2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 20-22

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PAD should be managed with an open surgery first approach

Emily Reardon, MD

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PAD should be managed with an open surgery first approach *in selective patients*

Open surgery vs endovascular

From the New England Society for Vascular Surgery

National trends in lower extremity bypass surgery, endovascular interventions, and major amputations

Philip P. Goodney, MD, MS,[a,b,c] Adam W. Beck, MD,[a] Jan Nagle, MS, RPh,[d] H. Gilbert Welch, MD, MPH,[b,c] and Robert M. Zwolak, MD, PhD,[a] *Lebanon and Hanover, NH; White River Junction, Vt; and Chicago, Ill*

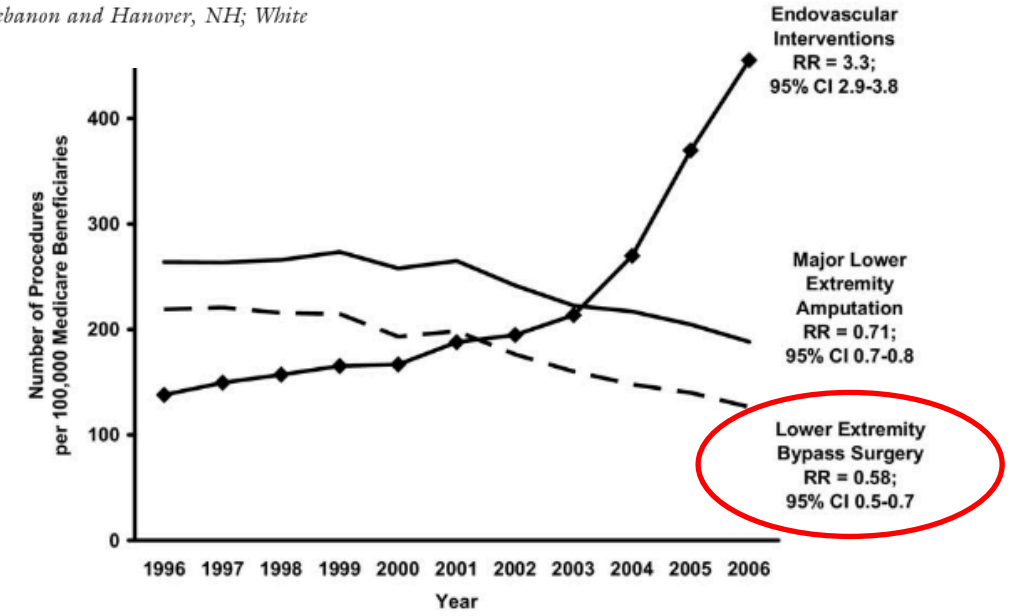


Fig 1. Trends in endovascular interventions, major amputation, and lower extremity bypass surgery, 1996-2006. *RR*, Risk ratio; *CI*, confidence interval.

Open surgery vs endovascular

Limited Level 1 Data

Problems with the literature

- Heterogenous population
  - Patient risk
  - Symptoms
  - Anatomy
  - Technique
- Variable outcomes
  - Endo lesion-centric

Design and Rationale of the Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischemia (BEST-CLI) Trial

Matthew T. Menard, MD; Alik Farber, MD; Susan F. Assmann, PhD; Niteesh K. Choudhry, MD, PhD; Michael S. Conte, MD; Mark A. Creager, MD; Michael D. Dake, MD; Michael R. Jaff Kaufman, MD; Richard J. Powell, MD; Diane M. Reid, MD; Flora Sandra Siami, MPI Sopko, MD; Christopher J. White, MD; Kenneth Rosenfield, MD

Background— Critical limb ischemia (CLI) is increasing in prevalence, and remains source of mortality and limb loss. The decision to recommend surgical or revascularization for patients who are candidates for both varies significantly among p driven more by individual preference than scientific evidence.

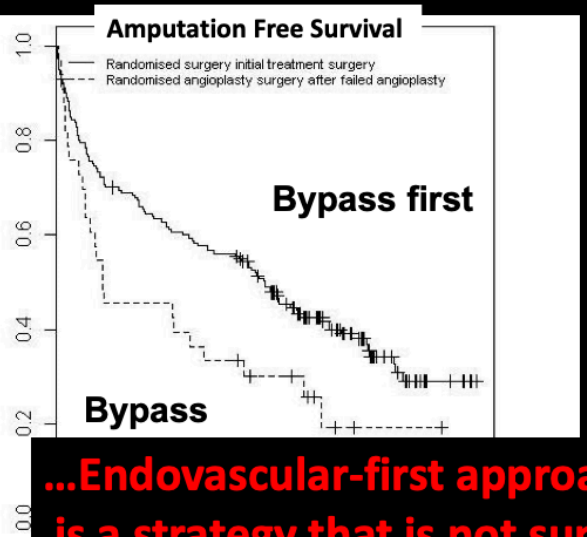
Methods and Results— The Best Endovascular Versus Best Surgical Therapy for Patie Critical Limb Ischemia (BEST-CLI) Trial is a prospective, randomized, multidisciplinary, co superiority trial designed to compare treatment efficacy, functional outcomes, quality of life, in patients undergoing best endovascular or best open surgical revascularization. Approxima clinical sites in the United States and Canada will enroll 2100 patients with CLI who are ca for both treatment options. A pragmatic trial design requires consensus on patient eligibil least 2 investigators, but leaves the choice of specific procedural strategy within the a revascularization approach to the individual treating investigator. Patients with suitable segment of saphenous vein available for potential bypass will be randomized within C (n=1620), while patients without will be randomized within Cohort 2 (n=480). The primary end point of the trial is Major Adverse Limb Event–Free Survival. Key secondary end points Re-intervention and Amputation-Free-Survival and Amputation Free-Survival.

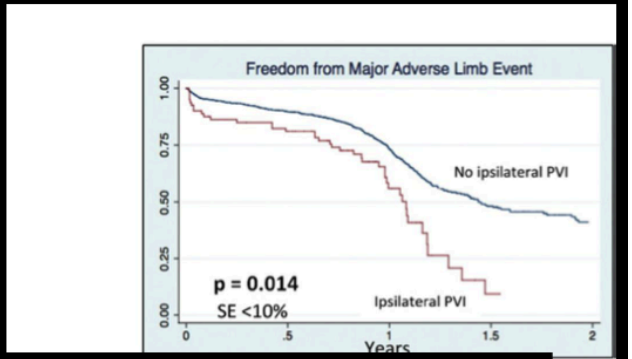
Conclusions— The BEST-CLI trial is the first randomized controlled trial comparing endovascular therapy to open surgical bypass in patients with CLI to be carried out in North America. This landmark comparative effectiveness trial aims to provide Level I data to clarify the appropriate role for both treatment strategies and help define an evidence-based standard of care for this challenging patient population.

"The decision to recommend surgical or endovascular revascularization for patients who are candidates for both varies significantly among providers and is driven more by individual preference than scientific evidence".

2016

Bypass after "endofailure" is significantly less successful than primary bypass





…Endovascular-first approach in all patients with CLI is a strategy that is not supported by good science...

42
1

Bradbury A. J Vasc Surg 2010; 51(5 Suppl)5S-17S

Nolan BW. J Vasc Surg 2011; 54:730-6

BEST-CLI Study Design: Two Parallel Trials

Patients with CLTI due to infrainguinal PAD
- not at excessive risk for surgery
- eligible for open and endo

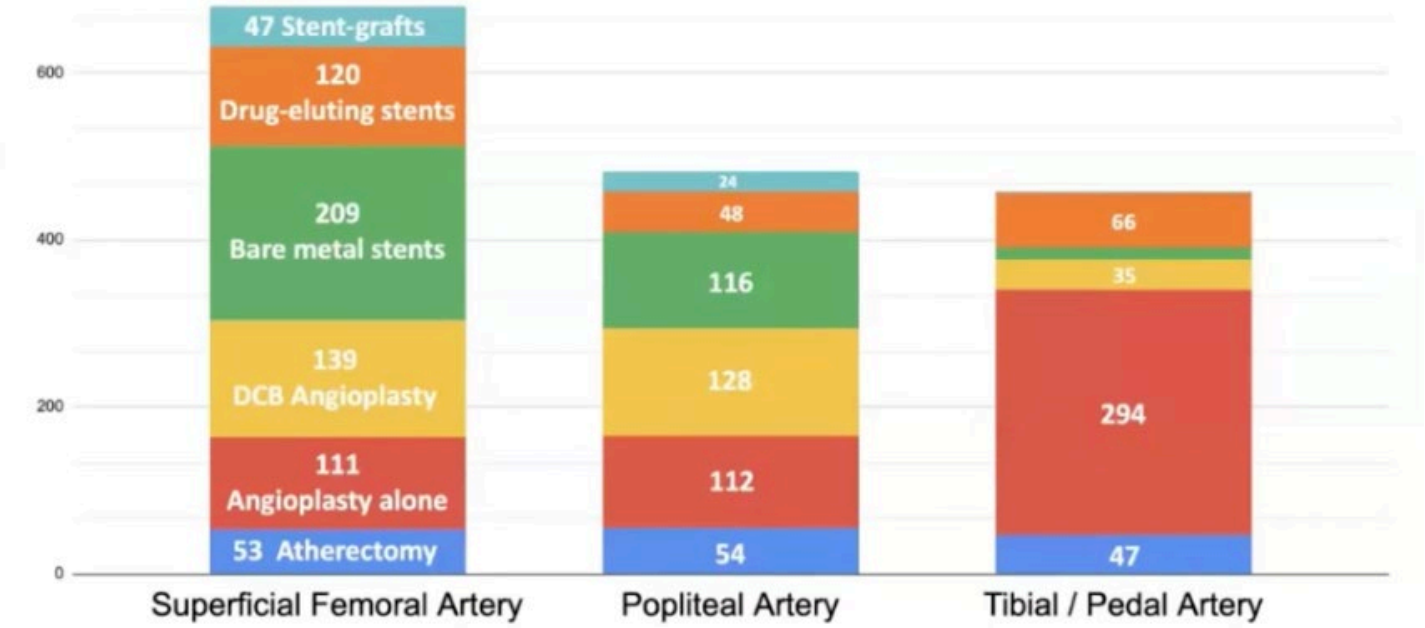
- Duplex of GSV
- Imaging of index leg arteries
- Review by open and endo credentialed investigators

Cohort # 1 SSGSV → **Stratification** → 1:1 → **Endovascular** / **Surgical**

Cohort # 2 Alternative Conduit → **Stratification** → 1:1 → **Endovascular** / **Surgical**

Strata: Ischemic Rest Pain Alone vs. Tissue Loss
Significant Tibial Occlusive Disease vs. No Tibial Occlusive Disease

Endovascular Interventions



Farber 2022

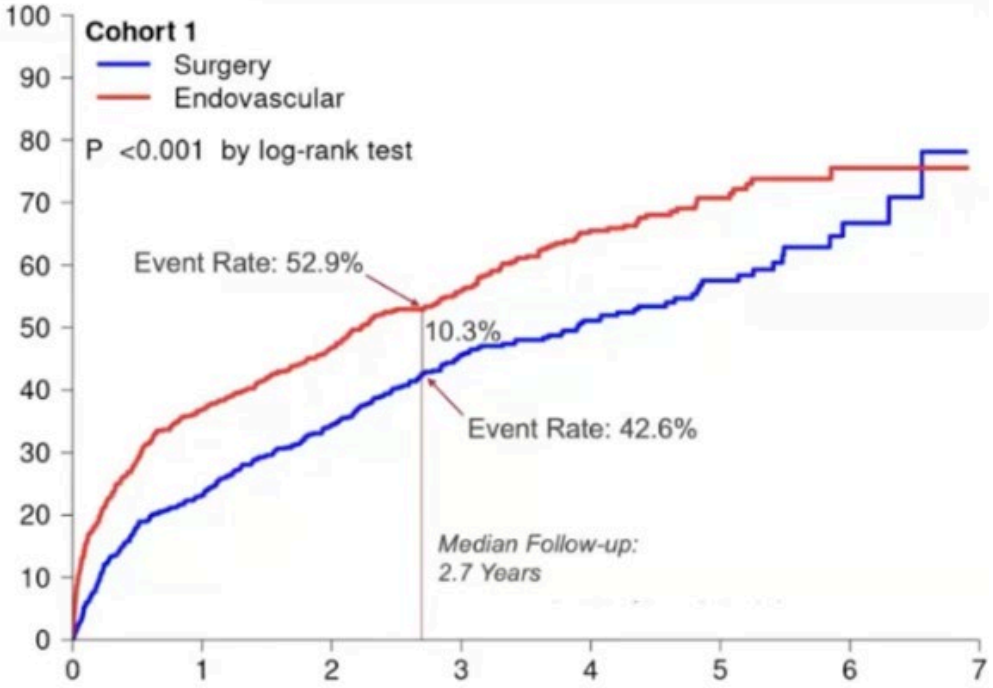
BEST-CLI

Primary Endpoint, and Components of the Primary Endpoint - Cohort 1

	Surgery (n=709)		Endovascular (n=711)		HR (95%CI)	P-value
Primary						
MALE or all cause death	302	42.6%	408	57.4%	**0.68 (0.59,0.79)**	<0.001
Secondary						
Major Reintervention on the Index Limb	65	9.2%	167	23.5%	**0.35 (0.27,0.47)**	<0.001
Above-ankle amputation of the index limb	74	10.4%	106	14.9%	**0.73 (0.54,0.98)**	0.04
All cause death	234	33.0%	267	37.6%	**0.98 (0.82,1.17)**	0.81

Primary Endpoint

MALE (Major Re-intervention, or Above-Ankle Amputation) or All-cause Death (%)

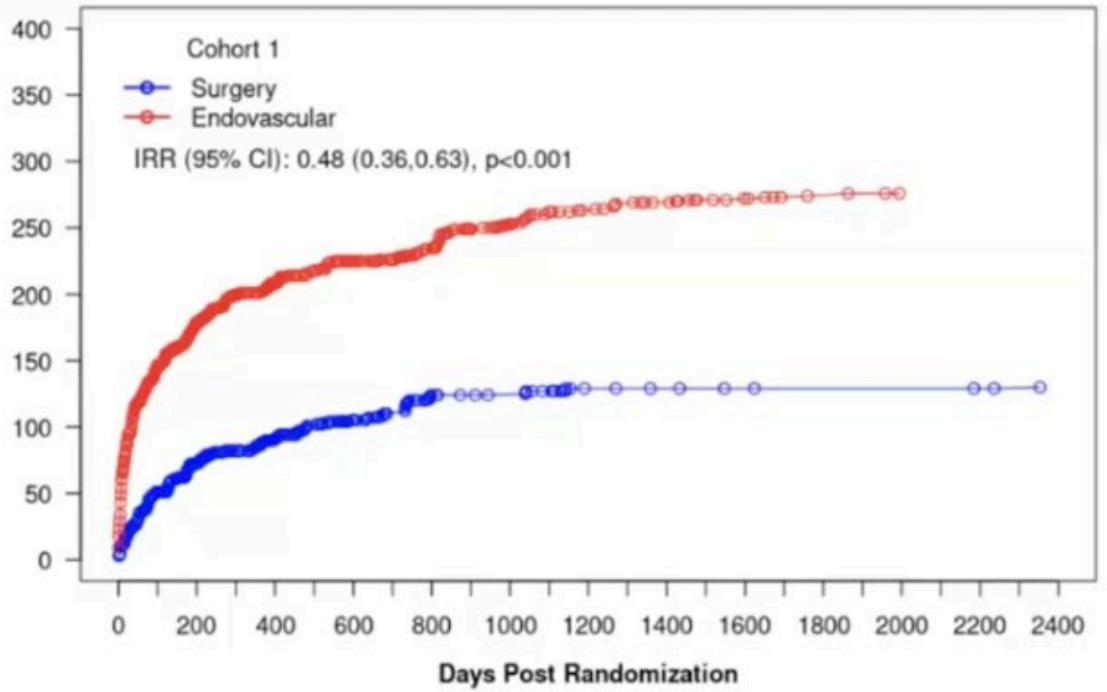


BEST-CLI

No. at Risk								
Surg.	718	463	349	204	117	52	12	0
Endo.	716	404	304	175	102	46	14	0

Secondary Endpoint

Total Number of Major Re-interventions



BEST-CLI

IRR: Incidence Rate Ratio

Conclusions

- In CLTI, both surgical and endovascular revascularization are effective and safe
- Bypass with **adequate saphenous vein** is a more effective strategy for patients deemed suitable for both open and endovascular approaches
- Patients who are candidates for limb salvage should undergo an evaluation of surgical risk and conduit availability
- Bypass with adequate saphenous vein should be offered as a first line treatment option for suitable candidates with CLTI, as part of fully informed, shared decision-making
- Level 1 evidence from BEST-CLI does not support an "endovascular-first" approach to all patients with CLTI
- BEST-CLI supports a complementary role for open and endovascular revascularization strategies and highlights need for expertise in both for optimal care of these patients

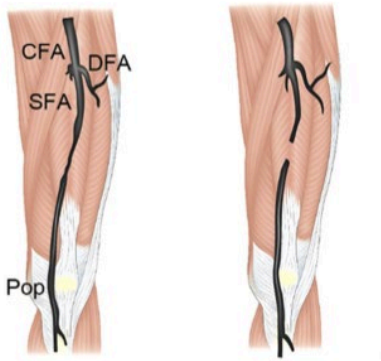
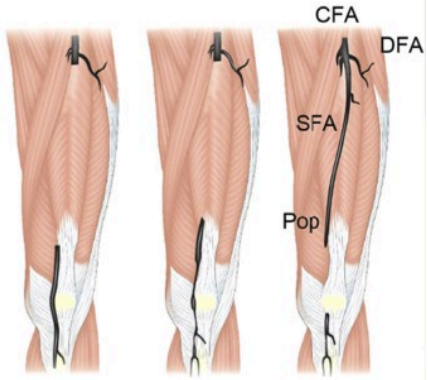
NCCN National Comprehensive Cancer Network®

JVS Journal of Vascular Surgery SVS Society for Vascular Surgery

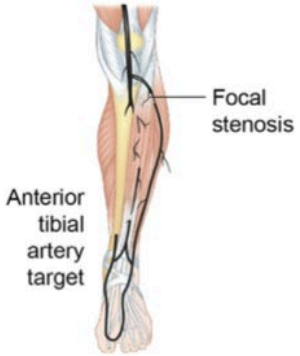
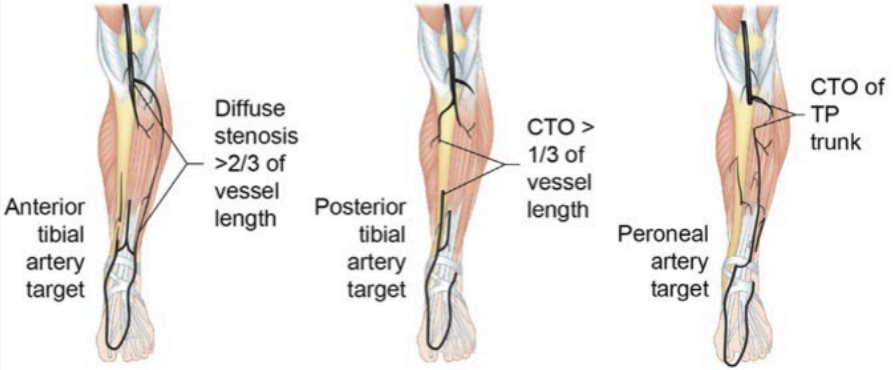
Global vascular guidelines on the management of chronic limb-threatening ischemia

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

- Patient with CLTI, candidate for revascularization
- Obtain high quality angiographic imaging including ankle and foot
- Define the target artery path (TAP)
- Grade the femoropoliteal (FP) segment (Fig 5.2)
- Grade the infrapopliteal (IP) segment (Fig 5.3)
- Look up the overall GLASS stage (Table 5.3)
- Define the preferred revascularization strategy by integrating patient risk, limb severity (WIfI) and anatomy (GLASS) according to the PLAN concept (Section 6)

1	• Total length SFA disease <1/3 (<10 cm) • May include single focal CTO (< 5 cm) as long as not flush occlusion • Popliteal artery with mild or no significant disease	
4	• Total length SFA occlusion > 20 cm • Popliteal disease >5 cm or extending into trifurcation • Any popliteal CTO	

Conte et al, 2019

1	• Focal stenosis of tibial artery < 3cm	
4	• Diffuse stenosis > 2/3 total vessel length • CTO > 1/3 vessel length (may include vessel origin) • Any CTO of tibioperoneal trunk if AT is not the target artery	

Conte et al, 2019

Infrainguinal GLASS stage (I-III)						
FP Grade	4	III	III	III	III	III
	3	II	II	II	III	III
	2	I	II	II	II	III
	1	I	I	II	II	III
	0	NA	I	I	II	III
		0	1	2	3	4
		IP Grade				

NA, Not applicable.
After selection of the target arterial path (TAP), the segmental femoropopliteal (*FP*) and infrapopliteal (*IP*) grades are determined from high-quality angiographic images. Using the table, the combination of FP and IP grades is assigned to GLASS stages I to III, which correlate with technical complexity (low, intermediate, and high) of revascularization.

Conte et al, 2019

Review > Eur J Vasc Endovasc Surg. 2022 Jul;64(1):32-40. doi: 10.1016/j.ejvs.2022.03.044. Epub 2022 Apr 11.

Predictability of the Global Limb Anatomic Staging System (GLASS) for Technical and Limb Related Outcomes: A Systematic Review and Meta-A

Takuro Shirasu [1], Hisato Takagi [2], Alexander Gregg [3], Toshiki Kuno [4], Jun Yasuha
K Craig Kent [6], W Darrin Clouse [6]

Conclusion: GLASS is predictive of LSR and MALE as v
meta-analysis suggests advanced GLASS stages favou

> Ann Vasc Surg. 2022 Apr;81:378-386. doi: 10.1016/j.avsg.2021.09.054. Epub 2021 Nov 12.

Validation of the GLASS Staging Systems in Patients With Chronic Limb-Threatening Ischemia Undergoing De Novo Infrainguinal Revascularization

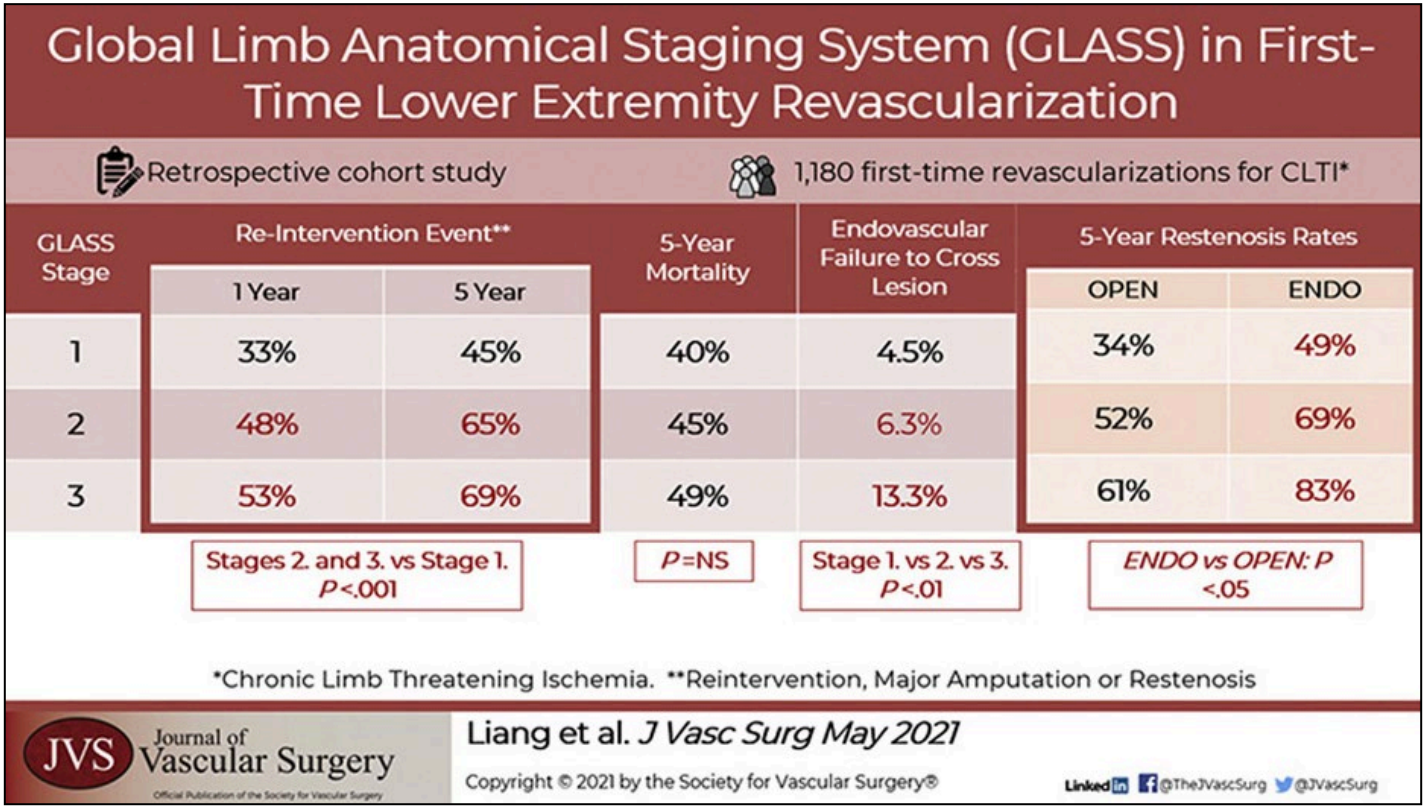
Koichi Morisaki [1], Yutaka Matsubara [2], Shinichiro Yoshino [2], Shun Kurose [2], Sho Yamashita [2], Tadashi Furuyama [2], Masaki Mori [2]

Conclusion: WIfI stage and IM disease predicted limb salvage and wound healing after infrainguinal revascularization in patients with CLTI. Although GLASS stage did not affect limb salvage or wound healing, it was a prognostic factor for poor OS. The GLASS staging could be useful for deciding between bypass surgery and endovascular therapy in prediction of prognosis.

> Eur J Vasc Endovasc Surg. 2022 Apr;63(4):58
Epub 2022 Feb 24.

Bypass Surgery Provides B with Endovascular Therap Endpoint Comprising Reli Healing, Limb Salvage, and Survival after Infra-inguinal Revascularisation in Patients with Chronic Limb Threatening Ischaemia

Koichi Morisaki [1], Yutaka Matsubara [2], Shun Kurose [2], Shinichiro Yoshino [2], Tadashi Furuyama [2]


Global Limb Anatomical Staging System (GLASS) in First-Time Lower Extremity Revascularization
Retrospective cohort study
1,180 first-time revascularizations for CLTI*
GLASS Stage
Re-Intervention Event**
1 Year
5 Year
5-Year Mortality
Endovascular Failure to Cross Lesion
5-Year Restenosis Rates
OPEN
ENDO
1
33%
45%
40%
4.5%
34%
49%
2
48%
65%
45%
6.3%
52%
69%
3
53%
69%
49%
13.3%
61%
83%
Stages 2. and 3. vs Stage 1. P <.001
P=NS
Stage 1. vs 2. vs 3. P <.01
ENDO vs OPEN: P <.05
*Chronic Limb Threatening Ischemia. **Reintervention, Major Amputation or Restenosis
JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery
Liang et al. J Vasc Surg May 2021
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Open surgery favored

- Need a durable result
- Anatomically complex

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Thank you