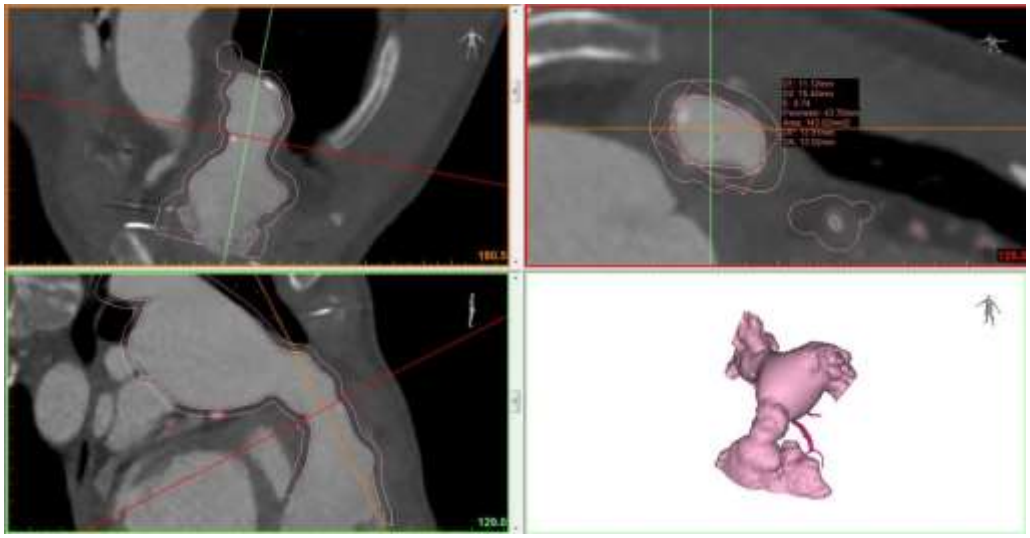
Taped Case & Lecture I – PPVI

PPVI case - Medtronic Melody Valve

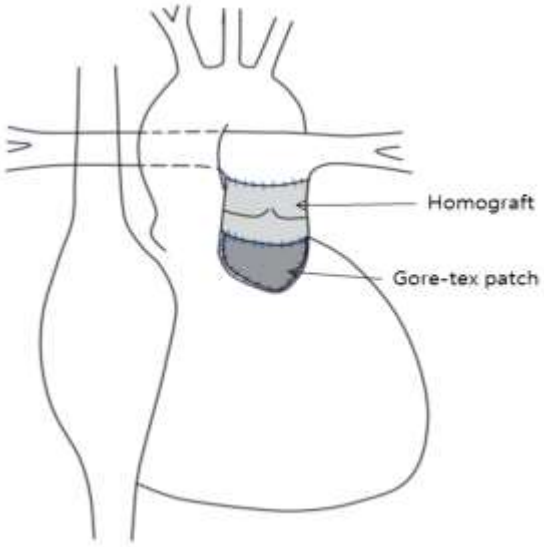


Jae Young Choi, MD, PhD, FSCAI
Severance Cardiovascular Hospital
Yonsei University Health System,
Seoul, Korea

CASE . 36 year-old male

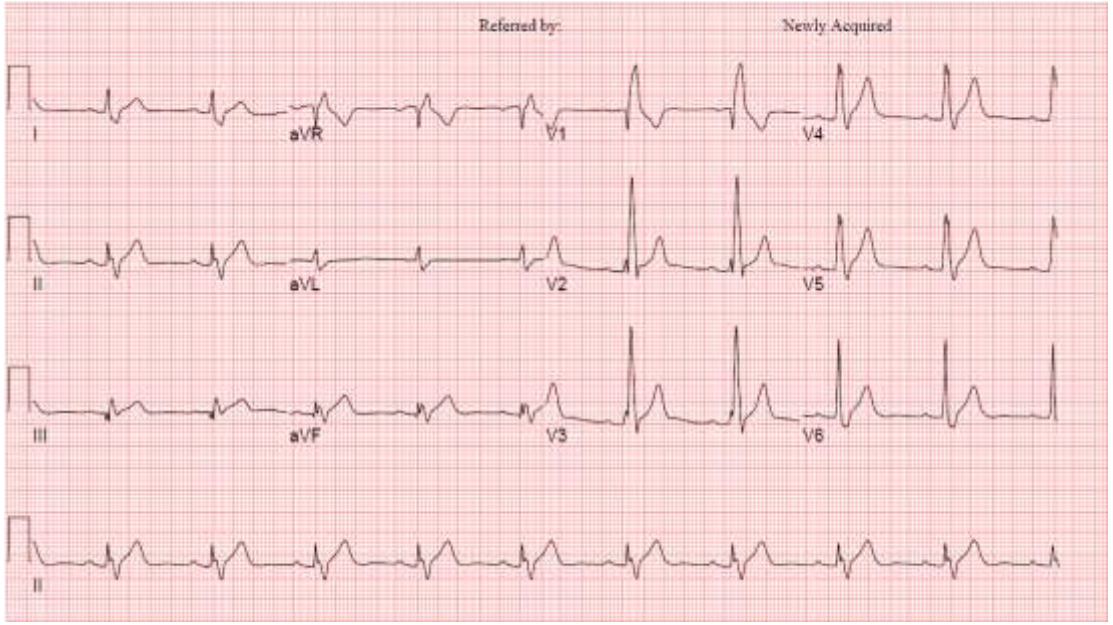
Homograft failure
(with RVE & RAE)

- 167cm, 58kg
- Initial diagnosis: TOF
- Brief past history
  - 1982 (3y3m) TOF repair
  - 2002 (23y) PVR (homograft 22.5mm)
    TV annuloplasty
    d/t *severe PI, severe TR*
    & progressive RAE ass with atrial flutter
  - 2009 (31y) RFCA d/t atrial flutter



CASE. 36 year-old male
Homograft failure (with RVE & RAE)

- Current symptoms and P/E
  - NYHA class II
  - G3/6 ejection syst murmur on LUSB
- Chest x-ray
  - mild cardiomegaly
- ECG
  - Sinus rhythm
  - HR 60bpm
  - RBBB
  - QRS duration: 158ms



CASE. 36 year-old male

Homograft failure (with RVE & RAE)

- **CPX : 34yrs (Oct. 2013)**
  - **VO2 peak : 31.85ml/kg/min (9.1 METs)**
  - **PER : 1.16**
  - **VE/VCO2 slope 31.9**
  - **Age predicted aerobic capacity: 73 %**
  - **No ST change**

- **Holter: 36yr (Aug. 2012)**
  - **Basically normal sinus rhythm (RBBB)**
  - **Heart rate**
    - Min. 52bpm
    - Avg. 68bpm
    - Max. 105bpm
  - **Asymptomatic PACs & PVCs (<1% of total QRS complexes)**

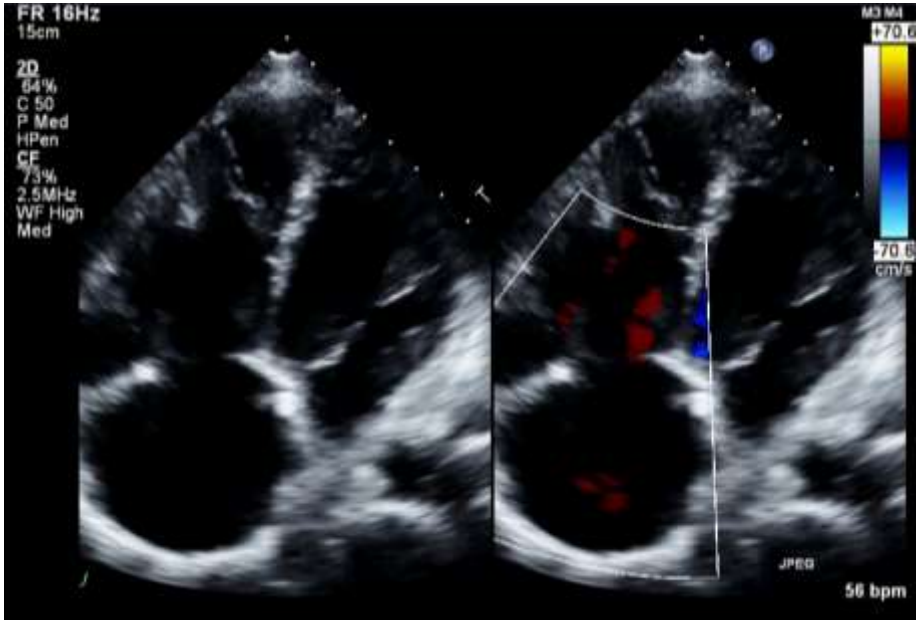
CASE. 36 year-old male

Homograft failure (with RVE & RAE)

- **TTE**

{S, D, S} TOF
s/p TOF total correction (1982)
s/p PVR with Homograft 22.5mm (2002)
Tricuspid annuloplasty d/t severe TR
Prosthetic valve stenosis
with PV thickening & restrictive motion
peak(mean) dp=45(25) ← 37(22)mmHg
PI (moderate)
TR (G2/4, dP=47mmHg ← G 1-2/4)
with RAE (d=60*56mm) & RVE
MR (G1/4) d/t MVP(AML)
LVEF=58 ← 62%

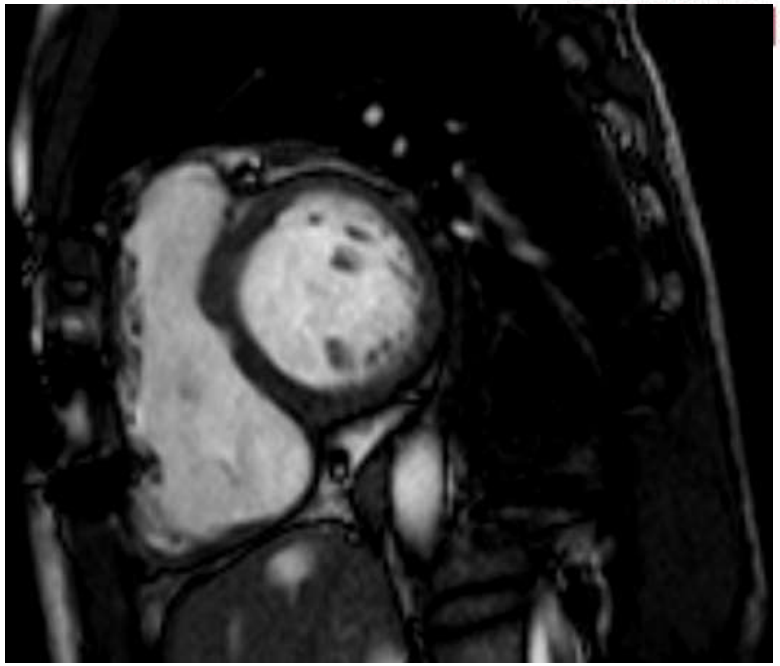
→ homograft failure with evidence of progressive RAE/RVE & RVOT obstruction

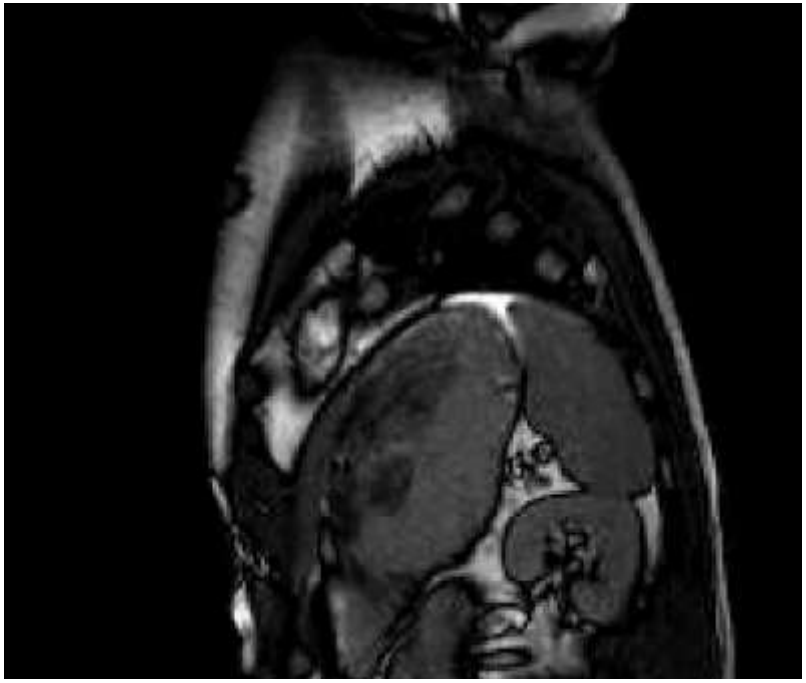


CASE. 36 year-old male
Homograft failure (with RVE & RAE)

- Cardiac MRI

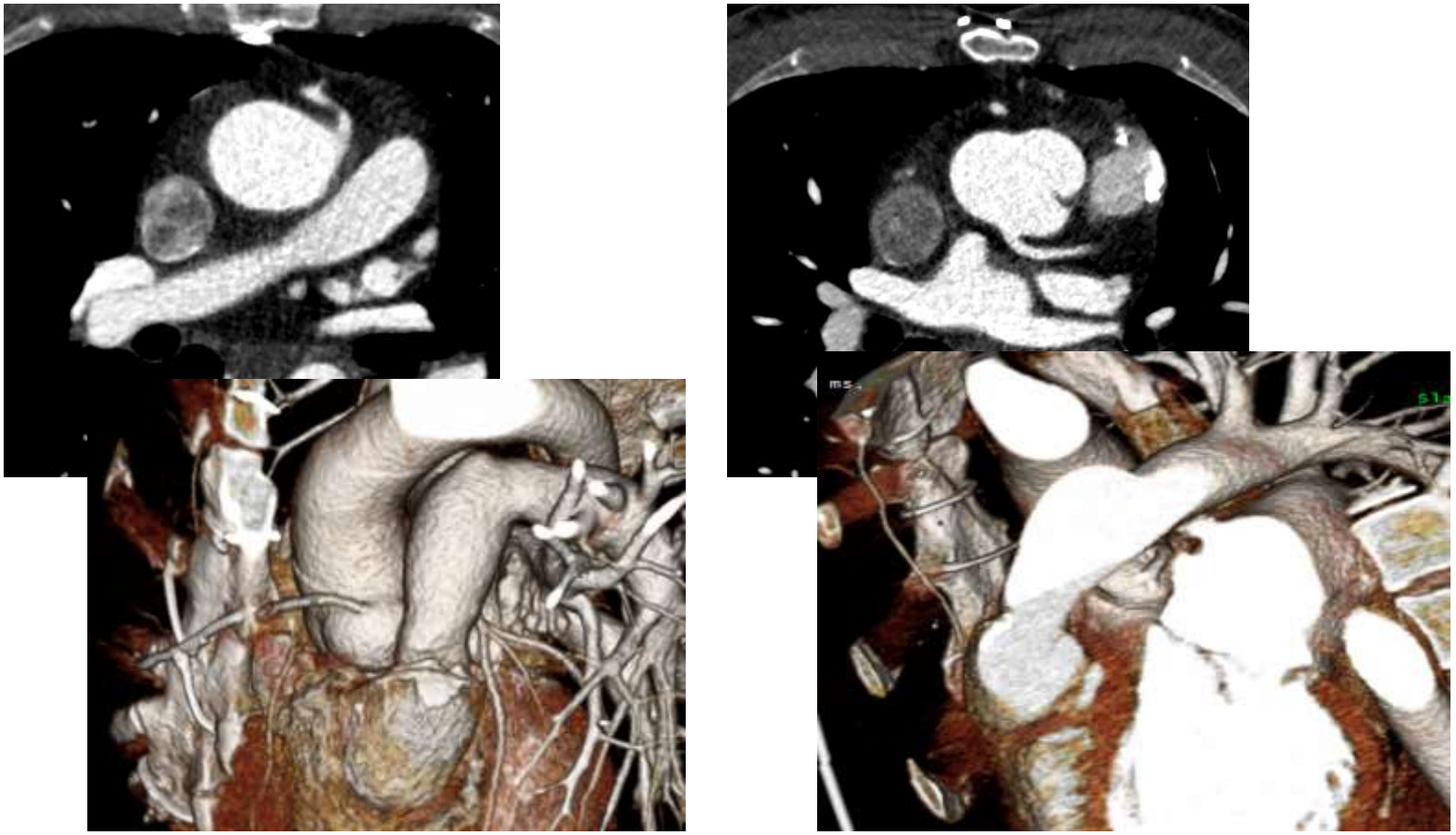
	6 year after PVR (2008)	11 year after PVR (2013)	Recent (2015)
RVEDVI	128ml/m2	135ml/m2	157ml/m2
RVESVI	73ml/m2	87ml/m2	91ml/m2
RVEF	43%	42%	37%
MPA regurgitation fraction	18%	25%	28%





CASE. 36 year-old male
Homograft failure (with RVE & RAE)

- **Cardiac CT** *(JUL. 2015)*

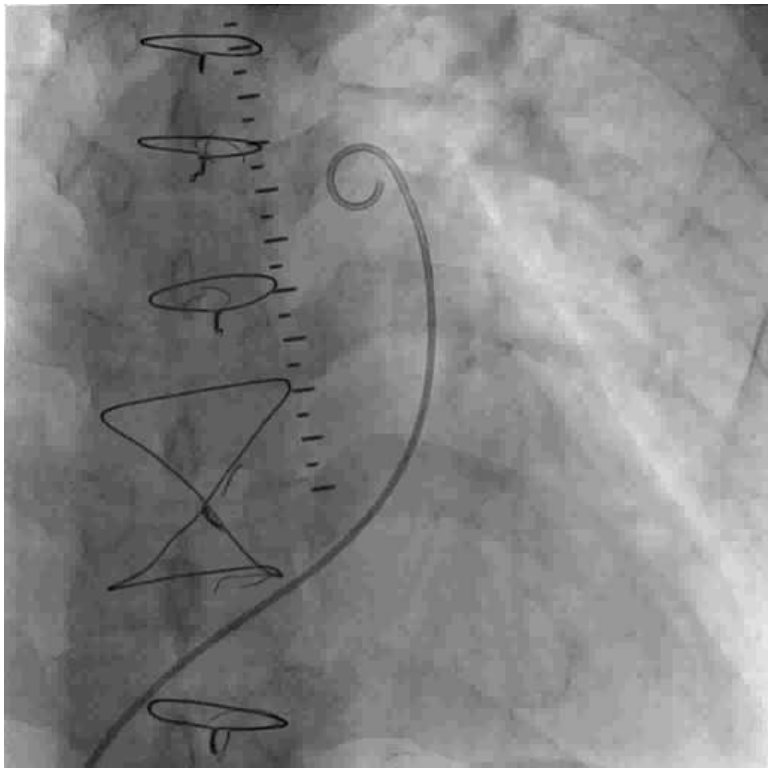


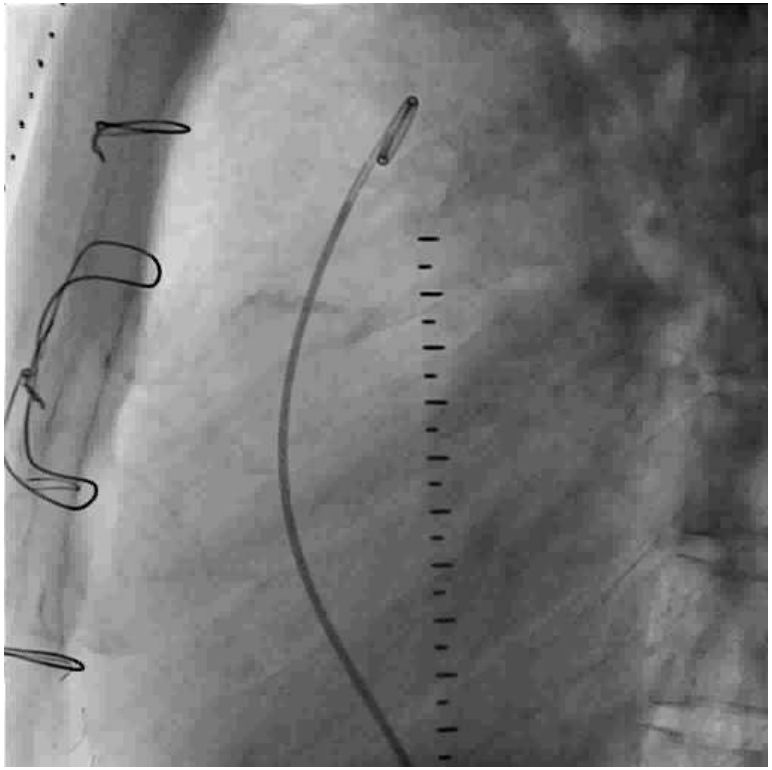
CASE. 36 year-old male

Homograft failure (with RVE & RAE)

- **F/U Cardiac Cath** *(Jul. 2015)*
  - Moderate to severe PI
  - Moderate conduit stenosis

	Pressure
	Pre (mmHg)
RV	70/0/12
MPA	20/5/10
Aorta	110/70(85)

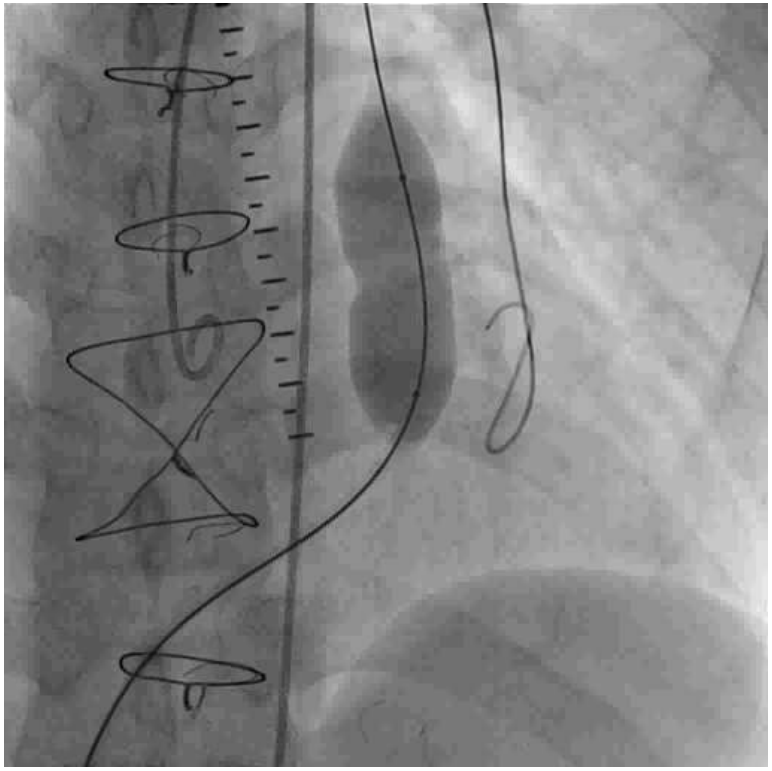


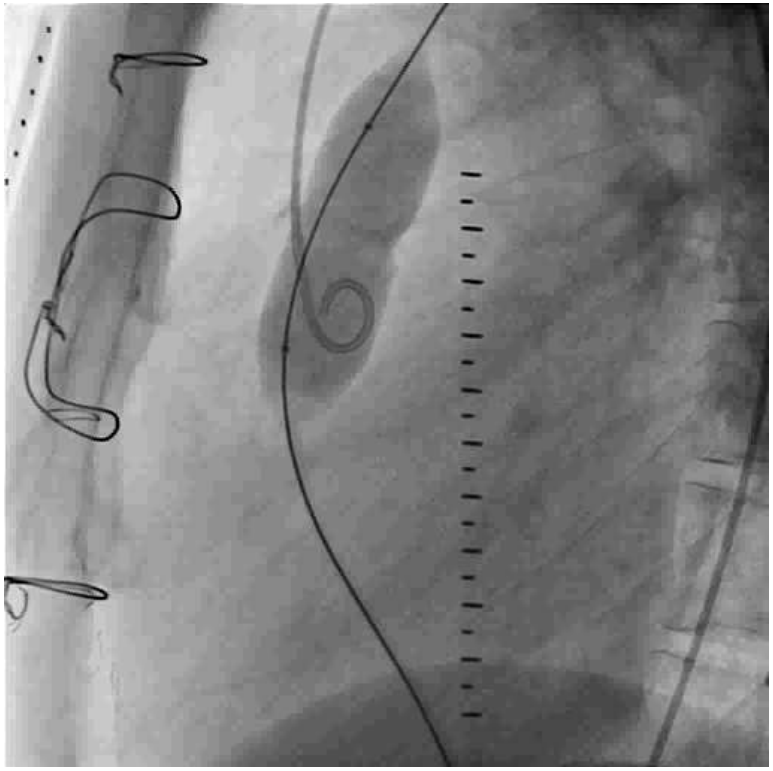


F/U Cath → PPV *(Jul. 2015)*

- Moderate to severe PI with moderate pressure overload
- PPV was performed : Z-med 22 x 40mm
- Sizing by balloon
  narrowest diameter 16mm
  (just below the calcified area)

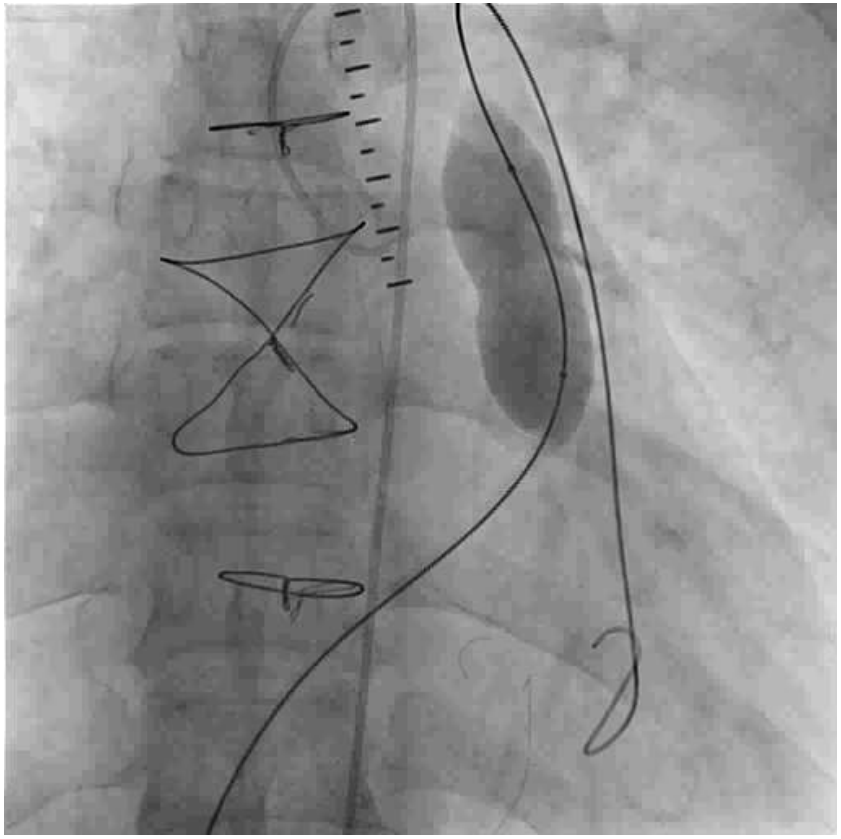
	Pressure	
	Pre (mmHg)	Post (mmHg)
RV	70/0/12	60/0/8
MPA	20/5/10	20/6/11
Aorta	110/70(85)	

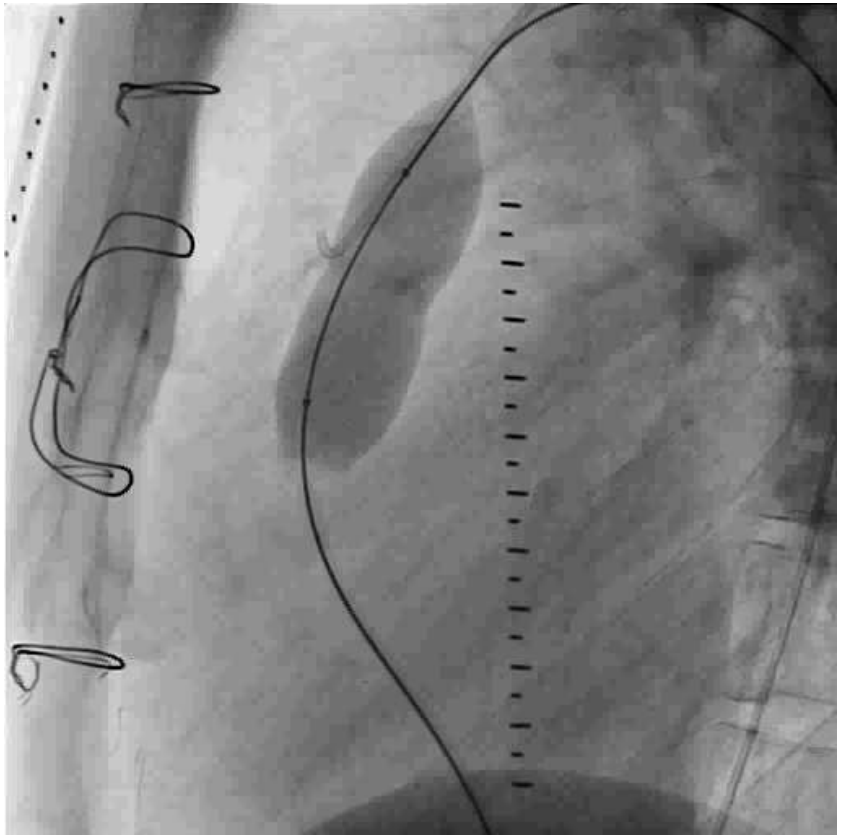




Coronary Compression Test

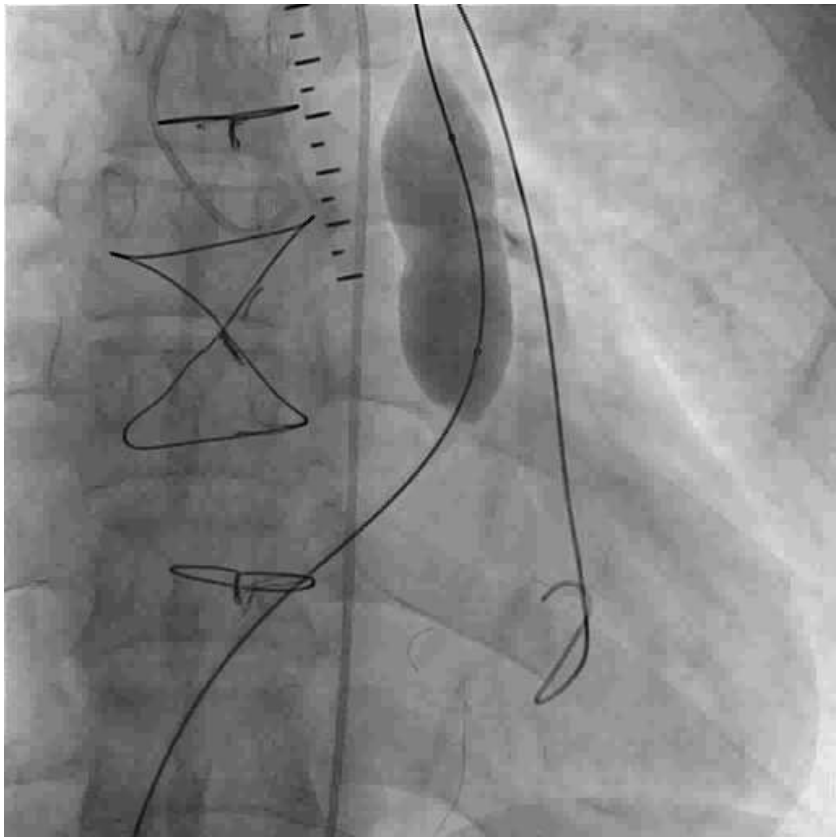
- ***No RCA compression on RVOT balloon dilation***

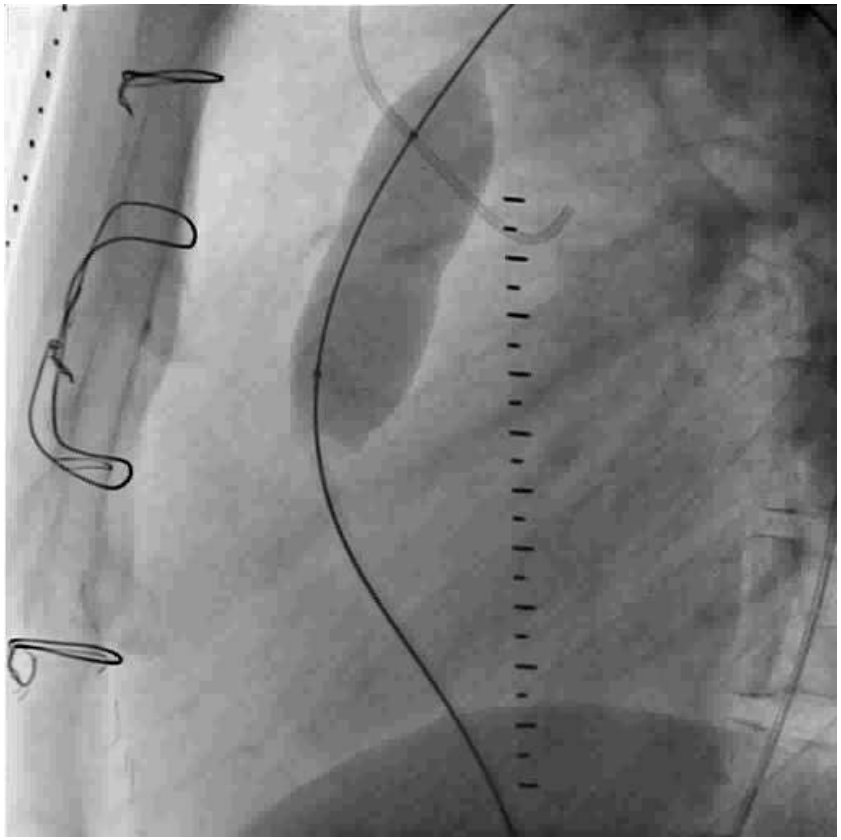




Coronary Compression Test

- ***No LCA compression on RVOT balloon dilation***





Listed as a candidate for PPVI :

1. Progressive RVE & Aggravating RV fc
2. Recently developed mild symptom
3. No Coronary compression
4. Narrowest diameter - 16mm

Question or Comment?

- Melody TPV -

Implant Procedure Overview

- Anesthesia – General
- Equipment: Catheters – Standard, ultra-stiff guidewires
- Vascular access – Femoral V & A, both Lt and Rt side prepped
- Heparinization to achieve a target ACT of >250 seconds
- Antibiotics per institutional protocol
- Hemodynamic and angiographic evaluation
- Balloon interogation / coronary compression test
- Preparation of proper landing zone - prestenting
- If anatomy is suitable, proceed with implantation of Melody®
- Hemodynamic and angiographic evaluation post-implantation
  → Post-dilation with UHP balloon if needed
- Hemostasis - manual pressure or closure device (22 Fr opening)

Setting : Hybrid suite
Skin Prep (preparing against emergency)
Preclosure of venous access using 2 x Perclose ProGlide

2nd Perclose
: 2 O'clock direction

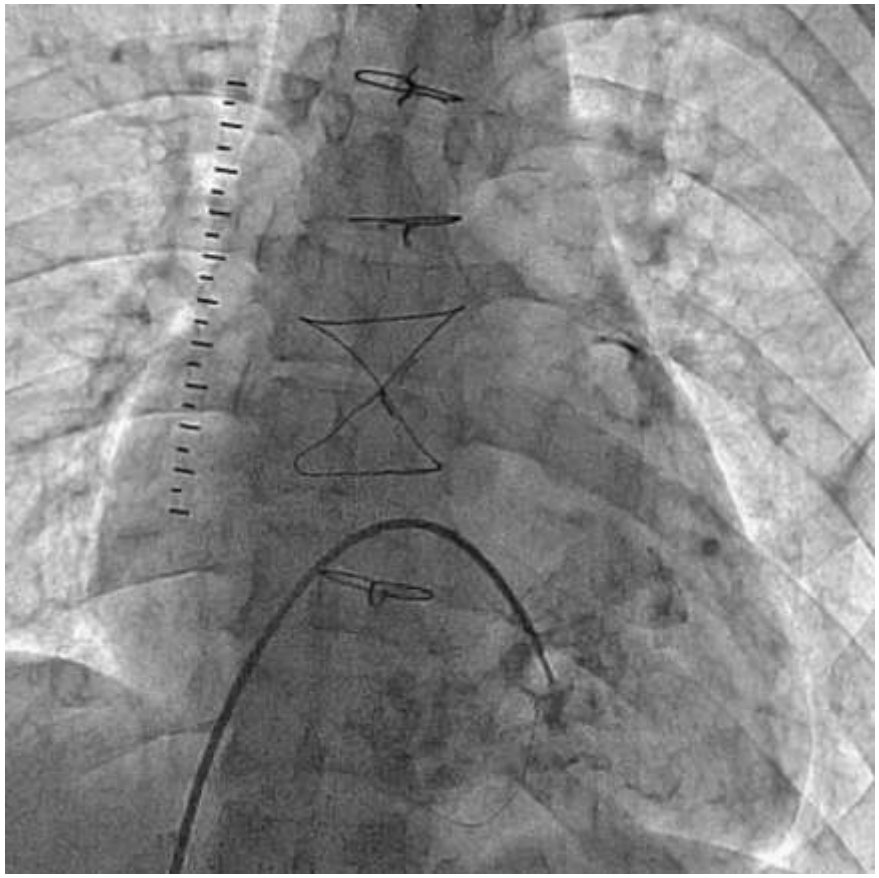
✓ **DrySeal sheath (Gore) for venous access**

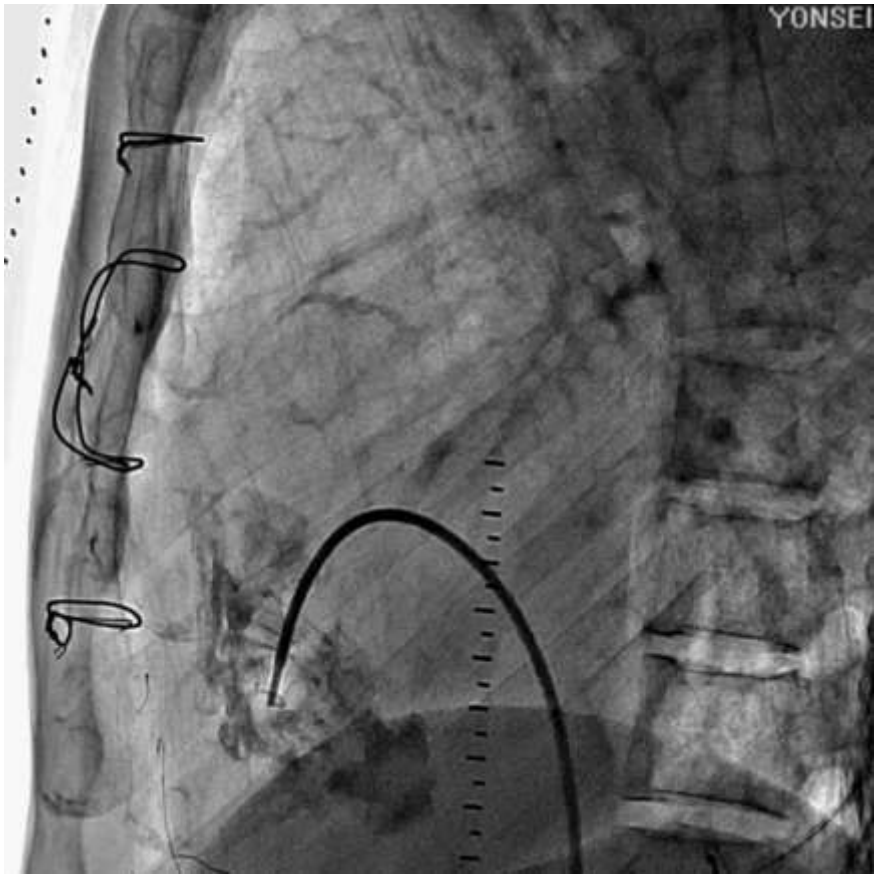
- easy introduction of Melody-Ensemble system (18Fr)

- enables wide access for multiple catheters/sheaths/wires

- prevents back-bleeding

Hemodynamic Assessment & RV Angiogram





Questions

- ✓ **Prestent or not?**
- ✓ **Which stent?**

  bear metal vs. covered?

  we don't have covered stent in Korea
- ✓ **Stent with bear metal stent → Melody**

  or

  Melody implantation?

→ *we decided to prestent with a bear metal stent*

✓ Prestenting

- *Preparation of 'landing zone'*
- *May reduce the incidence of stent fracture*
- *A covered stent may reduce the risk from RVOT rupture*

Loading the stent : Palmaz 4014(J&J) on Z-med 40x22mm balloon(NuMed)

✓ Prestenting

- Palmaz 4014 (J&J) mounted on Z-med 40x 22mm balloon (NuMed)

- delivery sheath – 14Fr Mullins sheath (COOK)

✓ Positioning the guide wire as distally as possible

- A Terumo wire was used to select distal branch, then exchange with a Lunderquist wire

- A syringe without the plunger filled with saline was used to prevent air embolism

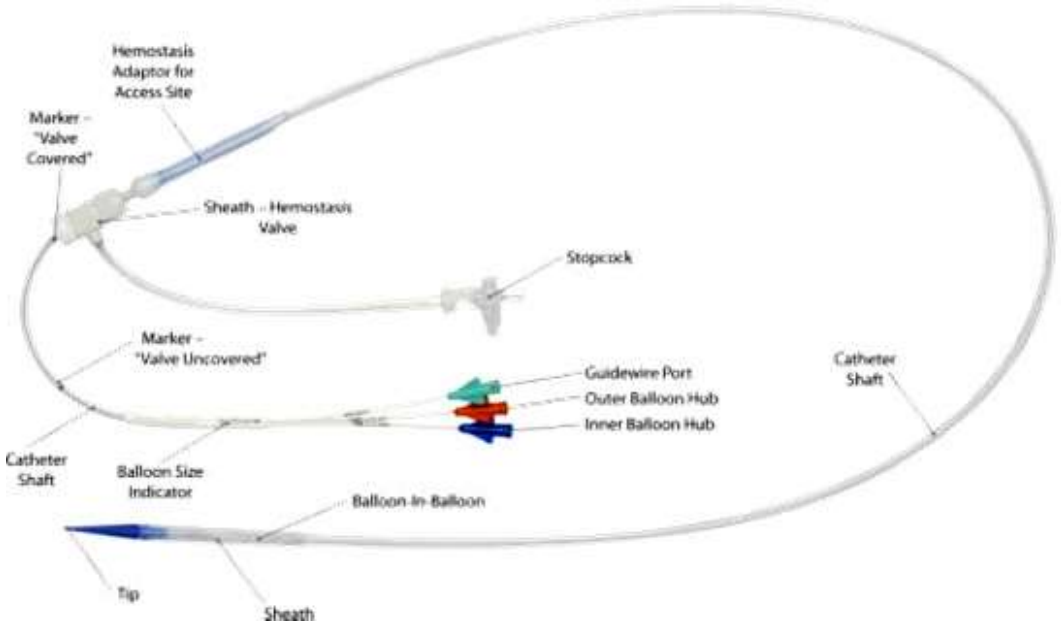
✓ Prestenting

- Palmaz 4014 (J&J) mounted on Z-med 40x 22mm balloon (NuMed)

- delivery sheath – 14Fr Mullins sheath (COOK)

Preparation:
Ensemble® Delivery System / Melody® Valve

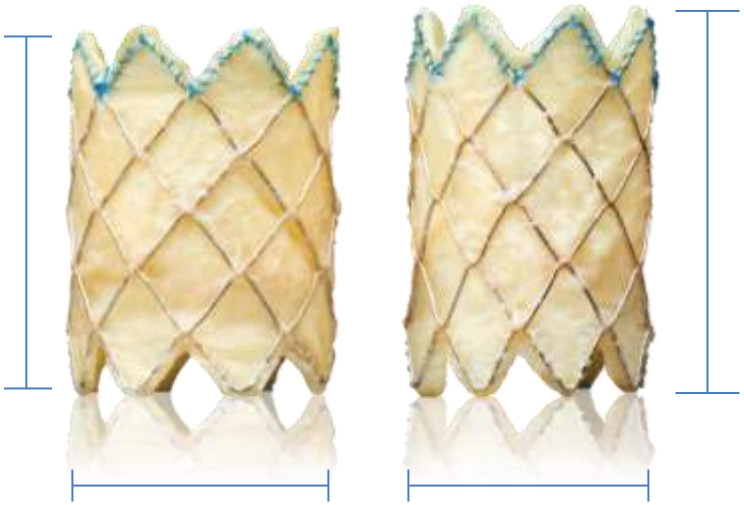
- **18Fr sheath for diagnostic cath – abolish the need of dilation of FV access (22 Fr dilator to FV)**
- **Delivery system prep**
- **Melody® valve "wash"**
- **Valve crimping**
  blue-blue, white-white



Melody® Transcatheter Pulmonary Valve

Melody TPV 22

- Bovine Jugular Vein: 18mm
- 28mm length out of the jar
- For deployment up to 22mm



Note: photos are not to scale

Melody TPV 20

- Bovine Jugular Vein: 16mm
- 30mm length out of the jar
- For deployment up to 20mm

- Bovine Jugular Vein Valve / NuMed Platinum Iridium Frame
- Both valve sizes are the same valve design & deployed with the same Ensemble Delivery System
- Valve performance for both sizes is comparable[1]

[1]Medtronic data on file

✓ Selecting the size of Melody valve

Table 1. Melody™ System Sizing Chart

Delivery System Size – Inner Balloon / Outer Balloon	Inner Balloon Maximum Applied Pressure (RBP)		Outer Balloon Applied Pressure		Corresponding Valve Outside Diameter (mm) (balloon inflated)
	atm	kPa	atm	kPa	
Size 18 mm Inner: 9 mm × 3.5 cm / Outer: 18 mm × 4 cm	5	506	1	101	17.9
			2	203	18.6
			3	304	19.4
			4 (RBP)	**405**	**20.1**
Size 20 mm Inner: 10 mm × 3.5 cm / Outer: 20 mm × 4 cm	5	506	1	101	19.7
			2	203	20.7
			3	304	21.7
			4 (RBP)	**405**	**22.4**
Size 22 mm Inner: 11 mm × 3.5 cm / Outer: 22 mm × 4 cm	4.5	456	1	101	21.8
			2	203	22.8
			3 (RBP)	**304**	**24.1**

Note:

Do not exceed bolded pressure values for either the inner or outer balloon of the delivery system size.

RBP = Rated Burst Pressure = Maximum Applied Pressure

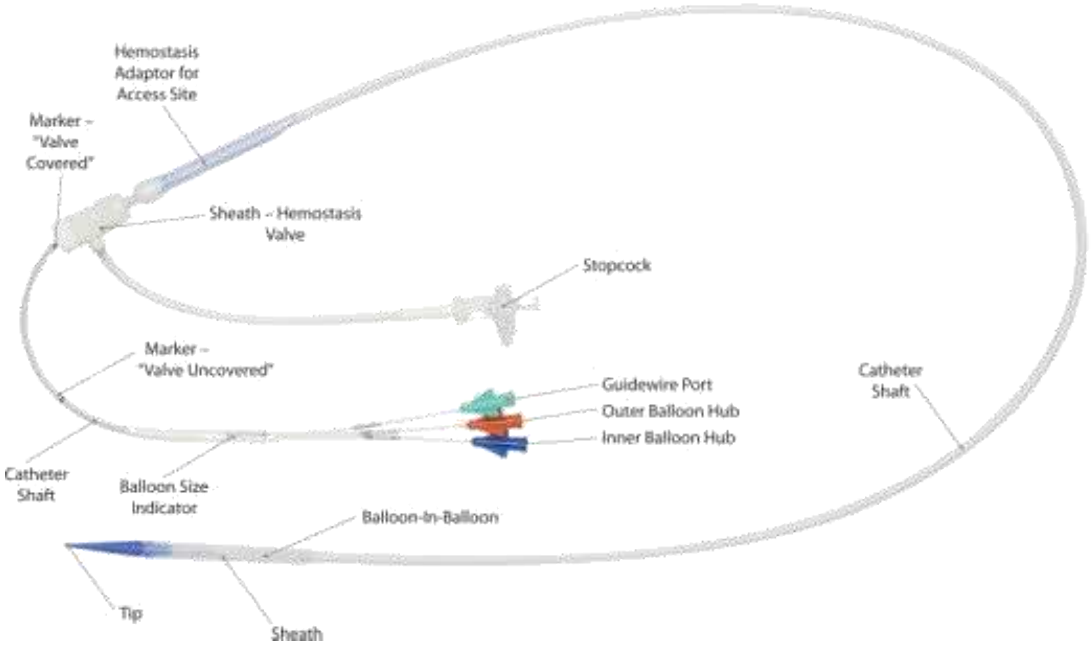
atm = atmosphere

kPa = kilopascal

Table 2. Approximate Length of the TPV Following Deployment with the Corresponding Ensemble™ Delivery System

Expanded Outer Balloon OD Size	Reference TPV Length (crimped/loaded on delivery system)	Reference TPV Length (after balloon deflation)
18 mm	33 mm	26 mm
20 mm	32 mm	24 mm
22 mm	32 mm	21 mm

Ensemble® Delivery System



- Balloon-in-balloon catheter
- 3 outer balloon diameters
  - 18 mm
  - 20 mm
  - 22 mm

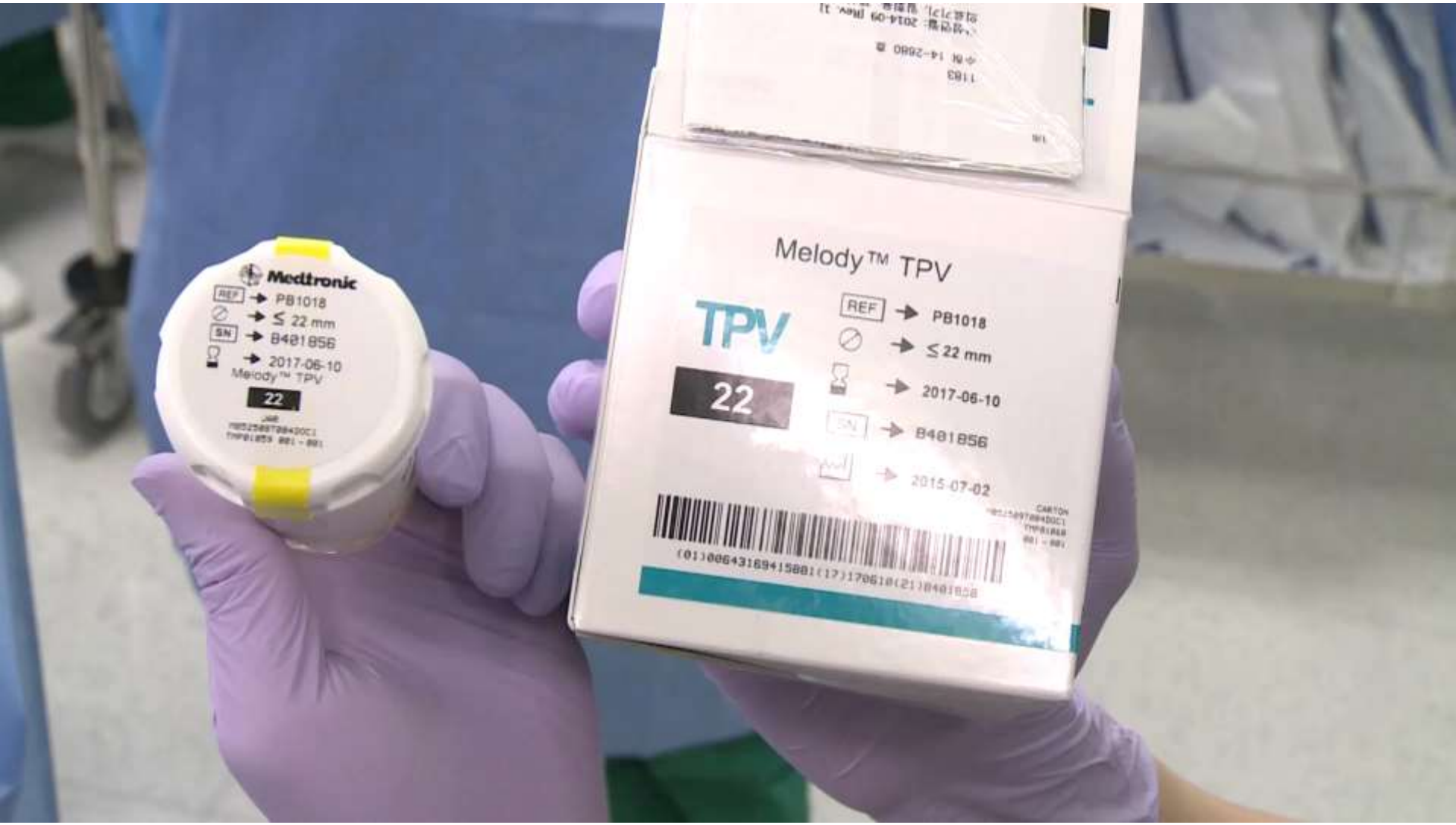
- 22 Fr crossing profile
- Retractable sheath

Please note: there are no radiopaque markers on the balloons

✓ Preparing the Melody valve

- Recheck the serial number of the product

- Wash the valve in 2-3 consecutive bowel with saline (1 minute each)



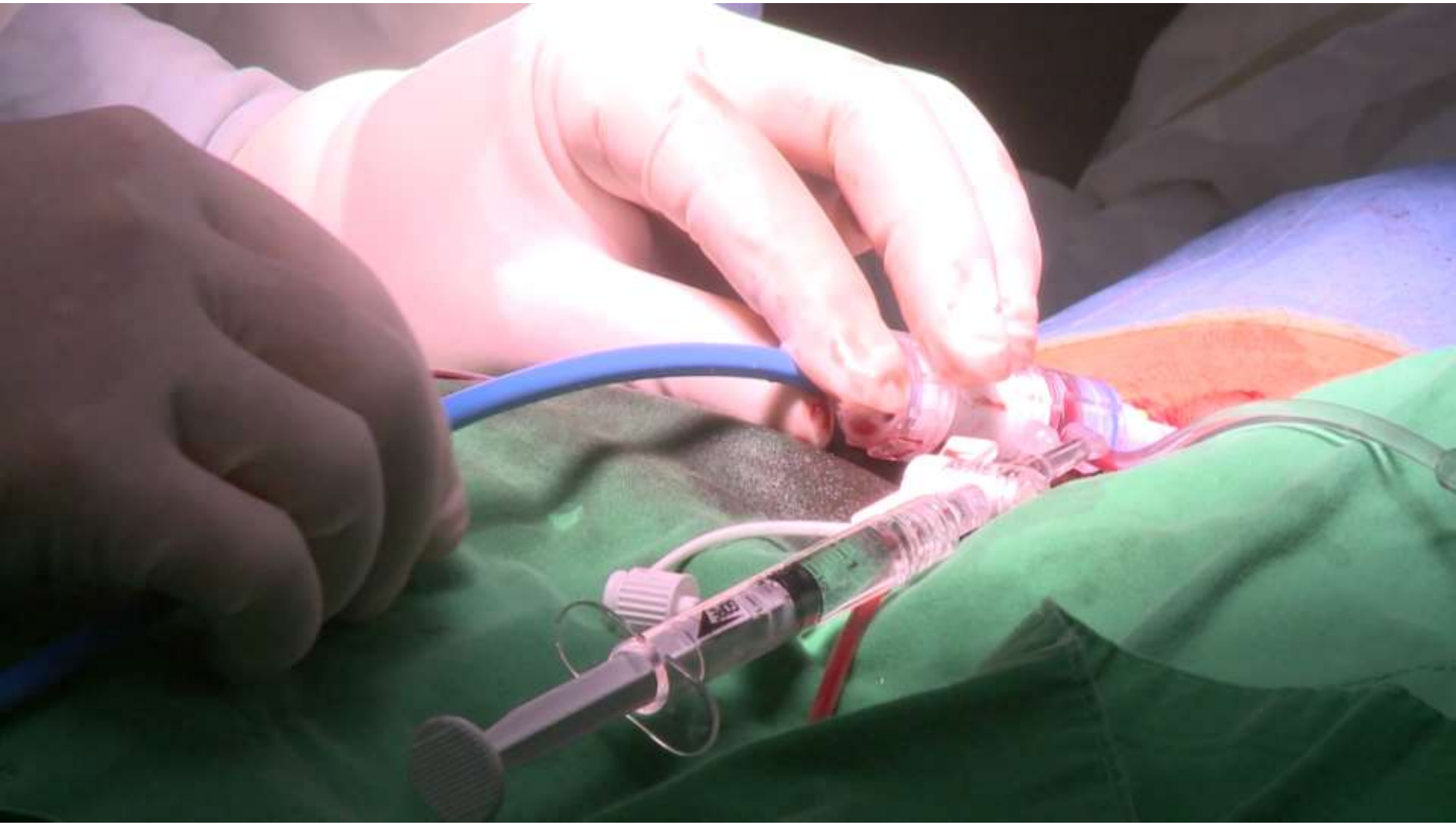
✓ Loading the Melody valve on Ensemble delivery system

- *The valve is crimped over the BIB balloon with symmetrical squeezing and elongating action ("blue to blue, white to white" direction)*
- *The outer shaft is flushed as it covers the BIB/valve assembly and engages the proximal end of the carrot*

✓ Implantation of the Melody valve

- The valve is uncovered by withdrawing the outer shaft over the shaft of the balloon catheter to the black double-ring marker on the shaft

- Positioning angio → inner balloon → check the position → outer balloon → deflate simultaneously → post-Melody angio thru the outer sheath



- ✓ **Residual gradient across the valve ≈ 10-15mmHg**
- ✓ **residual waist at the narrowest portion on pre-PPVI angio**

→ ***Post-dilate or Not? / which balloon to use?***

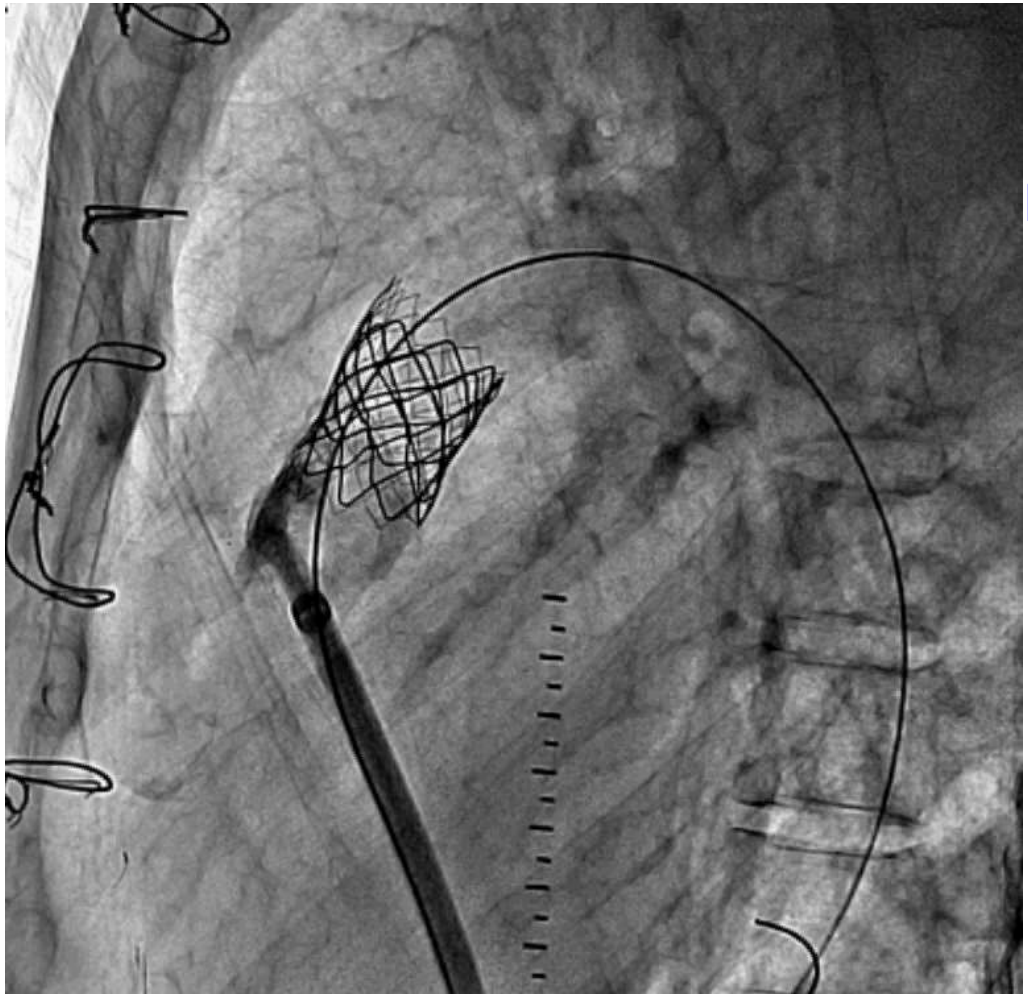
→ ***we decided to post-dilate with a 22mm Atlas balloon (Atlas Gold is not available)***

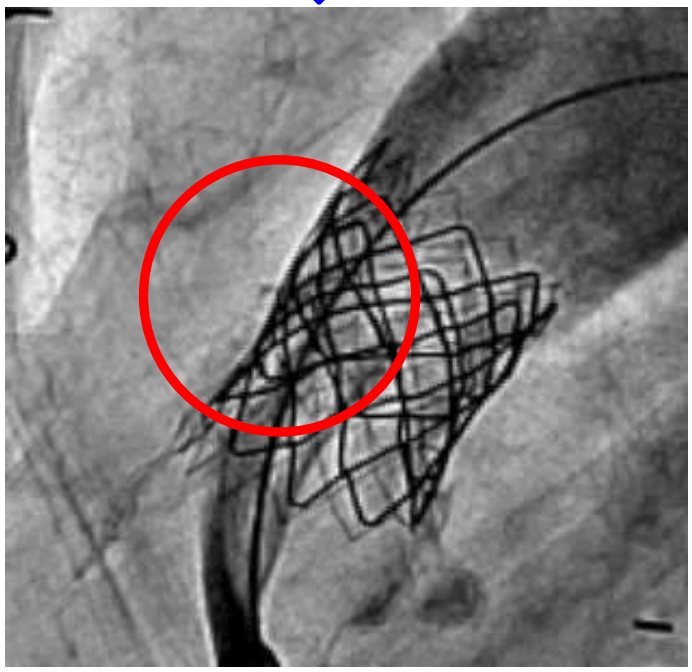
✓ Post-dilation

- Atlas balloon (ultra-high pressure balloon)
- No residual waist on lateral view / slight residual narrowing could be seen on frontal view / residual gradient≈5mmHg, peak RVP≈25mmHg

Post Implant RV Angiogram

something wrong!

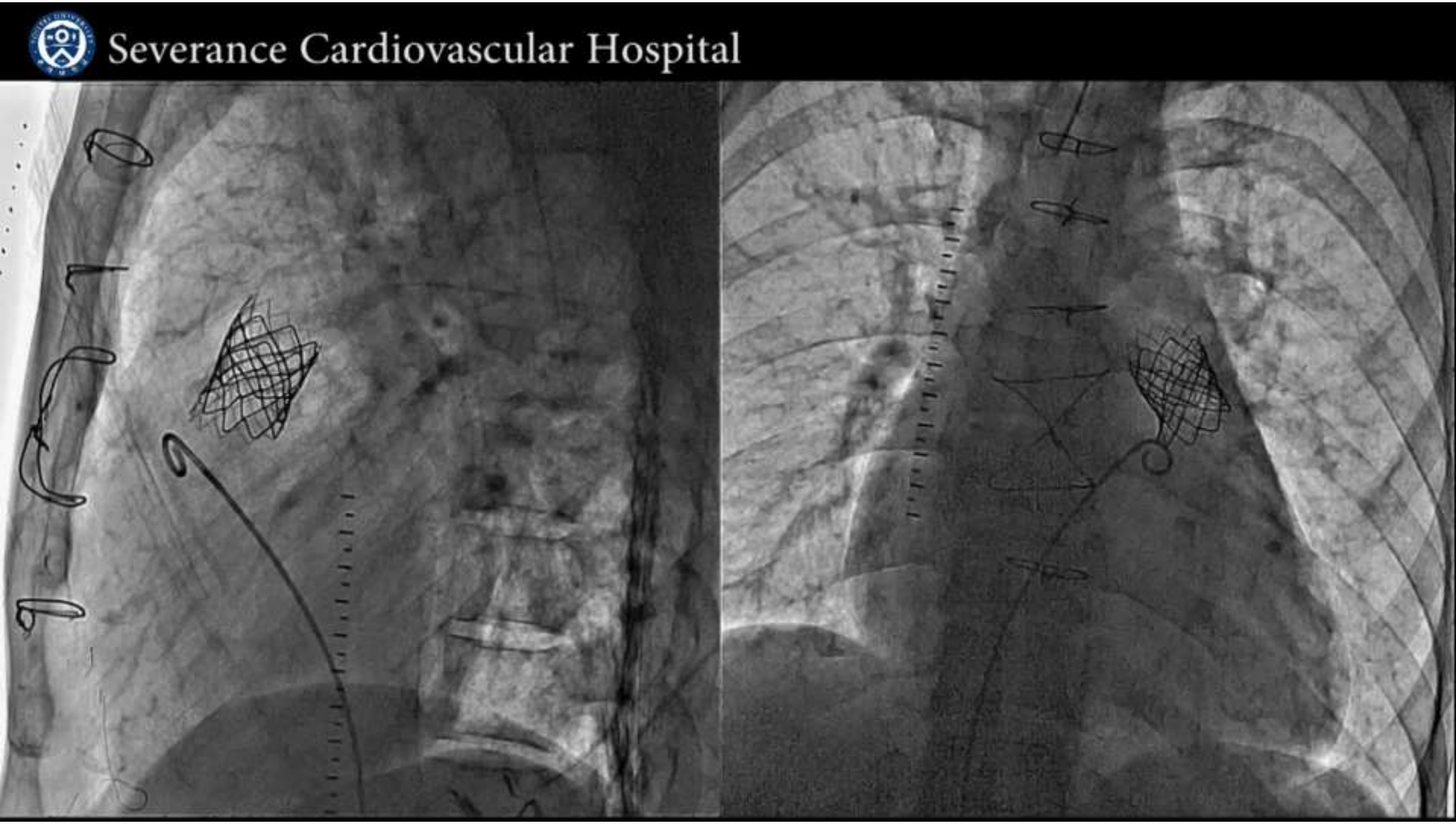




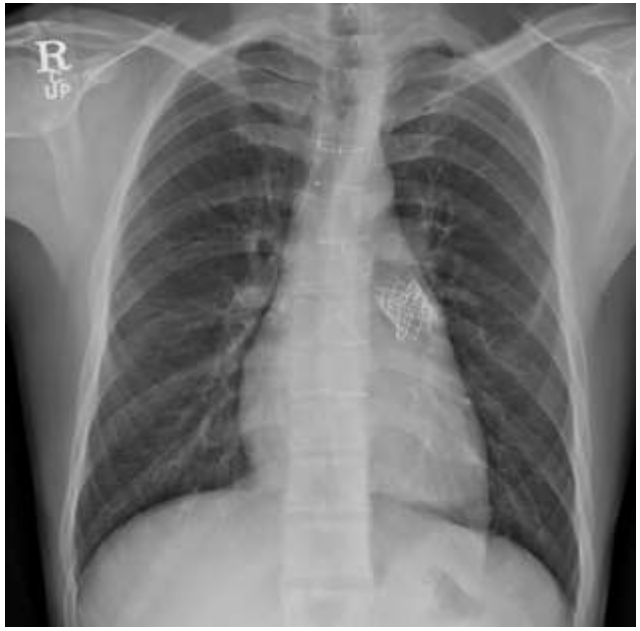
✓ Delayed RV angio & Hemostasis

- decreased leakage through small confined rupture

- Instantaneous hemostasis was achieved (pre-closure)



CXR before & 6mo after PPVI

	Before	After
		
RV pressure	60/0/8 (Aug. 2015) ← 70/0/10	25/0/5 (Feb. 2016)


Thank You
for Your Attention !