Lessons Learned from the IN.PACT DCB GLOBAL Registry - Chronic Total Occlusion (CTO) Imaging Cohort: How to make DCBs work best with CTOs

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DISCLOSURES
Consulting/Honoraria
• Medtronic
• BARD
• Spectranetics
• Intact Vascular
• Biotronik
• Bayer
• Daiichi
• Böhringer Ingelheim
• Astra Zeneca

Background
- No current 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
- Lack of evidence addressing CTO treatment outcomes: Existing CTO data focuses on access & lesion crossing
- Need exists to demonstrate evidence-based effectiveness of DCBs in the treatment of CTOs
- IN.PACT Global CTO imaging cohort allow sub-analysis to evaluate some aspects of procedural technique on outcomes

IN.PACT Global Study Overview and Architecture
Real-world, prospective, multicenter, single arm independently adjudicated femoropopliteal study
- Independent adjudication by Clinical Events Committee
- Prospective subset analysis with core lab reported results (de novo ISR, long lesions ≥15 cm, CTOs ≥5 cm)
- Safety and effectiveness data on 150 mm DCB

IN.PACT Global: CTO Imaging Cohort
Baseline Characteristics

Lesion and Procedural Characteristics
IN.PACT Global: CTO Imaging Cohort
Primary Patency Results Through 1 year

1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee)
2. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window and prior to each follow-up interval

IN.PACT Global: CTO Imaging Cohort
True Lumen vs Subintimal Sub-analysis
Primary Patency Results Through 1 year

IN.PACT Global Study: CTO Imaging Cohort
Subgroup Analysis With and Without Post Dilation
Primary Patency Results Through 1 year

IN.PACT Global: CTO Imaging Cohort
Summary
- IN.PACT global is the largest real-world study of DCB with independent clinical events committee and core-lab adjudication of outcomes in prespecified imaging subgroups
- 12-month results demonstrate remarkable effectiveness of the IN.PACT Admiral DCB in CTO lesions, irrespective of lesion crossing profile
- Further sub-analysis show a significant difference in patency outcomes between groups with and without post dilation stressing the need for adequate vessel preparation
- These finding elucidate the need for further research in procedural differences during drug-coated balloon angioplasty techniques.