

1 year result of multi-center trial of Hanchor Valve for treating patients with severe pure native Aortic Regurgitation (HAVE AR trial)

Wenzhi Pan, MD

On behalf of the investigators of HAVE AR trial



TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS®

*Director of Heart Valve Center,
Zhongshan Hospital, Fudan University
Shanghai Institute of Cardiovascular Diseases
China National Clinical Research Center for
Interventional Medicine*

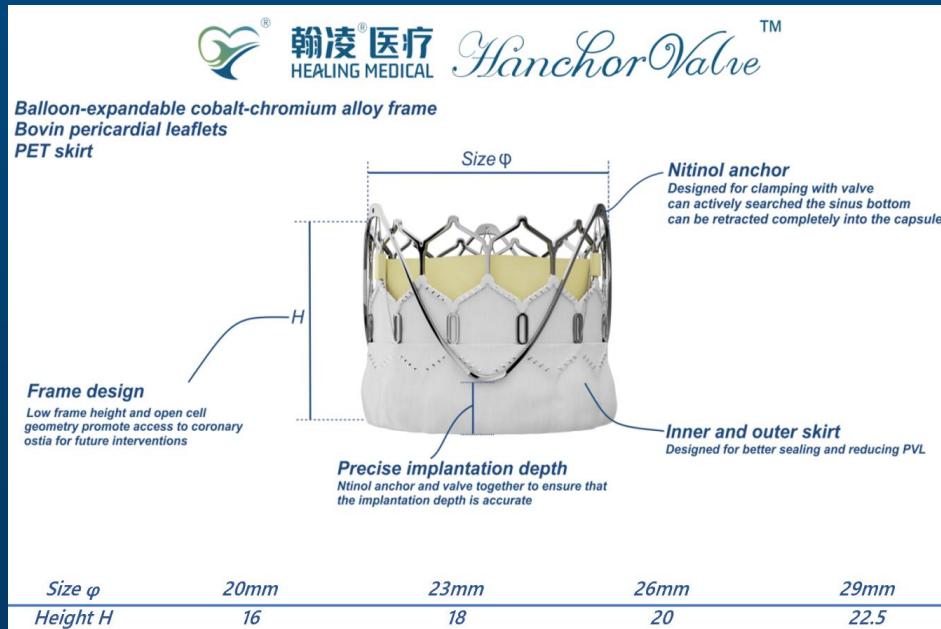
Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

<u>Nature of Financial Relationship</u>	<u>Ineligible Company</u>
Grant/Research Support	
Consultant Fees/Honoraria	Hanyu Medical, Shanghai
Individual Stock(s)/Stock Options	
Royalties/Patent Beneficiary	Hanyu Medical, Shanghai
Executive Role/Ownership Interest	
Other Financial Benefit	

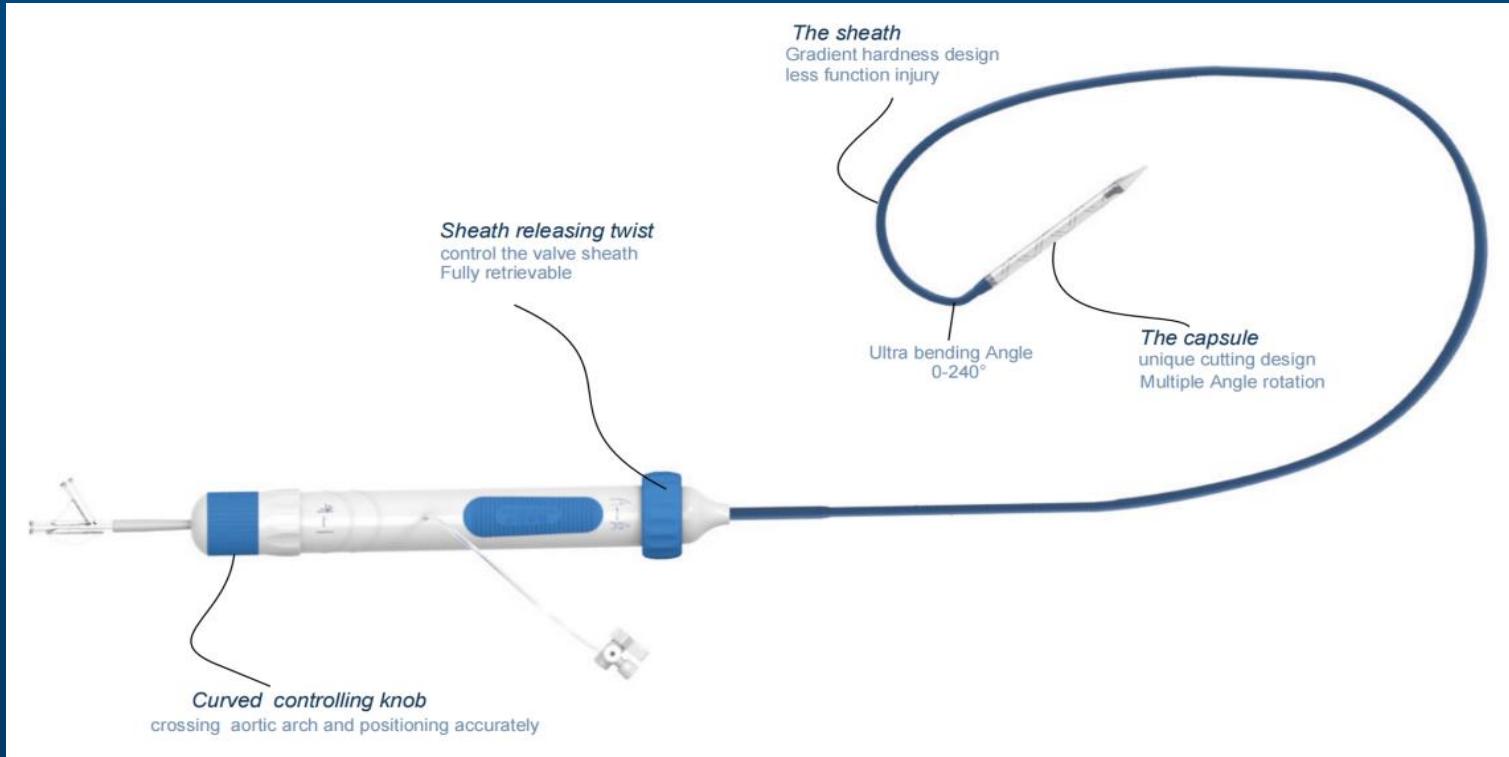
All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Device Introduction

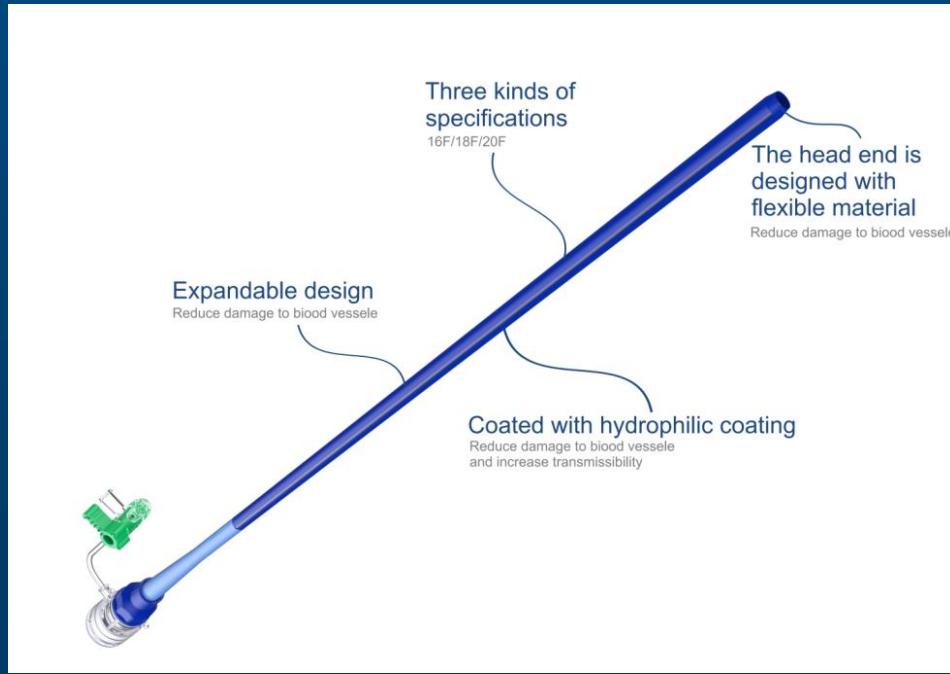


- Strong anchorage force provided by anchor element and balloon expanded frame.
- Precise implantation depth due to the drawing of the anchor element.
- Automatic commissure alignment realized by anchor locating to the sinus.
- Easier coronary re-entry because of short frame and large frame cell.
- Simple procedure by automatic locating of the semi-fixed anchor.
- Indications for both AR and AS.

Device Introduction

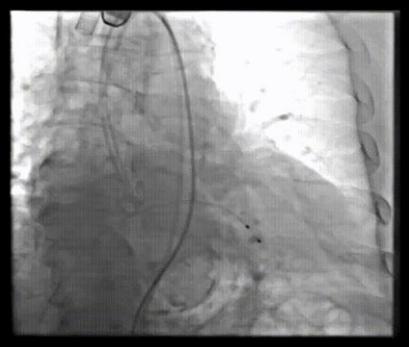


Device Introduction

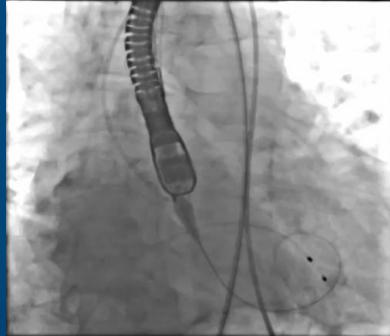


- **18 Fr. Expandable sheath**
- The maximum outside diameter (OD) after expansion : **9.2mm**
- Minimum vascular diameter requirement : **7mm**

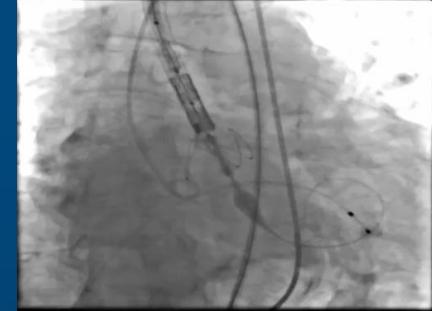
Case demonstration for Hanchor Valve



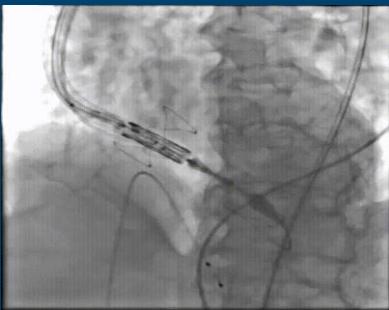
Pre-procedural angiography



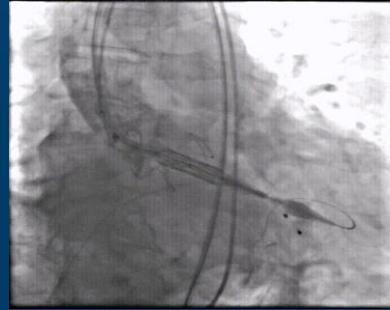
delivery system reached the root of the aorta



The anchor partially deployed and located into the aortic sinus



The anchor fully deployed and reached the bottom of sinus



The THV deployed by the balloon dilation



Final angiography

The HAVE AR trial (ChiCTR2400082887)

Multi-center trial of HAnchor ValvE for treating patients with severe pure native Aortic Regurgitation (PNAR) at intermediate or high surgical risk

Study design

Prospective, multicenter, single-arm objective performance criteria

Participating centers

13 hospitals in China

Enrollment period

Jan 2023 - Nov 2023

1 year result of HAVE AR trial

Multi-center trial of HAnchor ValvE for treating patients with severe pure native Aortic Regurgitation (PNAR) at intermediate or high surgical risk

Primary efficacy endpoint

Freedom from all-cause death at 12 months;

Primary safety endpoints

Composite of severe adverse events¹ (SAEs) at 12 months;

Secondary outcomes

Bioprosthetic valve dysfunction²;

Echo findings(LVEDD, LVESD, LVEF, mPG and EOA);

Cardiac function(NYHA) and quality of life(EQ-5D).

1: Including all-cause death, myocardial infarction, disabling stroke, major bleeding, acute kidney injury, new permanent pacemaker implantation(PPI), vascular complications requiring intervention, reintervention for valve dysfunction and re-hospitalization for heart failure(HF); 2: according to Valve Academic Research Consortium (VARC)3 criteria.

LVEDD: left-ventricular end diastolic dimension; LVESD: left-ventricular end systolic dimension; LVEF: left ventricular ejection fraction; mPG: mean pressure gradient; EOA: effective orifice area.

Inclusion & exclusion criteria

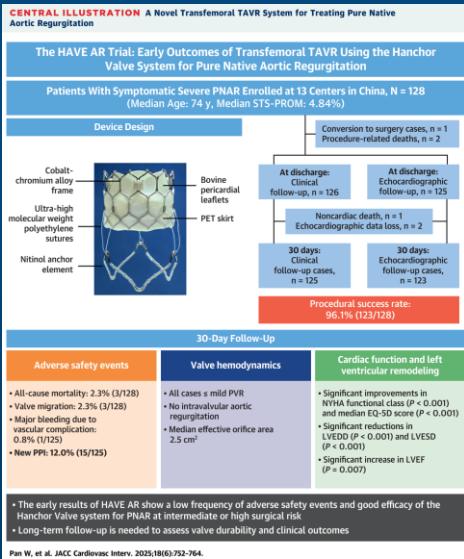
Inclusion criteria:

- 1) One of the following conditions is met:
Age \geq 70 yrs., STS score \geq 4
Age $<$ 70 years and Age \geq 60years,
Unassessed by the cardiac team for surgery
- 2) A diagnosis of severe aortic valve regurgitation (AR) and symptoms caused by AR;
- 3) NYHA Functional Class \geq II;
- 4) Expected survival time after corrective treatment of AR is more than 1 years.

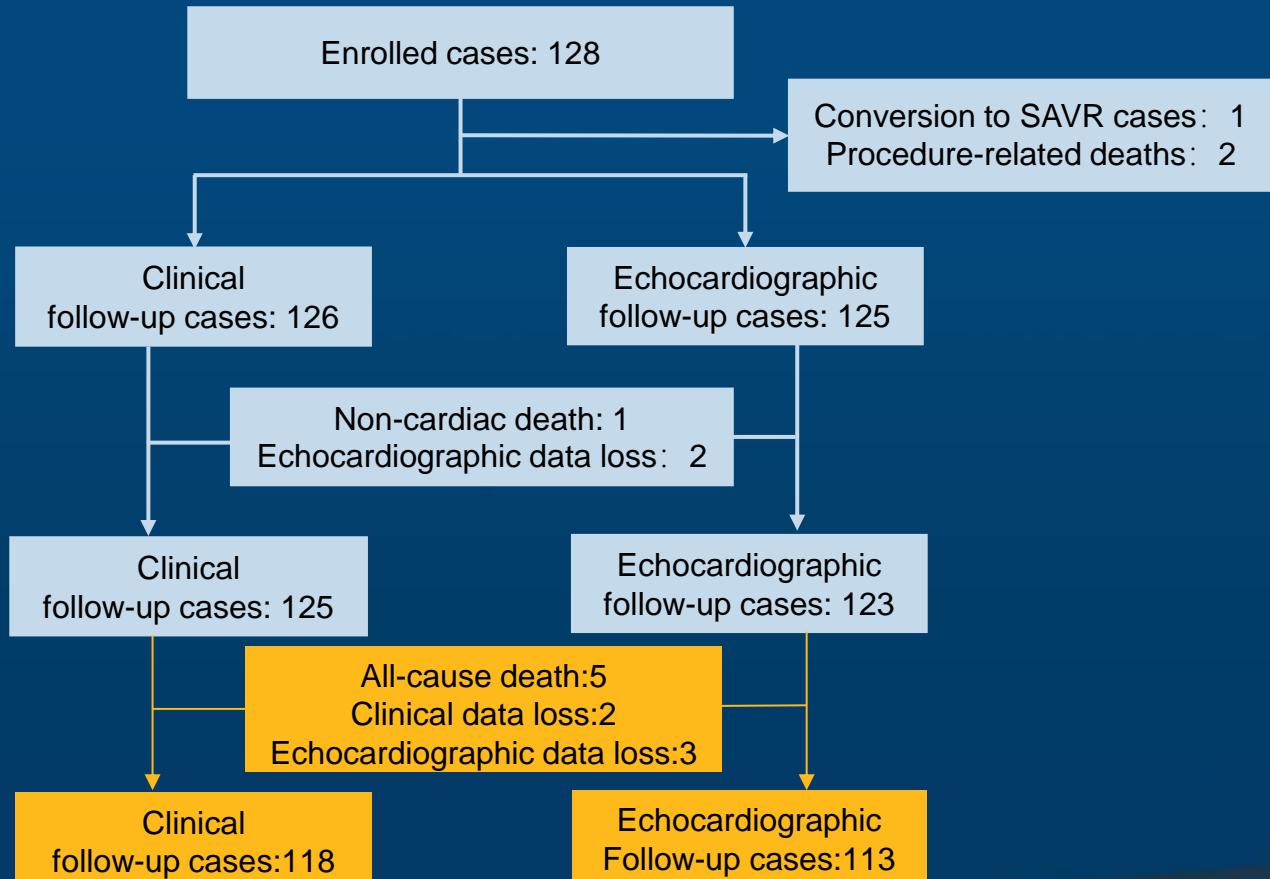
Main Exclusion criteria:

- 1) Untreated severe coronary artery stenosis;
 - 2) left ventricular ejection fraction (LVEF) \leq 30%;
 - 3) Severe pulmonary hypertension (mean pressure $>$ 30mmHg) or right ventricular dysfunction;
 - 4) The vascular approach or aortic root anatomy were not suitable for TAVI;
 - 5) Mitral regurgitation of moderate and above(regurgitant fraction \geq 30%) or organic mitral stenosis of moderate and above (valve orifice area $<$ 1.5cm 2) ;
-

Flowchart



1 year



*Wenzhi Pan, Shasha Chen, Wei Li, et al. Early Results of Multicenter Trial of a Novel Balloon-Expandable Valve With Anchor for Aortic Regurgitation. JACC Cardiovasc Interv. 2025;18(6):752-764.

Baseline characteristics

Clinical characteristics	All patients (n=128)
Age(y)	74(70-78)
Male	98(76.56)
BMI(kg/m ²)	22.46±3.38
STS score(%)	4.84(4.21-6.47)
NYHA functional class≥III	108(84.38)
Echocardiographic findings	All patients (n=128)
LVEF(%)	57.00(46.00-64.00)
LVEDD(mm)	59.00(54.50-63.00)
LVESD(mm)	40.00(36.00-46.75)
CT characteristics	All patients (n=128)
Aortic annulus diameter(mm)	26.40(25.28-27.33)
LVOT diameter(mm)	27.19±2.26
STJ diameter(mm)	37.78±5.64
LCA ostium height(mm)	14.54±5.11
RCA ostium height(mm)	18.96±4.25

Values are median(Q1-Q3), n(%), or mean ± SD.

LVEF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; CT: computed tomography; LVOT: left ventricular outflow tract; STJ: sinotubular junction; LCA: left coronary artery; RCA: right coronary artery.

Acute procedure outcomes

Procedural success	123(96.09)
Conversion to Surgery	1(0.78)
A second implantation	2(1.56)
Annulus rupture	1(0.78)
Aortic dissection	1(0.78)
Coronary obstruction	0
Intravalvular regurgitation	0
More than mild paravalvular aortic regurgitation	0
THV size (%)	
23mm	1(0.78)
26mm	17(13.28)
29mm	110(85.94)
Depth of implantation(mm)	5(2-6)
Diameter* oversizing ratio(%)	5.10(2.69-6.83)
Mean pressure gradient(mmHg)	4(3-5)
Effective orifice area(cm ²)	3.15(2.77-3.57)

Values are median(Q1-Q3), n(%), or mean± SD.

THV: transcatheter heart valve; *Diameter derived from annular area.

SAEs at 30 days, 6 months and 1 year follow-up

	30 days(n=125)	6 months(n=120)	1 year(n=118)
All-cause mortality	3(2.34)	7(5.47)	8(6.35)
Disabling stroke	0	0	1(0.85)
Myocardial infarction	0	0	0
Reintervention for valve dysfunction	0	0	0
Re-hospitalization for HF	0	0	0
Major bleeding	1(0.80)	1(0.83)	1(0.85)
Vascular complications requiring intervention	1(0.80)	1(0.83)	1(0.85)
New permanent pacemaker implantation	15(12.00)	15(12.50)	15(12.71)
Acute kidney injury	0	0	0
Valve migration and embolization	3(2.40)	3(2.50)	3(2.54)
TOTLE	22(17.19)	26(20.31)	27(21.43%)

Values are n(%)

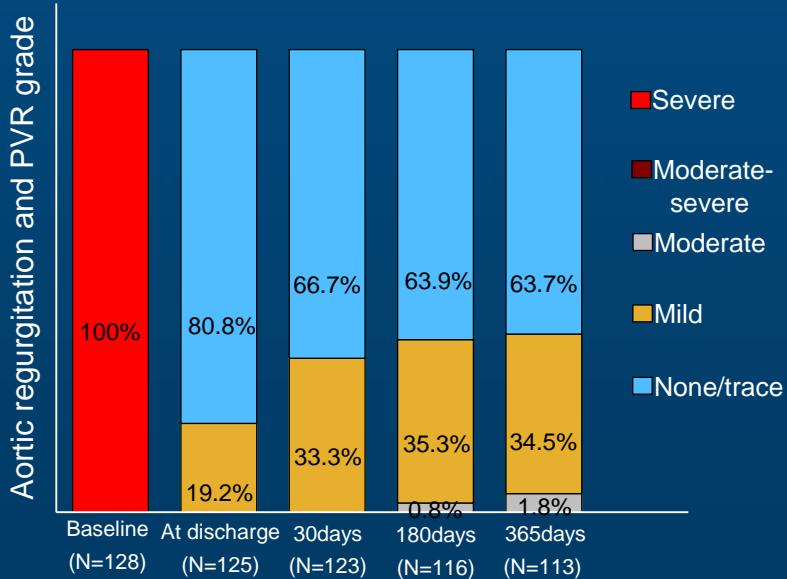
Bioprosthetic valve dysfunction

	1 year(n=113)
Bioprosthetic valve dysfunction	2(1.77)
Structural valve deterioration	1(0.88)
-Moderate	1(0.88)
-Severe	0(0)
Non-structural valve deterioration	1(0.88)
-Paravalvular leakage	1(0.88)
-Moderate	1(0.88)
-Severe	0(0)
-Patient-Prosthesis mismatch	0(0)
Clinical valve thrombosis	0(0)
Endocarditis	0(0)

Values are n(%)

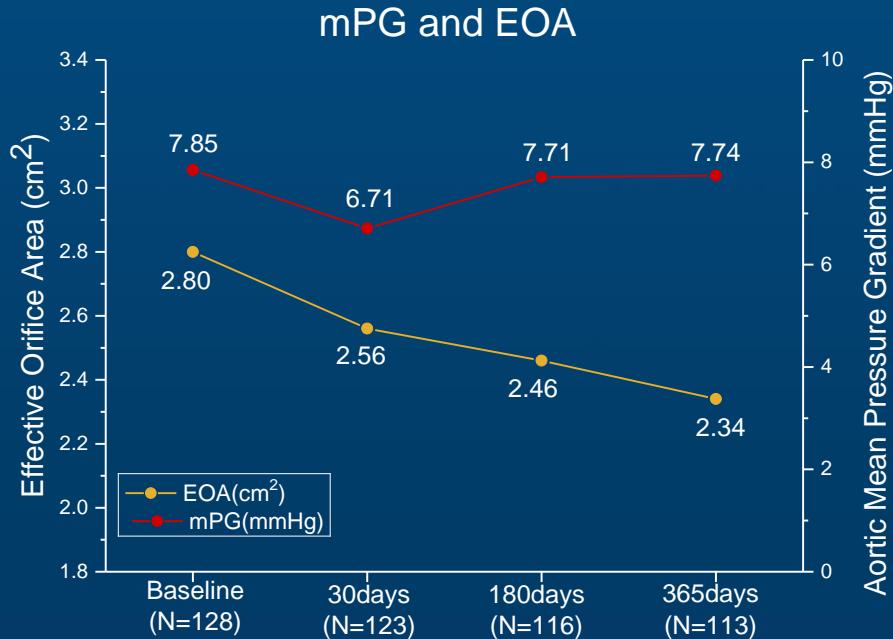
Echo findings : AR and PVR grade

Aortic regurgitation and PVR grade



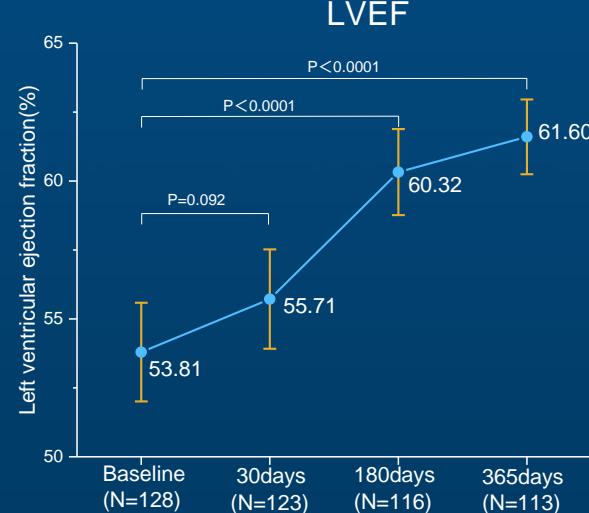
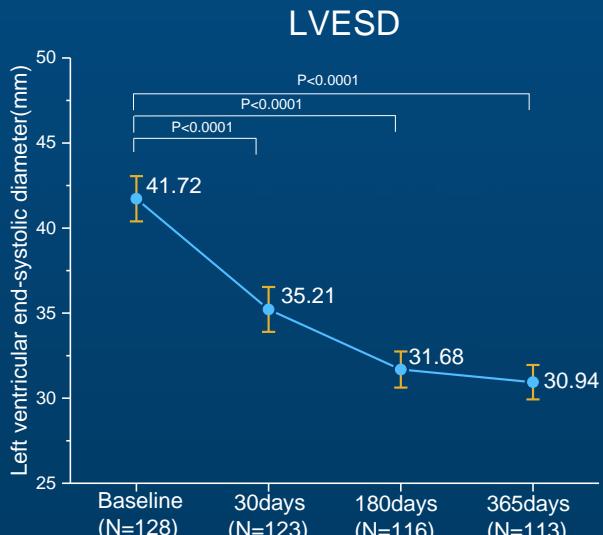
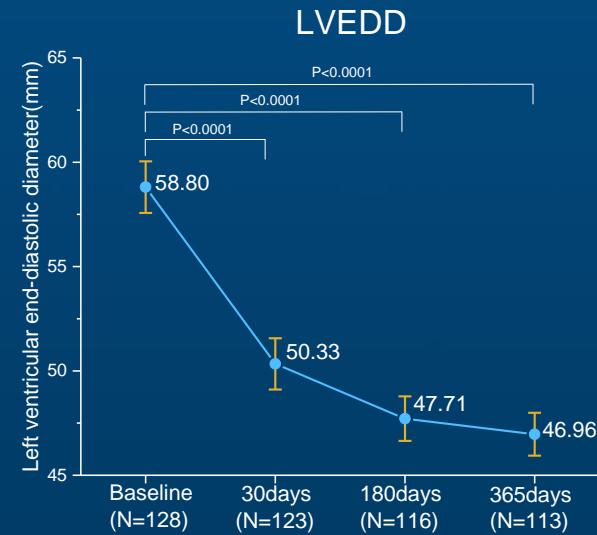
- At discharge: mild AR were observed in 24 patients, moderate AR in 0 .
- 30 days : mild AR were observed in 41 patients, moderate AR in 0 .
- 180 days: mild AR were observed in 41 patients, moderate AR in 1 .
- 365 days : mild AR were observed in 39 patients, moderate AR in 2.

Echo findings : mPG & EOA

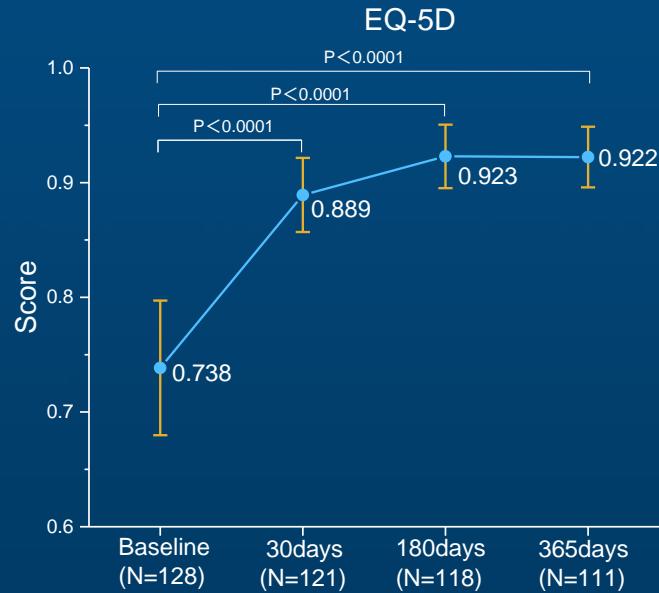
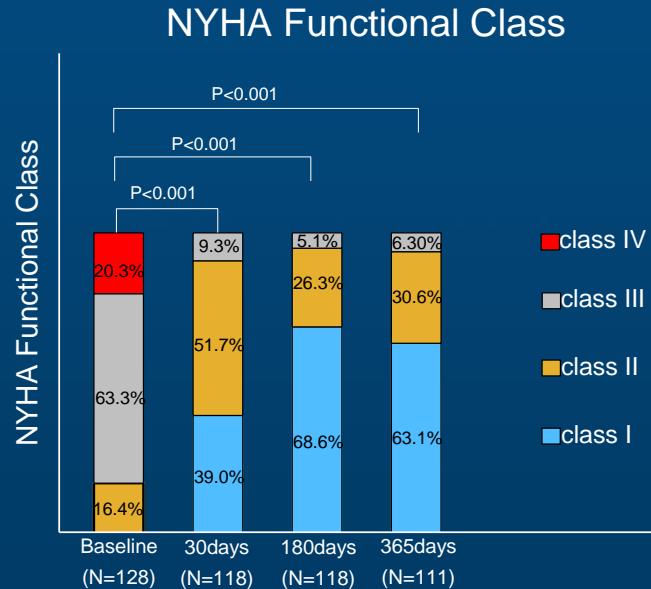


N: echocardiographic follow-up cases

Echo findings : Left ventricular diameter & LVEF



Cardiac function & Quality of life



Conclusion

- *The Hanchor Valve system had a high rate of procedural success for treating patients with severe PNAR;*
- *Low all-cause mortality at 1 year follow-up;*
- *Low incidences of SAEs at 30 days and 1 year, especially the low rate of new PPI;*
- *Maintained minimal aortic regurgitation, good valve hemodynamic performance and significant improvements left ventricular remodeling;*
- *Significant and sustained improvements in cardiac function and quality of life.*