Long Lesions: Primary stenting or DCB first?

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Disclosures
John R. Laird

- Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	Boston Scientific, Medtronic, Abbott, Bard/Becton Dicksenson Peripheral Intervention, Philips
Scientific Advisory board/stock options	Reflow Medical, Endoluminal Sciences, Syntervention, PQ Bypass, Eximo Medical, Shockwave Medical, NexGen

Board Member VIVA Physicians

Background

- The majority of data examining PAD treatment effectiveness is on short 5-15 cm lesions from IDE trials
- Real-world results from real-world patients demonstrate significantly worse outcomes for PTA and bare metal stent technologies. Promising results for DCB in real world registries
- With 1416 patients IN.PACT Global is the largest core-lab adjudicated trial of DCBs in the femoral-popliteal artery
- A sub-analysis of the patients with the longest and most complex lesions is presented here

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◆CLINICAL INVESTIGATION ◆

Nitinol Self-Expanding Stents vs. Balloon Angioplasty for Very Long Femoropopliteal Lesions

Ehrin J. Armstrong, MD, MSc[1]; Haseeb Saeed, MD[2]; Bejan Alvandi, BS[2]; Satinder Singh, MD[2]; Gagan D. Singh, MD[2]; Khung Keong Yeo, MBBS[2]; David Anderson, BA[2]; Gregory G. Westin, BA[2]; David L. Dawson, MD[3]; William C. Pevec, MD[3]; and John R. Laird, MD[2]

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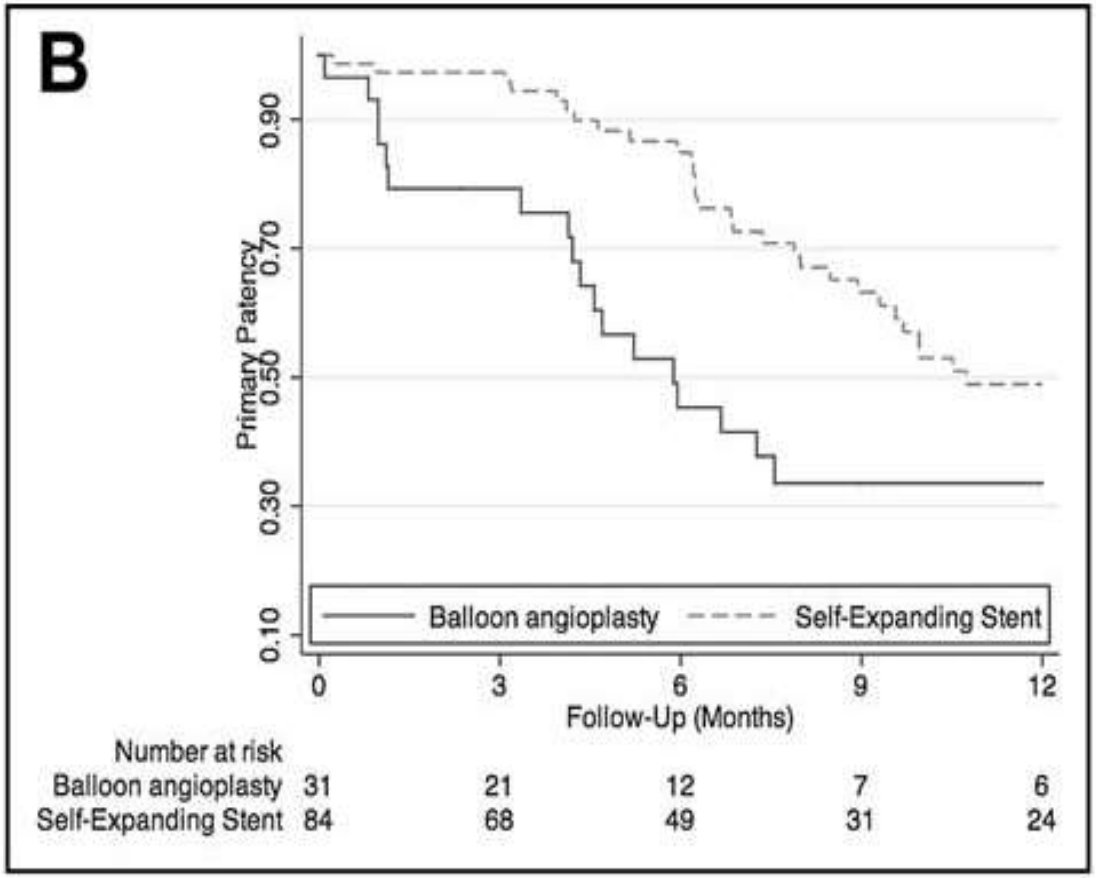
- The mean lesion length was 254±58 mm in the long FP lesion group
- 58% underwent stent placement

Results



Primary patency of balloon angioplasty vs. stenting was 34% vs. 49% (p = 0.006)

Primary Patency at 12 months

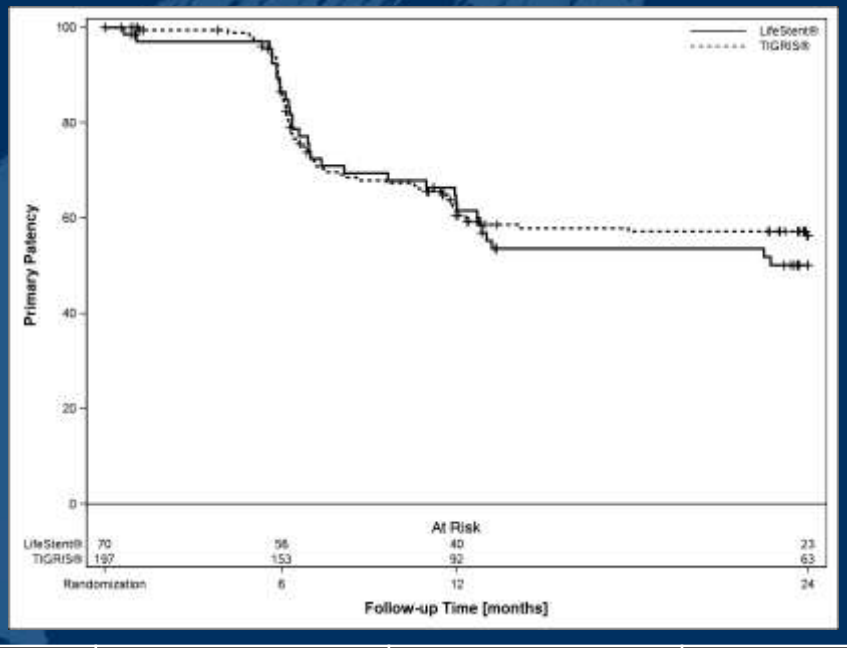
JEVT 2014;21:34-43

TIGRIS Trial
Long Lesion Stenting

- Randomized trial of TIGRIS stent vs. Bard LifeStent for long SFA Lesions (up to 24 cm)
- 274 patients randomized 3:1 between TIGRIS and LifeStent
- Total stented length 129.0 cm (TIGRIS) vs. 148.7 cm (LifeStent)
- CTO in 42.1% (TIGRIS) and 37.1% (Lifestent)

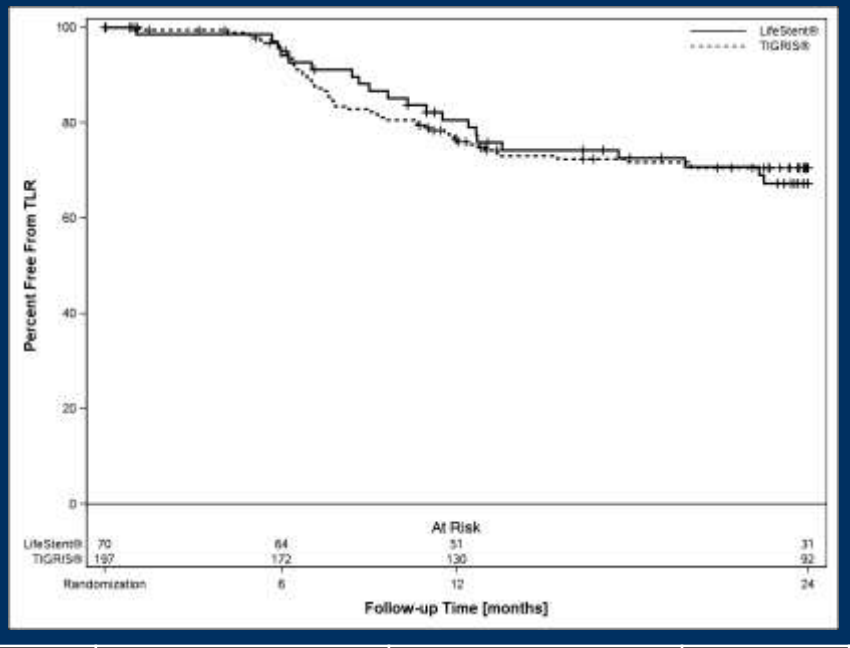
Kaplan-Meier Estimated 2-Year Primary Patency and fTLR

Primary Patency



Day	GORE® TIGRIS® Vascular Stent	BARD® LIFESTENT® Vascular Stent	p value
365	60.6%	63.2%	0.73
730	56.3%	50.2%	0.49

Freedom from TLR



Day	GORE® TIGRIS® Vascular Stent	BARD® LIFESTENT® Vascular Stent	p value
365	76.6%	80.6%	0.49
730	70.5%	67.2%	0.85

24 Month Fracture Rates

	GORE® TIGRIS® VASCULAR STENT*	BARD® LIFESTENT® VASCULAR STENT*
STENT FRACTURES OBSERVED AT 24-MONTH FOLLOW UP	**0%** (0/180)	28.8% (17/59)
Grade 1: single strut fracture	0 (0.0%)	1 (5.9%)
Grade 2: multiple strut fractures	0 (0.0%)	3 (17.6%)
Grade 3: stent fracture retaining alignment	0 (0.0%)	3 (17.6%)
Grade 4: misaligned stent fractures	**0 (0.0%)**	**5 (29.4%)**
Grade 5: transaxial-spiral fracture	**0 (0.0%)**	**5 (29.4%)**

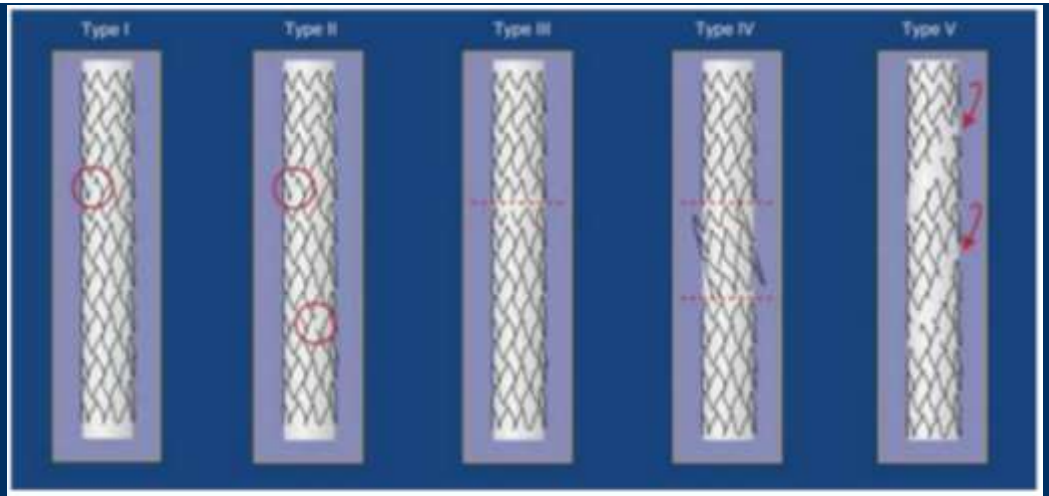


Fig. 2. Stent fracture grading (modified from Rocha-Singh, et al. Catheter Cardiovasc Interv 2007; published online March 21, 2007). [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

DCB for Long Fem-Pop Lesions

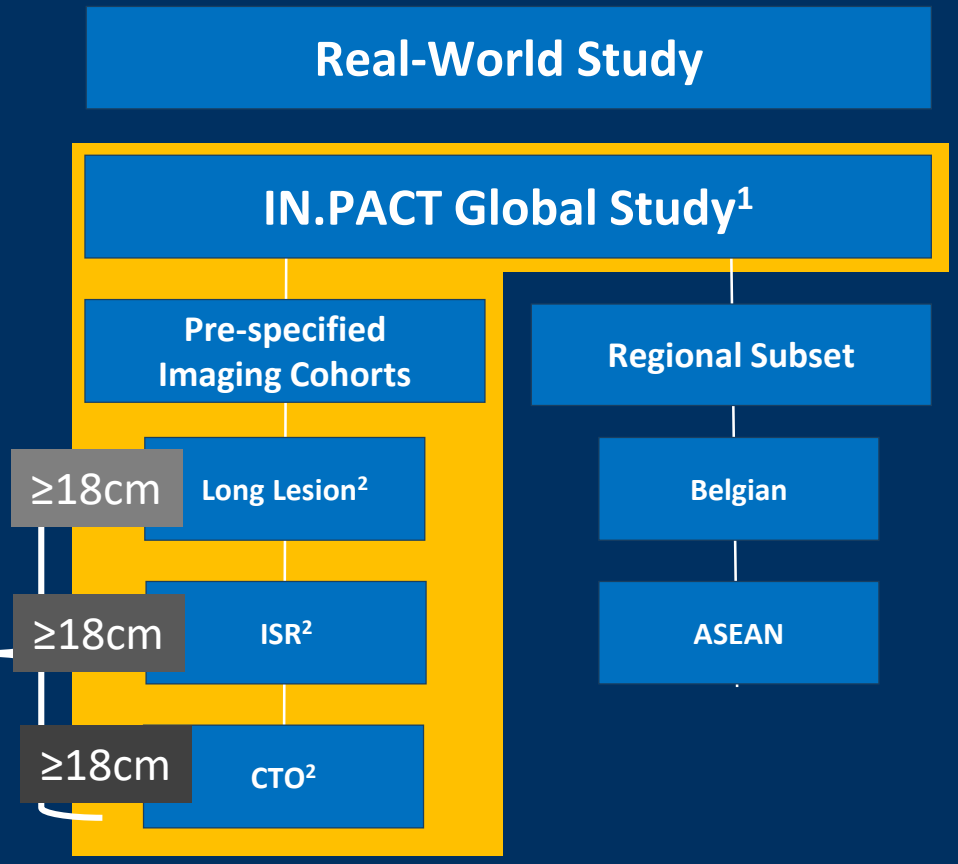
Long and Complex lesions drawn from IN.PACT Global imaging cohorts

Complex lesion pooled analysis

Mean Lesion Length 28.4cm

n=227

Subjects enrolled in IN.PACT Global imaging cohorts with single lesions >18cm were retrospectively analyzed
- 12-mo primary patency
- 12-mo safety composite endpoints



1. Core lab-adjudicated with clinical events committee oversight.
2. Clinical events committee oversight.

Baseline Patient Characteristics

Clinical Characteristics and ABI

	IN.PACT™ Admiral™ DCB n = 227 subjects
Age, ± SD	68.8 ± 9.7
Male Gender	67.4% (153/227)
Diabetes	38.7% (87/225)
Current Smoker	42.7% (97/227)
Hypertension	86.7% (197/227)
Hyperlipidemia	71.7% (157/219)
ABI / TBI, ± SD[1]	0.625 ± 0.214

Rutherford Class

	IN.PACT™ Admiral™ DCB n = 227 subjects
RCC 2	22.5% (51/227)
RCC 3	65.5% (148/227)
RCC 4	12.3% (28/227)
RCC 5	0.0% (0/227)

1. ABI for all target limbs treated during the 1st index procedure are included (can be bilateral).

Angiographic Characteristics

Angiographic Characteristics

	IN.PACT™ Admiral™ DCB n = 227 subjects and lesions
Lesion (N)	
De novo	67.0% (152/227)
Restenotic (non-stent)	12.8% (29/227)
In-stent restenotic	20.3% (46/227)
Lesion Length, ± SD	28.74 ± 7.11
Total Occlusions	70.1% (157/224)
RVD, ± SD	4.611 mm ± 0.896
Diameter Stenosis, ± SD	94.1% ± 10.7
Calcification (%)[1]	
None	26.9% (59/219)
Mild	37.4% (82/219)
Moderate	11.9% (26/219)
Moderately Severe	10.0% (22/219)
Severe	13.7% (30/219)

1. Dattilo R, et al. J Invasive Cardiol 2014;26:355-360. Severe calcium definition used by study sites and core laboratory as bilateral calcium at the same location (also measured in sections), ≥ half of the total lesion length, ≥180◦ (both sides of the vessel at the same location).

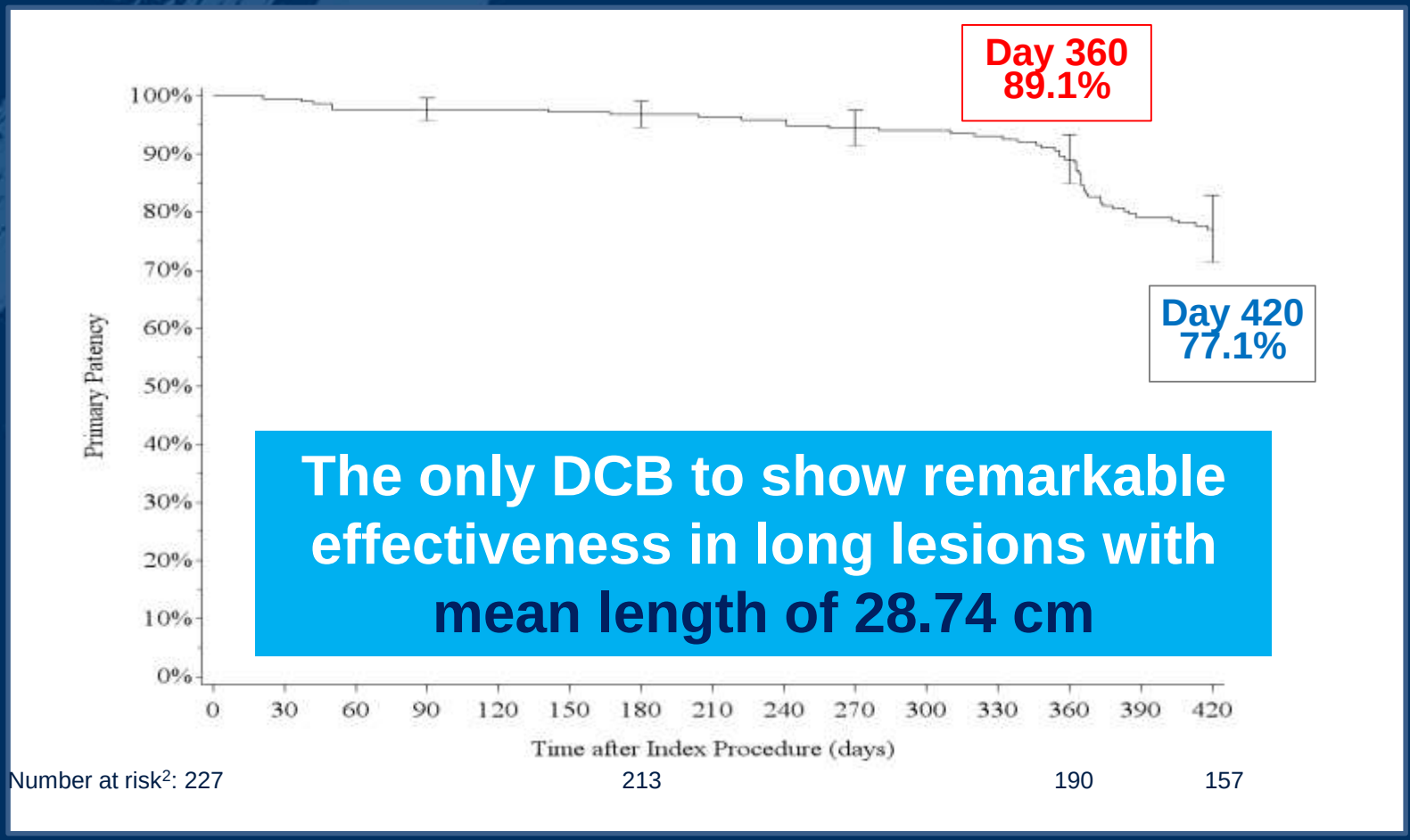
Procedural Characteristics

Procedural Characteristics[1]

	IN.PACT™ Admiral™ DCB n = 227 subjects
Pre-dilatation (%)	89.0% (202/227)
Post-dilatation (%)	44.7% (101/226)
Dissections(%)	
None	36.1% (82/227)
A-C	35.6% (81/227)
D-F	19.3% (44/227)
Provisional Stenting (%)	42.5% (96/226)
Device Success (%)[2]	99.2% (653/658)
Procedural Success (%)[3]	99.1% (224/226)
Clinical Success (%)[4]	99.1% (224/226)

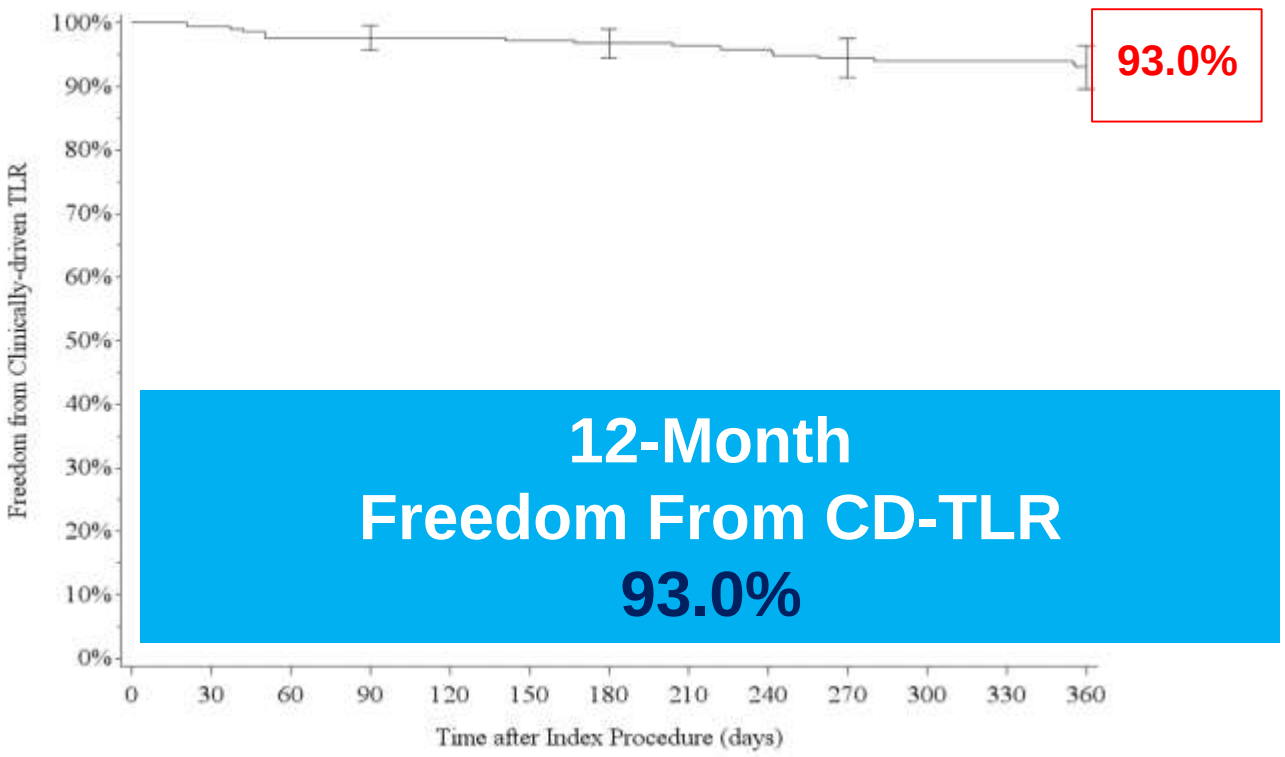
1. All ITT subjects (stented and non-stented)
2. Device success defined as successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP.
3. Procedure success defined as residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site-reported estimate was used).
4. Clinical success defined as procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge.

Primary Patency through 12-Months



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 36 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment).
2. Number at risk represents the number of evaluable subjects at the beginning of each 60-day window.

Freedom from CD-TLR through 12-Months



1. Clinically-driven TLR adjudicated by an independent Clinical Events 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. Number at risk represents the number of evaluable subjects at the beginning of each 30-day window.

Safety Outcomes through 12-Months

Safety Outcomes

12-Month Outcome	IN.PACT™ Admiral™ DCB (n = 227)
Primary Safety Composite[1]	92.9% (195/210)
Major Adverse Events[2]	10.5% (22/210)
All-cause Death	2.4% (5/210)
Device- and Procedure-related Death through 30 days	0.0% (0/225)
CD-TVR	7.1% (15/210)
Major Target Limb Amputation	0.0% (0/210)
Thrombosis	3.3% (7/210)

Rare Adverse Events

12-Month Outcome	IN.PACT™ Admiral™ DCB (n = 227)
Paclitaxel-related Thrombosis within 30 Days	0.0% (0/225)
Paclitaxel-related Distal Embolic Events within 360 Days	0.0% (0/210)
Paclitaxel-related Neutropenia within 360 Days	0.0% (0/210)
Paclitaxel-related Drug Hypersensitivity/Reaction within 360 Days	0.0% (0/210)

1. Safety Composite Endpoint consists of: freedom from device/procedure related death to 30 days; freedom from target limb amputation within 12 months; and freedom from clinically-driven TVR within 12 months.
2. Composite of death, clinically-driven TVR, target limb major amputation, and thrombosis.

Summary

- Retrospective analysis of IN.PACT Global Imaging Cohort patients exhibiting single lesions longer than 18cm
  - **28.74cm mean lesion length**
  - 70.1% CTO
  - 20.3% ISR
- Real-world use of DCB
  - 89.0% Pre-dilatation and 44.7% post-dilatation
  - 42.5% provisional stent

Effectiveness consistent to other IN.PACT Clinical cohorts

- Primary patency: 89.1%
- Freedom from CD-TLR 93.0%

- Demonstrated high degree of safety
  - Zero amputations
  - Zero paclitaxel-associated rare adverse events

Conclusions

- This data supports the use of DCB as primary therapy with stenting if and when needed
- Superior results compared to historical data for PTA and BMS for long fem-pop lesions
- DCBs are a safe and effective tool to treat even the most complex lesion types

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