12-month Outcomes of Post Dilatation in the IN.PACT Global CTO Cohort

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

Study support and Advisory Board Medtronic

Background

- Currently no standard identified for the treatment of complex femoropopliteal lesions including CTOs
- Challenging to treat CTOs due to long lesion length, calcification and correlation with future limb loss[1-4]
- Existing CTO data focuses on access & lesion crossing and not correlation of **procedural characteristics** to follow-up outcomes

1. Staniloae CS, et al. J Invasive Cardiol. 2011 Sep;23(9):359-62
2. Liang, GZ, et al. International Journal of Cardiology. 2013 May;165(3):423–429
3. Bishop PD, et al. Ann Vasc Surg. 2008;22:799-805.
4. Füessl HS, et al. Klinische Wochenschrift. 1985;63:211-216.

IN.PACT Global Study

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

- **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**

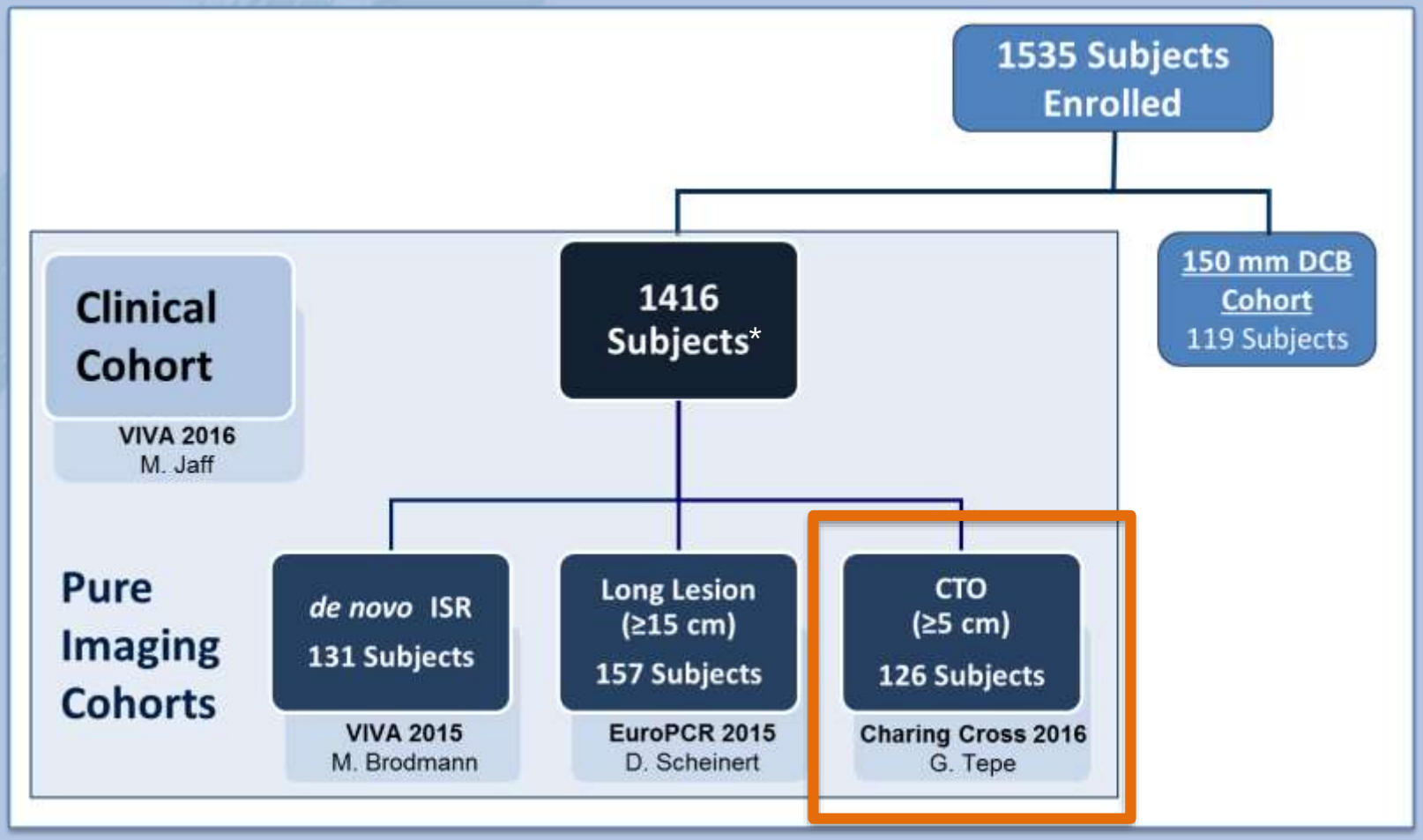
All-comers

- ✓ Bilateral disease
- ✓ Multiple lesions
- ✓ SFA and Popliteal Artery
- ✓ TASC A, B, C, D
- ✓ RCC 2-4
- ✓ De novo ISR
- ✓ Long Lesions
- ✓ CTOs

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

* Sponsored by Medtronic plc

IN.PACT Global Study Architecture



This presentation includes outcome data on the 126 subjects with pure CTO lesions enrolled in the CTO Imaging Cohort

* IN.PACT Global Clinical Cohort analysis based on the 1406 ITT subjects

IN.PACT Global Study
Primary Endpoints

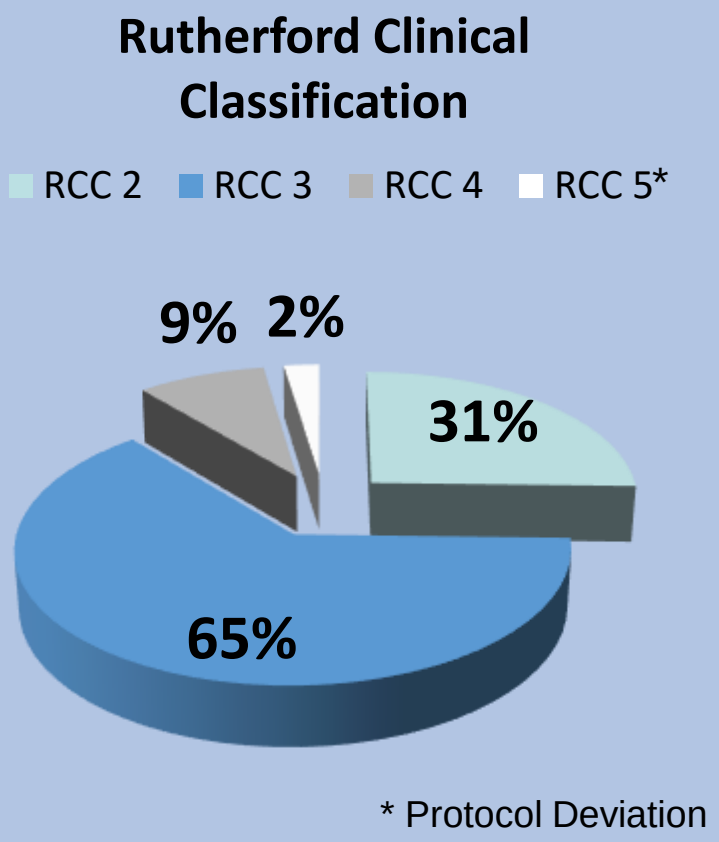
- **Primary Efficacy Endpoint:** Freedom from clinically-driven Target Lesion Revascularization[1] within 12 months

- **Primary Safety Endpoint:** Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven Target 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: CTO Imaging Cohort
Baseline Characteristics

Characteristics	N = 126 Subjects
Age (Y, Mean ± SD)	67.5 ± 10.4
Male % (n)	69.0% (87/126)
Diabetes % (n)	29.6% (37/125)
Hypertension % (n)	82.3% (102/124)
Hyperlipidemia % (n)	64.5% (78/121)
Current Smoker % (n)	49.2% (62/126)
Obesity % (n)	20.2% (25/124)
Coronary Heart Disease % (n)	24.1% (28/116)
Carotid Artery Disease % (n)	19.2% (19/99)
Renal Insufficiency[1] % (n)	10.0% (11/110)
Previous Peripheral Revasc. % (n)	33.3% (42/126)
Concomitant BTK Disease % (n)	41.0% (48/117)
ABI[2] (Mean ± SD)	0.593 ± 0.180



* Protocol Deviation

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 Study: CTO Imaging Cohort
Lesion and Procedural Characteristics

Lesion Characteristics	N = 126 Subjects N = 127 Lesions
Lesion Type: % (n)	
De novo	92.1% (117/127)
Restenotic (non-stented)	7.9% (10/127)
In-stent Restenosis	0.0% (0/128)
Lesion Length (cm ± SD)	22.83± 9.76
Occluded Lesion Length (cm ± SD)	11.86 ± 8.05
Calcification % (n)	71.0% (88/124)
RVD (mm ± SD)	5.049 ± 0.655
Diameter Stenosis (% ± SD)	100.0 ± 0.0
Dissections:	
0	32.3% (41/127)
A-C	44.1% (56/127)
D-F	23.6% (30/127)

Procedural Characteristics	N = 126 Subjects N = 127 Lesions
Device Success[1] % (n)	99.3% (283/285)
Procedure Success[2] % (n)	100% (125/125)
Clinical Success[3] % (n)	99.2% (124/125)
Pre-dilatation % (n)	94.4% (119/126)
Post-dilatation[4] % (n)	50.0% (63/126)
Provisional Stent % (n)	46.8% (59/126)

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) by core lab (if core lab was not available then the site-reported estimate was used).
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.
4. Post-dilatation is not required and is performed at the discretion of the investigator. In the event a post-dilatation is performed, it must be done with a balloon shorter than the lesion length to avoid geographic miss when initial DCB dilatation results in any of the following: Residual stenosis ≥ 50% (by visual estimate); Trans-lesional gradient is >10 mm Hg; Presence of a flow-limiting dissection.

Results Across IN.PACT Clinical Studies at 1 year

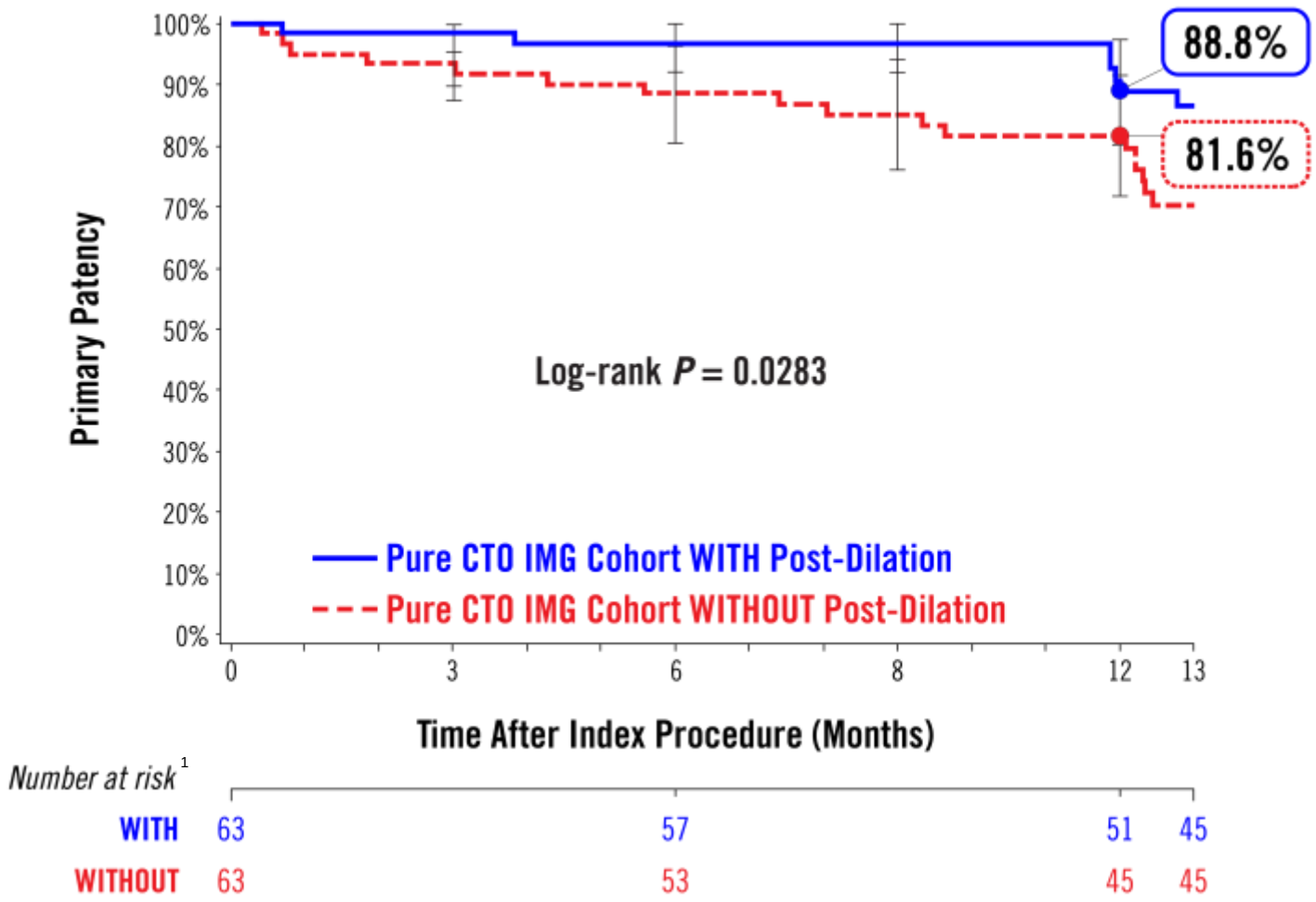
Consistent clinical outcomes with the IN.PACT™ Admiral™ DCB across studies and complex femoropopliteal lesions.

	IN.PACT SFA (DCB Arm) (N= 220)	IN.PACT GLOBAL Long Lesion Imaging Cohort (N= 157)	IN.PACT GLOBAL ISR Imaging Cohort (N= 131)	IN.PACT GLOBAL CTO Imaging Cohort (N= 126)
Lesion Length (Mean ± SD, cm)	8.94 ± 4.89	26.40 ± 8.61	17.17 ± 10.47	22.83 ± 9.76 (occluded length of 11.86 ± 8.05)
Primary Patency[1]	87.5%	91.1%	88.7%	85.3%
CD-TLR	2.4%	6.0%	7.3%	11.3%
Primary Safety Endpoint[2]	95.7%	94.0%	91.1%	88.7%
Major Target Limb Amputation	0.0%	0.0%	0.0%	0.0%

1. Kaplan-Meier survival estimate at 12 months
2. Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR.

IN.PACT Global Study: CTO Imaging Cohort (subgroup analysis with and without post dilation)

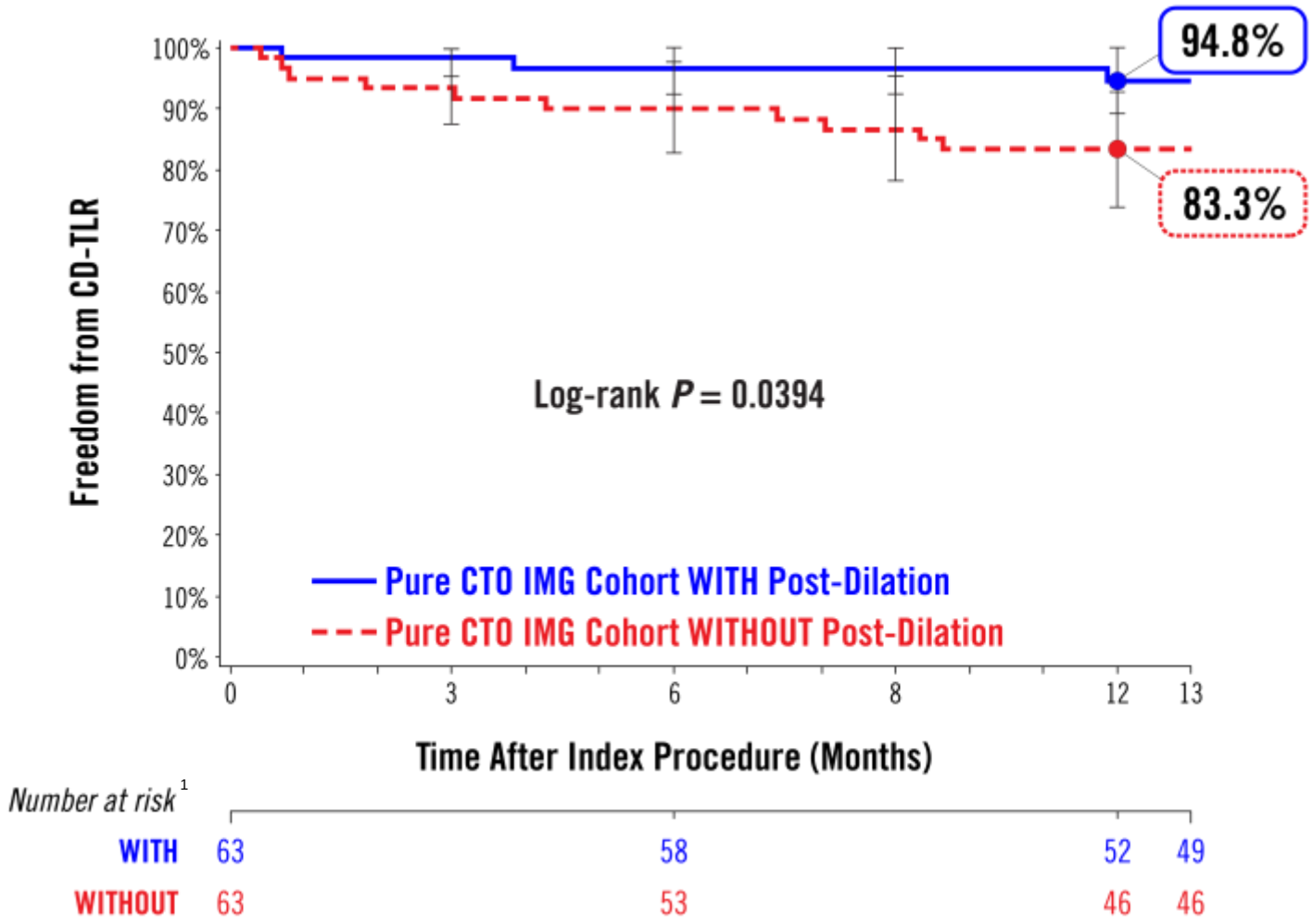
12 month Primary Patency



1. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window

IN.PACT Global Study: CTO Imaging Cohort (subgroup analysis with and without post dilation)

12 month Freedom from CD-TLR



1. Number at risk represents the number of evaluable subjects at the beginning of the each 30-day window

Summary

In this sub analysis of post dilation in the IN.PACT Global CTO imaging cohort, there was a significant difference between with and without post dilation groups.

12 month primary patency

88.8% with post dilation

81.6% without post dilation ❯ (P=0.0283)

12 month Freedom from CD-TLR

94.8% with post dilation

83.3% without post dilation ❯ (P=0.0394)

These finding elucidate the need for further research in procedural differences during drug-coated balloon angioplasty techniques.

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