IN.PACT SFA: 2 Year Data

Peter A. Schneider, MD
Kaiser Foundation Hospital
Honolulu, Hawaii

Disclosure

Peter A. Schneider

.....

I have the following potential conflicts of interest to report:

- ☑ Scientific Advisory Board (non-paid): Cardinal, Abbott, Medtronic
- ☑ Royalty (modest): Cook
- ☑ Co-founder and Chief Medical Officer: Intact, Cagent

IN.PACT SFA Trial Overview

Objective: Assess the safety and efficacy of IN.PACT Admiral DCB vs. standard PTA for the treatment of superficial femoral and proximal popliteal artery disease due to claudication and rest pain

- Prospective, multicenter EU and US, randomized (2:1), single-blinded trial
- 331 patients enrolled:
- IN.PACT DCB (n = 220) *vs.* PTA (n = 111)
- Rutherford Clinical Category 2-4
- Lesion lengths 4-18 cm or occlusions ≤ 10 cm
- Subjects followed up to 5 years
- Independent and blinded Duplex Ultrasound Core Lab,[1] Angiographic Core Lab,[2] and Clinical Events Committee[3]

1. VasCore DUS Core Laboratory, Boston, MA, US; 2. SynvaCor Angiographic Core Laboratory, Springfield, IL, US;
3. Clinical Events Committee and Data Safety Monitoring services provided by HCRI, Boston, MA, US

IN.PACT SFA: Investigators and Sites

IN.PACT SFA I

M.
G.
T. Z
D.
A.
I. B
S.

IN.PACT SFA II

M. Mewissen, Milwaukee, WI, USA
R. Brown, Waco, TX, USA
G. Petrossian, Roslyn, NY, USA
A. Patel, Morristown, NJ, USA

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. ■, NO. ■, 2015

PUBLISHED BY ELSEVIER INC.
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2015.08.063

Sustained Durability of Treatment Effect Using a Drug-Coated Balloon for Femoropopliteal Lesions

24-Month Results of IN.PACT SFA

John R. Laird, MD,* Peter A. Schneider, MD,† Gunnar Tepe, MD,‡ Marianne Brodmann, MD,§ Thomas Zeller, MD,‖ Christopher Metzger, MD,¶ Prakash Krishnan, MD,# Dierk Scheinert, MD,** Antonio Micari, MD, PhD,†† David J. Cohen, MD, MSc,‡‡ Hong Wang, MD, MPH,§§ Melissa S. Hasenbank, PhD,§§ Michael R. Jaff, DO,‖‖ for the IN.PACT SFA Trial Investigators

IN.PACT SFA Trial

Blinded, Independently Assessed Outcomes

Primary Efficacy Endpoint	Primary patency within 12 months, defined as freedom from clinically-driven TLR and DUS-derived restenosis (PSVR ≤ 2.4)
Primary Safety Endpoint	Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven TVR within 12 months

- MAEs (including all individual components of the primary endpoints and key secondary endpoints) are adjudicated by the blinded CEC through 5 years
- Restenosis is assessed by the blinded Duplex and Angiographic Core Labs through the 3-year follow-up visits

Baseline Clinical Characteristics

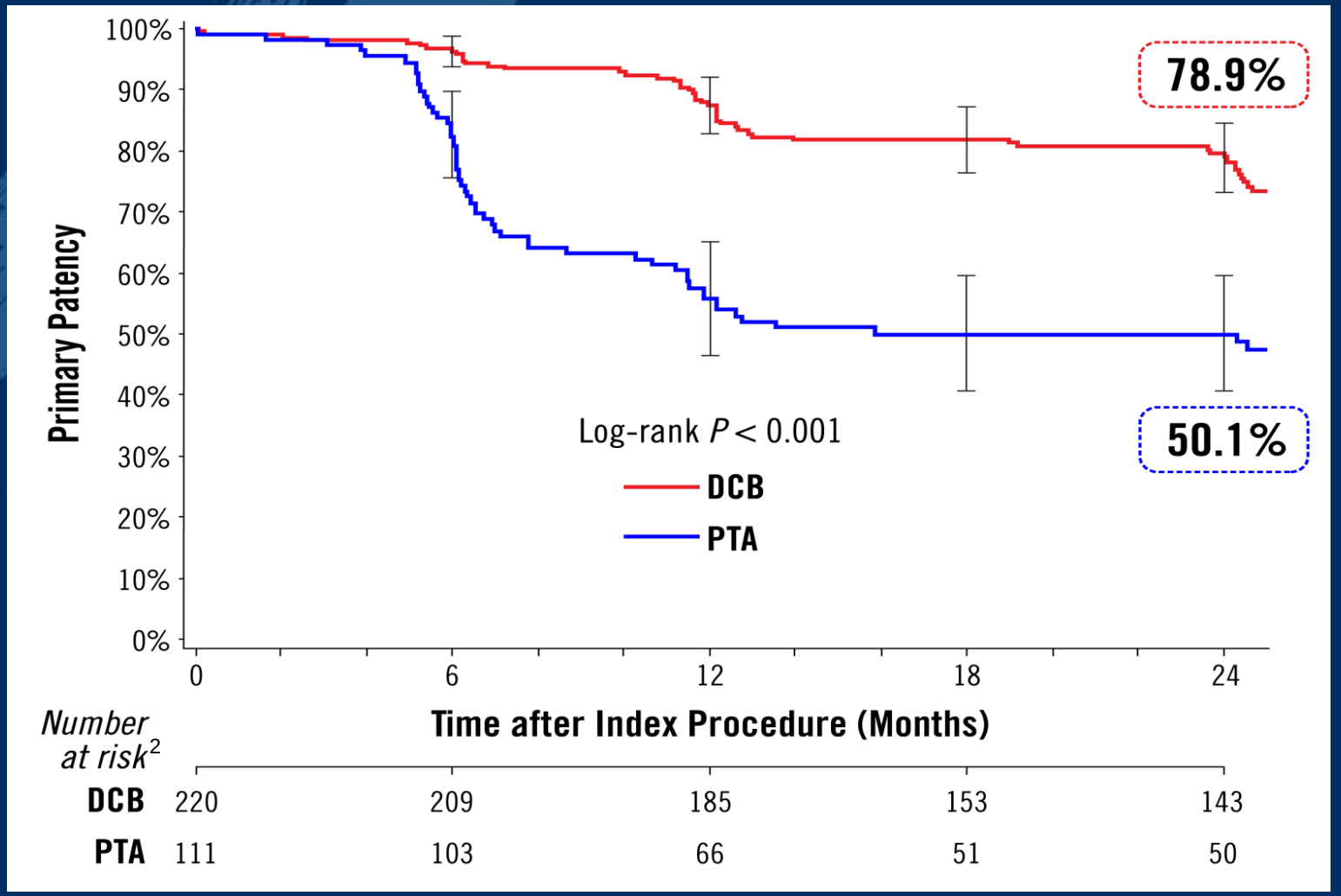
	IN.PACT n = 220 subjects	PTA n = 111 subjects	p
Age, Y ± SD	67.5 ± 9.5	68.0 ± 9.2	0.612
Male, % (n)	65.0% (143/220)	67.6% (75/111)	0.713
Diabetes, % (n)	40.5% (89/220)	48.6% (54/111)	0.161
Hypertension, % (n)	91.4% (201/220)	88.3% (98/111)	0.431
Current smoker, % (n)	38.6% (85/220)	36.0% (40/111)	0.719
Rutherford class, % (n) **2** **3** **4** **5**	 37.7% (83/220) 57.3% (126/220) 5.0% (11/220) 0.0% (0/220)	 37.8% (42/111) 55.9% (62/111) 5.4% (6/111) 0.9% (1/111)	0.898
ABI / TBI, ± SD [1]	0.769 ± 0.228	0.744 ± 0.189	0.308

1. TBI allowed in cases of incompressible vessels in IN.PACT SFA II phase

Baseline Lesion Characteristics

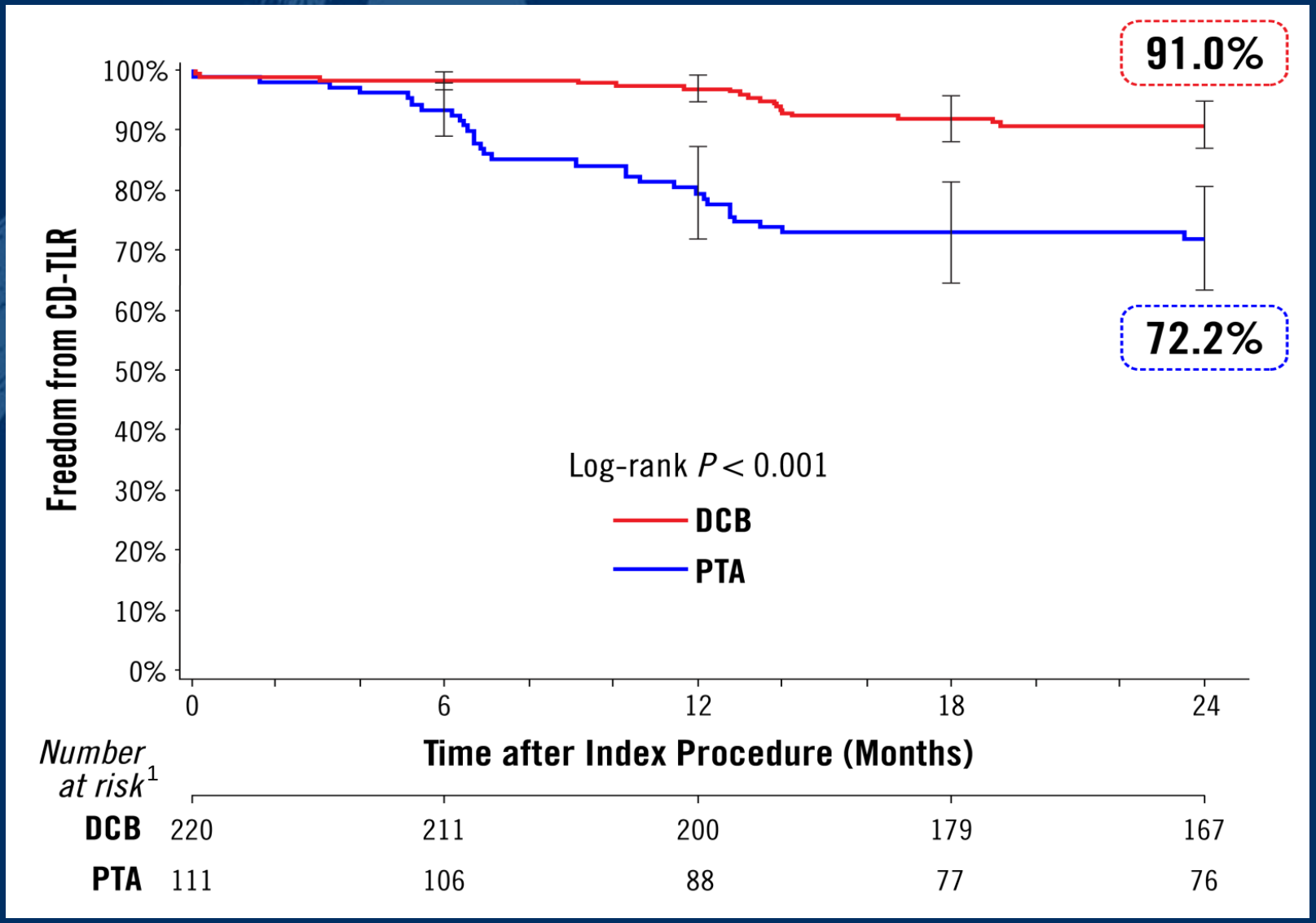
	IN.PACT n = 220 Subjects, n = 221 Lesions	PTA n = 111 Subjects, n = 113 Lesions	p
Lesion length (cm ± SD)	8.94 ± 4.89	8.81 ± 5.12	0.815
Total occlusions, % (n)	25.8% (57/221)	19.5% (22/113)	0.222
Calcification, % (n)	59.3% (131/221)	58.4% (66/113)	0.907
Severe calcification, % (n)	8.1% (18/221)	6.2% (7/113)	0.662
Provisional stenting, % (n)	7.3% (16/220)	12.6% (14/111)	0.110

Primary Patency[1] Results through 2 Years



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 24 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 the 30-day window prior to each follow-up interval

Freedom from CD-TLR through 2 Years



1. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval

IN.PACT SFA Trial

Effectiveness Outcomes Through 2 Years

2-Year Outcomes	IN.PACT n = 220	PTA n = 111	p*
Clinically-driven TLR [1]	9.1% (18/198)	28.3% (30/106)	< 0.001
All TLR [2]	10.1% (20/198)	29.2% (31/106)	< 0.001
Primary Sustained Clinical Improvement [3]	76.9% (133/173)	59.2% (61/103)	0.003

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. All TLR includes clinically-driven and incidental or duplex driven TLR
3. Freedom from target limb amputation, target vessel revascularization (TVR), and increase in Rutherford class

* Unless otherwise indicated, all tests were for superiority using the Fisher's exact test for binary variables and t-test for continuous variables

IN.PACT SFA Trial

Safety Outcomes through 2 Years

2-Year Outcomes	IN.PACT n = 220	PTA n = 111	p*
Primary Safety Composite [1]	87.4% (173/198)	69.8% (74/106)	< 0.001
Major Adverse Events [2]	19.2% (38/198)	31.1% (33/106)	0.023
All-cause Death †	8.1% (16/198)	0.9% (1/106)	0.008
Device or Procedure-related Death	0.0% (0/198)	0.0% (0/106)	> 0.999
Target Limb Major Amputation	0.0% (0/198)	0.0% (0/106)	> 0.999
Thrombosis	1.5% (3/198)	3.8% (4/106)	0.243

1. Freedom from 30-day device and procedure-related death and target limb major amputation and clinically-driven TVR within 12 (24) months
2. Composite of death, clinically-driven TVR, target limb major amputation, and thrombosis

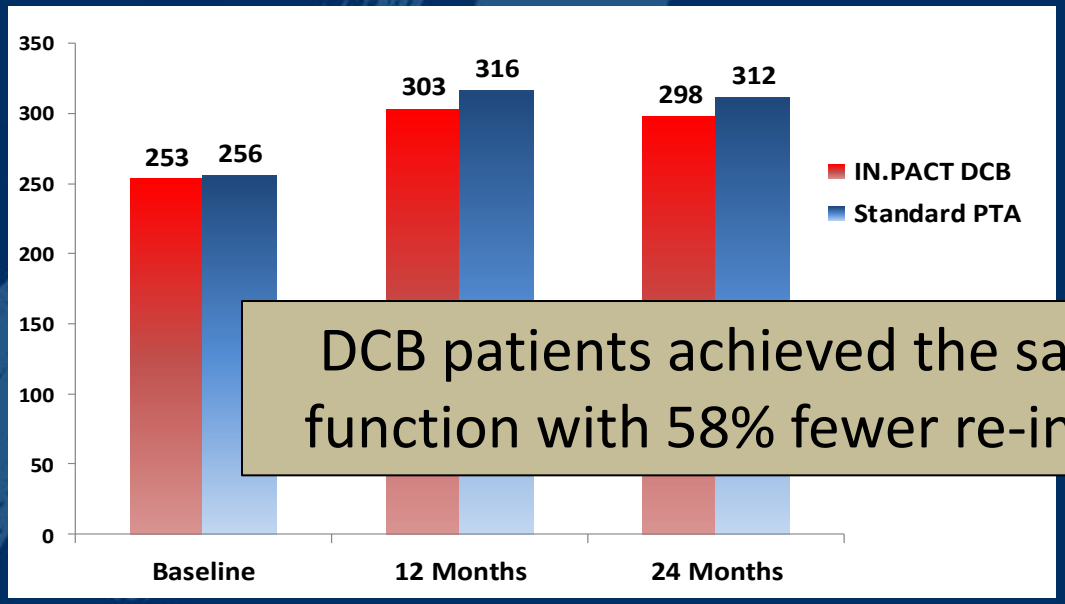
* p-values are based on Fisher's exact test for superiority with significance level of 0.05

† No deaths were adjudicated as device- or procedure-related by the CEC; Median post-index days to death: 564.5 days in DCB vs. 397 days in PTA

All-Cause Mortality through 2 Years

Causes of Death Through 2 Years	Treatment Group	Days to Death	CEC Adjudication	
			Procedure-related	Device-related
Cardiac-related				
Acute Diastolic Congestive Heart Failure	DCB	540	NO	NO
Cardiac Arrest	DCB	568	NO	NO
Cardiac Arrest	DCB	610	NO	NO
CAD	DCB	615	NO	NO
Ischemic Cardiomyopathy	DCB	699	NO	NO
Malignancy				
Metastatic Colon Cancer	PTA	397	NO	NO
GI Cancer	DCB	561	NO	NO
Respiratory-related				
Acute Respiratory Failure	DCB	657	NO	NO
Hypoxic Respiratory Failure	DCB	681	NO	NO
Other				
Infarction of Right Cerebral Hemisphere in Anterior & Medial Flow Region	DCB	127	NO	NO
Biliary Sepsis	DCB	168	NO	NO
Perforated Transverse Colon Secondary to Cecal Volvulus	DCB	314	NO	NO
Sepsis	DCB	374	NO	NO
Deterioration of General Condition	DCB	603	NO	NO
Dementia	DCB	679	NO	NO
Unknown				
Sudden Death	DCB	287	NO	NO
Unknown	DCB	541	NO	NO

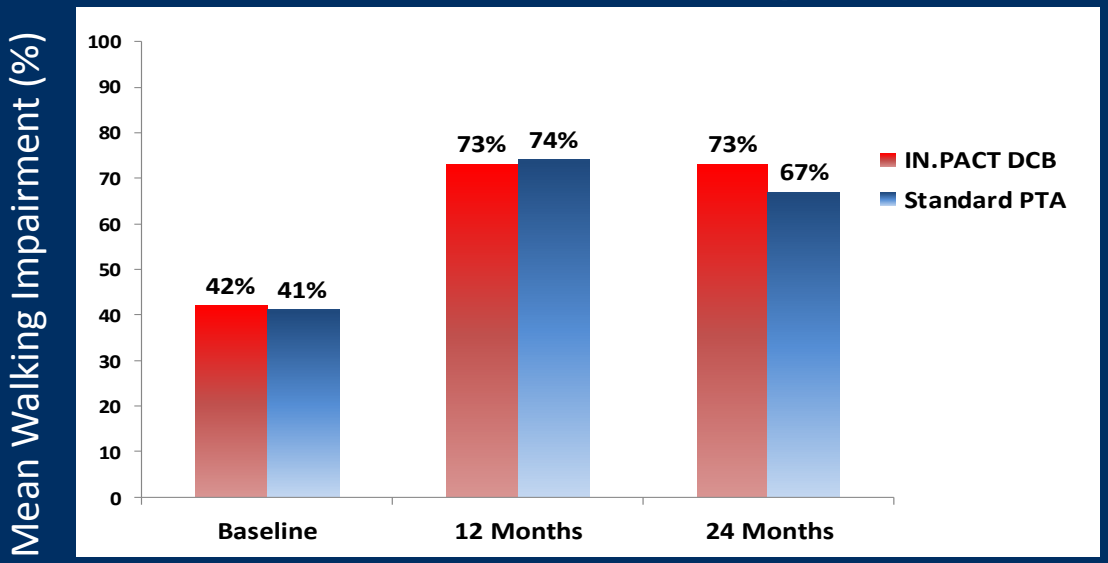
2-Year Functional Outcomes



6-Minute Walk Test

DCB patients achieved the same level of function with 58% fewer re-interventions

Walking Impairment



Conclusions

Two-year results demonstrate continued superiority of the IN.PACT DCB over PTA

- Sustained durability with no late catch-up through 2yrs.

	DCB	PTA	Δ	p-value
Primary Patency	**78.9%**	50.1%	**28.8%**	<0.001
CD-TLR	**9.1%**	28.3%	**19.2%**	<0.001

- DCB produced similar functional outcomes with 58% fewer re-interventions
- Driving a major change in SFA interventions

IN.PACT SFA: 2 Year Data

Peter A. Schneider, MD
Kaiser Foundation Hospital
Honolulu, Hawaii