

A Novel Vertical Spacer for Tricuspid Regurgitation

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Disclosure

➤ Grant support

- National Evidence-based Healthcare Collaborating Agency, Ministry of Health & Welfare, Republic of Korea
- Abbott Vascular, Biosensors, Biotronik, Boston Scientific, Daiichi Sankyo, Donga-ST, Hanmi Pharmaceutical, and Medtronic

➤ Consulting Fees/Honoraria

- Abbott Vascular, Amgen, Astra Zeneca, Biosensors, Biotronik, Boston Scientific, Daiichi Sankyo, MSD Korea, Novartis, Pfizer, and Sanofi-Aventis



Pivot-TR: concept & features

Spacer

- Atraumatic anchoring structure
- Vertical self centering spacer

Procedure

- Simple procedure less than 20 minutes
- No requiring complex imaging guidance (such as TEE or ICE)

TR

- can deal with TR with a large gap (torrential TR)
- less dependent on annular or RV size
- not dependent on IVC-RA geometry

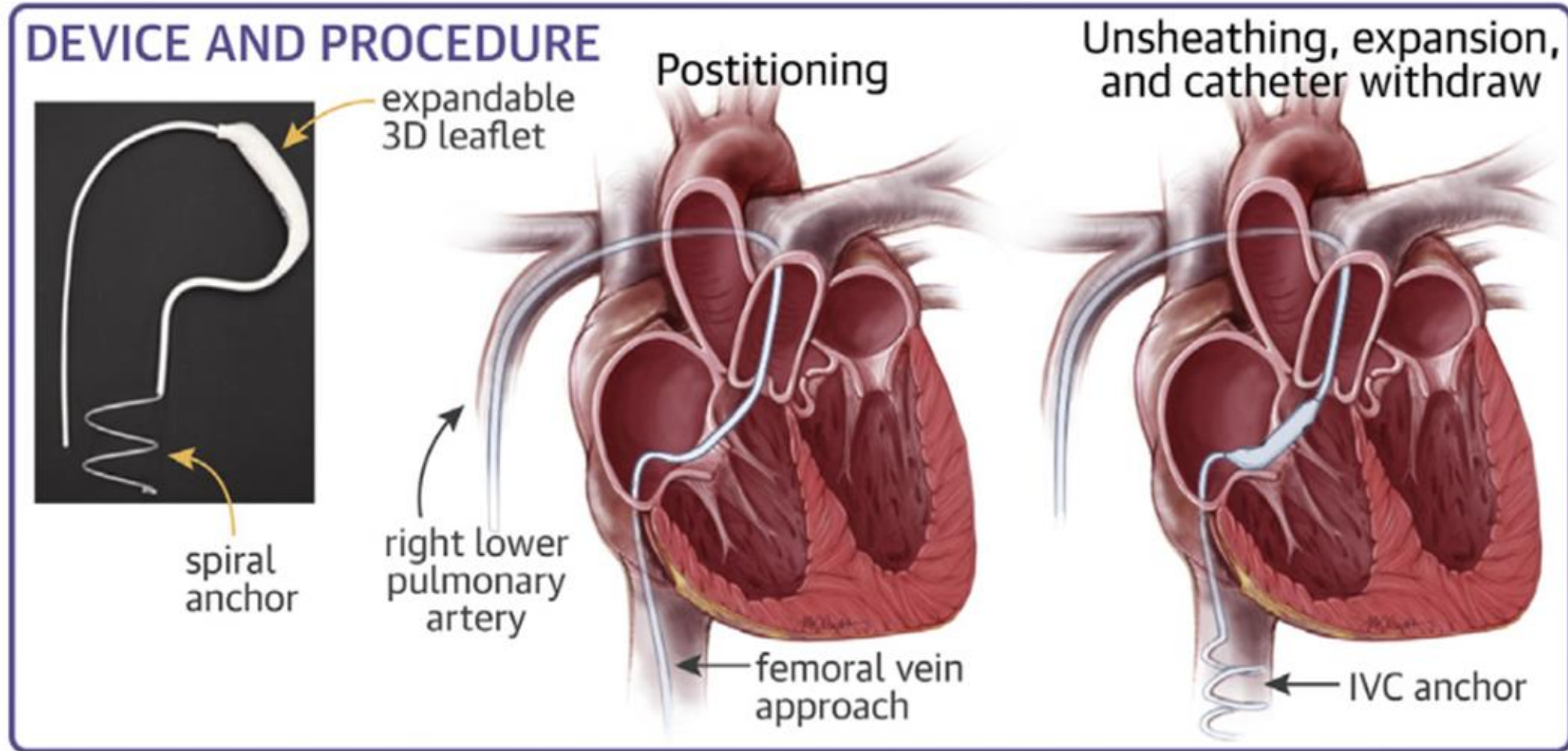
Retrievable

- Catheter retrieval if needed (within 2~4 weeks)

Pivot-TR device is made by Tau Medical Co, Yangsan, South Korea.



PIVOT-TR: device and procedure

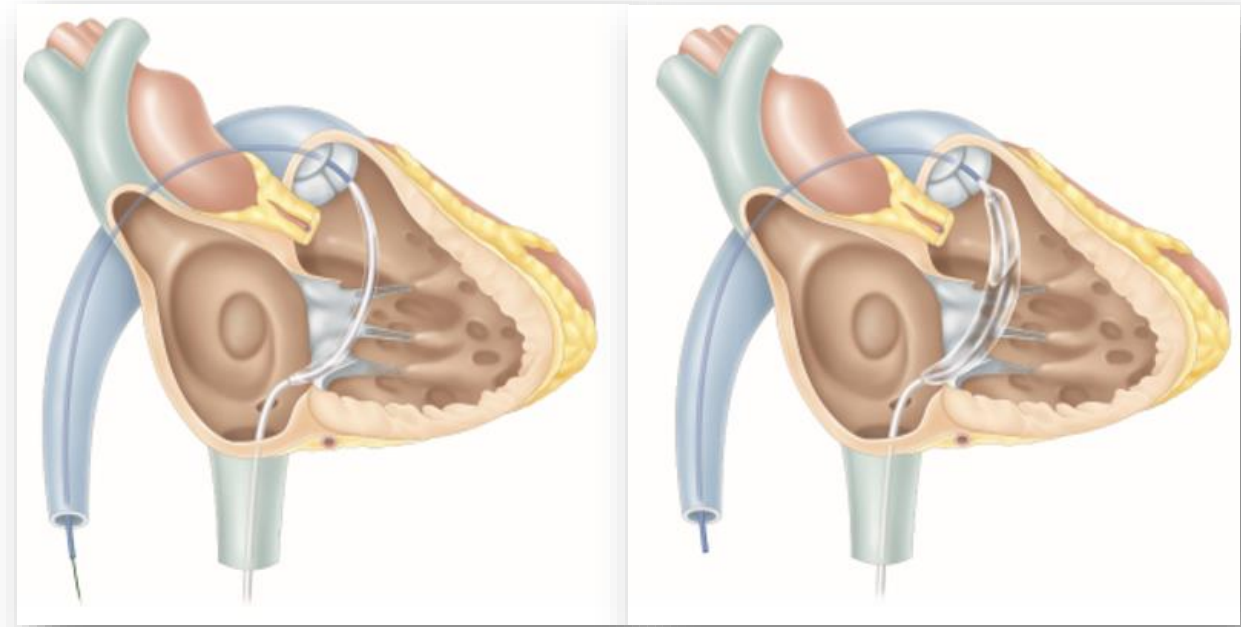
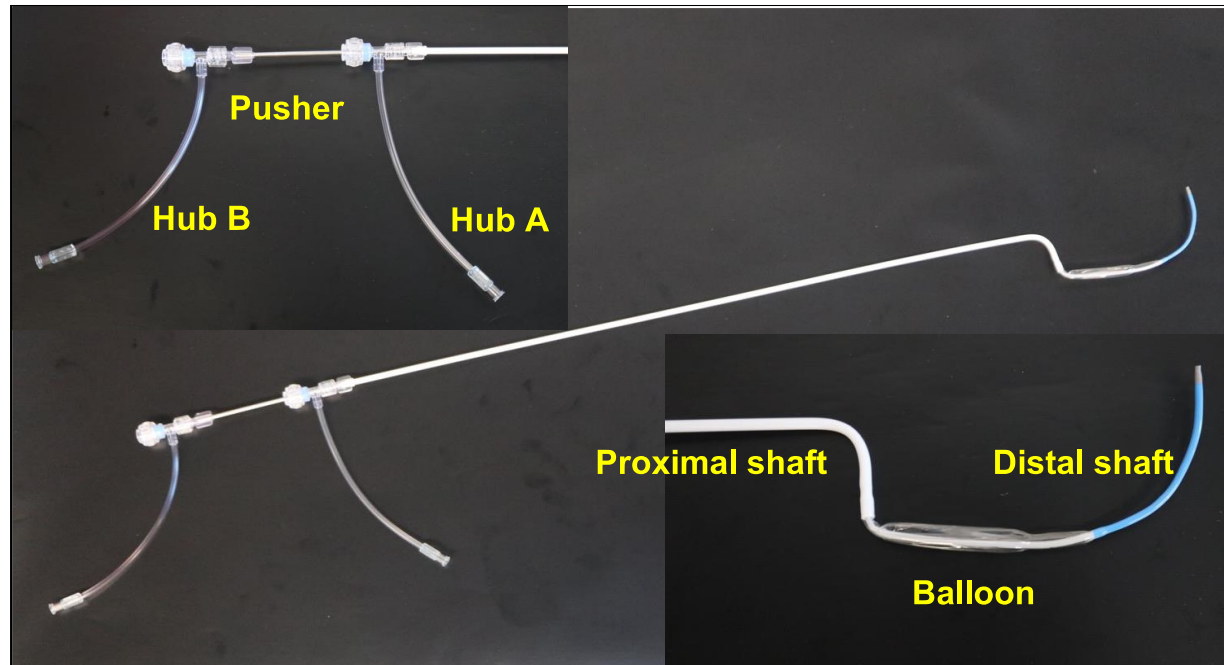




Pivot-TR: current status

- Pre-clinical proof of concept was published in JACC-BTS (Dec 2022).
- Pivot balloon clinical trial was done in South Korea.
 - Transient implementation of Pivot balloon for assessment of feasibility and safety.
- Pivot-TR bridge clinical trial is ongoing.
 - Implementation of Pivot-TR <1 week

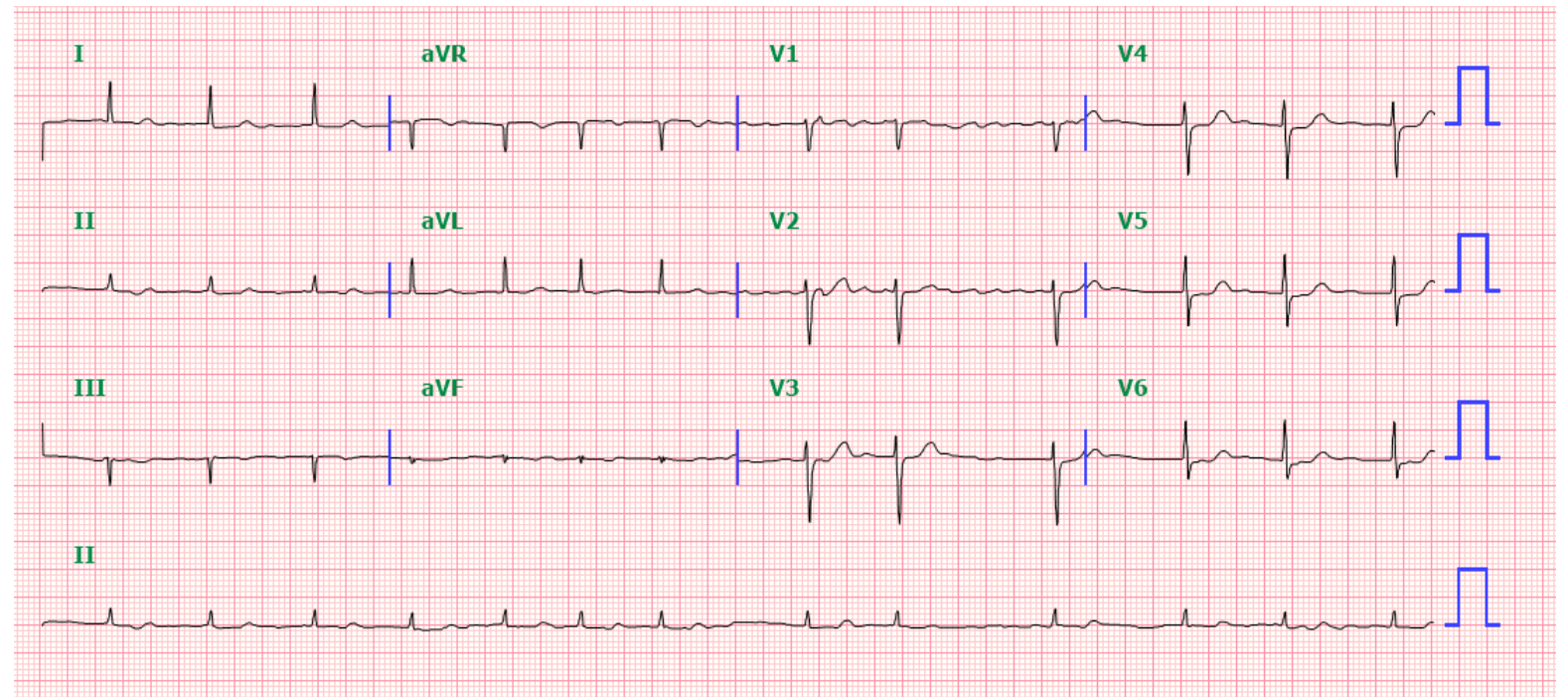
Pivot-balloon





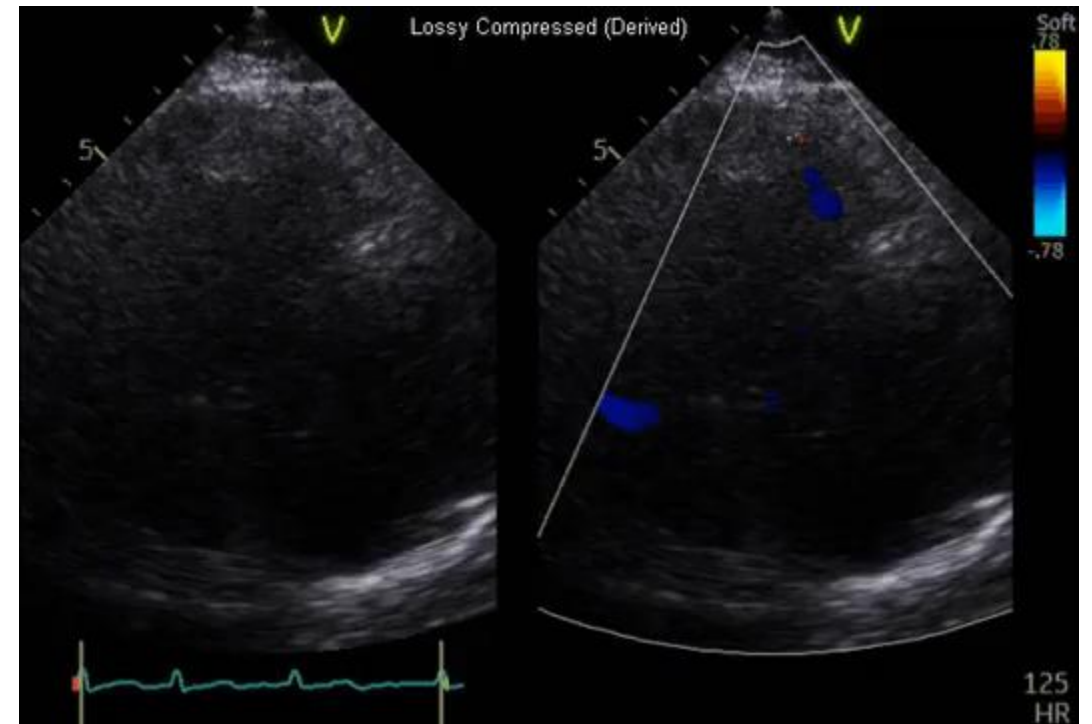
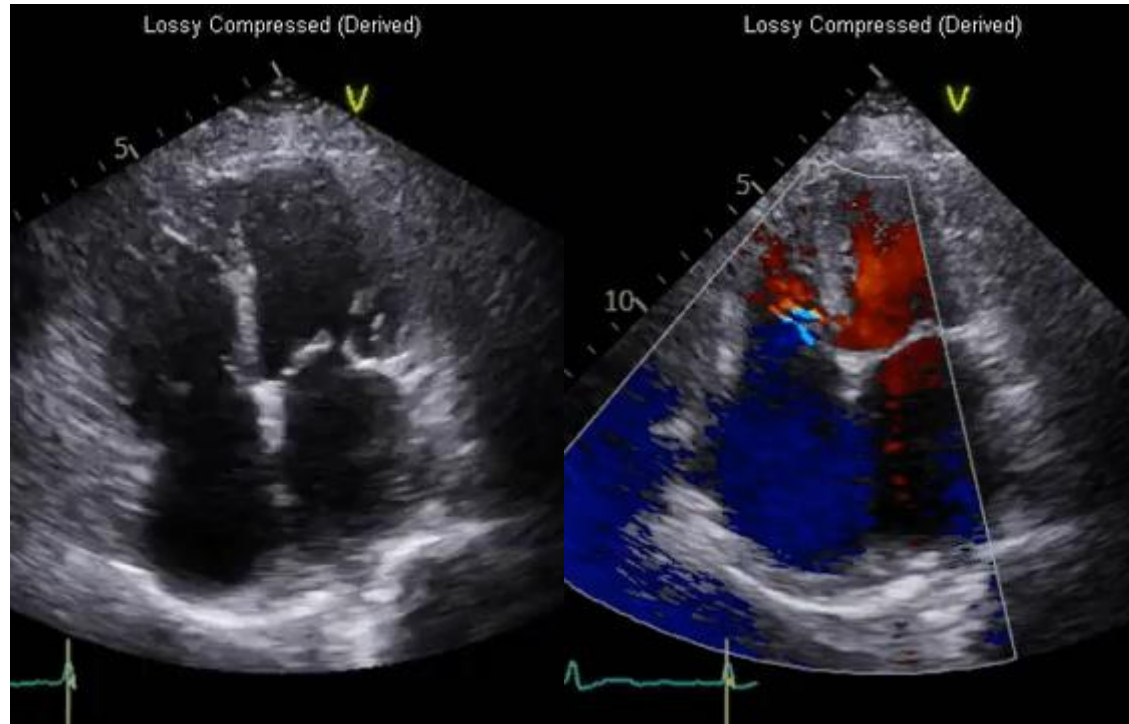
Case: F/74, Atrial functional TR

- Recurrent admission due to heart failure
- Long standing A fib
- Medical treatment
 - Anti-coagulation
 - Rate control
 - Diuretics
- A fib ablation → Recur



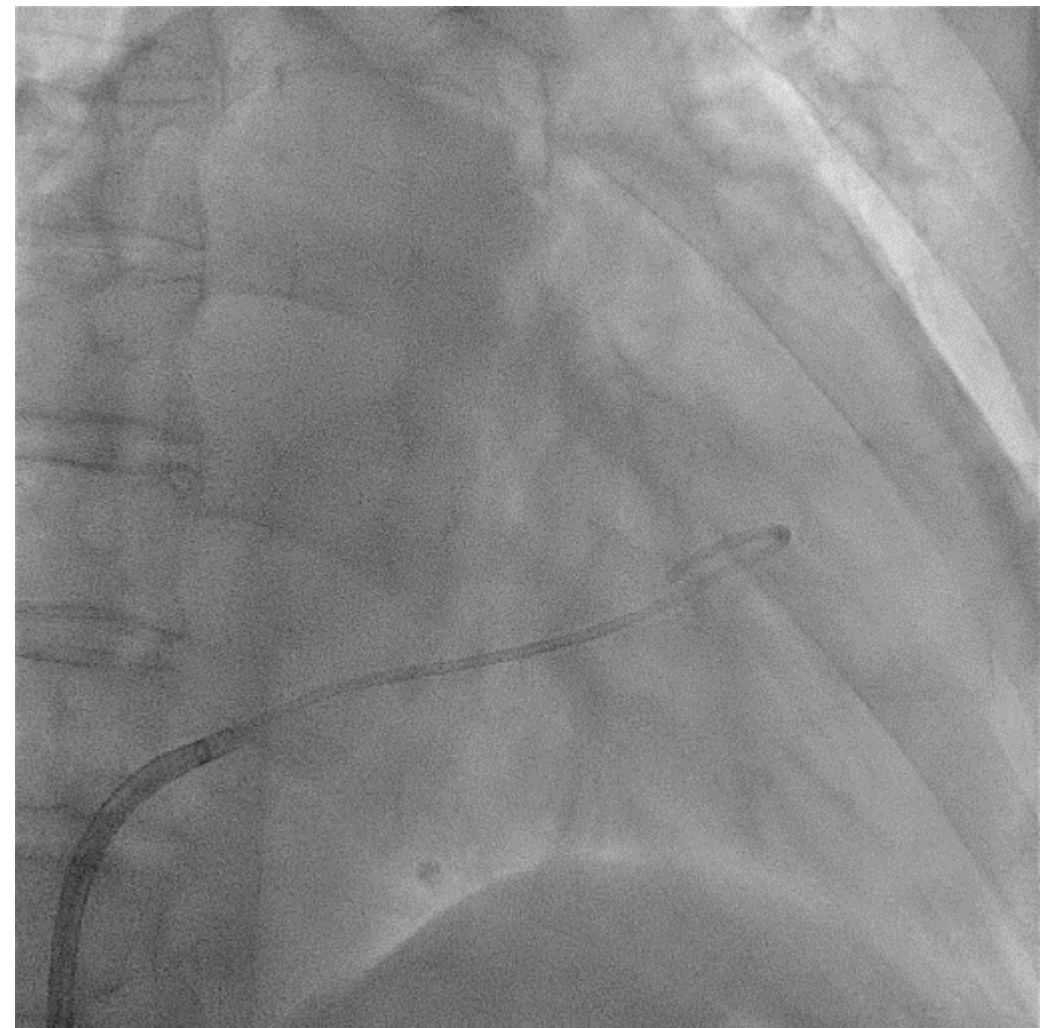
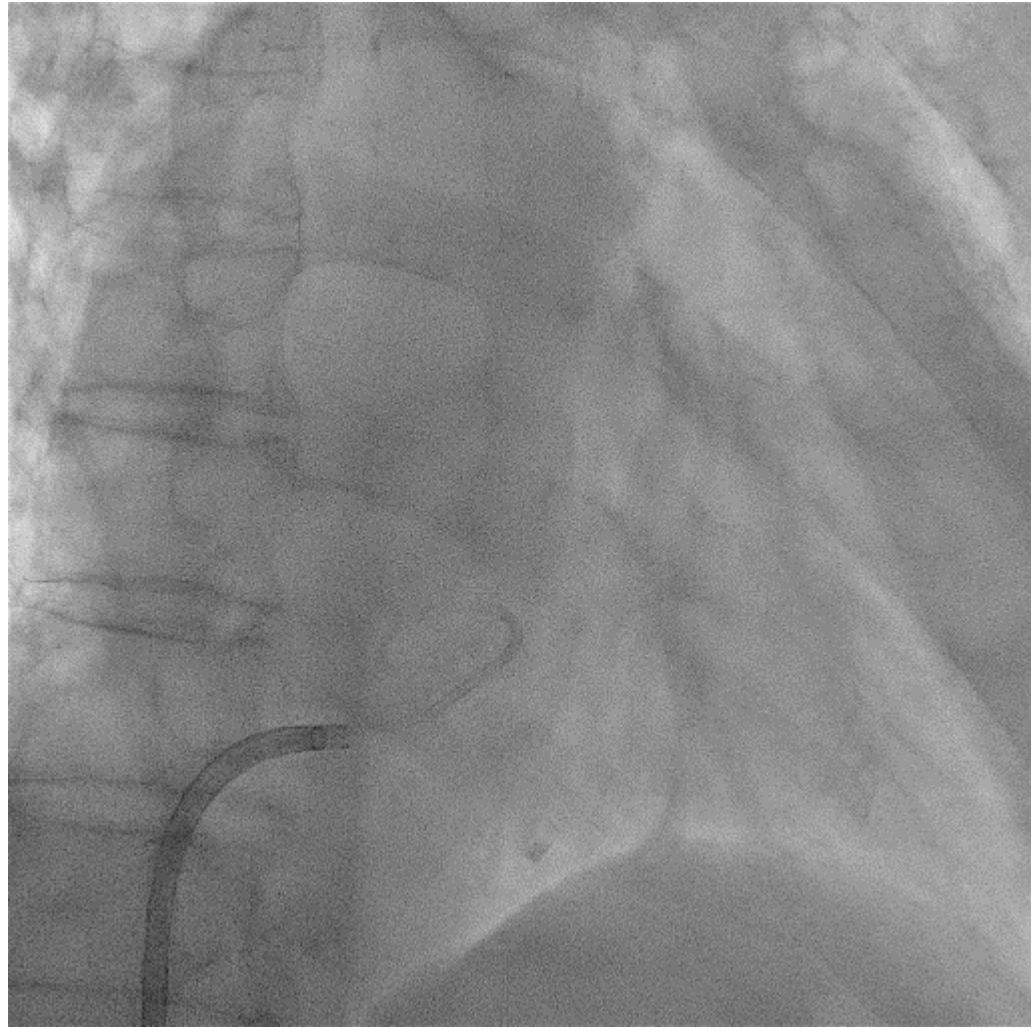


Case: F/74, Atrial functional TR



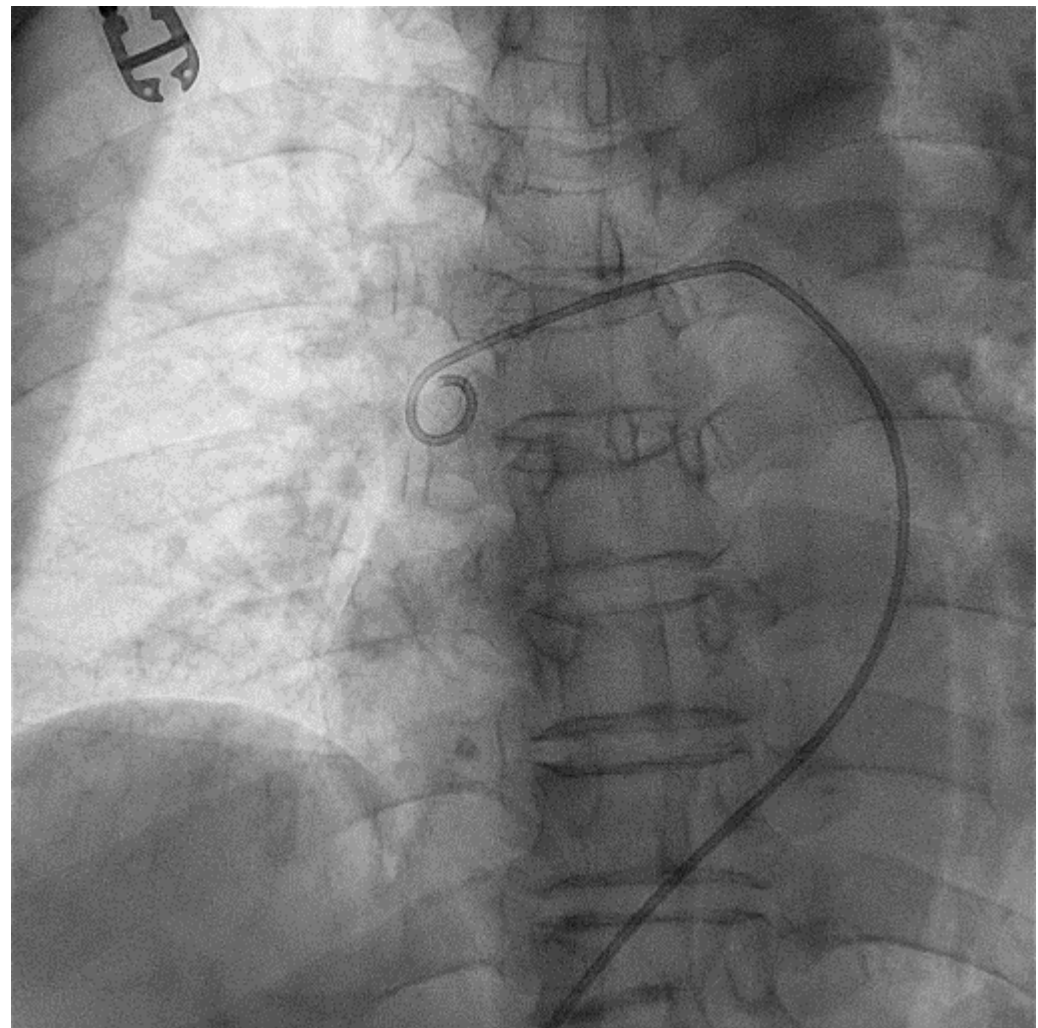
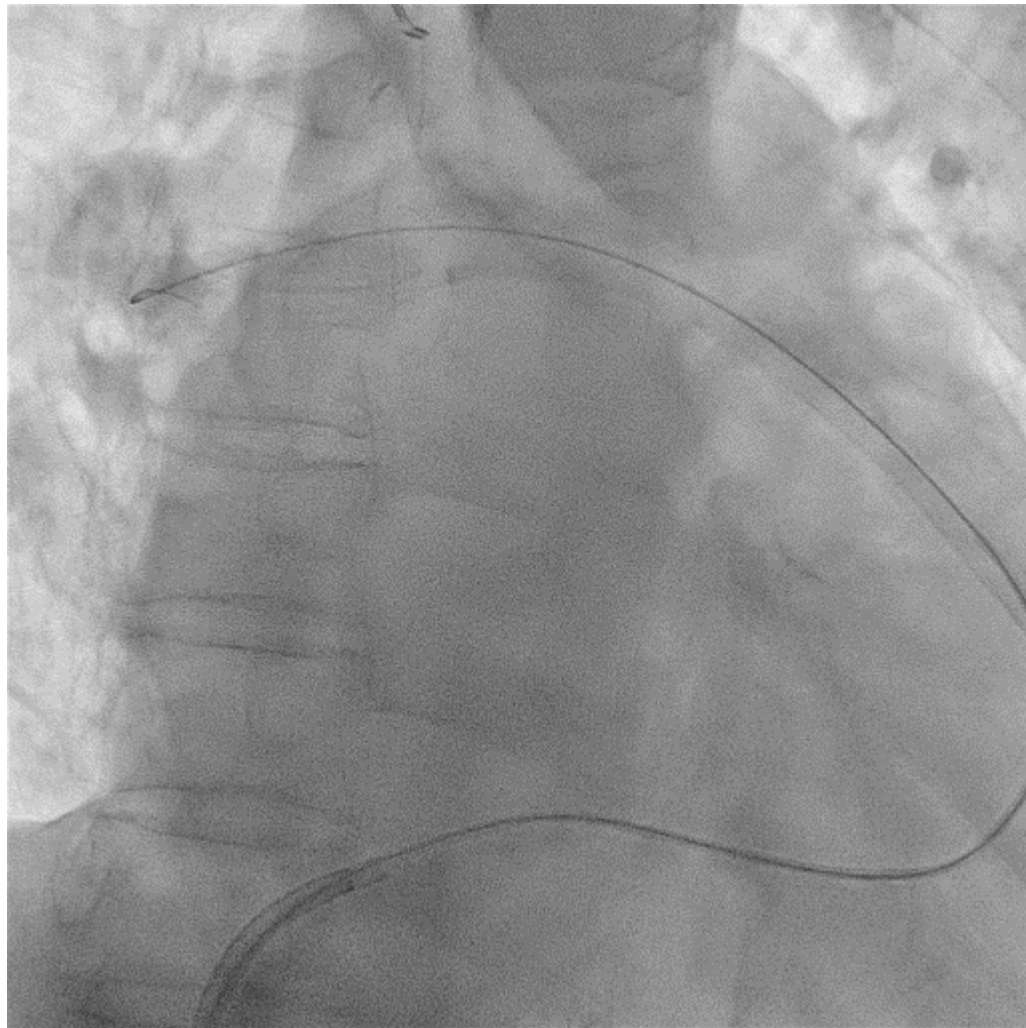


TV crossing using curved pigtail catheter



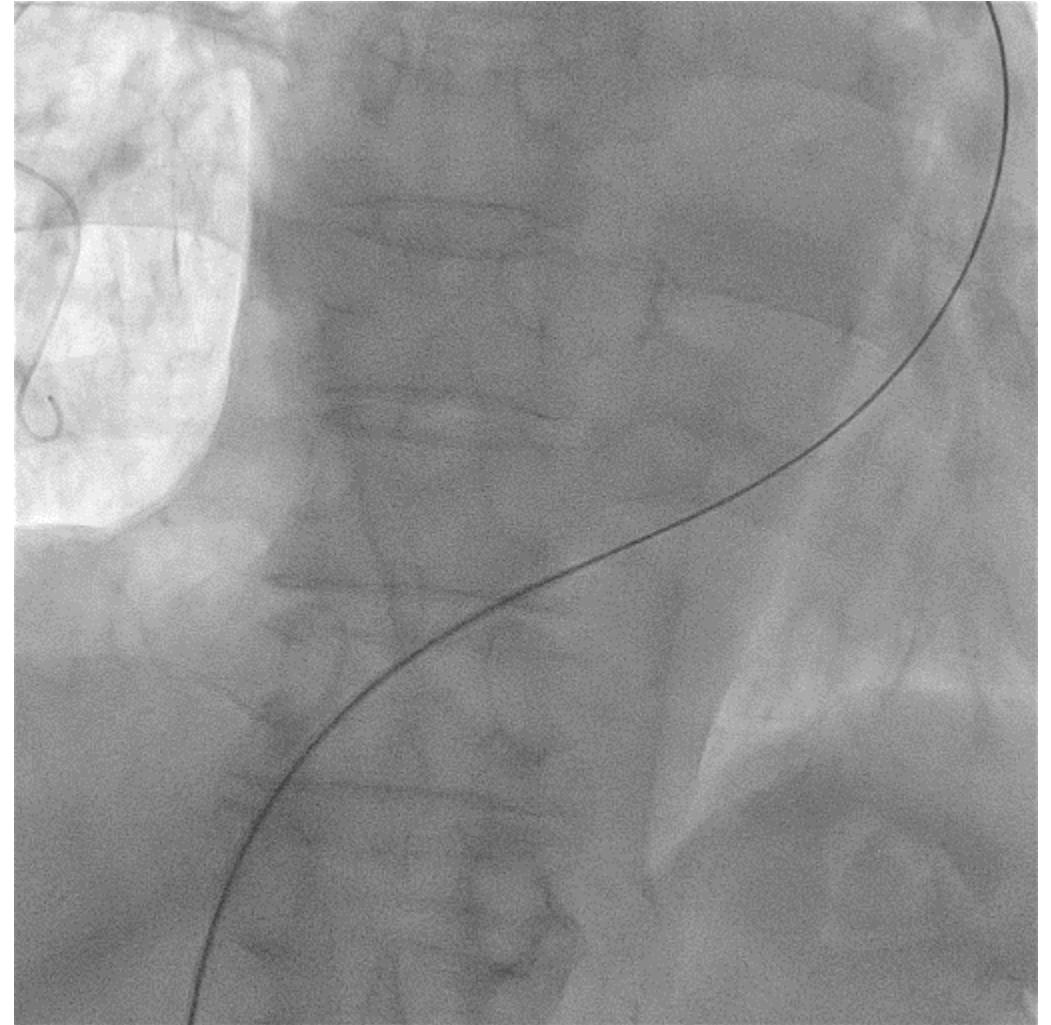
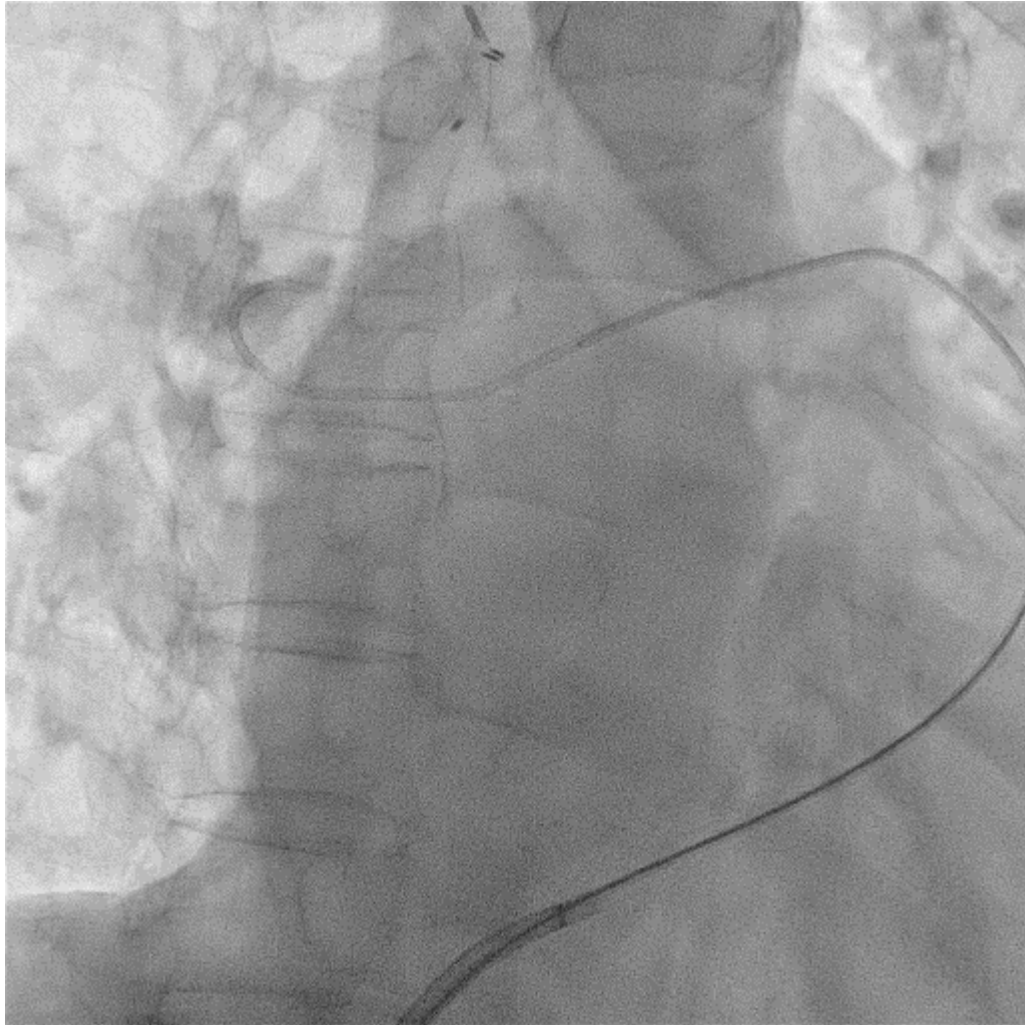


Advance of pigtail into the right lower PA



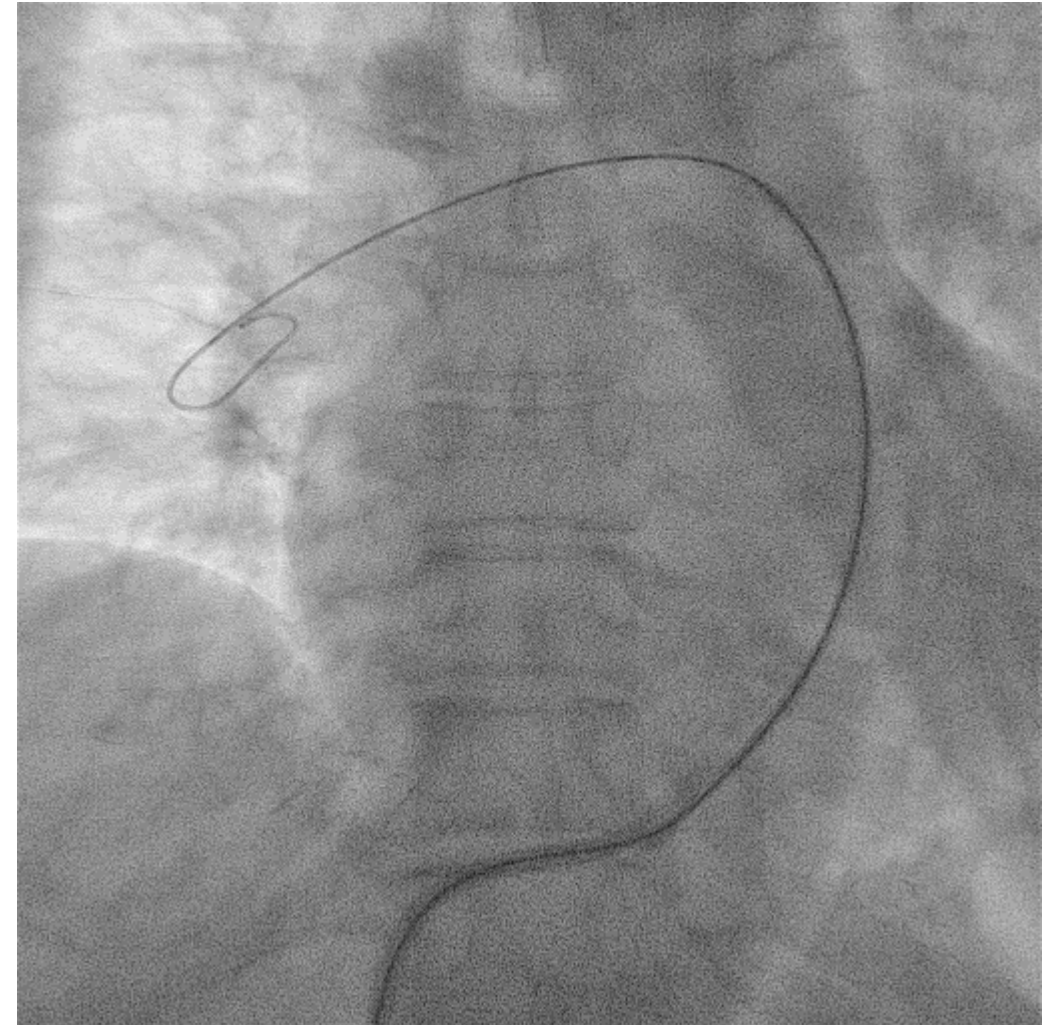
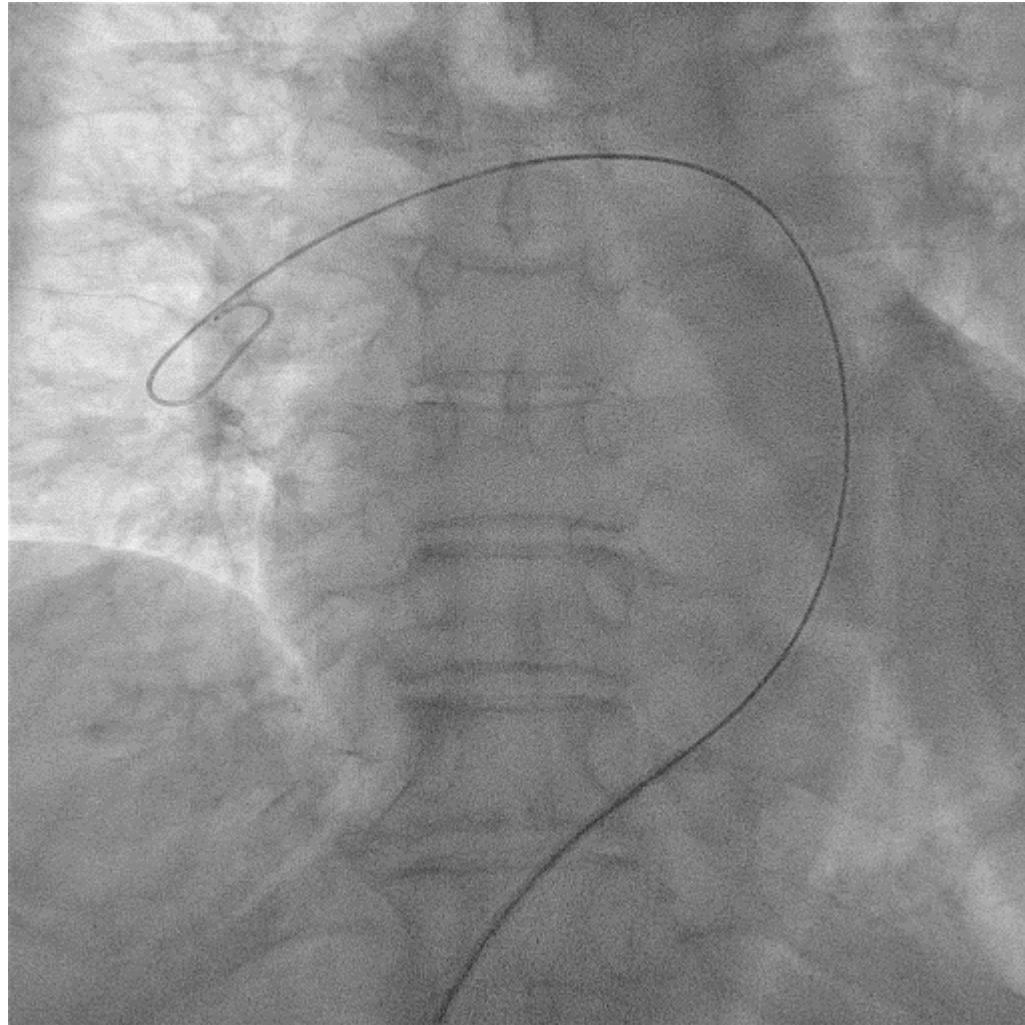


Stiff wire exchange and balloon wedge pressure catheter test



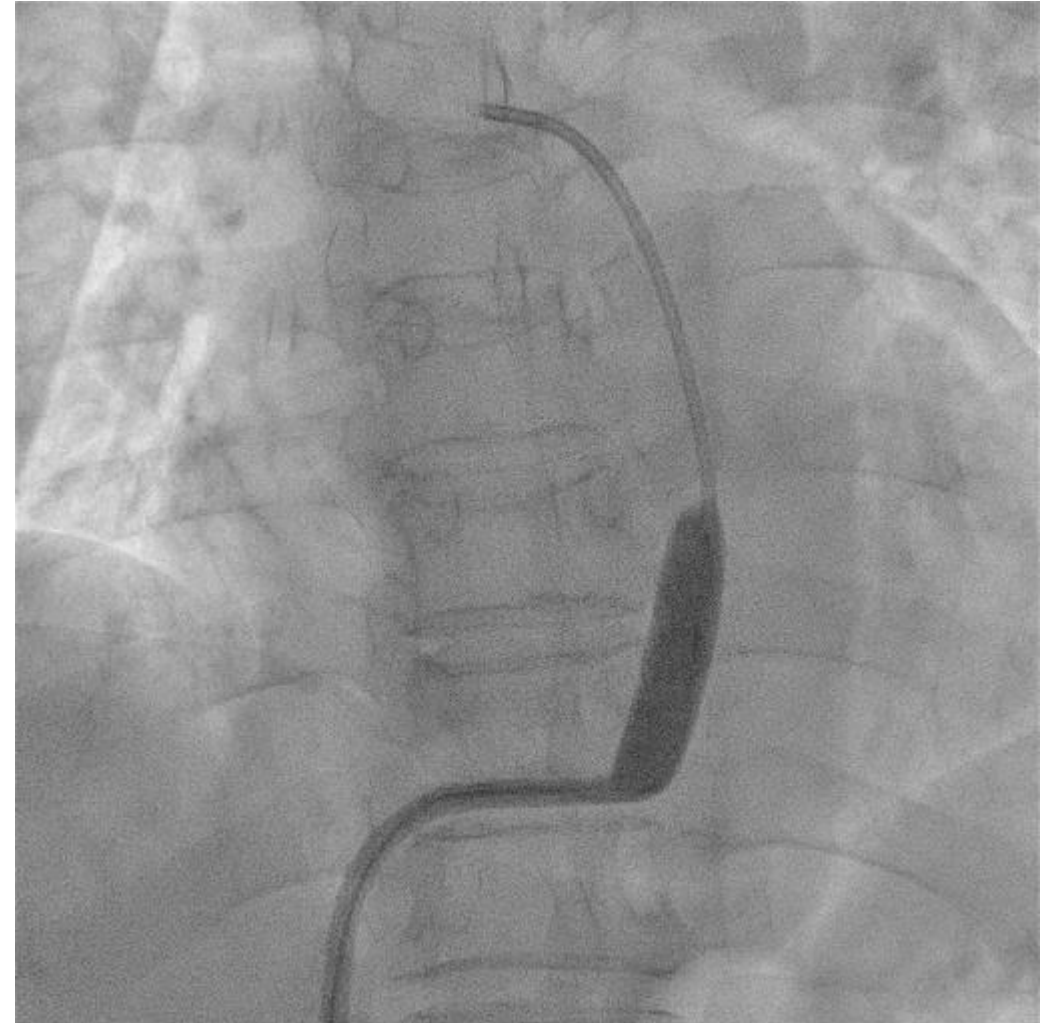
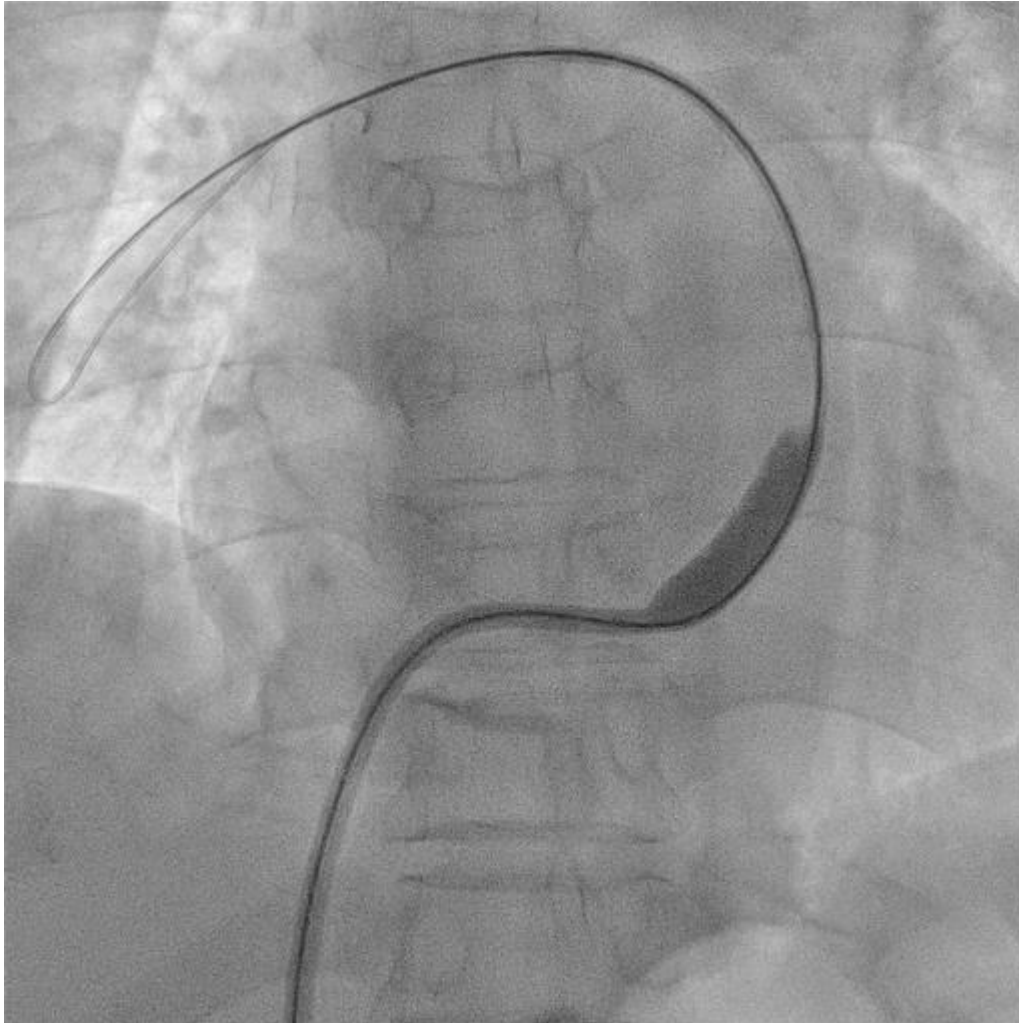


Delivery of Pivot Balloon device

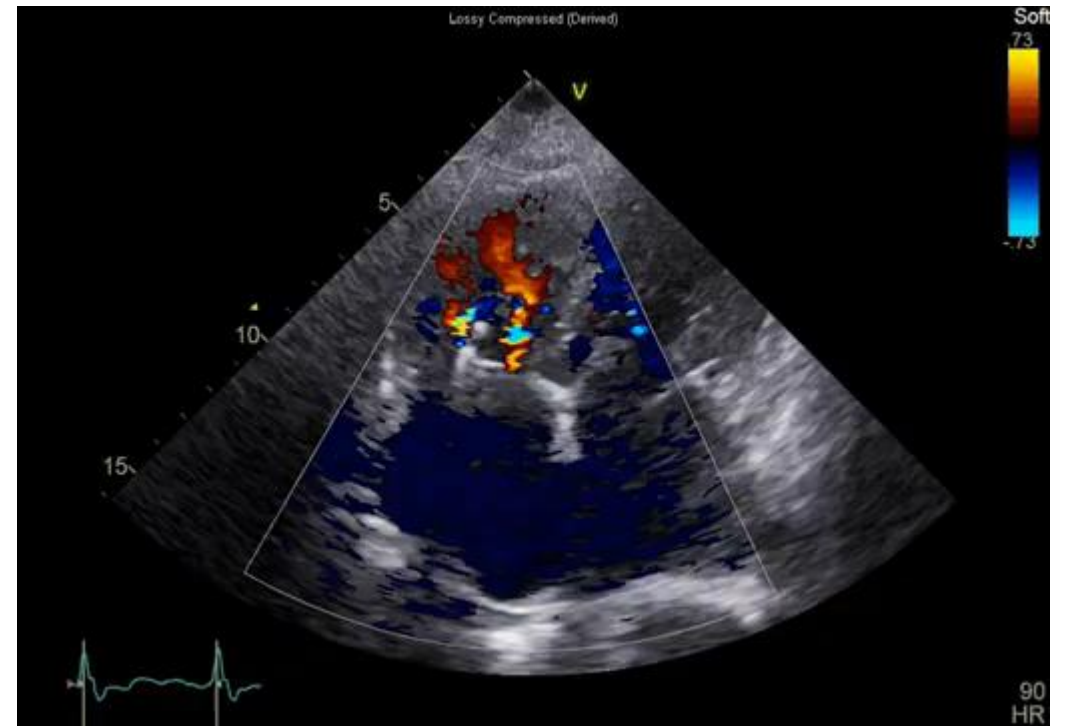




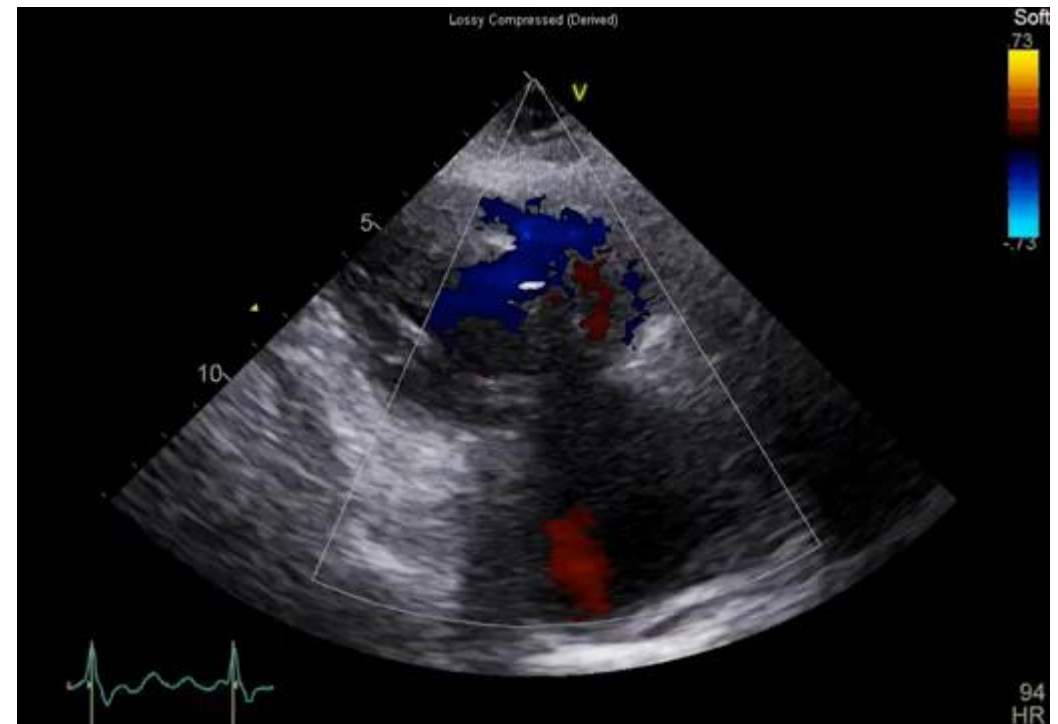
Adjustment of position and wire removal



During Pivot Balloon

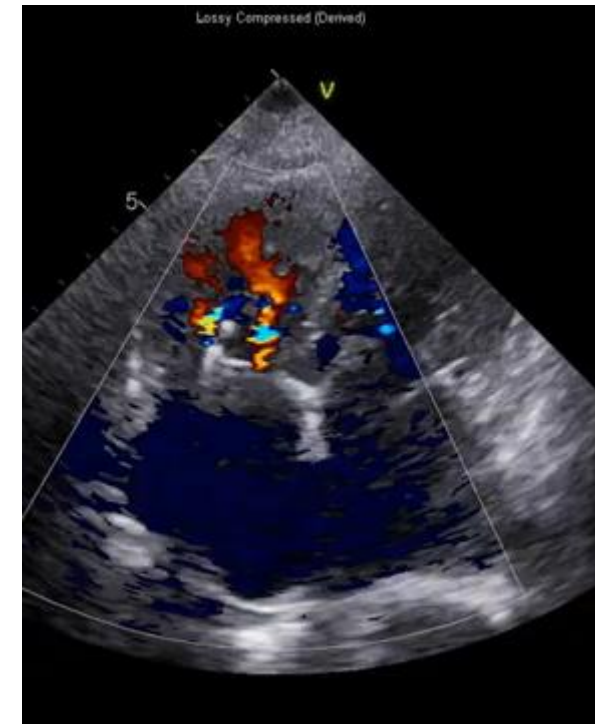
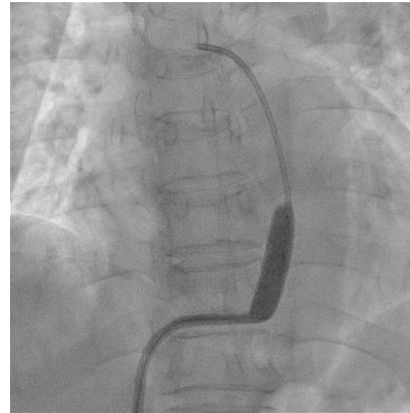
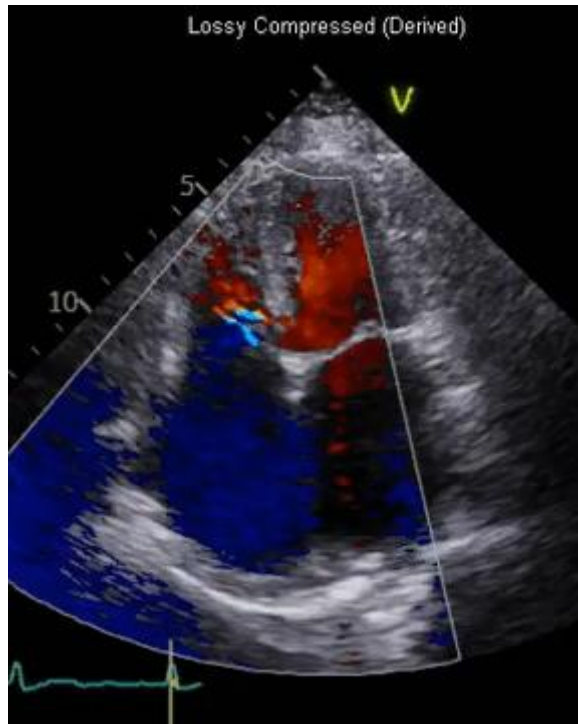


During Pivot Balloon





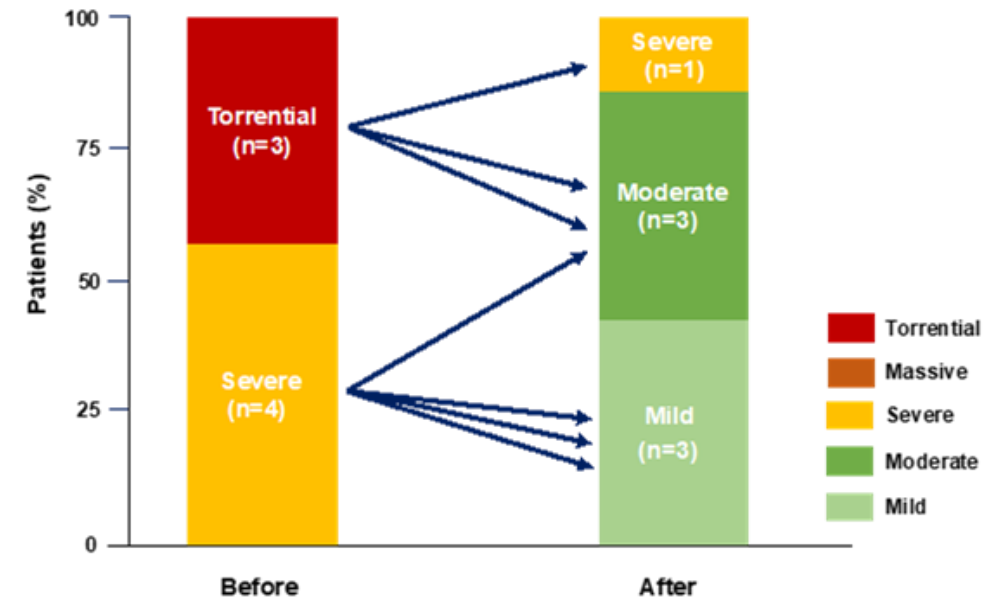
Marked reduction of TR by Pivot Balloon





Echocardiographic data (n=7)

	Before	After
LV ejection fraction, %	64.0±6.8	63.7±4.5
Vena contracta width of TR, cm	1.3±0.7	0.5±0.2
TR jet area, cm ²	21.1±5.2	10.4±7.5
EROA, mm ²	74.0±32.4	25.4±19.6
Fractional area change of RV, %	43.6±2.5	45.1±6.5
TAPSE, mm	15.9±4.2	18.1±2.6
Tricuspid annulus diameter	4.5±0.7	4.2±0.6
RV diameter, base	50.3±5.8	48.5±5.2.
IVC diameter	25.9±5.9	25.9±5.9
RA dimension, mm	60.2±9.7	54.2±10.3



Baseline characteristics and procedural data (n=7)



AGE	76±5
Female	6 (85.7)
Body mass index, kg/m ²	22.0±3.0
NYHA functional class ≥ III	4 (57.1)
Prior left-heart valve surgery	-
COPD	-
Chronic atrial fibrillation	6 (85.7)
Chronic kidney dysfunction	3 (42.9)
Hypertension	5 (71.4)
Diabetes	2 (28.6)
Liver cirrhosis	2 (28.6)

Successful device implantation	7 (100)
Adverse cardiovascular events during the procedure	-
Puncture to deploy time , min	20
Device information	
Balloon length	
70 mm	3 (42.9)
80 mm	4 (57.1)
Balloon diameter, mm	9.4±1.1
9 mm	6
12 mm	1
Ballooning time, min	32.1±4.3

The Pivot-balloon is safe, feasible, and effective for TR reduction in human

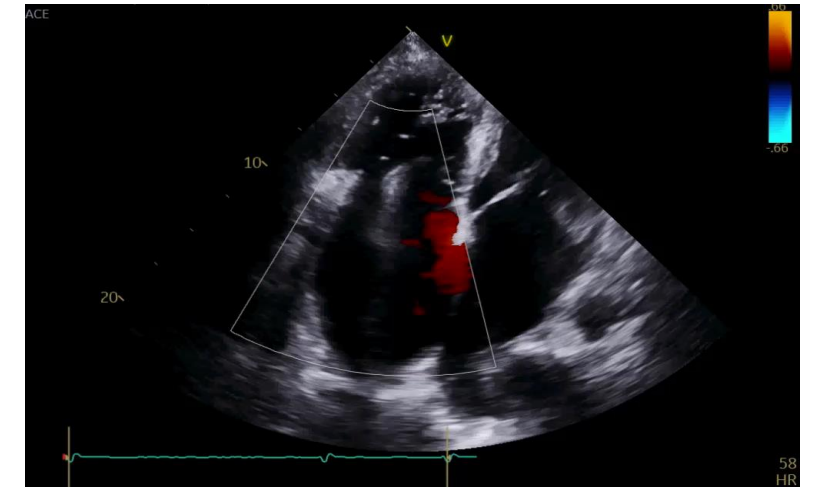
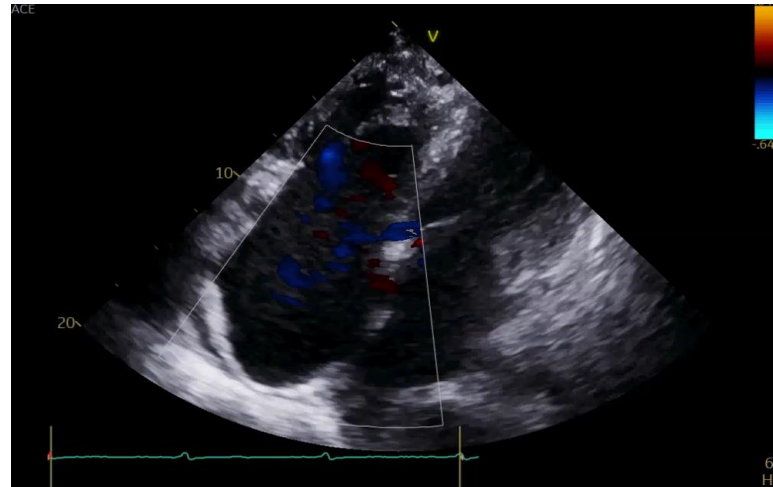


- The procedure was easily performed within a relatively short time frame under fluoroscopic and TTE guidance.
- After optimizing the device position, the average reduction in TR was 2 grades and no cases of RV intolerance were observed in any of the patients.
- TR reduction at the initial balloon deployment was sustained without any increase during the subsequent period of balloon maintenance.
- No adverse events were observed not only during the procedure but also at the time of device retrieval.



Pivot Bridge

Pre and post-TTE



Pivot Bridge movement

