DEBATE: OPEN BYPASS SHOULD BE USED FIRST IN MANY CLTI PATIENTS: HOW MANY AND WHICH ONES?

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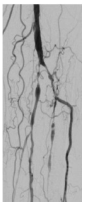
Disclosures

- Abbott Vascular
- BioGenCell (research grant)
- Medistim
- Co-Chair, SVS PAD Guidelines (2015) and Global Vascular Guidelines (2019)
- Co-Chair, Executive Committee, BEST-CLI trial

Evidence-Based Revascularization for CLTI

- **PLAN:**
  - ***P***atient Risk
  - ***L***imb threat severity: WIfI Staging
  - ***AN***atomic pattern of disease: **GLASS**

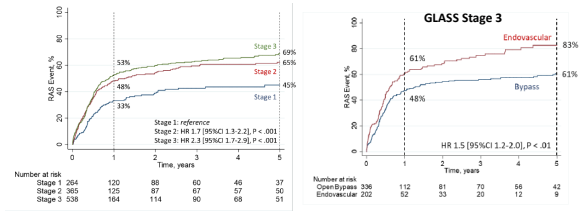




Differential Risk Factors and Complementary Roles: Endovascular Intervention vs Bypass

	Bypass	ENDO
High patient risk/advanced comorbidities		✓✓✓
More severe limb threat (e.g. WIfI Stage 4)	✓✓	
Greater TAP complexity (e.g. long occlusions; GLASS 3)	✓✓✓	
Lower TAP complexity (e.g. GLASS 1, 2)		✓✓
Prior failed implant (stent)	✓✓	
Poor runoff	------	-------
Good quality vein available	✓✓	
Good quality vein not available		✓✓

Open bypass is a more effective revascularization in Complex Disease (GLASS 3)



Liang P, et al. J Vasc Surg 2021 73:1683-91

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

Eur J Vasc Endovasc Surg 2022; PMID 35472449

Takuro Shirasu [a,b,*], Hisato Takagi [*], Alexander Gregg [a], Toshiki Kuno [d], Jun Yasuhara [e], K. Craig Kent [a,b], W. Darrin Clouse [a,b]

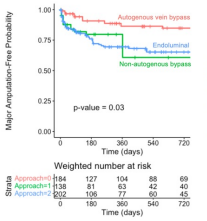
Table 2. Systematic review of survival, limb and technical outcomes by different global limb anatomic staging system (GLASS) stages in eight studies describing comparative outcomes of patients with chronic limb threatening ischaemia

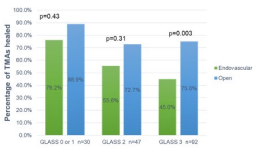
Outcome*	Follow up time	GLASS 1	GLASS 2	GLASS 3
AFS – %	1 year	78 (67–86)	74 (67–74)	68 (62–70)
	5 years	54 (46–65)	47 (39–64)	48 (37–54)
LSR – %	1 year	92 (84–95)	90 (89–95)	83 (54–89)
	5 years	89 (80–93)	90 (82–90)	78 (77–81)
MALE – %	1 year	78 (67–79)	67 (52–90)	63 (47–81)
	5 years	69 (55–71)	65 (35–90)	52 (31–74)
Overall survival – %	1 year	81 (62–91)	79 (68–82)	78 (73–80)
	5 years	63 (60–69)	55 (51–70)	59 (51–64)
ITF – %		3.3 (0–14)	6.3 (0–15)	28.4 (14–48)
LDP –%	1 year	60		40

Table 4. Meta-analysis of survival and limb related outcomes comparing global limb anatomic staging system (GLASS) 1+2 vs. GLASS 3 in the subgroups of endovascular treatment (EVT) and bypass surgery (BS) in eight studies describing comparative outcomes of patients with chronic limb threatening ischaemia

	EVT		BS	
	HR (95% CI)	*p* value	HR (95% CI)	*p* value
AFS	0.68 (0.49–0.94)	.020	1.00 (0.98–1.02)	1.0
LSR	0.54 (0.37–0.77)	<.001	0.71 (0.37–1.38)	.32
MALE	0.67 (0.52–0.87)	.003	0.87 (0.40–1.89)	.73
Overall survival	0.79 (0.41–1.51)	.47	0.94 (0.28–3.14)	.92

Limb staging in CLTI: Open bypass with vein is a more effective revascularization in WIFI 4



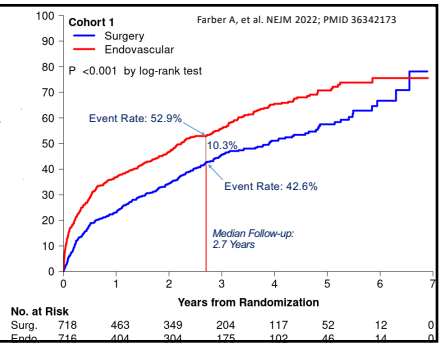


Liu I, et al. J Vasc Surg 2023 PMID 36584906

Gomez-Sanchez C, et al. J Vasc Surg 2023 PMID 36581012

Primary Endpoint

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



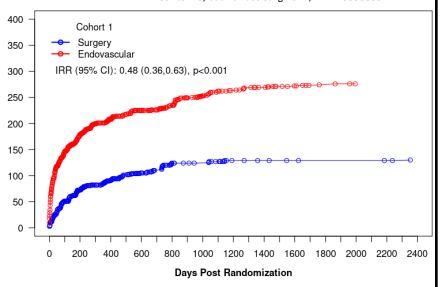
Farber A, et al. NEJM 2022; PMID 36342173

BEST-CLI

Secondary Endpoint

Total Number of Major Re-interventions

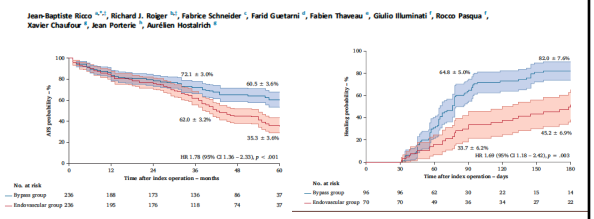
IRR: Incidence Rate I



Conte MS, et al. J Vasc Surg 2024; PMID 38368997

BEST-CLI

Editor's Choice – Infra-inguinal Endovascular Revascularisation and Bypass Surgery for Chronic Limb Threatening Ischaemia: a Retrospective European Multicentre Cohort Study with Propensity Score Matching



Endovascular therapy versus bypass for chronic limb-threatening ischemia in a real-world practice

Sina Zarrintan, MD, MS, MPH,[a] Shima Rahgozar, BA,[a] Elsie G. Ross, MD, MSc,[a] Alik Farber, MD, MBA, DFSVS,[b] Matthew T. Menard, MD,[c] Michael S. Conte, MD,[d] and Mahmoud B. Malas, MD, MHS, RPVI,[e] *San Diego and San Francisco, CA; and Boston, MA*

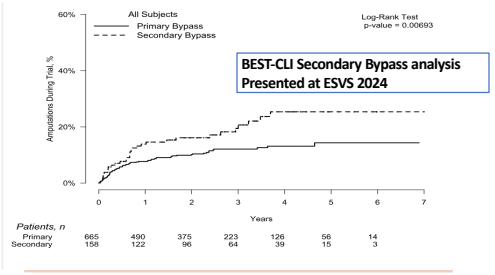
- VQI data (2010-2019) >36,000 first time infrainguinal procedures for CLTI

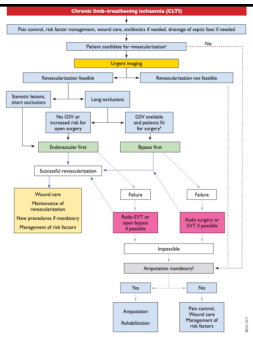
Table VII. Hazard ratios (*HR*) in cohorts of endovascular therapy (*ET*) vs bypass with great saphenous vein (*BWGSV*) and ET vs bypass with prosthetic graft (*BWPG*) after propensity score matching (PSM) (reference = bypass)

	Two years		Four years	
Outcome in matched cohorts	HR (95% CI)	*P* value	HR (95% CI)	*P* value
ET vs BWGSV				
All-cause mortality	1.44 (1.34-1.56)	**<.001**	1.34 (1.25-1.43)	**<.001**
Amputation	1.31 (1.17-1.46)	**<.001**	1.30 (1.17-1.44)	**<.001**
Amputation or death	1.38 (1.30-1.48)	**<.001**	1.32 (1.24-1.40)	**<.001**
ET vs BWPG				
All-cause mortality	1.11 (1.00-1.22)	**.042**	1.06 (0.98-1.16)	.156
Amputation	1.10 (0.95-1.29)	.198	1.07 (0.93-1.24)	.359
Amputation or death	1.07 (0.98-1.17)	.109	1.04 (0.96-1.12)	.322

CI, Confidence interval.
Boldface *P* values represent statistical significance.

Secondary bypass works, but its inferior





ıe Diagnosis and Arterial Diseases, European Society 'S)

How often is open bypass being used in CLTI?

Author (year)	Total N	%Open	Comments
Bisdas (2015)	1200	24%	German CRITISCH registry (27 centres)
Simons (2018)	38470	37%	VQI (2003-2017)
Lin (2019)	16800	36%	California hospital database (2005-2013)
Parvar (2022)	75189	20%	ANZ (2008-2015); includes IC patients
Ricco (2023)	952	44%	4 European vascular centres (France, Italy)
Cleman (2023)	10592	20%	VQI (2014-2019); below knee only
Liu (2023)*	413	41%	Single center study (UCSF)
POOLED	143703	**27%**	Excludes single center study

How many CLTI patients should be offered bypass?

- Surgical risk data (~80% are average surgical risk per VQI data)
- GLASS prevalence data (~60% are GLASS 3, several studies)
- GSV availability
  - Inadequate GSV incidence unknown; estimate 20-40% unusable
- 0.8 * 0.6 * 0.6 = 29%
- ***I believe that open bypass should be offered as initial treatment to roughly 30% of CLTI patients who are appropriate candidates for limb salvage***

We're talking about bypass "first"… what's really happening now in too many practice settings….

- Bypass "last"
- Multiple endovascular interventions and failures before an open bypass is even being offered to CLTI pts
- No meaningful surgical evaluation– patients not being adequately informed of treatment options and tradeoffs
- Never-ending cycles of recurrent or unresolved CLTI symptoms, and repetitive interventions
- Repetitive re-canalizations and treatments of thrombotic occlusions leading to progressive loss of runoff ("no option")
- Outcomes of secondary "rescue" bypass in these settings are likely a LOT WORSE than in BEST-CLI
- Economic disincentives to evidence-based practice