

Anatomically Challenging Lesion Locations: What are My Treatment Options?

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Disclosure

Speaker name:

.....G. Torsello.....

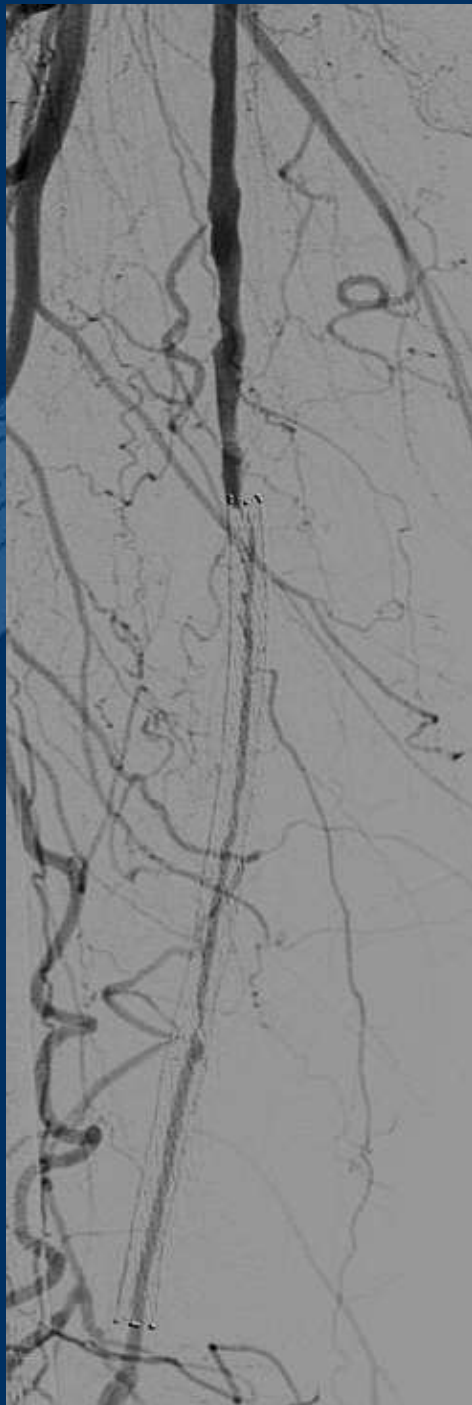
I have the following potential conflicts of interest to report:

- Consulting (Medtronic)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

What Does the Data say in challenging lesions?

- Long Lesions
- Total Occlusions
- Instant Restenosis



Femoro-popliteal ISR

Frequent (20-37% at 1 year)

Technically challenging

Recurrent (50-85% if occlusive)

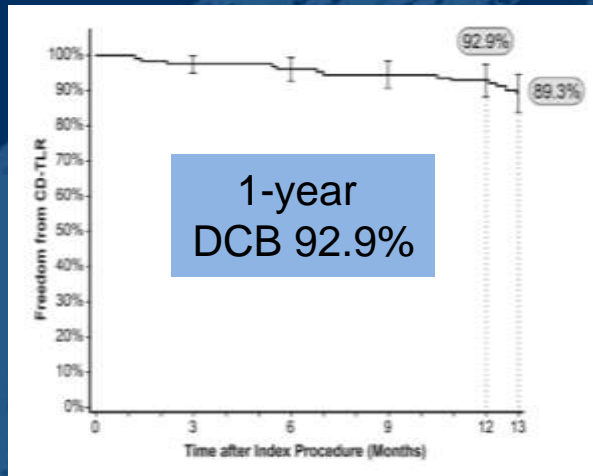
ISR: No strong evidence or consensus

- POBA
- Cutting balloon
- Atherectomy
- Rotational thrombectomy
- Cryoplasty
- Stent-in-stent
- Laser
- DES
- Covered stent
- **DCB**

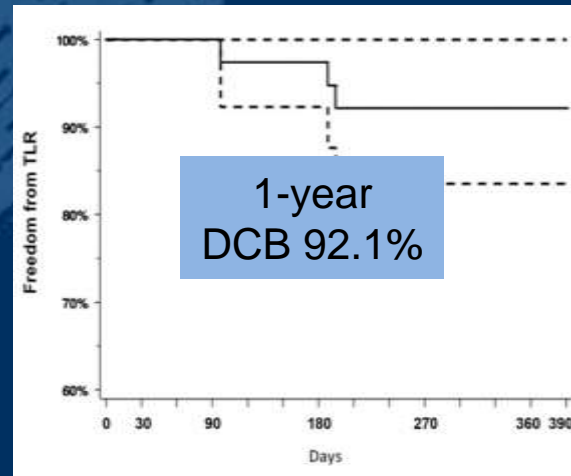
DCB for In-stent Restenosis (ISR)

Consistent Freedom from Reintervention

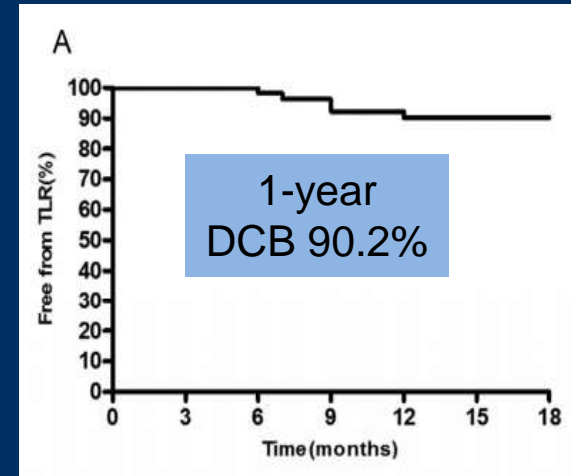
IN.PACT Global ISR¹



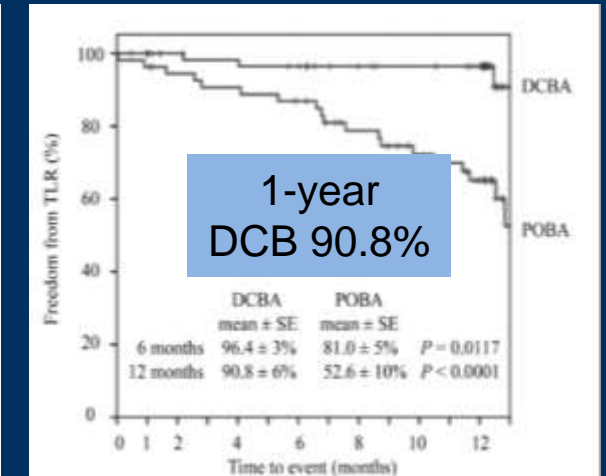
SFA-ISR²



PLAISIR³



FAIR⁴



Mean age = 68 y
 Diabetes = 35.1%
 LL = 17.2±10.5 cm
 CTO = 34.0%
 Prov. Stent = 13.4%

Mean age = 66 y
 Diabetes = 48.7%
 LL = 8.3±7.9 cm
 CTO = 20.5%
 Prov. Stent = 10.3%

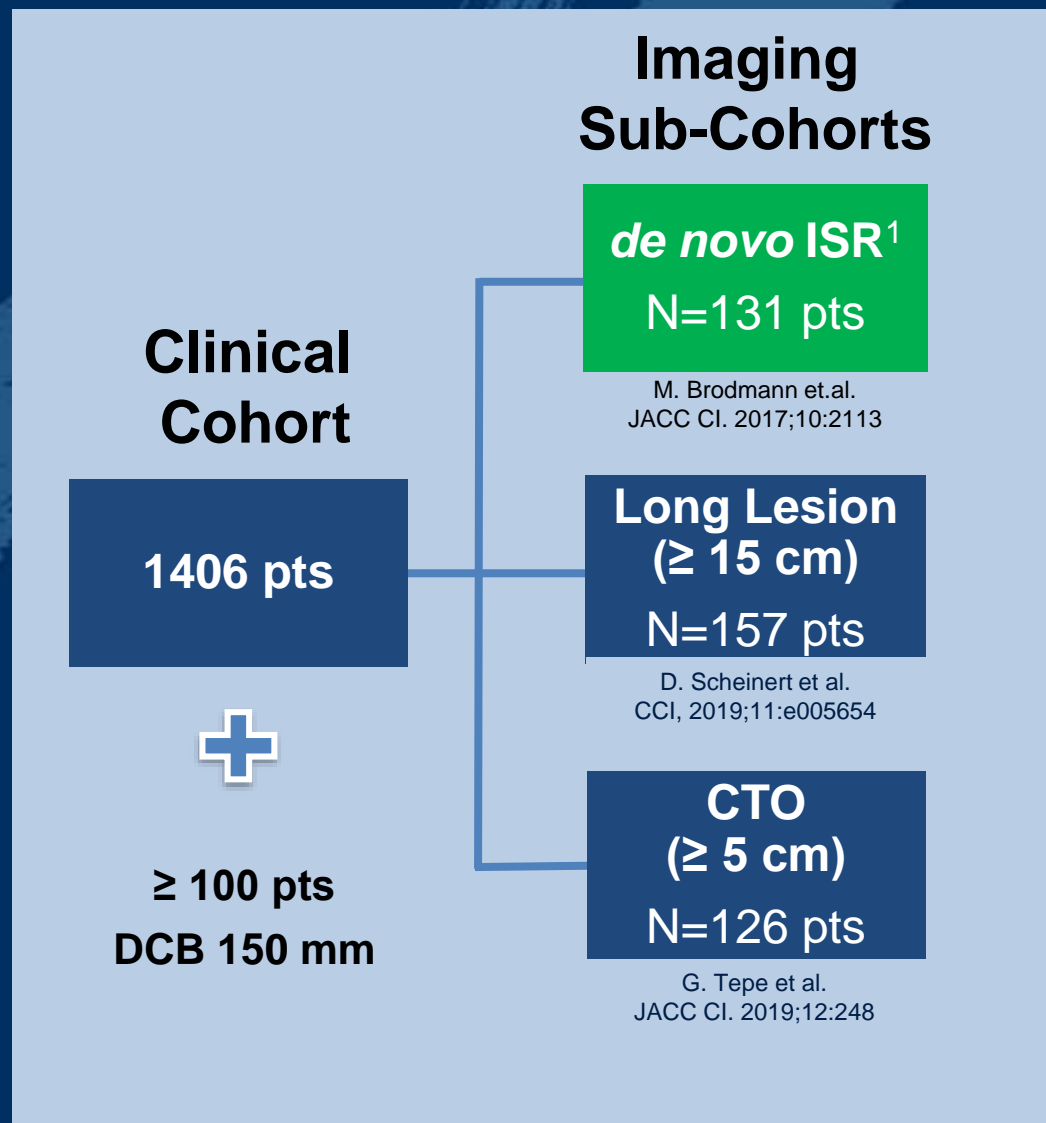
Mean age = 69 y
 Diabetes = 30%
 LL = 8.6±3.2 cm
 CTO = 2%

Mean age = 69 y
 Diabetes = 45%
 LL = 8.2±7.1 cm
 CTO = 28.6%
 Prov. Stent = 1.0%

1. Brodmann et al. *JACC Cardiovasc Interv.* 2017;10:2113-2123
 2. Stabile et al. *J Am Coll Cardiol.* 2012 Oct 30;60(18):1739-42

3. Bague et al. *Eur J Vasc Endovasc Surg.* 2017 Jan;53(1):106-113
 4. Krankenberg et al. *Circulation.* 2015 Dec 8;132(23):2230-6

IN.PACT Global ISR Imaging Cohort



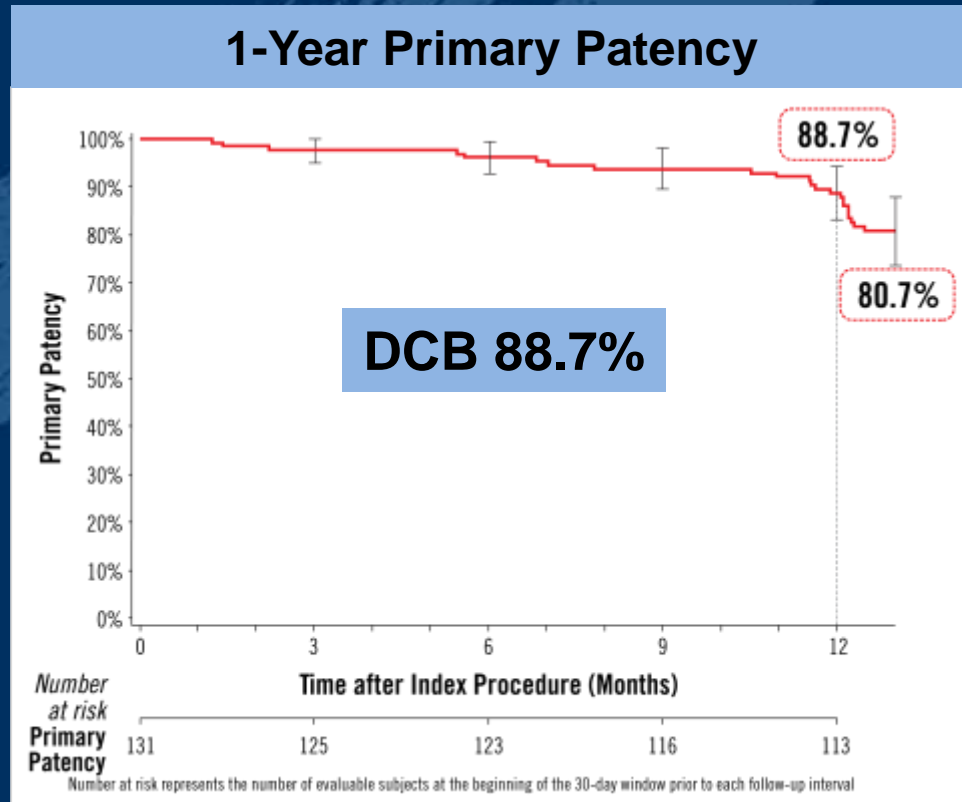
Baseline Characteristics	DCB (N=131 Subjects)
Age (Y)	67.8 ± 10.1
Diabetes (%)	35.1% (46/131)
Hypertension (%)	81.5% (106/130)
Hyperlipidemia (%)	72.1% (93/129)
Current Smoker (%)	35.9% (47/131)
Previous Peripheral Revasc. (%)	100.0% (131/131)
Concomitant BTK Disease (%)	43.3% (55/127)

Lesion Characteristics	DCB (N=149 Lesions)
Lesion type:	
De Novo	0.0% (0/149)
Non-stented Restenotic	0.0% (0/149)
In-Stent Restenosis	100.0% (149/149)
Lesion Length (cm)	17.17 ± 10.47
Total Occlusions (%)	34.0% (48/141)
Calcification (%)	59.1% (78/132)
Severe Calcification (%)	8.3% (11/132)

1. Brodmann et al. JACC Cardiovasc Interv. 2017;10:2113-2123

IN.PACT Global ISR Imaging Cohort¹

Effectiveness and Safety Outcomes



1-Year Outcomes	DCB (N=124 Subjects)*
Clinically-Driven TLR**	7.3% (9/124)
Primary Safety Endpoint†	92.7% (115/124)
Major Adverse Events‡	8.9% (11/124)
Death (all-cause)	0.0% (0/124)
Major Target Limb Amputation	0.0% (0/124)
Thrombosis	0.8% (1/124)
Any TLR	8.1% (10/124)
Any TVR	9.7% (12/124)

* Six subjects did not complete the study through the follow-up period

** Clinically Driven TLR: Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of $\geq 20\%$ or > 0.15 when compared to post-index procedure baseline ABI

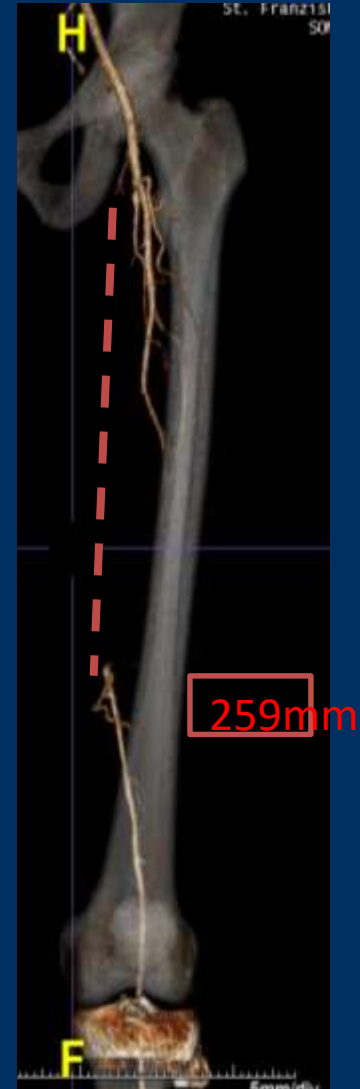
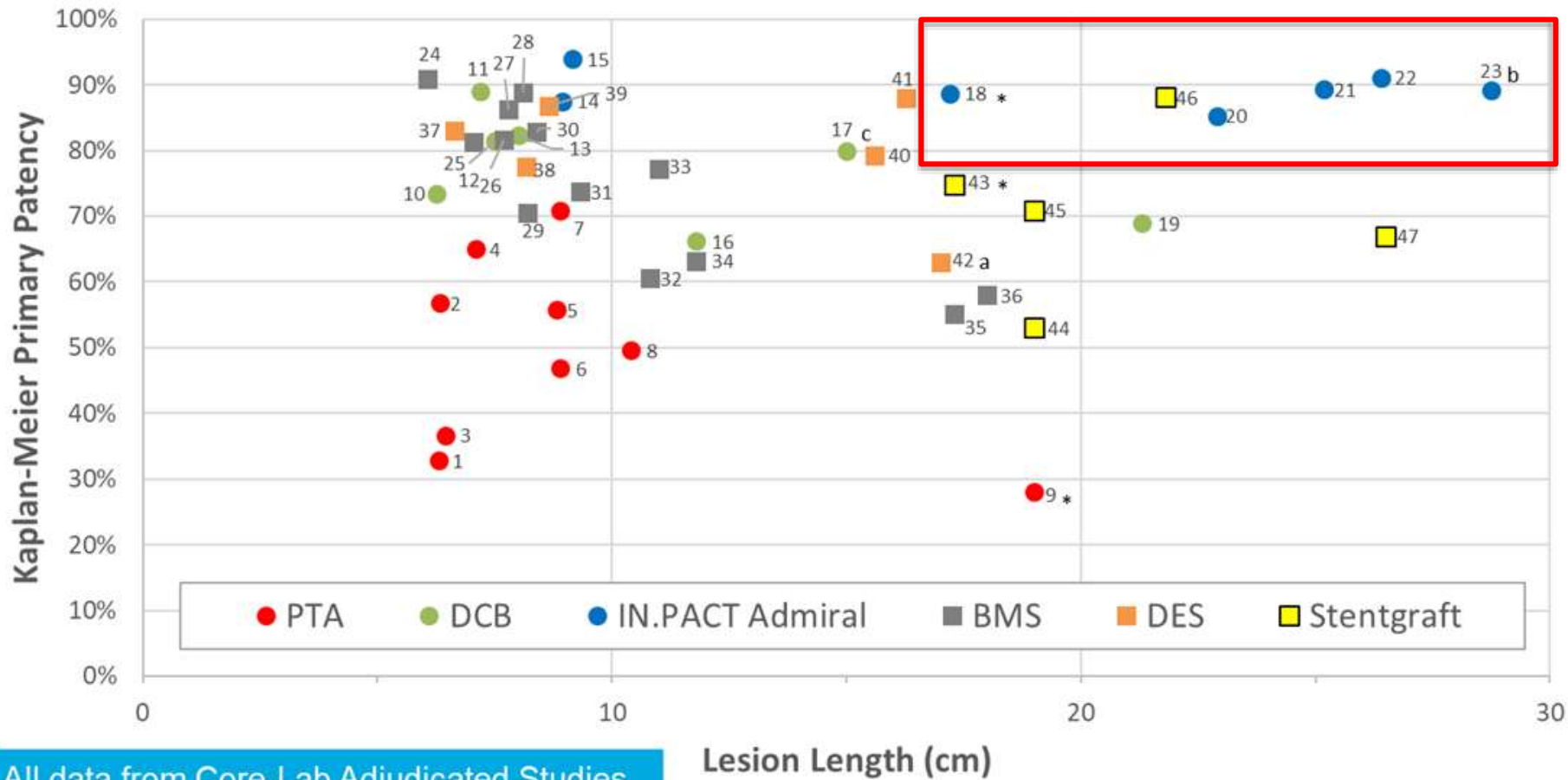
† Primary Safety Endpoint: Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR

‡ Major Adverse Events: Composite of death, major target limb amputation, clinically-driven TVR, and thrombosis

1. Brodmann et al. *JACC Cardiovasc Interv.* 2017;10:2113-2123

DCB for Long Lesions (LL)

Primary Patency



All data from Core-Lab Adjudicated Studies

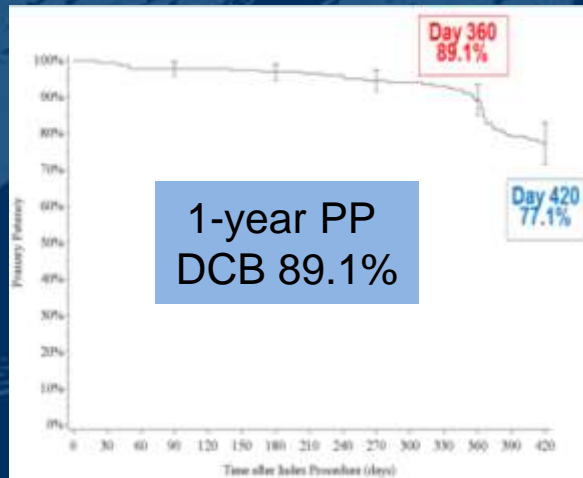
* ISR studies

- a. Iida O, et al., report proportion-based patency of the ZEPHYR study.
- b. Subset analysis of previously-reported data. IN.PACT Global Complex Lesion cohort consists of 227 subjects enrolled in the three IN.PACT Global pre-specified imaging cohorts (long lesion, chronic total occlusion, and in-stent restenosis) exhibiting lesion lengths >18cm.
- c. Bausback Y, et al., A mix of DCBs were used in the REAL PTX study.

DCB for Long Lesions (LL)

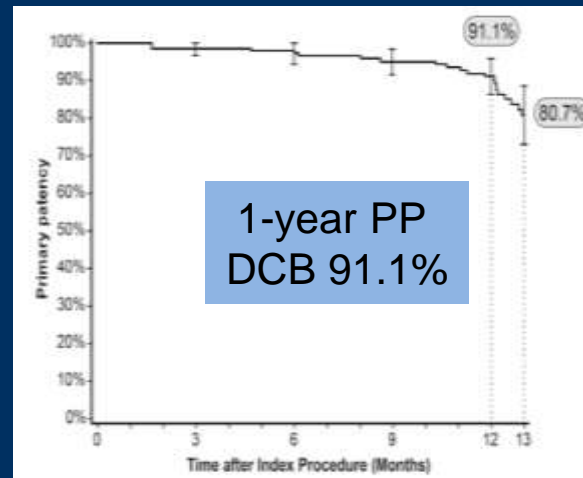
Primary Patency

IN.PACT Global Complex Long Lesions¹



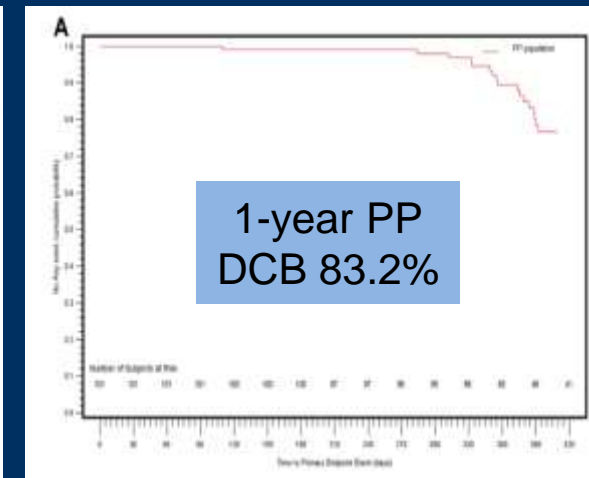
Mean age = 69 y
Diabetes = 38.7%
LL = 28.7 ± 7.1 cm
CTO = 70.1%
ISR = 20.3%
Severe calc = 13.7%

IN.PACT Global Long Lesions²



Mean age = 70 y
Diabetes = 41.0%
LL = 26.4 ± 8.6 cm
CTO = 60.4%
ISR = 0.0%
Severe calc = 19.6%
Prov. Stent = 39.4%

SFA-Long³

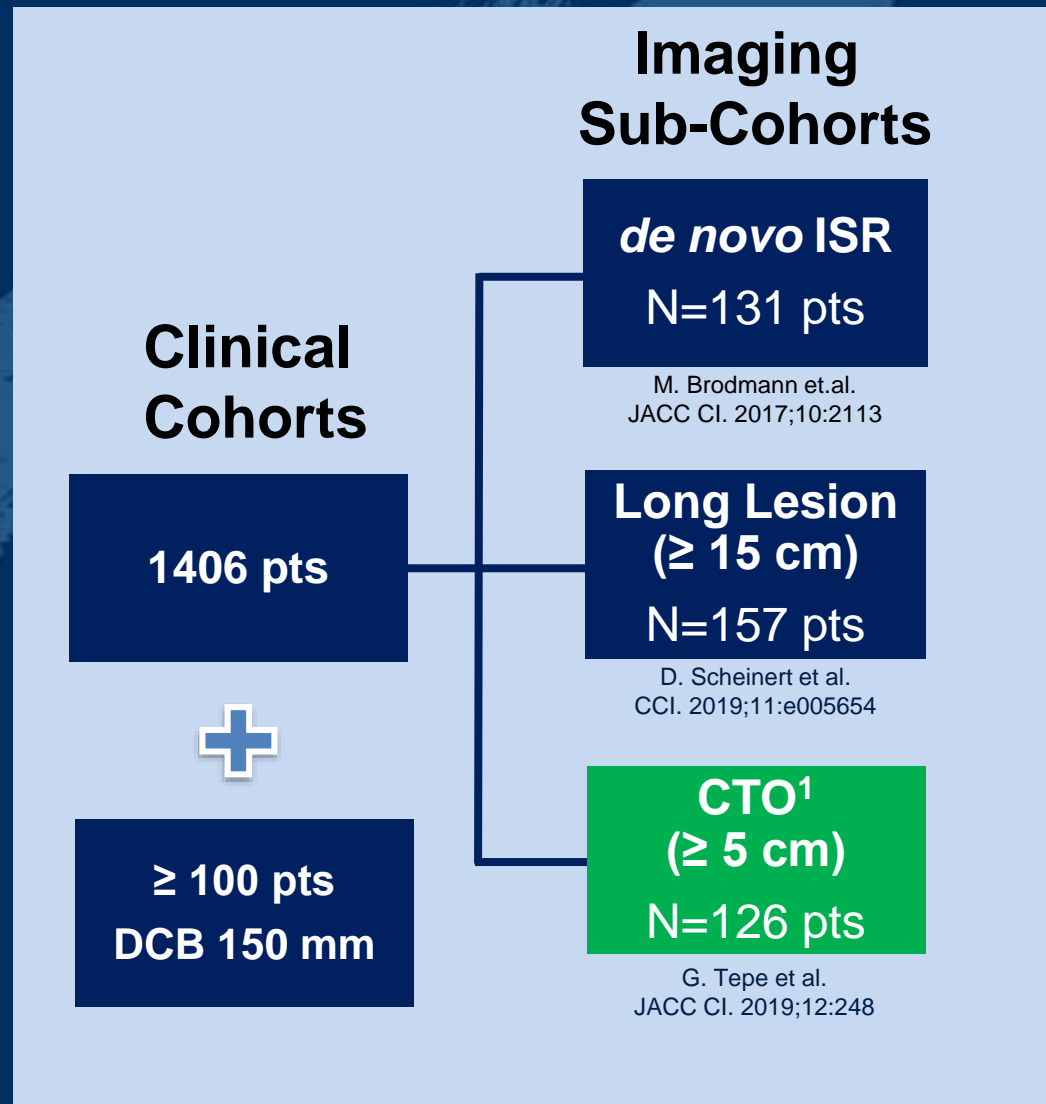


Mean age = 68 y
Diabetes = 57.2%
LL = 25.1 ± 7.9 cm
CTO = 49.5%
ISR = NA
Severe calc = 13.3%
Prov. Stent = 10.5%

1. IN.PACT Admiral paclitaxel-coated PTA balloon catheter instructions for use. M052624T001_Rev1G
2. D. Scheinert et al. *Circ Cardiovasc Interv.* 2018 Oct;11(10):e005654.

3. A. Micari et al. *JACC Cardiovasc Interv.* 2016 May 9;9(9):950-6

IN.PACT Global CTO Imaging Cohort



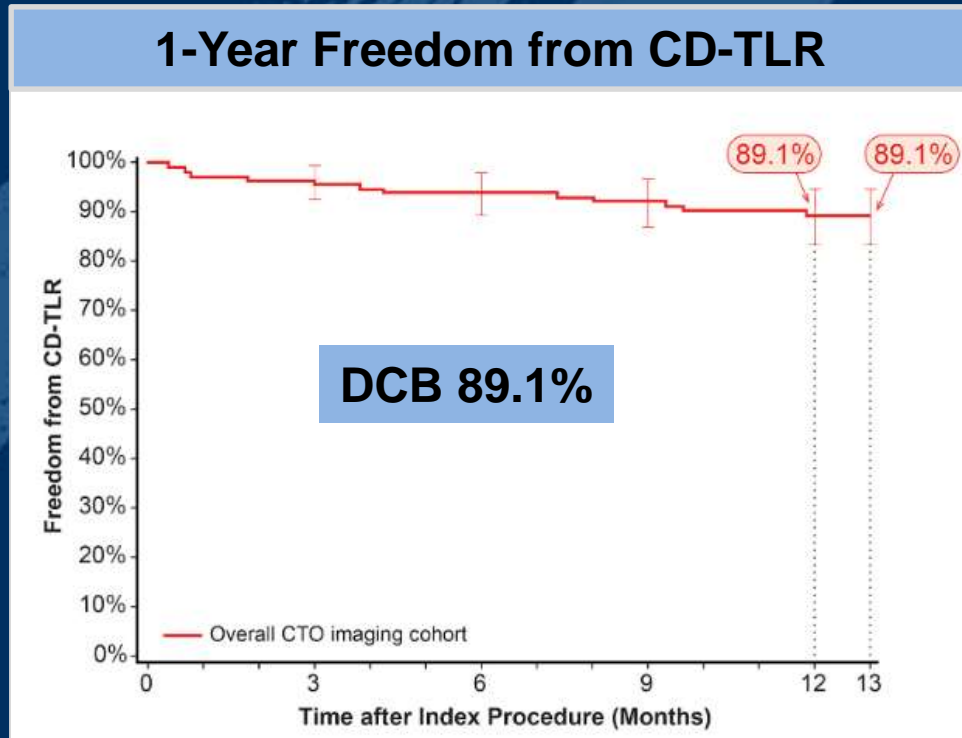
Baseline Characteristics	DCB (N=126 Subjects)
Age, Y	67.5 ± 10.4
Male, %	69.0% (87/126)
Diabetes, %	29.6% (37/125)
Hypertension, %	82.3% (102/124)
Hyperlipidemia, %	64.5% (78/121)
Current Smoker, %	49.2% (62/126)
Previous Peripheral Revasc., %	33.3% (42/126)
Concomitant BTK Disease, %	41.0% (48/117)

Lesion Characteristics	N = 127 Lesions
Lesion Type: % (n/N)	
De novo	92.1% (117/127)
Restenotic (non-stented)	7.9% (10/127)
In-stent Restenosis	0.0% (0/128)
Lesion Length, cm	22.83 ± 9.76 cm
Total Occlusions, %	100% (127/127)
Calcification, %	71.0% (88/124)
Severe Calcification, %	3.2% (4/124)

1. Tepe et al. JACC Cardiovasc Interv. 2019 Mar 11;12(5):484-493

IN.PACT Global CTO Imaging Cohort¹

Effectiveness and Safety Outcomes



1-Year Outcomes	DCB (N=126 subjects)
Clinically-Driven TLR*	11.3% (13/115)
Clinically-Driven TVR†	11.3% (13/115)
Primary Safety Endpoint‡	88.7% (102/115)
Major Adverse Events§	15.7% (18/115)
Death (all-cause)	4.3% (5/115)
Major Target Limb Amputation	0.0% (0/115)
Thrombosis	4.3% (5/115)

Provisional stenting = 46.5%

* Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of $\geq 20\%$ or > 0.15 when compared to post-index procedure baseline ABI.

† Any re-intervention within the target vessel due to symptoms or drop of ABI $\geq 20\%$ or > 0.15 when compared to post-index procedure baseline ABI.

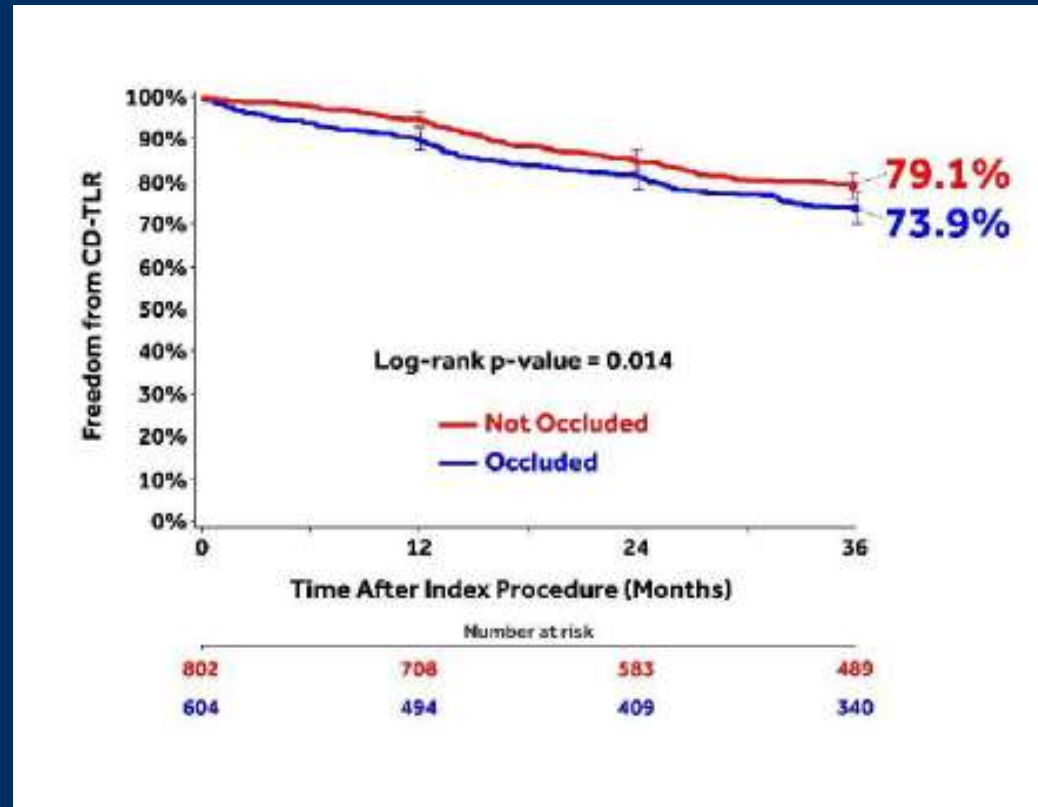
‡ Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR.

§ Major Adverse Events: Composite of death, major target limb amputation, clinically-driven TVR, and thrombosis.

1. Tepe et al. *JACC Cardiovasc Interv.* 2019 Mar 11;12(5):484-493

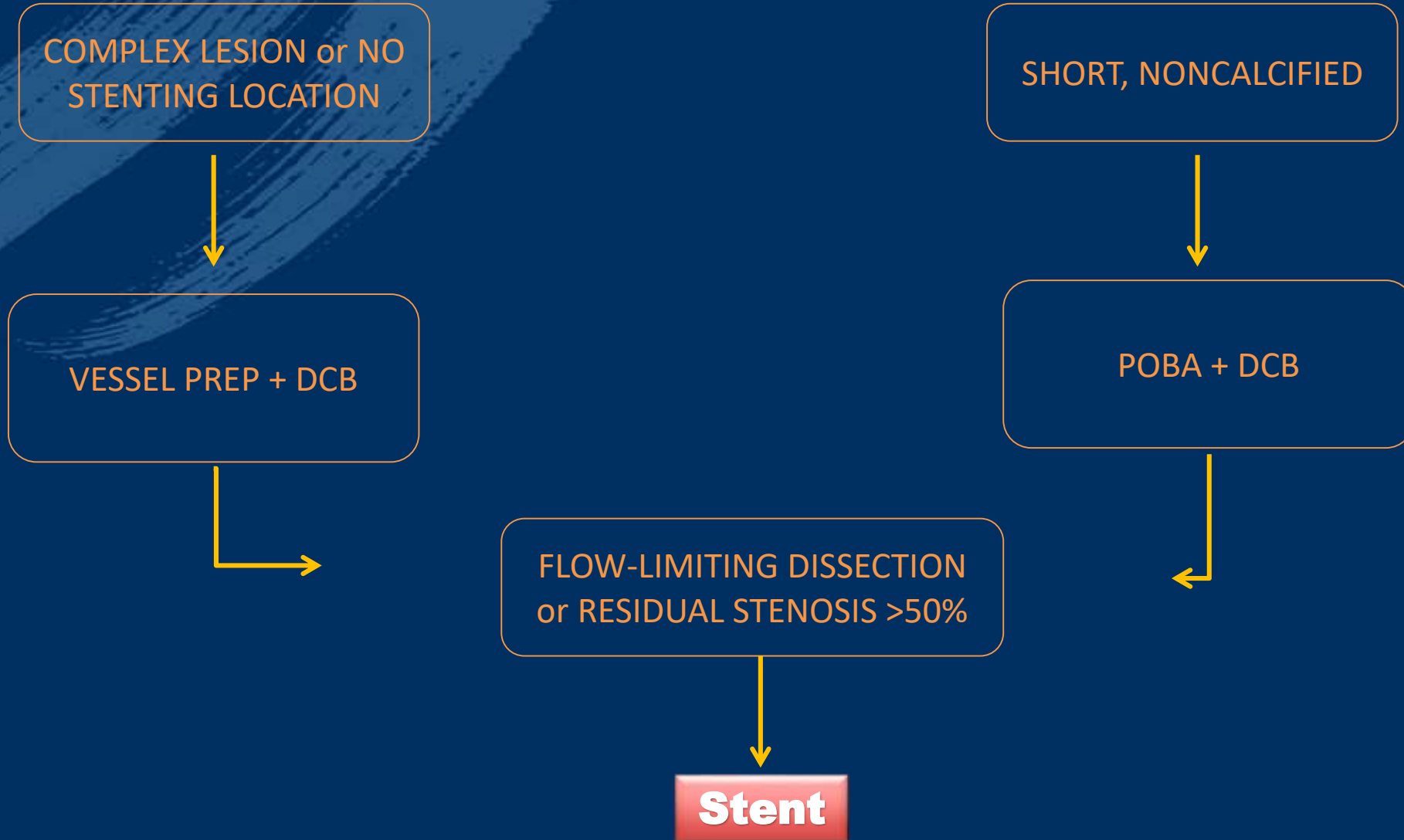
IN.PACT global – CTO- Subcohort

Three-year freedom from CD-TLR



G. Torsello et Al. Three-year sustained clinical efficacy of drug-coated balloon angioplasty in a real-world femoropopliteal cohort
JEVT 2019 conditionally accepted for publication

What are my treatment options?



Summary

- The IN.PACT Global Study remains the largest real-world drug-coated balloon (DCB) study with independent adjudication through 4 years.
- The results of subgroup analyses demonstrate durable effectiveness of the IN.PACT Admiral DCB also in patients with ISR, CTO and long fempop lesions
- The results are consistent with those of other studies showing that DCB is a viable solution for the treatment of complex femoropopliteal disease



homepage: www.gefaesschirurgie-muenster.de

Thank you!



St. Franziskushospital Münster



THANK YOU

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