ACC Latin America Conference 2017

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GLOBAL EXPERTS, LOCAL LEARNING

ACC Latin America Conference 2017

Revascularization for claudication and critical limb ischemia (CLI)

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Revascularization

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The goals of revascularization:

1. **Relief of pain.**
2. **Healing of ulceration.**
3. **Preservation of the limb from major amputation.**
4. **Improvement in the patient`s quality of life and functionality.**
5. **Prolonging survival.**

Gray B, et al. SCAI Expert Consensus Statement for infrapopliteal arterial intervention appropriate use. CCI 2014;84:539-545.

Revascularization

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Claudication

Recommendations for Endovascular Revascularization for Claudication

COR	LOE	RECOMMENDATIONS
I	A	Endovascular procedures are effective as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease (13,25,26,190,194,196,201).
IIa	B-R	Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease (190,197-200,205,206).
IIb	C-LD	The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown (211-213).
III: Harm	B-NR	Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLI (186-189,214-216).

Recommendations for Surgical Revascularization for Claudication

COR	LOE	RECOMMENDATIONS
I	A	When surgical revascularization is performed, bypass to the popliteal artery with autogenous vein is recommended in preference to prosthetic graft material (226-234).
IIa	B-NR	Surgical procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication with inadequate response to GDMT, acceptable perioperative risk, and technical factors suggesting advantages over endovascular procedures (190,230,235-237).
III: Harm	B-R	Femoral-tibial artery bypasses with prosthetic graft material should not be used for the treatment of claudication (238-240).
III: Harm	B-NR	Surgical procedures should not be performed in patients with PAD solely to prevent progression to CLI (186-189,241).

Gerhard-Herman M (Chair), et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: Executive Summary. J Am Coll Cardiol 2017;69:1465-1508.

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Critical limb ischemia

Recommendations for Endovascular Revascularization for CLI

COR	LOE	RECOMMENDATIONS
I	B-R	Endovascular procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene (242,243).
IIa	C-LD	A staged approach to endovascular procedures is reasonable in patients with ischemic rest pain (261,262).
IIa	B-R	Evaluation of lesion characteristics can be useful in selecting the endovascular approach for CLI (263,264).
IIb	B-NR	Use of angiosome-directed endovascular therapy may be reasonable for patients with CLI and nonhealing wounds or gangrene (245,247–249,251–253,255–257).

Recommendations for Surgical Revascularization for CLI

COR	LOE	RECOMMENDATIONS
I	A	When surgery is performed for CLI, bypass to the popliteal or infrapopliteal arteries (i.e., tibial, pedal) should be constructed with suitable autogenous vein (228,231,234,265).
I	C-LD	Surgical procedures are recommended to establish in-line blood flow to the foot in patients with nonhealing wounds or gangrene (266–268).
IIa	B-NR	In patients with CLI for whom endovascular revascularization has failed and a suitable autogenous vein is not available, prosthetic material can be effective for bypass to the below-knee popliteal and tibial arteries (269–271).
IIa	C-LD	A staged approach to surgical procedures is reasonable in patients with ischemic rest pain (272–274).

Gerhard-Herman M (Chair), et al. 2016 AHA/ACC Guideline on the management of patients with lower extremity peripheral artery disease: Executive Summary. J Am Coll Cardiol 2017;69:1465-1508.

Endovascular revascularization

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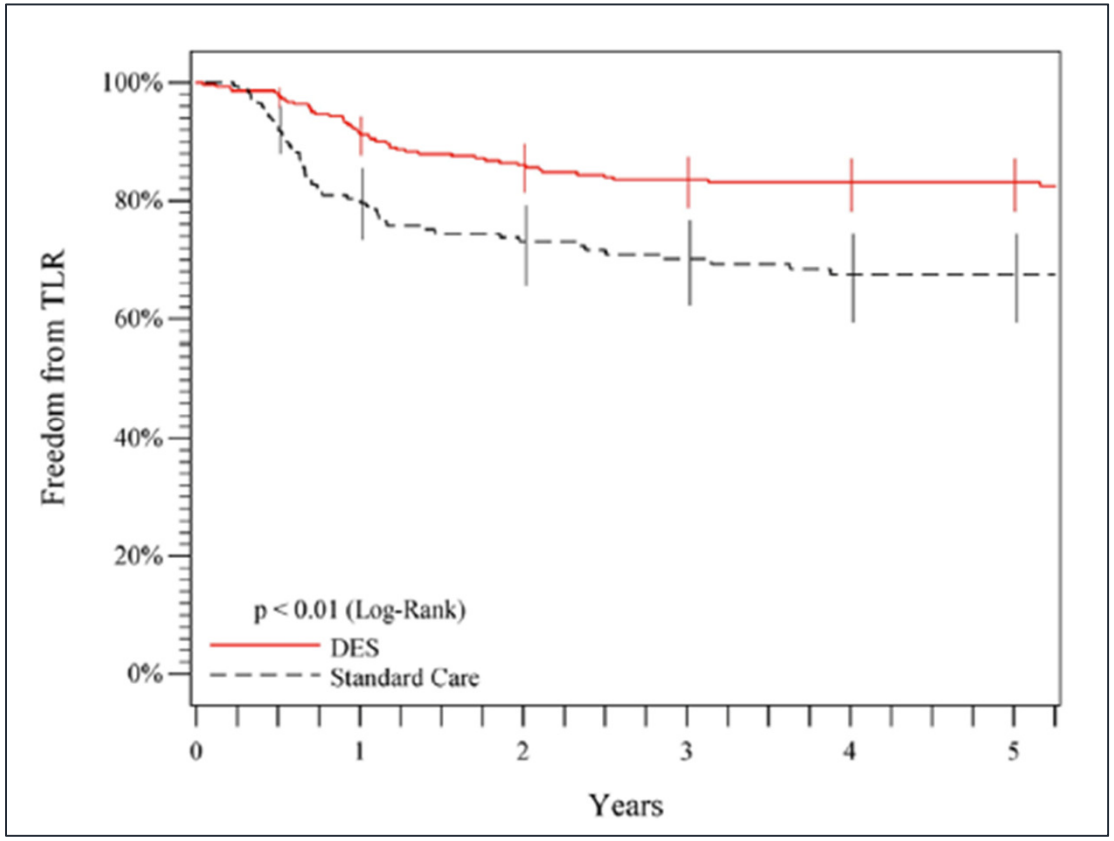
5-year results. Zilver PTX Randomized Study Claudication (Rutherford 2-3)



Dake M, et al. Circulation 2016;133:1472-1483.

Endovascular revascularization

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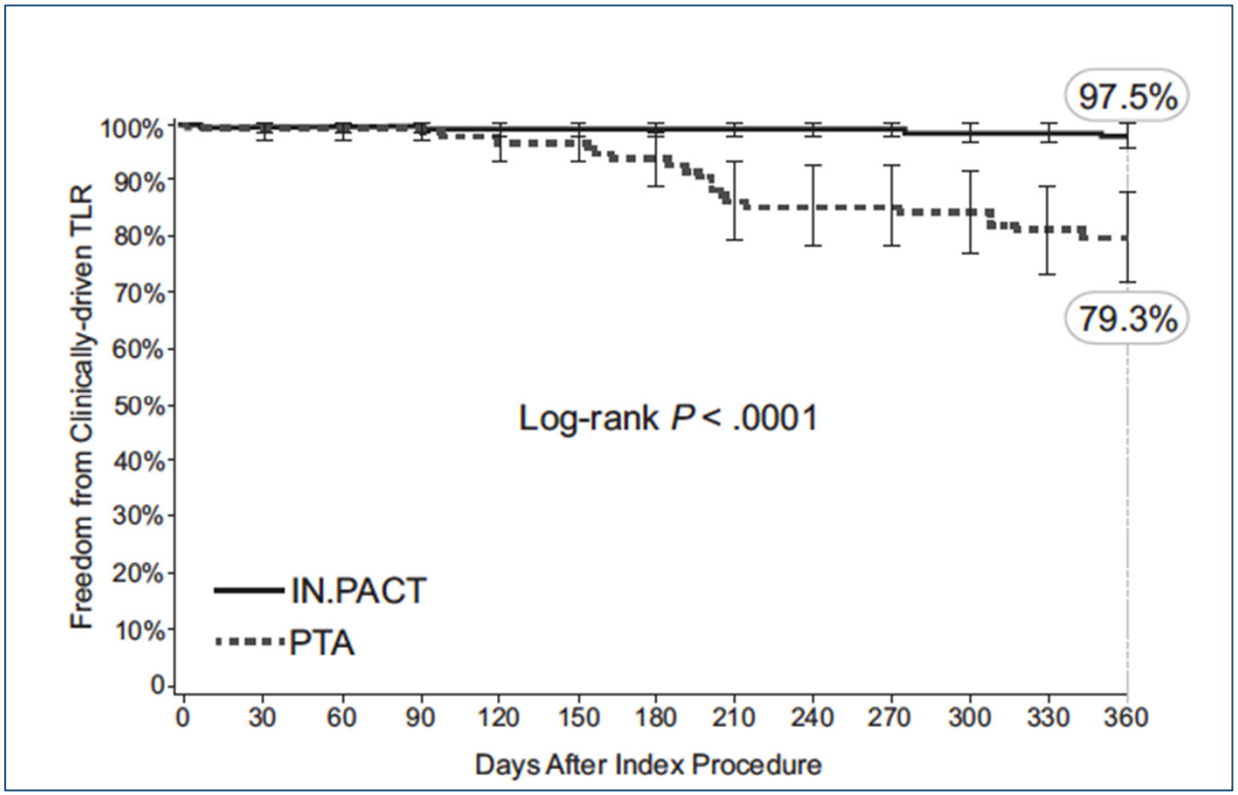
12-Month Results from the IN.PACT SFA Randomized trial. Claudication (Rutherford 2-3)



Tepe G, et al. Circulation 2015;131:495-502.

Endovascular revascularization

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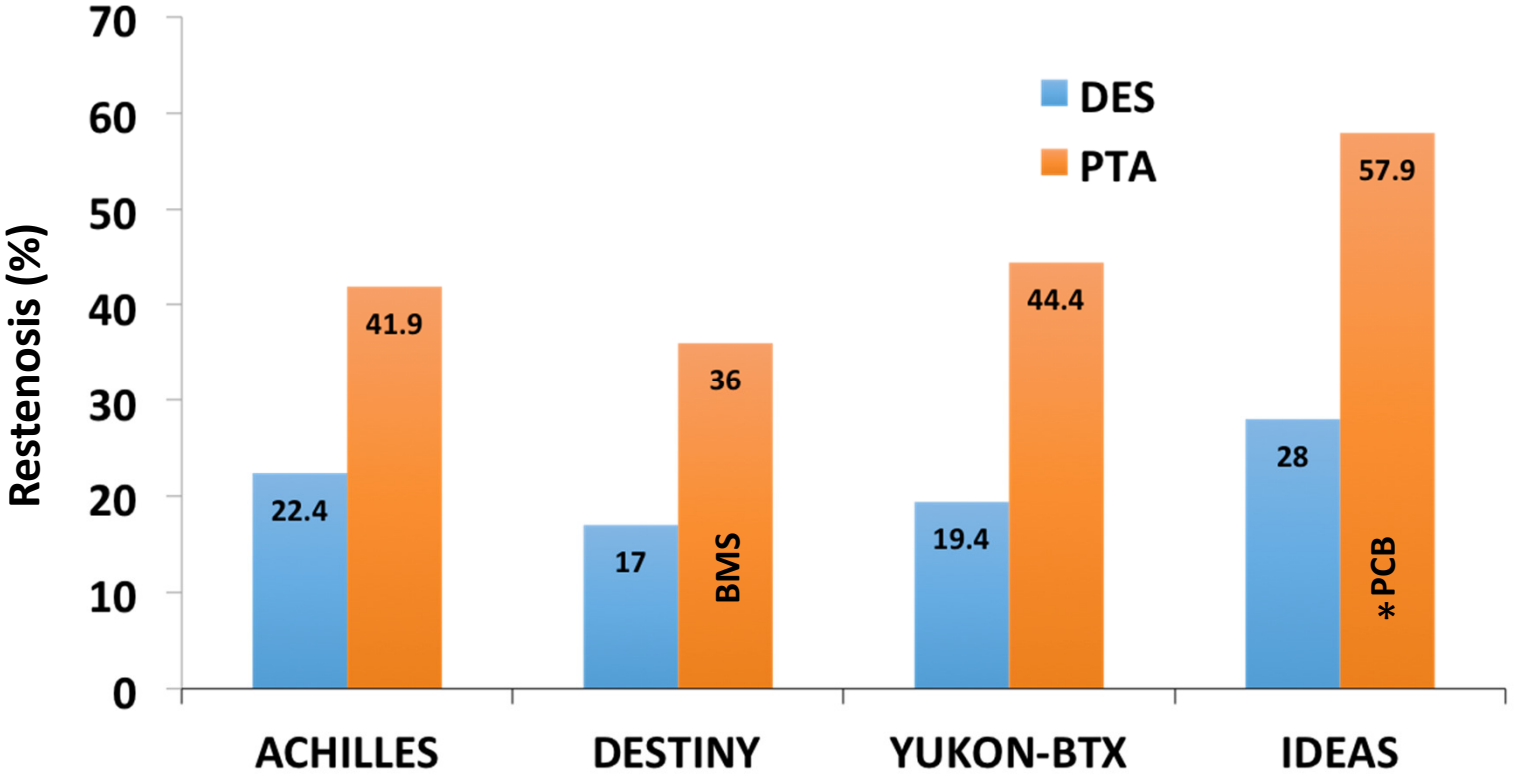
Randomized controlled trials of drug-eluting stents in infrapopliteal disease



*PCB: Paclitaxel-coated balloon
BMS:bare metal stent

Scheinert D, et al. J Asm Coll Cardiol 2012;60:2290-2295 Bosiers M, et al. J Vasc Surg 2012;55:390-399.. Rastan A, et al. J Am Coll Cardiol 2012;60:587-591. Siablis D, et al. J Am Coll Cardiol Intv 2014;7:1048-1056.

Endovascular revascularization

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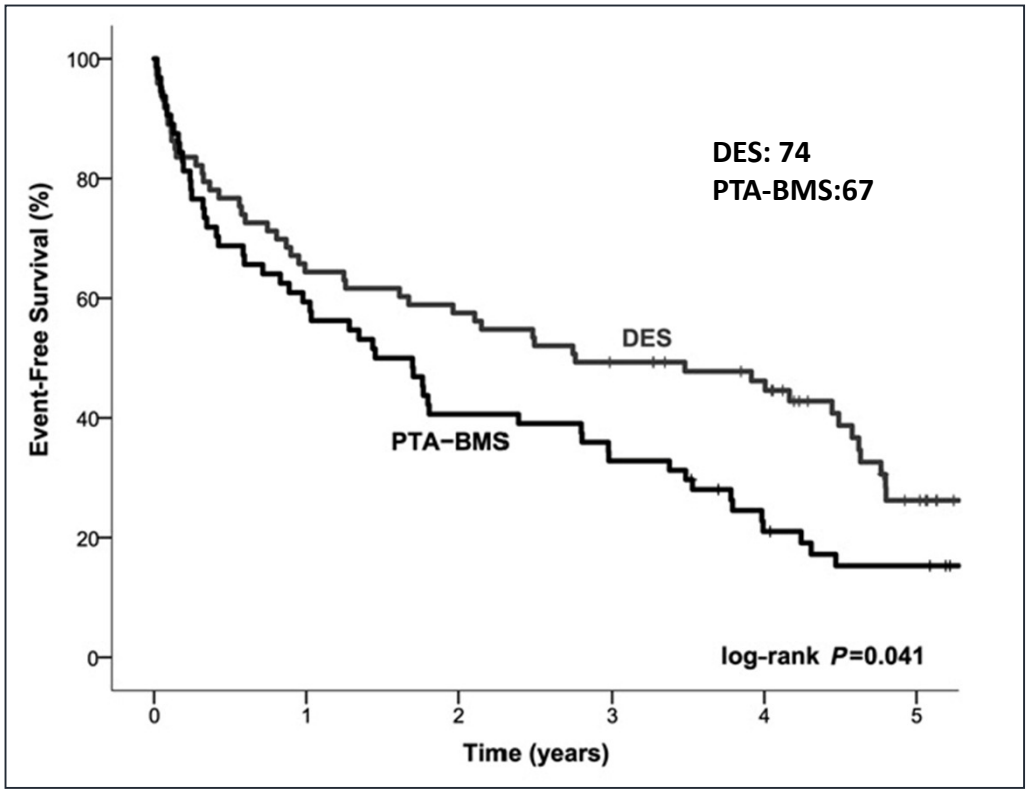
Long-term follow-up of the PADI Trial



Spreen M, et al. PADI: Percutaneous transluminal angioplasty versus drug-eluting stents for infrapopliteal limb ischemia. J Am Heart Assoc 2017;6:e004877

IN.PACT-DEEP Randomized Trial

Primary efficacy and safety results

12-month results Noninferiority hyphotesis	IA-DEB (n=165)	PTA (n=91)	p
TLR (%)	9.2	13.1	0.29
Restenosis (%)	41	35.5	0.60
Major amputation (%)	8.8	3.6	0.08
Death and amputation (%)	35.2	25.2	0.06

TLR: clinically driven target lesion revascularization.
PTA: percutaneous transluminal angioplasty.
IA-DEB: IN.PACT Amphirion drug-eluting balloon.

Zeller T, et al. J Am Coll Cardiol 2014;64:1568-1576.

Surgical revascularization

Primary patency rates (%) for open surgical revascularization modalities

	Graft Type	1y	2y	3y	4y	5y
Above the knee femoropopliteal grafts	Saphenous vein bypass	83	80	78	77	77
	PTFE	74	60	56	53	50
Below the knee femoropopliteal grafts	Saphenous vein bypass	83	78	75	72	67
	PTFE	88	81	54	54	-
Femoral-infrapopliteal grafts	Saphenous vein bypass	89	86	83	80	74
	PTFE	45	35	31	25	18

PTFE: polytetrafluoroethylene.

Shishehbor M, et al. Critical limb ischemia. An Expert Statement. J Am Coll Cardiol 2016;68:2002-2015.

Revascularization

Conclusions

1. **Revascularization is the cornerstone of therapy (Class I recommendation).**
2. **Revascularization options include endovascular, surgical, or the combination of both.**
3. **A single reversed or in situ saphenous vein bypass is recommended for surgical revascularization.**
4. **Drug eluting-stents have demonstated superior primary patency over balloon angioplasty, bare metal stent and drug-coated balloons.**
5. **BEST-CLI and the BASIL II and BASIL III trials will provide more definitive information to guide the treatment of CLI.**