

Cypher Stent Implantation Below- the-knee: 1-Year Results from a Consecutive Registry

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Purpose

- Prospective, single-centre study to report 12-month results after application of sirolimus-eluting stents in infrapopliteal arteries for treatment of intermittent claudication and critical limb ischemia.
- The cypher stent is approved for tibial use in CLI patients in Europe.

Study Endpoints

- **Primary endpoint:** Primary patency at 12 months, defined as freedom from restenosis of at least 70% detected with ultrasound (PVR >3.4) or angiography.
- **Secondary endpoints:**
 - 12-month secondary patency
 - 12-month TLR rate
 - Technical success rate (defined as a residual stenosis $<30\%$ of reference vessel diameter)
 - Major and minor complication rates according to the Society of Interventional Radiology reporting standards
 - Clinical stage of disease according to the Rutherford-Becker classification after 6 and 12 months
 - Ankle-brachial index (ABI) after 6 and 12 months

Patient Baseline Characteristics

Patient Baseline characteristics (n = 104)	
Age (mean \pm SD)	70.5 \pm 10.4
Male Gender (n)	72.1% (75)
BMI (mean \pm SD)	27.3 \pm 3.5
Hypertension (n)	89.4% (93)
Diabetes (n)	63.5% (66)
History of tobacco use (n)	37.5% (39)
Hypercholesterolemia (n)	72.1% (75)
Dialysis	7.7% (8)

Lesion Baseline Characteristics

Lesion Baseline characteristics (n = 104)	
Anterior tibial artery (n)	29.8% (31)
Tibioperoneal trunk (n)	37.5% (39)
Peroneal artery (n)	22.1% (23)
Posterior tibial artery (n)	10.6% (11)
Lesion length (mm)	36.6 ± 23.6
Reference diameter (mm)	3.1 ± 0.4
Total occlusions (n)	28.8% (30)
Diameter stenosis (%)	86 ± 5%

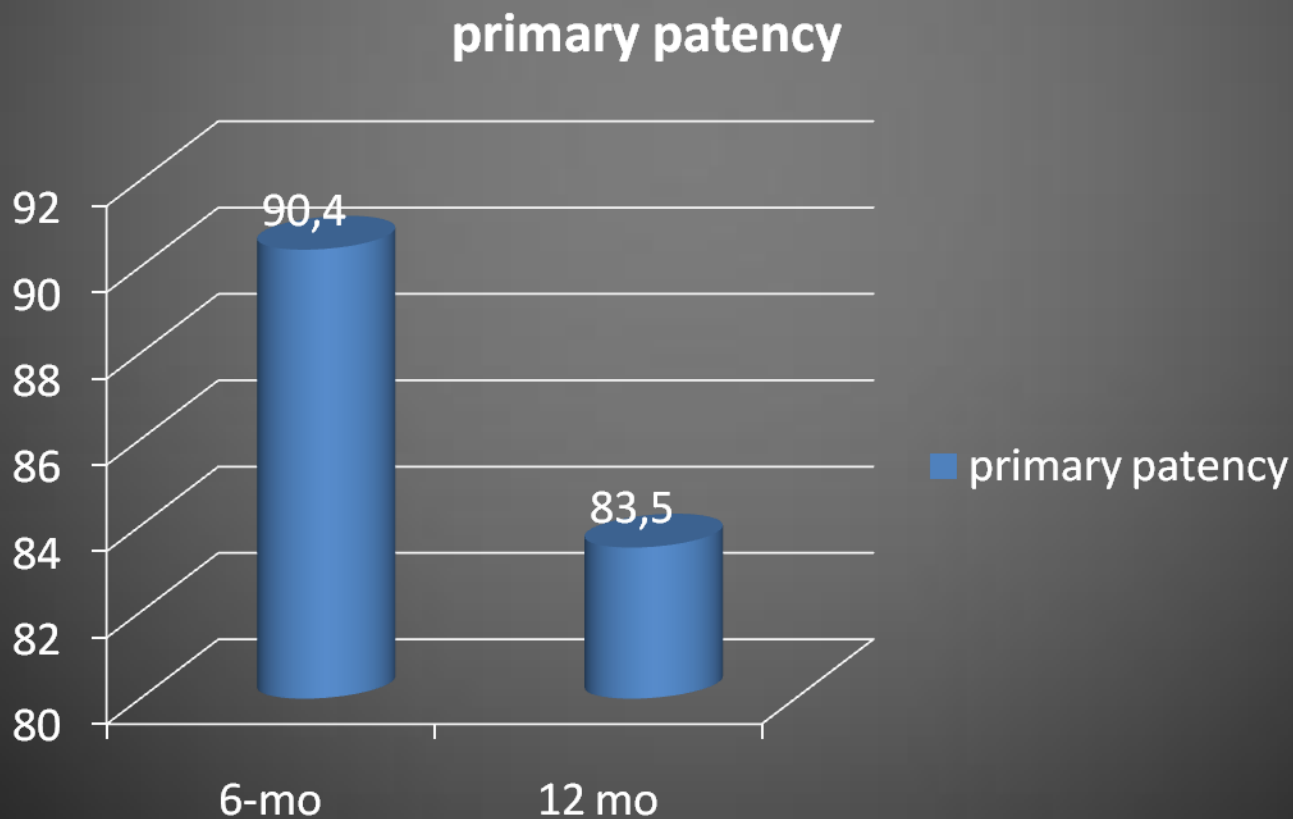
Medication

- 1. Preintervention:** Aspirin 100mg/d & 600mg bolus of clopidogrel.
- 2. Intervention:** Heparin Bolus 5000 IU
- 3. Postintervention:** Aspirin 100mg/d 75mg clopidogrel for 6 months.

Results – Primary Endpoint ≥ 70% Restenosis Rate & Primary Patency

6 months: 9.6% (10/104 lesions)

1-year: 16.4% (17/104 lesions)

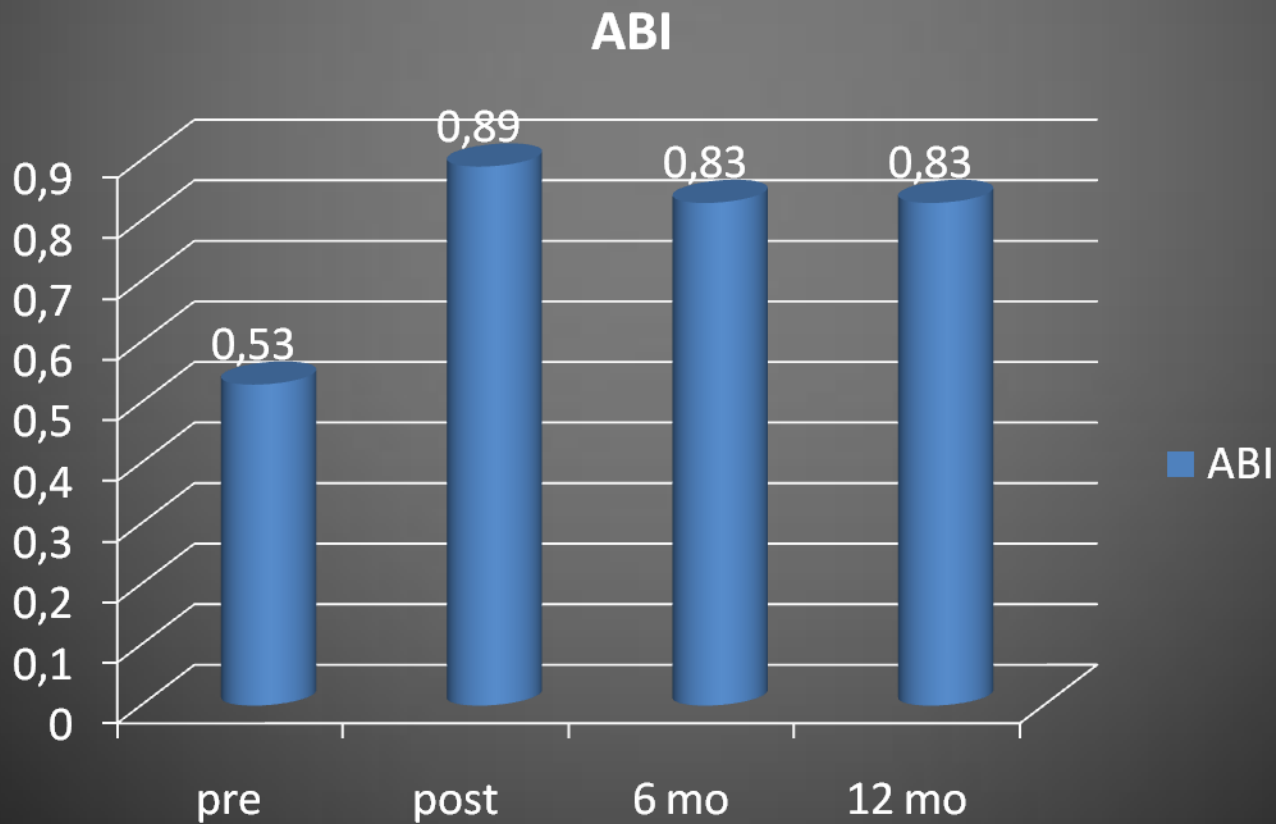


Results – Secondary Endpoints

TLR-Rate, Secondary Patency & ABI

1-year TLR-Rate: 9.8%

1-year secondary patency: 93.3%



Results – Secondary Endpoints Complications

Major complications:	0%
Minor complications:	5.8%
Groin hematoma > 3cm:	2.9%
Pseudoaneurysm:	2.9%

Cocclusions

- The results obtained in this study are very encouraging and provide relevant clinical evidence of the safety and satisfactory performance of Sirolimus-eluting Stents in the treatment of infrapopliteal critical limb ischemia. The results at 12-month follow-up appear to confirm that the restriction of neointimal hyperplasia, which has been extensively demonstrated in the coronary arteries, is also applicable to the infrapopliteal vascular bed.
- A randomized study comparing Cypher stent with POBA (ACHILLES) is on the way.