TAVR Challenges and Innovations in China

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Disclosures

- **Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.**

Financial relationship	Organization
Honoraria	Venus Medtech
Research support	VenusA Valve Research Institute

Outlines

- Challenges of TAVR in China
- Device Innovation of TAVR in China
- Technique Innovation of TAVR in China

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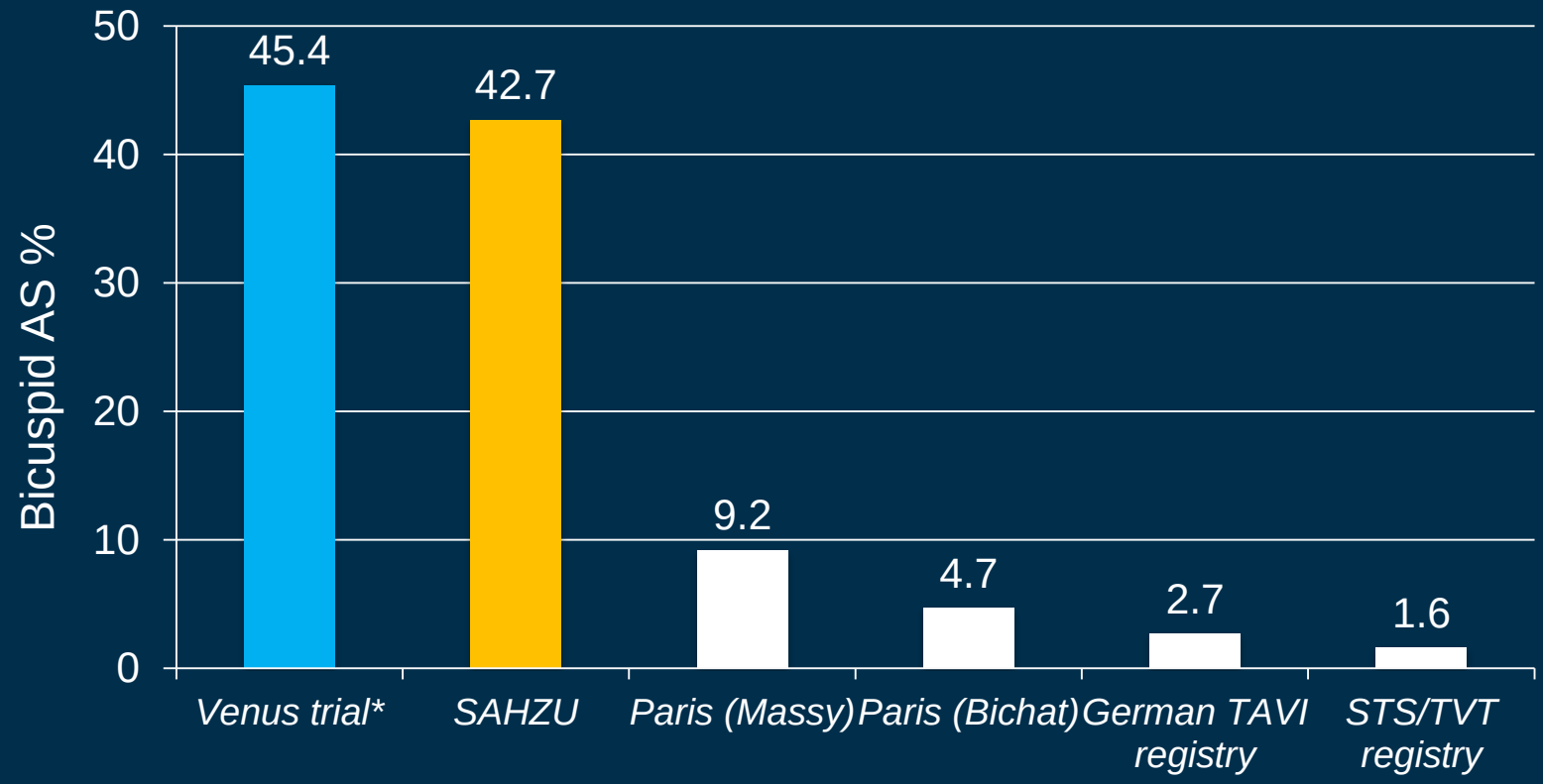
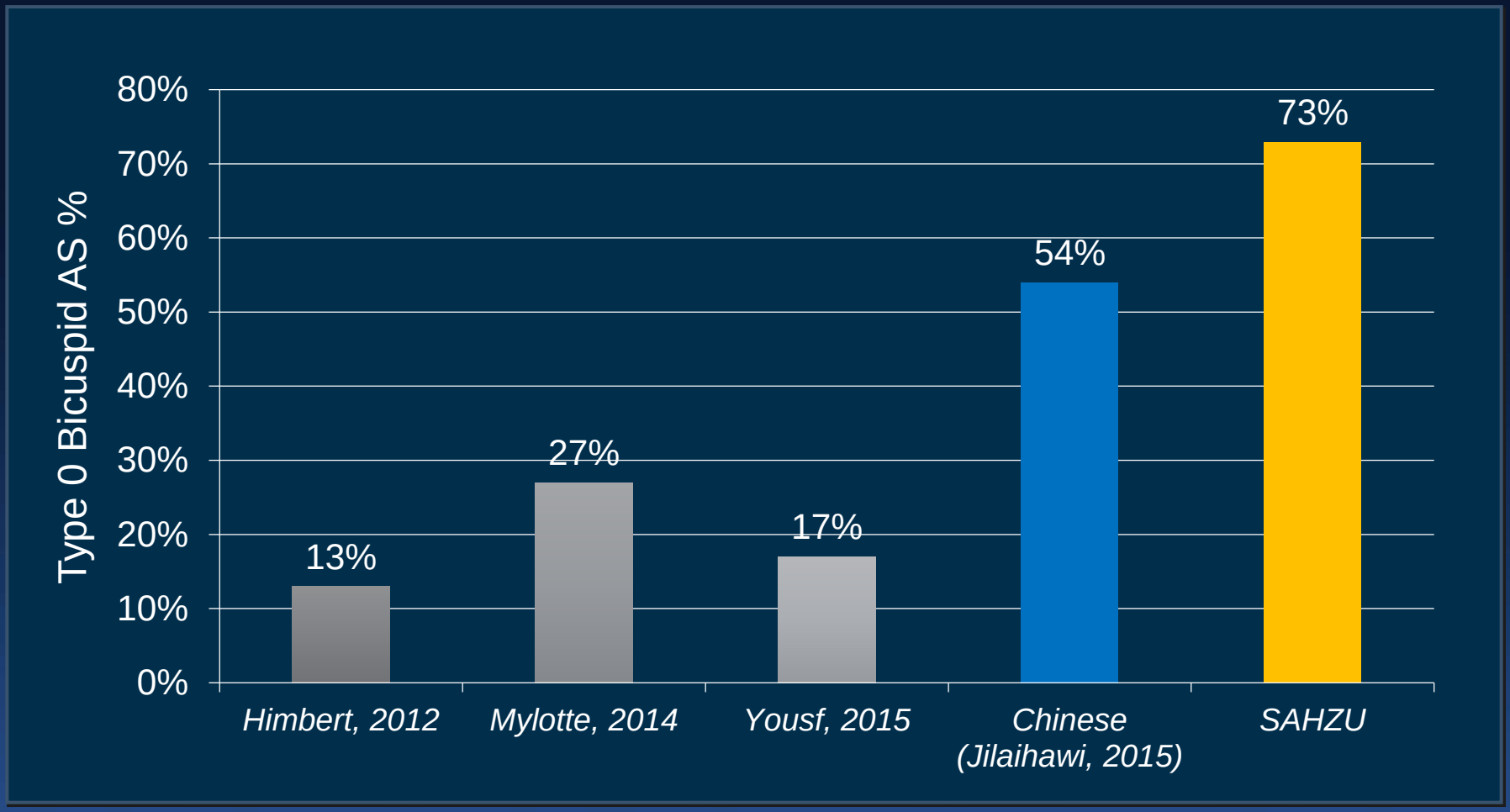
More Patients with Bicuspid AS



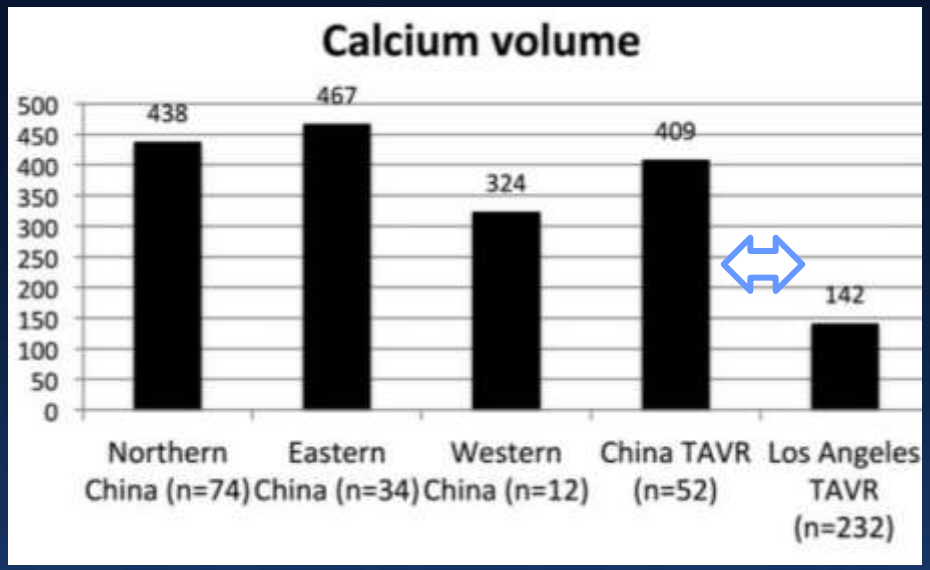
**Venus started in tricuspid valves only, bicuspid valves were enrolled only after January 2014*

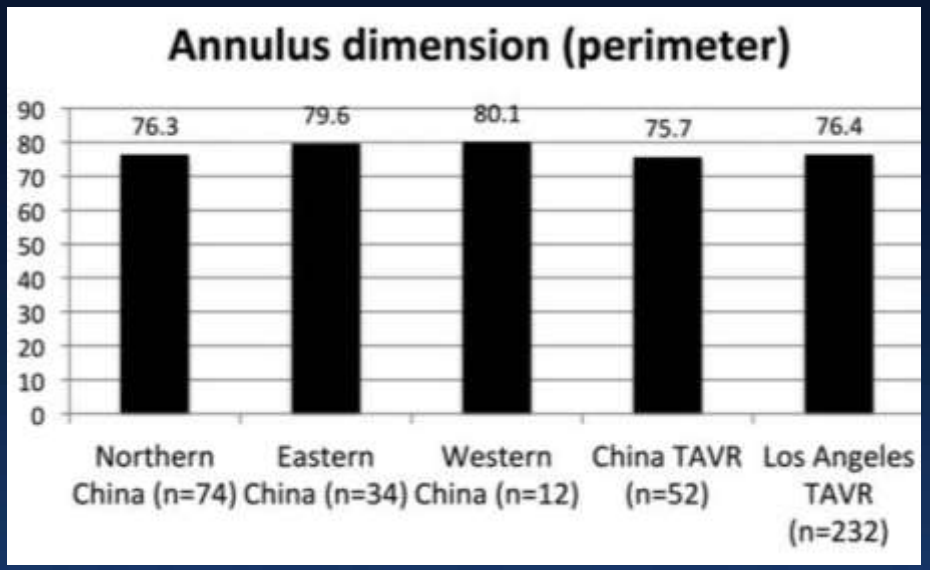
Hayashida et al, Circ Intv 2013
Himbert et al, AJC 2012
Bauer et al, AJC 2014
Mack et al, JAMA 2013

Dominance of No Raphe (type 0)



More case with severe calcification





Similar annulus size, but with more calcification.

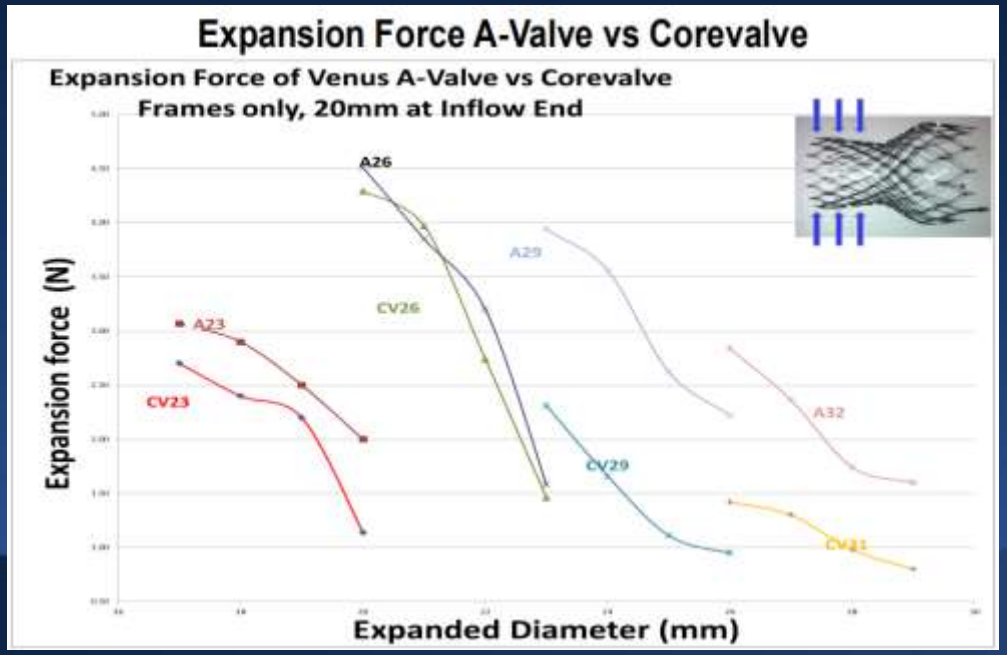
Jilaihawi, et al. Catheter cardiovas interv. 2015;85 Suppl 1:752-761.

Outlines

- Challenges of TAVR in China
- **Device Innovation of TAVR in China**
- Technique Innovation of TAVR in China

Venus A: first TAVR device approved by CFDA

- *Venus Medtech Inc., Hangzhou, China*
- *Special high radial force design for*
  - *Bicuspid AS*
  - *Severe calcification*



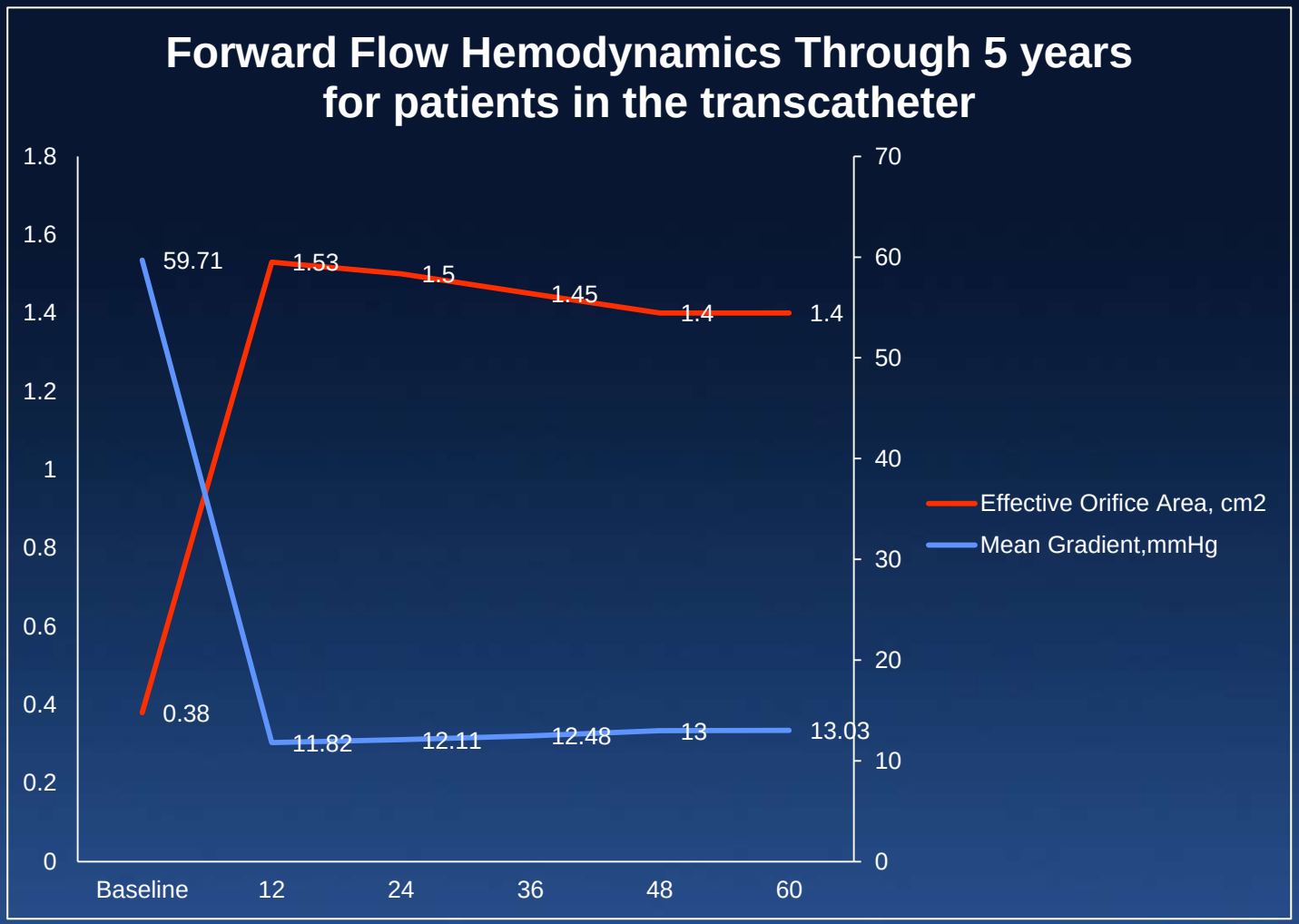
Venus A Clinical Result: Baseline

Characteristic, % or± SD	N=101
Age	75.86 ±6.45
Male	57.4%(58/101)
Height (cm)	161.95 ±8.97
Weight (kg)	59.24 ±10.38
BMI(kg/m2)	22.68±4.18
STS Score （%）	6.68±3.72
NYHA Class	
I	2.0%(2/101)
II	18.8%(19/101)
III	49.5%(50/101)
	29.7%(30/101)

Clinical Outcomes After 1 & 5y

n=101	1 year	5 years
All-cause mortality	6（5.9%）	21（20.8%）
Cardiovascular	4（4.0%）	15（14.9%）
MACCE	13（12.9%）	45（49.5%）
Stroke	1（1.0%）	4（4.0%）
Major	1（1.0%）	2（2.0%）
Minor	0	2（2.0%）
All-cause mortality or major stroke	7（6.9%）	25（24.8%）
Mycardial infarction	2（2.0%）	5（5.0%）
Reintervention	3（3.0%）	3（3.0%）
Major Bleeding	6（5.9%）	8（7.9%）
Major vascular complication	6（5.9%）	6（5.9%）
Endocarditis	0	0
Valve thrombosis	0	0
New pacemaker implantation	19（18.8%）	20（19.8%）

Aortic Valve Performance



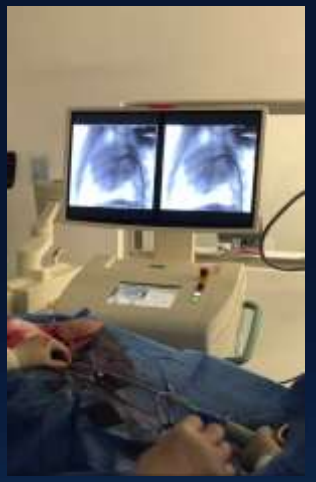
Development of 2nd generation VenusA pluse

Retrievable and Repositionable

Teamwork: Doctors & Engineers

Regular group meeting

Same VenusA valve



Animal study

Retrievable delivery system

FIM

VenusA plus Valve

Challenge 1: Deformation of proximal capsule

- **Cause**
  - Stent with high radial force

- **Solution**
  - From Pebax to Nitinol and Thermoplastic Urethane (TPU)
  - Metal cutting tube

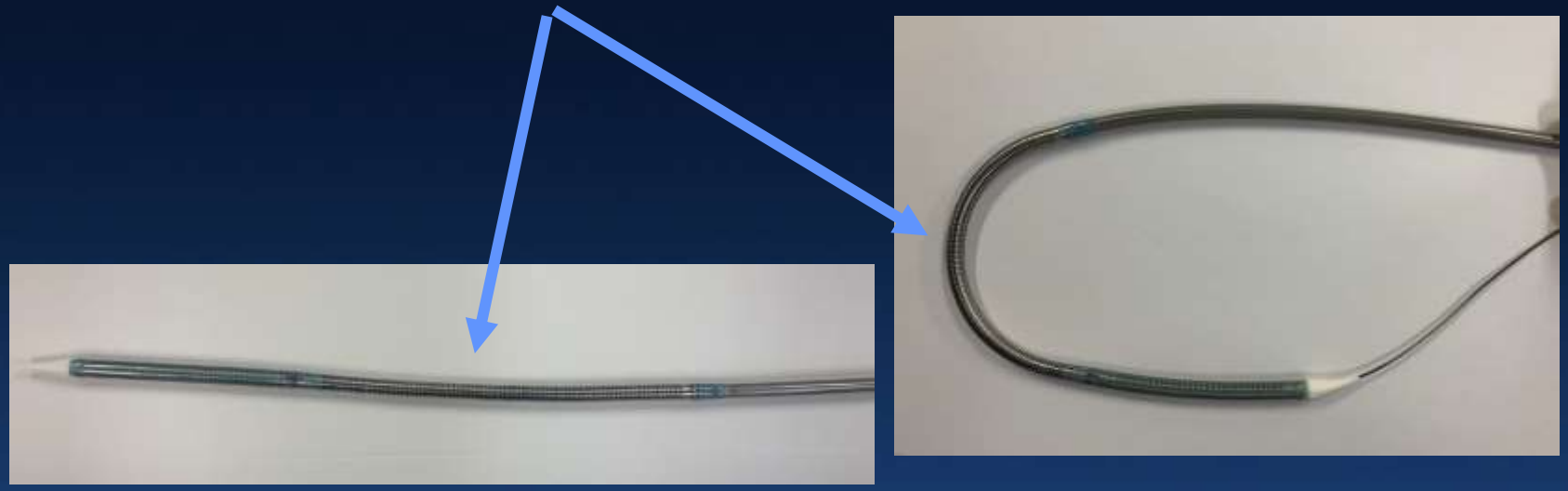
Challenge 2: releasing knob

- **Cause**
  - ✓ **Too small for valve retrieval**

- **Solution**
  - ✓ **Large handle**

Challenge 3: Deliverability

Improvement of deliverability



Other special design: Three guide rails in the capsule to facilitate valve retrieval

VenusA Plus CFDA Trial

Participating Centers and Investigators

Fuwai Hospital:
Yongjian Wu

Zhongshan Hospital:
Junbo Ge

West China Hospital:
Mao Chen

SAHZU: Jian'an Wang (PI)

VenusA Plus CFDA Trial

Combined safety endpoint:

- including mortality, stroke, vascular complication and new pacemaker implantation compared with the first generation device (Venus A system) at 30 days.

Efficacy endpoint:

• Hemodynamics endpoint:

- ***Effective orifice area change at 30 days***
- ***Transvalvular gradients change at 30 days***
- ***Freedom from moderate or severe AR or PVL at 30 days***

• Clinical improvement: Improvement in NYHA class at 30 days

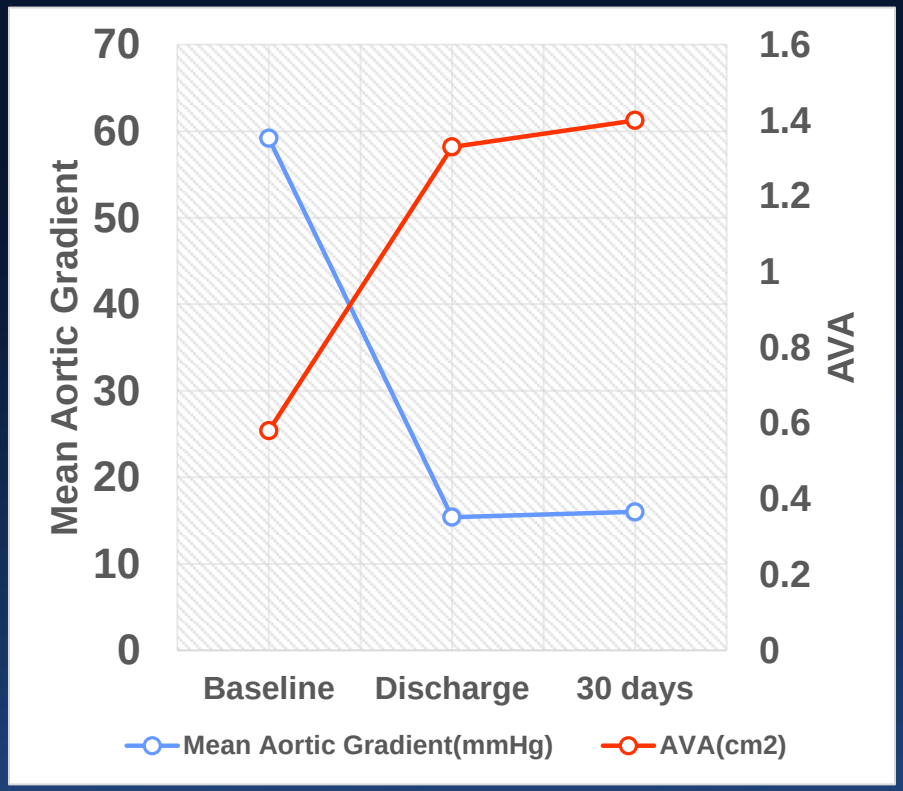
VenusA Plus trial: Baseline Characteristics

	N = 66
Age	76.2±5.33
Male	34（51.51%）
PCI history	10（15.15%）
Stroke	5（ 7.57 %）
Lung disease	30（45.45%）
PH（PASP＞60mmHg）	6（ 9.09 %）
CKD（eGFR60mL/min/1.73m^2）	32（48.48%）
Vascular Disease	9（13.63%）
NYHA III、IV	59（89.39%）
STS（%）	6.90±3.63
TTE	
Mean Aortic Gradient（mmHg）	62.6±19.2
AVA（cm^2）	0.58±0.32
Vmax（m/s）	5.14±0.70
LVEF(%)	57.8±13.2
Bicuspid Aortic Valve	43（66.67%）

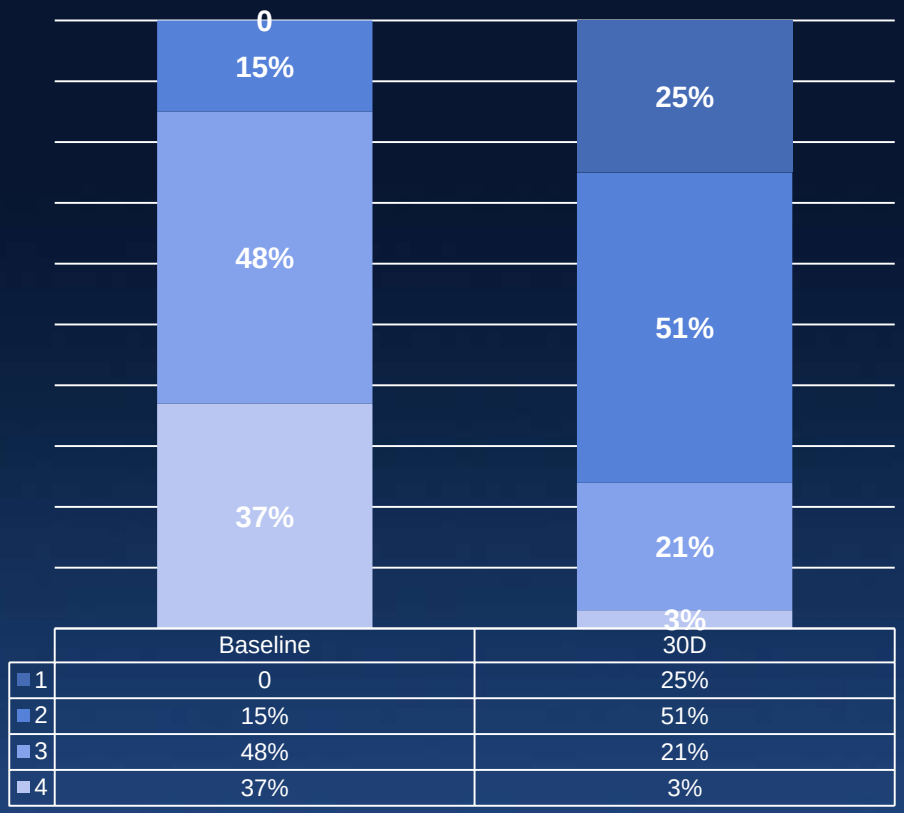
VenusA Plus trial: 30-day outcomes

	（N=66）
Device Deployment	63/66 (95.45%)
Device-related Death	1/66 (1.51%)
Major vascular complication	2/66 (3.03%)
Stroke	1/66 (1.51%)
Myocardial infarction	1/66 (1.51%)
New pacemaker implantation	7/66 (10.60%)
Reposition	28/66 (42.42%）

VenusA Plus trial: 30-day outcomes



Aortic Valve Performance



Improvement of NYHA Class

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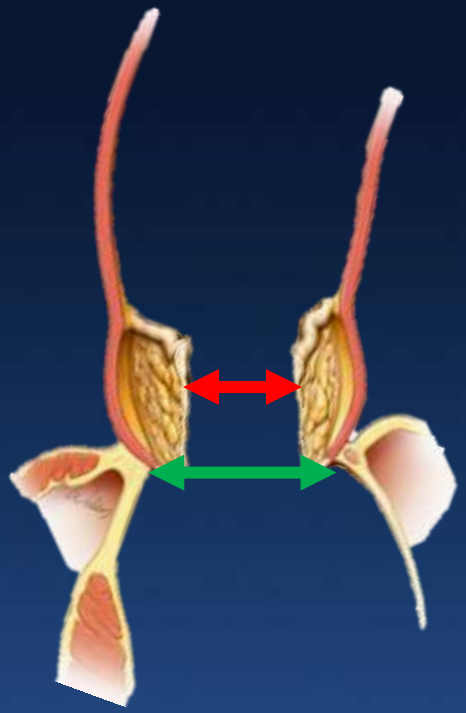
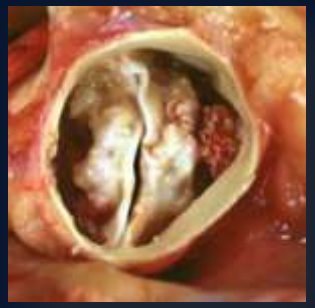
- **Technique Innovation of TAVR in China**

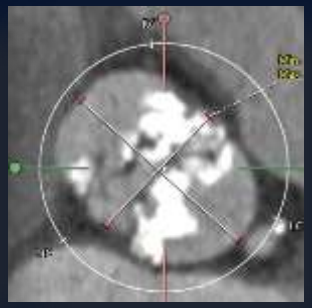
Supra-annular structure in bicuspid AS

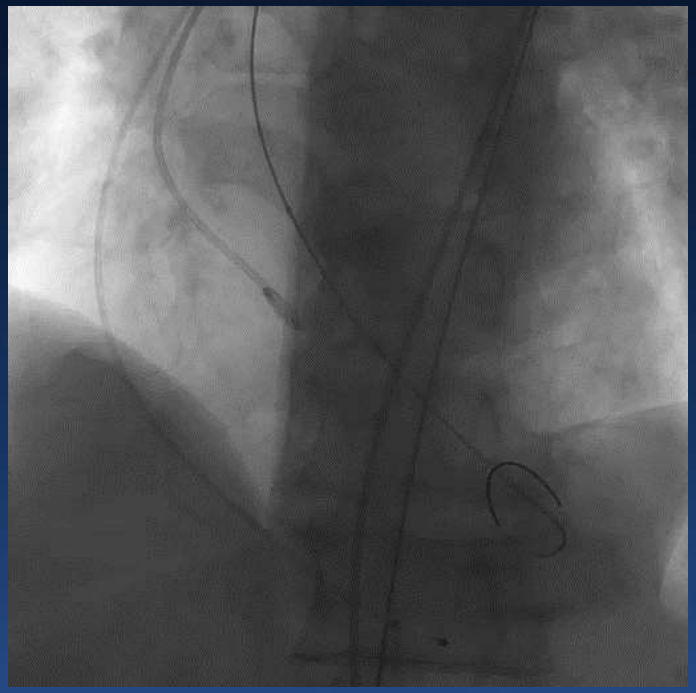
Annulus size ≠ supra-annular size



Supra-annular structure in bicuspid AS

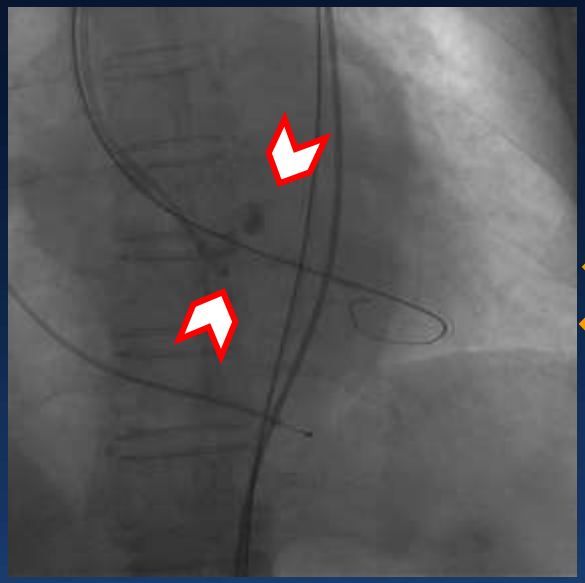


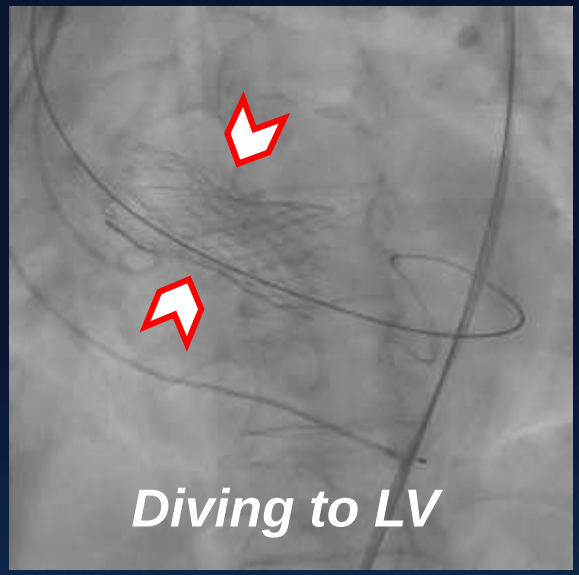


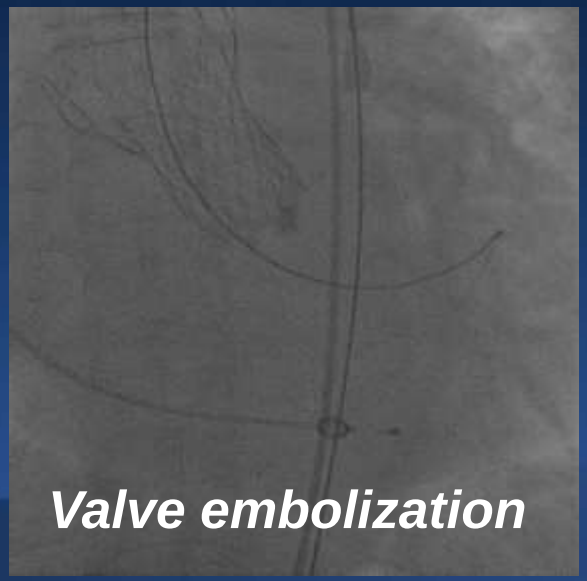


Unable to fully open supra-annular structure with currently available technology

Annulus based sizing of Bicuspid AS



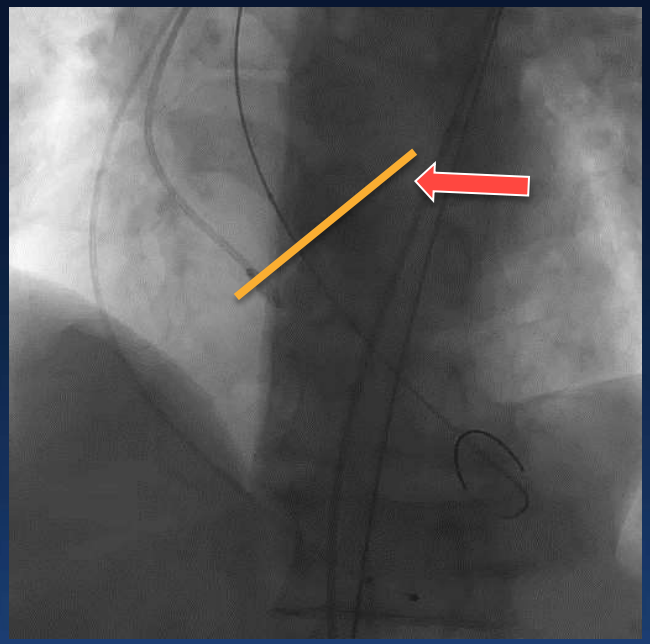




- *Waist sign indicates supra-annular structure playing important role in valve size decision of Bicuspid AS*

How to measure the supra-annular structure

➢ Balloon sizing



20mm Balloon Sizing

True supra-annular size

- Waist sign on the balloon
- About 10mm above annulus
- No leakage
- Balloon size much smaller than the annulus

Supra-annular structure based sizing strategy

Hangzhou Solution

- **Protocol of balloon sizing**

  Starting from small balloon (20mm)

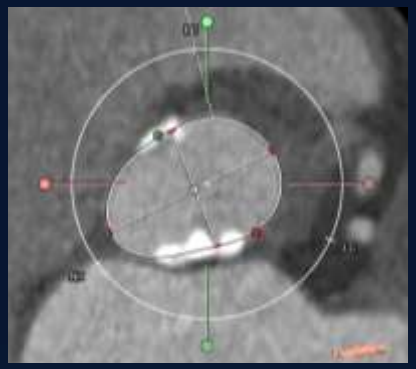
  Upgrade of balloon size until waist sign and no regurgitation

  Selection of Valve size based on final balloon size

  Balloon sizing：only once in 85% of patients

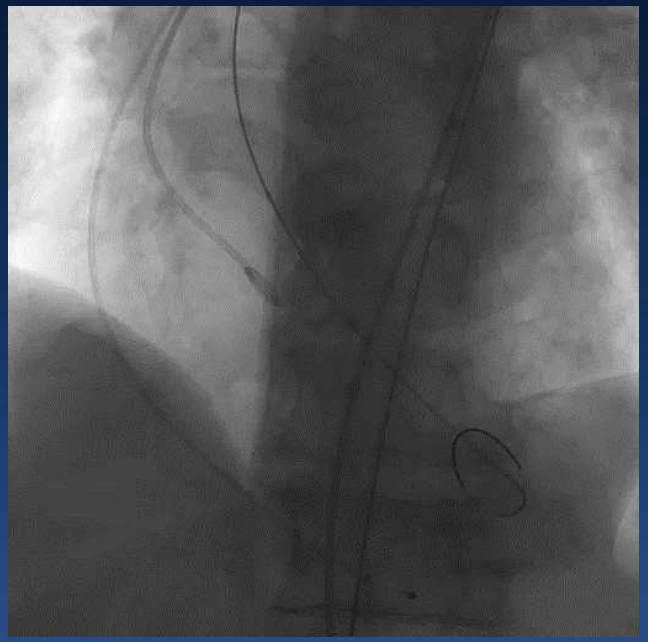
Liu X, Wang J, et al. ***Catheter Cardiovasc Interv.*** 2018;Apr, 91: 986-994.

How to perform Hangzhou solution

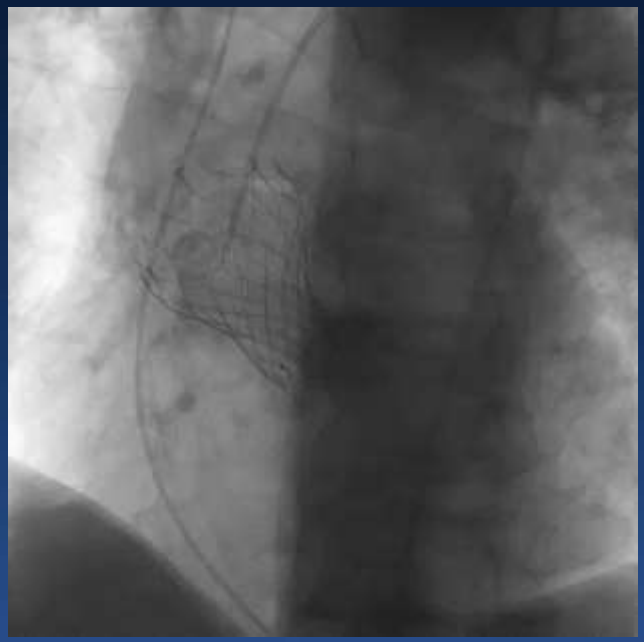


Annulus 27.8mm

SOV



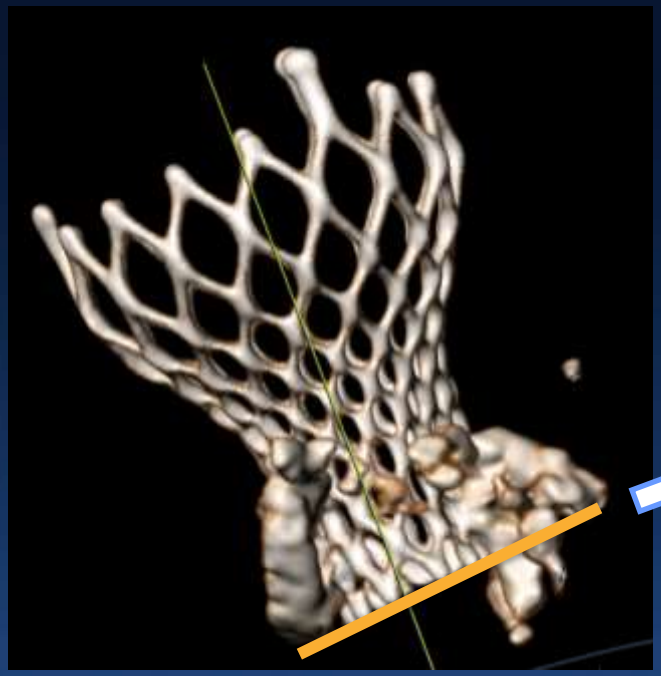
20mm Balloon Sizing

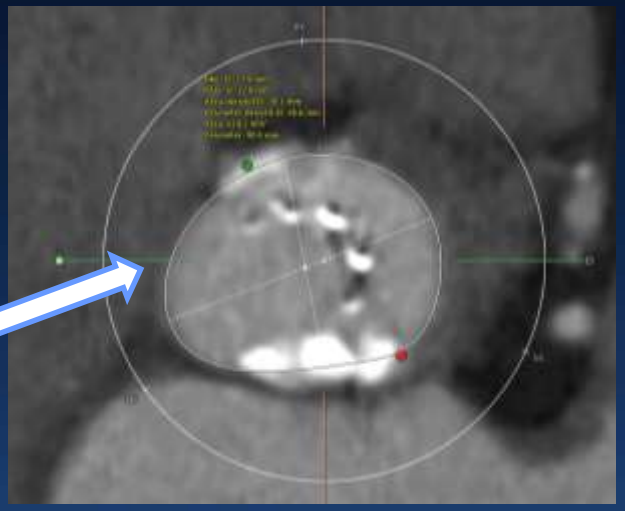


Final result
26mm Venus A valve
(downsize from 32mm)

How to perform Hangzhou solution

Pre-discharge CT





No attachment to native annulus

Hangzhou Solution for bicuspid AS

Single center- Self-expanding THVs first generation

Baseline Characteristics	Traditional sizing (n=44)	Hangzhou solution (n=77)	P value
Age (yr.)	75±6	76±6	0.383
Gender (Male)	47.7%	54.5%	0.470
BMI(kg/m2)	22.5±3.1	22.3±2.9	0.725
STS Score (%)	5.89±4.30	6.15±4.01	0.741
NYHA class III/IV	86.4%	90.9%	0.544

TORCH registry, Unpublished data

Hangzhou Solution for bicuspid AS

Single center- Self-expanding THVs first generation

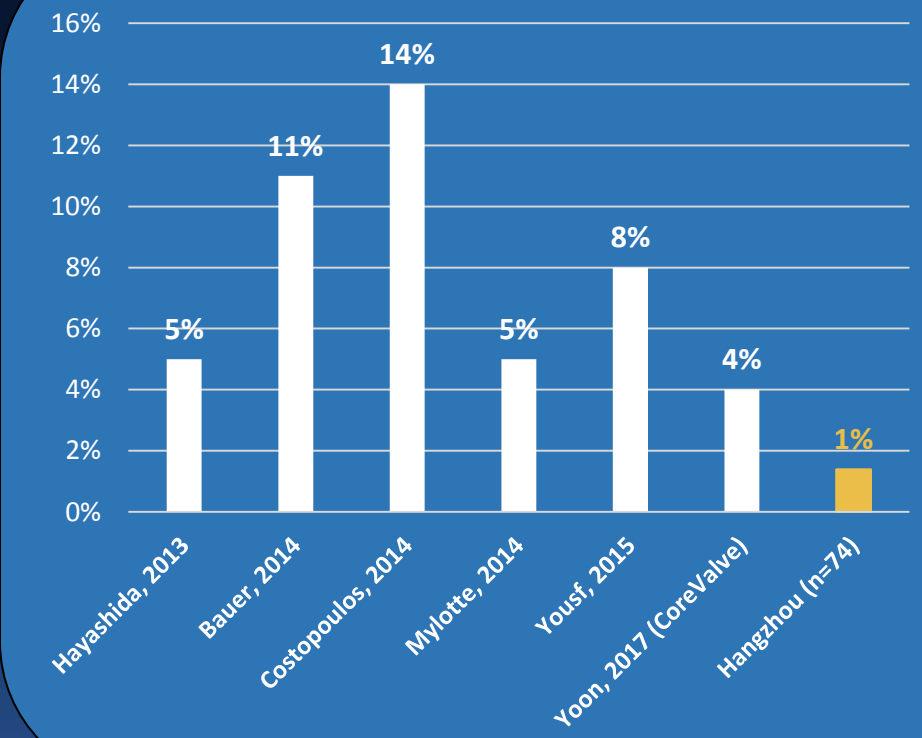
1-month outcomes	Traditional sizing (n=44)	Hangzhou solution (n=77)	P value
Mortality	2 (4.5%)	1 (1.3%)	0.299
Disabling stroke	1 (2.3%)	0 (0.0%)	0.364
Pacemaker	7 (15.9%)	1 (1.3%)	**0.003**
THV_in_THV	4 (9.5%)	4 (5.2%)	0.460
TTE results			
AVA (cm^2)	1.58±0.20	1.44±0.26	0.003
MeanG (mmHg)	12±4	14±8	0.125
Max V (m/s)	2.35±0.40	2.44±0.46	0.283
EF (%)	60.2±9.4	60.4±9.10	0.909
≥moderate PVL (%)	6 (13.6%)	7 (9.1%)	0.544

TORCH registry, Unpublished data

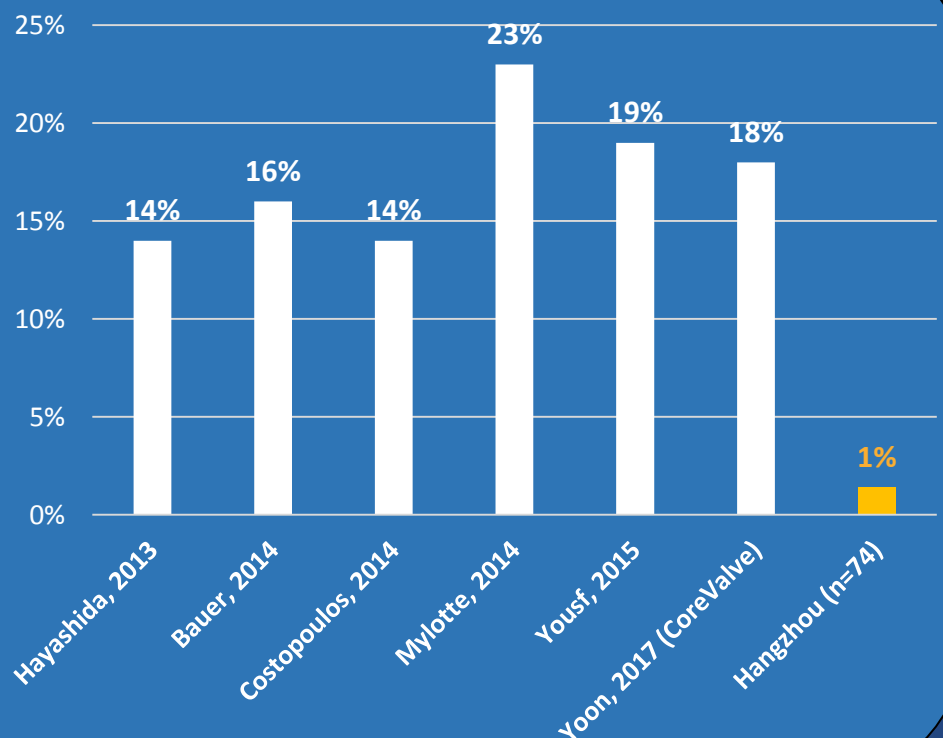
Hangzhou Solution

Single center- Self-expanding THVs first generation

30-day mortality



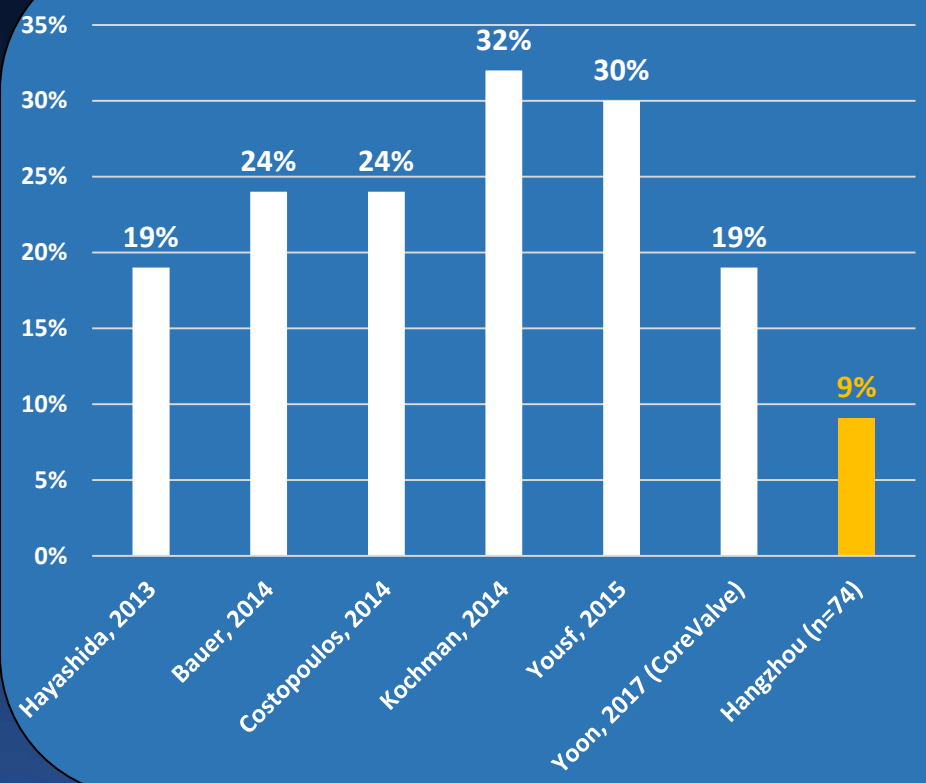
Permanent pacemaker implantation



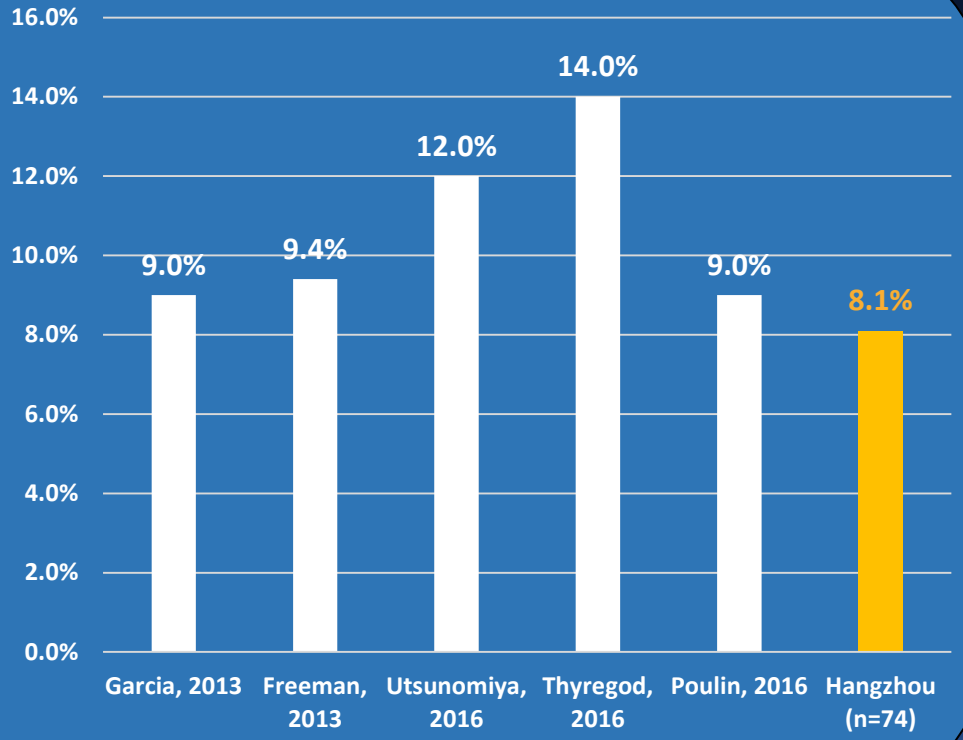
Hangzhou Solution for bicuspid AS

Single center- Self-expanding THVs first generation

PVL moderate or greater



Severe prosthesis-patient mismatch



Conclusions

- There are lots of Challenges of TAVR in China
- Bicuspid AS with severe calcification makes TAVR procedure much more complicated in China
- Venus series valves developed in Hangzhou contributes to solve the problem
- Hangzhou solution is feasible for patients with bicuspid AS