

Complications in TAVI

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On behalf of ICPS valve Team
Massy, France*

- In the last five years , I received research grants or speaker fees or I am/was consultant for: Abbott Vascular, Asahi, Astra Zeneca, AVI, Boston Scientific, Biotronik, Colibri, Cook, Cordis, Daichi-Sankyo, Eli-Lilly, Iroko, Medtronic, Terumo. I am currently minor shareholder & general manager of CERC (CRO)



FRANCE 2

Methods

- Consecutive and mandatory registry – no exclusion
- All events (VARC)
- Monitoring & central data management
- Clinical follow-up up to 5y & Echo up to 3y





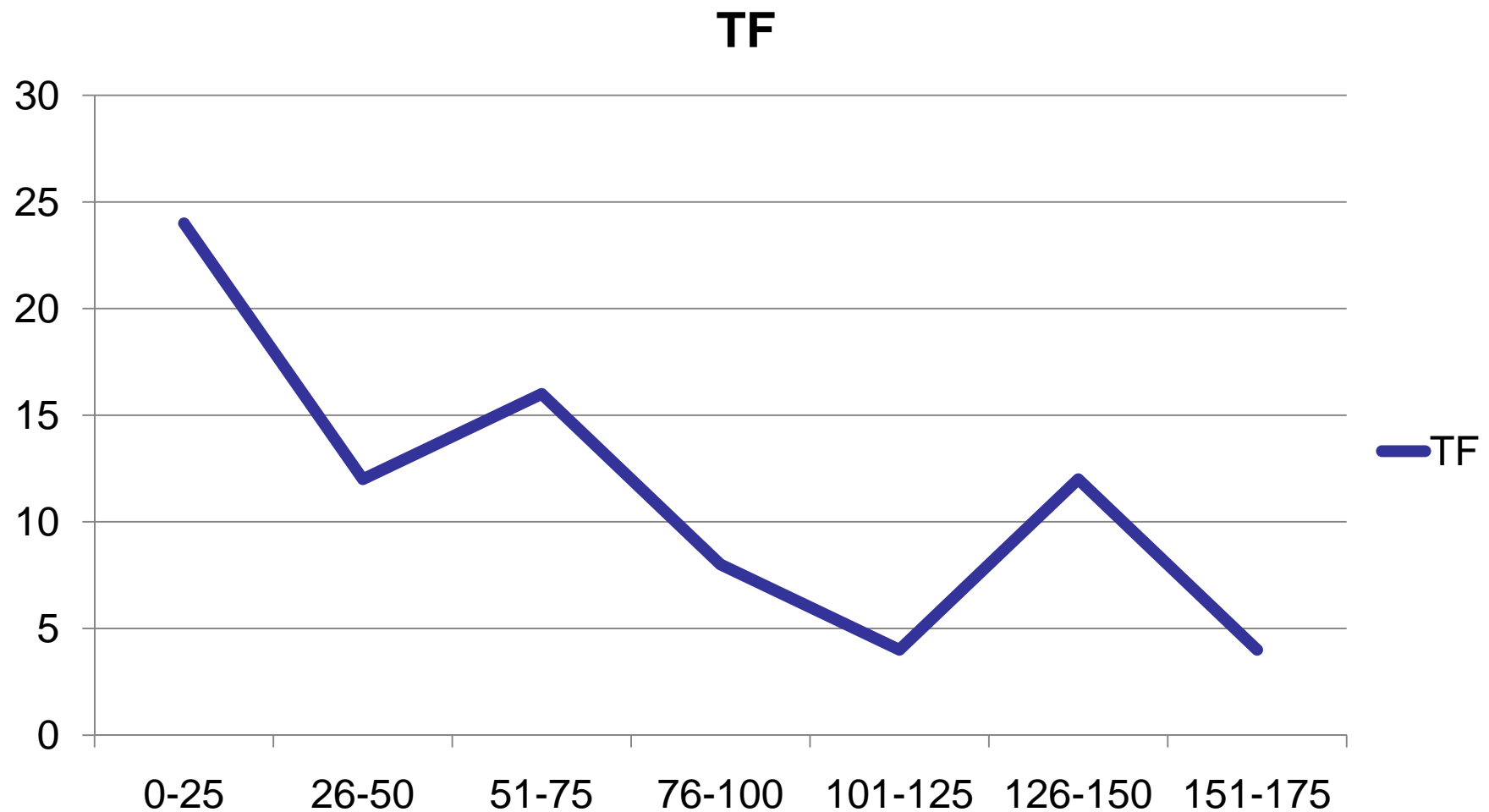
FRANCE 2

MAJOR COMPLICATIONS @ 30 d

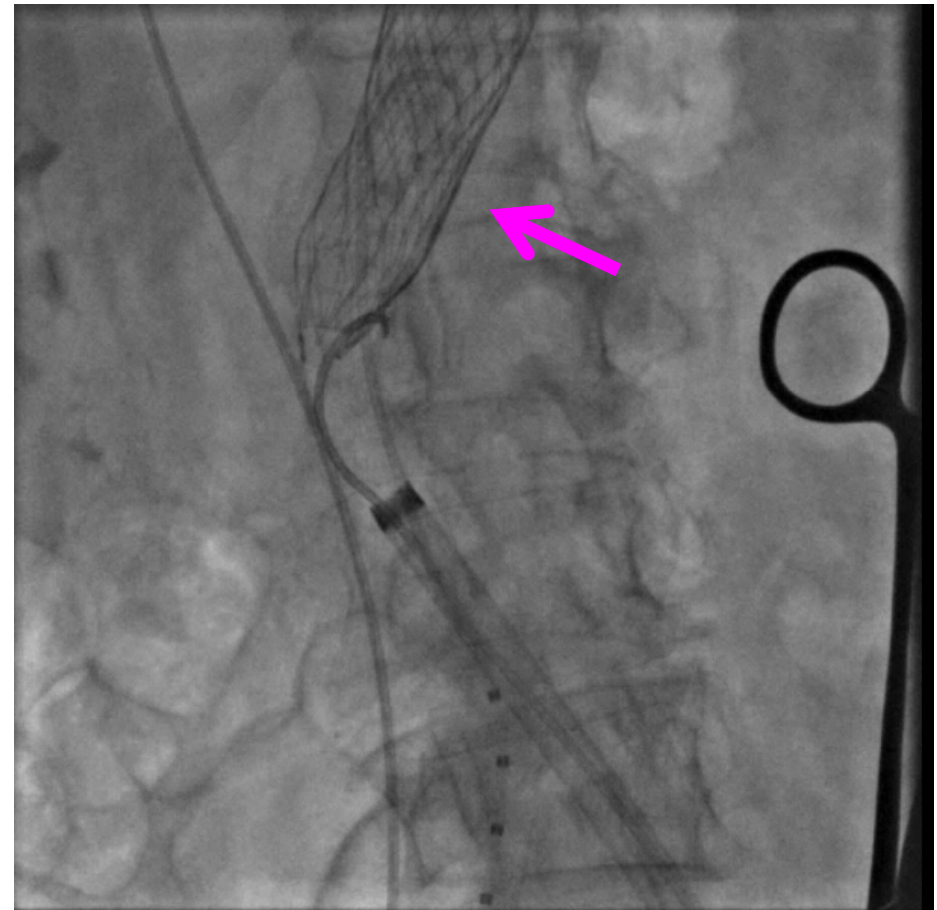
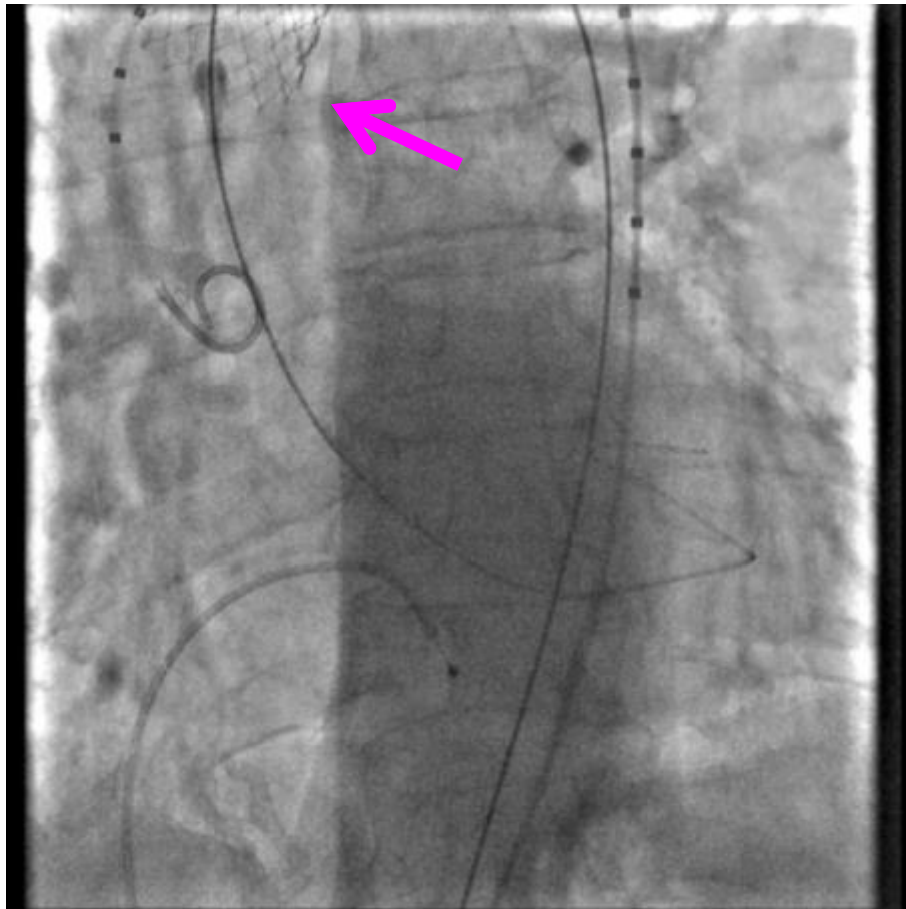
	Global N = 3195	Edwards N= 2107	CoreValve N=1043
Vascular	9.7%	10.7%	9.2%
New PM	15.6	11.5%	24.2%
Bleeding	11.4%	13.1%	8.8%
Stroke	4.1%	3.8%	4.3%

Learning Curve

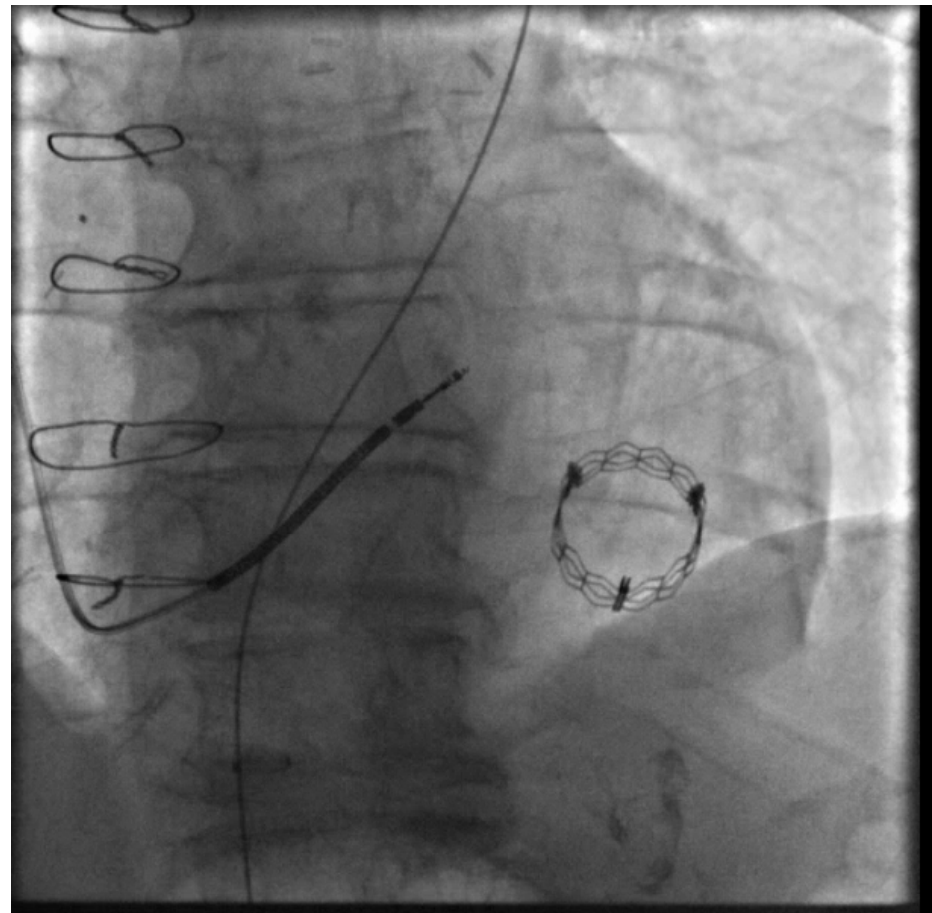
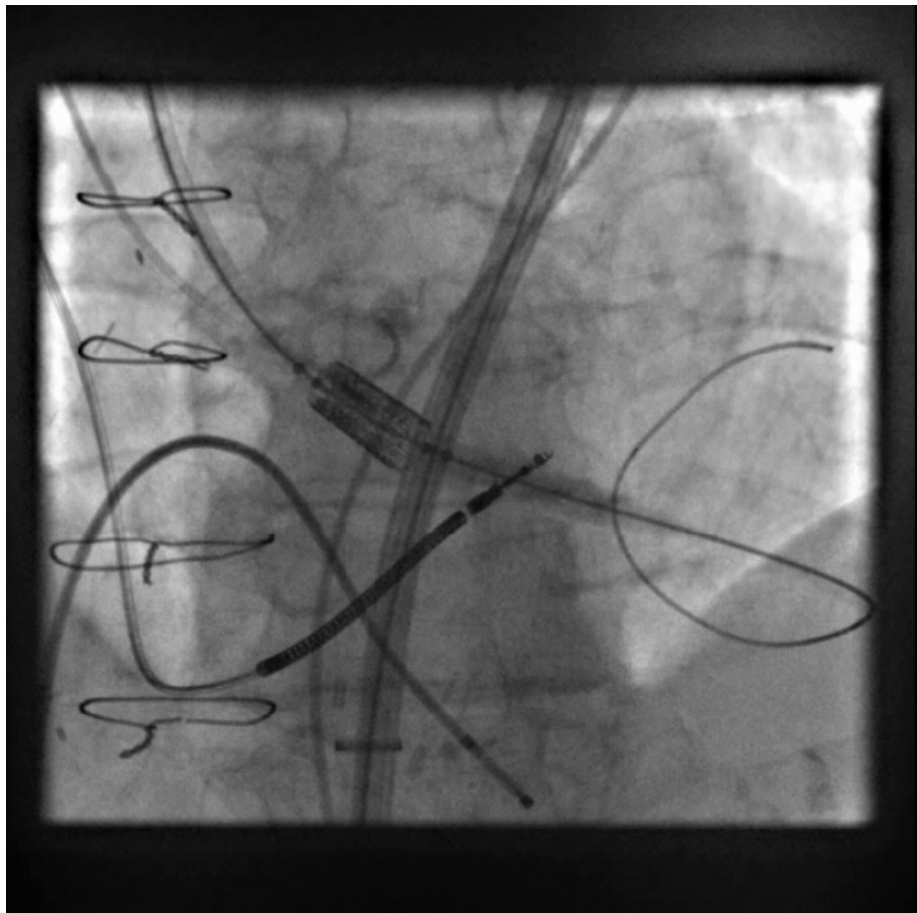
Learning curve effect on 30-d mortality



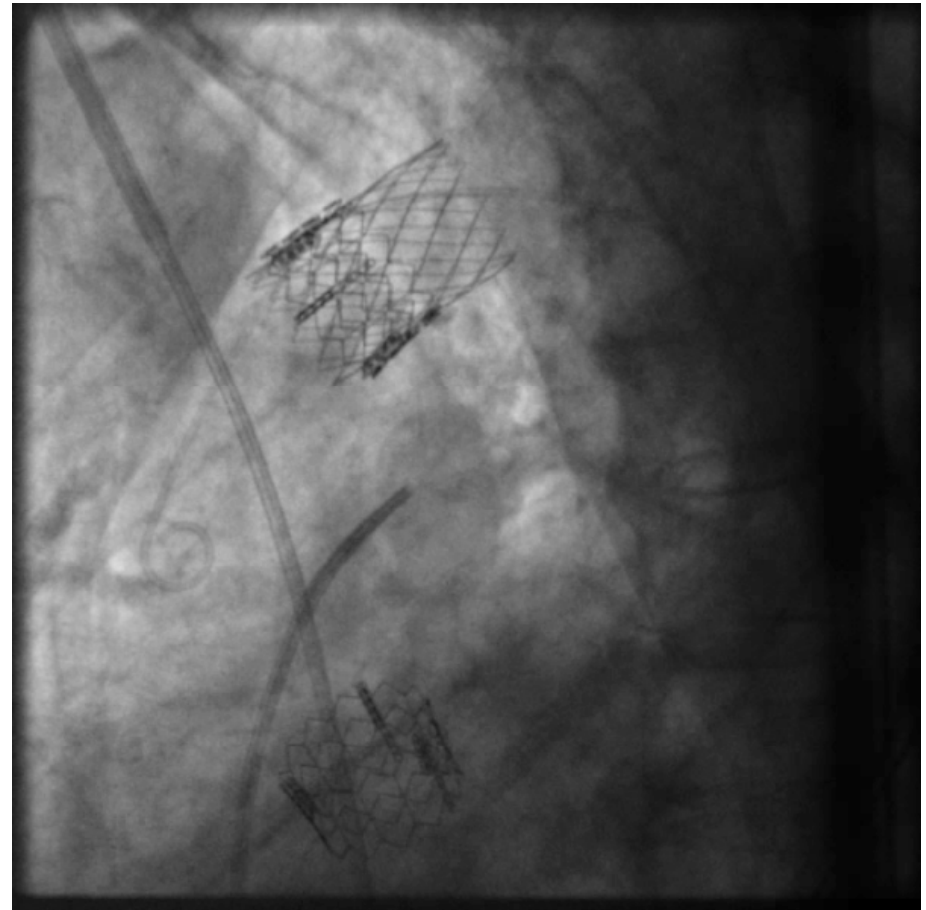
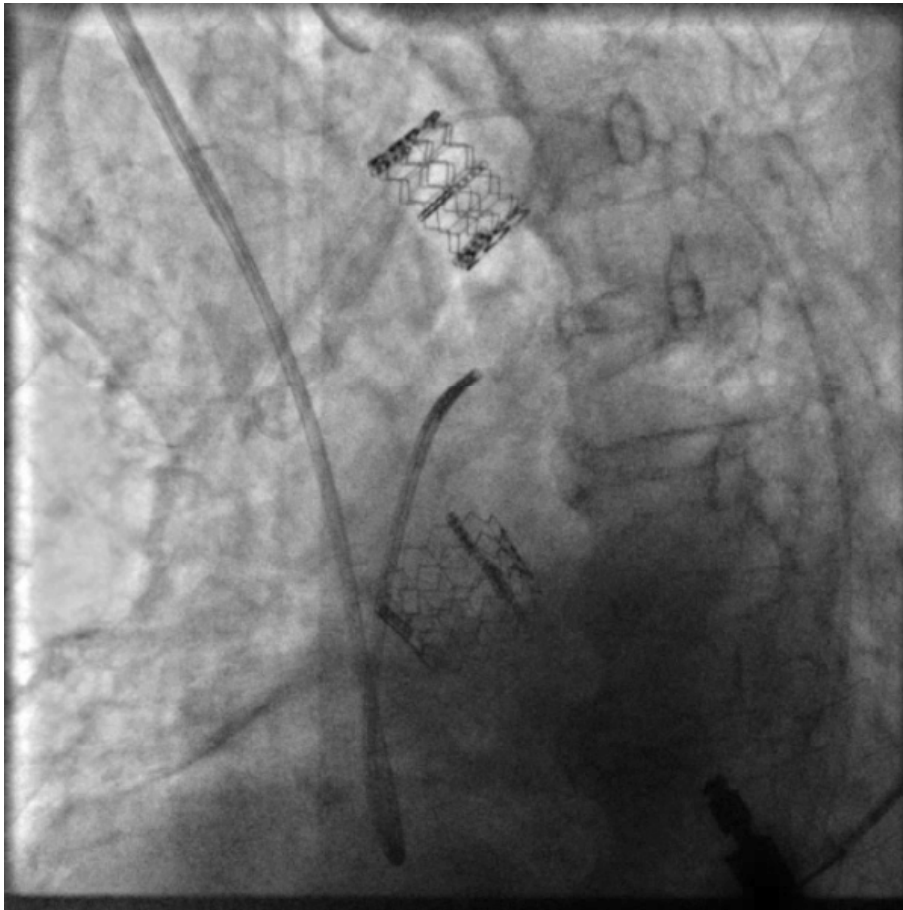
Migration of a CoreValve



Migration of Edwards valve into LV

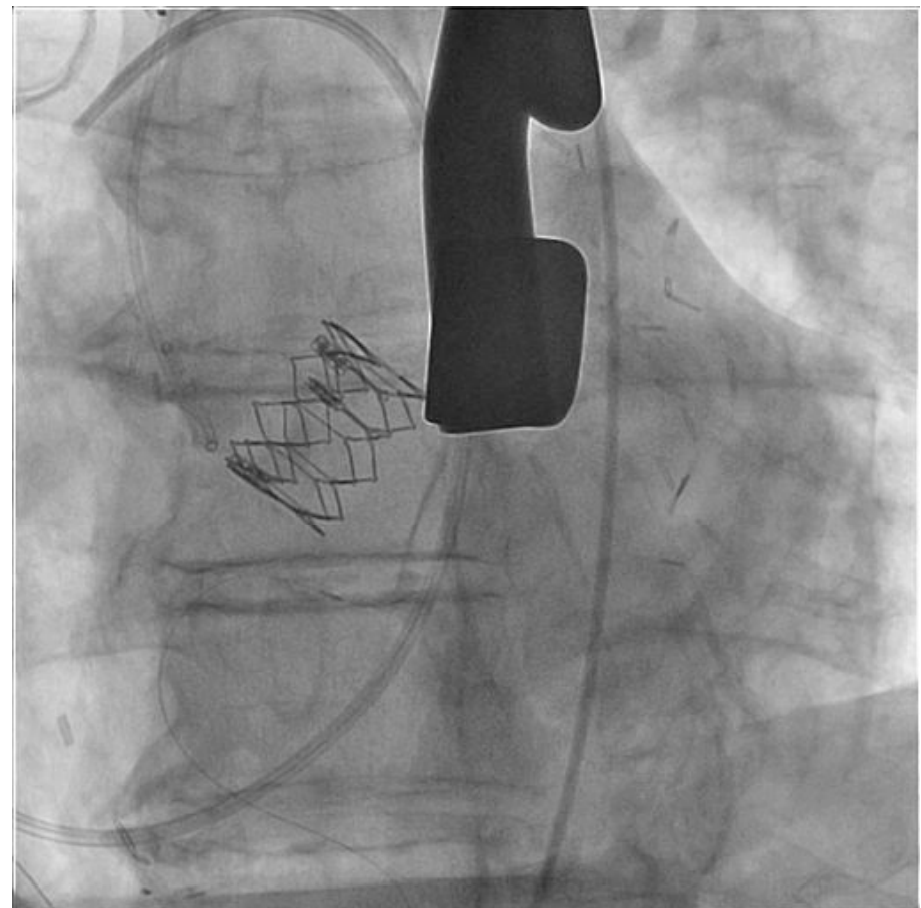
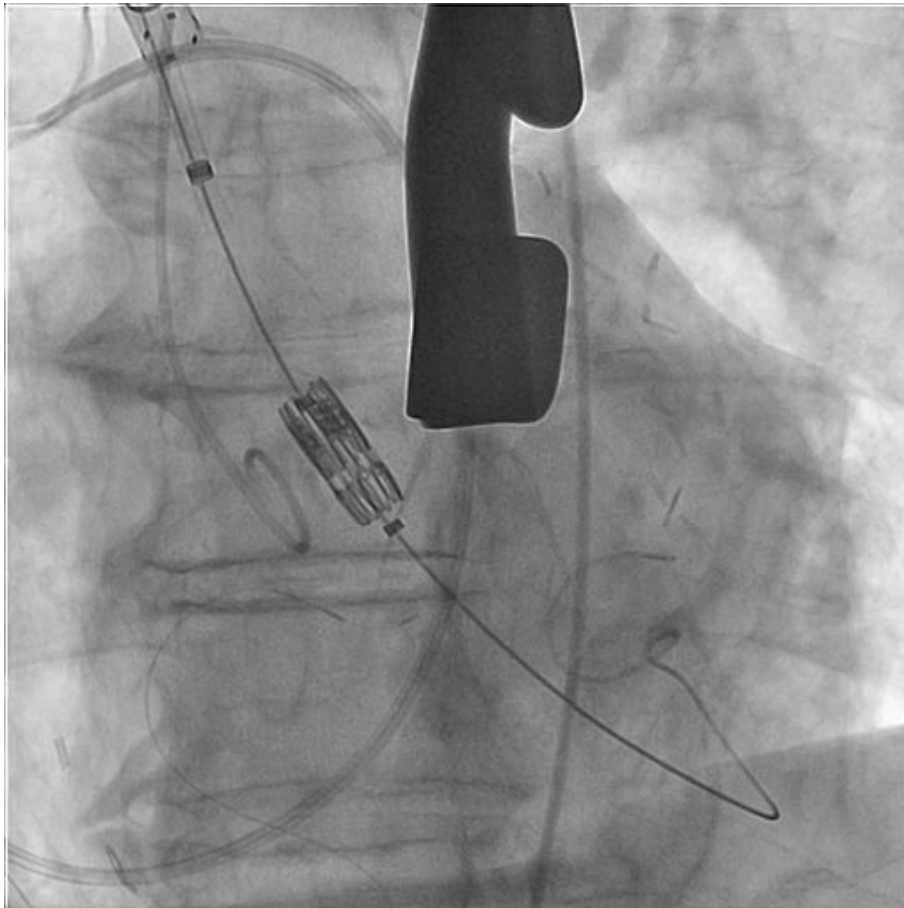


Migration of an Edwards valve into LV



Don't try to too hard to move a migrated valve!

Crimping is important



Valve selection

JACC Cardiovasc Interv. 2012 Feb;5(2):207-14.

True percutaneous approach for transfemoral aortic valve implantation using the Prostar XL device: impact of learning curve on vascular complications.

Hayashida K, Lefèvre T, Chevalier B, Hovasse T, Romano M, Garot P, Mylotte D, Uribe J, Farqe A, Donzeau-Gouge P, Bouvier E, Cormier B, Morice MC.

Institut Cardiovasculaire Paris Sud, Massy, France.

Abstract

OBJECTIVES: The purpose of this study was to evaluate the incidence of vascular complications and the predictors of Prostar failure for a "true percutaneous approach" in transfemoral transcatheter aortic valve implantation (TAVI).

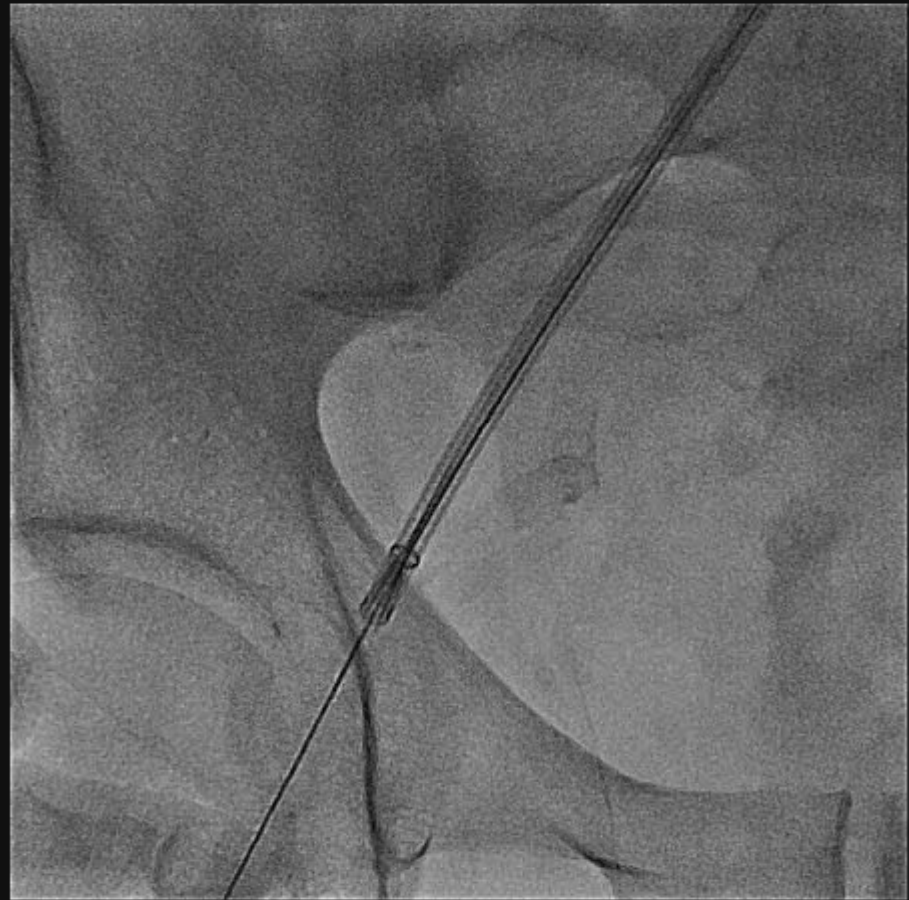
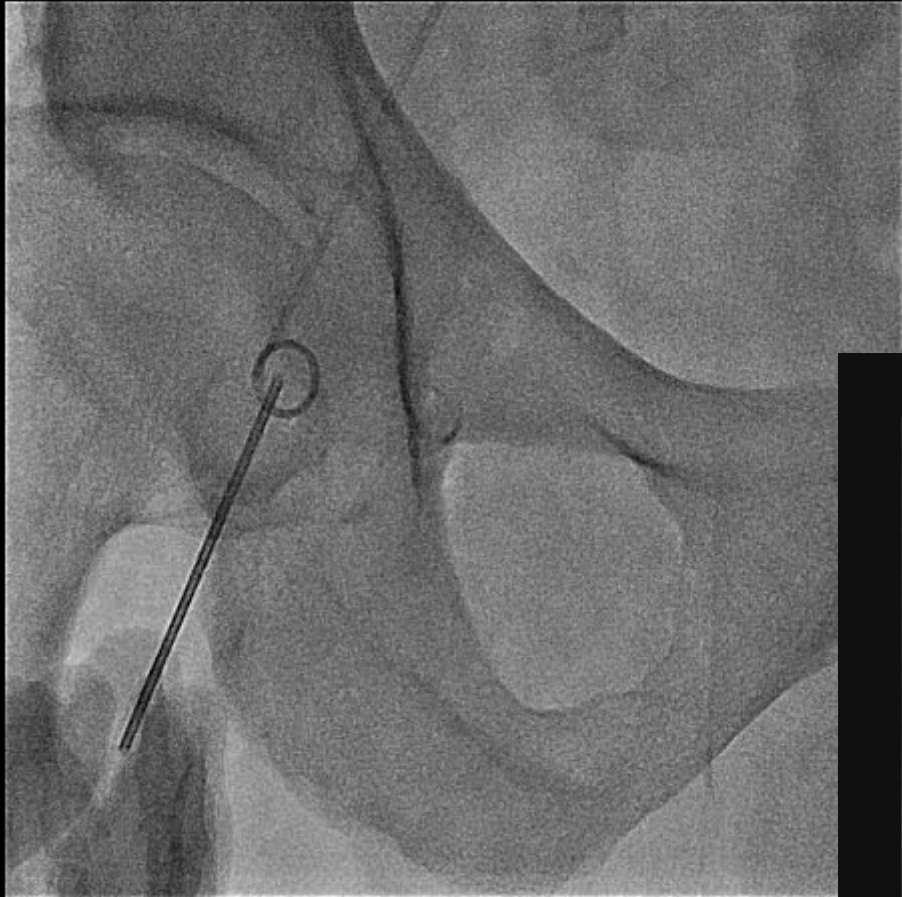
BACKGROUND: Safety and efficacy of a true percutaneous approach in transfemoral-TAVI has not been described in a large prospective cohort.

METHODS: Among 264 patients included in our prospective TAVI database (October 2006 to December 2010), transfemoral-TAVI was performed in 170 patients. True percutaneous approach was performed in 142 consecutive patients since March 2008. Successful closure with Prostar was defined as adequate hemostasis without Prostar-related vascular complications. We compared the incidence of vascular complications in our early and late experience.

RESULTS: Prostar (Boston Scientific, Fremont, California) (18- to 24-F) was used in 170 patients. The mean aortic diameter ratio was 1.14 (range 1.05 to 1.25) in the early experience group and 1.07 (range 1.05 to 1.15) in the late experience group (p=0.012). Major vascular complications (2.9% vs. 14.8%, p=0.018) were decreased in the late experience group. Early experience (hazard ratio [HR]: 3.66, 95% confidence interval [CI]: 1.04 to 13.89, p=0.047) and SFAR (HR: 110.80, 95% CI: 1.15 to 10,710.73, p=0.044) predicted Prostar failure by univariate analysis.

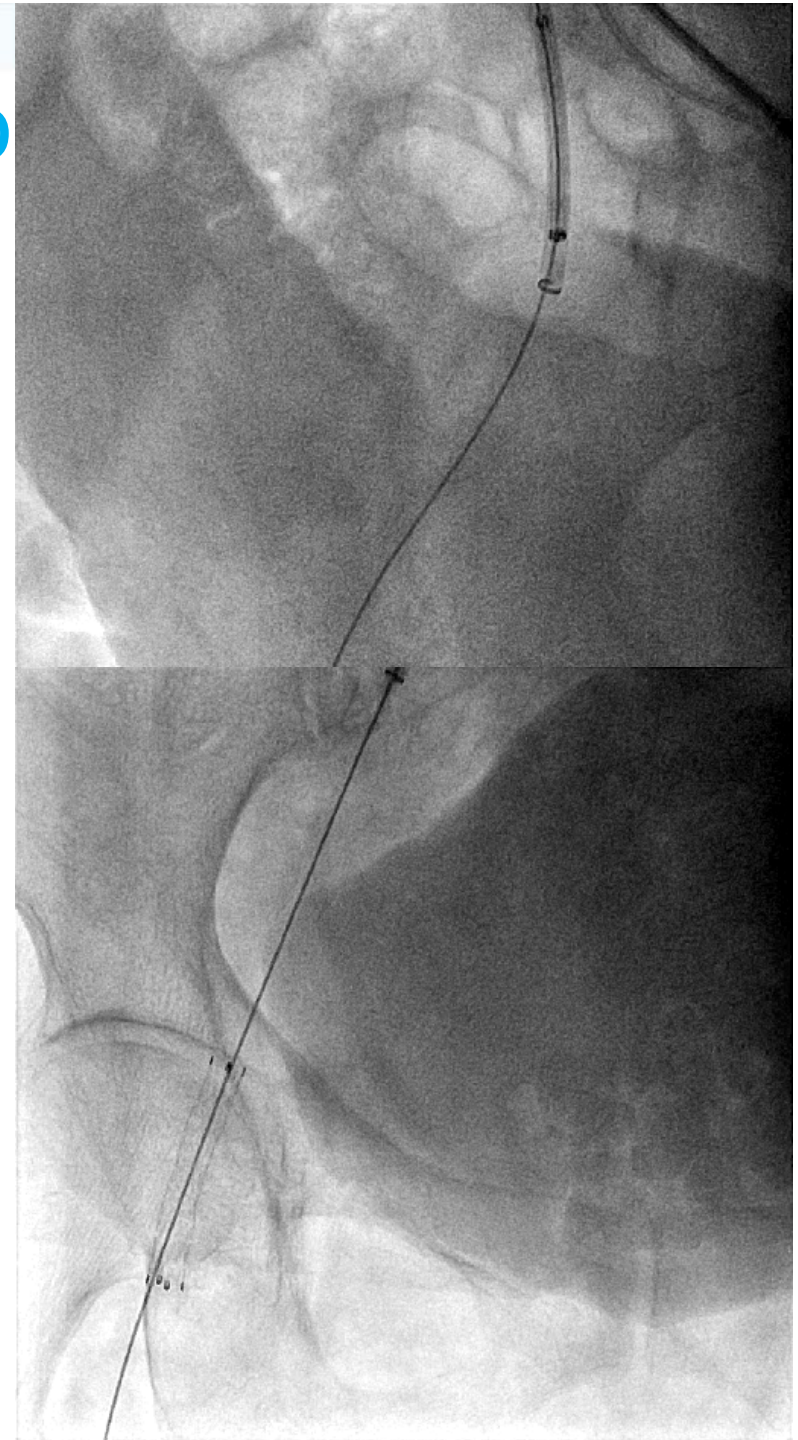
CONCLUSIONS: Experience reduced major vascular complications in a true percutaneous approach for transfemoral-TAVI. Further application of this less invasive strategy is feasible and may be beneficial, in this high-risk patient cohort.

Early percutaneous experience:
HR 3.6 for major vascular complications



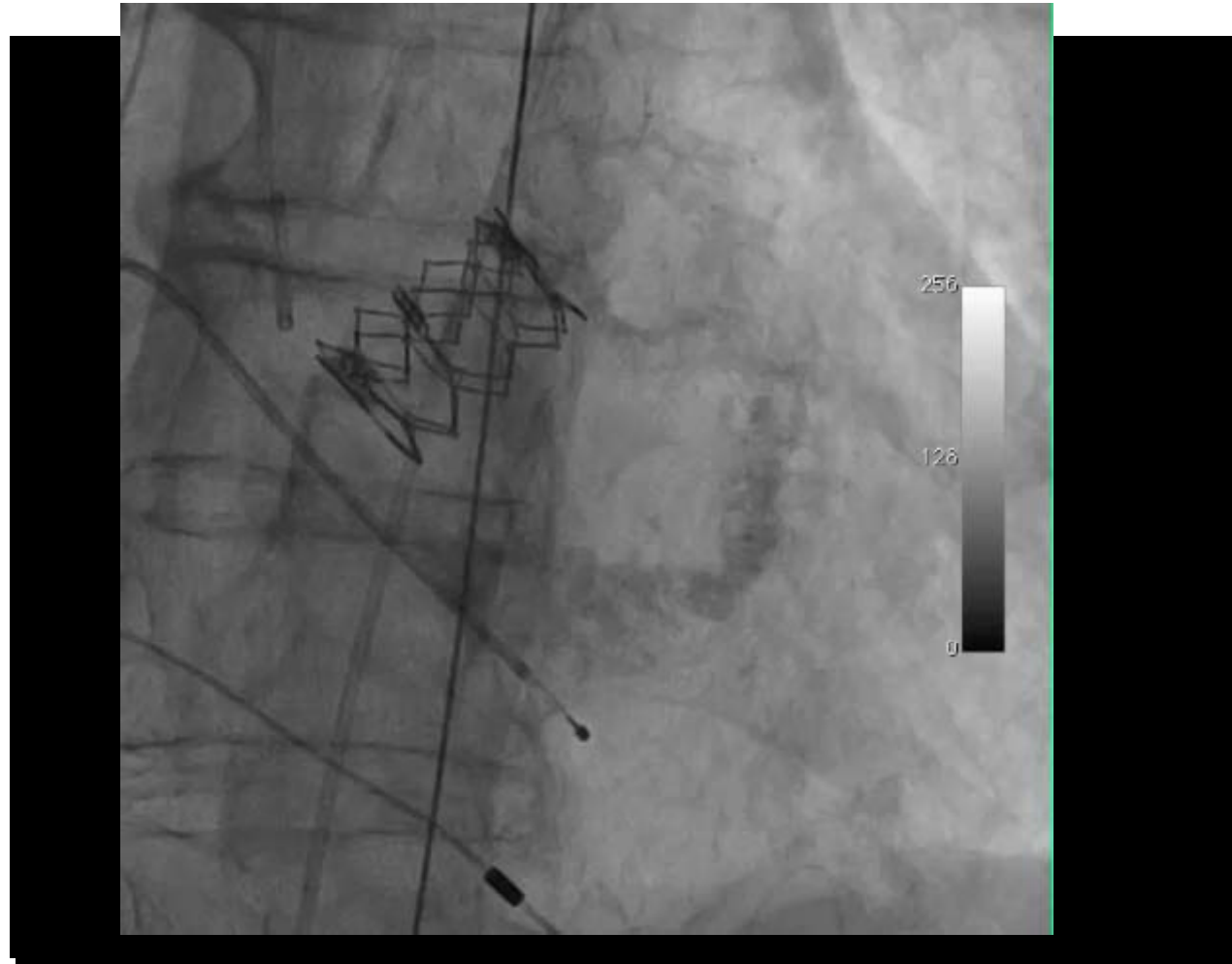


Anticipate worst scenario



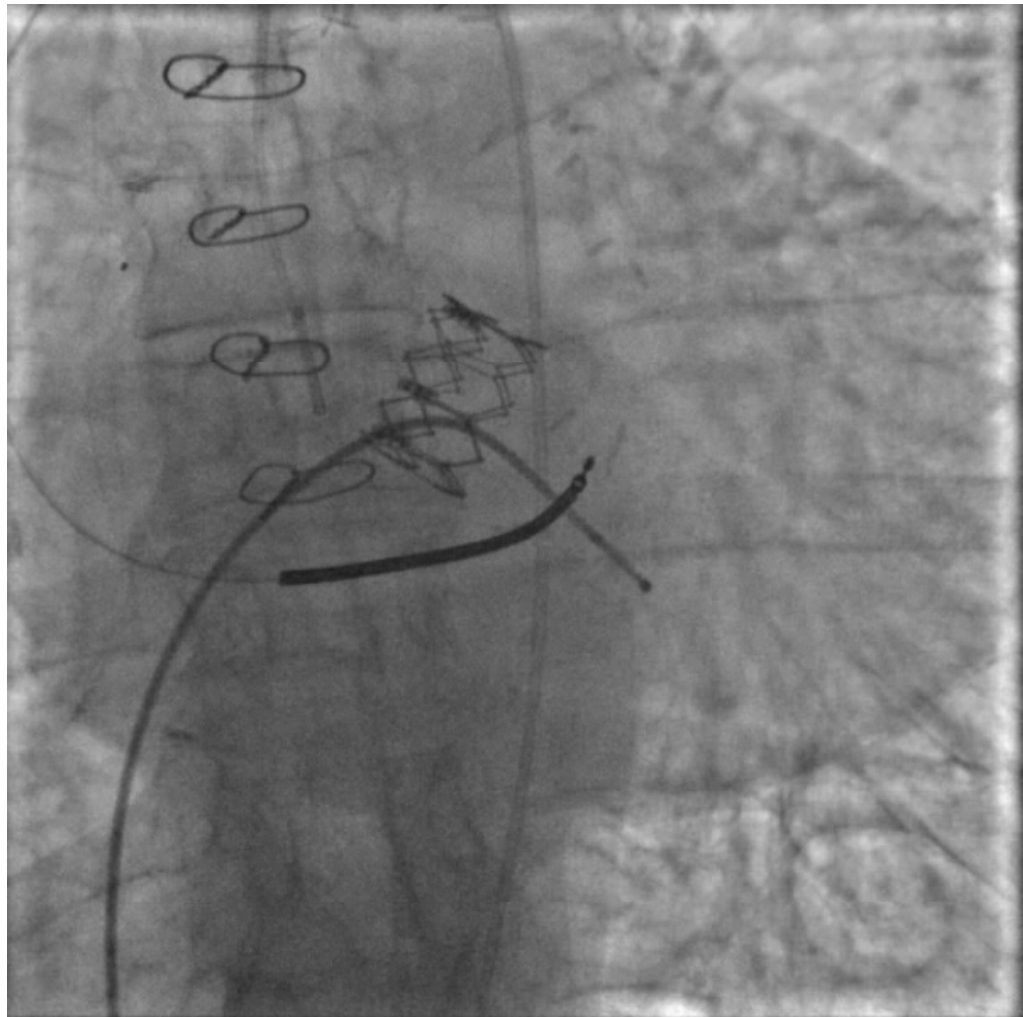
MSCT for sizing and more...

If you put a too large valve...



Annulus rupture leading to tamponade, shock

Or a too small !



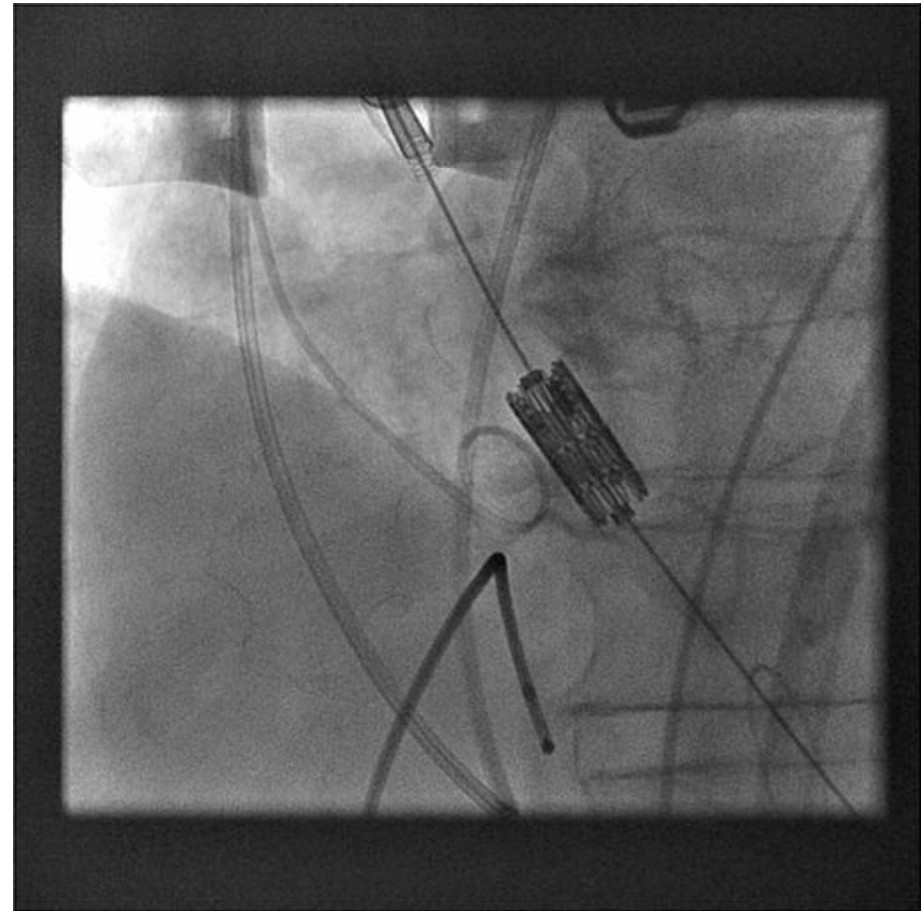
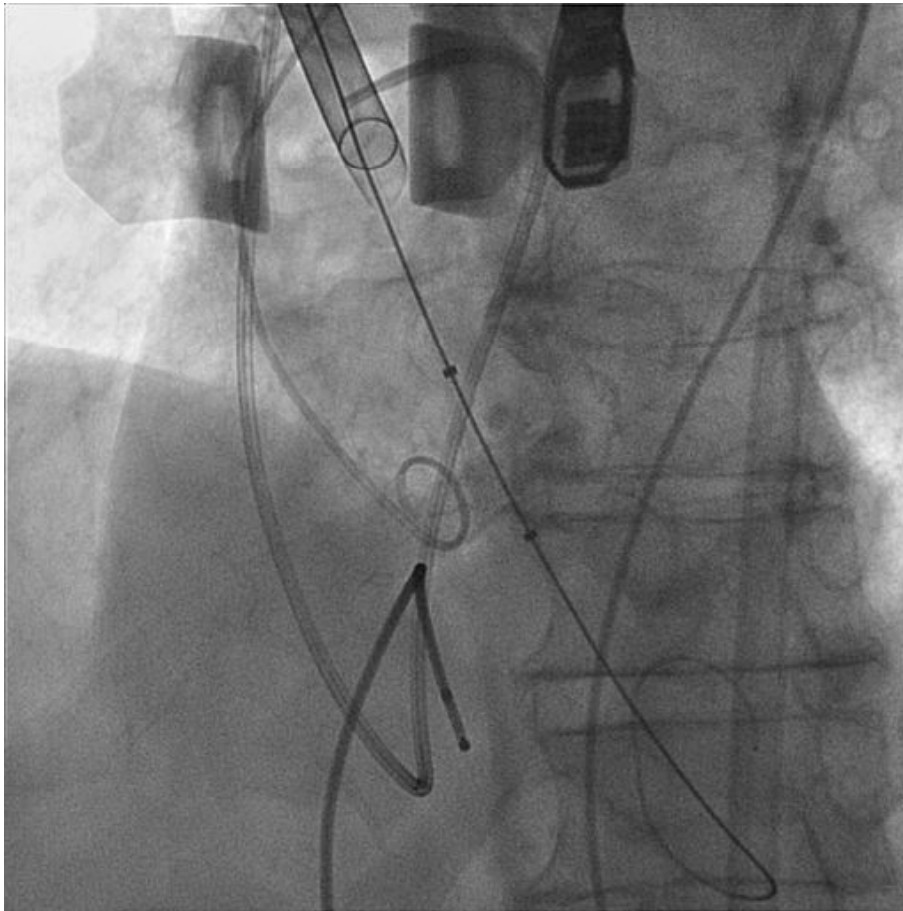
MSCT versus TEE guidance

	CT-guided	TEE-guided	P
Patient number	175	175	
Mean pressure gradient, mmHg	10.1 ± 4.0	11.3 ± 4.8	0.02
LVEF, %	55.0 ± 11.8	53.8 ± 13.1	0.43
Aortic regurgitation ≥2	27 (15.4%)	42 (24.0%)	0.04
Cardiac tamponade	5 (2.9%)	4 (2.3%)	0.74
Annulus rupture	1 (0.6%)	3 (1.7%)	0.31
Valve migration	1 (0.6%)	4 (2.3%)	0.19

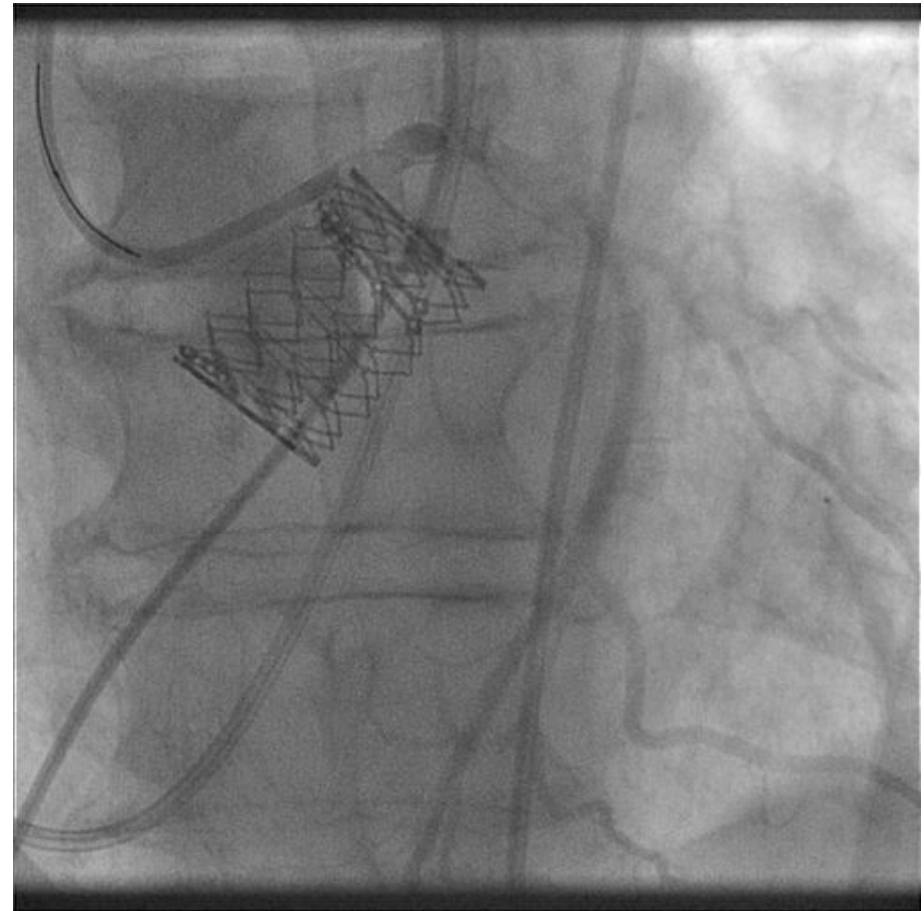
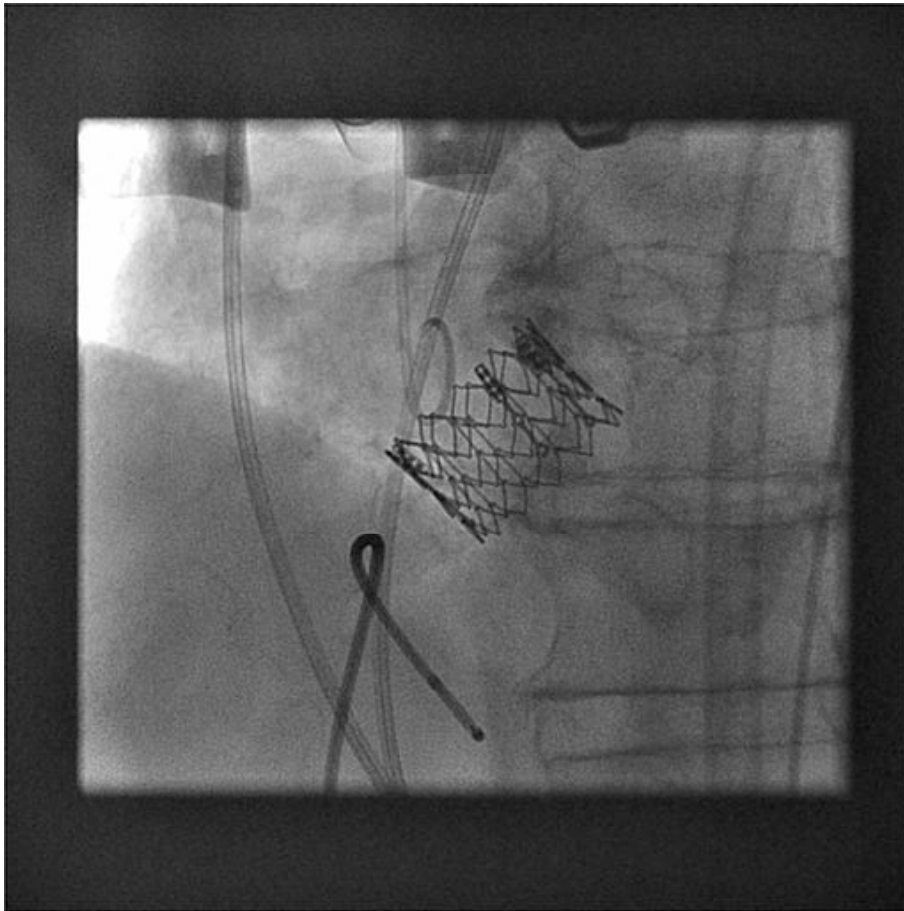
Diam-CT is the predictor of AR > 1

Variables	Univariate		Multivariate	
	Odds ratio	95%CI	Odds ratio	95%CI
Valve/mDiam-CT ratio	0.31	0.14-0.70	0.36*	0.17-0.77
Valve/lDiam-CT ratio	0.45	0.25-0.83	0.56	0.23-1.38
Valve/sDiam-CT ratio	0.45	0.15-1.07	0.67	0.23-2.00
Valve/Diam-TEE ratio	0.82	0.62-1.08		
Annulus calcification score	1.46	0.92-2.31		
Valve calcification score	1.03	0.97-1.08		
Early experience	0.34	0.09-1.16		

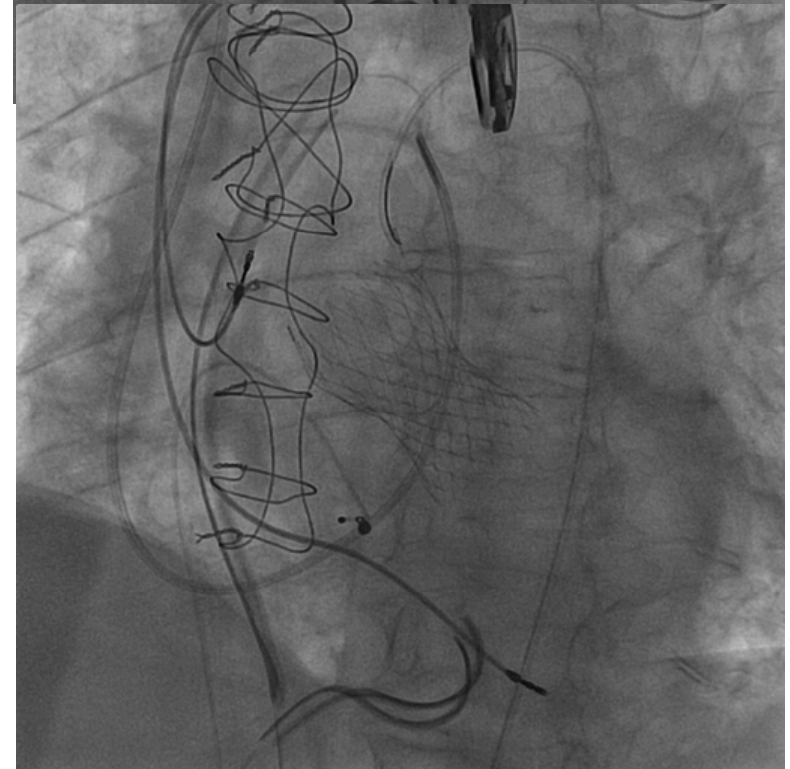
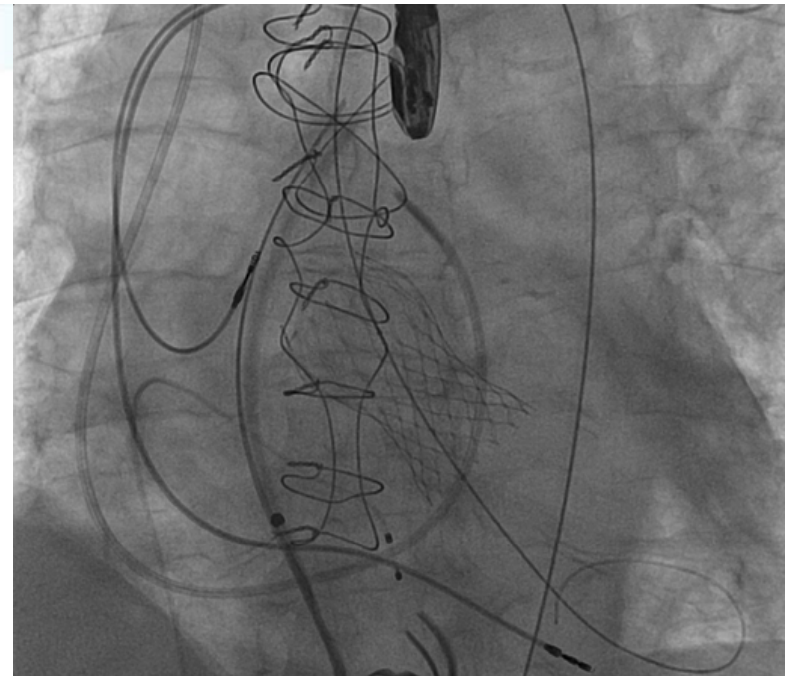
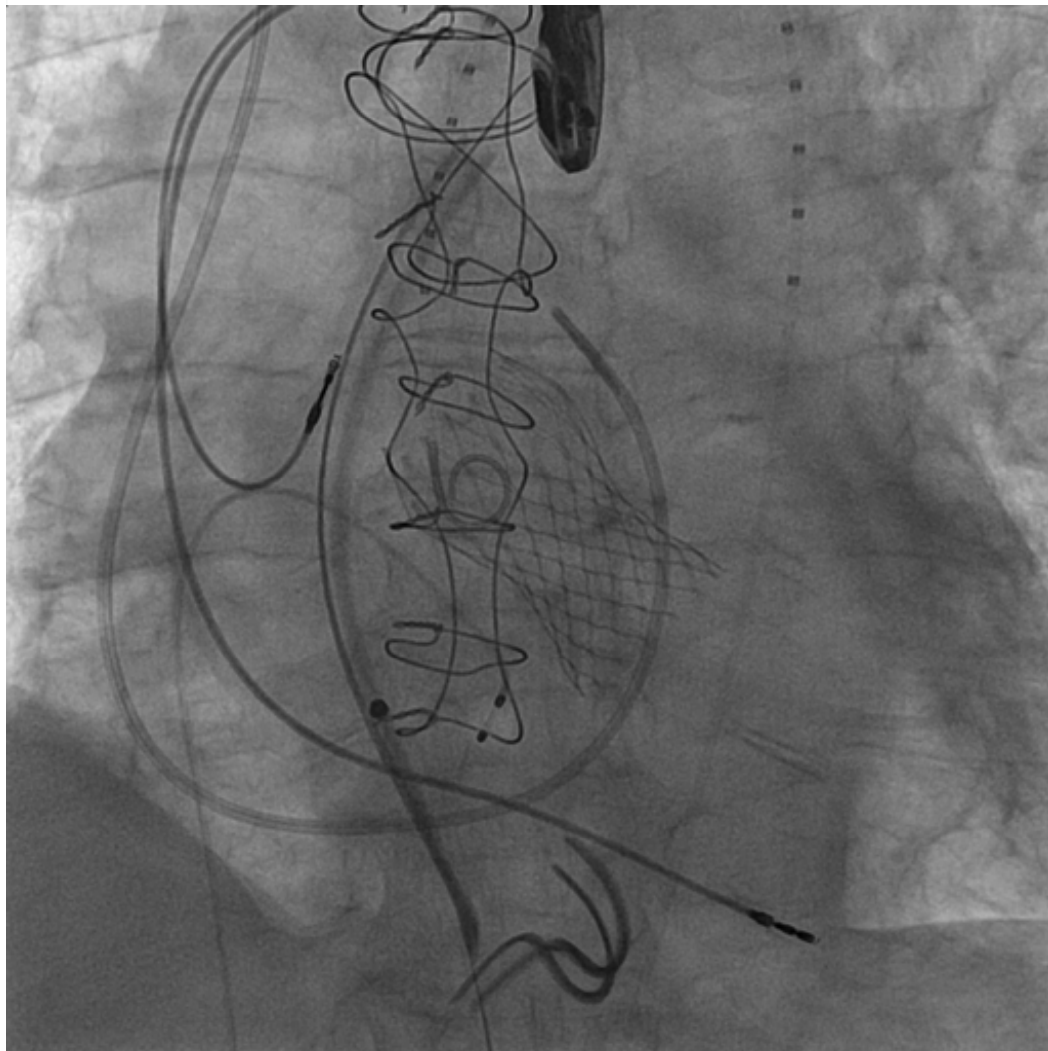
Bulky calcification on the aortic valve

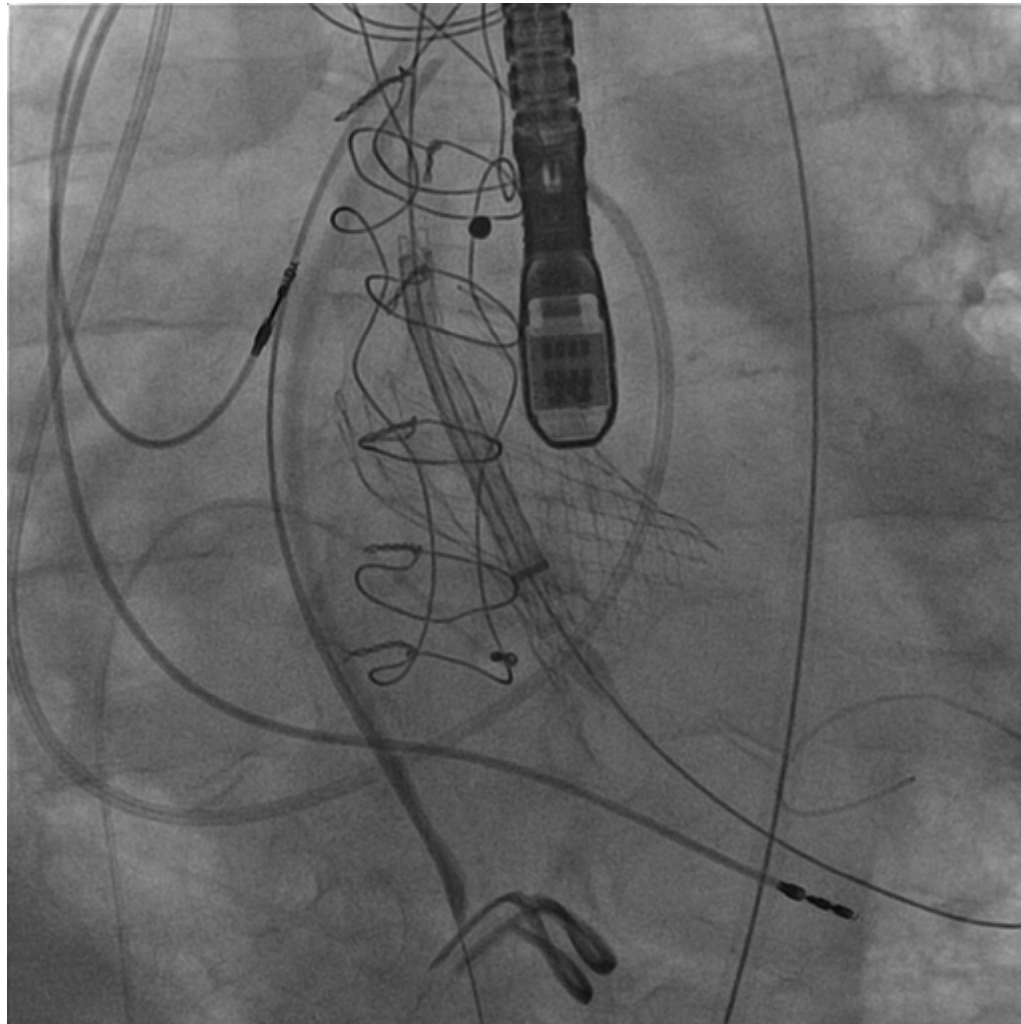


Be careful of the left main!

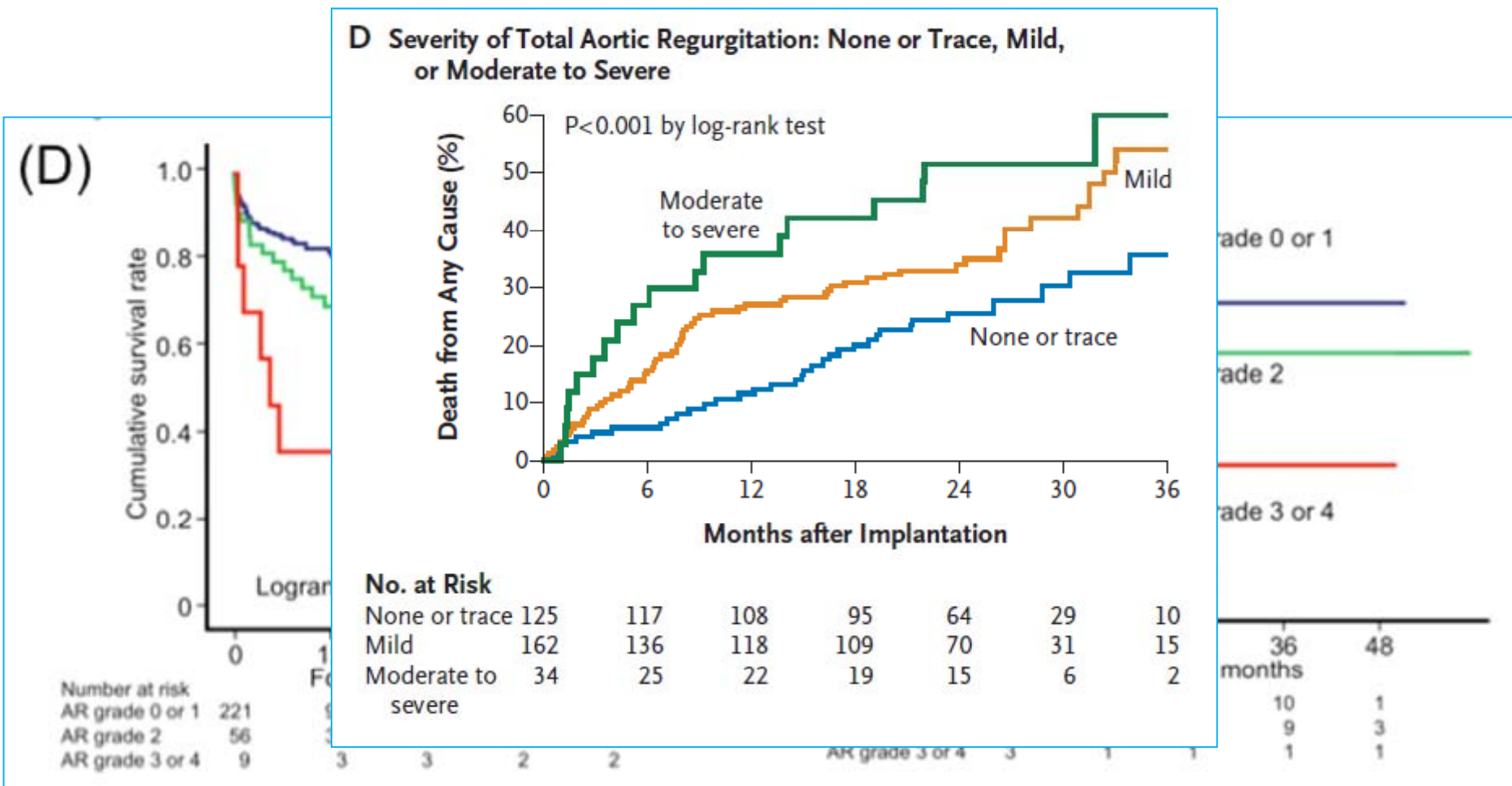


AR > 2





ICPS experience: Role of AR 2



EF > 40%

EF < 40%

Good screening of access

Calcified vascular access



After deployment of the valve...



Iliac rupture leading to hemorrhagic shock

Limitations of vascular events

- Outer sheath diameter / common femoral artery ratio

JACC: CARDIOVASCULAR INTERVENTIONS
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 PUBLISHED BY ELSEVIER INC.

VOL. 4, NO. 8, 2011
 ISSN 1556-0108/11/\$10.00
 DOI: 10.1016/j.jcin.2011.03.019

Interview

Transfemoral Aortic Valve Implantation
 New Criteria to Predict Vascular Complications

Kentaro Hayashida, MD, PhD, Thierry Lefèvre, MD, Bernard Chevalier, MD,
 Thomas Hovasse, MD, Mauro Romano, MD, Philippe Garot, MD, Darren Mylotte, MD,
 Jhonathan Uribe, MD, Arnaud Farge, MD, Patrick Donzeau-Gouge, MD,
 Erik Bouvier, MD, Bertrand Cormier, MD, Marie-Claude Morice, MD

Massy, France

Table 6. Comparison of the Clinical Outcomes According to SFAR Threshold

Variables	SFAR		p Value
	≥1.05 (n = 55)	<1.05 (n = 72)	
Any vascular complication	23 (41.8%)	12 (16.7%)	<0.001
VARC Major	17 (30.9%)	5 (6.9%)	0.001
VARC Minor	6 (10.9%)	7 (9.7%)	0.827
Femoral artery complication	15 (27.3%)	9 (12.5%)	0.035
Iliac artery complication	11 (20.0%)	2 (2.8%)	0.002
In-hospital mortality	11 (20.0%)	5 (6.9%)	0.033
30-day mortality	10 (18.2%)	3 (4.2%)	0.016

Values are n (%). p Values in **bold** are statistically significant.
 Abbreviations as in Tables 2 and 3.

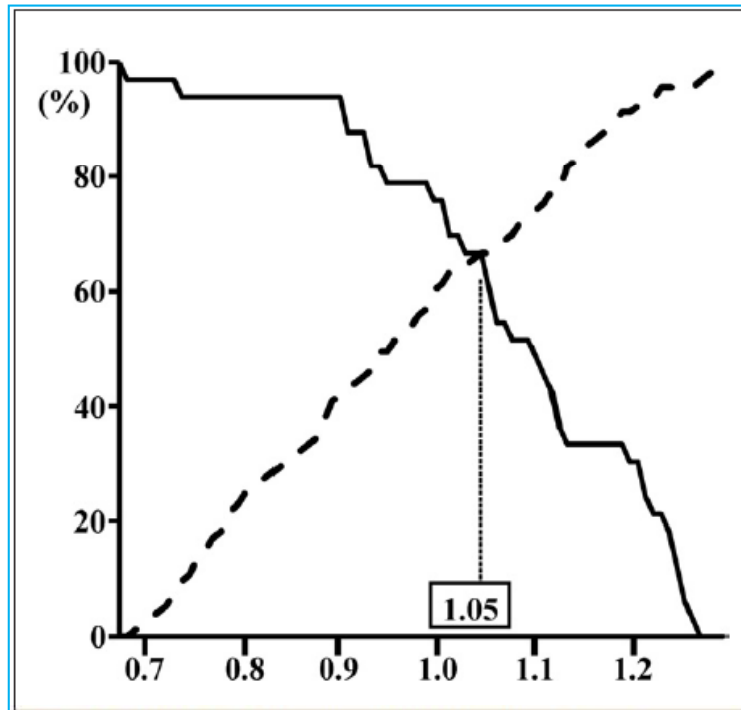


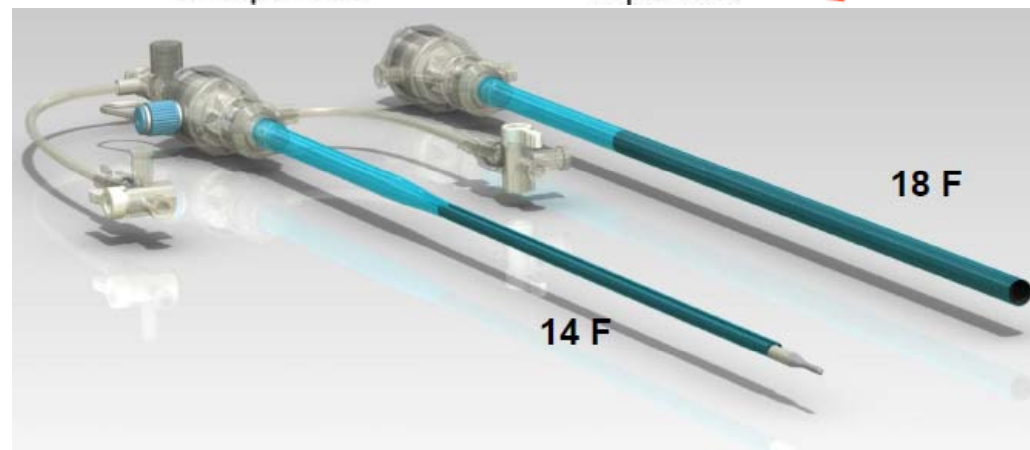
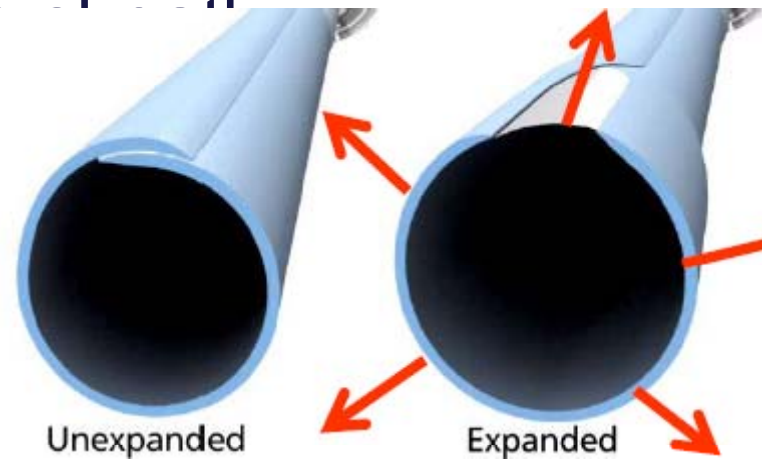
Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

The sensitivity and specificity curve identified the threshold sheath femoral

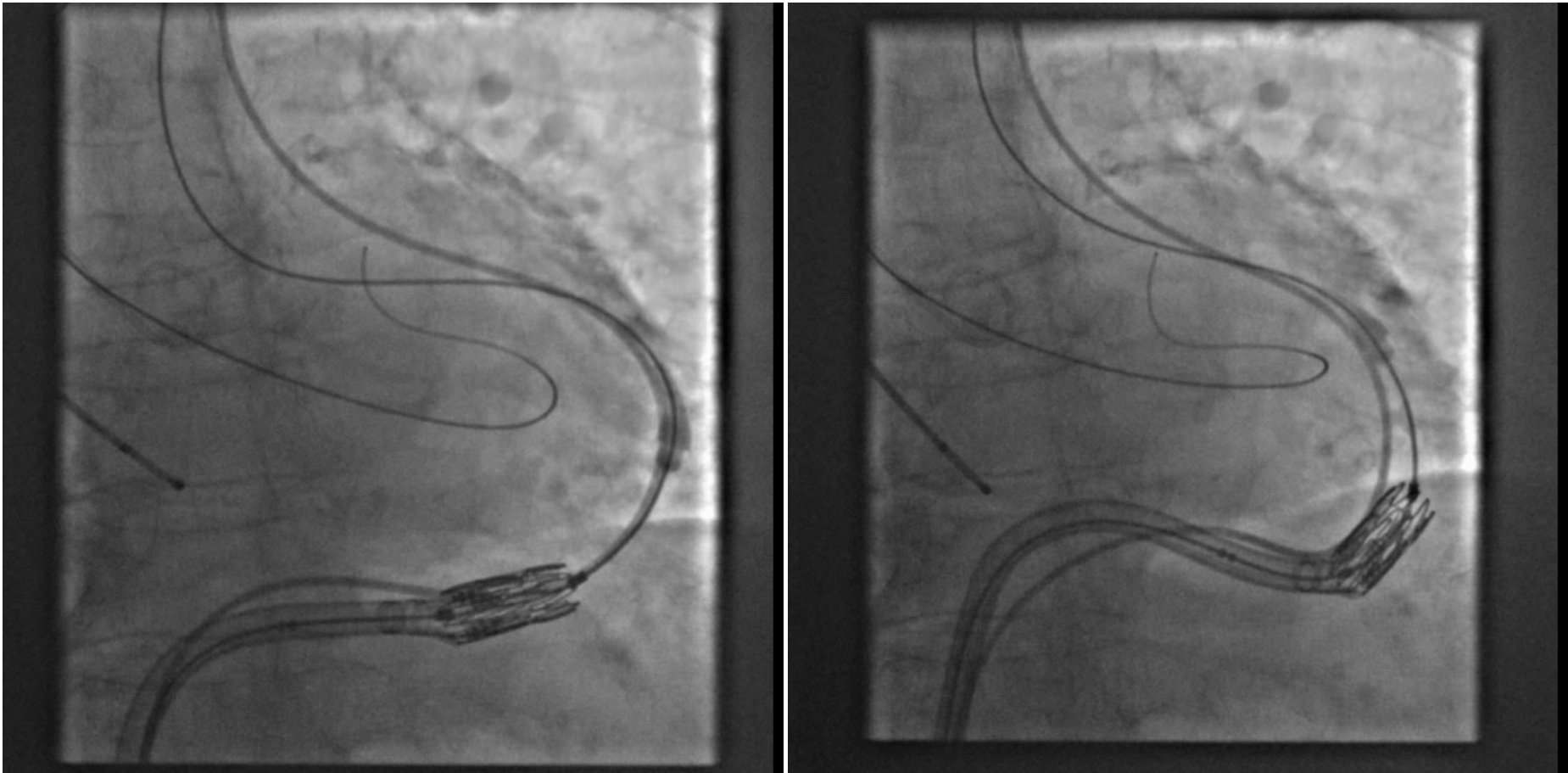
1.1 for non calcified and 1.0 for calcified
 6.5 mm and 7.2 mm

Downsizing

- Expandable



Tortuous thoracic aorta



Rupture of the thoracic aorta

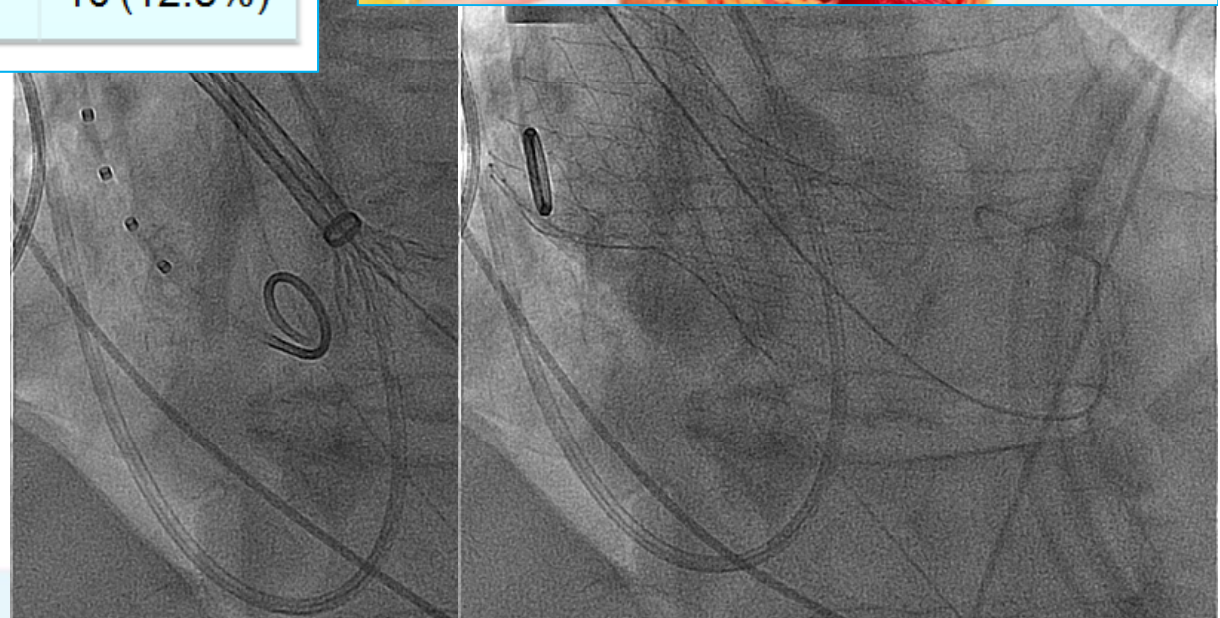
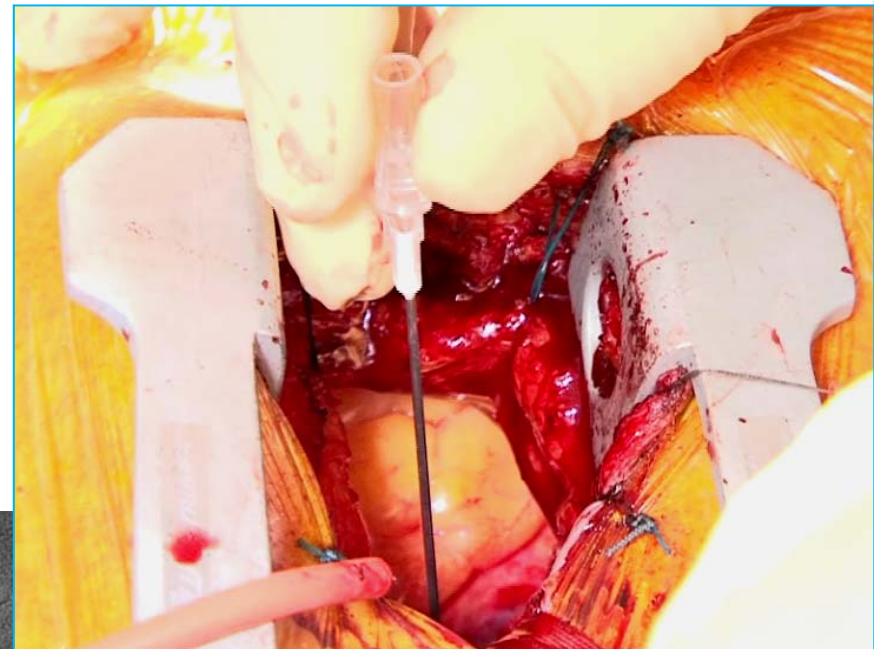


*Don't push the limit!
You have better alternatives*

Transaortic

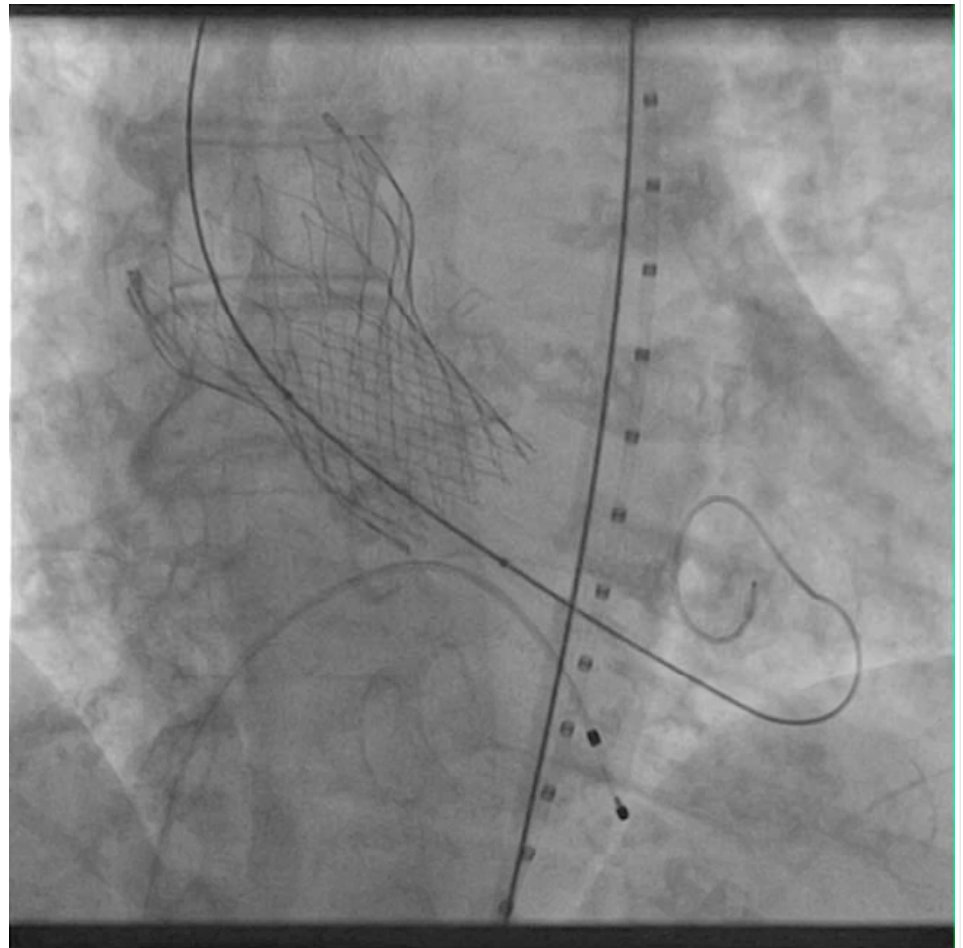
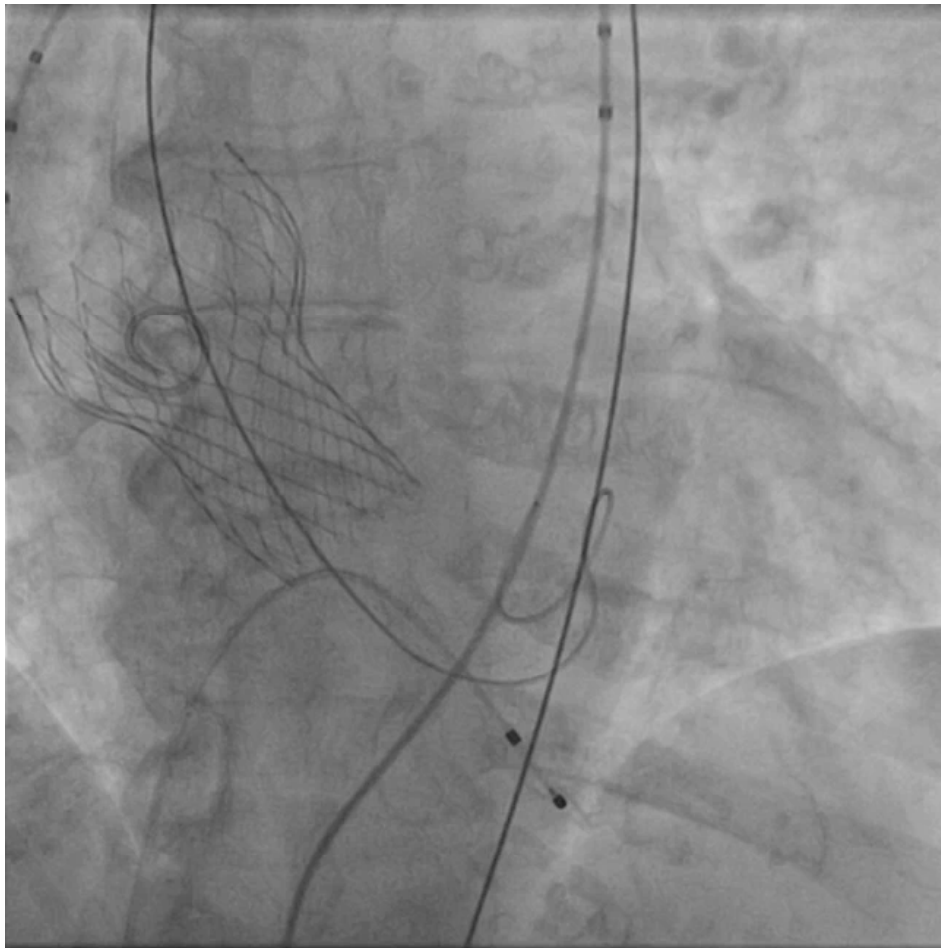
30-Day Clinical Outcome (n=78)

ICU stay, days	4.3 ± 2.6
Total In-hospital stay, days	12.2 ± 5.3
Pacemaker implantation, %	4 (5.1%)
Stroke, %	2 (2.6%)
30-day mortality, %	6 (7.7%)
30-day combined safety endpoint	10 (12.8%)



Good luck is important !

Be careful of the pacemaker !



Complication: prevention & management

