RIVASCOLARIZZAZIONE DEL PAZIENTE DIABETICO CON PAD

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UNIVERSITÀ DEGLI STUDI FIRENZE

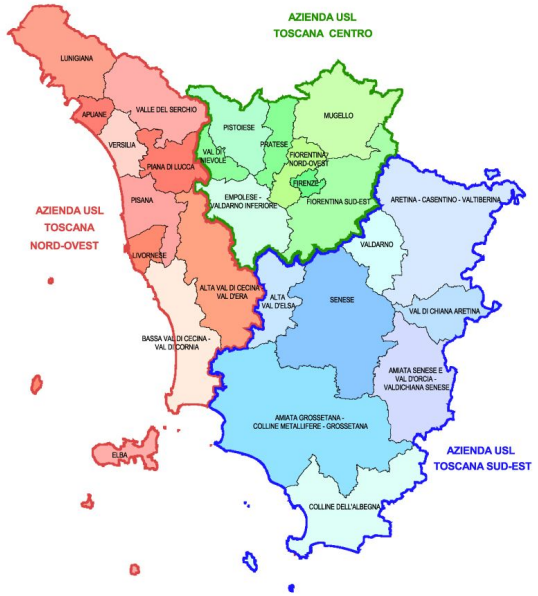
Tasso di amputazioni maggiori per Diabete per milione di residenti in Toscana

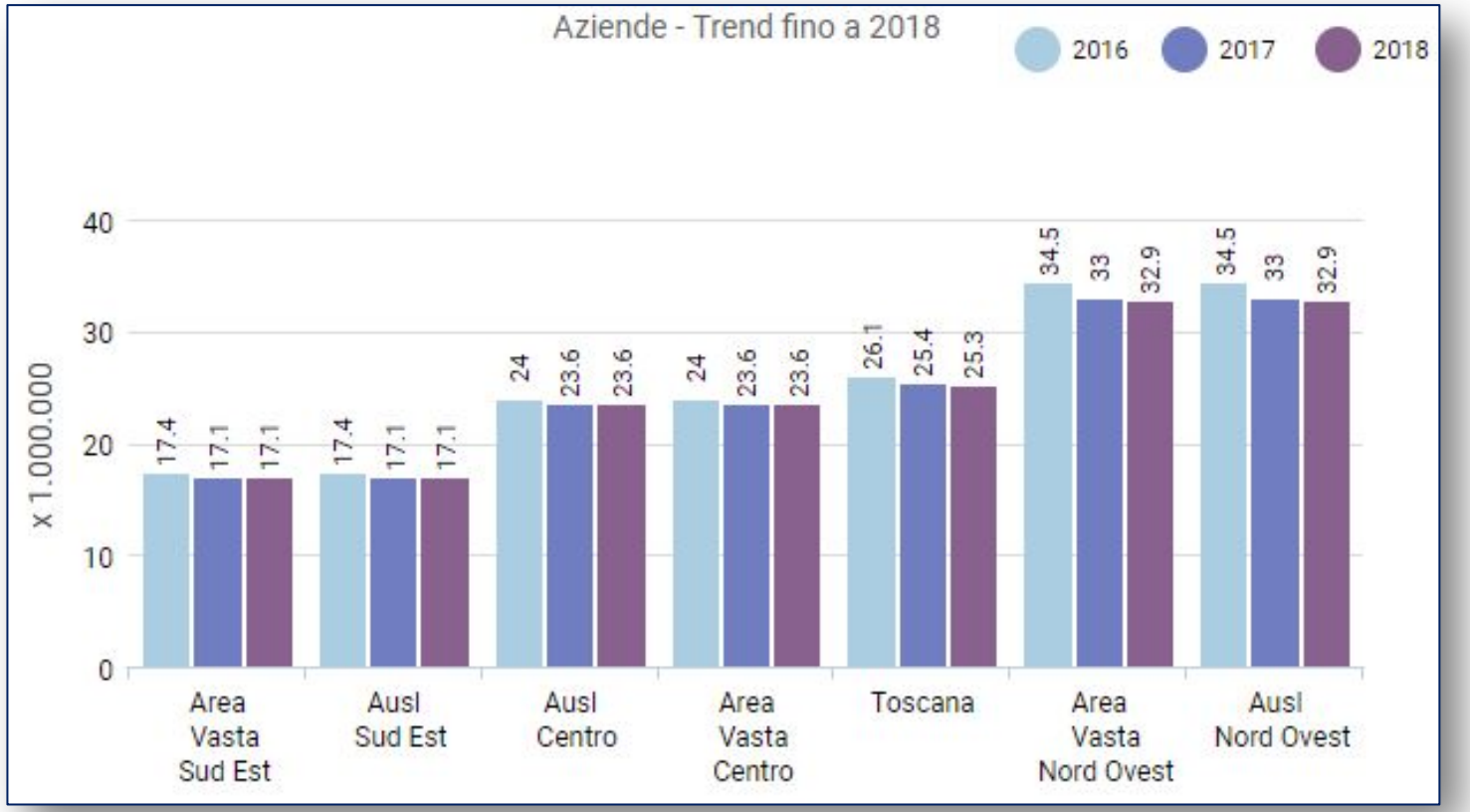
Confronto portato avanti su mandato della Regione Toscana dal Laboratorio MeS e dalla comunità professionale di riferimento

Target population

The target population of patients includes adults with CLTI, defined as a patient with objectively documented PAD and *any* of the following clinical symptoms or signs:

- Ischemic rest pain with confirmatory hemodynamic studies
- Diabetic foot ulcer (DFU) or any lower limb ulceration present for at least 2 weeks
- Gangrene involving any portion of the lower limb or foot





CLINICAL PRACTICE GUIDELINE DOCUMENT

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

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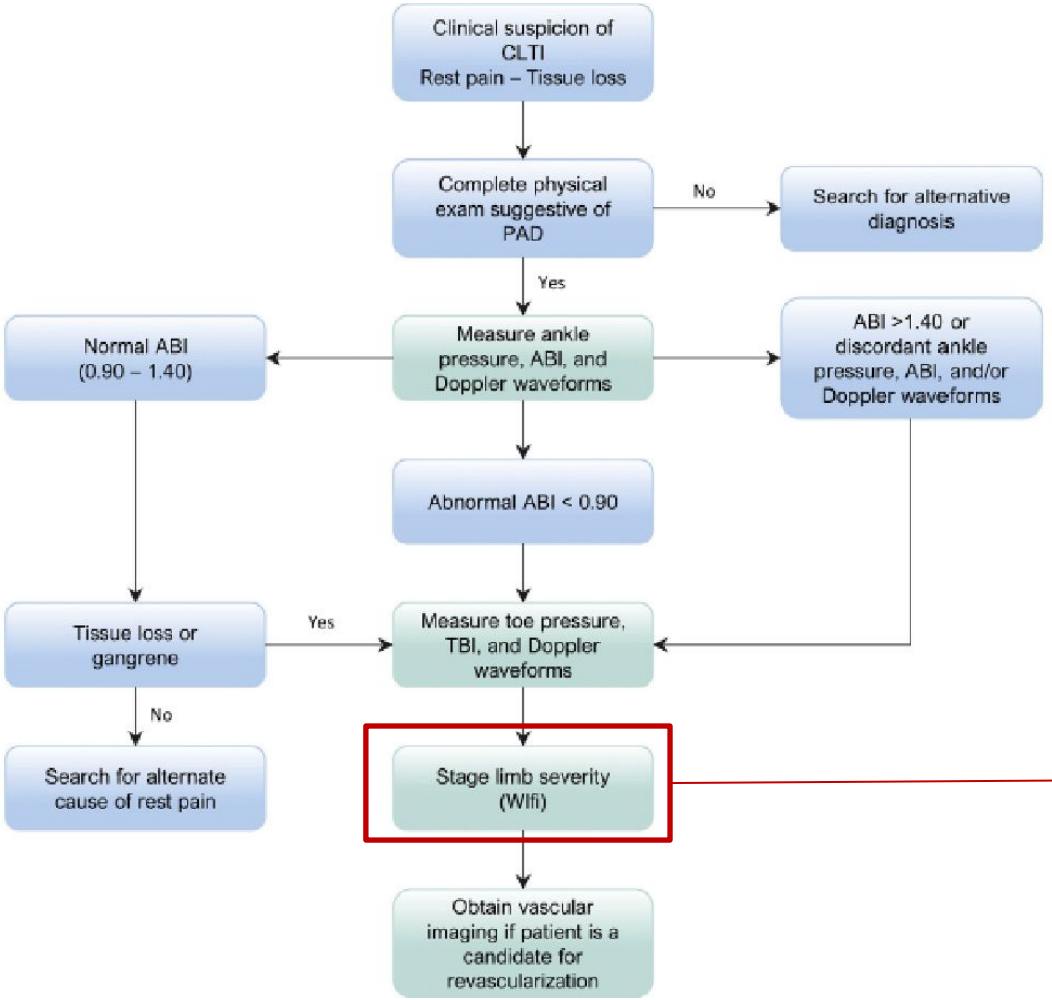
Joint guidelines of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies

Fig 3.1. Flow diagram for the investigation of patients presenting with suspected chronic limb-threatening ischemia (CLTI). *ABI*, Ankle-brachial index; *PAD*, peripheral artery disease; *TBI*, toe-brachial index; *WIfI*, Wound, Ischemia, and foot Infection.



a, Estimate risk of amputation at 1 year for each combination

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1				Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

fI, foot Infection; I, Ischemia; W, Wound.

Premises:

1. Increase in wound class increases risk of amputation (based on PEDIS, UT, and other wound classification systems)
2. PAD and infection are synergistic (Eurodiale); infected wound + PAD increases likelihood revascularization will be needed to heal wound
3. Infection 3 category (systemic/metabolic instability): moderate to high-risk of amputation regardless of other factors (validated IDSA guidelines)

Four classes: for each box, group combination into one of these four classes

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

Table 3.2. Wound grading in Wound, Ischemia, and foot Infection (WIfI) classification

Grade	Ulcer	Gangrene
0	No ulcer	No gangrene
Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.		
1	Small, shallow ulcer on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.		
2	Deeper ulcer with exposed bone, joint, or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
Clinical description: major tissue loss salvageable with multiple (≥3) digital amputations or standard TMA ± skin coverage.		
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full-thickness heel ulcer ± calcaneal involvement	Extensive gangrene involving forefoot and/or midfoot; full-thickness heel necrosis ± calcaneal involvement
Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction (nontraditional transmetatarsal, Chopart, or Lisfranc amputation); flap coverage or complex wound management needed for large soft tissue defect.		

TMA, Transmetatarsal amputation.

Table 3.3. Ischemia grading in Wound, Ischemia, and foot Infection (WIfI) classification

Grade	ABI	Ankle systolic pressure	TP, $TcPo_2$
0	≥0.80	>100 mm Hg	≥60 mm Hg
1	0.6-0.79	70-100 mm Hg	40-59 mm Hg
2	0.4-0.59	50-70 mm Hg	30-39 mm Hg
3	≤0.39	<50 mm Hg	<30 mm Hg

Table 3.4. Foot infection grading in Wound, Ischemia, and foot Infection (WIfI) classification

Clinical manifestation of infection	SVS	IDSA/PEDIS infection severity
No symptoms or signs of infection	0	Uninfected
Infection present, as defined by the presence of at least two of the following items: • Local swelling or induration • Erythema >0.5 to ≤2 cm around the ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous secretion)	1	Mild
Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis).		
Local infection (as described above) with erythema >2 cm or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis) and no systemic inflammatory response signs (as described below).	2	Moderate
Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: • Temperature >38°C or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $Paco_2$ <32 mm Hg • White blood cell count >12,000 or <4000 cells/mm^3 or 10% immature (band) forms	3	Severe[a]

Risk of amputation	Proposed clinical stages	WIfI spectrum score
Very low	Stage 1	W0 I0 fI0,1
		W0 I1 fI0
		W1 I0 fI0,1
		W1 I1 fI 0
Low	Stage 2	W0 I0 fI2
		W0 I1 fI1
		W0 I2 fI0,1
		Wo I3 fI0
		W1 I0 fI2
		W1 I1 fI1
		W1 I2 fI0
		W2 I0 fI0/1
Moderate	Stage 3	W0 I0 fI3
		W0 I2 fI1,2
		W0 I3 fI1,2
		W1 I0 fI3
		W1 I1 fI2
		W1 I2 fI1
		W1 I3 fI0,1
		W2 I0 fI2
		W2 I 1 fI0,1
		W2 I2 fI0
		W3 I0 fI0,1
High	Stage 4	W0 I1,2,3 fI3
		W1 I1 fI3
		W1 I2,3 fI2,3
		W2 I0 fI3
		W2 I1 fI2,3
		W2 I2 fI1,2,3
		W2 I3 fI0,1,2,3
		W3 I0 fI2,3
		W3 I1,2,3 fI0,1,2,3

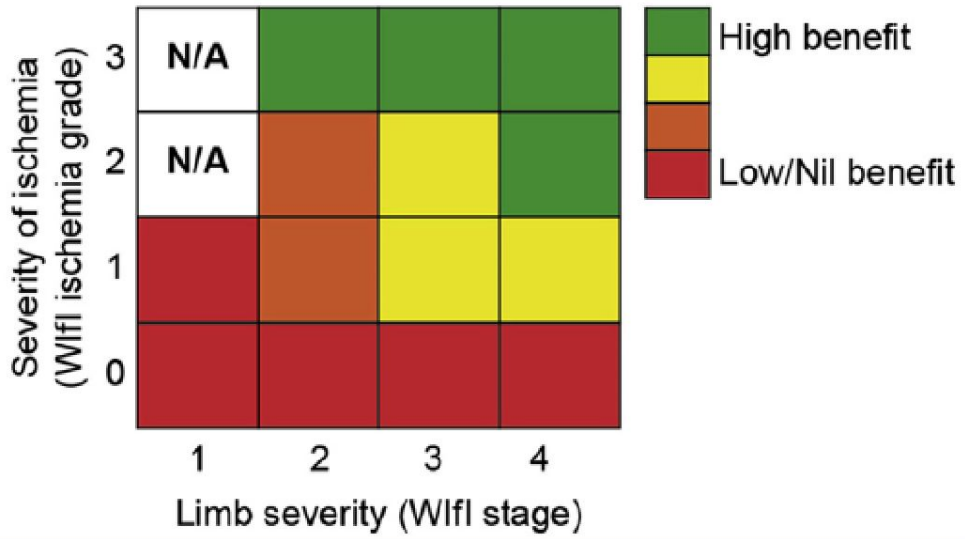
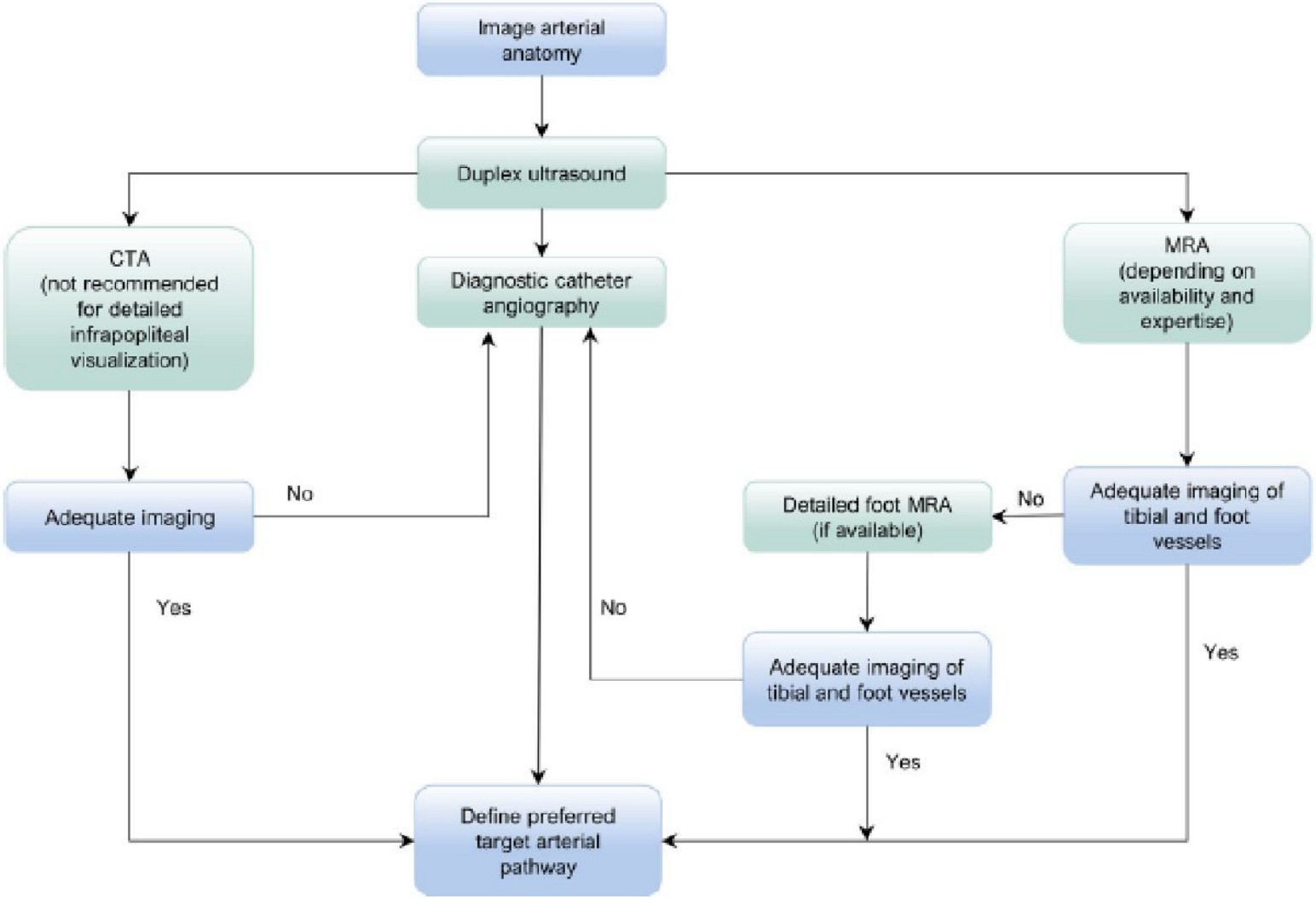


Fig 6.3. The benefit of performing revascularization in chronic limb-threatening ischemia (CLTI) increases with degree of ischemia and with the severity of limb threat (Wound, Ischemia, and foot Infection [*WIfI*] stage). WIfI stage 1 limbs do not have advanced ischemia grades, denoted as not applicable (*N/A*).

	Recommendations	Grade	Level of evidence	Key references
6.6	Use an integrated threatened limb classification system (such as WIfI) to stage all CLTI patients who are candidates for limb salvage.	1 (Strong)	C (Low)	Cull,[68] 2014 Zhan,[69] 2015 Causey,[70] 2016 Darling,[71] 2016 Robinson,[72] 2017
6.7	Perform urgent surgical drainage and débridement (including minor amputation if needed) and commence antibiotic treatment in all patients with suspected CLTI who present with deep space foot infection or wet gangrene.	Good practice statement		
6.8	Repeat limb staging after surgical drainage, débridement, minor amputations, or correction of inflow disease (AI, common and deep femoral artery disease) and before the next major treatment decision.	Good practice statement		
6.9	Do not perform revascularization in the absence of significant ischemia (WIfI ischemia grade 0), unless an isolated region of poor perfusion in conjunction with major tissue loss (eg, WIfI wound grade 2 or 3) can be effectively targeted and the wound progresses or fails to reduce in size by ≥50% within 4 weeks despite appropriate infection control, wound care, and offloading.	Good practice statement		
6.10	Do not perform revascularization in very-low-risk limbs (eg, WIfI stage 1) unless the wound progresses or fails to reduce in size by ≥50% within 4 weeks despite appropriate infection control, wound care, and offloading.	2 (Weak)	C (Low)	Sheehan,[73] 2003 Cardinal,[74] 2008 Lavery,[75] 2008 Snyder,[76] 2010
6.11	Offer revascularization to all average-risk patients with advanced limb-threatening conditions (eg, WIfI stage 4) and significant perfusion deficits (eg, WIfI ischemia grades 2 and 3).	1 (Strong)	C (Low)	Abu Dabrh,[5] 2015
6.12	Consider revascularization for average-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)	
6.13	Consider revascularization in average-risk patients with advanced limb threat (eg, WIfI stage 4) and moderate ischemia (eg, WIfI ischemia grade 1).	2 (Weak)	C (Low)	Zhan,[69] 2015 Causey,[70] 2016 Darling,[71] 2016 Robinson,[72] 2017
6.14	Consider revascularization in average-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.	2 (Weak)	C (Low)	

Fig 3.2. Suggested algorithm for anatomic imaging in patients with chronic limb-threatening ischemia (*CLTI*) who are candidates for revascularization. In some cases, it may be appropriate to proceed directly to angiographic imaging (computed tomography angiography [*CTA*], magnetic resonance angiography [*MRA*], or catheter) rather than to duplex ultrasound (DUS) imaging.



Recommendation		
5.1	Use an integrated, limb-based anatomic staging system (such as the GLASS) to define complexity of a preferred TAP and to facilitate EBR in patients with CLTI.	Good practice statement

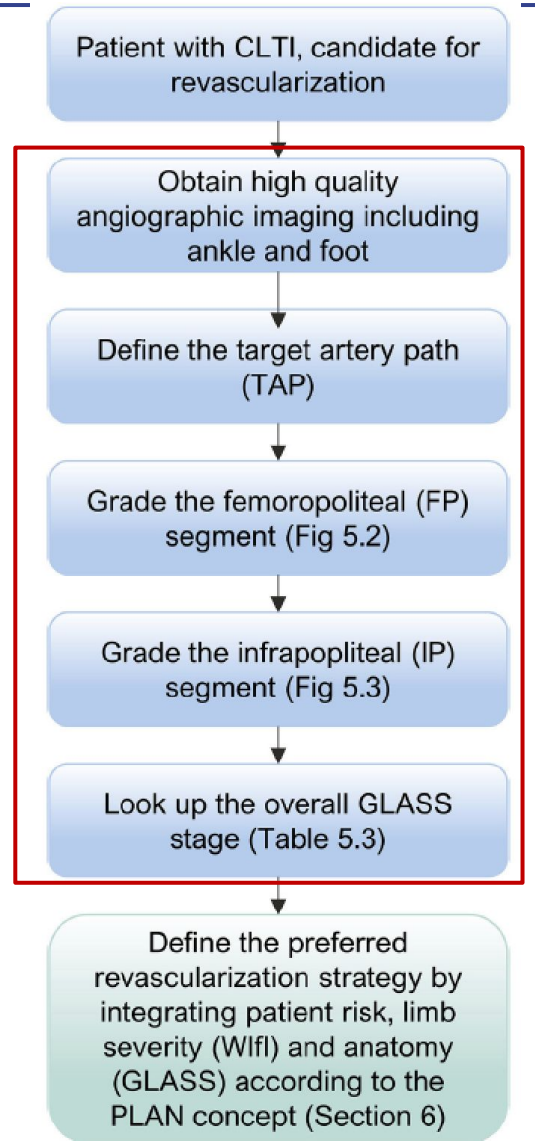
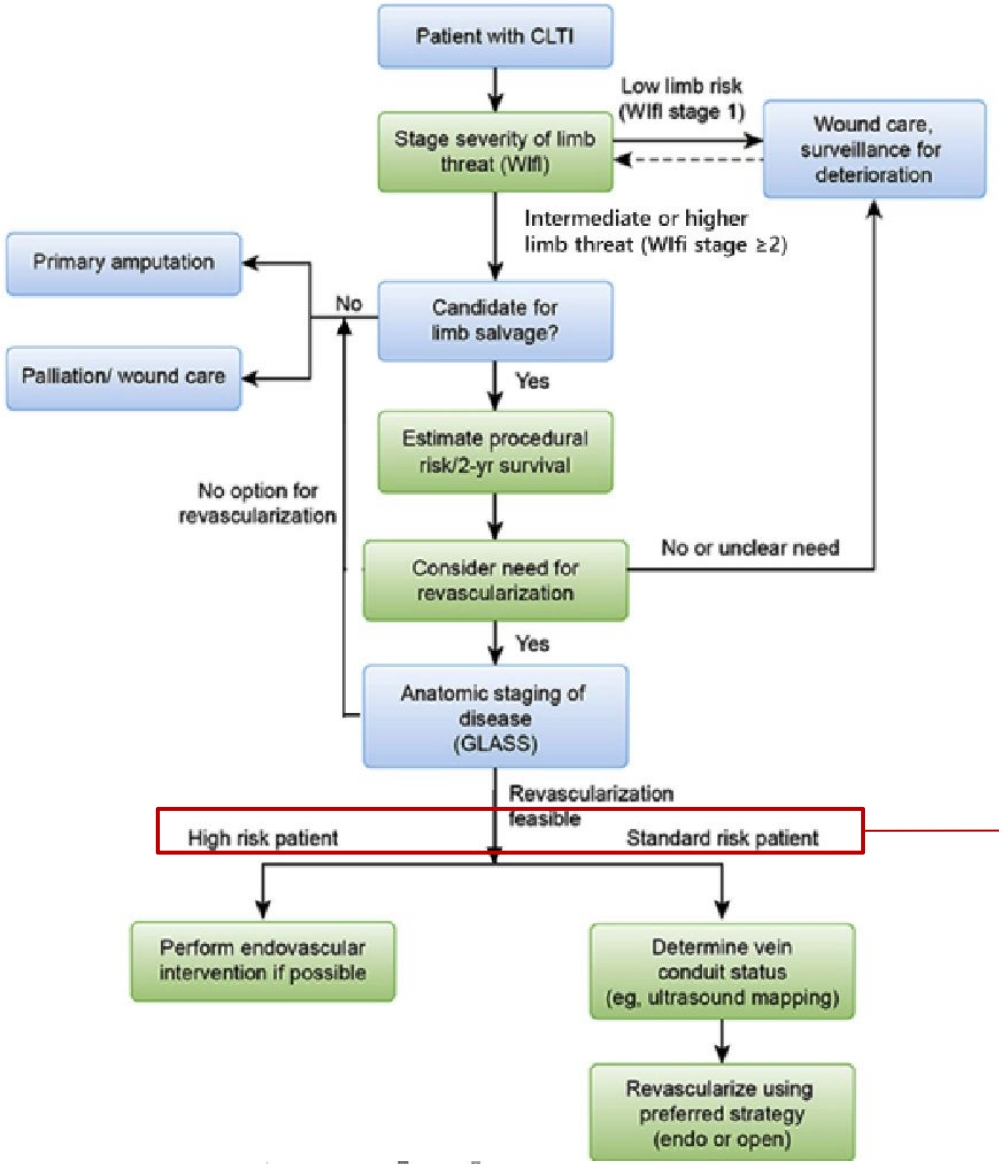


Fig 6.2. PLAN framework of clinical decision-making in chronic limb-threatening ischemia (CLTI); infrainguinal disease. Refer to Fig 6.4 for preferred revascularization strategy in standard-risk patients with available vein conduit, based on limb stage at presentation and anatomic complexity. Approaches for patients lacking suitable vein are reviewed in the text. *GLASS*, Global Limb Anatomic Staging System; *WIfI*, Wound, Ischemia, and foot Infection.



	Recommendations	
6.1	Refer all patients with suspected CLTI to a vascular specialist for consideration of limb salvage, unless major amputation is considered medically urgent.	Good practice statement
6.2	Offer primary amputation or palliation to patients with limited life expectancy, poor functional status (eg, nonambulatory), or an unsalvageable limb after shared decision-making.	Good practice statement

	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)	

5. THE GLOBAL LIMB ANATOMIC STAGING SYSTEM (GLASS)

Table 5.2. Aorto-iliac (inflow) disease staging in GLASS

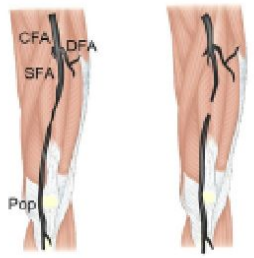
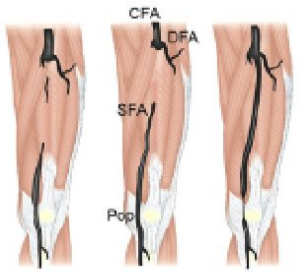
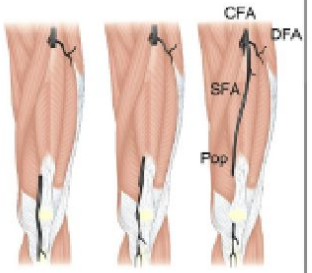
I	Stenosis of the common and/or external iliac artery, chronic total occlusion of either common or external iliac artery (not both), stenosis of the infrarenal aorta; any combination of these
II	Chronic total occlusion of the aorta; chronic total occlusion of common and external iliac arteries; severe diffuse disease and/or small-caliber (<6 mm) common and external iliac arteries; concomitant aneurysm disease; severe diffuse in-stent restenosis in the AI system
A, no significant CFA disease; B, significant CFA disease (>50% stenosis)	

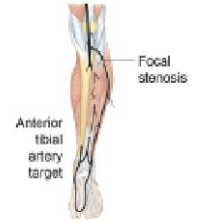
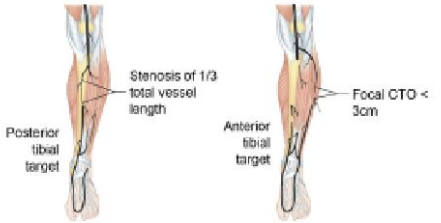
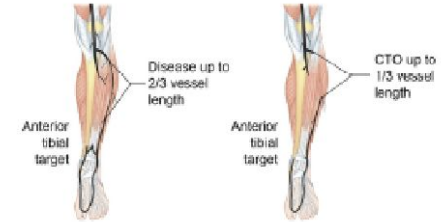
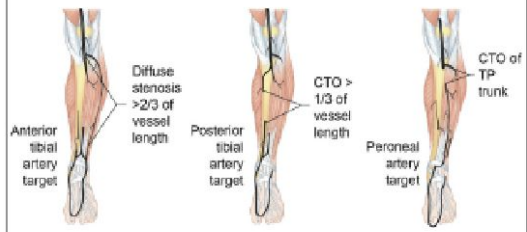
AI, Aortoiliac; *CFA*, common femoral artery.
A simplified staging system for inflow (AI and CFA) disease is suggested. Hemodynamically significant disease (>50% stenosis) of the CFA is considered a key modifier (A/B).

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.

0	Mild or no significant (<50%) disease	
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	
2	• Total length SFA disease 1/3-2/3 (10-20 cm) • May include CTO totaling < 1/3 (10 cm) but not flush occlusion • Focal popliteal artery stenosis <2 cm, not involving trifurcation	
3	• Total length SFA disease >2/3 (>20 cm) length • May include any flush occlusion <20 cm or non-flush CTO 10-20 cm long • Short popliteal stenosis 2-5 cm, not involving trifurcation	
4	• Total length SFA occlusion > 20 cm • Popliteal disease >5 cm or extending into trifurcation • Any popliteal CTO	

0	• Mild or no significant disease in the primary target artery path	
1	• Focal stenosis of tibial artery < 3cm	
2	• Stenosis involving 1/3 total vessel length • May include focal CTO (<3 cm) • Not including TP trunk or tibial vessel origin	
3	• Disease up to 2/3 vessel length • CTO up to 1/3 length (may include tibial vessel origin but not tibioperoneal trunk)	
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	

EBR: Treatment of inflow disease. Inflow disease is defined here as proximal to the origin of the SFA and meeting one or more of the following criteria:

- absent femoral pulse
- blunted CFA waveform on Doppler ultrasound
- >50% stenosis by angiography in the aorto-iliac arteries or CFA
- aorta to CFA systolic pressure gradient >10 mm Hg at rest

Table 5.2. Aorto-iliac (inflow) disease staging in GLASS

I	Stenosis of the common and/or external iliac artery, chronic total occlusion of either common or external iliac artery (not both), stenosis of the infrarenal aorta; any combination of these
II	Chronic total occlusion of the aorta; chronic total occlusion of common and external iliac arteries; severe diffuse disease and/or small-caliber (<6 mm) common and external iliac arteries; concomitant aneurysm disease; severe diffuse in-stent restenosis in the AI system
A, no significant CFA disease; B, significant CFA disease (>50% stenosis)	

AI, Aortoiliac; *CFA*, common femoral artery.
A simplified staging system for inflow (AI and CFA) disease is suggested. Hemodynamically significant disease (>50% stenosis) of the CFA is considered a key modifier (A/B).

	Recommendations	Grade	Level of evidence	Key references
6.20	Correct inflow disease first when both inflow and outflow disease are present in a patient with CLTI.	Good practice statement		
6.21	Base the decision for staged vs combined inflow and outflow revascularization on patient risk and the severity of limb threat (eg, WIfI stage).	1 (Strong)	C (Low)	
6.22	Correct inflow disease alone in CLTI patients with multilevel disease and low-grade ischemia (eg, WIfI ischemia grade 1) or limited tissue loss (eg, WIfI wound grade 0/1) and in any circumstance in which the risk-benefit of additional outflow reconstruction is high or initially unclear.	1 (Strong)	C (Low)	Harward,[80] 1995 Zukauskas,[81] 1995
6.23	Restage the limb and repeat the hemodynamic assessment after performing inflow correction in CLTI patients with inflow and outflow disease.	1 (Strong)	C (Low)	
6.24	Consider simultaneous inflow and outflow revascularization in CLTI patients with a high limb risk (eg, WIfI stages 3 and 4) or in patients with severe ischemia (eg, WIfI ischemia grades 2 and 3).	2 (Weak)	C (Low)	
6.25	Use an endovascular-first approach for treatment of CLTI patients with moderate to severe (eg, GLASS stage IA) AI disease, depending on the history of prior intervention.	1 (Strong)	B (Moderate)	Jongkind,[82] 2010 Ye,[83] 2011 Deloose,[84] 2017
6.26	Consider surgical reconstruction for the treatment of average-risk CLTI patients with extensive (eg, GLASS stage II) AI disease or after failed endovascular intervention.	2 (Weak)	C (Low)	Ricco,[85] 2008 Chiu,[86] 2010 Indes,[87] 2013
6.27	Perform open CFA endarterectomy with patch angioplasty, with or without extension into the PFA, in CLTI patients with hemodynamically significant (>50% stenosis) disease of the common and deep femoral arteries.	1 (Strong)	C (Low)	Kang,[88] 2008 Ballotta,[89] 2010
6.28	Consider a hybrid procedure combining open CFA endarterectomy and endovascular treatment of AI disease with concomitant CFA involvement (eg, GLASS stage IB inflow disease).	2 (Weak)	C (Low)	Chang,[90] 2008
6.29	Consider endovascular treatment of significant CFA disease in selected patients who are deemed to be at high surgical risk or to have a hostile groin.	2 (Weak)	C (Low)	Baumann,[91] 2011 Bonvini,[92] 2011 Gouëffic,[93] 2017 Siracuse,[94] 2017
6.30	Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.	Good practice statement		
6.31	Correct hemodynamically significant (≥50% stenosis) disease of the proximal deep femoral artery whenever technically feasible.	Good practice statement		

EBR: Treatment of infrainguinal disease in average-risk patients. Outflow (infrainguinal) disease starts at the SFA origin (Section 5). An average-risk patient is defined as one in whom the anticipated periprocedural mortality is <5% and the anticipated 2-year survival is >50% (Recommendation 6.4). These patients are potential surgical or endovascular candidates, depending on individual clinical and anatomic factors.

	Recommendation	Grade	Level of evidence	Key references
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

EBR: Treatment of infrainguinal disease in high-risk patients. A high-risk patient is defined as one in whom the anticipated perioperative mortality is >5% or the anticipated 2-year survival is <50%. Because endovascular intervention can be performed with reduced morbidity, it may often be preferred in high-risk patients who are otherwise candidates for functional limb salvage. Shared decision-making is of great importance in high-risk patients to allow the patient, family, and other stakeholders to express value judgments on the tradeoffs between risk and effectiveness in relation to the desired goals.

	Recommendations	Grade	Level of evidence	Key references
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)	
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)	Abu Dabrh,[5] 2015 Zhan,[69] 2015 Causey,[70] 2016 Darling,[71] 2016 Robinson,[72] 2017
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)	

TREATMENT OF INFRAINGUINAL DISEASE IN AVERAGE-RISK PATIENTS

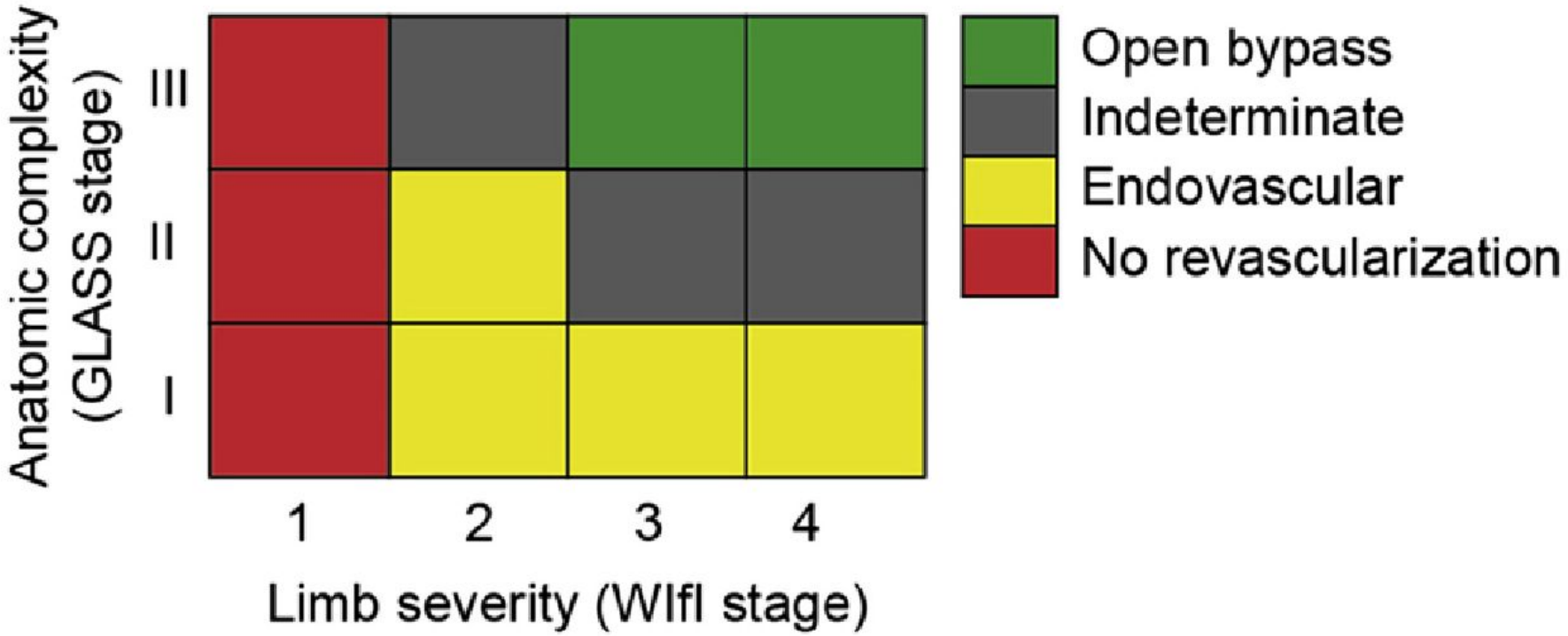


Fig 6.4. Preferred initial revascularization strategy for infrainguinal disease in average-risk patients with suitable autologous vein conduit available for bypass. Revascularization is considered rarely indicated in limbs at low risk (Wound, Ischemia, and foot Infection [*WIfI*] stage 1). Anatomic stage (*y-axis*) is determined by the Global Limb Anatomic Staging System (*GLASS*); limb risk (*x-axis*) is determined by WIfI staging. The *dark gray shading* indicates scenarios with least consensus (assumptions—inflow disease either is not significant or is corrected; absence of severe pedal disease, ie, no GLASS P2 modifier).

Table 12.2. Criteria for Center of Excellence designation in chronic limb-threatening ischemia (*CLTI*) or amputation prevention

Center of Excellence criteria	Description
Multidisciplinary team of specialists	Specialists who can surgically and medically manage PAD and infections and provide the general or intensive medical care needed for the complex CLTI patient
Protocol-driven care	A team that follows written, evidence-based clinical practice pathways, policies, and procedures
Outcomes monitoring and reporting	Establishes a process for data collection and reports that data to the community or in the literature
Methods of improvement	Establishes a process for continual improvement based on outcomes and new techniques or therapies
Educational resource	Serves as an educational resource for the medical community through mentoring, publishing, and symposia

PAD, Peripheral artery disease.

Table 12.1. The three tiers of care for amputation prevention and diabetic foot care centers

Clinical level of care	Setting	Potential clinicians	Role
Center of Excellence	Large teaching hospital, tertiary referral center	Endocrinologist Vascular surgeon Interventionalist Podiatric surgeon Orthopedic surgeon Infectious disease specialist Orthotist Diabetes educator Nutritionist Wound nurse Physical therapist	Collects and reports outcomes; facilitates regional education

Adapted from Rogers LC, Andros G, Caporusso J, Harkless LB, Mills JL Sr, Armstrong DG. Toe and flow. J Am Podiatr Med Assoc 2010;100:342-8.

Table 12.3. The nine essential skills to prevent amputations in diabetes and the possible specialty responsible

Essential skills	Possible team members
The ability to perform hemodynamic and anatomic vascular assessment	Vascular surgeon Interventionalist (cardiologist or radiologist) Vascular medicine
The ability to perform a peripheral neurologic workup	Neurologist Endocrinologist Podiatrist
The ability to perform site-appropriate culture technique	Infectious disease specialist Surgeon Wound nurse Physical therapist
The ability to perform wound assessment and staging or grading of infection and ischemia	Vascular surgeon Podiatrist Surgeon Infectious disease specialist Wound nurse Physical therapist
The ability to perform site-specific bedside and intraoperative incision and drainage or débridement	Podiatric surgeon Orthopedic surgeon Plastic surgeon Surgeon Vascular surgeon
The ability to initiate and to modify culture-specific and patient-appropriate antibiotic therapy	Infectious disease specialist Endocrinologist Primary care physician Vascular surgeon Podiatrist Surgeon
The ability to perform revascularization	Vascular surgeon Interventionalist (cardiologist or radiologist)
The ability to perform soft tissue or osseous reconstruction of deformities and defects	Podiatric surgeon Plastic surgeon Orthopedic surgeon Surgeon
The ability to perform appropriate postoperative monitoring to reduce risks of reulceration and infection	Podiatrist Wound nurse

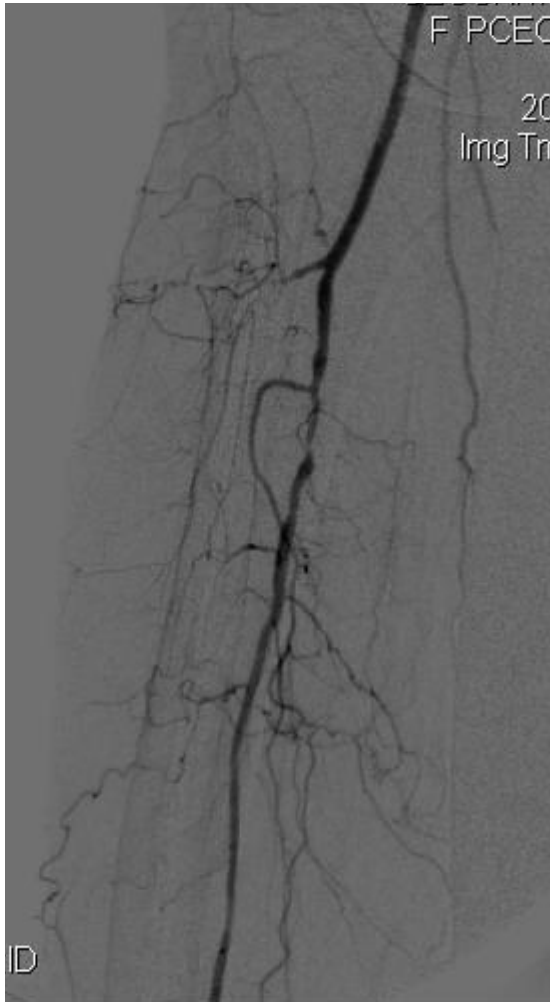
5/9

2/9

SALVATAGGIO D'ARTO NEL DIABETICO

- Trattamento chirurgico open
- Trattamento endovascolare
- Chirurgia ibrida

Sede della lesione (lesione tibiale isolata)

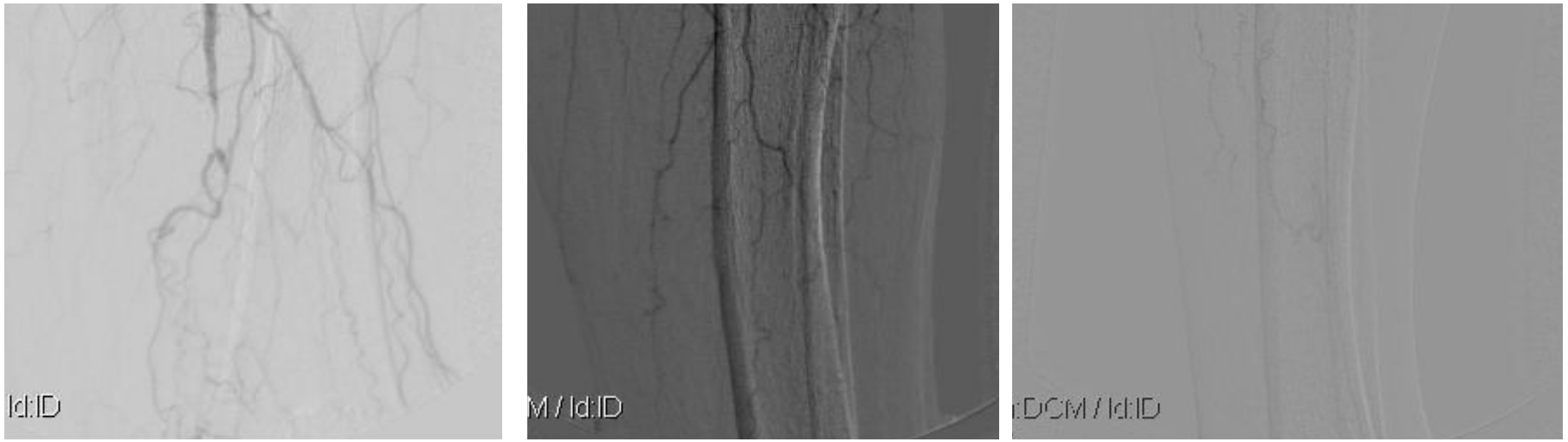


Sede della lesione (lesione tibiale isolata)

Sede della lesione (lesione tibiale isolata)

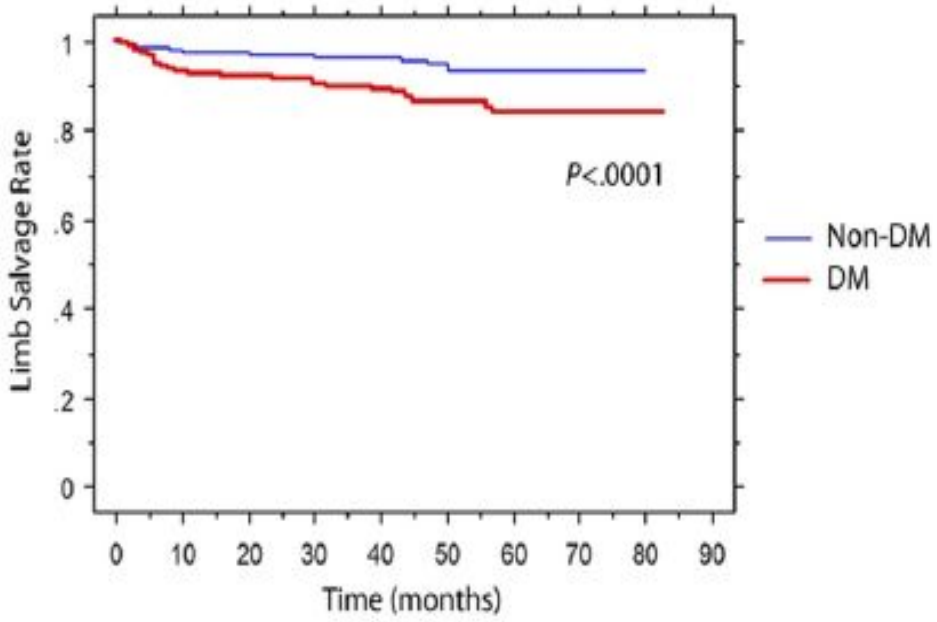
Estensione della patologia

Open bypass and endoluminal therapy: complementary techniques for revascularization in diabetic patients with critical limb ischaemia



Estensione della patologia

Long-term outcomes of diabetic patients undergoing endovascular infrainguinal interventions



Il diabete è un fattore predittivo indipendente di riduzione della pervietà a distanza del trattamento endovascolare. Sebbene tassi accettabili di pervietà assistita siano ottenibili con programmi di stretta sorveglianza e con i reinterventi, i tassi di salvataggio d'arto a distanza per i pazienti diabetici continuano a rimanere inferiori a causa della peggior presentazione clinica iniziale e dello scarso run-off distale.

(Abullarage, *J Vasc Surg 2010*)

Outcomes after endovascular intervention for chronic critical limb ischemia

Independent predictors of sustained clinical success (*SCS*) and secondary sustained clinical success (*SCSS*) and in Rutherford class (*RC*) 4 and 5 patients

RC	*Outcome*	*Predictor*	*OR (CI)*	P
5	SCS	DM	3.76 (1.04-13.69)	.04
	SSCS	DM	4.69 (1.42-15.63)	.01
		CHF	4.07 (0.99-16.67)	.05
4 and 5	SCS	RC-5	3.01 (1.12-8.13)	.029
	SSCS	DM	2.83 (1.07-7.46)	.036
		CHF	3.62 (1.19-10.99)	.023
		RC-5	5.5 (2.40-30.3)	.001

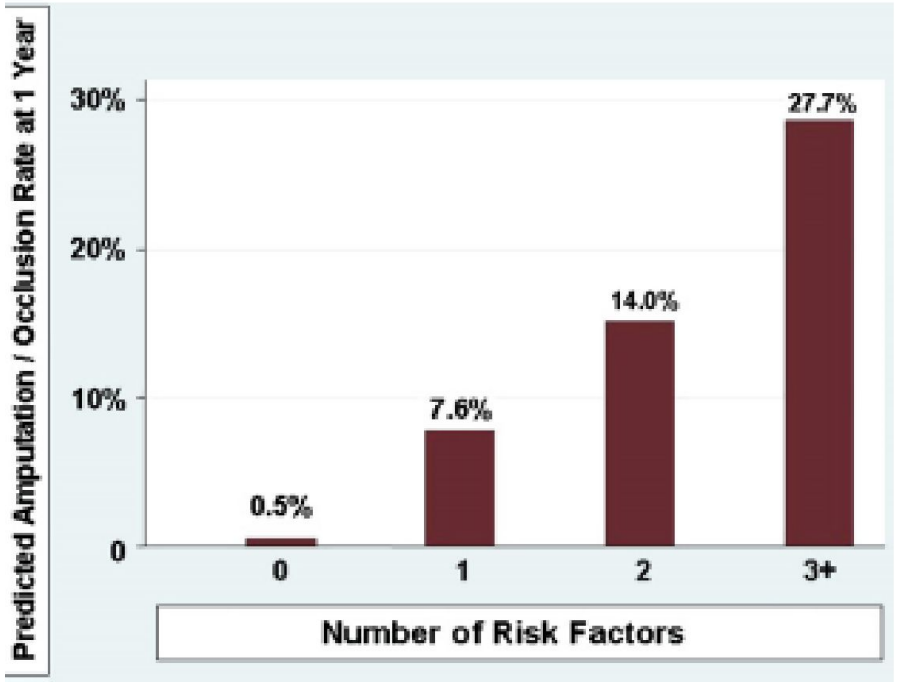
CHF, Congestive heart failure; *CI*, confidence interval; *DM*, diabetes mellitus.

Per migliorare i risultati serve una attenta selezione dei pazienti; nello specifico il Diabete e lo Scompenso cardiaco congestizio sono risultati predittori di un peggior risultato clinico nelle classi Rutherford 4 e 5.

(O'Brien-Irr, J Vasc Surg 2011)

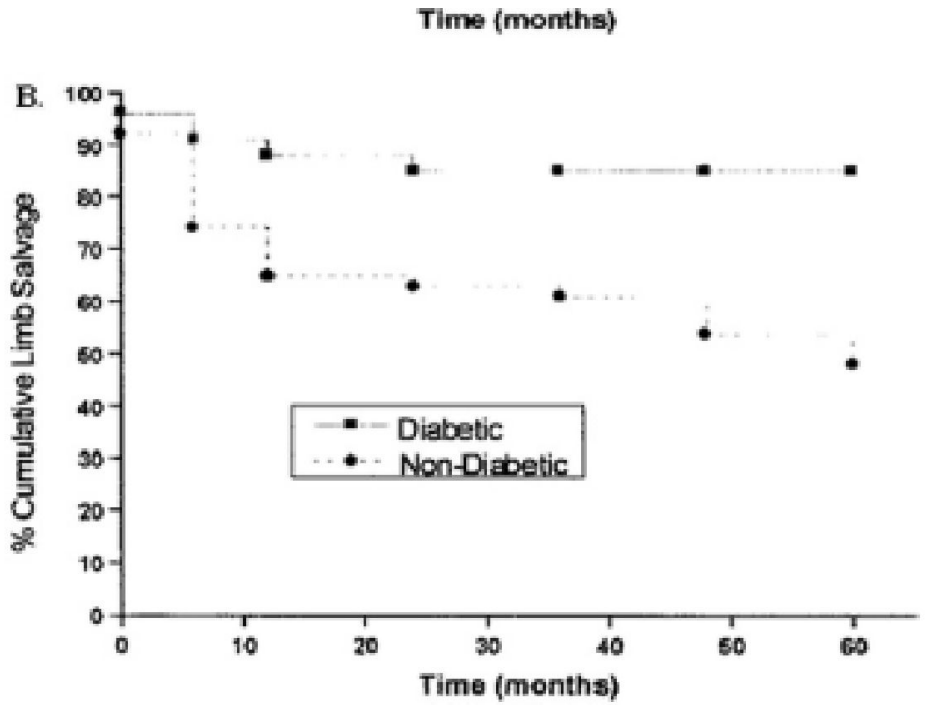
Factors Associated with Amputation or Graft Occlusion One Year after Lower Extremity Bypass in Northern New England

Variable	HR	95% CI	*p*
Age (years)			
<40	1.4	0.4-4.7	0.645
40-49	1.9	1.2-3.1	0.007
50-59	1.2	0.8-1.7	0.424
60-69	1.2	0.8-1.7	0.334
70+	1	0.7-1.5	0.757
Nonambulatory preoperatively	1.6	1-2.5	0.044
Dialysis	1.6	1.1-2.2	0.008
Diabetes	1.6	1.1-2.5	0.029
Critical limb ischemia	1.7	1.3-2.3	0.0001
Two vein segments	2	1.4-2.8	0.0001
Tarsal target for bypass	2.5	1.2-5.3	0.021
Nursing home residence	2.8	1.3-6	0.011



(Goodney, Ann Vasc Surg 2010)

Challenges of distal bypass surgery in patients with diabetes: Patient selection, techniques, and outcomes

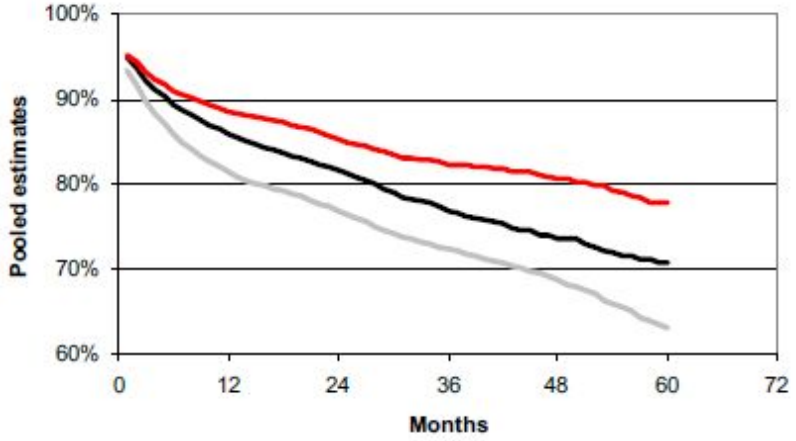


La vena grande safena (VGS) di buona qualità e di calibro adeguato rappresenta il miglior materiale per un by-pass nei pazienti diabetici. Purtroppo la disponibilità di tale materiale risulta ancora un limite per la chirurgia tradizionale in quanto in circa il 40% dei pazienti manca una buona VGS ipsilaterale. Inoltre la diretta correlazione tra pervietà e calibro della vena, anche nei pazienti ove essa fosse presente, esclude circa il 25% di pazienti affetti da ischemia critica.

(Conte, J Vasc Surg 2010)

BACKGROUND

Meta-analysis of popliteal-to-distal vein bypass grafts for critical ischemia



Month	*PP(%)*	*SP(%)*	*FP(%)*
	93.3 (1.1)	94.9 (1.0)	95.1 (1.2)
3	89.7 (1.5)	92.2 (1.4)	93.0 (1.6)
6	85.8 (2.1)	89.3 (1.6)	90.9 (1.9)
12	81.5 (2.0)	85.9 (1.9)	88.5 (2.2)
24	76.8 (2.3)	81.6 (2.3)	85.2 (2.5)
36	72.3 (2.7)	76.7 (2.9)	82.3 (3.0)
48	68.6 (3.3)	73.6 (3.5)	80.7 (3.6)
60	63.1 (4.3)	70.7 (4.6)	77.7 (4.3)

In the absence of bias and study invalidity, we conclude that tibial vein grafts for critical ischemia provide excellent outcomes and should be used confidently in suitable patients

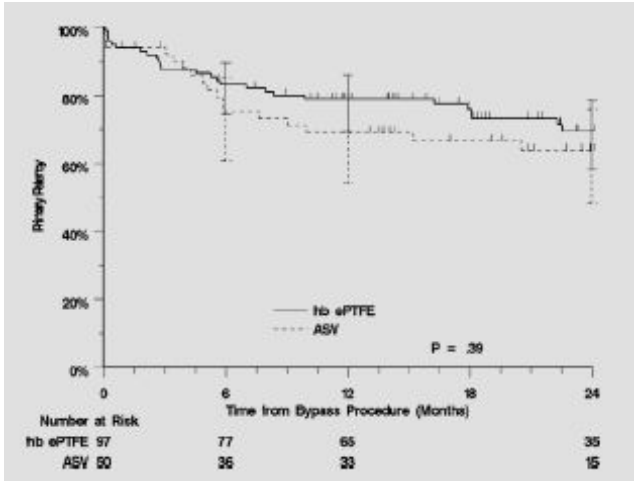
Albers et al., J Vasc Surg 2006

BACKGROUND

But what when a good quality autologous vein is not available?

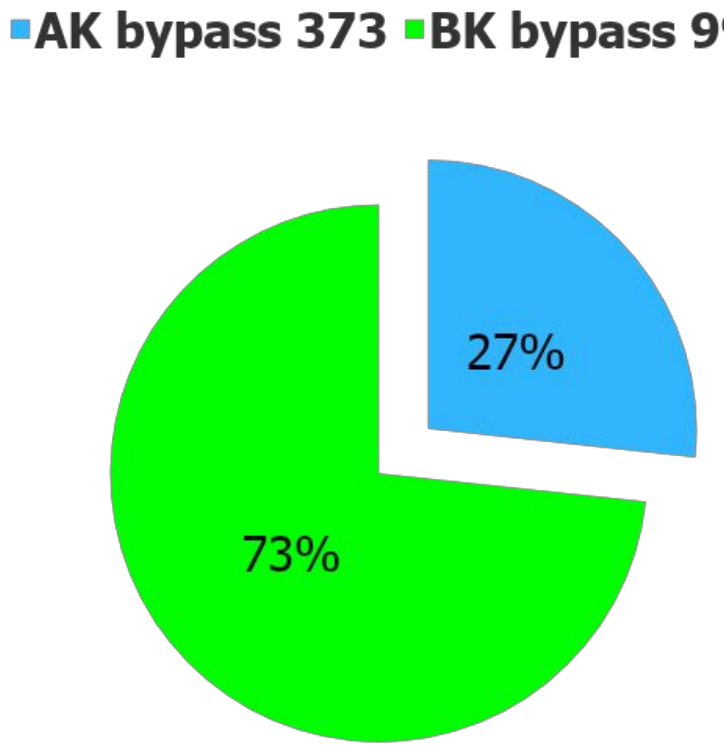
Heparin-bonded ePTFE grafts compared with vein grafts in femoropopliteal and femorocrural bypasses: 1- and 2-year results

Kim Daenens, MD, Stijn Schepers, MD, Inge Fourneau, MD, PhD, Sabrina Houthoofd, MD, and André Nevelsteen, MD, PhD, *Leuven, Belgium*



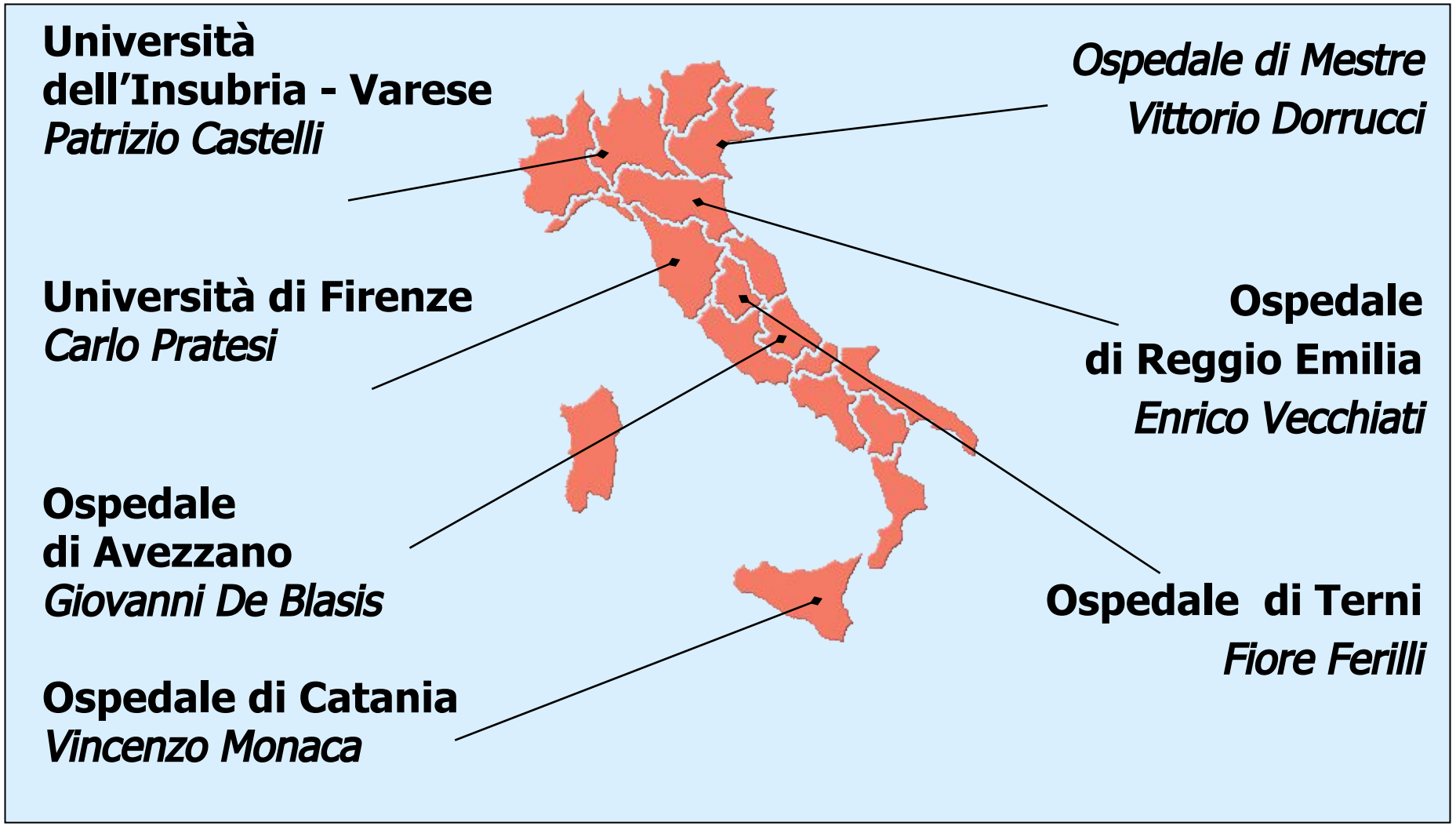
AIM OF THE STUDY

To compare early and late results of heparin-bonded expanded polytetrafluroethilene (He-ePTFE) graft and autologous saphenous vein (ASV) femoro-tibial bypasses performed for critical limb ischemia (CLI) in a retrospective multicentre registry-based case-control study



From January 2001 to December 2015, 426 consecutive femoro-tibial bypasses were performed for CLI in seven Italian vascular departments.

HePTFE Italian Registry: participating centers



RESULTS

MATCHED GROUPS

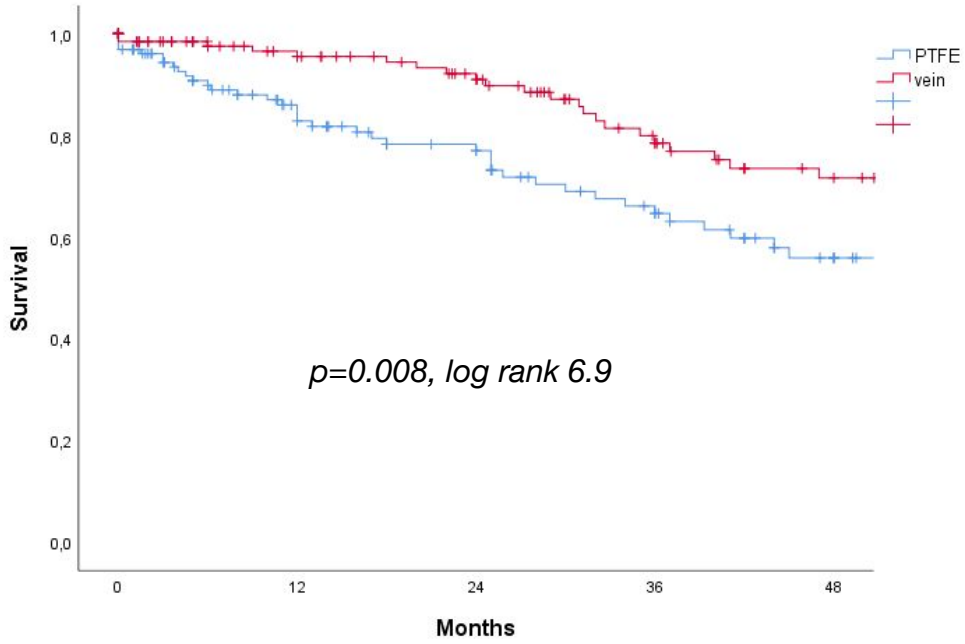
	HePTFE (129 int.)	ASV (130 int.)	p
Female gender	80 (62%)	80 (62%)	0.9
Mean age	74.9±8	73.2±9	0.1
Secondary intervention	39 (30%)	39 (30%)	0.9
Arterial hypertension	113 (88%)	112 (86%)	0.9
Diabetes	59 (46%)	64 (49%)	0.5
Coronary artery disease	59 (46%)	59 (46%)	0.9
Hyperlipemia	86 (67%)	85 (65%)	0.8
Rutherford's class 5-6	78 (60%)	68 (52%)	0.1
Less than 2 patent tibial vessels	109 (84%)	115 (88%)	0.4

PERIOPERATIVE RESULTS

	HePTFE (129 cases)	ASV (130 cases)	p
Mortality	4 (3.1%)	1 (0.7%)	0.2
Thrombosis	17 (13.1%)	12 (9.2%)	0.2
Amputation	9 (6.9%)	7 (5.4%)	0.4

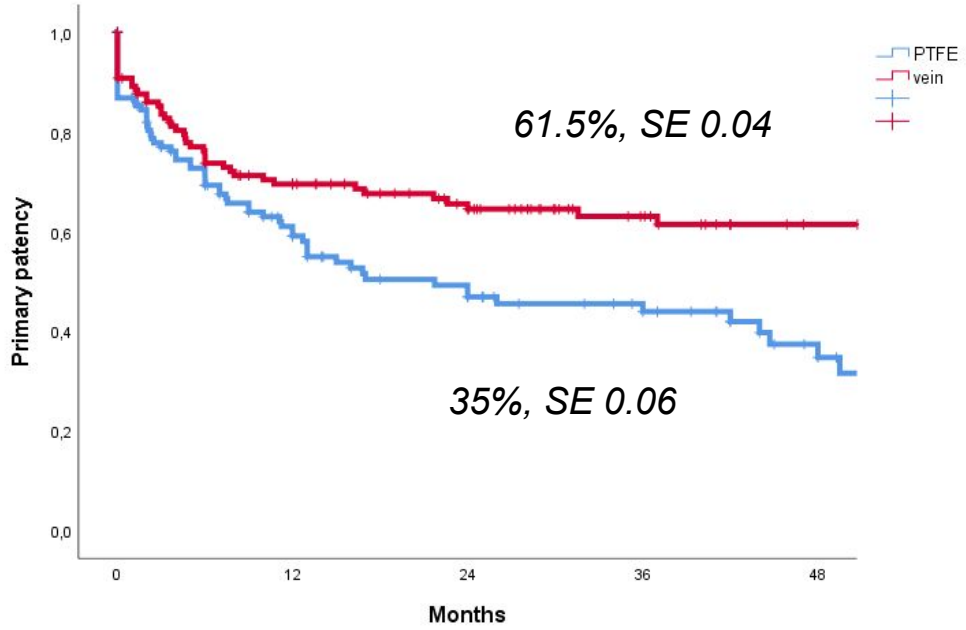
FOLLOW-UP

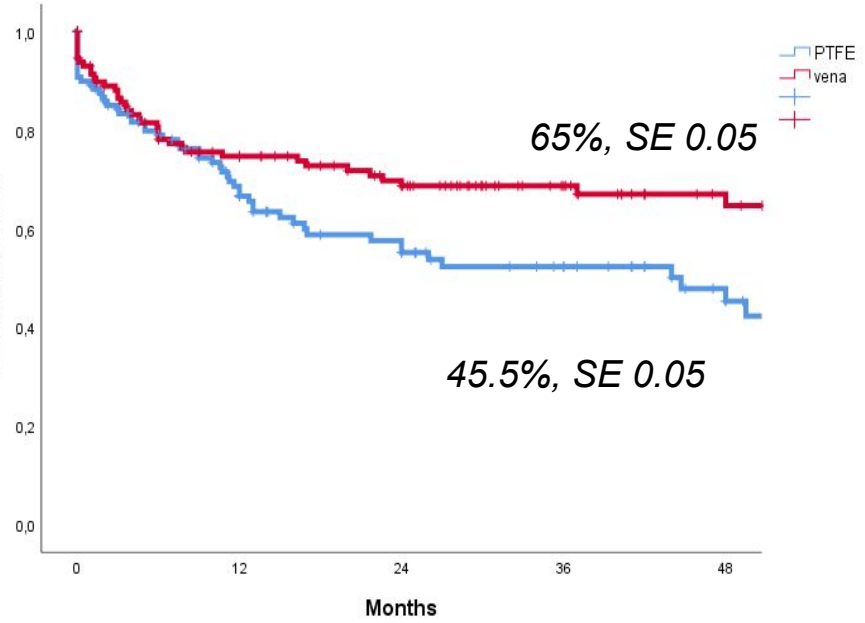
- Duplex-surveillance program consisted of DUS at 1-12 months and yearly thereafter
- Median duration of follow-up was 26 months (range 1-144)
- All patients had an available postoperative follow-up



p=0.008, log rank 6.9

FOLLOW-UP RESULTS

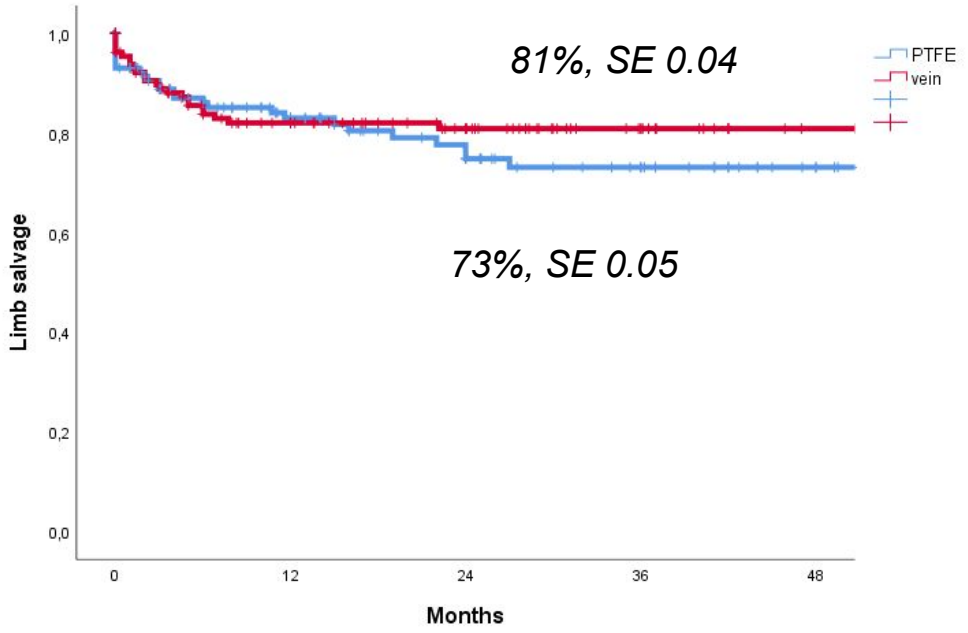


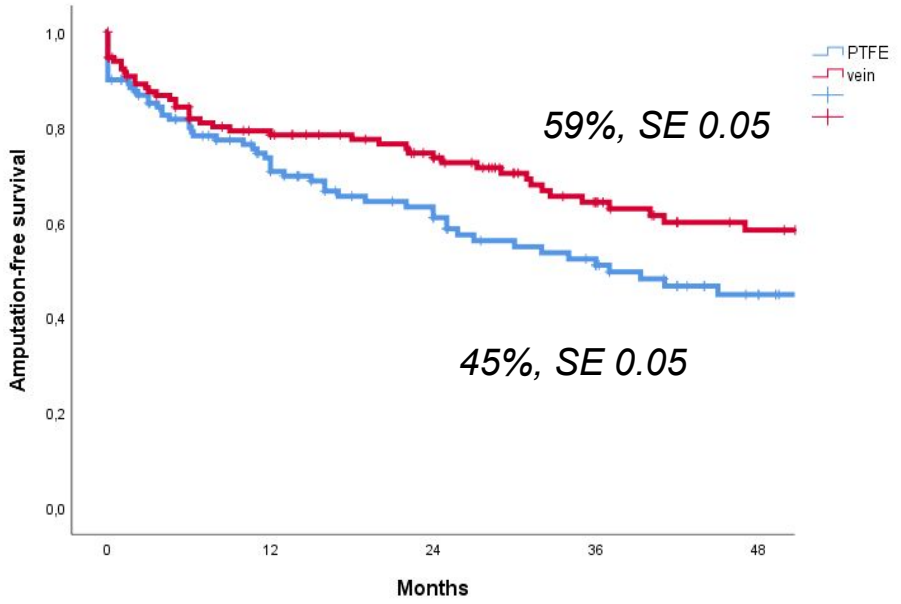


p=0.002, log rank 9.7

p=0.007, log rank 7.2

FOLLOW-UP RESULTS





p=0.3, log rank 0.9

p=0.03, log rank 4.6

CONCLUSIONI

- I pazienti diabetici affetti da ischemia critica possono essere trattati in modo efficace, con buoni tassi di salvataggio d'arto a distanza, con tecniche differenti
- La terapia endovascolare può essere proposta come strategia iniziale in molti pazienti
- Il trattamento chirugico rappresenta ancora un' ottima alternativa, non solo in caso di fallimento endovascolare, ma anche come prima opzione nei casi clinicamente ed anatomicamente complessi
- In questi pazienti, la protesi in ePTFE con superficie bioattiva eparinizzata è una valida alternative alla VGS, non solo quando questa manchi o sia di pessima qualità, ma come prima scelta in sottogruppi selezionati di pazienti

GRAZIE PER L' ATTENZIONE