



*1 year result of multi-center trial of **H**anchor **V**alve for treating patients with severe pure native **A**ortic **R**egurgitation (HAVE AR trial)*

Wenzhi Pan, MD

On behalf of the investigators of HAVE AR trial



TCT[®]

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:

Nature of Financial Relationship

Grant/Research Support

Consultant Fees/Honoraria

Individual Stock(s)/Stock Options

Royalties/Patent Beneficiary

Executive Role/Ownership Interest

Other Financial Benefit

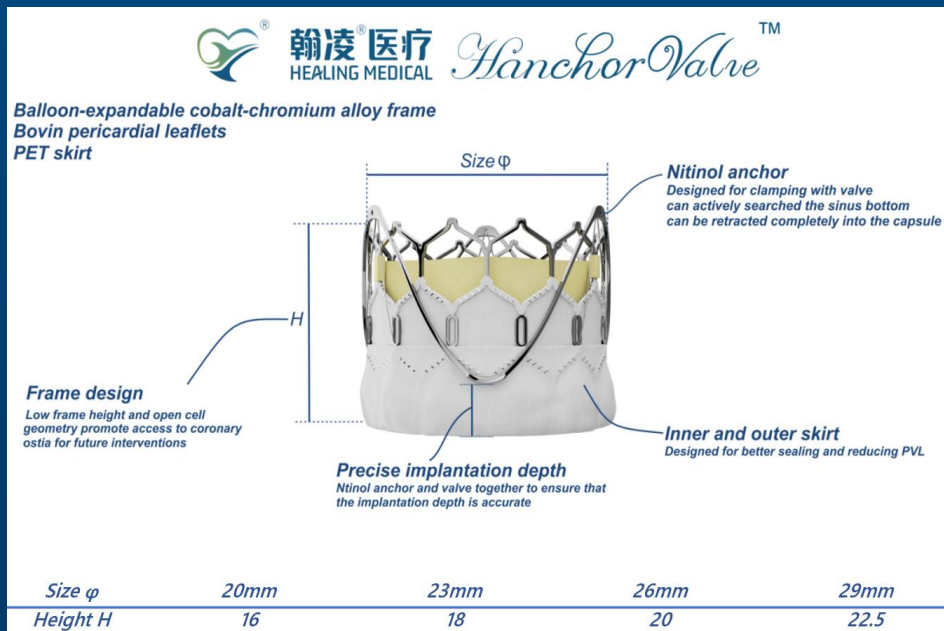
Ineligible Company

Hanyu Medical, Shanghai

Hanyu Medical, Shanghai

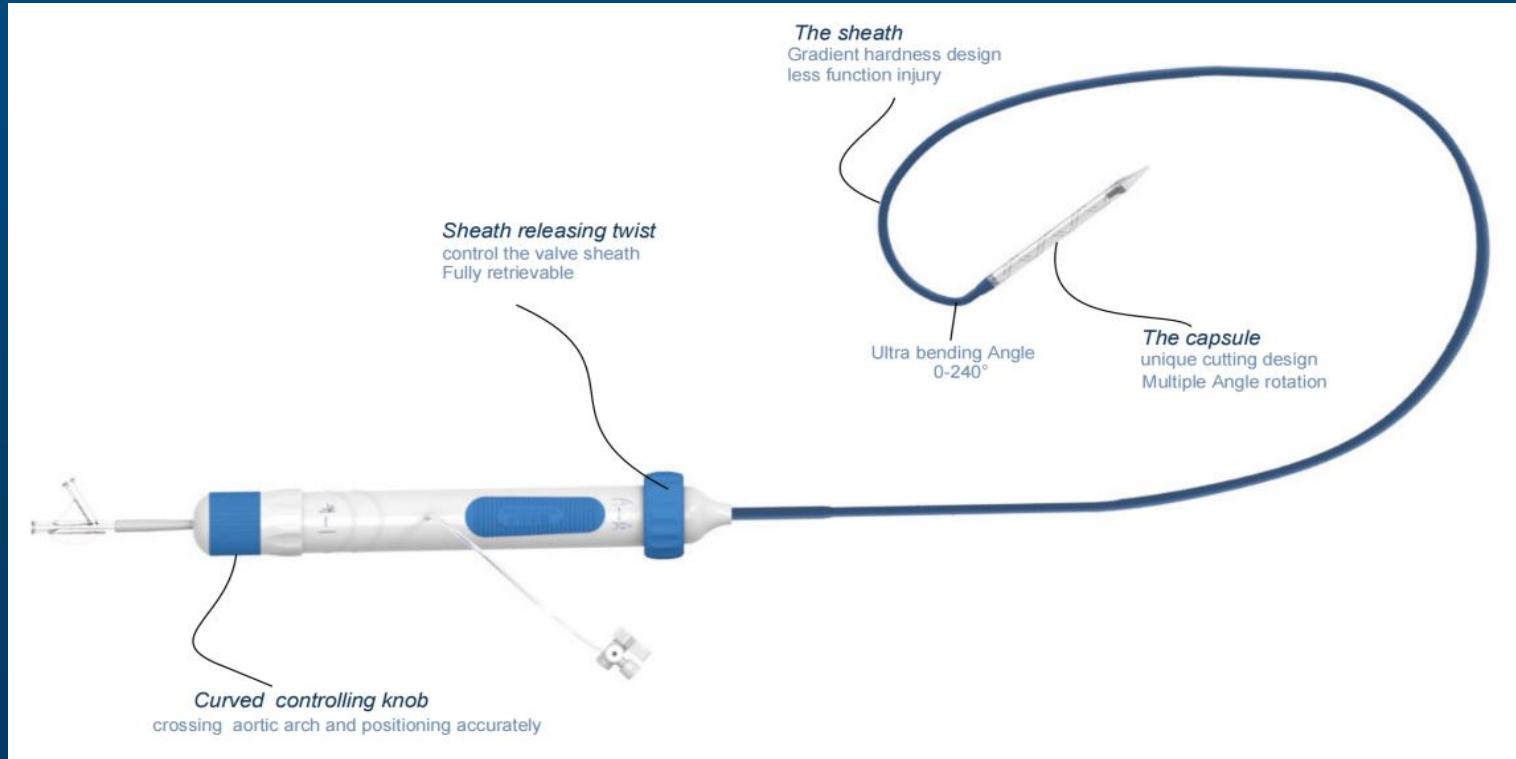
All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Device Introduction

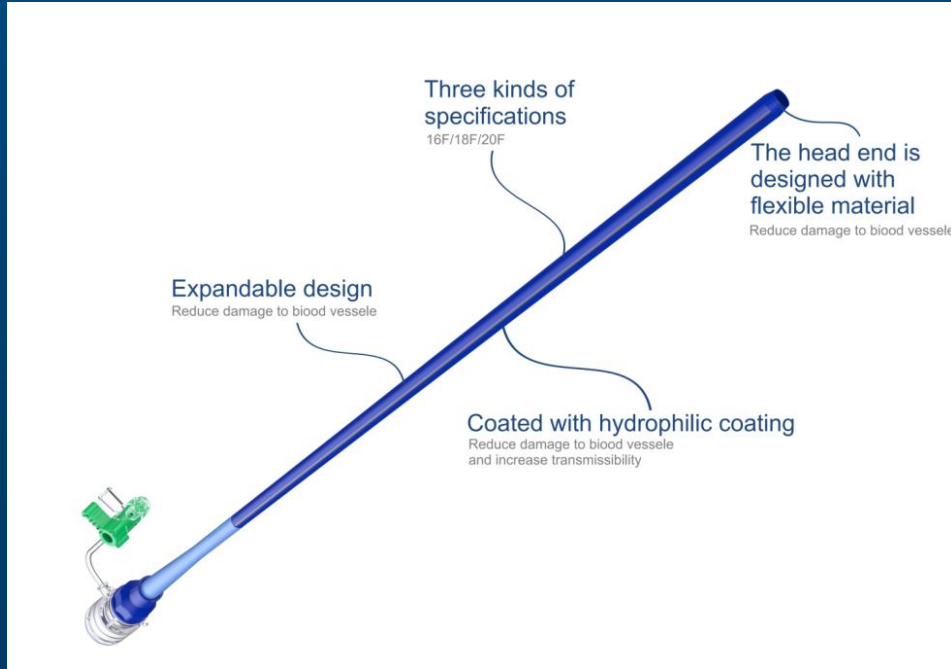


- **Strong anchorage force** provided by anchor element and balloon expanded frame.
- **Precise implantation depth** due to the drawing of the anchor element.
- **Automatic commissure alignment** realized by anchor locating to the sinus.
- **Easier coronary re-entry** because of short frame and large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

Device Introduction

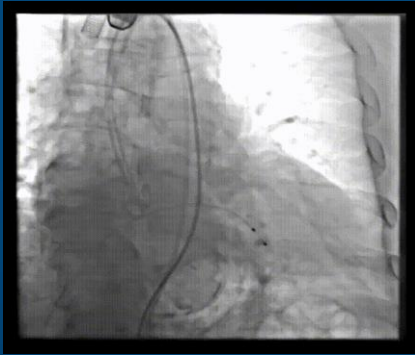


Device Introduction

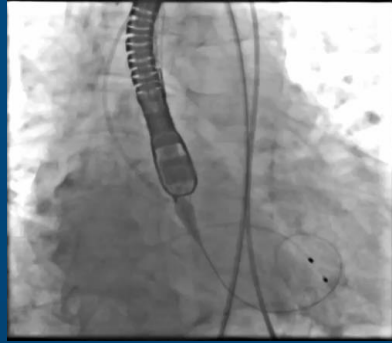


- 18 Fr. Expandable sheath
- The maximum outside diameter (OD) after expansion : 9.2mm
- Minimum vascular diameter requirement : 7mm

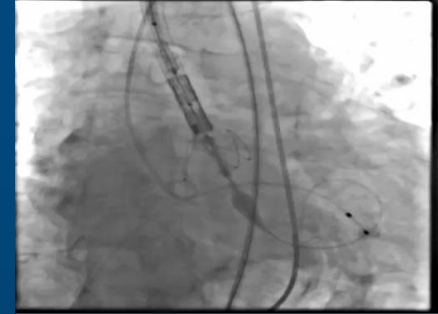
Case demonstration for Hanchor Valve



*Pre-procedural
angiography*



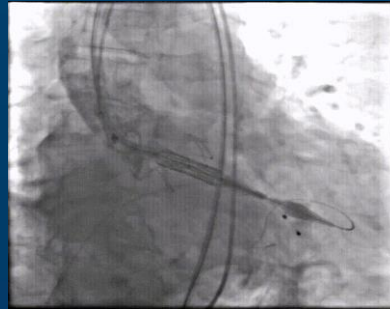
*delivery system reached
the root of the aorta*



*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 **HA**nchor **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 **H**Anchor **V**alve**E** for treating patients with severe pure native **A**ortic **R**egurgitation (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:

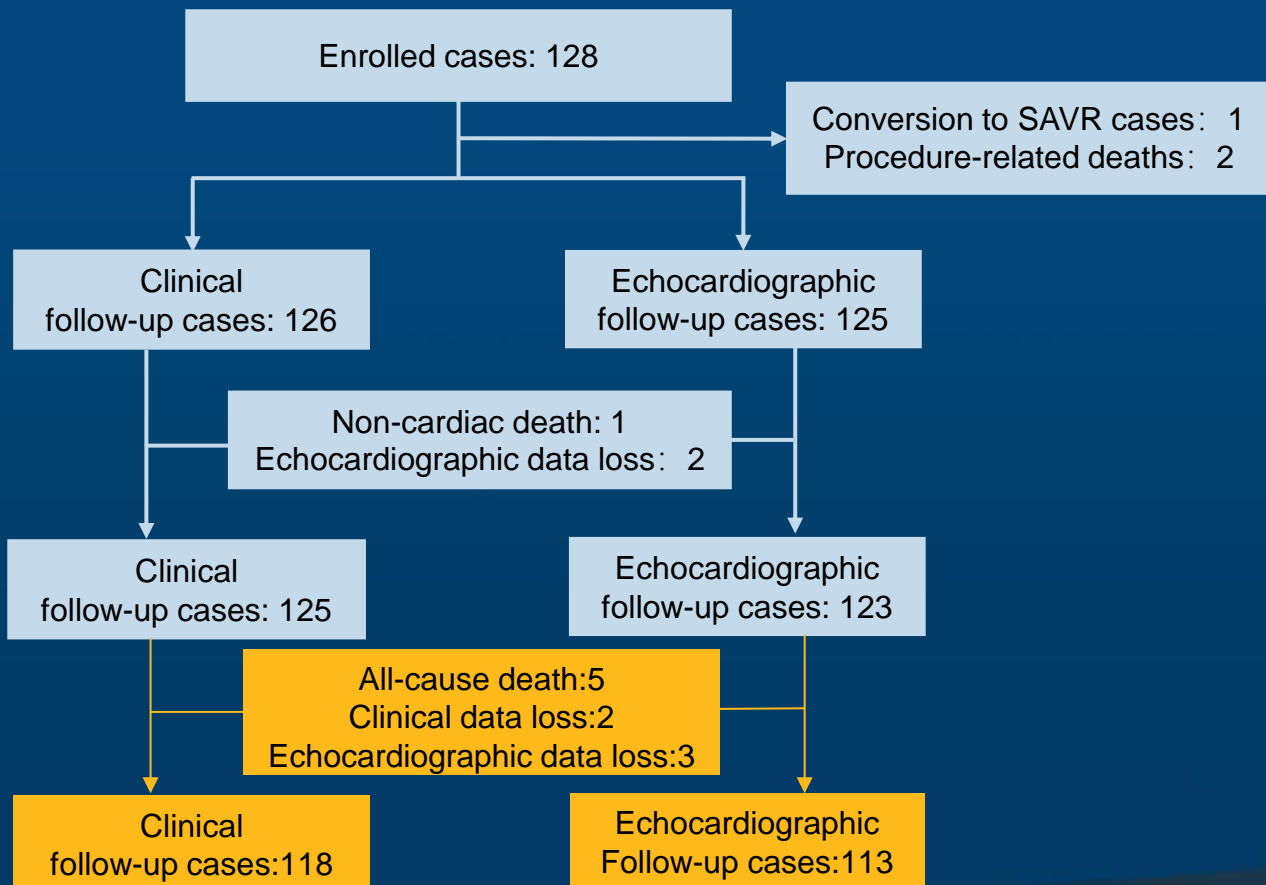
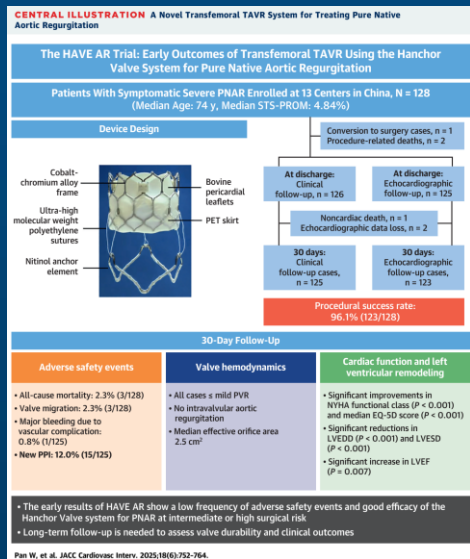
- 1) One of the following conditions is met:
Age ≥ 70 yrs., STS score ≥ 4
Age < 70 years and Age ≥ 60 years,
Unassessed by the cardiac team for surgery
- 2) A diagnosis of severe aortic valve regurgitation (AR) and symptoms caused by AR;
- 3) NYHA Functional Class $\geq II$;
- 4) Expected survival time 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 > 30 mmHg) 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 < 1.5 cm²) ;

....

Flowchart



1 year

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 \pm 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%)

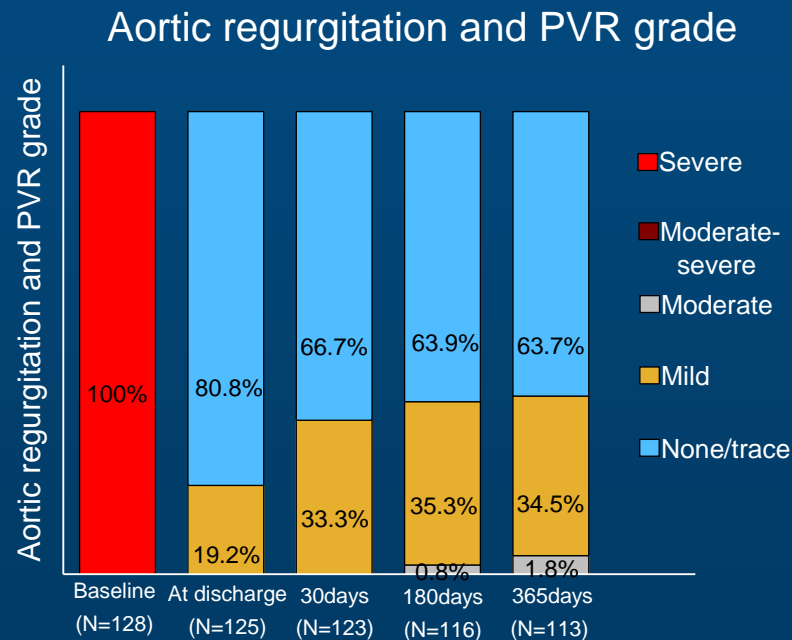
Values are n(%)

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)

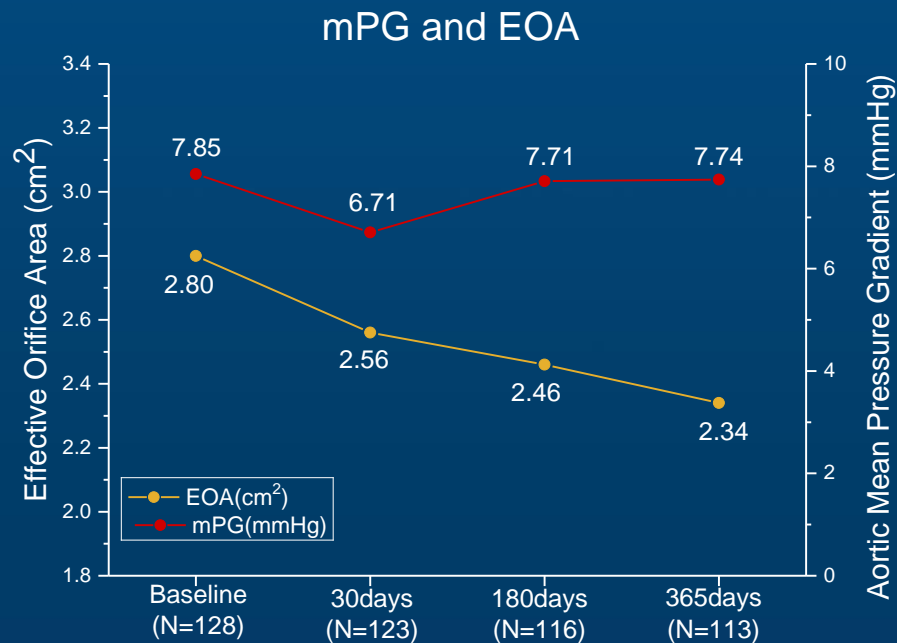
Values are n(%)

Echo findings : AR and PVR grade

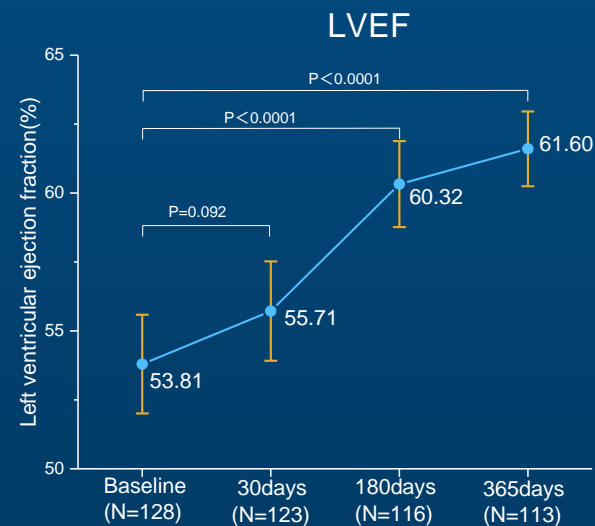
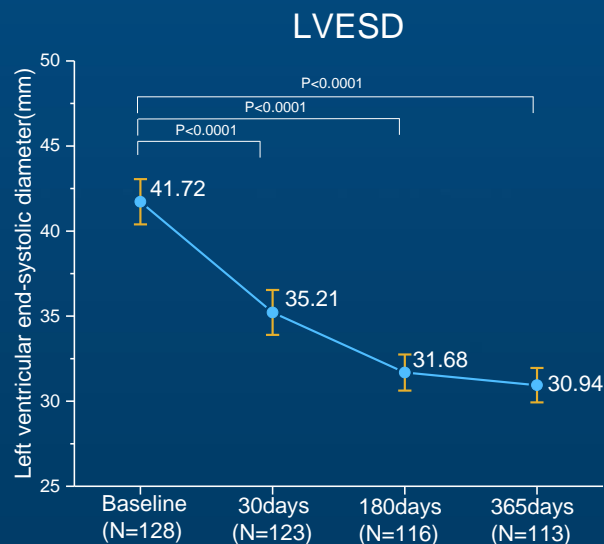
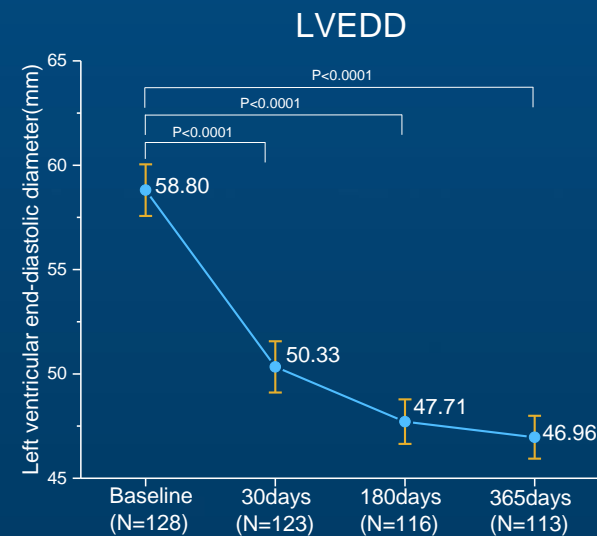


- At discharge: mild AR were observed in 24 patients, moderate AR in 0.
- 30 days : mild AR were observed in 41 patients, moderate AR in 0.
- 180 days: mild AR were observed in 41 patients, moderate AR in 1.
- 365 days : mild AR were observed in 39 patients, moderate AR in 2.

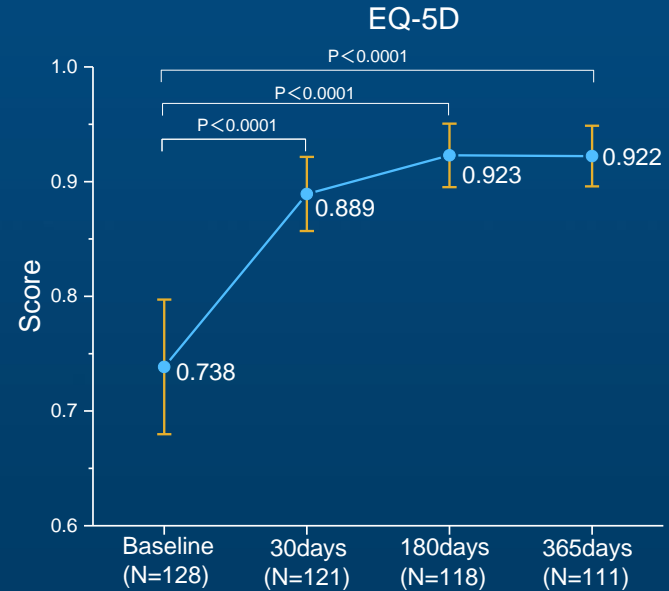
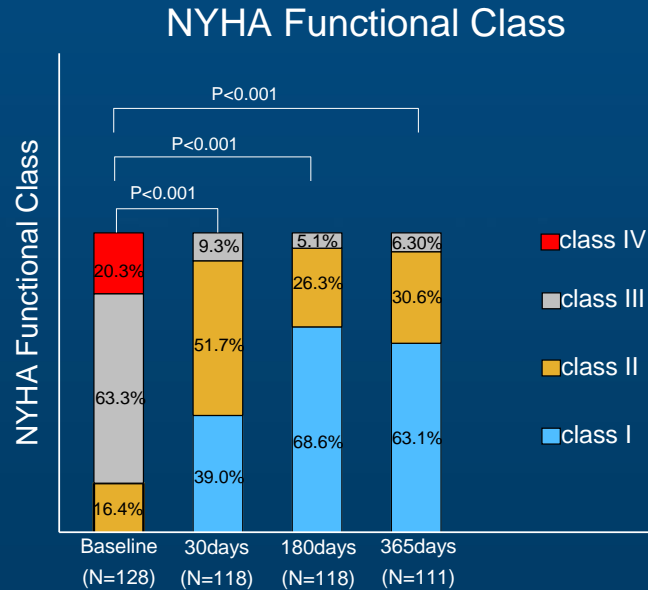
Echo findings : mPG & EOA



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.*