2023 MID-ATLANTIC CONFERENCE

11th ANNUAL CURRENT CONCEPTS IN

VASCULAR THERAPIES

2023

Endovascular First for the Management of PAD

Todd W Gensler MD

April 22, 2023

THE TALE OF THE SCALE
THE CASE FOR MINIMALLY INVASE(IVE)

- Define CLTI
- Review prior data
  - Basil 1 Trial
  - TASC II
  - GLASS
- Review most recent data—BEST CLI
- DRAW CONCLUSION FOR ENDO FIRST

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,

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Chronic Limb Threatening Ischemia

- Amputation risk
  - 25% at 1 year if untreated
- Mortality
  - 10-15%/yr w/ revasc
  - 22% @ 1 yr untreated

Circulation

AHA POLICY STATEMENT

Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet

A Policy Statement From the American Heart Association

Table I Published survival data after revascularization for chronic limb-threatening ischemia (CLTI)

Study	Year of publication	Cohort	End point
Baubeta Fridh et al[2]	2017	Swedish registry with 10,617 patients revascularized open or endovascularly	60% amputation-free survival by 2 years postoperatively
Iida et al[3]	2015	Japanese registry (OLIVE) with 314 patients revascularized	64% survival by 2 years postoperatively
Zeller et al[4]			urvival by 1 year postoperatively
Conte et al[5]			urvival by 1 year postoperatively
Adam et al[6]	2005	Randomized trial (BASIL) in 452 patients revascularized open or endovascularly	70% survival by 2 years postoperatively
Gruppo di Studio dell'Ischemia Cronica Critica degli Arti Inferiori[7]	1997	Italian registry of 522 patients	70% survival by 2 years

SUPPORTING REVIEW ARTICLE | VOLUME 69, ISSUE 6, SUPPLEMENT , 137S-151S.E3, JUNE 2019 Download Full Issue PDF [1 MB] Figures

Survival prediction in patients with chronic limb-threatening ischemia who undergo infrainguinal revascularization

Jessica P. Simons, MD, MPH • Andres Schanzer, MD • Julie M. Flahive, MS • ... Joseph L. Mills Sr., MD • Andrew W. Bradbury, MD • Michael S. Conte, MD • Show all authors

REVIEW ARTICLES

Richard P. Cambria, MD, Section Editor

The natural history of untreated severe or critical limb ischemia

Abd Moain Abu Dabrh, MBBCh, MS,[a,b] Mark W. Steffen, MD, MPH,[a] Chaitany Noor Asi, MD,[b] Zhen Wang, PhD,[b] Mohamed B. Elamin, MD,[b] Michael S. Cont Mohammad Hassan Murad, MD, MPH,[a,b] *Rochester, Minn; and San Francisco, Calif*

(J Vasc Surg 2015;62:1642-51.)

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

- UK trial- 452 pts randomized to surgical or endovascular therapy (angioplasty) for critical limb ischemia.
- Primary endpoint- Limb Salvage
- Similar rates of limb salvage & all-cause mortality at 1 & 3 years.
- More reinterventions after angioplasty (26% vs. 18%).
- Higher costs of surgery at 1 year.

- The most cu … infrainguinal saphenous … with PTA (BASIL) found that … based on amputation … a less morbid procedure … ficantly less costly than surger…
- At follow-up … **er overall survival and** … pared to the endovascul…
- A later suba… ears, there was a **7-month in**… t a significant difference i…

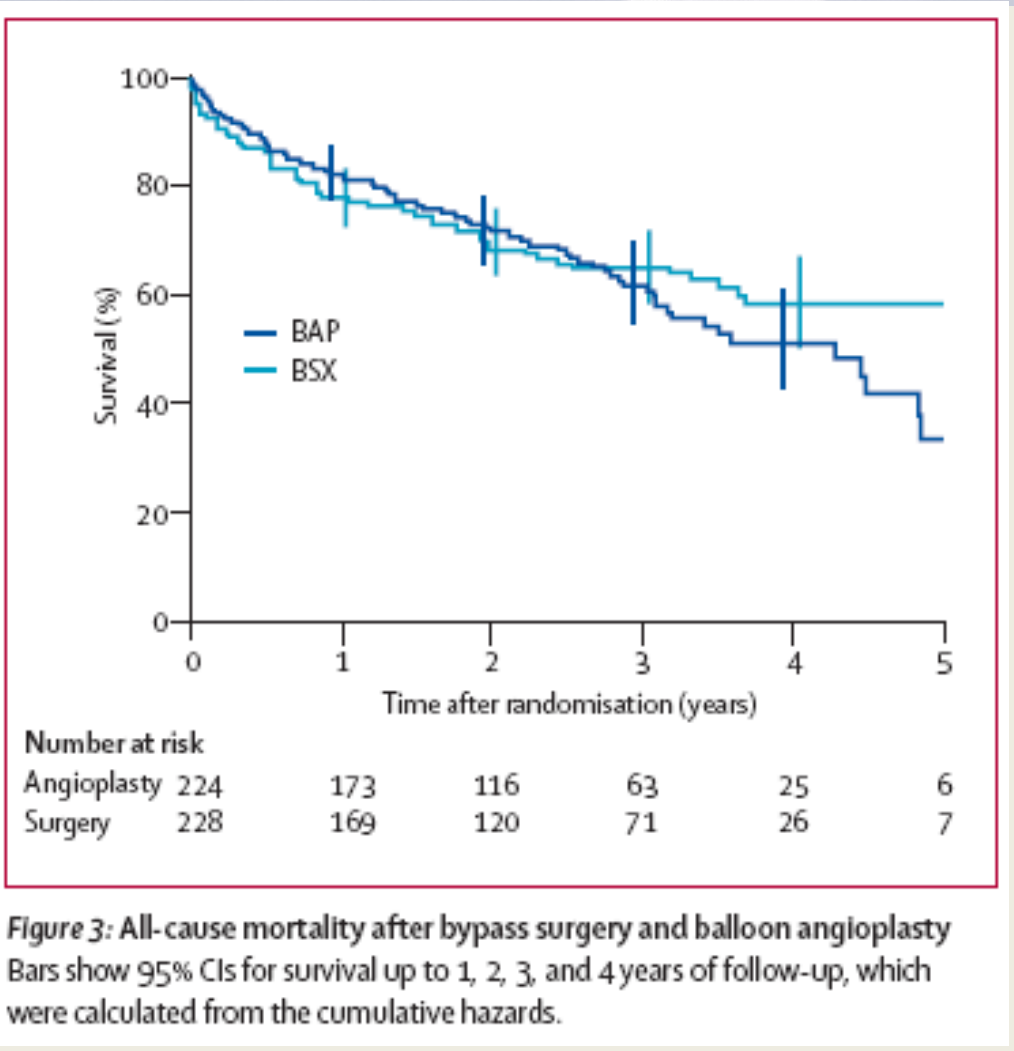

Figure 3: **All-cause mortality after bypass surgery and balloon angioplasty**
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

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BASIL (2005)

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

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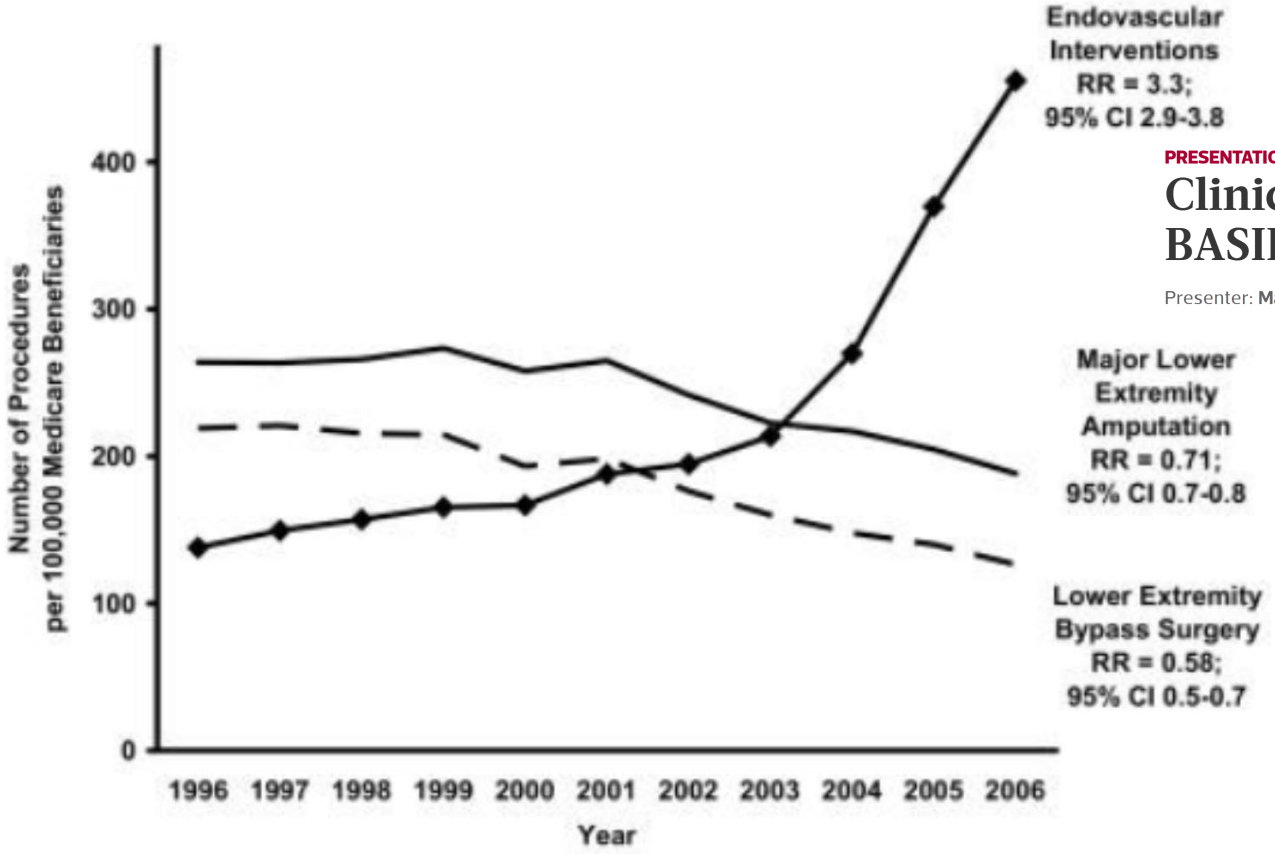
Rising use of endovascular therapy



PRESENTATION | TCT 2019

Clinical Trial Updates: BEST-CLI, BASIL-2 and BASIL-3

Presenter: Matthew Menard | SEPTEMBER 25, 2019

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2015 TASC II (TRANSATLANTIC INTERSOCIETY CONCENSUS) UPDATE

- In practical terms, although the level of evidence is low, the **initial revascularization strategy** for femoropopliteal disease is commonly an **endovascular approach**

2015 TASC II UPDATE
Infrapopliteal disease

- In practical terms, an “endovascular-first” approach is the current standard of care for symptomatic infrainguinal atherosclerotic disease strengthened by the recent technological advances of DES and DEBs. The Best Endovascular vs Best Surgical Therapy in patients with CLI (BEST-CLI) trial has just been launched and will answer the question of whether optimal surgery for selected patients with CLI and good quality saphenous vein available for bypass is a better choice than endovascular therapy.

Global Vascular Guideline (GVG) 2019

- Global Limb Anatomic Staging System (GLASS)
  - SVS, ESVS, WFVS
- Chronic Limb Threatening Ischemia (CLTI)
- Evidence Based Revascularization (EBR)
- SVS Lower Extremity Threatened Limb Classification System—(WIFI)
- Patient risk, Limb severity, and ANatomic pattern of disease (PLAN)
- Target Arterial Path (TAP)
- Limb Based Patency (LBP)
- Immediate Technical Failure (ITF)

GLASS—PATIENT RISK

	Recommendations	Grade	Level of evidence	Key references
6.3	Estimate periprocedural risk and life expectancy in patients with CLTI who are candidates for revascularization.	1 (Strong)	C (Low)	
6.4	Define a CLTI patient as average surgical risk when anticipated periprocedural mortality is <5% and estimated 2-year survival is >50%.	2 (Weak)	C (Low)	Biancari,[63] 2007 Schanzer,[64] 2008 Bradbury,[65] 2010 Meltzer,[66] 2013 Simons,[67] 2016
6.5	Define a CLTI patient as high surgical risk when anticipated periprocedural mortality is ≥5% or estimated 2-year survival is ≤50%.	2 (Weak)	C (Low)	

- LOW
  - PERI-PROC MORTALITY <1-2%
  - 2 YR SURVIVAL >70%
- MODERATE
  - PERI-PROC MORTALITY 2-5%
  - 2 YR SURVIVAL 50-70%
- HIGH
  - PERI-PROC MORTALITY >5%
  - 2 YR SURVIVAL $\leq$ 50%

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GLASS—SEVERITY OF LIMB THREAT

Table 2 Wound, Ischaemia, foot Infection (WIfI) scoring classification system

Wound		
Ulcer	Gangrene	score
No ulcer	None	0
Small shallow (subcutaneous)	None	1
Deeper (tendon or muscle)	Gangrenous changes to limited digits	2
Extensive (extending to bone)	Extensive gangrene	3

Ischaemia			
ABPI	Toe pressure	Ankle systolic pressure	score
≥0.8	≥60 mmHg	>100 mmHg	0
0.79–0.6	40–50 mmHg	70–100 mmHg	1
0.59–0.4	30–39 mmHg	50–70 mmHg	2
≤0.39	<30 mmHg	<50 mmHg	3

Foot infection	
Ulcer	score
No signs or symptoms of infection	0
Local infection involving skin and subcutaneous tissue only (<2 cm erythema)	1
Local infection involving deeper structures or with >2 cm erythema (ie, osteomyelitis)	2
As above with SIRS response	3

This table shows the WIfI classification scoring system derived from Mills *et al.*[4]

Table 3 Wound, Ischaemia, foot Infection (WIfI) clinical stage associated with amputation risk and revascularisation benefit

Stage	Major amputation risk at 1 year (estimated %)	Revascularisation benefit score
1	2–3	Very low
2	8–9	Low
3	25	Moderate
4	50	High

This table shows the clinical stages calculated from the WIfI system and how the stages are associated with amputation risk and revascularisation benefit.

WIfI scoring: a reliable tool for risk stratification in the diabetic foot clinic

Williams P,[1] Bakewell Z,[1] Akinlade B,[1] Russell DA[1,2]

Journal of VASCULAR SOCIETIES GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2022;1(3):71-76

GLASS—ANATOMIC PATTERN OF DISEASE

Table 5.3. Assignment of Global Limb Anatomic Staging System (*GLASS*) Stage

		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.

Table 5.4. Descriptive summary of Global Limb Anatomic Staging System (GLASS) stages of infrainguinal arterial disease

Stage	Estimated PVI outcomes		Anatomic pattern
	Technical failure	1-year LBP	
I	<10%	>70%	Short- to intermediate-length FP disease and/or short-length IP disease; no or minimal popliteal disease
II	<20%	50%-70%	Intermediate- to long-length FP disease; may include popliteal stenosis and/or short- to intermediate-length IP disease
III	>20%	<50%	Extensive FP or IP occlusions, alone or in combination with any disease in the other segment; popliteal CTO

CTO, Chronic total occlusion; *FP*, femoropopliteal; *IP*, infrapopliteal; *LBP*, limb-based patency; *PVI*, peripheral [endo-]vascular intervention.

GLASS Recommendations

6.32	In average-risk CLTI patients with infrainguinal disease, base decisions of endovascular intervention vs open surgical bypass on the severity of limb threat (eg, WIfI), the anatomic pattern of disease (eg, GLASS), and the availability of autologous vein.	1 (Strong)	C (Low)	Almasri,[7] 2018
6.33	Offer endovascular revascularization when technically feasible for high-risk patients with advanced limb threat (eg, WIfI stage 4) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).	2 (Weak)	C (Low)	Abu Dabrh,[5] 2015 Zhan,[69] 2015 Causey,[70] 2016 Darling,[71] 2016 Robinson,[72] 2017
6.34	Consider endovascular revascularization for high-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).	2 (Weak)	C (Low)	
6.35	Consider endovascular revascularization for high-risk patients with advanced limb threat (eg, WIfI stage 4) and moderate ischemia (eg, WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by ≥50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible.	2 (Weak)	C (Low)	

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GLASS Recommendations

6.36	Consider endovascular revascularization for high-risk patients with intermediate limb threat (eg, WIfI stages 2 and 3) and moderate ischemia (eg, WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by ≥50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible.	2 (Weak)	C (Low)	
6.37	Consider open surgery in selected high-risk patients with advanced limb threat (eg, WIfI stage 3 or 4), significant perfusion deficits (ischemia grade 2 or 3), and advanced complexity of disease (eg, GLASS stage III) or after prior failed endovascular attempts and unresolved symptoms of CLTI.	2 (Weak)	C (Low)	
6.38	Consider angiosome-guided revascularization in patients with significant wounds (eg, WIfI wound grades 3 and 4), particularly those involving the midfoot or hindfoot, and when the appropriate TAP is available.	2 (Weak)	C (Low)	Azuma,[95] 2012 Sumpio,[96] 2013 Biancari,[97] 2014 Chae,[98] 2016 Jongsma,[99] 2017

The Evidence Gap

	CAD Coronary Artery Disease	CVD Cerebral Vascular Disease	CLI Critical Limb Ischemia
Affected Individuals in the US	28.2 million†	7.8 million†	~10 million (JACC-Agarwal, 2016)
Completed Landmark RCTs	CAPRICORN (2001) EUROPA (2003) COURAGE (2007) PLATO (2009) ATLAS ACS (2012) [illegible]12) [illegible]14) PEGASUS-TIMI 54 (2015) IMPROVE-IT (2015) COMPASS (2017) CULPRIT-SHOCK (2017)	ACAS (1995) NASCET (1998) ARCHeR(2003) SAPPHIRE(2[illegible] SPARCL CRE[illegible] [illegible]) [illegible]RIS (2015) ACT-1 (2016)	BASIL (2005) 452

129,698

17,995

† Circulation. 2018;137:e558–e577, CDC Fact Sheet

PRESENTATION | TCT 2019

Clinical Trial Updates: BEST-CLI, BASIL-2 and BASIL-3

Presenter: **Matthew Menard** | SEPTEMBER 25, 2019

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BEST CLI TRIAL

- Intn'l, prospective, randomized trial (US, Canada, Finland, Italy, and New Zealand)— 150 centers
- 1830 patien disease
- 2 cohorts—
  - (1) Ade
  - (2) Inad conduit

FUNDING STOPPED/ ADD'L FUNDING FOR 24 MONTH F/U FOR COHORT 1

The NEW ENGLAND JOURNAL of MEDICINE

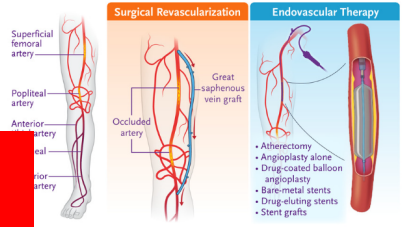
RESEARCH SUMMARY

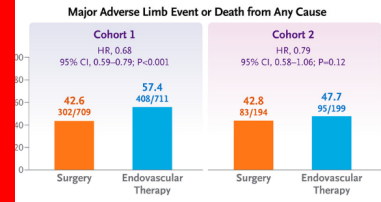
Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

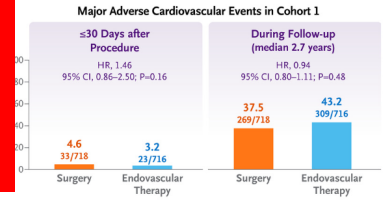
Farber A et al. DOI: 10.1056/NEJMoa2207899

CLINICAL PROBLEM

Patients with chronic limb-threatening ischemia (CLTI) require timely revascularization to improve perfusion and reduce the risk of amputation. Whether an initial strategy of surgical revascularization or endovascular therapy results in superior outcomes is unclear.







- Study results may have been influenced by selection or operator bias as a consequence of the pragmatic trial design and implementation.
- Patient suitability for procedures was determined locally and varied according to study site and individual investigator.
- Enrollment targets were not met for patients overall and for women.

CONCLUSIONS

Among patients with CLTI who had a great saphenous vein adequate for surgical revascularization, clinical outcomes with an initial treatment of surgery were superior to those with endovascular therapy; however, in patients who required an alternative bypass conduit, outcomes were similar with the two procedures.

Links: Full Article | NEJM Quick Take | Editorial

BEST-CLI Funding Sources

INITIAL NHLBI FUNDING: $27,300,000 (All values in USD)

(Includes contracts with Brigham and Women's Hospital & New England Research Institute/ HealthCore)

The views expressed in this article are solely those of the authors and do not necessarily represent official views of the National Heart, Lung, and Blood Institute or the National Institutes of Health.

Patient Follow-up Funding (Provided After 11/01/2019)

Industry

Janssen Pharmaceuticals	$2,200,000
Gore Medical	$1,500,000
Bard Pharmaceuticals	$500,000
Medtronic	$450,000
Cook Medical	$200,000
Boston Scientific	$100,000
Abbott Laboratories	$75,000
Cordis	$50,000
Cardiovascular Systems Inc (CSI)	$30,000

Physician Societies

Vascular InterVentional Advances	(VIVA)	$500,000
Society for Vascular Surgery	(SVS)	$100,000
New England Society for Vascular Surgery	(NESVS)	$20,000
Eastern Vascular Society		$20,000
Western Vascular Society		$16,620
Canadian Society for Vascular Surgery	(CSVS)	$15,794.74
Midwest Vascular Surgery Society		$10,000
Society for Clinical Vascular Surgery	(SCVS)	$10,000
Society of Interventional Radiology	(SIR)	$10,000
Vascular and Endovascular Surgery Society	(VESS)	$5,000
Southern Association of Vascular Surgeons		$5,000
Society for Vascular Medicine	(SVM)	$1,000

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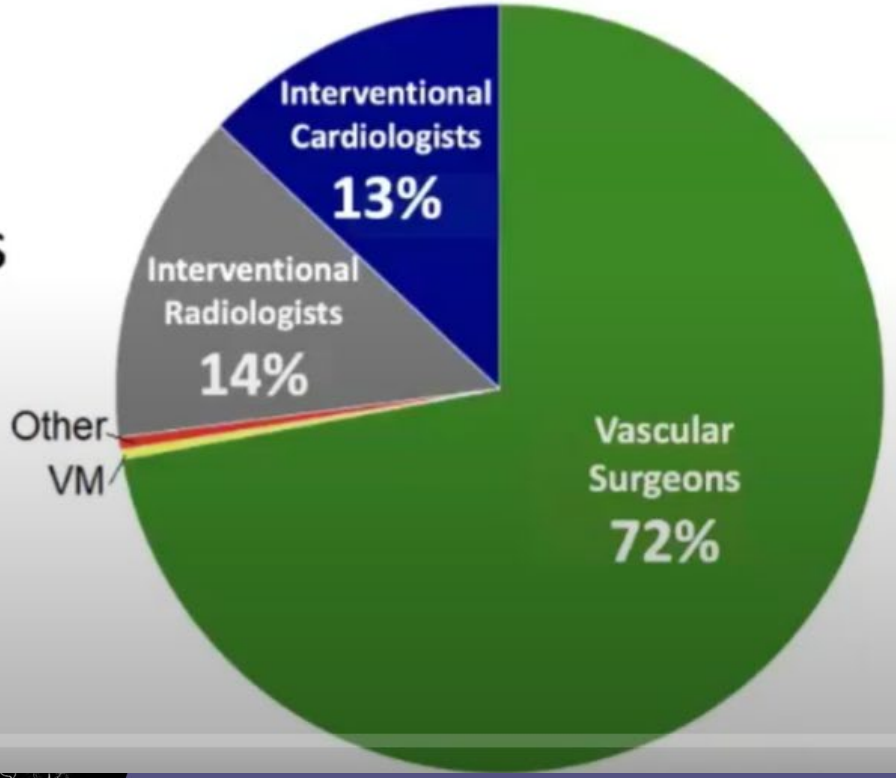
BEST-CLI Investigators by Specialty

BEST-CLI

1,096 Investigators

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



ENDPOINTS

- PRIMARY
  - Amputation above ankle
  - Major Limb ReIntervention
    - New bypass
    - Graft revision
    - Thrombectomy/thrombolysis
  - Death
- SECONDARY
  - Reintervention and Amputation Free Survival
  - MALE--POD
  - Death w/in 30 days of index procedure
  - Minor reinterventions
  - Adverse CV event (MI, Stroke, Death)
  - Serious adverse event

BEST-CLI

Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

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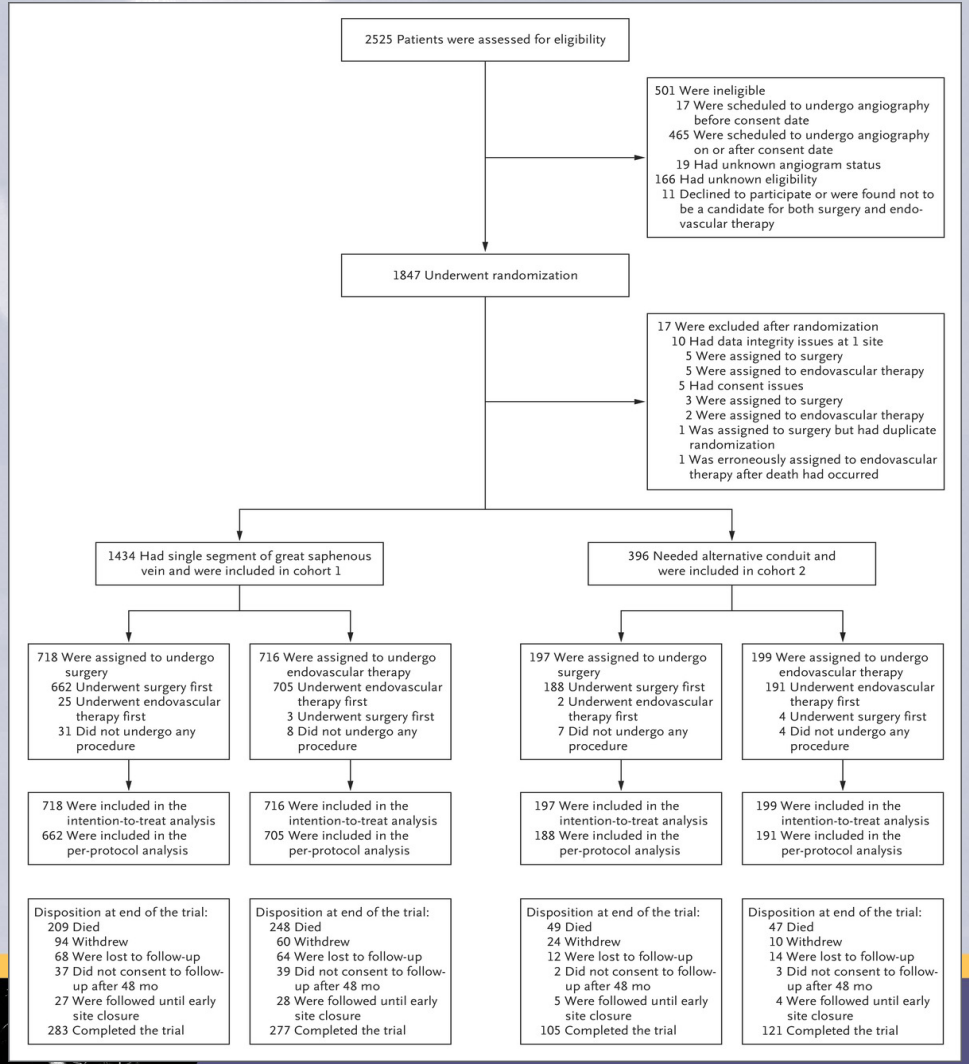
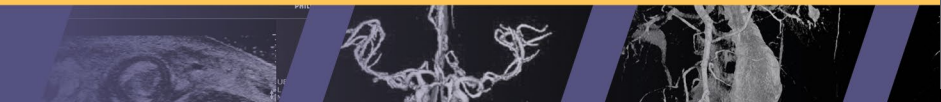
RANDOMIZATION

- 667/2525 (26.4%) EXCLUDED
- 1847 RANDOMIZED
  - 1434 COHORT 1
  - 396 COHORT 2

A Farber et al. N Engl J Med 2022;387:2305-2316.





usion Criteria

HIGH RISK > 15%

k

– Investigator assessment

RISK STRATIFICATION

- EAGLE

- Eagle Criteria:
  - Specific to cardiac risk after vascular surgery
  - Age > 70, Angina, Hx of MI or Q wave, CHF, DM
  - 0 factors = 3%, 1-2 factors = 8-15%, 3 factors = 18-50%
  - Intermediate risk then stress test
  - High risk then consider going straight to catheterization

HIGH RISK EAGLE
71yo diabetic w/ prior MI

RCRI

Elevated-risk surgery Intraperitoneal; intrathoracic; suprainguinal vascular (see 2014 ACC/AHA Guideline)	**No 0**	Yes +1
History of ischemic heart disease History of myocardial infarction (MI); history of positive exercise test; current chest pain considered due to myocardial ischemia; use of nitrate therapy or ECG with pathological Q waves	No 0	**Yes +1**
History of congestive heart failure Pulmonary edema, bilateral rales or S3 gallop; paroxysmal nocturnal dyspnea; chest x-ray (CXR) showing pulmonary vascular redistribution	**No 0**	Yes +1

3 points

Class IV Risk

15.0 %

30-day risk of death, MI, or cardiac arrest

From Duceppe 2017, based on pooled data from 5 high quality external validations (4 prospective). These numbers are higher than those often quoted from the now-outdated original study (Lee 1999). See Evidence for details.

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Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Cohort 1			Cohort 2		
	Overall (N=1434)	Surgery (N=718)	Endovascular Therapy (N=716)	Overall (N=396)	Surgery (N=197)	Endovascular Therapy (N=199)
Demographic						
Age — yr	66.9±9.9	66.9±9.8	67.0±10.0	68.6±9.2	68.4±8.8	68.8±9.6
Female sex — no./total no. (%)	408/1434 (28.5)	201/718 (28.0)	207/716 (28.9)	111/396 (28.0)	56/197 (28.4)	55/199 (27.6)
Race or ethnic group — no./total no. (%)†						
White	1028/1423 (72.2)	500/711 (70.3)	528/712 (74.2)	275/390 (70.5)	143/194 (73.7)	132/196 (67.3)
Black	275/1423 (19.3)	156/711 (21.9)	119/712 (16.7)	96/390 (24.6)	40/194 (20.6)	56/196 (28.6)
Asian	20/1423 (1.4)	13/711 (1.8)	7/712 (1.0)	2/390 (0.5)	2/194 (1.0)	0/196
Other	100/1423 (7.0)	42/711 (5.9)	58/712 (8.1)	17/390 (4.4)	9/194 (4.6)	8/196 (4.1)
Hispanic	187/1433 (13.0)	82/717 (11.4)	105/716 (14.7)	53/396 (13.4)	28/197 (14.2)	25/199 (12.6)
Medical history						
Body-mass index‡	28.2±6.0	28.2±6.3	28.3±5.8	26.9±5.7	26.8±5.1	27.0±6.2
Coexisting condition — no./total no. (%)						
Hypertension	1238/1424 (86.9)	620/712 (87.1)	618/712 (86.8)	350/395 (88.6)	171/196 (87.2)	179/199 (89.9)
Hyperlipidemia	1041/1423 (73.2)	521/712 (73.2)	520/711 (73.1)	300/395 (75.7)	147/196 (75.0)	153/199 (76.4)
Diabetes	1023/1424 (71.8)	513/712 (72.1)	510/712 (71.6)	238/395 (60.3)	122/196 (62.2)	116/199 (58.3)
Current smoking	509/1424 (35.7)	264/712 (37.1)	245/712 (34.4)	140/395 (35.4)	69/196 (35.2)	71/199 (35.7)
Coronary artery disease	617/1424 (43.3)	301/712 (42.3)	316/712 (44.4)	204/395 (51.6)	97/196 (49.5)	107/199 (53.8)
Congestive heart failure	79/1422 (5.6)	38/711 (5.3)	41/711 (5.8)	27/395 (6.8)	12/196 (6.1)	15/199 (7.5)
Stroke	190/1424 (13.3)	91/712 (12.8)	99/712 (13.9)	62/395 (15.7)	38/196 (19.4)	24/199 (12.1)
Chronic obstructive pulmonary disease	208/1424 (14.6)	100/712 (14.0)	108/712 (15.2)	69/395 (17.5)	34/196 (17.3)	35/199 (17.6)
End-stage kidney disease	151/1423 (10.6)	67/712 (9.4)	84/711 (11.8)	45/395 (11.4)	25/196 (12.8)	20/199 (10.1)
Medication						
Statin — no./total no. (%)	1001/1424 (70.3)	503/713 (70.5)	498/711 (70.0)	307/394 (77.9)	153/195 (78.5)	154/199 (77.4)
Aspirin — no./total no. (%)	953/1424 (66.9)	476/713 (66.8)	477/711 (67.1)	280/394 (71.1)	139/195 (71.3)	141/199 (70.9)
Clopidogrel — no./total no. (%)	312/1424 (21.9)	137/713 (19.2)	175/711 (24.6)	97/394 (24.6)	55/195 (28.2)	42/199 (21.1)
Prasugrel — no./total no. (%)	5/1424 (0.4)	2/713 (0.3)	3/711 (0.4)	1/394 (0.3)	0/195	1/199 (0.5)
Ticagrelor — no./total no. (%)	10/1424 (0.7)	4/713 (0.6)	6/711 (0.8)	4/394 (1.0)	0/195	4/199 (2.0)
Direct-acting oral anticoagulant — no./total no. (%)	55/1424 (3.9)	27/713 (3.8)	28/711 (3.9)	22/394 (5.6)	9/195 (4.6)	13/199 (6.5)
Warfarin — no./total no. (%)	93/1424 (6.5)	46/713 (6.5)	47/711 (6.6)	31/394 (7.9)	12/195 (6.2)	19/199 (9.5)
Previous intervention						
Tobacco cessation — no./total no. (%)	97/1424 (6.8)	49/712 (6.9)	48/712 (6.7)	26/395 (6.6)	11/196 (5.6)	15/199 (7.5)
Infrainguinal revascularization of index limb — no./total no. (%)	77/1423 (5.4)	40/711 (5.6)	37/712 (5.2)	40/393 (10.2)	20/194 (10.3)	20/199 (10.1)
Limb status						
Ankle–brachial index in index limb§	0.58±0.32	0.58±0.31	0.59±0.34	0.54±0.30	0.53±0.27	0.54±0.32
Ankle pressure — mm Hg¶	84.9±47.7	85.2±46.2	84.5±49.2	81.3±49.6	80.4±47.3	82.2±51.8
Toe pressure — mm Hg‖	36.3±25.7	36.5±27.7	36.1±23.5	31.0±21.7	37.0±23.5	25.5±18.4

ABI>0.5 in all groups
VERY FEW QUIT SMOKING
10% fewer Diabetics in Cohort 2
5% greater prior revasc in Cohort 2

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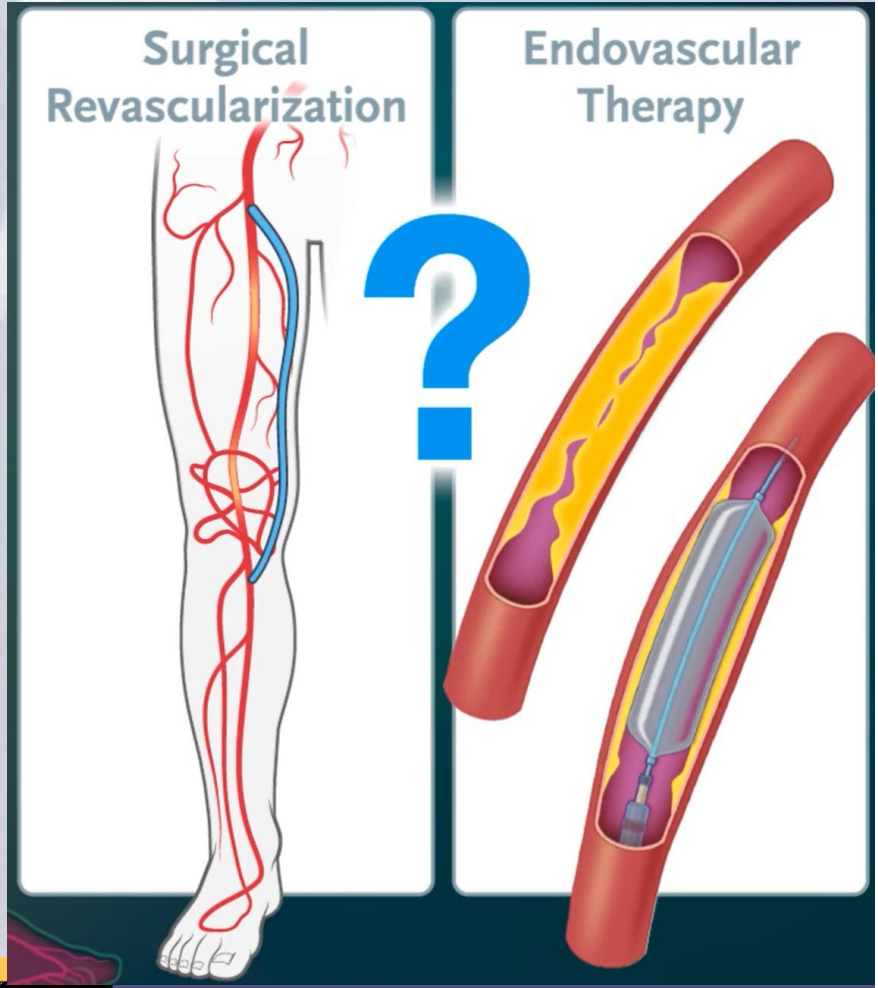
COHORT 1—ADEQ GSV

- 1434 PATIENTS—median f/u 2.7 yrs
- 718 SURGERY
  - 307 femoral–popliteal
  - 276 femoral–tibial or pedal
  - 115 popliteal–tibial or pedal
- 716 ENDO
  - 487 superficial femoral artery
  - 382 on the popliteal artery
  - 381 on the tibial or pedal arteries



COHORT 1—ADEQ GSV

- SURGERY—98% technical success
  - 85% single segment GSV
- ENDOVASC—85% technical success
  - 108 FAILURES
    - 66 (61%) TREATED w/ Bypass w/in 30 days

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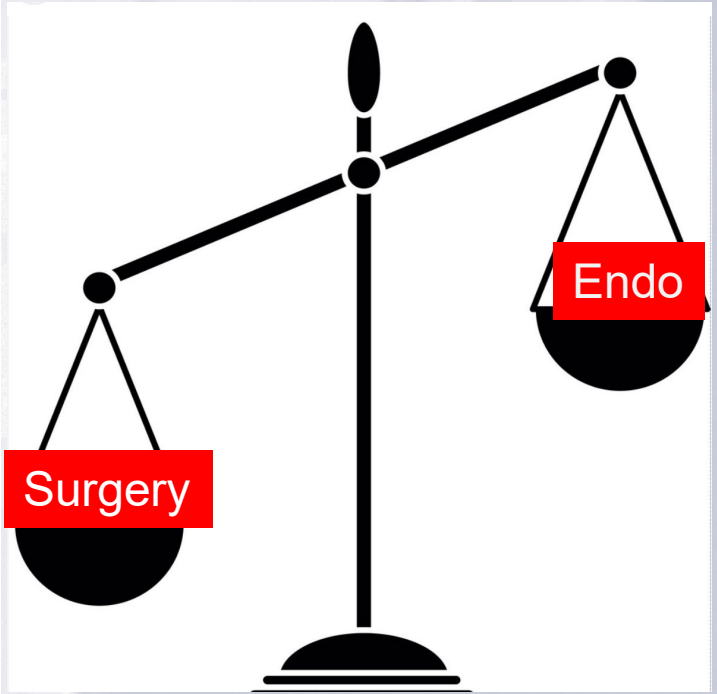
COHORT 1—ADEQ GSV

- 1° OUTCOME (MALE/Death)

Table 2. Efficacy and Safety Outcomes in Cohort 1.*

Outcome	Surgery	Endovascular Therapy	Hazard Ratio (95% CI)†	P Value
Efficacy				
Primary outcome: major adverse limb event or death from any cause — no./total no. (%)‡	302/709 (42.6)	408/711 (57.4)	0.68 (0.59–0.79)	<0.001
Secondary outcomes — no./total no. (%)				
Death from any cause	234/709 (33.0)	267/711 (37.6)	0.98 (0.82–1.17)	
Above-ankle amputation of the index limb	74/709 (10.4)	106/711 (14.9)	0.73 (0.54–0.98)	
Intervention in index limb				
Major	65/709 (9.2)	167/711 (23.5)	0.35 (0.27–0.47)	
Minor	205/718 (28.6)	237/716 (33.1)	0.85 (0.70–1.02)	
Perioperative death§	12/687 (1.7)	9/708 (1.3)	1.54 (0.64–3.68)	
Major adverse limb event or perioperative death	139/687 (20.2)	246/708 (34.7)	0.53 (0.43–0.65)	
Myocardial infarction	75/718 (10.4)	85/716 (11.9)	0.97 (0.71–1.33)	
Stroke	39/718 (5.4)	44/716 (6.1)	0.93 (0.60–1.43)	
Safety				
Major adverse cardiovascular event — no. of patients with ≥1 event/total no. of patients (%)				
Event ≤30 days after procedure¶	33/718 (4.6)	23/716 (3.2)	1.46 (0.86–2.50)	0.16
Event during follow-up	269/718 (37.5)	309/716 (43.2)	0.94 (0.80–1.11)	0.48
Serious adverse event				
Event occurred ≤30 days after index procedure — no. of patients with ≥1 event/total no. of patients (%)‖	244/718 (34.0)	226/716 (31.6)		0.34
No. of events ≤30 days after index procedure	427	379		0.10
No. of patients with ≥1 event/total no. of patients (%)	590/718 (82.2)	614/716 (85.8)		0.07
No. of events during follow-up	3141	3468		<0.001
Technical success of index procedure — no./total no. (%)**	651/662 (98.3)	596/704 (84.7)		
Length of hospital stay after index procedure††				
No. of days	7.5±6.2	5.9±7.3		
Median no. of days (IQR)	6 (4–9)	3 (1–8)		



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COHORT 1—ADEQ GSV

- 106 more MALE/death in ENDOVASCULAR pts
  - 33 more deaths (234 vs 267)
  - 32 more above ankle amputations (74 vs 106)
  - 102 more major interventions (65 vs 167)
    - 66 subsequent bypasses
- SURGERY vs ENDOVASCULAR OUTCOMES
  - DEATH—33% vs 37.6%
  - MAJOR AMP—10.4% vs 14.9%
  - MAJOR REINTERVENTION—9.2% vs 23.5%

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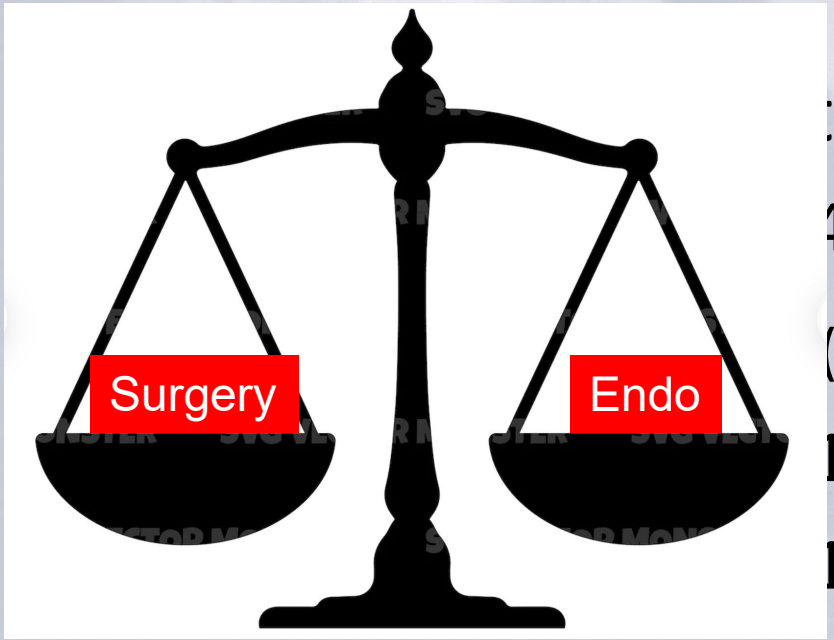
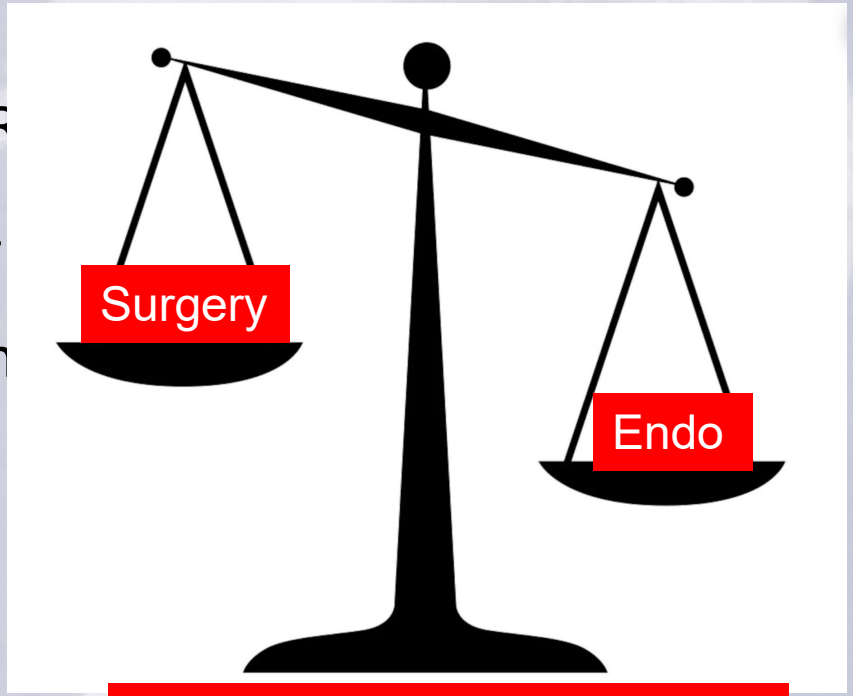
COHORT 1—ADEQ GSV—2° Outcomes

- S (F
- 434
- (Ran
- 18)
- 16)



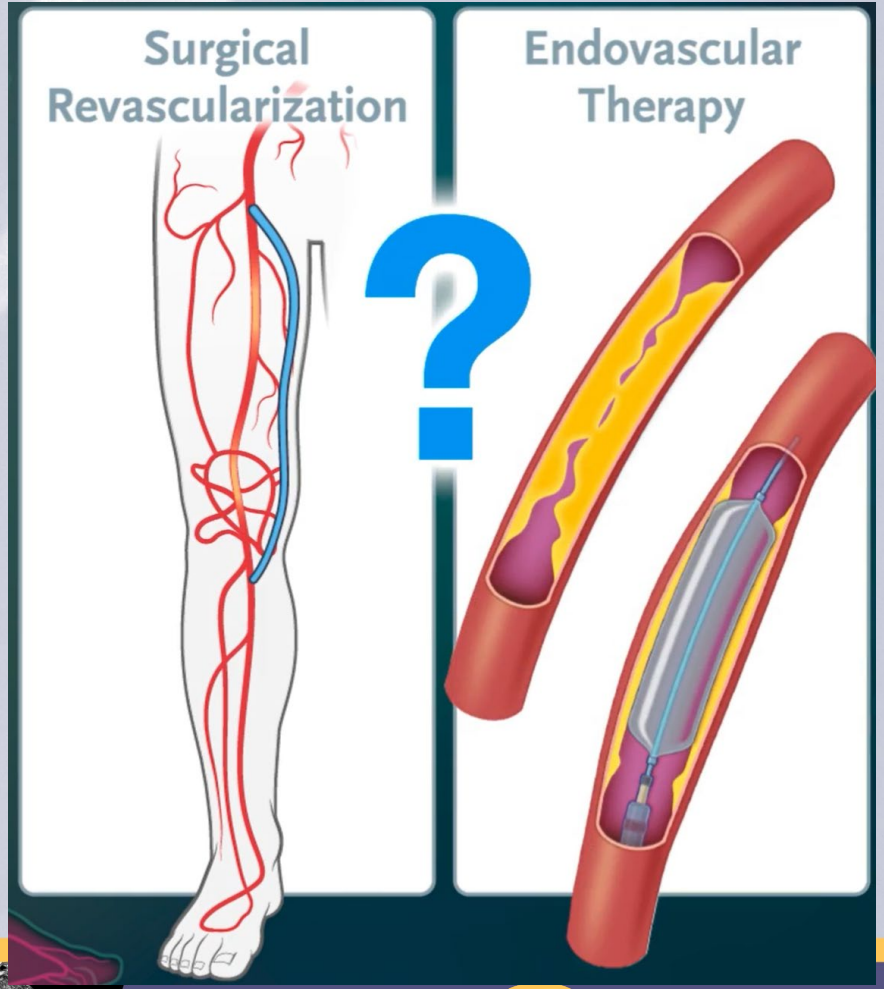
ADVERSE CV EVENT



SAFETY ADVERSE EVENT

COHORT 2—INADEQ GSV

- 396 PATIENTS—median f/u 1.6 yrs
- 197 SURGERY
  - 105 femoral–popliteal
  - 86 femoral–tibial or pedal
  - 18 popliteal–tibial or pedal
  - 48 alternative autogenous veins
  - 119 bypasses involving a prosthetic
  - 37 ADEQ GSV (19%)
- 199 ENDOVASCULAR
  - 133 SFA
  - 114 Popliteal
  - 88 tibial/pedal



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COHORT 2—INADEQ GSV

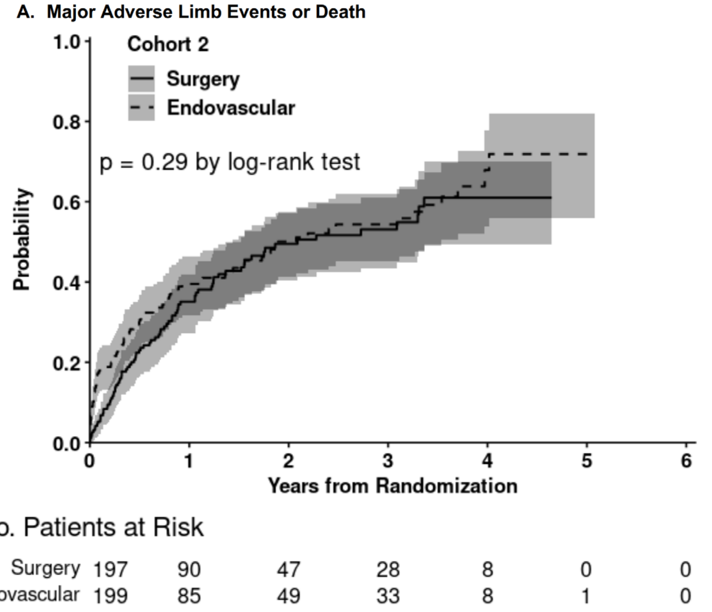
- SURGERY—100% technical success
  - 19% single segment GSV
- ENDOVASC—81% technical success
  - 37 FAILURES
    - 26 (70%) TREATED w/ Bypass w/in 30 days

COHORT 2—INADEQ GSV

MALE/Death p= 0.12

- Surgery--83/194 pts (42.8%)
- Endovascular--95/199 pts (47.7%)

Figure S3: Time to Event Curves of the Primary Endpoint and its Individual Components, Cohort 2



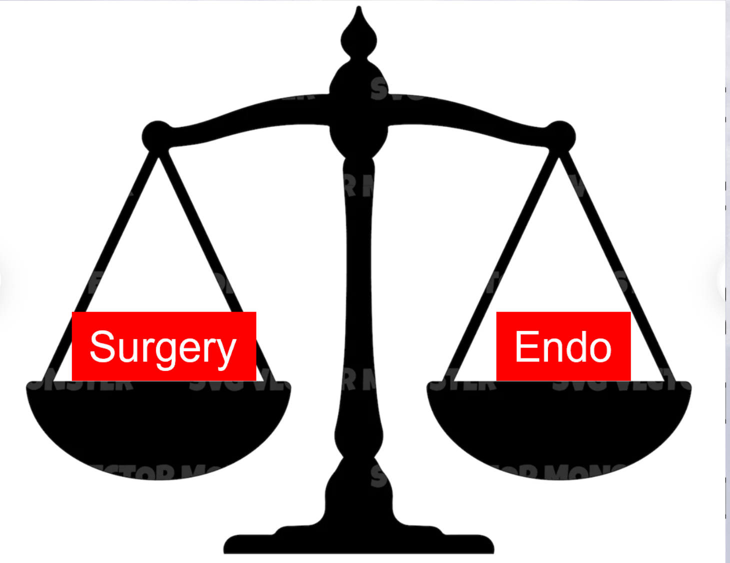
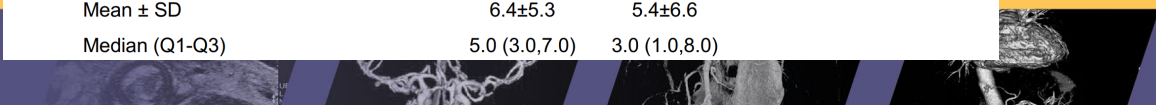


Table S10. Efficacy and Safety Endpoints for Cohort 2.

Outcomes	Surgery no. (%)	Endovascular no. (%)	HR (95% CI)**	P-value
Efficacy				
Primary outcome				
MALE or all-cause death*	83/194 (42.8)	95/199 (47.7)	0.79 (0.58,1.06)	0.12
Secondary outcomes				
All-cause death*	51/194 (26.3)	48/199 (24.1)	1.15 (0.77,1.72)	
Above-Ankle Amputation of the Index Limb*	29/194 (14.9)	28/199 (14.1)	1.10 (0.65,1.87)	
Major Reintervention on the Index Limb*	28/194 (14.4)	51/199 (25.6)	0.47 (0.29,0.76)	
Minor Reintervention on the Index Limb*	57/197 (28.9)	64/199 (32.2)	0.89 (0.62,1.27)	
MALE or POD‡	48/190 (25.3)	66/195 (33.8)	0.62 (0.43,0.91)	
POD†	5/190 (2.6)	1/195 (0.5)	-	
MI*	17/197 (8.6)	19/199 (9.5)	0.92 (0.47,1.81)	
Stroke*	5/197 (2.5)	7/199 (3.5)	0.82 (0.25,2.75)	
Safety				
MACE within 30 days¶	8/197 (4.1)	5/199 (2.5)	1.43 (0.44,4.63)	0.55
MACE*	61/197 (31.0)	63/199 (31.7)	1.06 (0.73,1.53)	0.76
SAE within 30 days, no. patients who had one or more event/no. patients§	50/197 (25.4)	49/199 (24.6)		0.91‡‡
SAE within 30 days, no. events§	84	94		0.50§§
Total SAE, no. patients who had one or more event/no. patients	151/197 (76.6)	154/199 (77.4)		0.91‡‡
Total SAE, no. events	694	749		0.21§§
Technical success of index procedure¶¶	188/188 (100.0)	154/191 (80.6)		
Length of hospital stay after index procedure§§				
Mean ± SD	6.4±5.3	5.4±6.6		
Median (Q1-Q3)	5.0 (3.0,7.0)	3.0 (1.0,8.0)		

COHORT 2

- 12 more MALE/Death in ENDO
  - 3 less Deaths (48 vs 51)
  - 1 less Major Amputation (28 vs 29)
  - 23 more Major Reinterventions (51 vs 28)
- MACE
  - SURGERY (31.0%)
  - ENDO (31.7%)
- Safety Adverse Events thru F/U
  - SURGERY (76.6%)
  - ENDO (77.4%)



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QUESTIONS

- COHORT 1 57% ENDO COHORT 2 47%

  COHORTS SO DISPARATE WHEN THEY ARE IDENTICAL FOR THE SURGERY COHORTS?

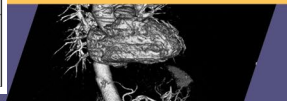
COHORT 1 43% SURGERY COHORT 2 43%

Table S4: Baseline Patient Characteristics

Characteristics	Cohort 1			Cohort 2		
	Overall (N=1434)	Surgery (N=718)	Endovascular (N=716)	Overall (N=396)	Surgery (N=197)	Endovascular (N=199)
Age — yr	66.9±9.9	66.9±9.8	67.0±10.0	68.6±9.2	68.4±8.8	68.8±9.6
Female Sex, no. (%)	408 (28.5)	201 (28.0)	207 (28.9)	111 (28.0)	56 (28.4)	55 (27.6)
Hispanic, no./total no. (%)	187/1433 (13.0)	82/717 (11.4)	105/716 (14.7)	53 (13.4)	28 (14.2)	25 (12.6)
Race, no./total no. (%)*						
White	1028/1423 (72.2)	500/711 (70.3)	528/712 (74.2)	275/390 (70.5)	143/194 (73.7)	132/196 (67.3)
Black	275/1423 (19.3)	156/711 (21.9)	119/712 (16.7)	96/390 (24.6)	40/194 (20.6)	56/196 (28.6)
Asian	20/1423 (1.4)	13/711 (1.8)	7/712 (1.0)	2/390 (0.5)	2/194 (1.0)	0 (0.0)
Other	100/1423 (7.0)	42/711 (5.9)	58/712 (8.1)	17/390 (4.4)	9/194 (4.6)	8/196 (4.1)
Body Mass Index, kg/m^2§	28.2±6.0	28.2±6.3	28.3±5.8	26.9±5.7	26.8±5.1	27.0±6.2
ASA Classification, no./total no. (%)						
1	95/1415 (6.7)	47/709 (6.6)	48/706 (6.8)	15/393 (3.8)	4/194 (2.1)	11/199 (5.5)
2	211/1415 (14.9)	89/709 (12.6)	122/706 (17.3)	55/393 (14.0)	28/194 (14.4)	27/199 (13.6)
3	910/1415 (64.3)	464/709 (65.4)	446/706 (63.2)	264/393 (67.2)	132/194 (68.0)	132/199 (66.3)
4	199/1415 (14.1)	109/709 (15.4)	90/706 (12.7)	59/393 (15.0)	30/194 (15.5)	29/199 (14.6)
Hypertension, no./total no. (%)	1238/1424 (86.9)	620/712 (87.1)	618/712 (86.8)	350/395 (88.6)	171/196 (87.2)	179/199 (89.9)
Hyperlipidemia, no./total no. (%)	1041/1423 (73.2)	521/712 (73.2)	520/711 (73.1)	299/395 (75.7)	147/196 (75.0)	152/199 (76.4)
Coronary Artery Disease, no./total no. (%)	617/1424 (43.3)	301/712 (42.3)	316/712 (44.4)	204/395 (51.6)	97/196 (49.5)	107/199 (53.8)
Congestive Heart Failure, no./total no. (%)	79/1422 (5.6)	38/711 (5.3)	41/711 (5.8)	27/395 (6.8)	12/196 (6.1)	15/199 (7.5)
Chronic Obstructive Pulmonary Disease, no./total no. (%)	208/1424 (14.6)	100/712 (14.0)	108/712 (15.2)	69/395 (17.5)	34/196 (17.3)	35/199 (17.6)

DIFFERENCES

- COHORT 1
  - More whites, fewer blacks
  - Better ASA class
  - Less HTN, HLD, CAD, CHF, COPD



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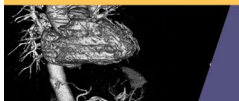
Characteristics	Cohort 1 Overall (N=1434)	Cohort 1 Surgery (N=718)	Cohort 1 Endovascular (N=716)	Cohort 2 Overall (N=396)	Cohort 2 Surgery (N=197)	Cohort 2 Endovascular (N=199)
History of Stroke, no./total no. (%)	190/1424 (13.3)	91/712 (12.8)	99/712 (13.9)	62/395 (15.7)	38/196 (19.4)	24/199 (12.1)
End Stage Kidney Disease, no./total no. (%)	151/1423 (10.6)	67/712 (9.4)	84/711 (11.8)	45/395 (11.4)	25/196 (12.8)	20/199 (10.1)
Current smoking, no./total no. (%)	509/1424 (35.7)	264/712 (37.1)	245/712 (34.4)	140/395 (35.4)	69/196 (35.2)	71/199 (35.7)
Diabetes, no./total no. (%)	1023/1424 (71.8)	513/712 (72.1)	510/712 (71.6)	238/395 (60.3)	122/196 (62.2)	116/199 (58.3)
Ambulatory Status, no./total no. (%)						
Ambulatory without assistance						
Ambulatory with assistance						
Non -ambulatory						
Living at Home, no./total no. (%)						
Medications, no./total no. (%)						
Treated pharmacologically for smoking						
At least one statin	1001/1424 (70.3)	503/713 (70.5)	498/711 (70.0)	307/394 (77.9)	153/195 (78.5)	154/199 (77.4)
At least one antiplatelet drug	1025/1424 (72.0)	508/713 (71.2)	517/711 (72.7)	303/394 (76.9)	153/195 (78.5)	150/199 (75.4)
At least one aspirin	953/1424 (66.9)	476/713 (66.8)	477/711 (67.1)	280/394 (71.1)	139/195 (71.3)	141/199 (70.9)
At least one clopidogrel	312/1424 (21.9)	137/713 (19.2)	175/711 (24.6)	97/394 (24.6)	55/195 (28.2)	42/199 (21.1)
At least one prasugrel	5/1424 (0.4)	2/713 (0.3)	3/711 (0.4)	1/394 (0.3)	0/195 (0.0)	1/199 (0.5)
At least one ticagrelor	10/1424 (0.7)	4/713 (0.6)	6/711 (0.8)	4/394 (1.0)	0/195 (0.0)	4/199 (2.0)
Dual Antiplatelet Therapy	254/1424 (17.8)	110/713 (15.4)	144/711 (20.3)	79/394 (20.1)	41/195 (21.0)	38/199 (19.1)

DIFFERENCES

- Cohort 1

COHORT 1 HEALTHIER THAN COHORT 2



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PRIMARY ENDPOINTS
ENDOVASCULAR COHORTS

	COHORT 1	COHORT 2
DEATH	37.6%	24.1%
MAJOR AMP	14.9%	14.1%
MAJOR REINT	23.5%	25.6%

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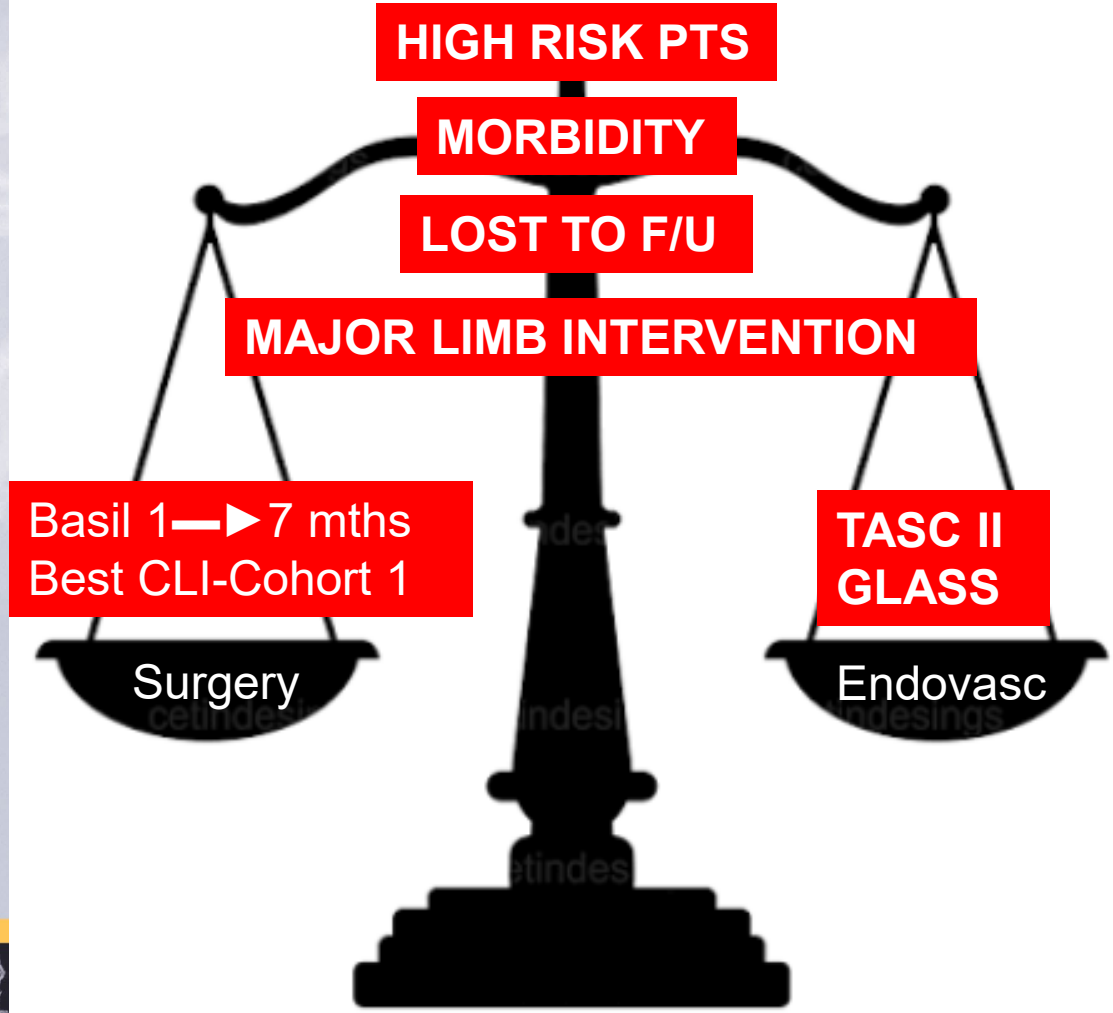
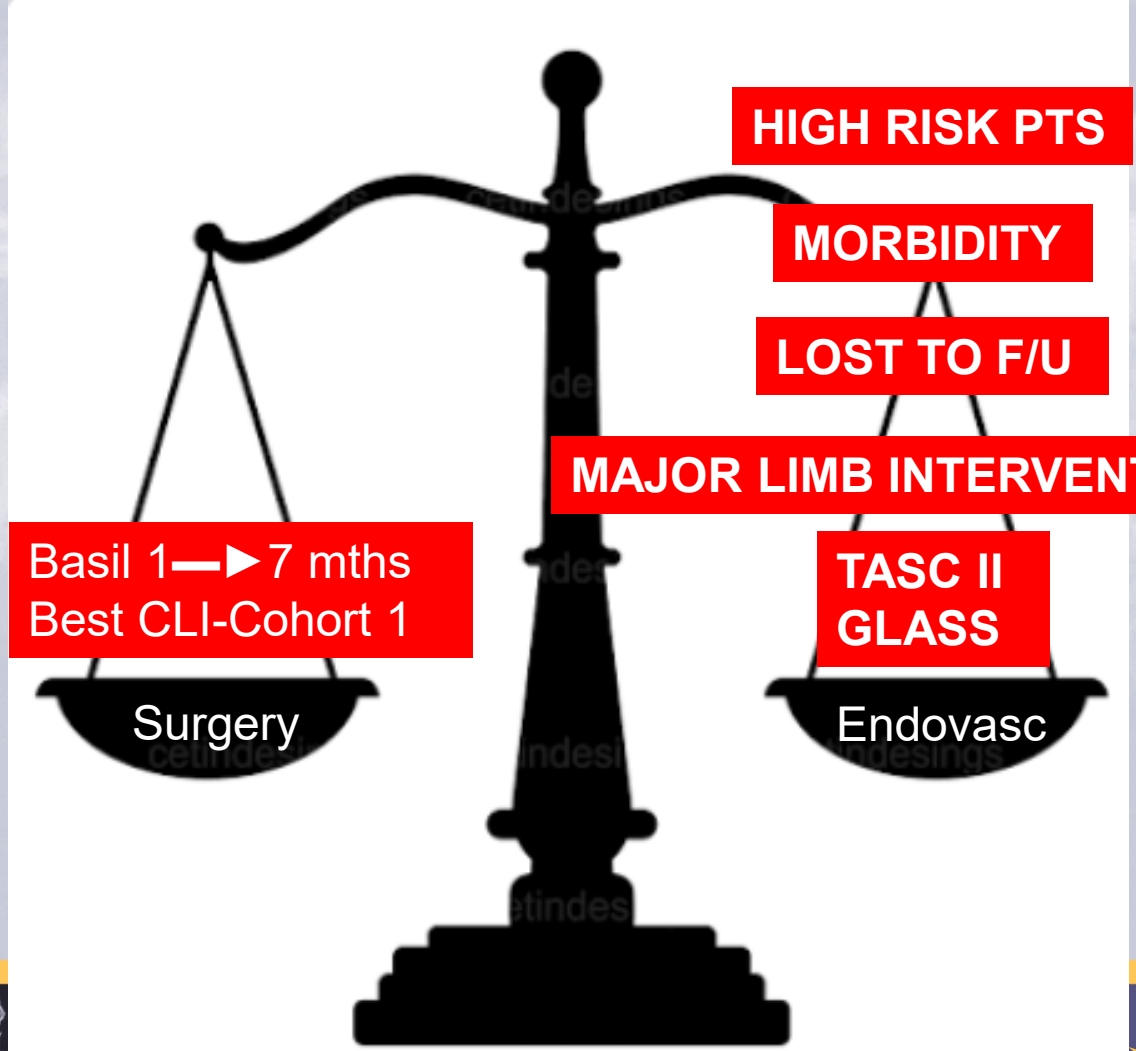
LIMITATIONS

- Planned number of patient enrollment not met
- 667/2525 (26.4%) EXCLUDED ➡ REGISTRY
- 363 pts lost to f/u (19.8%)
- Low technical success rates for endo (80-85%)
- 66% had infrapopliteal disease however complexity of disease not well defined


HIGH RISK PTS
MORBIDITY
LOST TO F/U
MAJOR LIMB INTERVENTION
Basil 1—►7 mths
Best CLI-Cohort 1
TASC II
GLASS
Surgery
Endovasc


HIGH RISK PTS
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Basil 1—►7 mths
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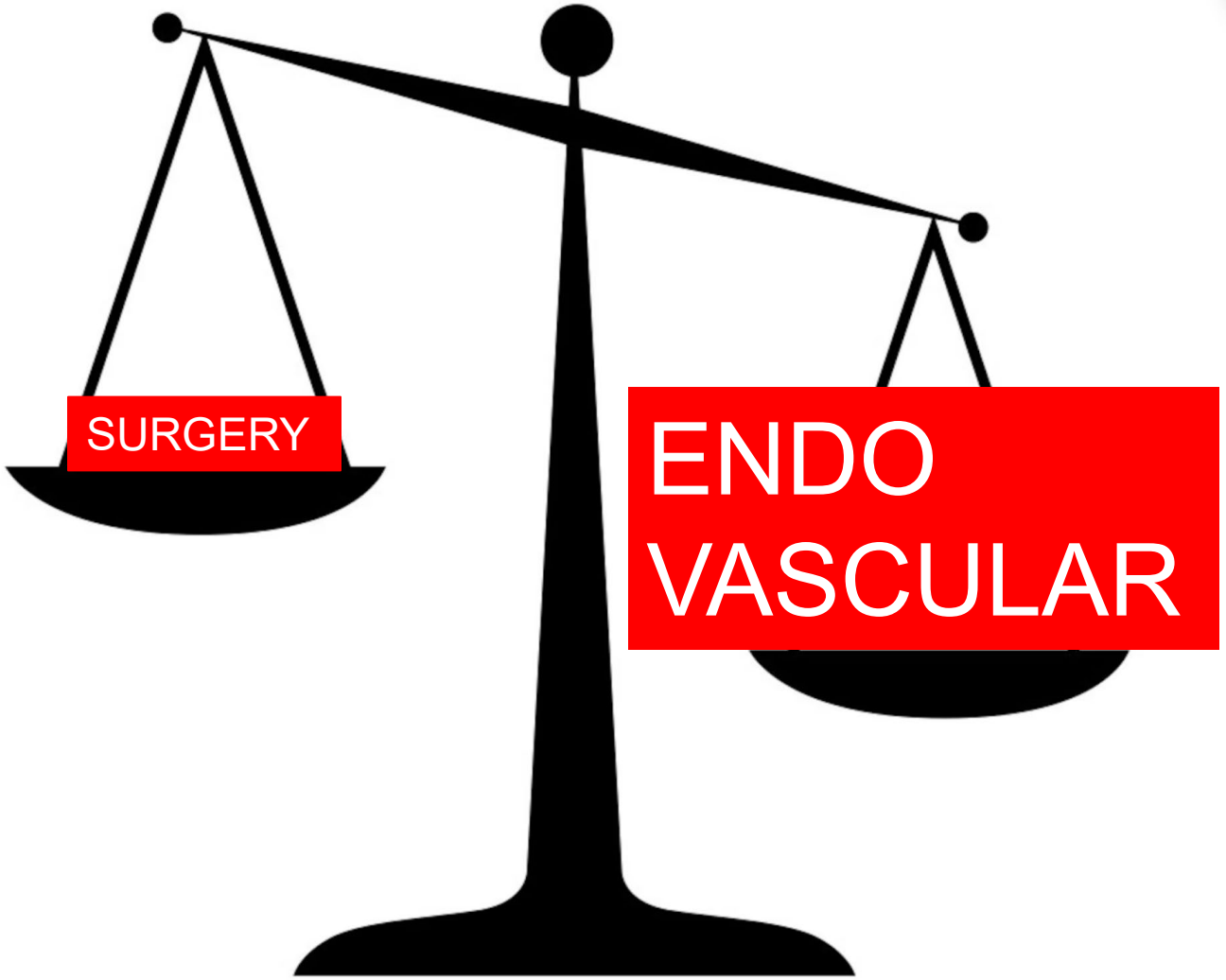
Surgery
Endovasc


SURGERY
ENDO
VASCULAR

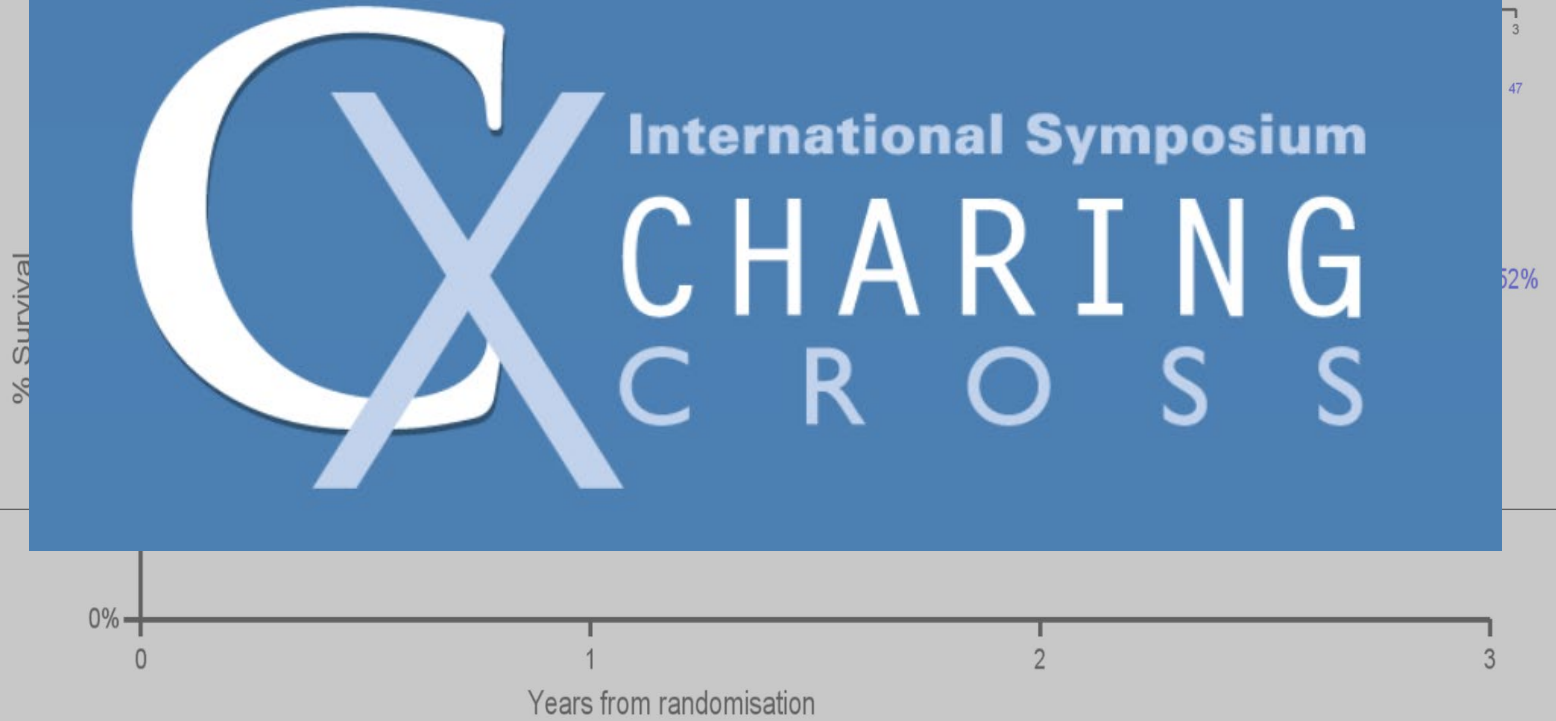
THANK YOU

twgensle@sentara.com

B-2 AFS/OS
(whole cohort)

Overall survival (OS)
60% at 3 years

International Symposium
CHARING CROSS



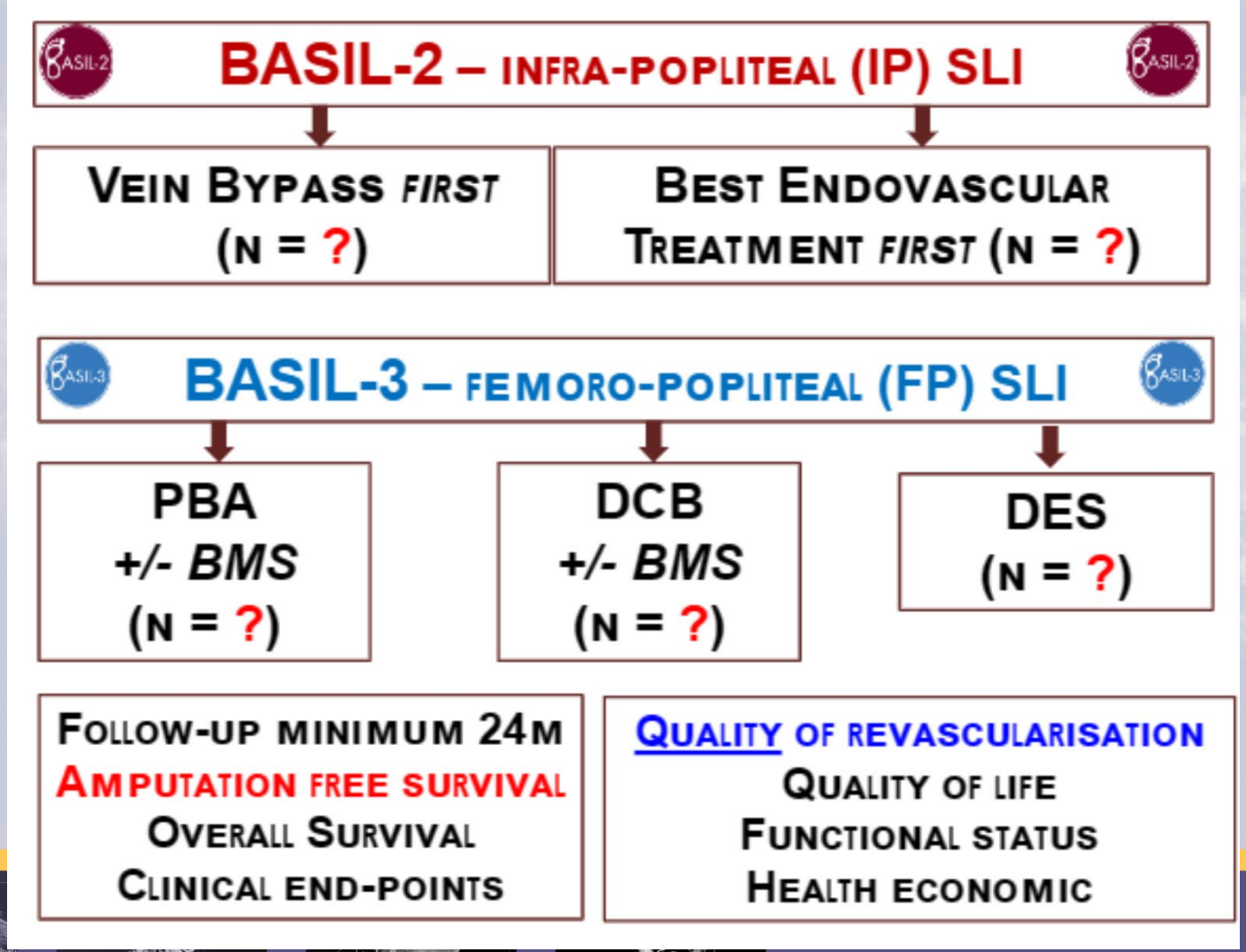

BASIL-2 – INFRA-POPLITEAL (IP) SLI
VEIN BYPASS FIRST (N = ?)
BEST ENDOVASCULAR TREATMENT FIRST (N = ?)
BASIL-3 – FEMORO-POPLITEAL (FP) SLI
PBA +/- BMS (N = ?)
DCB +/- BMS (N = ?)
DES (N = ?)
FOLLOW-UP MINIMUM 24M
AMPUTATION FREE SURVIVAL
OVERALL SURVIVAL
CLINICAL END-POINTS
QUALITY OF REVASCULARISATION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

Figure S4: Subgroup Analyses of the Primary Endpoint, Cohort 2

Subgroup	Surgery no. event/ no.total(%)	Endovascular no. event/ no.total(%)	HR (95% CI)
Overall	**83/194 (43)**	**95/199 (48)**	**0.79 (0.58,1.06)**
Infrainguinal PAD and infrapopliteal occlusive disease			
Yes	52/122 (43)	65/127 (51)	0.68 (0.47,0.99)
No	31/72 (43)	30/72 (42)	1.08 (0.64,1.84)
Rutherford category			
Rutherford category 4	20/57 (35)	29/60 (48)	0.66 (0.36,1.23)
Rutherford category 5 and 6	63/137 (46)	66/139 (47)	0.89 (0.62,1.26)
Gender			
Male	62/140 (44)	70/144 (49)	0.78 (0.55,1.10)
Female	21/54 (39)	25/55 (45)	0.96 (0.52,1.78)
Race			
White	61/141 (43)	63/132 (48)	0.73 (0.50,1.04)
Black	18/39 (46)	28/56 (50)	0.83 (0.44,1.56)
Asian	1/2 (50)		
All Others	2/9 (22)	3/8 (38)	
Ethnicity			
Hispanic	10/27 (37)	10/25 (40)	0.69 (0.23,2.05)
Non-Hispanic	73/167 (44)	85/174 (49)	0.73 (0.53,1.02)
Race/ethnicity			
Hispanic	10/27 (37)	10/25 (40)	0.69 (0.23,2.05)
Black Non-Hispanic	18/39 (46)	28/55 (51)	0.77 (0.41,1.45)
All Others	55/127 (43)	57/119 (48)	0.70 (0.48,1.04)
Age			
< 80 yr	75/177 (42)	78/173 (45)	0.82 (0.60,1.14)
≥ 80 yr	8/17 (47)	17/26 (65)	0.53 (0.19,1.48)
Age (Quartiles)			
< 60.96 yr	17/40 (43)	20/39 (51)	0.95 (0.48,1.88)
60.96 to 67.15 yr	18/51 (35)	17/47 (36)	0.82 (0.39,1.73)
67.16 to 73.82 yr	21/49 (43)	28/58 (48)	0.60 (0.31,1.15)
≥ 73.83 yr	27/54 (50)	30/55 (55)	0.70 (0.39,1.23)
Diabetes			
Diabetes	55/120 (46)	52/116 (45)	1.03 (0.70,1.53)
No Diabetes	28/74 (38)	43/83 (52)	0.63 (0.38,1.03)
WIfI Grade 3 wound on index limb			
Grade 3 wound	4/12 (33)	6/11 (55)	
Less than Grade 3 wound	76/178 (43)	86/180 (48)	0.80 (0.58,1.09)

COHORT 2—INADEQ GSV

- Endo
  - More infrapop dz (50% v 40%)

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MORBIDITY/MORTALITY OF OPEN SURGICAL BYPASS

BASIL (2005)	PREVENT III (2006)
• MORTALITY—5.5%	• MORTALITY—2.7%
• MI—7%	• MI—4.7%
• STROKE—1.5%	• STROKE—1.4%
• WND CMPLX—22%	• WND CMPLX—4.8%




REVIEW ARTICLES

Richard P. Cambria, MD, Section Editor

Bypass surgery versus endovascular interventions in severe or critical limb ischemia

Abd Moain Abu Dabrh, MBBCh, MS,[a,b] Mark W. Steffen, MD, MPH,[a] Noor Asi, MD,[b] Chaitanya Undavalli, MBBS,[b] Zhen Wang, PhD,[b] Mohamed B. Elamin, MD,[b] Michael S. Conte, MD,[c] and Mohammad Hassan Murad, MD, MPH,[a,b] *Rochester, Minn; and San Francisco, Calif*

JVS Journal of Vascular Surgery SVS Society for Vascular Surgery

VOLUME 63, ISSUE 1, P244-253.E11, JANUARY 2016

- Commissioned by SVS
- 9 studies/3071 subjects
- No significant difference
  - mortality (OR, 0.72; 95% confidence interval [CI], 0.44-1.16)
  - amputation (OR, 1.2; 95% CI, 0.87-1.65).
- Bypass surgery was associated with higher primary patency (OR, 2.50; 95% CI, 1.25 4.99) and assisted primary patency (OR, 3.39; 95% CI, 1.53-7.51).
- The quality of evidence was low for mortality and amputation outcomes and moderate for patency outcomes

2015 TASC II UPDATE
Infrapopliteal disease

- In a large meta-analysis of series using PTA as the primary treatment modality that included many older series, the 3-year limb salvage rate was 82.4%.

Romiti M, Albers M, Brochado-Neto FC, et al. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. *J Vasc Surg*. 2008;47:975–981.

Age

70 y

Gender ✓ Male F

Race ✓ Black Nor

Smoker ✓ Ye

CVD risk is reversed after 5-10 years of no s

Diabetes ✓ Ye

Systolic Blood Pressure

150 r

Enter present blood pressure regardless of t

120 mmHg is used for baseline risk

On treatment for BP ✓ Ye

Click YES if taking blood pressure medicatio

Total Cholesterol

116 mg/dL

Cholesterol should be prior to drug treatment

HDL Cholesterol

If father (< 55 yrs) increase risk 75%

10 years

HIGH RISK > 15%

45.1%	No event
54.9%	Total with an event
0.0%	Number who benefit from treatment
∞	Number needed to treat
9.0%	Baseline events using baseline factors alone

A systematic review and meta-analysis of revascularization outcomes of infrainguinal chronic limb-threatening ischemia

JVS Journal of Vascular Surgery SVS Society for Vascular Surgery

Jehad Almasri, MD • Jayanth Adusumalli, MBBS, MPH • Noor Asi, MD • Sumaya Lakis, MD • Mouaz Alsawas, MD, MSc • Larry J. Prokop, MLS • Andrew Bradbury, BSc, MB, ChB Honours, MD, MBA, FRCSEd • Philippe Kolh, MD, PhD • Michael S. Conte, MD • M. Hassan Murad, MD, MPH • Show less

Journal of Vascular Surgery, Vol. 68, Issue 2, p624–633, Published online: May 24, 2018

- 44 studies/8600 pts
- **Infrapopliteal disease**
  - GSV patency had higher patency rates at 1 and 2 years (Primary: 87%, 78%; Secondary: 94%, 87%, respectively) compared with all other interventions
- **DES**
  - improved patency over BMS in infrapopliteal dz (1°patency: 73% vs 50% at 1 yr), and was at least comparable to balloon angioplasty (66% primary patency)
- **Mortality**
  - NO SIGNIFICANT DIFFERENCE @ 1 AND 3 YRS

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A systematic review and meta-analysis of revascularization outcomes of infrainguinal chronic limb-threatening ischemia

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SUPPORTING REVIEW ARTICLE | VOLUME 69, ISSUE 6, SUPPLEMENT , 126S-136S, JUNE 2019 Download Full Issue

- Overall, it seems that major adverse events seen in patients with CTLI did not importantly differ between endovascular and open bypass. Increased patency did not always correlate with a significant effect on survival and risk of amputation, which may be a limitation of the available evidence.

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Age

50 years

Gender

Male ✓ Female

Race

Black ✓ Non-Black

Smoker

Yes ✓ No

CVD risk is reversed after 5-10 years of no smoking

Diabetes

Yes ✓ No

Systolic Blood Pressure

120 mmHg

Enter present blood pressure regardless of treatment

120 mmHg is used for baseline risk

On treatment for BP

Yes ✓ No

Click YES if taking blood pressure medication

Only applies if SBP is greater than 120 mmHg

Total Cholesterol

116 mg/dL

Cholesterol should be prior to drug treatment

HDL Cholesterol

50 mg/dL

HDL should be prior to drug treatment

50 mg/dL is used for baseline risk.

Chronic Kidney Disease

Yes ✓ No

CKD status is not part of the risk algorithm but is used for calculating the benefit of certain therapies

Family History of Early CHD

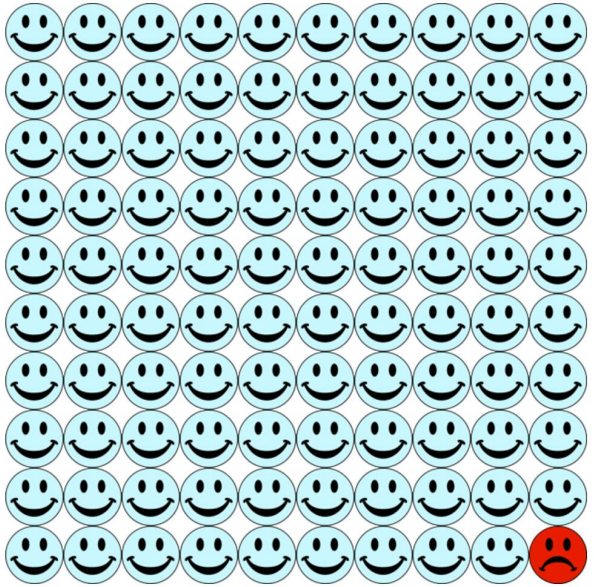
0 %

The amount of additional risk (relative increase in risk) conferred from a family member to a patient depends on: (1) how close a relative, (2) age of a relative, (3) number of affected family members.

If mother (< 65 yrs) increase risk 60%

If father (< 55 yrs) increase risk 75%

10 years



	99.4%	No event
	0.6%	Total with an event
	0.0%	Number who benefit from treatment
NNT	∞	Number needed to treat
	0.6%	Baseline events using baseline factors alone

Characteristics	Cohort 1 Overall (N=1434)	Cohort 1 Surgery (N=718)	Cohort 1 Endovascular (N=716)	Cohort 2 Overall (N=396)	Cohort 2 Surgery (N=197)	Cohort 2 Endovascular (N=199)
At least one DOAC	55/1424 (3.9)	27/713 (3.8)	28/711 (3.9)	22/394 (5.6)	9/195 (4.6)	13/199 (6.5)
At least one warfarin	93/1424 (6.5)	46/713 (6.5)	47/711 (6.6)	31/394 (7.9)	12/195 (6.2)	19/199 (9.5)
Previous infrainguinal revascularization on index limb, no./total no. (%)	77/1423 (5.4)	40/711 (5.6)	37/712 (5.2)	40/393 (10.2)	20/194 (10.3)	20/199 (10.1)
Randomization Stratum, no./total no. (%)						
Ischemic rest pain without significant infrapopliteal disease	127 (8.9)	64 (8.9)	63 (8.8)	49 (12.4)	24 (12.2)	25 (12.6)
Tissue loss without significant infrapopliteal disease	348 (24.3)	175 (24.4)	173 (24.2)	95 (24.0)	48 (24.4)	47 (23.6)
Ischemic rest pain with significant infrapopliteal disease	164 (11.4)	82 (11.4)	82 (11.5)	70 (17.7)	35 (17.8)	35 (17.6)
Tissue loss with significant infrapopliteal disease	795 (55.4)	397 (55.3)	398 (55.6)	182 (46.0)	90 (45.7)	92 (46.2)
SVS WIfI Stage, no./total no. (%)						
Stage 1	84/1223 (6.9)	46/606 (7.6)	38/617 (6.2)	15/345 (4.3)	9/172 (5.2)	6/173 (3.5)
Stage 2	321/1223 (26.2)	162/606 (26.7)	159/617 (25.8)	127/345 (36.8)	62/172 (36.0)	65/173 (37.6)
Stage 3	370/1223 (30.3)	167/606 (27.6)	203/617 (32.9)	94/345 (27.2)	48/172 (27.9)	46/173 (26.6)
Stage 4	448/1223 (36.6)	231/606 (38.1)	217/617 (35.2)	109/345 (31.6)	53/172 (30.8)	56/173 (32.4)
Mean index leg ABI ± SD§	0.58±0.32	0.58±0.31	0.59±0.34	0.54±0.30	0.53±0.27	0.54±0.32
Mean Ankle Pressure ± SD, mm Hg§	84.9±47.7	85.2±46.2	84.5±49.2	81.3±49.6	80.4±47.3	82.2±51.8
Mean Toe Pressure ± SD, mm Hg§*	36.3±25.7	36.5±27.7	36.1±23.5	31.0±21.7	37.0±23.5	25.5±18.4

DIFFERENCES

- COHORT 1
  - Less DOAC, Warfarin
  - Less previous infrainguinal revasc
  - Less infrapop dz in pts w/ rest pain (6%)
  - More infrapop dz in pts w/ tissue loss (9%)
  - More WIfI 1, 3, 4
  - Better ABI and toe pressures

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Characteristics	Cohort 1			Cohort 2		
	Overall (N=1434)	Surgery (N=718)	Endovascular (N=716)	Overall (N=396)	Surgery (N=197)	Endovascular (N=199)
Endovascular Therapy Details, no. (%)						
Location, no. (%)						
Superficial Femoral Artery	487 (34.9)	12 (1.7)	475 (67.1)	133 (34.5)	5 (2.6)	128 (65.6)
Popliteal Artery	382 (27.4)	6 (0.9)	376 (53.1)	114 (29.6)	2 (1.1)	112 (57.4)
Tibial/Pedal Arteries	381 (27.3)	17 (2.5)	364 (51.4)	86 (22.3)	2 (1.1)	84 (43.1)
Technique, no. (%)						
Atherectomy	102 (7.3)	6 (0.9)	96 (13.6)	31 (8.1)	1 (0.5)	30 (15.4)
Angioplasty alone	396 (28.4)	23 (3.3)	373 (52.7)	96 (24.9)	4 (2.1)	92 (47.2)
Drug-coated balloon angioplasty	206 (14.8)	9 (1.3)	197 (27.8)	50 (13.0)	1 (0.5)	49 (25.1)
Bare metal Stents	322 (23.1)	44 (6.4)	278 (39.3)	93 (24.2)	9 (4.7)	84 (43.1)
Drug-eluting stents	177 (12.7)	6 (0.9)	171 (24.2)	43 (11.2)	1 (0.5)	42 (21.5)
Stent-grafts	72 (5.2)	11 (1.6)	61 (8.6)	28 (7.3)	3 (1.6)	25 (12.8)
Superficial Femoral Artery, no. (%)						
Atherectomy	53 (3.8)	2 (0.3)	51 (7.2)	19 (4.9)	1 (0.5)	18 (9.2)
Angioplasty alone	111 (8.0)	2 (0.3)	109 (15.4)	27 (7.0)	0 (0.0)	27 (13.8)
Drug-coated balloon angioplasty	139 (10.0)	8 (1.2)	131 (18.5)	30 (7.8)	1 (0.5)	29 (14.9)
Bare metal Stents	209 (15.0)	2 (0.3)	207 (29.2)	64 (16.6)	2 (1.1)	62 (31.8)
Drug-eluting stents	120 (8.6)	3 (0.4)	117 (16.5)	30 (7.8)	1 (0.5)	29 (14.9)
Stent-grafts	47 (3.4)	1 (0.1)	46 (6.5)	19 (4.9)	0 (0.0)	19 (9.7)

DIFFERENCES

- COHORT 1
  - More SFA/tibial
  - More POBA—5%
  - More DCB—3%
  - Less BMS—4%
  - More DES—3%
  - Less stent grafts-4%

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      - Fourth level
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- Eagle Criteria:
  - Specific to cardiac risk after vascular surgery
  - Age > 70, Angina, Hx of MI or Q wave, CHF, DM
  - 0 factors = 3%, 1-2 factors = 8-15%, 3 factors = 18-50%
  - Intermediate risk then stress test
  - High risk then consider going straight to catheterization

- Goldman's risk index scoring
  - Age over 70 years (5 points)
  - Myocardial infarction occurring within the last 6 months (10 points)
  - Presence of heart failure signs (JVD, or ventricular gallop) (11 points)
  - Significant aortic stenosis (3 points)
  - Arrhythmia (other than sinus or premature atrial contractions) (7 points)
  - The presence of 5 or more PVCs per minute (7 points)

- Goldman's risk index scoring cont'd
  - Medical history or conditions including (3 points): Presence of PO2 less than 60; PCO2 greater than 50; K below 3; HCO3 under 20; BUN over 50 serum creatinine greater than 3; Elevated SGOT, chronic liver disease; Being bedridden
  - Type of operation:
    - Emergency (4 points)
    - Intraperitoneal, intrathoracic, or aortic (3 points)

- Goldman's risk index scoring
  - Class I (0 to 5 points): 1.0% risk of cardiac complications
  - Class II (6 to 12 points): 7.0% risk of cardiac complications
  - Class III (13 to 25 points): 14% risk of cardiac complications
  - Class IV (26 to 53 points): 78% risk of cardiac complications

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial

- UK trial- 452 p lovascular therapy (angioplasty) f
- Primary endpc
- Similar rates o lity at 1 & 3 years.
- More reinterv s. 18%).
- Higher costs o

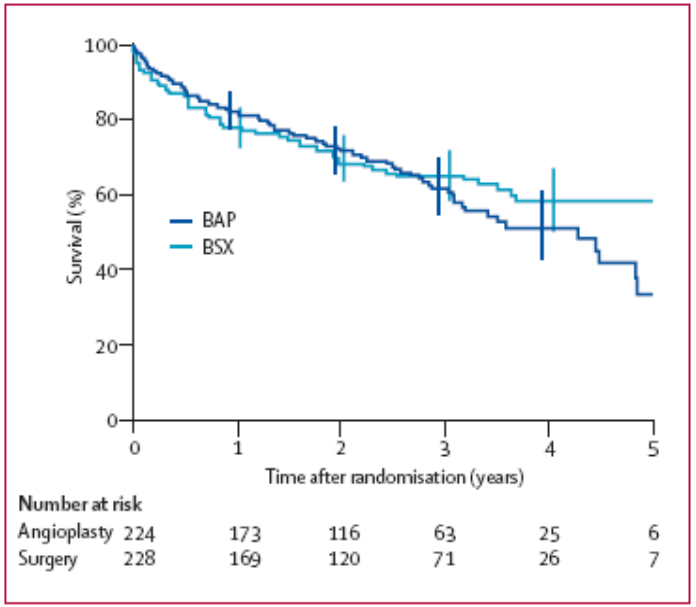

Figure 3: **All-cause mortality after bypass surgery and balloon angioplasty**
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

Lancet 2005; 366: 1925–34

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