Recorded Live Case:
IN.PACT AV Access Drug Coated Balloon

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Disclosures

Speaker name: Andrew Holden, MBChB, FRANZCR, EBIR

I have the following potential conflicts of interest to report:

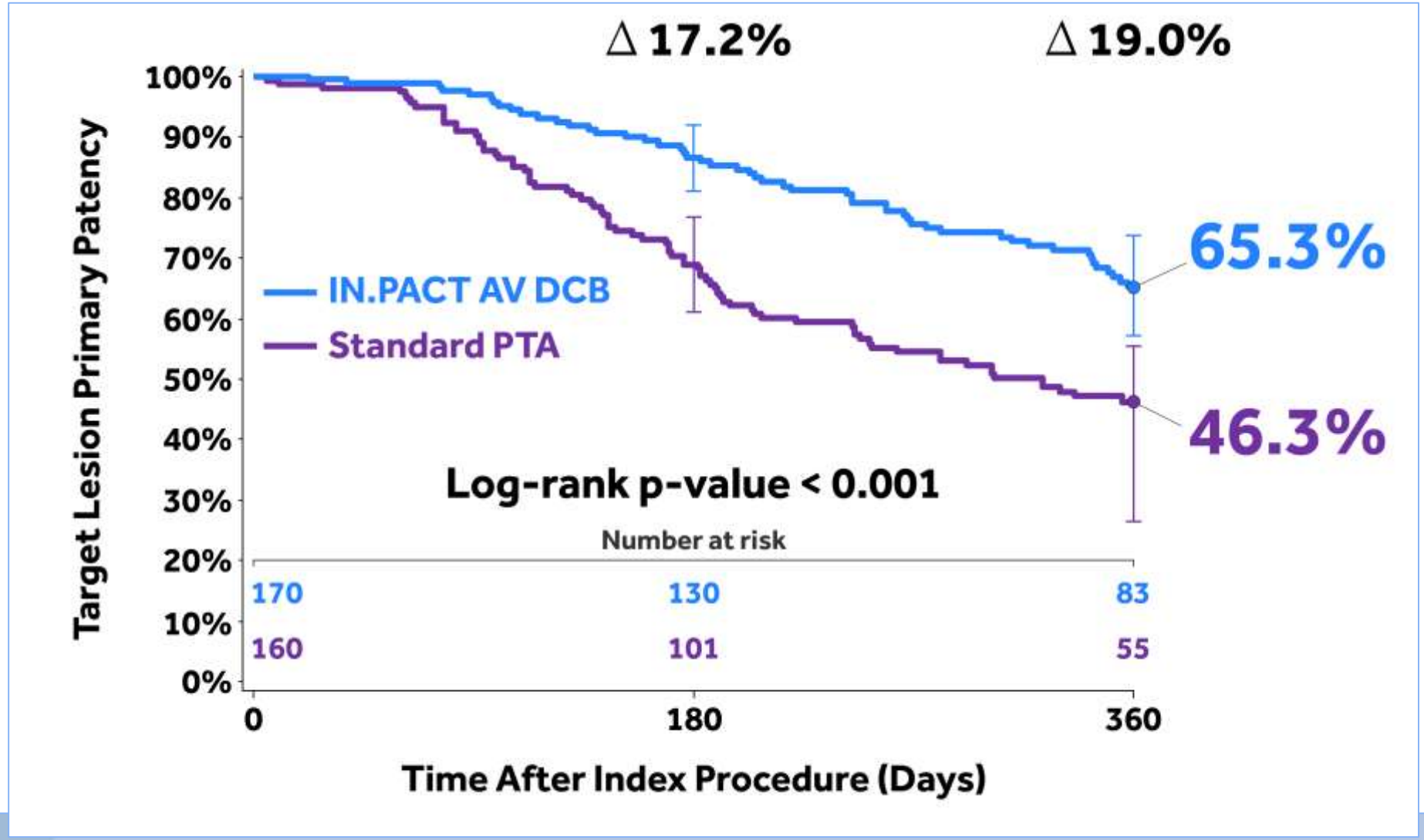
- ☒ Consulting – **Medical Advisory Board: Medtronic, Gore, Boston Scientific**
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest

IN.PACT ADMIRAL AV Access Product Specifications

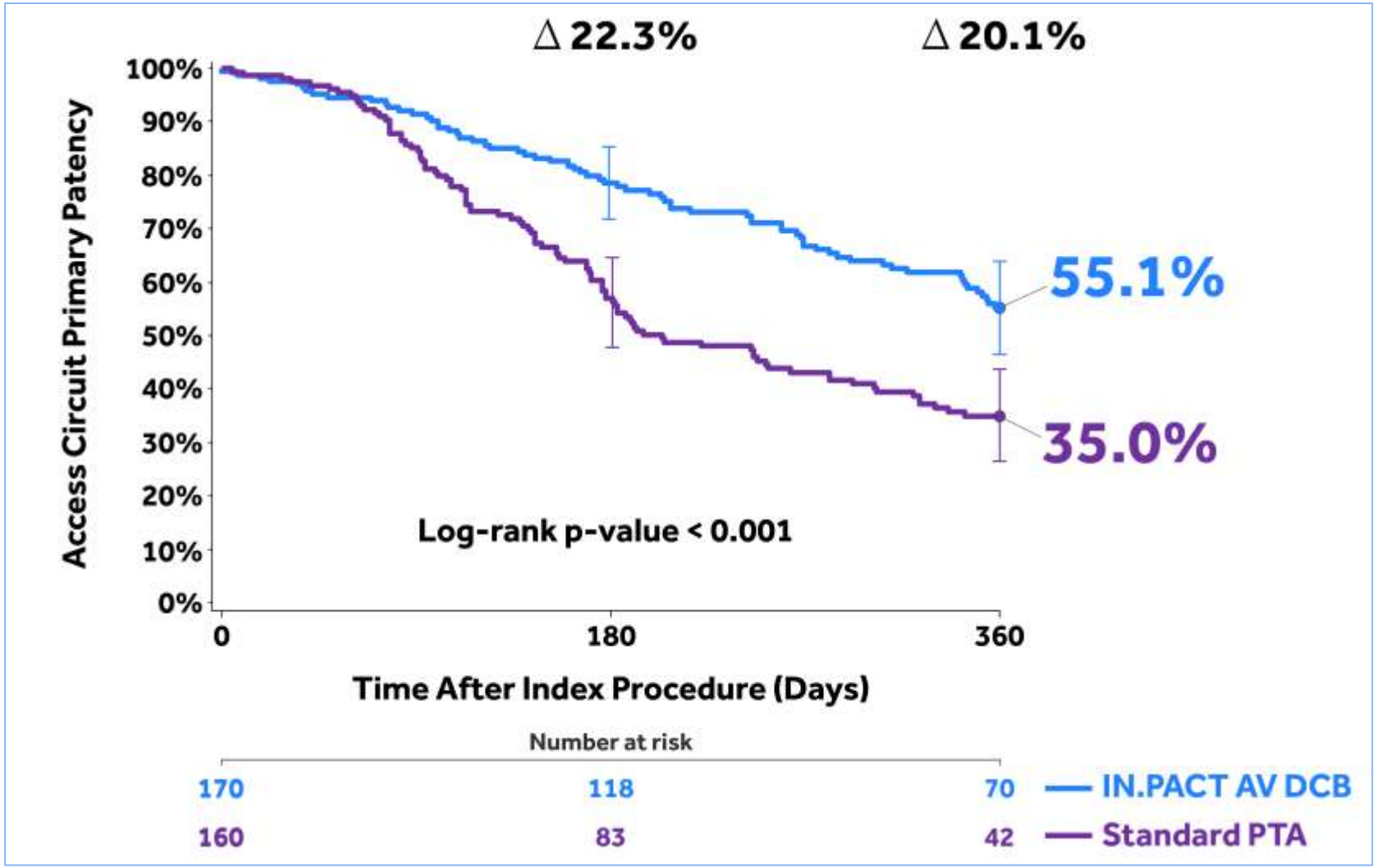
DCB Components	IN.PACT AV Access
Balloon (Based on 0.035" IN.PACT Admiral)	4.0 – 12.0 mm diameters 40,60.80.120,150 mm lengths 40*/ 80 / 130 cm shaft
Paclitaxel	Proven anti-proliferative drug 3.5 µg/mm²
Sheath Compatibility	5-7 French
Pressure Characteristics	Nominal pressure 8 ATM Rated burst pressure 14 ATM

* 40 cm shaft - unique feature of IN.PACT AV Access catheter

IN.PACT AV Access 12-Month Primary Effectiveness Endpoint



IN.PACT AV Access 12-Month Access Circuit Patency



Edited Live Case – Case Presentation

- 72 year old male
- Long-standing type-2 diabetic - on insulin
- History of hypertension, gout, peripheral neuropathy
- Diabetic nephropathy
- Left hand dominant
- Right brachiocephalic AV access created 9.25.16
- Hemodialysis commenced 2.9.17
- Juxta-anastomotic stenosis treated with POBA 11.23.17
- Presented with decreased blood flow in AV access 4.13.18

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 **- 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 - 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

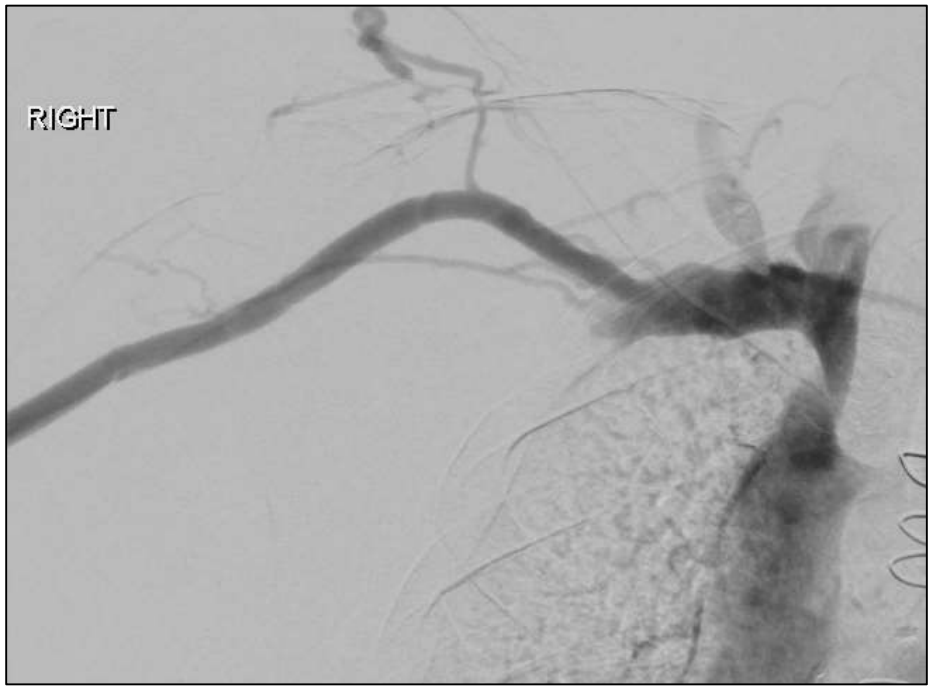
DCB, drug-coated balloon
PTA, percutaneous transluminal angioplasty

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	4.1% (7/170)	3.1% (5/160)	0.772

Edited Live Case – Diagnostic Imaging 4.13.18

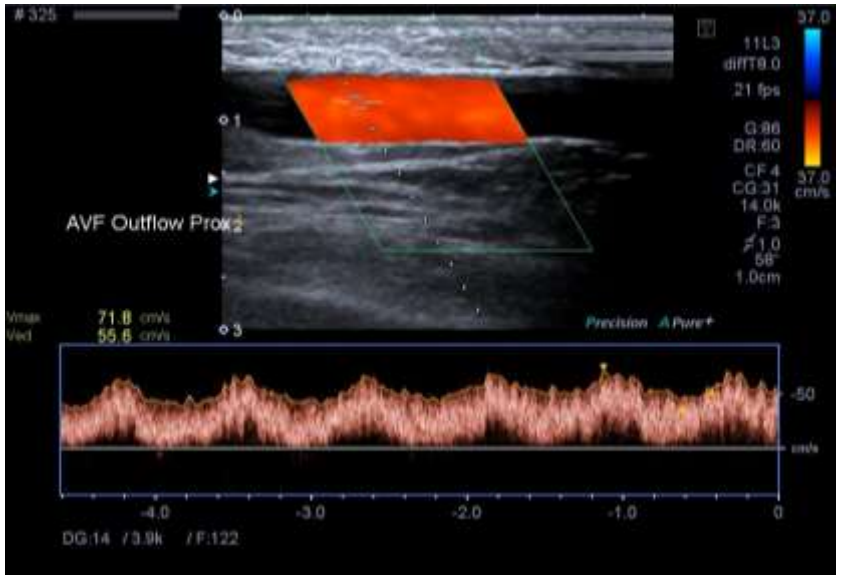
The entire access circuit, from the AV anastomosis to the superior vena cava should ideally be imaged, particularly to exclude occult central venous stenoses

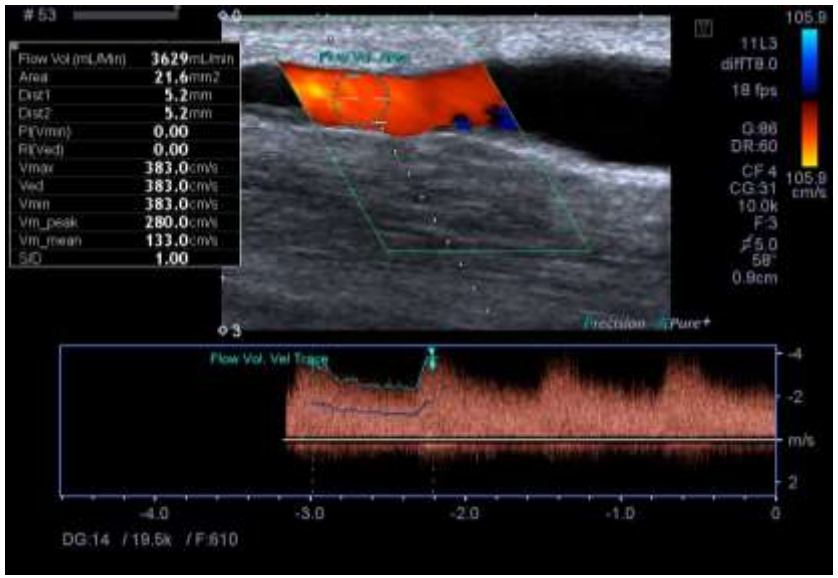


Edited Live Case

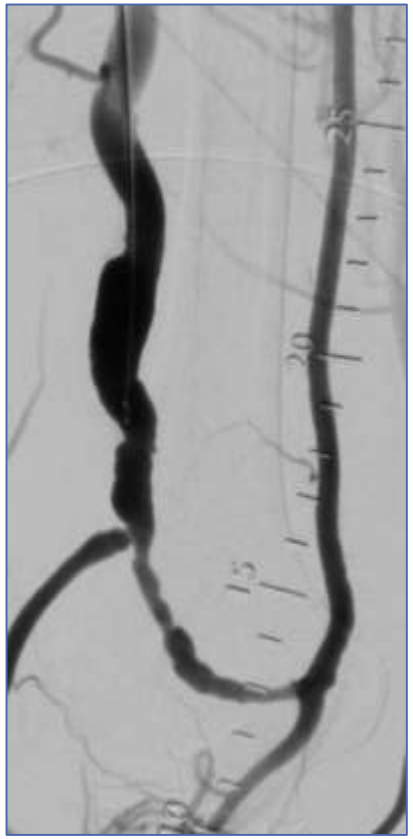
Edited Live Case – Post-procedure Outcome

- Dialysis commenced immediately post-procedure
- Blood flow and venous pressures normal at 6 months
- Duplex US satisfactory at 3 and 6 months
- Routine AV access contrast study at 8 months satisfactory



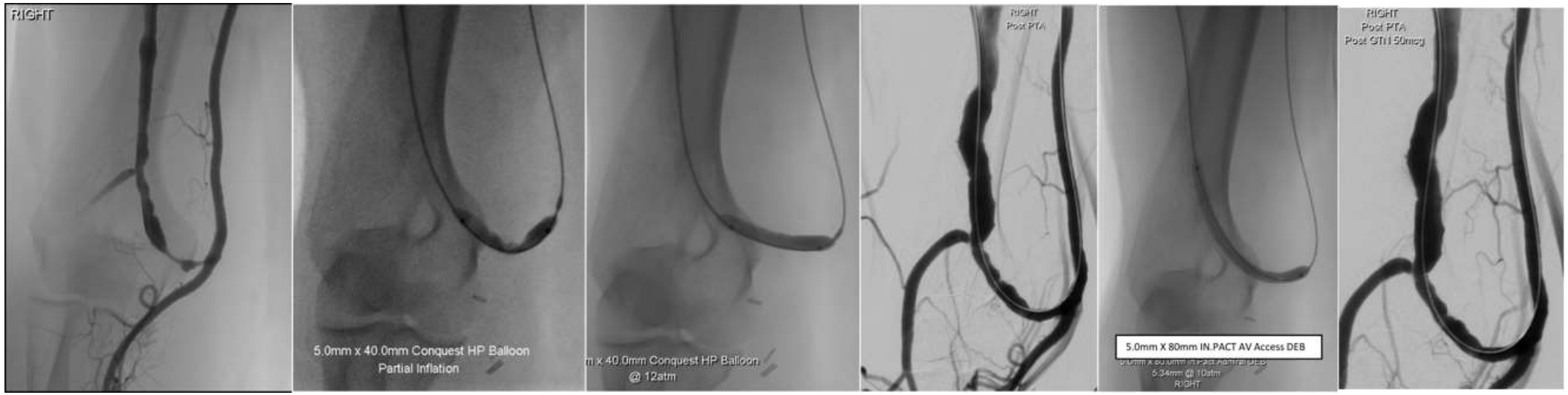


12.12.18



Conclusions

- Stenosis is a major challenge to AV access circuit patency
- The IN.PACT AV Access IDE RCT has, for the first time shown a highly significant target lesion and access circuit patency compared to plain balloon angioplasty
- HP balloon angioplasty followed by DCB angioplasty holds considerable promise in improving AV access patency and dialysis patients quality of life



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