TAVI for Pure Aortic Regurgitation

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

TCTAP 2018, Seoul

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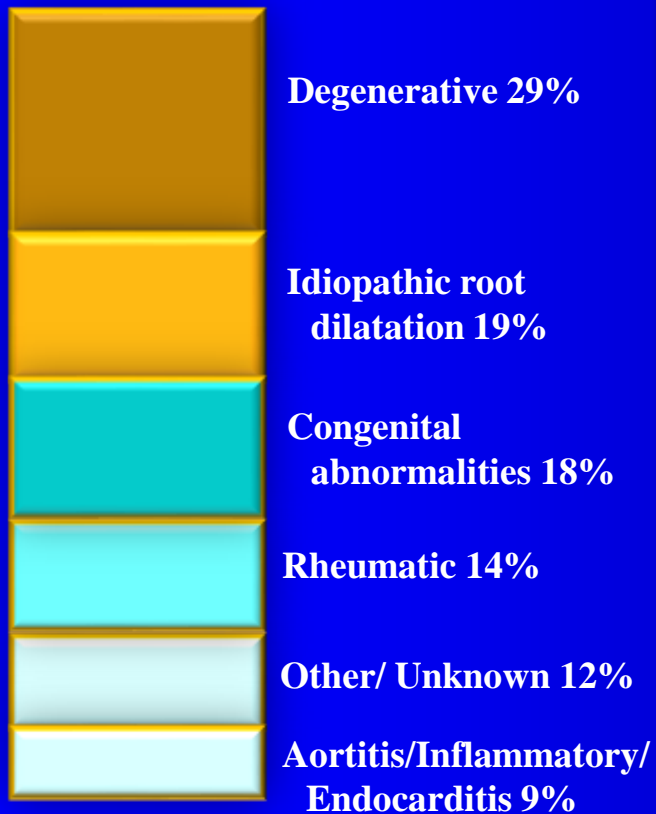St. Paul's Hospital, Vancouver

UBC

HEART CENTRE
AT ST. PAUL'S HOSPITAL

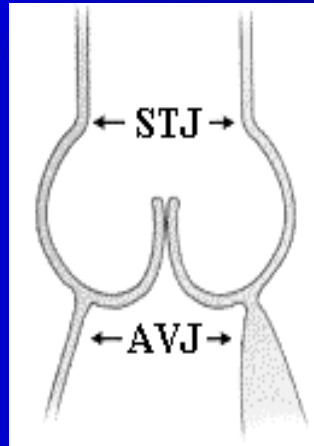# Disclosure Statement of Financial Interest

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**

← STJ →

← AVJ →

- 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?

Valves used for AI

FIGURE 1 Transcatheter Heart Valves for Pure Aortic Regurgitation
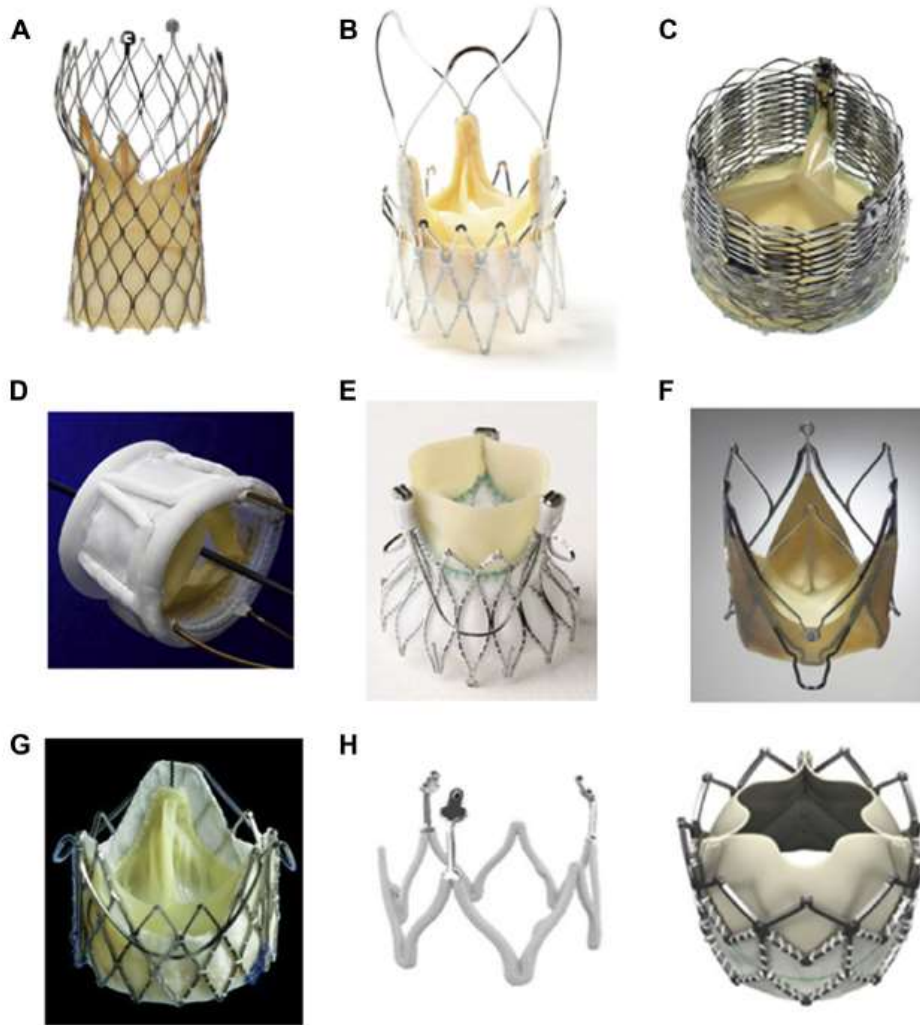
(A) CoreValve Evolut R (Medtronic). (B) Acurate (Symetis SA). (C) Lotus (Boston Scientific). (D) Direct Flow (Direct Flow Medical Inc.). (E) Engager (Medtronic). (F) JenaValve (JenaValve Technology). (G) J-Valve (JieCheng Medical Technology). (H) Helio dock (**left**) and SAPIEN XT valve (**right**) (Edwards Lifesciences).

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Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation

Sung-Han Yoon, MD,[a] Tobias Schmidt, MD,[b] Sabine Bleiziffer, MD,[c] Niklas Schofer, MD,[d] Claudia Fiorina, MD,[e] Antonio J. Munoz-Garcia, MD,[f] Ermela Yzeiraj, MD,[g] Ignacio J. Amat-Santos, MD,[h] Didier Tchetche, MD,[i] Christian Jung, MD,[j] Buntaro Fujita, MD,[k] Antonio Mangieri, MD,[l] Marcus-Andre Deutsch, MD,[g,m] Timm Ubben, MD,[b] Florian Deuschl, MD,[d] Shingo Kuwata, MD,[n] Chiara De Biase, MD,[i] Timothy Williams, MD,[o] Abhijeet Dhoble, MD,[p] Won-Keun Kim, MD,[q] Enrico Ferrari, MD,[r] Marco Barbanti, MD,[s] E. Mara Vollema, MD,[t] Antonio Miceli, MD,[u] Cristina Giannini, MD,[v] Guiherme F. Attizzani, MD,[w] William K.F. Kong, MD,[x] Enrique Gutierrez-Ibanes, MD,[y] Victor Alfonso Jimenez Diaz, MD,[z] Harindra C. Wijeysundera, MD,[aa] Hidehiro Kaneko, MD,[bb] Tarun Chakravarty, MD,[a] Moody Makar, MD,[a] Horst Sievert, MD,[cc] Christian Hengstenberg, MD,[m,dd] Bernard D. Prendergast, MD,[ee] Flavien Vincent, MD,[ff] Mohamed Abdel-Wahab, MD,[gg] Luis Nombela-Franco, MD,[hh] Miriam Silaschi, MD,[ii] Giuseppe Tarantini, MD,[jj] Christian Butter, MD,[bb] Stephan M. Ensminger, MD,[k] David Hildick-Smith, MD,[o] Anna Sonia Petronio, MD,[v] Wei-Hsian Yin, MD,[kk] Federico De Marco, MD,[ll] Luca Testa, MD,[ll] Nicolas M. Van Mieghem, MD,[mm] Brian K. Whisenant, MD,[nn] Karl-Heinz Kuck, MD,[b] Antonio Colombo, MD,[l] Saibal Kar, MD,[a] Cesar Moris, MD,[oo] Victoria Delgado, MD,[t] Francesco Maisano, MD,[n] Fabian Nietlispach, MD,[n] Michael J. Mack, MD,[pp] Joachim Schofer, MD,[g] Ulrich Schaefer, MD,[d] Jeroen J. Bax, MD,[t] Christian Frerker, MD,[b] Azeem Latib, MD,[l] Raj R. Makkar, MD[a]

TABLE 2 Procedural Data

	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
General anesthesia	192 (58.0)	58 (48.7)	134 (63.2)	0.01
Local anesthesia	139 (42.0)	58 (51.3)	78 (36.8)	0.01
Access site				
Transfemoral access	233 (70.4)	104 (87.4)	129 (60.8)	<0.001
Non-transfemoral access	98 (29.6)	15 (12.6)	83 (39.2)	<0.001
Transapical access	80 (24.2)	4 (3.4)	76 (35.8)	<0.001
Trans-subclavian access	10 (3.0)	4 (3.4)	6 (2.8)	0.79
Transaortic access	6 (1.8)	5 (4.2)	1 (0.5)	0.02
Transcarotid access	2 (0.6)	0 (0.0)	2 (1.7)	0.13
Device type				
Sapien XT	9 (2.7)	9 (7.6)	—	
Sapien 3	41 (12.4)	—	41 (19.3)	
CoreValve	110 (33.2)	110 (92.4)	—	
Evolut R	50 (15.1)	—	50 (23.6)	
JenaValve	64 (19.3)	—	64 (30.2)	
Direct Flow	35 (10.6)	—	35 (16.5)	
J-Valve	1 (0.3)	—	1 (0.5)	
Engager	7 (2.1)	—	7 (3.3)	
Portico	3 (0.9)	—	3 (1.4)	
Acurate	5 (1.5)	—	5 (2.4)	
Lotus	6 (1.8)	—	6 (2.8)	
Procedure time, min	102.1 ± 65.6	89.8 ± 50.2	109.1 ± 72.1	0.047
Fluoroscopy time, min	22.2 ± 17.8	29.1 ± 23.2	18.4 ± 12.5	<0.001
Contrast agent, ml	162.2 ± 88.7	180.1 ± 95.2	150.9 ± 82.7	0.01
Balloon pre-dilation	26 (7.9)	7 (5.9)	19 (9.0)	0.32
Balloon post-dilation	47 (14.2)	23 (19.3)	24 (11.3)	0.045

TABLE 3 Procedural and Clinical Outcomes

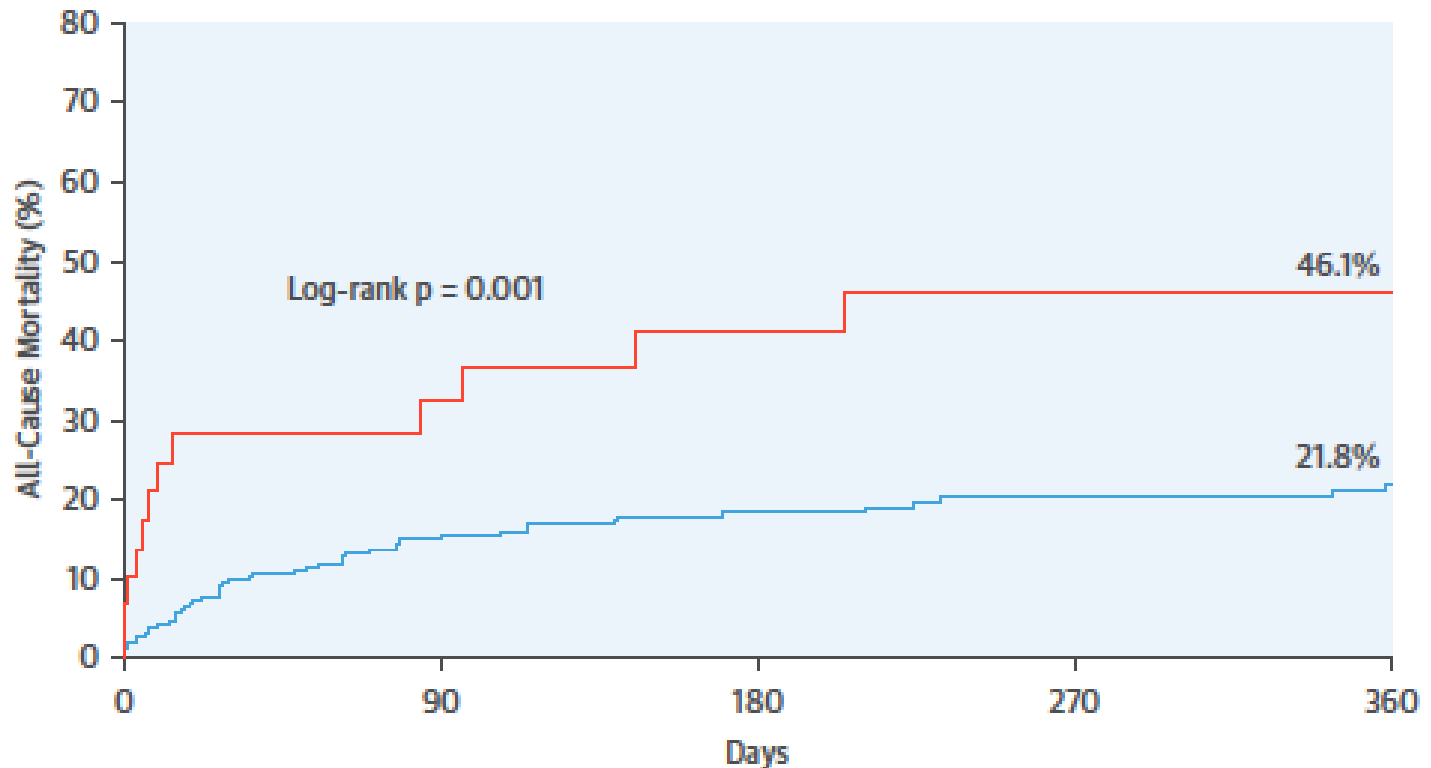|	Overall (N = 331)	Early-Generation Devices (n = 119)	New-Generation Devices (n = 212)	p Value
Procedural outcomes				
Procedure-related death	10 (3.0)	5 (4.2)	5 (2.4)	0.35
Conversion to conventional surgery	12 (3.6)	4 (3.4)	8 (3.8)	0.85
Coronary obstruction	4 (1.2)	0 (0.0)	4 (1.9)	0.30
Aortic root injury	5 (1.5)	2 (1.7)	3 (1.4)	>0.99
Need for second valve implantation	55 (16.6)	29 (24.4)	27 (12.7)	0.007
New permanent pacemaker*	51 (18.2)	17 (17.5)	34 (18.6)	0.83
Re-intervention	14 (4.2)	6 (5.0)	8 (3.8)	0.58
Echocardiographic findings at discharge				
Mean gradient, mm Hg	9.3 ± 4.8	7.7 ± 4.9	10.2 ± 4.5	<0.001
LVEF, %	44.0 ± 14.3	43.5 ± 14.2	44.3 ± 14.5	0.68
Aortic regurgitation ≥ moderate	29 (9.6)	21 (18.8)	8 (4.2)	<0.001
Device success	246 (74.3)	73 (61.3)	172 (81.1)	<0.001
Clinical outcomes at 30 days				
All-cause mortality	36 (10.9)	16 (13.4)	20 (9.4)	0.26
Cardiovascular mortality	32 (9.7)	14 (11.8)	16 (8.5)	0.33
Stroke	14 (4.2)	2 (1.7)	12 (5.7)	0.08
Bleeding	39 (11.8)	18 (15.1)	21 (9.9)	0.16
Major	25 (7.6)	12 (10.1)	13 (6.1)	0.19
Life-threatening	14 (4.2)	6 (5.0)	8 (3.8)	0.58
Major vascular complication	14 (4.2)	7 (5.9)	7 (3.3)	0.26
Acute kidney injury (stage 2 or 3)	27 (8.2)	14 (11.8)	13 (6.1)	0.07

Outcomes According to Devices
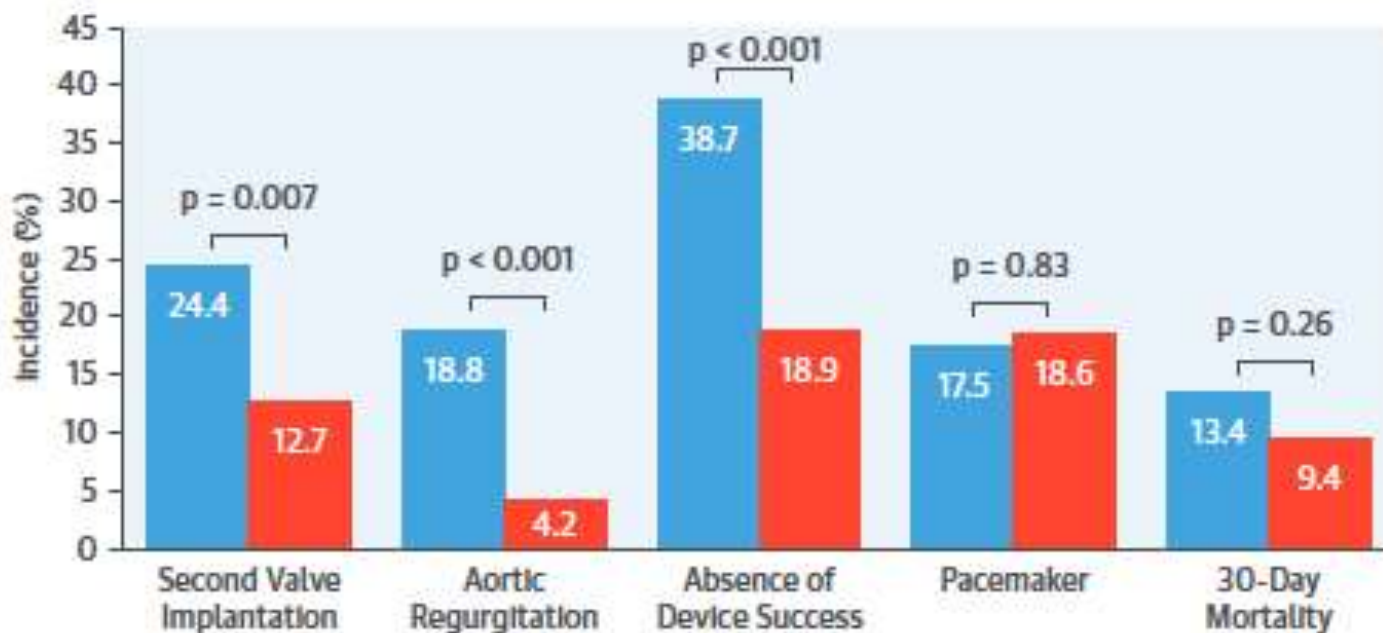
Mortality and Post-Procedural Aortic Regurgitation

A Second Valve Implantation

overall p = 0.05

p = 0.007

p = 0.06

	CoreValve (n = 110)	Evolut R (n = 50)	Sapien 3 (n = 41)	JenaValve (n = 64)	Direct Flow (n = 35)
Incidence (%)	26.4	18.0	12.2	9.4	17.1

B Post-Procedural Aortic Regurgitation

overall p < 0.001

p = 0.001

p = 0.003

p = 0.016

p = 0.04

p = 0.05

	CoreValve (n = 110)	Evolut R (n = 50)	Sapien 3 (n = 41)	JenaValve (n = 64)	Direct Flow (n = 35)
Incidence (%)	18.2	4.0	0.0	1.6	11.4

C Device Success

overall p < 0.001

p = 0.025

p = 0.001

p = 0.002

p = 0.04

	CoreValve (n = 110)	Evolut R (n = 50)	Sapien 3 (n = 41)	JenaValve (n = 64)	Direct Flow (n = 35)
Incidence (%)	59.1	76.0	85.4	82.8	77.1

D New Permanent Pacemaker

overall p = 0.71

	CoreValve (n = 88)	Evolut R (n = 42)	Sapien 3 (n = 34)	JenaValve (n = 47)	Direct Flow (n = 31)
Incidence (%)	17.0	21.4	18.2	15.8	9.7
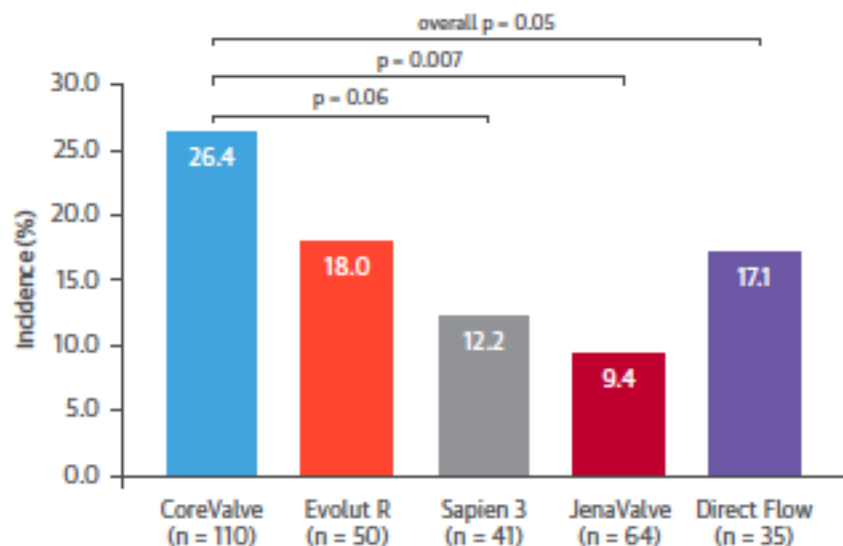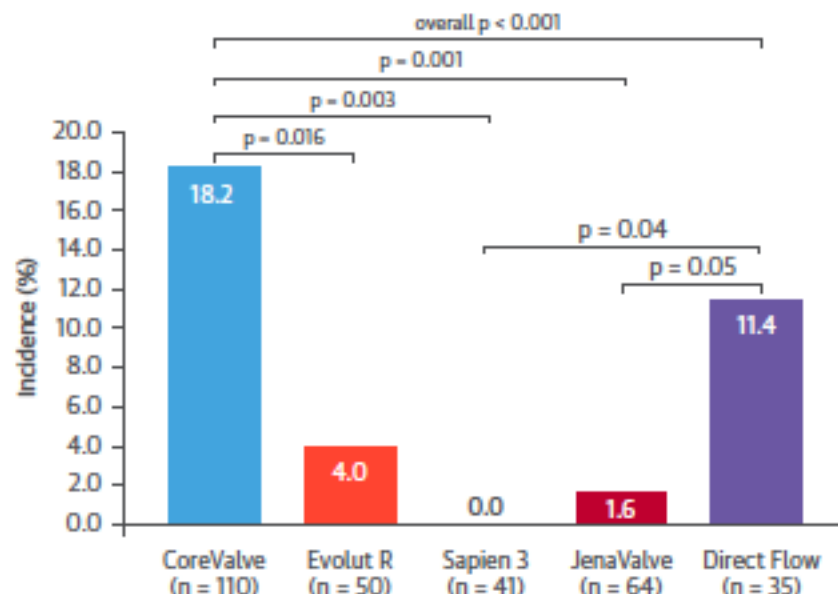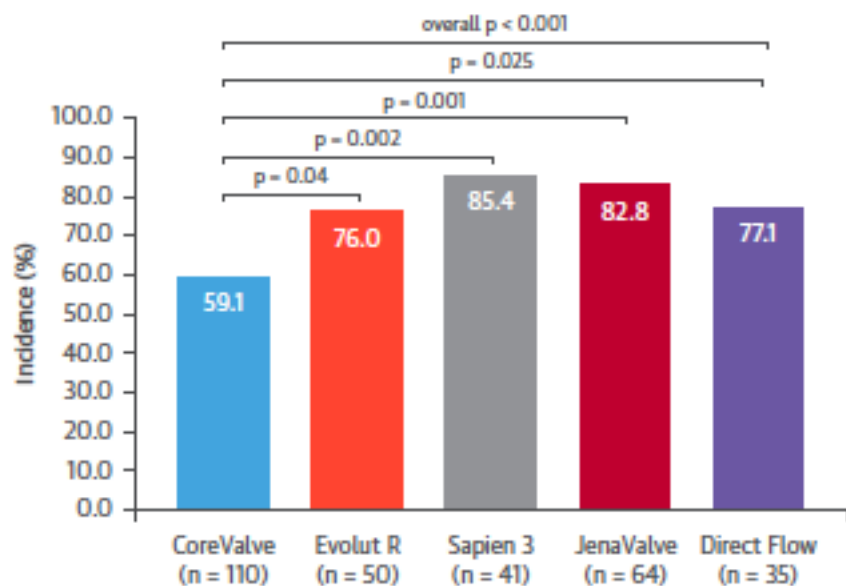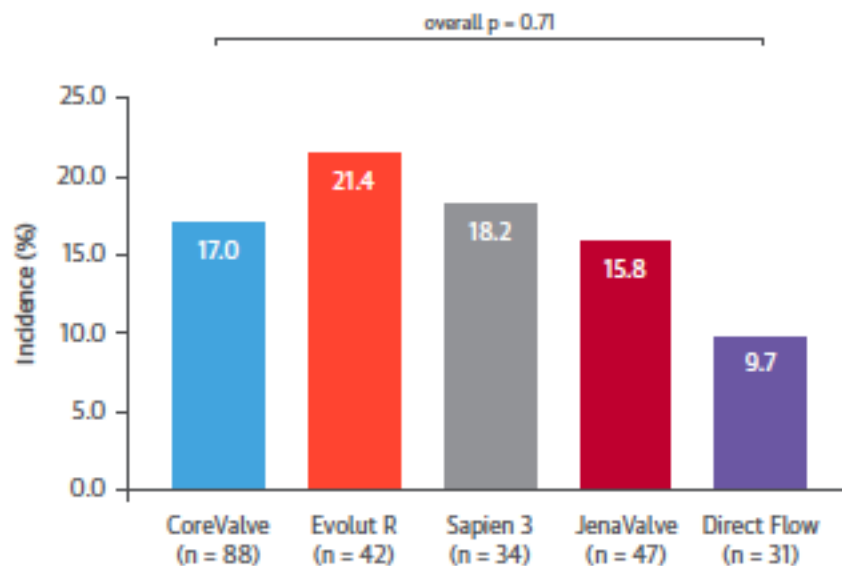
CONCLUSIONS

Compared with the early-generation devices, TAVR using the new-generation devices was associated with improved procedural outcomes in treating patients with pure native AR. In patients with pure native AR, significant post-procedural AR was independently associated with increased mortality.
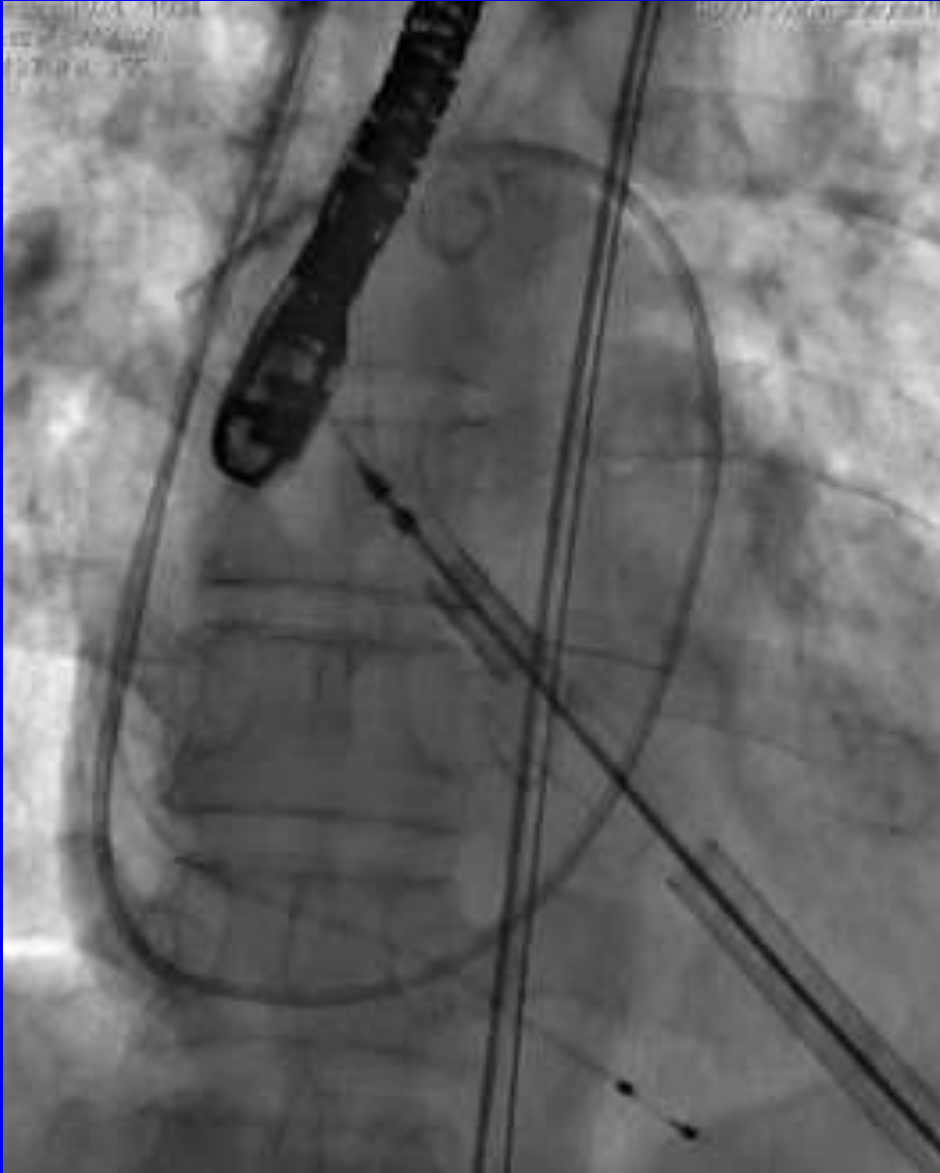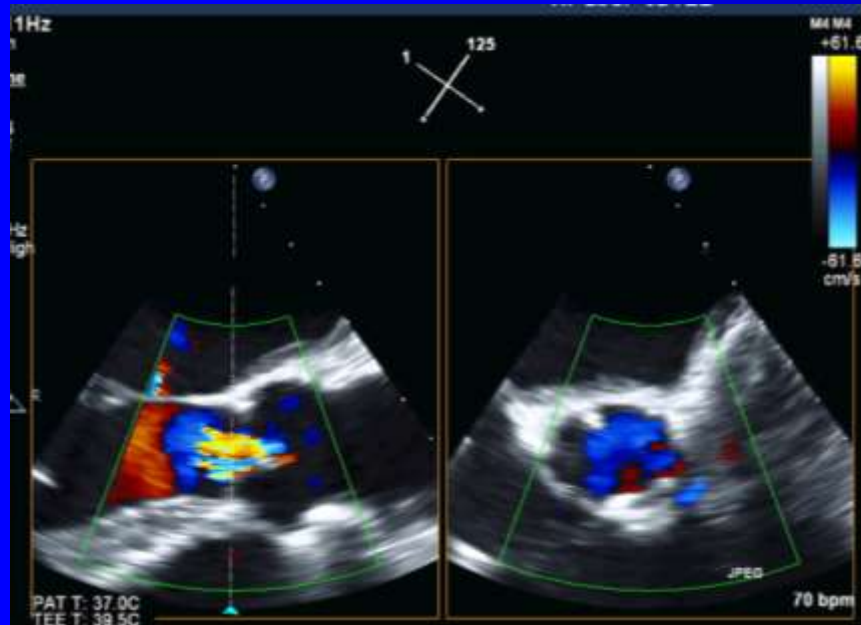
J-Valve™
JC Medical Technology

Clasper

Connection to delivery system
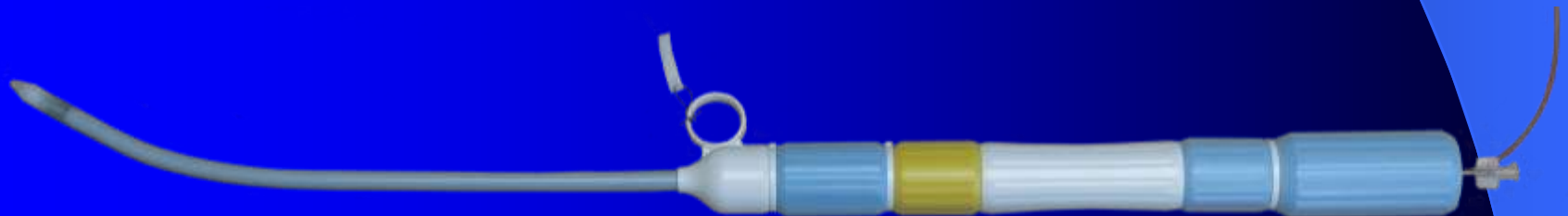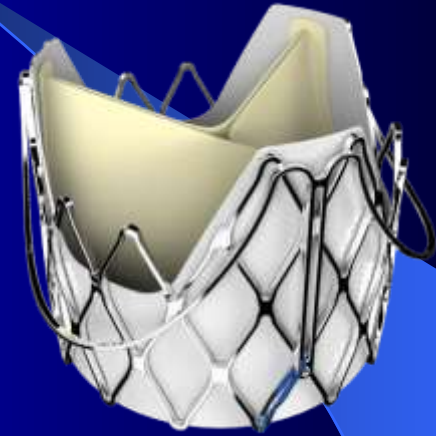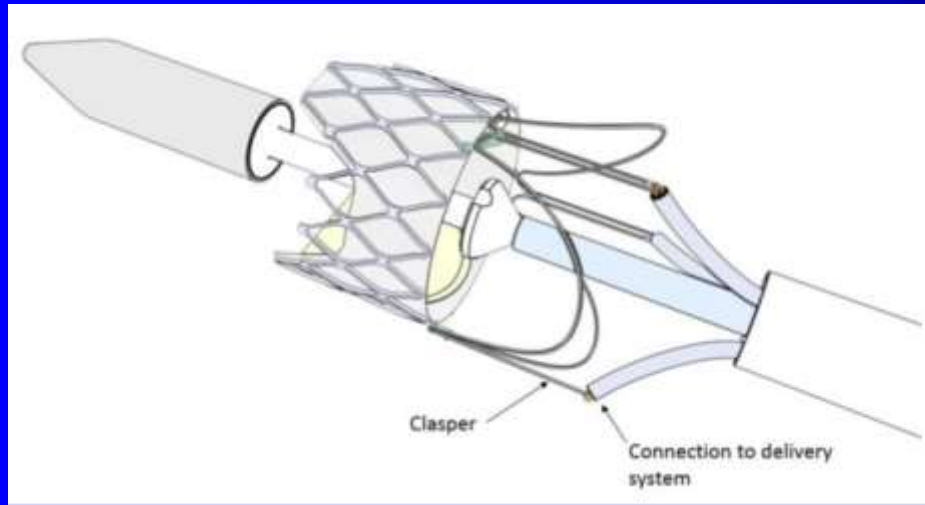
Designed for both AS and AI

Implantation

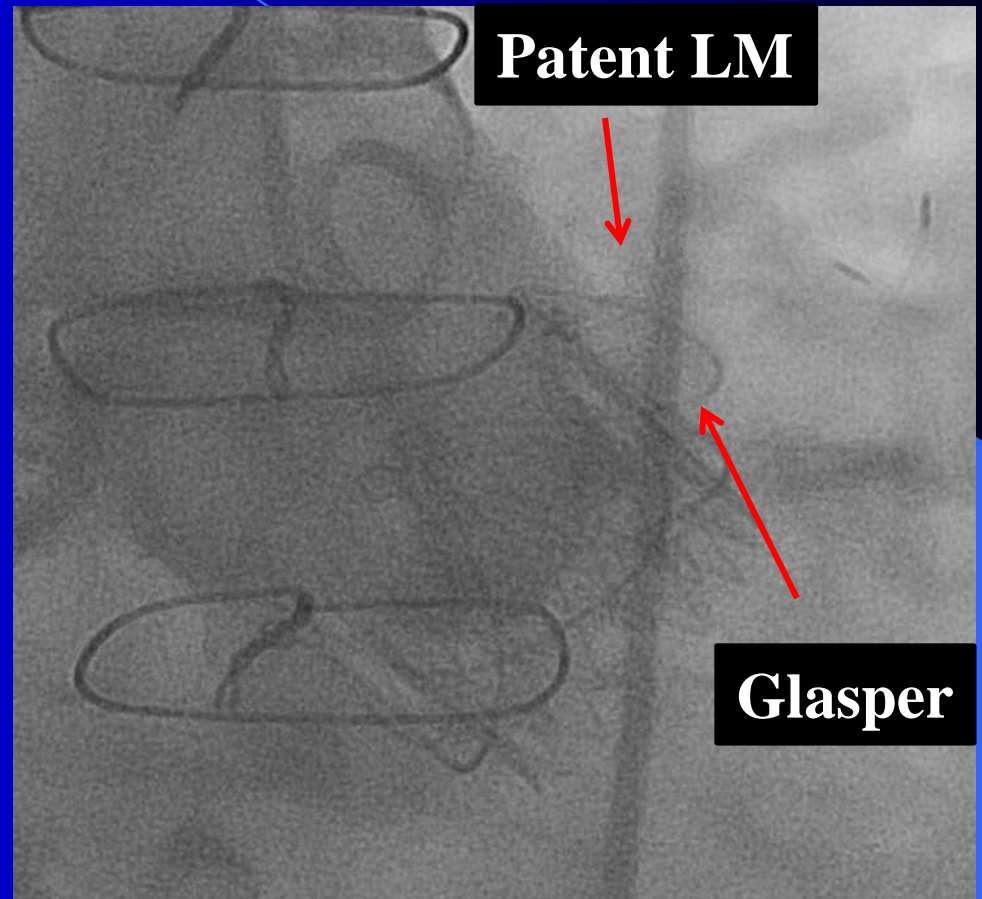# AI patient without any valve calcification

Pure aortic regurgitation

Post implantation of J-valve

Patient with bioprosthetic AI and risk of coronary obstruction
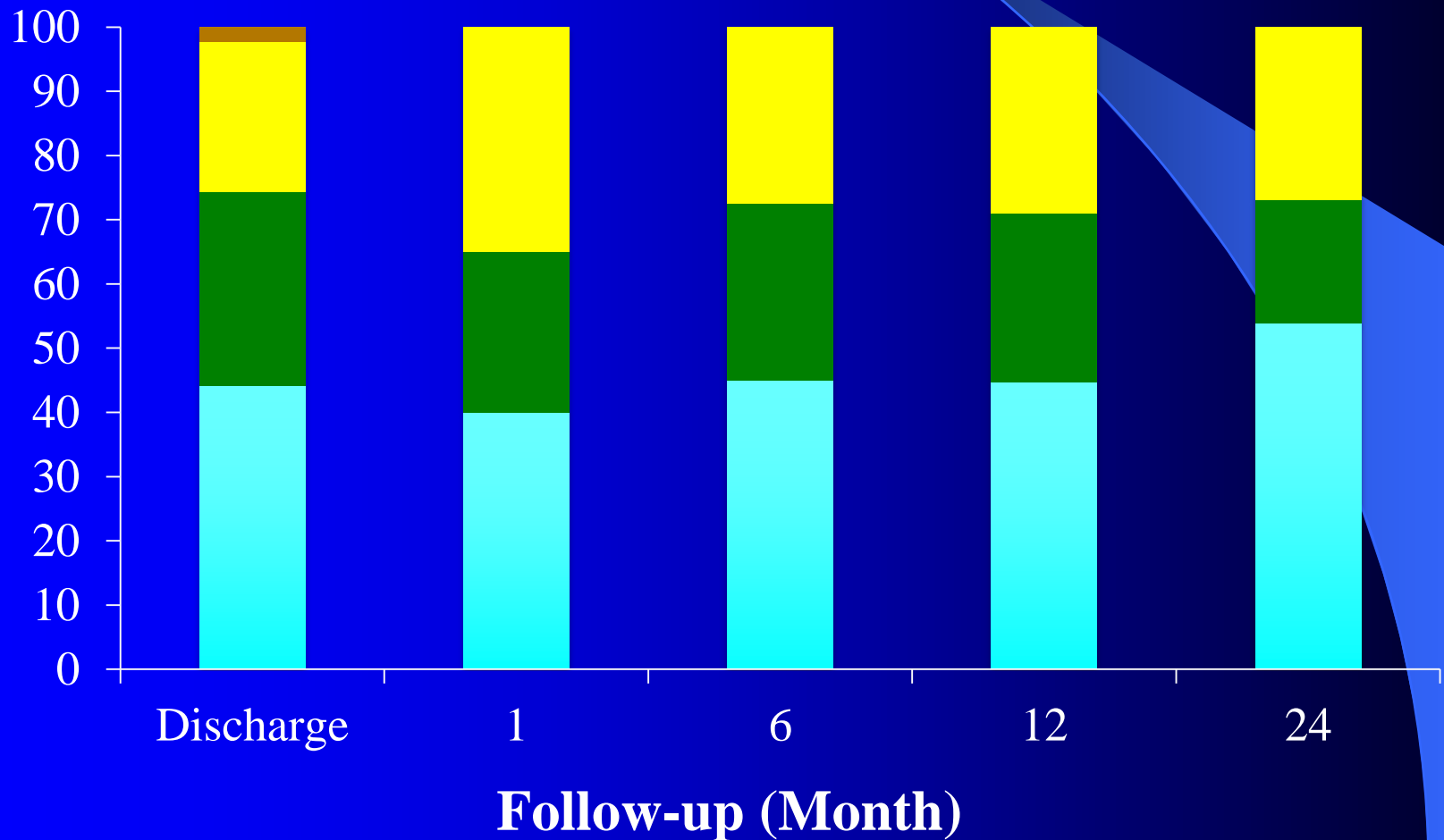

Stenotic bioprosthesis

Patent LM

Glasper

Post implantation of J-valve

Chinese Clinical Trial 2 Year Outcome

Paravlvular Leak

■ None ■ Trivial ■ Mild ■ Moderate ■ Severe

Follow-up (Month)

(x-axis: Discharge, 1, 6, 12, 24)
(y-axis: 0 to 100)

Chinese Clinical Trial
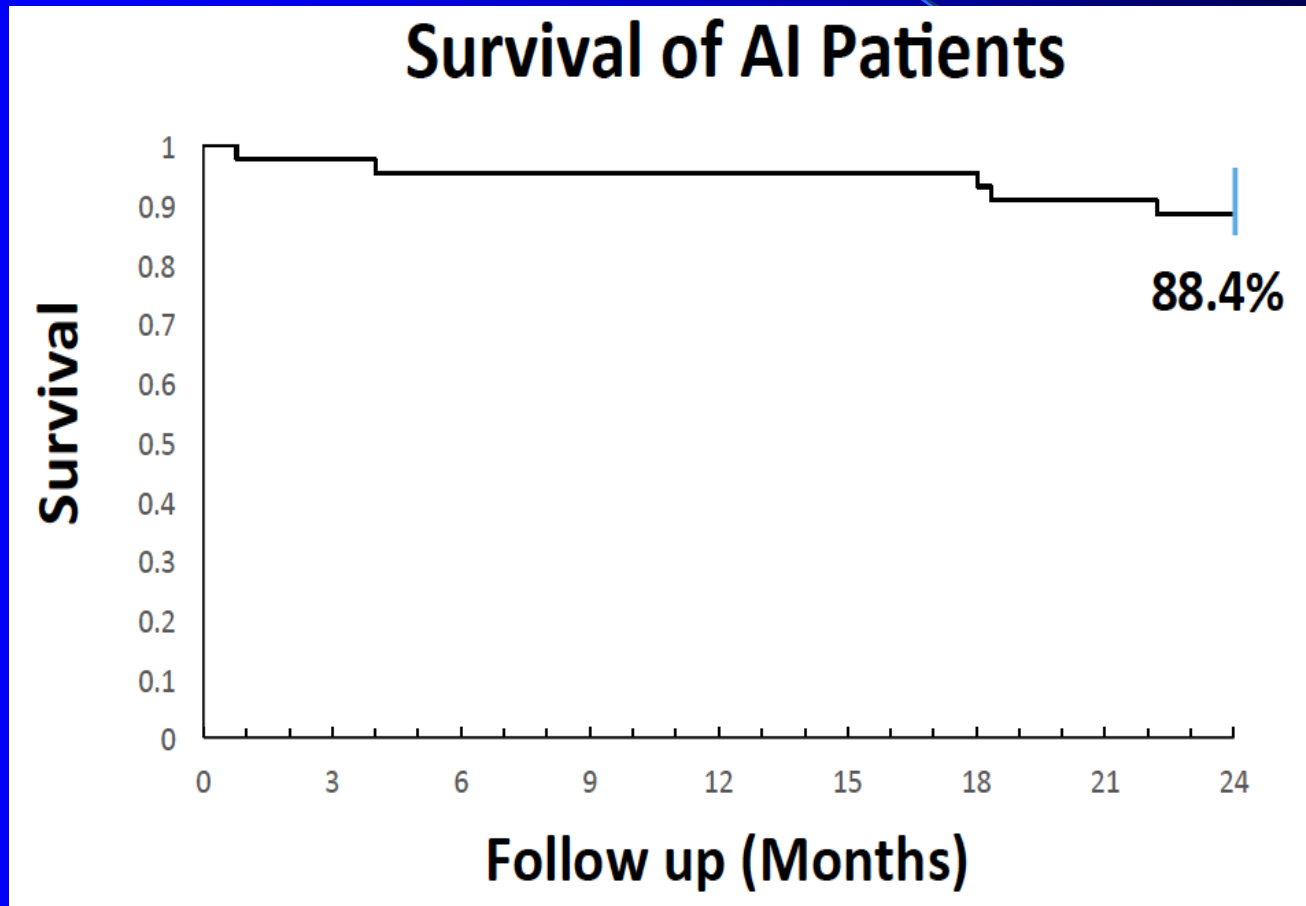# 2 Year Outcome

30-day all cause mortality   2.5%

CVA   0.0%

2-year accumulated III° AVB   4.7%

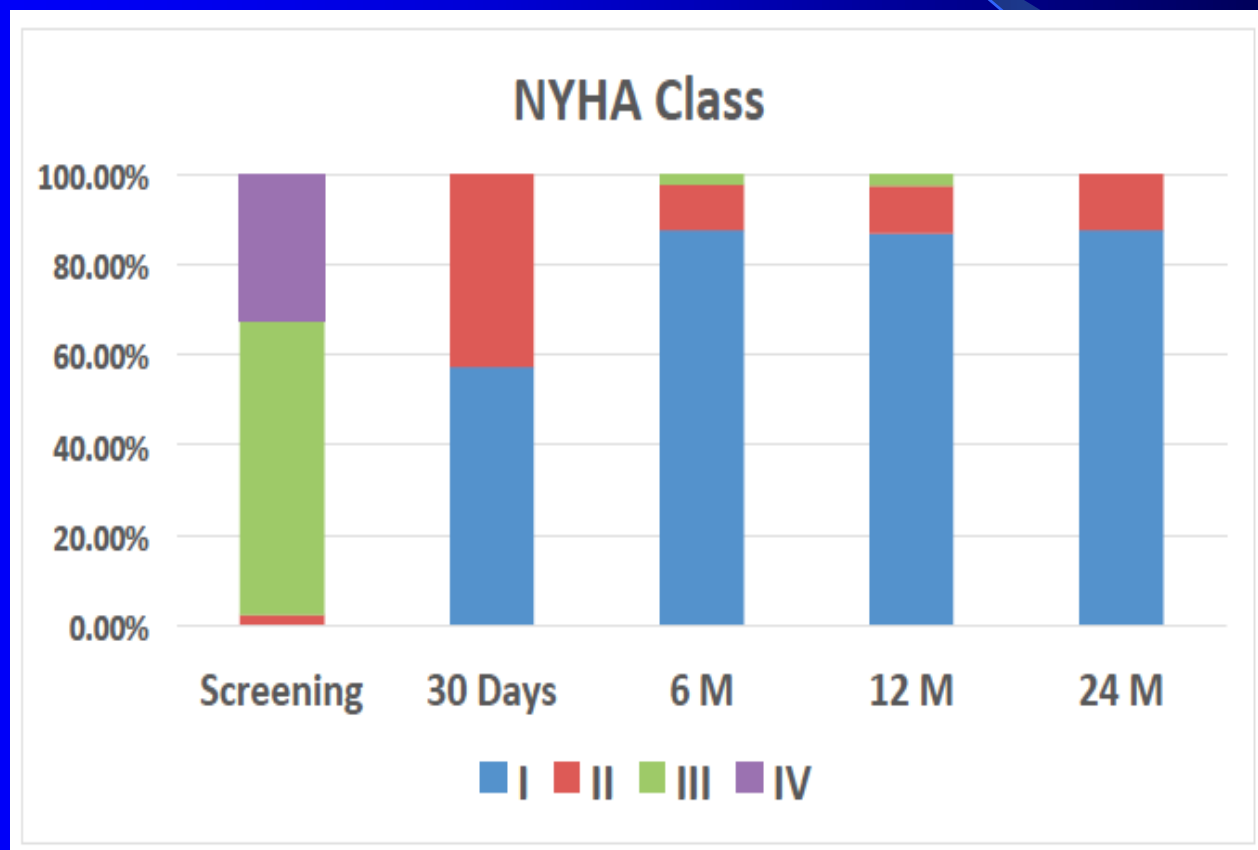Paravalvular leak >mild at 30 days and 2 yrs   0.0%

Chinese Clinical Trial 2 Year Outcome
Survival

Mean Follow-up: 24.9±2.6 months

Chinese Clinical Trial 2 Year Outcome

NYHA Class

AI Patients

Mean Follow-up: 24.9±2.6 months

Conclusion

Excellent 30 days and 2-year outcomes with J-Valve were demonstrated in pure AI patients

TAVI with J-Valve system is a viable alternative therapy for high-risk patients with non-calcified, pure AI

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

Transcatheter aortic valve replacement for isolated aortic regurgitation is coming!

Jian Ya. MD