

# 6-MONTH RESULTS OF THE LEVANT I TRIAL

*A Comparison of the  
Moxy™ Drug Coated Balloon Catheter vs.  
Standard PTA for Femoropopliteal Disease*

NCT# 00930813

**Dierk Scheinert, Principal Investigator**

on behalf of the LEVANT I Investigators

Heart Center Leipzig/Park Hospital, Leipzig Germany



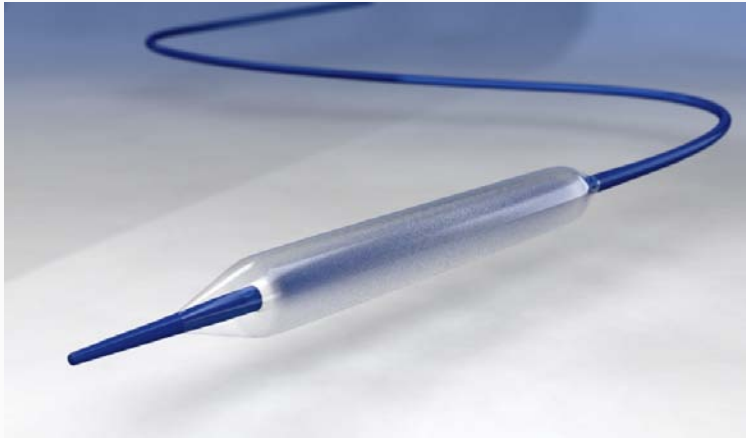
# DISCLOSURE STATEMENT OF FINANCIAL INTEREST

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

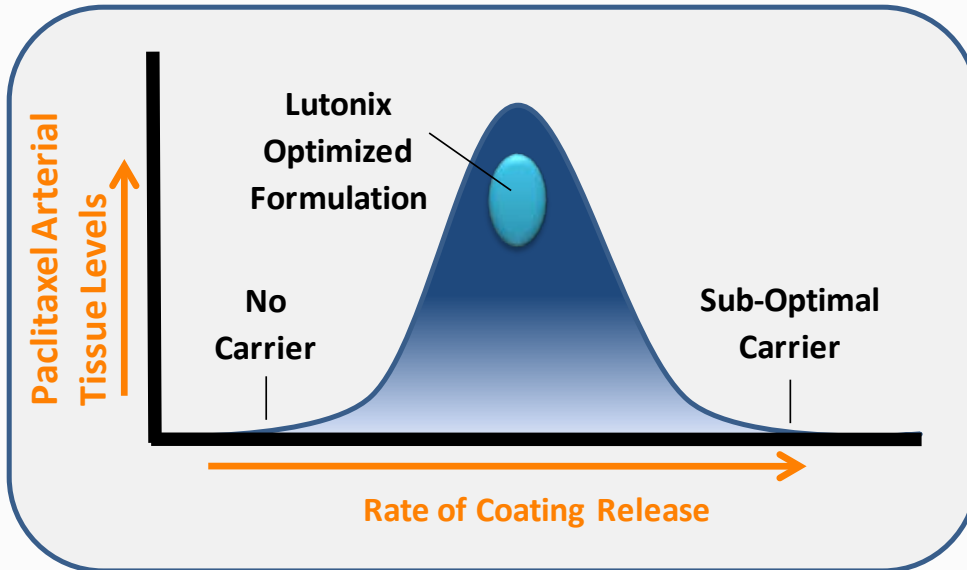
- *Abbott Advisory Board*
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- *Angioscore Consultant*
- *Cook Medical Consultant*
- *Invatec Consultant*
- *Ev3 Consultant*
- *Pathway Medical Consultant*
- *IDEV Techn. Stockholder*
- *CSI Stockholder*



# TECHNOLOGY OVERVIEW



- Proprietary 2  $\mu\text{g}/\text{mm}^2$  paclitaxel coating with hydrophilic non-polymeric carrier
- Formulation balances drug *retention* during transit and *uptake* upon inflation
- Drug delivered during single 30 second inflation
- Robust, uniform coating



CAUTION: Investigational Device – Limited by Federal (USA) Law to Investigational Use



# LEVANT I STUDY SUMMARY

<b>DESIGN</b>	A Prospective, Multicenter, Single Blind, Randomized, Controlled Trial Comparing the Moxy™ Catheter vs. Standard Balloon Angioplasty for Treatment of Femoropopliteal Arteries With and Without Stenting
<b>OBJECTIVE</b>	Assess the safety and efficacy of the Moxy™ Catheter for treatment of stenosis of the femoropopliteal arteries by direct comparison to standard PTA
<b>PRIMARY ENDPOINT</b>	Late Lumen Loss at 6 Months
<b>MAJOR SECONDARY</b>	TLR, TVR, Primary Patency, Safety



# LEVANT I STUDY MANAGEMENT

## DATA MANAGEMENT & MONITORING

genae associates (Antwerp, Belgium)

## CORE LABS ANGIOGRAPHIC, DUPLEX

genae associates  
J.B. Dahm MD, *Director*

## CLINICAL EVENTS COMMITTEE

J. Balzer MD; F. Mahler MD;  
F. Vermassen MD

## DATA SAFETY MONITORING BOARD

P. Pattynama MD, *Chairperson*

## SPONSOR

Lutonix, Inc. (Minneapolis, MN)



# LEVANT I MAJOR STUDY CRITERIA

## INCLUSION

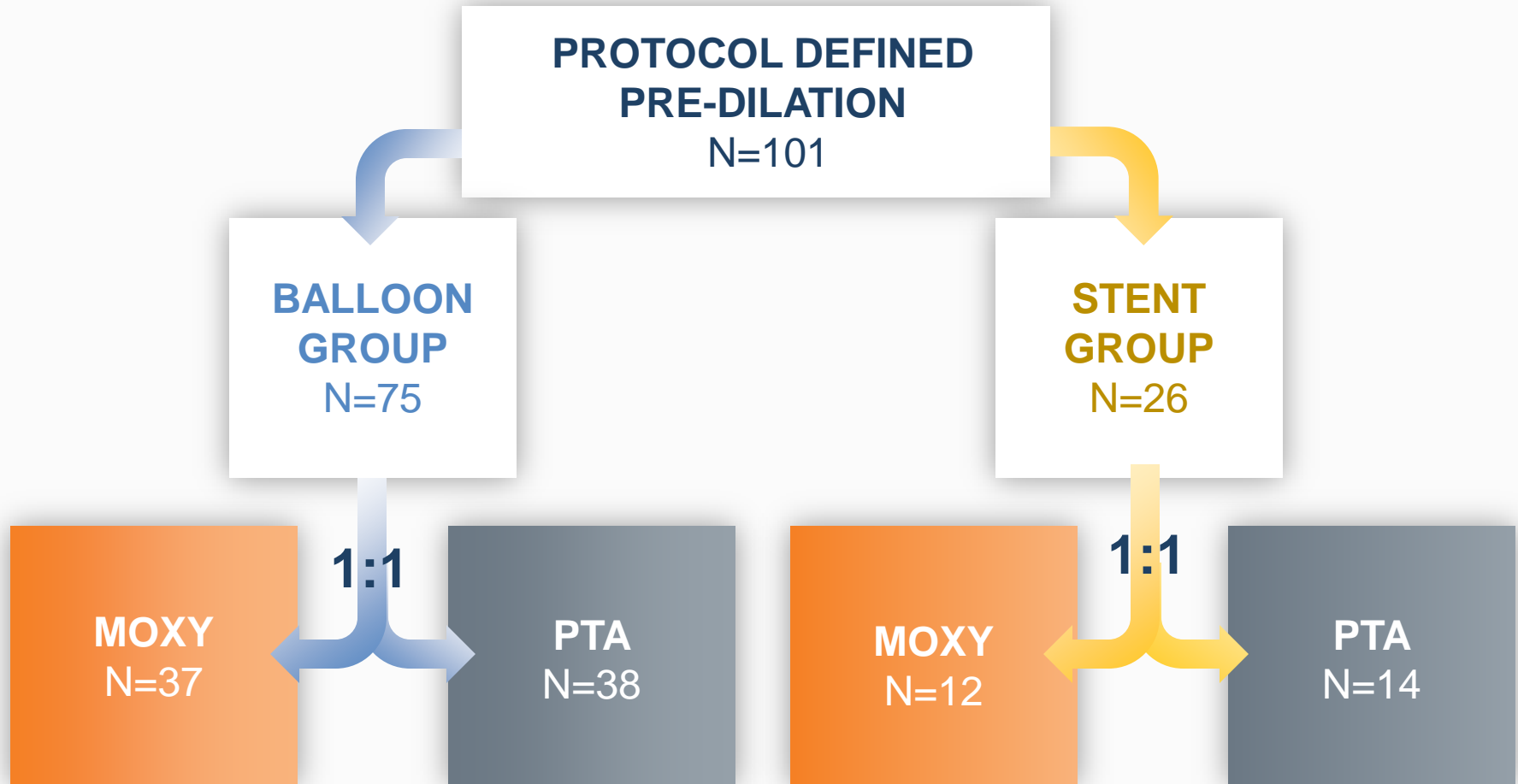
- Rutherford 2–5
- >70% Stenosis
- Lesion Length 4-15 cm
- RVD 4-6 mm

## EXCLUSION

- Inadequate distal outflow
- Severe Calcification
- Previous surgery of target lesion
- Acute/sub-acute thrombosis



# LEVANT I TRIAL STUDY DESIGN



# LEVANT I SITE ENROLLMENT

INVESTIGATOR	LOCATION	ENROLLMENT
T. Zeller	Bad Krozingen	22
D. Scheinert	Leipzig	18
S. Duda	Berlin	16
H. Krankenberg	Hamburg	15
G. Tepe	Rosenheim	13
J. Ricke	Magdeburg	9
M. Bosiers	Dendermonde	5
H. Sievert	Frankfurt	2
G. Torsello	Munster	1
		<b>TOTAL 101</b>



# LEVANT I DEMOGRAPHICS

	MOXY N=49	PTA N=52	P VALUE
MEAN AGE	67±8	70±10	0.08
MALE GENDER	69%	58%	0.22
SMOKER	68%	70%	0.69
DIABETES MELLITUS	45%	50%	0.61
HYPERTENSION	96%	87%	0.10
DYSLIPIDEMIA	59%	69%	0.29
RUTHERFORD			0.80
Class 2	22%	21%	
Class 3	71%	71%	
Class 4	2%	4%	
Class 5	4%	4%	

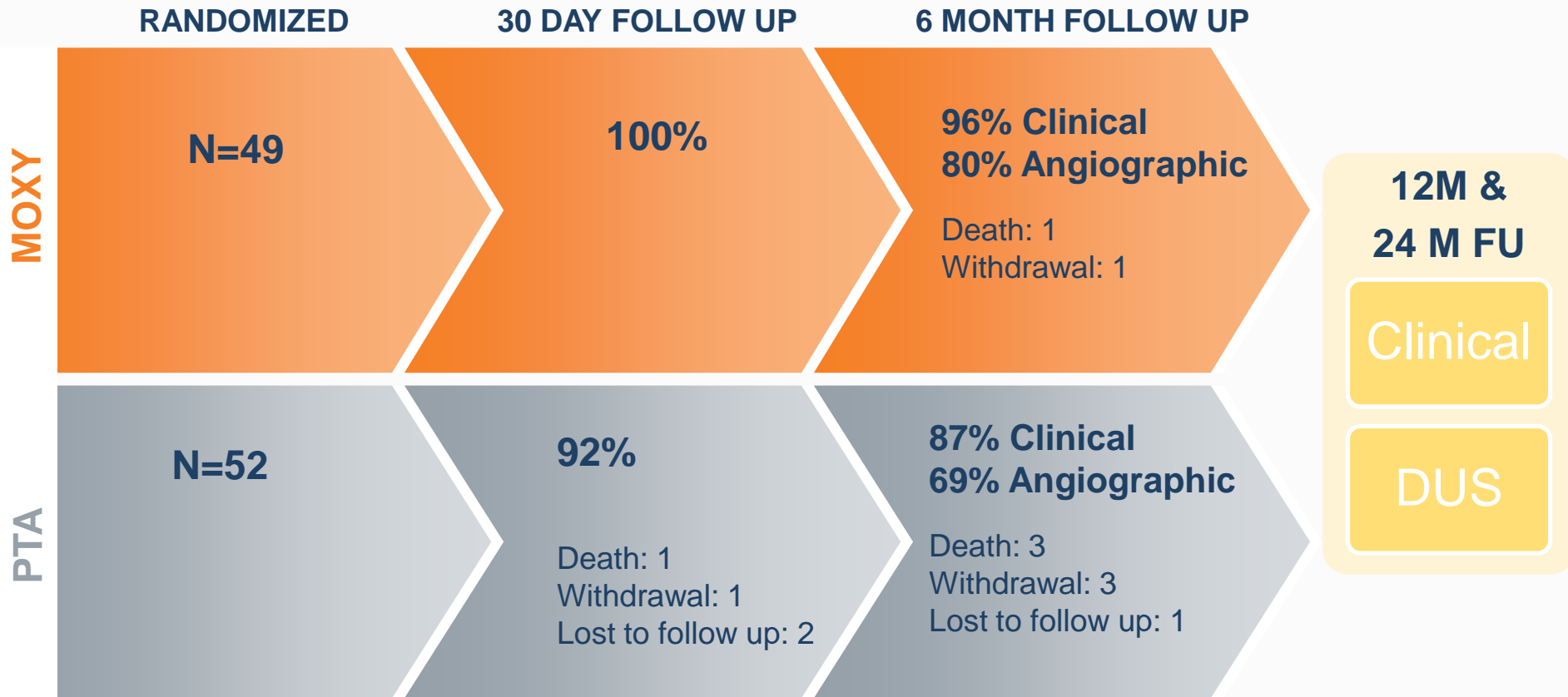


# LEVANT I BASELINE QVA ASSESSMENT

	<b>MOXY</b> N=49	<b>PTA</b> N=52
<b>LESION TYPE</b>		
De novo (%)	89%	88%
Restenotic (%)	11%	12%
<b>LESION LOCATION</b>		
SFA	92%	94%
Popliteal	8%	6%
<b>CTO</b>	40%	42%
<b>REFERENCE VESSEL DIAMETER</b>	4.1 mm ± 0.6	4.2mm ± 0.7
<b>LESION LENGTH</b>	8.1 cm ± 3.7	8.0 cm ± 3.7
<b>IN-SEGMENT DIAMETER STENOSIS</b>	85% ± 17	85% ± 17



# LEVANT I SUBJECT DISPOSITION



# LEVANT I 6-MONTH RESULTS OVERVIEW

## Primary endpoint

Late Lumen Loss objective was met.

- ITT Analysis: 0.46 mm (Moxy) vs 1.09 (PTA)  $p=0.016$
- PP Analysis: 0.36 mm (Moxy) vs 1.08 (PTA)  $p=0.016$

## Secondary Endpoint

Target lesion revascularization

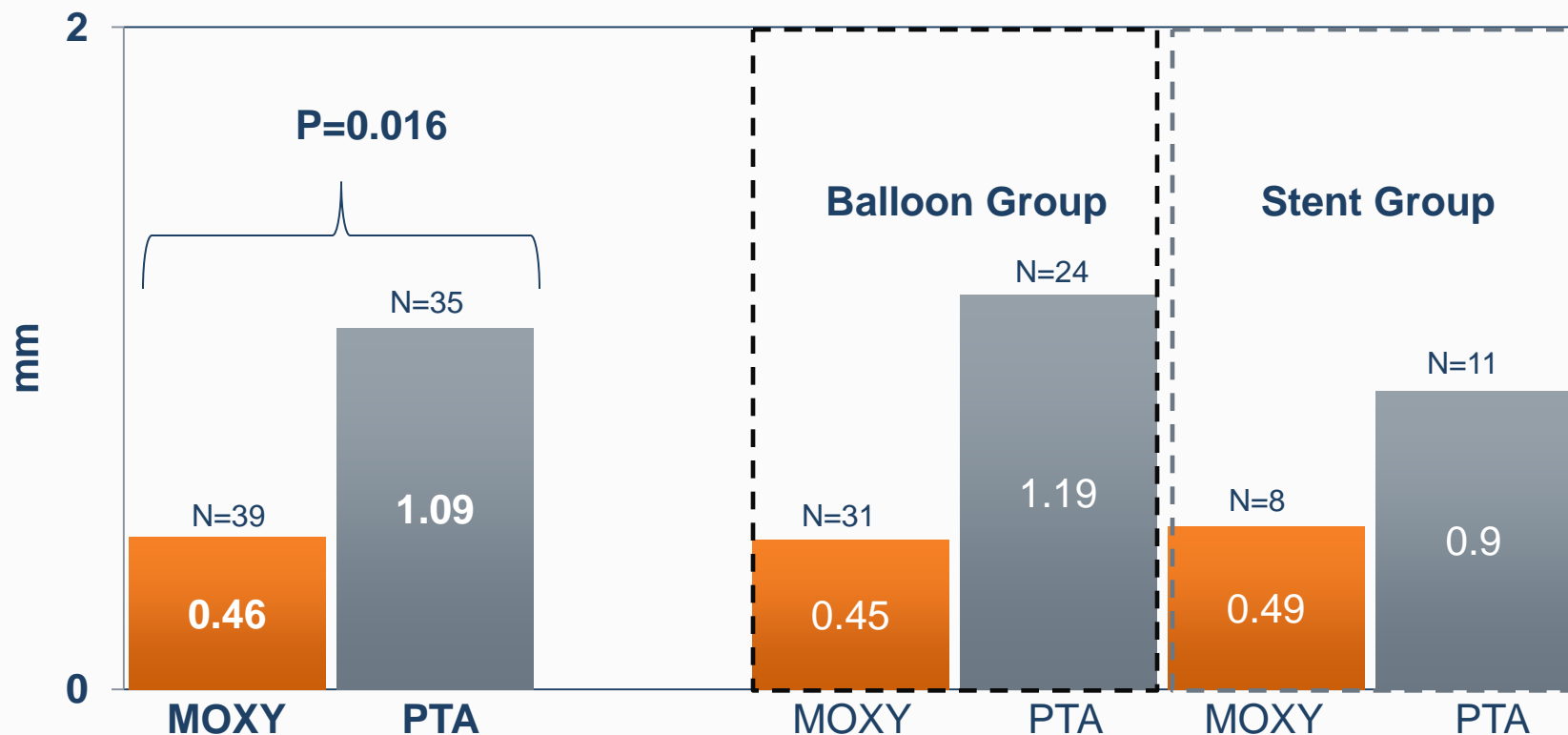
- ITT Analysis: 13% (Moxy) vs. 22% (PTA)
- PP Analysis: 6% (Moxy) vs. 21% (PTA)

1 month (no stent) and 3 month (stent) clopidogrel regimen

- No reported incidents of acute or late thrombosis in Moxy group

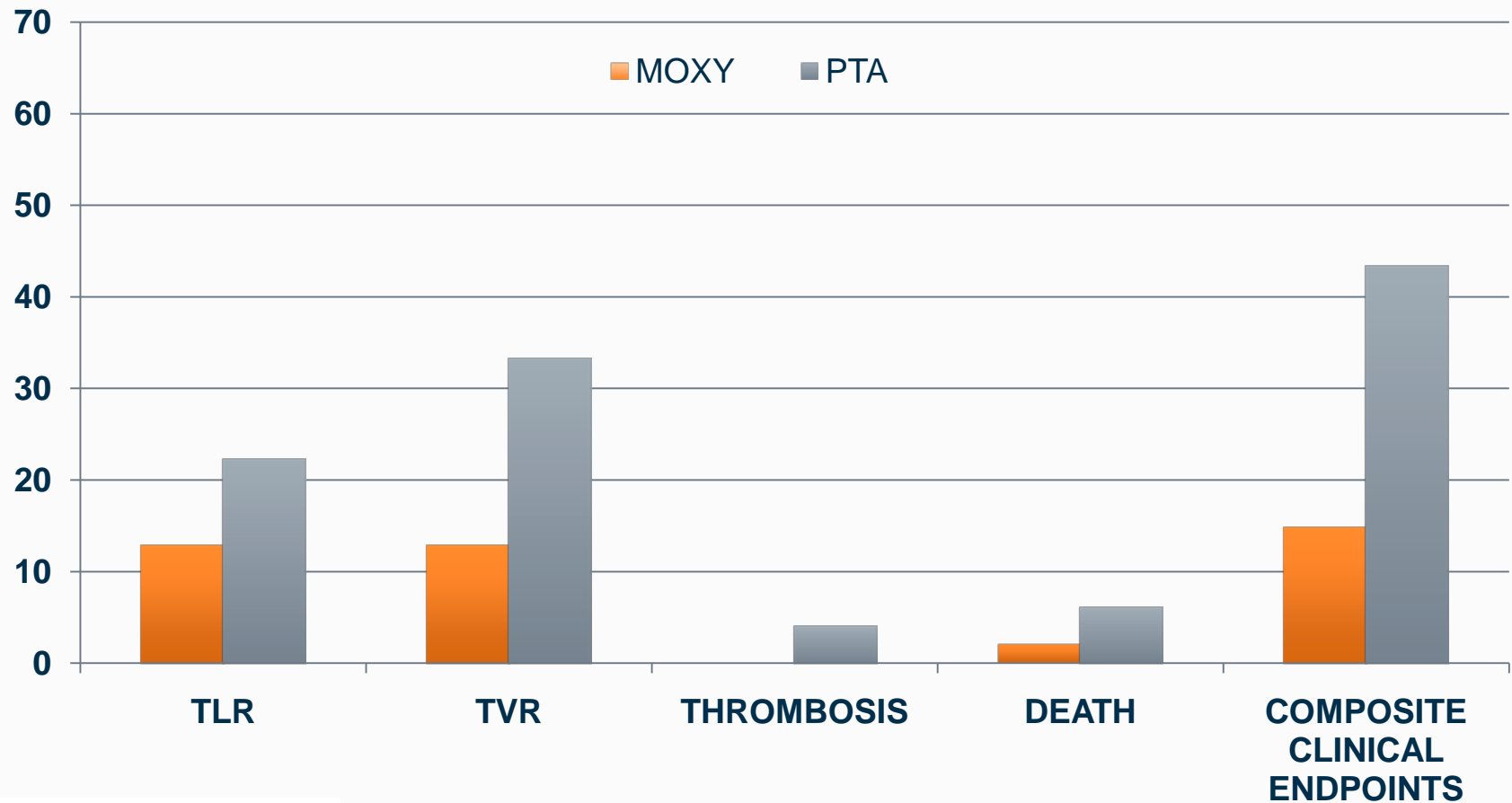


# LEVANT I LATE LUMEN LOSS AT 6 MONTHS ITT ANALYSIS



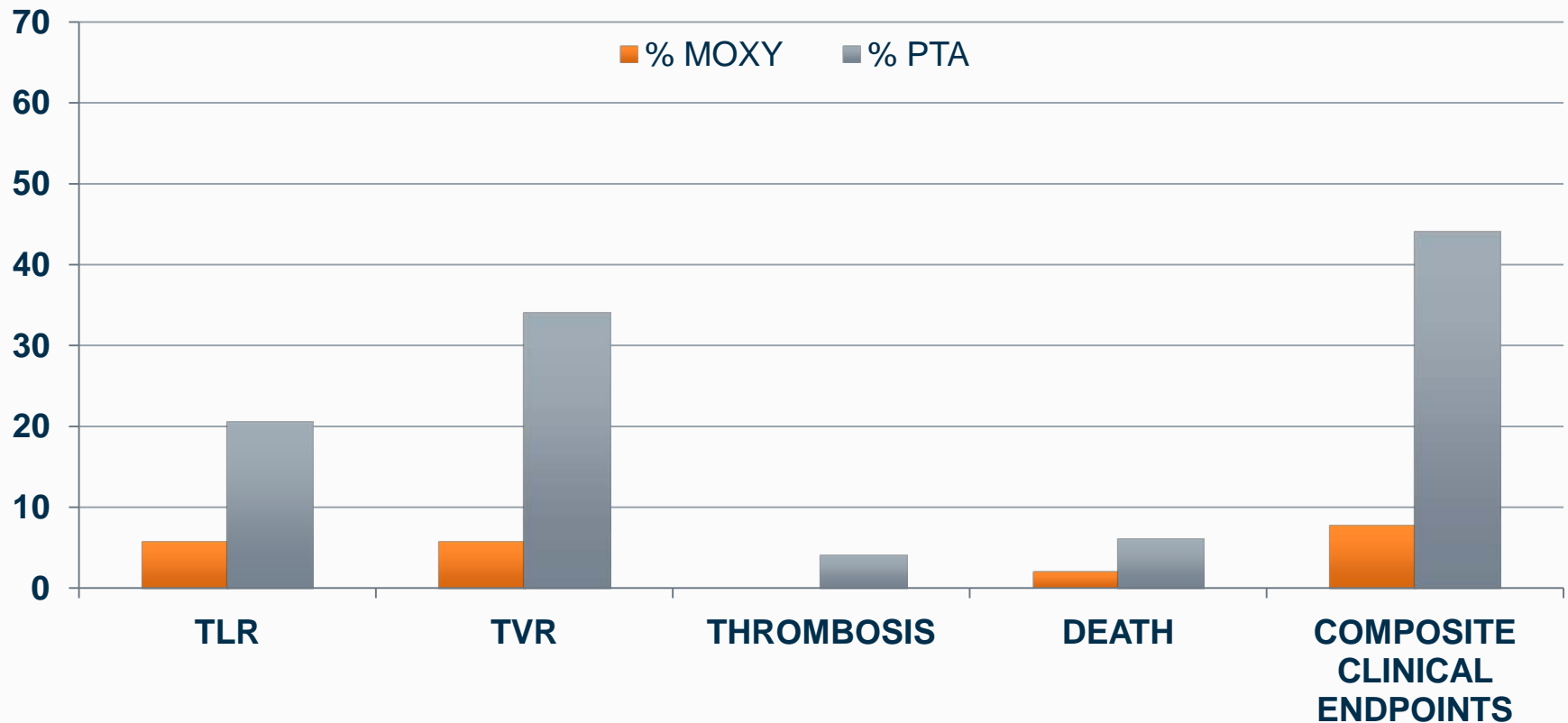
# LEVANT I SECONDARY CLINICAL ENDPOINTS ITT ANALYSIS

(%) at 6 months



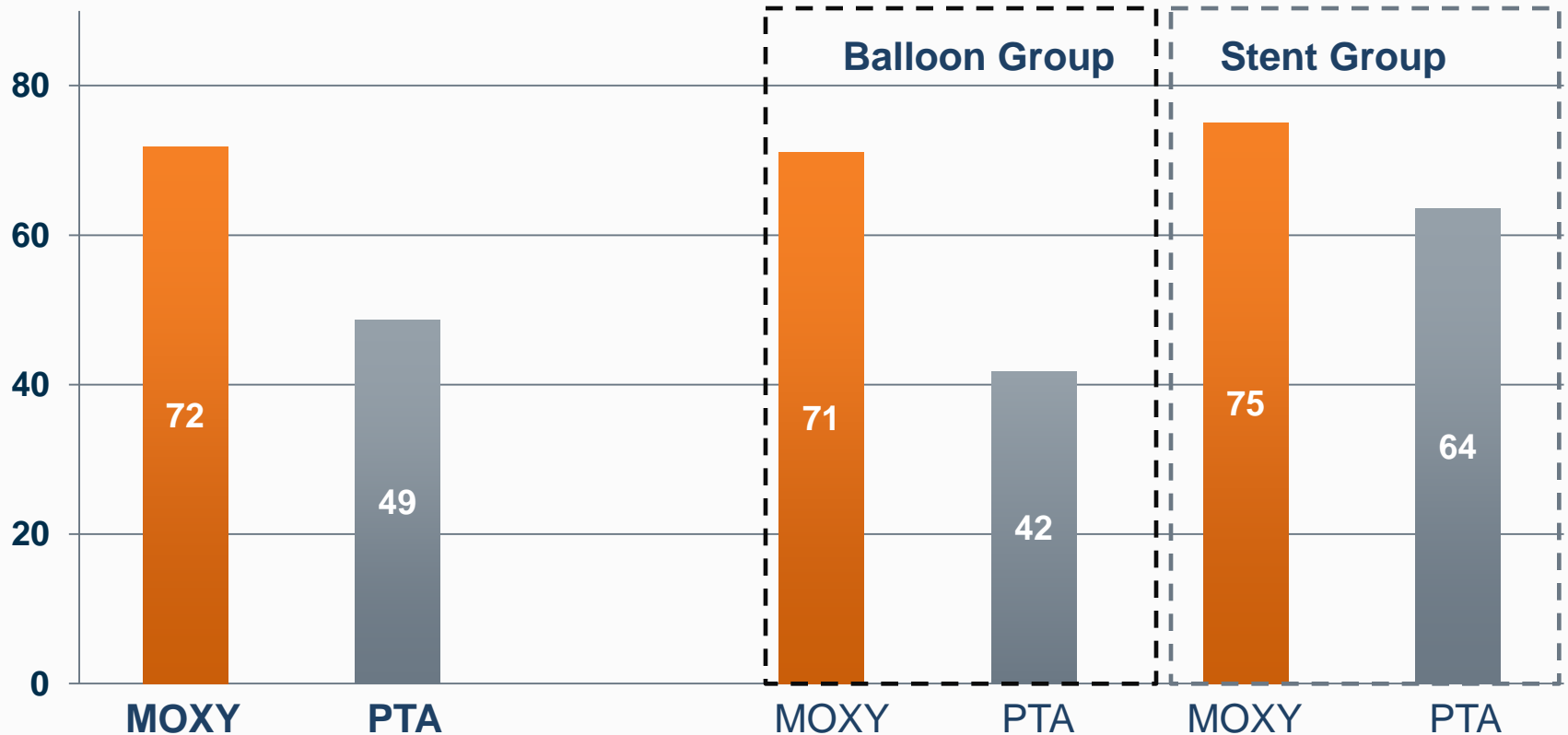
# LEVANT I SECONDARY CLINICAL ENDPOINTS PER PROTOCOL ANALYSIS

(%) at 6 months



# LEVANT I ANGIOGRAPHIC-BASED PRIMARY PATENCY

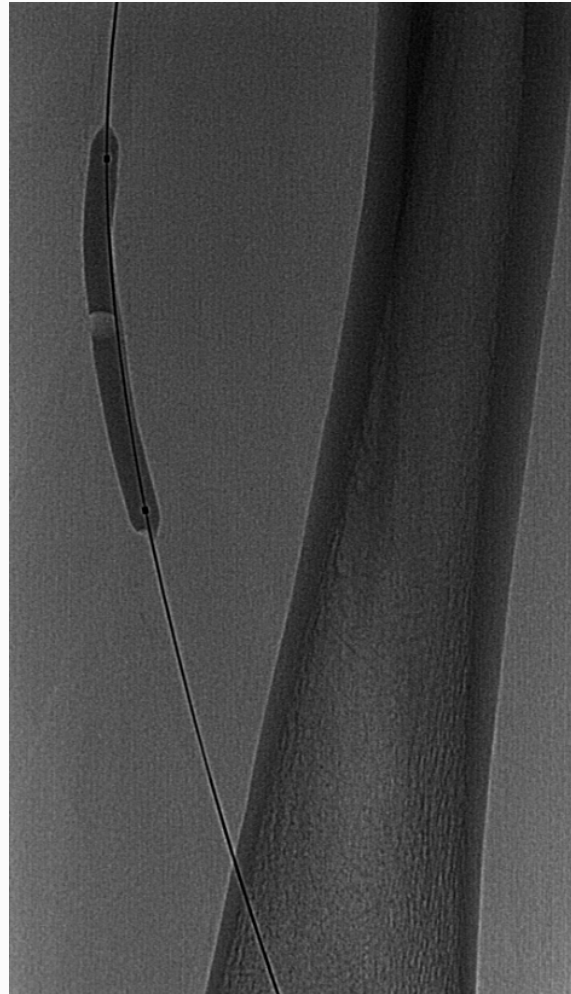
FREEDOM FROM TLR AND > 50% DS



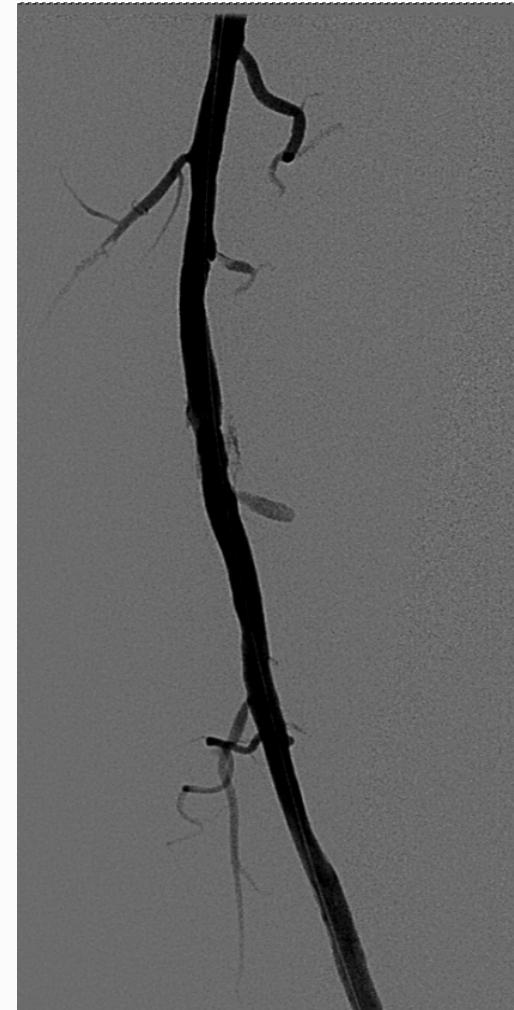
# MOXY CATHETER SUBJECT, LEIPZIG



Pre Procedure

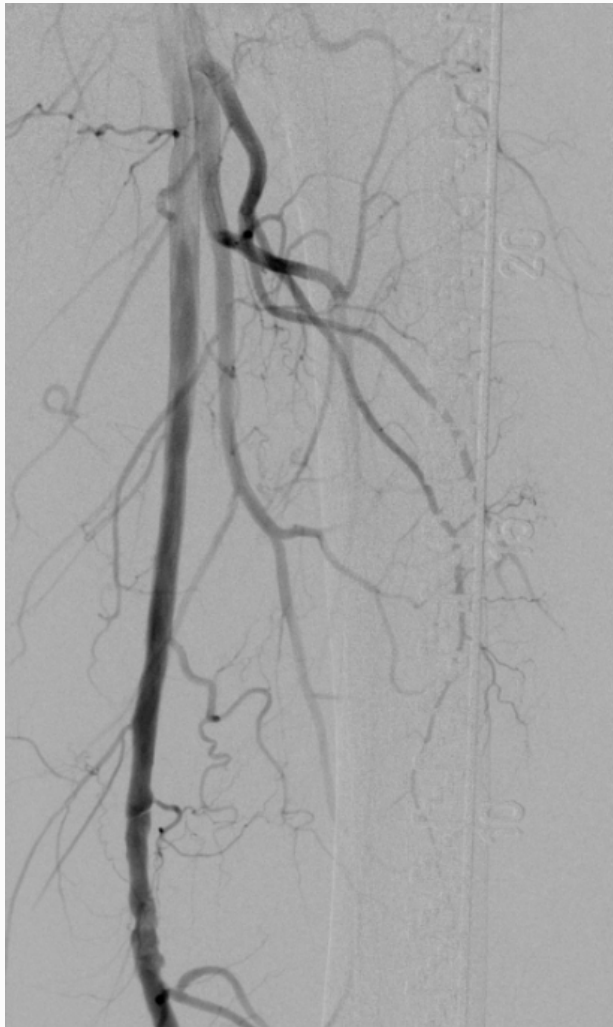


Moxy Catheter



Post-Procedure

# 6 MONTH FOLLOW-UP ANGIOGRAM



# LEVANT I CONCLUSIONS

**\*ACHIEVED PRIMARY  
ENDPOINT OF IMPROVED  
LATE LUMEN LOSS**

1. Strong biologic effect demonstrated on the inhibition of neointimal hyperplasia.
2. Data suggests the Moxy DCB is safe with a marked decrease in clinical events compared to PTA
3. Shorter duration anti-platelet therapy appears feasible in the peripheral vasculature.
4. Large pivotal trial is warranted to further confirm the benefit of treating SFA-popliteal lesions with a drug-coated balloon.



# LEVANT<sup>2</sup>

CLINICAL TRIAL

## Indication: Femoropopliteal

Patients	300 Subjects
Randomization	Moxy™ Balloon vs. Standard PTA
Endpoints	1 <sup>0</sup> : Composite Safety & Efficacy @ 1 Year 2 <sup>0</sup> : Safety, Efficacy, Economic
Follow-Up	5 Years
Principal Investigators	K. Rosenfield (US), Boston, MA D. Scheinert (EU), Leipzig, Germany

*IDE Pending.*

*For sites interested in participating, email [research@lutonix.com](mailto:research@lutonix.com)*