

A study of hemodialysis arteriovenous stenosis
treated with APERTO DCB

- APERTO AVF RCT CHINA -

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Disclosure

Speaker name: Qizhuang Jin

I have the following potential conflicts of interest to report:

- √ Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company-sponsored speaker bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company

√ I do not have any personal potential conflict of interest

Background

- Stenosis of an arteriovenous fistula (AVF) is a serious problem for patients undergoing maintenance hemodialysis. Drug Coated balloon (DCB) has a good track record but still lacks of prospective RCT.
- **APERTO** (Cardionovum, Germany) is a new high-pressure DCB with a SAFEPAX[®] shellac-ammonium salt excipient that can avoid drug wash-off during catheter delivery to the target lesion site.
- This multicenter, RCT evaluates the safety and efficacy of Aperto in hemodialysis fistula–related venous stenosis and it also designed to meet Chinese regulatory requirements for the approval of this device in China.

Background

- The gold standard to diagnose stenosis of AVF is angiogram. However, this procedure is invasive and costly. Duplex ultrasound as a non-invasive tool is the first line imaging method in patients with suspected VA dysfunction¹;
- In reality, the diameter of the fistula vein may vary significantly along its length, therefore, making the diameter-based approach difficult²;
- PSVR (Peak Systolic Velocity Ratio) shows good agreement when compared to the angiogram and PSVR ≥ 2 is used to define an US stenosis of $\geq 50\%$ in several publications^{2,3}.

Study Design

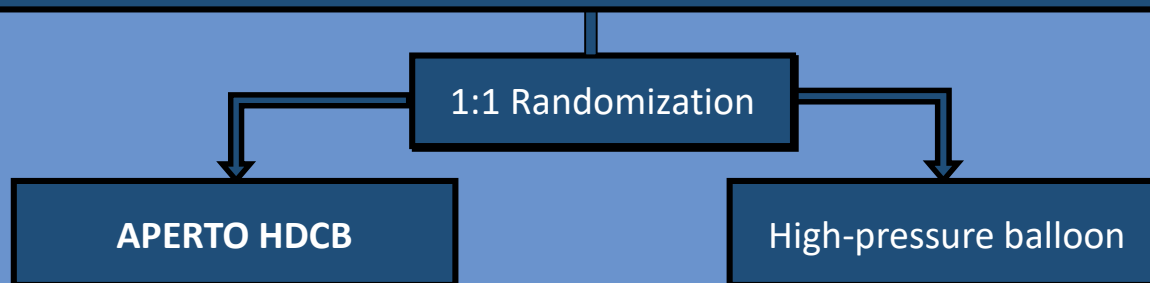
A prospective, multicenter, randomized, controlled trial

Inclusion:

- Age ≥ 18 years and ≤ 75 years
- Angiography, ultrasound or clinical diagnosis shows that patients have hemodialysis access dysfunction due to stenosis lesions
- Patients with indications of the percutaneous endovascular therapy, that is, the AVF stenosis is related to hemodynamics and $\geq 50\%$, and with any of the following clinical and physiological abnormalities (referred to NKF-K/DOQI guideline definitions)
- Target lesion is a de novo or restenosis. The target lesions is located in venous outflow.
- Target lesion consists of a single lesion or a multiple lesions with target lesion length ≤ 40 mm

Exclusion:

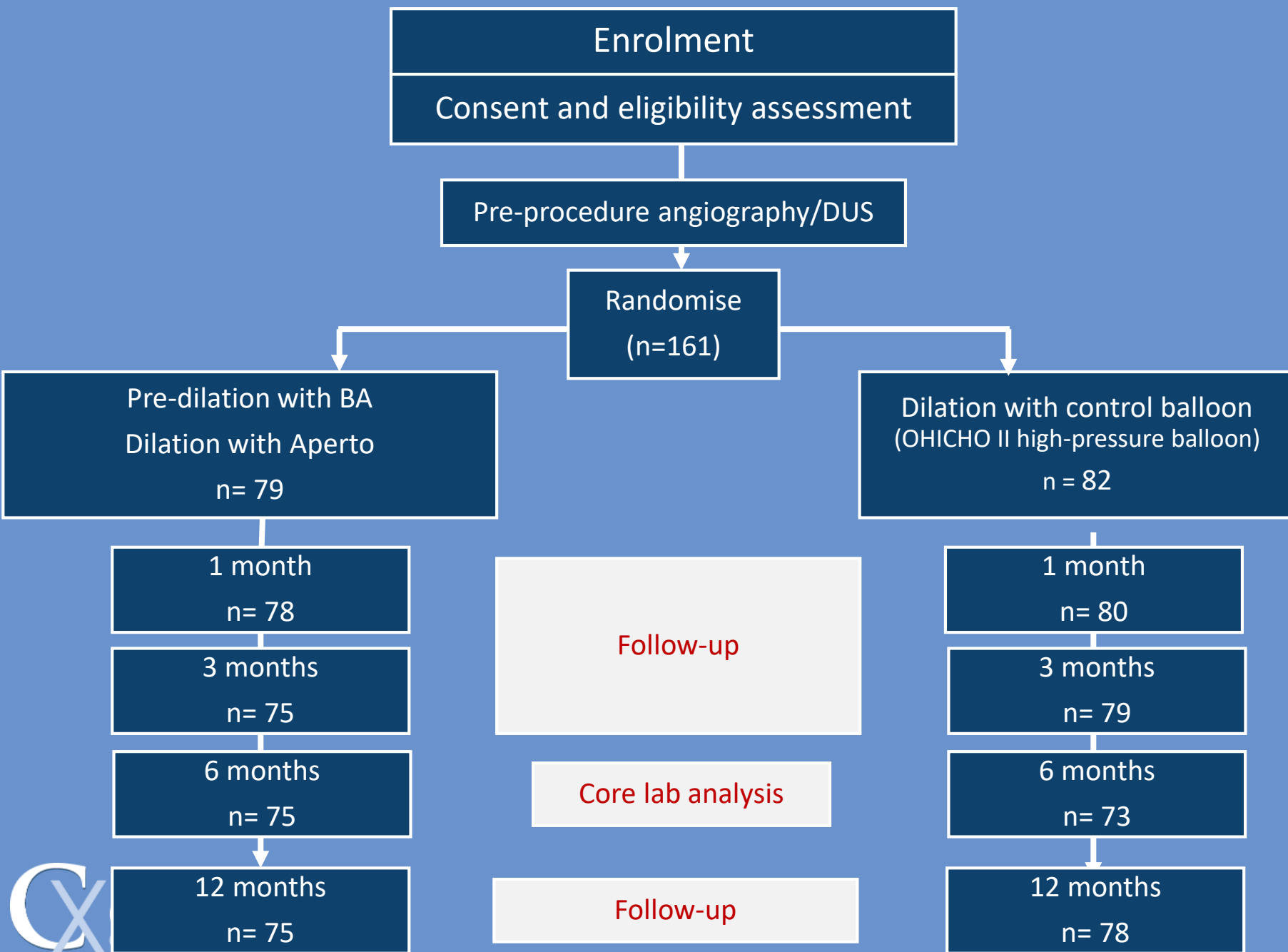
- Patients with AVG
- Lesion in AVF has been previously treated with DCB
- Target lesion is located in the anastomosis of native AVF
- AVF has been previously implanted with stent



Primary Endpoint:

Freedom from restenosis (PSVR ≤ 2.0) of the target lesion at 6 months

Study flow diagram



Baseline Patient Characteristics

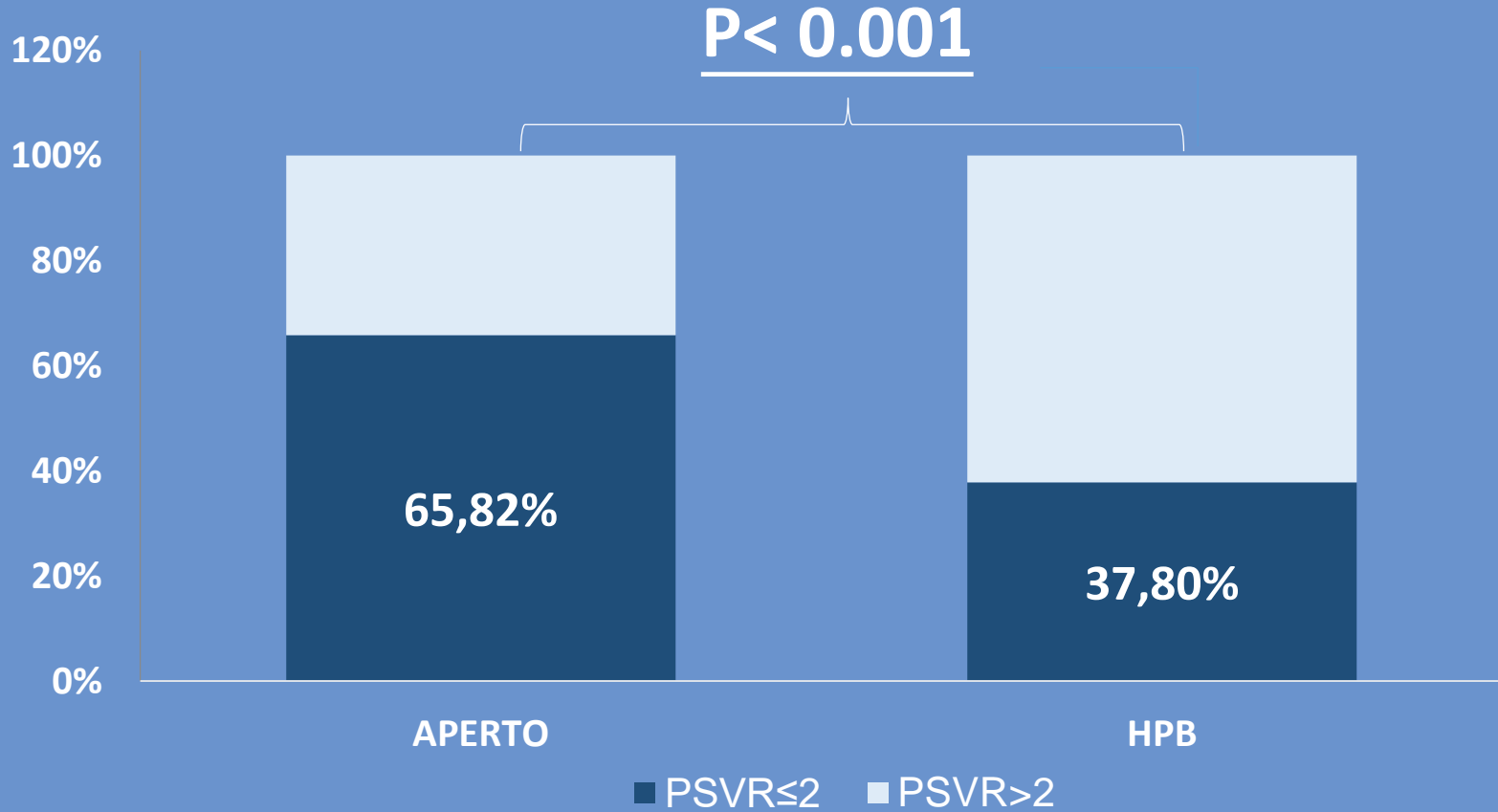
	APERTO (N=79)	HPB (N=82)	P value
Age, year, mean \pm SD	61 \pm 13	58 \pm 12	N.S
Male, (%)	45(57%)	41(50%)	
BMI, mean \pm SD	21.1 \pm 5.3	20.5 \pm 5.5	
Diabetes Mellitus, (%)	27(34.2%)	29(35.4%)	
Hypertension, (%)	66(83.5%)	69(84.1%)	
Hyperlipidemia, (%)	10(12.7%)	16(19.5%)	
Current & former cigarette smoking, (%)	14 (17.7)	20 (24.4)	

Baseline Lesion Characteristics

	APERTO (N=79)	HPB (N=82)	P value
Fistula location, n (%)			N.S
Left arm	57(72.2%)	62(75.6%)	
Right arm	22(27.8%)	20(24.4%)	
Access site, n (%)			
forearm	62(78.5%)	61(74.4%)	
Wrist	13(16.5%)	17(20.7%)	
other	4(5.1%)	4(4.9)	
Stenosis type, n (%)			
De novo	70(88.6%)	73(89.0%)	
Recurrent	9(11.4%)	9(11.0%)	
Diameter stenosis (%)	70.3±9.8	70.8±10.6	
Lesion length, mm	19.3±10.4	18.9±9.7	

Primary Endpoint:

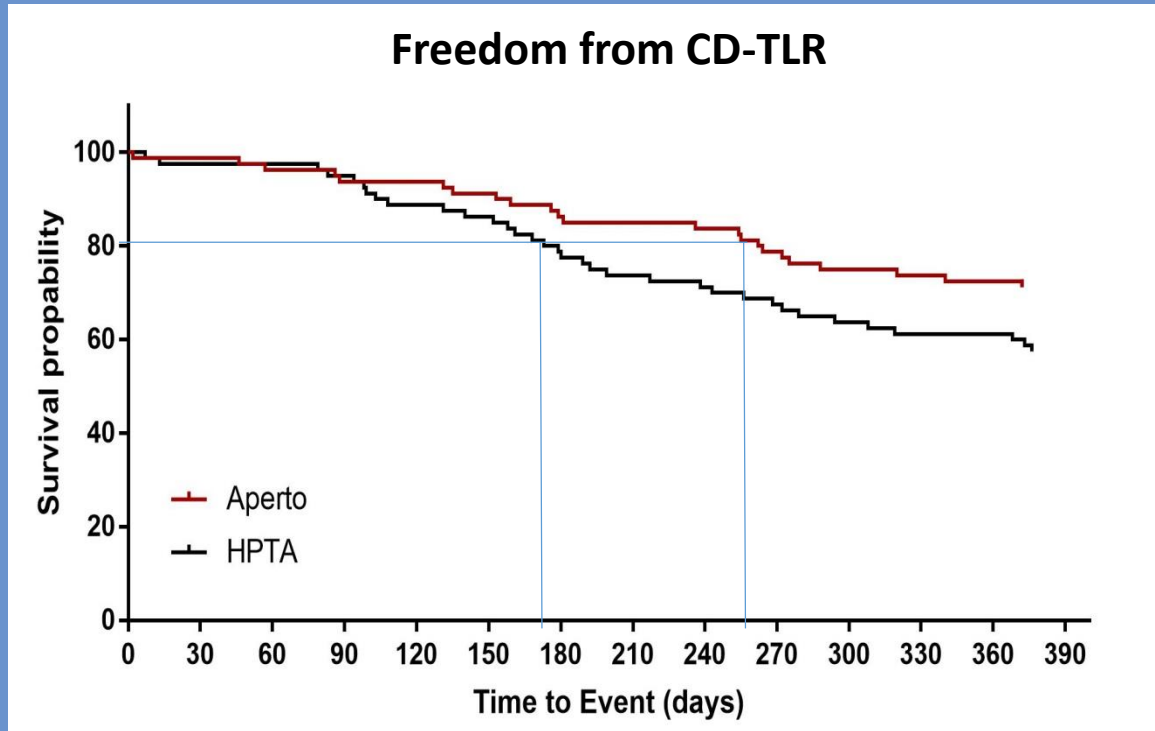
- Freedom from restenosis @ 6m



	APERTO	HPB	p
PSVR ≤ 2	65.82%	37.80%	<0.001

Secondary Endpoint:

- Target Lesion Primary Patency @12M

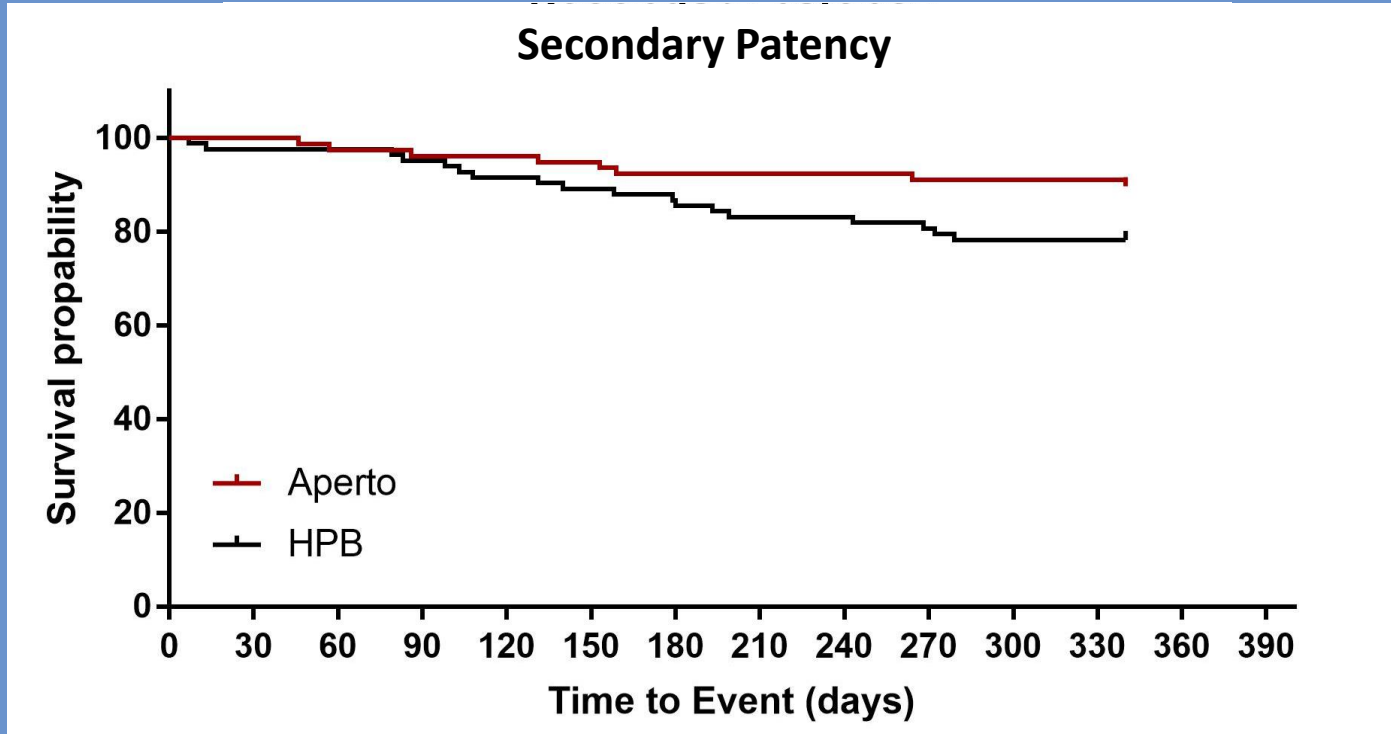


APERTO HDCB could maintain the target lesion patency over 262 days in 80% of patients. (vs. HPB 172 d, HR: 1.643, 95%CI: 0.98, 2.76)

		1m	3m	6m	12m	p
APERTO	79(100%)	77(97.4%)	74(93.6%)	69(85.9%)	57(75.6%)	0.06
HPB	82(100%)	79(97.6%)	77(93.9%)	64(79.2%)	47(58.2%)	

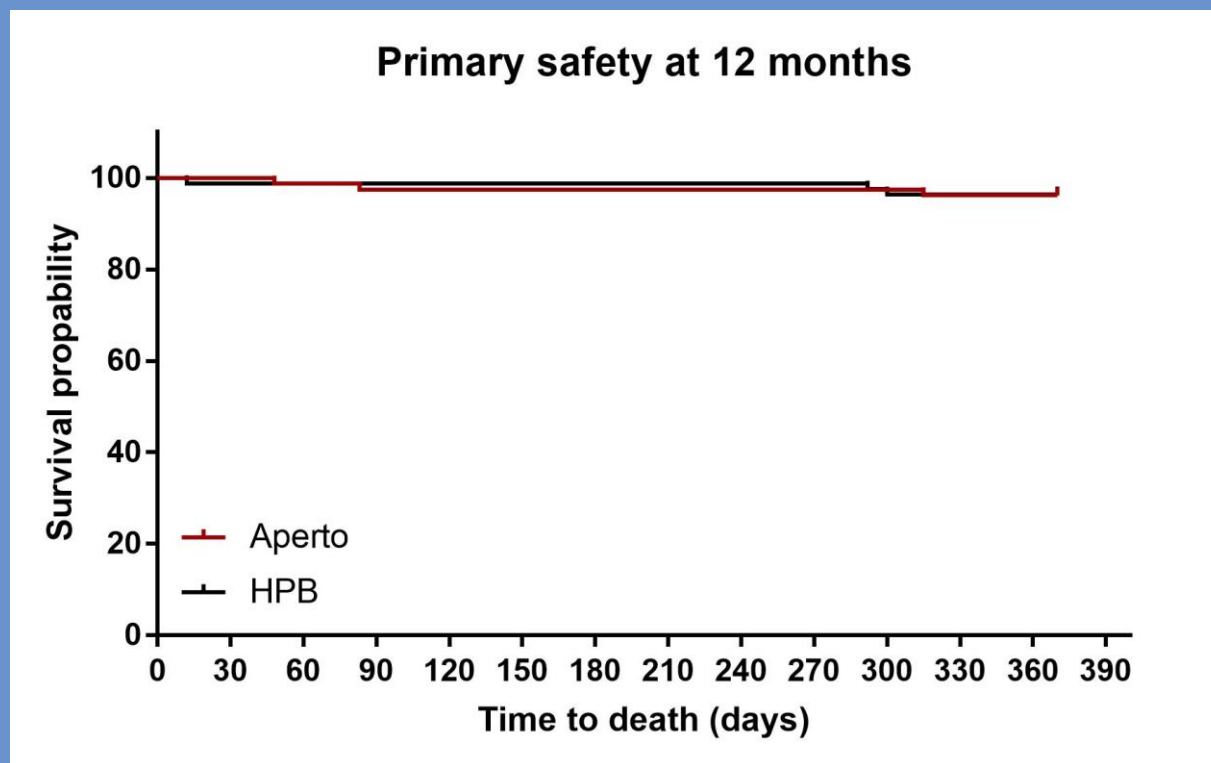
Secondary Endpoint:

- Target Lesion Secondary Patency @12M



		1m	3m	6m	12m	p
APERTO	79(100%)	79 (100%)	76(96.2%)	73(92.4%)	71(89.9%)	0.038
HPB	82(100%)	80 (97.6%)	78 (95.1%)	70(85.4%)	63(76.8%)	

Primary Safety @ 12 months



		1m	3m	6m	12m	p
APERTO	79(100%)	79 (98.7%)	78 (97.5%)	77 (96.2%)	76 (96.2%)	N.S
HPB	82(100%)	81 (98.8%)	81 (98.8%)	81 (98.8%)	79 (96.3%)	

Conclusion

- In this randomized trial, **APERTO** paclitaxel-coated balloon in AVF stenosis was shown to be superior to a high-pressure balloon using the PSVR of the 6-month end point.
- The **APERTO HDCB** arm showed benefit in terms of target lesion primary patency and secondary patency.
- The **APERTO HDCB** is as safe as the high-pressure balloon.

Aperto AVF China Trial Organizations

Principal Investigator: Professor Qizhuang Jin, Peking University First Hospital

Participating Centres:	Longhua Hospital Shanghai University of Traditional Chinese Medicine
	West China Hospital, Sichuan University
	Sir Runrun Hospital, Zhejiang University
	The First Affiliated Hospital, Zhejiang University
	The First Hospital of Hebei Medical University
	Beijing Tongren Hospital, Capital Medical University
	The First Affiliated Hospital, Nanchang University
	Hainan People's Hospital
	The Third Xiangya Hospital of Central South University

CORE LAB: CCRF(Beijing) Inc.