

Case Examples

Prof. Dr. Giuseppe Sangiorgi
Chief Cardiac Cath Lab University of Rome Tor Vergata
Associate Professor of Cardiology
gsangiorgi@gmail.com
www.dottgiuseppesangiorgi.it



Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting and Research Grant from Concept Medical
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
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- I do not have any potential conflict of interest

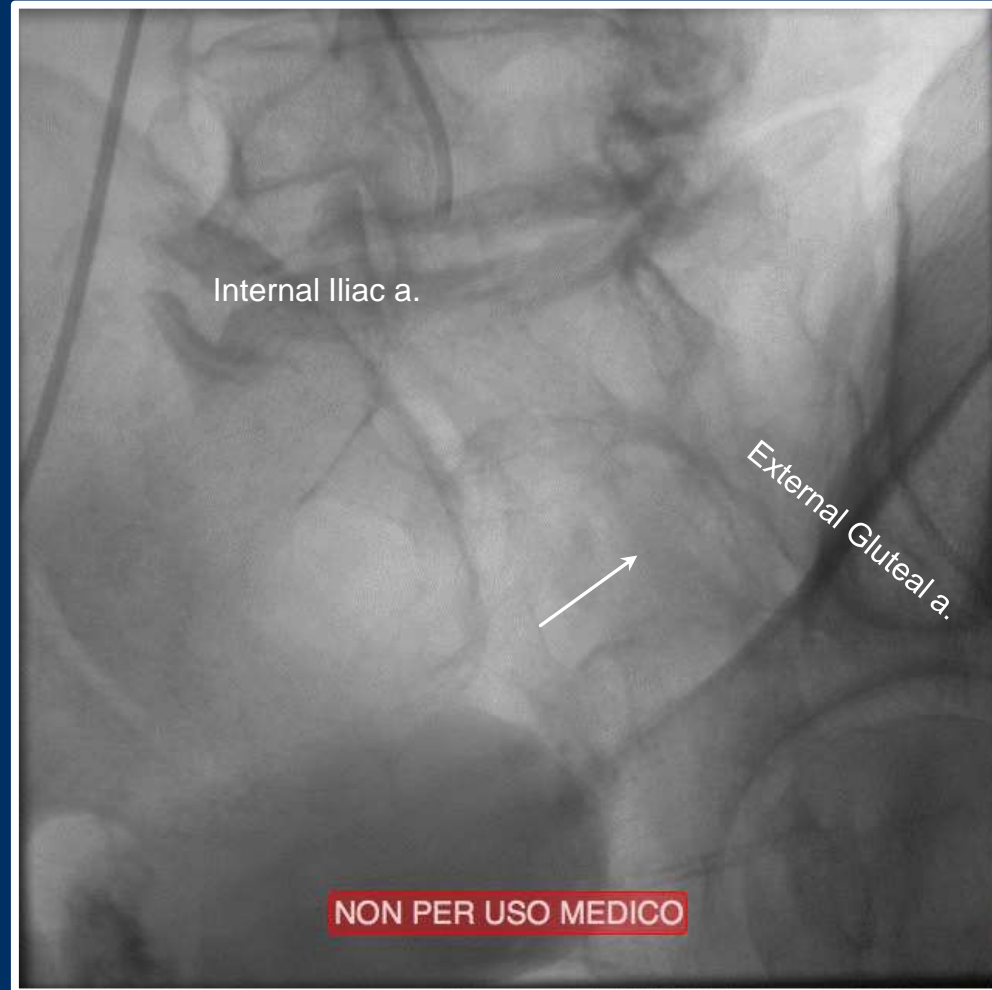


Case 1

- ♂ 61 yo hypertensive, diabetic NID for 10 years now ID, hypercholesterolemic
- ♂ 2017 for NSTEMI 2 DES on LAD and LCX
- ♂ Erectile dysfunction since 2016, not responding anymore to PDEF5i from 8 mos (Cialis 20 mg on demand + Cialis 5 mg once daily)
- ♂ IEF-5 score = 8 (severe erectile dysfunction)
- ♂ Submitted to selective pudendal angiography



Basal Angiography

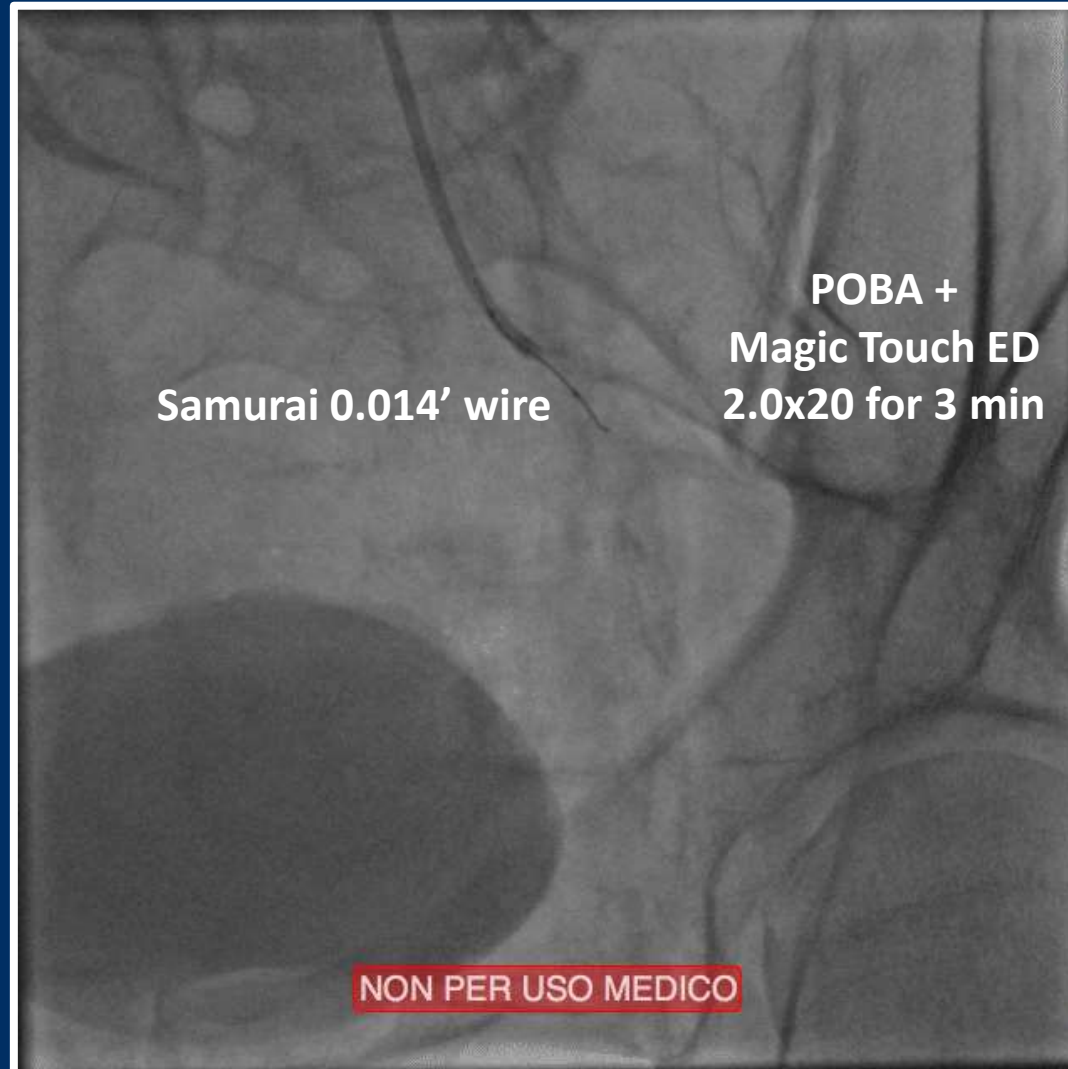


POBA +
SEB 2.0x20

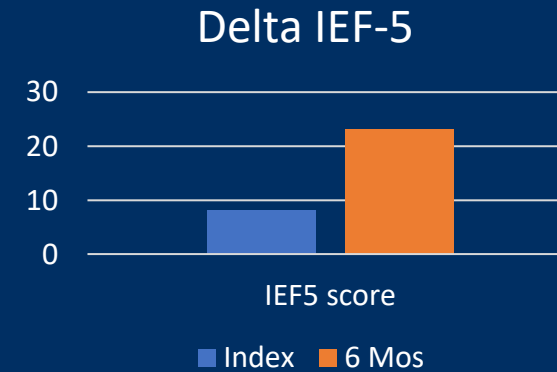
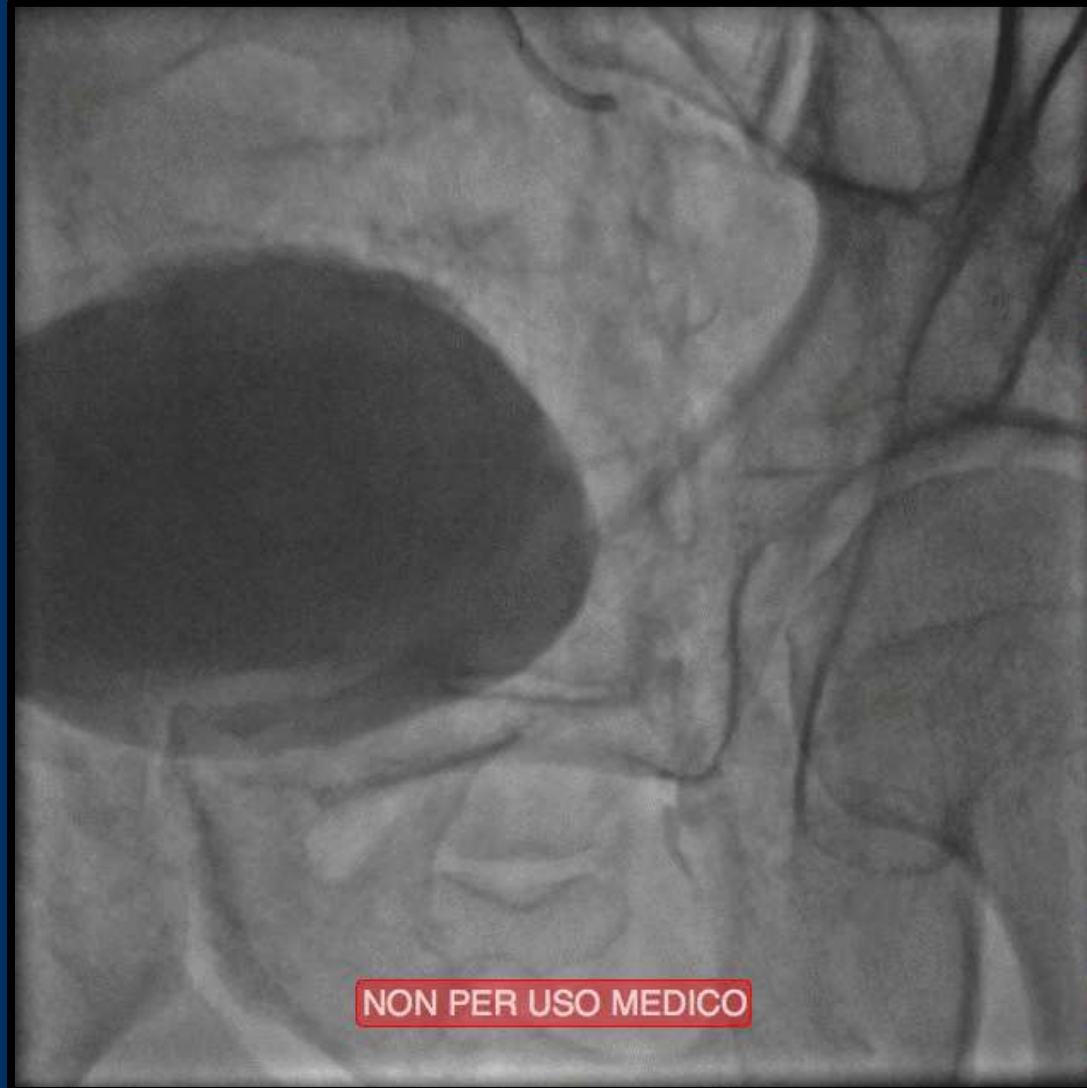
Basal IEF-5 score = 8



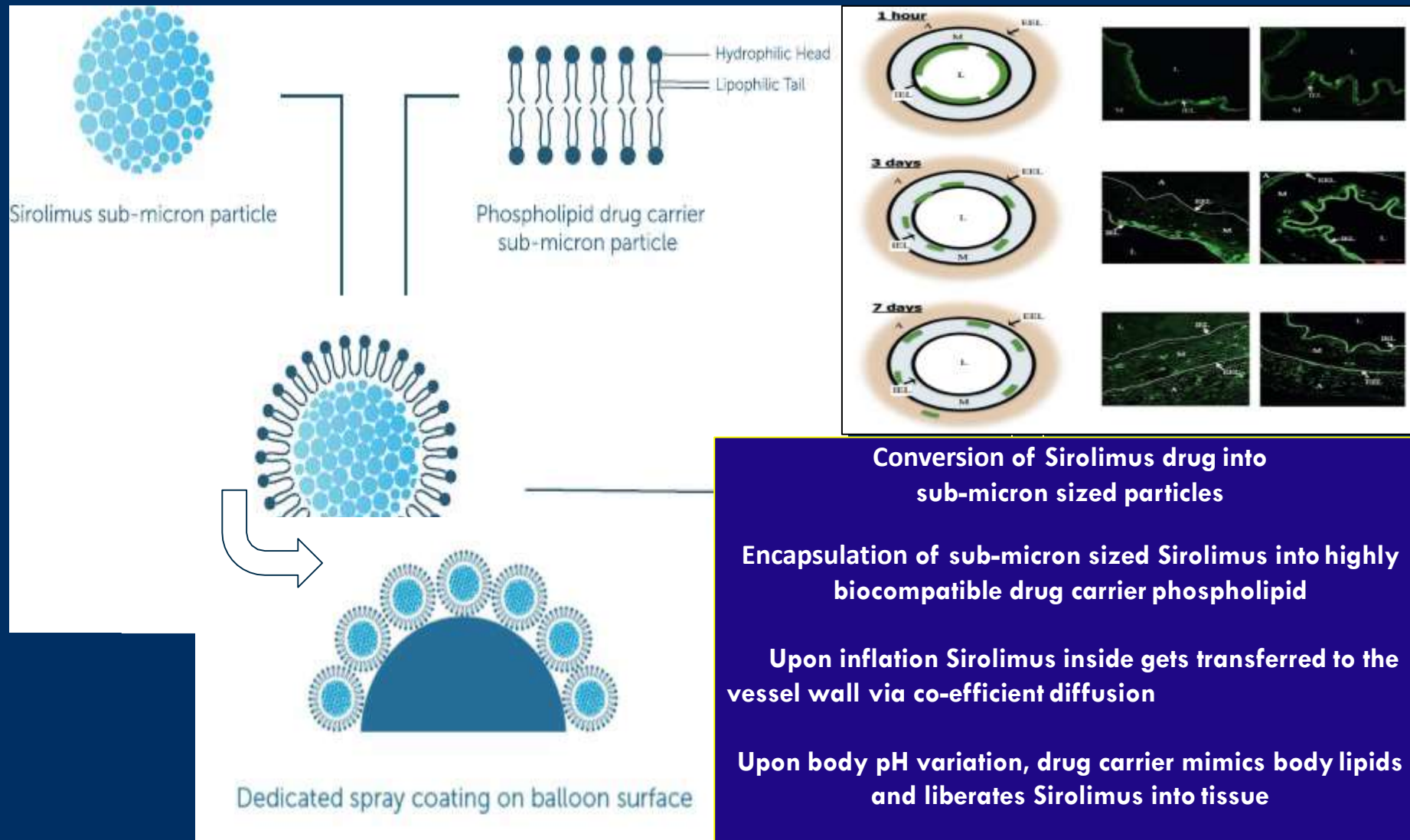
Pudendal Artery CTO



Final Result and 6 mos Clinical Follow-up



Nanolute Technology for Sirolims Delivery



Lemos et al, Eurointervention 2013



2° Case

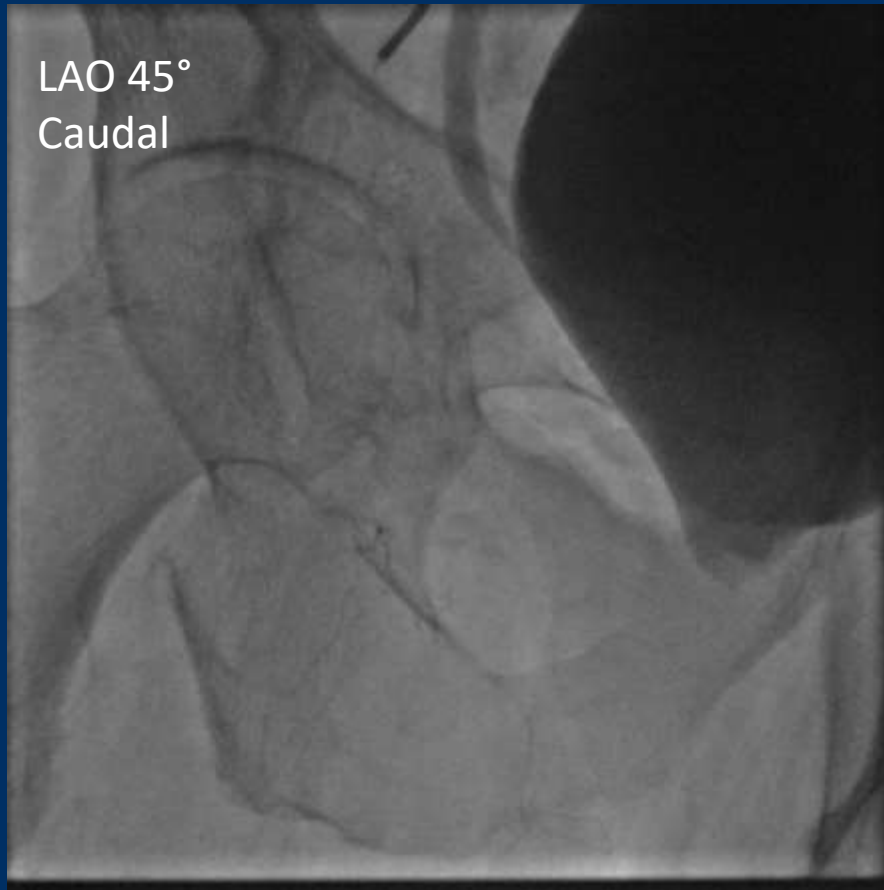
- ♂ 54 yo hypertensive, diabetic NID for 22 years, normocholesterolemic.
- ♂ No cardiovascular events. Coronary angio-CT negative.
 - Erectile dysfunction since 2018, not responding anymore to PDEF5i from 1 year (Spedra on demand + Cialis 5 mg once daily).
 - Patient attempted 6 applications of LiSW with no beneficial effect
 - IEF-5 score = 6 (severe erectile dysfunction)
- ♂ Submitted to selective pudendal angiography
- ♂



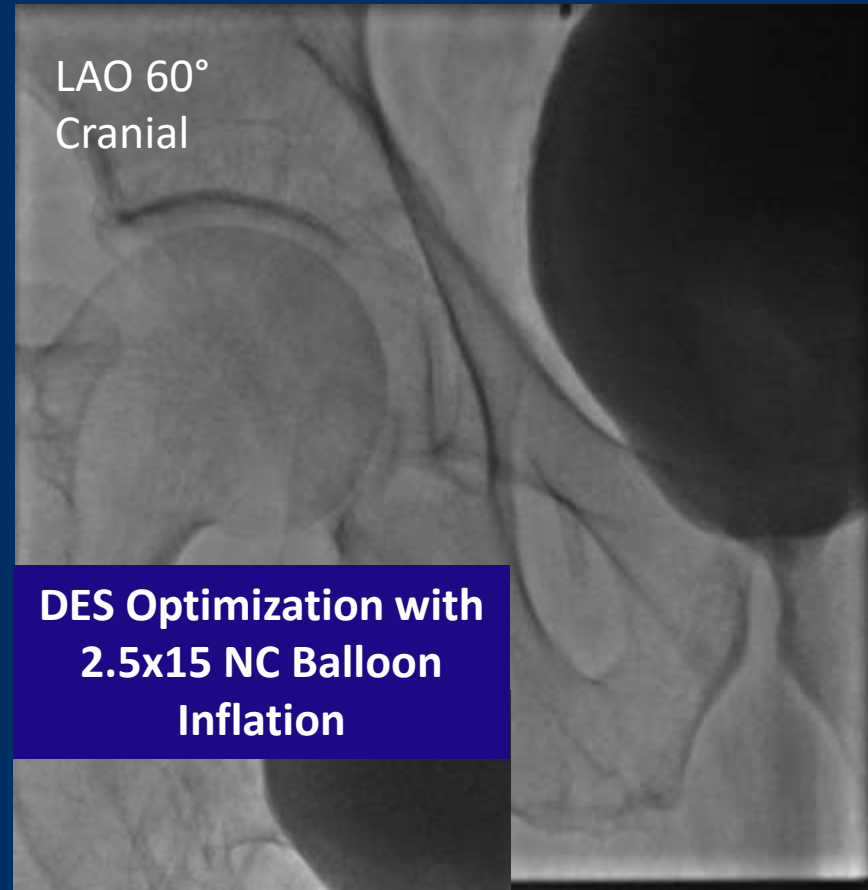
Basal Angiography



Pudendal and Dorsalis Penis aa. Treatment



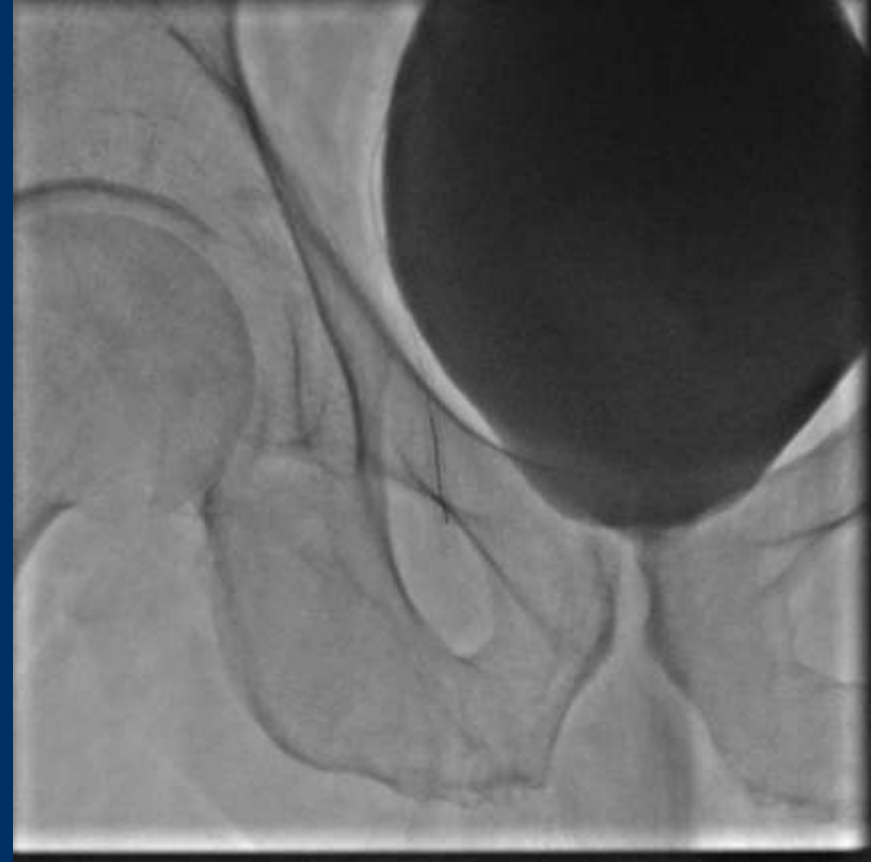
**DES Crutz 2.5x18 mm
Implantation**



Final Result



After DES Optimization
with NC balloon



After Magic Touch ED 2.0x20 mm
inflation for 2 min

What is the Future?



Giuseppe
Sangiorgi

The **SUASION** study Sirolimus Eluting Balloon Utilization for Treatment of Vasculogenic Erectile Dysfunction



Design: Prospective, post-market, non-randomized, all-comers, multicenter single-arm study



Target
N=100



Efficacy End-points

Composite of:

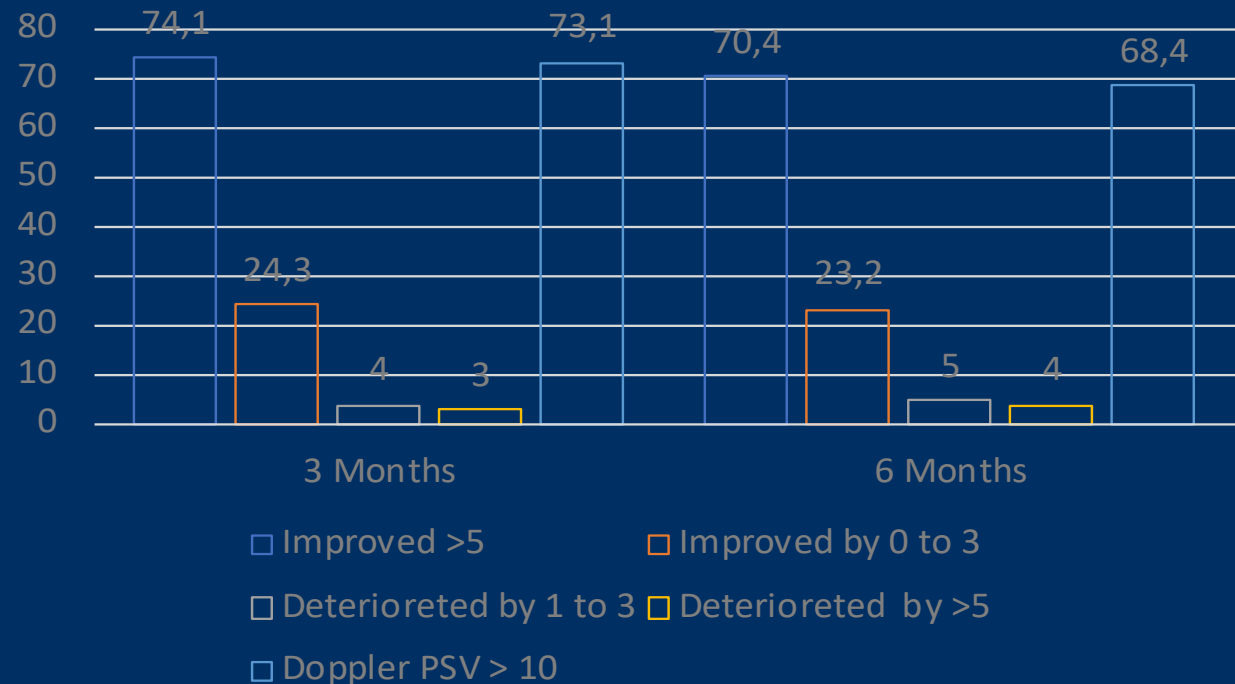
- 1) Delta International Index of IEF-5 ≥ 5 (Erectile Function-5 score) at 6 mos FU
- 2) Delta Doppler PSV velocity $>5\text{cm/s}^{-1}$ at 6 mos FU

Safety End-point

Freedom from target lesion revascularization (TVR) at 8 months FU

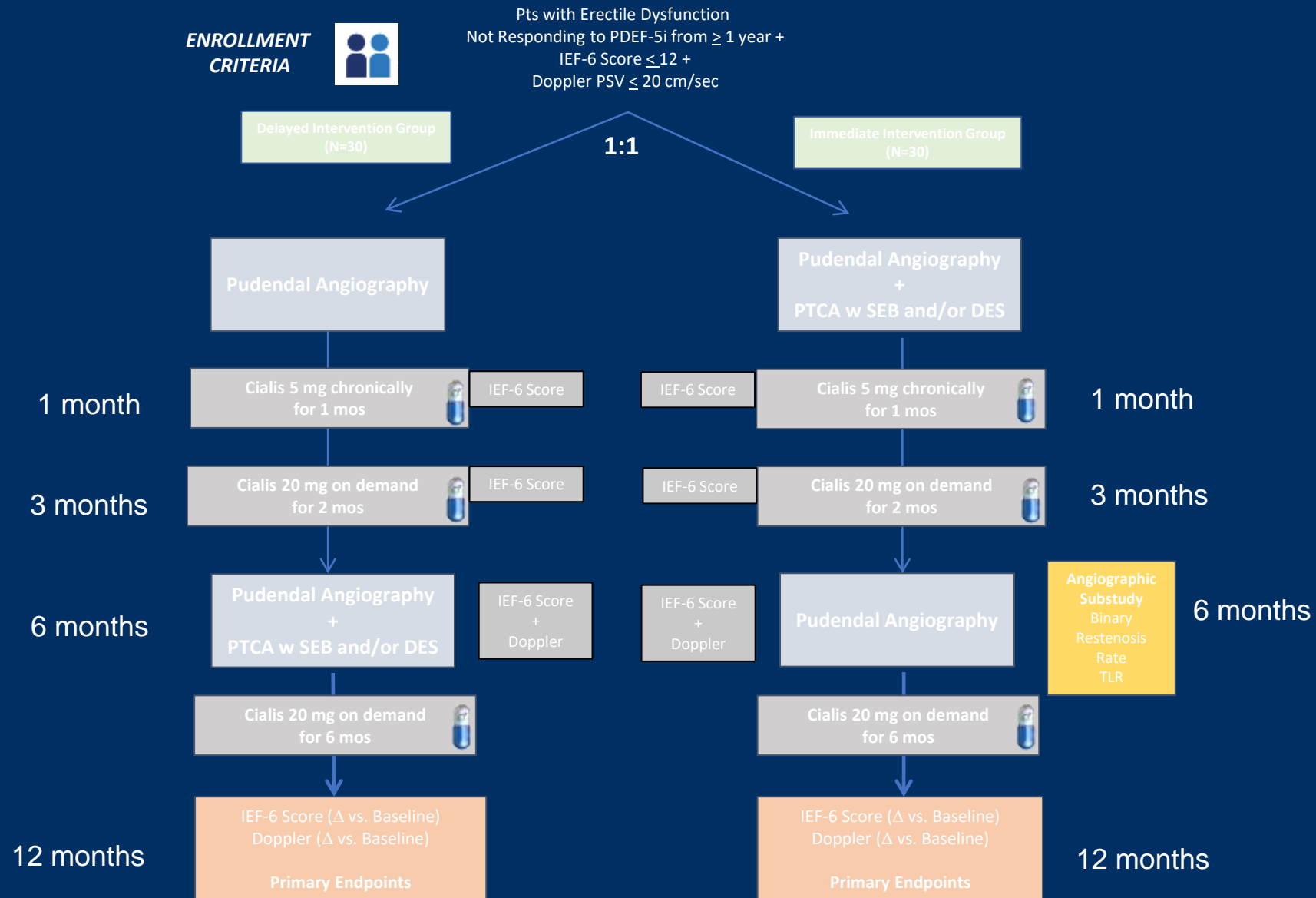
What are the Preliminary Results in the First 37 pts Enrolled ?

Treatment Success Reflected by Minimal Clinical Relevant Improvement in the International Index of Erectile Function -5 (IIEF-5) and Dynamic Doppler PSV between baseline and 6 mos FU



The LIBIDO Study (Cross-Over Pilot RCT Study)

Sirolimus Eluting Balloon Utilization for Treatment of Vasculogenic Erectile Dysfunction



Conclusions

- ♂ PTA of pudendal district could be technically demanding
- ♂ Good results could be obtained with SEB and/or stenting as ITT or bailout strategy
- ♂ Future registries and RCT will prove if percutaneous mechanical revascularization of pudendal district can be adopted as second line therapy of vasculogenic erectile dysfunction

