

TAVI Case Complicated with Valve Infold and Dislodgement

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

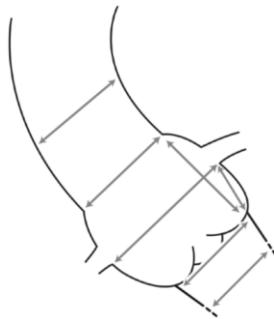
<u>Nature of Financial Relationship</u>	<u>Ineligible Company</u>
Grant/Research Support	-
Consultant Fees/Honoraria	Abbott, Ancora Heart, Edwards Lifescience, Meril, Medtronic,
Individual Stock(s)/Stock Options	-
Royalties/Patent Beneficiary	-
Executive Role/Ownership Interest	-
Other Financial Benefit	-

Patient data

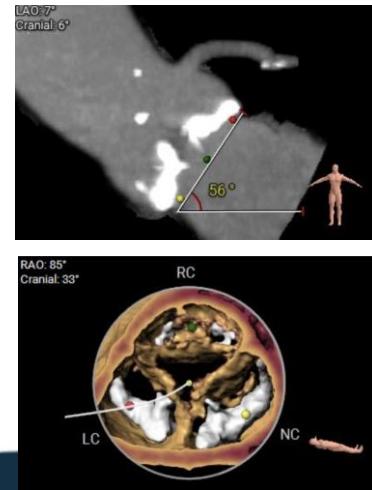
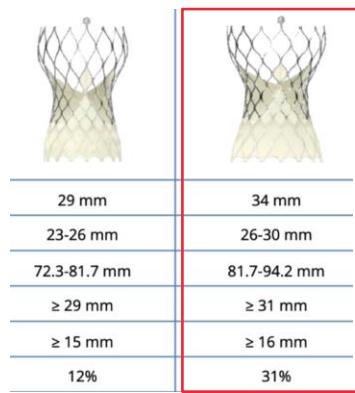
- Male, 81 y/o
- *HfPEF (60%), coronary atherosclerosis w/o significance, peripheral arteries atherosclerosis, carotid arteries atherosclerosis;*
CKD C2, GFR 73 ml/min/1.73 sq.m
- *EuroSCORE II – 3.47%*
- AS 0.9 sq.cm, systolic gradient 82 mm Hg, mean gradient 48 mm Hg

ANNULUS			
Diameter (mm)	22.5	x	29.4 , 26.0
Perimeter (mm)	Min	Max	Mean
Area (mm ²)	81.7	, Derived Ø (mm)	26.0

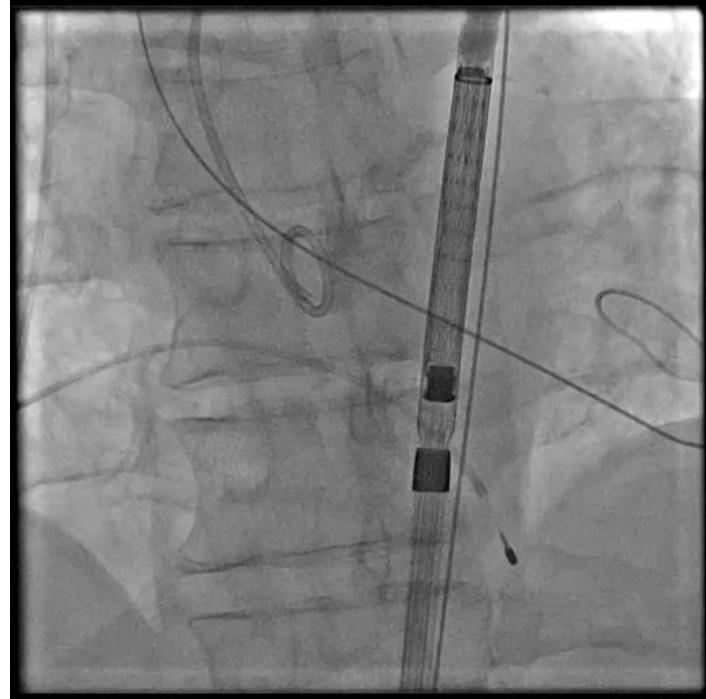
LVOT			
Diameter (mm)	21.8	x	31.3 , 26.5
Perimeter (mm)	Min	Max	Mean
Area (mm ²)	83.9	, Derived Ø (mm)	26.7



Max Ascending Aorta Diameter (mm)	35.0	
Sinotubular Junction Diameter (mm)	31.0 x 32.1	
Min	Max	
Sinus of Valsalva Diameter (mm)	36.7 31.1 35.8	
LCC	RCC	NCC
Sinus of Valsalva Height (mm)	22.5 23.3 22.1	
LCC	RCC	NCC
Coronary Ostia Height (mm)	14.2 18.7	
Left	Right	

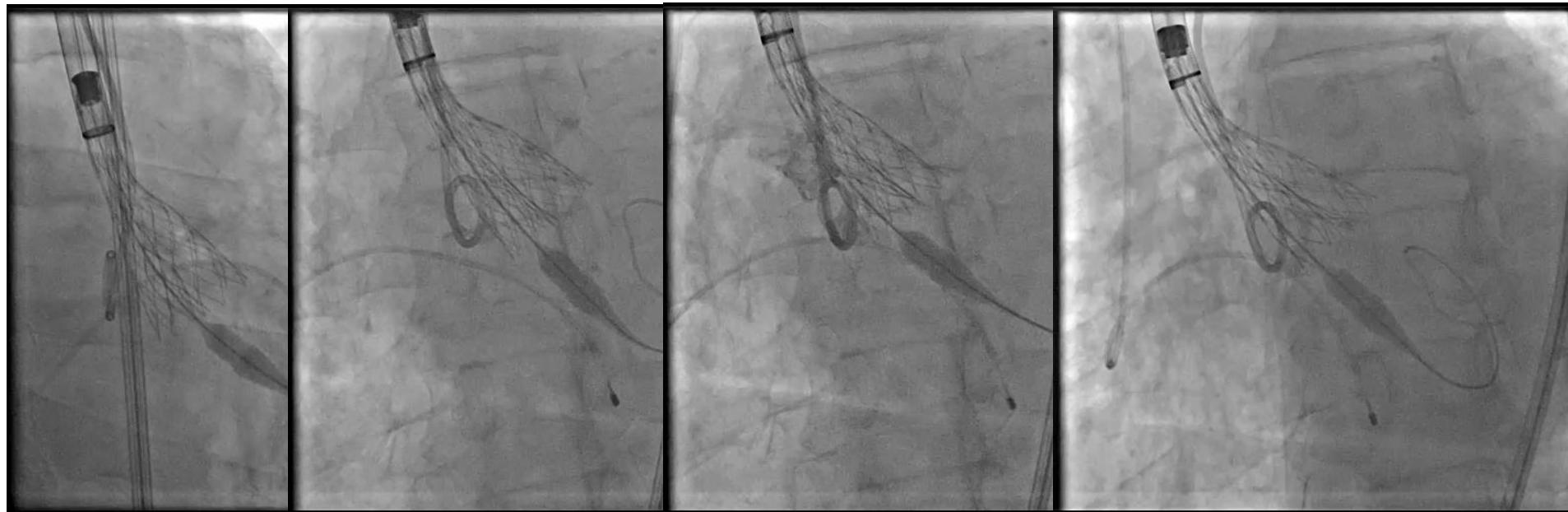


Case description



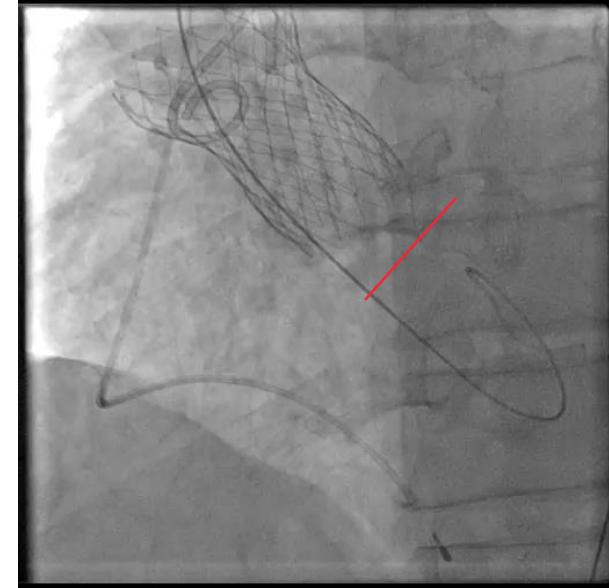
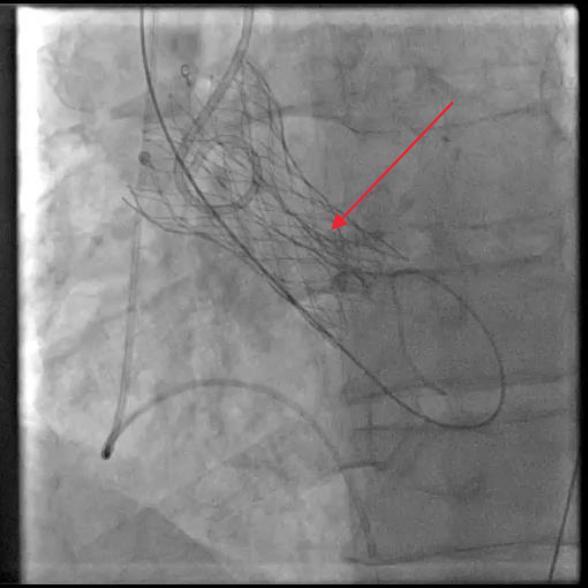
1st mistake: very formal inspection of the loaded valve

Case description



2nd mistake: concentration on the height and ignoring of other important signs and parameters

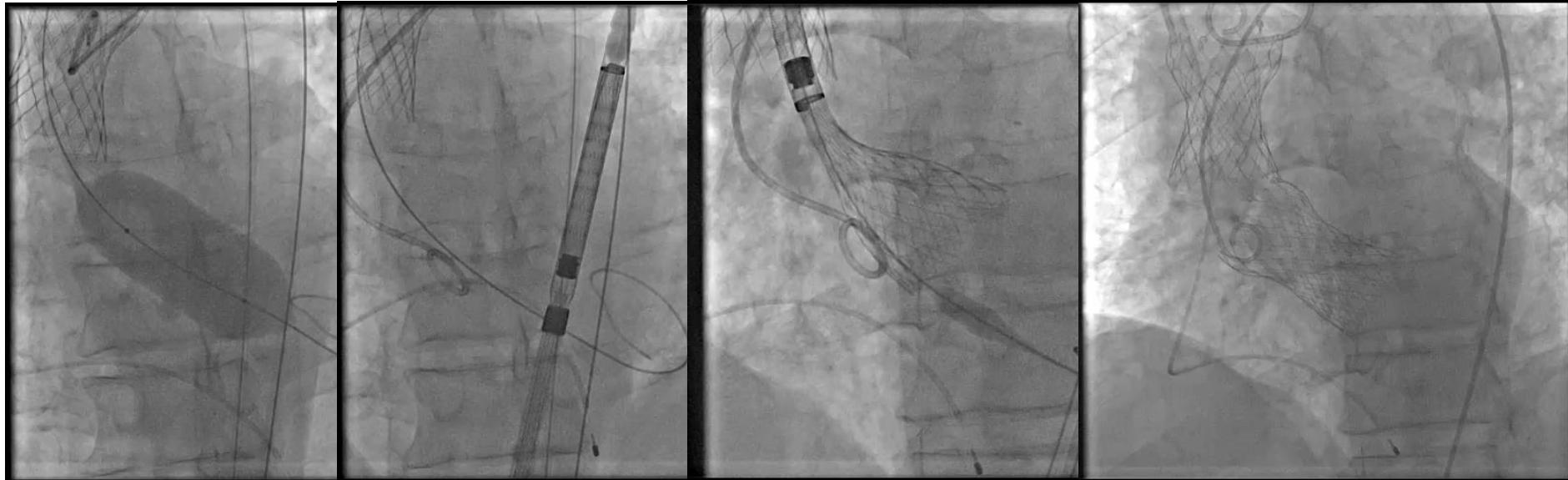
Case description



3rd mistake: infold wasn't recognized and TAV was released

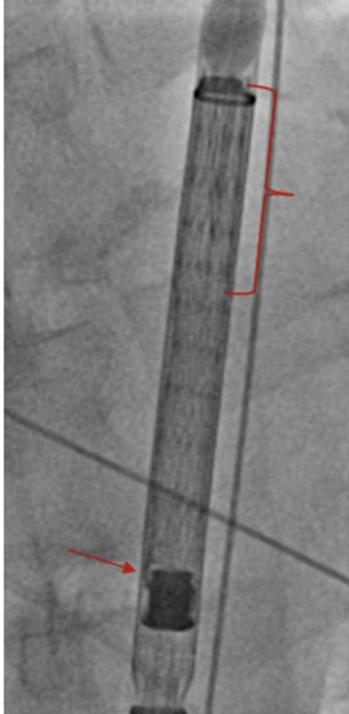
4th mistake (?): attempt to fix infold with the postdilatation, which led to the popping out of the entire TAV to the aorta

Case description



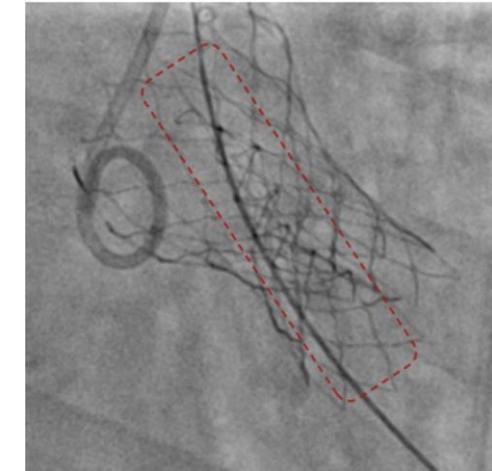
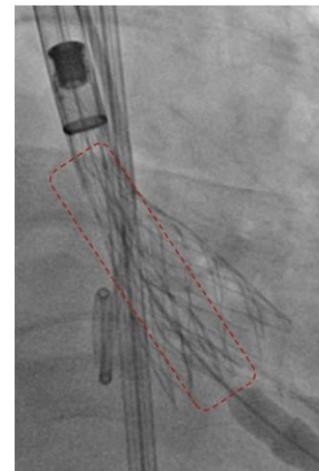
Dislodged valve was pulled up to the ascending aorta, second BAV was performed and then second valve was successfully implanted (after the careful inspection of the load)

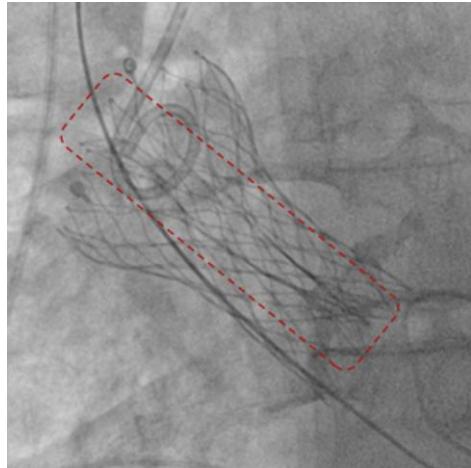
Case discussion



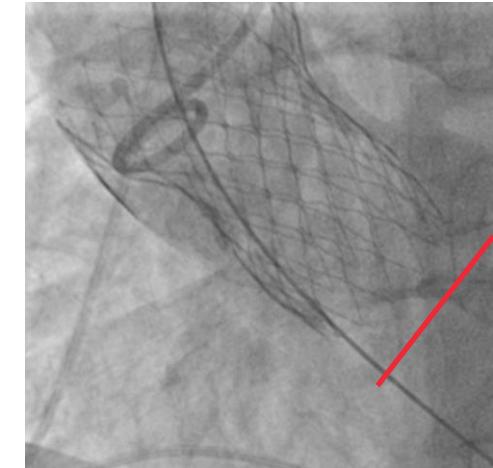
Signs of the misloaded TAV:

- Inflow crown overlap seeing as non-uniform shadow starting at inflow edge and not ended before the fourth node;
- Outflow crown misalignment and/or not parallel to the paddle attachment
- Curved or bent capsule





Case discussion



- Once misload is detected, the TAV shouldn't be released or attempted to reload!
- Entire system should be discarded, valve, delivery catheter, loading system, loading tray and saline should be replaced with the new sterile components according the manufacturer recommendations

Summary

Valve infolding is a serious and potentially life-threatening complication which is typically related to patient anatomical factors and/or procedural factors (i.e., sizing, loading, technique, etc.).

Risk mitigation measures should include:

- Patient anatomy assessment with special attention to excessive annulus calcinosis and eccentricity
- Careful inspection of the loaded valve (visually, tactiley, and by fluoroscopy)
- Assessment of potential infolding at every step of the procedure prior to the release of the valve with the valve resheathing and reloading if the problem is suspected