The ABISS Trial

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for the ABISS investigators

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Disclosure

Speaker's name : Raphael Coscas

☑ I have the following potential conflicts of interest to declare:

Receipt of honoraria or consultation fees: Bard/BD, Medtronic

Données du registre national REIN - 2019

92 000 patients IRCT dont **50 000 dialysés**

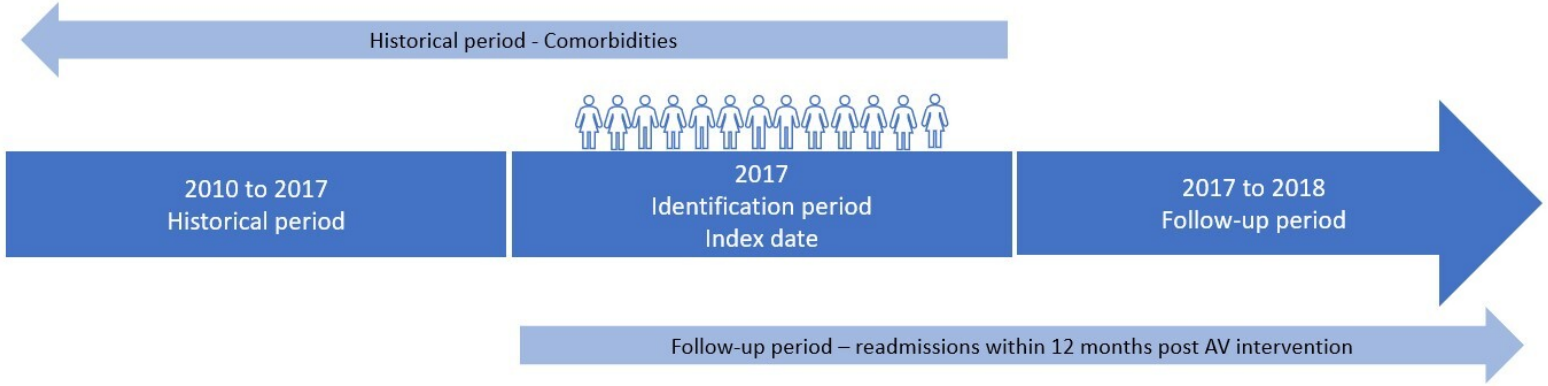
Prévalence en augmentation

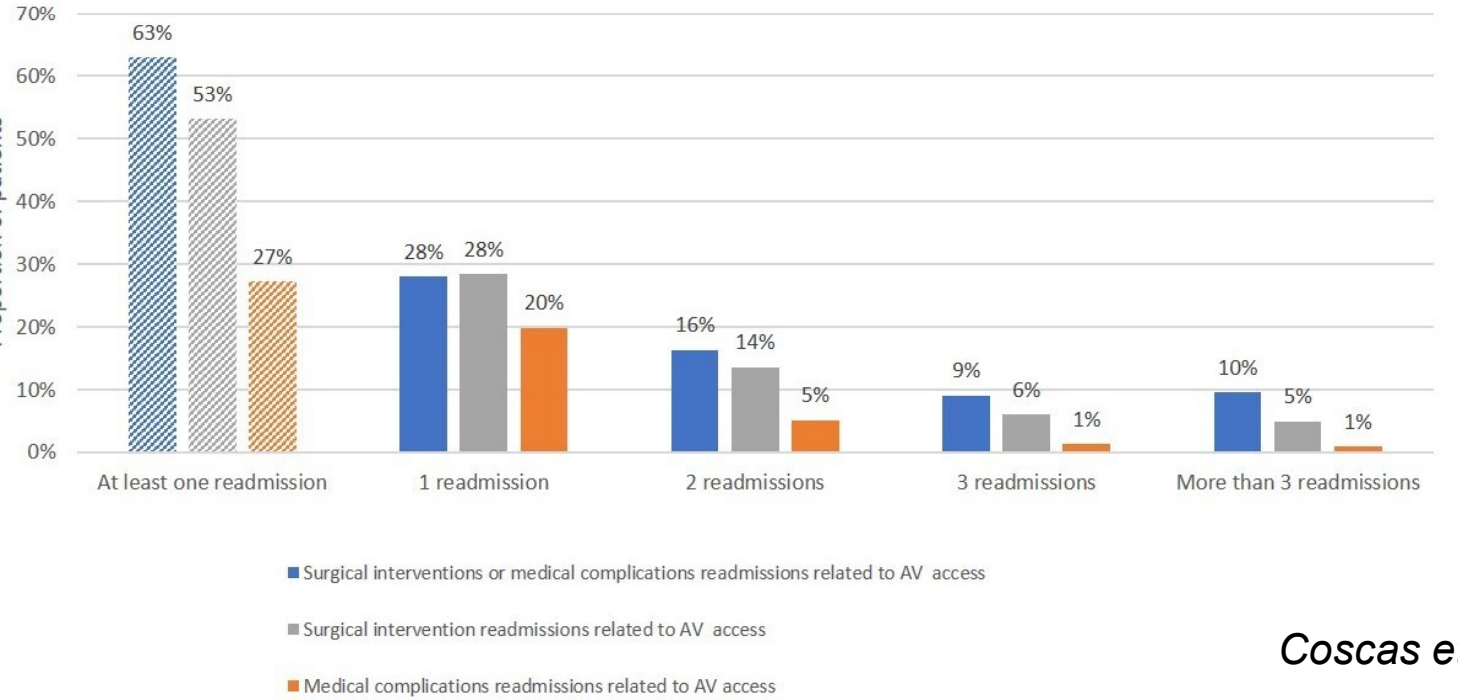
11 000 nouveaux patients vs. 7 750 décès

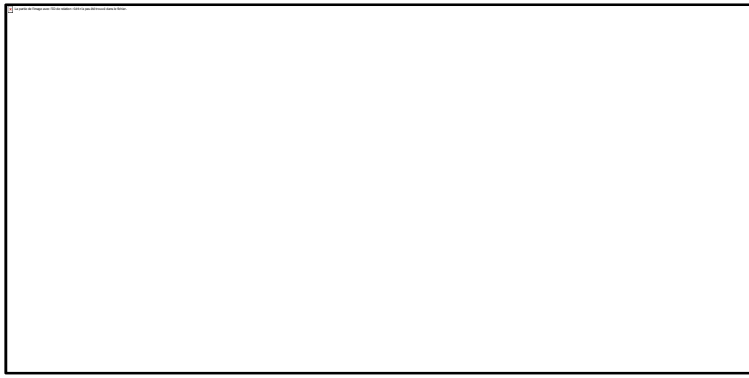
90 % hémodialyse vs. 10 % dialyse péritonéale

Rapport Registre REIN - 2019

Incidence des sténoses sur FAV





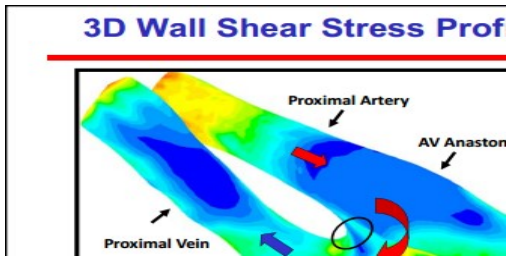


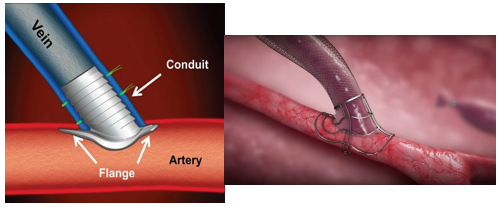
Coscas et al, Eur J Vasc Endovasc Surg 2022

Readmissions	De novo	Secondary	*p*-value	Total
Readmissions related to the vascular access (surgical/interventional procedure or medical complication readmissions related to the AV access)	5,375 (61.9%)	1,216 (68.2%)	<0.001	6,591 (63%)
Readmissions categories				
Medical complications readmissions related to the AV access (without a surgical/interventional procedure related to AV access during the same stay)	2,323 (26.8%)	529 (29.7%)	0.013	2,852 (27.3%)
Surgical/interventional procedure readmissions related to the AV access	4,498 (51.8%)	1,059 (59.4%)	<0.001	5,557 (53.1%)
Surgical/interventional procedure readmission categories				
Surgical/interventional procedure for treatment of a stenosis	2,305 (26.6%)	550 (30.8%)	<0.001	2,855 (27.3%)
Surgical/interventional procedure for vascular access creation (AVF or AVG)	1,657 (19.1%)	352 (19.7%)	0.532	2,009 (19.2%)
Surgical/interventional procedure for superficialization	1,108 (12.8%)	236 (13.2%)	0.595	1,344 (12.8%)
Surgical/interventional procedure for treatment of high flow fistula / vascular steal / AVF closure	903 (10.4%)	258 (14.5%)	<0.001	1,161 (11.1%)
Surgical/interventional procedure for CVC	779 (9%)	240 (13.5%)	<0.001	1,019 (9.7%)
Surgical/interventional procedure for treatment of a thrombosis	633 (7.3%)	265 (14.9%)	<0.001	898 (8.6%)
Surgical/interventional procedure for pseudoaneurysm formation	134 (1.5%)	52 (2.9%)	<0.001	186 (1.8%)

Multiples causes aux (re)sténoses sur FAV

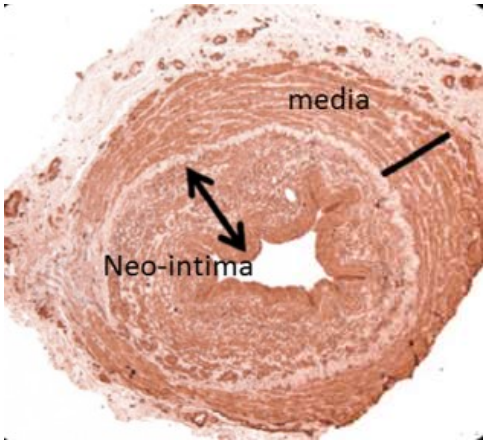
Forces de cisaillement liées au gradient de pression





Angle fermé de l'anastomose influence défavorablement l'hémodynamique

Différences histologiques veine/artère
Incongruence à l'étirement



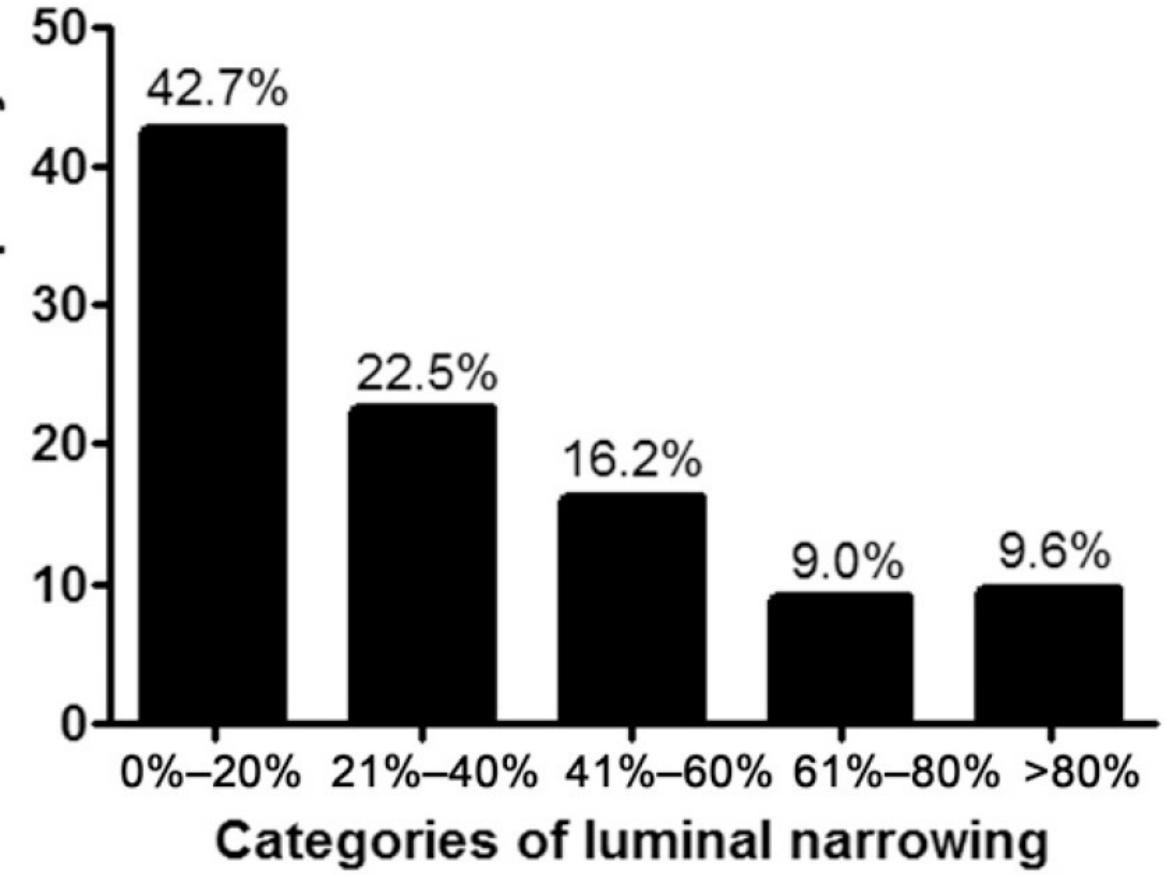
Traumatismes liées aux ponctions répétées et aux angioplasties

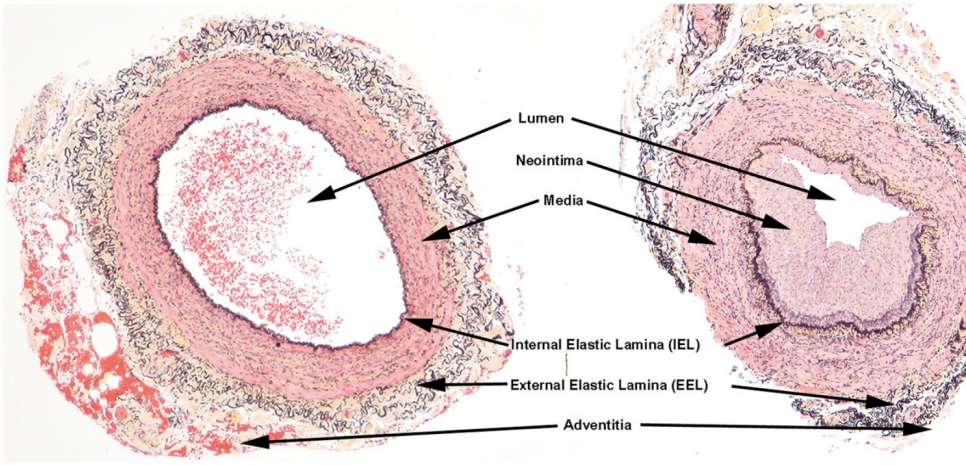
Profondeur de l'IRC
Urémie + stress oxydatif + Inflammation

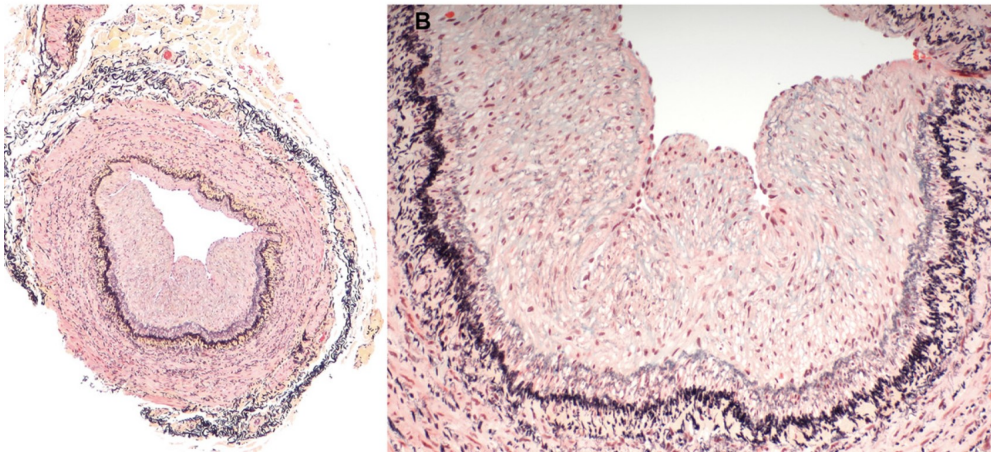
Hyperplasie myointimale

stopathology of Veins Obtained at Hemodialysis teriovenous Fistula Creation Surgery

rles E. Alpers,* Peter B. Imrey,[†‡] Kelly L. Hudkins,* Tomasz A. Wietecha,*
na Radeva,[†] Michael Allon,[§] Alfred K. Cheung,[‖¶**] Laura M. Dember,[††‡‡]
ir Roy-Chaudhury,[§§‖‖] Yan-Ting Shiu,[‖¶¶] Christi M. Terry,[‖¶¶] Alik Farber,***
ald J. Beck,[†‡] Harold I. Feldman,[†††‡‡‡] John W. Kusek,[†††] Jonathan Himmelfarb,[‡‡‡]
the Hemodialysis Fistula Maturation Study Group

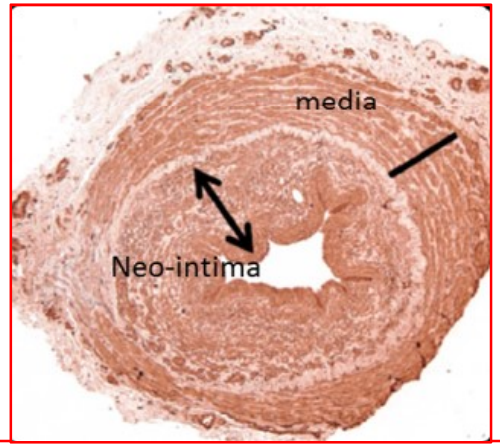


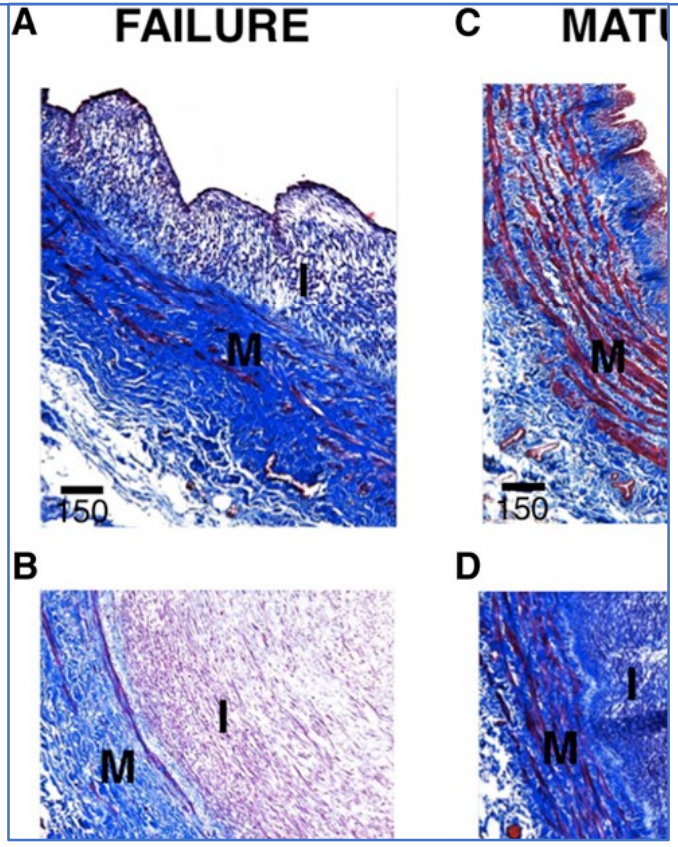




Alpers et al, J Am Soc Nephrol 2017

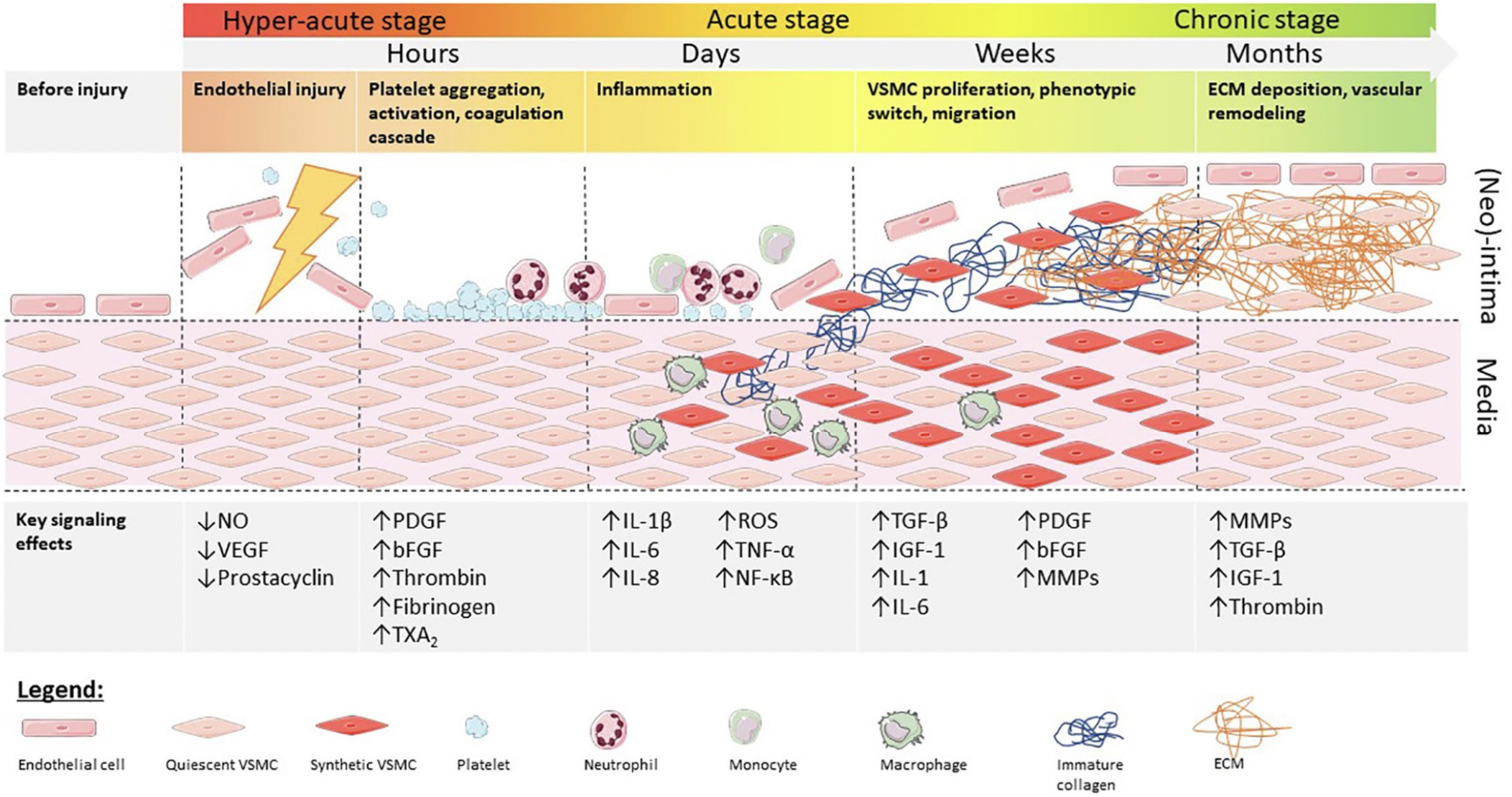
Haut degré de fibrose médiale



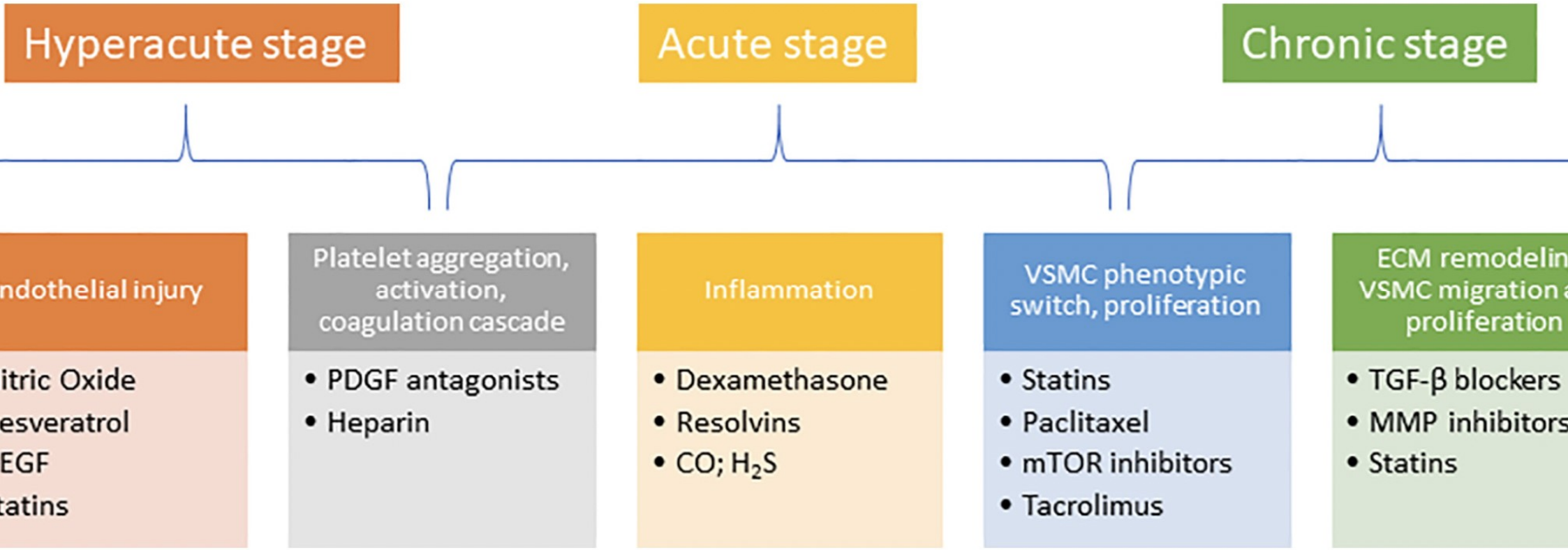


Hyperplasie myointimale

Martinez et al, J Am Soc Nephrol 2018

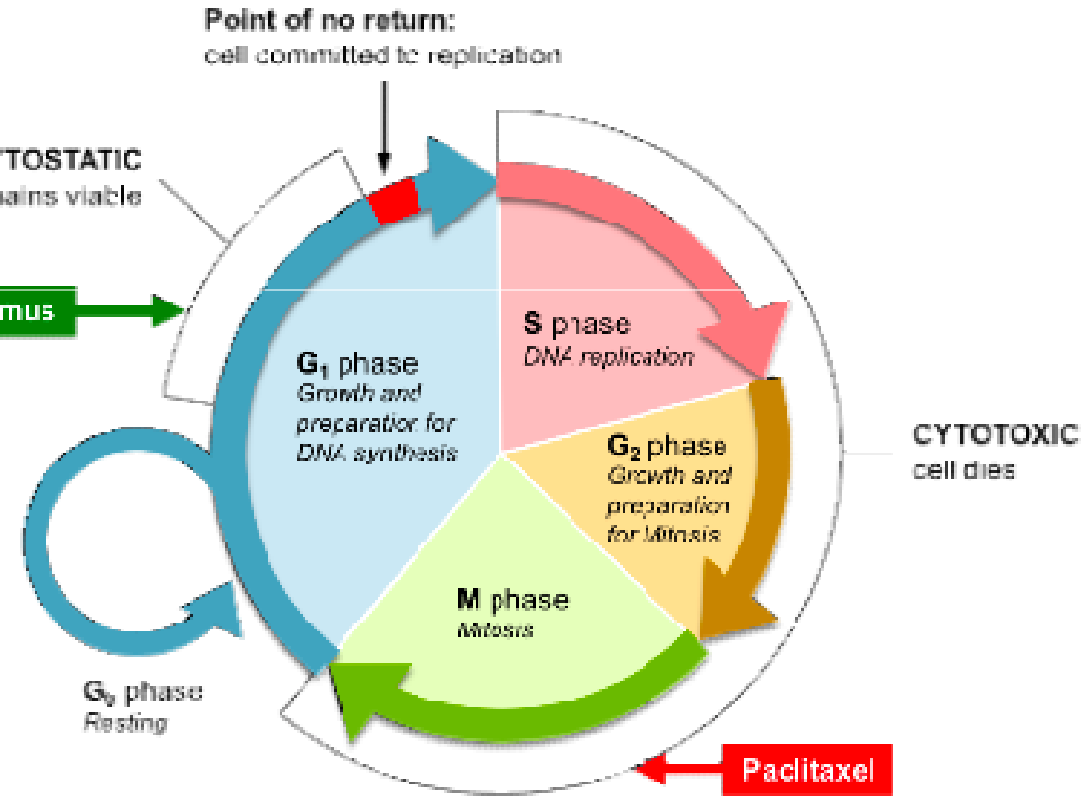


Melnik et al, Pharmacol Ther 2022



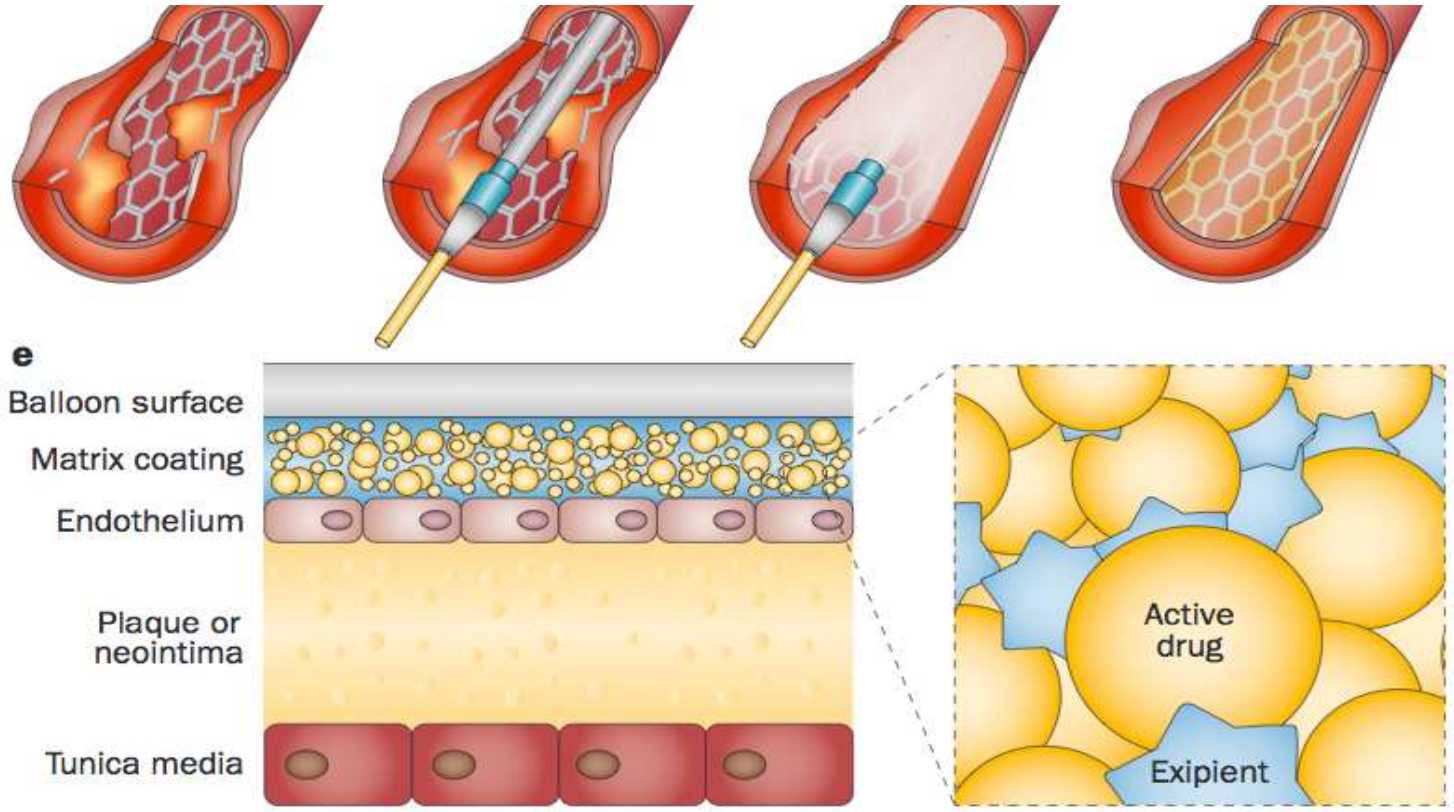
Melnik et al, Pharmacol Ther 2022

PTX and Limus both target the acute and the chronic stages by inhibiting smooth muscle cells division



	Limus	Paclitaxel
Action	Cytostatic	Cytotoxic
Margin of safety	Very high (10 000 fold)	High (100 fold)
Anti-inflammatory	Yes	No
Tissue absorption	Slow	Fast
Tissue retention	Short	Long

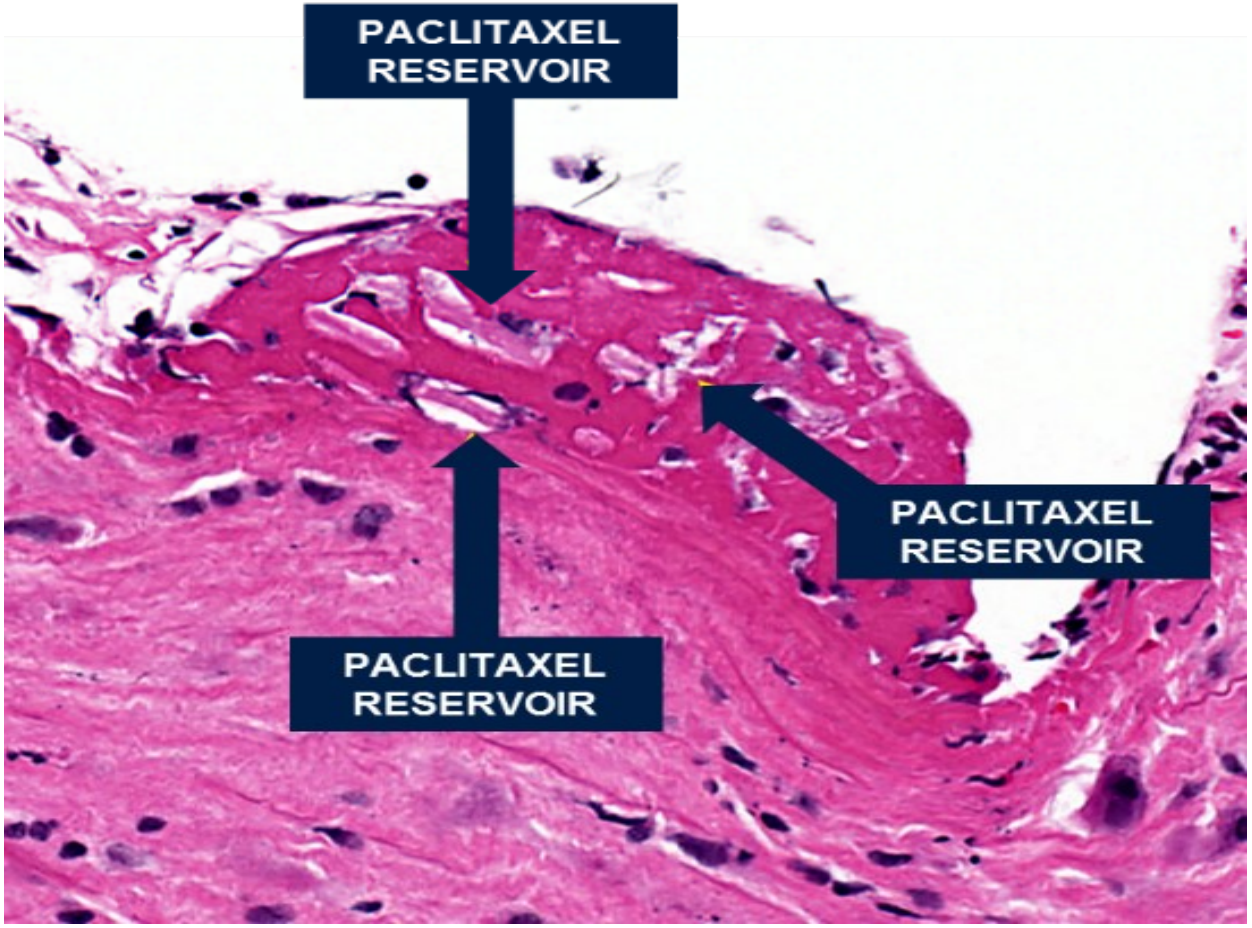
Dumont FJ et al, Life Sci. 1996

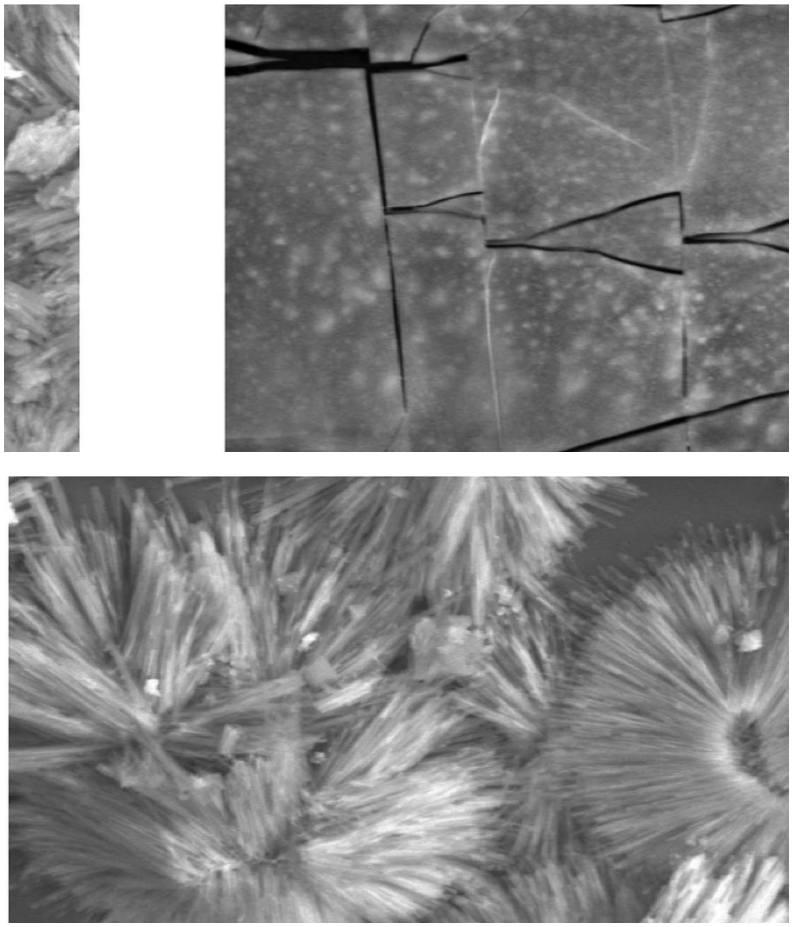


Balloon + **Drug (PTX)** + **Excipient** = **DCB**

Byrne et al, Nat Rev Cardiol 2014

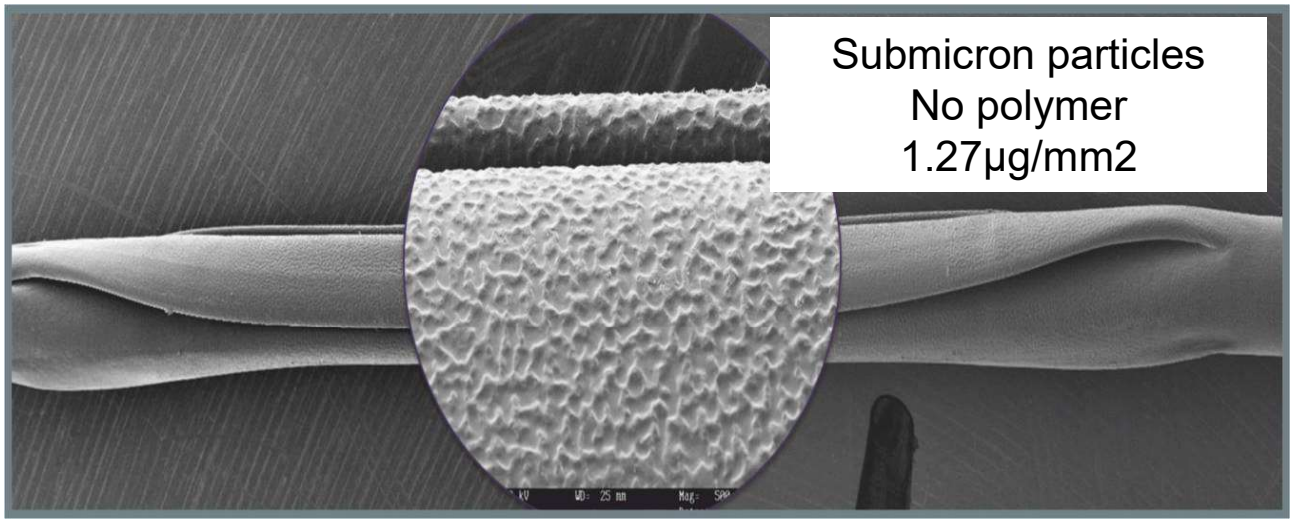
PTX reservoirs (crystals/microcrystals) allow prolonged effects

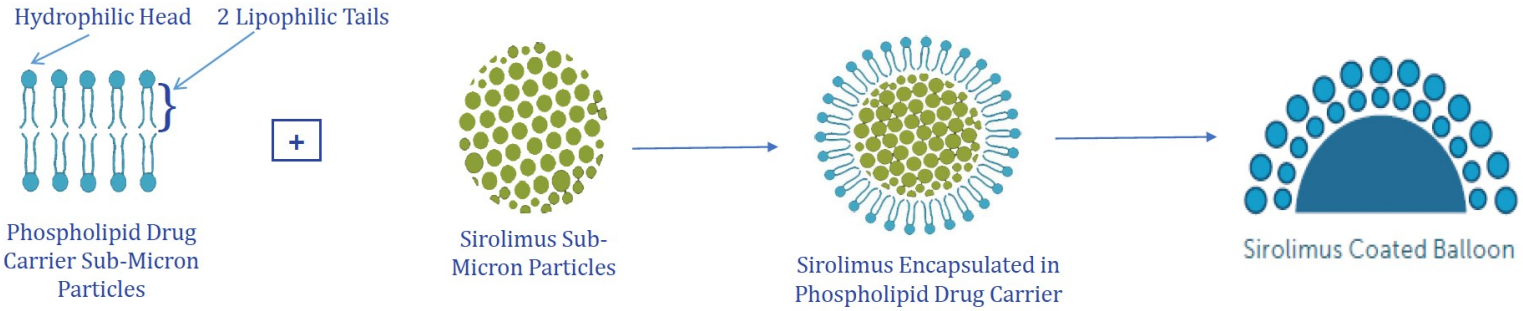




Torii et al, J Endovasc Ther 2017

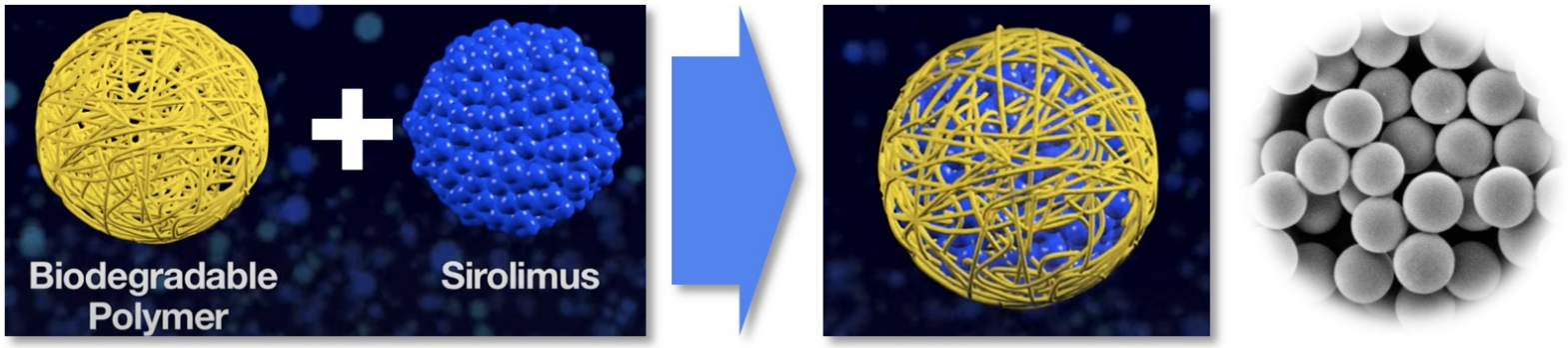
MagicTouch Sirolimus coated balloon (Concept Medical)

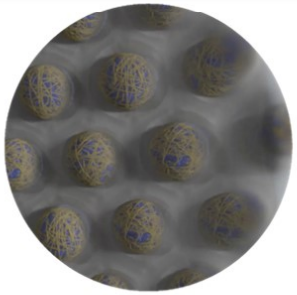




Teichgräber et al. Trials. 2021

Selution Sirolimus coated balloon (Cordis)





Proprietary amphipathic lipid technology which binds MicroReservoirs to the balloon surface

Enhances drug retention and bioavailability, allowing for a lower drug dose concentration on the balloon surface (1 µg/mm²)

PTX avoids initimal hyperplasia on AV grafts

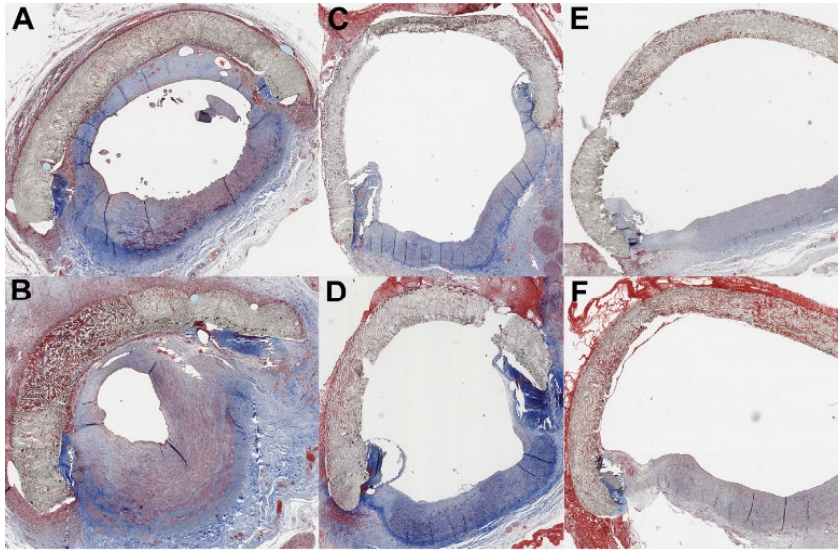
oating with paclitaxel improves graft survival in a porcine model of emodialysis graft stenosis

Paclitaxel coating on the terminal portion of hemodialysis grafts effectively suppresses neointimal hyperplasia in a porcine model

Paclitaxel coating of the luminal surface of hemodialysis grafts with effective suppression of neointimal hyperplasia

hibition of neointimal hyperplasia in vascular grafts by stained perivascular delivery of paclitaxel

Paclitaxel-coated expanded polytetrafluoroethylene aemodialysis grafts inhibit neointimal hyperplasia n porcine model of graft stenosis

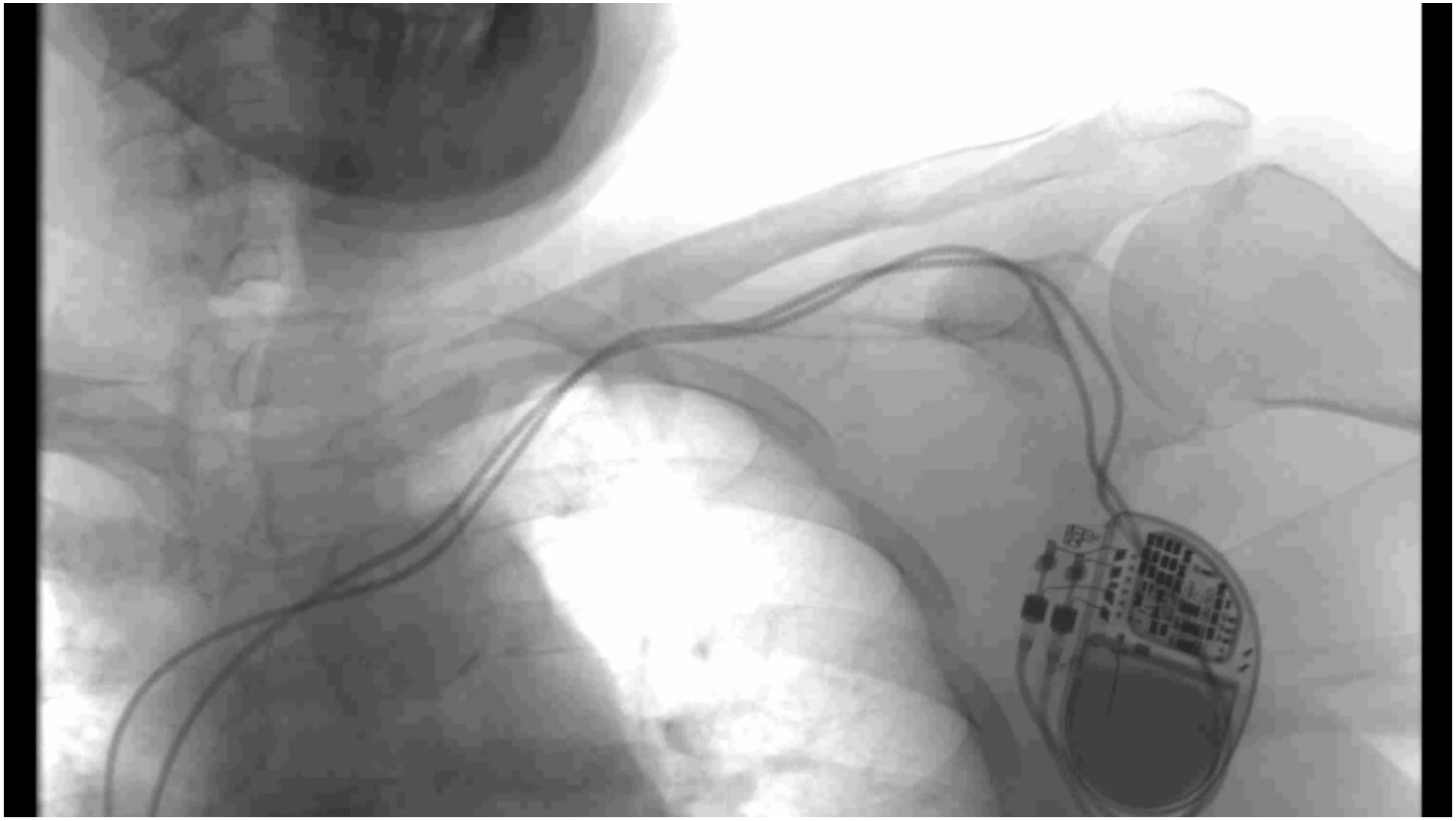


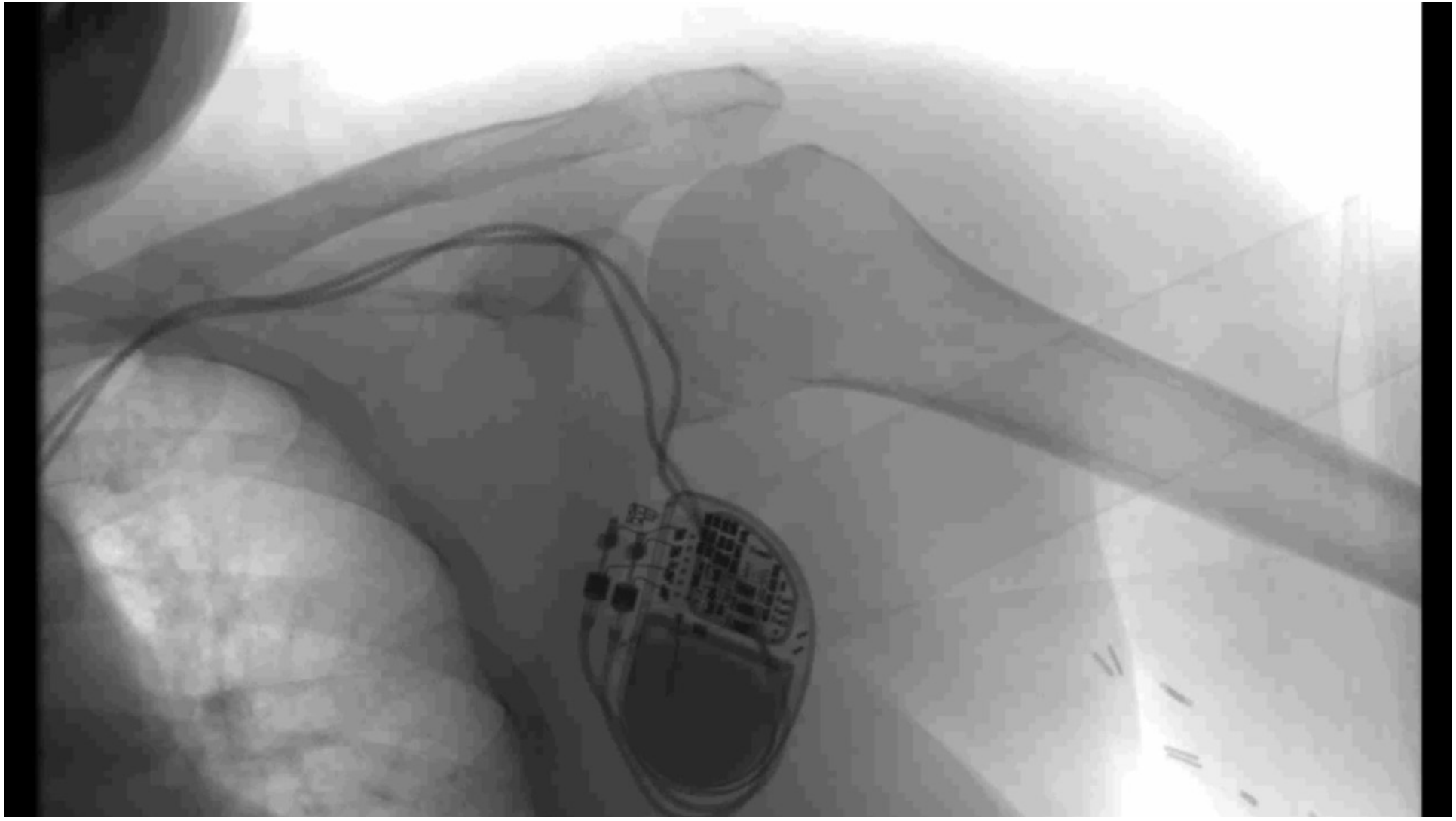
Masaki T, Kidney Int. 20
Lee BH, Nephrol Dial Transplant. 20
Lee BH, Nephrol Dial Transplant. 20
Baek I, Nephrol Dial Transplant. 20
Baek I, J Vasc Surg. 20
Baek I, J Vasc Surg. 20

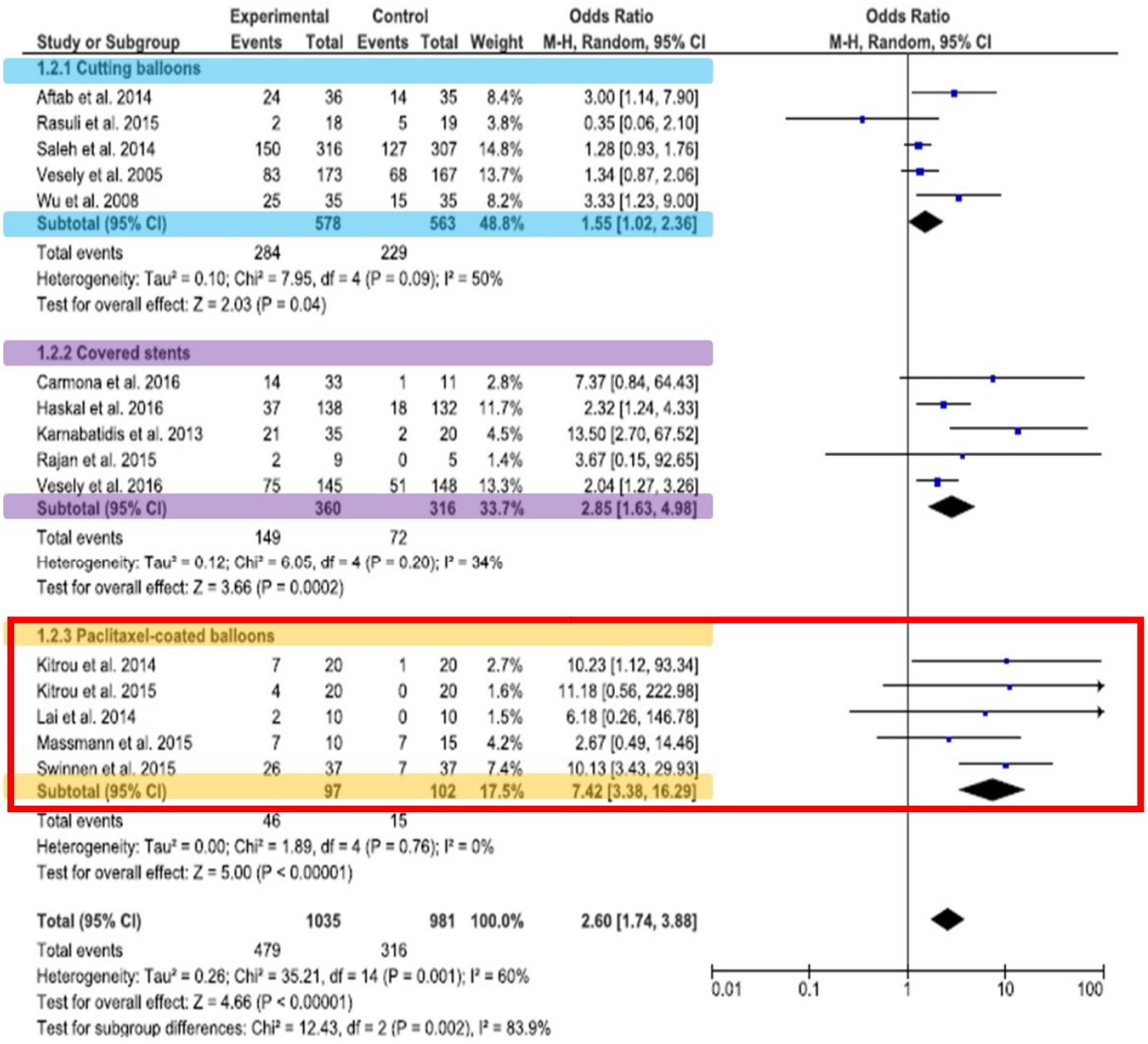
Ballons actifs et FAV: des séries initiales prometteuses

Auteur	Katsanos	Kitrou	Patanè	Swinnen	Verbeeck
Design	Prospective RCT	Prospective RCT	Prospective Bras unique	Prospective Bras unique	Prospective Bras unique
Uni/Multi centrique	Unicentrique	Unicentrique	Unicentrique	Unicentrique	Unicentrique
N patients	40	40	25	37	41
Type de FAV	FAV (14) PAV (26)	FAV	FAV	FAV et RIS	FAV
Localisation des lésions	Bras	Bras	Avant-bras	Avant-bras (54%) Bras (46%)	Avant-bras (58.5%) Bras (41.5%)
Endpoint Primaire	**Perméabilité primaire**	**TLR**	**Perméabilité primaire**	**TLR**	**Perméabilité primaire**
Resultats	PP 12-m: ▪ DCB: 35% ▪ PTA: 5% (p<0.001)	Perméabilité circuit: ▪ DCB: 308 j ▪ PTA: 161 j (p<0.05)	PP 12-m: 90.9% PP 24-m: 57.8%	Indemnité de TLR: ▪ DCB: 69% ▪ Non-DCB: 19%	PP 6-m: 81.4% PP 12-m: 60%

Boitet A, Coscas R. Semin Vasc Surg. 2016







Kitrou et al. Expert Rev Med Devices 2016

Drug Coated Balloon Angioplasty in Failing AV Fistulas
A Randomized Controlled Trial

Scott O. Trerotola,[1] Jeffrey Lawson,[2,3] Prabir Roy-Chaudhury,[4] and Theodore F. Saad,[5] for the Lutonix AV Clinical Trial Investigators

Abstract

Background Restenosis remains a problem in hemodialysis access interventions. Paclitaxel-coated balloons have shown promise in reducing access-related restenosis in small trials. The primary hypotheses for our multicenter trial were superior effectiveness at 180 days and noninferior safety at 30 days of a drug-coated balloon compared with conventional angioplasty for treatment of dysfunctional arteriovenous fistulas.

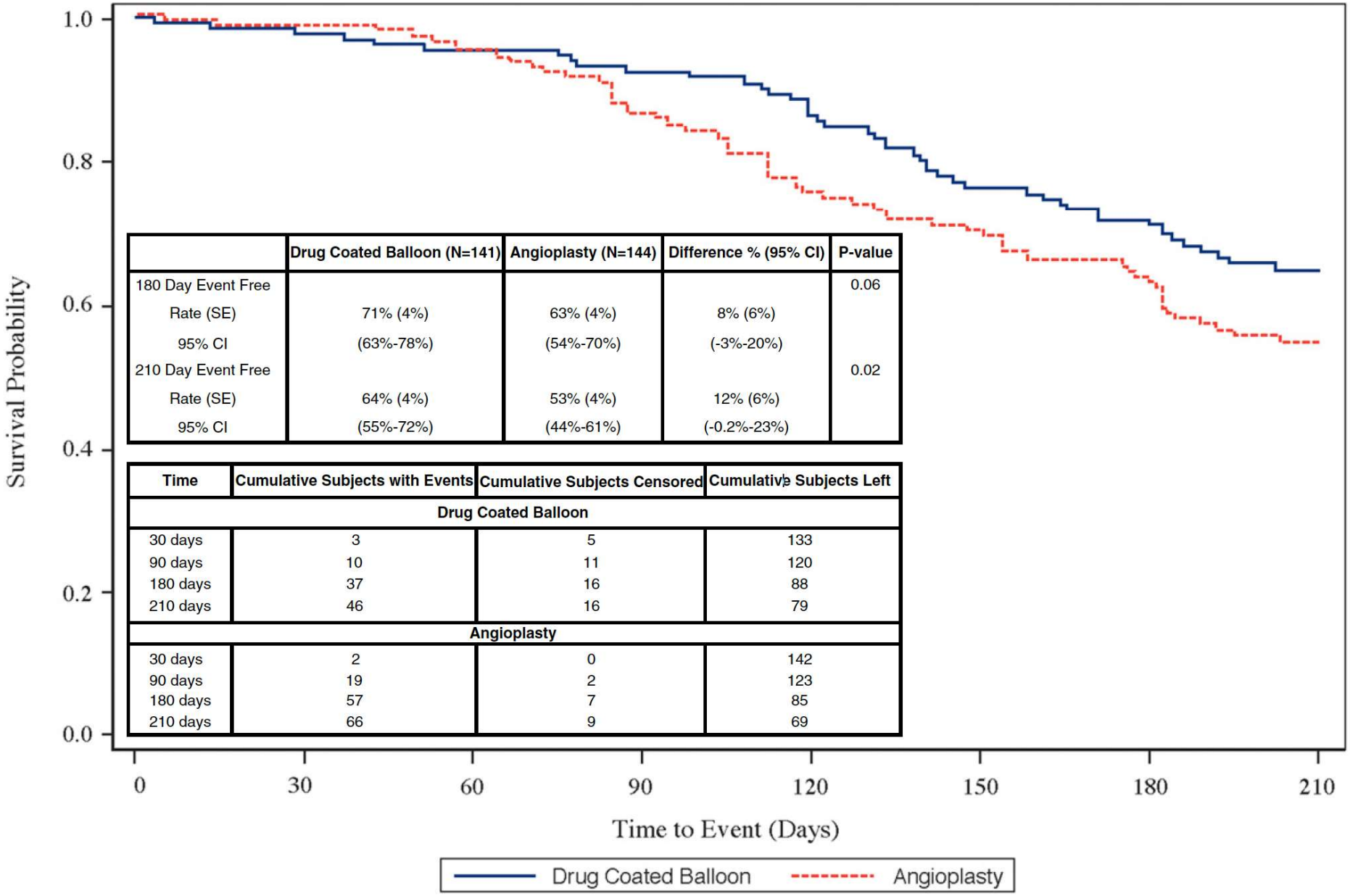
Design, setting, participants, & measurements This randomized trial enrolled 285 patients with dysfunctional arteriovenous fistulas at 23 centers. Grafts, central venous stenoses, thrombosed fistulas, and immature fistulas were excluded. All patients received angioplasty of the lesion responsible for access dysfunction. After successful angioplasty (≤30% residual stenosis), lesions were treated with either a paclitaxel-coated balloon or an uncoated control balloon of similar design to the drug-coated balloon. Access function during follow-up was determined per centers' usual protocols; reintervention was clinically driven. The primary efficacy outcome assessment was done at 6 months, and the safety assessment was done within 30 days of the procedure. Prespecified secondary end points included assessment of postintervention target lesion primary patency and access circuit primary patency at 6 months.

Results The 180-day end point was not met with target lesion primary patency (71%±4% for the drug-coated balloon and 63%±4% for control; P=0.06), representing a difference of 8%±6% (95% confidence interval, −3% to 20%). Access circuit primary patency did not differ between groups. Interventions to maintain target lesion patency were fewer for the drug-coated balloon at 6 months (0.31 versus 0.44 per patient; P=0.03). The primary safety noninferiority end point was met and did not differ between groups (P=0.002).

Conclusions Paclitaxel-coated balloon–assisted angioplasty did not meet the primary effectiveness end point at 180 days compared with conventional angioplasty. Both arms showed equivalent safety (ClinicalTrials.gov number NCT02440022).

Trerotola et al. Clin J Am Soc Nephrol 2018

Target Lesion Primary Patency at 6 Months (210 Days)



	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

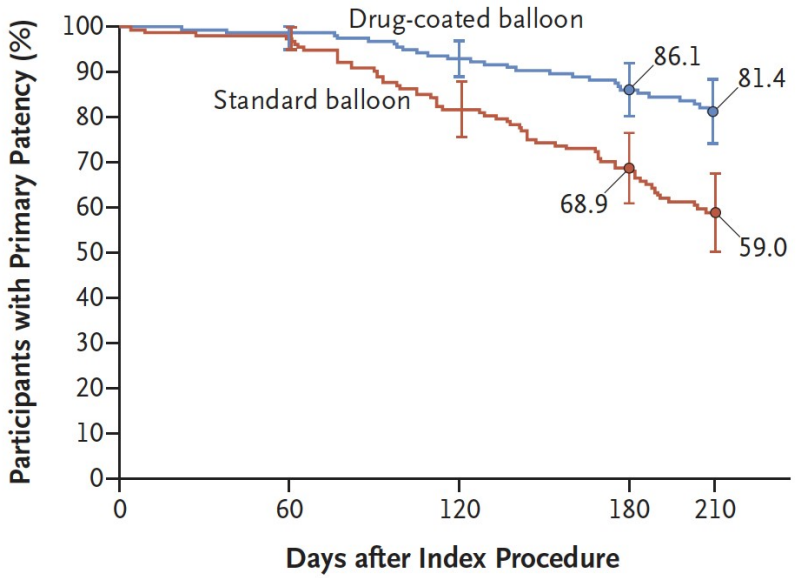
Trerotola et al. Clin J Am Soc Nephrol 2018

ORIGINAL ARTICLE

Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas

Robert A. Lookstein, M.D., M.H.C.D.L., Hiroaki Haruguchi, M.D., Kenneth Ouriel, M.D., M.B.A., Ido Weinberg, M.D., Lanyu Lei, Ph.D., Stephanie Cihlar, B.S., and Andrew Holden, M.B., Ch.B., for the IN.PACT AV Access Investigators*

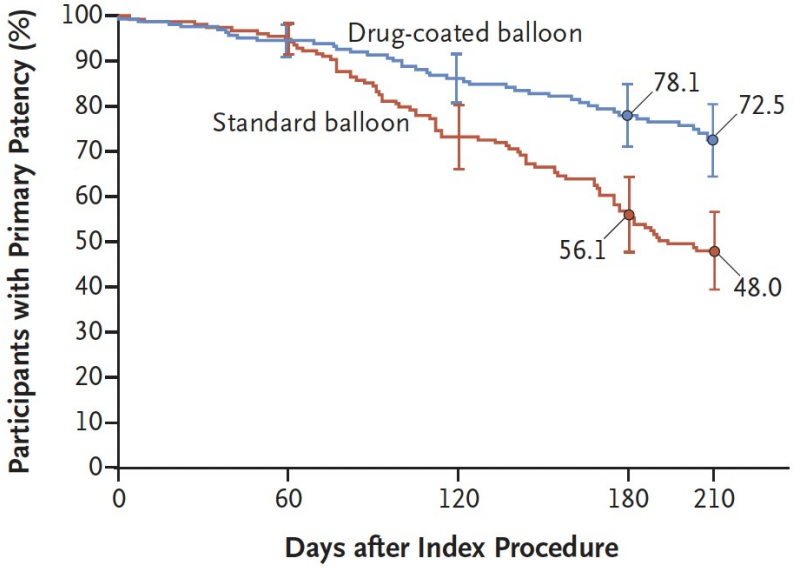
A **Target-Lesion Primary Patency**



No. at Risk

Drug-coated balloon	170	158	144	115	95
Standard balloon	160	152	123	93	72

B **Access-Circuit Primary Patency**



No. at Risk

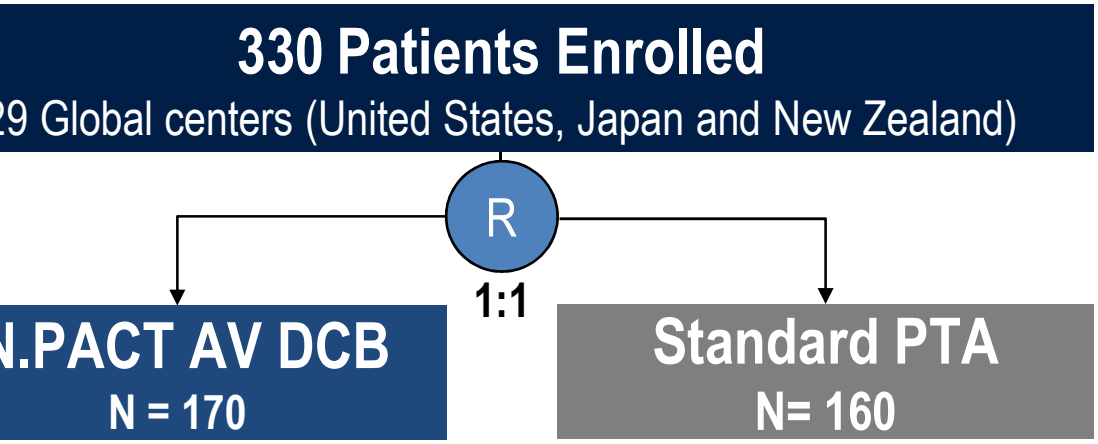
Drug-coated balloon	170	151	133	106	86
Standard balloon	160	148	110	78	62

Lookstein et al. NEJM 2020

N.PACT AV Access IDE Trial
verview and Primary Endpoints

jective:

spective, global multicenter, single-blinded study to luate the safety and effectiveness of the IN.PACT AV B compared to PTA for treatment of *de-novo* or *enotic* obstructive lesions of *native* AVF in the upper remity



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

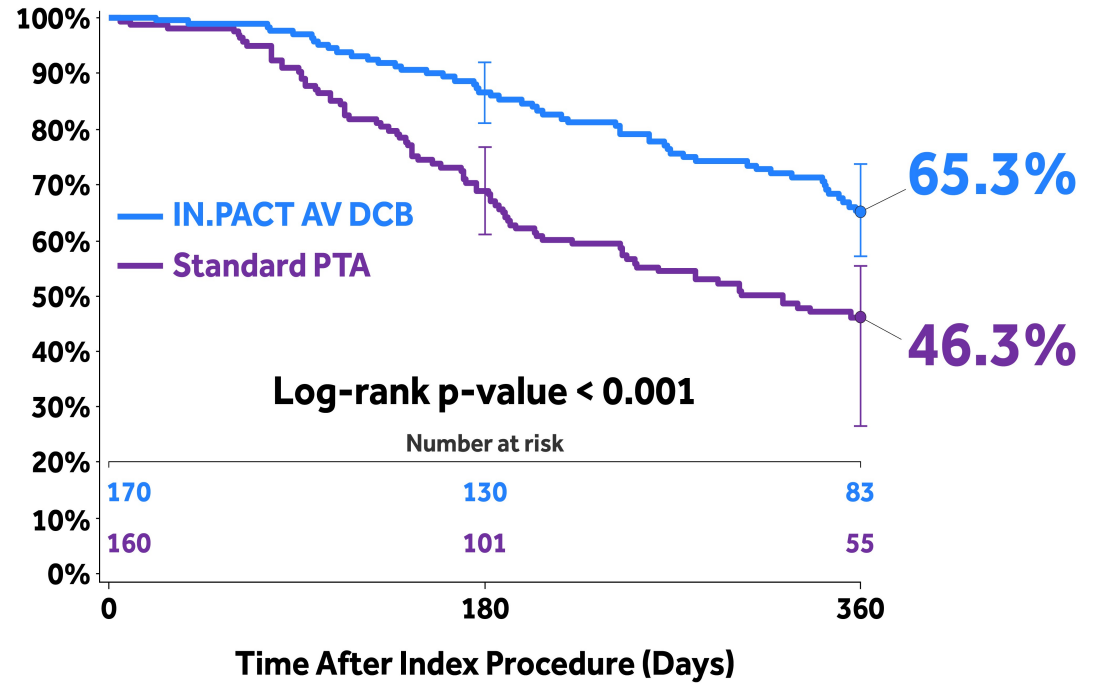
Target Lesion Primary Patency Rate through 6 Mont

- Defined as freedom from clinically-driven target lesion revascularization (CD-TLR) or access circuit thrombo measured through 6 months post-procedure

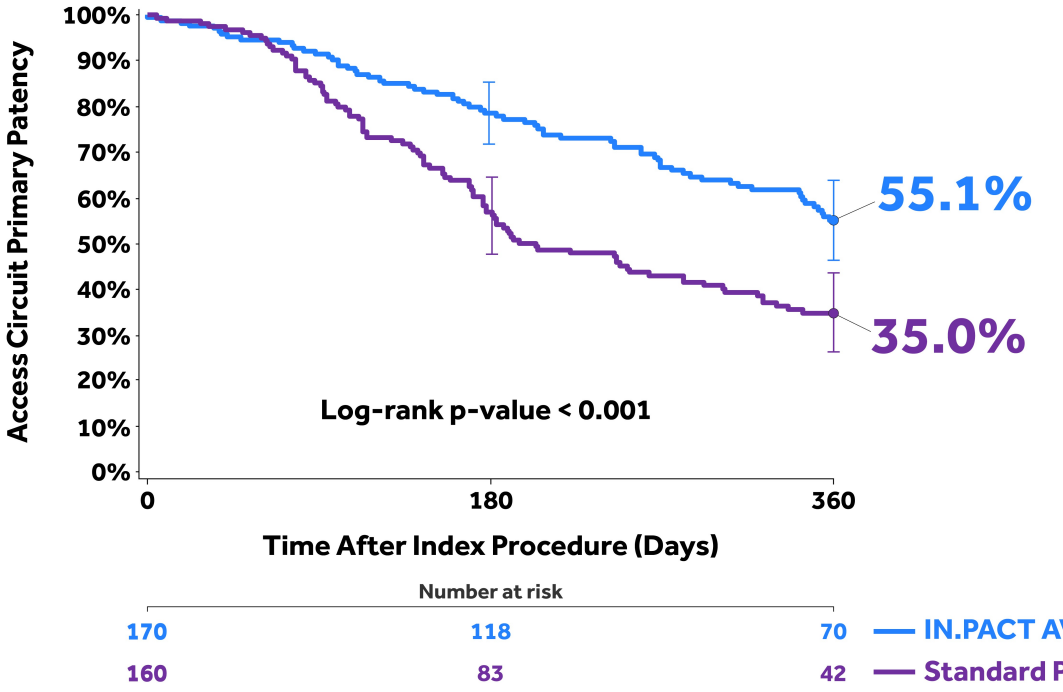
.PACT AV Access IDE Trial

tency Outcomes through 12 Months published in the JVIR

Target Lesion Primary Patency



Access Circuit Primary Patency



Target Lesion Revascularizations

Total number of interventions required to maintain target lesion patency through 360 days[1]

N.PACT AV DCB (n=170)	93	35.4% reduction
Standard PTA (n=160)	144	

Access Circuit Revascularizations

Total number of interventions required to maintain access circuit patency through 360 days[2]

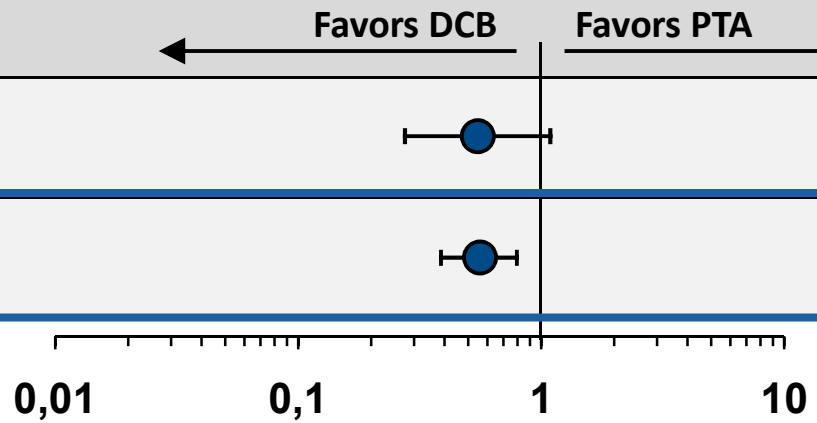
IN.PACT AV DCB (n=170)	110	34.5% reduction
Standard PTA (n=160)	168	

mber of interventions required to maintain target lesion patency is defined as number of target lesion revascularizations post index procedure.
mber 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

N.PACT AV Access IDE Trial

arget Lesion Primary Patency: DCB vs PTA by Lesion Type

group (N_{DCB}/N_{PTA})	% Kaplan-Meier Estimate (number of participants with an event) IN.PACT AV Access DCB	Standard PTA	Hazard Ratio [95% CI]
on type			
Novo (51/49)	**67.5%** (13)	**50.7%** (21)	**0.54** [0.27, 1.07]
tenotic 9/111)	**46.0%** (55)	**30.2%** (70)	**0.55** [0.38, 0.78]



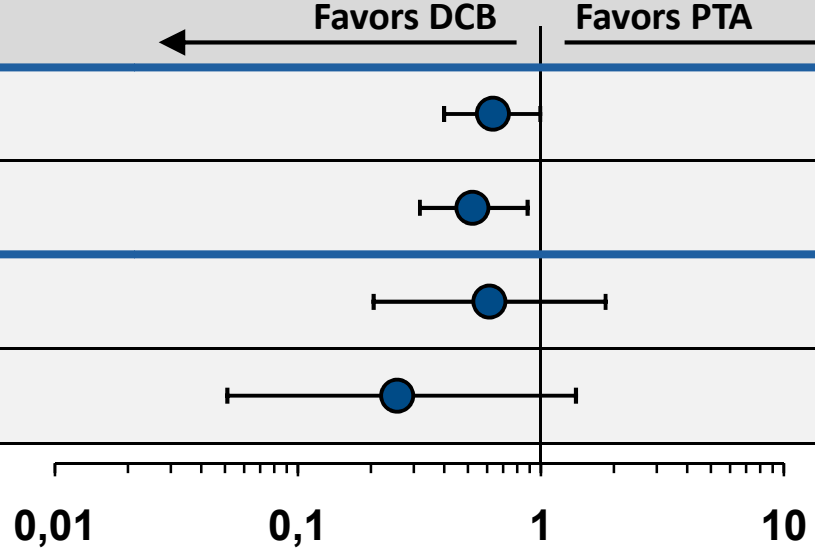
drug-coated balloon; PTA, percutaneous transluminal angioplasty

x- and twelve-month forest plot comparisons were reported using proportion rates and percent difference; 24-month forest plot comparisons were done using Kaplan-Meier rates to account for missing

N.PACT AV Access IDE Trial

arget Lesion Primary Patency: DCB vs PTA by AVF Type

bgroup (N_{DCB}/N_{PTA})	% Kaplan-Meier Estimate (number of participants with an event) IN.PACT AV Access DCB	Standard PTA	Hazard Ratio [95% CI]
F Type			
diocephalic (86/80)	**53.6%** (35)	**43.0%** (42)	**0.62** [0.39, 0.97]
chiocephalic (62/58)	**48.5%** (25)	**27.3%** (37)	**0.51** [0.31, 0.86]
chiobasilic (17/15)	**54.2%** (6)	**32.2%** (7)	**0.60** [0.20, 1.80]
ner (5/7)	**60.0%** (2)	**16.7%** (5)	**0.25** [0.05, 1.36]

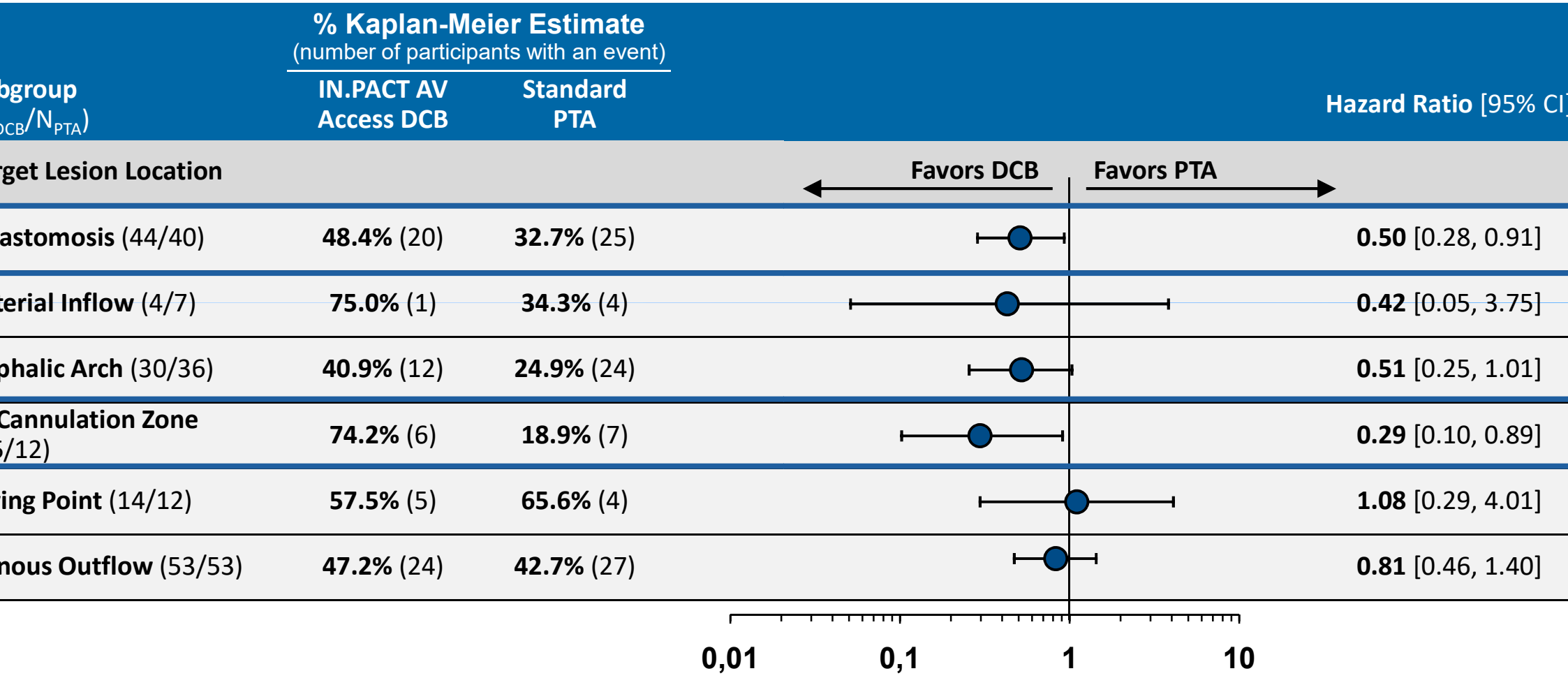


drug-coated balloon; PTA, percutaneous transluminal angioplasty

x- and twelve-month forest plot comparisons were reported using proportion rates and percent difference; 24-month forest plot comparisons were done using Kaplan-Meier rates to account for missing

N.PACT AV Access IDE Trial

arget Lesion Primary Patency: DCB vs PTA by Lesion Location

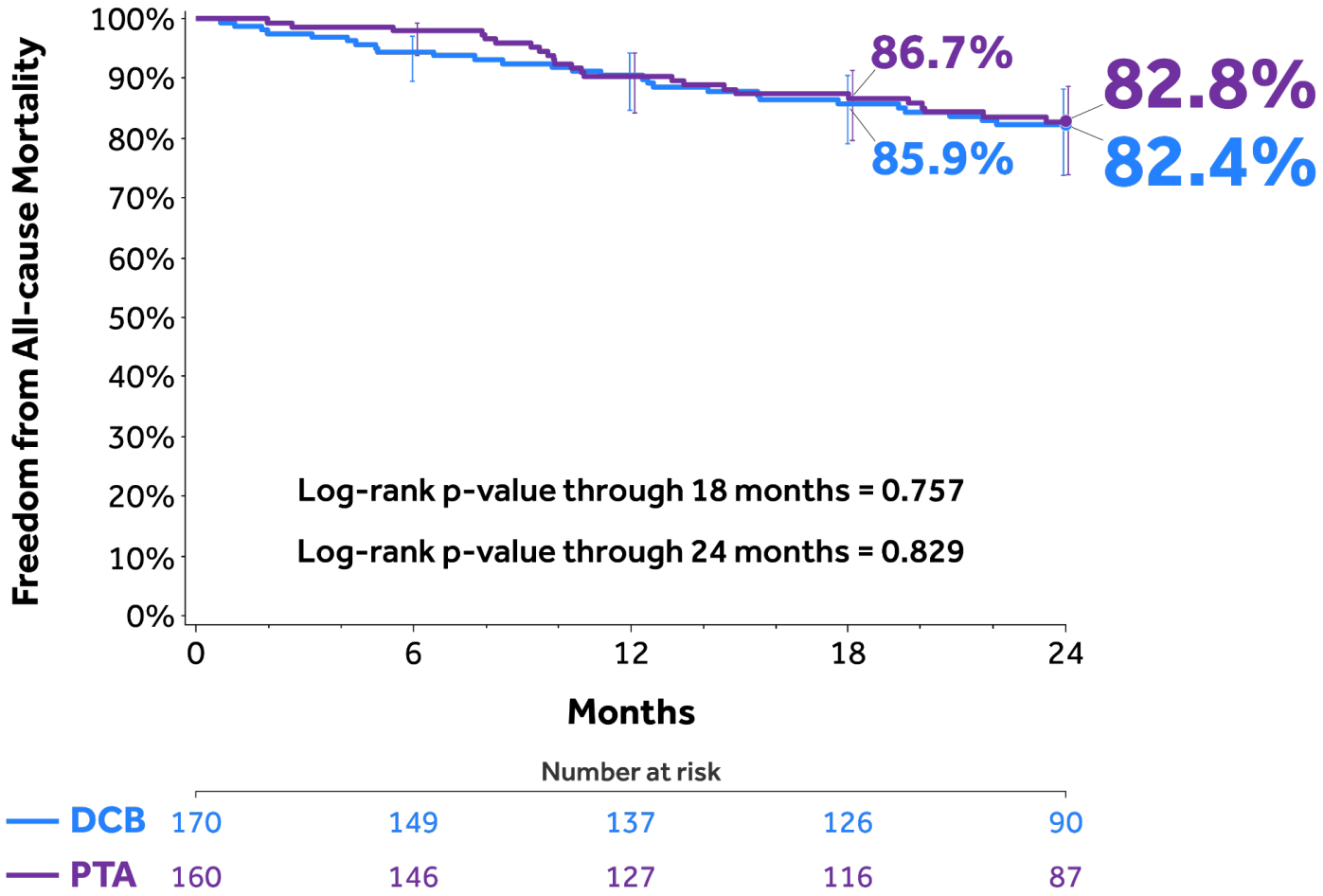


drug-coated balloon; PTA, percutaneous transluminal angioplasty

x- and twelve-month forest plot comparisons were reported using proportion rates and percent difference; 24-month forest plot comparisons were done using Kaplan-Meier rates to account for missing

I.PACT AV Access IDE Trial

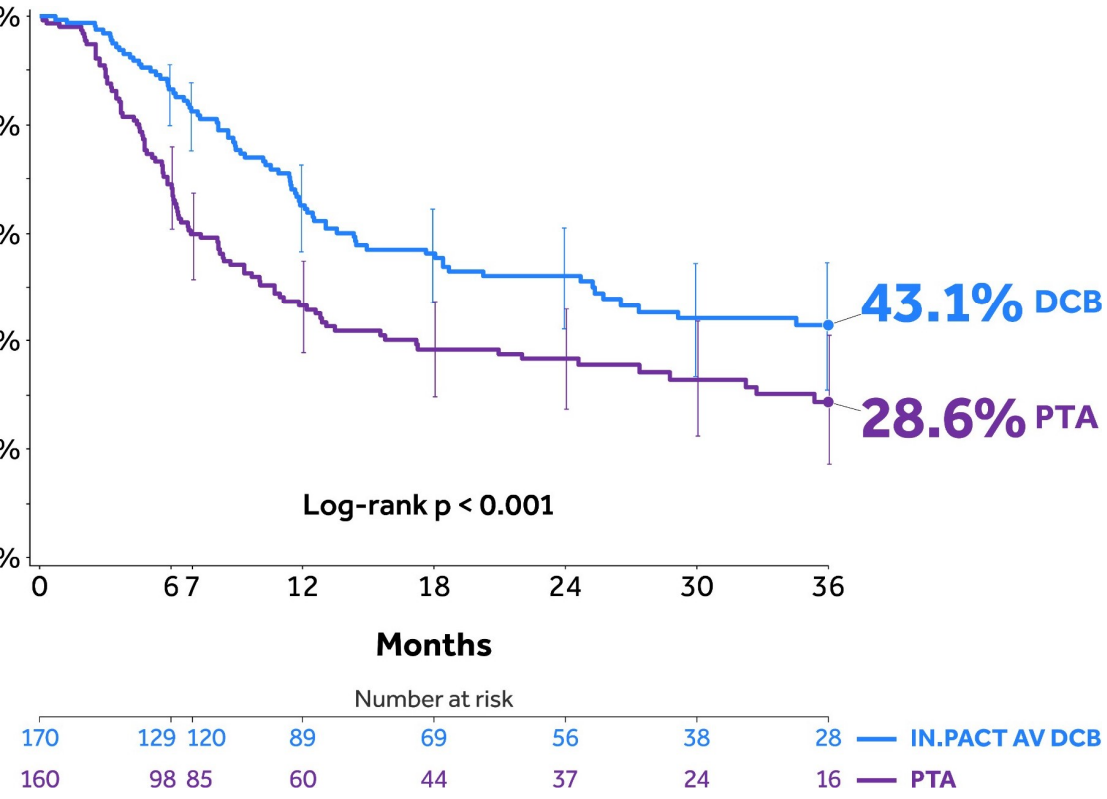
reedom from All-cause Mortality Through 24 Months



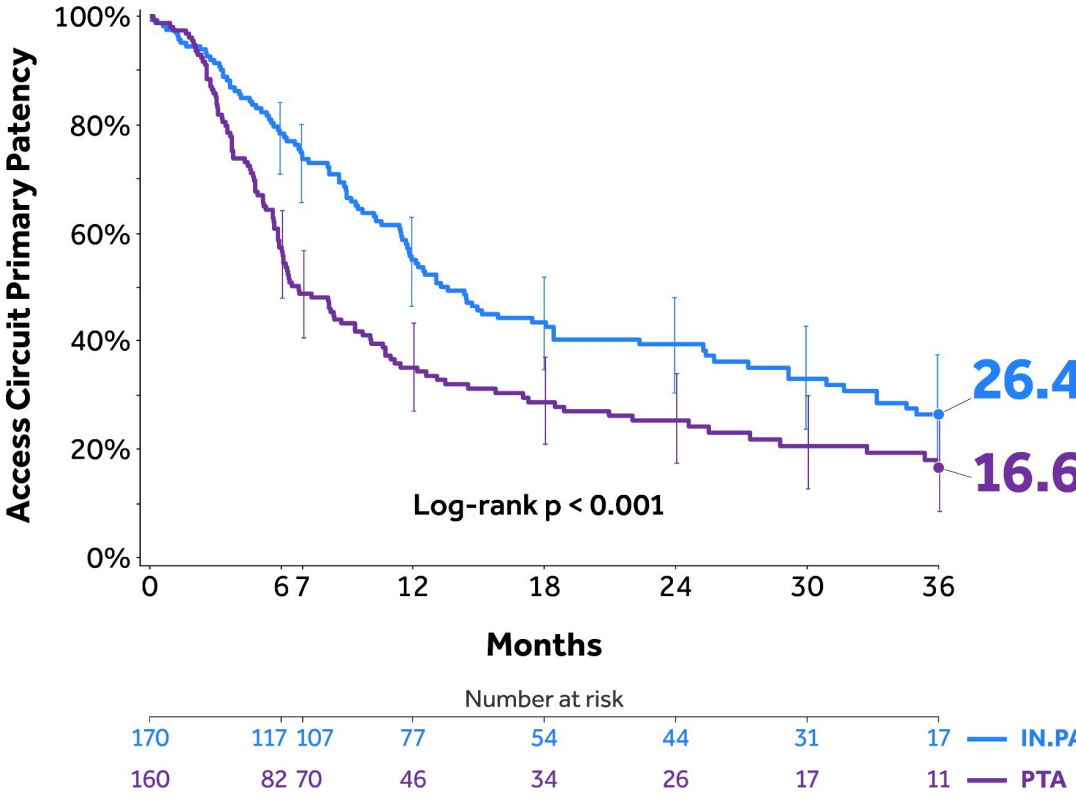
.PACT AV Access IDE Trial

tency Outcomes through 36 Months

Target Lesion Primary Patency



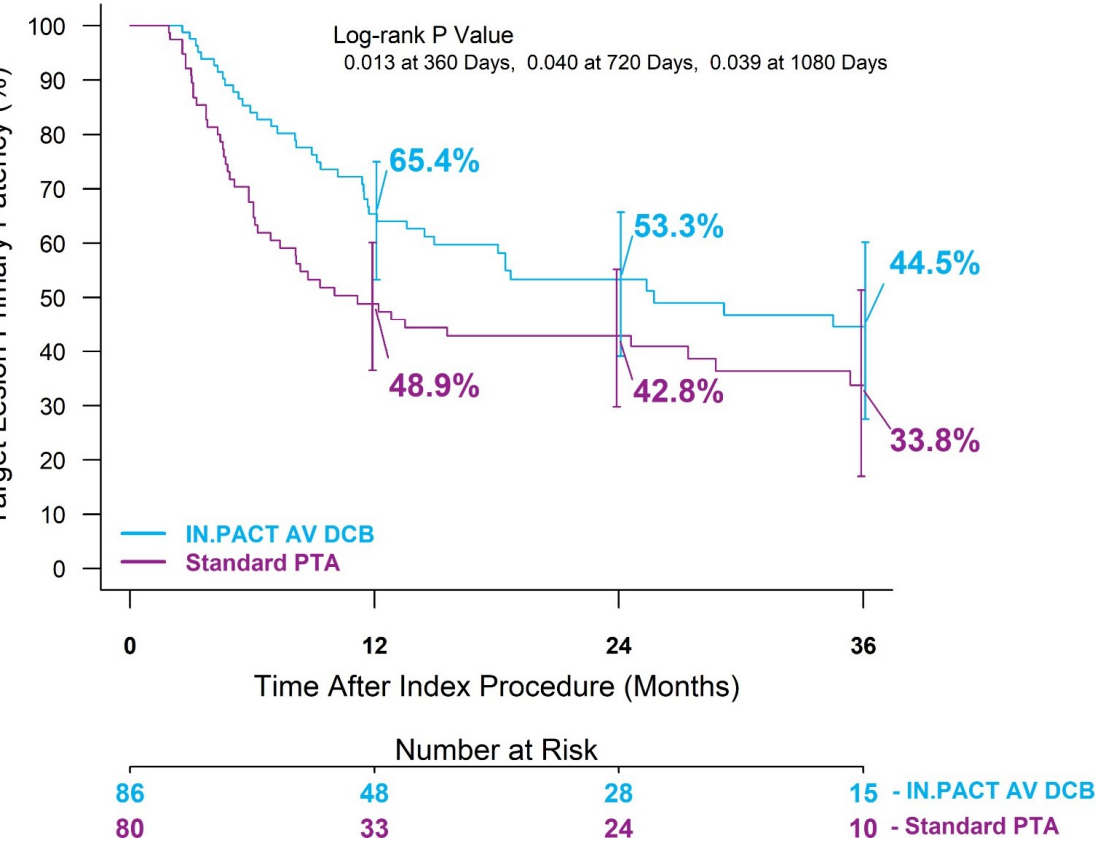
Access Circuit Primary Patency



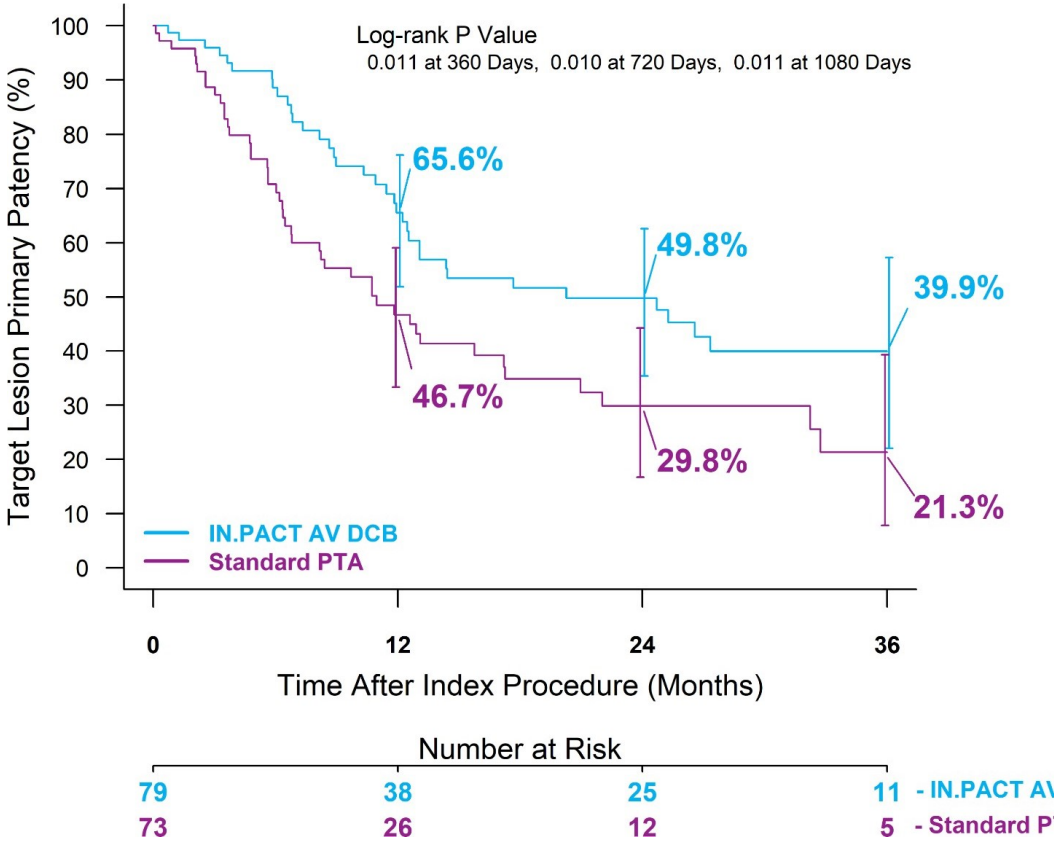
.PACT AV Access IDE Trial

tency Outcomes through 36 Months

Radiocephalic (Forearm)

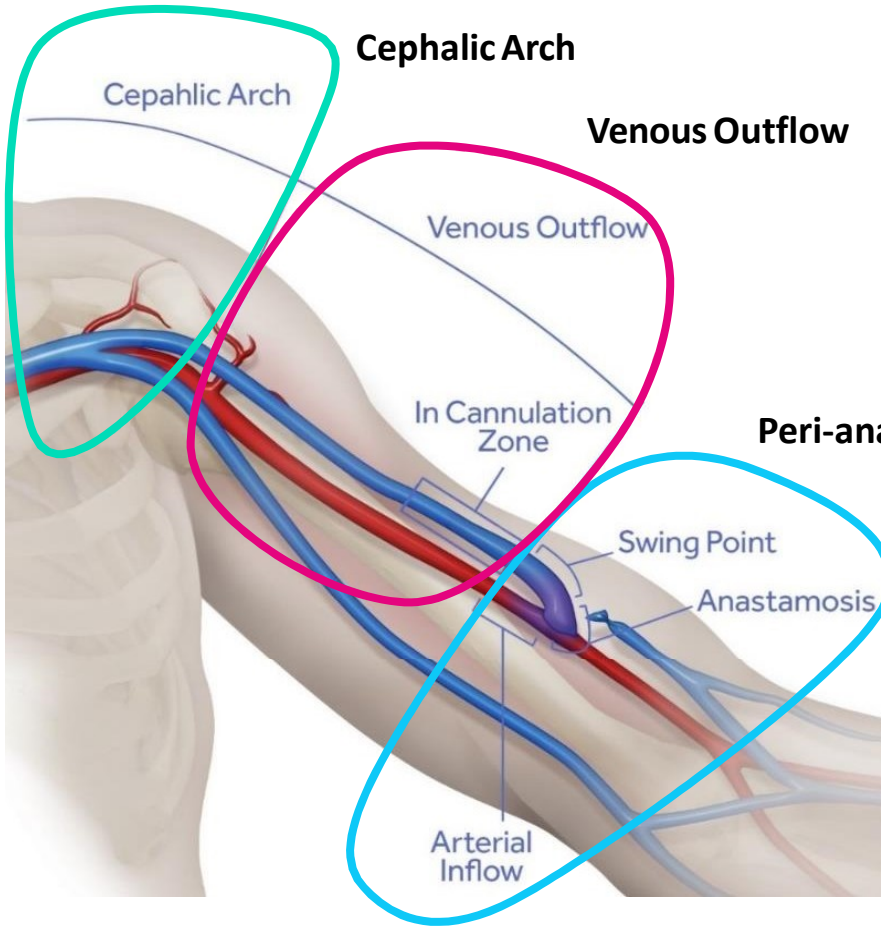


Brachiocephalic and Brachiobasilic (Upper Arm



Lesion Location Groups

Baseline Demographics	IN.PACT AV DCB (n=170)	Standard PTA (n=160)
Target Lesion Location†		
Peri-anastomotic	**36.5% (62/170)**	**36.9% (59/160)**
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)
Venous Outflow	**45.9% (78/170)**	**40.6% (65/160)**
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)**

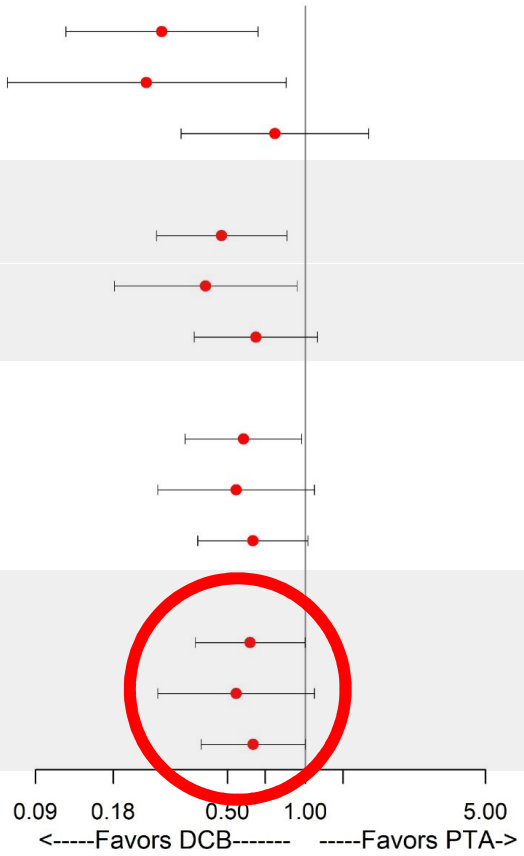


Arterial Inflow: treated segment is isolated to the arterial side
Anastomosis: treated segment crosses or meets the AV anastomosis
Swing Point: treated segment includes the curved segment of mobilized vesse
Cannulation Zone: treated segment is isolated to straight segment of vessel w cannulation is performed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

.PACT AV Access IDE Trial

tency Outcomes through 36 Months – Subgroups analysis

Subgroups (N DCB/N PTA)	IN.PACT AV DCB*	Standard PTA*	Hazard Ratio [95% CI]
6 Months			
Peri-anastomotic (62/59)	87.5% (7)	61.6% (21)	0.278 [0.118, 0.656]
Cephalic Arch (30/36)	89.3% (3)	59.7% (14)	0.242 [0.070, 0.842]
Venous Outflow (78/65)	85.1% (11)	81.4% (11)	0.762 [0.330, 1.758]
12 Months			
Peri-anastomotic (62/59)	65.3% (19)	45.8% (29)	0.474 [0.265, 0.848]
Cephalic Arch (30/36)	64.2% (8)	37.6% (21)	0.411 [0.182, 0.928]
Venous Outflow (78/65)	65.9% (24)	52.9% (27)	0.644 [0.371, 1.116]
24 Months			
Peri-anastomotic (62/59)	51.3% (26)	39.4% (32)	0.576 [0.342, 0.968]
Cephalic Arch (30/36)	40.9% (12)	27.9% (23)	0.540 [0.268, 1.086]
Venous Outflow (78/65)	56.0% (30)	39.3% (34)	0.626 [0.383, 1.023]
36 Months			
Peri-anastomotic (62/59)	40.4% (30)	31.1% (35)	0.612 [0.375, 0.998]
Cephalic Arch (30/36)	40.9% (12)	27.9% (23)	0.540 [0.268, 1.086]
Venous Outflow (78/65)	45.6% (34)	25.5% (37)	0.628 [0.394, 1.001]



rug-eluting balloon (DEB) ersus plain old balloon ngioplasty (POBA) in the eatment of failing dialysis ccess: A prospective ndomized trial

rbjörn Fransson[1,6], Anders Gottsäter[2,6], hammad Abdulrasak[2,6], Martin Malina[3] and nothy Resch[4,5]

Paclitaxel-Coated Balloon versus Plain Balloon Angioplasty for Dysfunctional Autogenous Radiocephalic Arteriovenous Fistulas: A Prospective Randomized Controlled Trial

ong Woo Kim, MD, PhD[1], Jeong Ho Kim, MD[2], Sung Su Byun, MD[3], in Mo Kang, MD, PhD[4], Ji Hoon Shin, MD, PhD[1]

Efficacy of Paclitaxel Balloon for Hemodialysis Stenosis Fi After One Year Compared to High-Pressure Balloons: A Controlled, Multicenter, Randomized Trial

T. Moreno-Sánchez[1] · M. Moreno-Ramírez[2] · F. H. Machancoses[3] · P. Pardo-Moreno[4] · P. F. Navarro-Vergara[5] · J. García-Revillo[6]

Safety and Efficacy of Paclitaxel-E Balloon Angioplasty for Dysfunc Hemodialysis Access: A rando trial Comparing with Angioplasty

Eric Therasse, MD, Véronique Caty, MD, Patrick Gilb Marie-France Giroux, MD, Pierre Perreault, MD, Louis Bouch Vincent L. Oliva, MD, Jacques Lespérance, MD, Jean Eth Georges Ouellet, MD, Martin Francoeur, MD, Serge Cournoyer, Gilles Soulez, M

34 studies, 1900 participants receiving a DCB

Available Studies					
Study	Type	Device	Country(ies)	Pts with PCB	VA Circuit
nos, Kitrou 12, 2015)	SC-RCT	IN.PACT	Greece	20	AVF, AVG
nè (2014)	SC-SA-PS	IN.PACT	Italy	26	AVF
i (2014)	SC-DA-PS	SeQuent Please	Taiwan	10	AVF
ou (2015)	SC-RCT	IN.PACT	Greece	20	AVF
nann (2015)	SC-DA-RS	Elutax-SV	Germany	10	AVF
nen (2015)	SC-DA-RS	IN.PACT	Australia	37	AVF
eeck (2016)	SC-SA-PS	IN.PACT	Luxemburg	41	AVF
ou (2016)	SC-SA-RS	Lutonix	Greece	39	AVF, AVG
eux (2017)	MS-RCT	IN.PACT	Belgium, Luxemburg	33	AVF
sen (2017)	MS-RCT	IN.PACT	Netherlands	16	AVF, AVG
ou (2017)	SC-RCT	Lutonix	Greece	20	AVF, AVG
si (2017)	SC-DA-RS	Freeway	Italy	27	AVF
rdi (2017)	SC-SA-PS	Aperto	Italy	50	AVF, AVG
erotola 18, 2020)	MS-RCT	Lutonix	USA	141	AVF
hi (2018)	SC-RCT	IN.PACT	Singapore	59	AVF, AVG
ev (2018)	SC-DA-PSHG	IN.PACT	Slovenia	31	AVF

Hongsakul (2018)	SC-SA-RS	IN.PACT	Thailand	16	AV
Swinnen (2018)	MC-RCT	IN.PACT	Australia	70	
Kitrou (2019)	SC-SA-RS	Lutonix	Greece	38	AV
Gulcu (2019)	SC-SA-RS	IN.PACT, Elutax SV	Turkey	42	
Bjorkman (2019)	SC-RCT	IN.PACT	Finland	19	
Tozzi (2019)	MS-SA-PS	Aperto	Italy	200	AV
Kocaaslan (2019)	SC-DA-RS	IN.PACT	Turkey	44	
Karnabatidis (2020)	MS-SA-PS	Lutonix	Global (Exc. USA)	320	AV
Moreno-Sancez (2019)	MC-RCT	Lutonix	Spain	61	AV
Liao (2019)	SC-RCT	IN.PACT	Taiwan	22	
Kitrou (2020)	MS-SA-RS	Lutonix, IN.PACT, Elutax SV	European	86	AV
Lookstein (2020)	MS-RCT	IN.PACT	USA. Japan, New Zealand	170	
Kim (2020)	MS-RCT	IN.PACT	Korea	20	
Pang (2020)	SC-RCT	IN.PACT	Hong Kong	20	AV
Chong (2020)	SC-DA-RS	Lutonix	Singapore	30	AV
Karunanithy (2021)	MS-RCT	Lutonix	UK	106	
Therasse (2021)	MS-RCT	Passeo 18	Canada	60	AV
Yin (2021)	MS-RCT	Aperto	China	79	

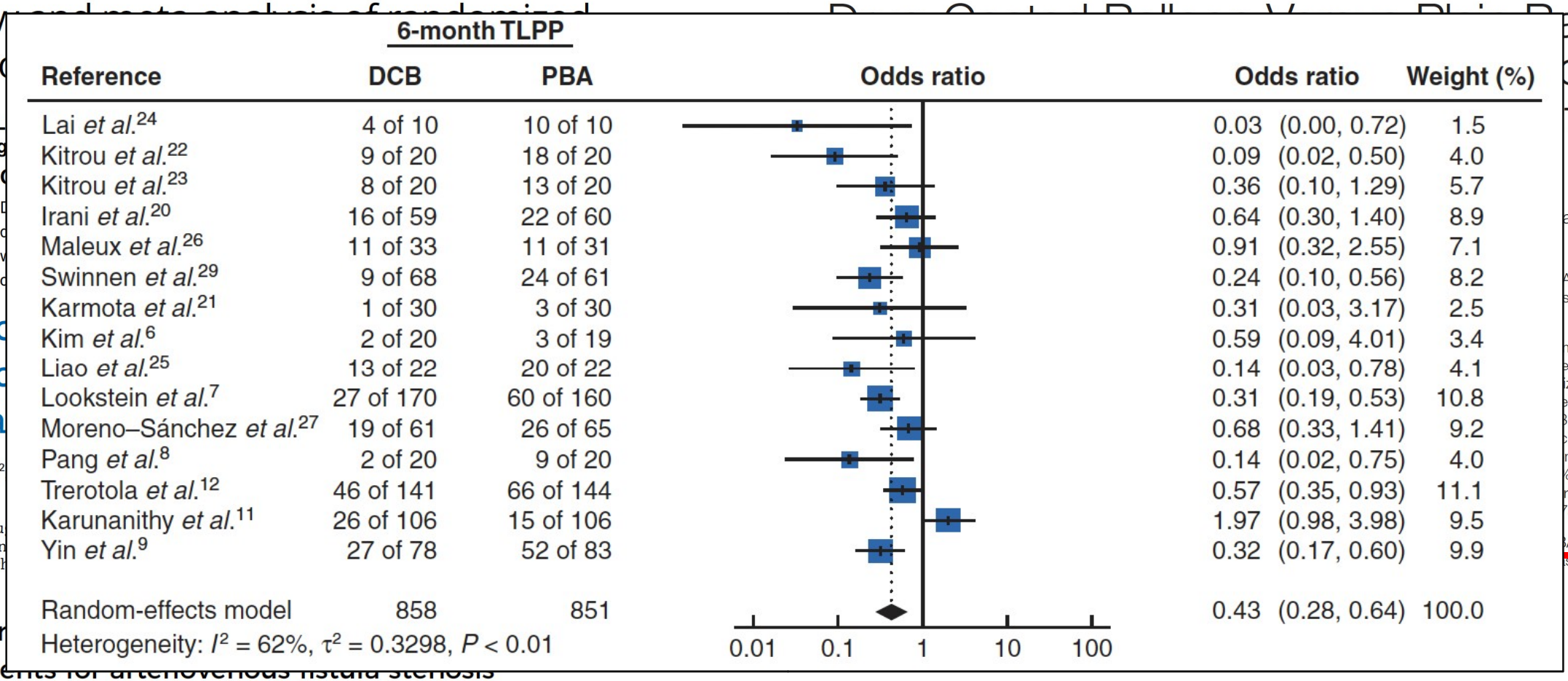
Kitrou et al. Drug-Coated Balloons for the Dysfunctional Vascular Access. An Evidence-Based Road Map to Treatment and the Existin
Semin Intervent Radiol. 2022 Feb 18;39(1):56-65. doi: 10.1055/s-0042-1742483. PMID: 35210734; PMCID: PM

7 devices were studies

ces Used in Vascular Access Studies

Device	Company	Dose ($\mu g/mm^2$)	Excipient	Diameter (min-max)	# of studies	pa
Lutonix™	Becton Dickinson, Franklin Lakes, NJ, USA	2	Polysorbate/Sorbitol	4-12mm	9	
IN.PACT™	Medtronic, Dublin, Ireland	3.5	Urea	4-12mm	19	
Aperto™	Cardionovum, Bonn, Germany	3.0	Ammonium Salt		3	
sseo-18 Lux®	Biotronik SE & Co. KG, Berlin, Germany	3.0	Butyryl-tri-hexyl citrate	2-7mm	1	
Elutax-SV	Aachen Resonance, Aachen, Germany	2.2	No Excipient/Dextran coating	4-7mm	3	
Freeway™	Eurocor GmbH, Bonn, Germany	3	Shellac	4-8mm	1	
uent Please®	B Braun, Berlin, Germany	3.55	Iopromide	4-8mm	1	

g-coated balloon versus conventional
oon angioplasty of hemodialysis
eriovenous fistula or graft: A systematic



y Tripsianis, PhD,[a] Eleni Christaina, MSc,[a] Christos Argyriou, MD, PhD,[b]
os Georgakarakos, MD, PhD,[b] George S. Georgiadis, MD, PhD,[b] *and*
K. Lazarides, MD, PhD, FEBVS,[b] *Alexandroupolis, Greece*

ons: In failing AVFs with outflow stenosis, DCBA was significantly superior to PBA, with improved 6-month failure
vever the effectiveness of DCBA in the long term deserves further investigation. (J Vasc Surg 2021;73:2198-203.)

Hu et al. Br J surg 2021

Tripsianis et al. J Vasc Surg 2021

Liu et al. J Am Heart Assoc 2021

Liao et al. Plos One 2020

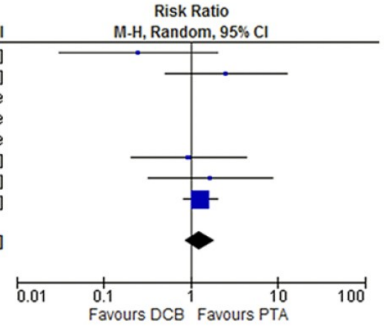
lortality After Paclitaxel-Coated Device se in Dialysis Access: A Systematic eview and Meta-Analysis

rystal Dinh, BMed, MTrauma[1], Alexandra M. Limmer, MBBS, MS[2],
harath C. V. Paravastu, MBBS, PGDip, MD, FRCS[3],
hannon D. Thomas, BSc Med Hons, MBBS, FRACS[4,5,6],
ichael H. Bennett, MBBS, FANZCA, MD[5,7],
ndrew Holden, MBChB, FRANZCR, EBIR[8],
d Ramon L. Varcoe, MBBS, MS, FRACS, PhD[4,5,6]

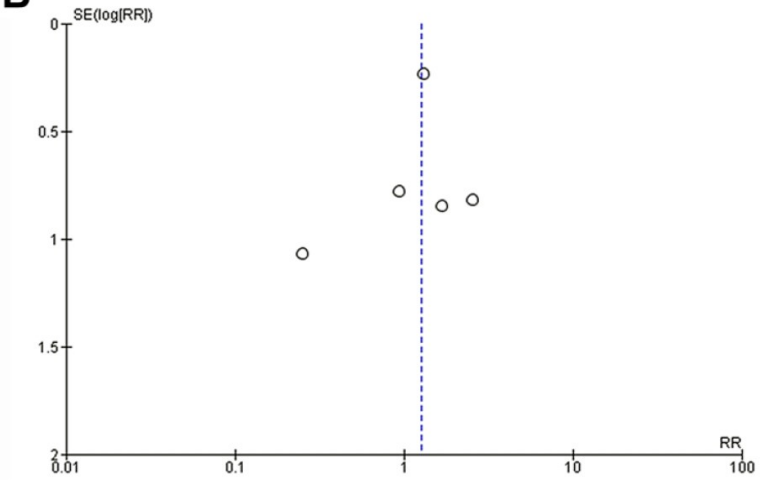
A

Study or Subgroup	DCB Events	DCB Total	PTA Events	PTA Total	Weight	Risk Ratio M-H, Random, 95% CI
Bjorkman 2018	1	18	4	18	3.7%	0.25 [0.03, 2.02]
Irani 2018	5	59	2	60	6.3%	2.54 [0.51, 12.59]
Kitrou 2015	0	20	0	20		Not estimable
Kitrou 2015 (2)	0	20	0	20		Not estimable
Kitrou 2017	0	20	0	20		Not estimable
Maleux 2018	3	33	3	31	7.0%	0.94 [0.20, 4.31]
Roosen 2017	3	16	2	18	5.9%	1.69 [0.32, 8.85]
Trerotola 2018	33	141	26	144	77.1%	1.30 [0.82, 2.05]
Total (95% CI)		327		331	100.0%	1.26 [0.85, 1.89]
Total events	45		37			

Heterogeneity: Tau² = 0.00; Chi² = 3.32, df = 4 (P = 0.51); I² = 0%
Test for overall effect: Z = 1.14 (P = 0.25)



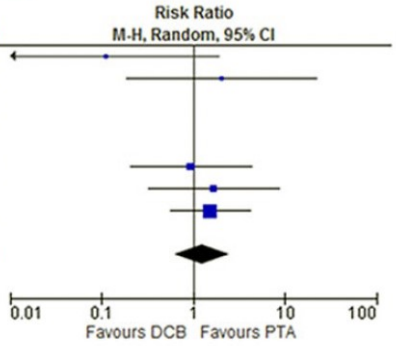
B



A. 6-Month All Cause Mortality

Study or Subgroup	DCB Events	DCB Total	PTA Events	PTA Total	Weight	Risk Ratio M-H, Random, 95% CI
Bjorkman 2018	0	18	4	18	5.9%	0.11 [0.01, 1.92]
Irani 2018	2	59	1	60	8.5%	2.03 [0.19, 21.83]
Kitrou 2015	0	20	0	20		Not estimable
Kitrou 2015 (2)	0	20	0	20		Not estimable
Kitrou 2017	0	20	0	20		Not estimable
Maleux 2018	3	33	3	31	20.7%	0.94 [0.20, 4.31]
Roosen 2017	3	16	2	18	17.5%	1.69 [0.32, 8.85]
Trerotola 2018	9	141	6	144	47.4%	1.53 [0.56, 4.19]
Total (95% CI)		327		331	100.0%	1.24 [0.62, 2.47]
Total events	17		16			

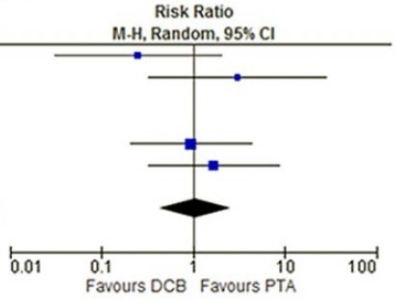
Heterogeneity: Tau² = 0.00; Chi² = 3.49, df = 4 (P = 0.48); I² = 0%
Test for overall effect: Z = 0.60 (P = 0.55)



B. 12-Month All Cause Mortality

Study or Subgroup	DCB Events	DCB Total	PTA Events	PTA Total	Weight	Risk Ratio M-H, Random, 95% CI
Bjorkman 2018	1	18	4	18	18.7%	0.25 [0.03, 2.02]
Irani 2018	3	59	1	60	16.4%	3.05 [0.33, 28.50]
Kitrou 2015	0	20	0	20		Not estimable
Kitrou 2015 (2)	0	20	0	20		Not estimable
Maleux 2018	3	33	3	31	35.1%	0.94 [0.20, 4.31]
Roosen 2017	3	16	2	18	29.7%	1.69 [0.32, 8.85]
Total (95% CI)		166		167	100.0%	1.06 [0.43, 2.63]
Total events	10		10			

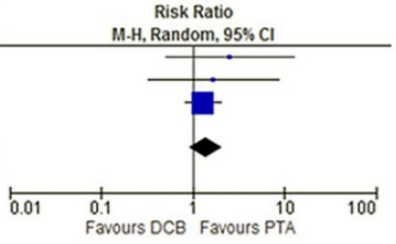
Heterogeneity: Tau² = 0.01; Chi² = 3.03, df = 3 (P = 0.39); I² = 1%
Test for overall effect: Z = 0.12 (P = 0.90)



C. 24-Month All Cause Mortality

Study or Subgroup	DCB Events	DCB Total	PTA Events	PTA Total	Weight	Risk Ratio M-H, Random, 95% CI
Irani 2018	5	59	2	60	7.1%	2.54 [0.51, 12.59]
Roosen 2017	3	16	2	18	6.6%	1.69 [0.32, 8.85]
Trerotola 2018	33	141	26	144	86.3%	1.30 [0.82, 2.05]
Total (95% CI)		216		222	100.0%	1.38 [0.90, 2.12]
Total events	41		30			

Heterogeneity: Tau² = 0.00; Chi² = 0.69, df = 2 (P = 0.71); I² = 0%
Test for overall effect: Z = 1.49 (P = 0.14)



Dinh et al. J Endovasc ther 2019
Dinh et al. J Endovasc ther 2020
Dinh et al. J Endovasc ther 2021

Problèmes des études randomisées actuelles

Critères d'interventions et de réinterventions mal définis

Pas d'analyse hémodynamique

Financement industriel → Nécessité d'une étude académique

- Sans financement principal par l'industrie
- Difficulté du double aveugle

Questions médico-économiques à l'échelle française

ABISS Trial

Angioplastie au Ballon Imprégné de paclitaxel versus angioplastie Standard pour le traitement des Sténoses sur fistule artério-veineuse

Physician-designed

Prospective Randomized

Multicenter

« Double » blinded

N = 150

Primary Outcome

Primary Patency at 6 months

PP = Reintervention or back to initial AVF flow

Governmental funding (PHRC)

Bard/BD France supported the study by providing the balloons free of charge

Secondary outcomes

Primary patency at 3 and 12 months

Reinterventions at 3, 6 and 12 months

Restenosis > 50% at 3, 6 and 12 months

Return to baseline AVF flow at 3, 6 and 12 months

AVF flow < 500 ml/minute at 3, 6 and 12 months

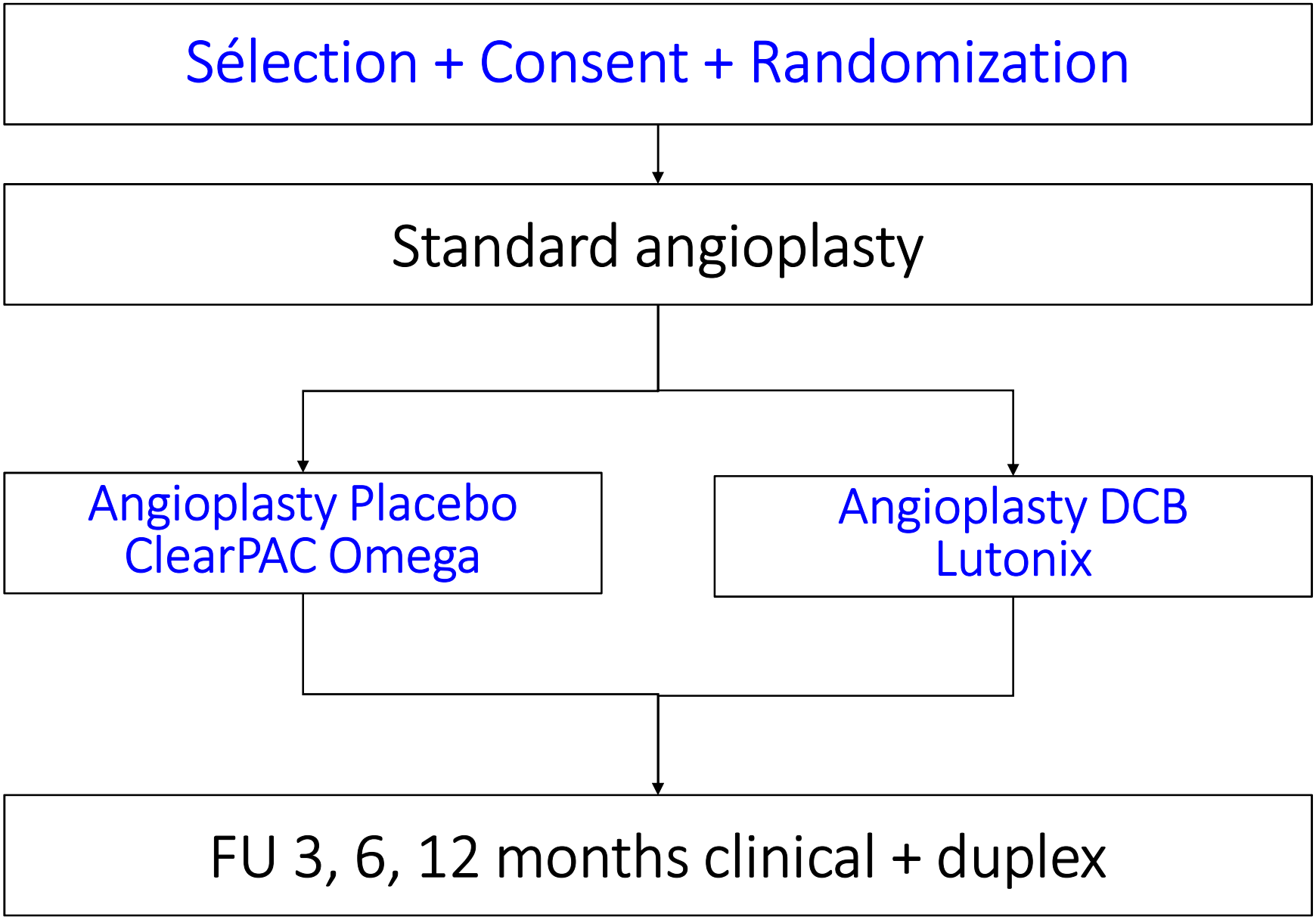
Thrombosis at 3, 6 and 12 months

Costs at 3, 6 and 12 months

ABISS Trial

Angioplastie au Ballon Imprégné de paclitaxel versus angioplastie Standard pour le traitement des Sténoses sur fistule artério-veineuse

Inclusion	Non inclusion
Native AVF	Multiple stenoses
AVF **already punctured**	Arterial stenosis
Preop **fistula flow**	Central stenosis
Hemodynamic stenosis	Stent in AVF
Unique stenosis	AVF lower limb
Length < 120 mm	
Diameter < 12 mm	


Sélection + Consent + Randomization
Standard angioplasty
Angioplasty Placebo
ClearPAC Omega
Angioplasty DCB
Lutonix
FU 3, 6, 12 months clinical + duplex

Management of blinding

Selection + Consent + Randomization + Intervention

by an investigator **« Operator »**

Follow-up 3, 6, 12 months clinical + duplex (flow)

by an investigator **« Evaluator »**

Indications for (re)interventions

Stenosis > 50 %

+

1 clinical or hemodynamic criteria

Venous Pressure > 150 mmHg if flow 200-225 ml/min

VP > 230 mmHg if flow 400 ml/min

No thrill

Hemostasis > 20 minutes or 50 % usual time

Recirculation > 20 %

AVF flow < 500 ml/minute

Enrollment and Follow-up completed

Inclusions per center

Center number	Total (N=145)	Arm A (N=73)	Arm B (N=72)	p value
N Total	145	73	72	
1 (%)	24 (16.6)	13 (17.8)	11 (15.3)	
2 (%)	12 (8.3)	6 (8.2)	6 (8.3)	
3 (%)	4 (2.8)	3 (4.1)	1 (1.4)	
4 (%)	11 (7.6)	5 (6.8)	6 (8.3)	
5 (%)	17 (11.7)	8 (11.0)	9 (12.5)	
6 (%)	7 (4.8)	3 (4.1)	4 (5.6)	0.992
7 (%)	52 (35.9)	26 (35.6)	26 (36.1)	
8 (%)	6 (4.1)	4 (5.5)	2 (2.8)	
9 (%)	1 (0.7)	0 (0.0)	1 (1.4)	
10 (%)	4 (2.8)	2 (2.7)	2 (2.8)	
13 (%)	7 (4.8)	3 (4.1)	4 (5.6)	

Demographics at inclusion

Variable	Total (N=145)	Arm A (N=73)	Arm B (N=72)	p value
Age (mean SD)	69.3 (13.6)	69 (14.2)	69.6 (13)	0.871*
Male gender	99 (68.3)	47 (64.4)	52 (72.2)	0.403
Hypertension	117 (80.7)	60 (82.2)	57 (79.2)	0.798
Diabetes	69 (47.6)	32 (43.8)	37 (51.4)	0.453
Coronary artery disease	41 (28.3)	20 (27.4)	21 (29.2)	>0.999
Congestive heart failure	11 (7.6)	7 (9.6)	4 (5.6)	0.546
Arrythmia	32 (22.1)	20 (27.4)	12 (16.7)	0.174
Cerebrovascular disease	13 (9.0)	7 (9.6)	6 (8.3)	>0.999
PAD	28 (19.3)	14 (19.2)	14 (19.4)	>0.999

AVF flow and lesions

Variables	Total (N=145)	Arm A (N=73)	Arm B (N=72)	p value
AVF flow (ml/min)	533.4 (284.4)	535.5 (269.7)	531.2 (300.4)	0.859
Maximal percentage of stenosis	72.5 (11)	72.3 (11)	72.7 (11.1)	0.978
Lesion length (mm)	16.2 (12.3)	15.5 (11.1)	16.8 (13.5)	0.858
Restenosis	59 (40.7)	30 (41.1)	29 (40.3)	>0.999

Variables		Total (N=145)	Arm A (N=73)	Arm B (N=72)	p value
AVF location	Radio-cephalic (%)	78 (53.8)	39 (53.4)	39 (54.2)	0.599
	Ulno-basilic (%)	3 (2.1)	0 (0.0)	3 (4.2)	
	Brachio-cephalic (%)	34 (23.4)	18 (24.7)	16 (22.2)	
	Brachio-basilic (%)	25 (17.2)	13 (17.8)	12 (16.7)	
	Other (%)	3 (2.1)	2 (2.7)	1 (1.4)	
	Unknown (%)	2 (1.4)	1 (1.4)	1 (1.4)	
tenosis type	Anastomotic	1 (0.7)	1 (1.4)	0 (0.0)	0.833
	Juxta-anastomotic	94 (64.8)	49 (67.1)	45 (62.5)	
	Basilic proximal	12 (8.3)	5 (6.8)	7 (9.7)	
	Cephalic arch	9 (6.2)	5 (6.8)	4 (5.6)	
	Other	29 (20.0)	13 (17.8)	16 (22.2)	

Vessel preparation

Variables		Total (N=145)	Arm A (N=73)	Arm B (N=72)	p value
ntraoperative Heparin		92 (63.4)	41 (56.2)	51 (70.8)	0.088
Preparation Balloon	Standard balloon	46 (31.7)	22 (30.1)	24 (33.3)	0.814
	High pressure balloon	50 (34.5)	26 (35.6)	24 (33.3)	0.909
	Cutting balloon	53 (36.6)	26 (35.6)	27 (37.5)	0.95
	Other balloon	2 (1.4)	1 (1.4)	1 (1.4)	>0.999
Residual stenosis >30%		23 (15.9)	14 (19.2)	9 (12.5)	0.382

Study balloon (Lutonix vs ClearPac Omega)

Variables		Total (N=145)	Arm A (N=73)	Arm B (N=72)	p valu
alloon from the randomization		134 (92.4)	68 (93.2)	66 (91.7)	0.745
	30	4 (2.8)	3 (4.1)	1 (1.4)	0.71
	60	5 (3.4)	3 (4.1)	2 (2.8)	
nflation time sec)	120	44 (30.3)	20 (27.4)	24 (33.3)	
	180	85 (58.6)	43 (58.9)	42 (58.3)	
	unknown	7 (4.8)	4 (5.5)	3 (4.2)	
	< 8	10 (6.9)	7 (9.6)	3 (4.2)	0.633
nflation ressure (atm)	8 or more	125 (86.2)	62 (84.9)	63 (87.5)	
	unknown	10 (6.9)	4 (5.5)	6 (8.3)	

Pre-specified methodology and statistical analysis in ITT and PP

Number patients to treat : Power 80% - Alpha 5% - Anticipated absolute difference of 25% in favor of DCB

Pre-specified ITT :

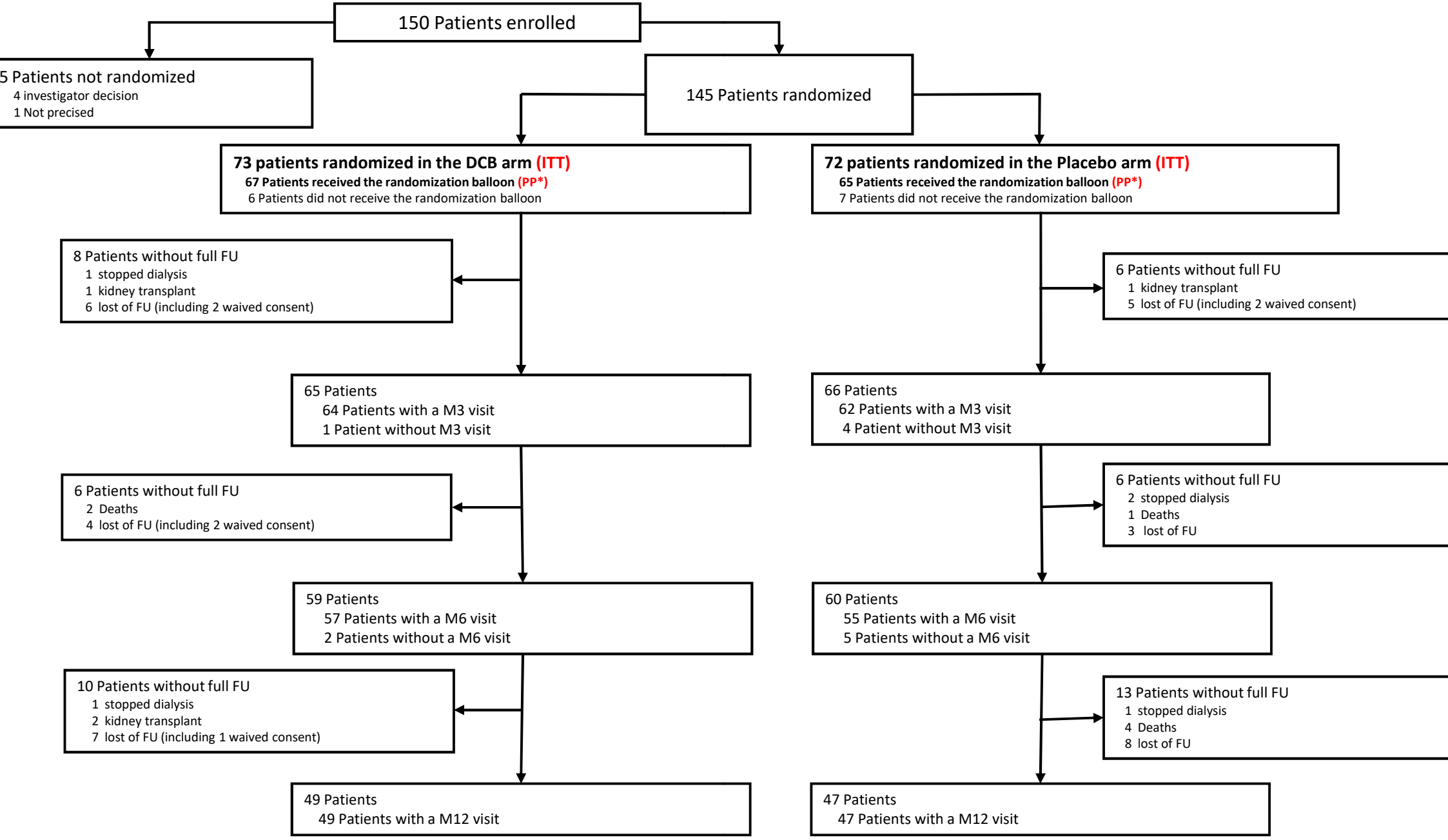
- Data of 145 patients could be used for the intention to treat analysis (73 DCB arm and 72 Placebo arm).
- 141 patients were analysed because 2 waived consent before M3 and 2 did not have the index angioplasty
- Missing data, patients lost of FU or who waived consent after M3 were imputated to the worst case scenario (loss of patency if DCB arm and patency if placebo arm).

Pre-specified PP :

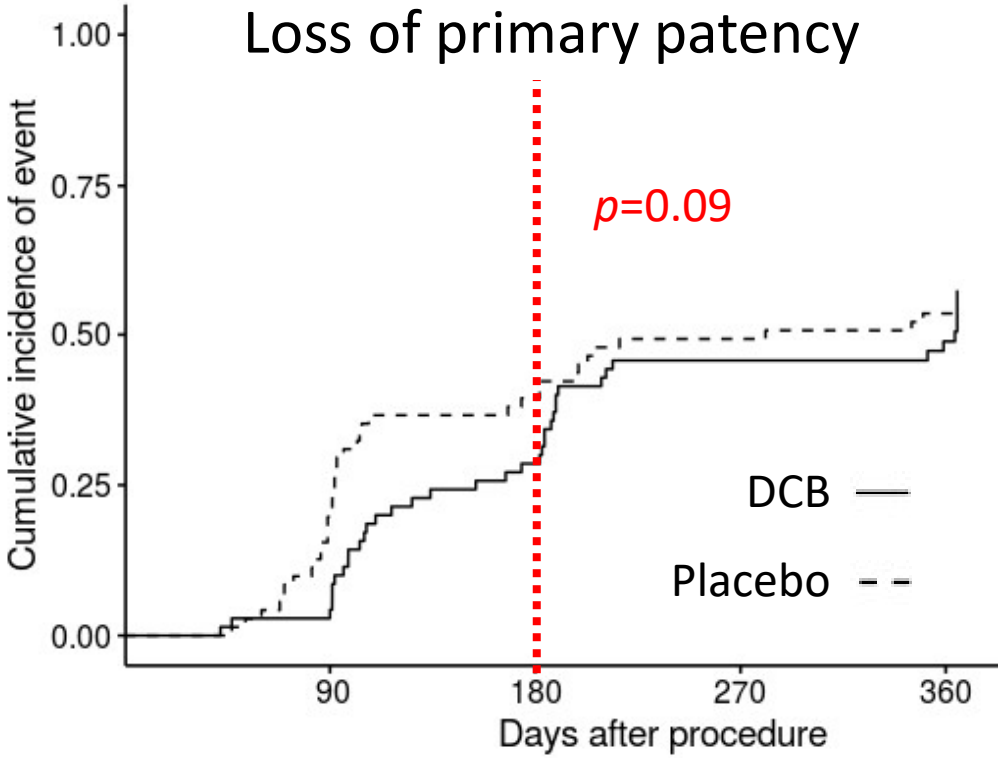
- Data of 132 patients could be used for the intention to treat analysis (67 DCB arm and 65 Placebo arm).
- Patients that were included by mistake (no respect of the randomisation arm, inclusion/exclusion criteria not met), lost of FU or who missed a visit were excluded from the PP analysis.

Statistical tests

- Comparison of the outcomes using the Gray test to take in account the competitive events (death, interrupted dialysis, kidney transplant).


150 Patients enrolled
5 Patients not randomized
4 investigator decision
1 Not precised
145 Patients randomized
73 patients randomized in the DCB arm (ITT)
67 Patients received the randomization balloon (PP*)
6 Patients did not receive the randomization balloon
72 patients randomized in the Placebo arm (ITT)
65 Patients received the randomization balloon (PP*)
7 Patients did not receive the randomization balloon
8 Patients without full FU
1 stopped dialysis
1 kidney transplant
6 lost of FU (including 2 waived consent)
6 Patients without full FU
1 kidney transplant
5 lost of FU (including 2 waived consent)
65 Patients
64 Patients with a M3 visit
1 Patient without M3 visit
66 Patients
62 Patients with a M3 visit
4 Patient without M3 visit
6 Patients without full FU
2 Deaths
4 lost of FU (including 2 waived consent)
6 Patients without full FU
2 stopped dialysis
1 Deaths
3 lost of FU
59 Patients
57 Patients with a M6 visit
2 Patients without a M6 visit
60 Patients
55 Patients with a M6 visit
5 Patients without a M6 visit
10 Patients without full FU
1 stopped dialysis
2 kidney transplant
7 lost of FU (including 1 waived consent)
13 Patients without full FU
1 stopped dialysis
4 Deaths
8 lost of FU
49 Patients
49 Patients with a M12 visit
47 Patients
47 Patients with a M12 visit

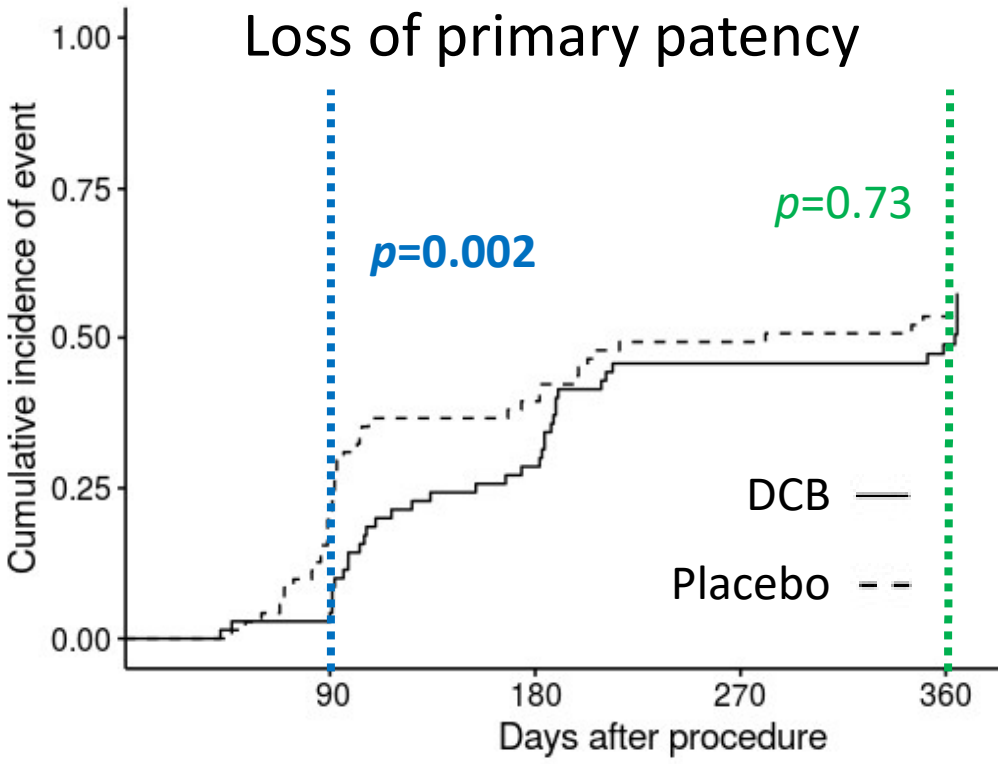
Main Outcome
Primary Patency at 6 months ITT



Events M6	Total (N=141)	DCB (N=70)	Placebo (N=71)
Patency (%)	83 (58.9)	45 (64.3)	38 (53.5)
Patency loss (%)	50 (35.5)	21 (30.0)	29 (40.9)
Concurrent events* (%)	8 (5.6)	4 (5.7)	4 (5.6)

* Death, Interrupted dialysis, Kidney transplant

Secondary Outcomes
Primary Patency at 3 and 12 months ITT

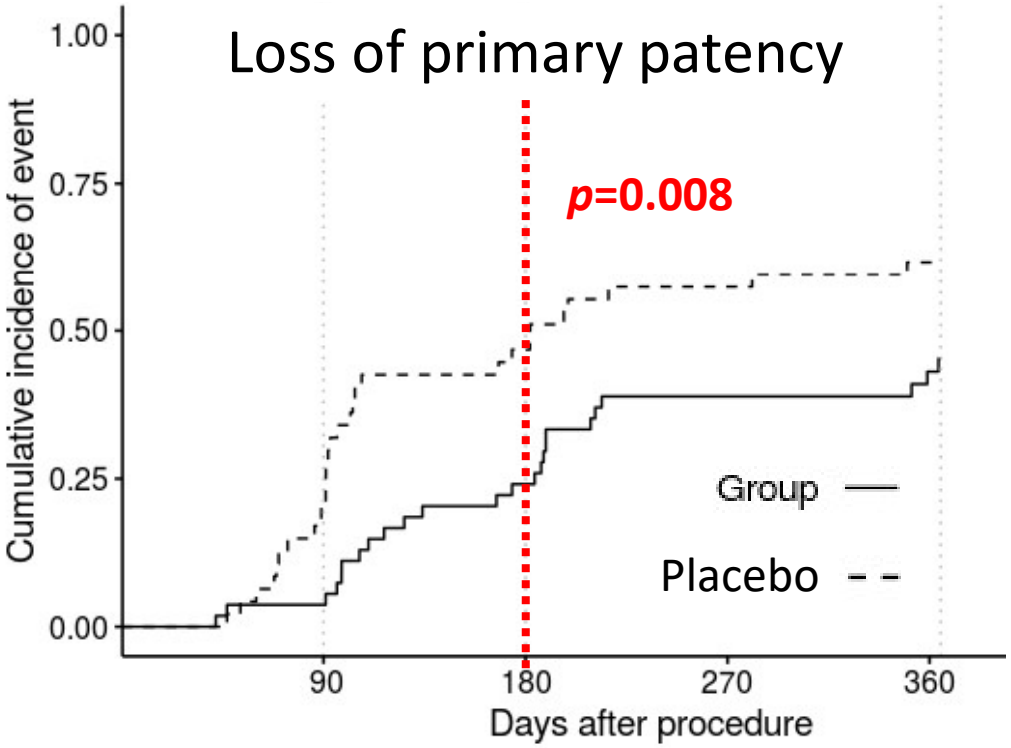


Events M3	Total (N=141)	DCB (N=70)	Placeb (N=71
Patency (%)	119 (84.4)	65 (92.9)	54 (76.
Patency loss (%)	19 (13.5)	3 (4.2)	16 (22.
Concurrent events* (%)	3 (2.1)	2 (2.9)	1 (1.4

Events M12	Total (N=141)	DCB (N=70)	Placeb (N=71
Patency (%)	48 (34.0)	24 (34.3)	24 (33.
Patency loss (%)	77 (54.6)	39 (55.7)	38 (53.
Concurrent events* (%)	16 (11.4)	7 (10.0)	9 (12.7

* Death, Interrupted dialysis, Kidney transplant

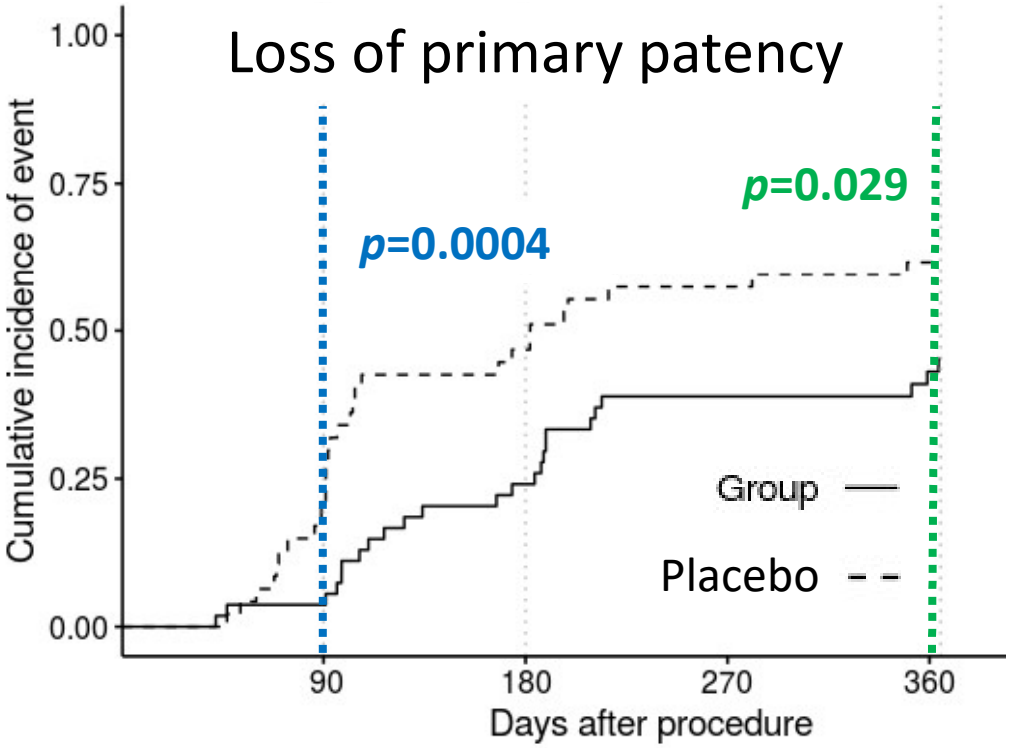
Main Outcome
Primary Patency at 6 months PP



Events M6	Total (N=113)	DCB (N=59)	Placebo (N=54)
Patency (%)	63 (55.7)	39 (66.1)	24 (44.4)
Patency loss (%)	42 (37.2)	16 (27.1)	26 (48.2)
Concurrent events* (%)	8 (7.1)	4 (6.8)	4 (7.4)

* Death, Interrupted dialysis, Kidney transplant

Secondary Outcomes
Primary Patency at 3 and 12 months PP



Events M3	Total (N=116)	DCB (N=61)	Placebo (N=55)
Patency (%)	96 (82.7)	57 (93.4)	39 (70.9
Patency loss (%)	17 (14.7)	2 (3.3)	15 (27.3
Concurrent events* (%)	3 (2.6)	2 (3.3)	1 (1.8)

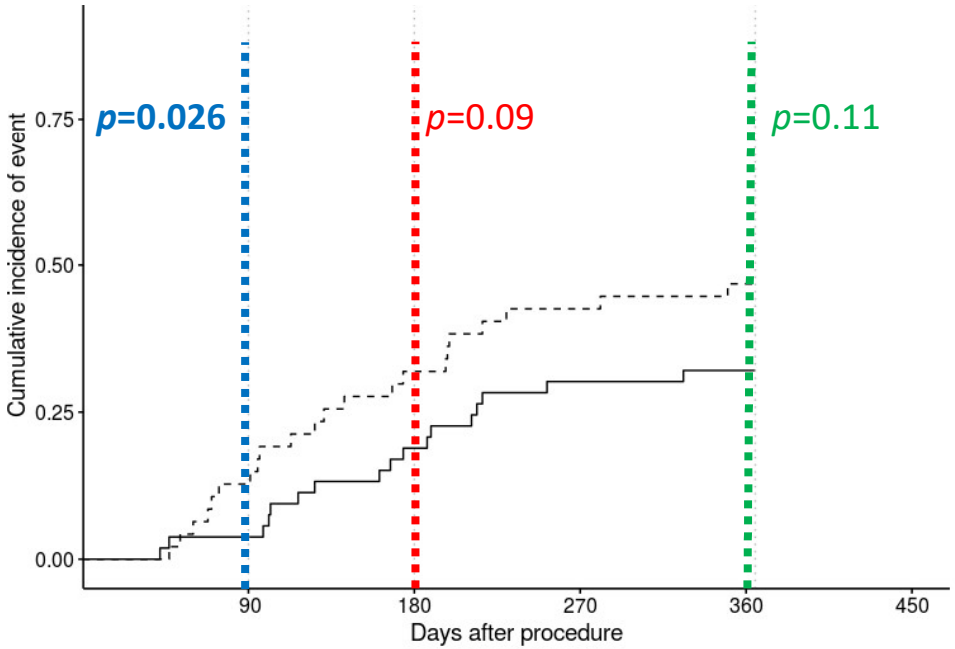
Events M12	Total (N=101)	DCB (N=54)	Placebo (N=47)
Patency (%)	35 (34.6)	23 (42.6)	12 (25.5
Patency loss (%)	53 (52.5)	24 (44.4)	29 (61.7
Concurrent events* (%)	13 (12.9)	7 (13.0)	6 (12.8)

* Death, Interrupted dialysis, Kidney transplant

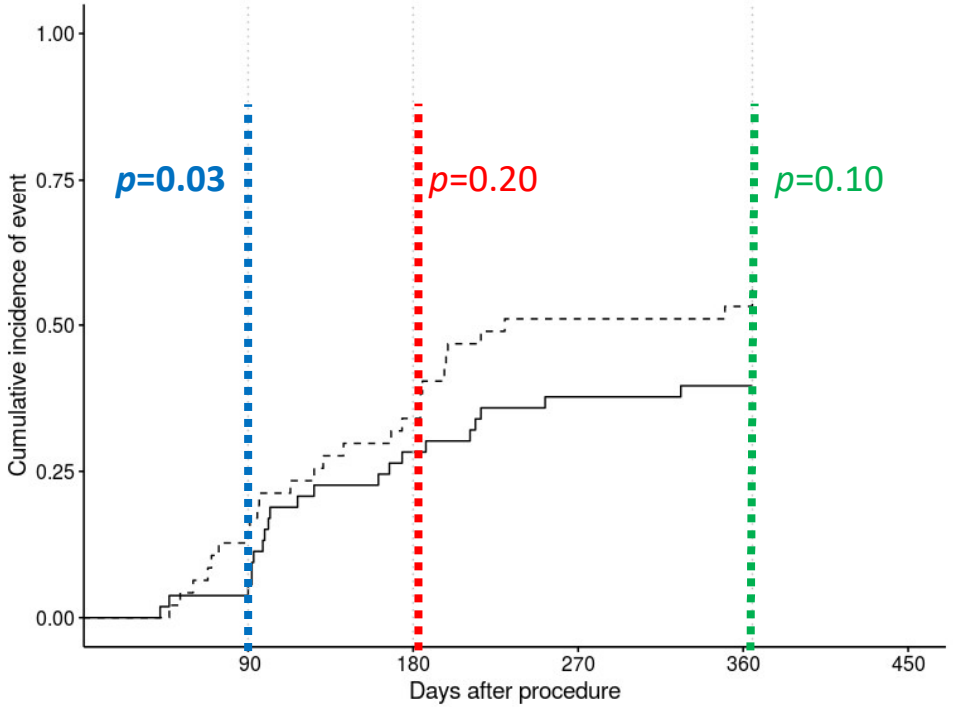
Model	Description	M3	M6	M12
ABISS ITT	Competitive risk model. Worst case scenario for loss of FU[a]. All randomised patients are included.	**Favors DCB, p<0.05** N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71
ABISS Per-protocol	Competitive risk model. Exclusion of patients lost of FU, patients who did not have the balloon of the randomisation, patients included despite exclusion criteria, patients with protocol deviation[b].	**Favors DCB, p<0.05** N=116, N bras A=61, N bras B =55	**Favors DCB, p<0.05** N=113, N bras A=59, N bras B =54	**Favors DCB, p<0.05** N=101, N bras A=54, N bras B =47
Analysis accoring to In.Pact AV Lookstein et al, NEJM 2020	Comparaison of proportions. Patients who did not reach the main outcome timepoint (death, dialysis,transplant and lost of FU) were removed from the analysis.	**Favors DCB, p<0.05** N=129, N bras A=64, N bras B =65	**Favors DCB, p<0.05** N=117, N bras A=59, N bras B =58	No difference N=95, N bras A=49, N bras B =4
Analysis accoring to Lutonix AV Trerotola et al, Clin J Am Soc Nephrol 2018	Log-rank test. Patients who did not reach the main outcome timepoint (death, dialysis,transplant and lost of FU) were censored from the main analysis, they have a patent AVF.	**Favors DCB, p<0.05** N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71
Analysis accoring to PAVE Karunanithy et al, Kidney International 2021	Cox model[c]. Patients who did not reach the main outcome timepoint (death and lost of FU) were censored from the main analysis, they have a patent AVF.	**Favors DCB, p<0.05** N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71	No difference N=141, N bras A=70, N bras B =71

Secondary Outcomes
Reinterventions: significant effect at 3 months

Reinterventions at the angioplasty site

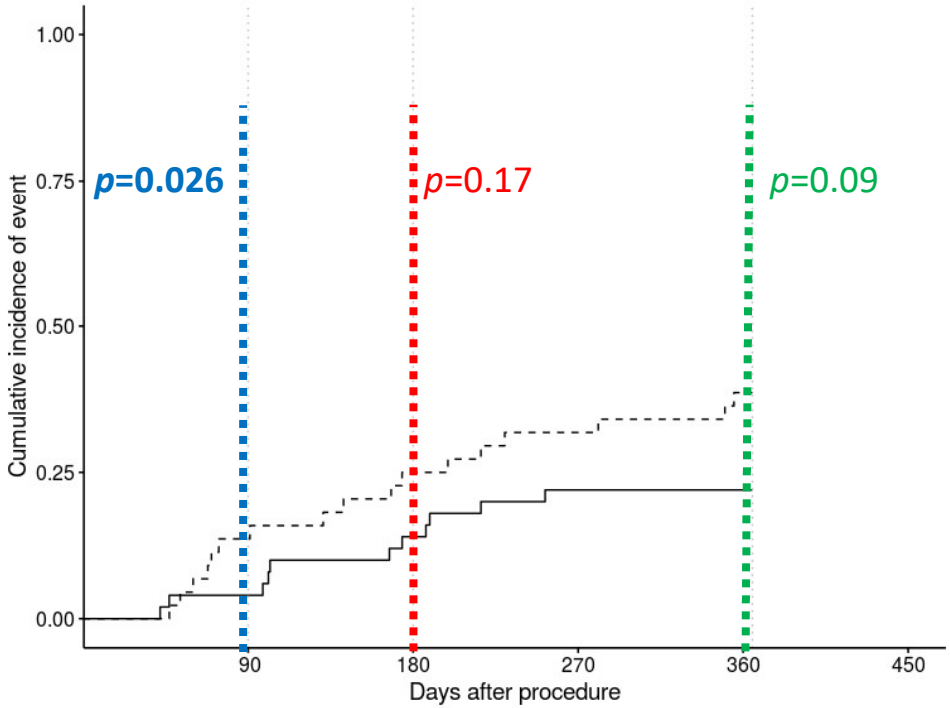


All reinterventions

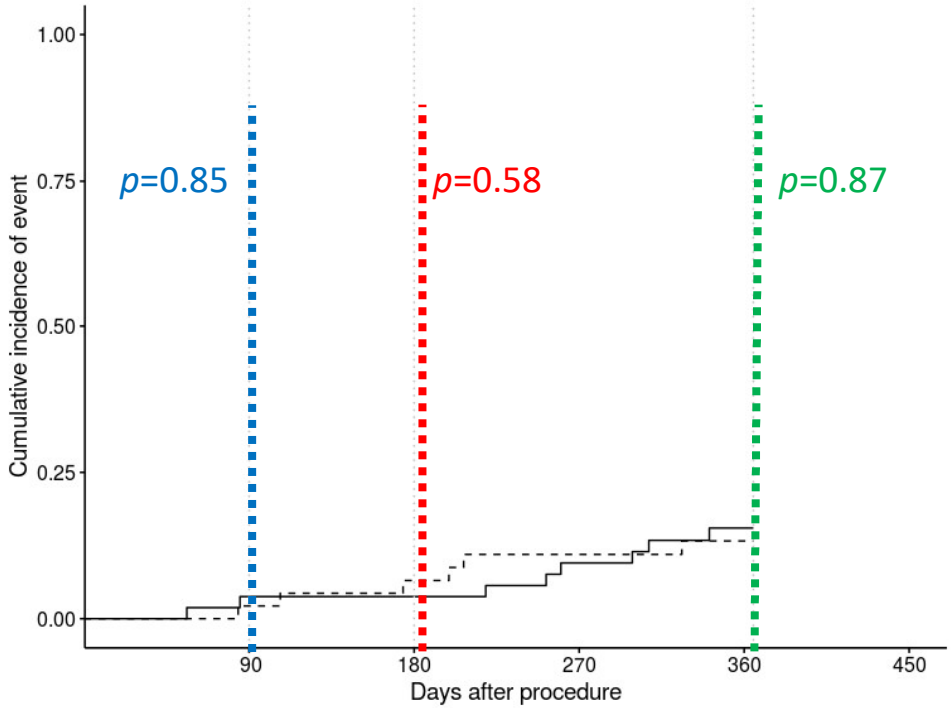


Secondary Outcomes
Restenosis: significant effect at 3 months at the angioplasty site

Restenosis at the angioplasty site

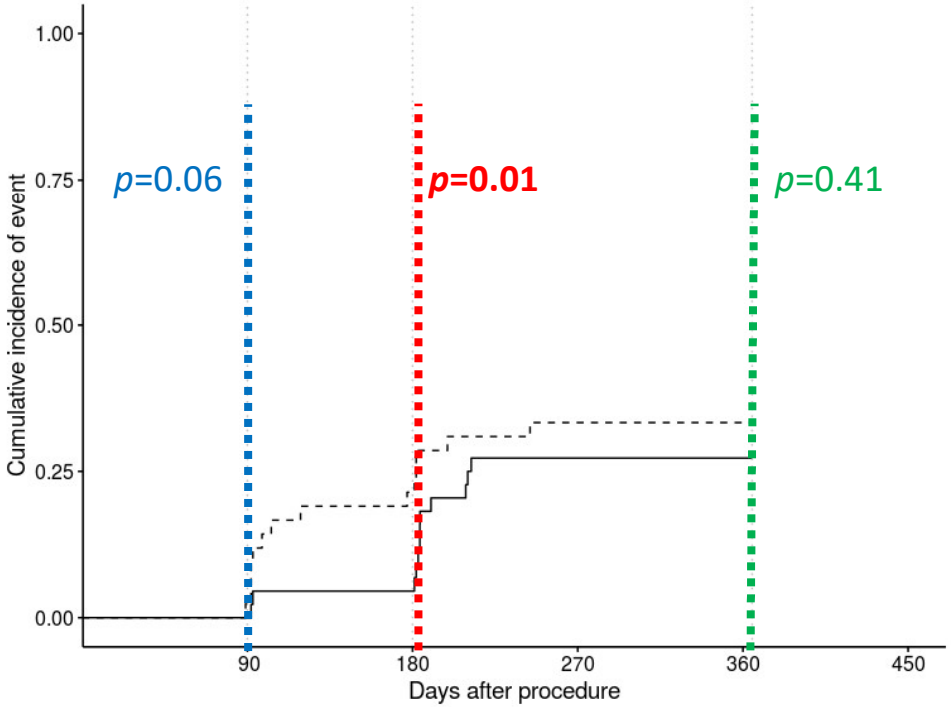


All restenoses

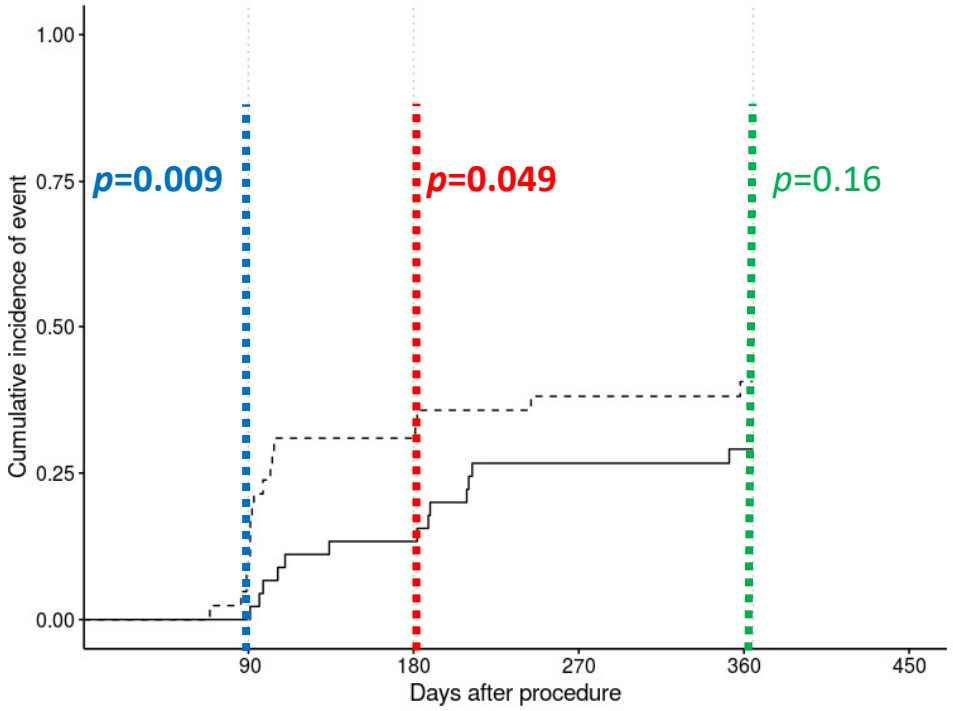


Secondary Outcomes
AVF Flow: significant effect at 3 and 6 months

AVF Flow < 500 ml/min

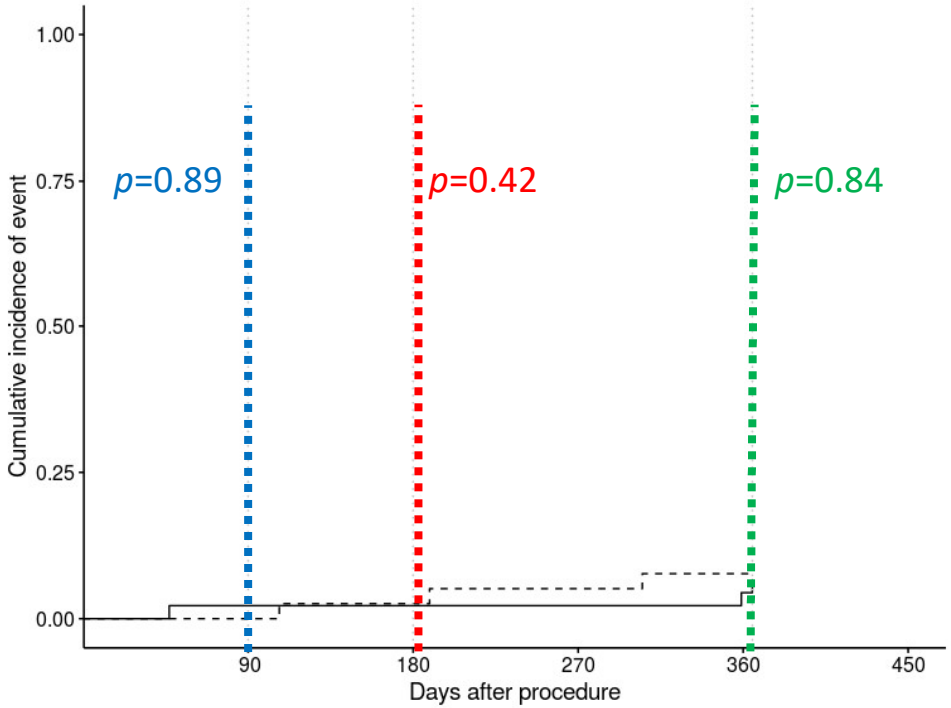


Return to initial AVF Flow

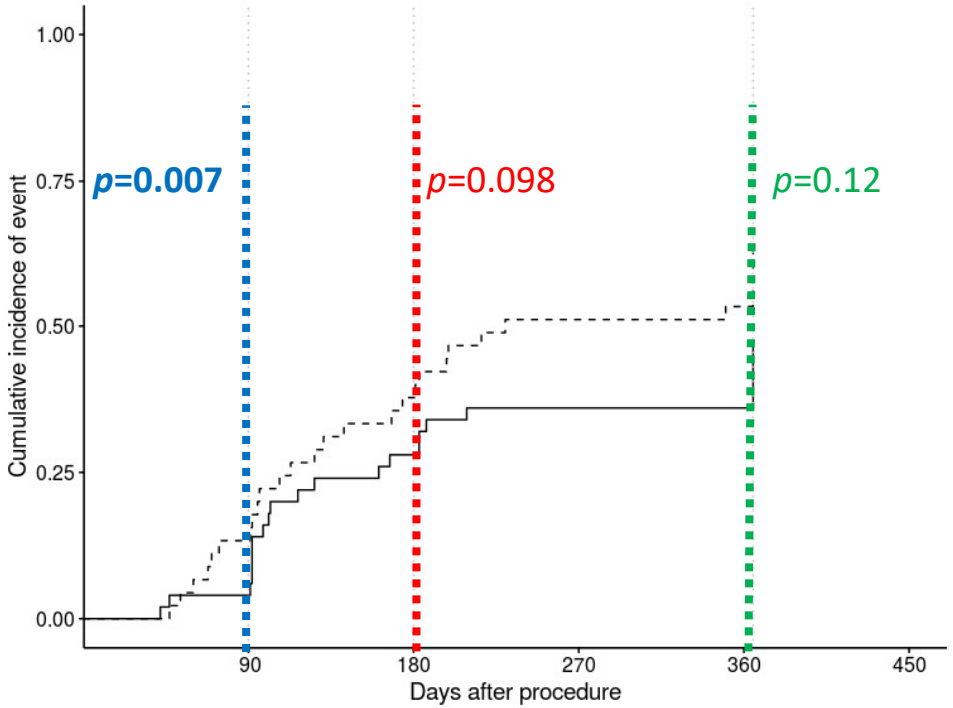


Secondary Outcomes
AVF Thrombosis and Dialysis circuit patency

AVF Thrombosis

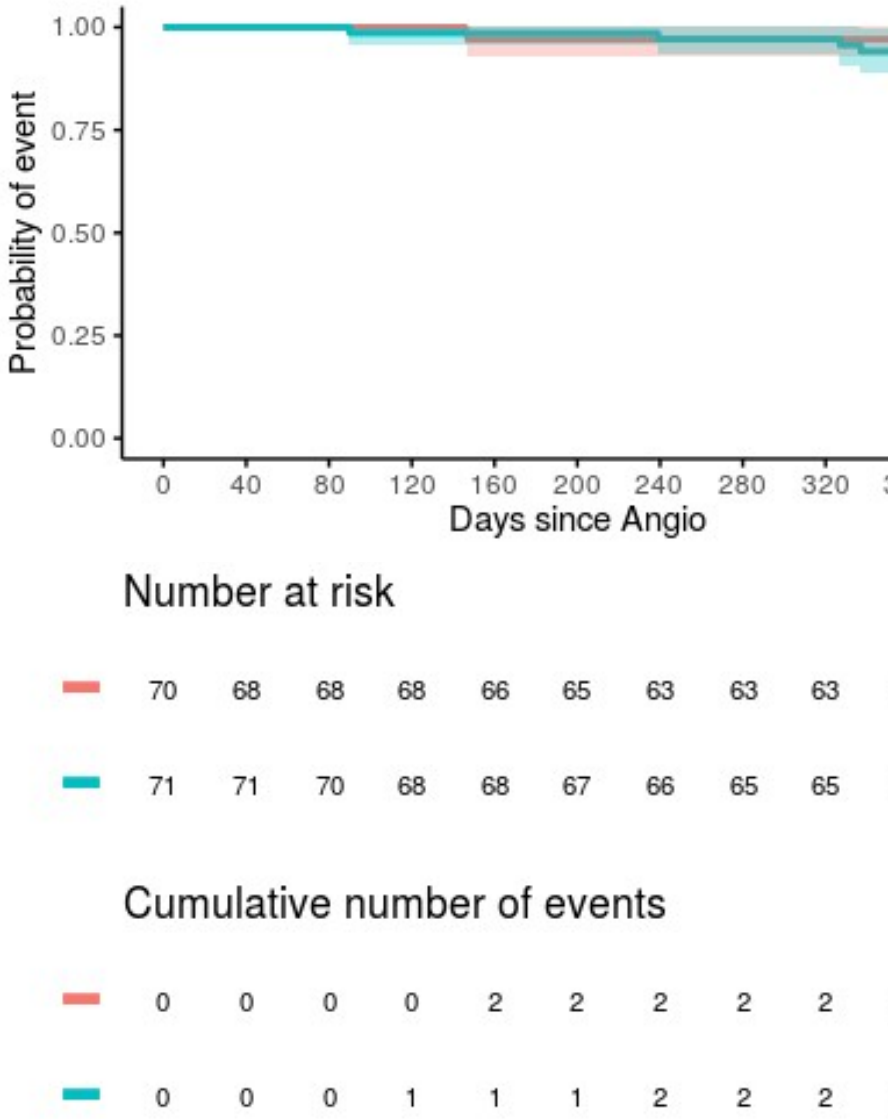


Dialysis circuit patency



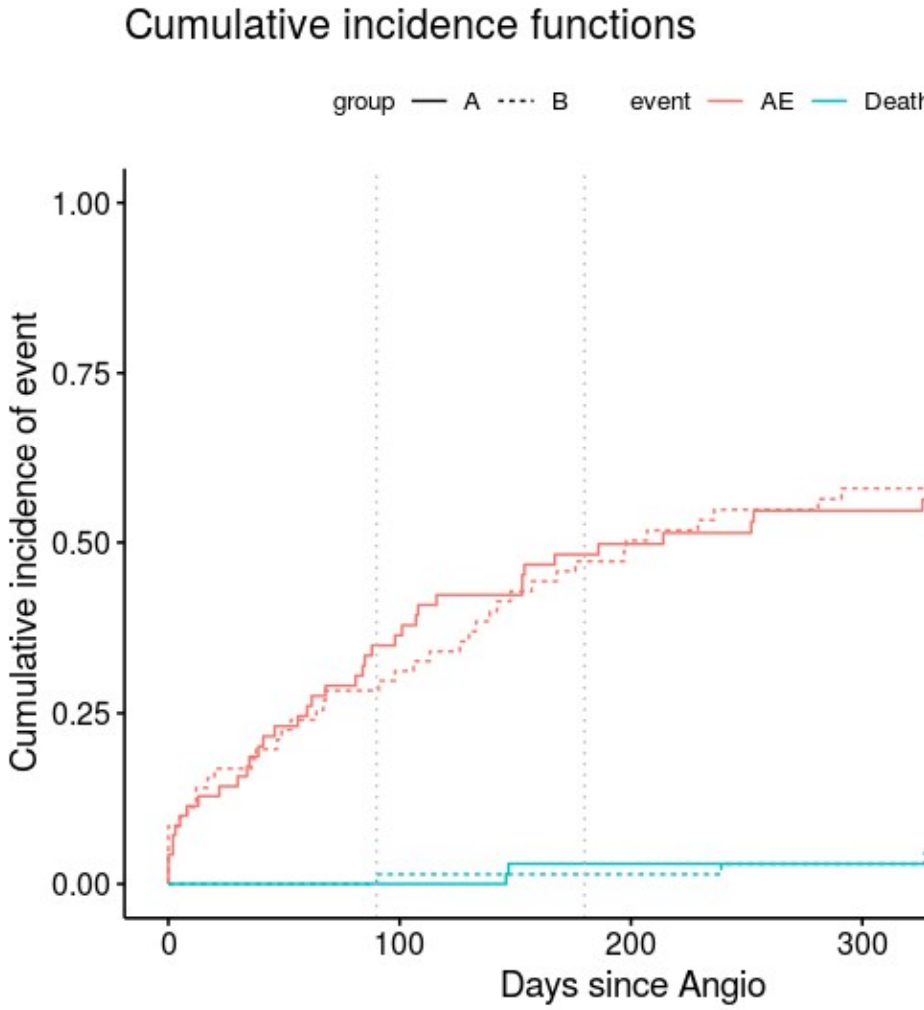
Death risk

Outcome	Total (N=141)	DCB (N=70)	Placebo (N=71)	p-value
Alive, under dialysis	125 (88.6)	63 (90.0)	62 (87.3)	
Death	7 (5.0)	2 (2.9)	5 (7.0)	0.26
Kidney transplant or stopped dialysis	9 (6.4)	5 (7.1)	4 (5.6)	0.71



Adverse Events

Outcome	Total (N=141)	DCB (N=70)	Placebo (N=71)	p-value
ive, no AE	50 (35.5)	28 (40.0)	22 (31.0)	
AE	84 (59.6)	40 (57.1)	44 (62.0)	0.90
Death	7 (5.0)	2 (2.9)	5 (7.0)	0.26



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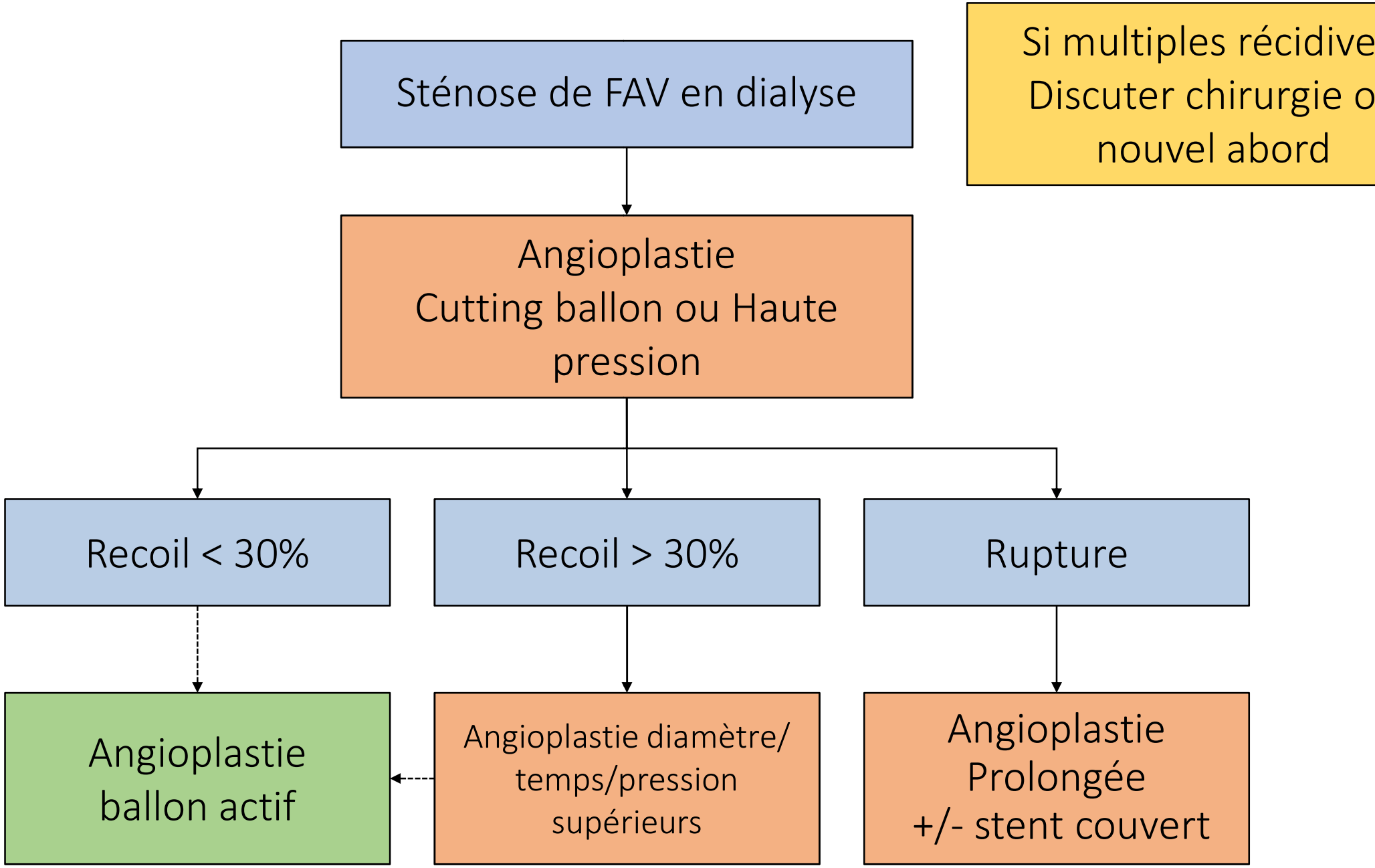
Take Home Messages

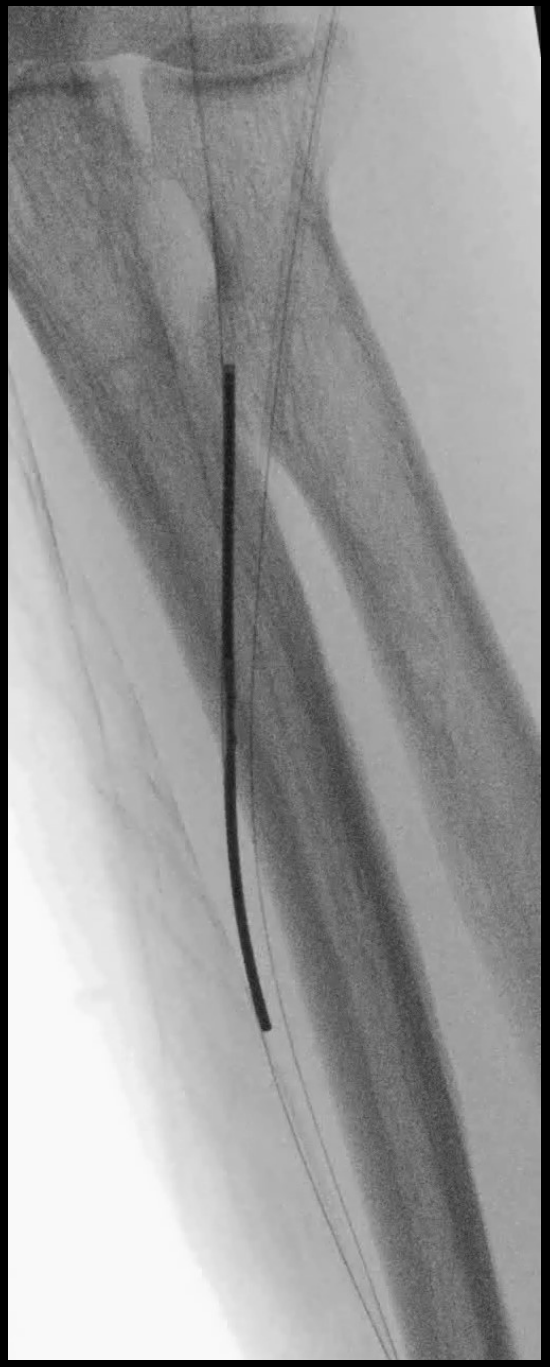
In the ABISS trial, the primary endpoint (primary patency at 6 months) was not met in the ITT analysis. It was however met in the PP analysis (pre-specified) where DCB was superior to POBA at 3, 6 and 12 months.

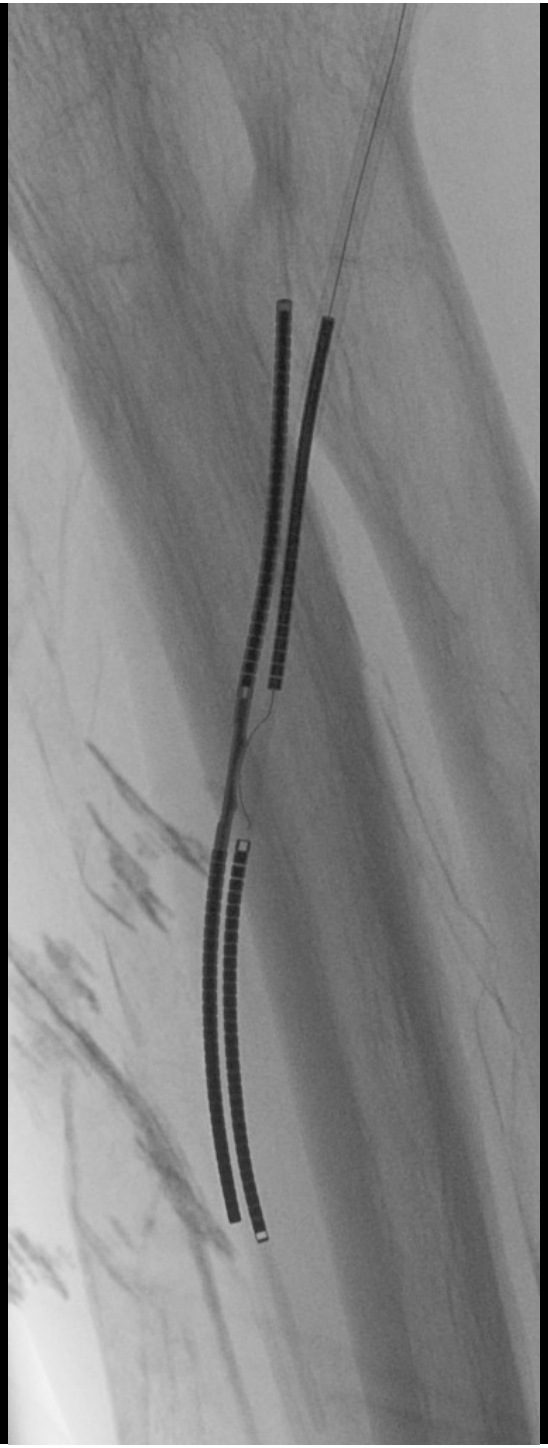
Reasons for differences between ITT and PP analyses may be related to the imputation to the worst case scenario in the ITT analysis in case of loss of FU/missing data/consent waived (Covid period).

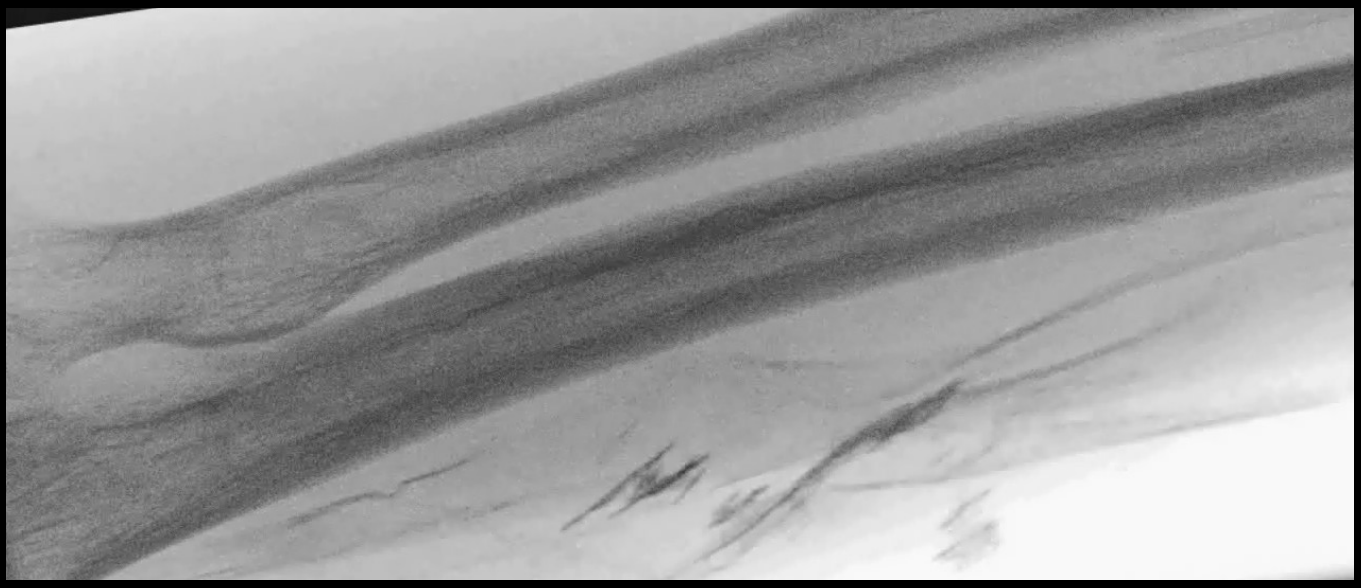
Post hoc analyses based on analysis methods used in other large DCB trials show that different methodologies of analysis lead to different conclusions

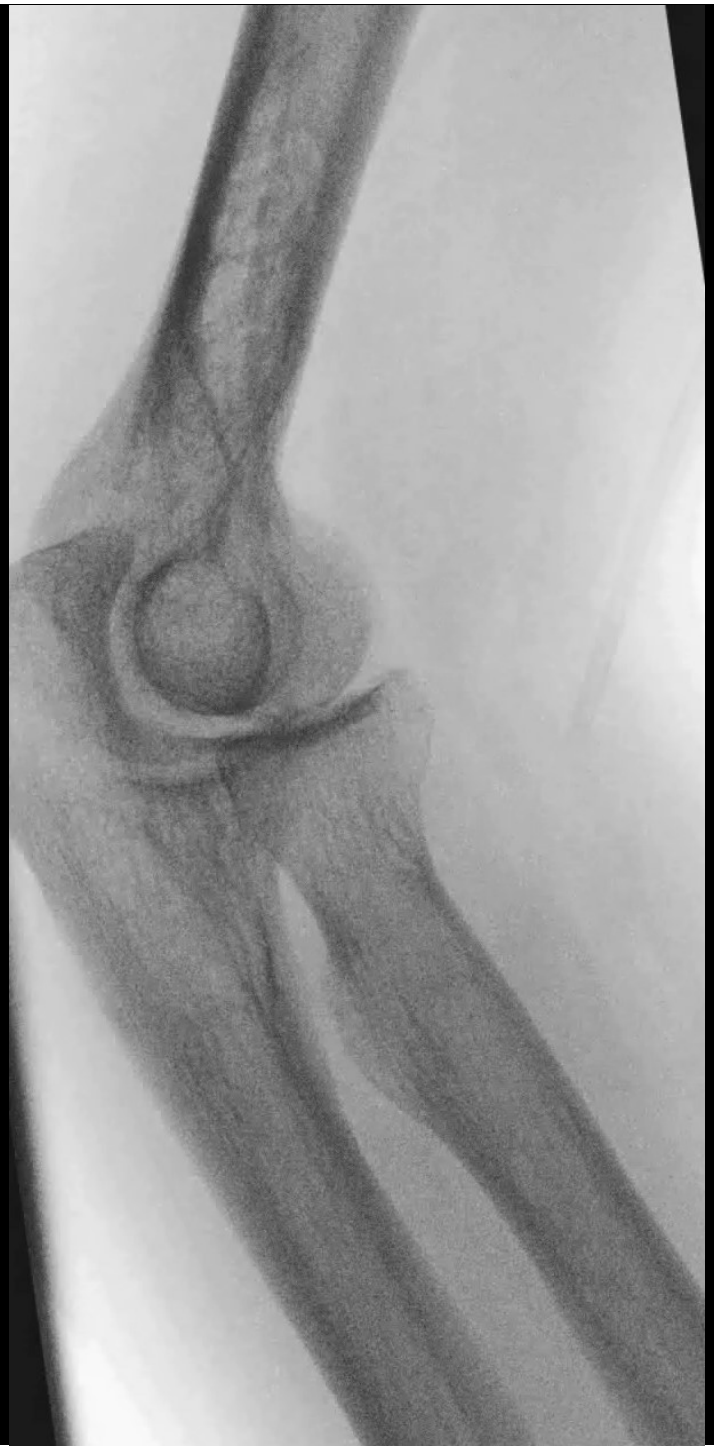
DCB demonstrates a positive effect over POBA in terms of reinterventions, restenosis and dialysis circuit patency at 3 months, and for AVF flow at 6 months. This benefit is lost during FU.

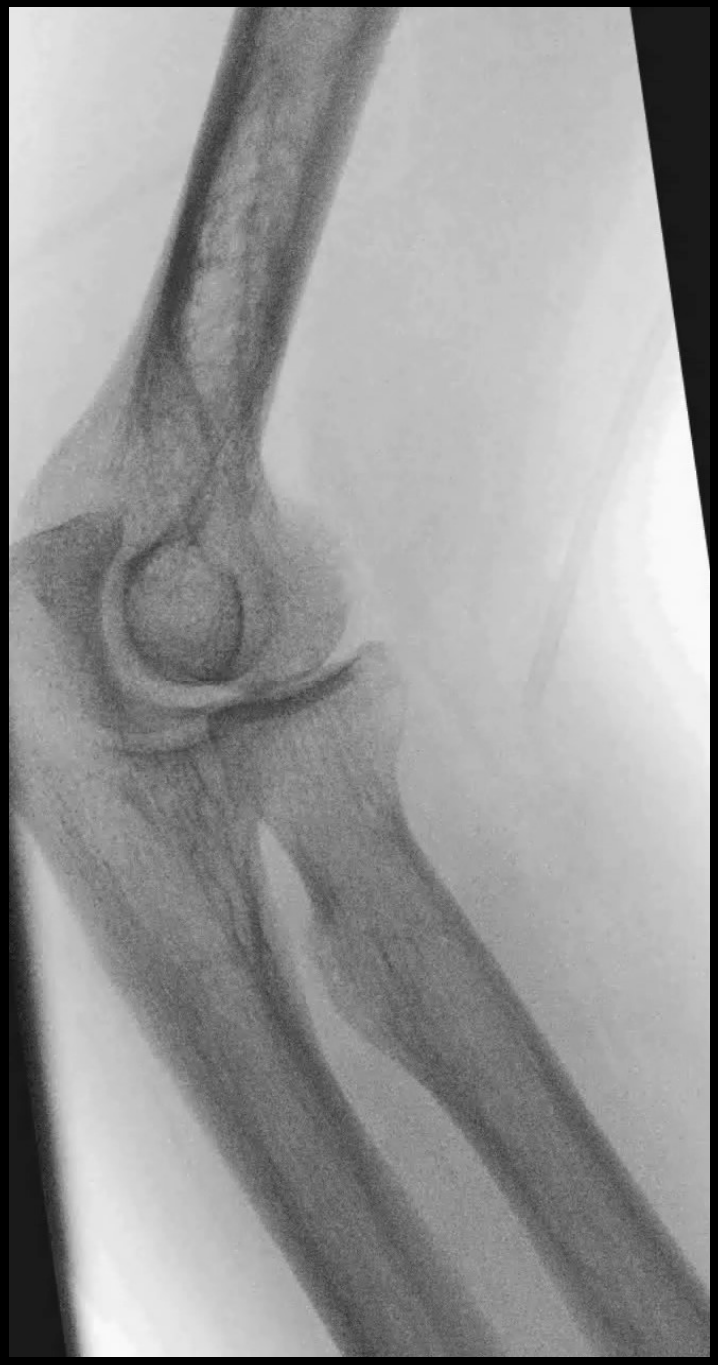

Si multiples récidive
Discuter chirurgie o
nouvel abord
Sténose de FAV en dialyse
Angioplastie
Cutting ballon ou Haute
pression
Recoil < 30%
Recoil > 30%
Rupture
Angioplastie
ballon actif
Angioplastie diamètre/
temps/pression
supérieurs
Angioplastie
Prolongée
+/- stent couvert

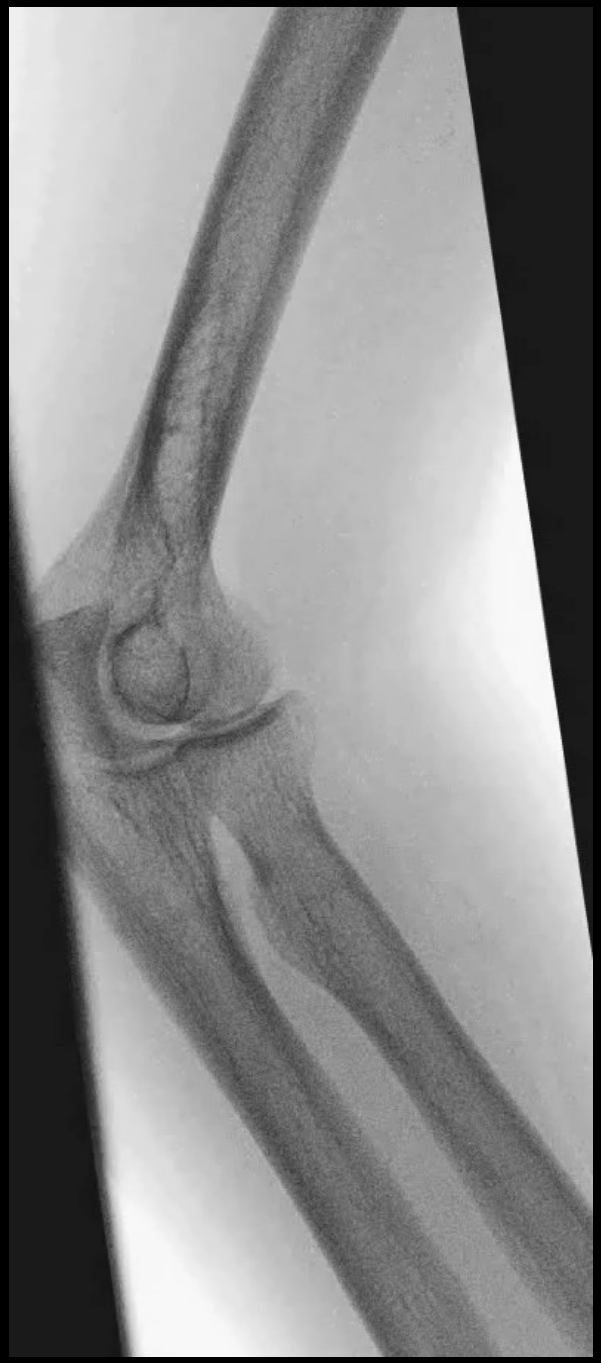


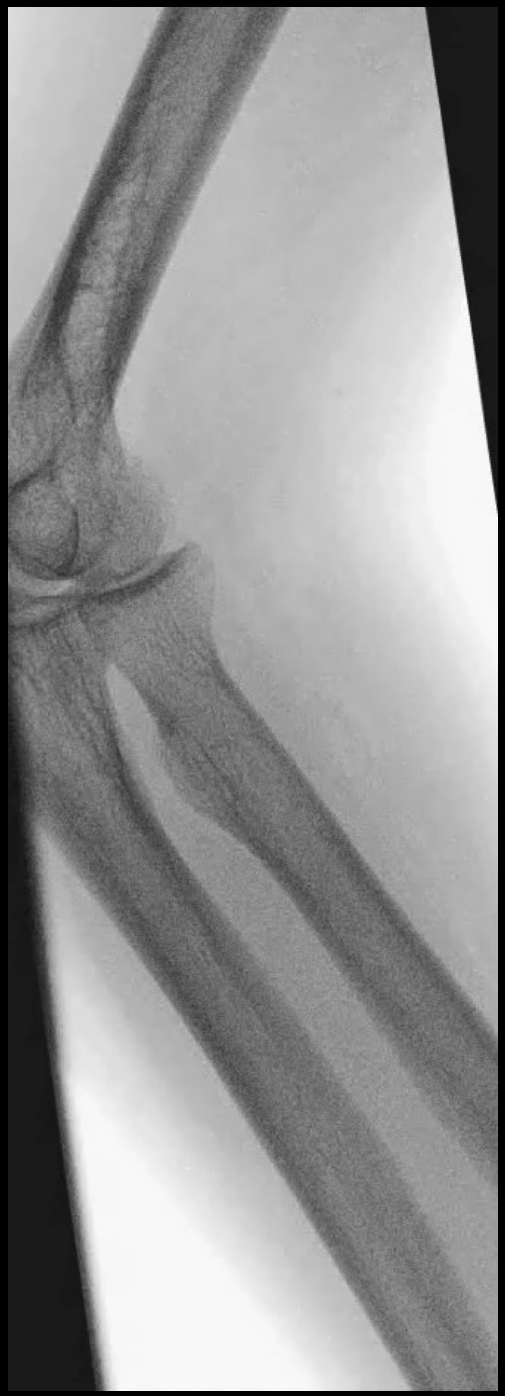


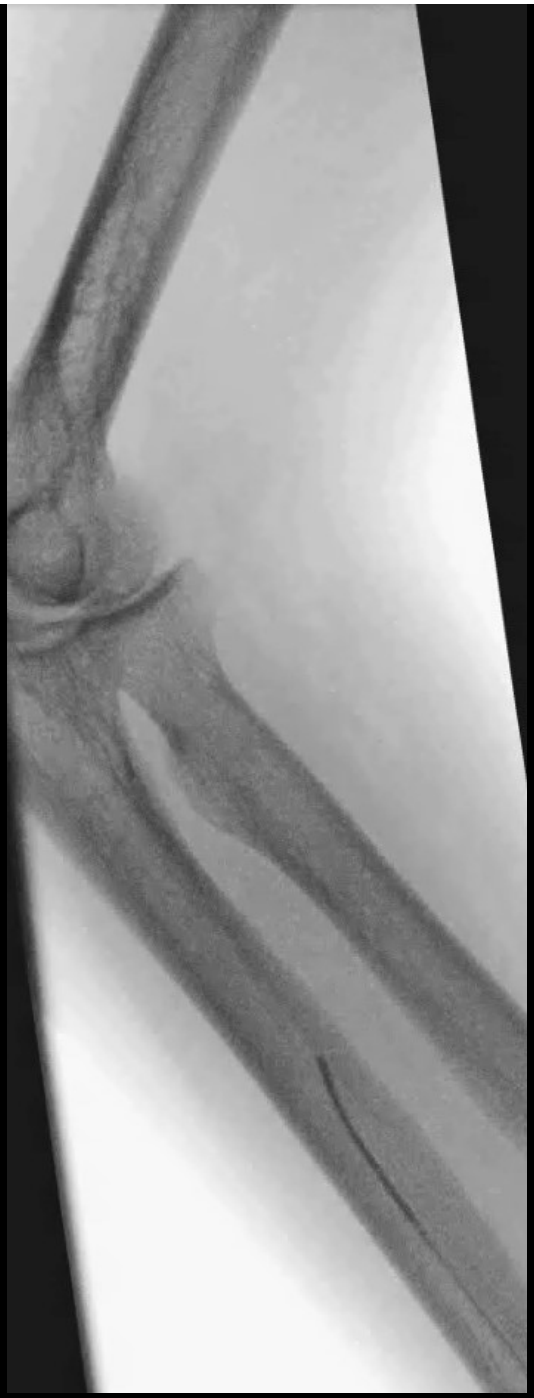


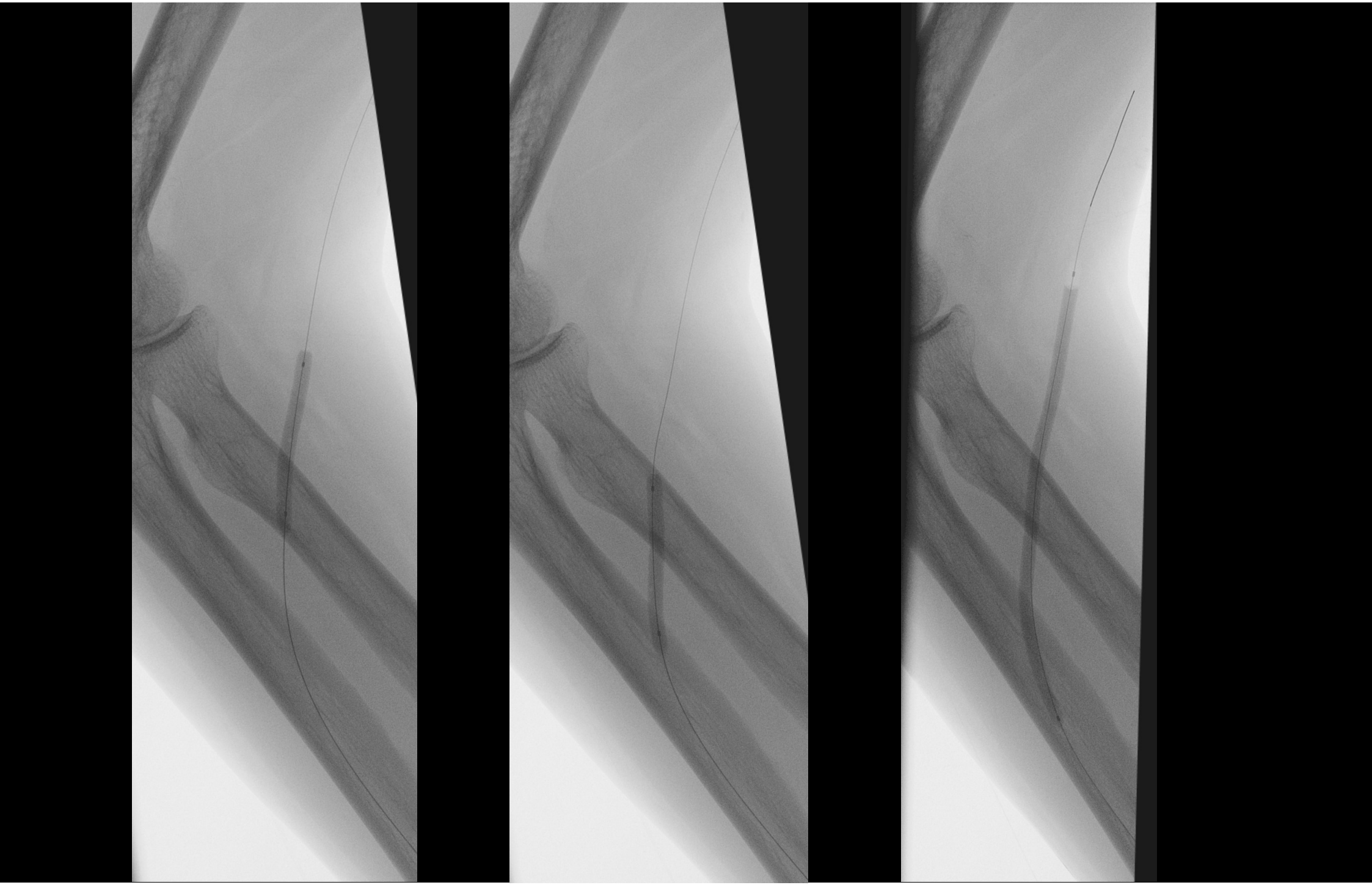


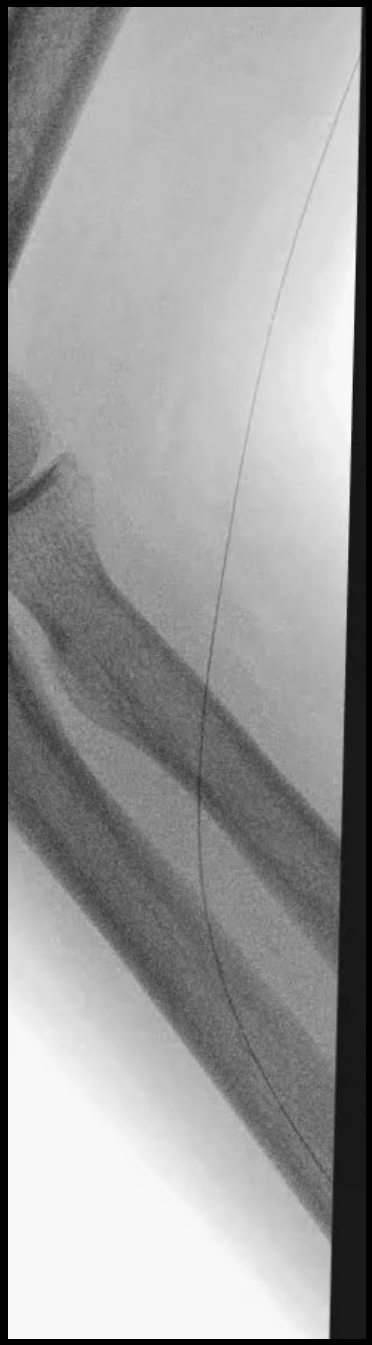


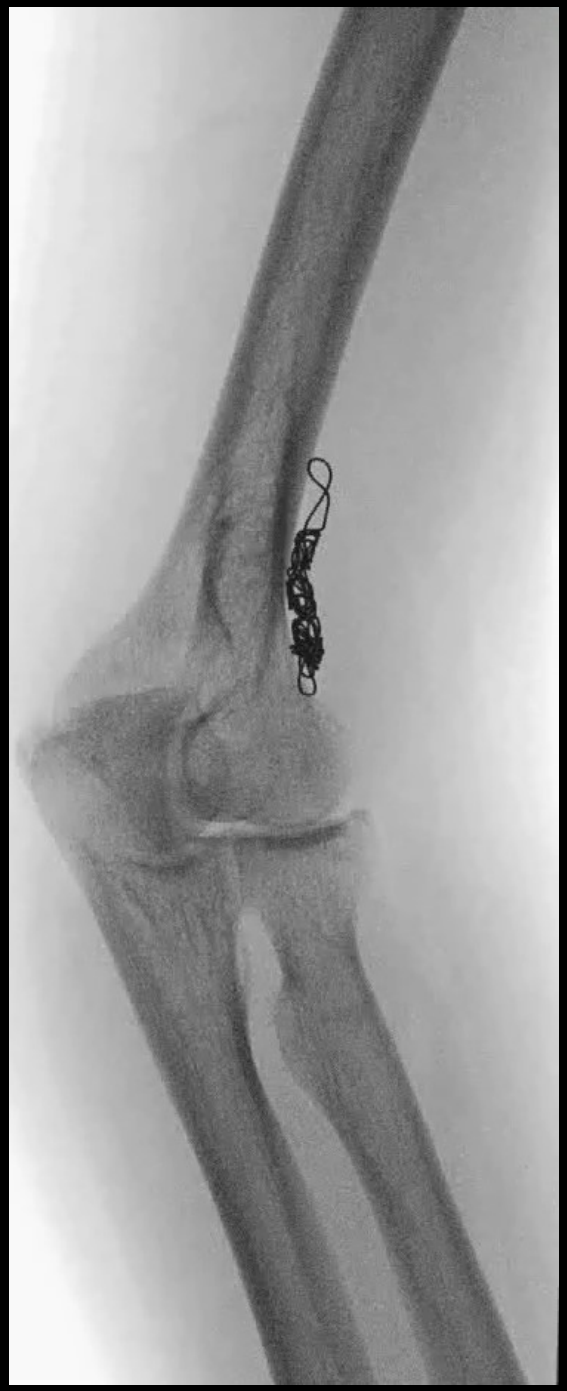


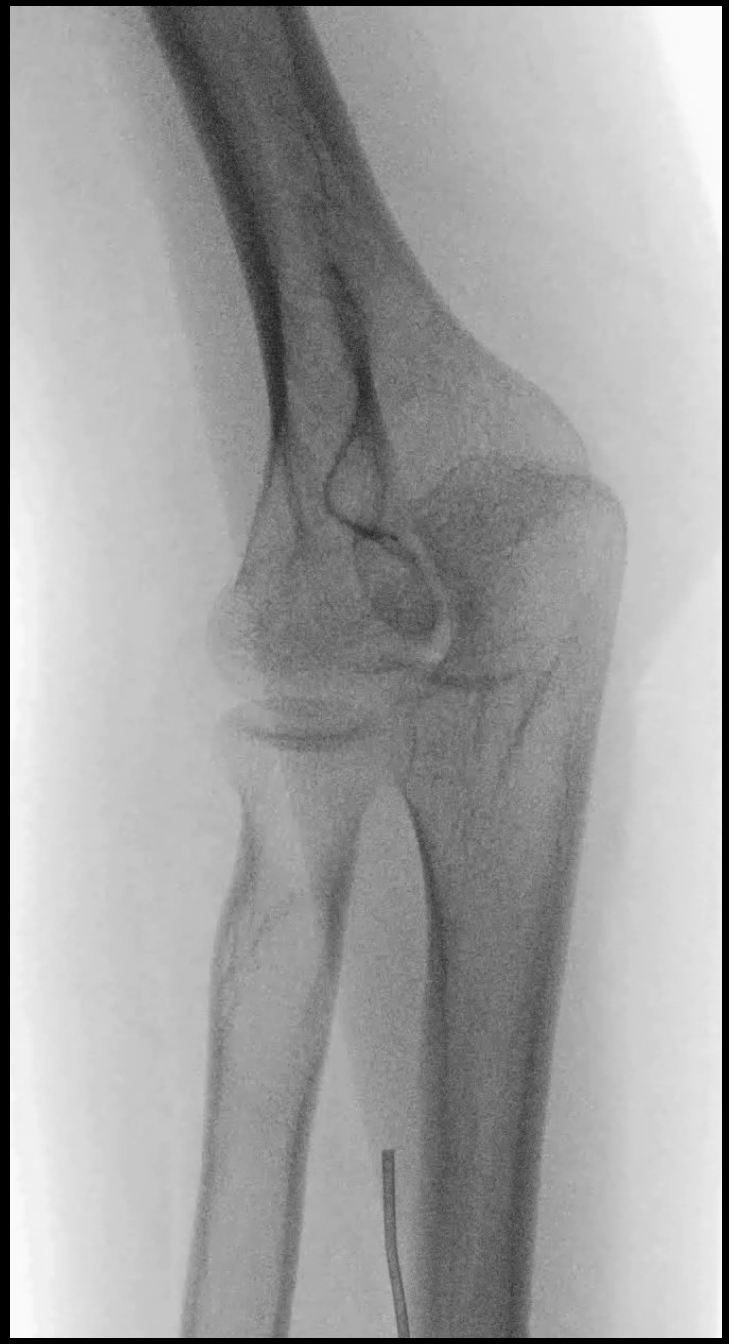


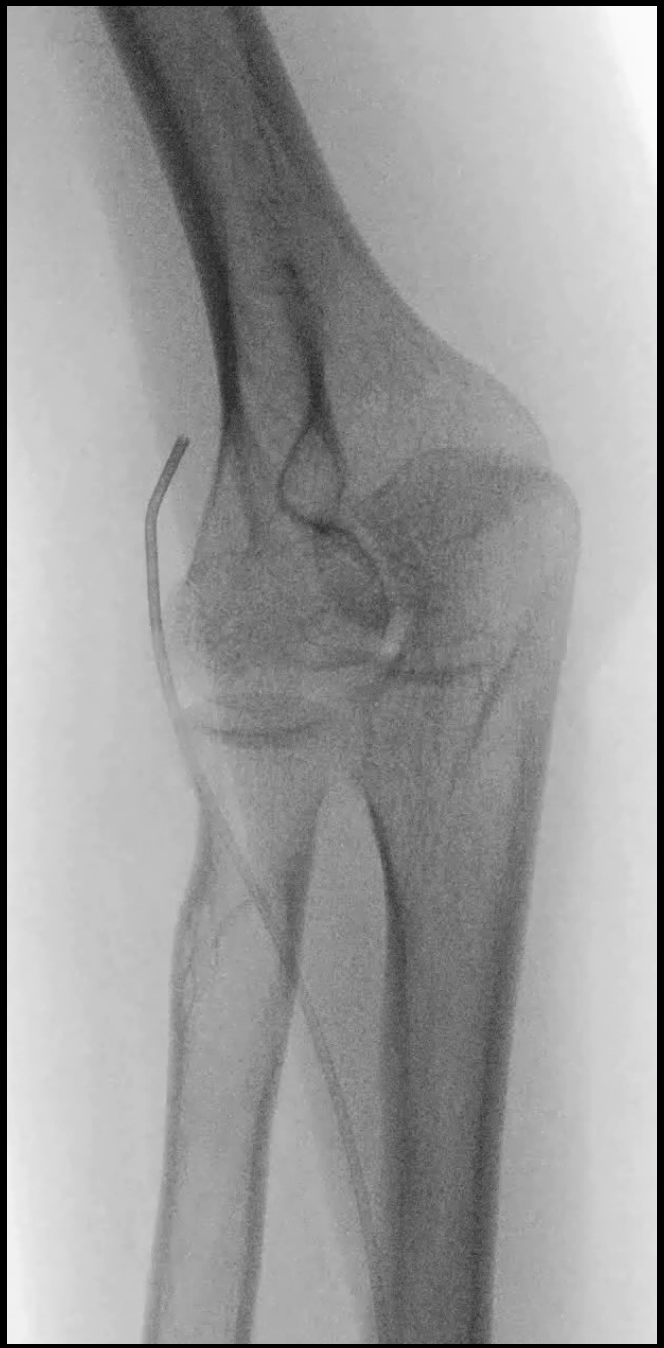


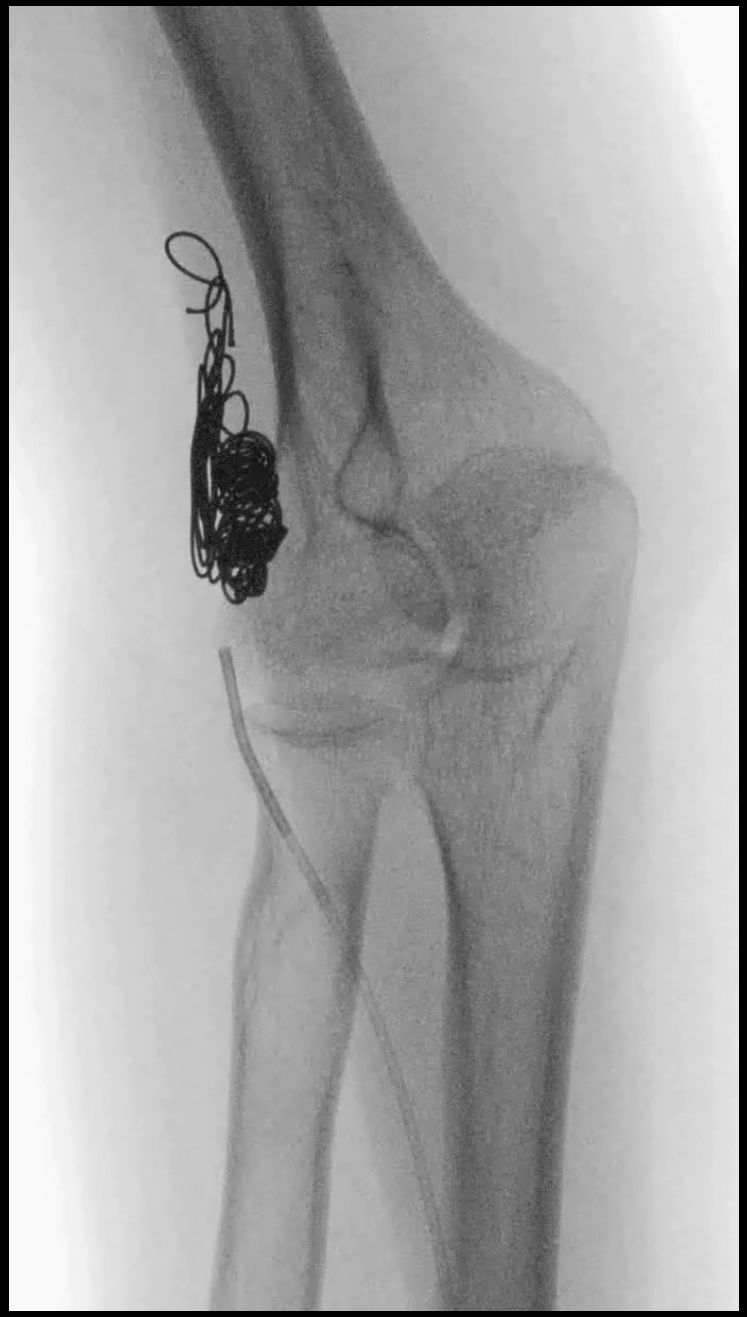


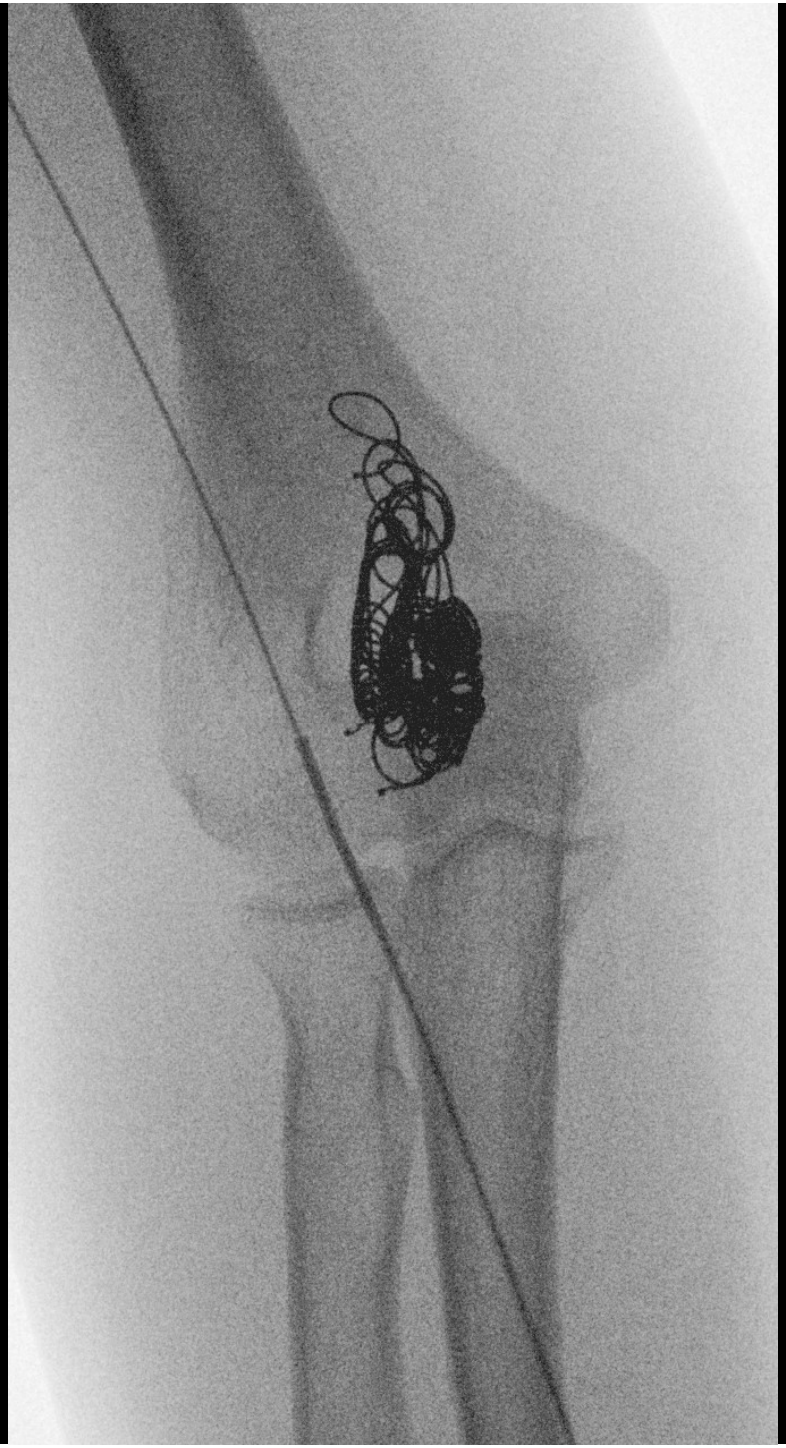


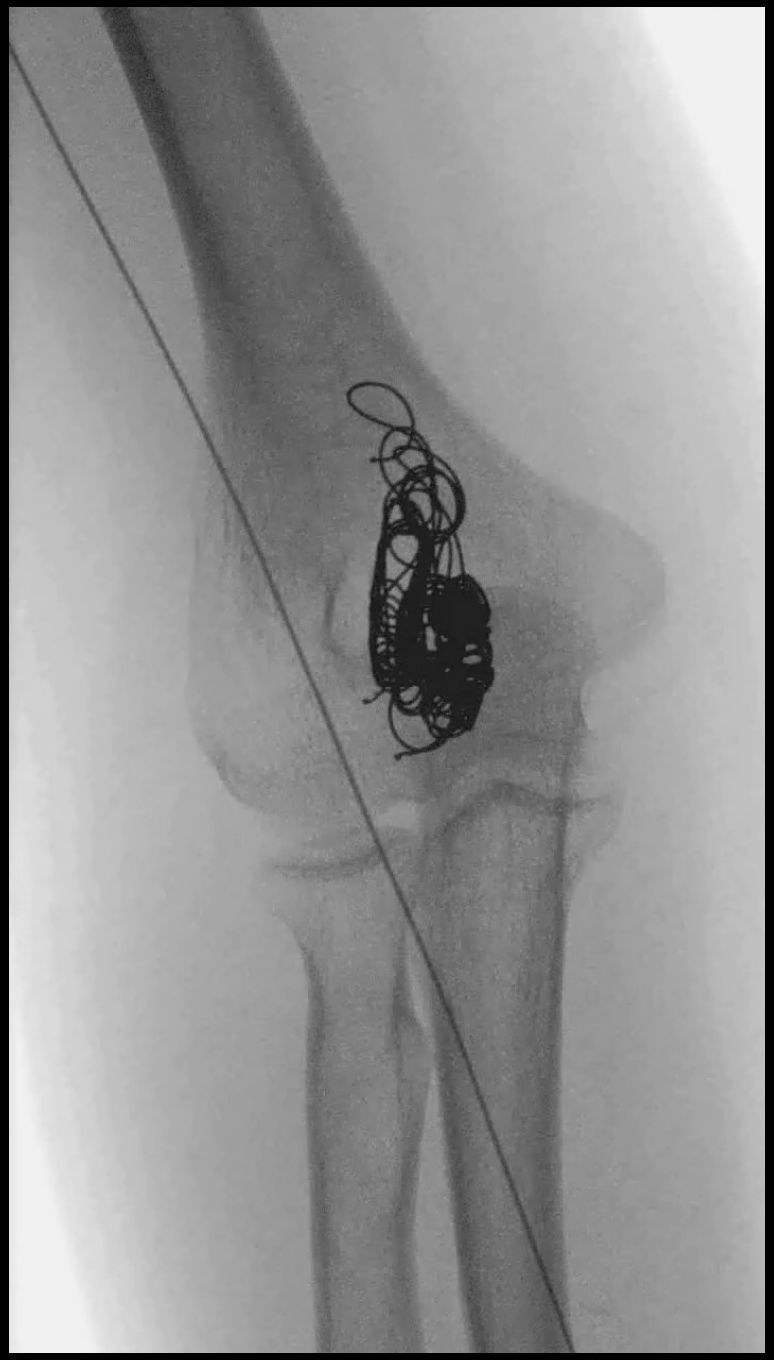


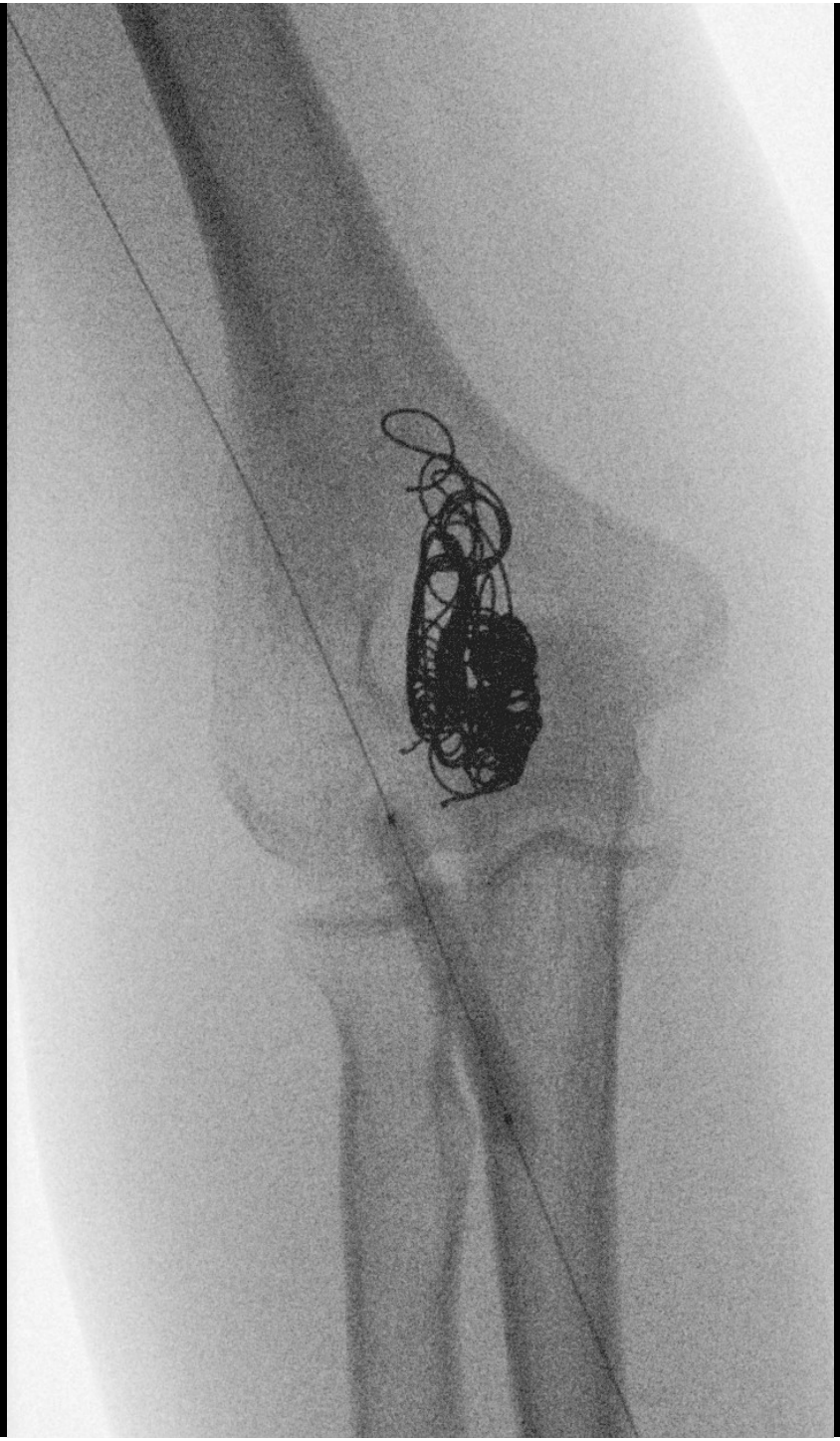


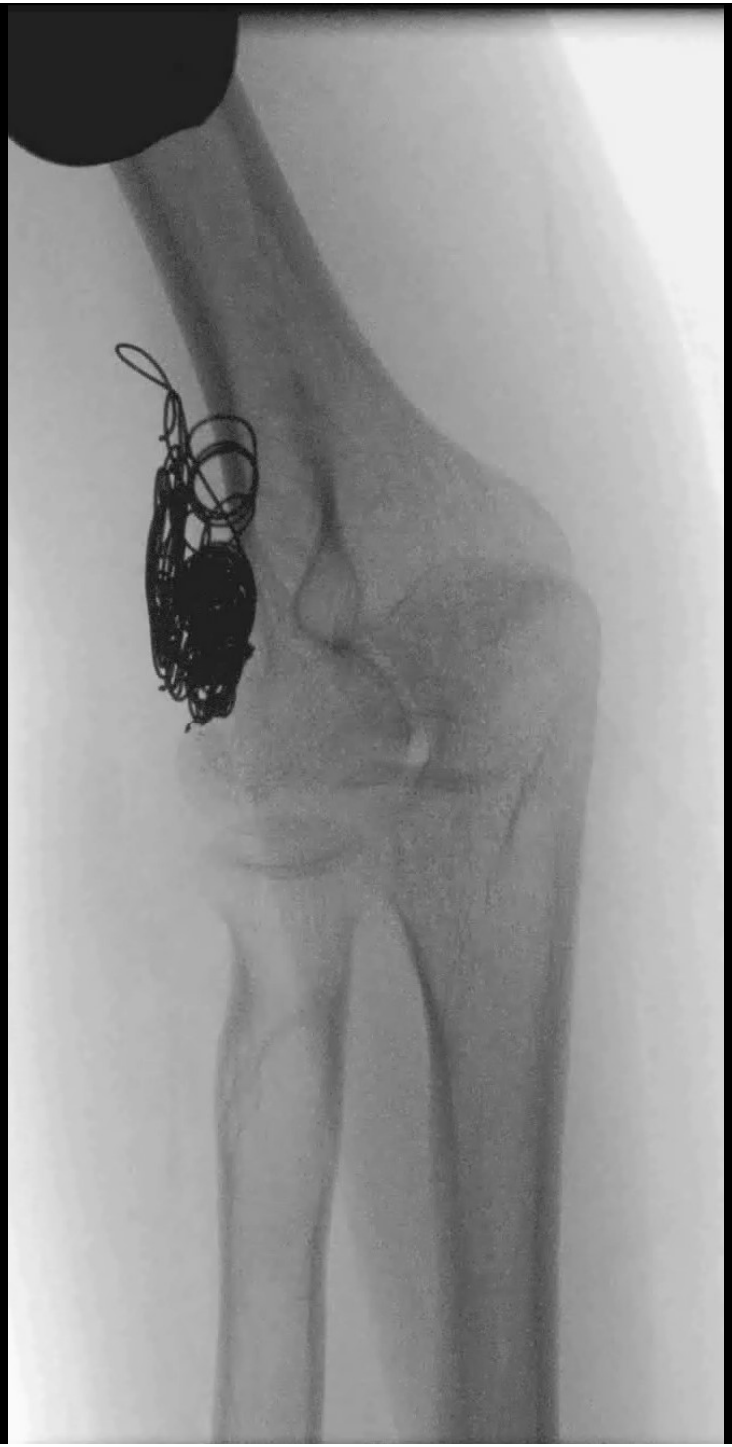












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