Safe and efficacy of the use of covered stent for the treatment of iliofemoral disease

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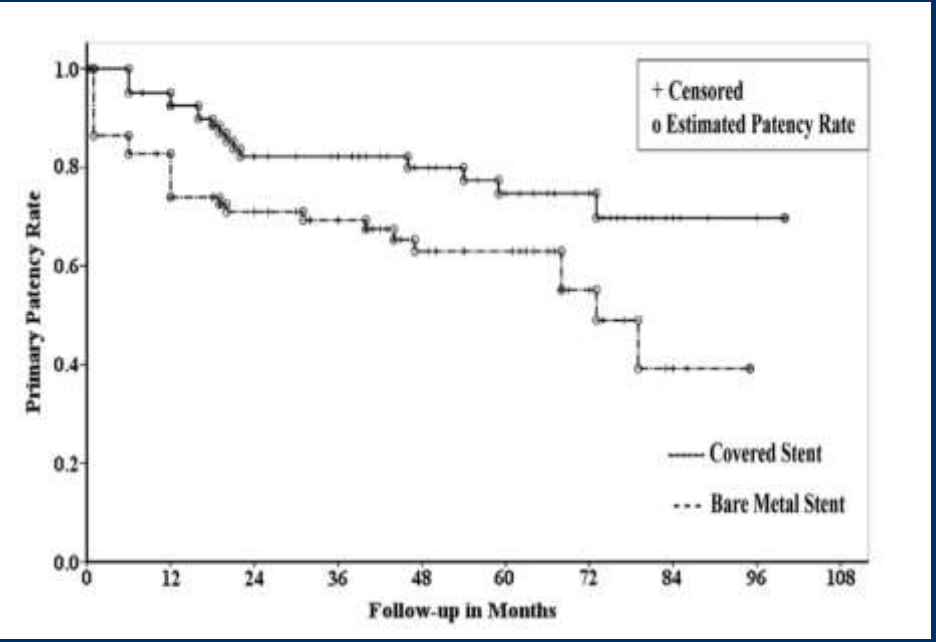
Background

In the treatment of aorto-iliac lesions, Covered stent are preferred when the risk of vessel rupture is high (i.e calcific, EIA) and when there is a risk for peripheral embolization (i.e. thrombus, friable plaques) through the mesh of conventional the stents

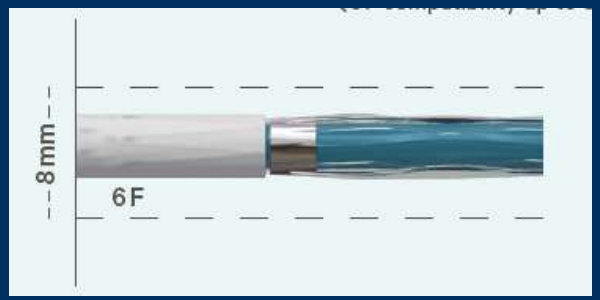
In the COBEST trial, the use of covered stent was associate to an increased patency rate at follow up



The Be Graft® Peripheral stent system

This peripheral stent graft system has a cobalt-chrome stent platform is covered with a micro-porous ePTFE membrane

These features allows to have at the same time a proper radial force, an adequate flexibility and a low profile.



The BeGRAFT -PAD FED II Registry

Aim of this prospective registry was to evaluate safety and efficacy, at one year, of the use of PTFA covered balloon expandable stent the treatment of aortoiliac lesions.

All procedures was performed in AOU Federico II, Naples

From January 2017 to December 2017, 28 patients with symptomatic due Lower Extremity Artery Disease (LEAD) at the aortoiliac locations underwent PTA with implant of a covered stent (Be-Graft, Bentley Innomed GmbH, Germany).

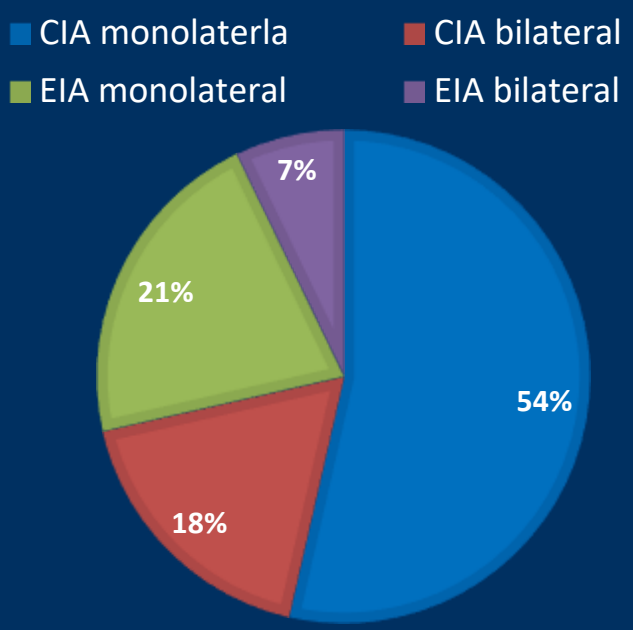
The BeGRAFT -PAD FED II Registry

Patients were evaluated up to 12 months with clinical assessment and duplex ultrasound.

1. Primary endpoint of the study is primary patency at 12 months, which is defined by the absence hemodynamically significant target lesion stenosis on duplex ultrasound (>50%, Peak systolic velocity ratio ≤ 2.4).
2. Secondary endpoint is freedom from target Lesion Revascularization (TLR) at 12 months

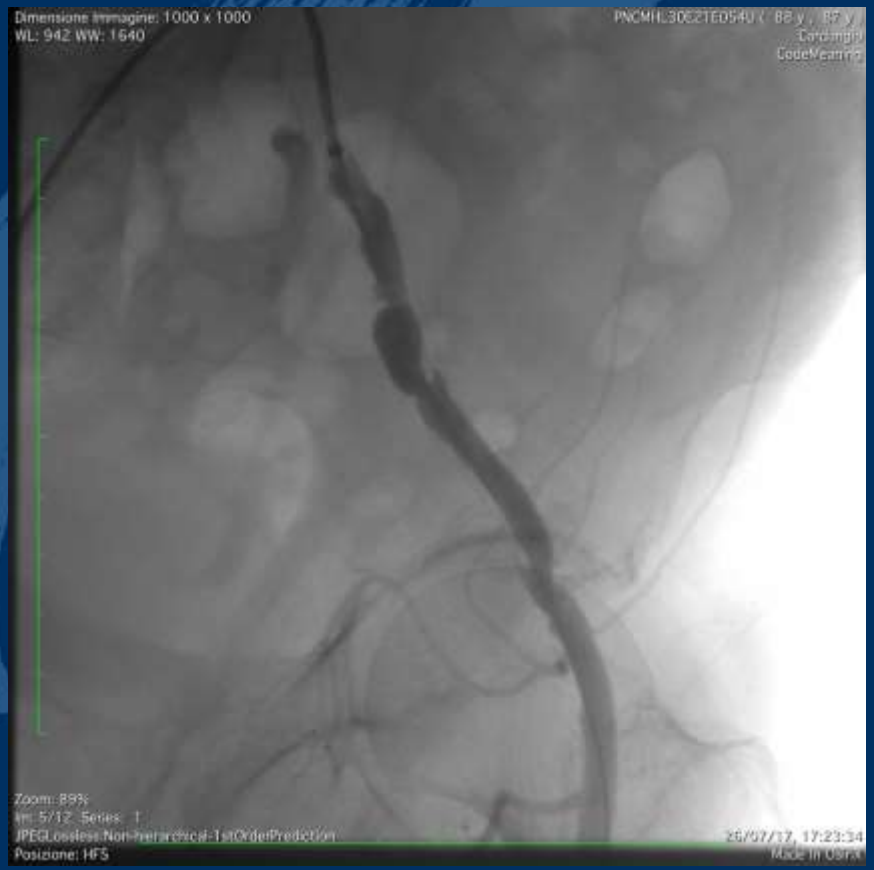
Baseline characteristic

Male	92.8%
Age	64 ± 0.7
Diabetes	45.8%
Hypertension	91.6%
Hypercholesterolaemia	87.5%
Smoking history	87.5%

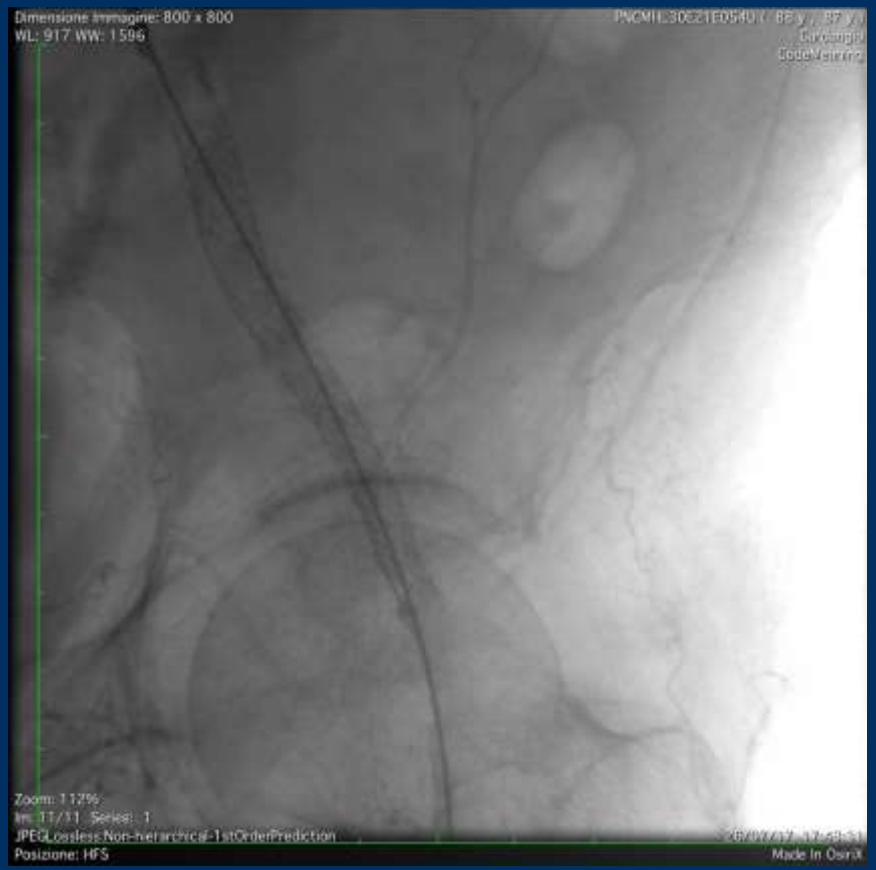


CLI (Rutherford Class ≥4)	36.4 %
de novo lesions	92.8%
Restenosis	7.2%
ISRS	7.2%
Mean lesion Length (mm)	44 ± 32
PACS	2,8 ± 0.4

M.P. 87 y.o: index procedure



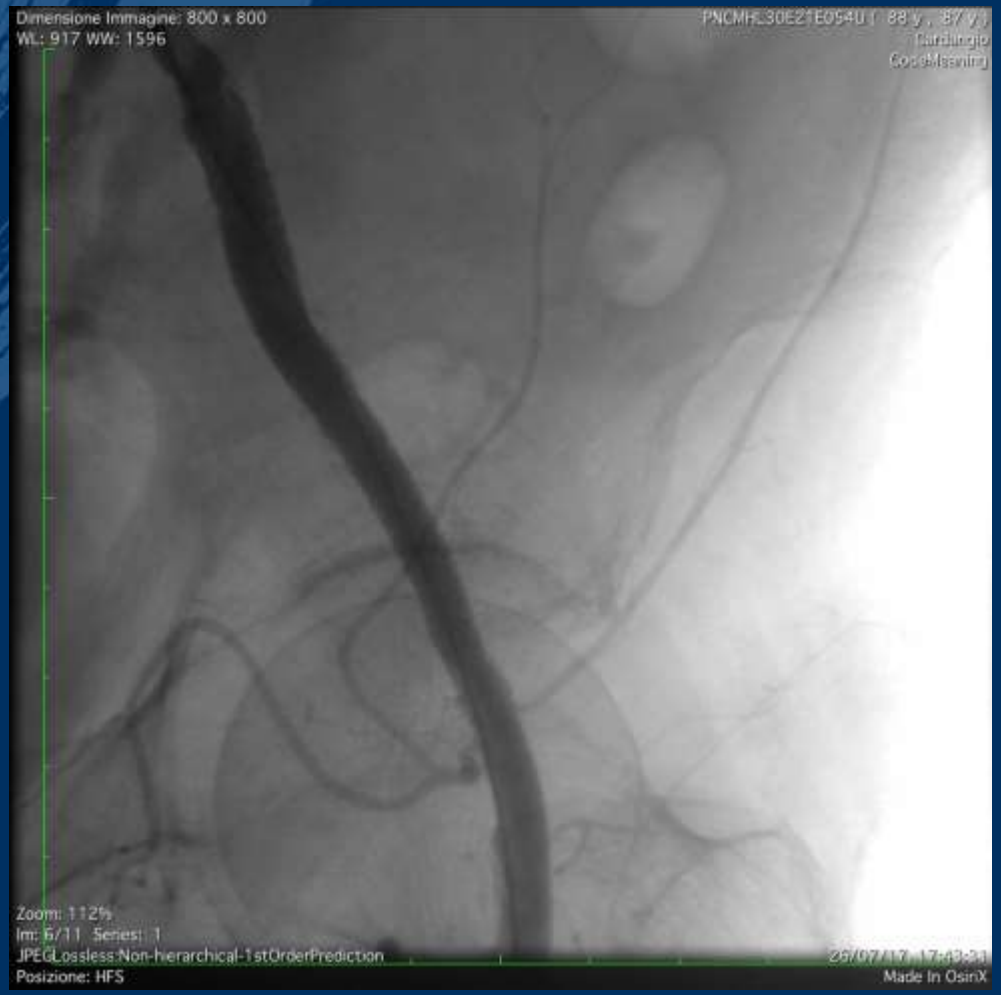
LEFT EXTERNAL ILIAC ARTERY ANGIOGRAM



PTA

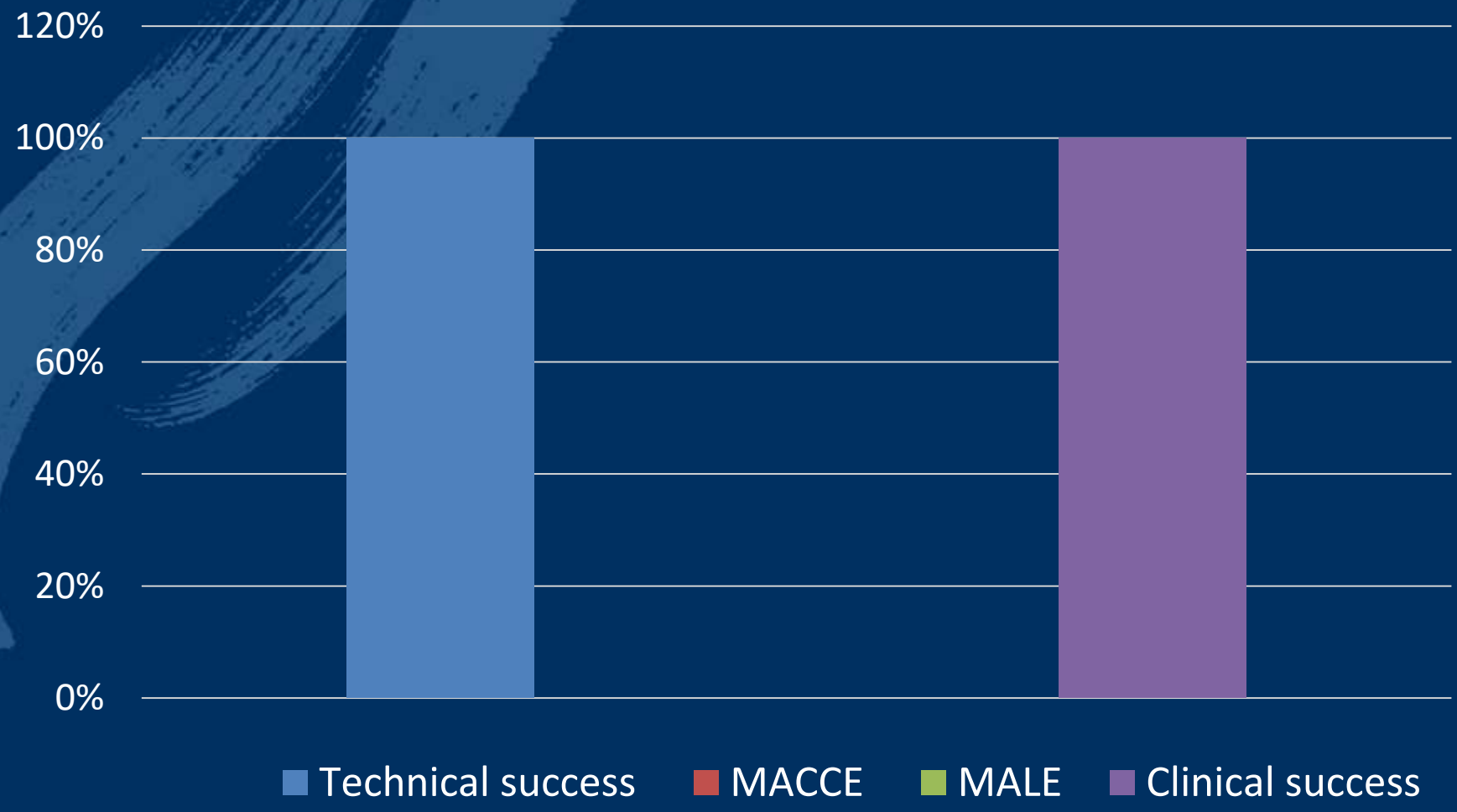
- BEGRAFT 8 x 37 mm
- BEGRAFT 6 x 38 mm

M.P. 87 y.o: index procedure

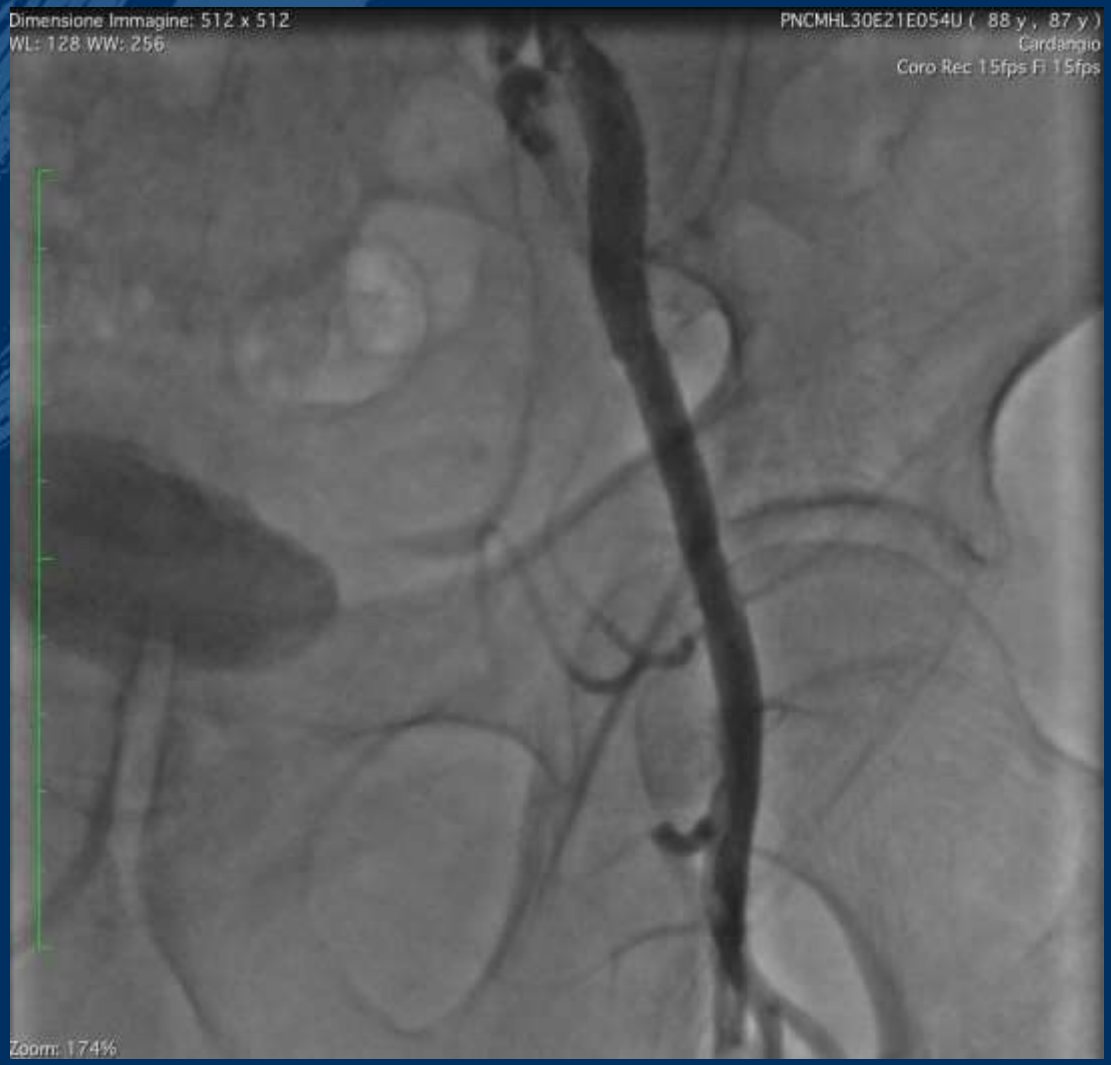


FINAL RESULT

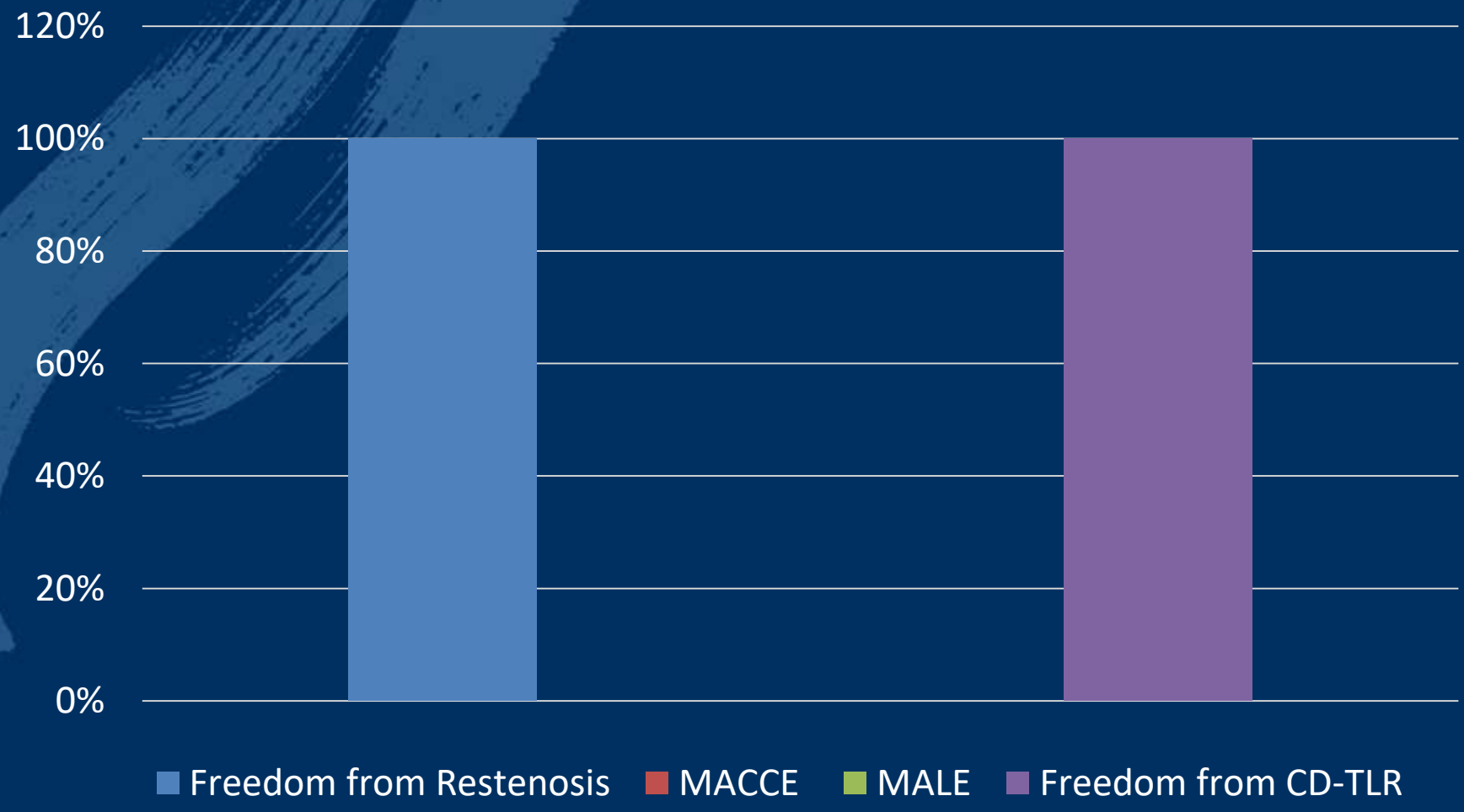
Results - In hospital



M.P. 87 y.o: 12-months follow-up



Results - At 12 Months



Conclusion

The resusts of the Be-Graft PAD FED II Registry suggest that the use of new generation balloon expandable covered stents can be considered a a safe a and effective therapeutic strategy for the treatment of patients with LEAD at the aortoiliac locations.

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

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