TAVI for Pure Aortic Regurgitation

Taped demonstration and clinical experience

Jian Ye, MD, FRCSC

Clinical Professor of Surgery

Division of Cardiac Surgery

St. Paul's Hospital and Vancouver General Hospital

University of British Columbia, Vancouver, Canada

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Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

UBC

HEART CENTRE AT ST. PAUL'S HOSPITAL

Disclosure Statement of Financial Interest

Consultant:

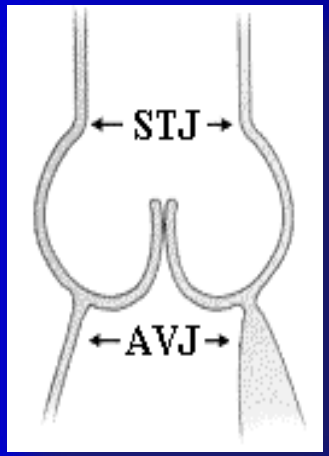
- **Edwards Lifesciences**
- **JC Medical Inc.**

Aortic Regurgitation

Etiologies

- Degenerative 29%
- Idiopathic root dilatation 19%
- Congenital abnormalities 18%
- Rheumatic 14%
- Other/ Unknown 12%
- Aortitis/Inflammatory/ Endocarditis 9%

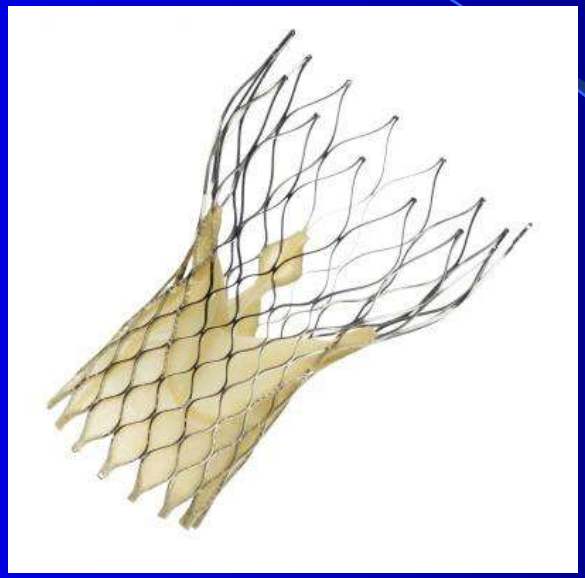
Challenges in TAVI for AI



- Lack of calcification – fixation of valve
- Dilated annulus and aorta - Stabilization of dilating structure
- Destruction of cusps – fixation and PVL
- Multiple etiologies
- Sizing
- Aortic pathology – intimal tear/dissection

Can you use the same devices for AI and AS?

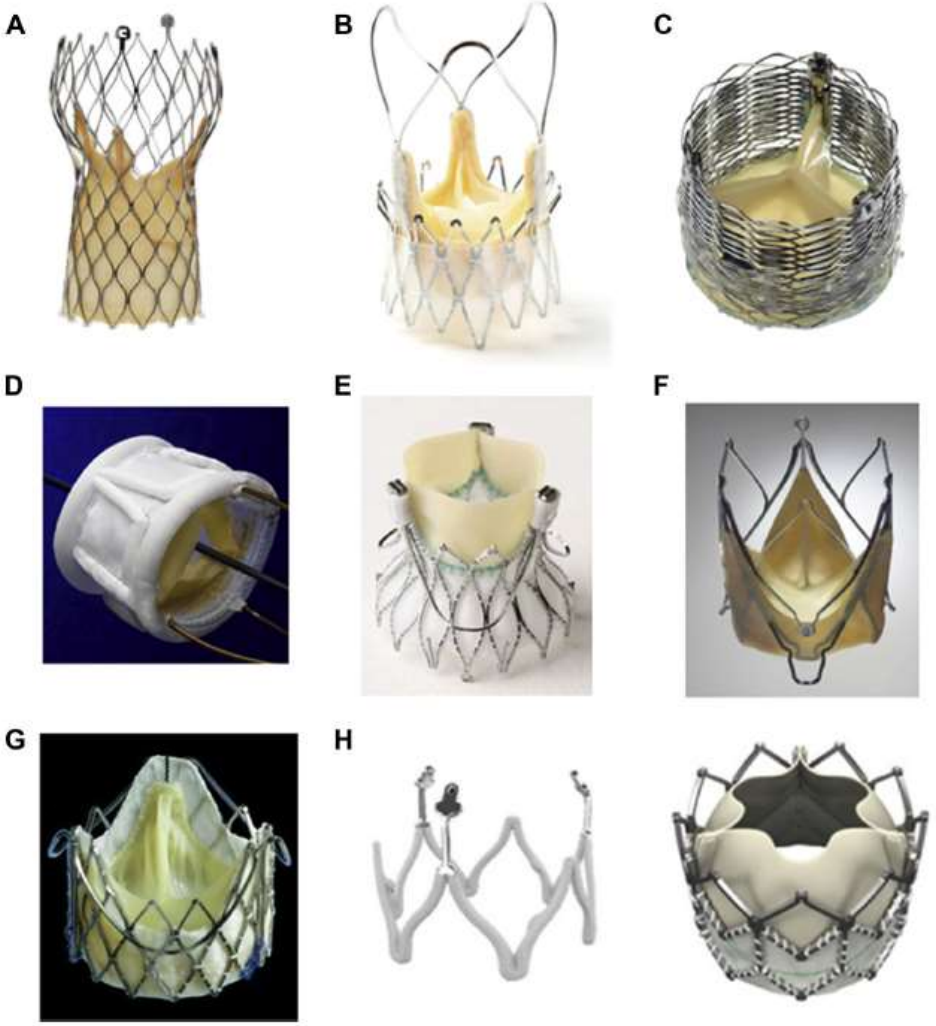
Early Experience



Author	n	Valve	Access	Post dilation	2nd valve	Conversion to SAVR	Device success
Testa et al	26	CoreValve	TF,SC, TAo	3	5	0	20(77%)
Roy et al	43	CoreValve	TF, SC,TAo	4	8	1	32(74%)

Valves used for AI

FIGURE 1 Transcatheter Heart Valves for Pure Aortic Regurgitation



(A) CoreValve Evolut R (Medtronic). **(B)** Acurate (Symetis SA). **(C)** Lotus (Boston Scientific). **(D)** Direct Flow (Direct Flow Medical Inc.). **(E)** Engager (Medtronic). **(F)** JenaValve (JenaValve Technology). **(G)** J-Valve (JieCheng Medical Technology). **(H)** Helio dock **(left)** and SAPIEN XT valve **(right)** (Edwards Lifesciences).

JACC CI 2015;8:1850-53

Safety and Efficacy of Transcatheter Aortic Valve Replacement in the Treatment of Pure Aortic Regurgitation in Native Valves and Failing Surgical Bioprostheses

Results From an International Registry Study

Sawaya FJ, et al. JACC Cardiol Intv 2017;10:1048-56

Procedure Characteristics and Outcomes

	Pure Severe NAVR (n = 78)
General anesthesia	49/78 (63%)
Access route	
Transfemoral	51/78 (65%)
Transsubclavian	2/78 (3%)
Direct aortic	2/78 (3%)
Transapical	23/78 (29%)
THV device	
CoreValve	33/78 (42%)
Evolut R	5/78 (6%)
JenaValve	23/78 (29%)
Direct Flow	6/78 (8%)
Lotus	6/78 (8%)
SAPIEN XT	4/78 (5%)
SAPIEN 3	1/78 (1%)
Contrast, ml	182 ± 72
Fluoroscopy time, min	26 ± 12

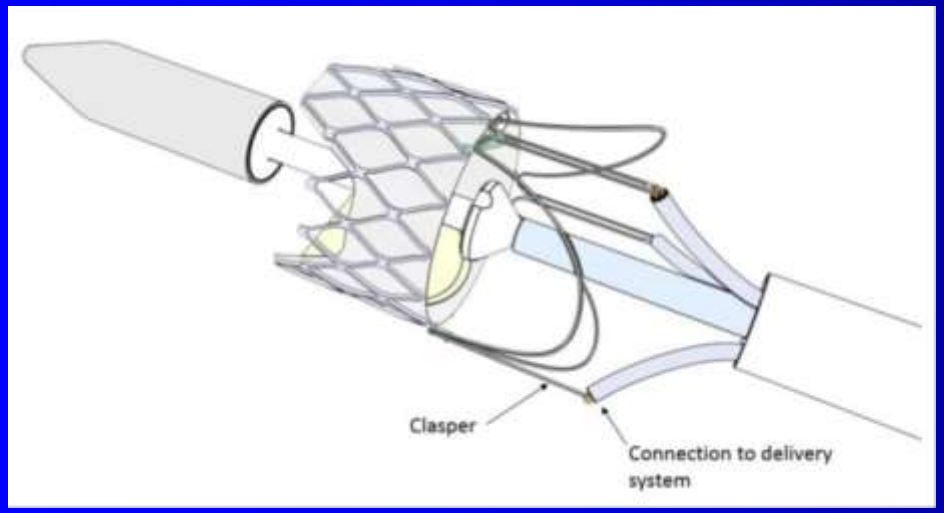
	Pure Severe NAVR (n = 78)
New pacemaker implantation	12/65 (18%)
Device success (VARC-2)	55/78 (72%)
Absence of procedural mortality	78/78 (100%)
Successful access, delivery, deployment, and system retrieval	76/78 (97%)
Correct positioning of a single valve into proper location	65/78 (83%)
Intended THV performance*	63/76 (83%)
Mean gradient <20 mm Hg or peak velocity <3 m/s	74/76 (97%)
No moderate or severe AR	65/76 (86%)

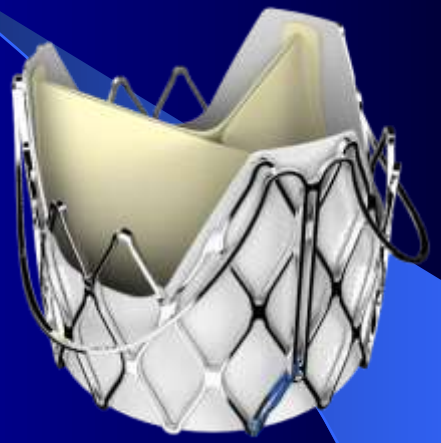
Early Safety and Clinical Efficacy at 30 Days

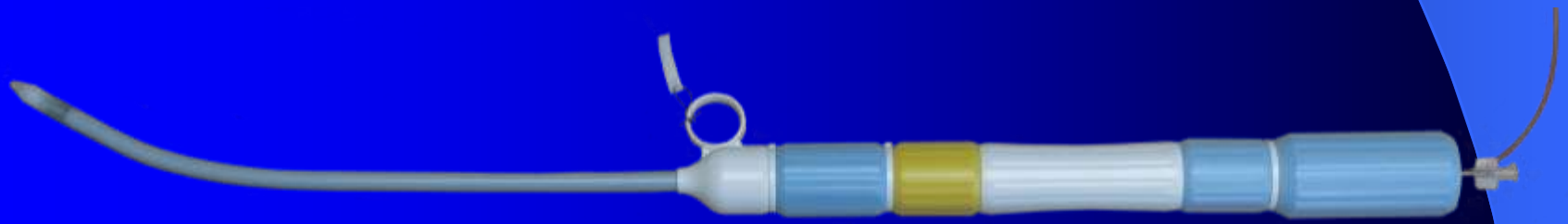
	Pure Severe NAVR (n = 78)
Early safety at 30 days	50/76 (66%)
All-cause mortality	11/77 (14%)
All stroke	3/76 (4%)
Major vascular complications	6/77 (8%)
Life-threatening bleeding	2/76 (3%)
Acute kidney injury stage ≥2	8/76 (11%)
Coronary artery obstruction requiring intervention	0/77 (0%)
Repeat procedure for valve-related dysfunction	2/77 (3%)
Clinical efficacy at 30 days	47/77 (61%)
All-cause mortality	11/77 (14%)
Cardiac mortality	6/77 (8%)
Noncardiac mortality	5/77 (6%)
All stroke	3/76 (4%)
Valve-related dysfunction	11/67 (16%)
Mean gradient ≥20 mm Hg or EOA ≤0.9-1.1 cm^2	2/66 (3%)
Moderate or severe AR	9/67 (13%)
NYHA functional class III or IV	10/66 (15%)

J-Valve™

JC Medical Technology



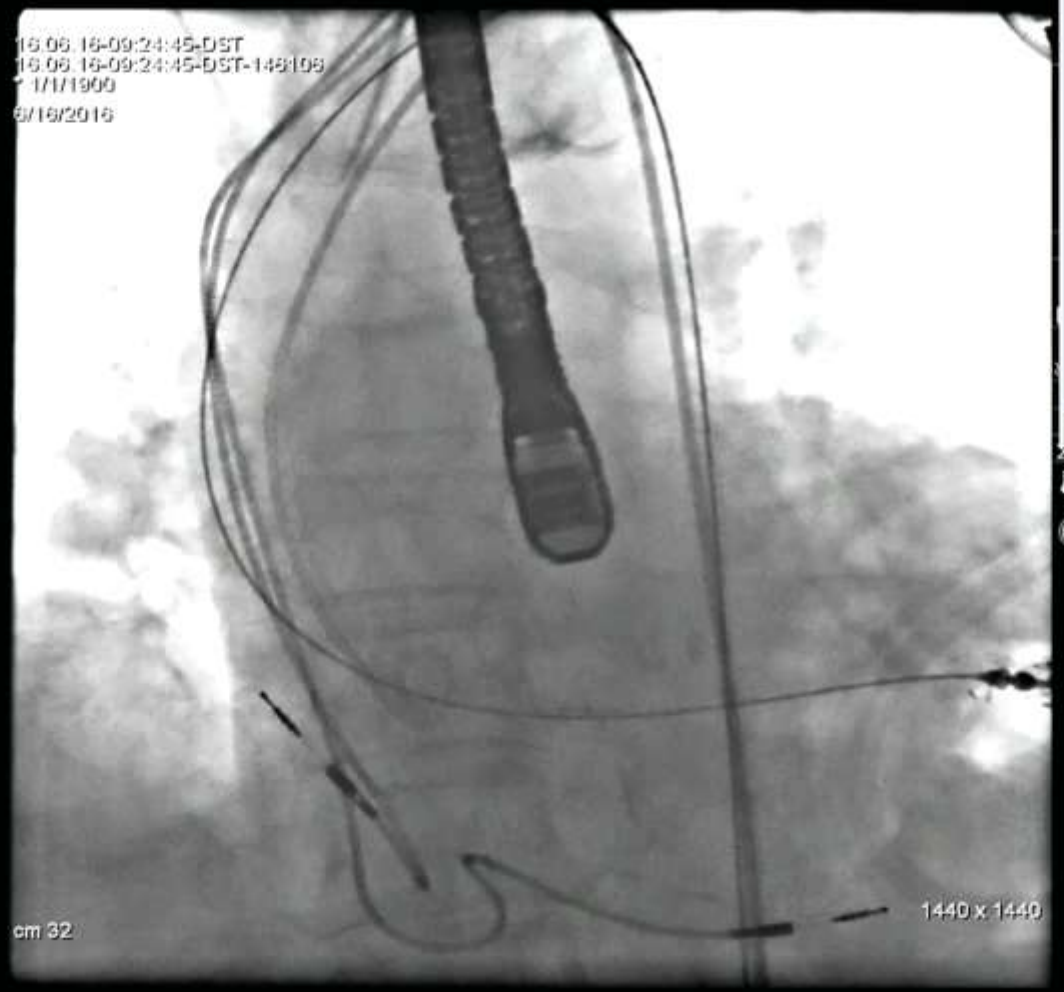


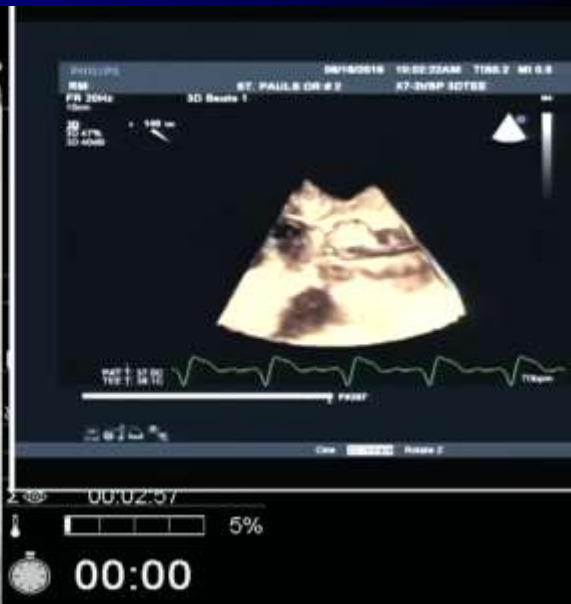


Designed for both AS and AI

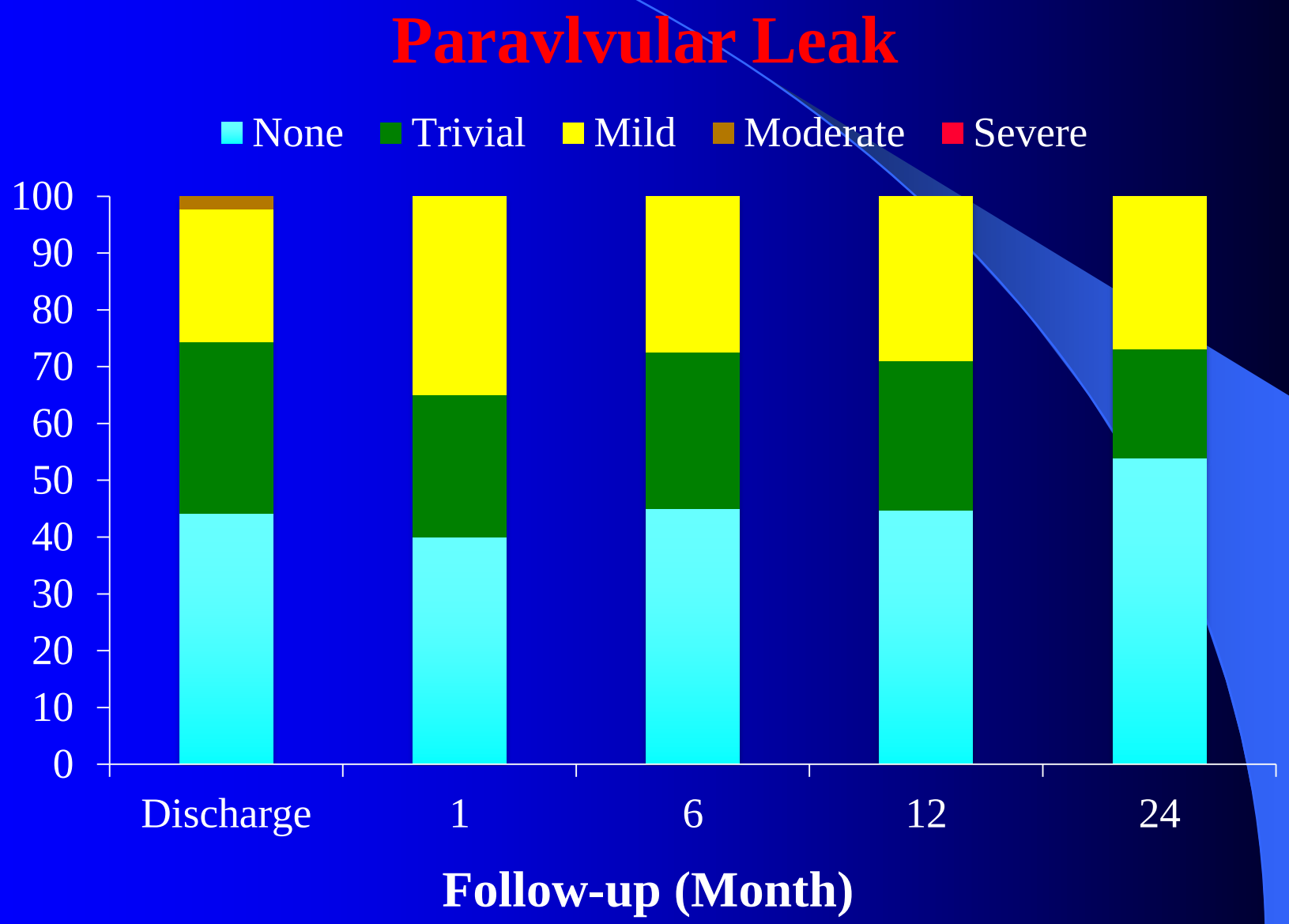
Recorded Live Case

Implantation





Chinese Clinical Trial 2 Year Outcome

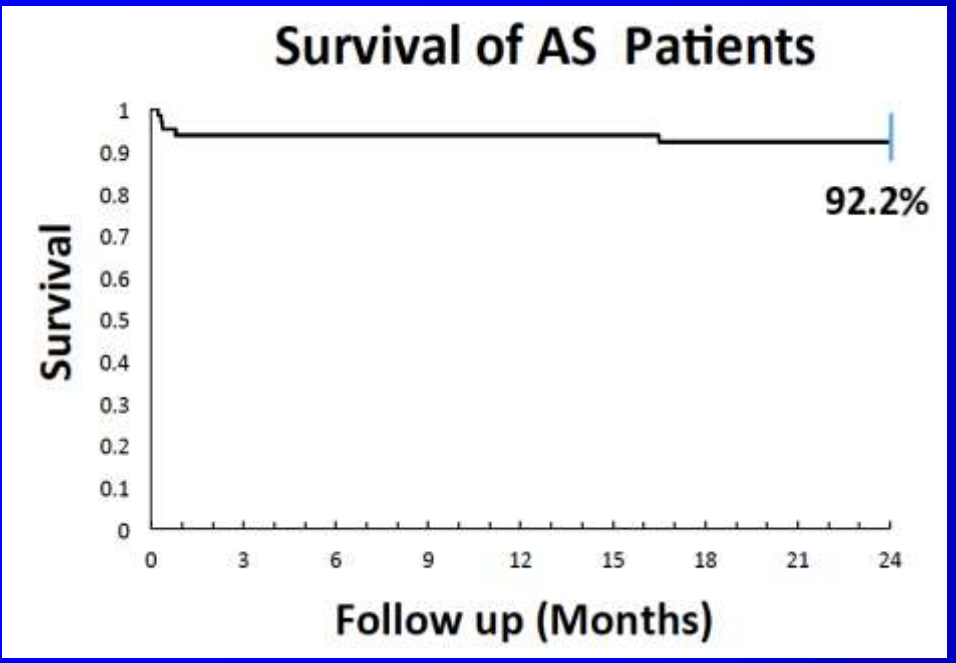


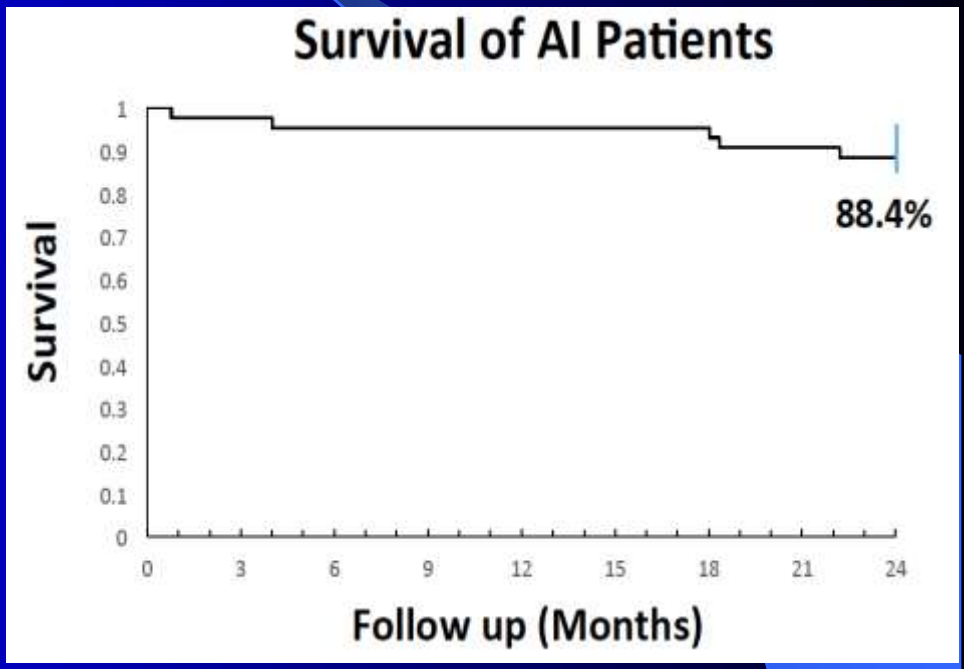
Chinese Clinical Trial
2 Year Outcome

30-day all cause mortality	2.5%
CVA	0.0%
2-year accumulated III^{o} AVB	4.7%
Mean transaortic pressure gradient (30days) (stable at 2 years)	8.9 mmHg

Chinese Clinical Trial 2 Year Outcome

Survival



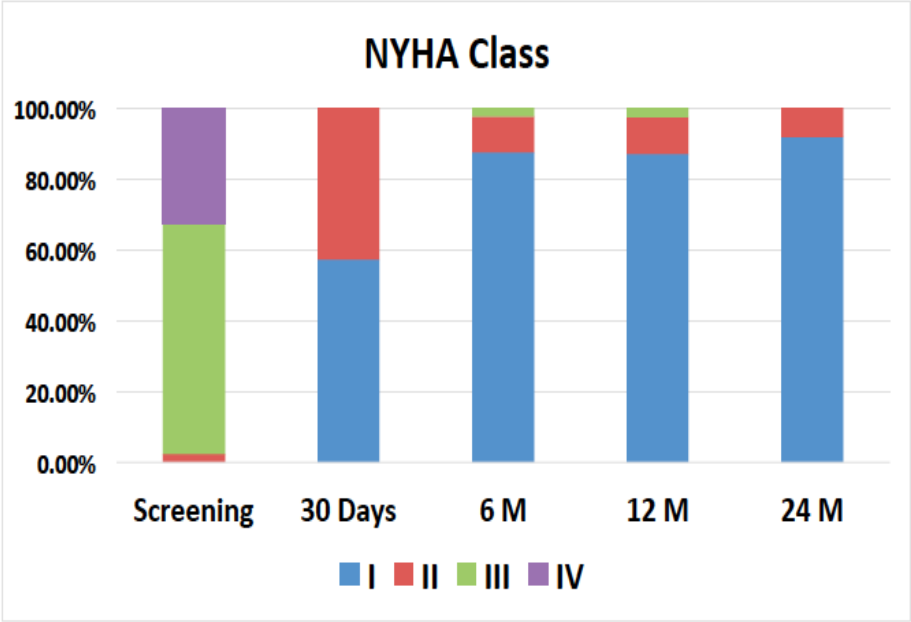


Mean Follow-up: 24.9±2.6 months

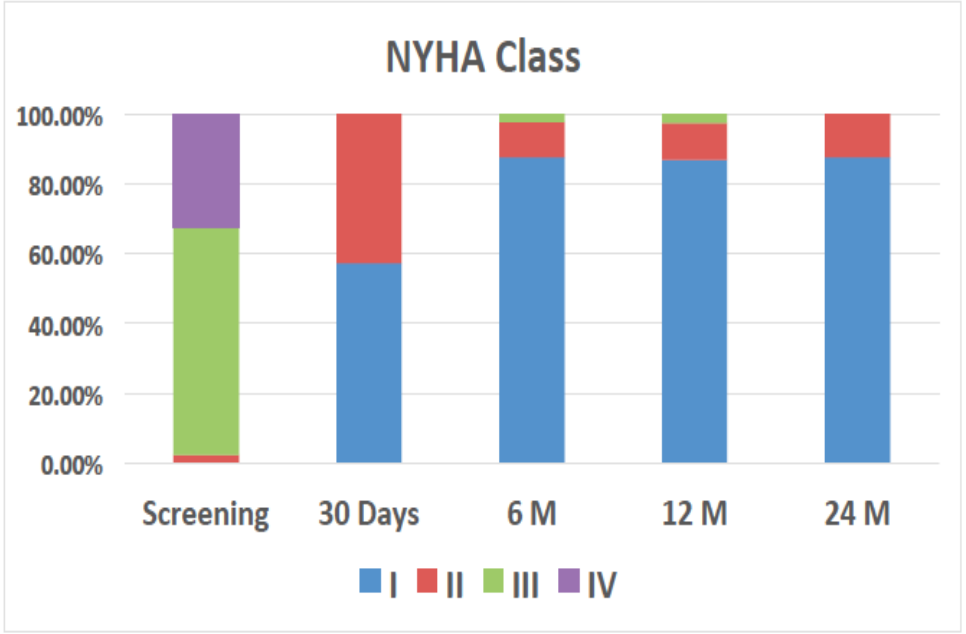
Chinese Clinical Trial 2 Year Outcome

NYHA Class

AS patients



AI Patients



Mean Follow-up: 24.9±2.6 months

Conclusion

At present, J-Valve is probably the only available valve, which is designed for both AS and AI patients.

J-Valve recently received the approval for both AS and AI patients from Chinese FDA.

TAVI with J-Valve is a viable alternative for the treatment of non-calcified, pure AI in high risk patients.


THANKS!