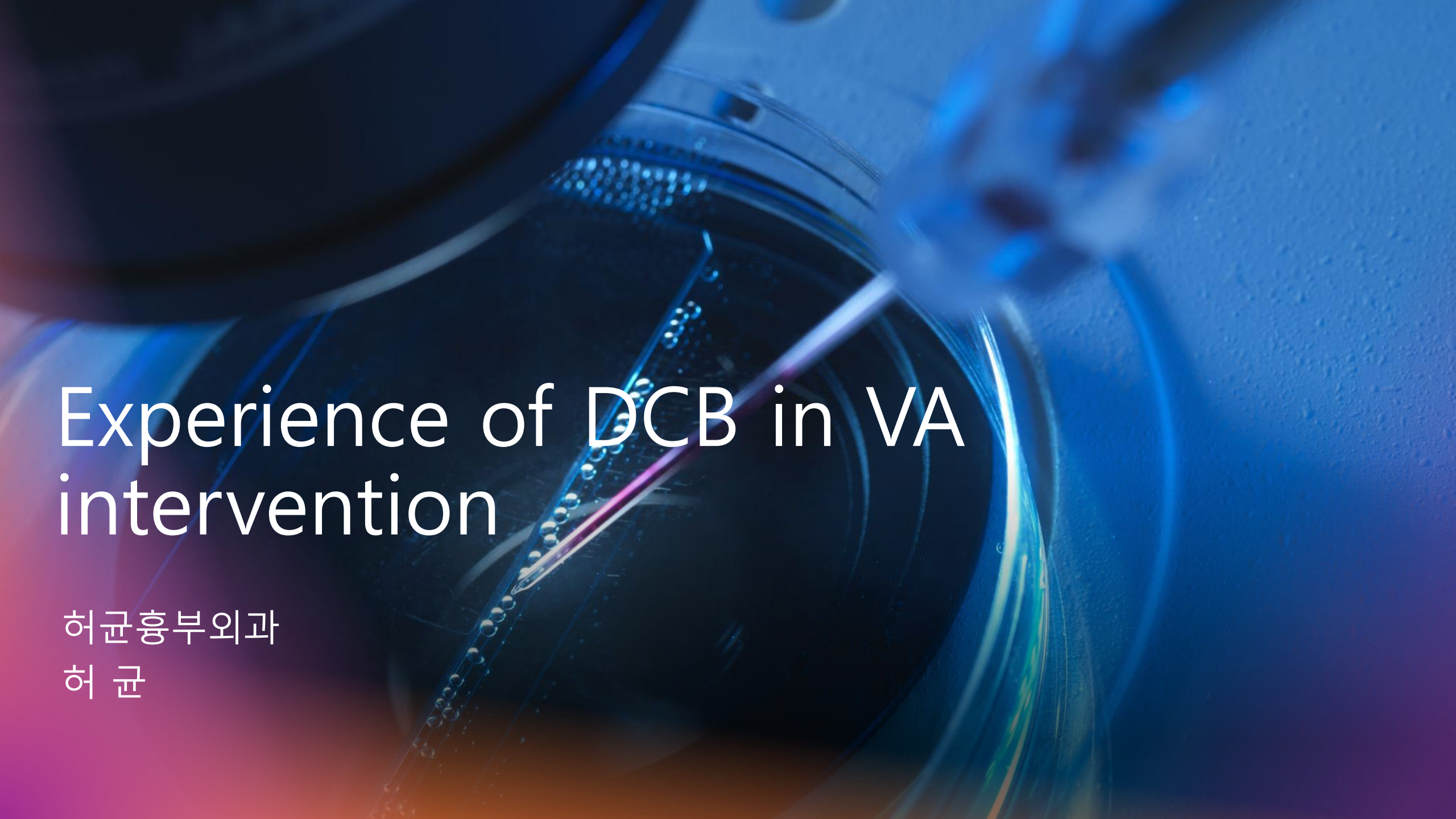


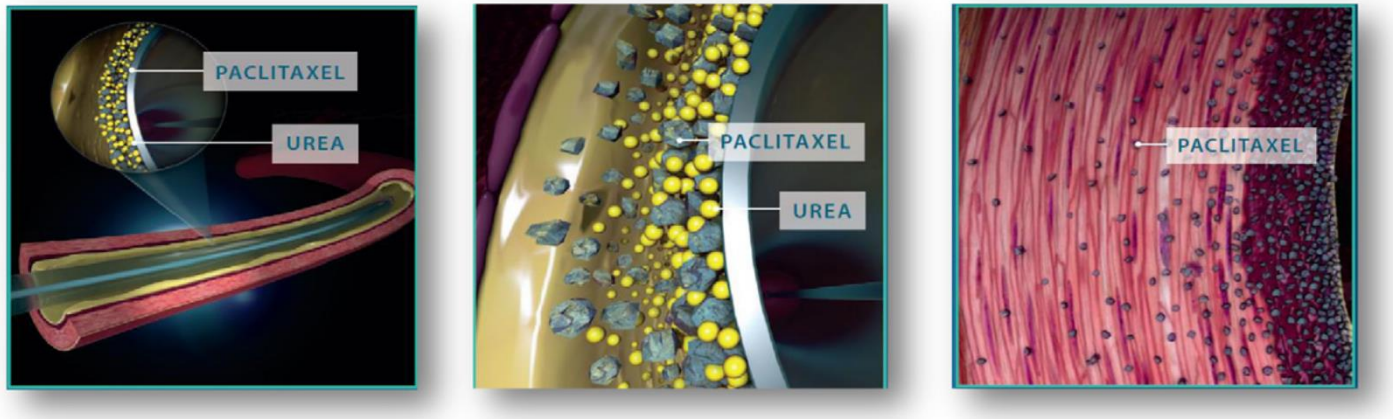
Experience of DCB in VA intervention

허균흉부외과
허 균

Hemodialysis access (HD access)

- **Non tunneled catheter (JVC etc..)**
- **Tunneled catheter (perm catheter etc..)**
- **AV fistula**
- **AV graft**

Drug Coating Balloon



IN.PACT Admiral balloon matrix coating:
- Paclitaxel
- Urea - excipient that controls drug release

DCB inflation:
- Matrix coating contact with the blood
- Urea hydrates causing the release of paclitaxel
- Paclitaxel binds to the wall due to its hydrophobic and lipophilic properties

Paclitaxel penetration:
- Through vessel wall deep into the media and adventitia
- Interferes with the causes of restenosis
- Can remain in the vessel wall for over 180 days at therapeutic levels

Fig. 1. Mechanism of action for IN.PACT Admiral DCB.

KDOQI 2019

Statements: Treatment of Clinically Significant AV Access Stenosis

Angioplasty

15.5 KDOQI considers it reasonable to use balloon angioplasty (with high pressure as needed) as primary treatment of AVF and AVG stenotic lesions that are both clinically and angiographically significant. *(Expert Opinion)*

Note: Angiographically present stenosis without accompanying clinical signs and symptoms is inadequate to treat/intervene upon.

15.6 There is inadequate evidence for KDOQI to make a recommendation regarding the use of specialized balloons (drug-coated or cutting) versus standard high-pressure balloons in the primary treatment of AVF and AVG stenosis.

15.7 There is inadequate evidence for KDOQI to make a recommendation regarding the optimal duration of balloon inflation time during angioplasty to improve intervention primary patency in the treatment of AVF or AVG stenosis.

15.8 KDOQI considers it reasonable that a careful patient-individualized approach to the choice of balloon type for angioplasty of clinically significant AVF and AVG stenosis be based on the operator's best clinical judgment and expertise. *(Expert Opinion)*

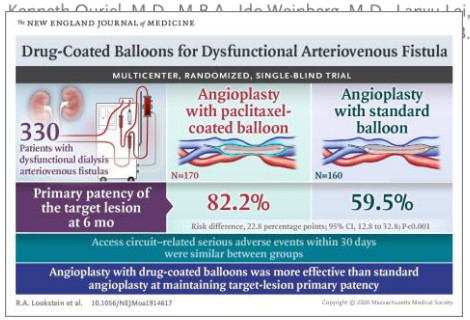
NEJM 2020

The NEW ENGLAND JOURNAL of MEDICINE

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.,



Kidney International. 2021

www.kidney-international.org clinical trial

A multicenter randomized controlled trial indicates that paclitaxel-coated balloons provide no benefit for arteriovenous fistulas

Check for updates

see commentary on page 278

OPEN

Narayan Karunanithy[1,25], Emily J. Robinson[2,25], Farhan Ahmad[3], James O. Burton[4,5], Francis Calder[6], Simon Coles[7], Neelanjan Das[8], Anthony Dorling[2,6], Colin Forman[9], Ounali Jaffer[10], Sarah Lawman[11], Raghuram Lakshminarayan[12], Rhys Lewlellyn[13], Janet L. Peacock[2,14], Raymond Ramnarine[15], Irene Rebollo Mesa[2], Shoaib Shaikh[16], James Simpson[17], Kate Steiner[18], Rebecca Suckling[19], Laszlo Szabo[20], Douglas Turner[21], Ashar Wadoodi[22], Yanzhong Wang[2], Graeme Weir[23], C. Jason Wilkins[6,24], Leanne M. Gardner[2] and Michael G. Robson[2,6]

[1]Department of Interventional Radiology, Guy's and St Thomas' NHS Foundation Trust, London, UK; [2]Faculty of Life Sciences and Medicine, King's College London, London, UK; [3]Department of Radiology, Royal Berkshire NHS Foundation Trust, Reading, UK; [4]Department of Cardiovascular Sciences, University of Leicester, Leciester, UK; [5]Department of Renal Medicine, University Hospitals of Leicester NHS Trust, Leicester, UK; [6]Department of Nephrology and Transplantation, Guy's and St Thomas' NHS Foundation Trust, London, UK; [7]Department of Radiology, Portsmouth Hospitals NHS Trust, Portsmouth, UK; [8]Department of Nephrology, East Kent Hospitals NHS Foundation Trust, Canterbury, UK; [9]Department of Nephrology and Transplantation, Royal Free London NHS Foundation Trust, London, UK; [10]Department of Radiology, Barts Health NHS Trust, London, UK; [11]Department of Nephrology, Brighton and Sussex University Hospitals NHS Trust, Brighton, UK; [12]Department of Radiology, Hull University Teaching Hospitals NHS Trust, Hull, UK; [13]Department of Radiology, Royal Devon and Exeter NHS Foundation Trust, Exeter, UK; [14]Department of Epidemiology, Dartmouth College, Hanover, New Hampshire, USA; [15]Department of Radiology, Gloucestershire Hospitals NHS Foundation Trust, Gloucester, UK; [16]Department of Radiology, Bradford Teaching Hospitals NHS Foundation Trust, Bradford, UK; [17]Department of Radiology, Lancashire Teaching Hospitals NHS Trust, Preston, UK; [18]Department of Radiology, East and North Hertfordshire NHS Trust, Stevenage, UK; [19]Department of Nephrology, Epsom and St Helier University Hospitals NHS Trust, Carshalton, UK; [20]Department of Nephrology and Transplantation, Cardiff and Vale University Health Board, Cardiff, UK; [21]Department of Radiology, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK; [22]Department of Nephrology and Transplantation, St George's Healthcare NHS Trust, London, UK; [23]Department of Radiology, Lothian NHS, Edinburgh, UK; and [24]Department of Radiology, King's College Hospital NHS Foundation Trust, London, UK

Claude

When it comes to the patency rates of arteriovenous (AV) fistulas treated with drug-coated balloons (DCBs), several studies have reported the following:

1. Primary Patency: Primary patency refers to the fistula remaining open and functional without any intervention after the initial DCB angioplasty.
   - At 6 months: Primary patency rates range from approximately 50% to 70%.
   - At 12 months: Primary patency rates range from approximately 30% to 50%.
2. Target Lesion Primary Patency: Target lesion primary patency refers to the treated lesion (stenosis) remaining open and functional without the need for repeat intervention.
   - At 6 months: Target lesion primary patency rates range from approximately 60% to 80%.
   - At 12 months: Target lesion primary patency rates range from approximately 40% to 60%.

It's important to note that these patency rates can vary across different studies and patient populations. Some factors that can influence the patency rates include the location and severity of the stenosis, the type of AV fistula (radiocephalic, brachiocephalic, or graft), and the patient's comorbi ↓ es.

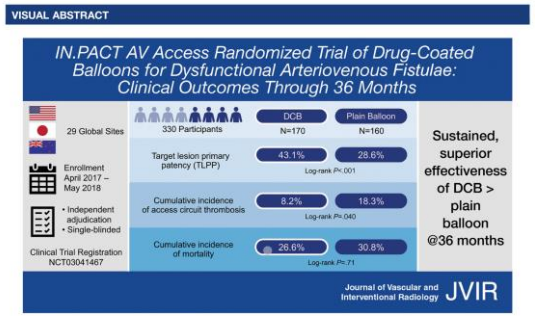


Table 1 | Randomized controlled trials with 3 different DCBs

No.	Name or country or both	Investigators	Journal and year	Subjects	Balloon	Primary endpoint	Result	Comments
1	PAVE (United Kingdom)	Karunanithy *et al.*[5]	*Kidney Int.* 2021	212	Lutonix	Time to loss of TLPP at 6 mo	Negative: $P = 0.44$ (159 d [P] vs. 215 d [C])	75% of operators blinded Included maturing AVF
2	Lutonix IDE	Trerotola *et al.*[3]	*Clin J Am Soc Nephrol.* 2018	285	Lutonix	TLPP at 6 mo	Negative: $P = 0.06$ (62% [P] vs. 58% [C])	No maturing AVF
3	Medtronic IDE (United States, New Zealand, Japan)	Lookstein *et al.*[4]	*N Engl J Med.* 2020	330	IN.PACT	TLPP at 6 mo	Positive: $P < 0.001$ (82.2% [P] vs. 59.5% [C])	No maturing AVF
4	Australian	Swinnen *et al.*[S1]	*J Vascular Access.* 2018	132	IN.PACT	LLL at 6 mo	Positive: $P = 0.0002$ (0.045 mm/mo [P] vs. 0.23 [C])	Mandated ultrasonogram 48% in-stent restenosis
5	Singapore	Irani *et al.*[S2]	*Radiology.* 2018	119	IN.PACT	TLPP at 6 mo	Positive: $P = 0.03$ (81% [P] vs. 61% [C])	Mandated angiogram at 6 mo; AVG = 21
6	Spain	Moreno-Sanchez *et al.*[S3]	*Cardiovasc Intervent Radiol.* 2020	136	Passeo-18 Lux	Time to loss of TLPP at 6 mo	Negative: $P = 0.068$ (153 d [P] vs. 142 d [C])	Mandated angiogram at 6 mo; AVG = 12
7	France	Therasse *et al.*[S4]	*J Vasc Interv Radiol.* 2021	120	Passeo-18 Lux	LLL at 6 mo	Negative: $P = 0.082$ (0.64 mm [P] vs. 1.13 mm [C])	Mandated angiogram at 6 mo

AVF, arteriovenous fistula; AVG, arteriovenous graft; C, control; DCB, drug-coated balloon; IDE, investigational device exemption; IN.PACT, IN.PACT AV Access Study; LLL, late lumen loss; PAVE, Paclitaxel-coated Balloons and Angioplasty of Arteriovenous Fistulas (study); Rx, different drug-coated balloons; TLPP, target lesion primary patency.
Note the variation and differences in the balloons used, the endpoints, the use of a mandated angiographic or ultrasonogram procedure at 6 months, the presence or absence of maturing AVFs and AVGs, and the final results.

Purpose of the study

- Comparison of the effects of **plane old balloons** and **drug coated balloons** in the **same patient**

Method

- Single center, retrospective study
- Inclusion criteria
  - 2022.01 ~2023.07
  - AVF patency after the most recent PTA <180 days
    or average patency after the last three PTAs is <180 days
  - High pressure balloon angioplasty with drug coated balloon
- Exclusion criteria
  - No information for previous PTA

Method

- Drug coated balloon size
  - Only drug coated balloons with a diameter of 7mm or less can be used
  - If suitable sized drug-coated balloons exist:
    : use proper sizes of drug-coated balloons
  - If vessel dilatation of more than 7 mm is required:
    : angioplasty with available drug coated balloon followed by a larger sized high pressure balloon

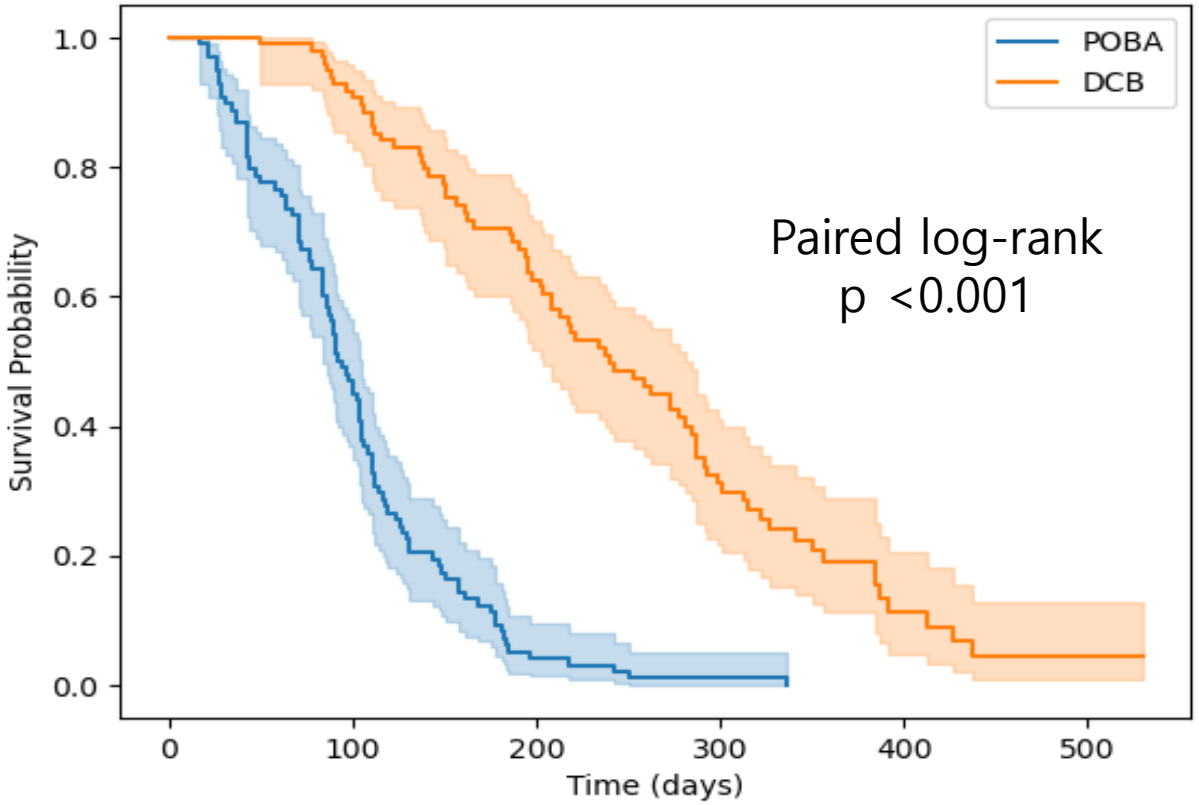
Method

- Statistical analysis
  - Kaplan-Meier Survival curve
  - Paired Log-Rank Test
  - Cox Proportional Hazards Model for Paired Data

Baseline characteristics

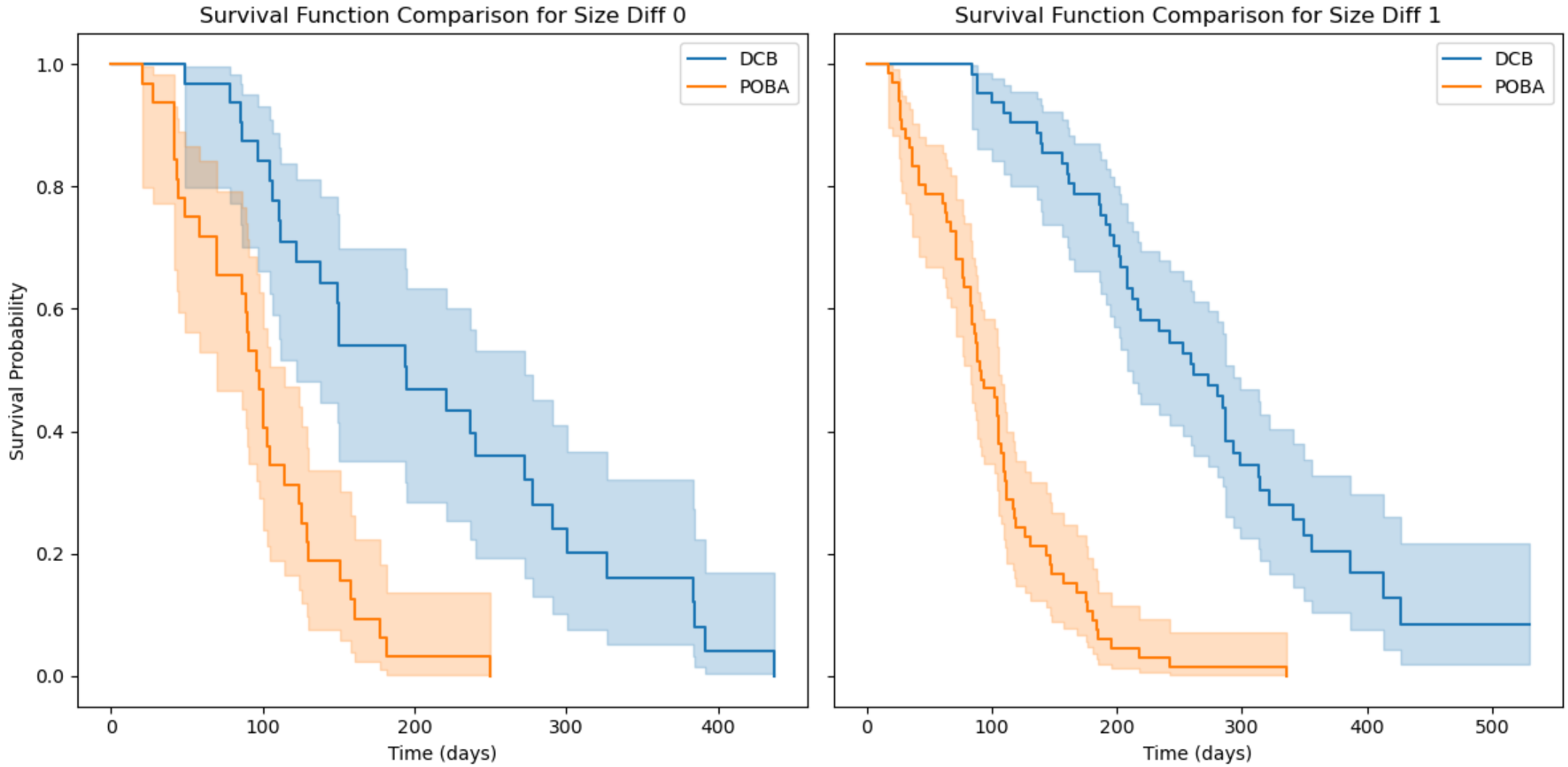
Variables		n=98
age, mean ± SD		65.1 ± 10.5
sex, n (%)	F	54 (55.1)
	M	44 (44.9)
HTN, n (%)	0	19 (21.6)
	1	69 (78.4)
DM, n (%)	0	40 (45.5)
	1	48 (54.5)
DCB site	cephalic vein	26 (26.5)
	basilic vein	31 (31.6)
	brachial vein	1 (1.0)
	cephalic arch	37 (37.8)
	central vein	3 (3.1)
DCB_size, n (%)	5/120	2 (2.0)
	6/120	5 (5.2)
	7/120	30 (30.6)
	7/80	61 (62.9)
Use of standard balloon	DCB only	32(32.7)
	DCB + standard balloon	66 (67.3)

Target-Lesion Primary Patency

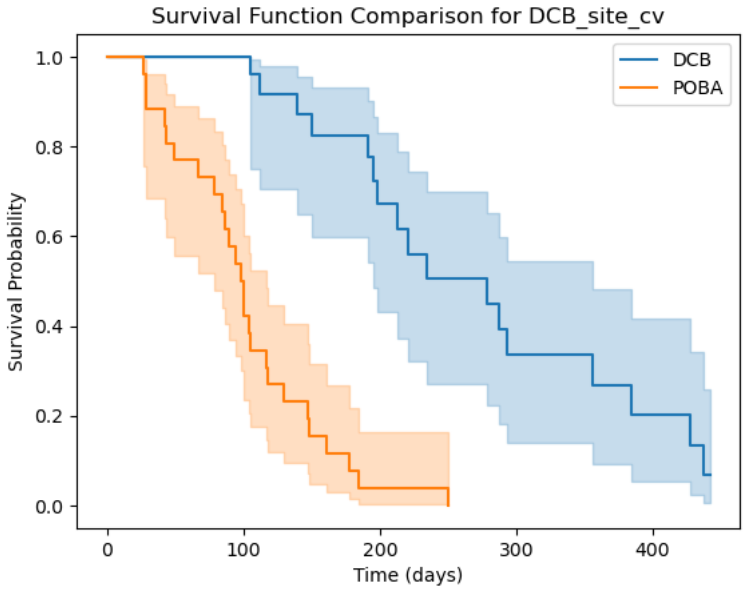


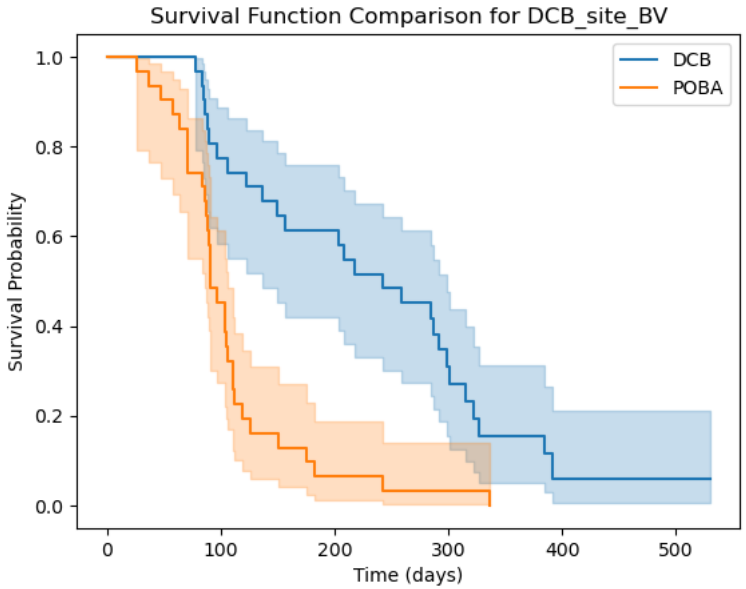
	Hazard ratio	CI lower 95%	CI upper 95%	P-value
DCB patency (vs. standard balloon)	0.08	0.04	0.16	<0.005

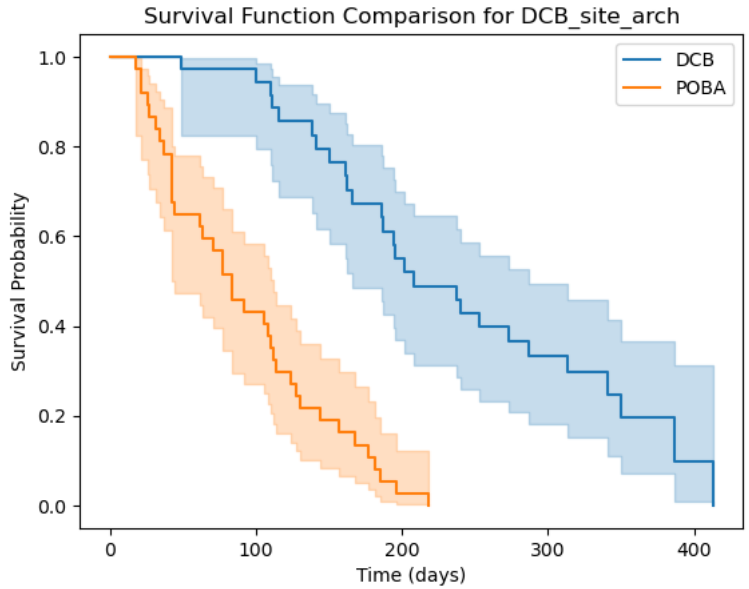
Target-Lesion Primary Patency according to the use of large sized balloons



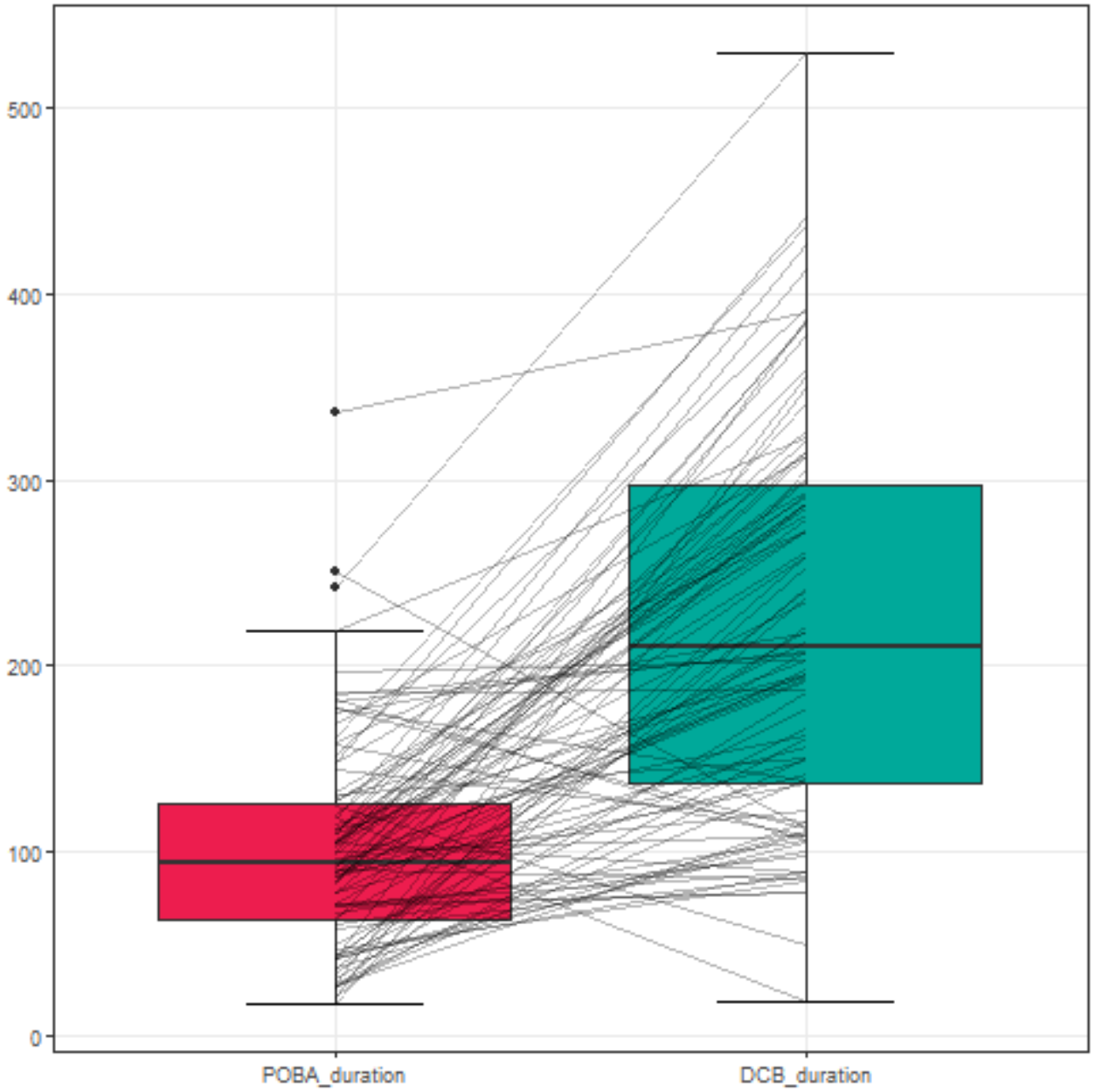
Target-Lesion Primary Patency by lesions







DCB patency (vs. standard balloon)	Cephalic vein	Basilic vein	Cephalic arch
HR (95% CI)	0.04 (0.01-0.30)	0.11 (0.04-0.32)	0.09 (0.03-0.27)
P-value	<0.005	<0.005	<0.005



	Mean ± SD
POBA	100 ± 56
DCB±POBA	224 ± 106

Drug-coated balloons and dialysis vascular access: is there light at the end of the tunnel . . .

Prabir Roy-Chaudhury[1,2], Theodore F. Saad[3] and Scott Trerotola[4]

This commentary uses the negative results of the PAVE (Paclitaxel-coated Balloons and Angioplasty of Arteriovenous Fistulas) study to (i) discuss the role of drug-coated balloons in the armamentarium of therapies for dialysis vascular access stenosis and (ii) suggest a more patient centered, individualized, and precision medicine–based approach for the future care of patients with dialysis vascular access dysfunction.

Kidney International (2021) **100,** 278–280; https://doi.org/10.1016/j.kint.2021.06.009

primary endpoint of the study was the time in days to a loss of target lesion primary patency, with secondary endpoints of time to loss of dialysis access circuit primary and cumulative patency.

The PAVE study had a number of positive attributes, in that it (i) was an investigator-initiated study; (ii) had a study design that mandated that ≥75% of the repeat interventions would be performed by a different interventionalist from the one who had performed the index procedure (thus partly addressing the operator blinding issue); and (iii) had strict inclusion, exclusion, and design criteria that allowed for a focus on the target lesion.

The PAVE study, however, did not show any improvement in target lesion primary patency using the Lutonix DCB

감사합니다