

Con il Patrocinio di



Malattia coronarica cronica in paziente già sottoposto a PCI: dallo studio Compass alla pratica clinica

Strategie vincenti nella gestione
della terapia antitrombotica nel paziente
con cardiopatia ischemica cronica

Caso Clinico 1

Paziente con vasculopatia periferica e coronaropatia trattata con PCI

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Cardiologia Interventistica

Azienda USL Toscana Sudest

Arezzo

Clinical History

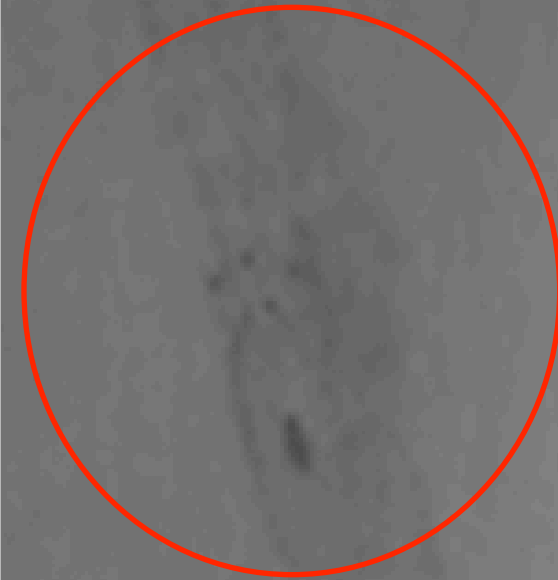
- 80 years old male
- DM type 2
- Anterior MI treated with PPCI in 2004 in multivessel disease
- PVD with previous Stent implantation on left SFA-POP (2006)
- PCI of RCA in 2016 for positive stress test
- Left Ventricular Dysfunction: LVEF 45%
- Mild renal failure (VFG 40ml/min)

Clinical Presentation

- Presenting with CLI left limb
- Rest pain
- ABI: 0.30 (ATA)
- Duplex: SFA occlusion 20cm from ostium, in stent for 40mm, distal reperfusion with postocclusive flow. ATA patent. Left CFA patent (antegrade access possible)



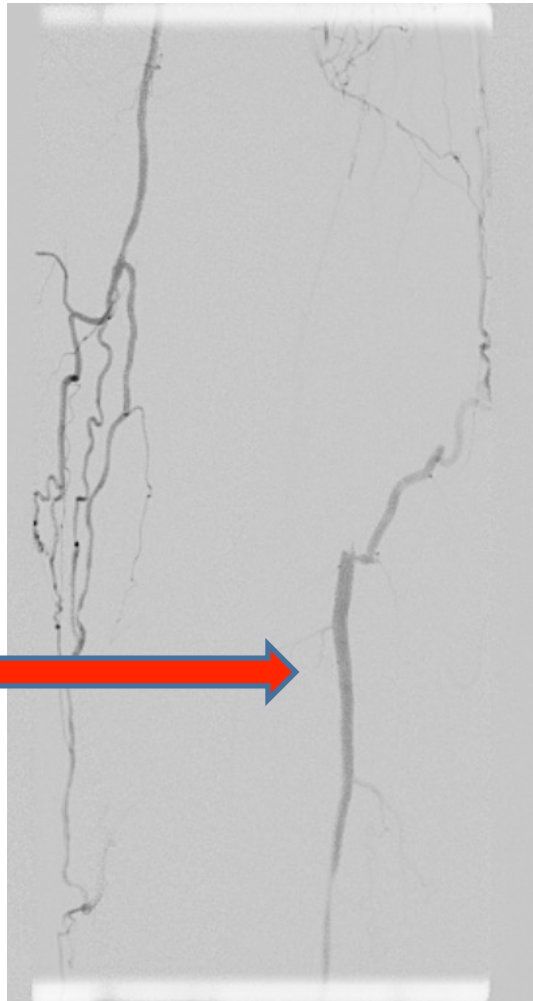
Angiography



Excentric Calcification
Stent distorsion
Stent fracture

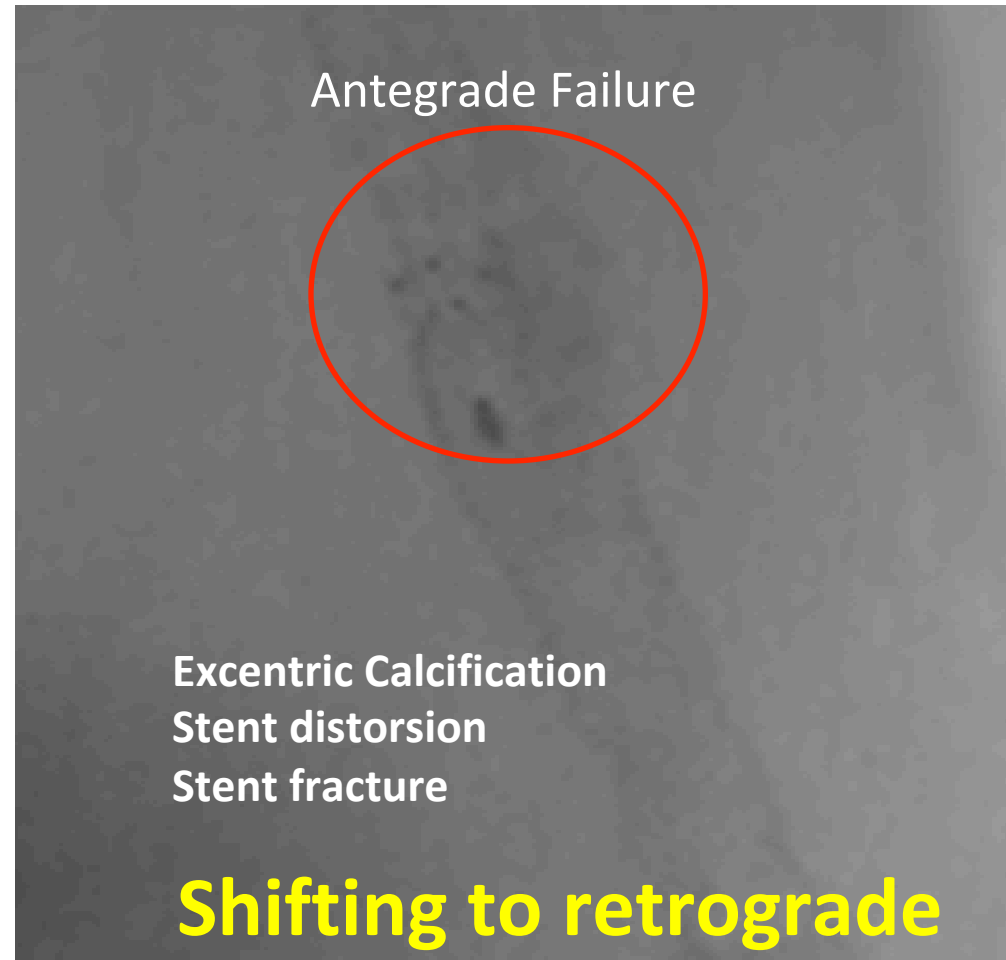
Popliteal and BTK at baseline

Antero
Tibial

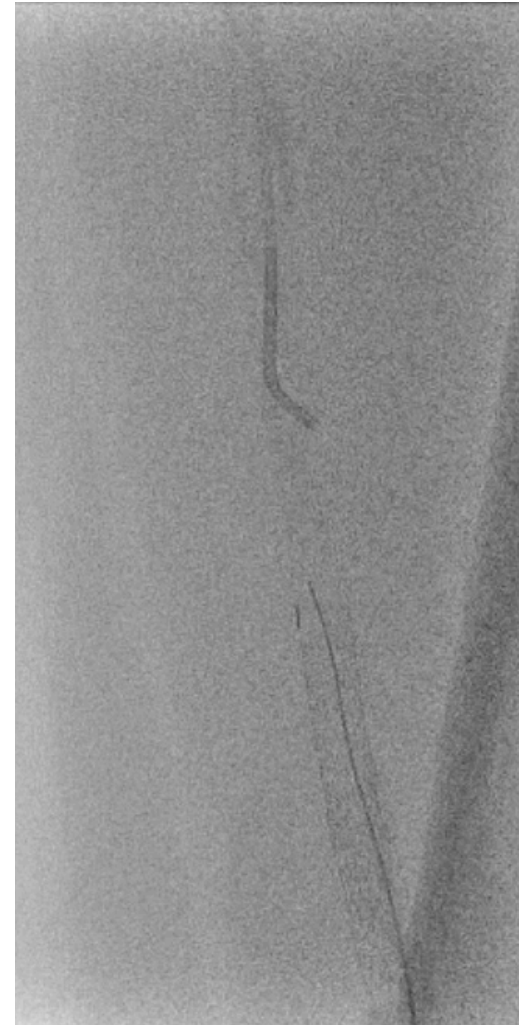


Interventional Strategy

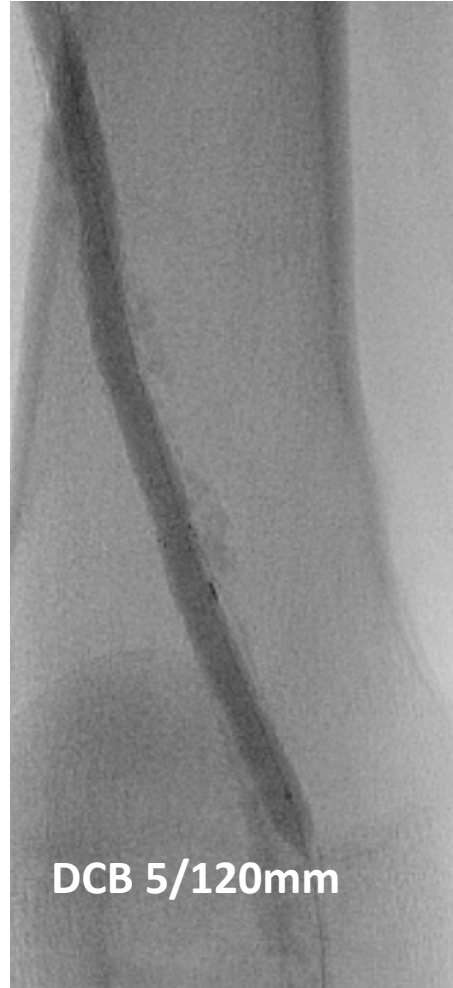
- Antegrade stent ricanalization and PTA with non compliant balloon 5.0mm
- PTA of P3 segment and ATA post SFA ricanalization
- DCB angioplasty in the occluded segment
- New stent implantation in the distorted-fractured stent segment



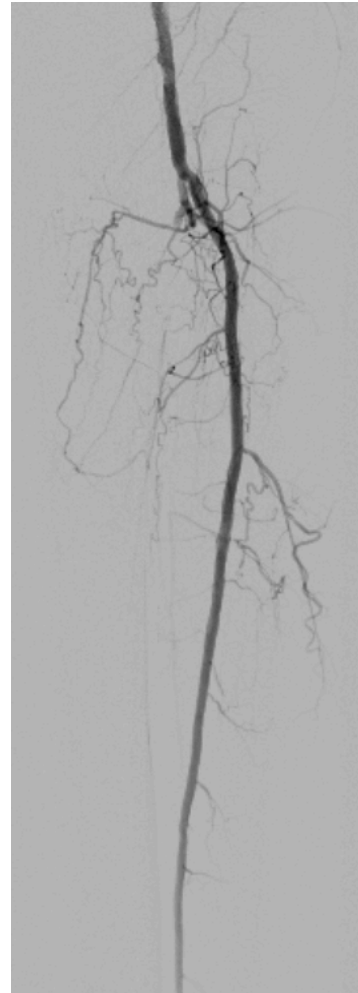
Retrograde Crossing



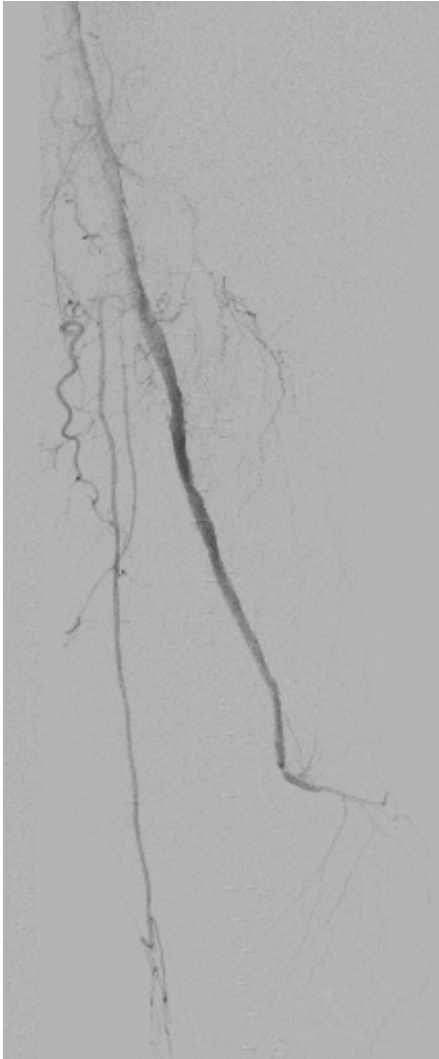
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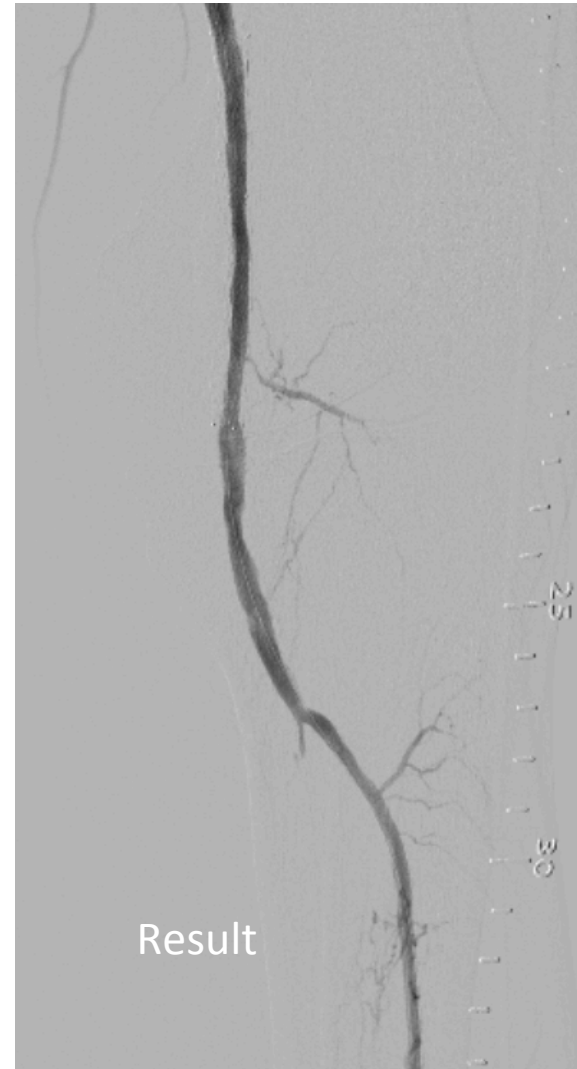
Final Result



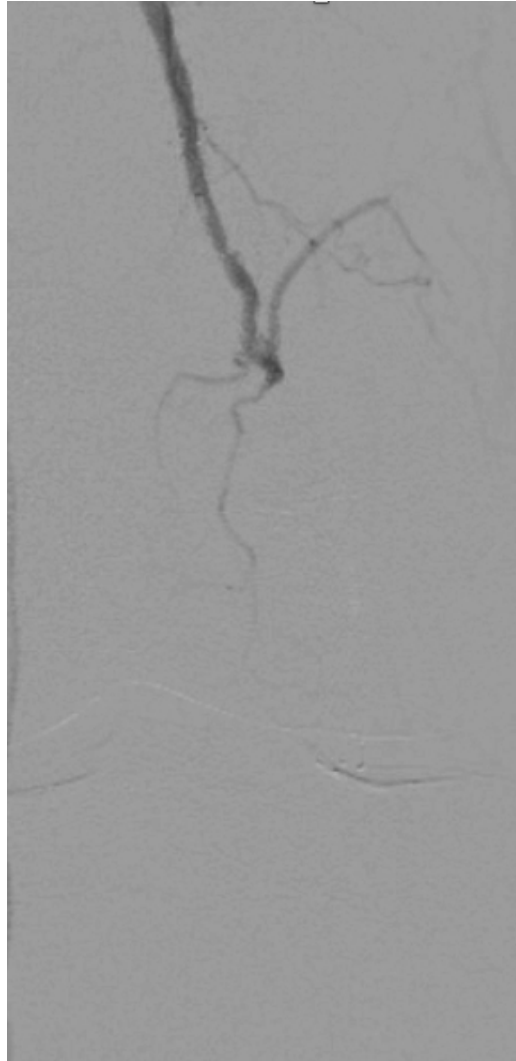
2 months later



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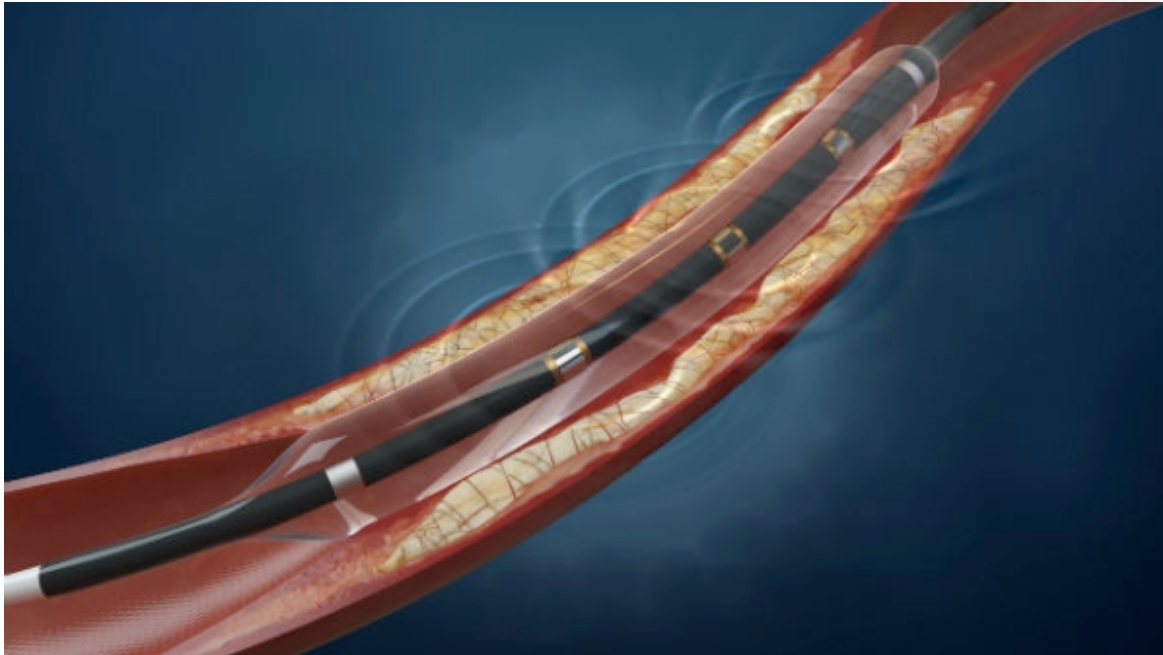


1 month later: Second Reocclusion



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SHOCKWAVE
MEDICAL INC

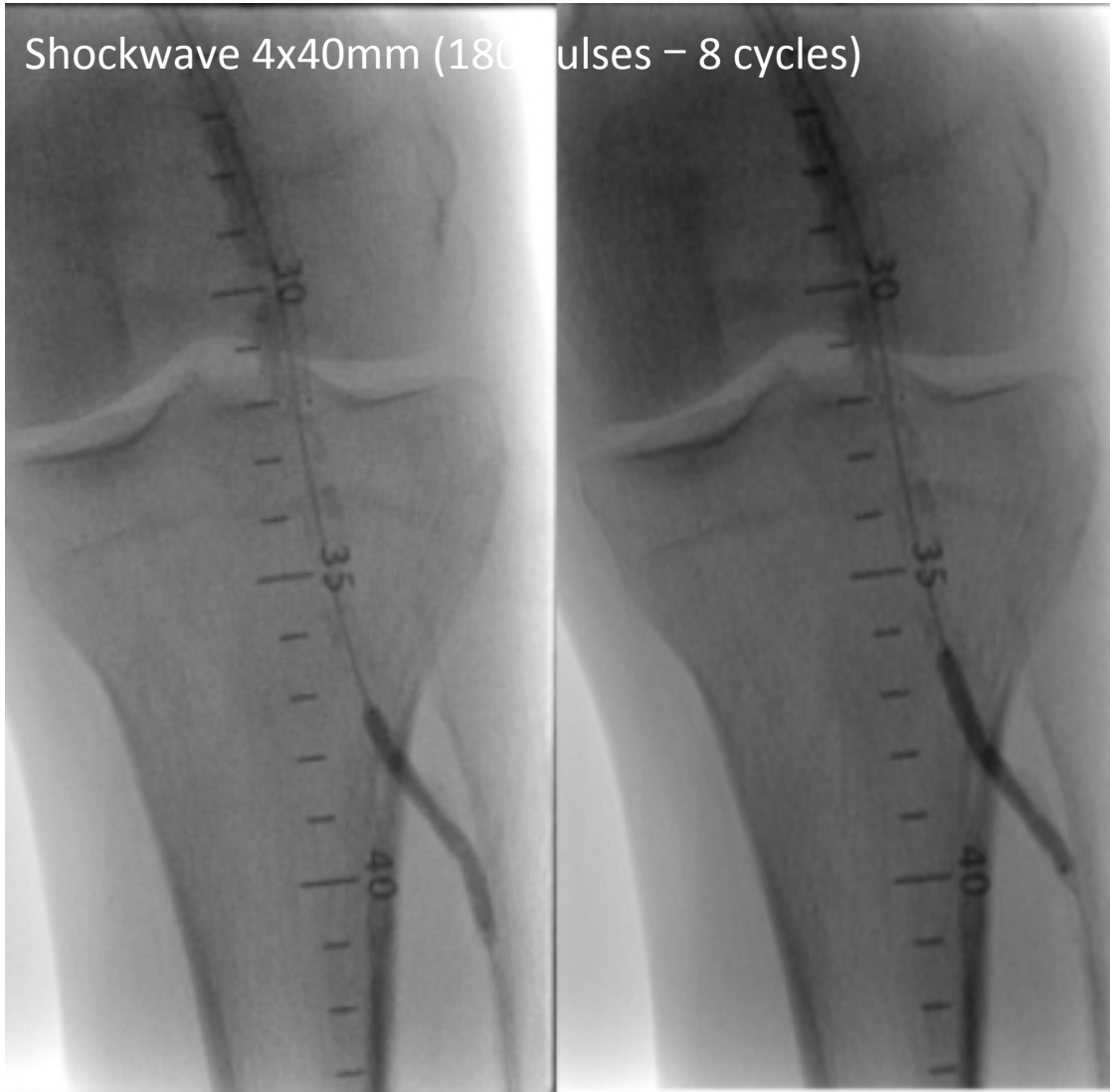


Lithoplasty in stent and in POP

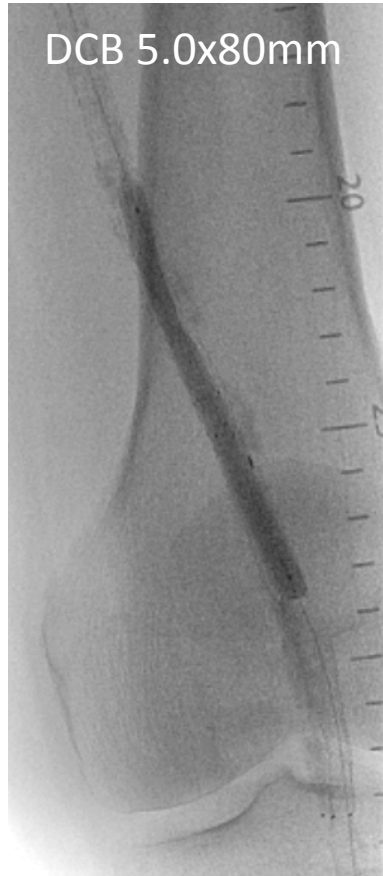


Lithoplasty in ATA

Shockwave 4x40mm (1800 pulses – 8 cycles)

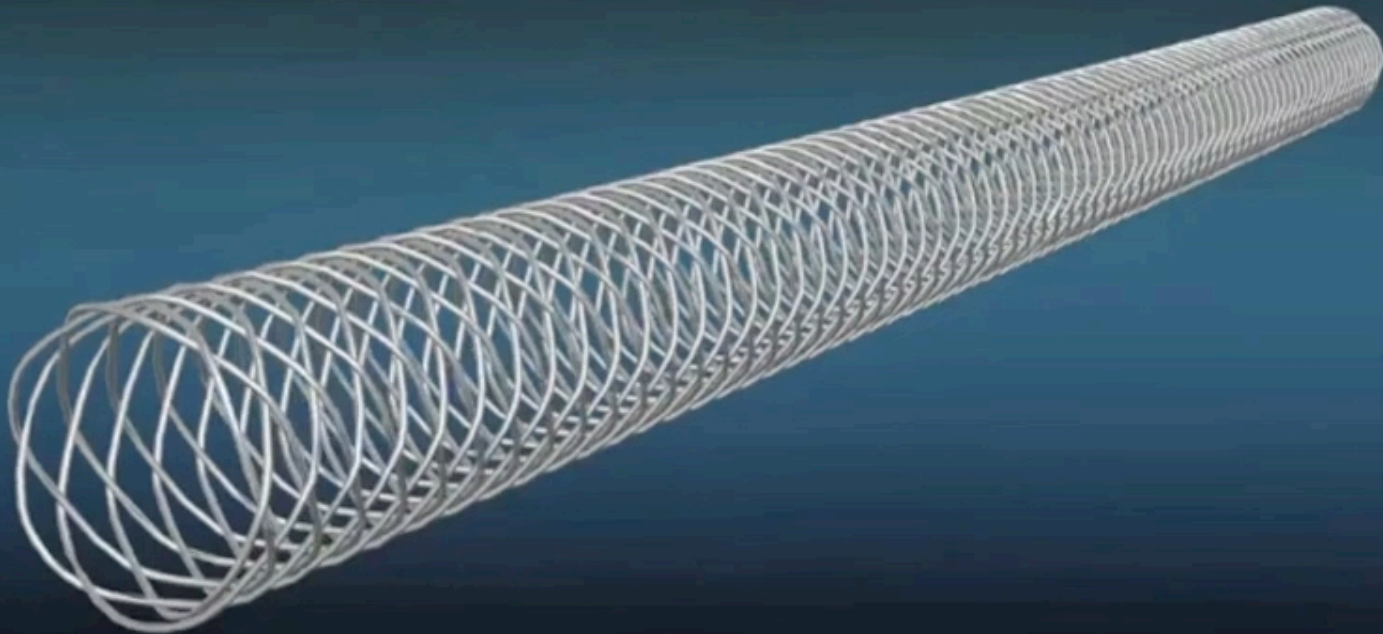


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SUPERA STENT

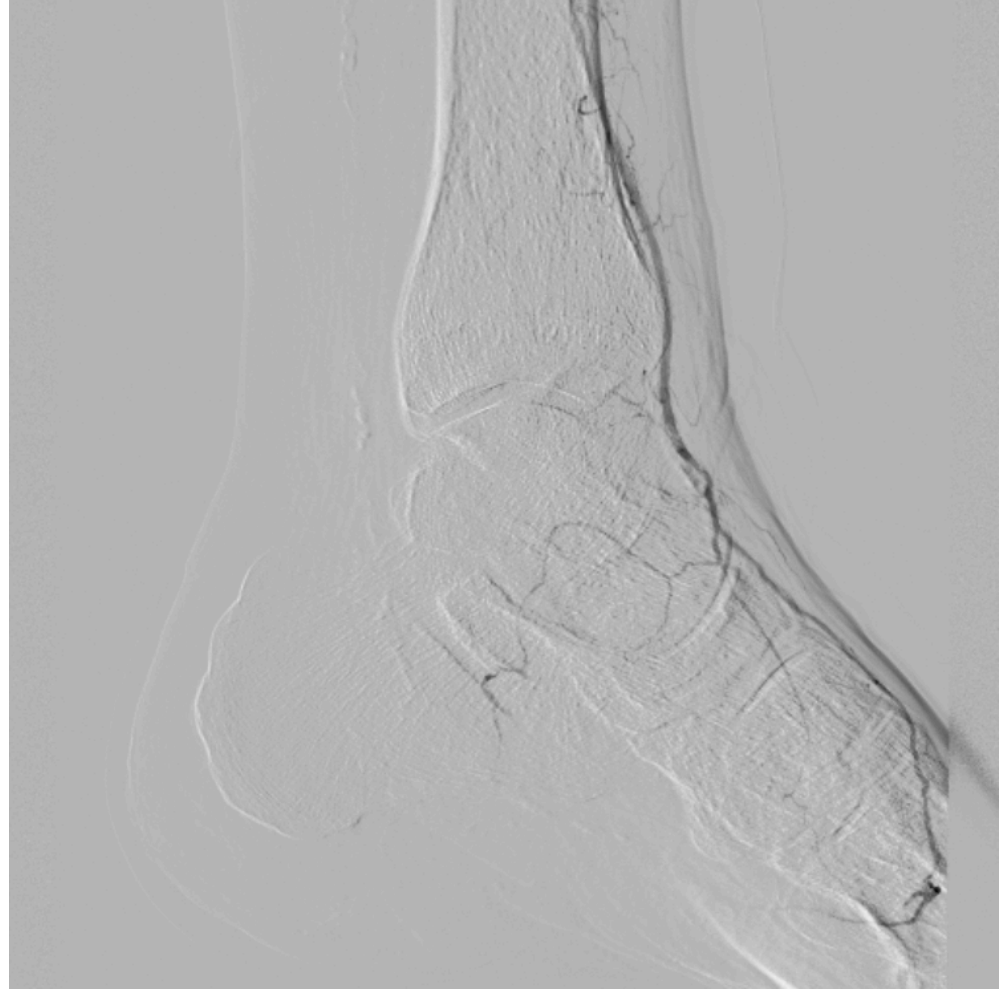
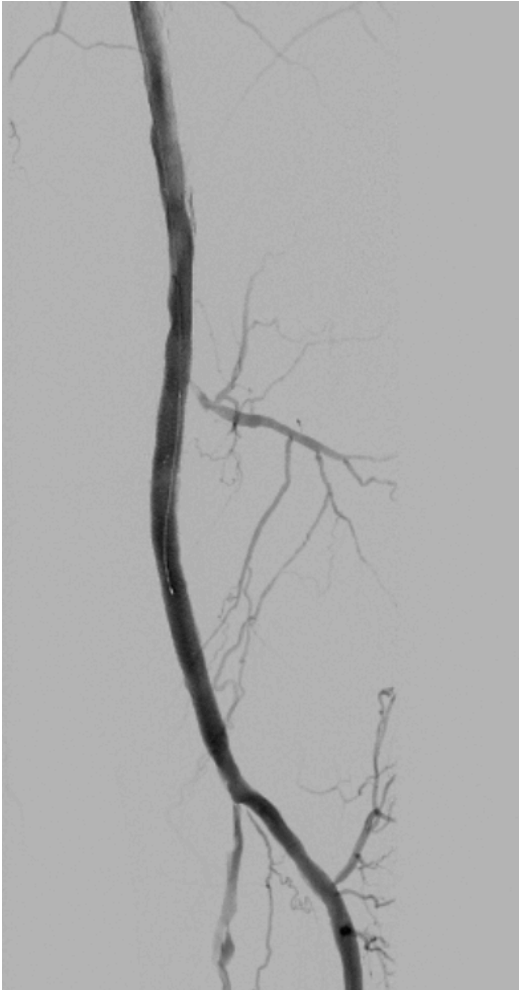
self expanding nitinol interwoven *stent* design for high vessel support



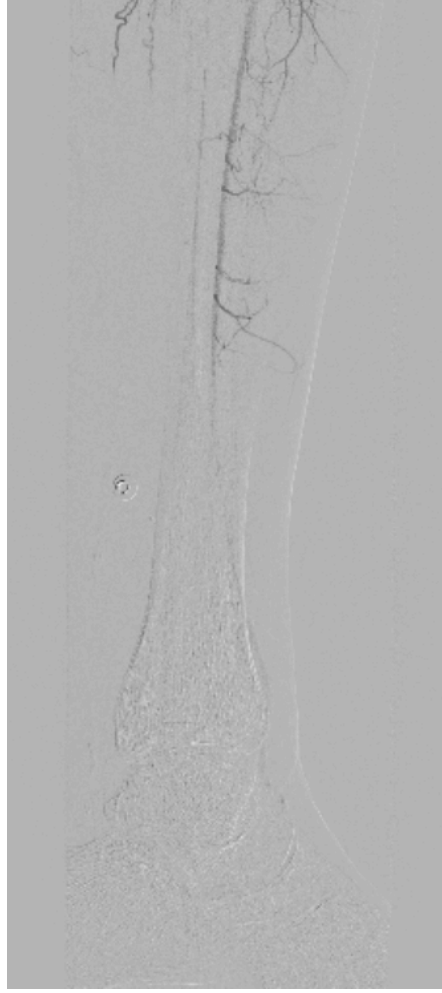
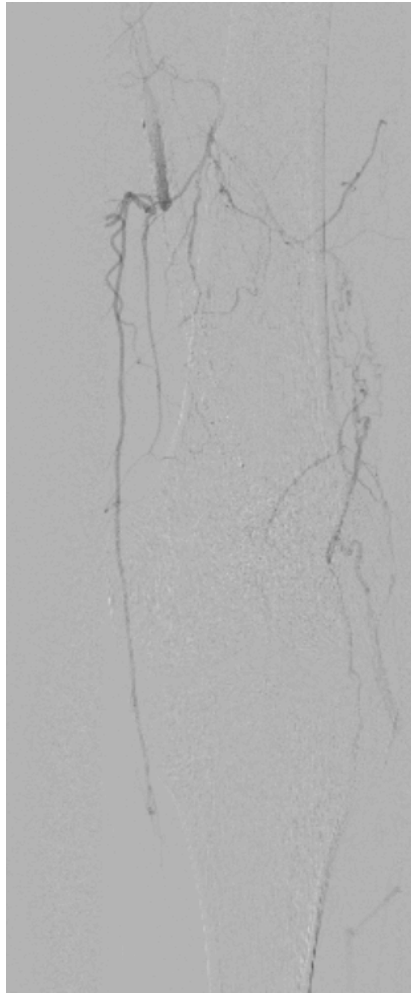
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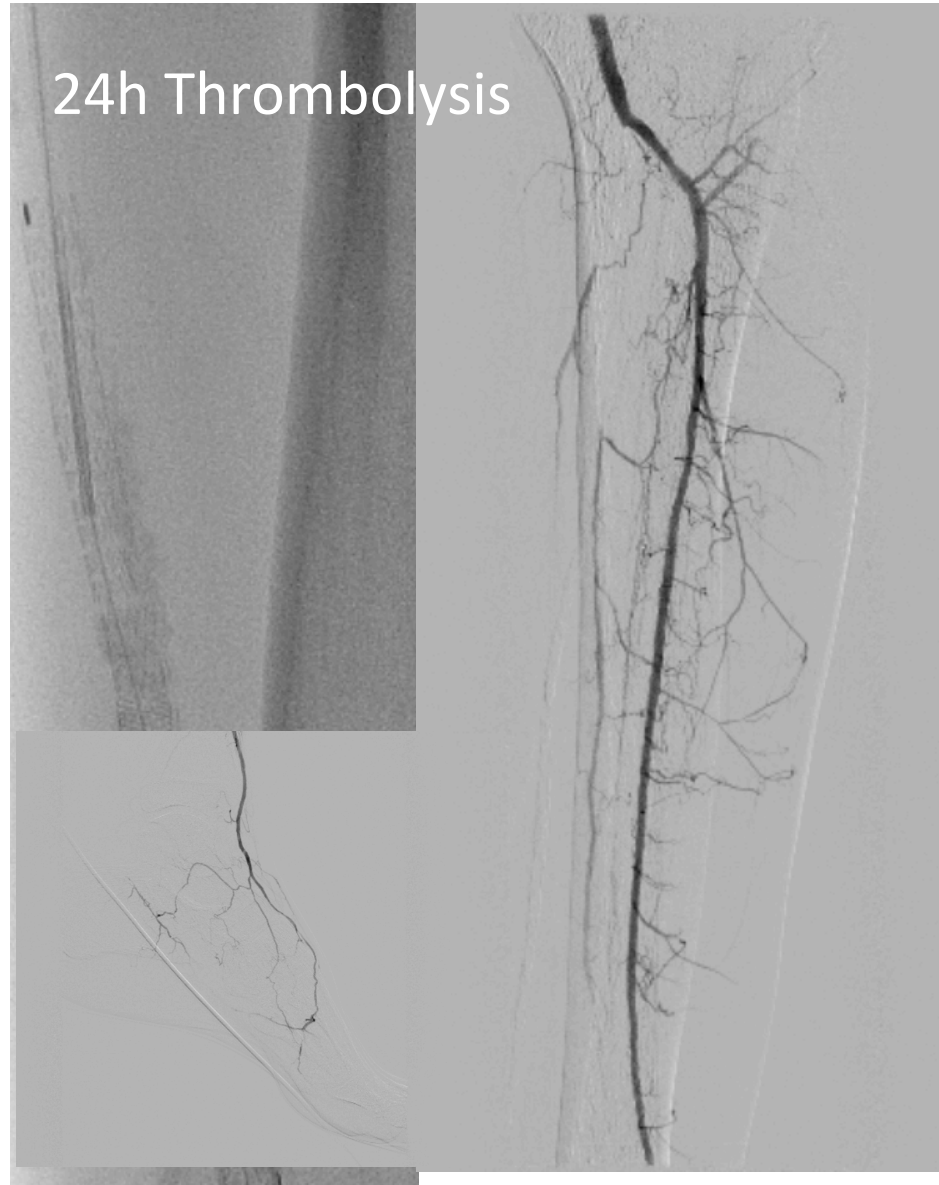
Final Result



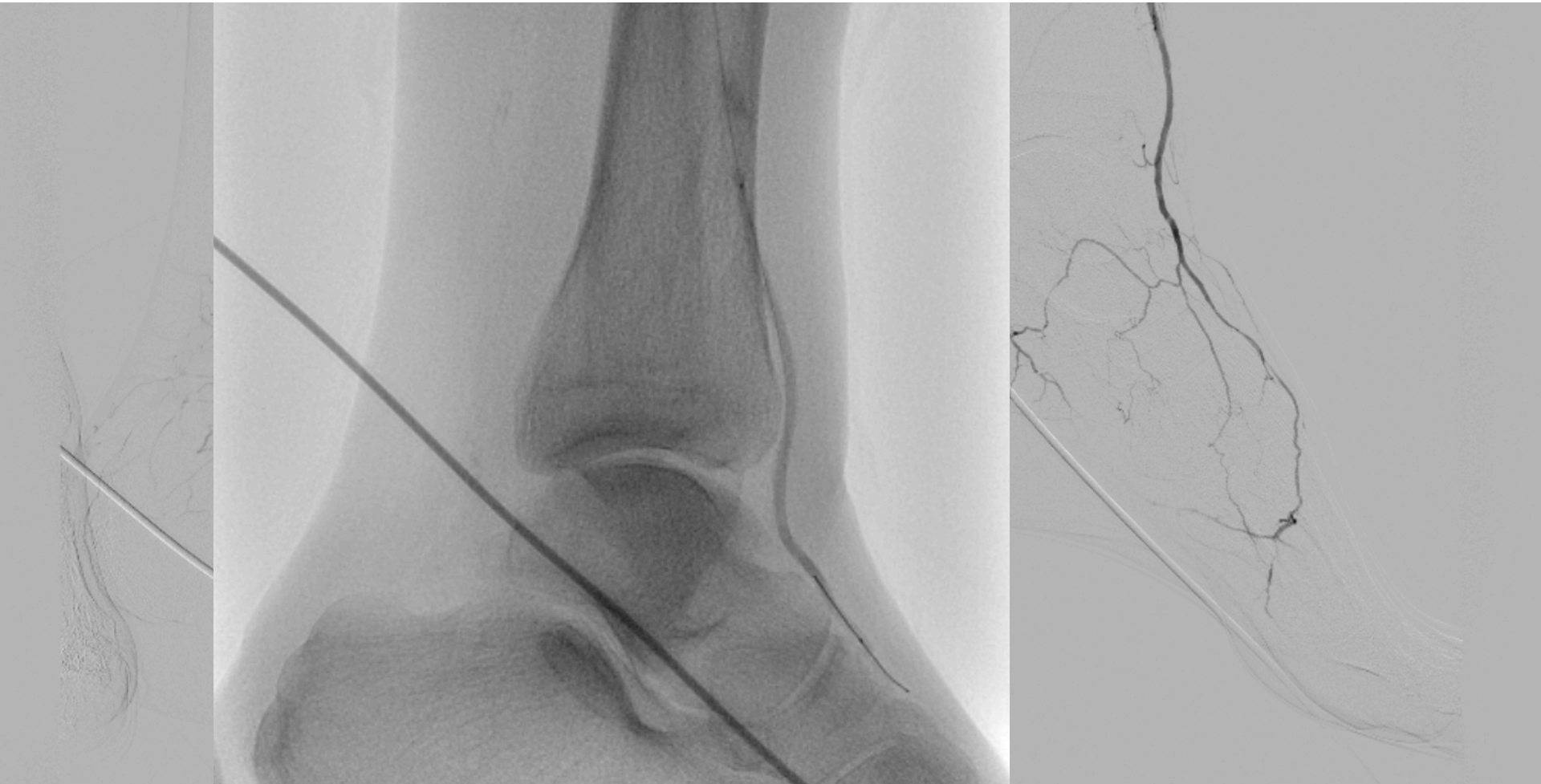
The morning after



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Optimizing outflow: PTA of anteropedis artery



Guidelines on Antithrombotic Therapy in PAD

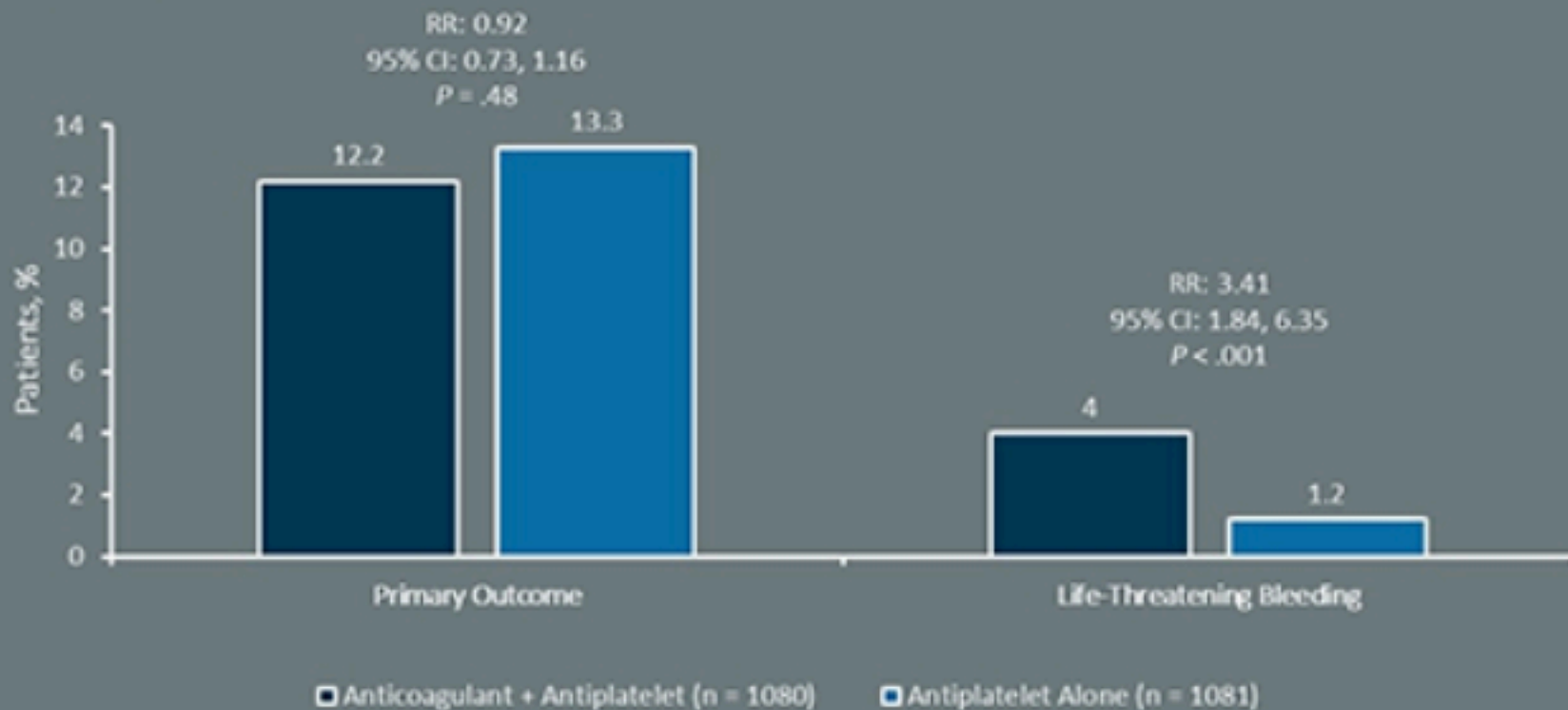
	SVS 2015	AHA/ACC 2016	ESC 2017
Asymptomatic PAD	No recommendation	Antiplatelet therapy is reasonable in ABI ≤ 0.90 (IIa, C-EO) Usefulness of antiplatelet therapy is uncertain in ABI 0.91–0.99 (IIb, B-R)	Antiplatelets not routinely recommended (III, A)
Symptomatic PAD	Aspirin 75–325 mg (I, A) Clopidogrel 75 mg is an effective alternative to aspirin (I, B) Warfarin should not be used to reduce cardiovascular events (I, C)	Aspirin (75–325 mg) or clopidogrel (75 mg) SAPT (I, A) Usefulness of aspirin + clopidogrel DAPT is not well established (IIb, B-R) Anticoagulation should not be used to reduce ischemic events (III, A)	Aspirin or clopidogrel SAPT (I, A) Clopidogrel may be preferred over aspirin (IIb, B)
Surgical revascularization	Treatment with antiplatelet therapy (aspirin, clopidogrel, or aspirin + clopidogrel DAPT) for venous and prosthetic bypass (II, B)	Aspirin + clopidogrel DAPT may be reasonable to reduce limb events (IIb, C-LD) Usefulness of anticoagulation to improve bypass patency is uncertain (IIb, B-R)	Aspirin or clopidogrel SAPT (I, A) VKA may be considered after vein bypass (IIb, B) Aspirin + clopidogrel DAPT may be considered after below-knee prosthetic bypass (IIb, B)
Endovascular revascularization	Aspirin + clopidogrel DAPT for ≥ 1 month (II, B)	Aspirin + clopidogrel DAPT may be reasonable to reduce limb events (IIb, C-LD)	Aspirin + clopidogrel DAPT for ≥ 1 month after stent placement (IIb, B) followed by long-term aspirin or clopidogrel SAPT (I, A)
Specific antithrombotics	—	Benefit of vorapaxar added to existing antiplatelet therapy is uncertain (IIb, B-R)	—

Values in parentheses are Class, Level of Evidence.

AHA/ACC = American Heart Association/American College of Cardiology; B-R = level B randomized controlled trial; C-LD = level C limited data; C-EO = level C expert opinion; ESC = European Society for Cardiology; SAPT = single antiplatelet therapy; SVS = Society for Vascular Surgery; VKA = vitamin K antagonist; other abbreviations as in Table 1.

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WAVE



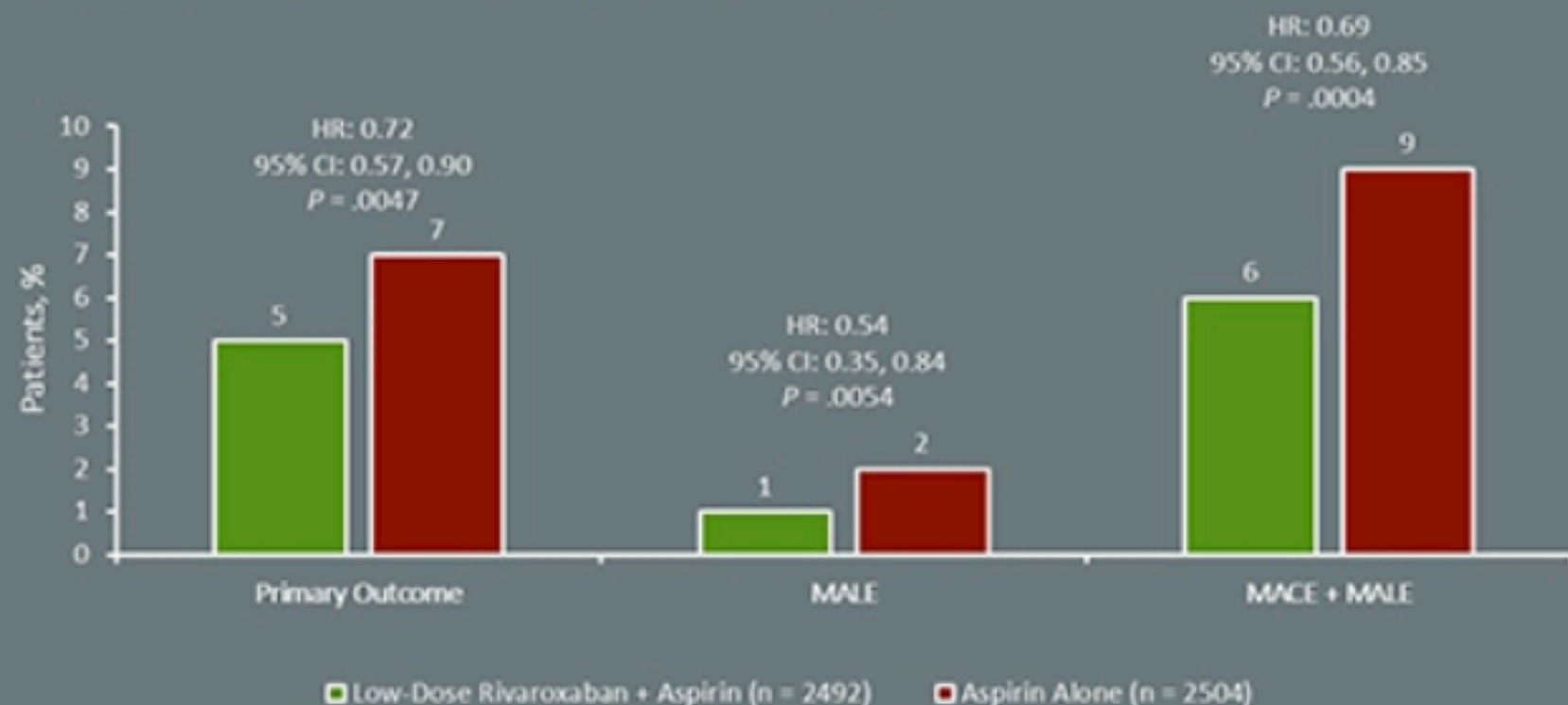
Primary outcome 1: MI, stroke, or death from CV causes

WAVE Trial Investigators. *N Engl J Med.* 2007;357:217-227.

Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial

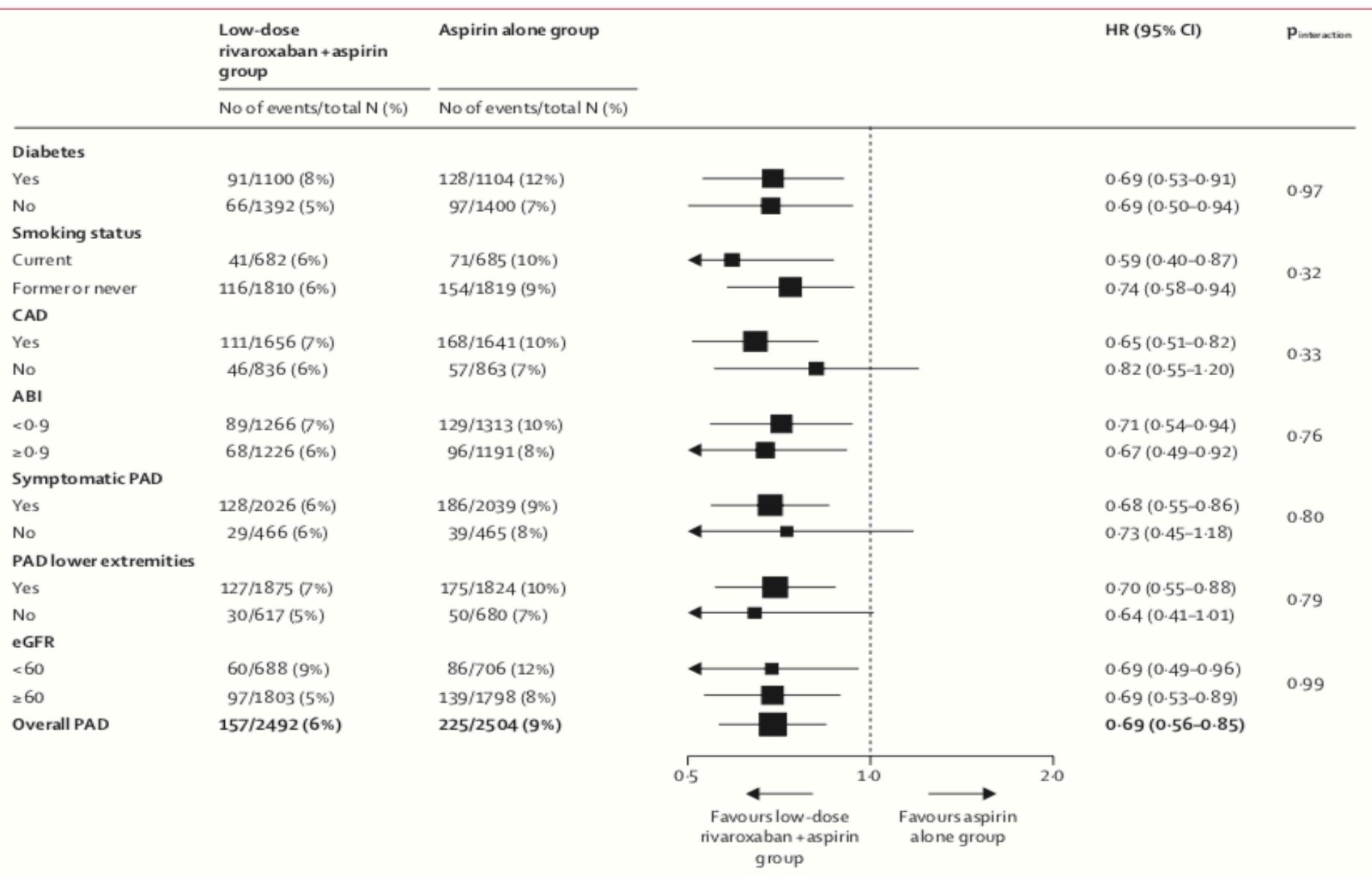
Sonia S Anand, Jackie Bosch, John W Eikelboom, Stuart J Connolly, Rafael Diaz, Peter Widimsky, Victor Aboyans, Marco Alings, Ajay K Kakkar, Katalin Keltai, Aldo P Maggioni, Basil S Lewis, Stefan Störk, Jun Zhu, Patricio Lopez-Jaramillo, Martin O'Donnell, Patrick J Commerford, Dragos Vinereanu, Nana Pogossova, Lars Ryden, Keith A A Fox, Deepak L Bhatt, Frank Misselwitz, John D Varigos, Thomas Vanassche, Alvaro A Avezum, Edmond Chen, Kelley Branch, Darryl P Leong, Shrikant I Bangdiwala, Robert G Hart, Salim Yusuf; on behalf of the COMPASS Investigators*

COMPASS: PAD Subgroup



Primary outcome: CV death, MI, or stroke

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PAD COMPASS BLEEDING

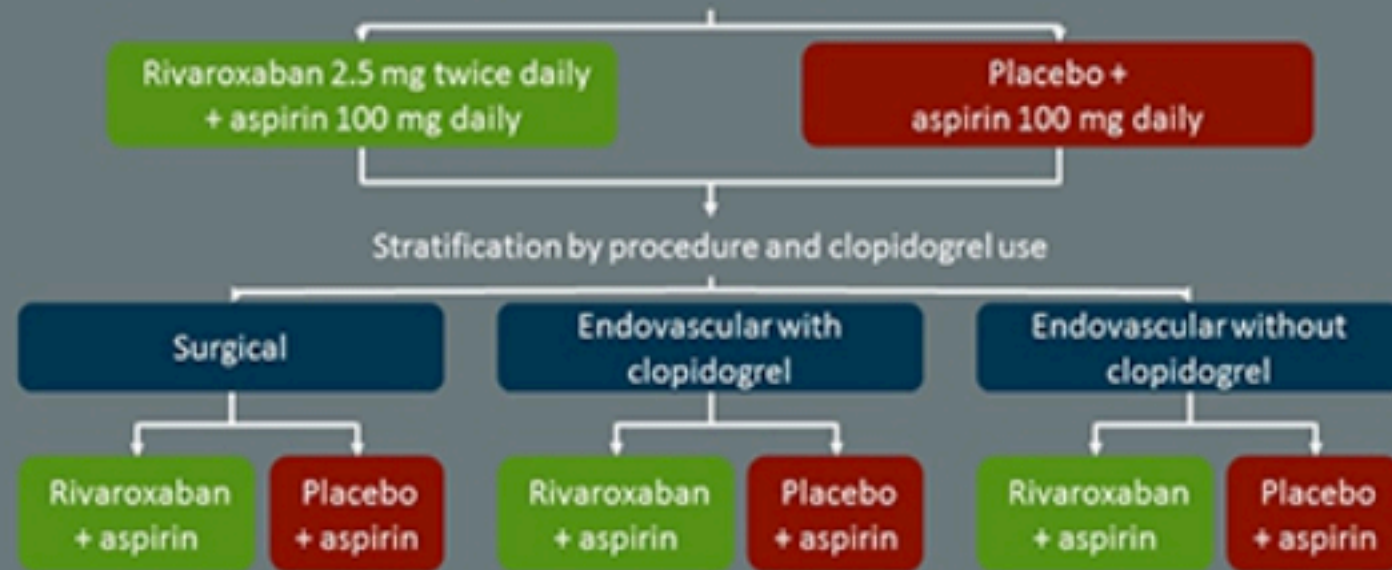
	Low-dose rivaroxaban plus aspirin group (n=2492)	Rivaroxaban alone group (n=2474)	Aspirin alone group (n=2504)	Low-dose rivaroxaban plus aspirin versus aspirin alone		Rivaroxaban alone versus aspirin alone	
				HR (95% CI)	p value	HR (95% CI)	p value
Major bleeding*	77 (3%)	79 (3%)	48 (2%)	1.61 (1.12-2.31)	0.0089	1.68 (1.17-2.40)	0.0043
Fatal bleeding	4 (<1%)	5 (<1%)	3 (<1%)
Non-fatal symptomatic intracranial haemorrhage	4 (<1%)	3 (<1%)	8 (<1%)
Non-fatal, non-intracranial haemorrhage symptomatic bleeding into a critical organ	13 (1%)	18 (1%)	8 (<1%)	1.55 (0.64-3.74)	0.33	2.15 (0.94-4.96)	0.065
Other major bleeding (surgical site bleeding requiring reoperation or bleeding leading to hospitalisation)	56 (2%)	53 (2%)	29 (1%)	1.94 (1.24-3.04)	0.0031	1.86 (1.18-2.92)	0.0064
Fatal or symptomatic bleeding into a critical organ	21 (1%)	26 (1%)	19 (1%)	1.10 (0.59-2.05)	..	1.39 (0.89-3.09)	..
Fatal or symptomatic bleeding into a critical organ or surgical site bleeding leading to re-operation	25 (1%)	29 (1%)	22 (1%)	1.13 (0.64-2.01)	..	1.34 (0.77-2.52)	..
ISTH major bleeding	64 (3%)	53 (2%)	40 (2%)	1.61 (1.08-2.39)	0.0089	1.34 (0.89-2.02)	..
Sites of bleeding							
Gastrointestinal	41 (2%)	26 (1%)	18 (1%)	2.28 (1.31-3.96)	0.0027	1.46 (0.80-2.66)	0.22
Intracranial	5 (<1%)	6 (<1%)	9 (<1%)	0.56 (0.19-1.66)	..	0.68 (0.24-1.91)	..
Genitourinary	3 (<1%)	14 (1%)	2 (<1%)
Ocular	7 (<1%)	8 (<1%)	3 (<1%)
Skin	5 (<1%)	6 (<1%)	8 (<1%)
Respiratory	4 (<1%)	4 (<1%)	0
Other	15 (1%)	15 (1%)	10 (<1%)
Minor bleeding	198 (8%)	170 (7%)	141 (6%)	1.43 (1.15-1.77)	0.0011	1.23 (0.98-1.54)	0.069
Net benefit							
Cardiovascular death, myocardial infarction, stroke, and critical organ or fatal bleeding†	140 (6%)	168 (7%)	185 (7%)	0.75 (0.60-0.94)	0.011	0.92 (0.75-1.13)	0.43
Cardiovascular death, myocardial infarction, stroke or major adverse limb events, major amputation, or fatal or critical organ bleeding	169 (7%)	207 (8%)	234 (9%)	0.72 (0.59-0.87)	0.0008	0.89 (0.74-1.07)	0.23

Data are n (%) unless otherwise indicated. HR=hazard ratio. ISTH=International Society of Thrombosis and Hemostasis.*Includes four components of prespecified major bleeding definition summarised hierarchically. †Prespecified net clinical benefit outcome.

Table 3: Safety outcomes and net benefit for patients with peripheral artery disease

VOYAGER PAD: Study Design

Patients with symptomatic PAD undergoing recent (≤ 10 days) peripheral revascularization, randomized 1:1



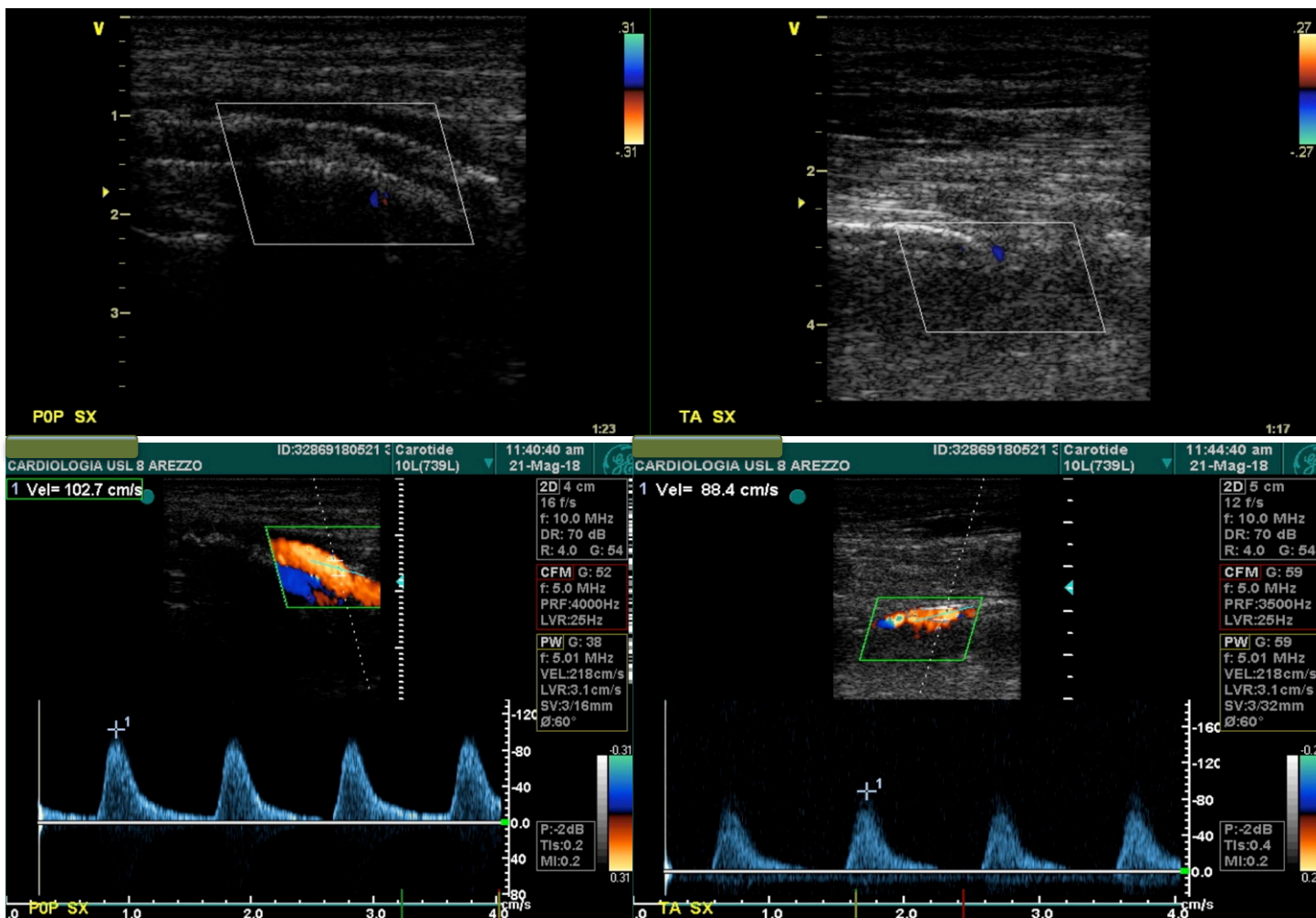
- Event-driven: MI, ischemic stroke, CV death, acute limb ischemia, major amputation
- All patients receive standard DAPT

Capell WH, et al. *Am Heart J.* 2018;199:83-91; ClinicalTrials.gov. NCT02504216.

Discharged on



6-moth Duplex scan



Conclusioni



CONCLUSIONS

- Patients with PAD are at a high risk for MI, stroke, and CV-related death as well as chronic and acute limb ischemia.
- Until recently, our antithrombotic options for reducing these risks in our PAD patients have mostly been limited to DAPT just after revascularization and clopidogrel or aspirin monotherapy in the long period.
- With the completion of the COMPASS trial, we now have a new therapeutic option that significantly reduces the 2 key risks associated with PAD -- MACE and MALE -- without a significantly increased risk of fatal, intracranial, or critical organ bleeding events.