

**Percutaneous Transluminal Angioplasty versus Drug Eluting Stents
for Infrapopliteal Lesions in Critical Limb Ischemia, PADI trial**

SUPPLEMENTAL MATERIAL

Supplemental Tables

Supplemental table 1A. Inclusion criteria

Inclusion criteria

- Age > 18 years.

 - If female patient with child-bearing potential, patient may not be pregnant at the study entry and must utilize reliable birth control for the duration of her participation in the study.

 - Patient is willing and able to comply with the specified follow-up evaluation.

 - Critical limb ischemia, defined as Rutherford category 4 (ischemic rest pain), 5 (minor tissue loss), or 6 (major tissue loss).

 - Stenosis (>50% luminal loss) or occlusion of an infrapopliteal artery, including the tibiofibular trunk, the anterior tibial artery, the posterior tibial artery, and the peroneal artery.

 - Target lesion length ≤ 90 mm.

 - Artery to be treated with a diameter ≥ 2 mm and ≤ 6 mm.

 - Patent common iliac, external iliac, superficial femoral and popliteal artery on the ipsilateral side prior to randomization, possibly after treatment during the same session.

 - At least 1 patent crural (anterior tibial, posterior tibial, or peroneal) artery with expected unobstructed runoff to ankle level after treatment.
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Supplemental table 1B. Exclusion criteria

Exclusion criteria

- Acute limb ischemia.
- Previous amputation of affected limb at or above ankle level.
- Subacute limb ischemia which requires thrombolysis as first treatment modality.
- Active bleeding or bleeding diathesis.
- Recent (≤ 3 months) hemorrhagic stroke or any other CNS abnormality with increased risk of hemorrhage, such as intracranial neoplasm, arteriovenous malformation, intracranial aneurysm, or aneurysm repair.
- Gastrointestinal or genitourinary bleeding of clinical significance within the previous 6 weeks before treatment.
- Aneurysm in common femoral, superficial femoral, or popliteal artery on the ipsilateral side.
- Surgical revascularization involving the same limb within 30 days prior to the index procedure or planned surgical revascularization of the same limb within 30 days of the index procedure.
- Previous implanted stent at the index site.
- Life expectancy of less than 6 months or other factors making clinical follow-up difficult.
- Known allergy to acetylsalicylic acid (aspirin), clopidogrel, heparin, or paclitaxel.
- Known allergy to contrast media.
- Known heparin-induced thrombocytopenia (HIT type 2).
- Patient unable or unwilling to tolerate anticoagulant, anti-platelet therapy or contrast media.
- Creatinine clearance 20 mL/minute (as derived from Cockcroft-Gault formula).
- Severely calcified lesions with expected resistance to stenting.

- Poor inflow due to ipsilateral stenoses or occlusions of the iliac or femoropopliteal arteries that cannot be treated during the same session.
 - Significant vessel tortuosity or other parameters prohibiting access to the lesions and/or delivery of the stent.
 - Patients without (expected) distal runoff to the index site.
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Supplemental table 2. Mean Rutherford score, ankle brachial index and toe pressure at 6 and 12 months post treatment

	PTA±BMS	DES	p value *
Rutherford score			
	n=43 limbs	n=53 limbs	
mean (s.e.) at month 6	2.81 (0.32)	3.11 (0.29)	0.49
	n=37 limbs	n=45 limbs	
mean (s.e.) at month 12	1.81 (0.34)	1.87 (0.30)	0.90
Ankle brachial index			
	n=32 limbs	n=39 limbs	
mean (s.e.) at month 6	0.83 (0.05)	0.85 (0.04)	0.74
	n=26 limbs	n=33 limbs	
mean (s.e.) at month 12	0.91 (0.06)	0.94 (0.07)	0.74
Toe pressure (mmHg)			
	n=34 limbs	n=40 limbs	
mean (s.e.) at month 6	63.7 (6.2)	69.5 (5.7)	0.49
	n=24 limbs	n=31 limbs	
mean (s.e.) at month 12	78.1 (6.6)	78.3 (6.2)	0.98

* T-test.

PTA: percutaneous transluminal angioplasty; BMS: bare metal stent; DES: drug-eluting stent, s.e.: standard error.

Supplemental table 3. Complications and serious adverse events

	PTA±BMS n=66 limbs	DES n=74 limbs	p value*
Periprocedural complications †			
Hematoma	8 (12.1)	7 (9.5)	0.61
Material dysfunction	0	3 (4.1)	0.10
Acute thrombosis	4 (6.1)	5 (6.8)	0.87
Distal emboli	3 (4.5)	4 (5.4)	0.82
Pseudo aneurysm	0	1 (1.4)	0.34
Complications until 12 months			
Acute thrombosis	1 (1.5)	0	0.29
Wound infection	3 (4.5)	8 (10.8)	0.17
Serious adverse events			
Gastrointestinal bleeding	3 (4.5)	2 (2.7)	0.56
Ischemic cerebral event	1 (1.5)	2 (2.7)	0.63
Cerebral hemorrhage	2 (3.0)	0	0.13
Pneumonia	1 (1.5)	3 (4.1)	0.37
Decubitus	1 (1.5)	0	0.29
Cardiac disease	1 (1.5)	5 (6.8)	0.13
Renal failure	2 (3.0)	1 (1.4)	0.49
Non CLI related infection	4 (6.1)	2 (2.7)	0.33

Values are number (%). *Chi-square test. †<30 days post procedural.

PTA: percutaneous transluminal angioplasty; BMS: bare metal stent; DES: drug-eluting stent; CLI: critical limb ischemia.