



Venus P-Valve: Updating Outcome

Worakan Promphan, MD.FSCAI.

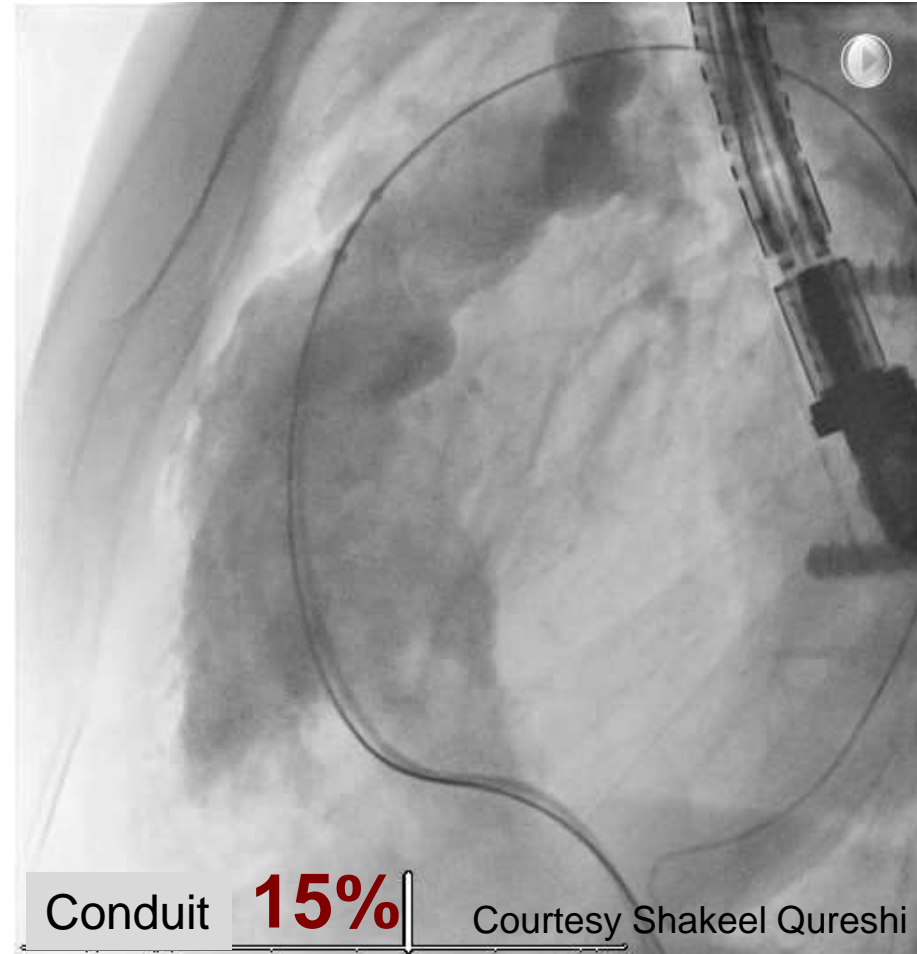
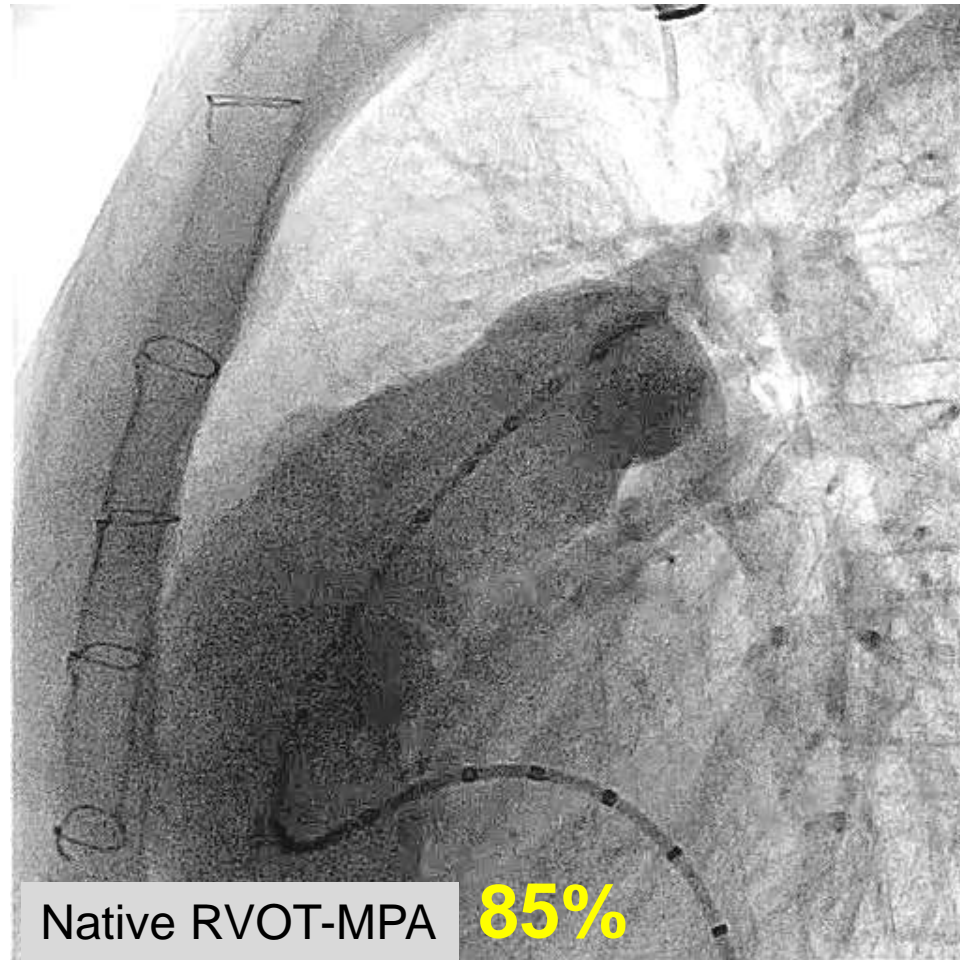
Pediatric Heart Center

Queen Sirikit National Institute of Child Health

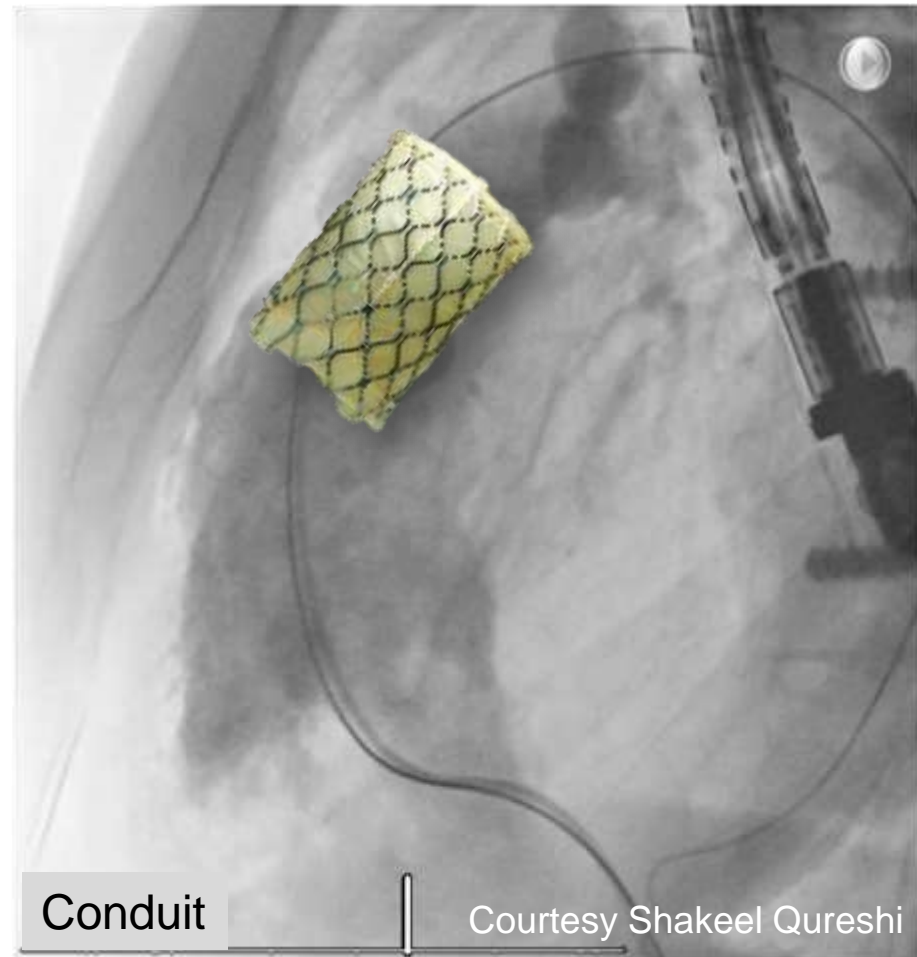
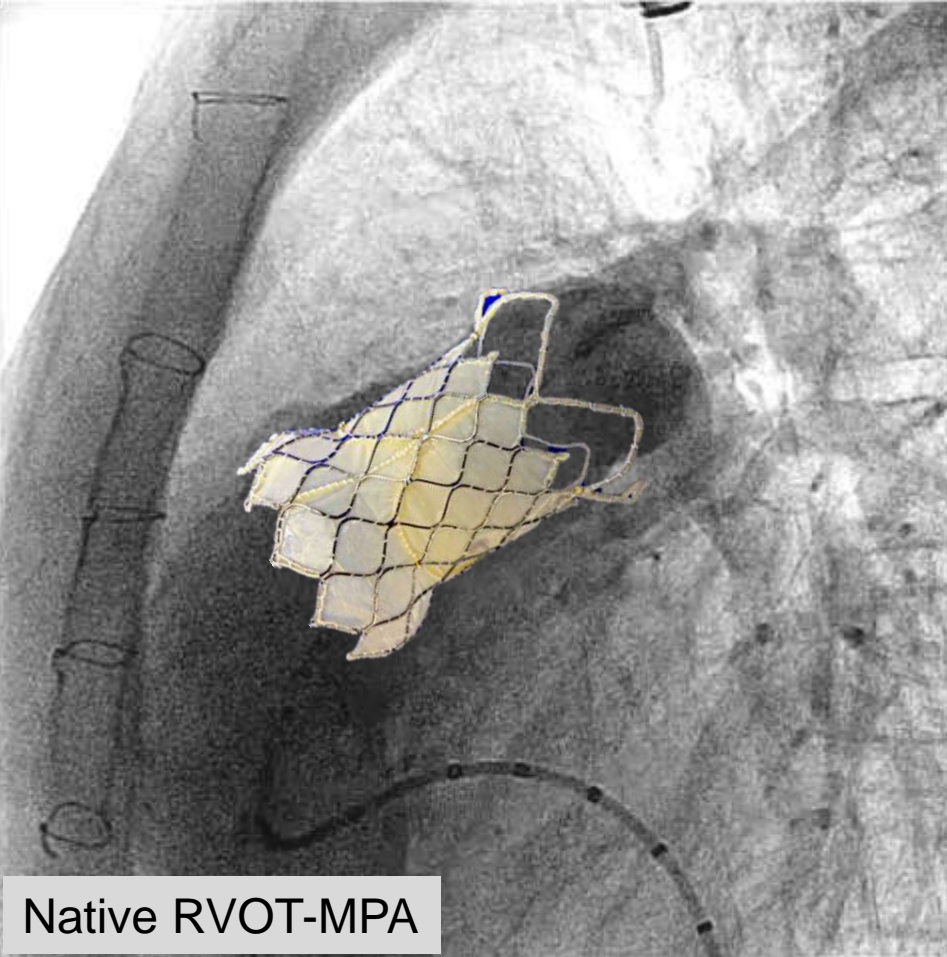
Bangkok, Thailand

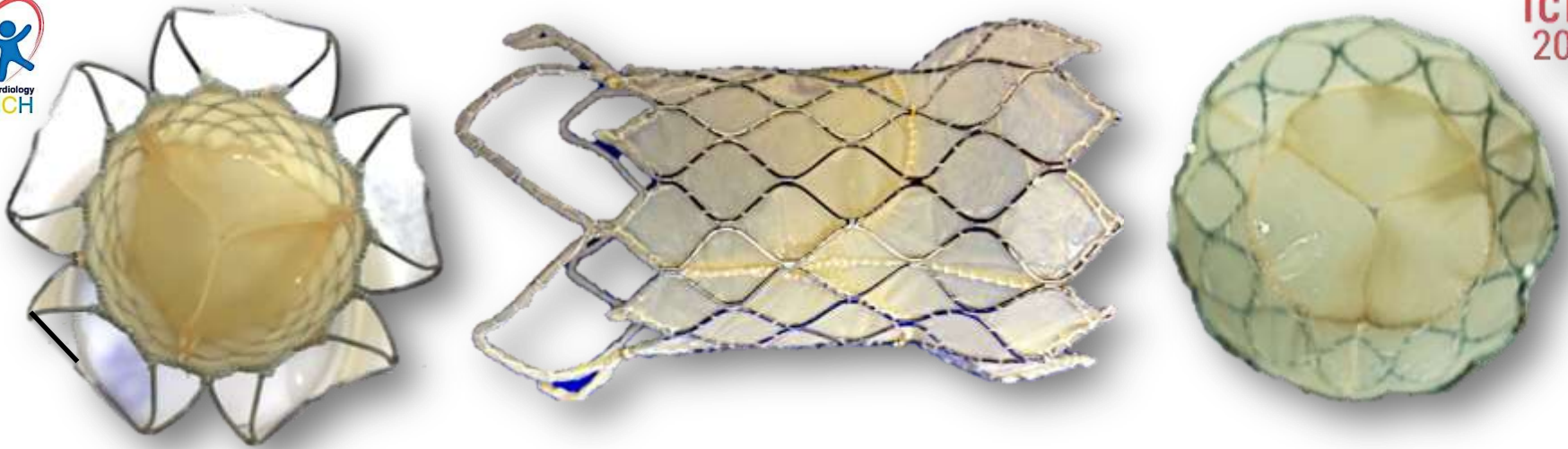
Consultant of Venus Medtech

Two groups of post-surgical severe PR



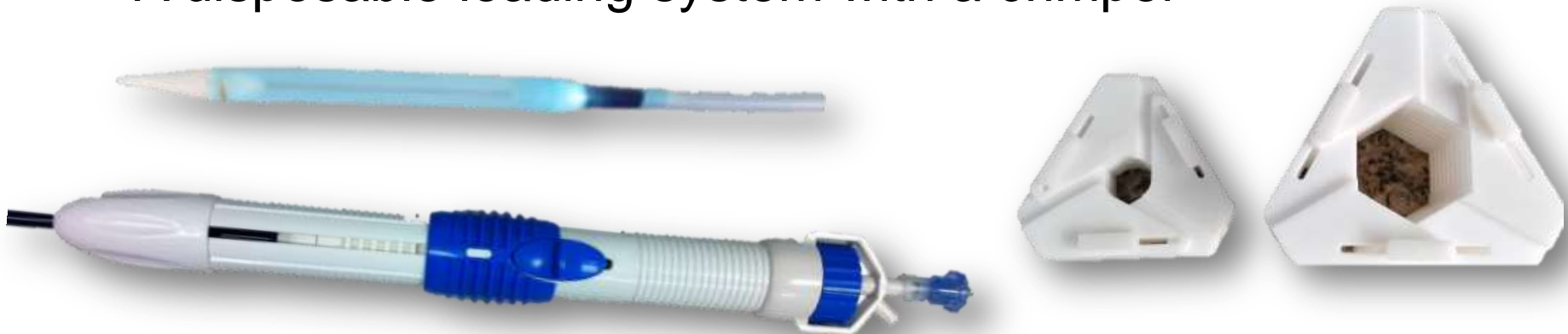
Two groups of post-surgical severe PR



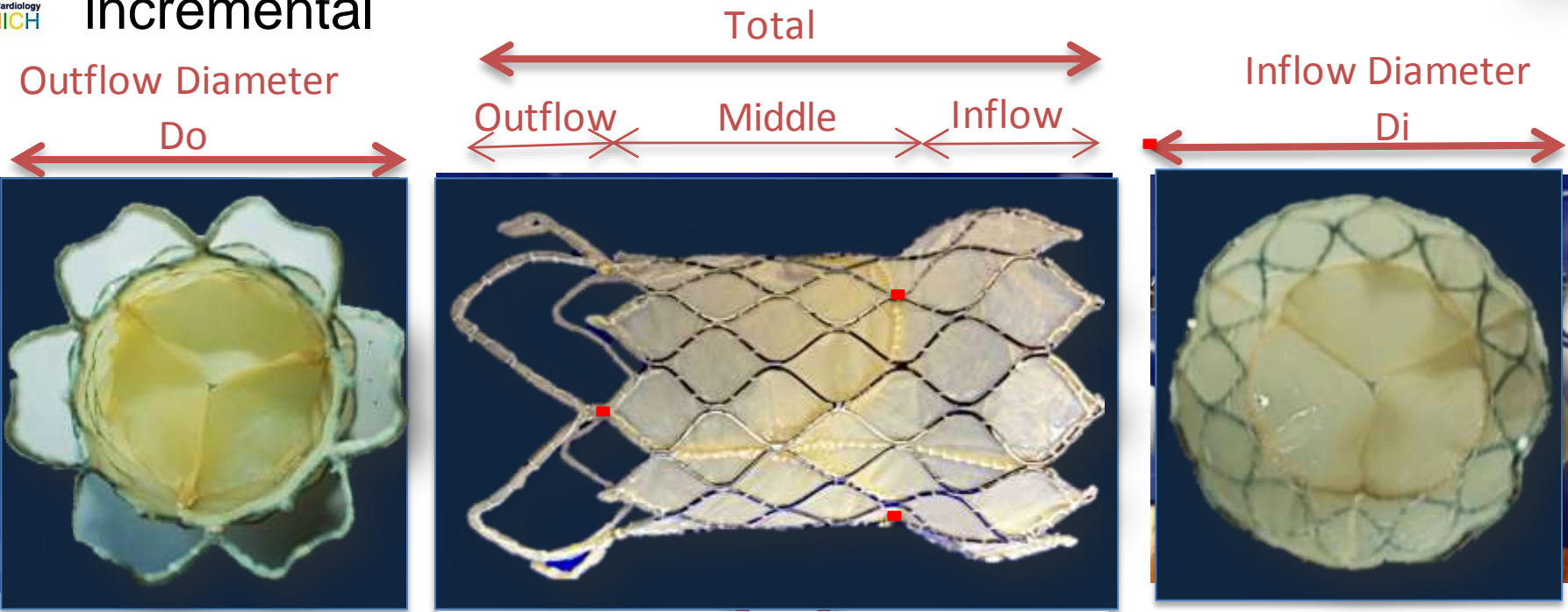


The Venus P-Valve[®] System for Native RVOTs

- A unibody self-expanding Nitinol frame with a tri-leaflet porcine pericardial tissue valve
- A 19-24 French catheter delivery system
- A disposable loading system with a crimper



Venus P-Valve[®] Sizes, Middle section varies with 5 mm incremental



30 mm middle section	Expanded Length				Diameter			Loaded(mm) Length
	Outflow	Middle	Inflow	Total	D_o	D	D_i	
P32-30	13	30	18	61	42	32	42	77
P30-30	13	30	18	61	40	30	40	76
P28-30								
P26-30								
P24-30								
P22-30								
P20-30	10	30	12	52	30	20	30	72
P18-30	10	30	12	52	28	18	28	72
P16-30	10	30	12	52	26	16	26	70

Valve diameter 16-36 mm
Length at straight part 25,30,35 mm

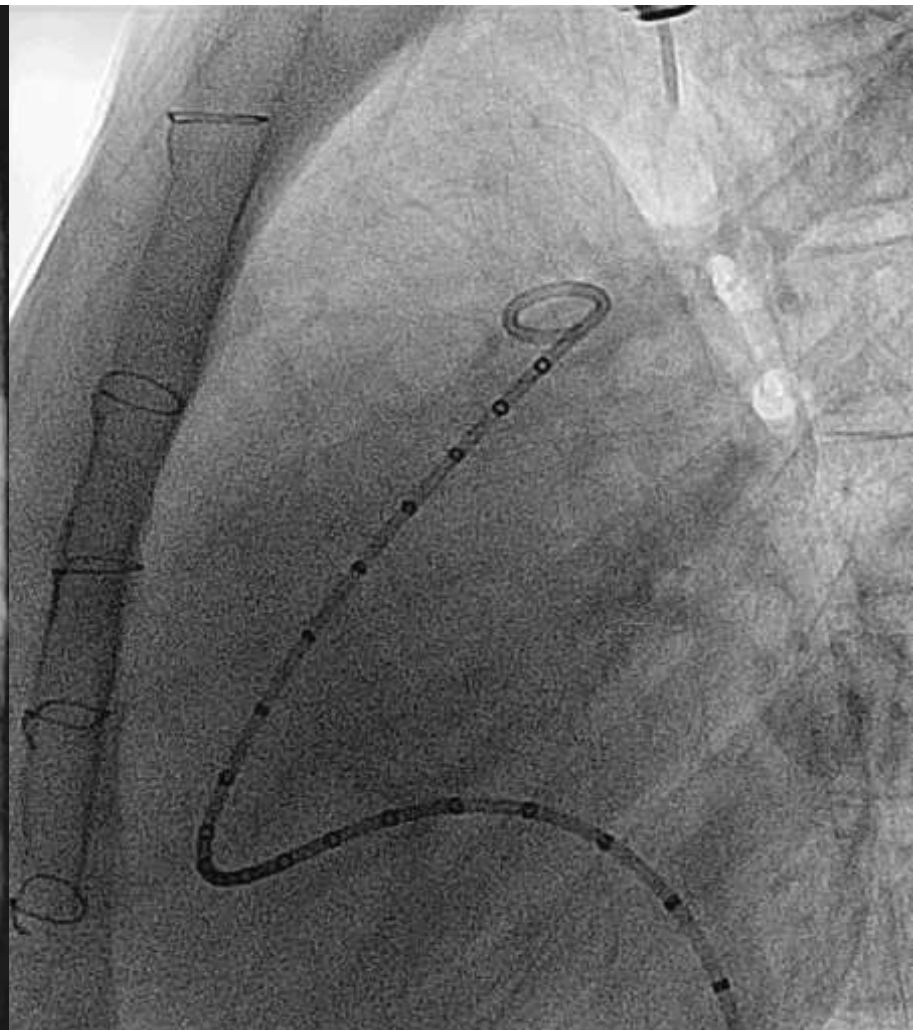
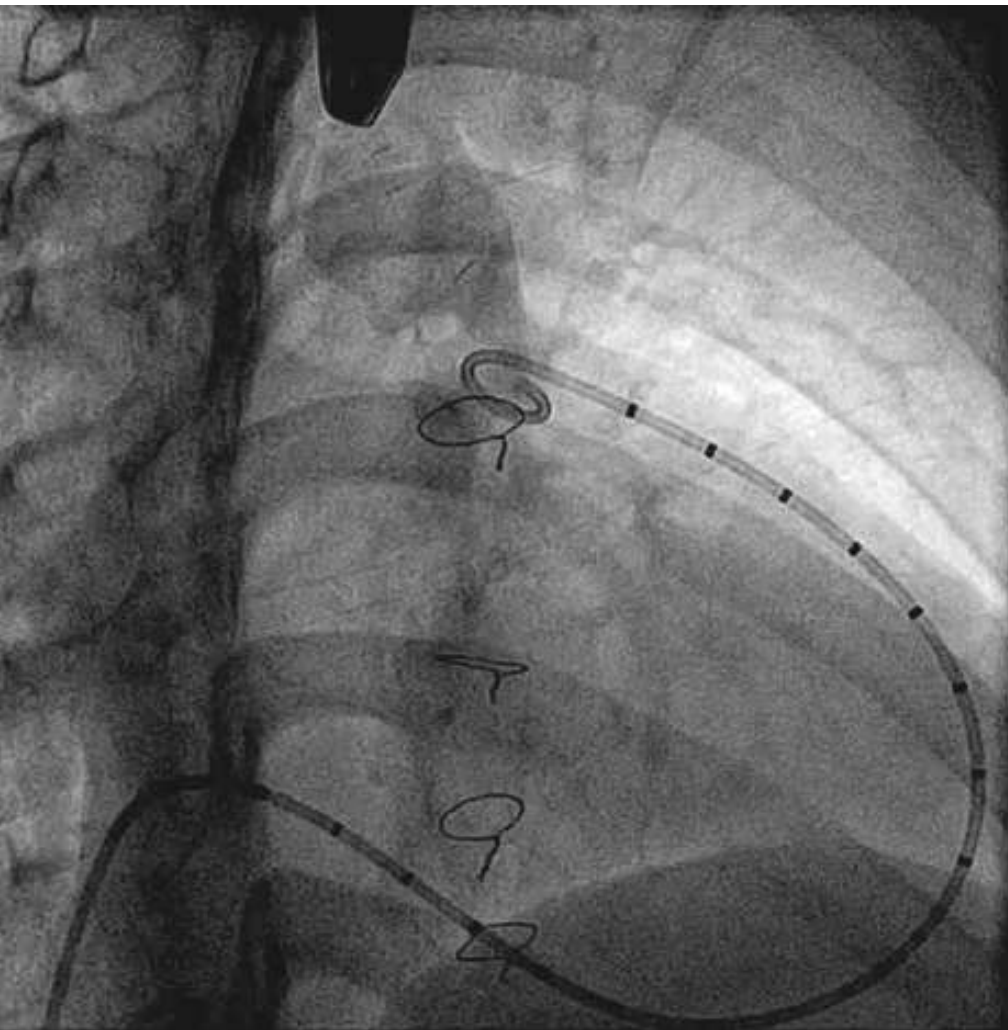


Patient selection for Flared Design

1. $BW \geq 30$ kg
2. Non-conduit RVOT with
 - a. Symptoms related to pulmonary regurgitation
 - b. severe PR (PRF > 30%) or
 - c. $RVEDVi > 150$ mL/m² or
 - d. $RVEF < 45\%$
3. MPA diameter 18-32 mm
4. No significant RVOT/PA narrowing

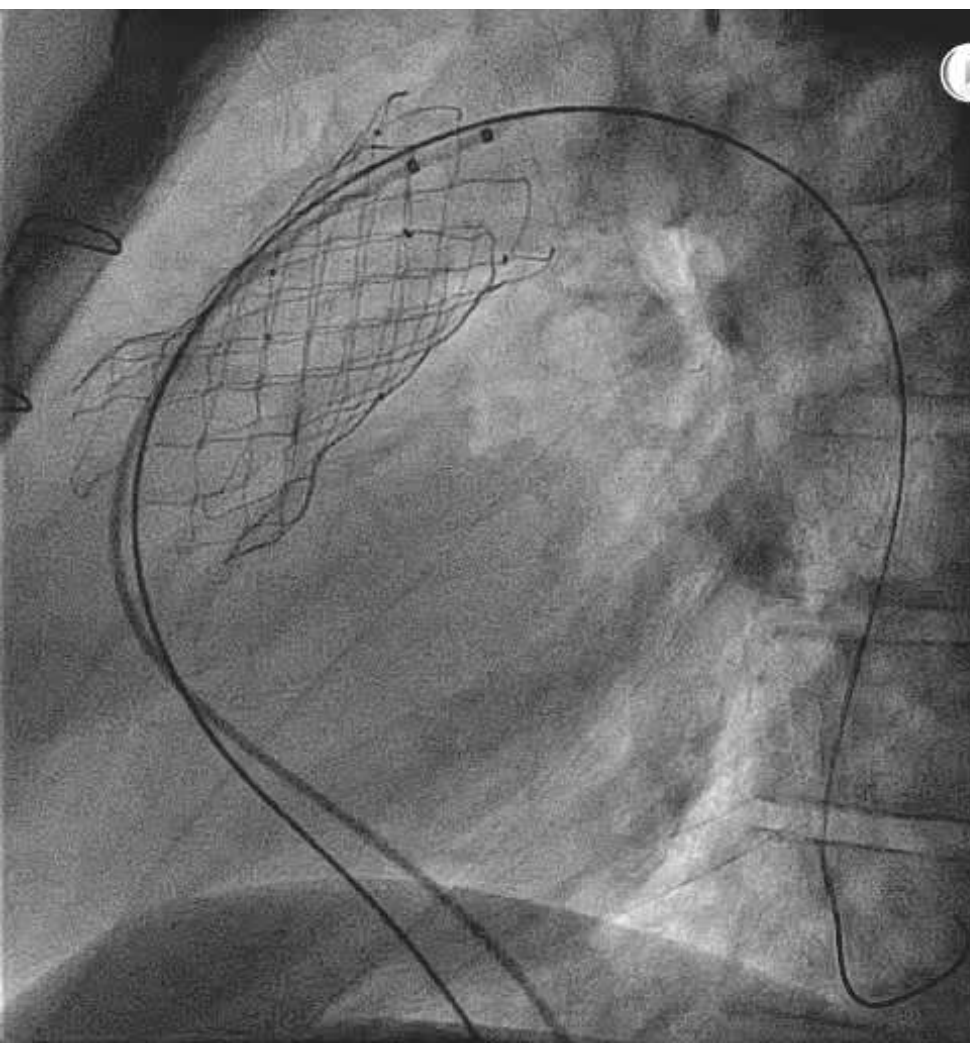
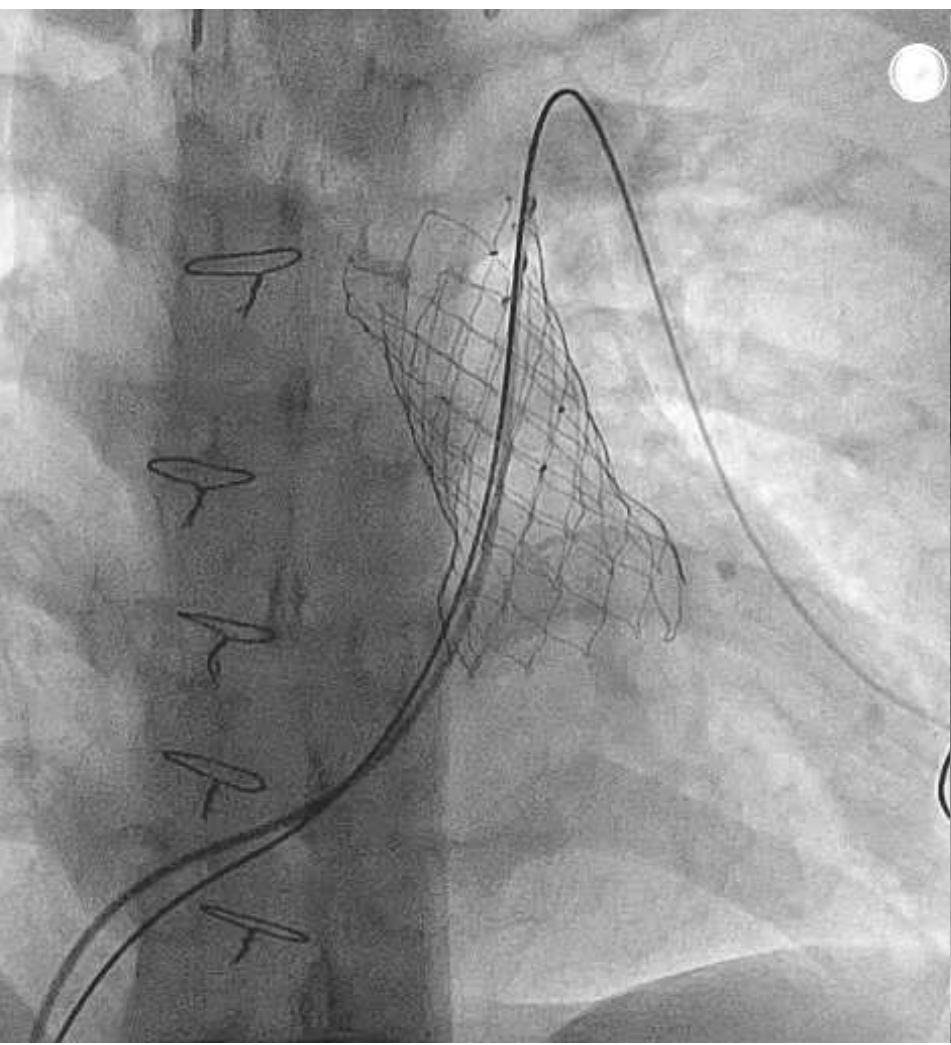
Exclusion

1. Short and wide pyramidal shape RVOT
2. Proximal stenosis or prestenosed RPA-LPA
3. Unsuitable femoral venous access

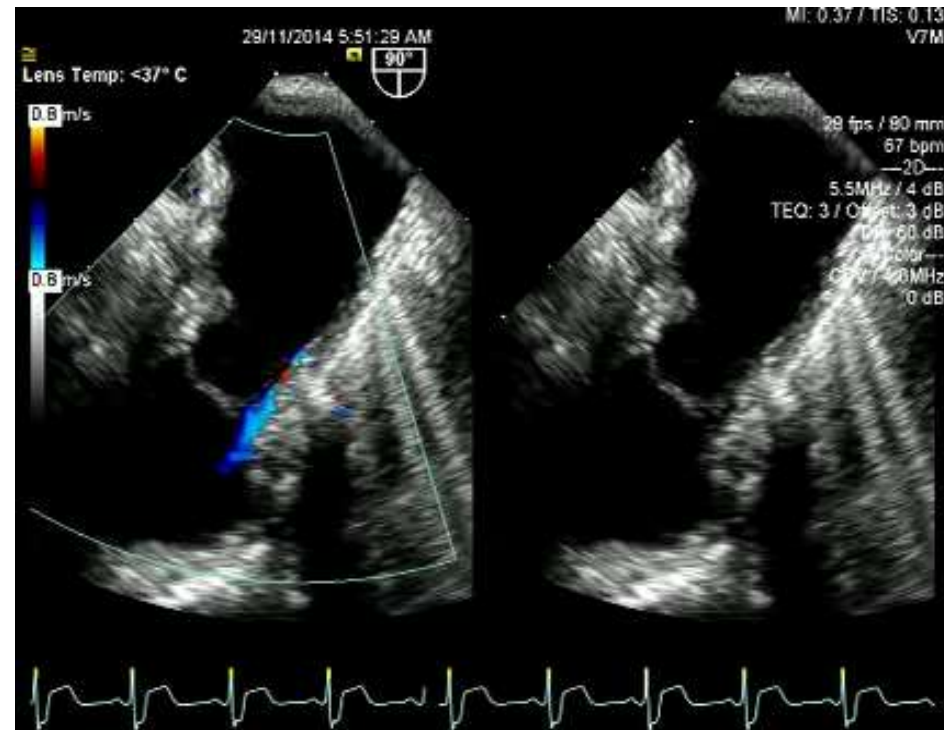
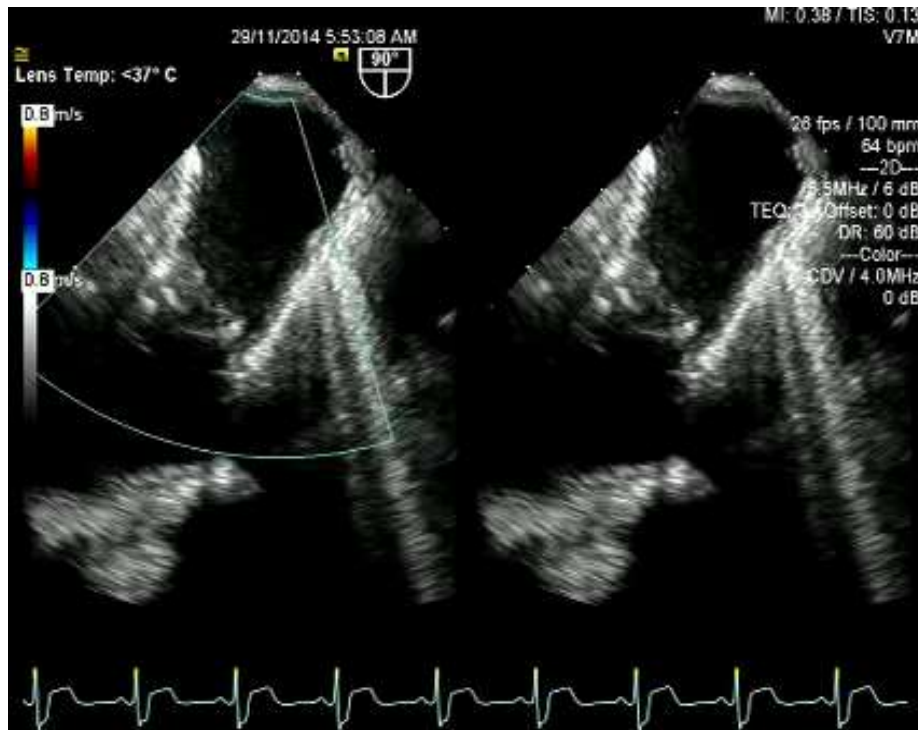


RAO 20, Cranial 15

LAO 90



TEE after implantation



The Venus P-Valve[®] System for Conduit RVOTs

- A straight body self-expanding Nitinol frame with a tri-leaflet porcine pericardial tissue valve
- A 19-24 French catheter delivery system
- A disposable loading system with a crimper

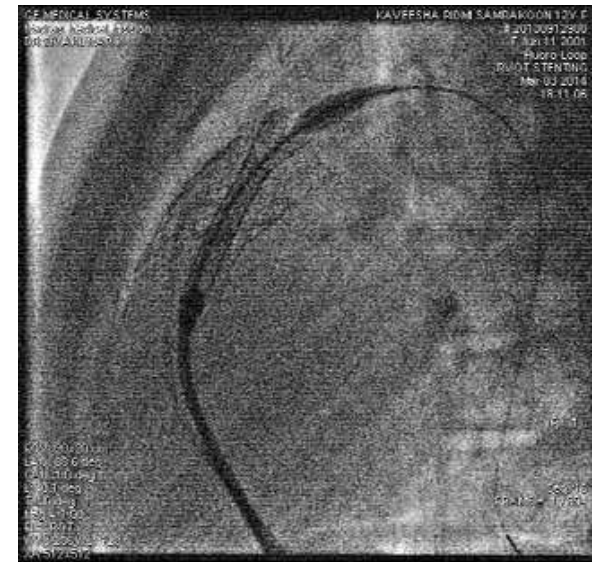
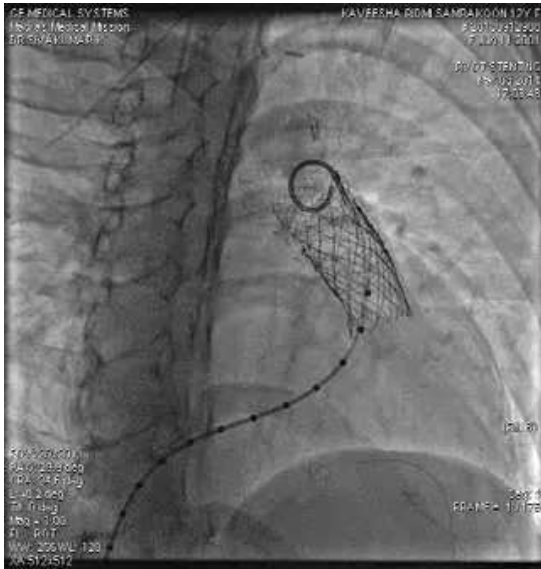
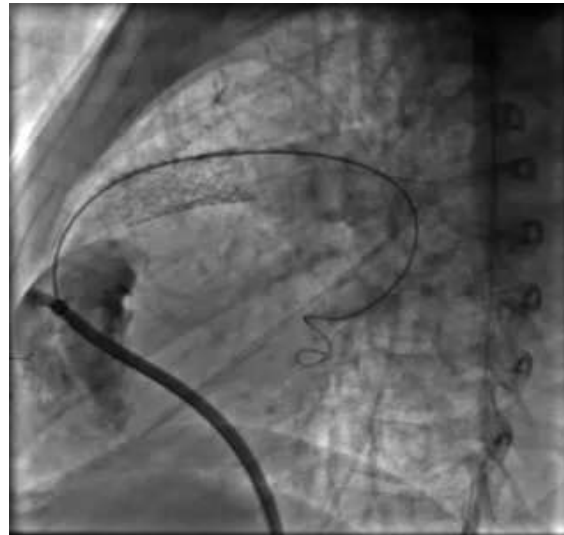
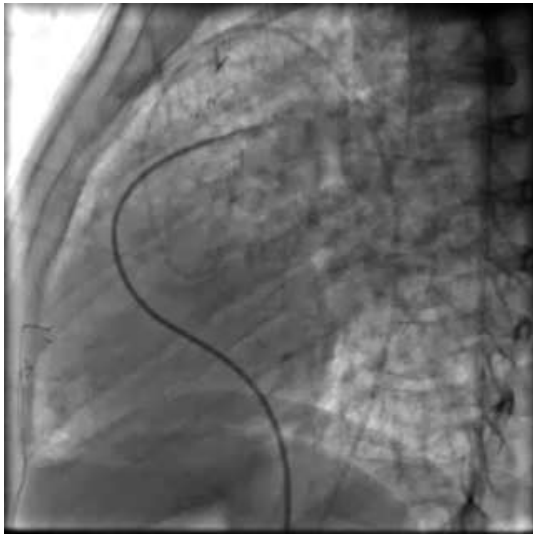


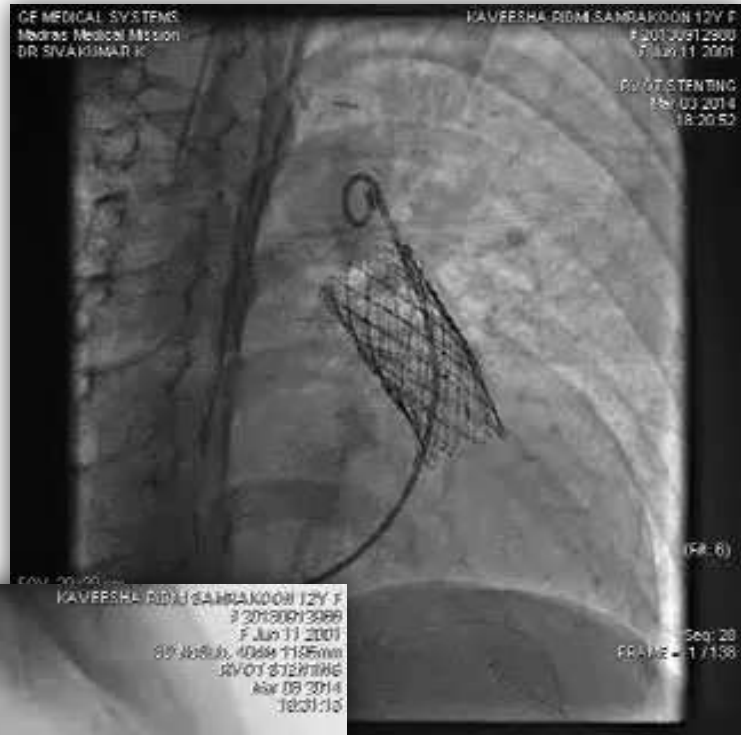
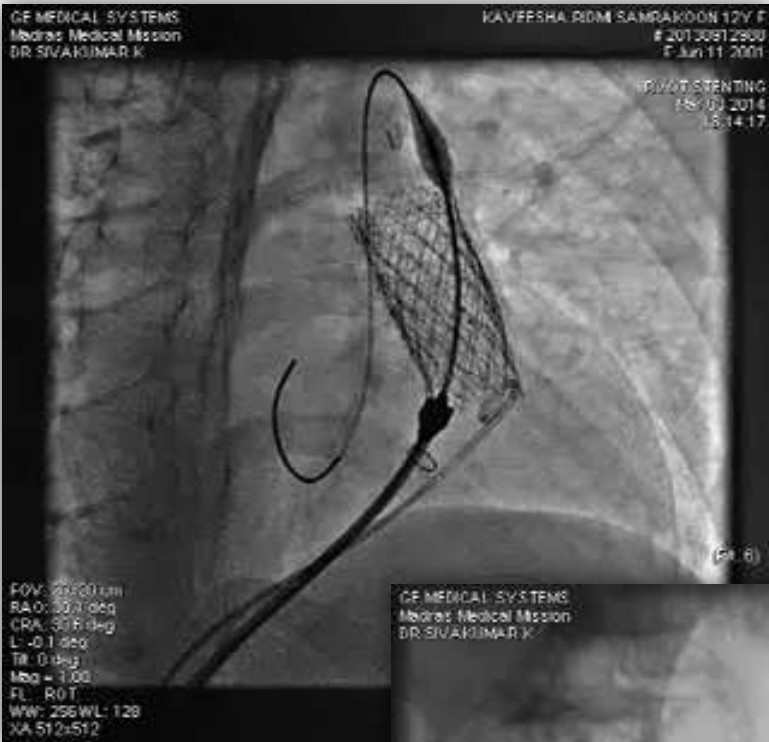
Venus P Valve[®]

Straight body for
pre-stented conduit
Max diameter 30 mm

Pre-stented RVOT

Courtesy of Sivakumar K, MMM, Chennai





Courtesy of Sivakumar K, MMM, Chennai

Global Implantation, Venus P-Valve



City/Country	Number	Aborted/com plicated	Valve size	Incidence	Hospital
Shanghai, China	14			Valve malposition 48 hours after implantation, requiring surgical valve suture 1 patient collapsed while riding a motorbike 4 mo later, unidentifiable cause	Zhongshan Hospital
Beijing, China	17				Fuwai Hospital
Chengdu, China	7				West China Hospital
Shanghai, China	6				SCH, SCMC
Xian	2				Xijing Hospital
Total	46				



Fuwai Hospital, Beijing



Clinical Data, China

24 cases were successfully done (May 2013 - Feb 2015)

- **Gender:** 19 Female
- **Age:** 14- 48 years (mean 29.92 yrs)
- **Weight:** 40-74 kg (mean 54.48 kg)
- **Height:** 152-173 cm (mean 161.91cm)

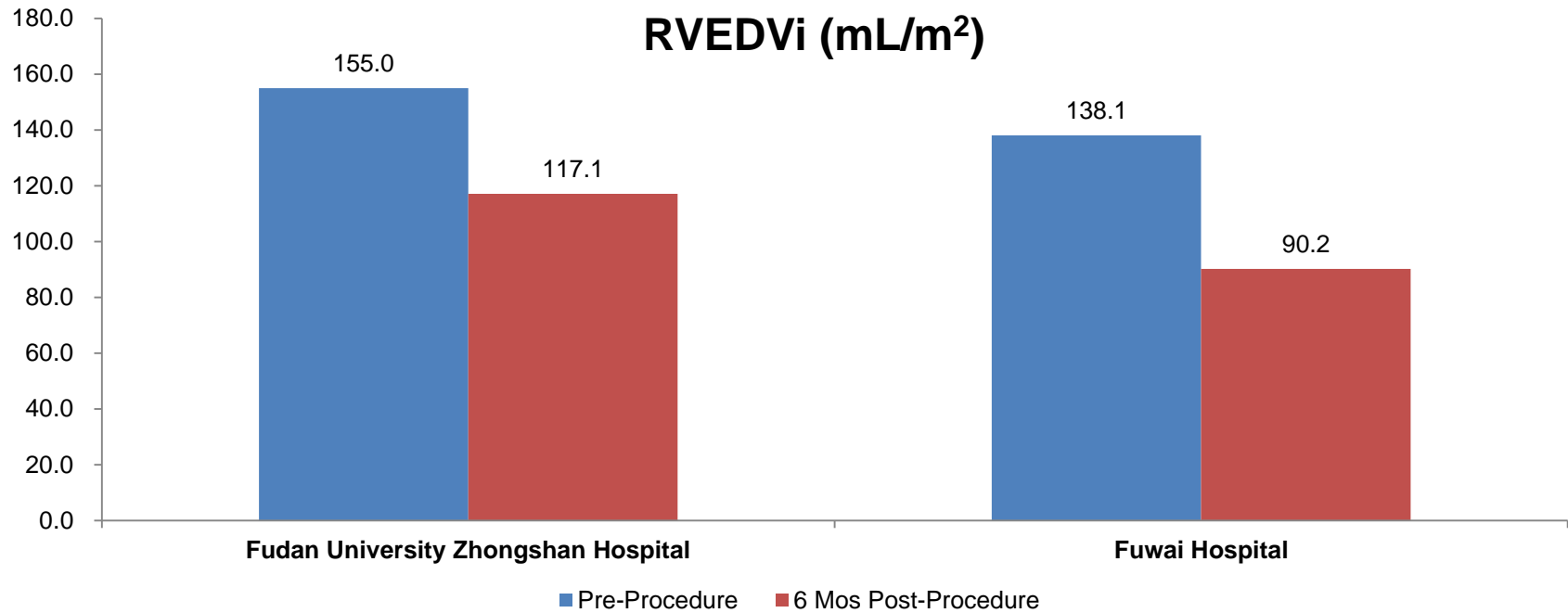
	Hospital	N	Investigators
1	Fudan University Zhongshan Hospital	10	Junbo Ge, Daxin Zhou, Wenzhi Pan, Lihua Guan
2	Fuwai Hospital	8	Shengshou Hu, Shiliang Jiang, Gejun Zhang, Xiangbin Pan
3	West China Hospital, Sichuan University	3	Mao Chen, Yuan Feng
4	Shanghai Chest Hospital	3	Weiwei Fang, Xin Pan

4 pts already completed 12 month FU

	Hospital	1M	3M	6M	12M
1	Fudan University Zhongshan Hospital	10	9	6	4
2	Fuwai Hospital	6	6	3	-
3	West China Hospital, Sichuan University	3	2	-	-
4	Shanghai Chest Hospital	3	3	-	-

Valve Size Distribution

Valve Model	32-30 mm	26-30 mm	30-30 mm	28-30 mm	24-30 mm	28-25 mm	30-35 mm
No.	8	6	4	3	1	1	1



Hospital	RVEDVi		% Decrease
	Before	6 mo. after	
Fudan University Zhongshan Hospital	154.98	117.08	24
Fuwai Hospital	138.06	90.20	35

Venus P- Valve outside China

- Total of 37 cases (2012-2016)
- Age 11-61 yrs (Mean 22 yrs 4 mos)
- Mean BW: 63 kg (min 28 kg)
- Vietnam, Thailand, India, The UK, Indonesia, Ireland, and Chile
- 2 aborted cases

QSNICH, Bangkok, Thailand



Amarita Institute of Medical Science and Research Centre, Kelera



Harapan Kita, Jakarta



Evelina London Children's Hospital

Global Implantation, Venus P-Valve

City/Country	Number	Aborted/com plicated	Valve size	Incidence	Hospital
Hanoi, Vietnam	1	-			HMU
Bangkok, Thailand	14	C2 A1	30-30 30-30	I. Incomplete detachment of the ear, slight proximal valve migration. II. Piercing of the capsule from the stent strut III. Splitting of the sheath. Need surgery. LPA pre-stented	QSNICH
Jakarta, Indonesia	1	-		BW 28 kg	Harapan Kita
Kochi, India	2	C1	30-30	proximal migration of valve, needing surgery, but same valve sutured in place	AIMS
Chennai, India	6	A1	34-30	Failure to uncover the capsule	MMM
Hyderabad, India	1			First 36-30 successfully implanted	CARE Hospital
London, UK	8	C1	28-35	Prior RPA stenosis occluded by Valve, needed RPA stent	ELCH
Dublin, Ireland	1	-			Crumlin Hospital
Santiago, Chile	3	N/A			Pontificia Universidad Católica de Chile
Total	37	A2 C3			

Flare: 29
Straight: 7

Commonly used size:
Flare: 32-30
Straight: 30-30



Immediate follow up

* Not include data from Chile

Fever (1-2 days)	(8/34)
Transient PVC	(1/34)
Groin hematoma	(1/34)
Severe TR	(1/34)
Para-valvar leakage	(0/34)
PR and RVOT obstruction	(0/34)

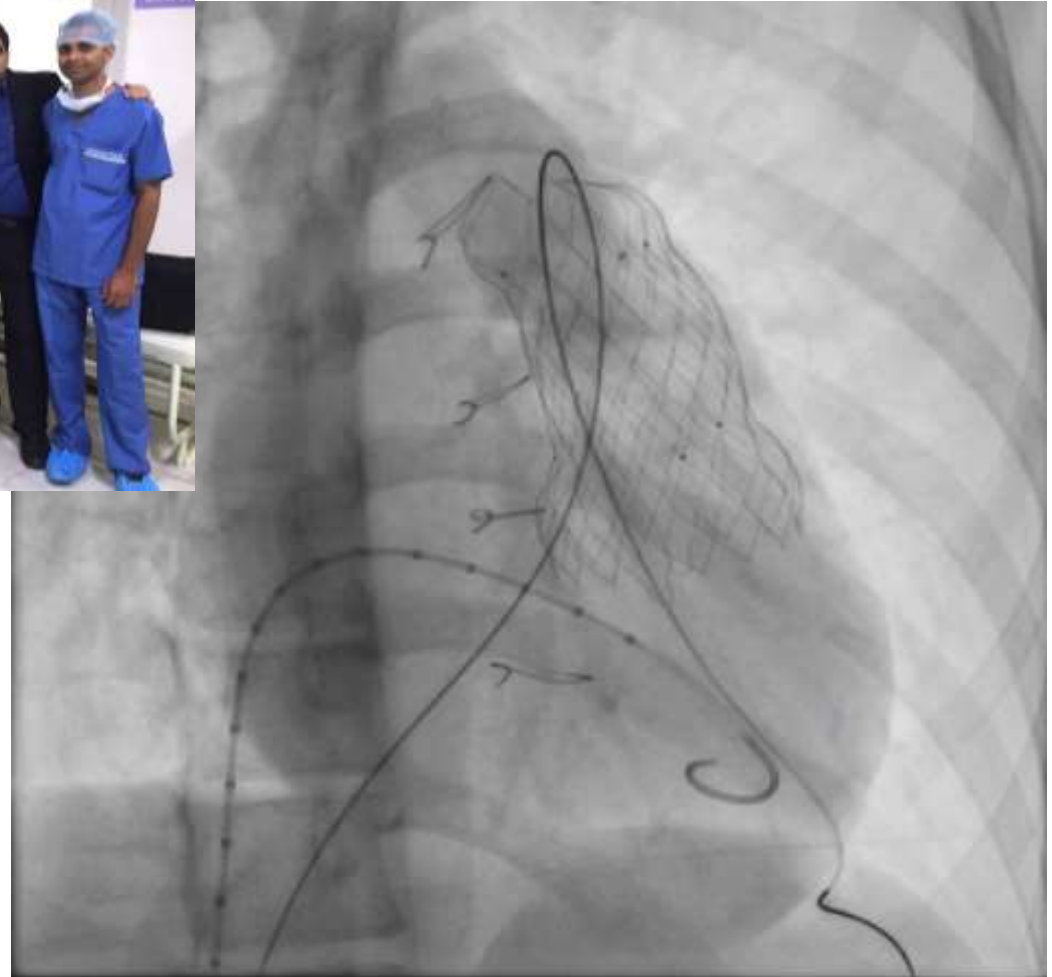
Venus P-valve implanted in 28 kg boy (November 2014)



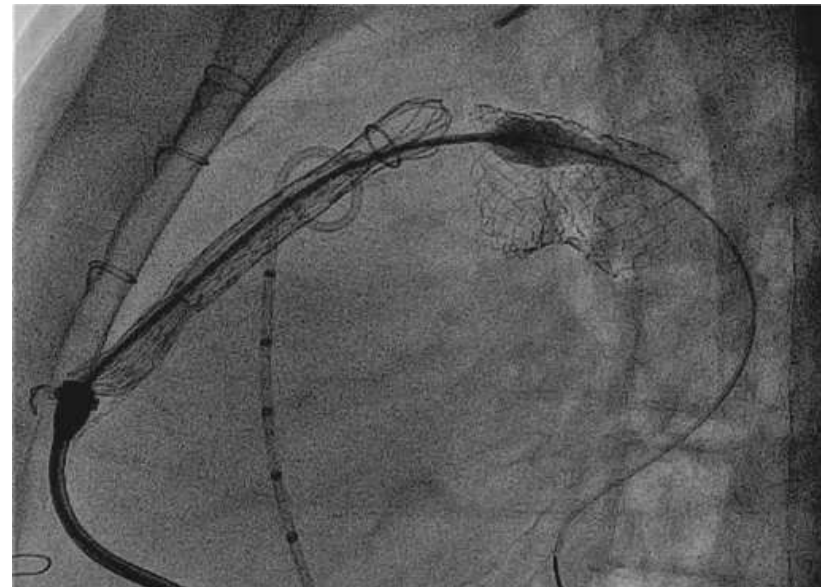
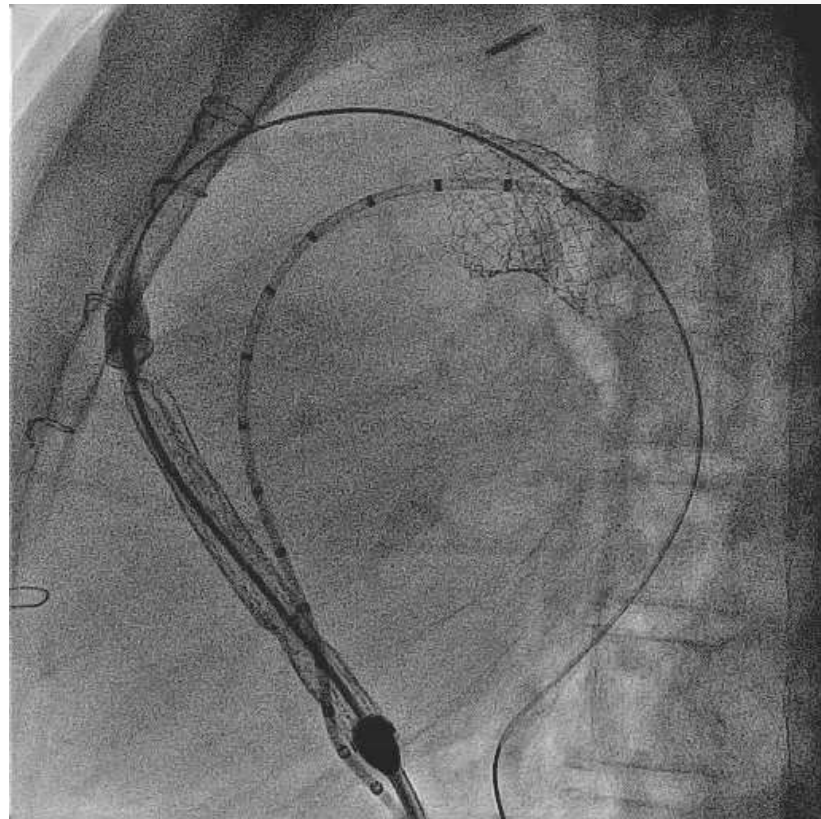
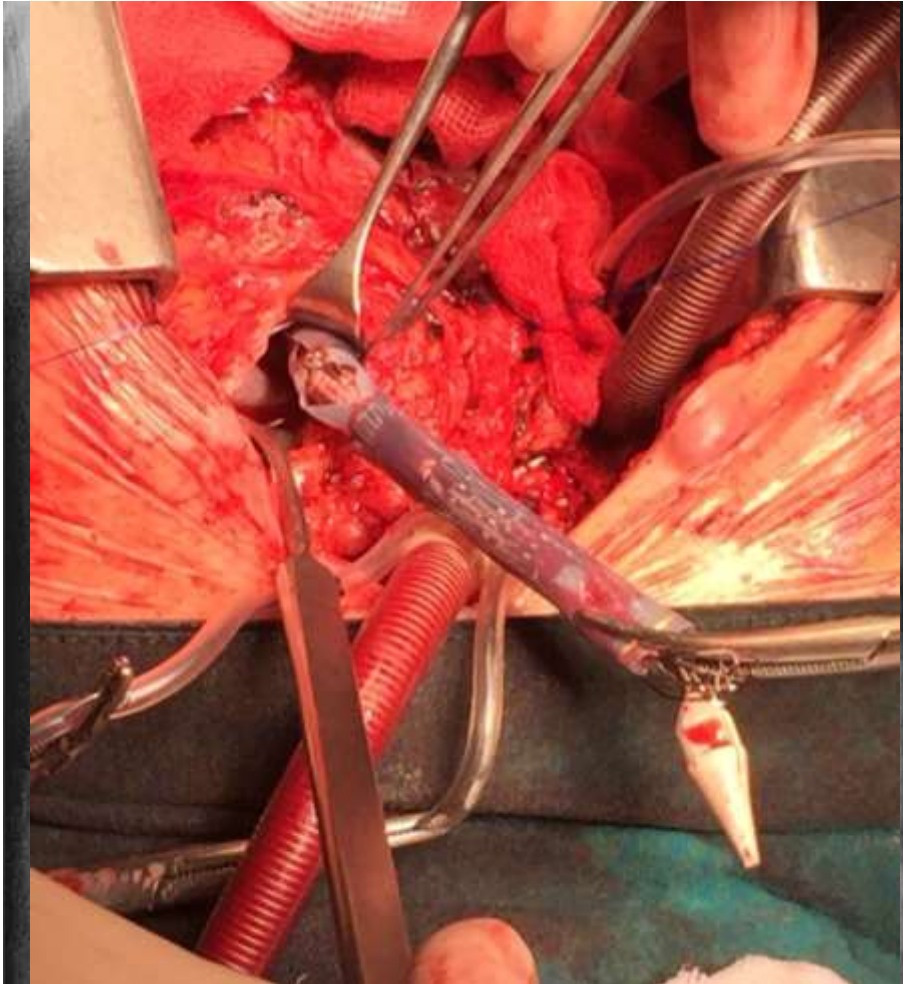
Venus P-valve 36-30 (October 2015)



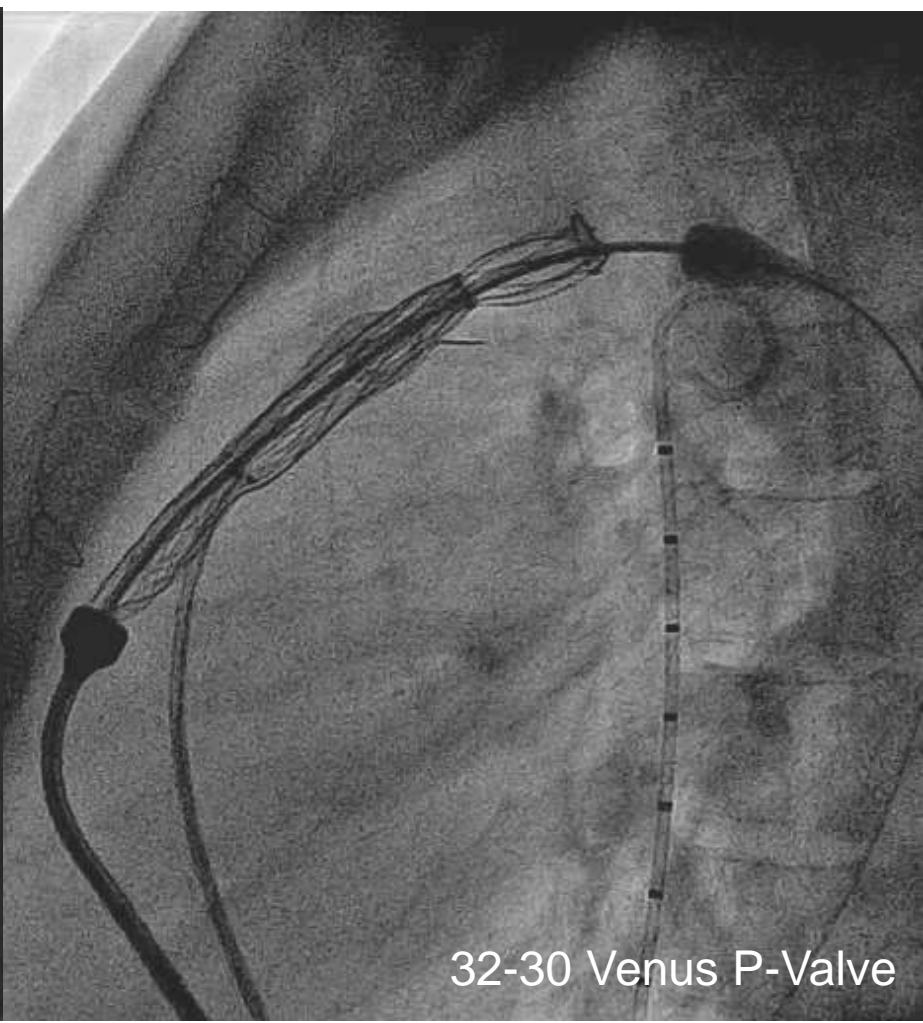
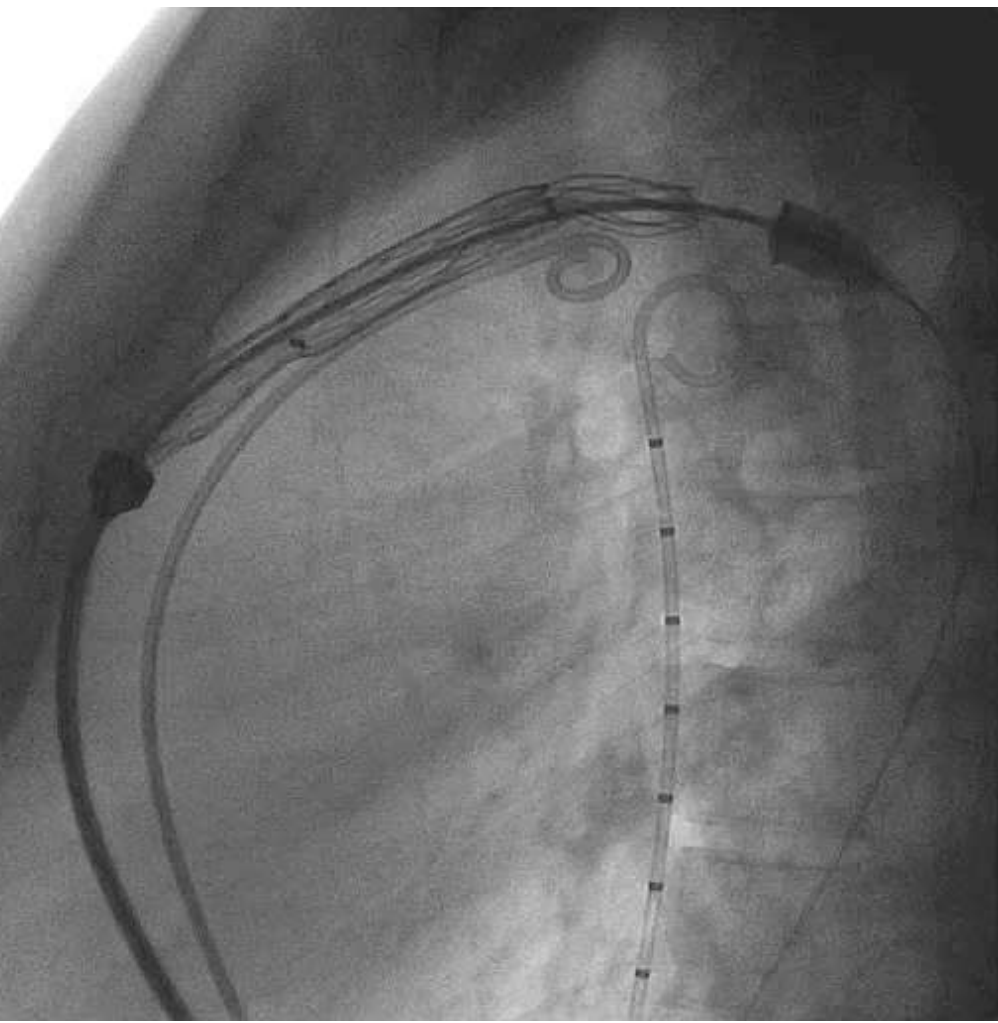
CARE, Hyderabad



Aborted case: Breaking of the capsule



Piercing of the stent strut out of the capsule while uncovering the sheath



32-30 Venus P-Valve

Piercing of the stent strut out of the capsule while uncovering the sheath



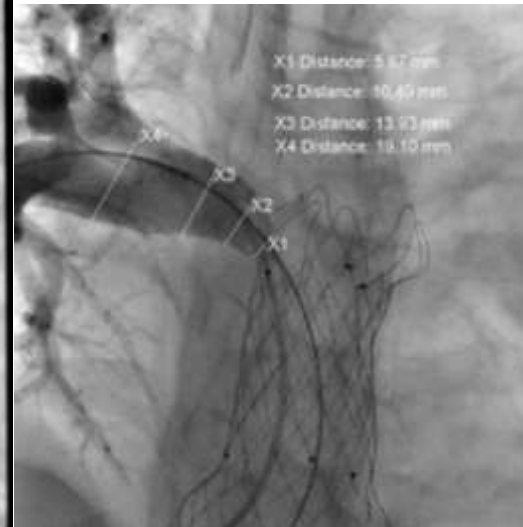
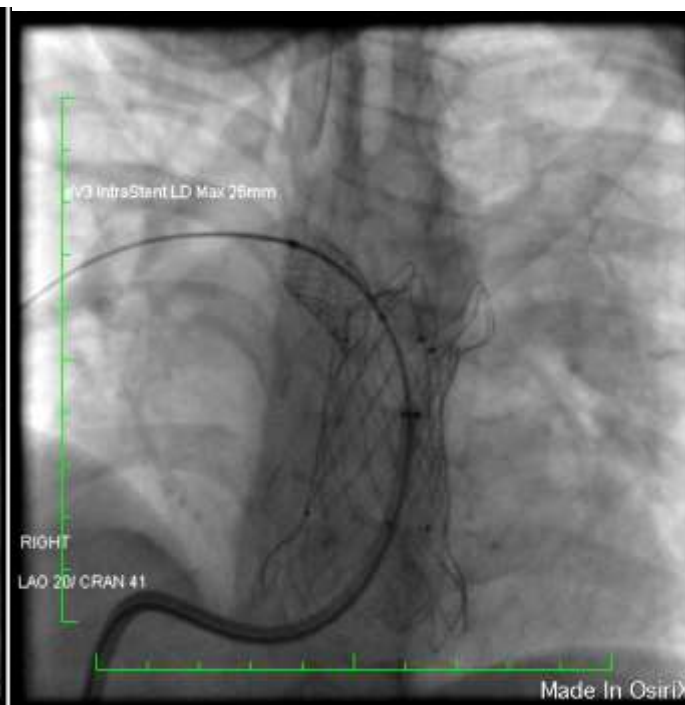
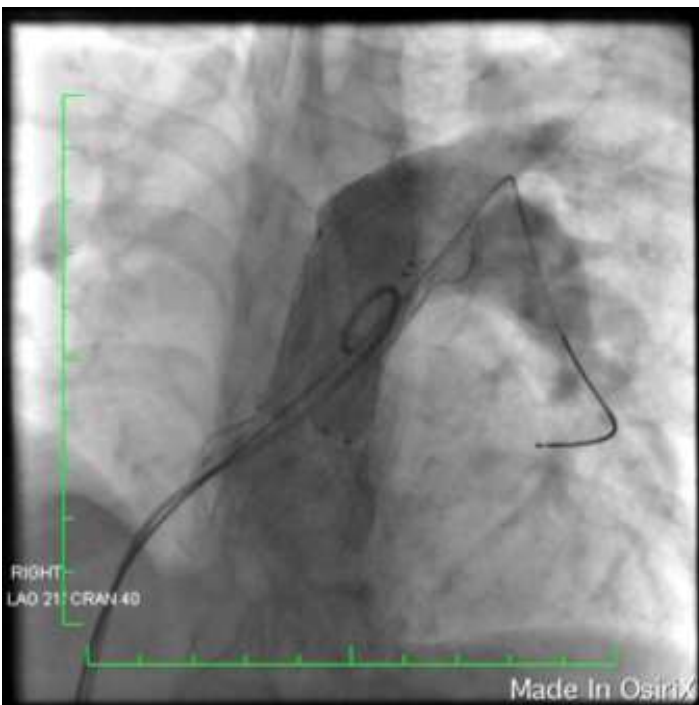
Piercing of the stent strut out of the capsule while uncovering the sheath



Delivery system modifications

1. Braiding/thickened capsule
2. Longer and softer carrot
3. Seamless carrot-capsule connection

Prior RPA stenosis occluded by Venus P-valve needing stenting



LD max 26 mm on 15 mm x 3 cm Cristal balloon



6 month-follow-up

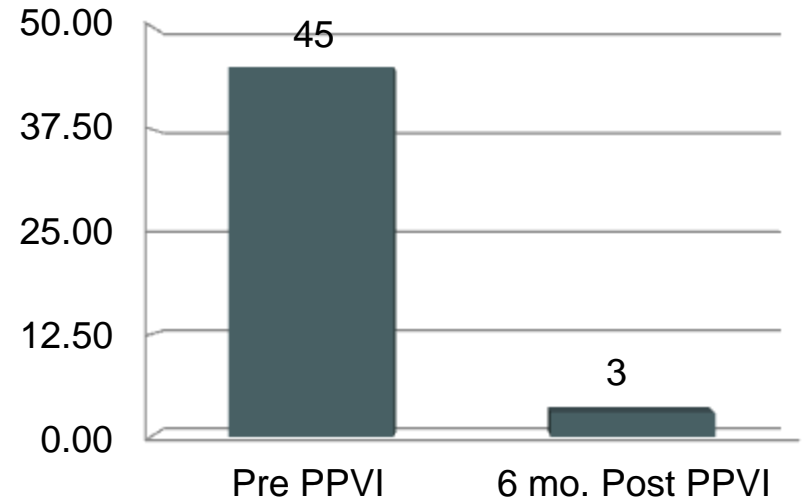
* Not include data from Chile

RVEDVi (mL/m²)



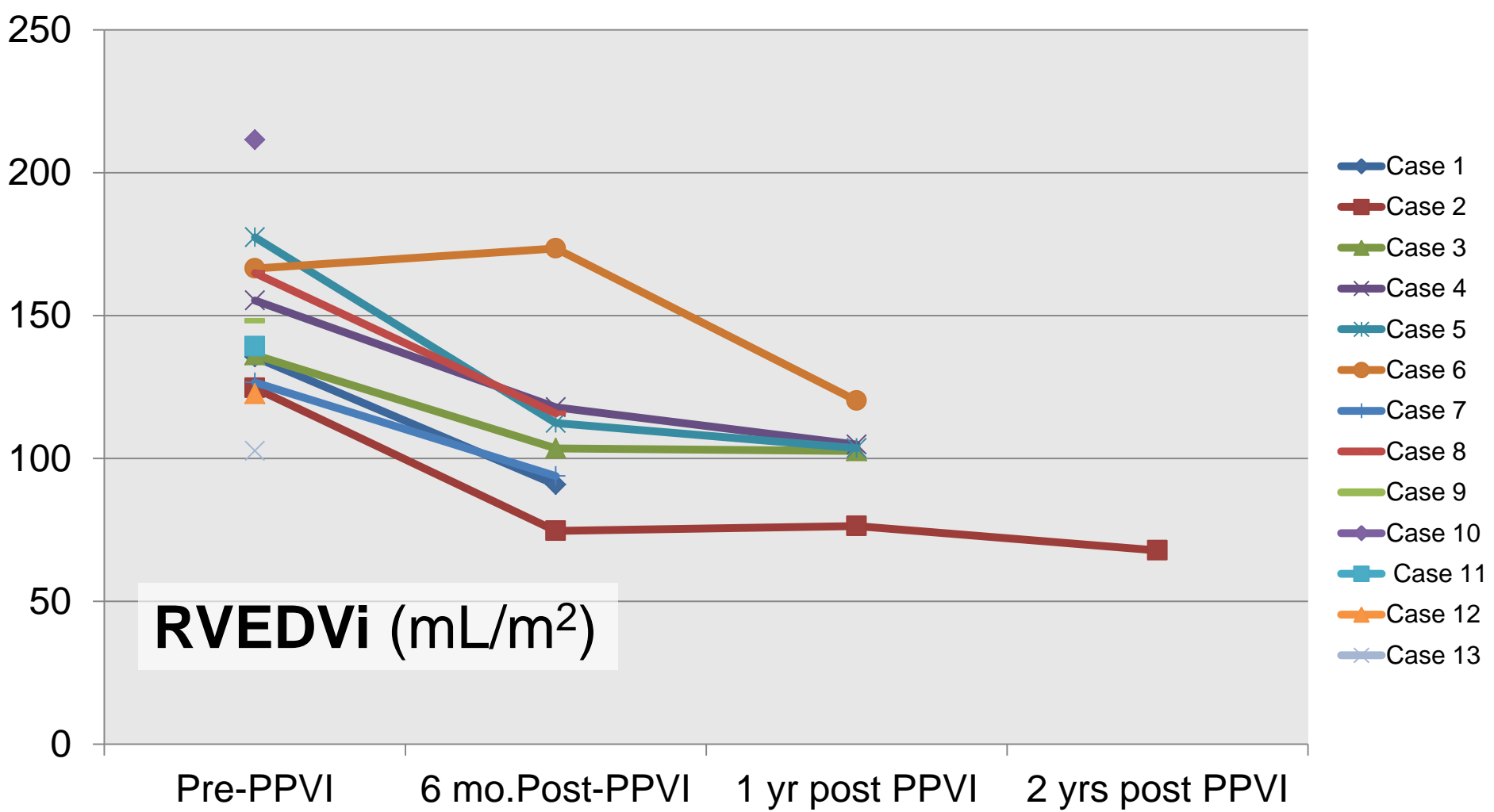
	Pre-PPVI	6 mo. Post PPVI
■	145.8	109.5

PRF (%)

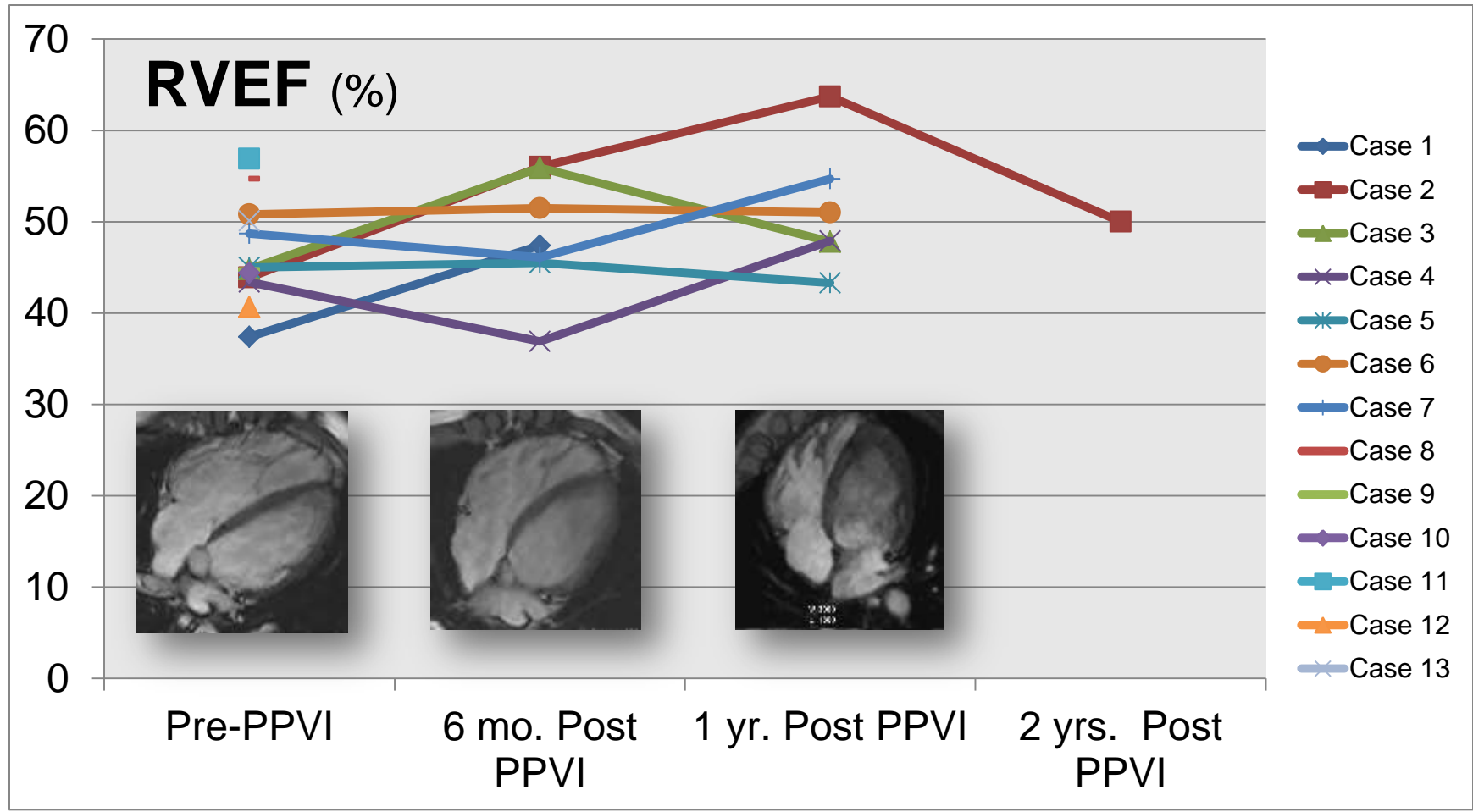




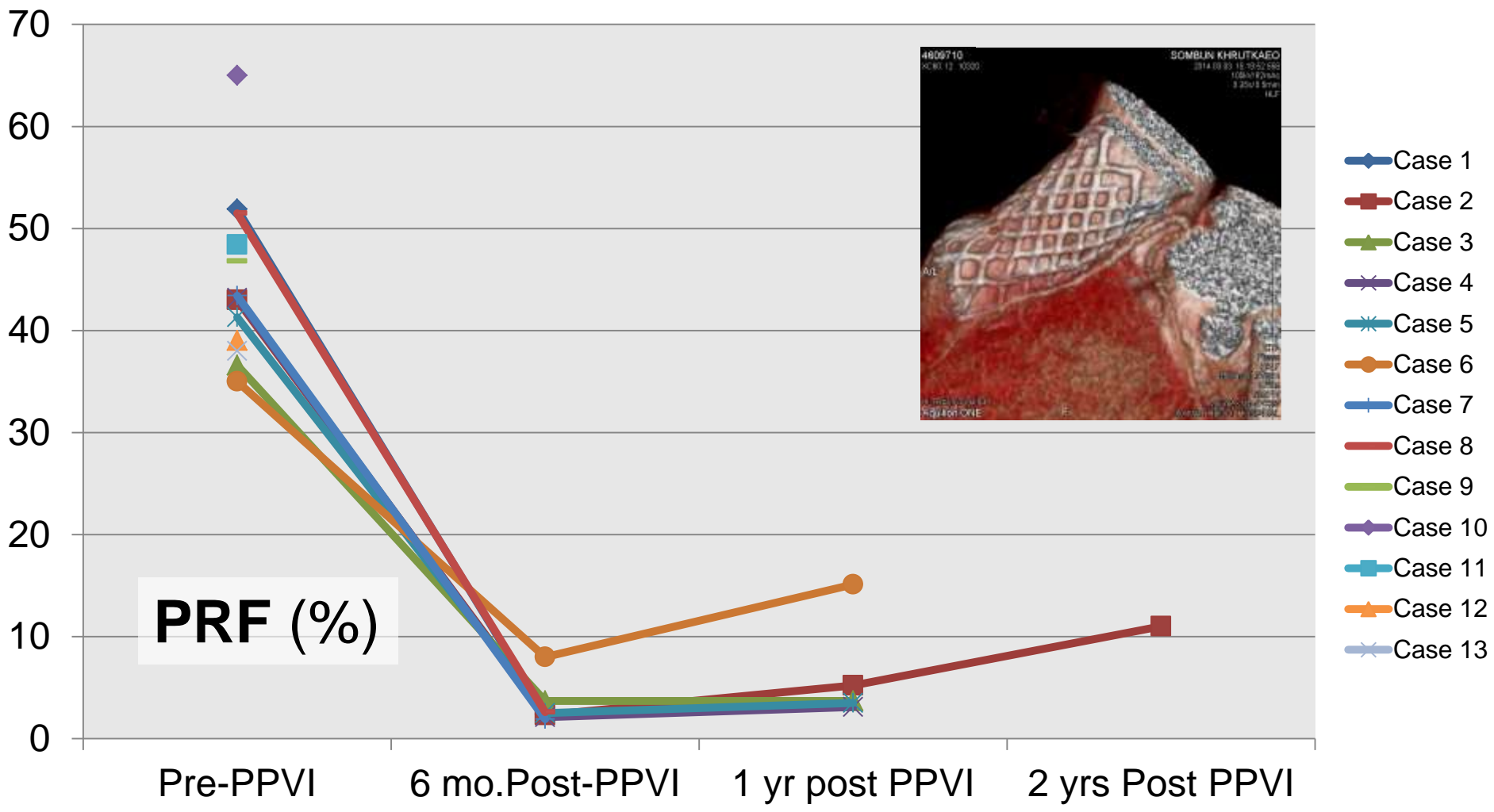
Venus P-Valve[®] Follow-up: QSNICH series (n=13)



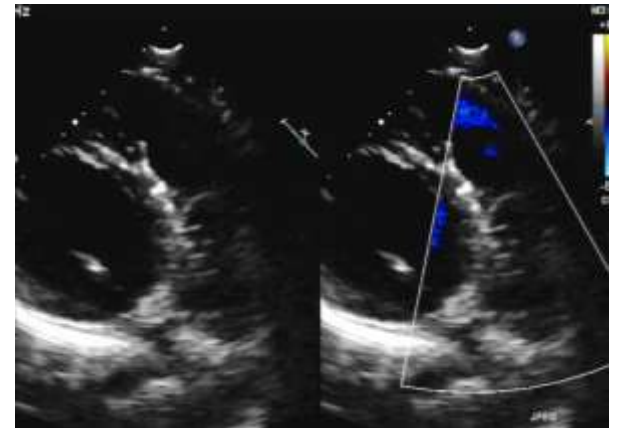
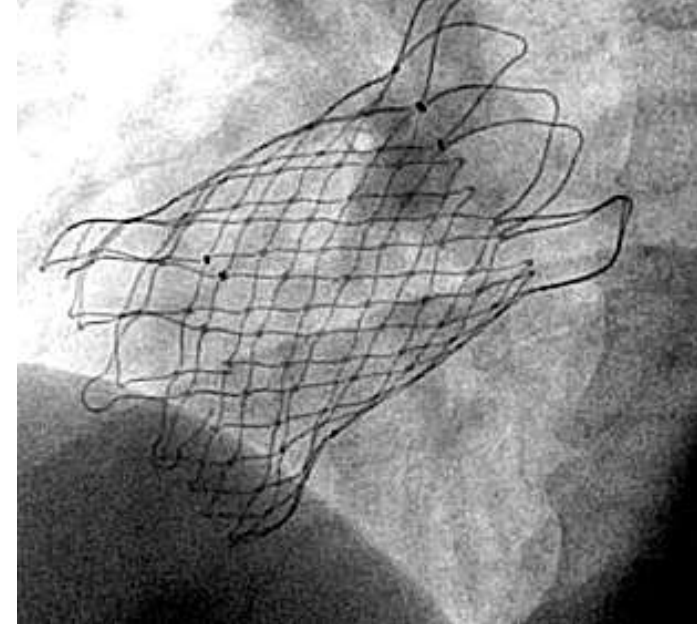
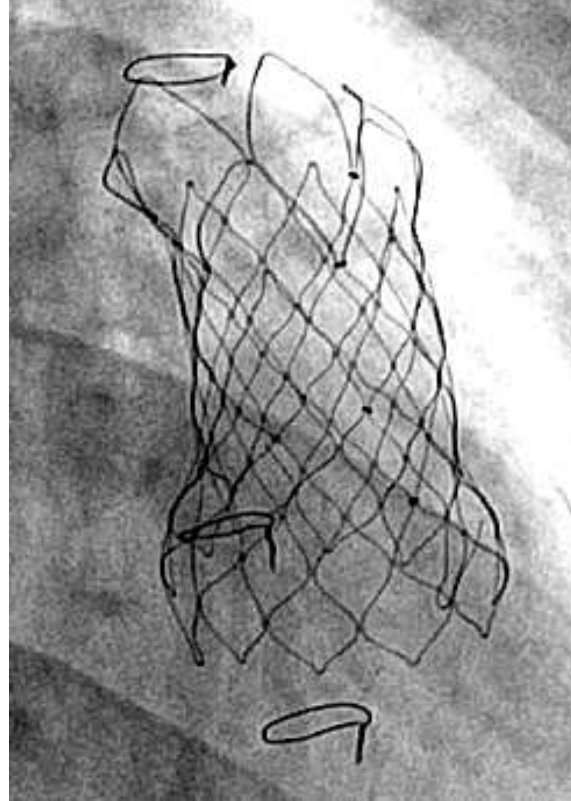
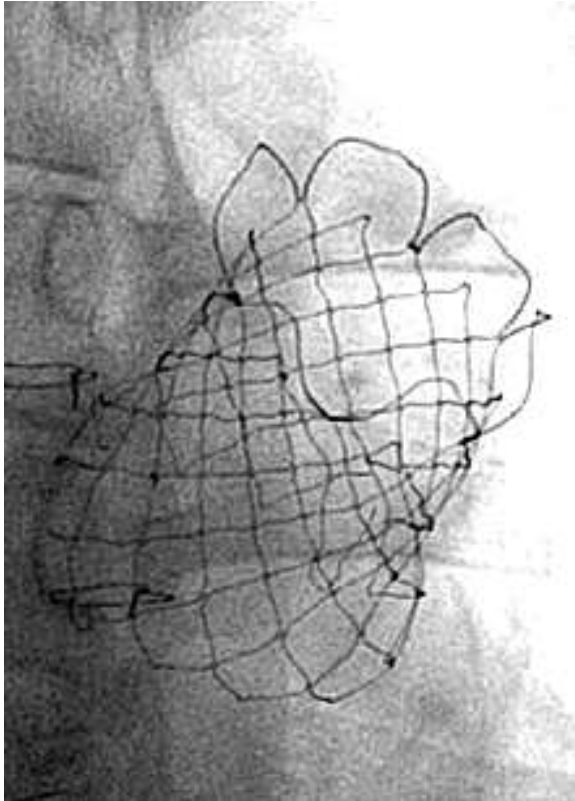
Venus P-Valve[®] Follow-up: QSNICH series (n=13)



Venus P-Valve[®] Follow-up: QSNICH series (n=13)



Fluoroscopy and Echocardiogram follow up



Max PS PPG 30 mmHg (1/7)

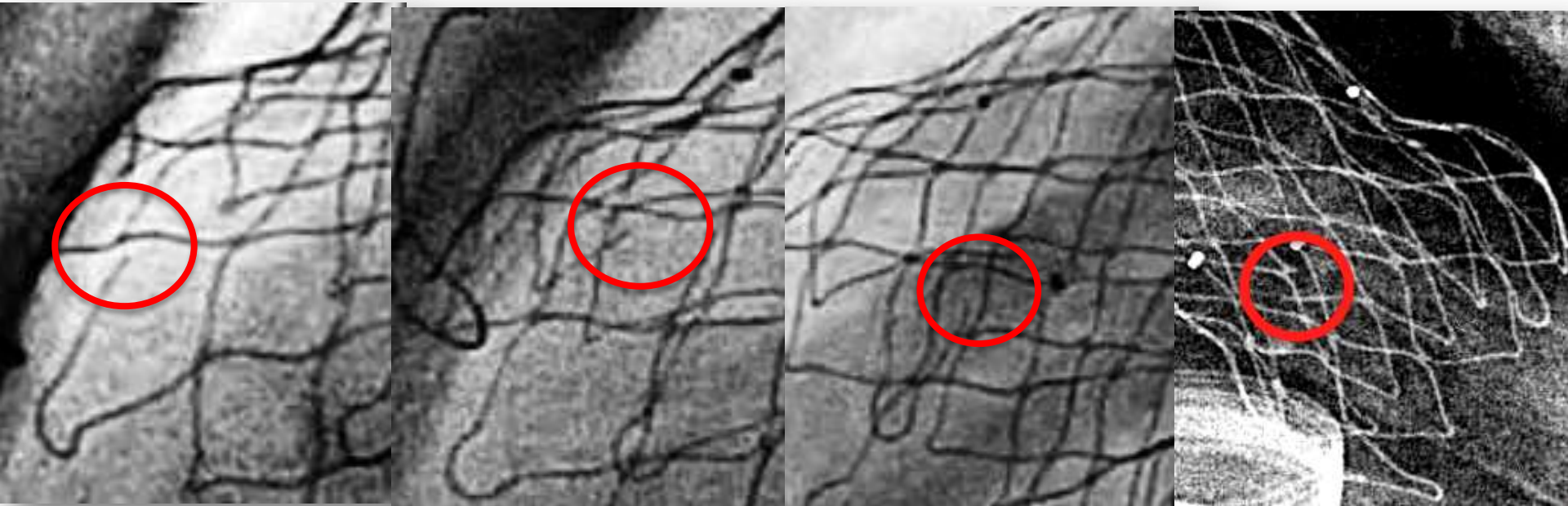
Trivial PR (2/7)

Moderate TR (1/7)

QSNICH cases @ 1 year

Fluoroscopy follow-up

* Not include data from Chile



Single wire fracture 4 cases
(earliest @ 3 months)



Venus P-Valve: Updating Outcome

In a very early experimental and clinical study

- Feasibility is satisfactory
- Valve integrity is well preserved (at 1 year F/U)
- Design modification of the valve and delivery system will expand the indications and improve the outcomes



2017

March 02 – 04, 2017
Bangkok, Thailand



CSI Asia-Pacific
March 02 – 04, 2017
Bangkok, Thailand

Please keep me
updated
▼
subscribe now