Total IN.PACT 1-Year Results: Long Lesion Outcomes from the IN.PACT Study Series

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Disclosure

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Potential conflicts of interest to report:

Consulting: Silk Road, Surmodics, Profusa, CSI, Cardinal, Terumo

Chief Medical Officer: Intact Vascular, Cagent, Vesper

Scientific Advisory Board: Abbott, Medtronic, Boston Scientific

Background

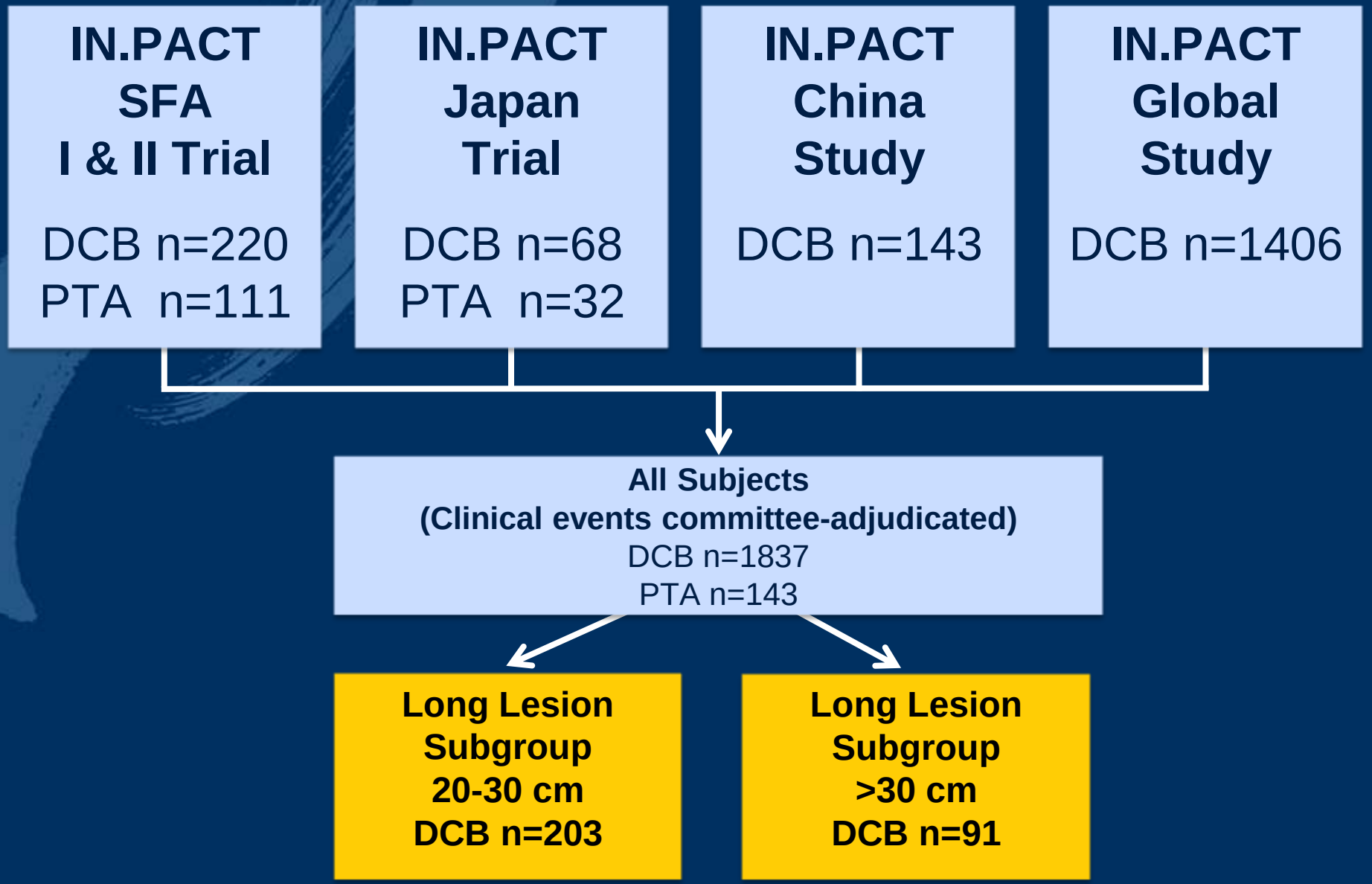
- Numerous RCTS have reported the superiority of drug-coated balloons (DCB) over PTA.[1-4]
- Complex femoral-popliteal lesions, especially TASC D lesions, are under represented in these trials.
- TASC D lesions are challenging to treat and published data regarding use of DCBs are limited.[5-7]

1. Tepe G. et al. Circulation. 2015
2. Laird J. et al. JACC. 2015
3. Schneider P. et al. Circ-CI. 2018
4. Rosenfield K. et al. NEJM. 2015
5. Scheinert D. et al. Circ-CI 2018
6. Micari A. et al. JACC-CI 2016
7. Micari A. et al. JACC-CI 2017

Total IN.PACT Pooled Analysis Initiative

- 1,837 pooled subjects from a diverse population across 147 sites, 28 countries, and 6 continents
- Gain insights into outcomes across a broad spectrum of patient and lesion types
- Offer an independent data analysis (Baim Institute for Clinical Research formerly known as HCRI)

Total IN.PACT Architecture



Total IN.PACT Primary Endpoints

Primary Efficacy Endpoint	•Freedom from clinically-driven target lesion revascularization[1] within 12 months
Primary Safety Endpoint	•Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven target lesion revascularization within 12 months

These endpoints were prospectively defined in all individual studies pooled within the Total IN.PACT analyses

All revascularization and safety events were adjudicated by a Clinical Events Committee

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

Total IN.PACT: Long Lesions

Baseline Clinical Characteristics

TASC D-Total IN.PACT DCB Subjects		
Baseline Characteristics	**20-30 cm lesions (N=203 Subjects)**	**>30 cm lesions (N=91 Subjects)**
Age (Y, Mean ± SD)	68.9±9.7	68.1±10.5
Male (%)	65.0% (132/203)	76.9% (70/91)
Hypertension (%)	87.7% (178/203)	84.6% (77/91)
Hyperlipidemia (%)	65.0% (132/203)	76.9% (70/91)
Diabetes (%)	42.9% (87/203)	35.2% (32/91)
Active Smoker (%)	37.4% (76/203)	40.7% (37/91)
Previous Peripheral Revascularization (%)	60.1% (122/203)	63.7% (58/91)
Below-the-knee Disease of Target Leg (%)	47.9% (92/192)	45.6% (41/90)
Rutherford Category **2** **3** **4** **5**	 22.8% (46/202) 60.4% (122/202) 13.4% (27/202) 3.5% (7/202)	 16.5% (15/91) 67.0% (61/91) 14.3% (13/91) 2.2% (2/91
ABI/TBI*(mmHg)	0.6±0.2	0.5±0.2

*TBI allowed / used in case of incompressible vessels in IN.PACT SFA II phase

Total IN.PACT: Long Lesions

Baseline Lesion/Procedural Characteristics

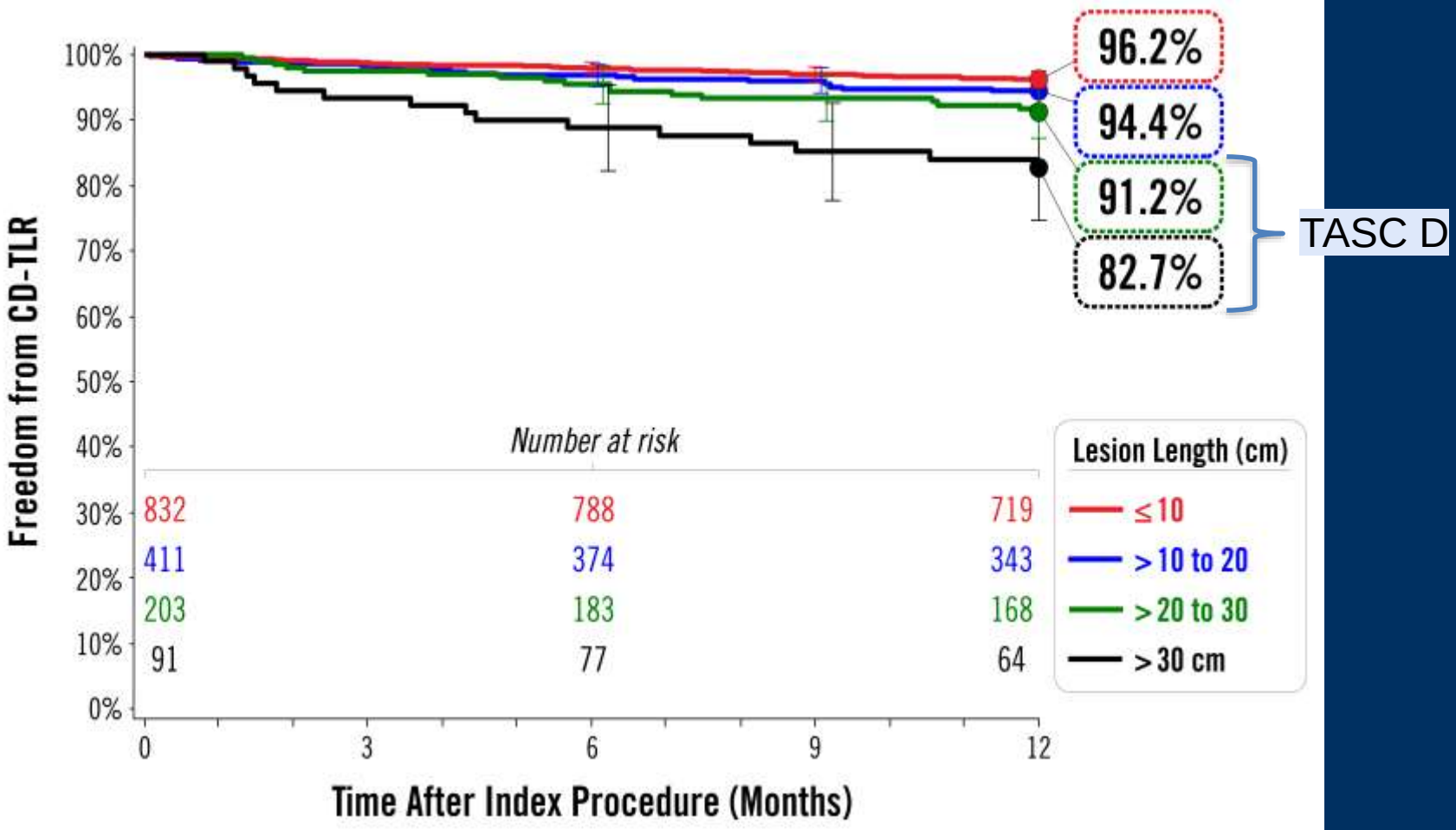
TASC D-Total IN.PACT DCB Subjects		
Lesion/Procedural Characteristics*	**20-30 cm lesions (N=203)**	**>30 cm lesions (N=91)**
Lesion Characteristics		
Lesion Type		
De Novo	64.5% (131/203)	57.1% (52/91)
Restenotic (non-stented)	8.9% (18/203)	8.8% (8/91)
In-stent restenosis	26.7% (54/202)	34.1% (31/91)
Lesion Length (cm)	25.24±2.96	34.75±4.17
Calcification	70.9% (144/203)	71.4% (65/91)
Occluded Lesion (100% stenosis)	70.0% (142/203)	76.9% (70/91)
Procedural Characteristics		
Provisional Stent	37.1% (75/202)	50.5% (46/91)

* Site reported

Total IN.PACT: Long Lesions

Primary Effectiveness Outcomes

Total IN.PACT All-Subjects: Long Lesion Subgroup
Freedom From CD-TLR through 12 months



Total IN.PACT: Long Lesions

Safety Outcomes

Total IN.PACT DCB Subjects		
12-month Outcomes	**20-30 cm lesions (N=203 Subjects)**	**>30 cm lesions (N=91 Subjects)**
Effectiveness		
Clinically-driven TLR[1]	8.9% (17/192)	17.6% (15/85)
Safety		
Primary Safety Composite[2]	91.1% (175/192)	82.4% (70/85)
Device- or procedure- related death (30 days)	0.5% (1*/201)	0.0% (0/91)
Major Adverse Events[3]	13.0% (25/192)	23.5% (20/85)
All-cause death	4.2% (8/192)	5.9% (5/85)
Major Target Limb Amputation	0.0% (0/192)	0.0% (0/85)
Clinically-driven TVR[4]	9.4% (18/192)	17.6% (15/85)
Thrombosis	1.6% (3/192)	7.1% (6/85)

* Procedure-related

1. Clinically-driven TLR defined as any re-intervention within the target lesion(s) due to symptoms or drop of ABI ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.
2. Primary Safety Endpoint is a composite of freedom from device- and procedure-related mortality through 30 days, freedom from major target limb amputation and TLR within 12 months post-index procedure
3. Major adverse events is defined as all-cause mortality, clinically-driven TVR, major target limb amputation, thrombosis at the target lesion site
4. Clinically-driven TVR is defined as any re-intervention within the target vessel due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI

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CONCLUSION

- The Total IN.PACT Pooled Analysis is the largest, most diverse, independently-adjudicated drug-coated balloon (DCB) series to date.
- TASC D lesions (20-30 cm) treated with IN.PACT Admiral DCB had a positive safety profile with no major target limb amputations and CD-TLR rate of 8.9% .
- TASC D+++ lesions (>30 cm);
  - 17.6% CD-TLR rate
  - No Major target limb amputations and low thrombosis
  - 50.5% of these long lesions received a provisional stent.

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