

# The LEGDEB registry – 12-month results with the Legflow<sup>®</sup> DCB in femoropopliteal de novo and restenotic lesions

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# Disclosure

Speaker name: Eugenio Stabile, MD, PhD

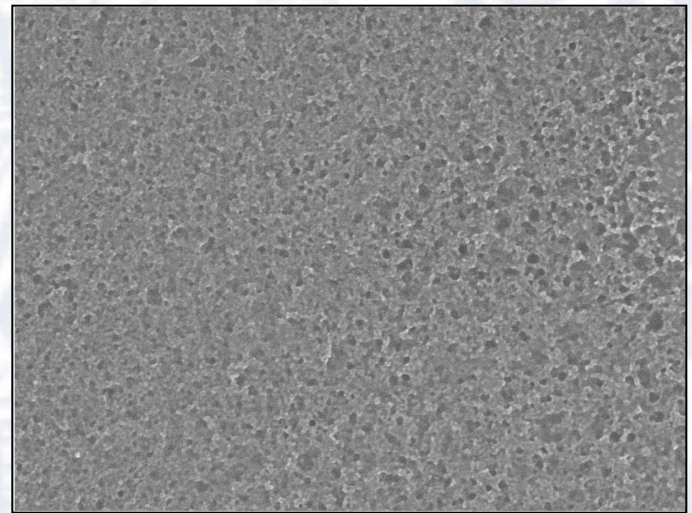
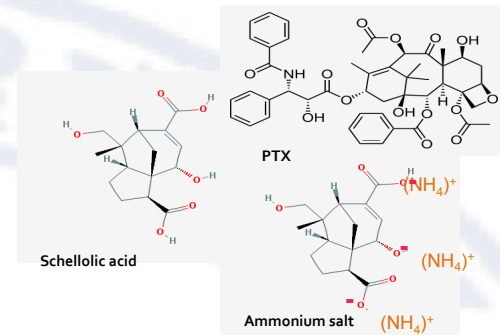
I have the following potential conflicts of interest to report:

Consulting: Amaranth, Boston Scientific, Cardionovum, Daychi Sankyo.

# LEGFLOW®

Paclitaxel releasing PTA balloon dilatation catheter using the SafePax PTX technology (Cardionovum, Inc, Bohn, Germany)

A coating formulation mixture based on a novel Ammonium Salt compound allowing to achieve a stable hydrophobic and lipophilic coating with non visibly (0.1 µm) PTX particulates



# LEGDEB Registry

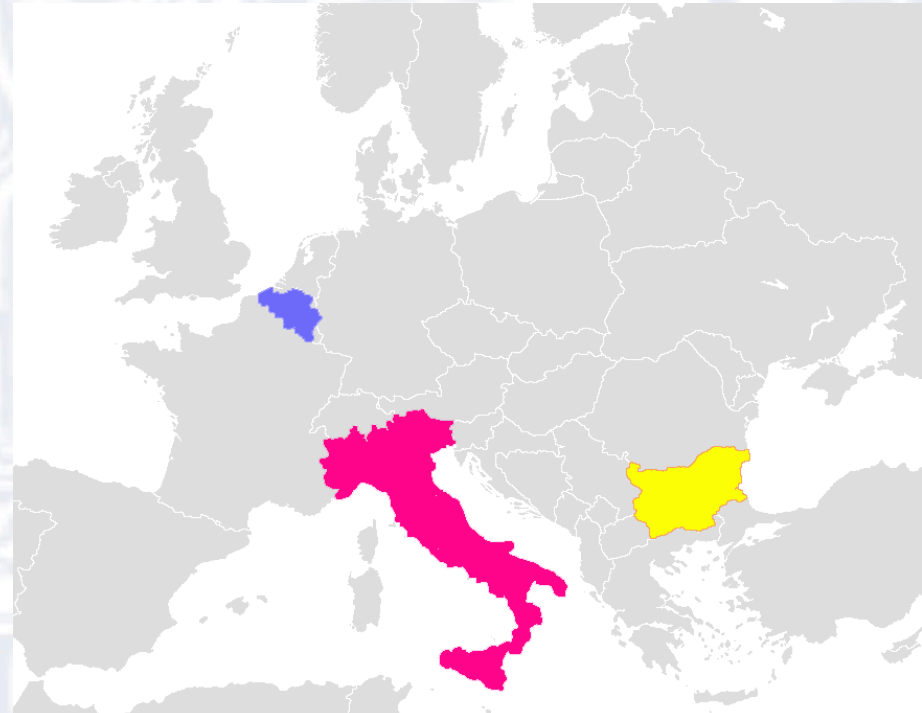
Investigator driven Prospective registry in 4 European centres  
139 patients with femoropopliteal artery disease undergoing PTA  
with Legflow Jan 2014 – June 2016

Treatment according to standard practice of each institution

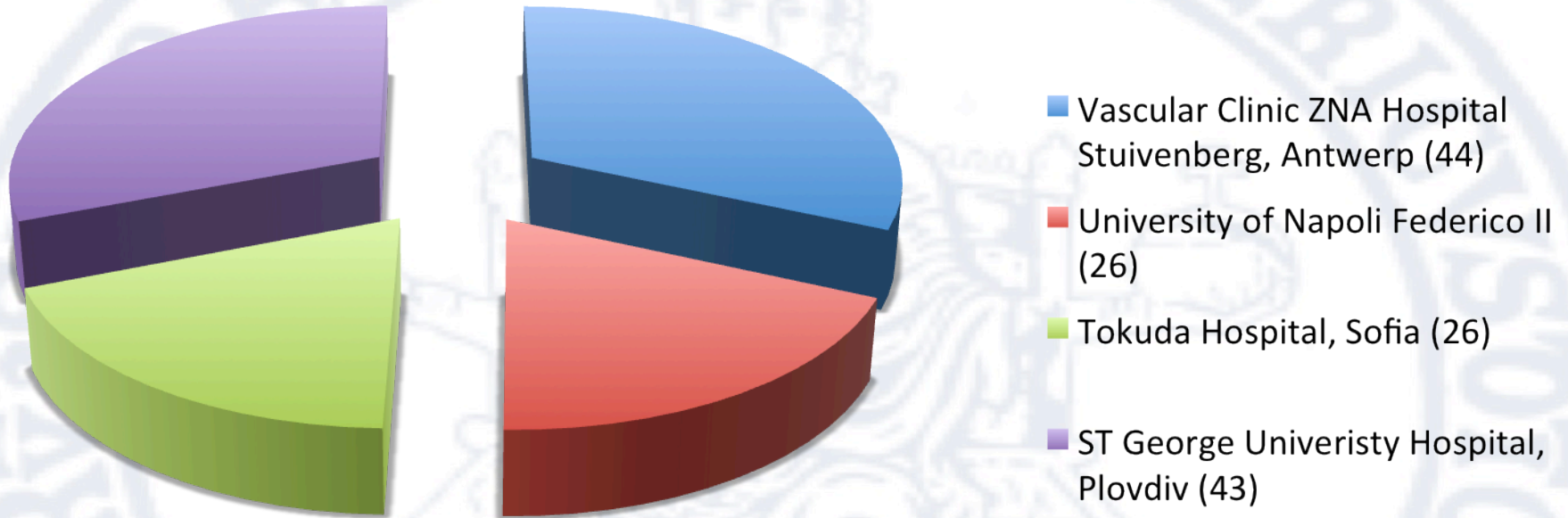
Follow-up by clinical examinations  
and DUS

Repeated angiography in presence  
of intermediate or severe  
restenosis

Primary end point: freedom from  
clinically driven TLR at 12 months



# LEGDEB Registry



Eugenio Stabile, MD, Giovanni Esposito, MD - *University Federico II, Naples, Italy*

Drago Zhelev, MD - *UMBAL Sv. Georgi EAD, Plovdiv, Bulgaria*

Vassil Chervenkov, MD - *Tokuda Hospital, Sofia, Bulgaria*

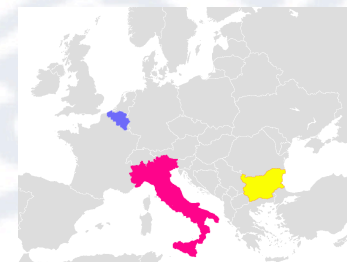
Kim Taeymans, MD, Peter Goverde, MD - *ZNA Hospital Stuivenberg, Antwerp, Belgium*

Independent Data collection and analysis: *Clinica Montevergine, Mecogliano, Italy*

# Clinical Characteristics

Male	78%
Age	67 ± 10.8
Diabetes	50%
Hypertension	79%
Hypercholesterolaemia	49%
Smoking history	51%
Rutherford Class	3.5 ± 0.9
CLI (Rutherford Class ≥ 4)	43%
Claudicants (Rutherford Class < 4)	57%

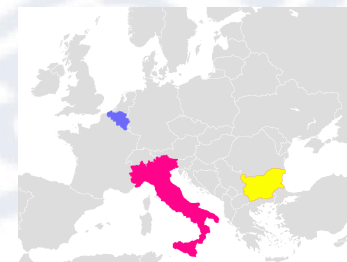
**LEGDEB Registry**



# Lesion Characteristics

Type	
<i>de novo</i> lesions	58%
Restenosis	21%
In-stent restenosis	21%
Site	
SFA	80,5%
Popliteal	19,5%
Length (mm)	
<i>de novo</i>	83.2 ± 42.1
Restenosis	88.2 ± 30.9
In-stent restenosis	117.0 ± 39.5

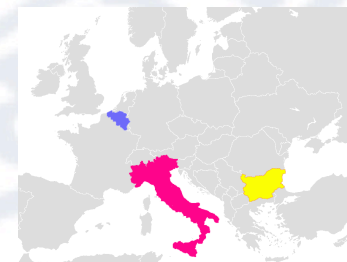
**LEGDEB Registry**



# Procedural Characteristics

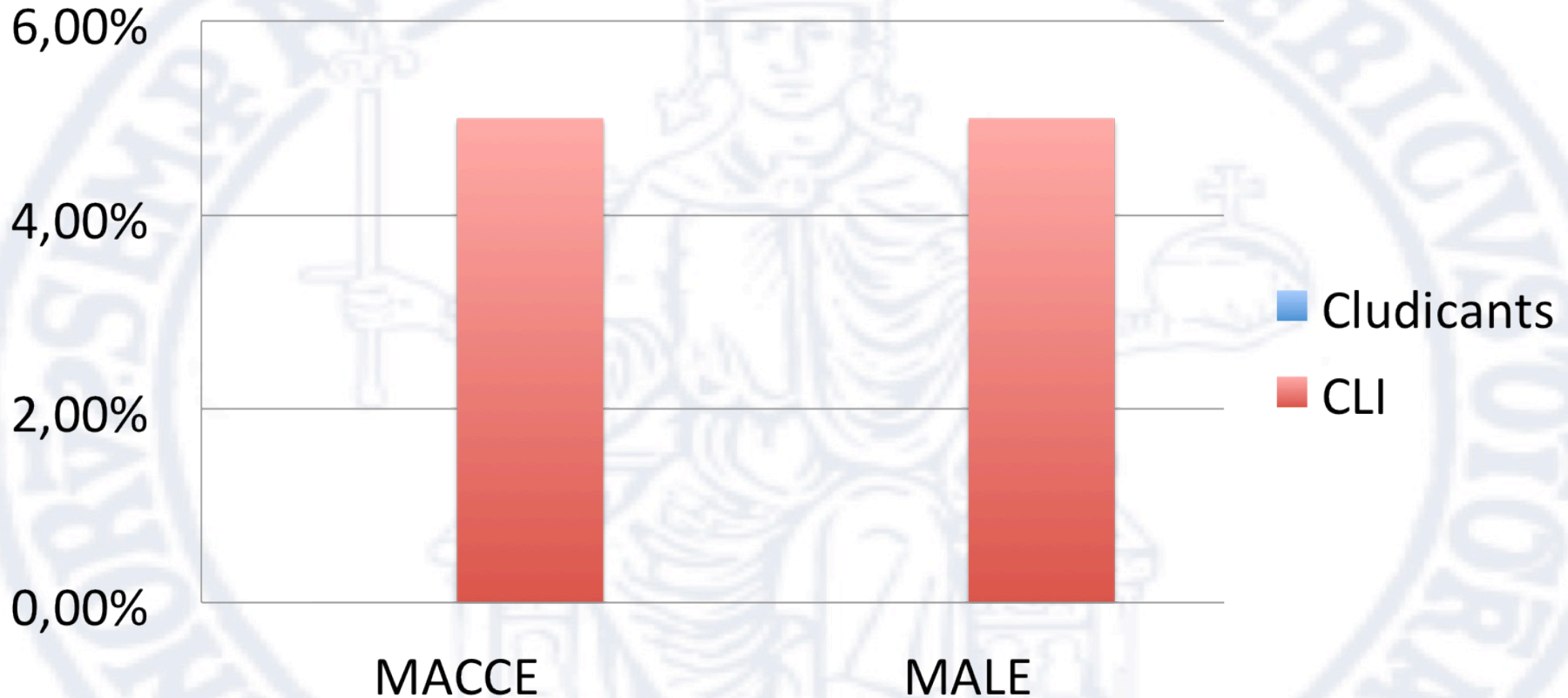
	N (%)
Homolateral access	71 (51.1)
DCB Diameter (mm)	5.0 ± 0.9
Cumulative DCB Length (mm)	113.5 ± 48.0
Bail-out Stenting	39 (28.1)
Associated Procedures	
Inflow	23 (16.5)
Outflow	19 (13.6)
Combined	5 (3.6)

**LEGDEB Registry**



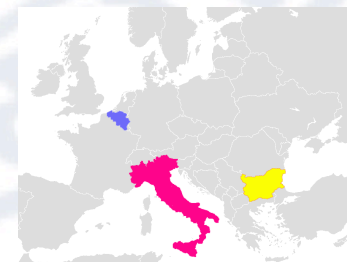


# In Hospital Outcome

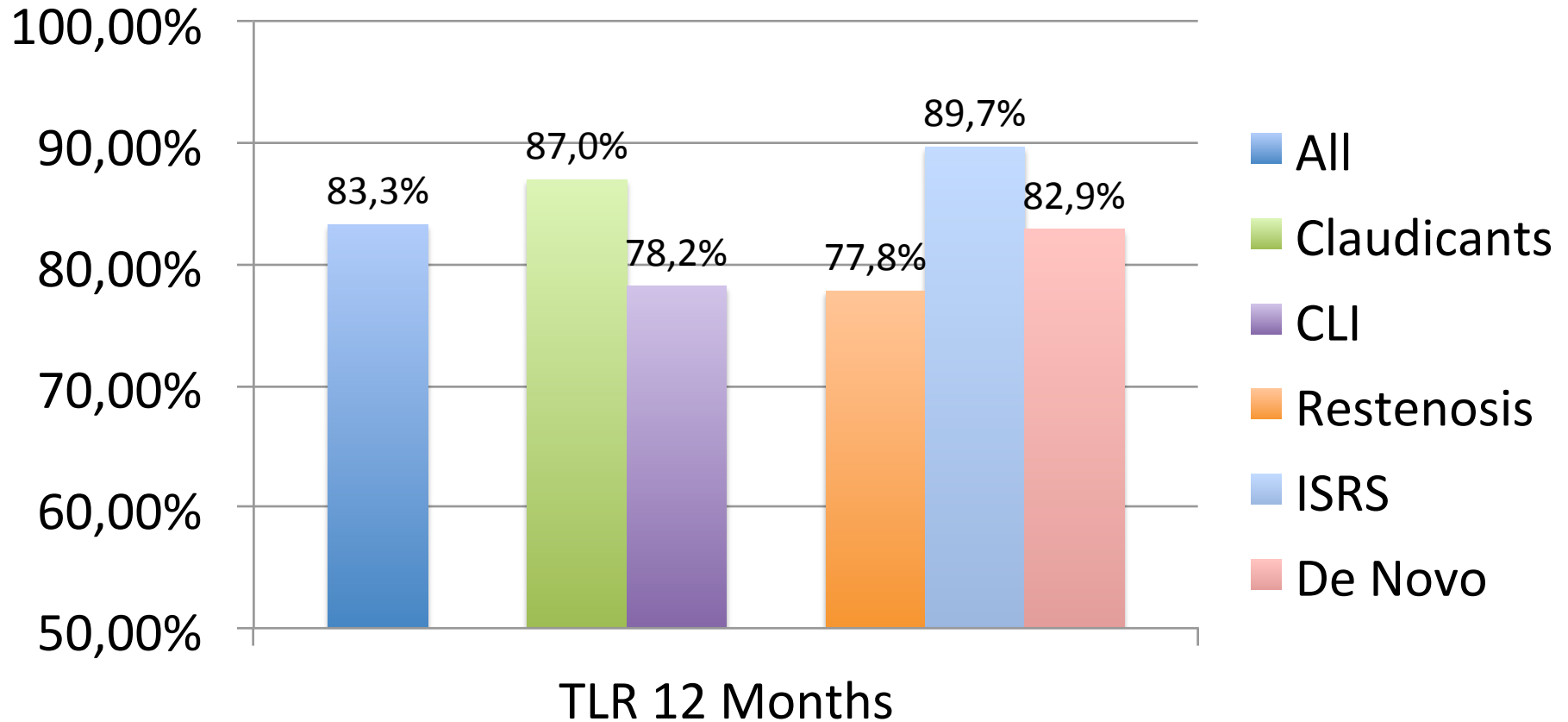


Clinical success = 96.4 % (134 pts)

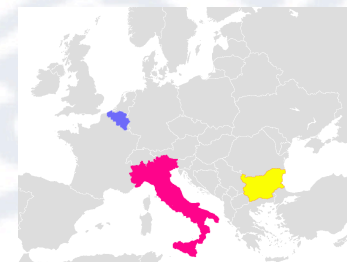
**LEGDEB Registry**



# 12 Months Outcome

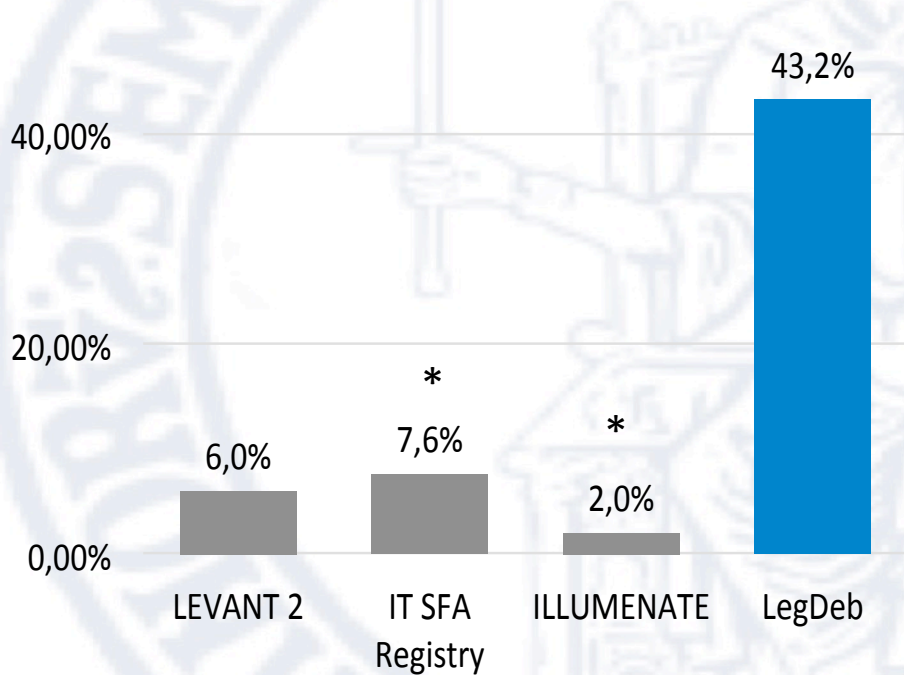


**LEGDEB Registry**

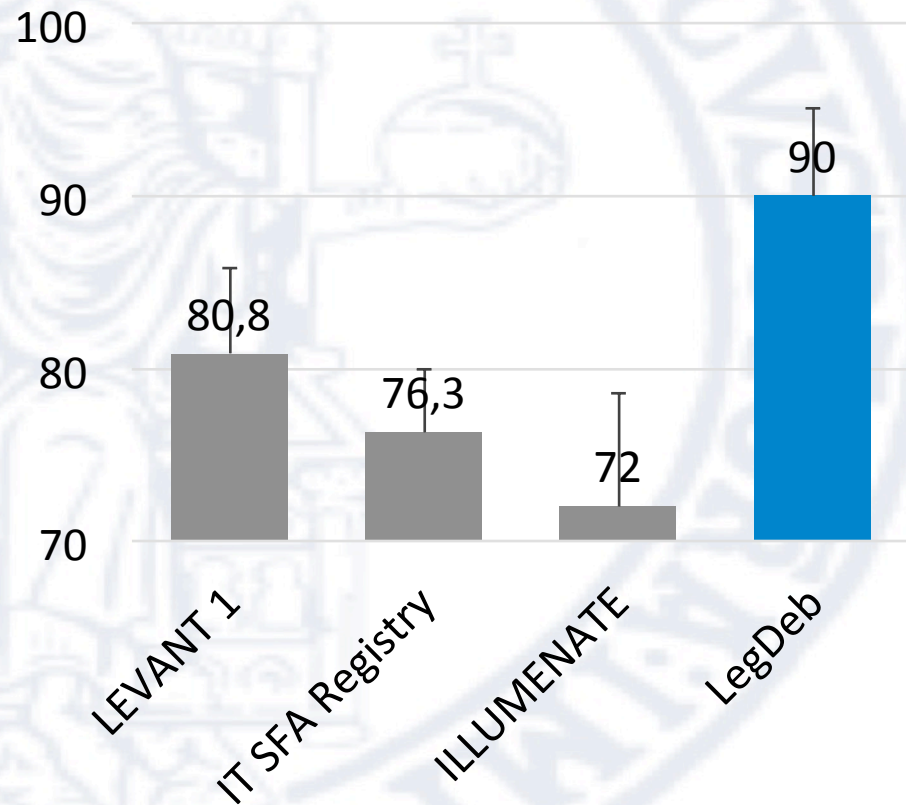


# Peculiarities of the LEGDEB Registry

Percent CLI



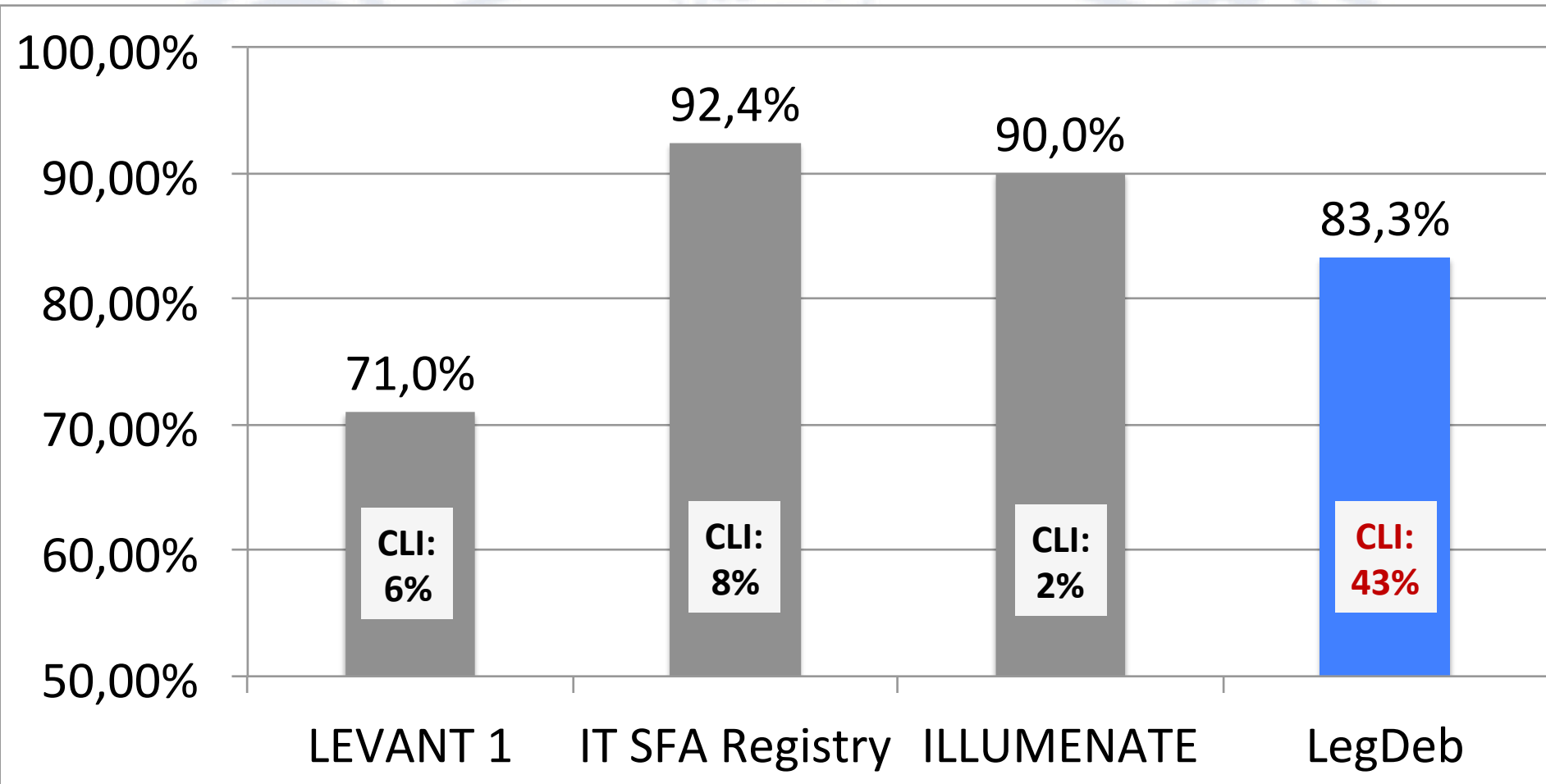
Lesion length mm (SEM)



\* No patients enrolled in Rutherford class >4

Scheinert et al. JACC: Cardiovasc Int 2014; Micari et al. JACC Cardiovasc Int 2012; Schroeder et al. Cath Cardiovasc Int 2016

# 12 Months Outcome



Scheinert et al. JACC: Cardiovasc Int 2014; Micari et al. JACC Cardiovasc Int 2012;  
Schroeder et al. Cath Cardiovasc Int 2016

# Conclusions

- In a real-world population with SFA, Legflow achieved favourable outcomes:
  - 100 % technical success rates
  - 96.4 % Clinical success rate
  - 83.3% freedom from TLR at 12 months
- This was achieved in a population with a complex clinical status:
  - 43% had CLI
  - 90 mm average lesion length
  - 40% of restenosis lesion
- These results should be confirmed in a randomized trial