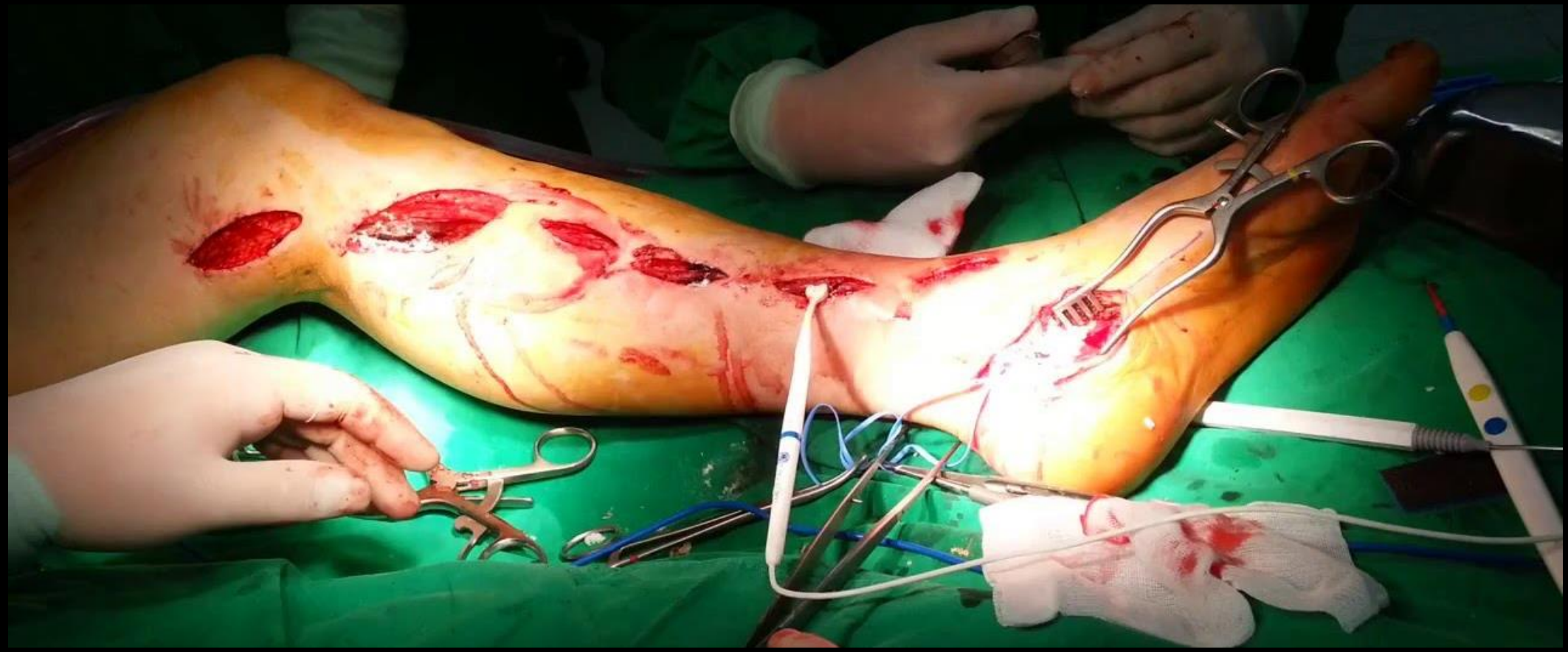


Habibi R, Krishnam MS, Lohan DG, Barkhordarian F, Jalili M, Saleh R, Ruehm S, Finn JP. High-Spatial-Resolution Lower Extremity Magnetic Resonance Angiography at 3.0 Tesla: A Contrast Dose Comparison Study. Radiology; 2008 Aug;248(2):680-92.

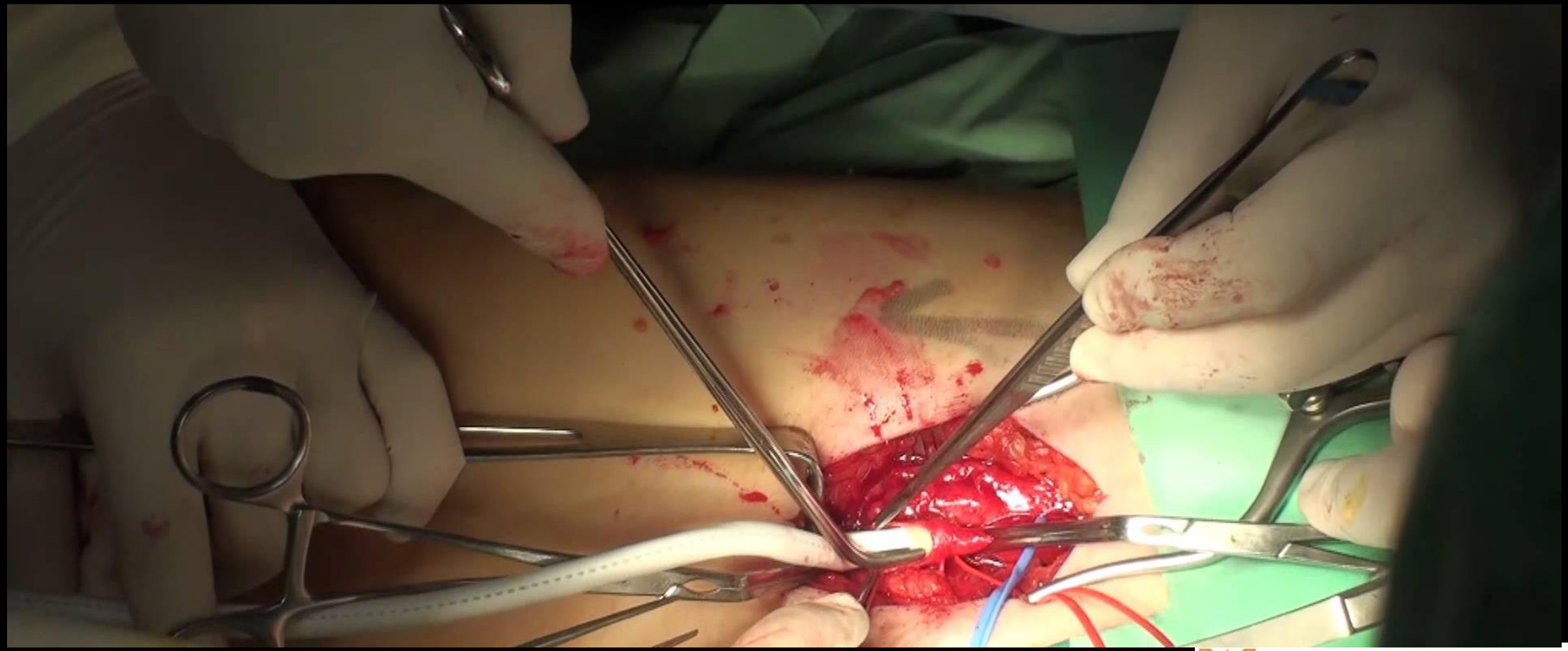
Your options?

- Lower-extremity bypass grafting with or without femoral endarterectomy, with or without adjunctive inflow (aortoiliac) treatment.
- The preferred graft conduit for infrainguinal bypass is autogenous saphenous vein followed by other autogenous venous conduits. Prosthetic or other nonautogenous conduits should be considered significantly inferior secondary choices for infrainguinal bypass in the CLI patient.

Open Intervention



Open Intervention

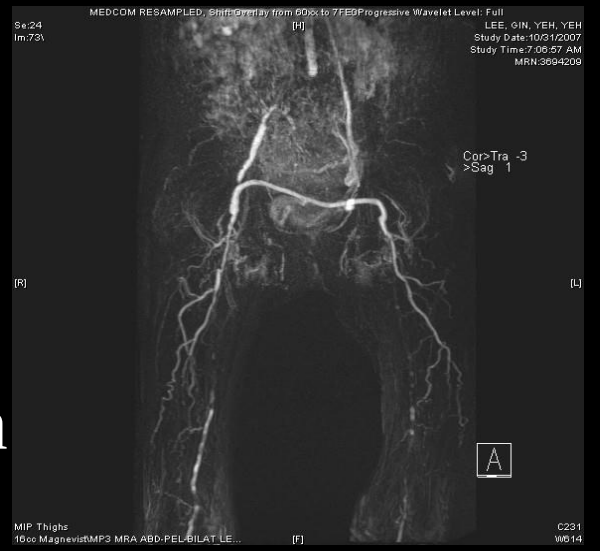


Situations Where Open Surgery Should Be the First Option (Opinion of "Endovascular First" VS)

- Anatomy
  - Extensive disease of the common femoral artery which extends proximally under the inguinal ligament and distally into the profunda femoris artery
  - Long segment occlusions of the infrapopliteal arteries (TASC D)
- Pathology
  - Extrinsic compression of lower extremity arteries
- Physiology
  - Extensive foot sepsis or gangrene
- Durability
  - When combined with another bypass procedure

Situations Where Open Surgery Should Be the First Option (Anatomy)

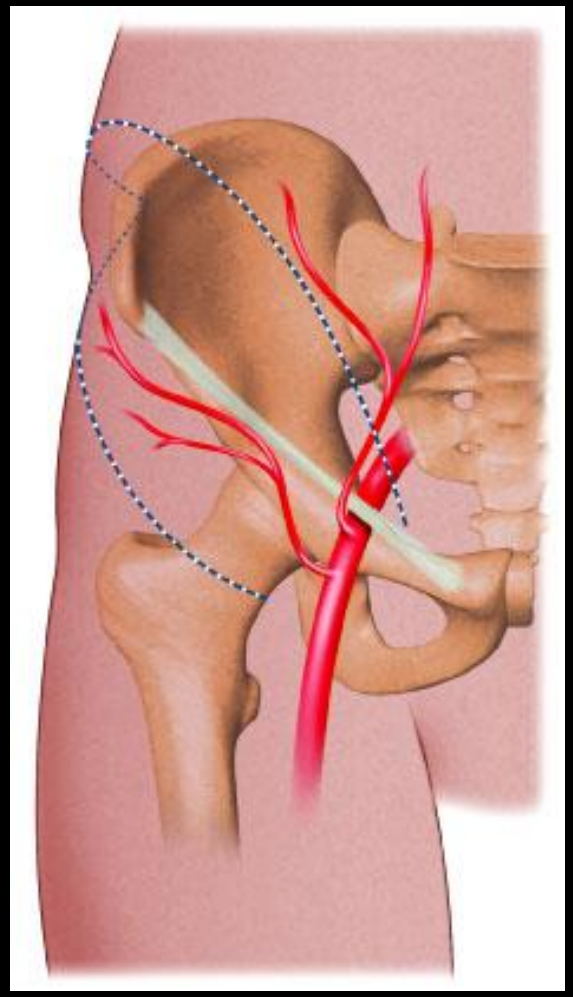
- Extensive disease of the common femoral artery
  - Stents ineffective
    - Calcified vessels difficult to dilate
    - Fracture with inguinal ligament compression
    - Self-expanding have inadequate radial strength
  - Atherectomy channel is too small
- Extensive disease of the infrapopliteal arteries
  - Restenosis rate high with endo
  - Difficult to establish durable pulsatile flow to the foot

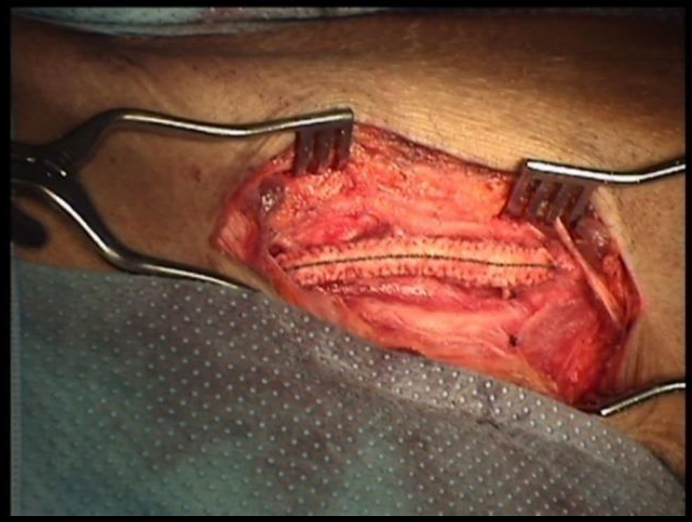


Lawrence, et al; Eur J Vasc Surg 2010

Femoral Endarterectomy

- Simple anatomic procedure
- Low risk
- Anesthesia with local or regional





Open Surgery :

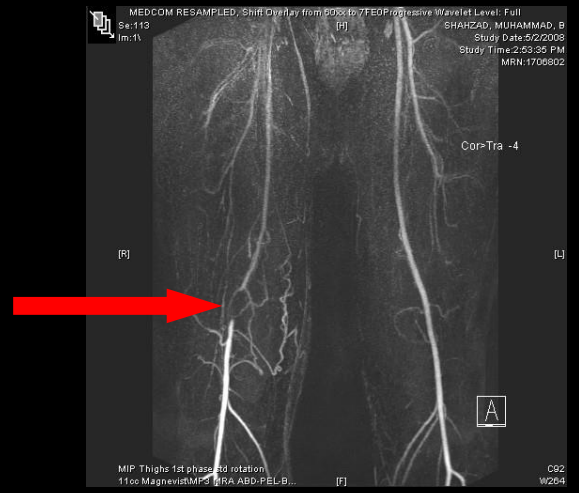
- Inflow or outflow reconstruction is of primary importance for the long-term fate of the limb in CLI patients.

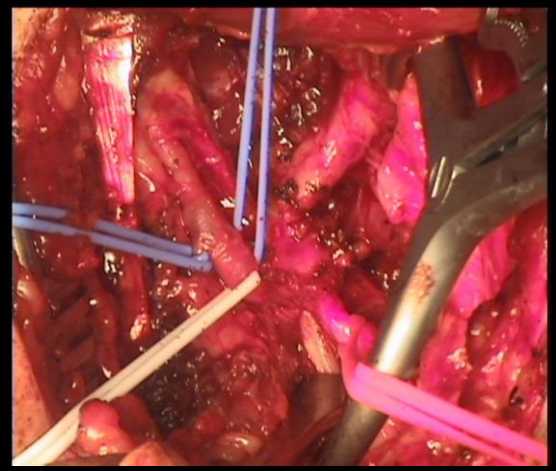
- A recent meta-analysis in patients with CLI undergoing infrainguinal bypass demonstrated 5-year primary patency, secondary patency, and limb salvage rates of 63%, 71%, and 78%, respectively

- *Schanzer A, Hevelone N, Owens CD, et al. Technical factors affecting autogenous vein graft failure: observations from a large multicenter trial. J Vasc Surg. 2007;46:1180–1190. doi: 10.1016/j.jvs.2007.08.033.*

Situations Where Open Surgery Should Be the First Option Pathology

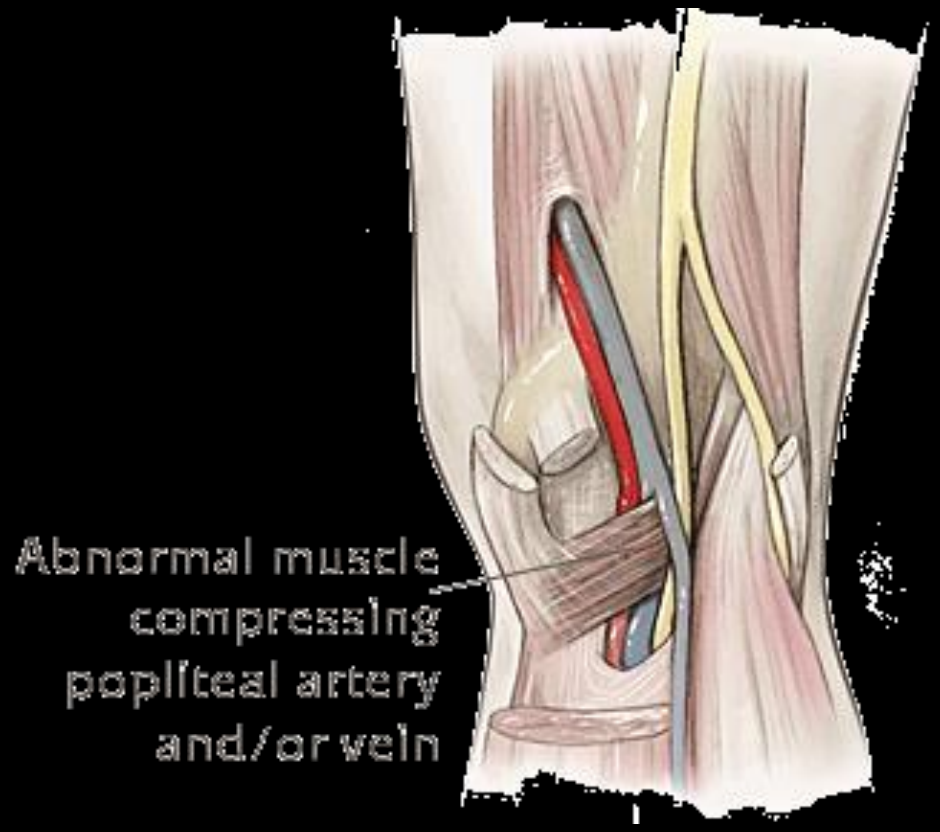
- Extrinsic compression
  - Popliteal entrapment
  - Adventitial cystic disease
  - Bony abnormalities (e.g. exostosis)

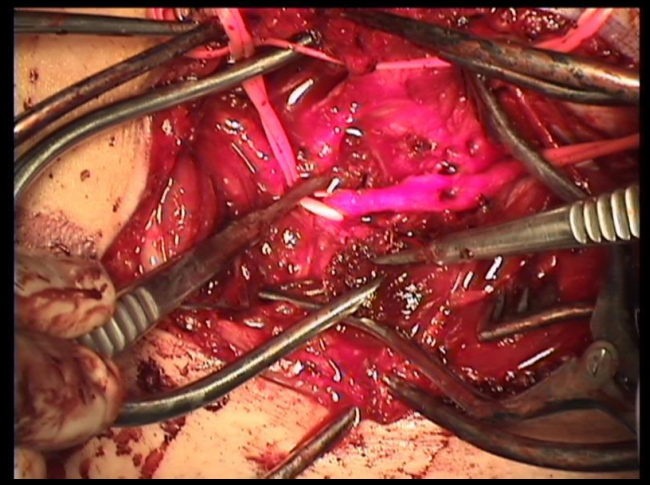


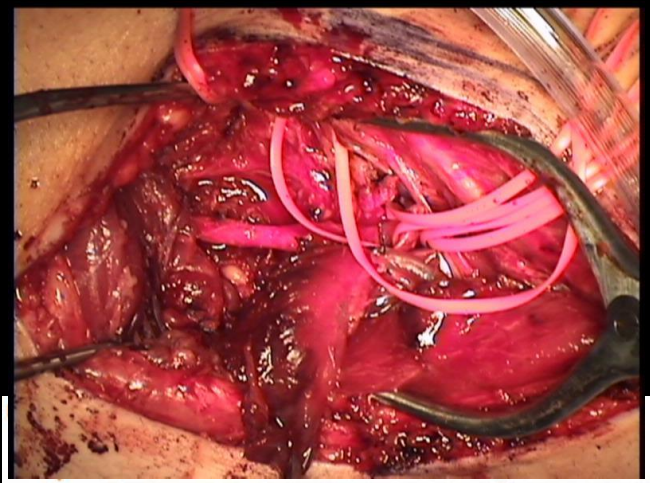


Popliteal Entrapment

- Posterior Approach to popliteal artery
- Division of aberrant muscle
- Release of artery or bypass

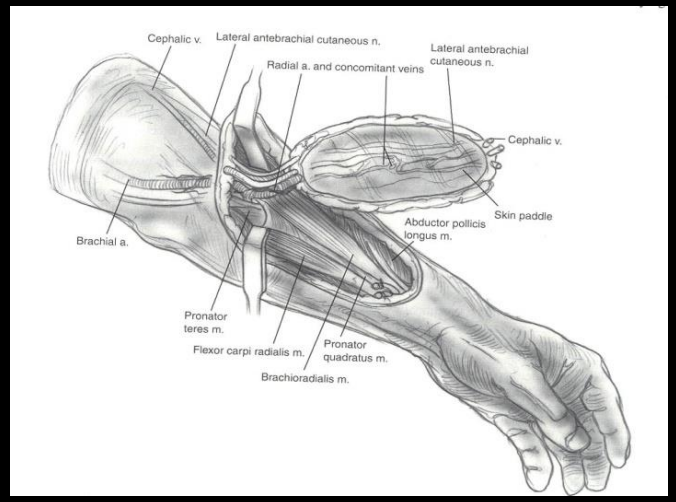






Situations Where Open Surgery Should Be the First Option (Durability)

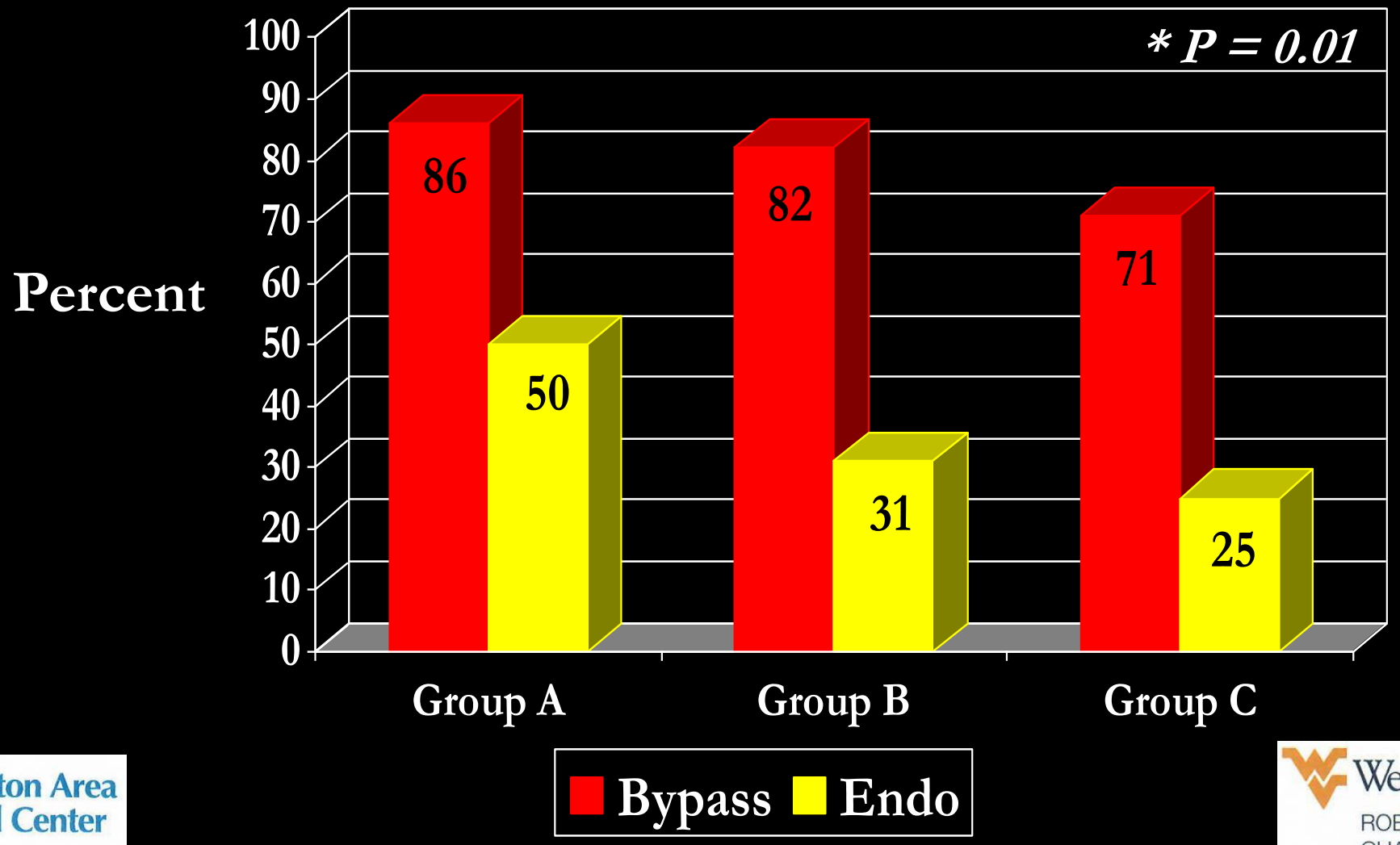
- Patients undergoing free tissue transfer
  - Need combination of durable bypass and tissue transfer
- Young patients with longer life expectancy
  - Unwilling to undergo multiple procedures for the same pathology
  - Infrapopliteal disease (extensive) in a young patient



Situations Where Open Surgery Should Be the First Option (Physiology)

- Diabetic patients with:
  - Extensive tissue loss
  - Forefoot sepsis
  - Extensive forefoot gangrene
- Need immediate and maximum blood flow to foot- “pulsatile blood flow”

Degree of complete healing
Type of Revascularization vs. Initial Size Wound



R Neville , et al Georgetown Diabetic Foot Center

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General Recommendations:

- CLI patients predicted to live more than 2 years, and with a useable vein, should usually have bypass surgery first. This is because the long term results of saphenous vein bypass surgery are good, the rate of balloon angioplasty failure is high, and the results of bypass surgery after failed balloon angioplasty are significantly worse than for bypass surgery.
- However, patients expected to live less than 2 years, and those without a useable vein, should usually have balloon angioplasty first as they will not survive to reap the longer term benefits of surgery and the results of prosthetic bypass surgery are poor" [8]

My Recommendations:

- Tx decisions in CLI are individualized, based on life expectancy, functional status, anatomy of the arterial occlusive disease, and surgical risk.

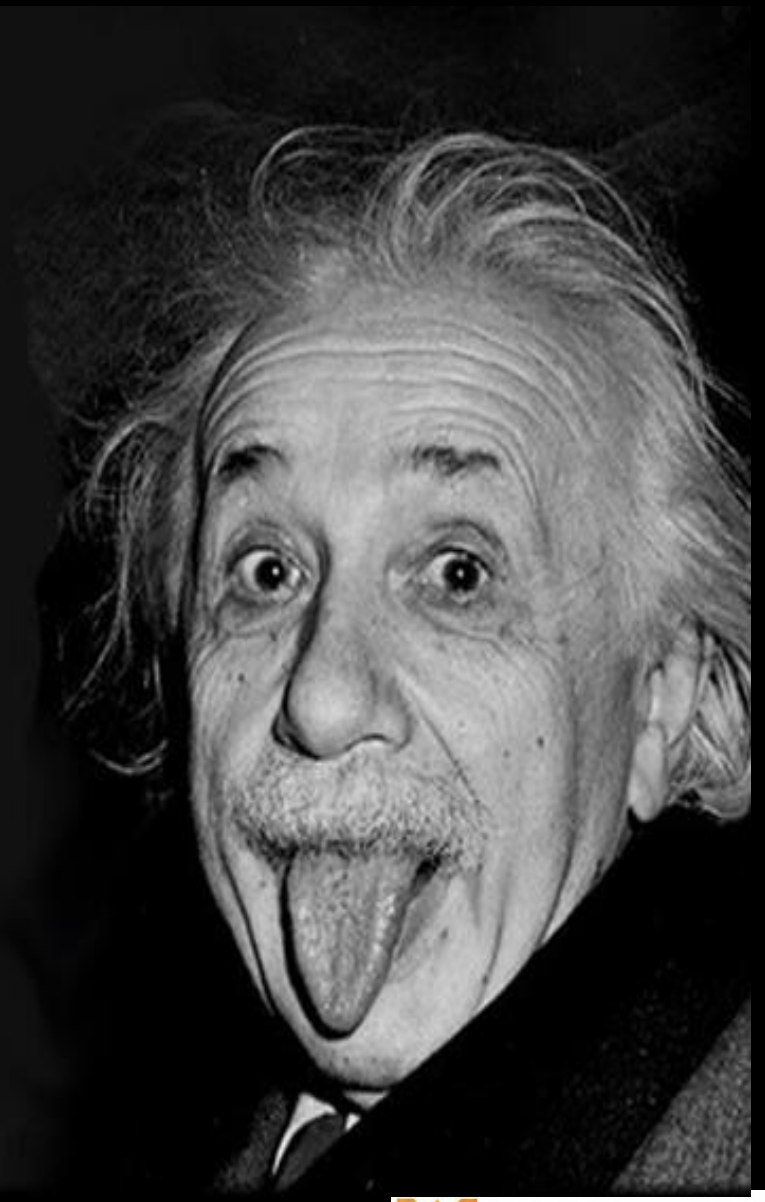
- For infrainguinal disease, the available data suggest that ***surgical bypass with vein*** is the preferred therapy for CLI patients likely to survive ***≥ 2 years***, and for those with long segment occlusions or severe infrapopliteal disease who have and acceptable surgical risk

Conclusions

- In spite of current practice guidelines, most patients undergo an “endo first’ approach for CLI
- Imaging with MRA and/or CTA is critical in determining the extent of disease
- CLI patients must be stratified; there are four situations in which an open first approach is preferable:
  - Common femoral and extensive infra-popliteal disease
  - Extrinsic compression
  - Young patients who need durability
  - Extensive tissue loss and sepsis (e.g. ischemic, septic diabetic foot)

ONLY TWO THINGS ARE INFINITE, THE UNIVERSE AND HUMAN STUPIDITY, AND I'M NOT SURE ABOUT THE FORMER.

~ALBERT EINSTEIN



Vascular Center of Excellence

Thank You

Annual Virginia Vascular Symposium