Outcomes Of DCB Use In Real World Registries: 2 Year Results From The INPACT Global Registry

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Background

- Advances in endovascular procedures have markedly broadened options for treating symptomatic SFA disease
- Drug-coated balloons (DCBs) have demonstrated promising results at 1- and 2-years in randomized trials,[1-7] with IN.PACT™ Admiral™ DCB showing sustained and durable benefit through 4 years [8, 9]
- Evidence with DCBs has been greatly expanded in real-world registries[10-13] but longer-term data remains limited

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IN.PACT Global Study
Overview

Real-world, prospective, multicenter, single arm independently-adjudicated femoropopliteal study

All-comers (RCC 2-4)

- ✓ **Bilateral disease**
- ✓ **Multiple lesions**
- ✓ **SFA and Popliteal**
- ✓ **TASC A, B, C, D**
- ✓ ***de novo* ISR**
- ✓ **Long Lesions**
- ✓ **CTOs**

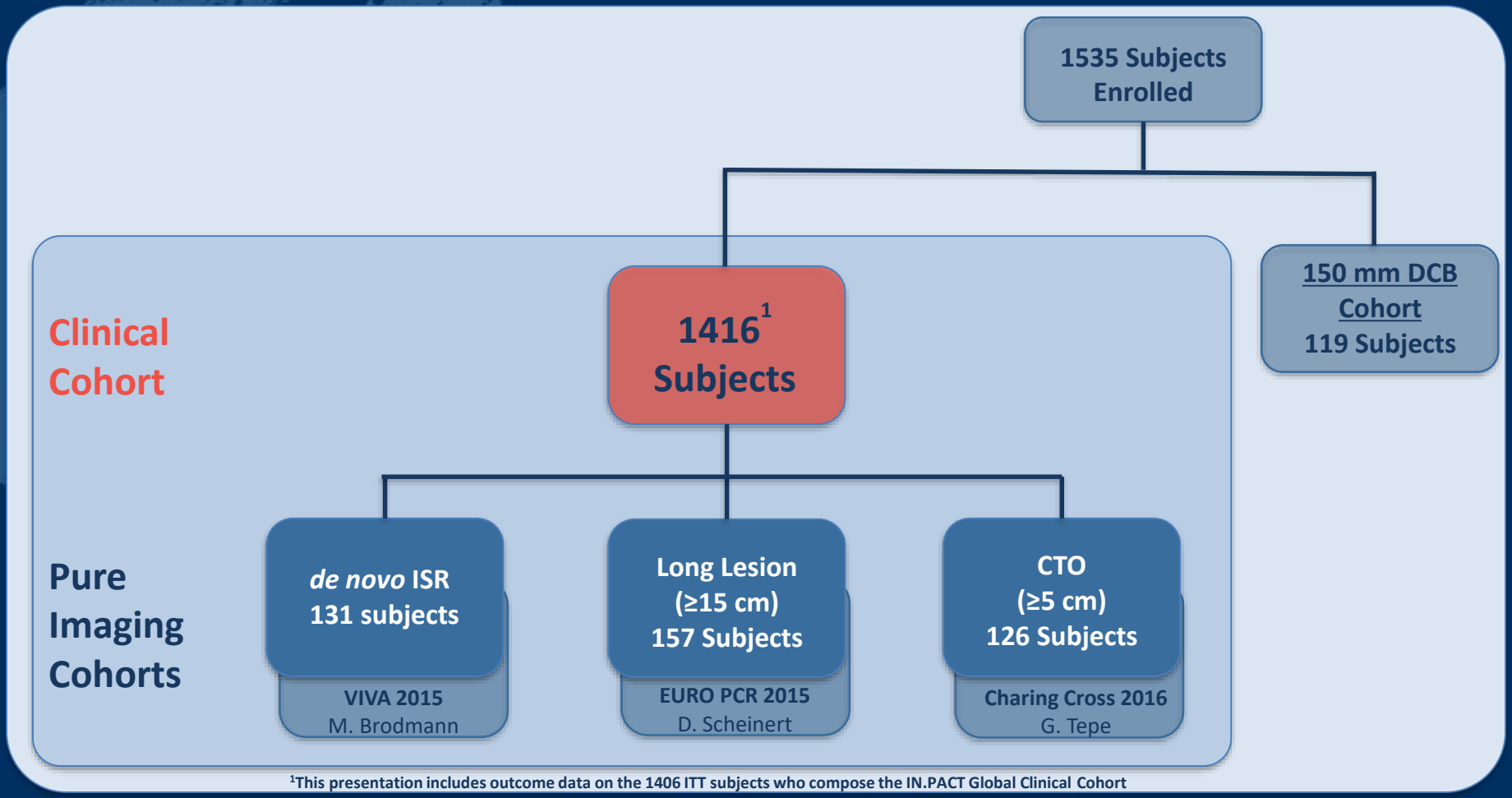
- **1535 patients enrolled**
- **64 sites in EU, Mid-East, Latin America, Asia**
- **Independent adjudication by Clinical Events Committee[1]**
- **Prospective subset analysis with core lab[2,3] reported results**
  (*de novo* ISR, long lesions ≥15 cm, CTOs ≥5 cm)
- **Safety and effectiveness data on 150 mm DCB**

1. Syntactx Clinical Events Committee, New York, NY, US
2. VasCore DUS Core Lab, Boston, MA, US
3. SynvaCor Angiographic Core Lab, Springfield, IL, US

IN.PACT Global Study

Architecture

Purpose: To expand the clinical evidence with the IN.PACT™Admiral™ DCB in the treatment of real-world patients with symptomatic femoropopliteal disease. This analysis reports longer-term outcomes through 2 years.



[1]This presentation includes outcome data on the 1406 ITT subjects who compose the IN.PACT Global Clinical Cohort

IN.PACT Global Study

Primary Endpoints

Primary Efficacy Endpoint

- Defined as freedom from clinically-driven Target Lesion Revascularization[1] within 12 months

Primary Safety Endpoint

- Defined as freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven Target Vessel Revascularization within 12 months

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.

IN.PACT Global Study

Key Eligibility Criteria

Inclusion and exclusion criteria are intended to allow for evaluation of the IN.PACT™ Admiral™ DCB in a complex, real-world patient population

Inclusion Criteria

- Rutherford Class 2, 3 and 4
- Lesion(s) in SFA and/or popliteal artery
- Single or multiple stenosis or occlusions of any lesion length ≥ 2 cm
- De novo or restenotic (including ISR)
- At least one infrapopliteal run-off vessel

Exclusion Criteria

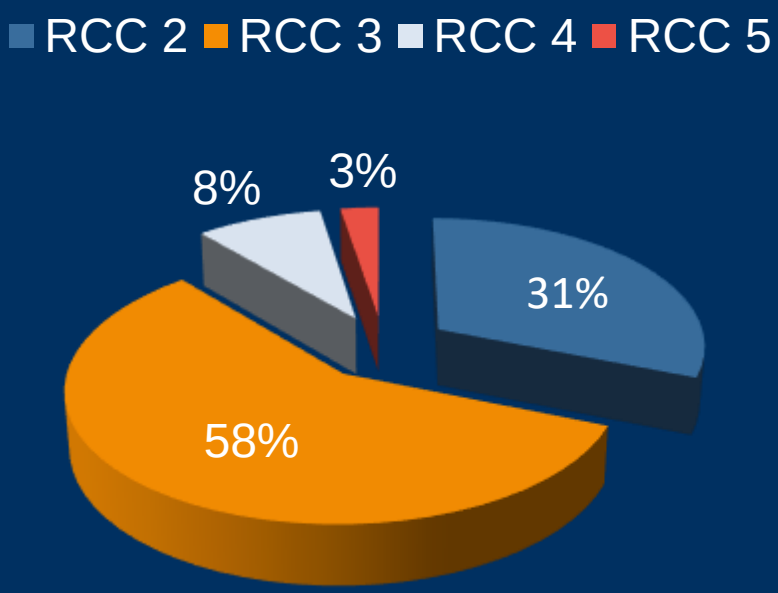
- Rutherford Class 5 and 6
- Acute or sub-acute thrombus in the target vessel
- Previous surgical bypass to the target lesion
- Failure to successfully cross the target lesion with a guidewire

IN.PACT Global Clinical Cohort

Baseline Characteristics

Characteristics	N=1406 Subjects
Age (Y, Mean ± SD)	68.6 ± 10.1
Male (%)	67.8% (953/1406)
Diabetes (%)	39.9% (560/1402)
Hypertension (%)	83.4% (1169/1401)
Hyperlipidemia (%)	70.5% (960/1362)
Current Smoker (%)	31.8% (447/1406)
Obesity (BMI ≥ 30 kg/m^2, %)	20.5% (285/1391)
Coronary Heart Disease (%)	40.5% (540/1332)
Carotid Artery Disease (%)	20.2% (241/1196)
Renal Insufficiency [1] (%)	11.2% (136/1217)
Previous Peripheral Revasc (%)	52.4% (737/1406)
Concomitant BTK Disease (%)	45.3% (594/1310)
ABI[2] (Mean ± SD)	0.678 ± 0.218

Rutherford Clinical Classification



1. Baseline serum creatinine ≥ 1.5 mg/dl
2. ABI for all target limbs treated during the 1st index procedure are included (can be bilateral)

IN.PACT Global Clinical Cohort

Lesion and Procedural Characteristics

Lesion Characteristics	N=1406 Subjects N=1773 Lesions
Lesion Type: % (n)	
De novo	74.4% (1326/1773)
Restenotic (non-stented)	7.7% (136/1773)
In-stent Restenosis	18.0% (320/1773)
Lesion Length (cm ± SD)	12.09 ± 9.54
Total Occlusions % (n)	35.5% (629/1773)
Calcification % (n)	68.7% (1217/1773)
Severe % (n)	10.2% (181/1771)
RVD (mm ± SD)	5.186 ± 0.681
Diameter Stenosis (% ± SD)	88.8% ± 12.3
Dissections:	
0	56.8% (1006/1772)
A-C	35.4% (627/1772)
D-F	7.8% (139/1772)

Procedural Characteristics	N=1406 Subjects N=1773 Lesions
Device Success [1] % (n)	99.4% (2984/3002)
Procedure Success [2] % (n)	99.3% (1386/1396)
Clinical Success [3] % (n)	98.8% (1379/1396)
Pre-dilatation % (n)	78.0% (1097/1406)
Post-dilatation % (n)	35.1% (491/1397)
Provisional Stent % (n)	25.3% (353/1397)

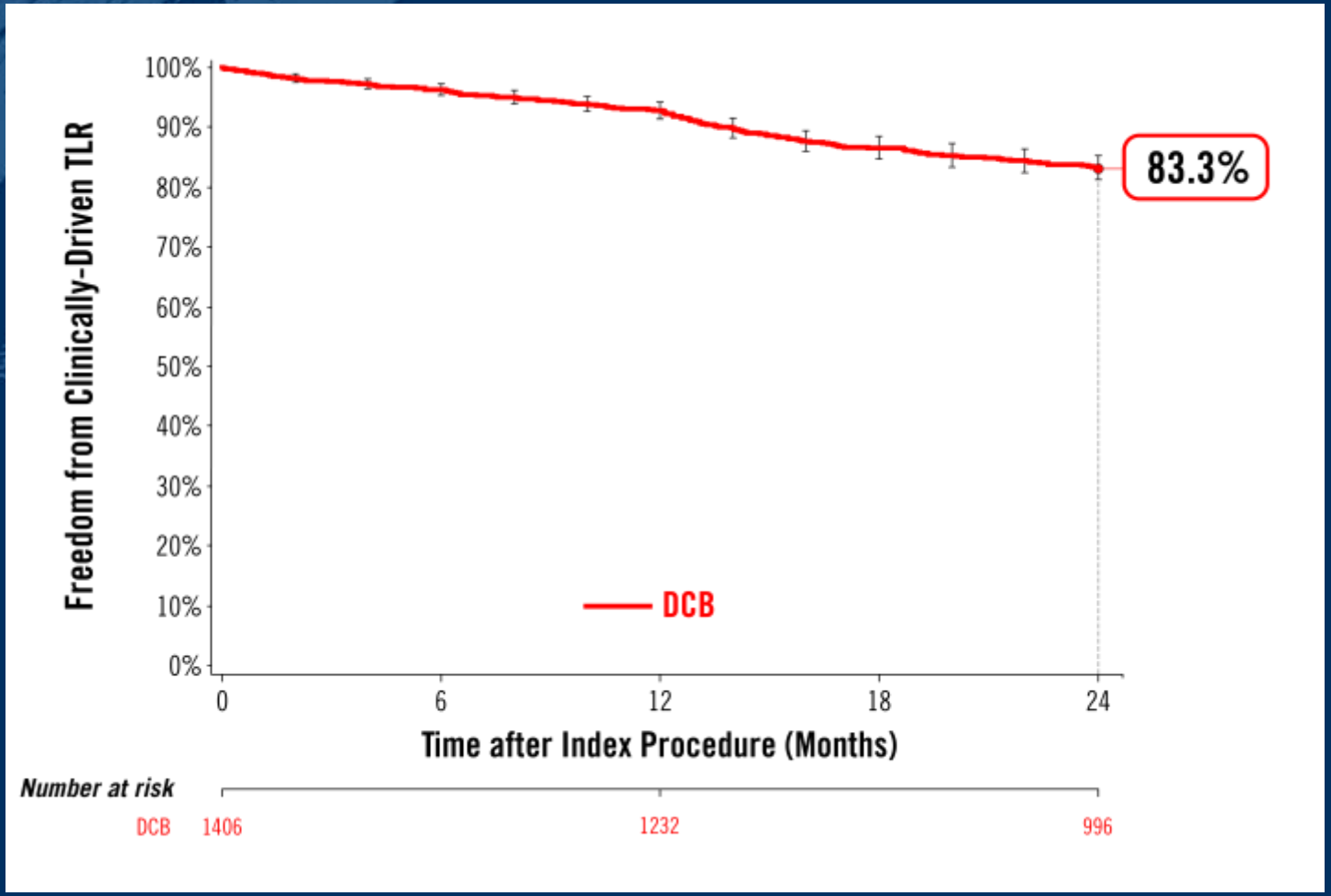
1. Device success defined as successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP.

2. Procedure success defined as residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects)

3. Clinical success defined as procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge.

IN.PACT Global Clinical Cohort

Freedom from CD-TLR through 2 Years



1. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window

IN.PACT Global Clinical Cohort

Additional Effectiveness Outcomes

	IN.PACT Global N= 1406 Subjects
Clinically-driven TLR[1]	16.9% (214/1269)
Any TLR[2]	17.2% (218/1269)
Primary Sustained Clinical Improvement[3]	68.6% (737/1075)

1. Clinically-driven TLR adjudicated by an independent Clinical Event Committee, blinded to the assigned treatment based on any re-intervention at the target lesion due to symptoms or drop of ABI of ≥20% or >0.15 when compared to post-procedure baseline ABI
2. Any TLR includes clinically-driven and incidental or duplex driven TLR
3. Primary sustained clinical improvement defined as freedom from target limb amputation, freedom from target vessel revascularization, and increase in Rutherford class at 24 months

IN.PACT Global Clinical Cohort

Safety Outcomes through 2 Years

	IN.PACT Global N= 1406 Subjects
Primary Safety Composite[1]	81.7% (1037/1269)
Major Adverse Events[2]	24.7% (314/1269)
All-cause Death	7.0% (89/1269)
Device or Procedure related Death (@ 30 days)	0.2% (3/1402)
CD-TVR	17.7% (224/1269)
Major Target Limb Amputation	0.7% (9/1269)
Thrombosis	4.5% (57/1269)

1. Safety composite endpoint consists of: Freedom from device- and procedure-related to 30 days, freedom from target limb amputation within 24 months; and freedom from clinically-driven TLR within 24 months.
2. Major Adverse Events (MAE) defined as all-cause death, clinically-driven TVR, major target limb amputation, thrombosis at the target lesion site at 720 days

IN.PACT Global Clinical Cohort

2-Year Outcomes Across IN.PACT Studies

Consistent performance of the IN.PACT™ Admiral™ DCB across SFA studies, with durable safety and effectiveness outcomes through 2 years.

	IN.PACT SFA (DCB ARM) (N=220)	IN.PACT Global Clinical Cohort (N= 1406)
Lesion Length (Mean ± SD, cm)	8.94 ± 4.89	12.09 ± 9.54
In-stent Restenosis (ISR) %	0.0%	18.0%
Chronic Total Occlusion (CTO) %	25.8%	35.5%
Primary Patency (KM @ 720 days)	78.9%	N/A
CD-TLR	**9.1%**	**16.9%**
Thrombosis	1.5%	4.5%
Major Amputation Target Limb	0.0%	0.7%

IN.PACT Global Clinical Cohort

Summary

- IN.PACT Global is the largest real-world study of DCB in patients with symptomatic femoropopliteal PAD, with independent clinical events committee and core-lab adjudication of outcomes in pre-specified imaging subgroups
- Results demonstrate durable treatment effect with the IN.PACT™ Admiral™ DCB in the clinical cohort, with a low reintervention rate of **16.9%** at 2 years
- Beneficial DCB treatment effect in diabetic patients who typically present with advanced, complex PAD
- Robust data set that continues to confirm safety and strong performance of the IN.PACT™ Admiral™ DCB in this cohort of real world patients

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