# TAVR experience from China

# in patients with bicuspid valve

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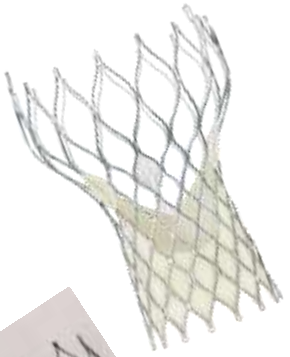
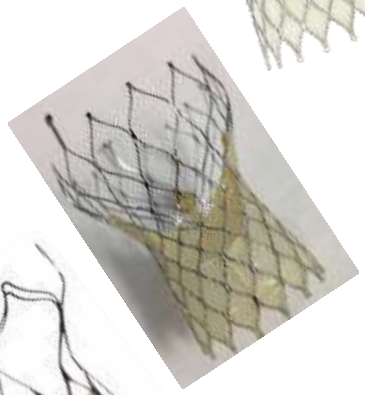
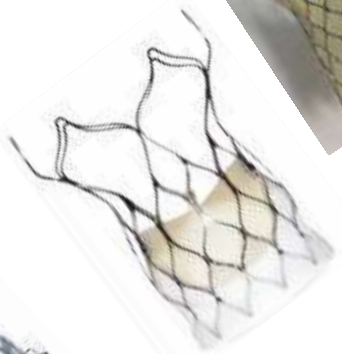
# Disclosures

I DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.



# TAVR in China

- First TAVR case was performed by Prof. Junbo Ge in Oct. 2010.
- About 500 cases in total (100 cases with trans apical)
- Prosthesis type
  - Self Expandable
    - CoreValve
    - Domestic made valves: Venus A, Microport valve, J-valve (TA)
  - Balloon Expandable: Edwards Sapien
  - Mechanical Expandable: Lotus
- Access
  - Trans-femoral: 77%
  - Trans-subclavian: 1%
  - Trans-aortic: 1%
  - Trans-carotid: 1%
  - Trans-apical: J-Valve  20%


# TAVR with Venus-A Valve for Treatment of Severe Aortic Stenosis in Chinese Patients
## One Year Outcomes from the First Multicenter Trial in China

| | Venus A-Valve (N=101) |
|---|---|
| Age | 75.86 ±6.45 |
| Gender (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 | |
| I | 2.0%(2/101) |
| II | 18.8%(19/101) |
| III | 49.5%(50/101) |
| IV | 29.7%(30/101) |
| Syncope | 20.8%(21/101) |

# CT Data

| | Venus A-Valve (N=101) |
|---|---|
| Valve Type | |
| Tricuspid | 55.2%(53/96) |
| Bicuspid | 44.8%(43/96) |
| Annulus Diameter MAX | 26.98 ±2.97 |
| Annulus Diameter MIN | 20.99 ±2.74 |
| Sinus of Valsalva | 32.73±4.58 |
| Ascending Aorta MAX | 36.62±4.54 |
| Ascending Aorta MIN | 35.41±4.42 |
| Height of LM to anunlus | 15.22±3.44 |
| Height of RCA to annulus | 16.98±3.21 |
| Calcium Score | 497.34±383.04 |

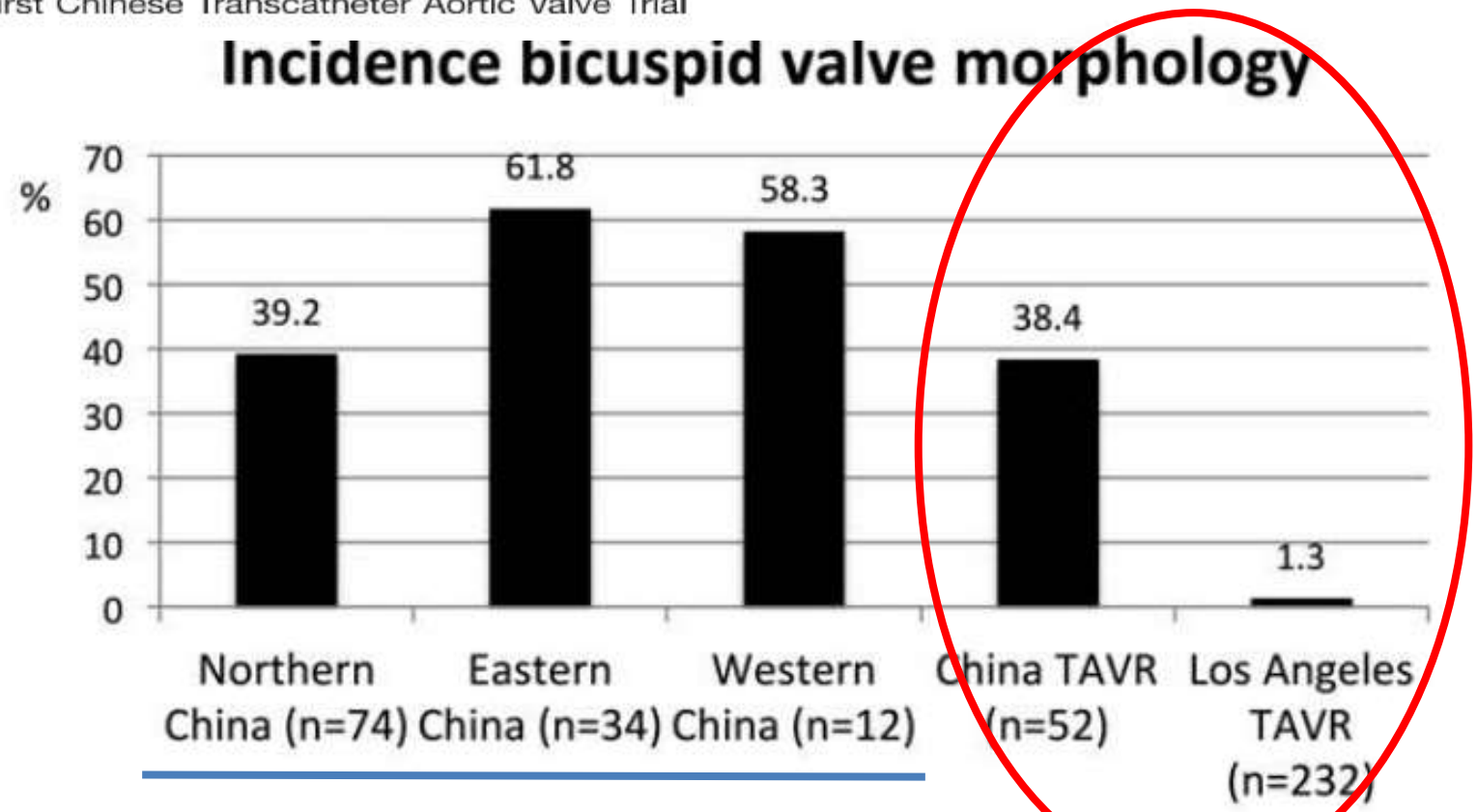
# Outcomes（N=101）

| | |
|---|---|
| Immediate Procedural Success | 95 (95%) |
| Death | |
| Cardiac Death | 3 (3.0%) |
| Non-cardiac Death | 2 (2.0%) |
| Myocardial Infarction | 2 (2.0%) |
| Stroke (TIA) | 1 (1.0%) |
| Complication at Puncture Sites | 6 (6.1%) |
| Surgical Intervention | 3 (3.0%) |
| Renal Failure | 2 (2.0%) |
| Permanent Pacemaker | 19 (18.8%) |

# Morphological Characteristics of AS in China

Catheterization and Cardiovascular Interventions 85:752–761 (2015)

**Morphological Characteristics of Severe Aortic Stenosis in China:** Imaging Corelab Observations From the First Chinese Transcatheter Aortic Valve Trial




**TAVR candidates**

Jilaihawi H, CCI 2015: 85(4):752-761

*The Needs of The Patients and The Customers Come First*

# Prevalence of BAV

- Bicuspid aortic valve (BAV) is a heritable disease with a prevalence of 0.5 to 2% in the general population in western countries [1-3].
- No epidemiology data in China. One Chinese hospital-based echo survey indicated 0.85% of patients were BAV in 287,556 cases from 2004 to 2011 [4].


1. Steinberger et al. Pediatrics 2000;105:815-8.
2. Roberts et al. Circulation 2005;111:920-5.
3. Sievers et al. J Thorac Cardiovasc Surg 2007;133:1226-33.
4. Pan et al. Int J Cardio 2013; 168:e133-134.




- The prevalence of patients with BAV may be same between China and Western.
- The cause for more number of patients with BAV for TAVR in China may be from the Chinese culture and long-term poor economy state 20 year ago



European Heart Journal
doi:10.1093/eurheartj/ehs109



**Table 10 Contraindications for transcatheter aortic valve implantation**

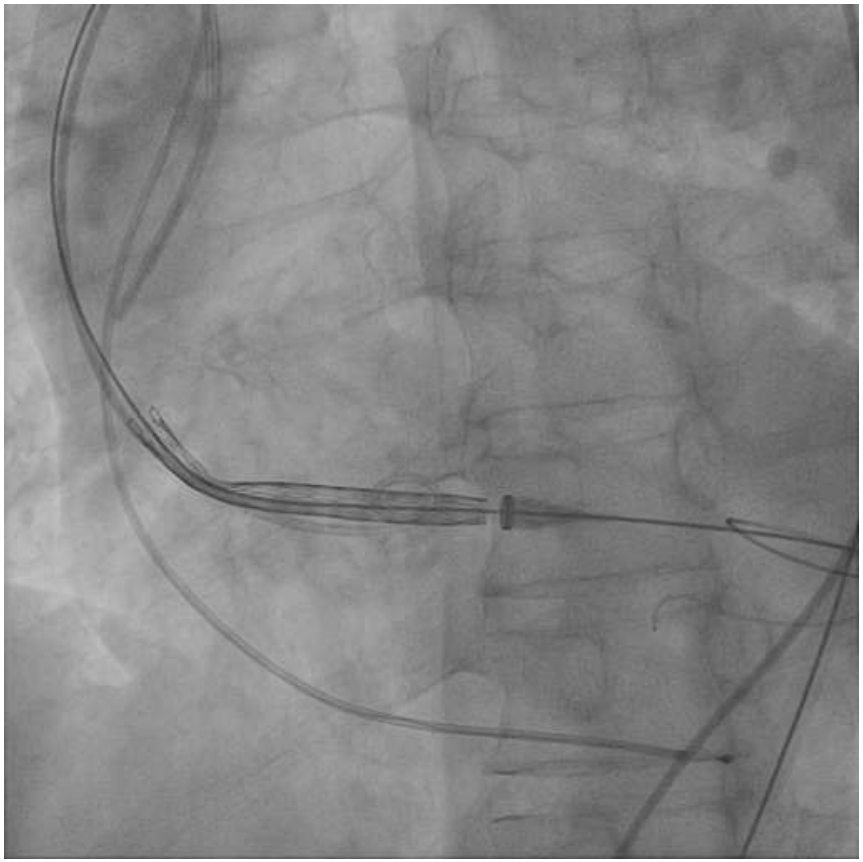
| |
|---|
| **Absolute contraindications** |
| Absence of a 'heart team' and no cardiac surgery on the site |
| Appropriateness of TAVI, as an alternative to AVR, not confirmed by a 'heart team' |
| *Clinical* |
| Estimated life expectancy <1 year<br>Improvement of quality of life by TAVI unlikely because of comorbidities<br>Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery |
| *Anatomical* |
| Inadequate annulus size (<18 mm, >29 mm[a]) |
| Thrombus in the left ventricle |
| Active endocarditis |
| Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses) |
| Plaques with mobile thrombi in the ascending aorta, or arch |
| For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity) |
| **Relative contraindications** |
| Bicuspid or non-calcified valves |
| Untreated coronary artery disease requiring revascularization |
| Haemodynamic instability |
| LVEF <20% |
| For transapical approach: severe pulmonary disease, LV apex not accessible |

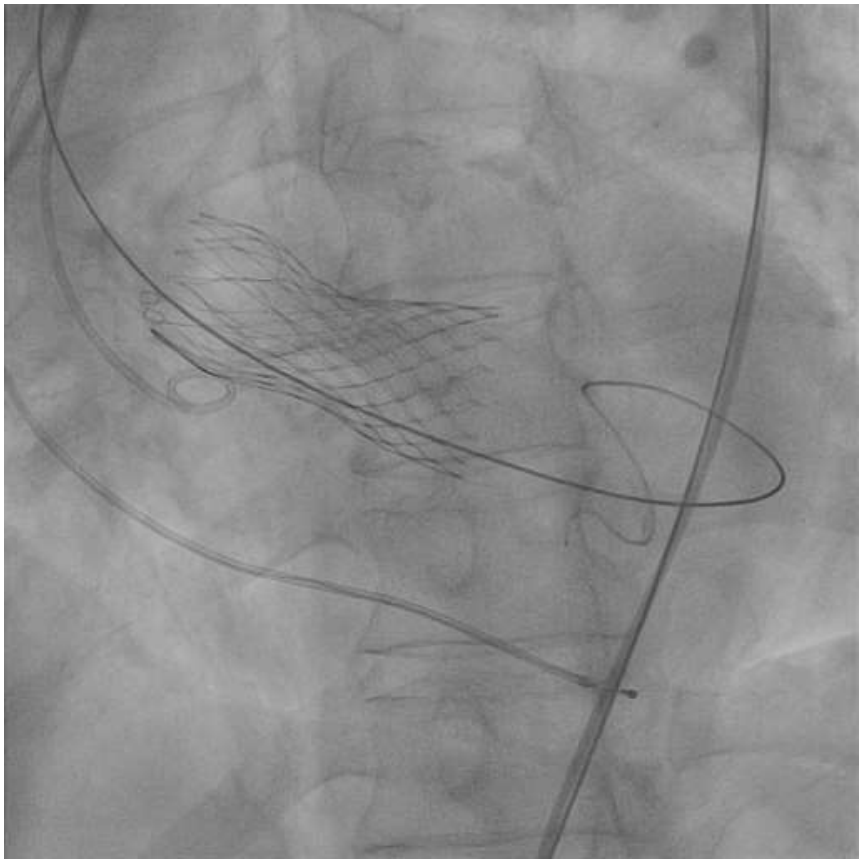
# Why relative contraindication?

- Challenges
  - Asymmetric calcification and leaflet closure
  - Frequent highly angulated annulus
  - More likely to have aortic pathology: aneurysms, dissections
  - Residual aortic regurgitation
  - Valve malpositioning
  - Possible more incidence of annulus rupture and aortic dissection
  - ……

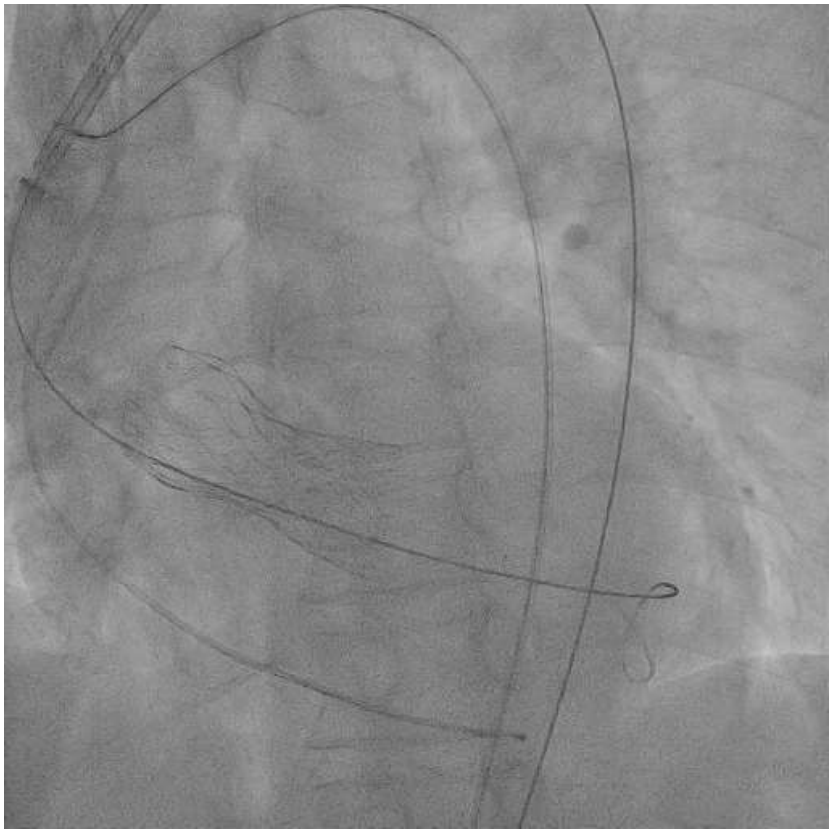


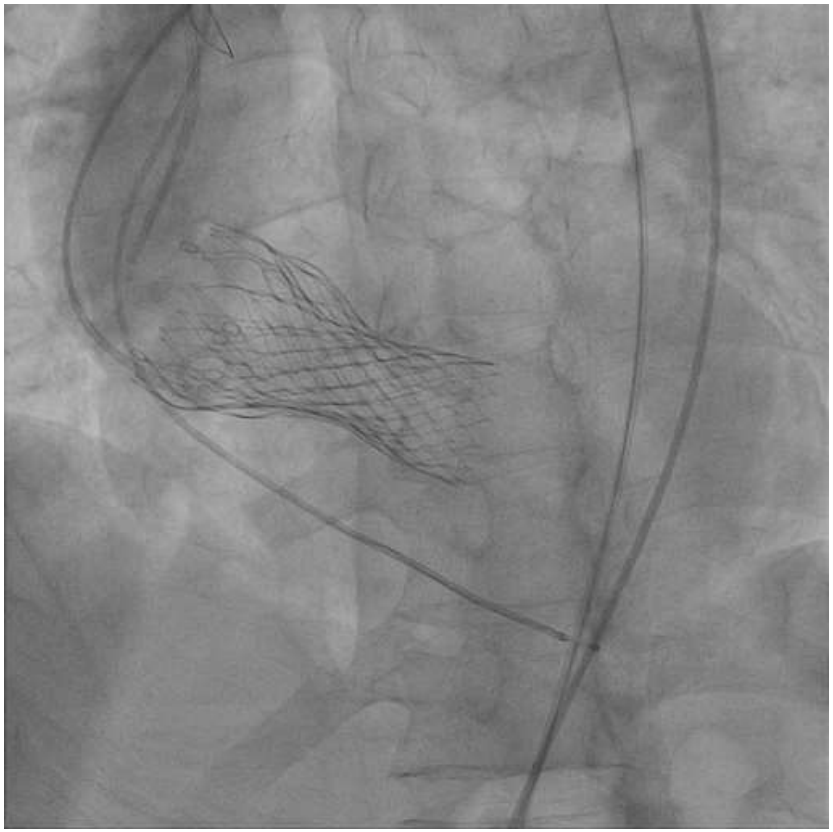
# Always deeper implantation and more PVL





Horizontal aorta, Valve in Valve





Horizontal aorta, Valve in Valve

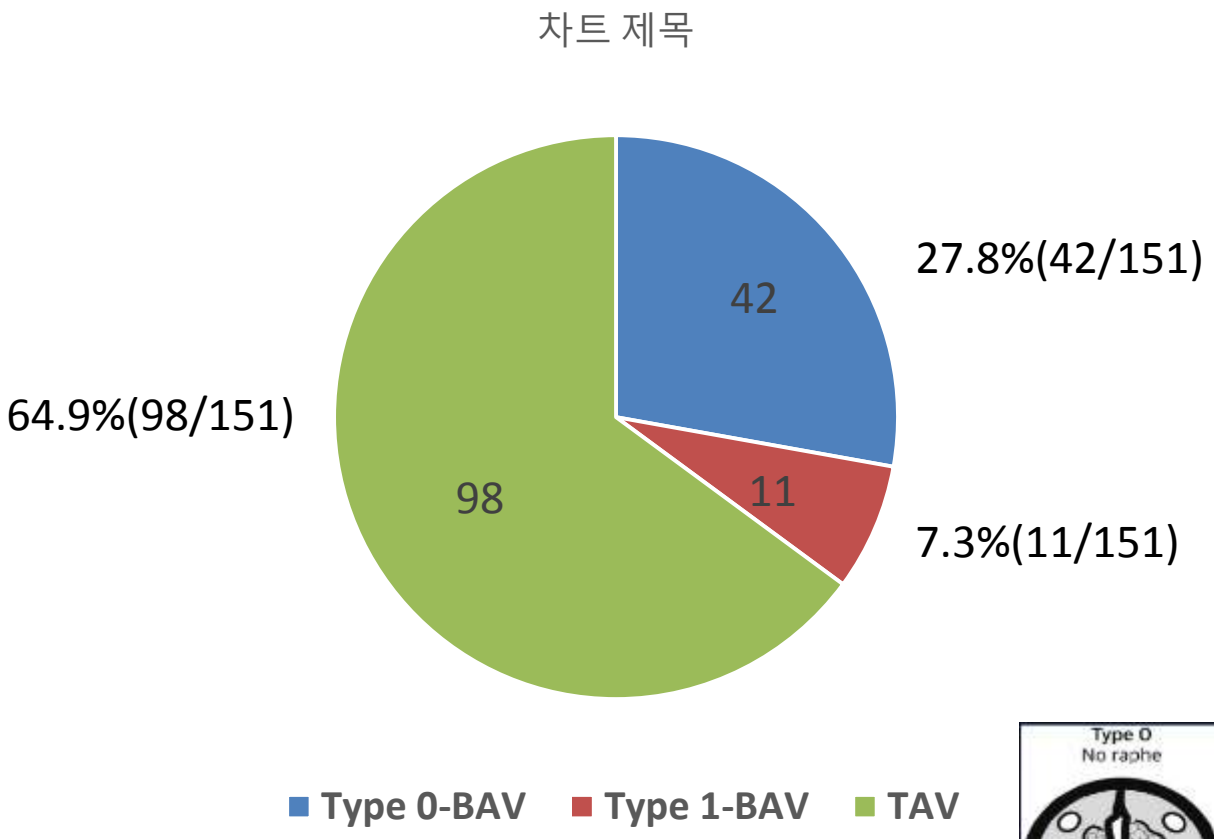
# How to  solve the problem?

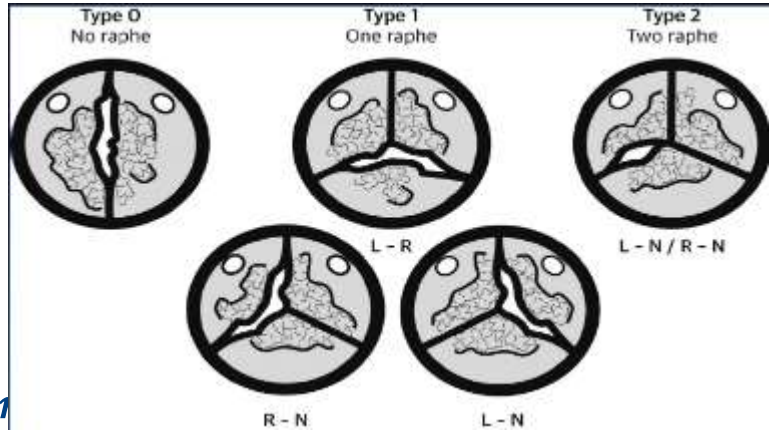


# Single Center Experience from SAHZU

- One of the 3 leading TAVR centers in China
- 151 cases in total
- First pure AR case and  in first Lotus implantation in China
- Prosthesis Type: CoreValve, Venus A, Microport Valve, Lotus
- Access: TF (96%), DAA (2%), Subclavian (1.3%), Carotid (0.7%)
- Outcomes:
  - Immediate procedural success: 98.7%
  - 30d mortality: 3.9%
  - Pacemaker implantation: 16.6%
  - Stroke (minor): 3.3%

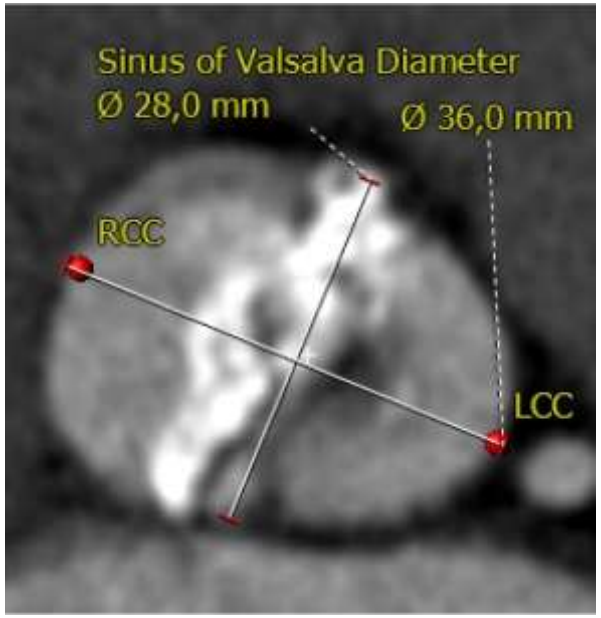
# TAVR in SAHZU

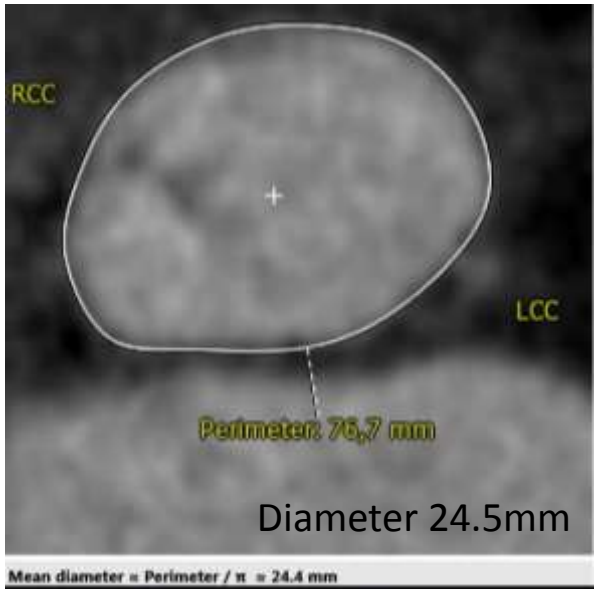


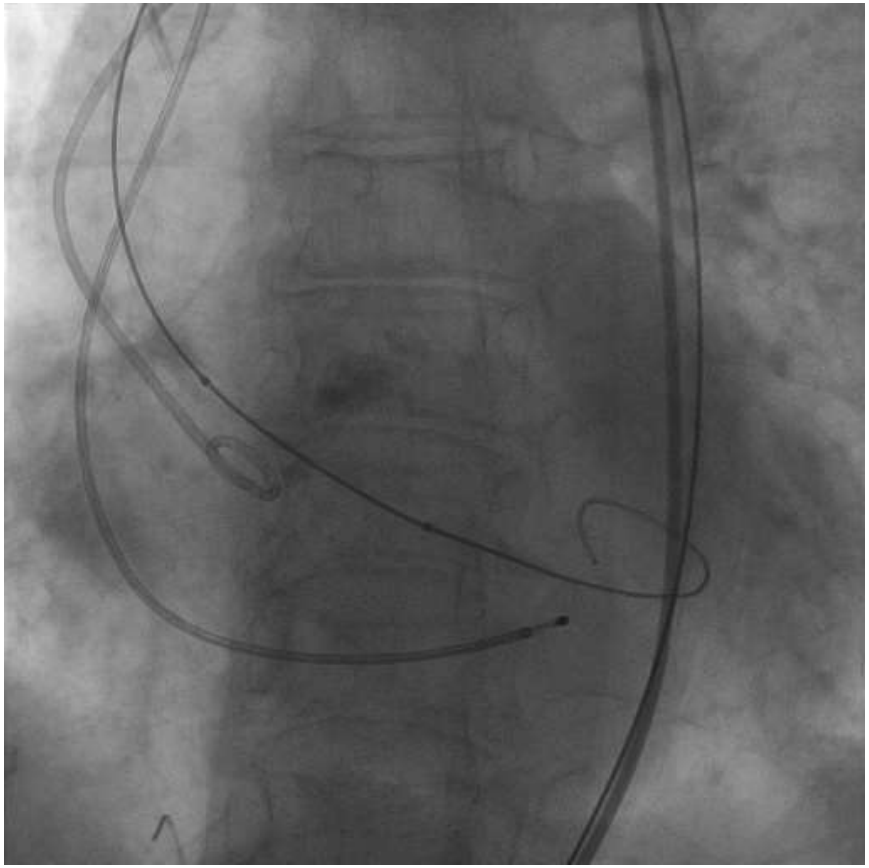

*The Needs of The Patients ar*

# Balloon sizing to downsize the valve



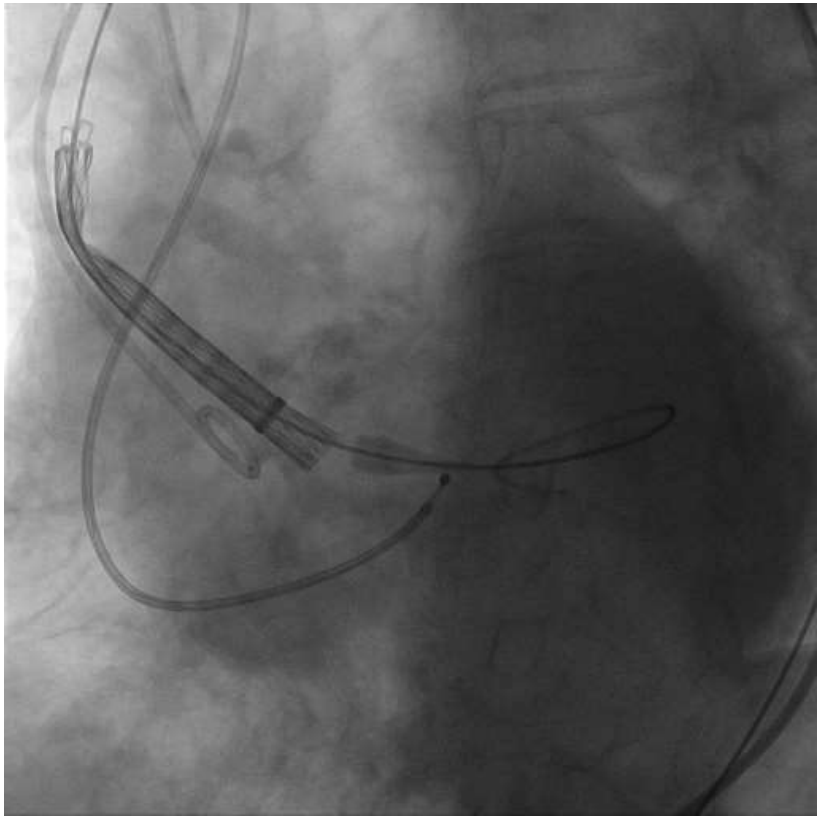



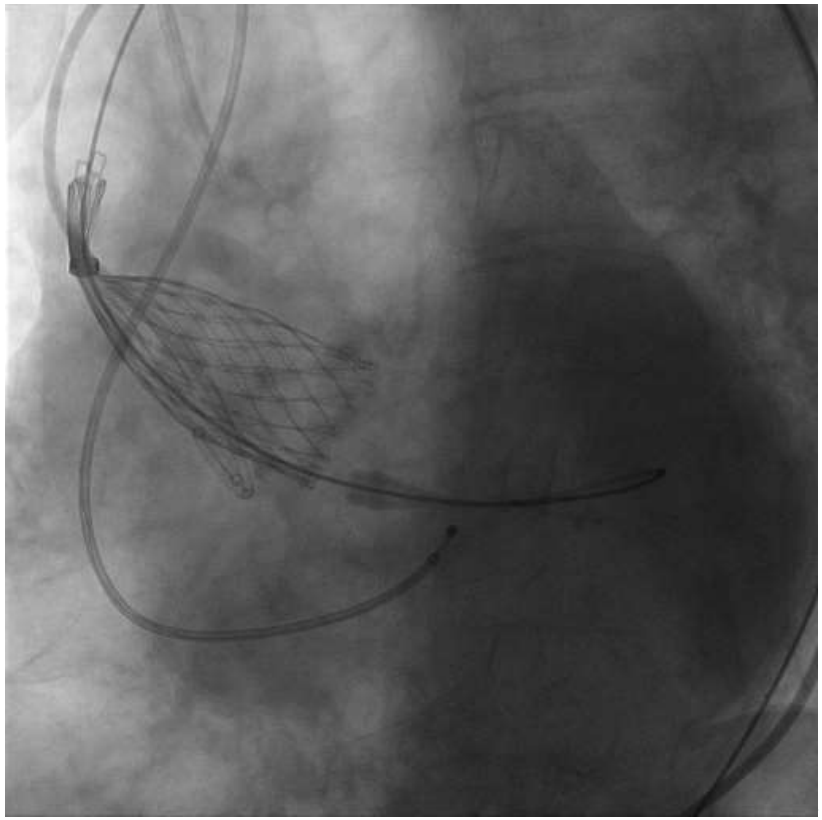

Diameter 24.5mm



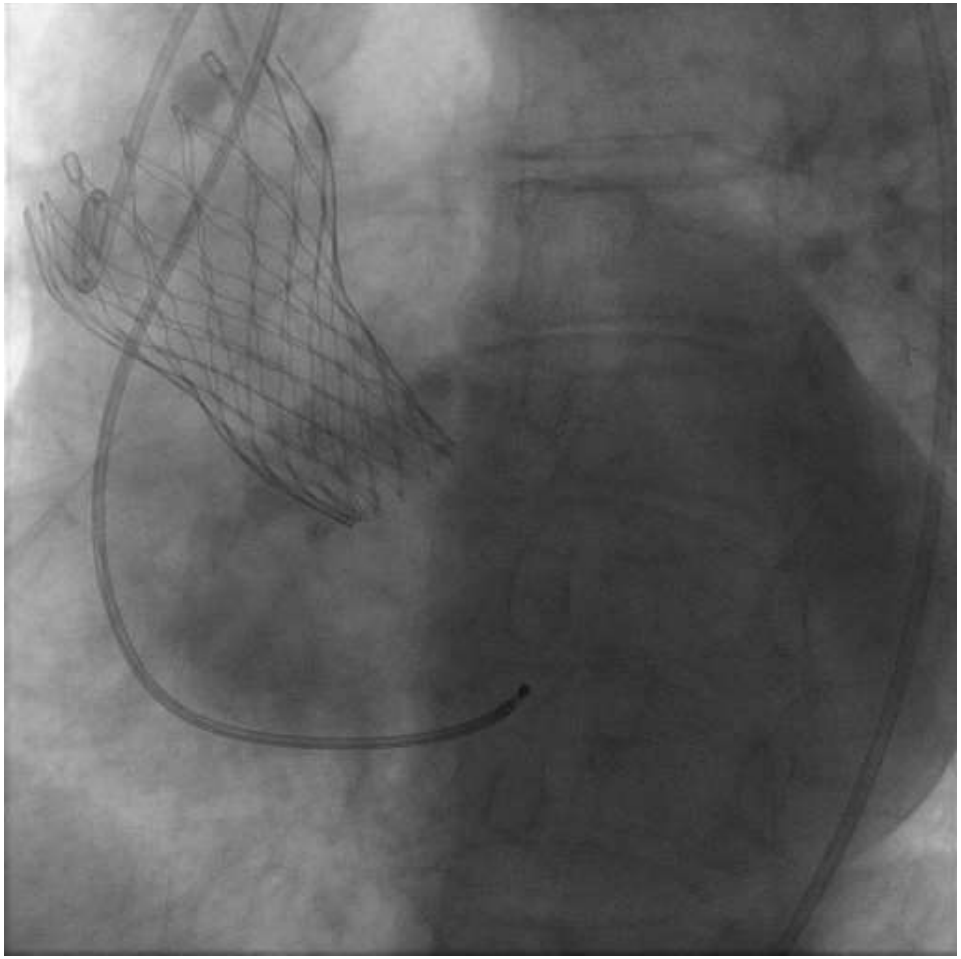
Downsize to 26 mm CoreValve

# Higher implantation





# Final Result



# Single Center Experience

| Characteristics% or Mean±SD | BAV (n=50) | TAV (n=93) | *P* value |
|---|---|---|---|
| Age (yrs) | 74.4±6.5 | 75.4±5.5 | 0.233 |
| Male | 48.0 | 74.2 | 0.003 |
| STS Score | 7.4±4.0 | 7.6±5.4 | 0.872 |
| Logistic EuroSCORE | 19.5±10.5 | 21.5±13.4 | 0.721 |
| NYHA III or IV | 86.0 | 92.5 | 0.214 |



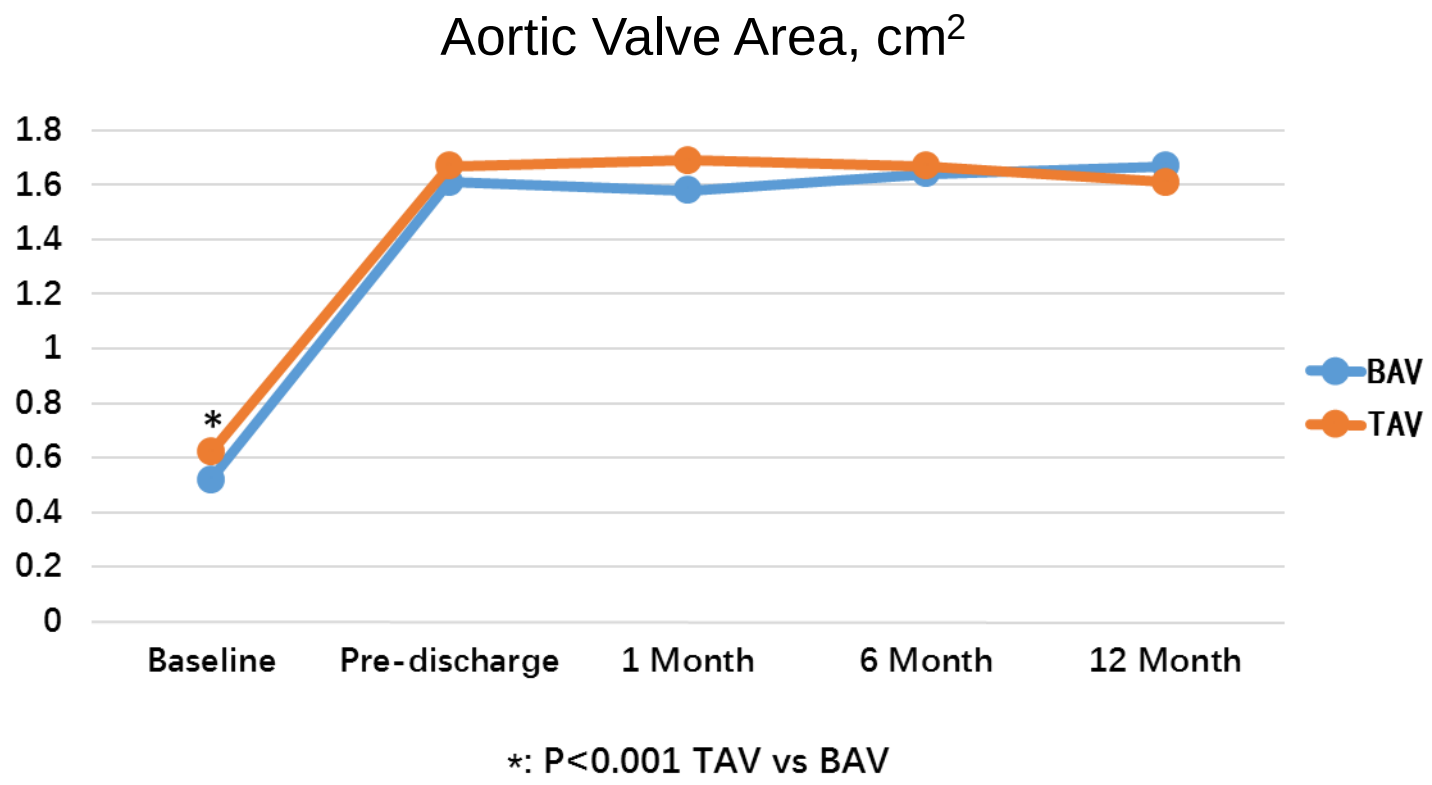
# 30d outcomes

| Outcome, % | BAV (n=50) | TAV (n=93) | P value |
|---|---|---|---|
| 30d mortality | 6.0* | 3.2* | 0.415 |
| Stroke (minor) | 6.0 | 2.2 | 0.343 |
| Myocardial Infarction | 2.0 | 0.0 | 0.143 |
| Pacemaker | 10.0 | 20.4 | 0.122 |

*Only two patients died in 30 days in latest 100 cases, 1 in BAV and 1 in TAV, respectively.

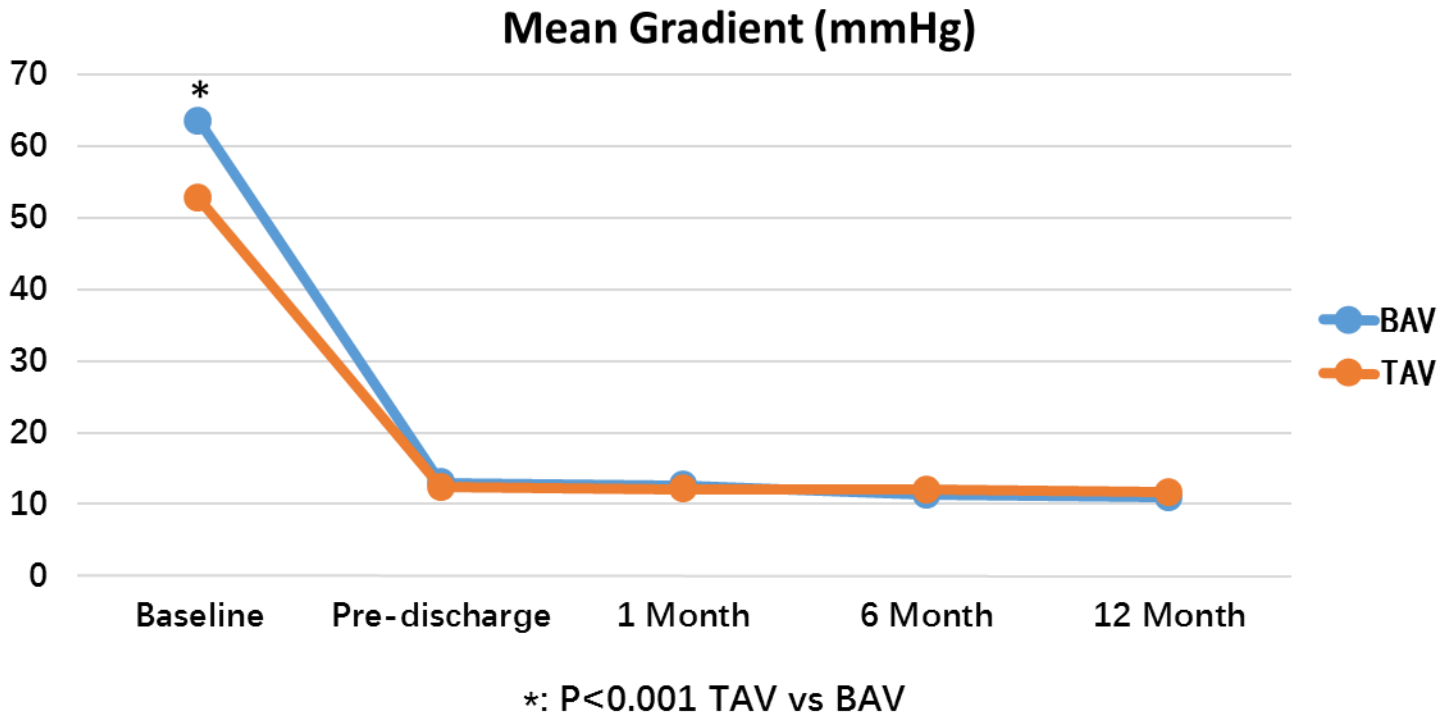


# Aortic Valve Area



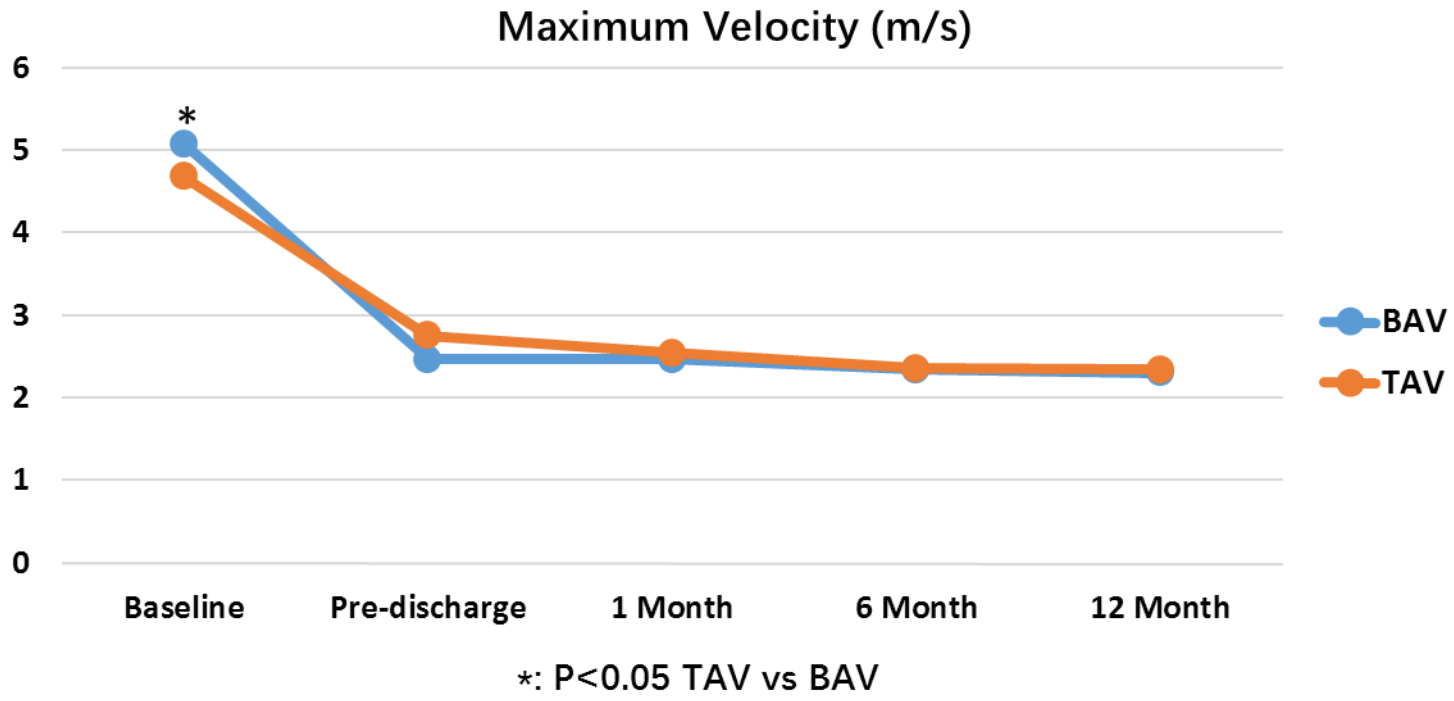

*: P<0.001 TAV vs BAV

# Mean Gradient




*: P<0.001 TAV vs BAV

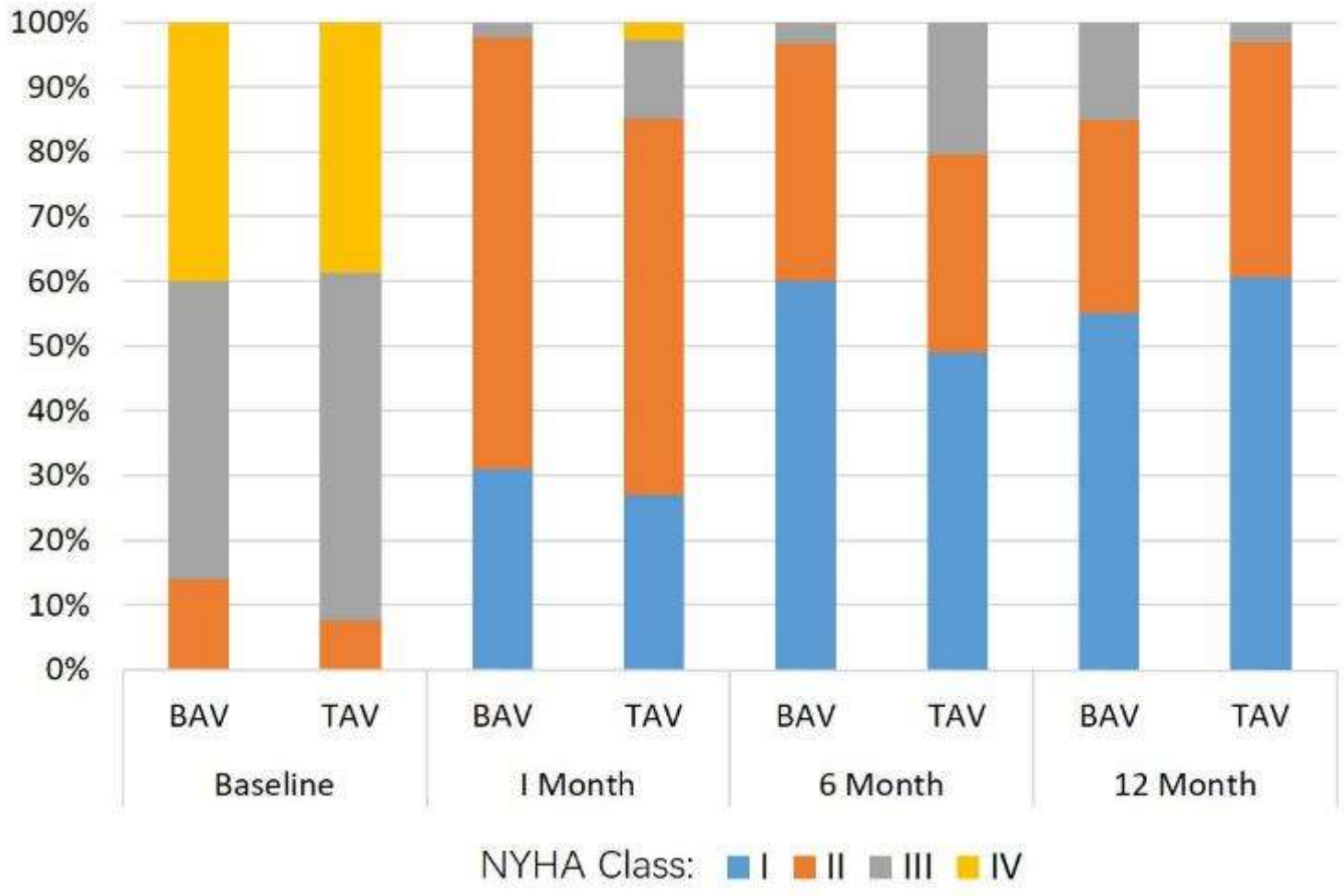
# Maximum Velocity




*: P<0.05 TAV vs BAV

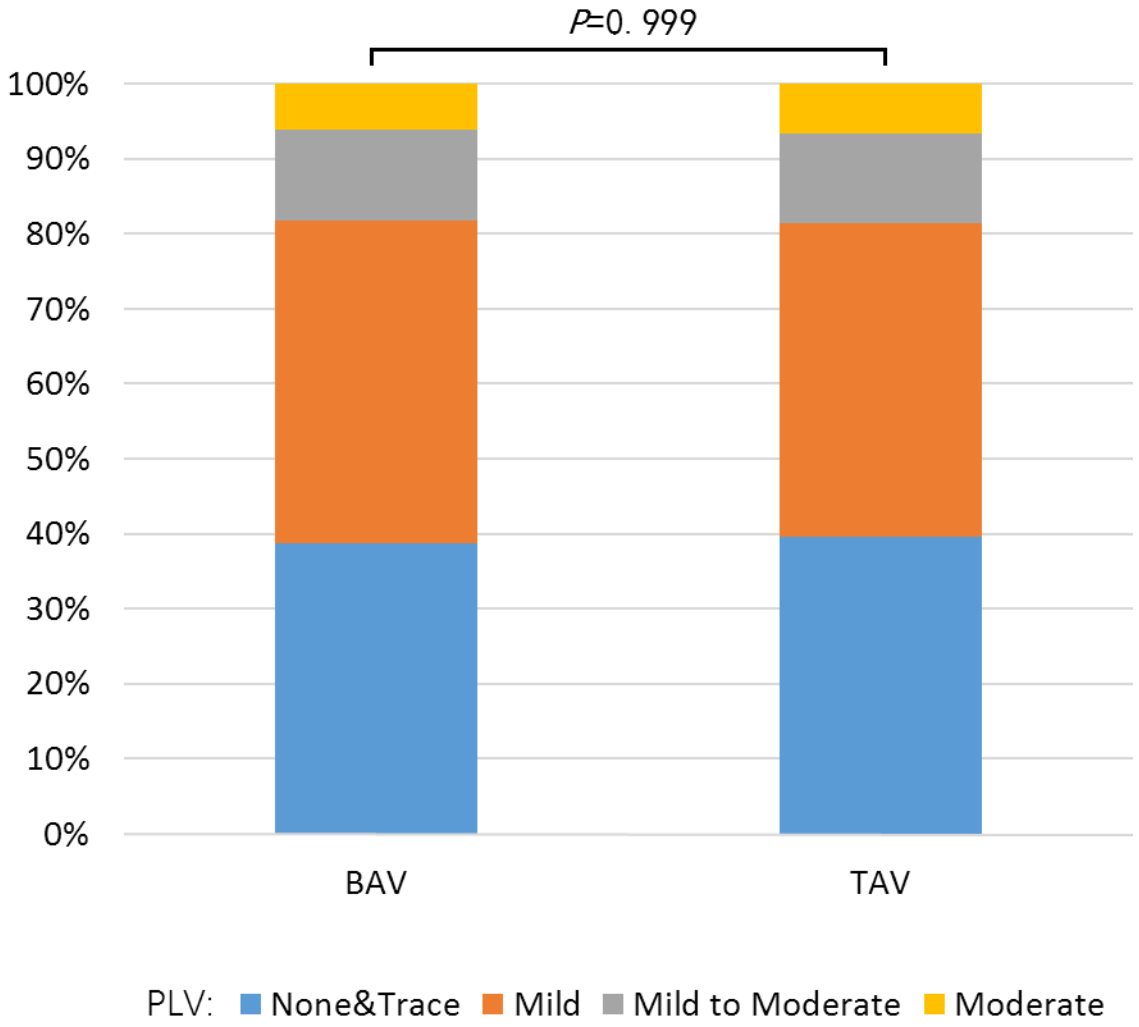
# NYHA

No differences in heart function recovery



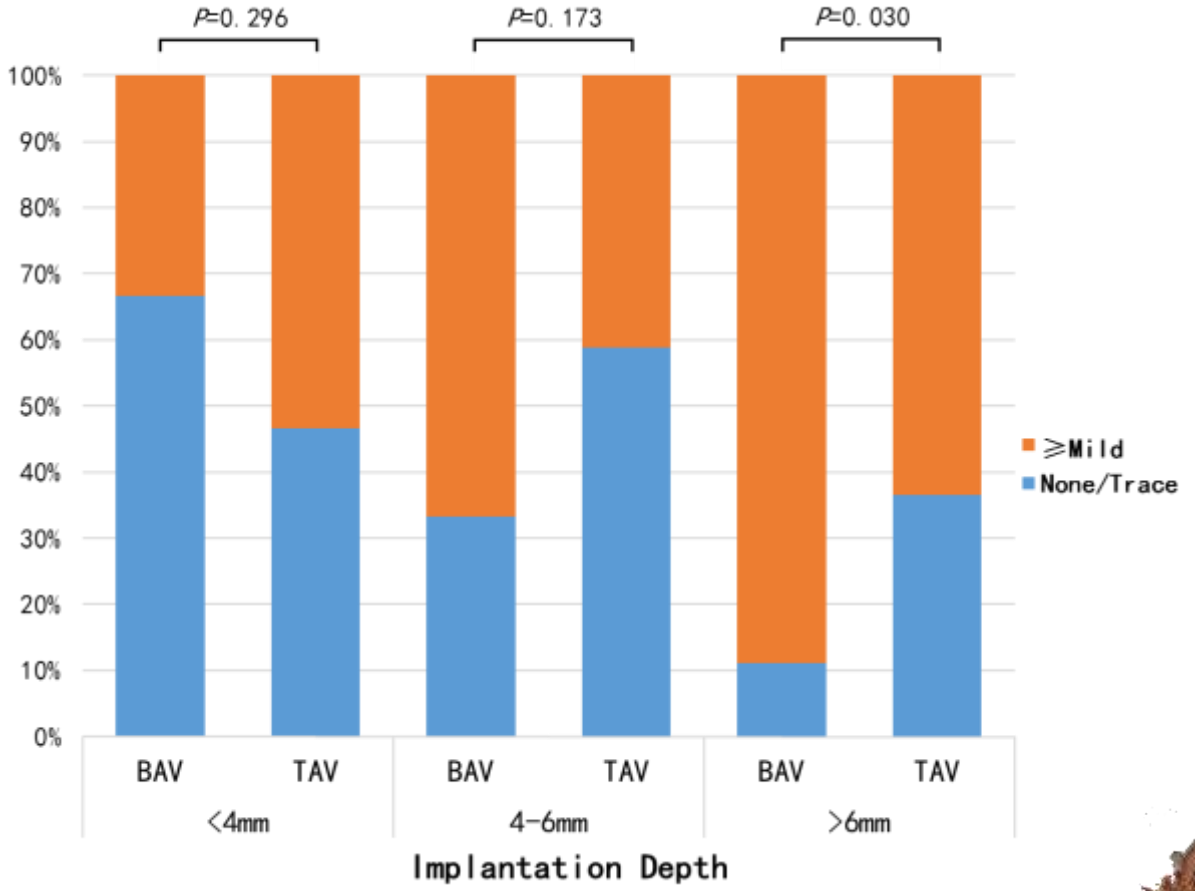

*The Needs of The Patients and The Customers Come First*

# PVL

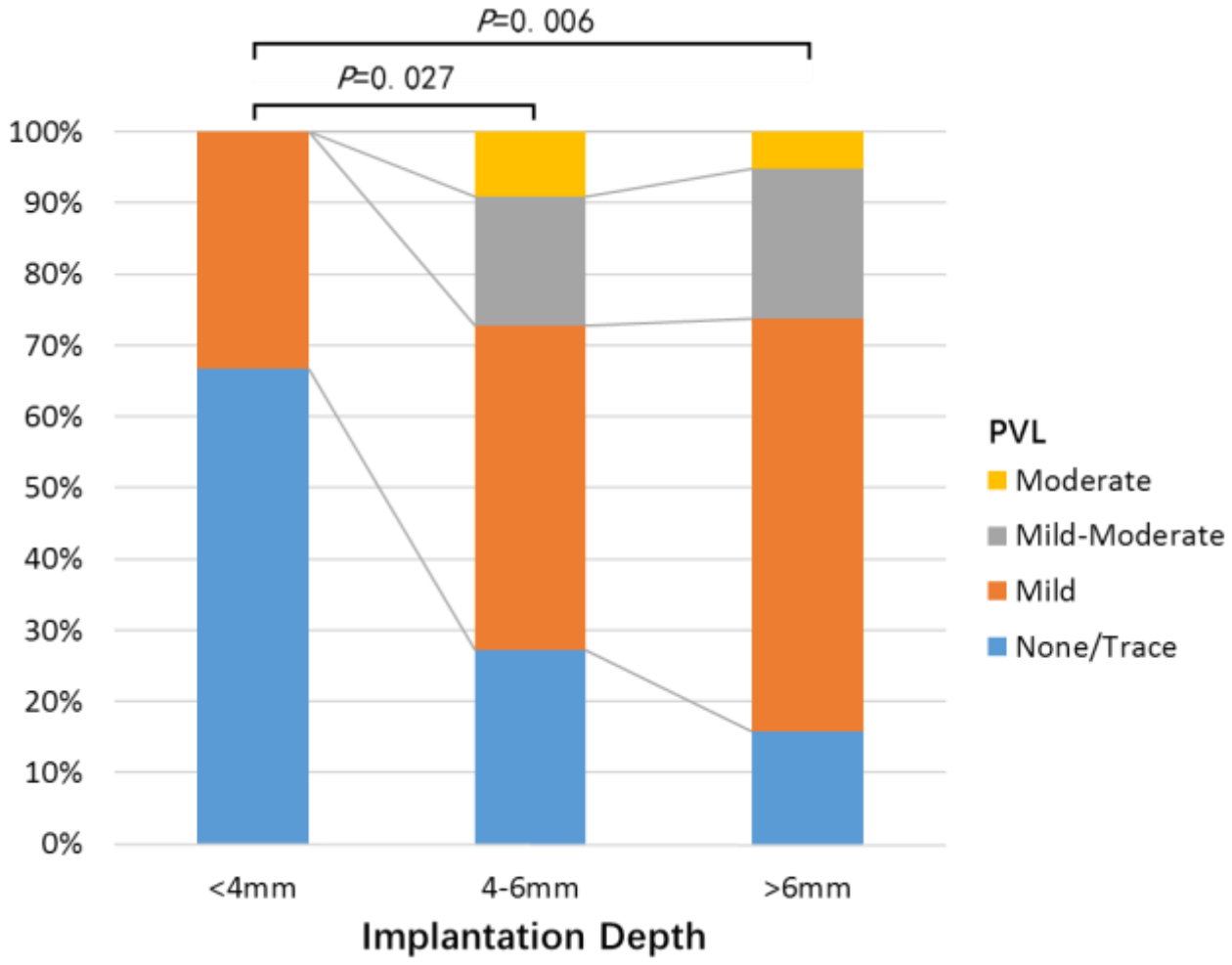

P=0. 999
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
BAV
TAV
PLV:
None&Trace
Mild
Mild to Moderate
Moderate

# Effect of Implantation Depth on PVL

- There is a trend of more PVL in BAV group in case of standard deployment (4-6mm)
- More PVL in BAV group in case of deeper implantation (>6mm)



# PVL in BAV

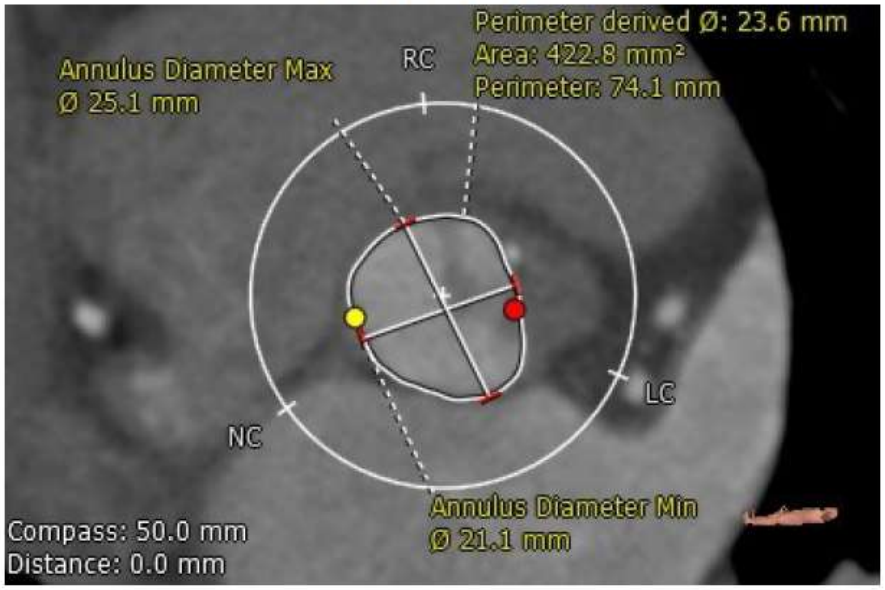

P=0. 006
P=0. 027
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
<4mm
4-6mm
>6mm
Implantation Depth
PVL
Moderate
Mild-Moderate
Mild
None/Trace

# New Device

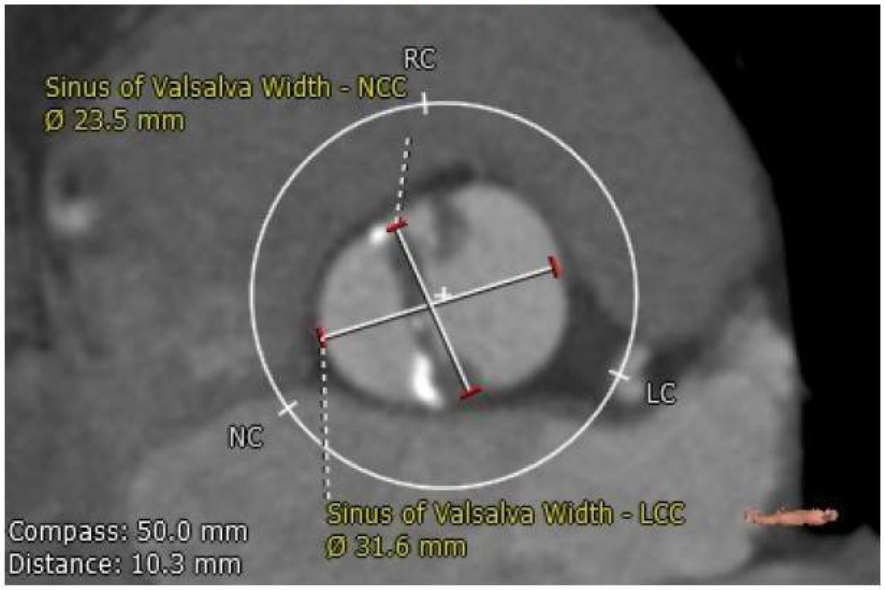
- 2nd Nov. 2015
- Type 0 BAV

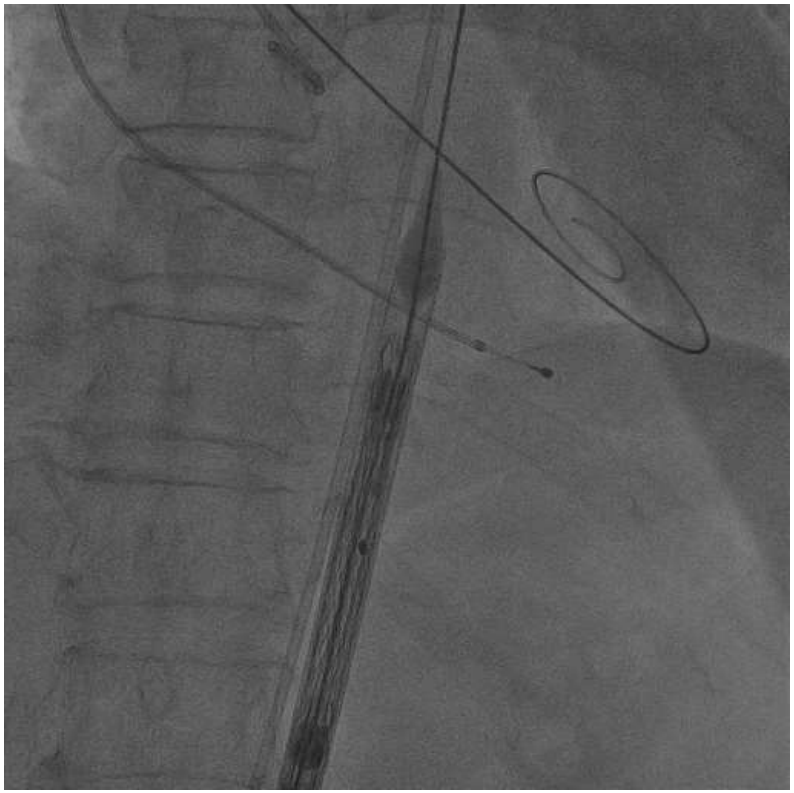
## Aorta

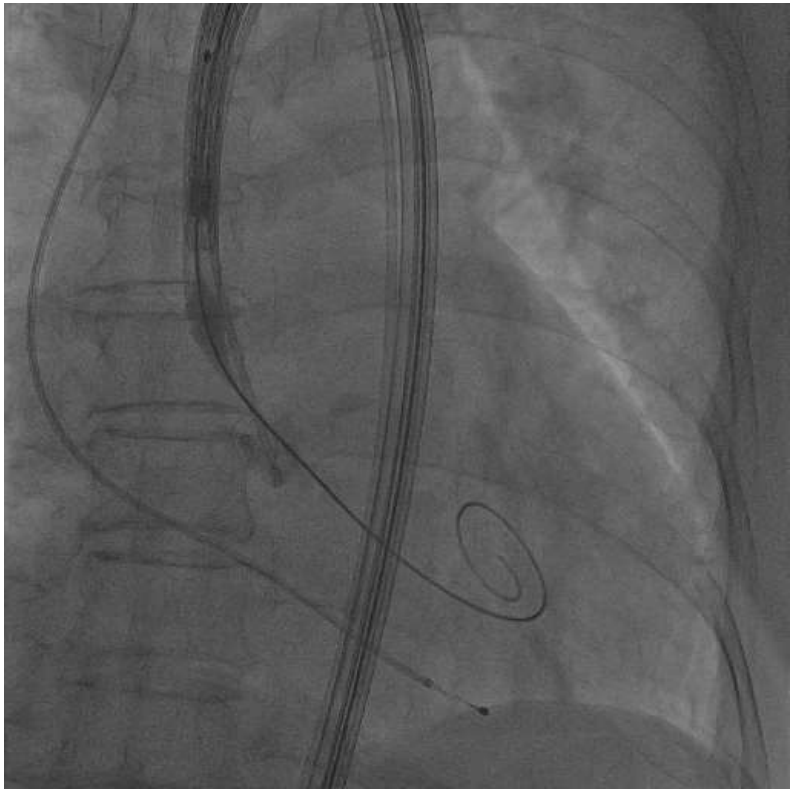
ANNULUS

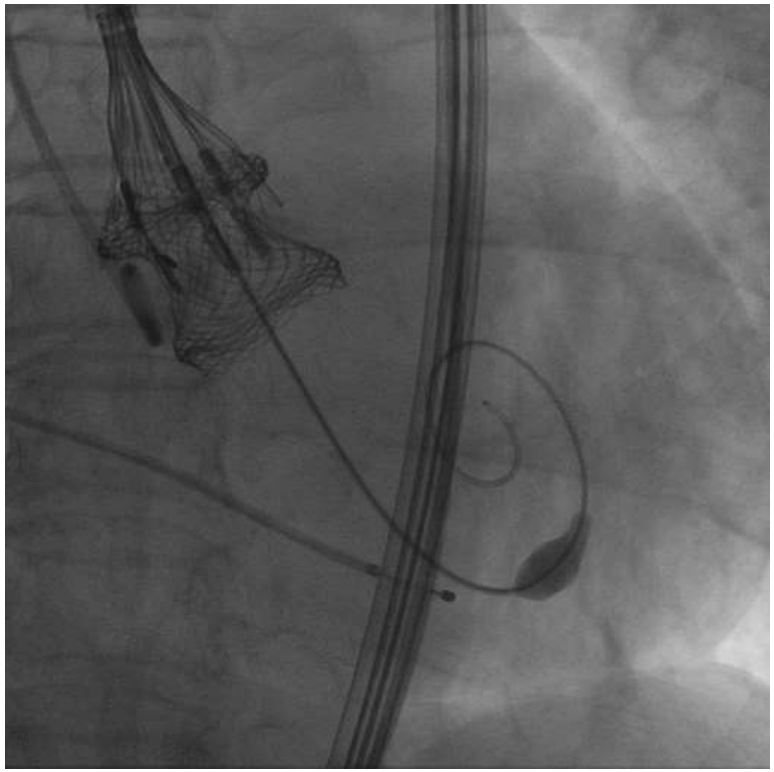


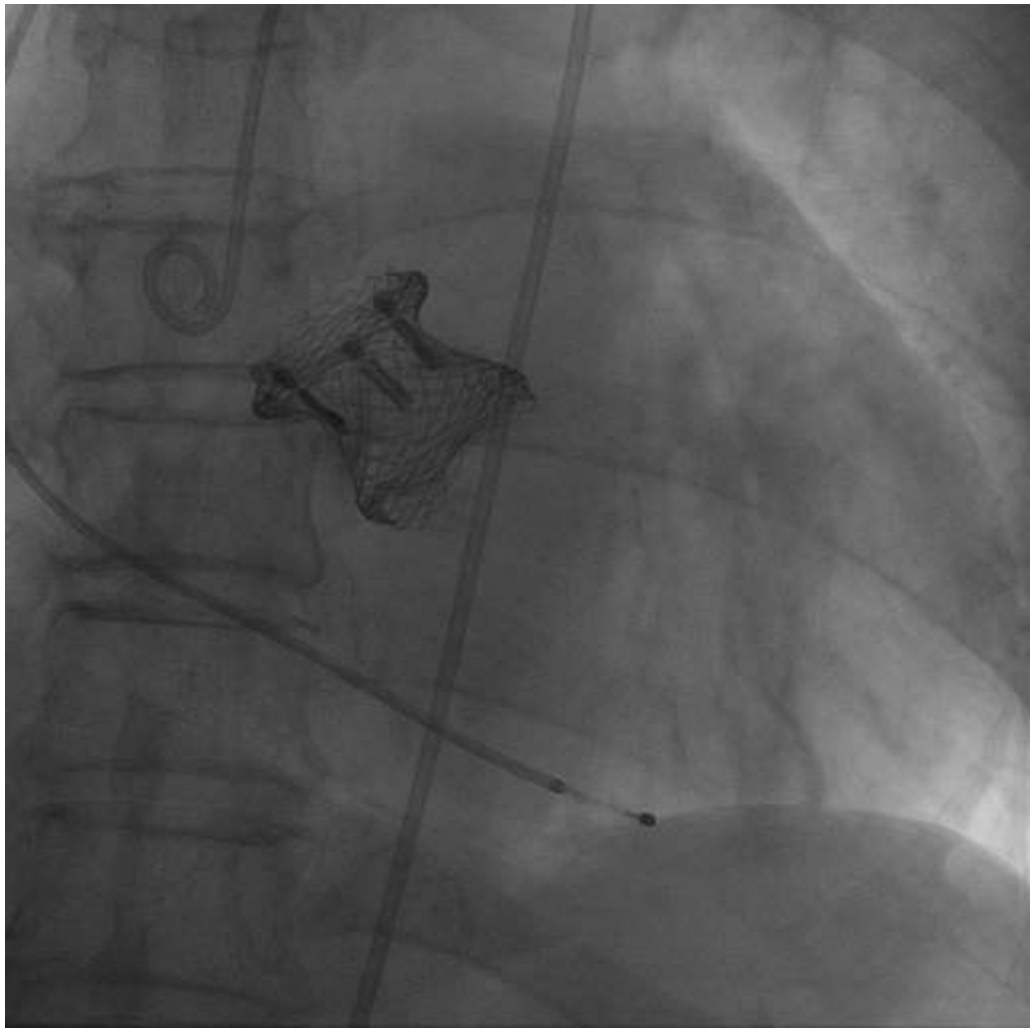

SOV DIAMETER











# Conclusions

- The proportion of BAV is higher in Chinese TAVR centers.
- We found higher implantation and downsize of valve might be the solution to TAVR for BAV.
- Thirty-day outcomes of our experience indicates TAVR can be safely performed in patients with BAV.
- Newer generation valves with sealing technology and repositionability may be better for this morphology.