PERVIDEO I Registry

The Moxy Drug-Coated PTCA Balloon Catheter for the Treatment of In-Stent Restenosis within Bare Metal Stents

Clinical Trials.gov: NCT00916279

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PERVIDEO I Investigators
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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest/arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship	Company
Grant/ Research Support:	Abbott, Boston Scientific, Bristol Myers Squibb/sanofi-aventis, Cordis, Eli Lilly/Daiichii Sankyo, Lutonix, Medtronic, (to institution)
Consulting Fees/Honoraria:	Cordis

PERVIDEO I Design

Design	Prospective Registry
Objective	Assess angiographic and clinical outcomes after treatment of ISR of a prior BMS in the native coronary system with the Moxy Balloon
Patients/Sites	41 Patients Enrolled at 7 Sites
Endpoints	Angiographic, IVUS (n=20), & Clinical
Antiplatelets	6 Months
Follow-Up	Clinical: 1, 6, 12 & 24M Angiographic: 6M IVUS: 6M
CRO/Core Labs/Safety	Cardialysis BV (Rotterdam, NL)

MOXY™

DRUG COATED BALLOON

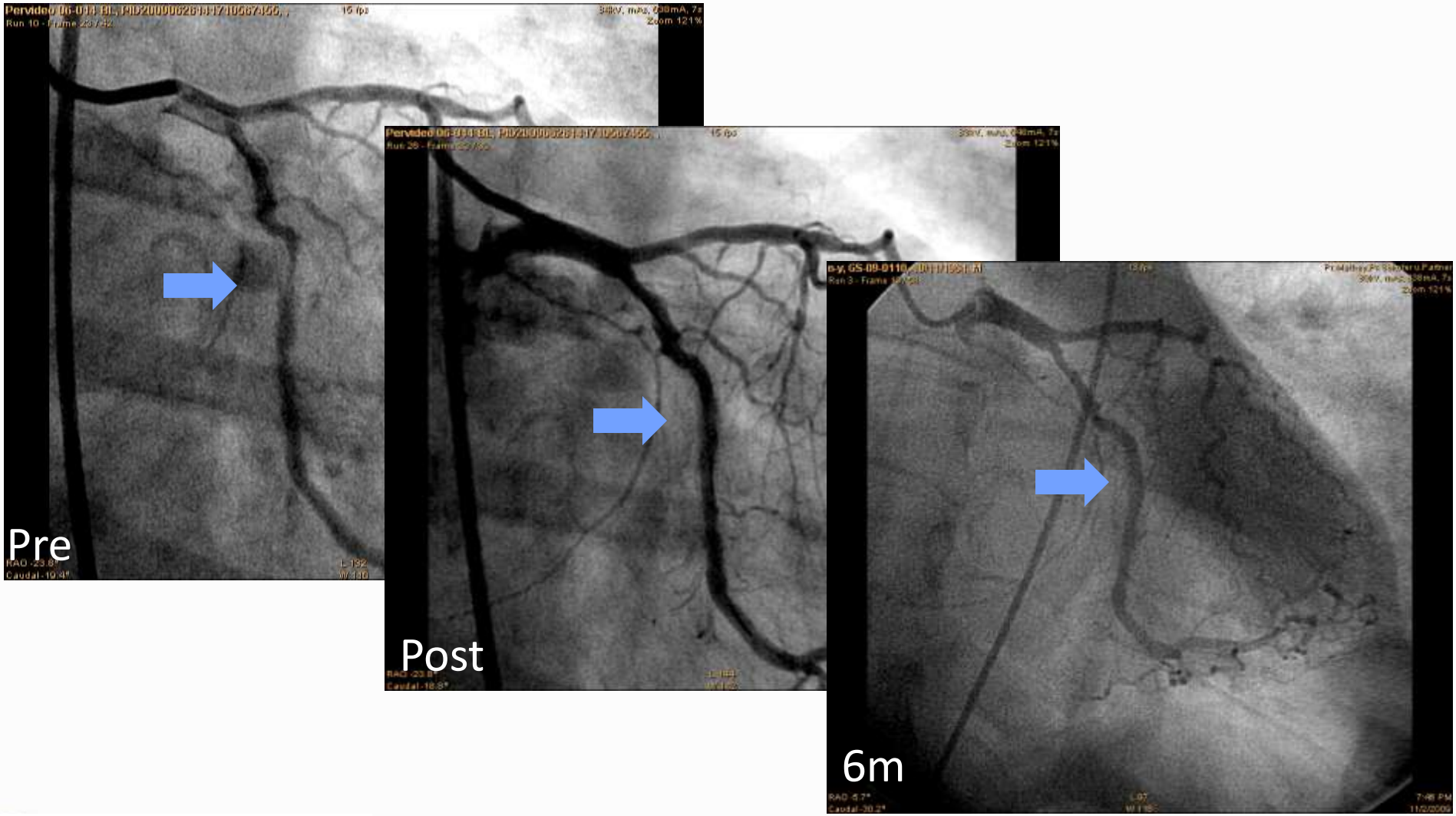
- Low drug-load balloon with 2µg per mm^2 of paclitaxel
- Hydrophilic, highly transfer-efficient drug carrier from IV-approved list
- Formulation designed to balance optimize drug *retention* during transit and drug *uptake* during inflation
- Robust, uniform coating

PERVIDEO I Centers

INVESTIGATORS	LOCATION	ENROLLMENT
Prof. Dr. med. Detlef Mathey*	Germany	26
Dr. Holger Eggebrecht	Germany	4
Dr. Helge Moellmann	Germany	4
Dr. Karel Koch	Netherlands	2
Prof. Gerhard Schuler	Germany	2
Dr. Benno Rensing	Netherlands	2
Prof. William Wijns	Belgium	1

**Co-Principal Investigator*

Angiographic Summary: Subject 6-14



PERVIDEO I Endpoints

Primary Endpoint:

- % Diameter Stenosis at 6 Months

Major Secondary Endpoints:

- Late Lumen Loss
- Ischemia-Driven Target Lesion Revascularization
- Ischemia-Driven Target Vessel Revascularization
- Composite of Cardiac Death, MI, ID-TLR
- IVUS Endpoints

PERVIDEO I Entry Criteria

- Major Inclusion
  - Single native BMS with ISR ≥ 60 days
  - ≥50% and <100% Stenosis
  - RVD ≥ 2.5 and ≤ 3.25
  - Length ≤40 mm
  - Treatment of ≤2 non-study lesions allowed
- Exclusion
  - MI/thrombolysis within 72 hrs
  - DES ISR or Stent sandwich
  - Planned use of adjunctive device(s)

PERVIDEO I: Baseline Characteristics

	n = 41
Mean Age, *yrs* *SD*	64.4 11.0
Male Sex	31 (75.6%)
Diabetes	12 (29.3%)
Hypertension	38 (92.7%)
Hypercholesterolemia	30 (73.2%)
Stable Angina	39 (95.1%)
Smoking (previous and current)	25 (68.3%)
Previous MI	13 (31.7%)

PERVIDEO I: Procedure Characteristics

Non-target(s) treated before target lesion	9 (22.0%)
Average # Moxy Balloons /subject	1.1
Average Transit Time	00:56±00:35 sec.
Average Inflation Time	00:57±00:18 sec.
Average Maximum Inflation Pressure, *mean (SD)*	11.4 ±(3.7)
Additional Post-Dilatation	3 (7.3%)
Bailout Stenting	2 (4.9%)
Clinical Device Success per Investigator	41 (100%)

PERVIDEO I: Baseline QCA

Treatment Vessel	-LAD 13 (31.7%) -LCX 17 (41.5%) -RCA 11 (26.8%)	
Lesion Length, *median*	13.08 mm	
RVD, *median*	2.44 mm	
MLD	Pre: 0.86mm	Post: 1.72mm
% Diameter Stenosis, *mean*	Pre: 64.78%	Post: 25.23%
Procedural Thrombus/No Reflow	0 (0%)	
Geographic Miss	7 (18.05)	

PERVIDEO I: Subject Disposition

Enrolled Per Inclusion/Exclusion

n = 41

30 Day Follow-Up

Clinical: n=41 (100%)

6 Month Follow-Up

Clinical: n = 39 (95%)
Angiography: n=39 (95%)
Analyzable IVUS: n=11/20 (55%)

PERVIDEO I: 6 Month QCA

Angiographic Endpoints	PERVIDEO I n=39	
Reference Vessel Diameter (median)	2.44 mm	
Diameter Stenosis	Post 27.5%	6m 35.6%
% Change In Diameter Stenosis (paired data)	-	8.5%
In-Segment Late Lumen Loss	0.16±0.40 mm	

PERVIDEO I: Clinical Endpoints

	Procedure to Discharge n=41	Discharge to 30 Days n=41	30 Days to 6 Months n=39
Cardiac Death	0%	0%	0%
Myocardial Infarction	0%	0%	0%
Ischemia Driven-TLR	-	-	2 (5.1%)*
Ischemia Driven-TVR	-	-	2 (5.1%)

**Both subjects with geographical miss related to bailout stenting.*
TLRs occurred at time of scheduled 6 month angiography.

PERVIDEO I: IVUS OUTCOMES

	Post- Index Procedure mean SD n=11	6 Months Post-Procedure mean SD n=11	Δ
In-Stent Obstruction Volume (%)	20.15 8.16	22.89 6.67	2.74 1.49
In-Stent Minimal Lumen Area	2.16 0.22	2.09 0.19	-0.07 0.3

PERVIDEO I in Context of Prior DCB for ISR Trials

Angiographic Endpoints	PERVIDEO I n=39		Paccocath ISR I&II n=54	PEPCAD II n=66	
Reference Vessel Diameter (mean)	2.44 mm		2.94 mm	2.85 mm	
Diameter Stenosis	Post 27.5%	6m 35.6 %	-	Pre 19.5%	Post 29.4%
% Change In Diameter Stenosis (paired data)	8.5%		-	9.9%	
In-Segment Late Lumen Loss	0.16±0.40 mm		0.11±0.44mm	0.17±0.42mm	

The PERVIDEO I Registry

Conclusions

- Good results in difficult population (ISR, with mean RVD 2.4)
- Demonstrated biological effect
  - Very low LLL and small change in % diameter stenosis at 6 months
- Established safety and feasibility through 6 months
  - No embolization or thrombus reported
- Even better results may be possible with improved acute gain
- Future ISR trial warranted