PRIMARY ENDPOINT RESULTS OF THE IN.PACT AV ACCESS RANDOMIZED TRIAL: OUTCOMES THROUGH SIX MONTHS

Andrew Holden, MBChB, FRANZCR, EBIR
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Medtronic
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DISCLOSURES

Speaker name: Andrew Holden, MBChB, FRANZCR, EBIR

I have the following potential conflicts of interest to report:

X **Consulting – Medtronic, Gore, Boston Scientific**

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

- In 2016, 500,000 patients in the United States received hemodialysis at least three times a week to treat ESRD[1]
- Hemodialysis arteriovenous fistula and grafts experience high rates of dysfunction[2-5]
  - Primary patency AVF/AVG through 12 months: 48-80%

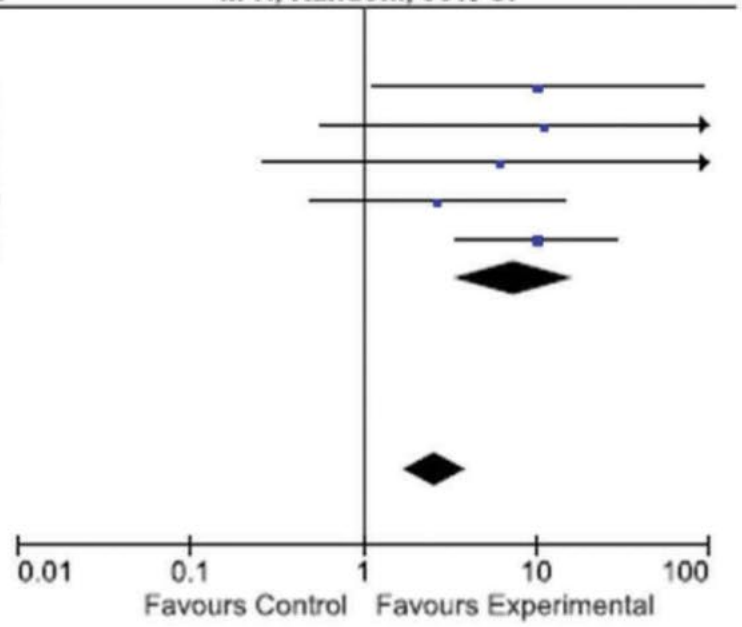
    24 months: 50-80%

1. United States Renal Data System. 2018 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. Available at https://www.usrds.org/adr.aspx
2. Almasri J, Alsawas M, Mainou M et al. Outcomes of vascular access for hemodialysis: A systematic review and meta-analysis. J Vasc Surg 2016;64:236-43.
3. Al-Jaishi AA, Oliver MJ, Thomas SM et al. Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis. Am J Kidney Dis 2014;63:464-78.
4. Palder SB, Kirkman RL, Whittemore AD, Hakim RM, Lazarus JM, Tilney NL. Vascular access for hemodialysis. Patency rates and results of revision. Ann Surg 1985;202:235-9.Lumsden AB, et al. J Vasc Surg 1997;26:382-390.
5. Lumsden AB, MacDonald MJ, Kikeri D, Gotsonis GA, Harker LA, Martin LG. Prophylactic balloon angioplasty fails to prolong the patency of expanded polytetrafluoroethylene arteriovenous grafts: Results of a prospective randomized study J Vasc Surg 1997;26:382-392.

HISTORICAL USE OF DCBS IN AVF[1]

The **primary outcome** measure was set at **primary patency @ 1 year** defined as freedom from symptomatic recurrent stenosis within the treated circuit area or repeat TLR and was summarized with the odds ratio (OR) and accompanying 95% CI

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
1.2.3 Paclitaxel-coated balloons						
Kitrou et al. 2014	7	20	1	20	2.7%	10.23 [1.12, 93.34]
Kitrou et al. 2015	4	20	0	20	1.6%	11.18 [0.56, 222.98]
Lai et al. 2014	2	10	0	10	1.5%	6.18 [0.26, 146.78]
Massmann et al. 2015	7	10	7	15	4.2%	2.67 [0.49, 14.46]
Swinnen et al. 2015	26	37	7	37	7.4%	10.13 [3.43, 29.93]
Subtotal (95% CI)		**97**		**102**	**17.5%**	**7.42 [3.38, 16.29]**
Total events	46		15			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.89$, df = 4 (P = 0.76); $I^2 = 0\%$						
Test for overall effect: Z = 5.00 (P < 0.00001)						
Total (95% CI)		**1035**		**981**	**100.0%**	**2.60 [1.74, 3.88]**
Total events	479		316			
Heterogeneity: $Tau^2 = 0.26$; $Chi^2 = 35.21$, df = 14 (P = 0.001); $I^2 = 60\%$						
Test for overall effect: Z = 4.66 (P < 0.00001)						
Test for subgroup differences: $Chi^2 = 12.43$, df = 2 (P = 0.002), $I^2 = 83.9\%$						



1. Kitrou P, Spiliopoulos S, Karnabatidis D, Katsanos K. Cutting balloons, covered stents and paclitaxel-coated balloons for the treatment of dysfunctional dialysis access. Expert Rev Med Devices 2016;13:1119-1126.

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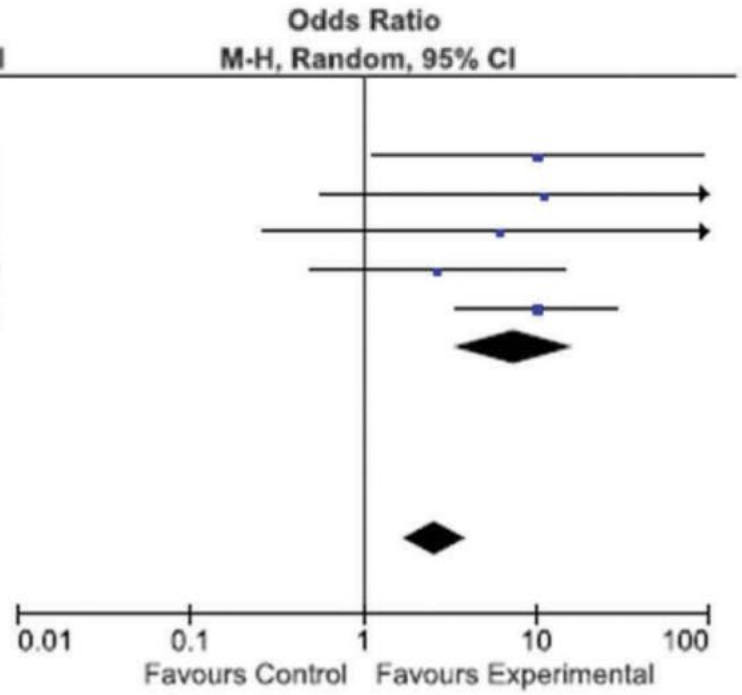

Authors' Conclusion: "The body of published evidence remains limited, and large scale multi-center studies are warranted"

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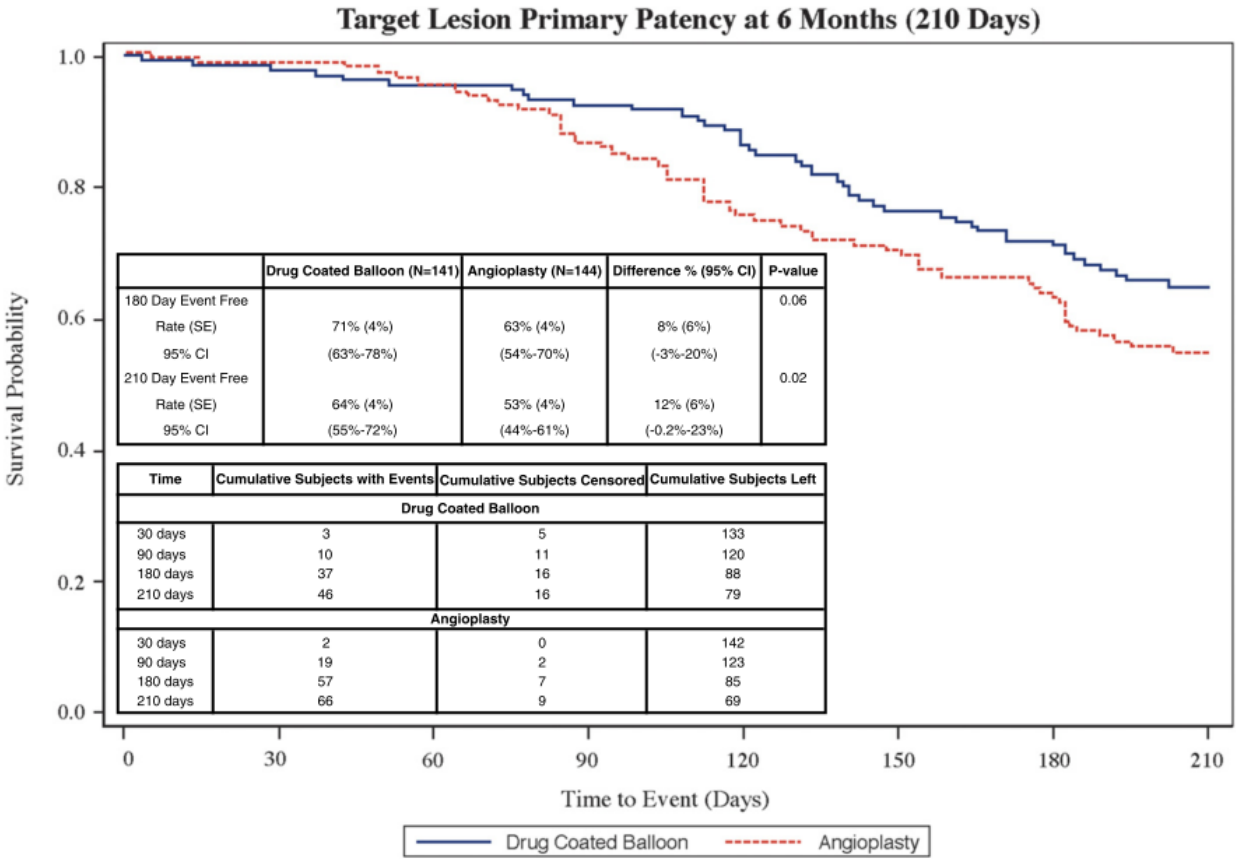
LUTONIX AV IDE[1]

- Multicenter, prospective, randomized, core laboratory and clinical events committee adjudicated trial of 285 subjects

- The **primary efficacy endpoint** was **target lesion primary patency at 6 months** defined as freedom from clinically driven reintervention on the target lesion or access thrombosis



	Drug Coated Balloon (N=141)	Angioplasty (N=144)	Difference % (95% CI)	P-value
180 Day Event Free				0.06
Rate (SE)	71% (4%)	63% (4%)	8% (6%)	
95% CI	(63%-78%)	(54%-70%)	(-3%-20%)	
210 Day Event Free				0.02
Rate (SE)	64% (4%)	53% (4%)	12% (6%)	
95% CI	(55%-72%)	(44%-61%)	(-0.2%-23%)	

Time	Cumulative Subjects with Events	Cumulative Subjects Censored	Cumulative Subjects Left
Drug Coated Balloon			
30 days	3	5	133
90 days	10	11	120
180 days	37	16	88
210 days	46	16	79
Angioplasty			
30 days	2	0	142
90 days	19	2	123
180 days	57	7	85
210 days	66	9	69

1. Trerotola SO, Lawson J, Roy-Chaudhury P, Saad TF, et al. Drug Coated Balloon Angioplasty in Failing AV Fistulas: A Randomized Controlled Trial. Clin J Am Soc Nephrol 2018;13:1215-1224.

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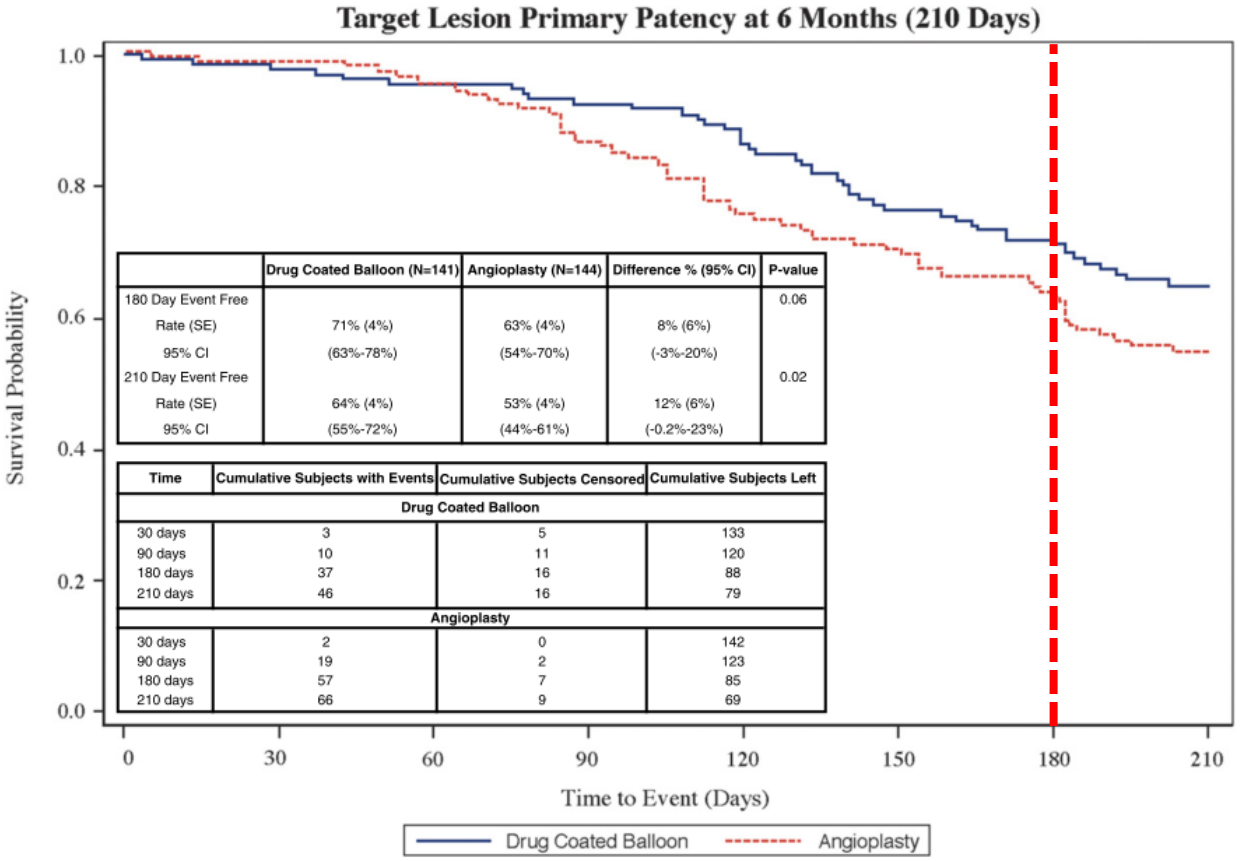
- **Primary efficacy endpoint not met**



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CURRENT USE OF DCBS IN AVF

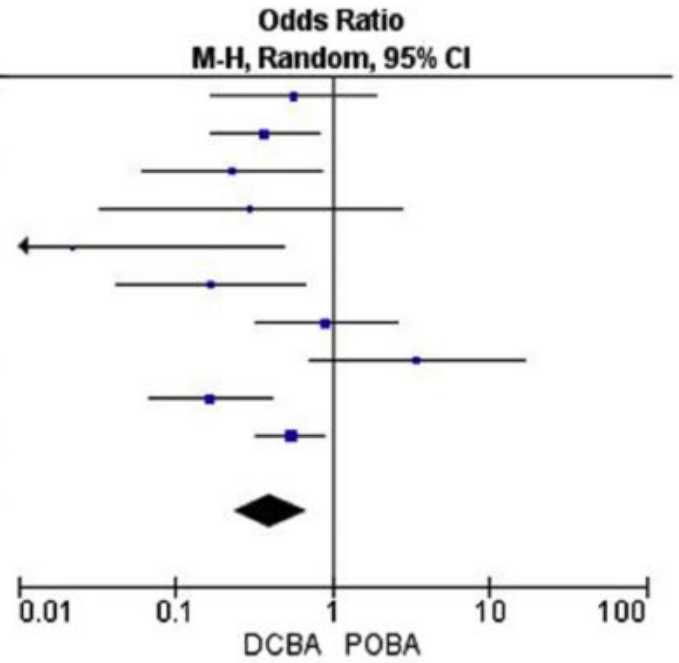
Meta-analysis of DCB vs POBA for loss of primary patency in AVF at 6 months

Six Months

Study or Subgroup	DCBA Events	DCBA Total	POBA Events	POBA Total	Weight	Odds Ratio M-H, Random, 95% CI
Cildag (2016)	6	26	9	26	10.1%	0.57 [0.17, 1.92]
Irani (2018)	12	63	24	62	14.2%	0.37 [0.17, 0.84]
Kitrou (2015) (2)	7	20	14	20	9.3%	0.23 [0.06, 0.87]
Kitrou (2015) AVFs only	3	7	5	7	4.6%	0.30 [0.03, 2.76]
Lai (2014)	3	10	10	10	2.7%	0.02 [0.00, 0.50]
Lucev (2018)	3	31	12	31	8.8%	0.17 [0.04, 0.68]
Maleux (2017)	11	33	11	31	11.8%	0.91 [0.32, 2.55]
Roosen (2017)	13	16	10	18	7.6%	3.47 [0.73, 16.53]
Swinnen (2018)	8	68	27	61	13.3%	0.17 [0.07, 0.41]
Trerotola 2018	37	141	57	144	17.6%	0.54 [0.33, 0.90]
Total (95% CI)		**415**		**410**	**100.0%**	**0.40 [0.23, 0.70]**
Total events	103		179			

Heterogeneity: $Tau^2 = 0.37$; $Chi^2 = 20.45$, df = 9 (P = 0.02); $I^2 = 56\%$

Test for overall effect: Z = 3.27 (P = 0.001)



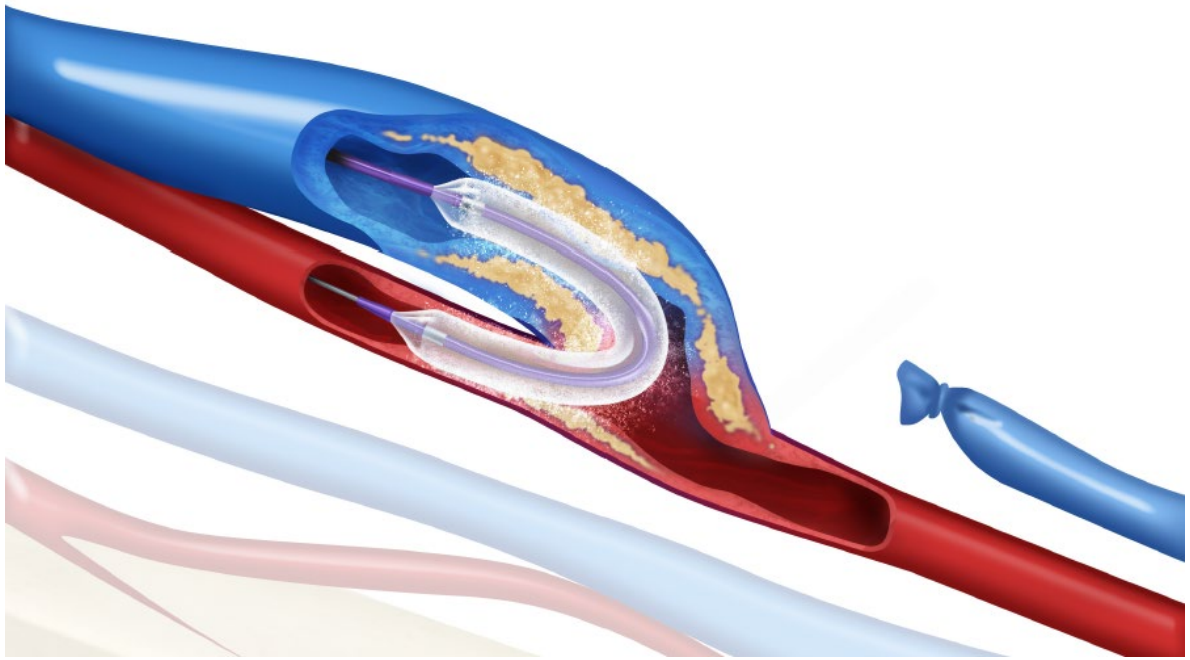
"In conclusion, DCB angioplasty use in AVF resulted in significant improvement in lesion patency at 3, 6, 12, and 24 months… Ongoing large multi-center RCTs will provide further clarity on the benefit of such balloons in hemodialysis circuits."

1. Kennedy SA, Mafeld S, Baerlocher MO, Jaberi A, Rajan DK. Drug-Coated Balloon Angioplasty in Hemodialysis Circuits: A Systematic Review and Meta-Analysis. J Vasc Interv Radiol 2019;30:483-494 e1.

IN.PACT AV ACCESS IDE STUDY

Objective:

Evaluate the safety and effectiveness of the IN.PACT™ AV drug-coated balloon (DCB) compared to percutaneous transluminal angioplasty (PTA) for treatment of *de-novo* or *restenotic* obstructive lesions of *native* arteriovenous fistulae (AVF) in the upper extremity



Principal Investigators:

- Robert Lookstein, MD *(USA)*
- Andrew Holden, MD *(New Zealand)*
- Hiroaki Haruguchi, MD *(Japan)*

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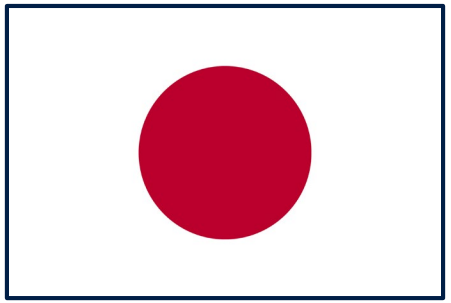
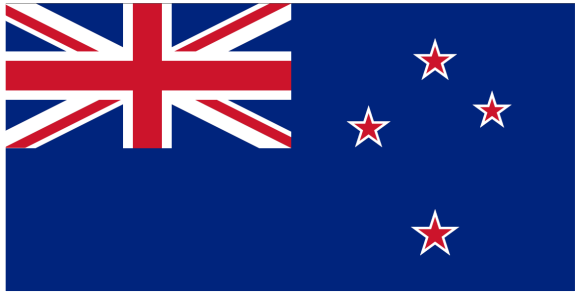
IN.PACT AV ACCESS IDE STUDY DESIGN

- Prospective, global, multicenter, 1:1 randomized, single-blinded study
- 330 patients
- Up to 5-year follow-up
- Lesions up to 10 cm in length in the native AVF
- Independent and blinded Duplex Ultrasound Core Lab[1], Angiographic Core Lab[2], and Clinical Events Committee[3]
- Patients enrolled at 29 Global Sites (United States, Japan and New Zealand)





1. VasCore DUS Core Laboratory
2. SYNTACTX Angiographic Core Laboratory
3. Clinical Events Committee and Data Safety Monitoring services provided by SYNTACTX

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IN.PACT AV ACCESS INVESTIGATORS

Investigator	Site	Location
Levester Kirksley	Cleveland Clinic	Cleveland, OH
Sanjay Misra	Mayo Clinic	Rochester, MN
Angelo Santos	Sanford University of South Dakota (USD) Medical Center	Sioux Falls, SD
Omran Abul-Khoudoud	King's Daughters Medical Center	Ashland, KY
Adie Friedman	The Mount Sinai Hospital	New York, NY
Vincent Gallo	Holy Name Medical Center	Teaneck, NJ
Ahmed Kamel Abdel Aal	University of Alabama at Birmingham (UAB) Hospital	Birmingham, AL
Mel Sharafuddin	University of Iowa Hospitals and Clinics	Iowa City, IA
Sreekumar Madassery	Rush University Medical Center	Chicago, IL
David Dexter	Sentara Vascular Specialists	Norfolk, VA
Charles Joels	University Surgical Associates	Chattanooga, TN
Syed Hussain	Christie Clinic Vein and Vascular Center	Champaign, IL
Sandeep Bagla	Vascular Institute of Virginia	Woodbridge, VA
Jeffrey Hull	Richmond Vascular Center	North Chesterfield, VA

Investigator	Site	Location
John Ross	Dialysis Access Institute	Orangeburg, SC
Jeffrey Hoggard	North Carolina Nephrology	Raleigh, NC
Bret Wiechmann	Florida Research Network LLC	Gainesville, FL
Naveen Atray	Capital Nephrology Medical Group	Sacramento, CA
Randy Cooper	SKI Vascular Center	Tempe, AZ
Neghae Mawla	Dallas Nephrology Associates	Plano, TX
Fernando Kafie	Coastal Vascular and Interventional	Pensacola, FL
Shohei Fuchinoue	Tokyo Women's Medical Hostpital	Shinjuku-ku, Japan
Kotaro Suemitsu	Kansai Rosai Hospital	Amagasaki, Japan
Naoko Isogai	Shonan Kamakura General Hospital	Kamakura, Japan
Masahiko Fujihara	Kishiwada Tokushukai Hospital	Kishiwada, Japan
Masaaki Muramaki	Shizuoka General Hospital	Shizuoka, Japan
Tomonori Ogawa	Saitama Medical Center Saitama Medical University	Kawagoe, Japan
Andrew Holden	Auckland City Hospital	Auckland, NZ
Kes Wicks	Capital and Coast District Health	Wellington, NZ

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IN.PACT AV ACCESS KEY INCLUSION/EXCLUSION CRITERIA

Inclusion

- Life expectancy of ≥ 12 months
- Native AV fistula created ≥ 60 days prior to the index procedure
- Target AV fistula has undergone dialysis for at least 8 of 12 sessions during a four week period
- Target vessel diameter of 4 – 12 mm
- Patient underwent successful crossing of the target lesion with the guide wire and pre-dilatation with a HP balloon:
  - stenosis of ≤ 30% in the absence of a flow limiting dissection (Grade ≥ C) or perforation

Exclusion

- Undergone prior intervention of access site within 30 days of index procedure
- Target AVF previously had or currently has a thrombosis
- Planned surgical revision of access site
- Hemodynamically significant central venous stenosis that cannot be successfully treated prior to treatment of target lesion
- Presence of a stent located in the target AV access circuit
- Secondary non-target lesion requiring treatment within 30 days post index procedure
- Judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Presence of pseudoaneurysm or aneurysm requiring treatment at the lesion site

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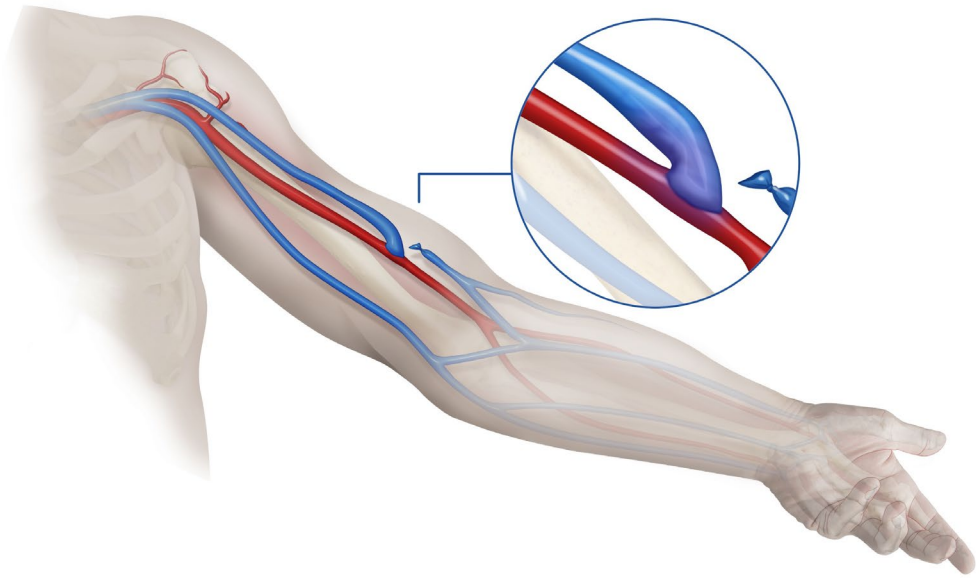
IN.PACT AV ACCESS KEY LESION CRITERIA

Inclusion

- Patient has a ***de novo and/or non-stented restenotic*** lesion located between the arteriovenous anastomosis and axillosubclavian junction with **≥ 50% stenosis**
- Target lesion or a tandem lesion that is **≤ 100 mm** in length
  - *Note*: Tandem lesions may be enrolled provided they meet all of the following criteria:
    - Separated by a gap of ≤ 30mm (3 cm)
    - Total combined lesion length, including 30 mm gap, is less than 100 mm
    - Able to be treated as a single lesion



Exclusion

- Significant arterial inflow lesion requiring treatment more than 2 cm upstream from the anastomosis in the AV access

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IN.PACT AV ACCESS PRIMARY ENDPOINTS

Primary Safety Endpoint: *Serious Adverse Event Rate within 30 Days*

- Defined as the Serious Adverse Event (SAE) rate involving the AV access circuit through 30 days post-procedure

Primary Effectiveness Endpoint: *Target Lesion Primary Patency Rate through 6 Months*

- Defined as freedom from clinically-driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured through 6 months post-procedure
  - *Clinically-Driven Target Lesion Revascularization (CD-TLR)*: Any re-intervention involving the target lesion in which:
    - The subject has a ≥ 50% diameter stenosis (per angiographic core lab assessment) in the presence of clinical or physiologic abnormalities that indicate dialysis access dysfunction *OR*
    - ≥ 70% stenosis without the presence of clinical or physiologic abnormalities indicating dialysis access dysfunction
- IN.PACT AV access target lesion primary patency is measured out to **210 days endpoint (rather than 180 days)**

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IN.PACT AV ACCESS BASELINE CHARACTERISTICS

Baseline Demographics	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value
Age (yrs) (mean ± SD)	65.8 ± 13.1	65.5 ± 13.4	0.837
Male	65.9% (112/170)	63.1% (101/160)	0.646
Hypertension	91.2% (155/170)	94.4% (151/160)	0.295
Hyperlipidemia	54.1% (92/170)	52.5% (84/160)	0.825
Diabetes Mellitus - Type 1 Diabetes Mellitus - Type 2	2.4% (4/170) 60.6% (103/170)	3.8% (6/160) 65.0% (104/160)	0.532 0.427
Renal Insufficiency	100.0% (170/170)	100.0% (160/160)	> 0.999
Carotid Artery Disease	4.1% (7/170)	8.8% (14/160)	0.114
Congestive Heart Failure	22.9% (39/170)	24.4% (39/160)	0.796
Coronary Heart Disease	35.9% (61/170)	38.8% (62/160)	0.649
Peripheral Artery Disease	19.4% (33/170)	15.1% (24/159)	0.312
Smoker - Current Smoker - Former	11.2% (19/170) 37.6% (64/170)	16.3% (26/160) 28.1% (45/160)	0.201 0.079
Previous AV Access Endovascular Procedure	74.1% (126/170)	75.0% (120/160)	0.900

DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty

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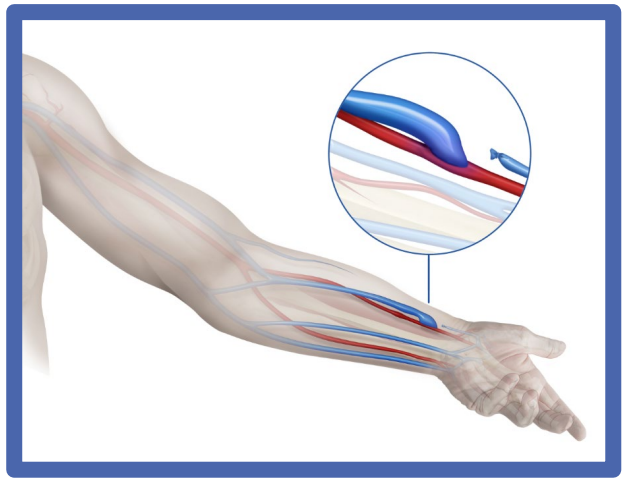
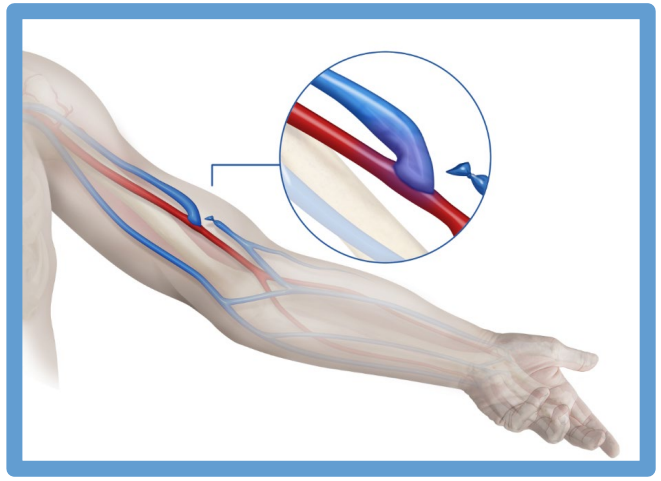
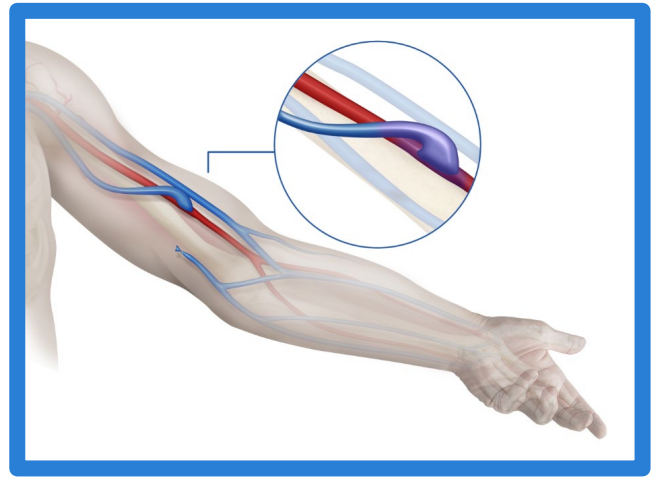
IN.PACT AV ACCESS AVF TYPE



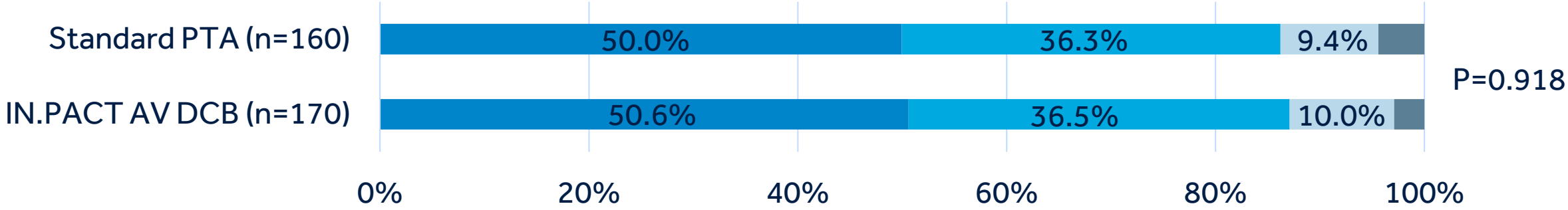
Radiocephalic



Brachiocephalic



Brachiobasilic



AVF type locations are site-reported ; AVF, arteriovenous fistula; DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty

*Other AVF types included radial-perforative vein (3), ulnar-basilica (2), basilobrachial, radialbasilic, high bifurcated ulnar artery to cephalic vein, distal radial artery to median vein, proximal radial artery to perforating vein, Gracz, left radiocephalic

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS AVF CHARACTERISTICS

AVF Characteristics[1]	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value
Lesion Length (mm; mean ± SD)	**46.9 ± 28.1**	**40.0 ± 25.7**	**0.021**
Target Arm			0.449
Right	23.5% (40/170)	27.5% (44/160)	
Left	76.5% (130/170)	72.5% (116/160)	
Dominant Arm	22.4% (38/170)	24.4% (39/160)	0.697
Age of AVF (years; mean ± SD)	3.2 ± 3.0	3.5 ± 3.8	0.436
Years of Hemodialysis (mean ± SD)	4.3 ± 5.1	4.2 ± 5.2	0.755

AVF, arteriovenous fistula
DCB, drug-coated balloon
PTA, percutaneous transluminal angioplasty
1. These AVF characteristics were site-reported

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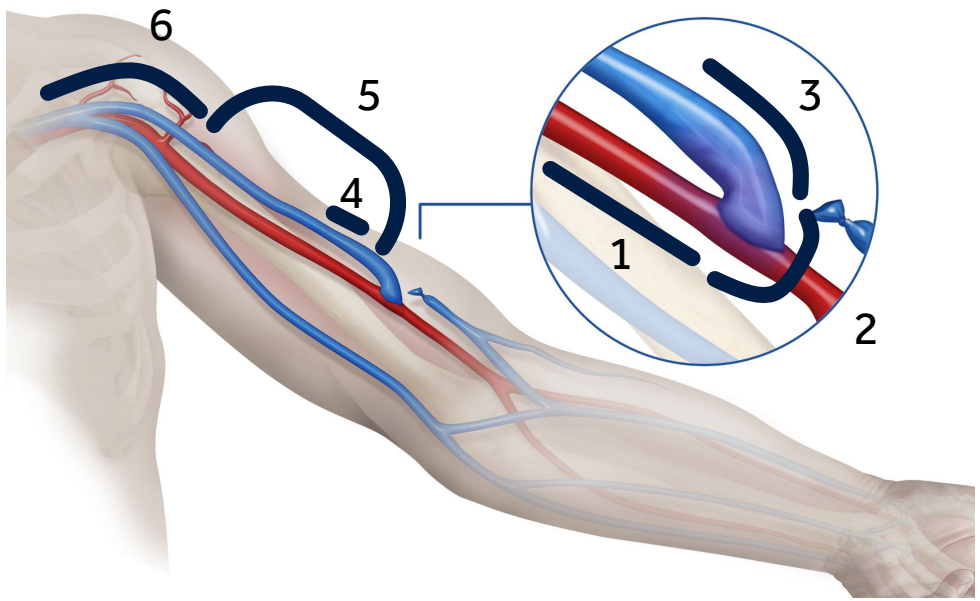
IN.PACT AV ACCESS LESION CHARACTERISTICS

Lesion Characteristics[1]	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value
Lesion Type			0.905
De Novo	30.0% (51/170)	30.6% (49/160)	
Restenotic	70.0% (119/170)	69.4% (111/160)	
Target Lesion Location[1]			0.310
Arterial Inflow	2.4% (4/170)	4.4% (7/160)	
Anastomosis	25.9% (44/170)	25.0% (40/160)	
Swing Point	8.2% (14/170)	7.5% (12/160)	
In Cannulation Zone	14.7% (25/170)	7.5% (12/160)	
Venous Outflow	31.2% (53/170)	33.1% (53/160)	
Cephalic Arch	17.6% (30/170)	22.5% (36/160)	

DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty

1. Target lesion location was site-reported



1. Arterial Inflow: treated segment is isolated to the arterial side
2. Anastomosis: treated segment crosses or meets the AV anastomosis
3. Swing Point: treated segment includes the curved segment of mobilized vessel
4. In Cannulation Zone: treated segment is isolated to straight segment of vessel where cannulation is performed
5. Venous Outflow: treated segment is in basilic vein (non-mobilized) or distal to the cephalo-axillary junction
6. Cephalic Arch: treated segment includes curved segment of cephalic vein as the vein crosses between the pectoralis major and deltoid muscles

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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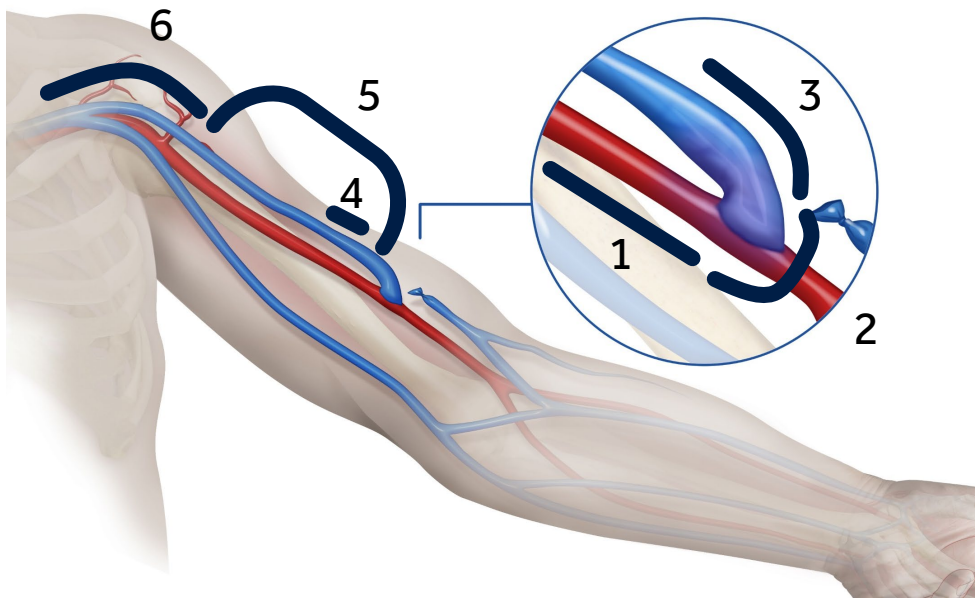

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IN.PACT AV ACCESS CLINICAL CHARACTERISTICS

Clinical Characteristics	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value
Presenting Clinical Symptoms Indicating AV Access Dysfunction			
Decreased Blood Flow	63.5% (108/170)	55.0% (88/160)	0.118
Elevated Venous Pressures	15.9% (27/170)	20.0% (32/160)	0.389
Unexplained Reduction in Hemodialysis Dose (Kt/V)	2.9% (5/170)	3.1% (5/160)	1.000
Abnormal Recirculation Values	1.2% (2/170)	3.1% (5/160)	0.271
Swollen Extremity or Aneurysm Formation	6.5% (11/170)	5.6% (9/160)	0.820
Elevated Negative Arterial Pre-pump Pressures	8.2% (14/170)	9.4% (15/160)	0.846
Unexplained Reduction of Dialysis Efficiency	3.5% (6/170)	5.0% (8/160)	0.590
Abnormal Physical Findings (thrill, murmur, arm swelling, etc)	43.5% (74/170)	44.4% (71/160)	0.912
Abnormally High BUN	0.0% (0/170)	1.3% (2/160)	0.234
Other[1]	4.1% (7/170)	3.1% (5/160)	0.772

1. Other symptoms indicating dialysis dysfunction: (6) prolonged bleeding after dialysis, (4) difficult cannulation, elevated velocities on duplex, no diastolic bruit

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS PROCEDURAL CHARACTERISTICS

Procedural Characteristics[1]	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value
Minimum Lumen Diameter (mm)			
Pre-procedure	2.7 ± 1.6 (170)	2.8 ± 1.7 (159)	0.731
After pre-dilatation	4.9 ± 1.9 (167)	5.2 ± 2.0 (159)	0.269
After index procedure	5.5 ± 1.9 (170)	5.7 ± 2.1 (158)	0.584
Percent Diameter Stenosis			
Pre-procedure	64.8 ± 13.3 (170)	64.8 ± 14.5 (159)	0.986
After pre-dilatation	34.6 ± 14.0 (167)	32.4 ± 13.5 (159)	0.160
After index procedure	26.8 ± 10.8 (170)	26.3 ± 10.9 (158)	0.653
Device Success[2]	**100.0% (212/212)**	**100.0% (162/162)**	**> 0.999**
Procedural Success[3]	**73.5% (125/170)**	**76.9% (123/160)**	**0.482**
Clinical Success[4]	**100.0% (159/159)**	**100.0% (154/154)**	**> 0.999**

1. Procedural characteristics were core-lab reported.
2. Device Success is successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst at or below rated burst pressure (RBP) at index procedure.
3. Procedural Success is maintenance of patency (≤ 30% residual stenosis as reported by the core lab or by investigator if core lab data is not available) in the absence of peri-procedural serious adverse device effect.
4. Clinical Success is resumption of successful dialysis for at least one session after index procedure.

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS PRIMARY EFFECTIVENESS ENDPOINT

Primary Effectiveness Endpoint	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	Difference [95% CI]	P-value[1]
Target Lesion Primary Patency[2] through 210 days[3]	82.2% (125/152)	59.5% (88/148)	**22.8% [12.8%, 32.8%]**	< 0.001
Clinically-driven target lesion revascularization	16.4% (25/152)	38.5% (57/148)	**-22.1% [-31.9%, -12.3%]**	< 0.001
Access circuit thrombosis	2.0% (3/151)	3.4% (5/146)	-1.4% [-5.1%, 2.3%]	0.222

1. P-values for the primary effectiveness endpoint were based on one-sided Z-test
2. Target lesion primary patency is defined as freedom from clinically-driven target lesion revascularization or access circuit thrombosis post index procedure.
3. For 6-months endpoints, all participants with events or participants without events but had at least 150 days of clinical follow-up were counted as evaluable participants. If a participant had no event and abandoned arteriovenous access circuit within 150 days the participant will be considered not evaluable for 6-months effectiveness endpoints. "Through 6 months" refers to 210 days for the patency-related endpoints and their components, including target lesion primary patency, CD-TLR, access circuit thrombosis, access circuit primary patency and re-intervention in access circuit; 180 days was used for all the other endpoints through 6 months.

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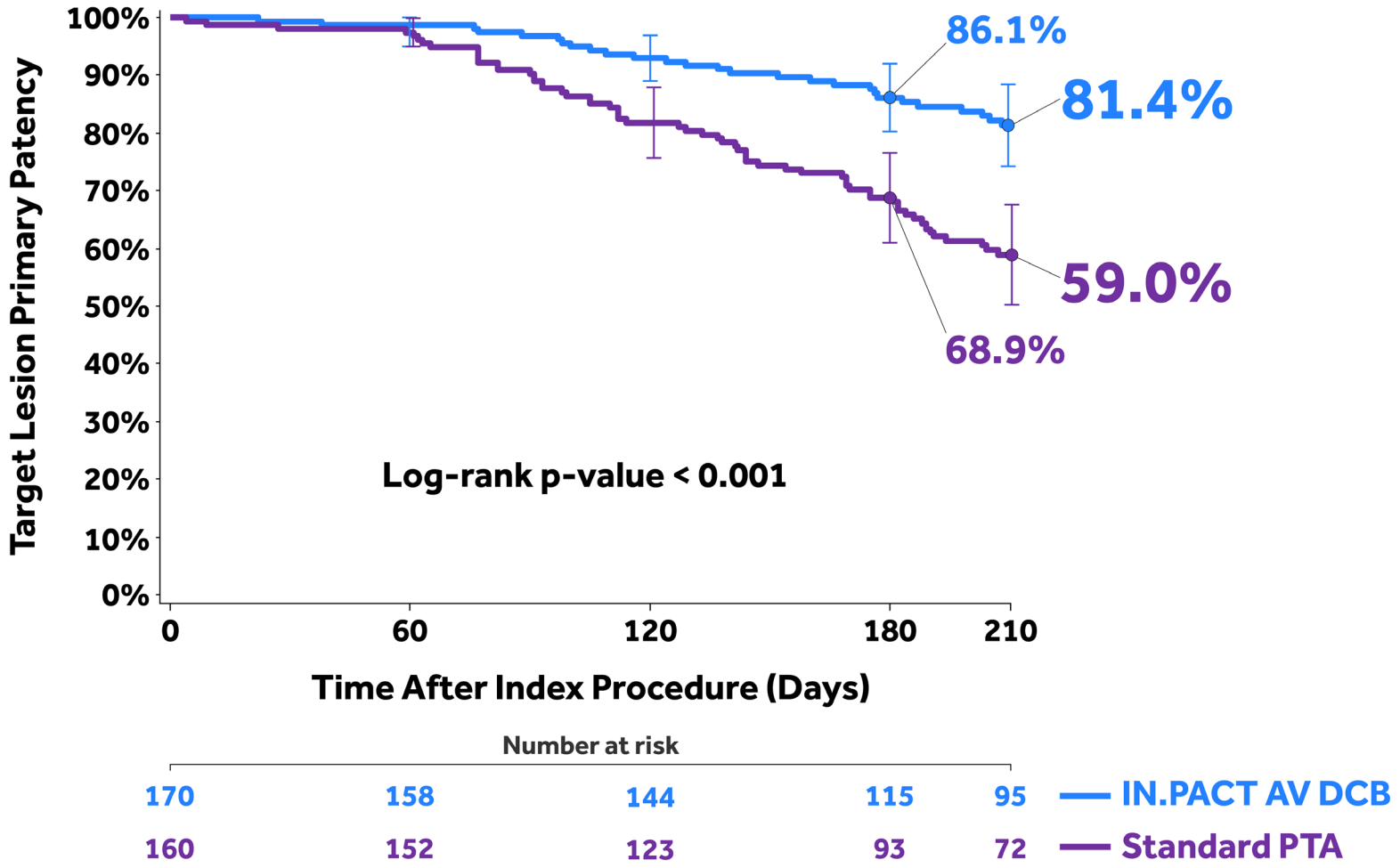
IN.PACT AV ACCESS - PRIMARY EFFECTIVENESS ENDPOINT

6-MONTH KAPLAN-MEIER PLOT



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IN.PACT AV ACCESS – ACCESS CIRCUIT PATENCY

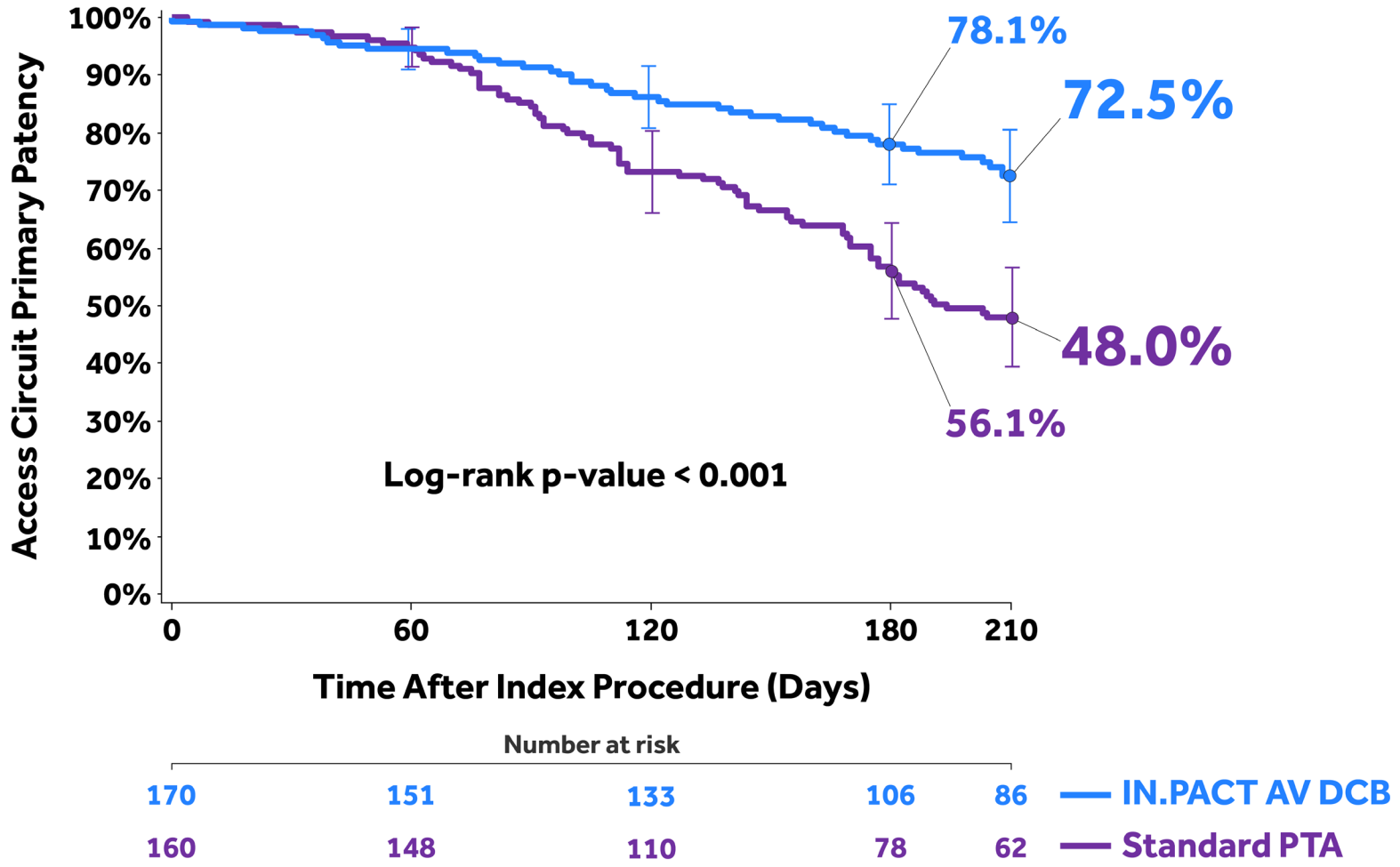
Access Circuit Patency	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	Difference [95% CI]	P-value[1]
Access circuit primary patency[2]	73.2% (112/153)	48.0% (71/148)	**25.2% [14.6%, 35.9%]**	< 0.001
Re-intervention in access circuit	25.5% (39/153)	50.7% (75/148)	**-25.2% [-35.8%, -14.6%]**	< 0.001
Access circuit thrombosis	2.0% (3/151)	3.4% (5/146)	-1.4% [-5.1%, 2.3%]	0.222

1. P-values for access circuit patency were based on one-sided Z-test
2. Access circuit primary patency is defined as freedom from re-intervention in the access circuit or access circuit thrombosis post index procedure

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS - ACCESS CIRCUIT PATENCY

6-MONTH KAPLAN-MEIER PLOT



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IN.PACT AV ACCESS PRIMARY SAFETY ENDPOINT

Primary Safety Endpoint	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	P-value[1] for non-inferiority
Serious adverse events involving the arteriovenous access circuit within 30 days[2,3]	4.2% (7/166)	4.4% (7/158)	0.002
Arteriovenous fistula occlusion	0.6% (1/166)	0.0% (0/158)	
Arteriovenous fistula site complication	3.0% (5/166)	2.5% (4/158)	
Arteriovenous fistula thrombosis	0.6% (1/166)	0.6% (1/158)	
Hemodialysis complication	0.6% (1/166)	0.0% (0/158)	
Vasospasm	0.0% (0/166)	0.6% (1/158)	
Vessel puncture site hematoma	0.0% (0/166)	0.6% (1/158)	

1. P-value is based on the Farrington-Manning non-inferiority test that the DCB is non-inferior to PTA in 30-day access-circuit-related SAE by a margin of 7.5%
2. For the 30-day endpoint, all subjects with events or subjects without events but had at least 23 days of clinical follow-up were counted as evaluable subjects.
3. There is one DCB subject who had two access-circuit-related serious adverse event

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

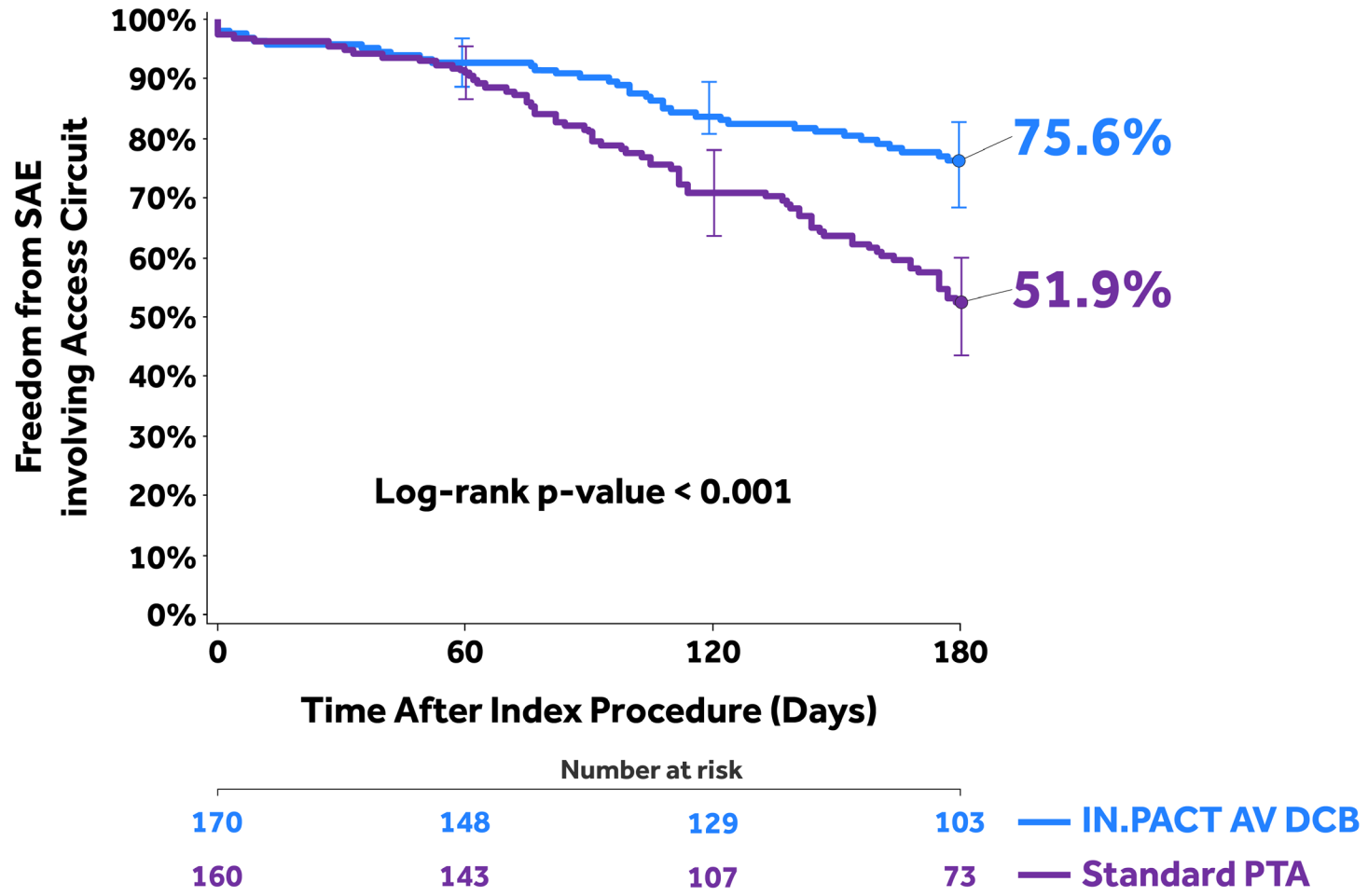
IN.PACT AV ACCESS REVASCULARIZATIONS

Revascularizations	IN.PACT AV DCB (n=170)	Standard PTA (n=160)	Difference [95% CI]	P-value[1]
Any target lesion revascularization	16.3% (25/153)	39.9% (59/148)	-23.5% [-33.4%, -13.7%]	< 0.001
Number of interventions required to maintain target lesion patency through 210 days[2]				
Total number of reinterventions	40	91	**56.0% reduction**	--
Mean ± SD	0.2 ± 0.6 (170)	0.6 ± 0.7 (160)	-0.3 [-0.5, -0.2]	<0.001
Subjects with at least one intervention	18.2% (31/170)	43.8% (70/160)		< 0.001
Number of interventions required to maintain access circuit patency through 210 days[3]				
Total number of reinterventions	54	103	**47.6% reduction**	--
Mean ± SD	0.3 ± 0.7 (170)	0.6 ± 0.8 (160)	-0.3 [-0.5, -0.2]	<0.001
Subjects with at least one intervention	22.9% (39/170)	46.9% (75/160)		< 0.001

1. P-values for the endpoints on number of interventions required were based on one-sided Wilcoxon sum rank test
2. Number of interventions required to maintain target lesion patency is defined as number of target lesion revascularizations post index procedure
3. Number of interventions required to maintain access circuit patency is defined as number of re-interventions in the target lesion and/or access circuit post index procedure

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS - FREEDOM FROM SAE
6-MONTH KAPLAN-MEIER PLOT



Freedom from SAE through 180 days is compared using a log-rank test and it is tested for superiority between two treatment groups

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

FDA PANEL QUESTION: PACLITAXEL IN OTHER VESSEL BEDS

24 Hour Summary of the Circulatory System Devices Panel Meeting
Paclitaxel-Coated DCB and DES Late Mortality
General Issues Panel
June 19-20, 2019

Question 12. Other Indications

The panel indicated that the recommendations for paclitaxel-coated devices for the SFA should also apply to clinical studies, informed consent, and labeling for paclitaxel-coated devices used in other indications (e.g., AVF and CLI). The panel noted that the benefit-risk profile for these patients may be different given the high mortality rates for these patients within 2-3 years.

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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US 2-year mortality of patients on hemodialysis 33.2%[1]

1. USRDS 2018 Chapter 5: Mortality, Table 5.3

MORTALITY WITH PACLITAXEL DEVICES IN DIALYSIS ACCESS

Original Clinical Studies

JOURNAL OF ENDOVASCULAR THERAPY
A SAGE Publication
An official publication of the ISEVS

Journal of Endovascular Therapy
1–13

DOI: 10.1177/1526602819872154
www.jevt.org
SAGE

Mortality After Paclitaxel-Coated Device Use in Dialysis Access: A Systematic Review and Meta-Analysis

Krystal Dinh, BMed, MTrauma[1], Alexandra M. Limmer, MBBS, MS[2], Sharath C. V. Paravastu, MBBS, PGDip, MD, FRCS[3], Shannon D. Thomas, BSc Med Hons, MBBS, FRACS[4,5,6], Michael H. Bennett, MBBS, FANZCA, MD[5,7], Andrew Holden, MBChB, FRANZCR, EBIR[8], and Ramon L. Varcoe, MBBS, MS, FRACS, PhD[4,5,6]

"The analysis found no difference in short- to midterm mortality among patients treated with a drug-coated balloon compared with PTA. With proven benefit and no evidence of harm, the authors recommend ongoing use of PCB for the failing dialysis access."

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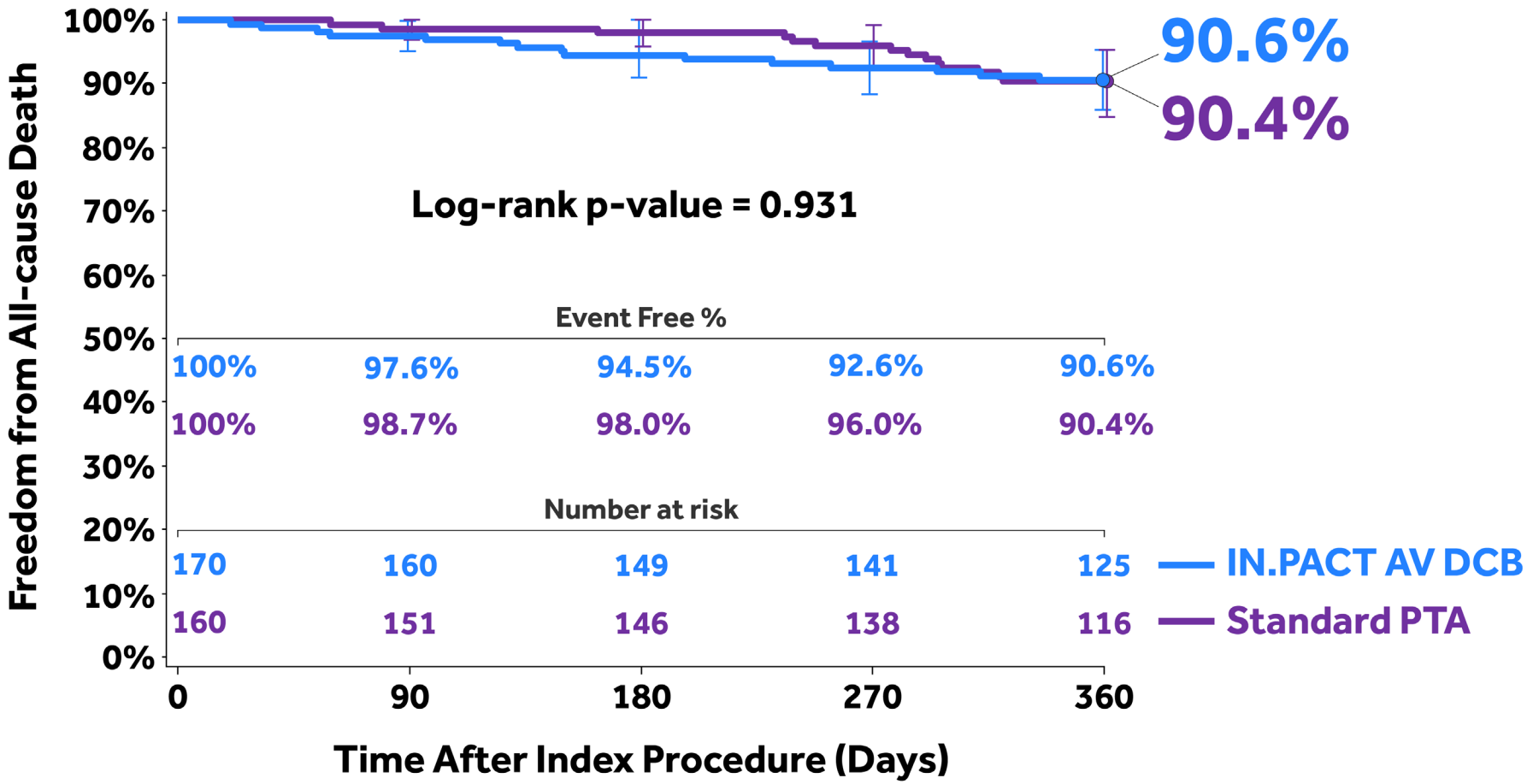
IN.PACT AV ACCESS KM MORTALITY THROUGH 12 MONTHS



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IN.PACT AV ACCESS CONCLUSIONS

- The IN.PACT AV Access Trial is a multi-center, prospective RCT comparing DCB to standard PTA in AV access that met its primary effectiveness endpoint

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

IN.PACT AV ACCESS CONCLUSIONS

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  - Primary effectiveness endpoint met: 6-month target lesion primary patency was 82.2% in DCB compared to 59.5% in PTA ($p<0.001$)

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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  - Primary safety endpoint met: 30-day serious adverse event rate was 4.2% in DCB compared to 4.4% in PTA (non-inferiority $p=0.002$)

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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- 56.0% reduction in reinterventions following use of IN.PACT AV DCB compared to standard PTA

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

PRIMARY ENDPOINT RESULTS OF THE IN.PACT AV ACCESS RANDOMIZED TRIAL: OUTCOMES THROUGH SIX MONTHS

Andrew Holden, MBChB, FRANZCR, EBIR

Director of Interventional Radiology

Auckland Hospital, Auckland, New Zealand

BRIEF STATEMENT

Indications for Use:
The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

Contraindications

The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

Warnings

- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.**
- Use the product prior to the Use-by date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 µg paclitaxel has not been evaluated clinically.

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

BRIEF STATEMENT

Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
- This product is not intended for the expansion or delivery of a stent.
- Do not use the IN.PACT AV DCB for pre-dilatation or for post-dilatation.
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

Potential Adverse Effects

Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms or recoil.
Potential complications of peripheral balloon catheterization include, but are not limited to, the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse effects.
Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthralgia, myelosuppression, peripheral neuropathy.
Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Holden, A. Primary Endpoint Results of the IN.PACT AV Access Randomized Trial: Outcomes Through Six Months. CIRSE 2019

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