Solutions to complex TAVI

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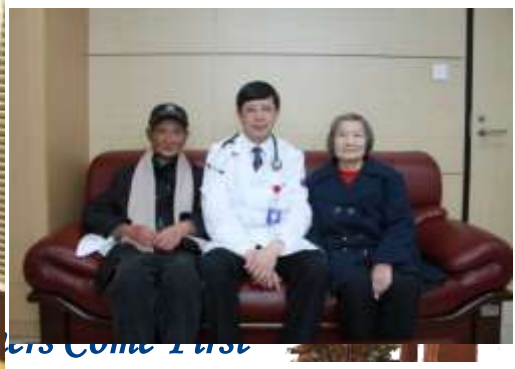
Disclosure Statement of Financial Interest

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.

Single Center Experience

- One of the top TAVI centers in China.
- 64 cases in total.
- First 3 cases of TF-TAVI for pure non-calcified AR in China.
- TAVI live demo in annual scientific session of China Society of Cardiology in 2014.

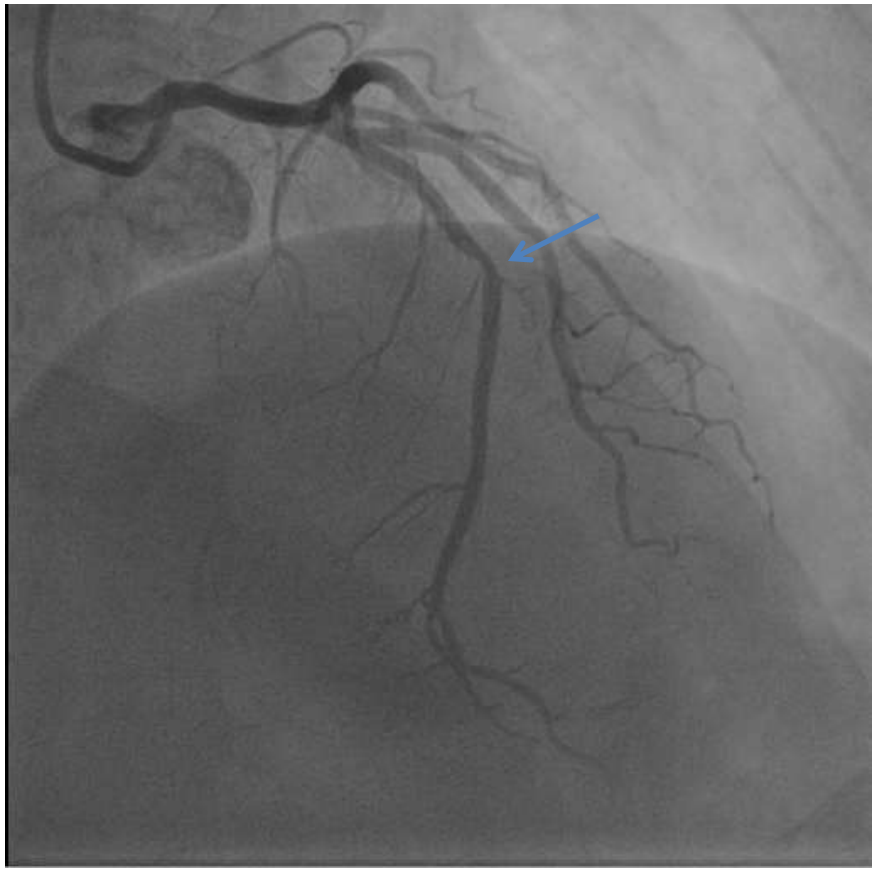


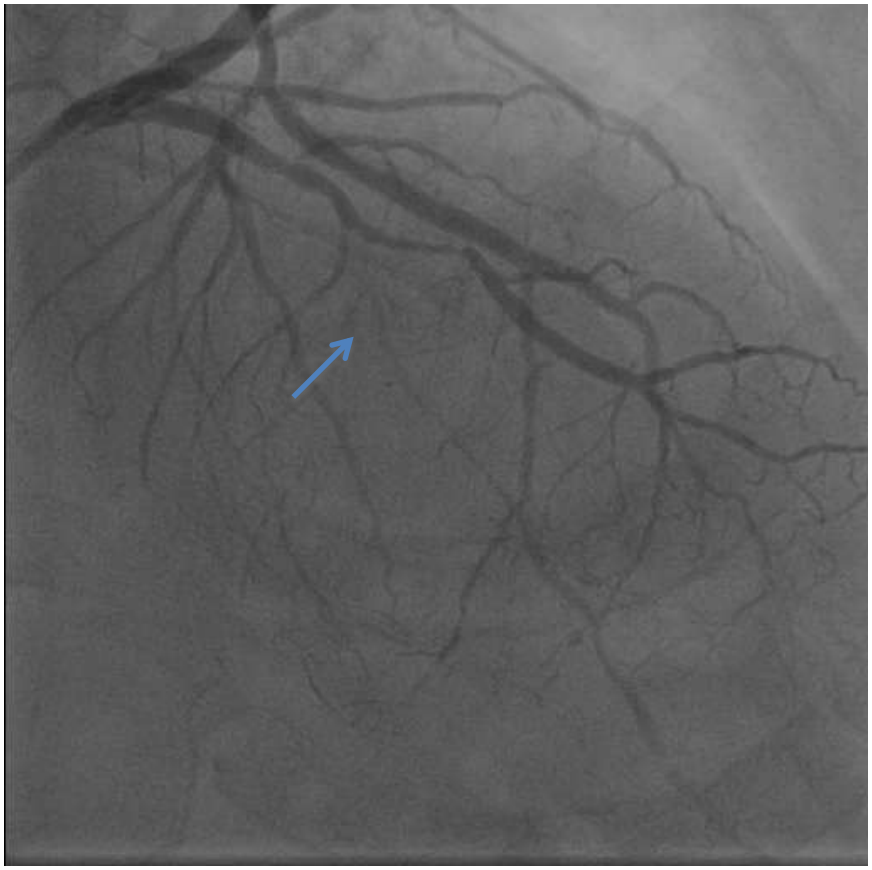



Procedural Results

Immediate procedural success	98.4%
30d mortality	4.7%
Major vascular complications	1.9%
Stroke (major/minor)	4.7 %(minor)
Permanent pacemaker implantation	15.6%

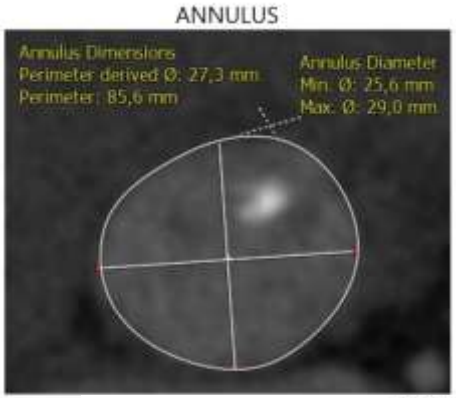
Type A and C coronary lesions

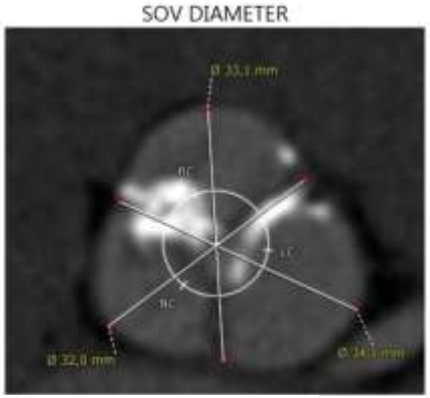


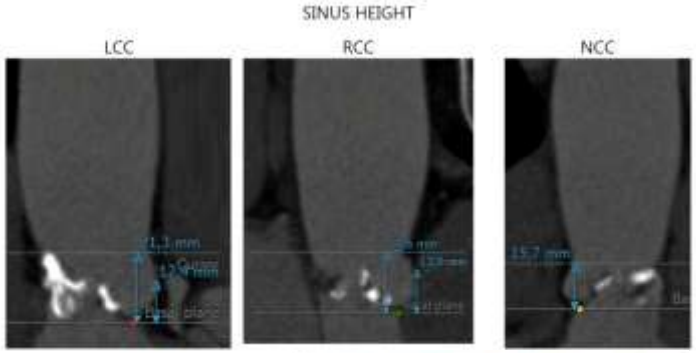


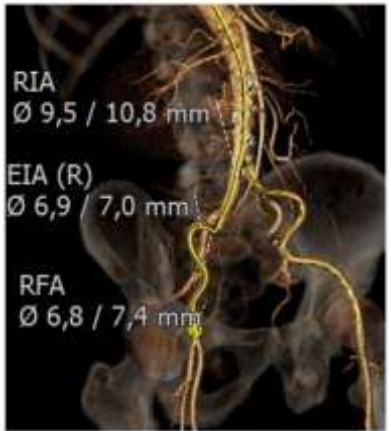
“Type A” TAVI lesion

- Tricuspid aortic valve
- Annulus diameter 20-26mm
- Round annulus
- Moderate calcification
- Width of valsalva sinus > 27mm
- Coronary height > 10mm
- Small angulation
- Femoral artery > 6mm
- No obvious tortuousness, calcification and dilation of aorta.









Characteristics of complex TAVI

- “Type C” TAVI lesion （one or more items as shown below）
  - Bicuspid aortic valve
  - Large annulus
  - No or severe calcification
  - Small vascular access
  - Tortuous vascular pathway
  - Horizontal aorta
  - Porcelain aotra
  - Low height of coronary artery
  - ……

Solutions to Complex TAVI

- Bicuspid Aortic Valve
- Pure non-calcified aortic regurgitation
- Paravalvular leakage
- Small vascular access
- Low height of coronary artery

Solutions to Complex TAVI

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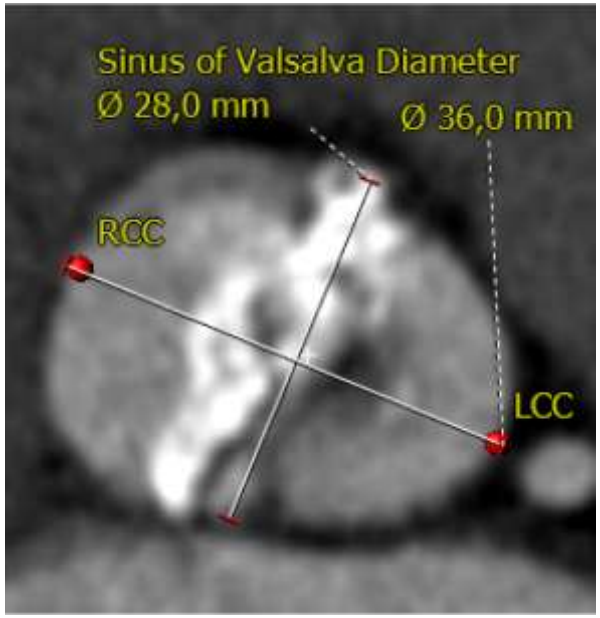
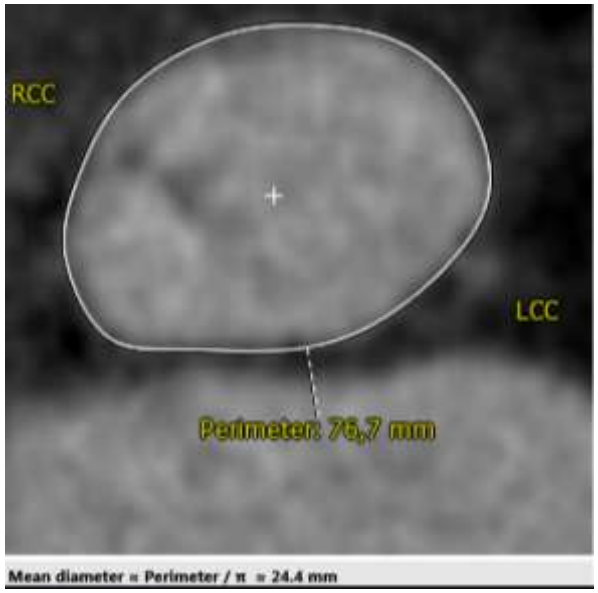
TAVI in BAV

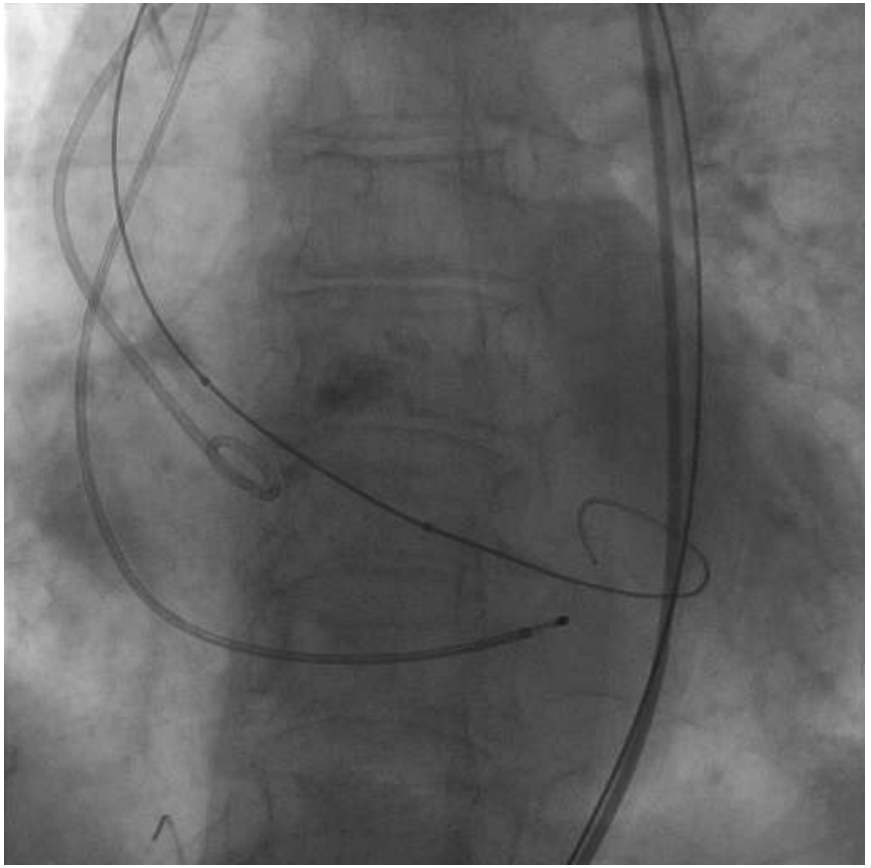
- Excluded from TAVI trials, such as PARTNER.
- Considered as a relative contraindication for TAVI.
- Challenges
  - Calcified raphe
  - Asymmetric aortic root calcification
  - Asymmetric leaflet closure
  - Frequent highly angulated annulus
  - Dilatation of the aortic root
- Procedural considerations
  - Oval deployment
  - Residual aortic regurgitation
  - Valve malpositioning
  - Annulus rupture
  - Aortic dissection

Smith CR et al. N Engl J Med 2011;364:1686-1695.
Leon MB et al. N Engl J Med 2010;363:1597-1607.

Balloon sizing to downsize the valve





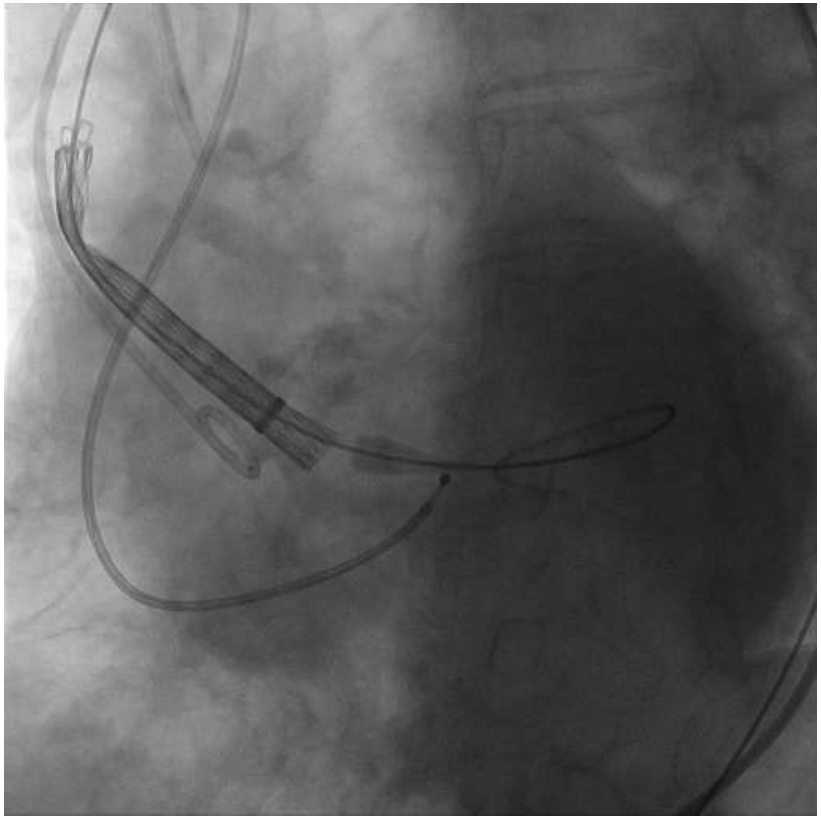


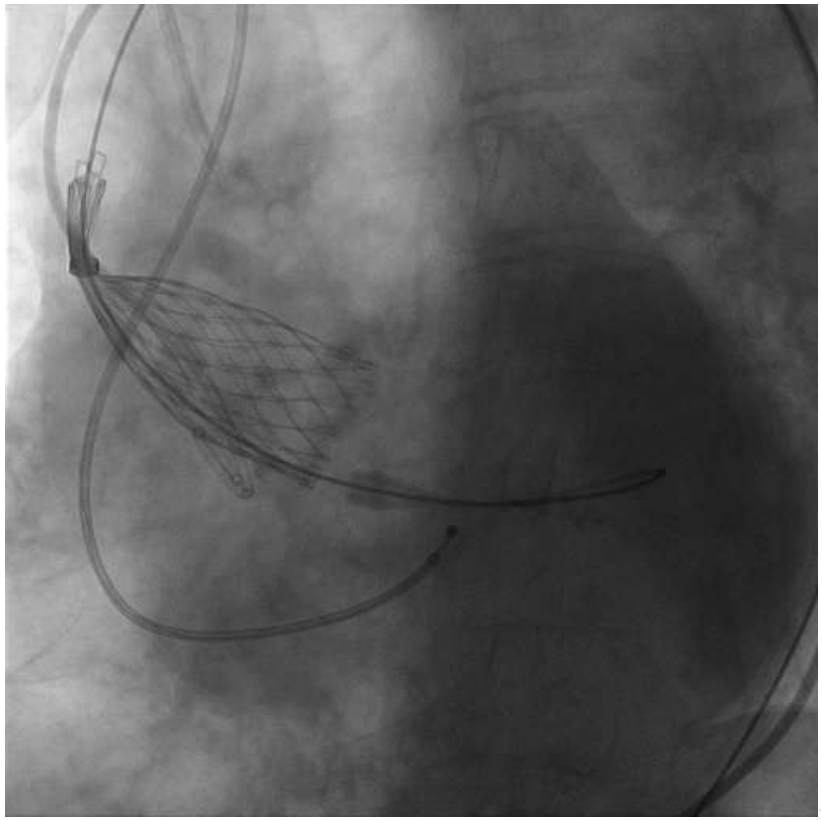
Z-MED II 23*40mm balloon

The Needs of The Patients and The Customers Come First

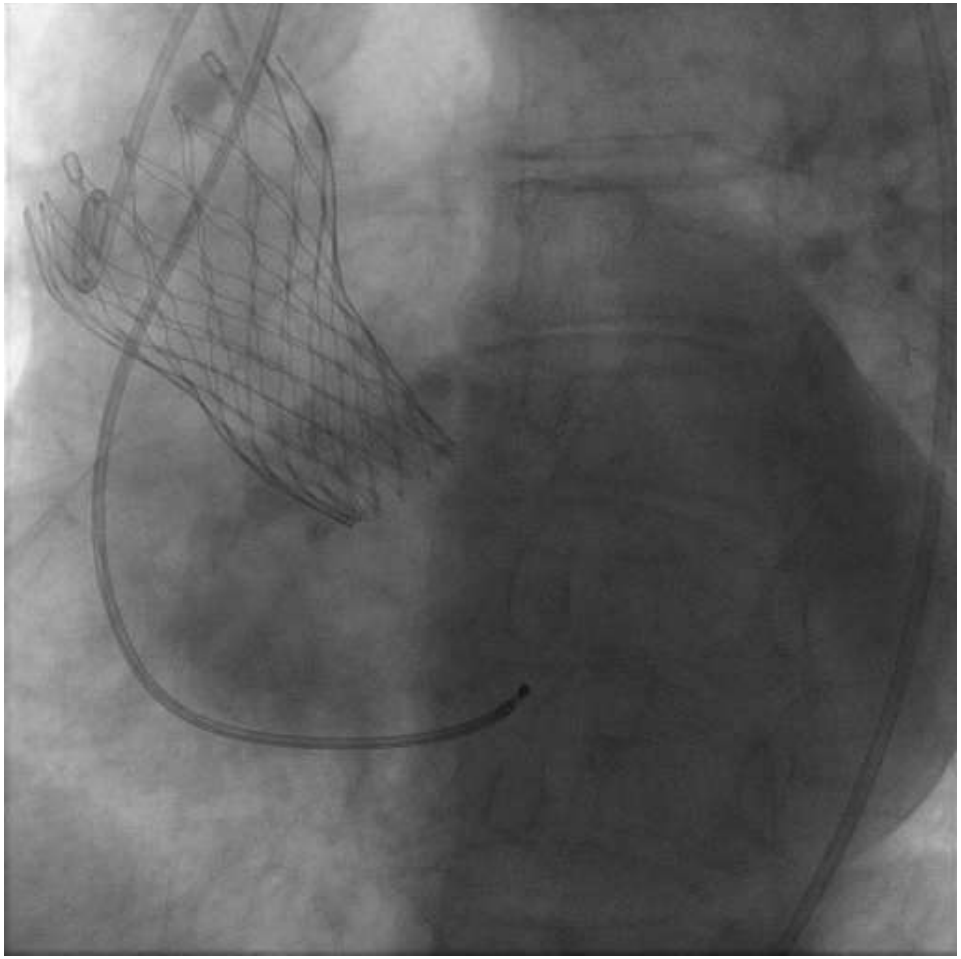
CoreValve 26mm

Starting to deploy at 0-2mm



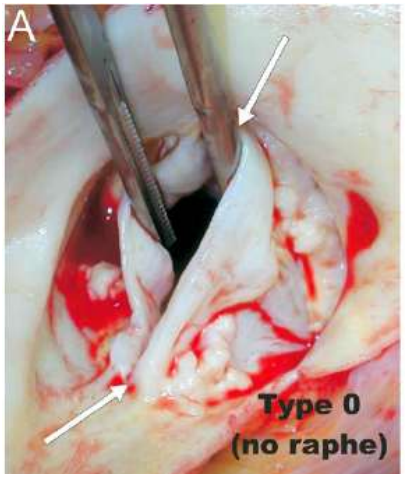


Final Result

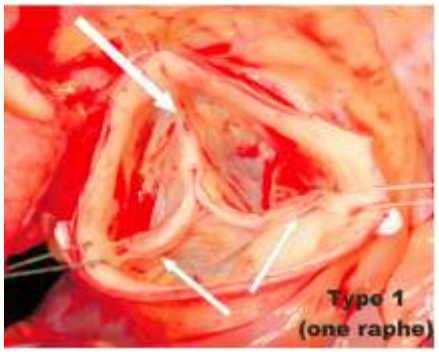


Our Experience

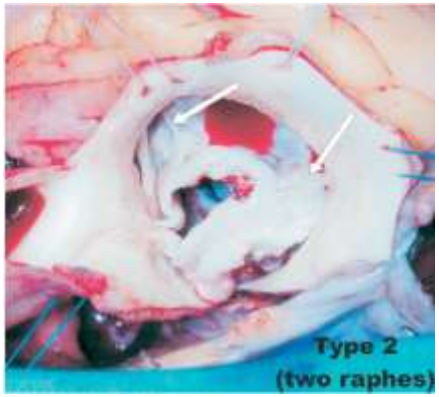
- 61 AS patients in total
  - BAV 25 (41%)
  - TAV 36



Type0 16 cases



Type1 9 cases



Type2 0 case

Sievers et al. J Thorac Cardiovasc Surg 2007;133:1226-33.

Our Experience

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Evaluation of the safety and efficacy of transcatheter aortic valve implantation in patients with a severe stenotic bicuspid aortic valve in a Chinese population*

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Transcatheter aortic valve implantation for Chinese patients with bicuspid aortic valve

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The recent paper by the corresponding author Jian-an WANG and his team entitled "Evaluation of the safety and efficacy of transcatheter aortic valve implantation in patients with a severe stenotic bicuspid aortic valve in a Chinese population" (Liu *et al.*, 2015), published in the *Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology)*, is very impressive. They evaluated the safety and efficacy of transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valve (BAV) and tricuspid aortic valve (TAV) for the first time in the Chinese population. This paper reported 40 cases of clinical experience of TAVI, and first explicitly put forward the indication of stenosis in the BAV. The early and mid-term outcomes between BAV and TAV groups are almost the same, and the high procedural success rate and low complication rate of their study are encouraging.

However, they found that the diameter of the ascending aorta in the BAV group ((40.4±4.4) mm) is larger than that in the TAV group. As we know, the BAV is often associated with ascending aortic dilatation that might be the result of hemodynamic changes and genetic backgrounds (Loscalzo *et al.*, 2007). Replacement of the ascending aorta is indicated in patients with a BAV who are undergoing surgical aortic valve replacement (SAVR) if the diameter of the ascending aortic is >45 mm (Erbel *et al.*, 2014). In their study, patients with ascending aortic diameter >50 mm were excluded, but two patients with dilated ascending aorta (48.4 and 49.4 mm, respectively) who were evaluated as surgical high risk (advanced age and poor heart function, etc.) underwent TAVI. However, there is still no clear evidence about the remodeling of ascending aorta and long-term outcomes of BAV patients with dilated ascending aorta after TAVI treatment. Follow-up research of the diameter of the ascending aorta and survival in these patients will be necessary and also very interesting.

BAV is still deemed as a relative contraindication for TAVI (Vahanian *et al.*, 2012), while the corresponding author Jian-an WANG and his team noted that patients with a severely stenotic BAV can be safely and effectively treated by TAVI (Liu *et al.*, 2015). Meanwhile, 37.5% of the patients with BAV in their study were much higher than previous reports in Europe (3.6% to 9.2%) (Hayashida *et al.*, 2013; Bauer *et al.*, 2014). Therefore, evaluation of the safety and efficacy of TAVI in patients with a severe stenotic BAV in the Chinese population is valuable for clinical practice and clinical trials to expand the indication for TAVI.

Compared with TAV patients, SAVR is generally performed at a younger age and lower surgical risk among BAV patients (Michelena *et al.*, 2008; Lange *et al.*, 2012). The clinical trials of TAVI in the lower surgical risk and younger patients are ongoing, which might expand the indication for TAVI. Accordingly, this study should contribute to the application of TAVI in more patients with aortic stenosis in the future.

References

Bauer, T., Linke, A., Sievert, H., *et al.*, 2014. Comparison of the effectiveness of transcatheter aortic valve implantation in patients with stenotic bicuspid versus tricuspid

ORCID: Yu-guo WENG, http://orcid.org/0000-0002-9970-9479

They evaluated the safety and efficacy of transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valve (BAV) and tricuspid aortic valve (TAV) for the first time in the Chinese population.

Therefore, evaluation of the safety and efficacy of TAVI in patients with a severe stenotic BAV in the Chinese population is valuable for clinical practice and clinical trials to expand the indication for TAVI.

Patients and The Customers Come First

Summary

- There are more patients with bicuspid aortic valve among who received TAVI procedure in Chinese population.
- TAVI can be performed safely and effectively for the symptomatic severe AS patients with bicuspid aortic valve.
- Downsize for the choice of valve and higher initial deployment will be helpful for the procedural success.

Solutions to Complex TAVI

- Bicuspid Aortic Valve
- Pure non-calcified aortic regurgitation
- Paravalvular leakage
- Small vascular access
- Low height of coronary artery

TAVI in pure AR

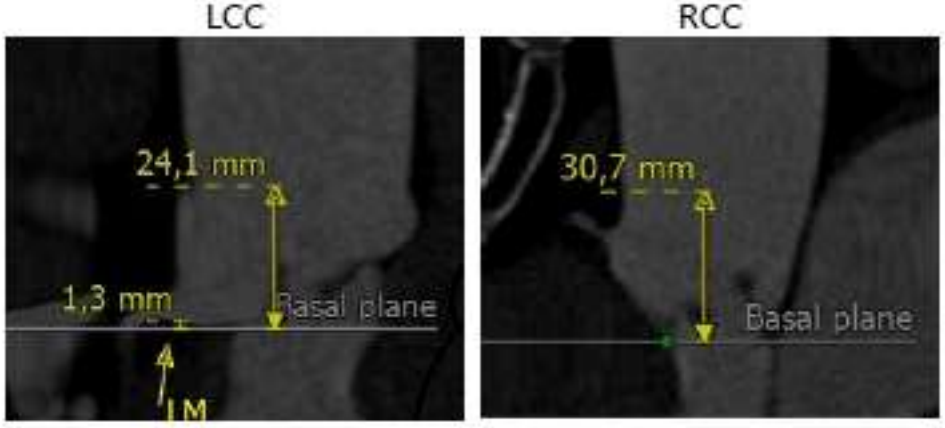
- NOT recommended by the guidelines.
- However, large amount of symptomatic patients who are surgical high risk or in-operable in clinical practice.
- Challenges and procedural considerations
  - Non-calcification
  - Difficult to fixation
  - Paravalvular leakage

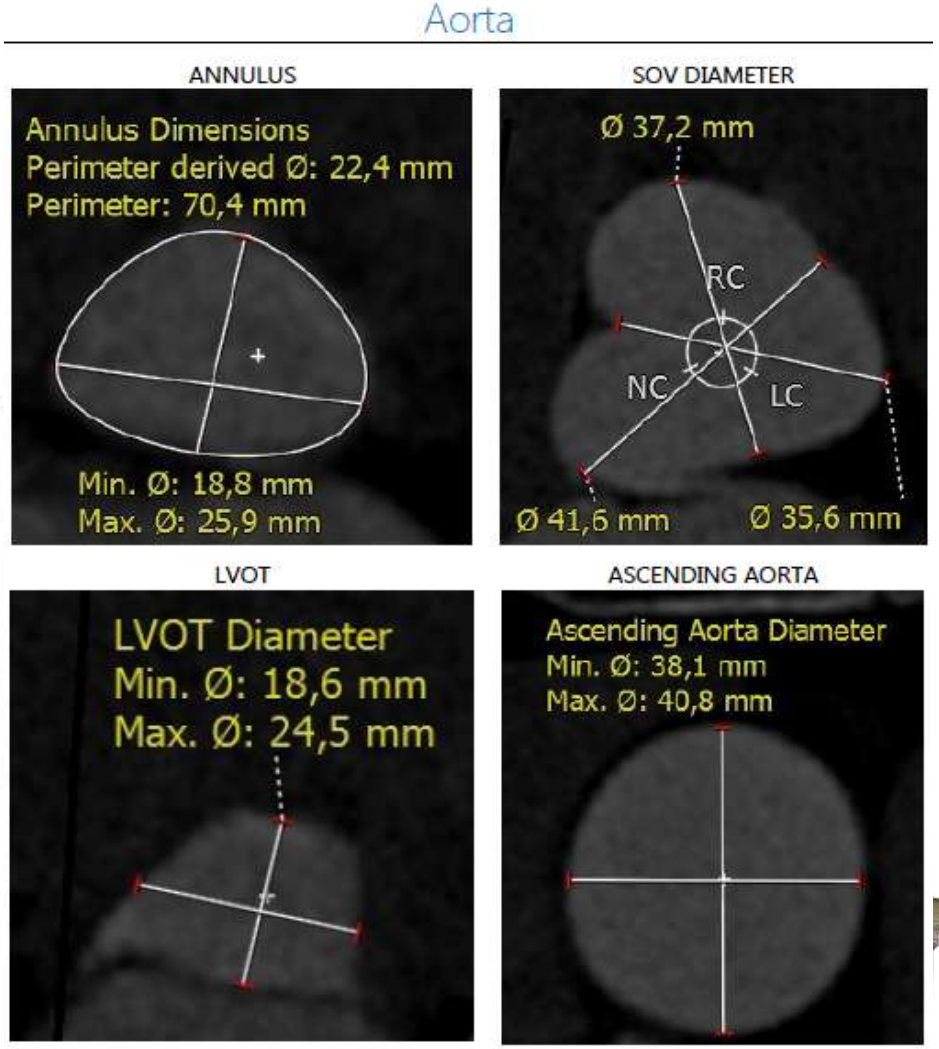
Smith CR et al. N Engl J Med 2011;364:1686-1695.
Leon MB et al. N Engl J Med 2010;363:1597-1607.

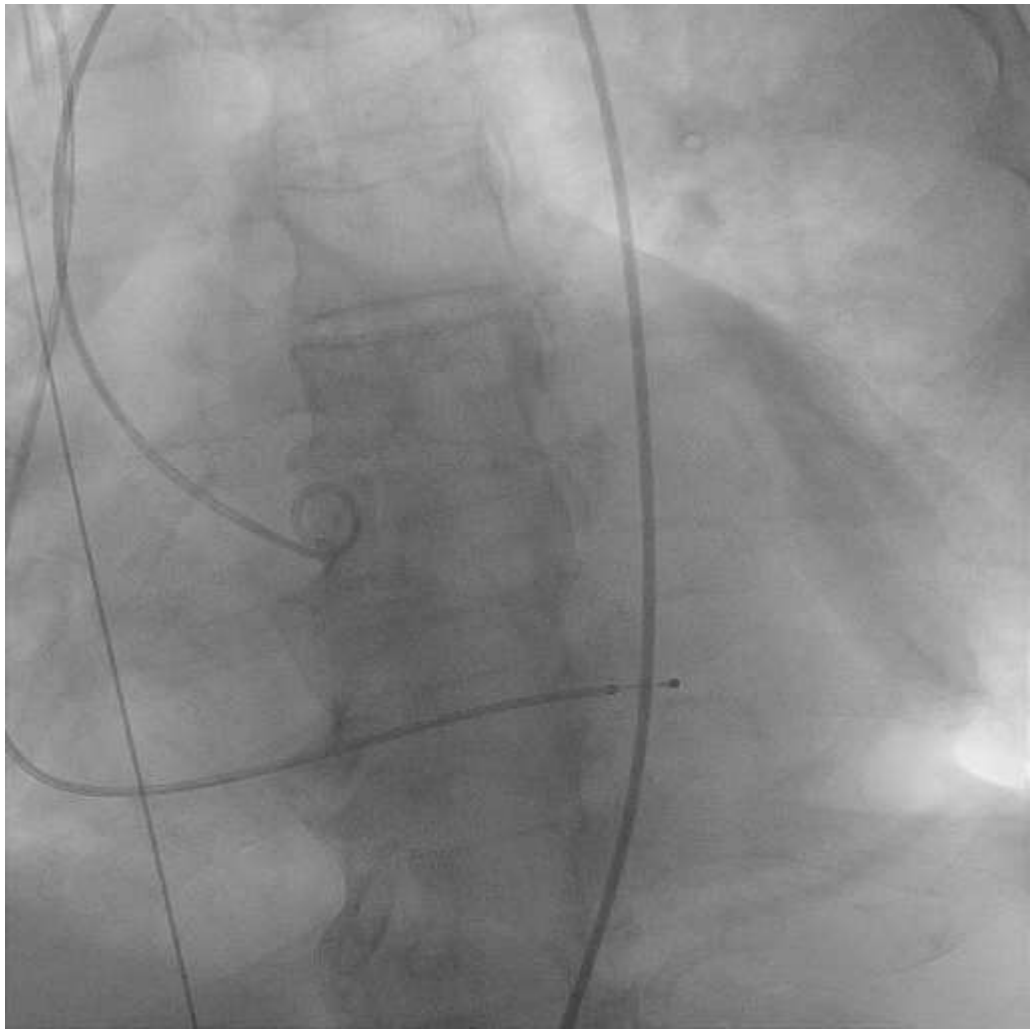
First Pure AR Case in China

- Male，80 yrs
- Recurrent chest discomfort for 3 years, aggravated for 2 month, edema in lower extremities for 20 days
- NYHA IV
- PMH
  - CAD，post-PCI in RCA
  - Hypertension
  - COPD
  - Chronic renal failure
- Log EuroScore = 39.50% STS = 11.63%
- Surgical extreme risk
- Heart valve team suggested TAVI.

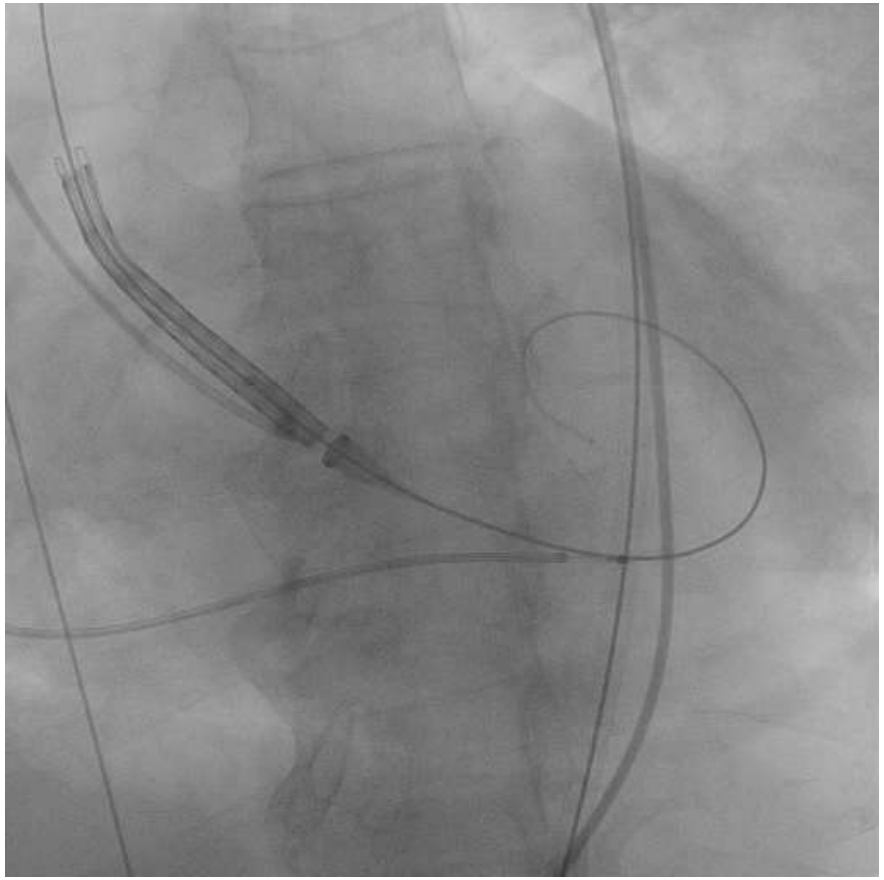
CT

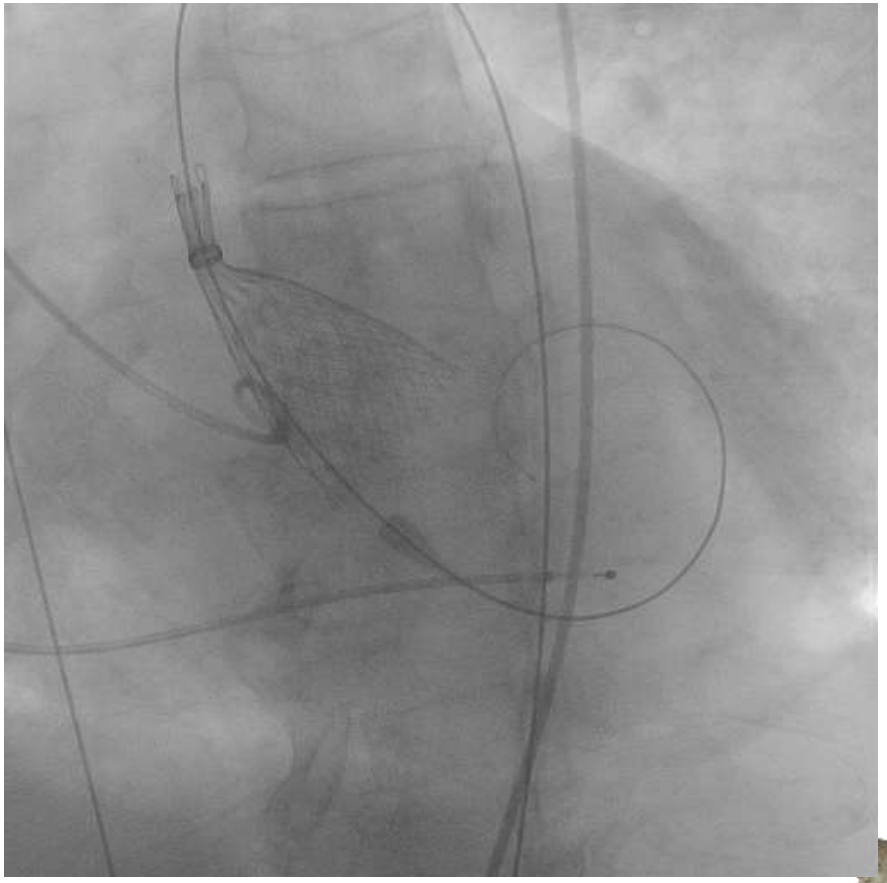

SINUS HEIGHT
LCC
RCC
24,1 mm
1,3 mm
Basal plane
M
30,7 mm
Basal plane


Aorta
ANNULUS
Annulus Dimensions
Perimeter derived Ø: 22,4 mm
Perimeter: 70,4 mm
Min. Ø: 18,8 mm
Max. Ø: 25,9 mm
SOV DIAMETER
Ø 37,2 mm
RC
NC
LC
Ø 41,6 mm
Ø 35,6 mm
LVOT
LVOT Diameter
Min. Ø: 18,6 mm
Max. Ø: 24,5 mm
ASCENDING AORTA
Ascending Aorta Diameter
Min. Ø: 38,1 mm
Max. Ø: 40,8 mm



CoreValve 29mm





Final Result

3 cases

	Age (years)	Gender	NYHA	Co-Morbidities	STS	Log EuroSCORE
Case 1	80	M	IV	Hypertension, CAD, CKD3, COPD	11.63	39.50
Case 2	81	M	IV	Spinal deformity, CAD, PAH	9.96	29.88
Case 3	84	M	III	CAD, COPD, PVD	8.71	27.95

- Procedural Success: 100%
- No complications
- Valve in valve for 2 cases

30d Follow up

		AR	LV	LA	MR	PASP(mmHg)	NYHA
Case1	Pre-TAVI	4+	6.34cm	4.53cm	4+	58	IV
	Post-TAVI	2+	6.23cm	4.26cm	3+	24	III
Case2	Pre-TAVI	4+	6.76cm	5.89cm	4+	68	IV
	Post-TAVI	2+	6.22cm	5.18cm	3+	21	II
Case3	Pre-TAVI	4+	5.95cm	3.87cm	2+	24	III
	Post-TAVI	1+	4.77cm	3.66cm	1+	22	II

Echo performed by the same doctor

Summary

- TAVI for surgical high risk or in-operable patients with pure severe AR is acceptable, although CoreValve is not the perfect choice.
- Oversize for the choice of valve should be applied for better valve fixation.
- Diameter of LVOT is important for the decision of TAVI for the patient with pure non-calcified AR.

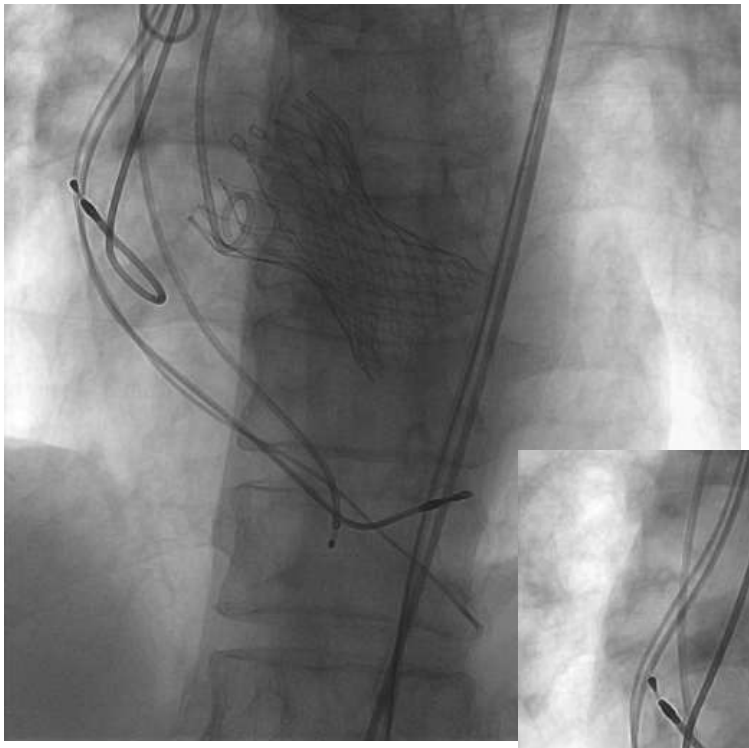
Solutions to Complex TAVI

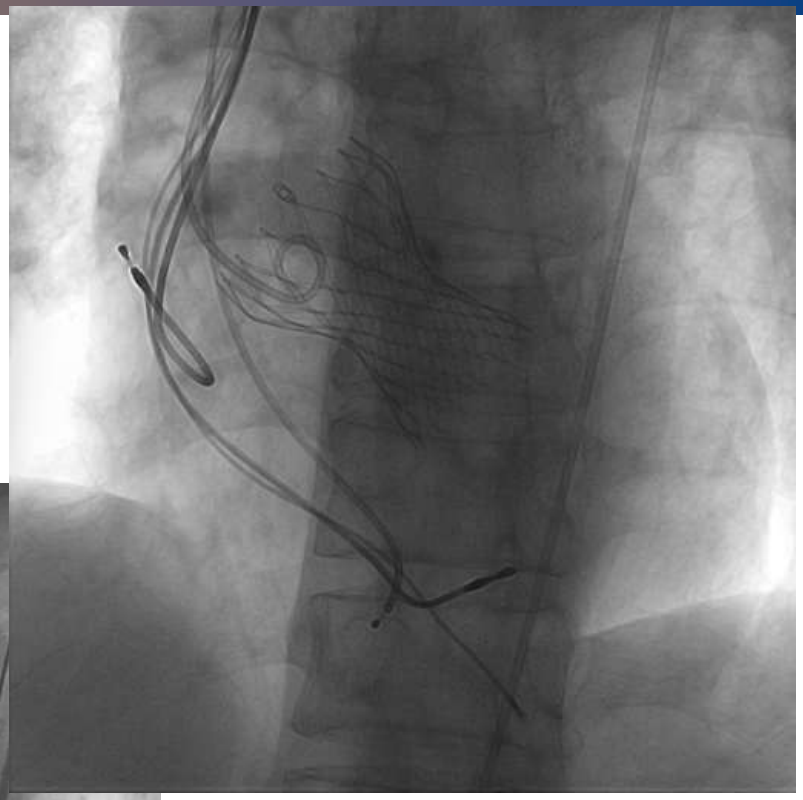
- Bicuspid Aortic Valve
- Pure non-calcified aortic regurgitation
- Paravalvular leakage
- Small vascular access
- Low height of coronary artery

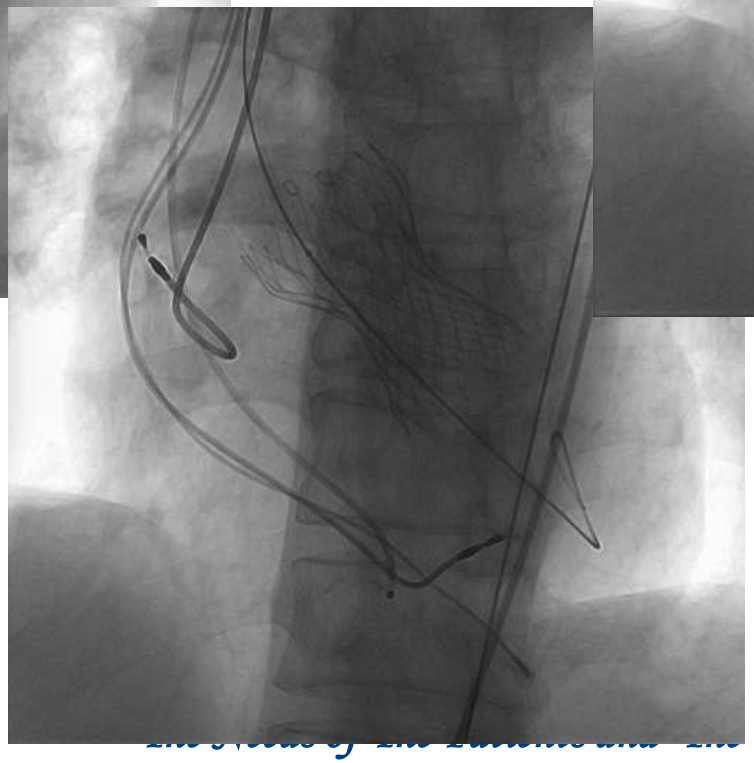
Causes for paravalvular leakage

- Malposition with infra or supra-annular implantation
- Prosthesis undersizing or underexpansion
- Severe calcification protruding circumferential apposition of the valve frame
- Oval annulus
- Asymmetric calcification

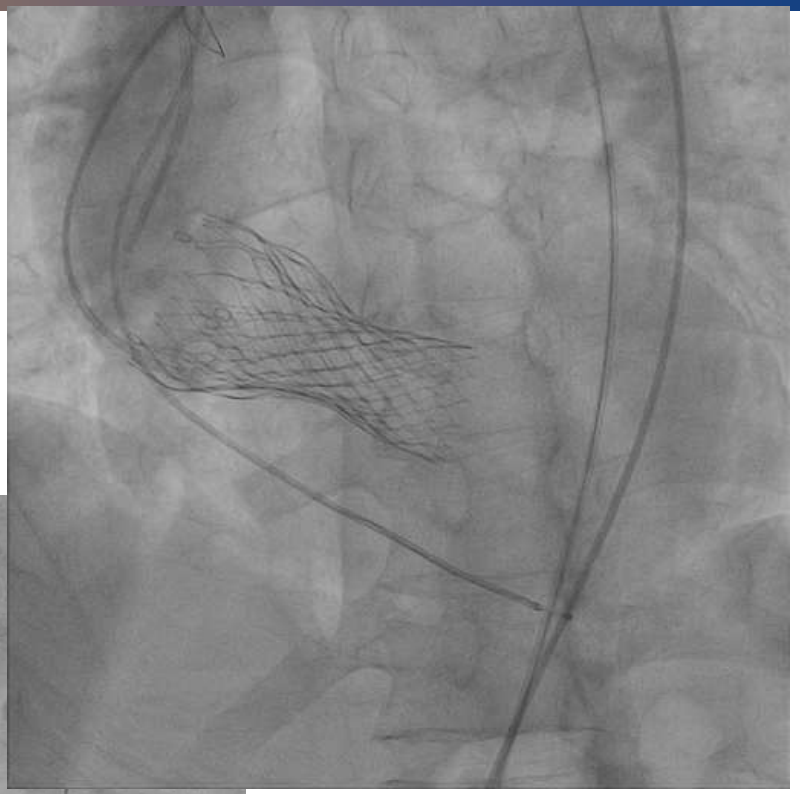
Post-dilation

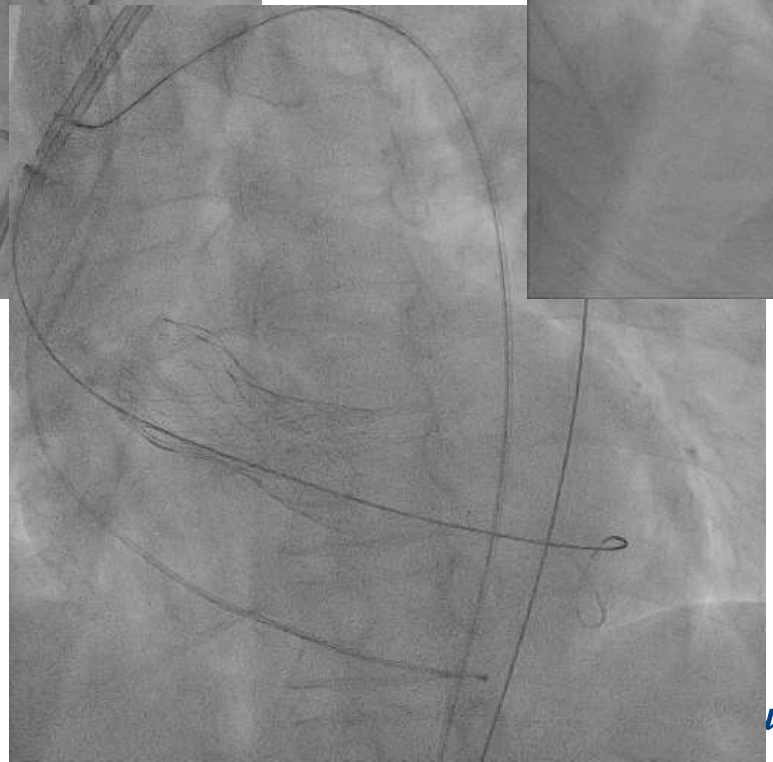




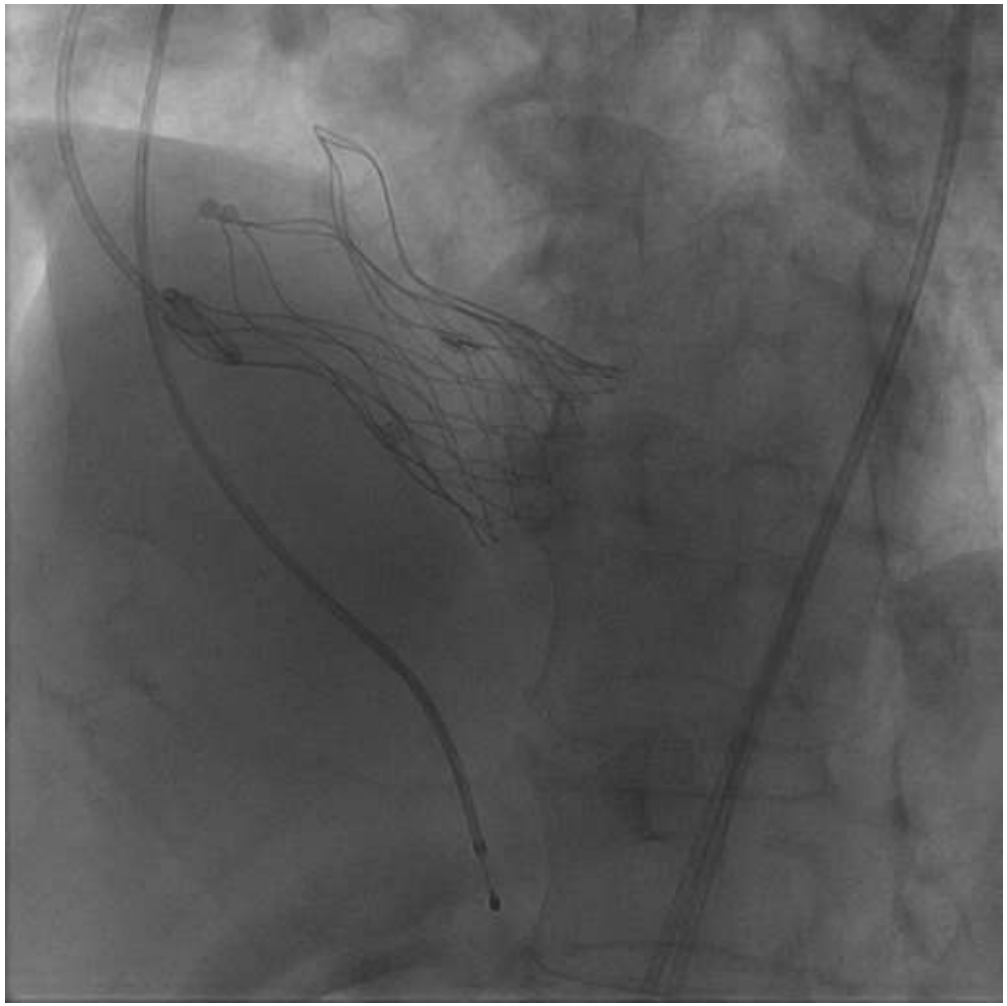


Valve in valve

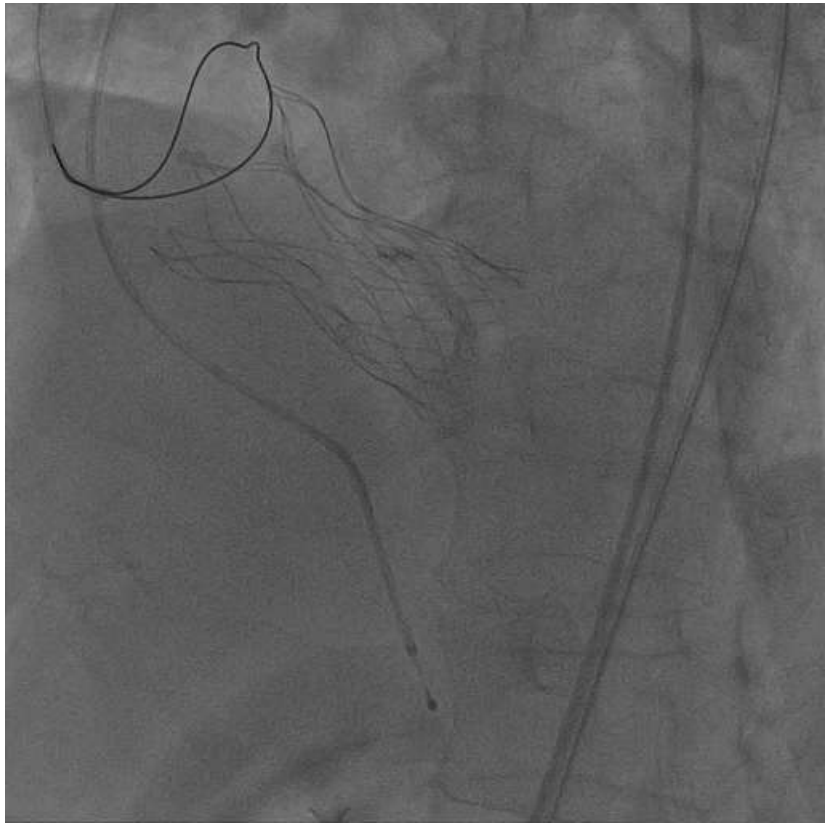




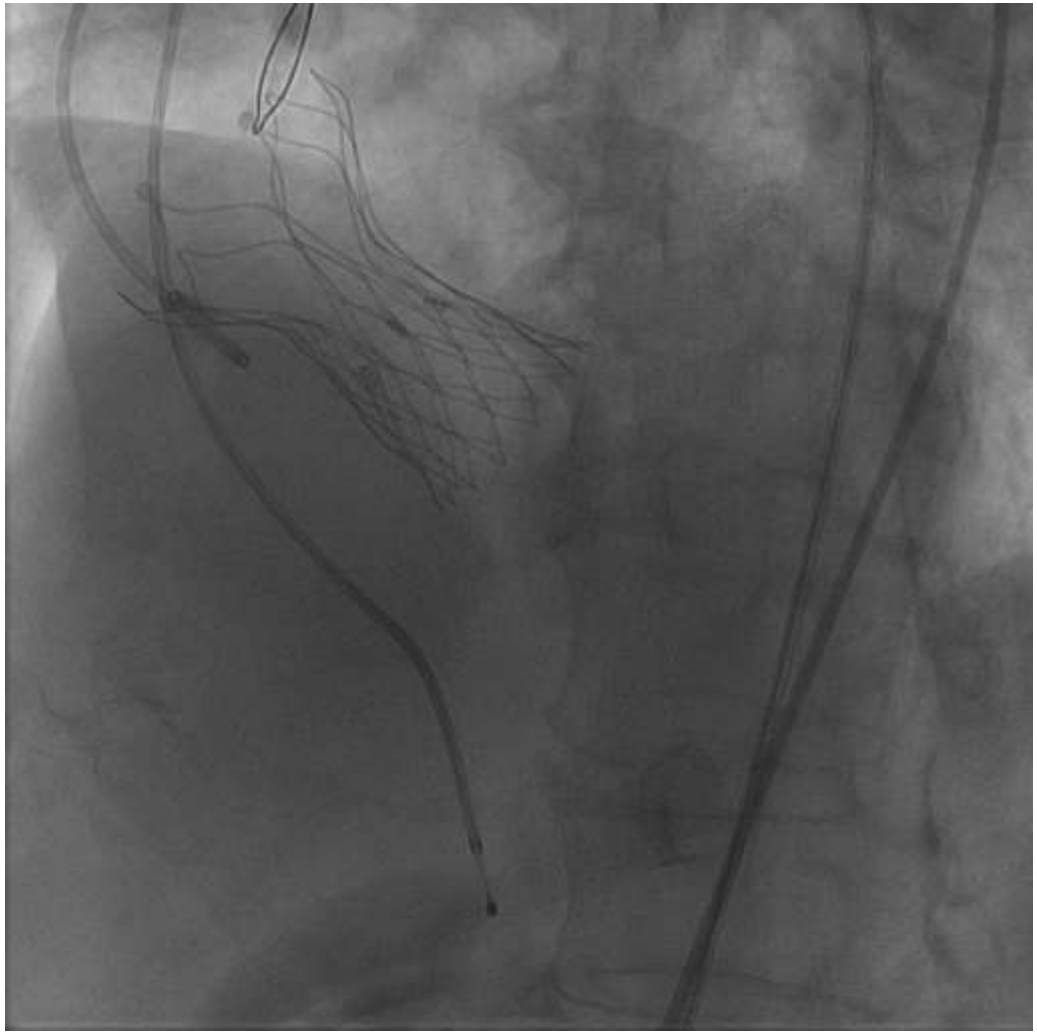
Snare



Snare



Final Result



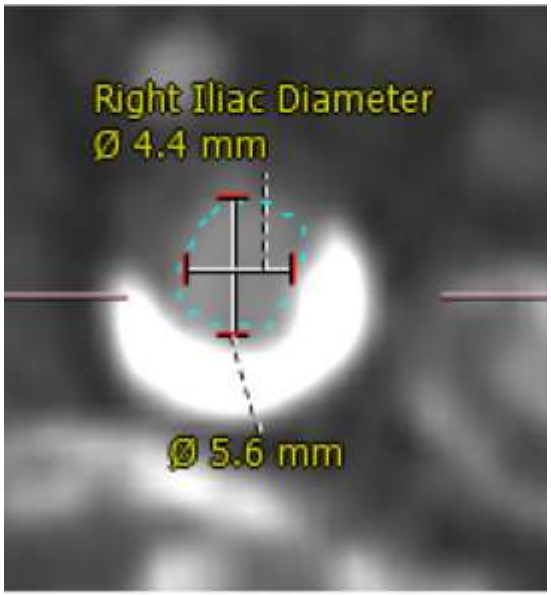
Summary

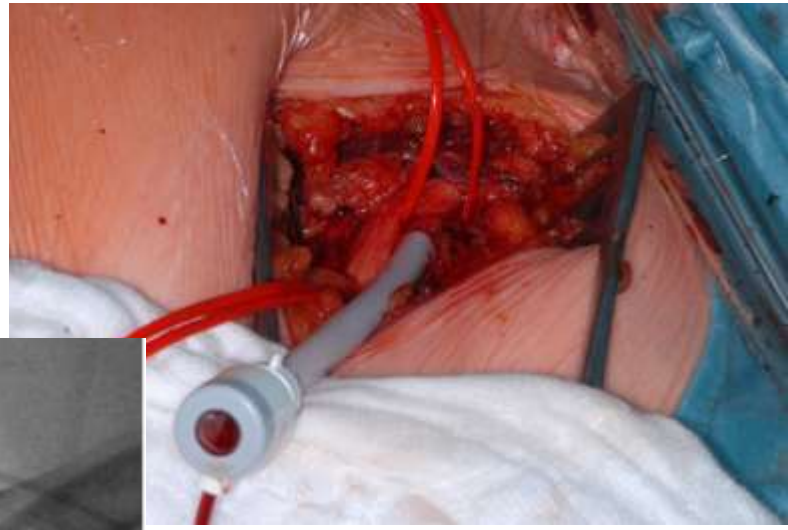
- Post-dilation, valve in valve and snare are useful approaches for treatment of paravalvular leakage due to prothesis malposition and undersizing or underexpansion.
- Severe calcification protruding circumferential apposition of the valve frame
  - Post-dilation might be helpful. However, it increases the risk of annulus rupture.
  - Valve in valve will be little benefit.

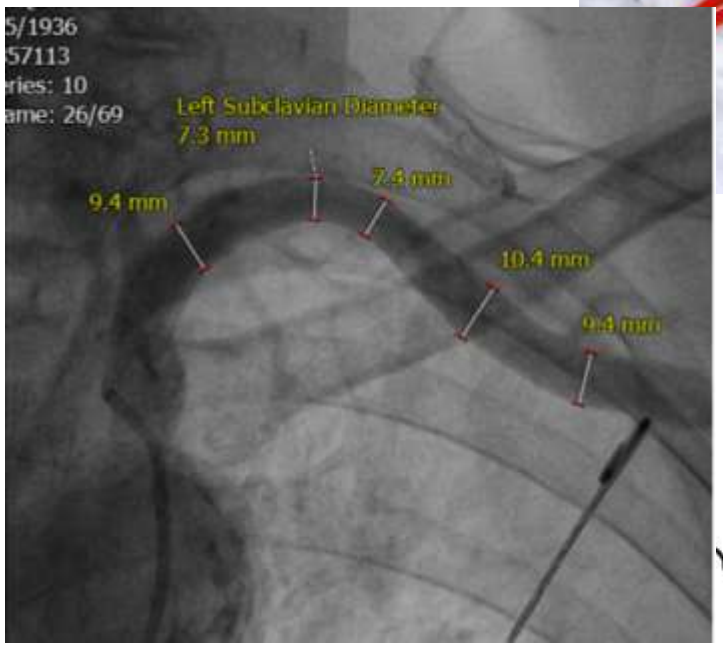
Solutions to Complex TAVI

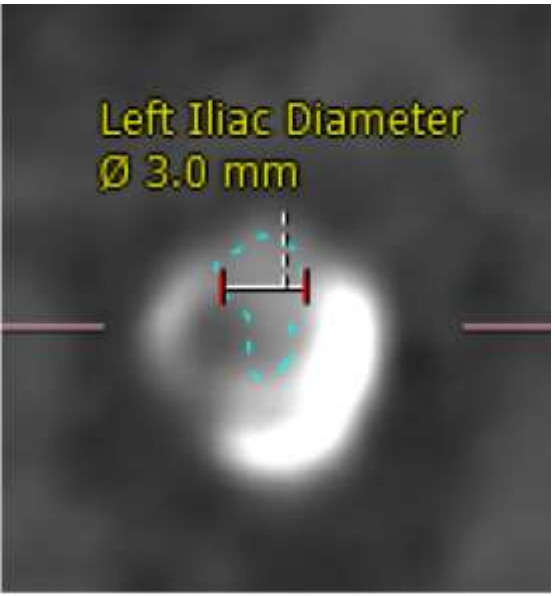
- Bicuspid Aortic Valve
- Pure non-calcified aortic regurgitation
- Paravalvular leakage
- Small vascular access
- Low height of coronary artery

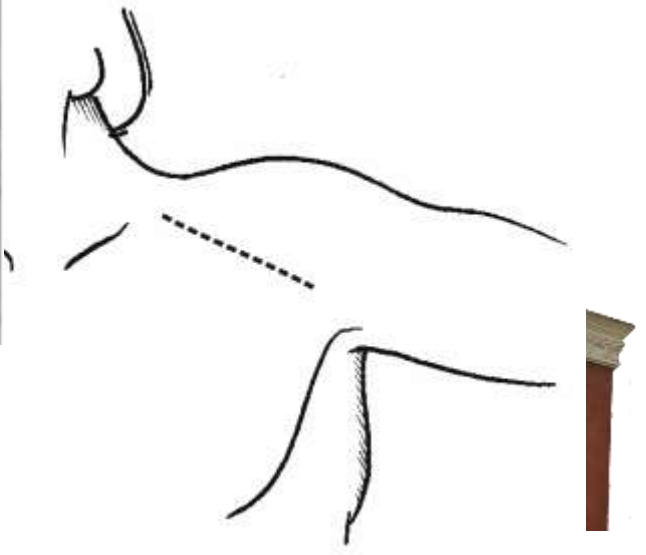
Trans-subclavian



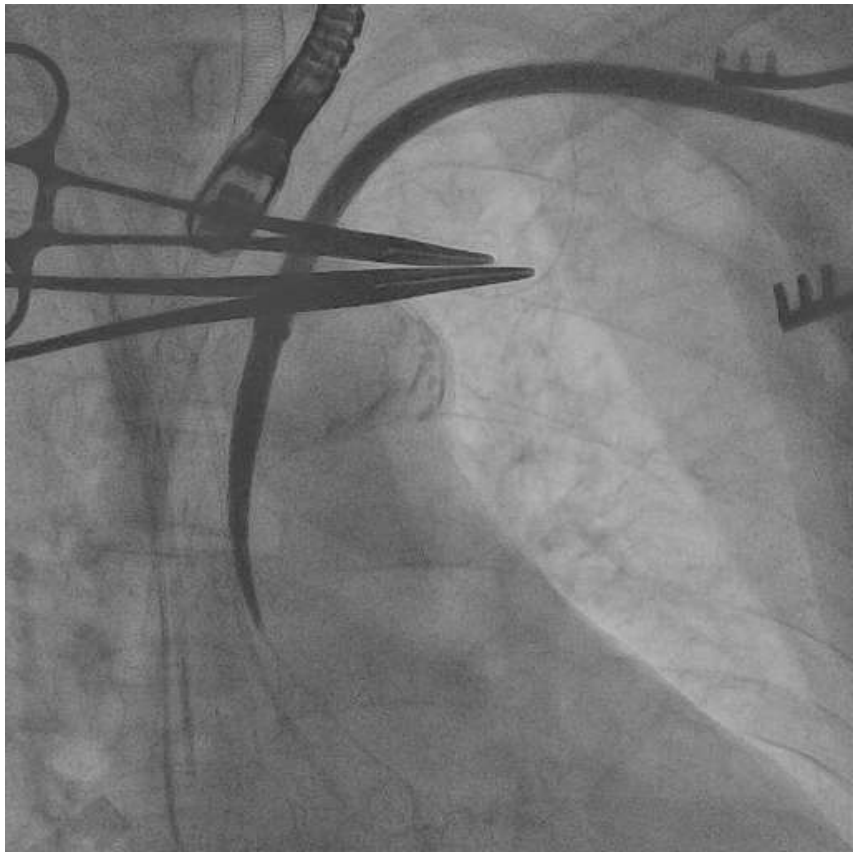


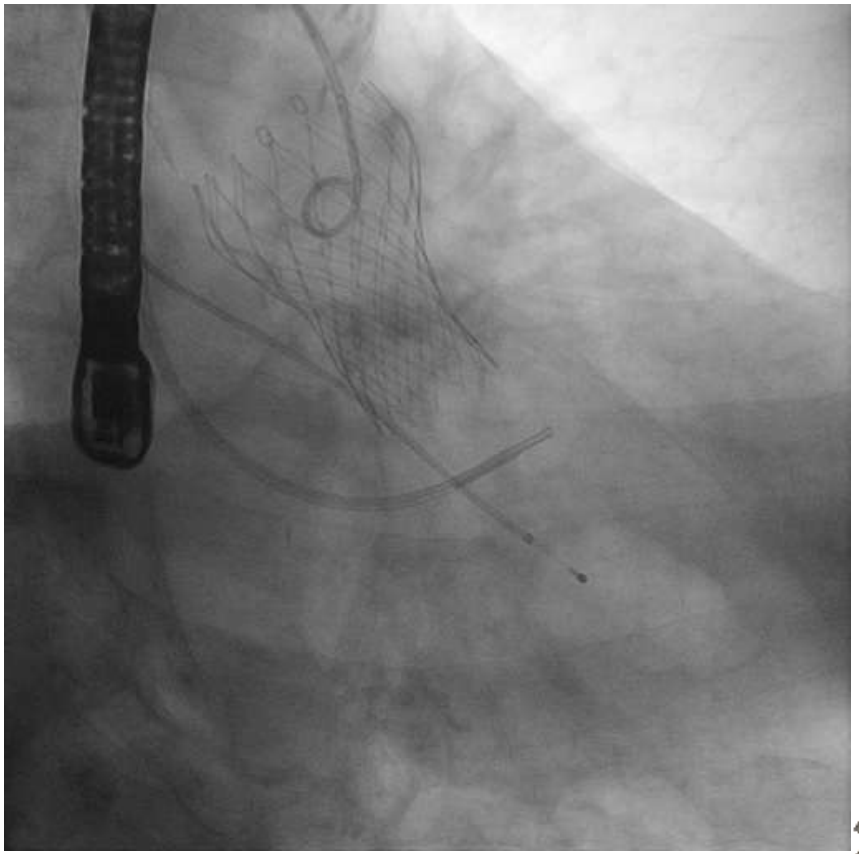


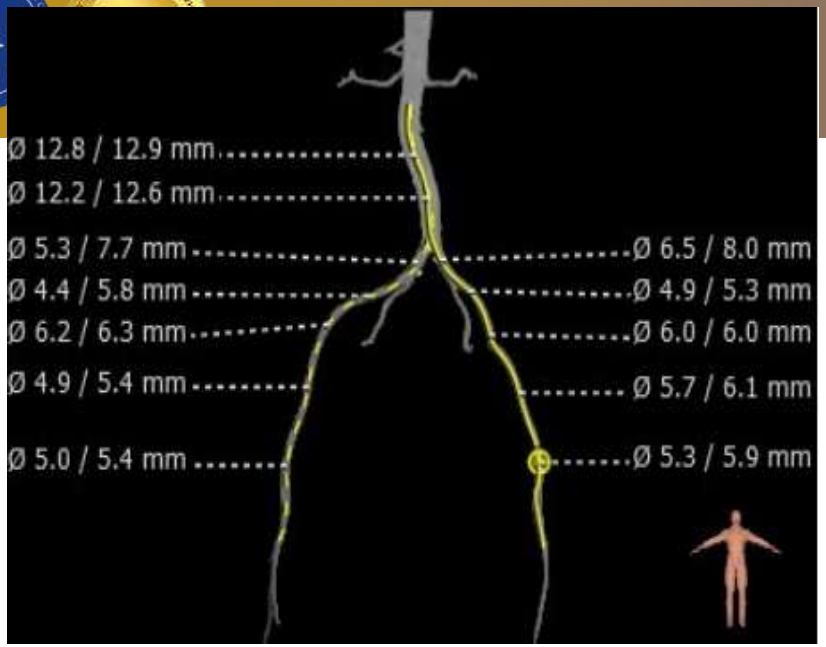


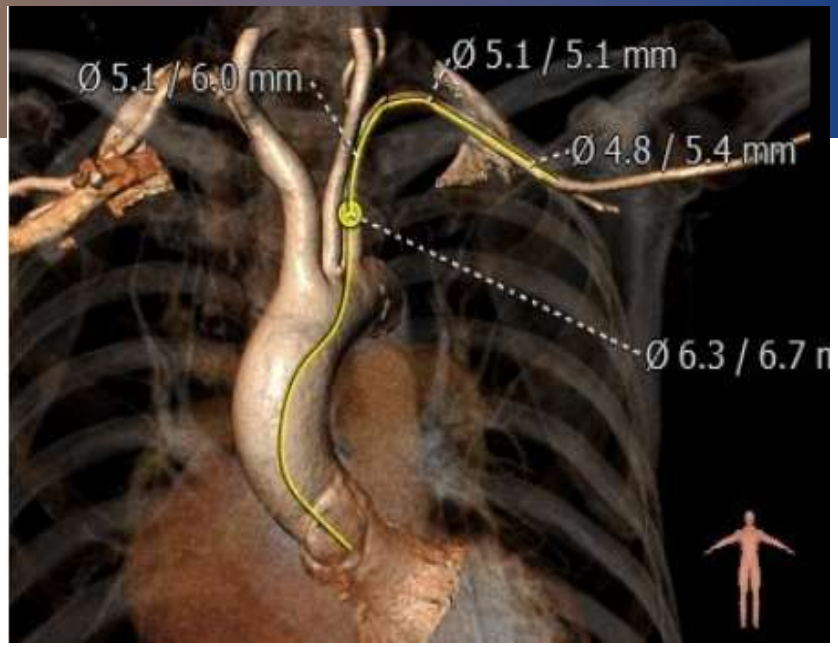


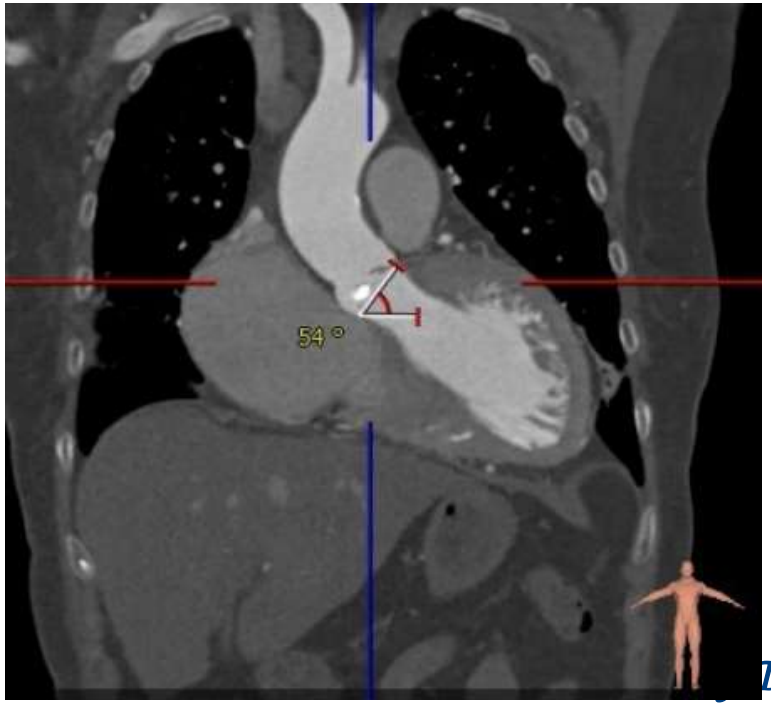
The Needs of The Patients an





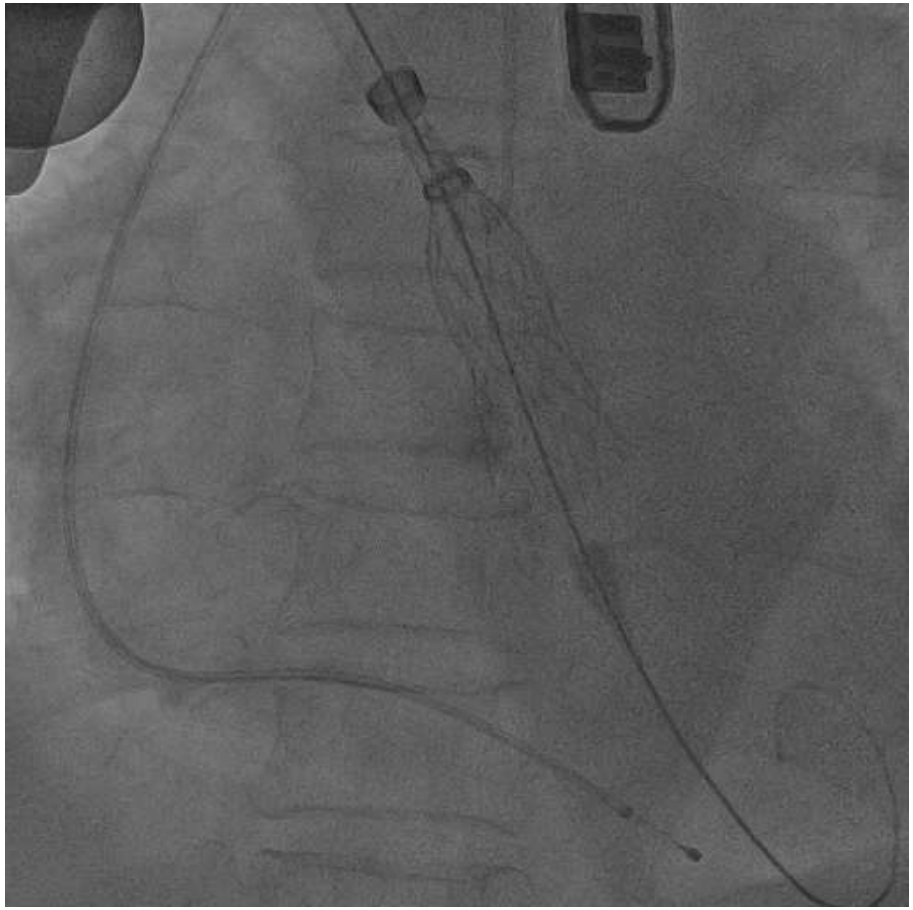

Ø 12.8 / 12.9 mm
Ø 12.2 / 12.6 mm
Ø 5.3 / 7.7 mm
Ø 4.4 / 5.8 mm
Ø 6.2 / 6.3 mm
Ø 4.9 / 5.4 mm
Ø 5.0 / 5.4 mm
Ø 6.5 / 8.0 mm
Ø 4.9 / 5.3 mm
Ø 6.0 / 6.0 mm
Ø 5.7 / 6.1 mm
Ø 5.3 / 5.9 mm


Ø 5.1 / 6.0 mm
Ø 5.1 / 5.1 mm
Ø 4.8 / 5.4 mm
Ø 6.3 / 6.7 m


54 °


23 Fr (7.7 mm)
70.3 mm

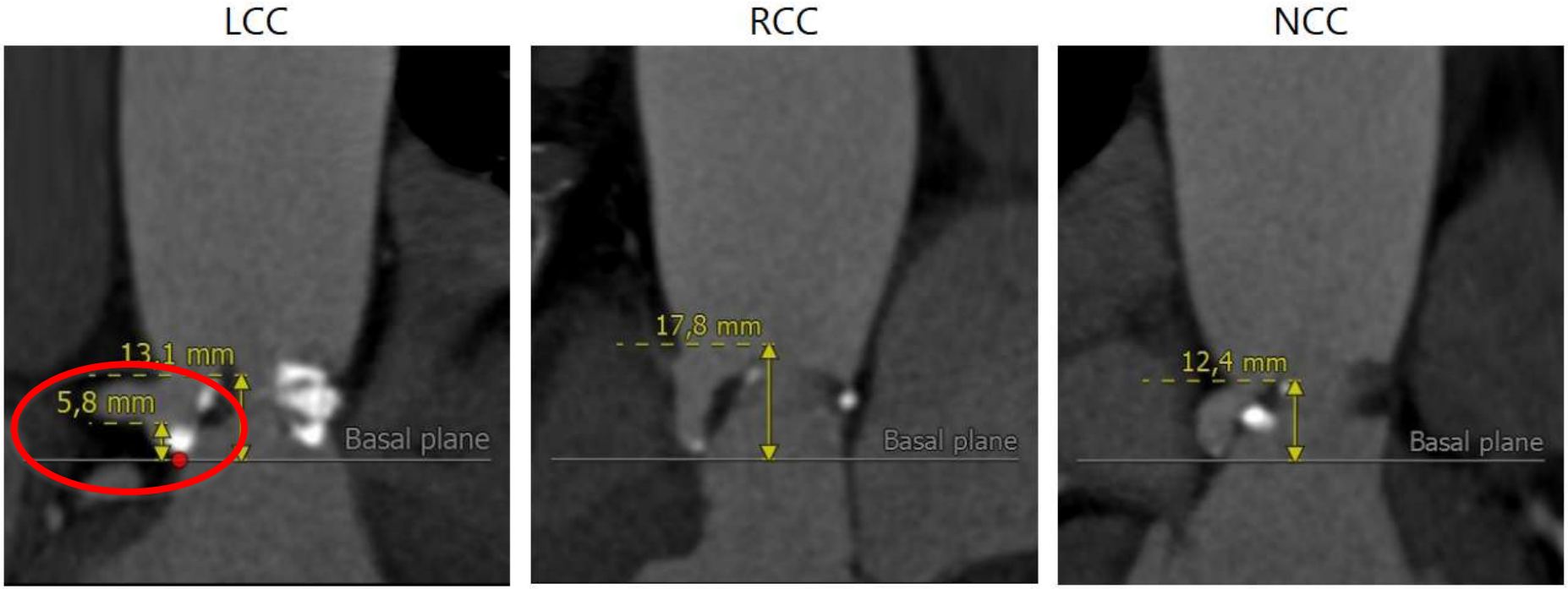
Direct aorta access



Solutions to Complex TAVI

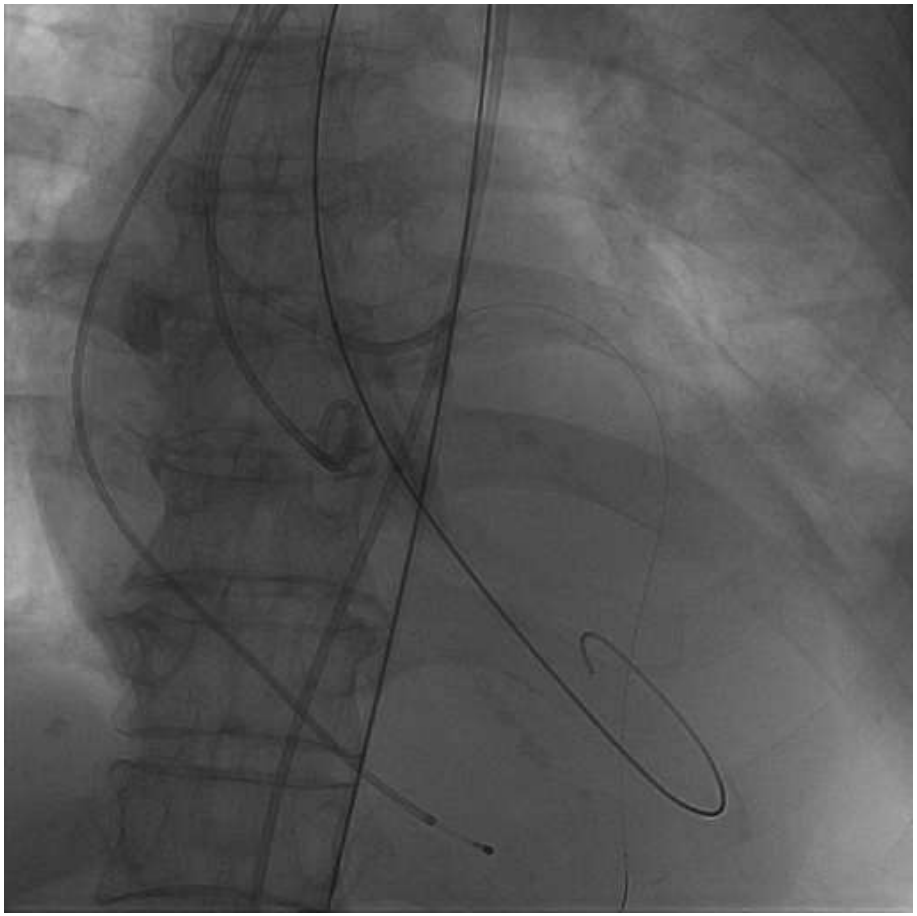
- Bicuspid Aortic Valve
- Pure non-calcified aortic regurgitation
- Paravalvular leakage
- Small vascular access
- Low height of coronary artery

Very low height of LM

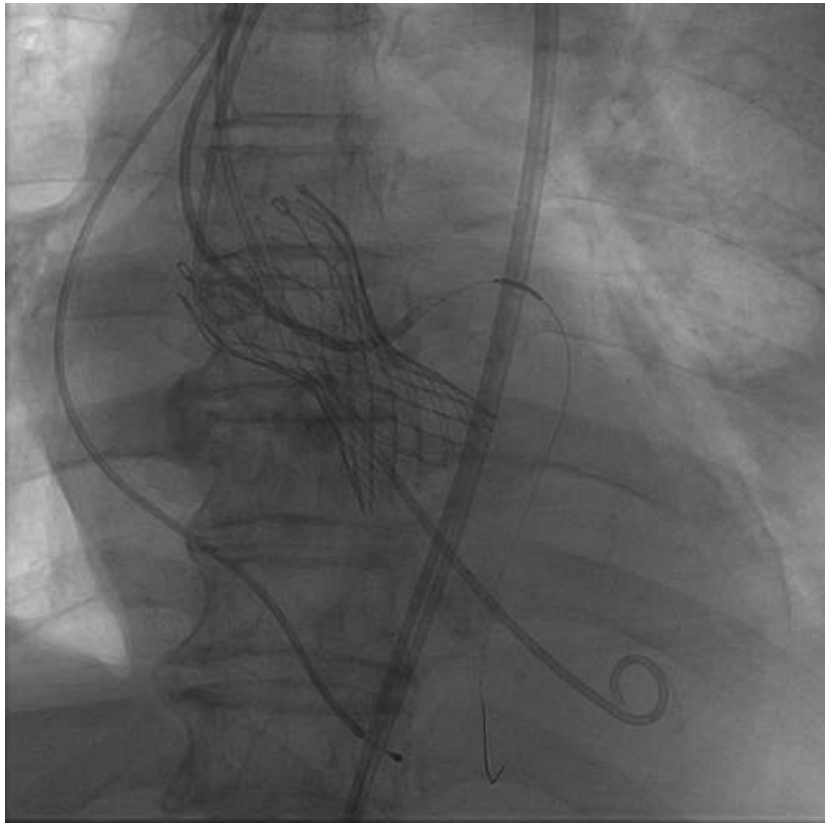


- In-operable severe AS patient
- Very severe symptomatic
- TAVI is the only way out

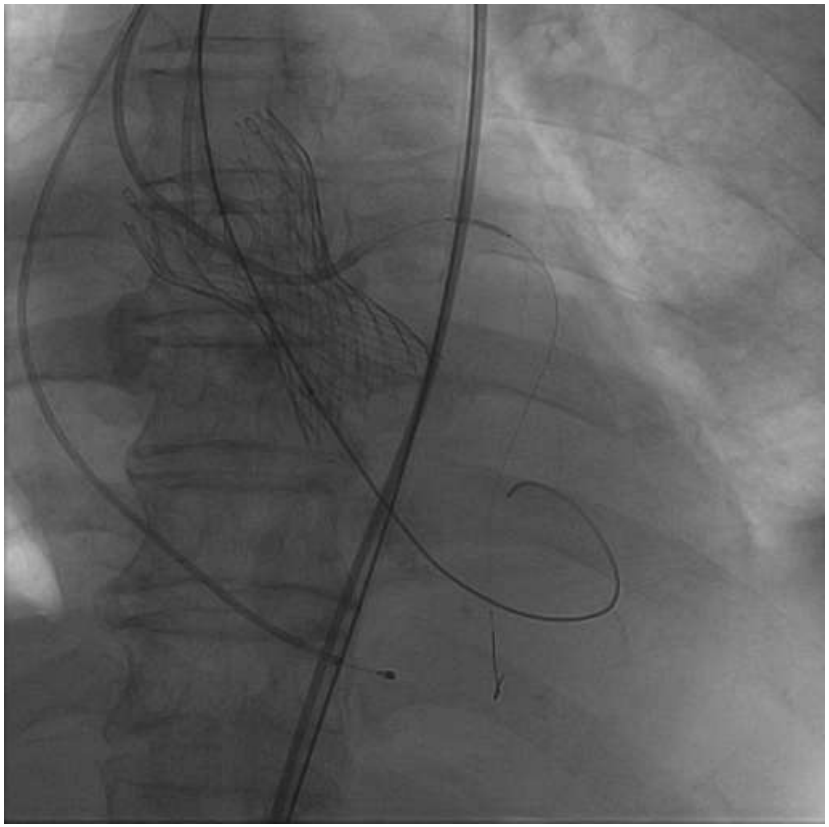
Z-MED II 22*40mm Balloon

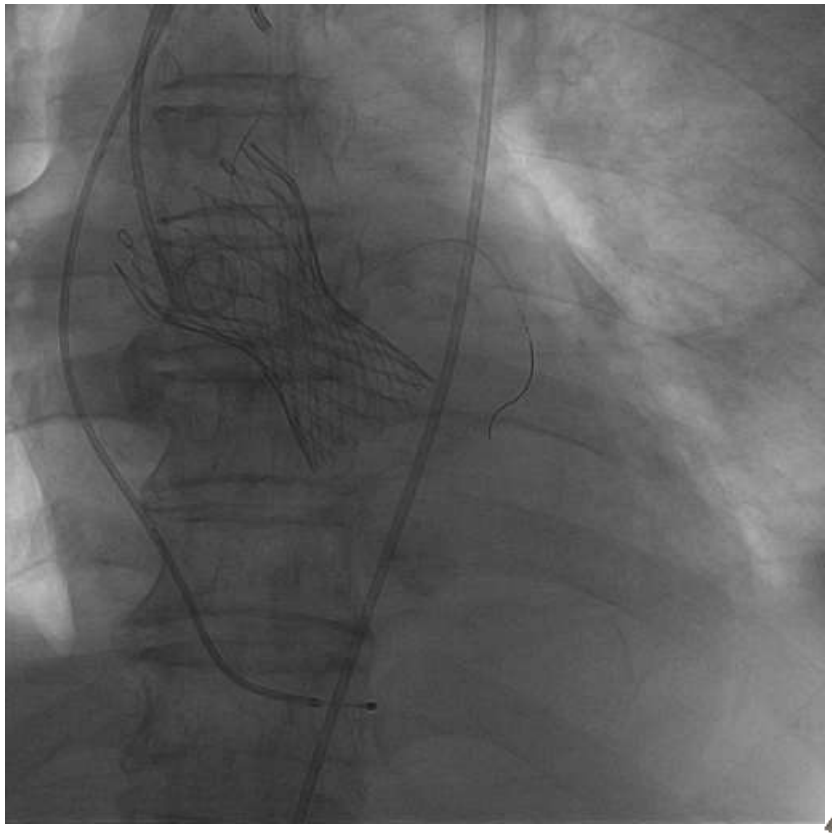


- Guiding catheter: JL 3.5
- Runthrough wire to distal LAD



- Stent in proximal LAD for protection
- A little bit lower for deployment





Conclusions

- TAVI is safe and effective for surgical high risk or in-operable patients with severe aortic stenosis.
- For complex TAVI, team is very important.
- For complex TAVI, skill is very important.
- For complex TAVI, experience is very important.