Sirolimus eluting coronary self expanding system for the treatment of iliofemoral disease

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Disclosure

Speaker name:

Eugenio Stabile

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ■ do not have any potential conflict of interest

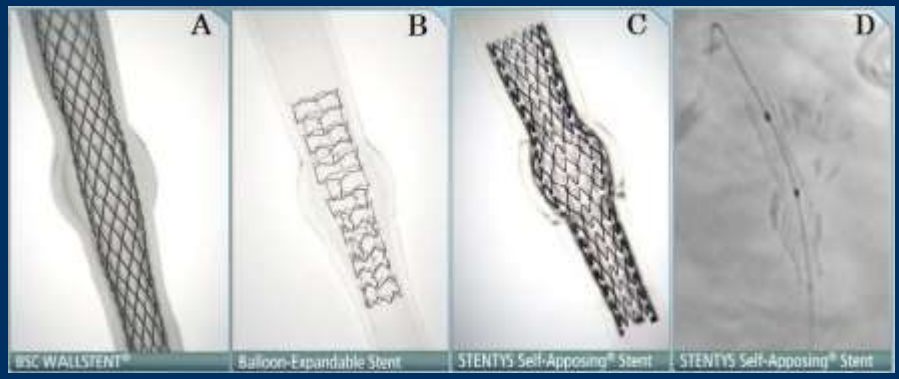
STENTYS Self-Apposing® stent

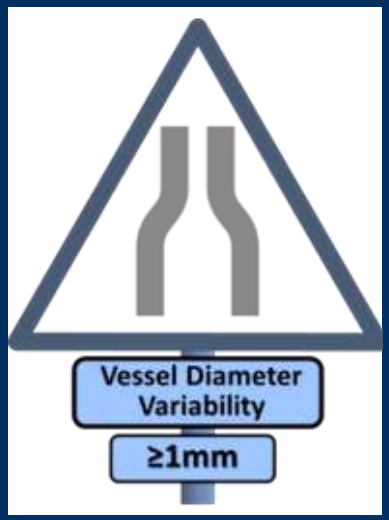
- The nitinol self apposing stents **STENTYS** is coated with a drug with a durable polymer formulation including Sirolimus and a polymer blend carrier (composed of Polysulfone (PSU) and soluble Poly-vinyl-pyrrolidone (PVP) as excipient). The stent is loaded with 1.4 µg of Sirolimus per mm^2.
- The **Xposition delivery system** consists of a balloon catheter with a nominal sized delivery balloon, covered with a distal splittable 0.0032-inch-thick sheath assembly that keeps the stent in a compressed condition.

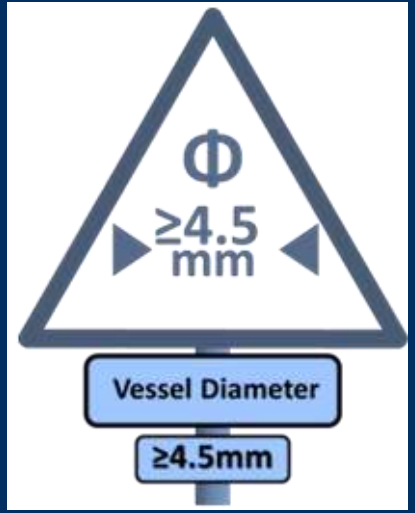
- The expansion of the balloon causes the sheath to split, allowing stent deployment. The jailed sheath with the delivery balloon is retracted after stent deployment.

STENTYS Self-Apposing® stent

- The rationale for the self-apposing nitinol platform is to achieve optimal stent strut apposition in arterial segments with varying lumen diameters or stressed by different mechanical forces (i.e. bending)
- The device has never been tested in the treatment of iliofemoral disease.







The Stentys PAD Fed II registry

- All procedures have been executed at University of Napoli “Federico II”.
- From January 2017 to October 2018, 7 claudicant patients, due LEAD at the iliofemoral locations, underwent PTA with the implant of self expandable drug eluting stent (Xposition, Stentys, France).
- Follow-up to 12 months by clinical assessment and duplex ultrasound.

Primary endpoint

Primary patency at 12 months, which is defined by the absence hemodynamically significant target lesion stenosis on duplex ultrasound (>50%, Peak systolic velocity ratio no greater than 2.4).

Secondary endpoint

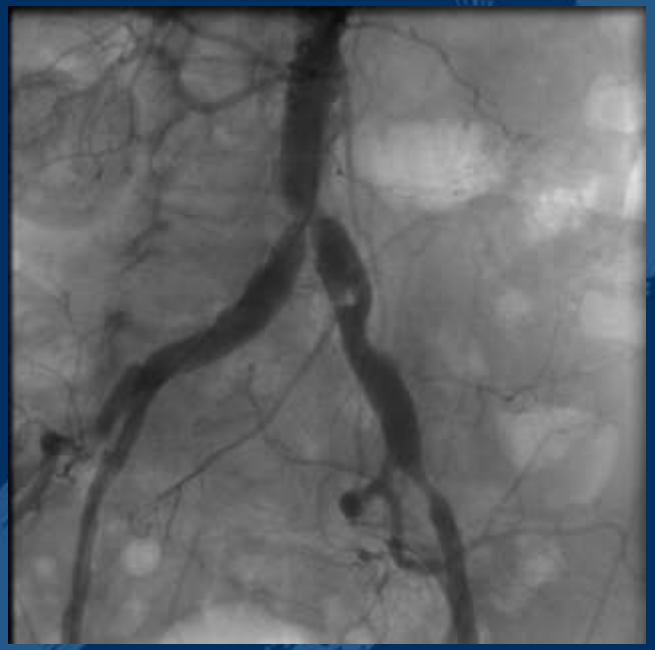
Freedom from Target Lesion Revascularization (TLR) at 12 months.

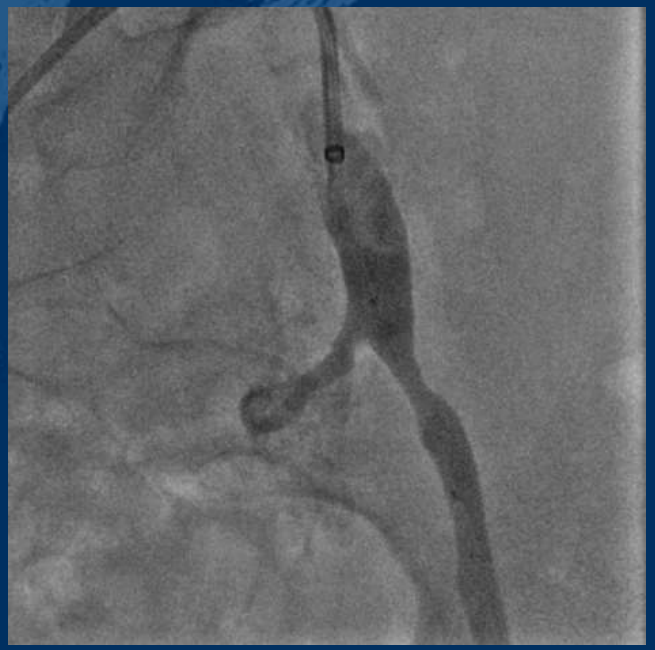
Baseline characteristics

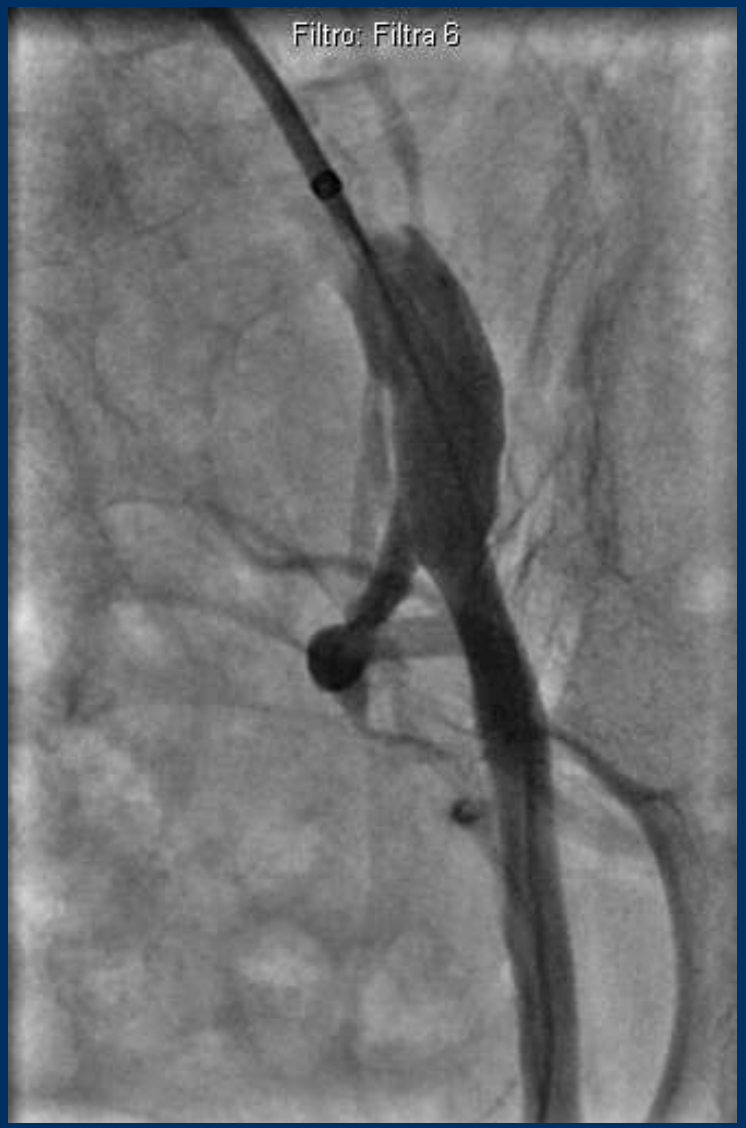
Male	71,4%
Age	66 ± 7,07
Diabetes	14,3%
Hypertension	71,4%
Hypercholesterolaemia	71,4%
Smoking history	85,7%
CLI (RC ≥4)	0 %
Rutherford Class	1,7 ± 2.82

Mean lesion Length (mm)	19 ± 4.4
de novo lesions	100%
External iliac artery	71,4%
Common iliac artery	14,3%
Isolating lesions	42,8%
Outflow lesions	42,8%
Inflow lesions	14,3%

Example case

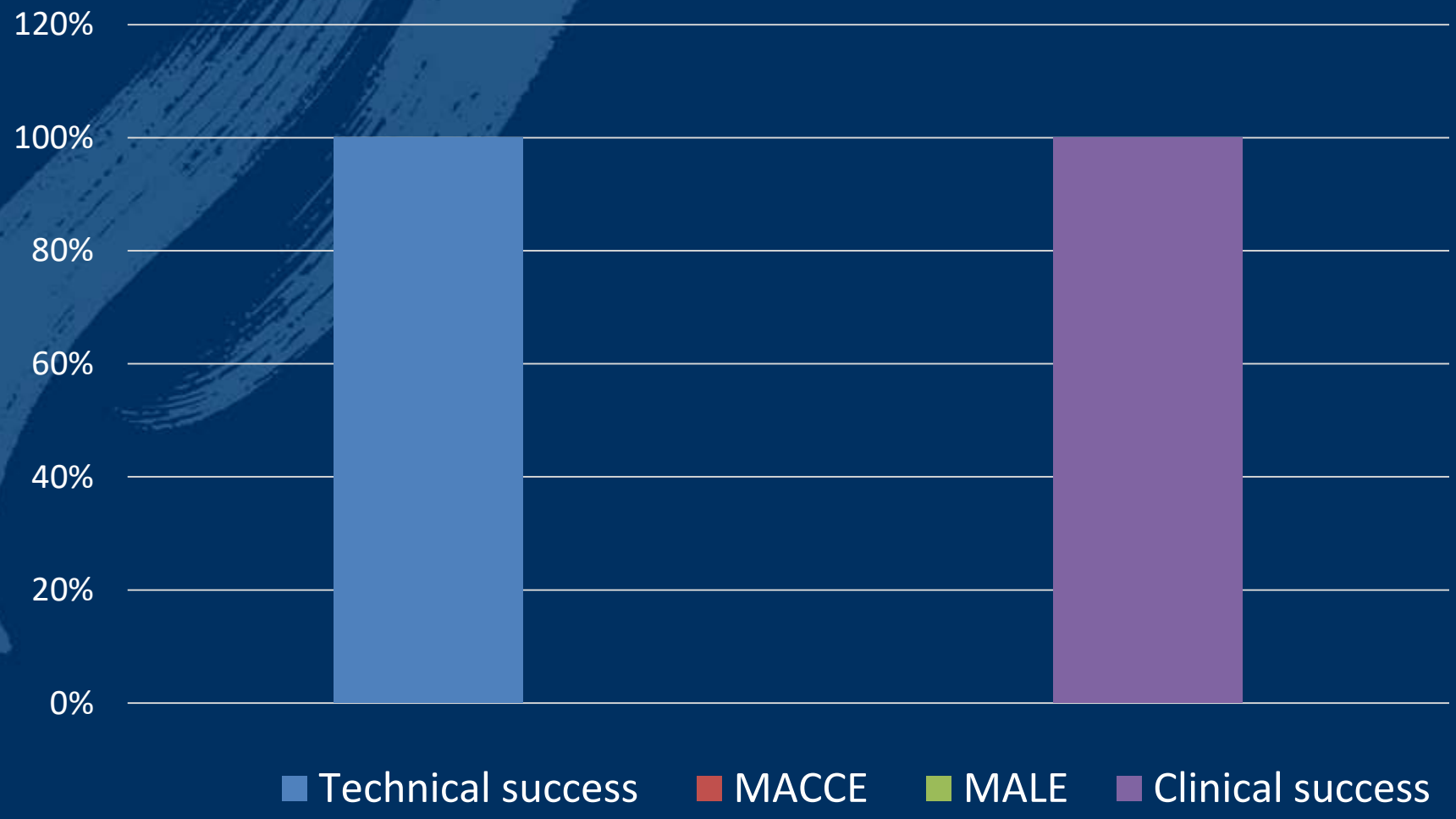




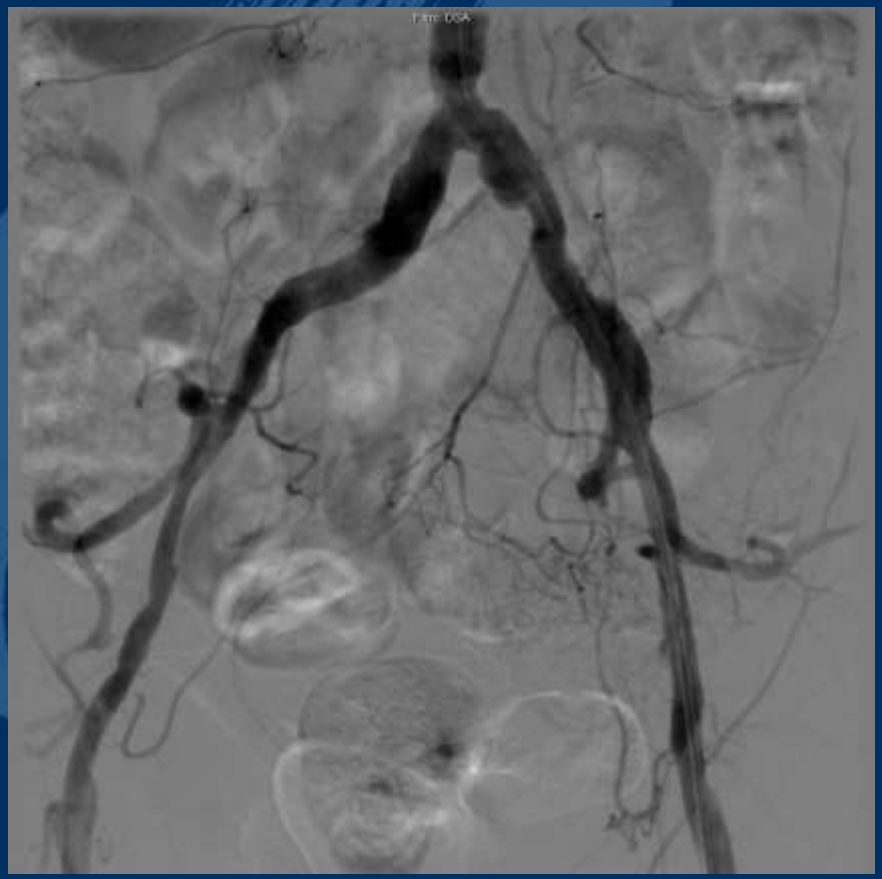


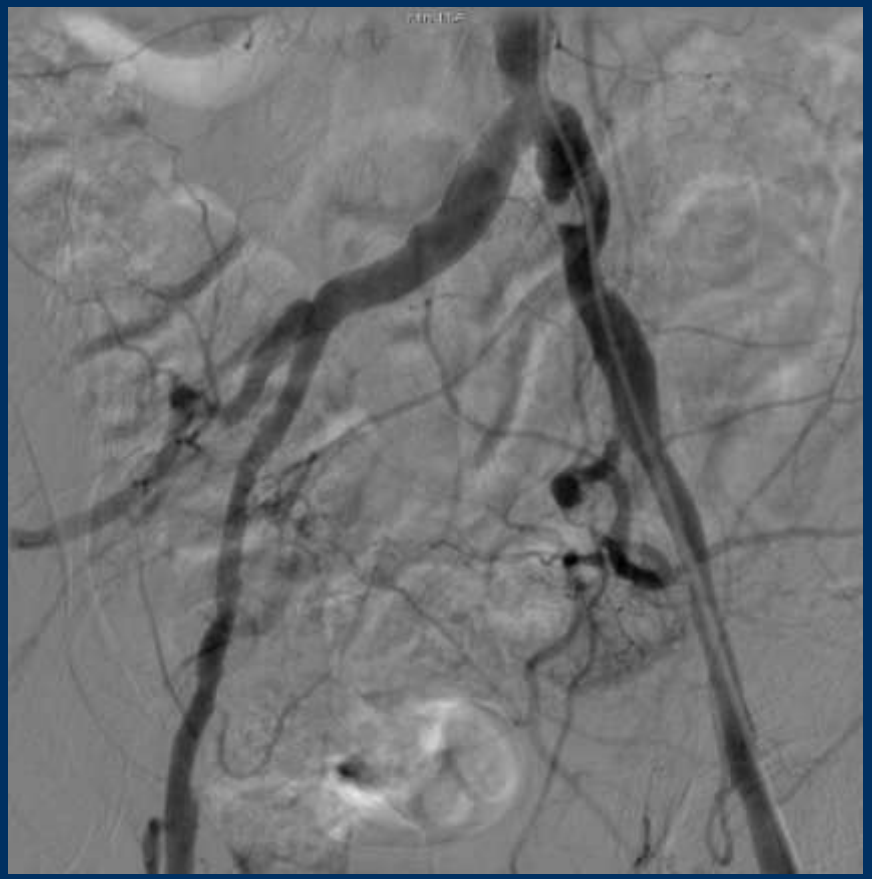
Stentys 3.5 – 4.5 / 27 mm

Results - In hospital

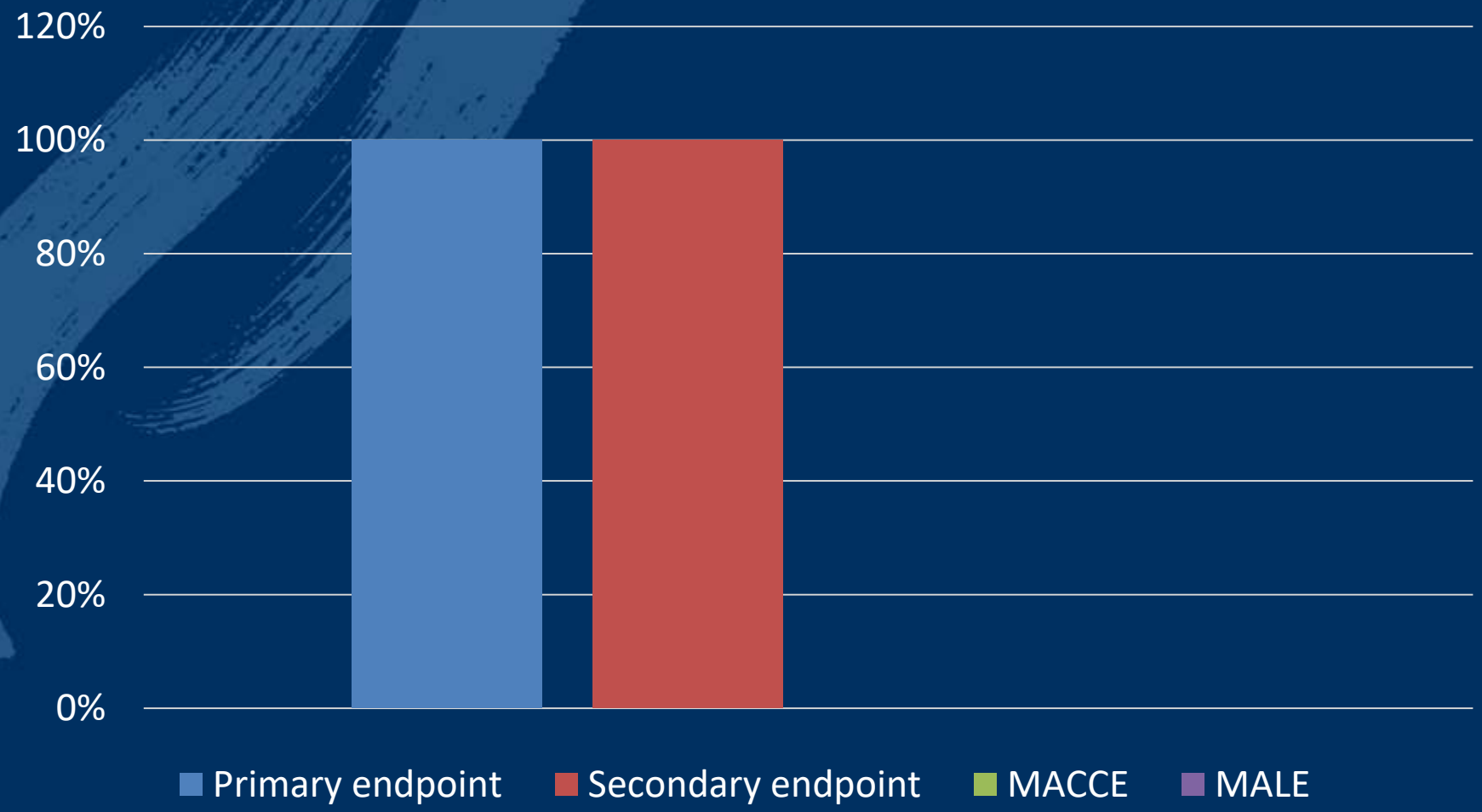


Example case 12-months Follow up





Results up to one year



Conclusions

Drug eluting self expandable stents are a safe and effective therapeutic strategy for the treatment of patients with LEAD at the iliofemoral location.

These data should be considered hypothesis generators to design large scale registries.

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