



# ***Venus P-Valve: The valve and initial clinical worldwide experience***

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## ***Disclosure information***

***Lecture title:***

***Venus P-Valve:  
The valve and initial clinical worldwide  
experience***

***Alejandro Peirone MD, FSCAI***

***As a faculty member for this program, I disclose the following relationships  
with industry:***

***None***

# *Background*

- *Percutaneous PVR is a recognized alternative to repeated surgery after development significant PR , RV dilation and / or dysfunction.*
- *The overall safety and effectiveness of the interventional procedure has compared favourably with surgical repair.*
- *Limitations for PVR using Melody® & Edwards-Sapien® valves include unfavourably large RVOT, native RVOT and pts with no stenosis in the outflow tract.*
- *The Venus P-valve is a recently developed self-expanding porcine heart valve designed to adapt to a dilated RVOT.*

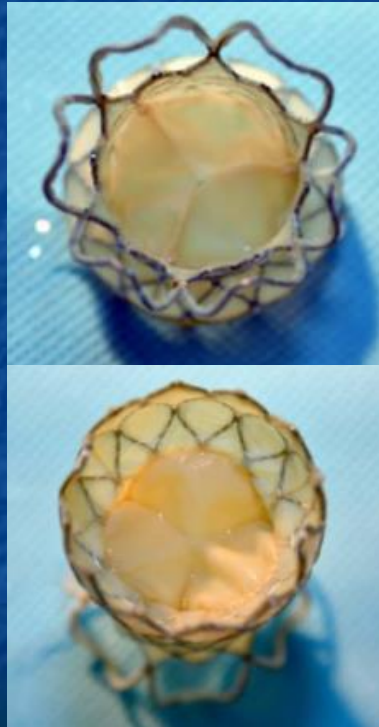


# **History**

- ***Developed by Dr. Qi-Ling Cao & Venus MedTech Team.***
- ***First in-man implantation: female pt in 2011 in Hanoi.  
Vietnam Heart Institute.***
- ***First pt in China: 14 yo girl in 2013 in Shanghai.  
Shanghai Zhongshan Hospital.***
- ***Trial in China started in 2013 and enrolled @ 45 pts.***
- ***First pt in LATAM: Pontificia Universidad Católica de Chile  
Dr. F. Garay & team. March 2016.***

## Venus P-valve

# The valve:

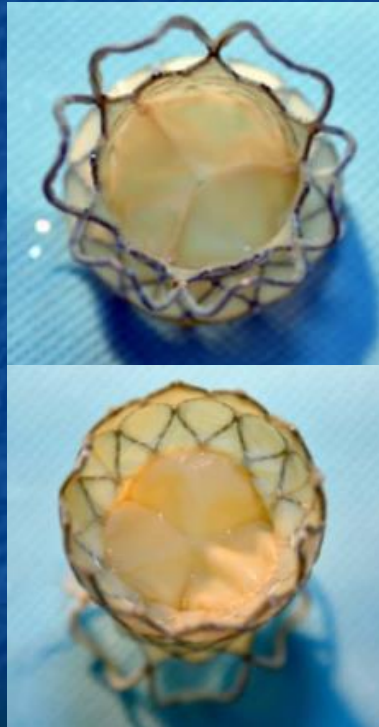


- *Self-expandable Nitinol multi-level support frame.*
- *Tri-leaflet porcine pericardial tissue.*
- *Preserved in low-concentration solutions of buffered gluteraldehyde .*
- *19–24 Fr catheter delivery system.*
- *The entire stent is covered (except the distal cells) by hand-sewn porcine pericardial tissue.*



## Venus P-valve

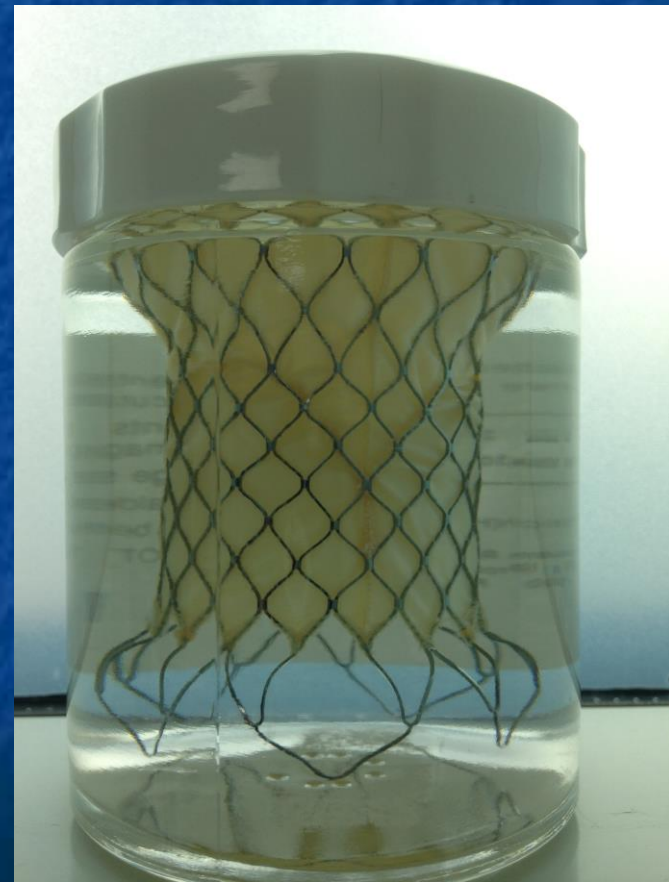
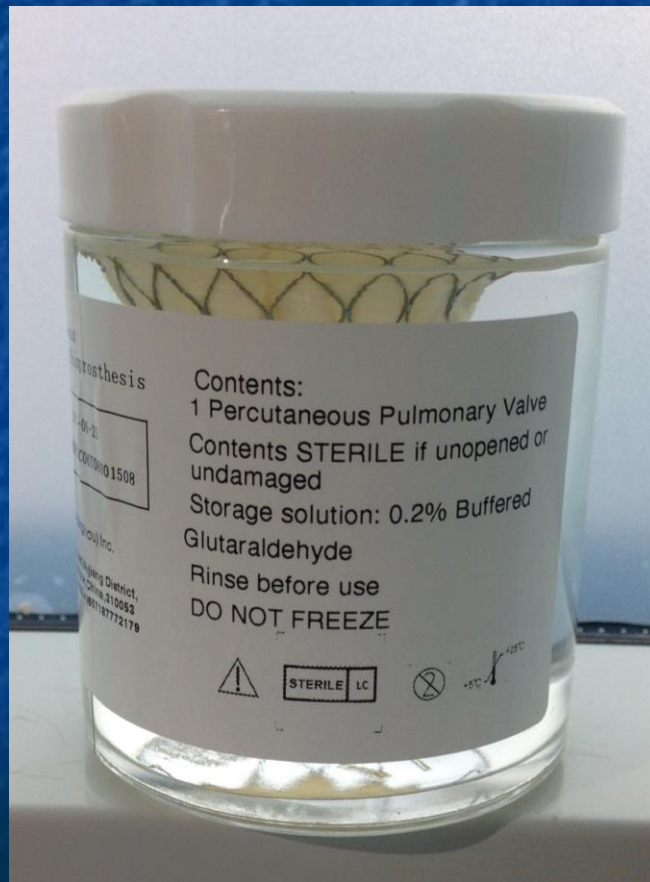
# The valve:



- **Flared uncovered distal end secures anchoring at PA bifurcation with radiopaque markers .**
- **Flared covered proximal end allowing conformability with the dilated RVOT with two “ears”.**
- **Stent valve diameters range from 20 to 34 mm (in 2 mm increments) with each diameter available in 20 and 30 mm straight sections lengths. Add 10 mm in length for each distal flare portion.**

## Venus P-valve

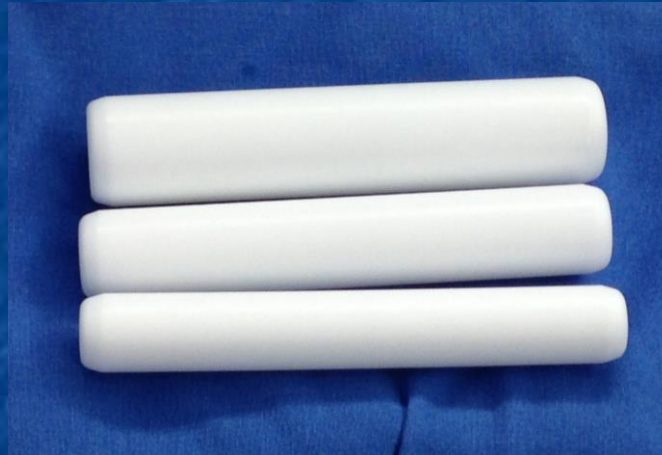
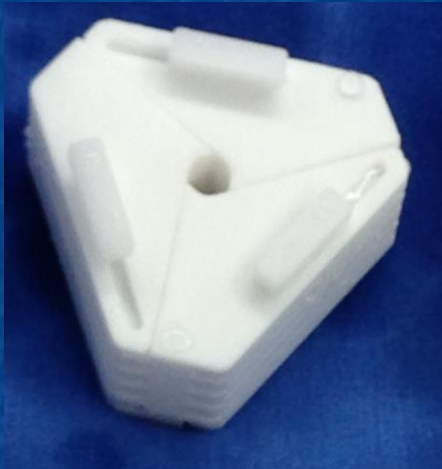
# The valve:



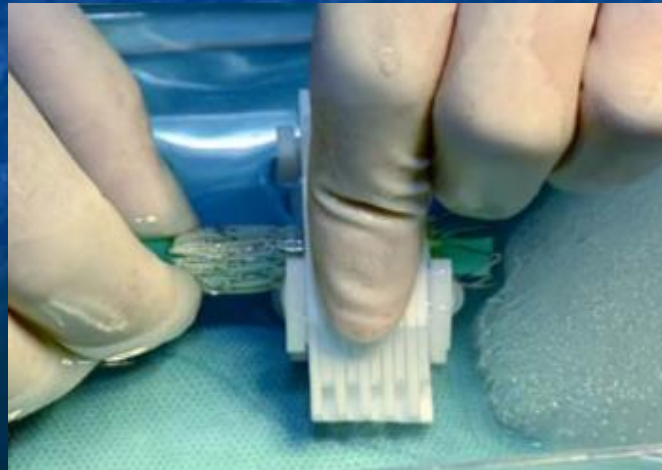
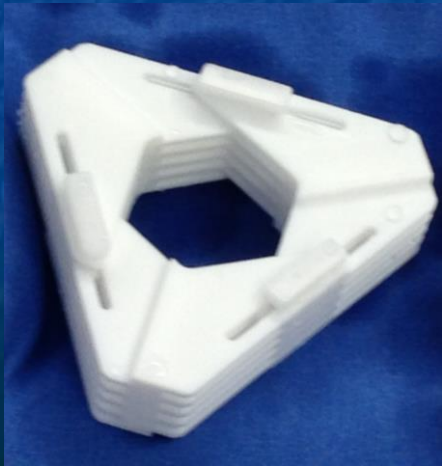


## Venus P-valve

# The valve: Valve crimper



➤ *The crimper is a non-patient contacting compression device .*

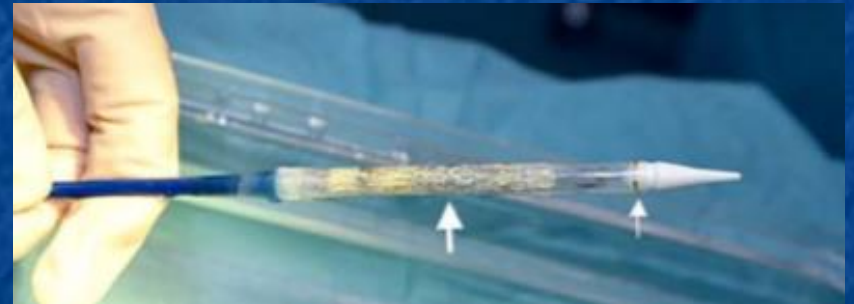
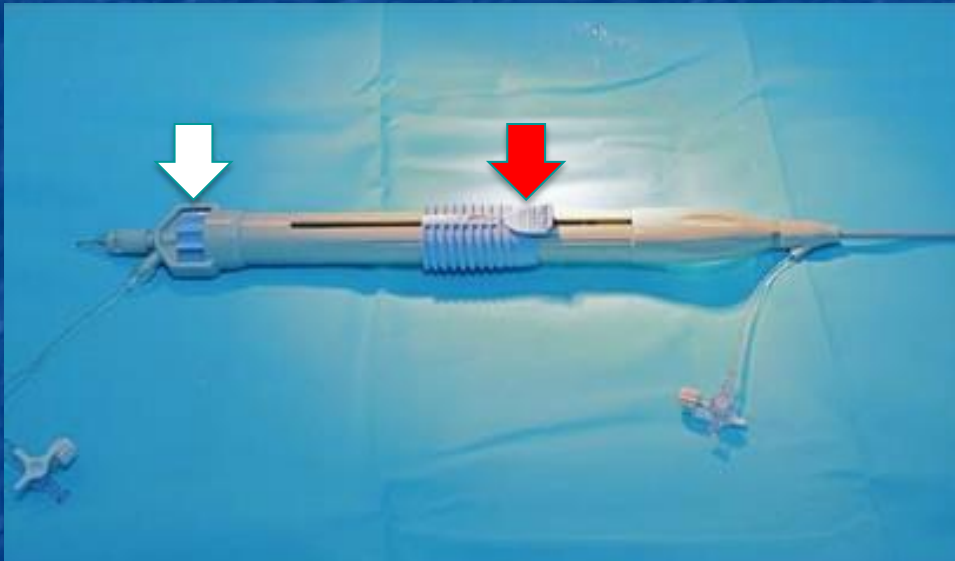


➤ *Symmetrically reduces the diameter/profile of the valve when loaded inside the catheter .*



## Venus P-valve

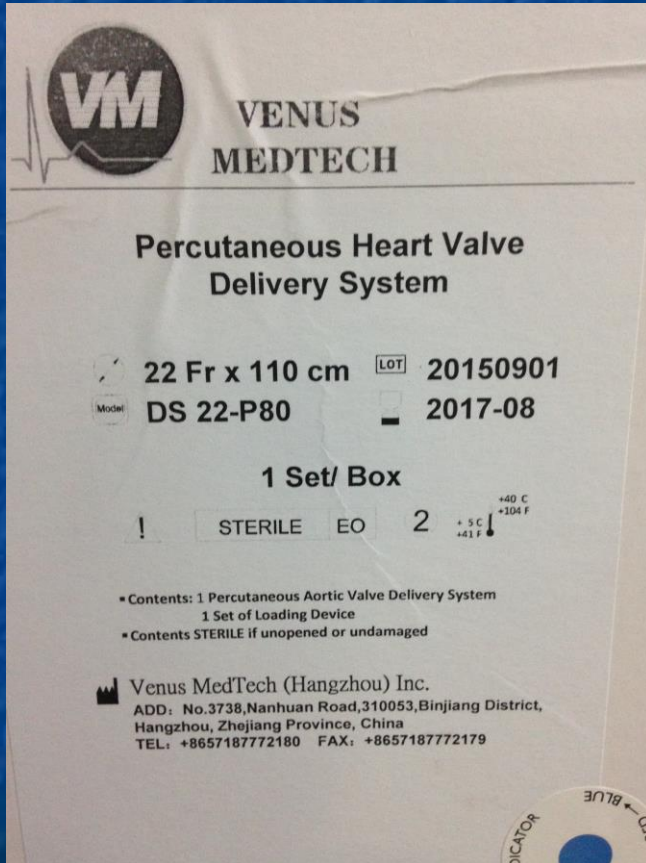
# The valve: Delivery system



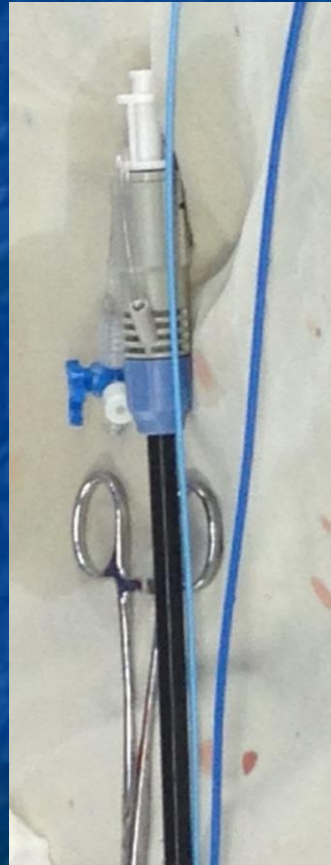
*The delivery system consists of a 20–22 Fr capsule and a 16 Fr 100 cm long shaft, with a rotating handle for deployment of the valve with a slow (white arrow) and fast valve (red arrow) deployment*

## Venus P-valve

# The valve:



*Delivery system*



*22F – 24F  
introducer*

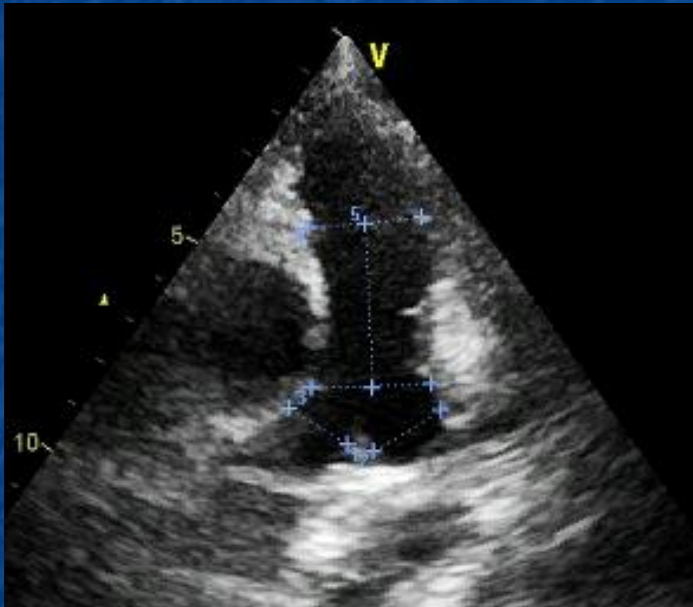


*Once crimped in ice-water,  
the valve maintains its shape*



## Venus P-valve

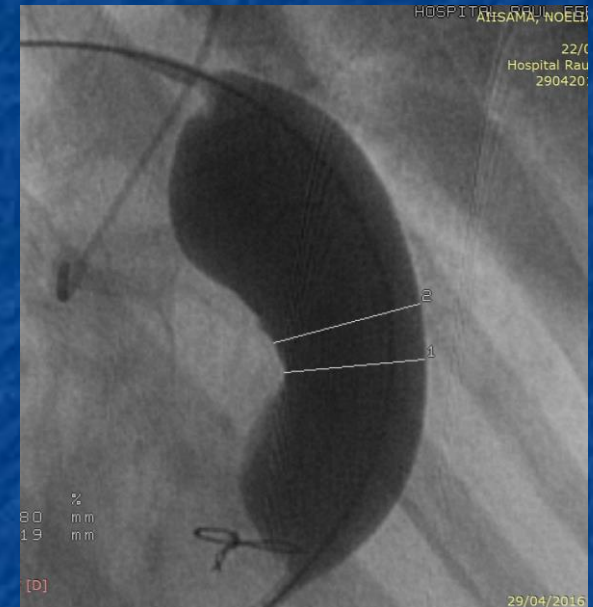
# The procedure:



**Echocardiography**



**MRI**



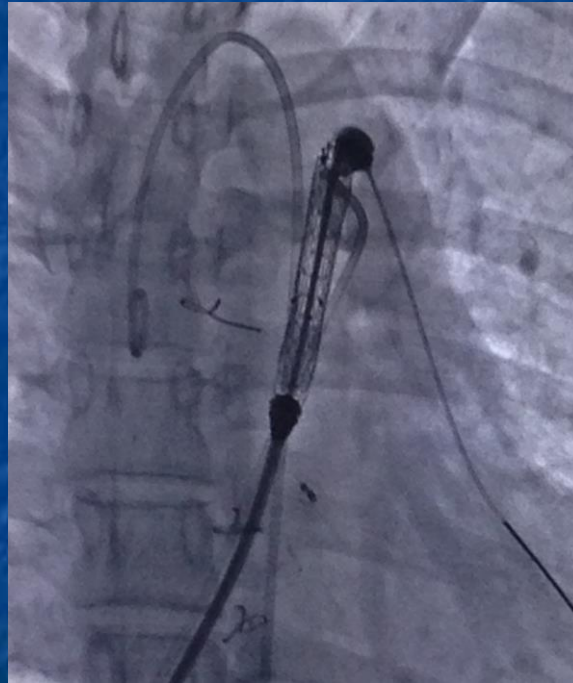
**Balloon sizing**

## Venus P-valve

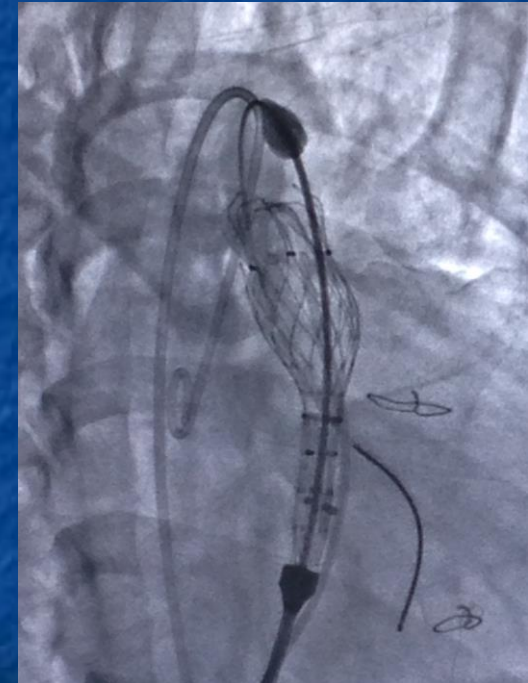
# The procedure:



*LCA angiography*



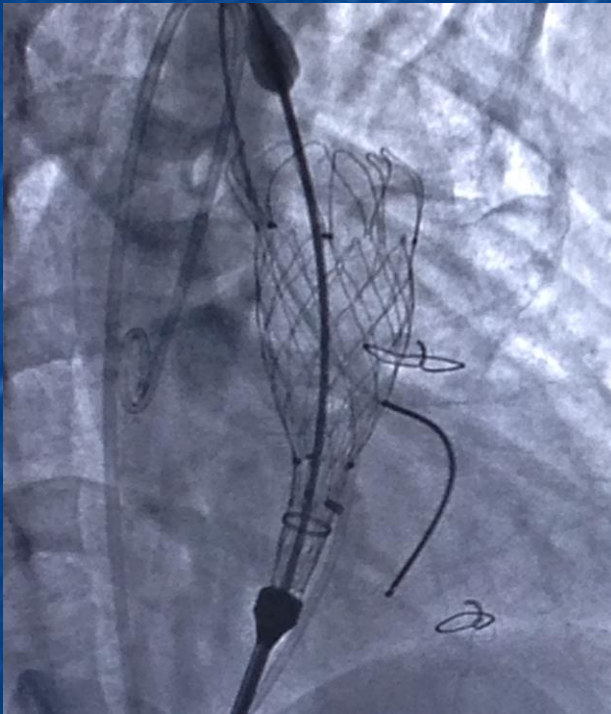
*Position and initial deployment*





## Venus P-valve

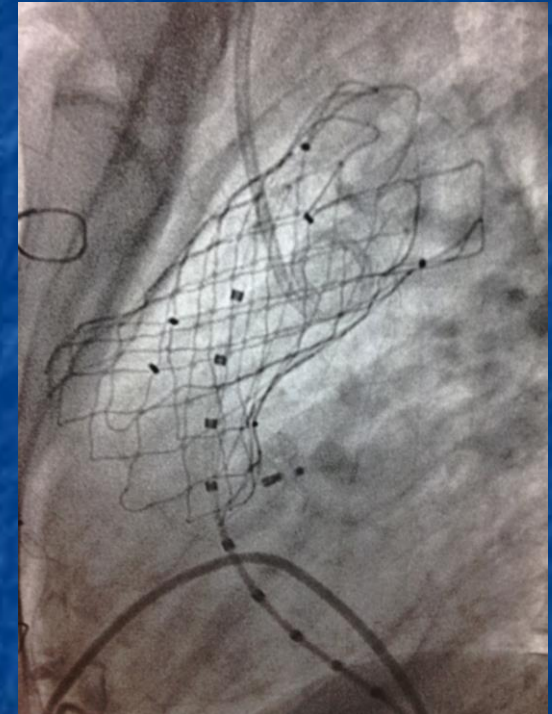
# The procedure:



*Partial deployment*



*Final position*



## Venus P-valve

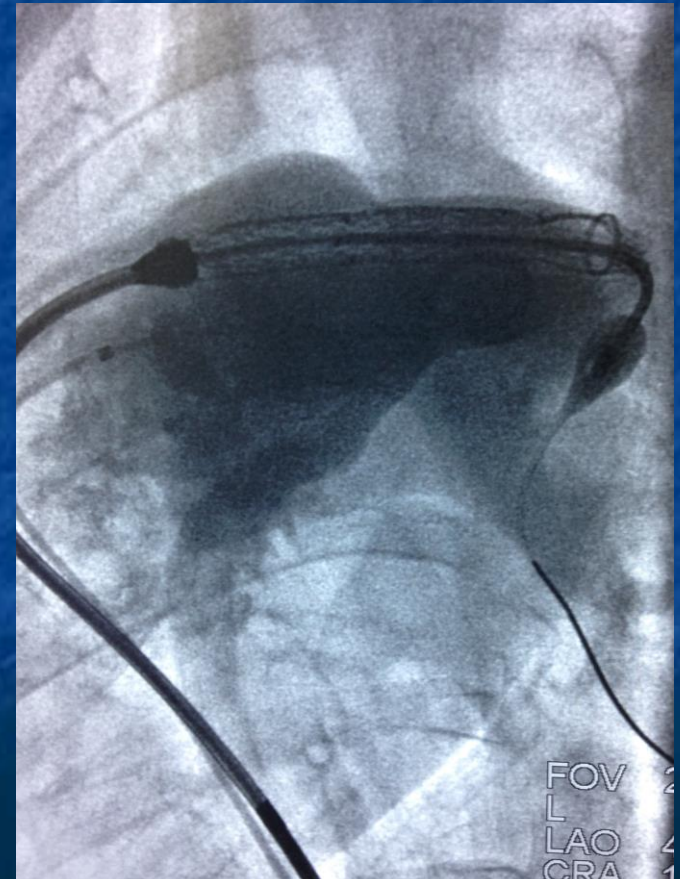
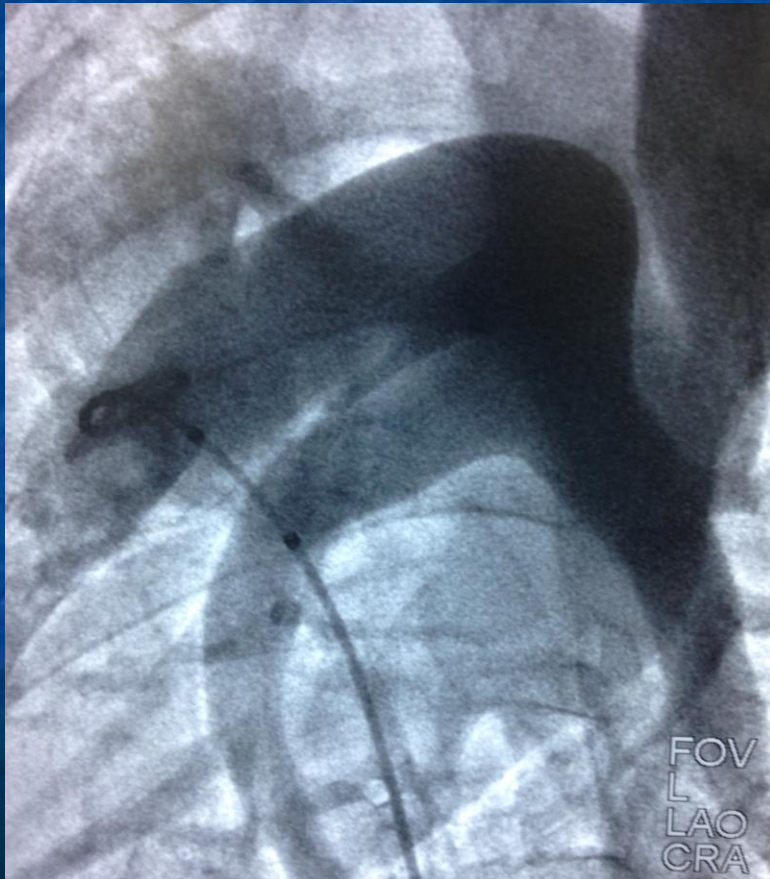
# Animal lab experience





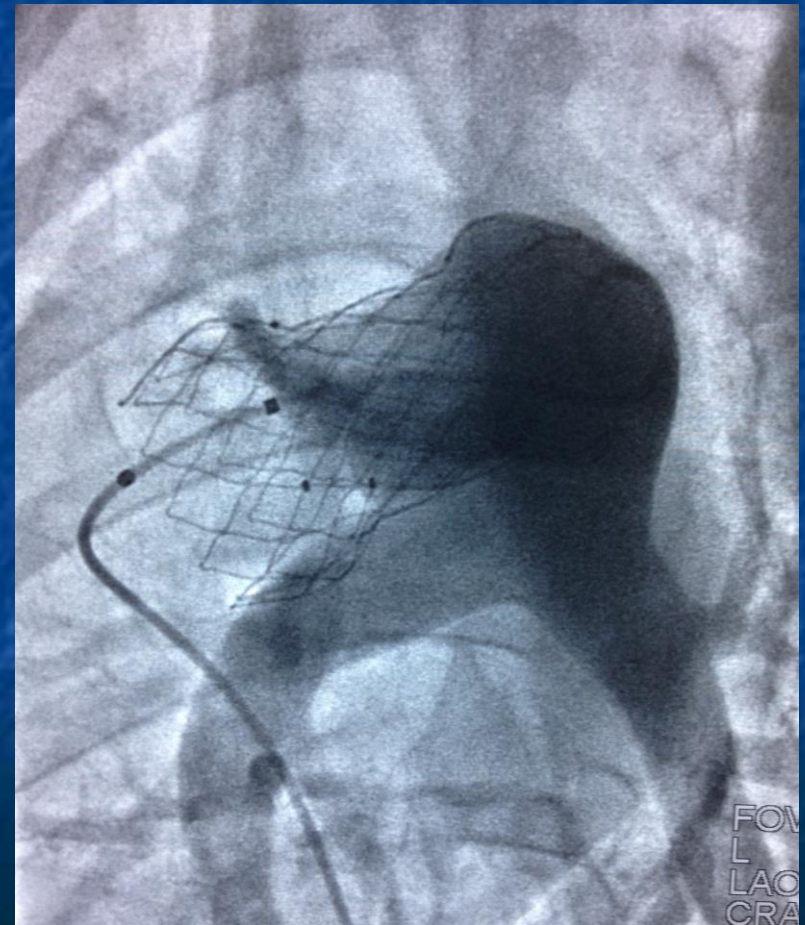
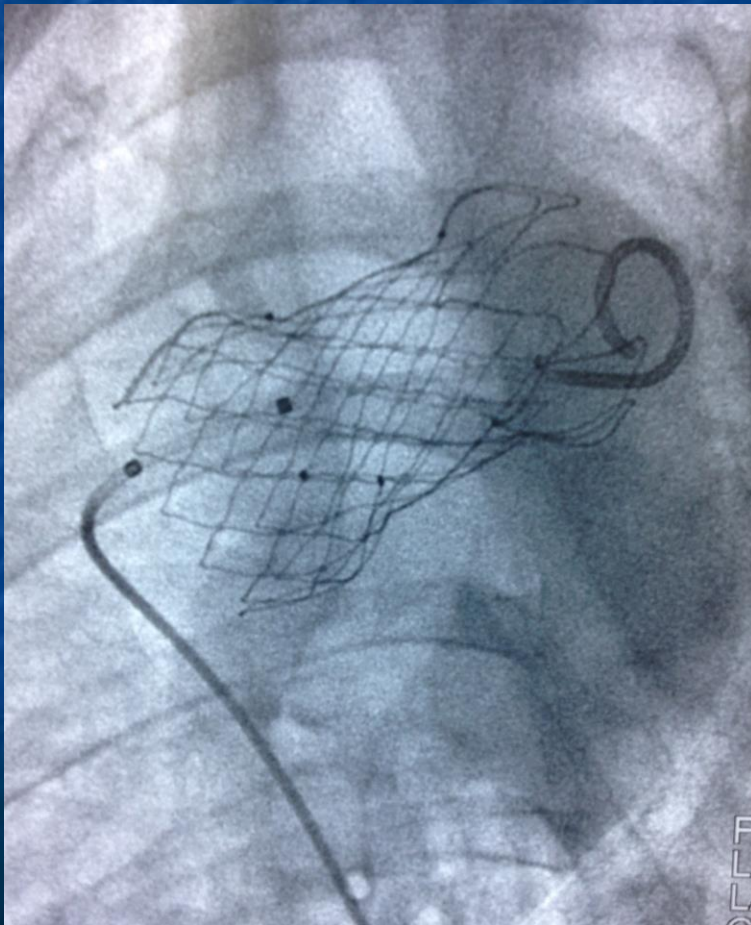
Venus P-valve

*Animal lab experience*



Venus P-valve

*Animal lab experience*



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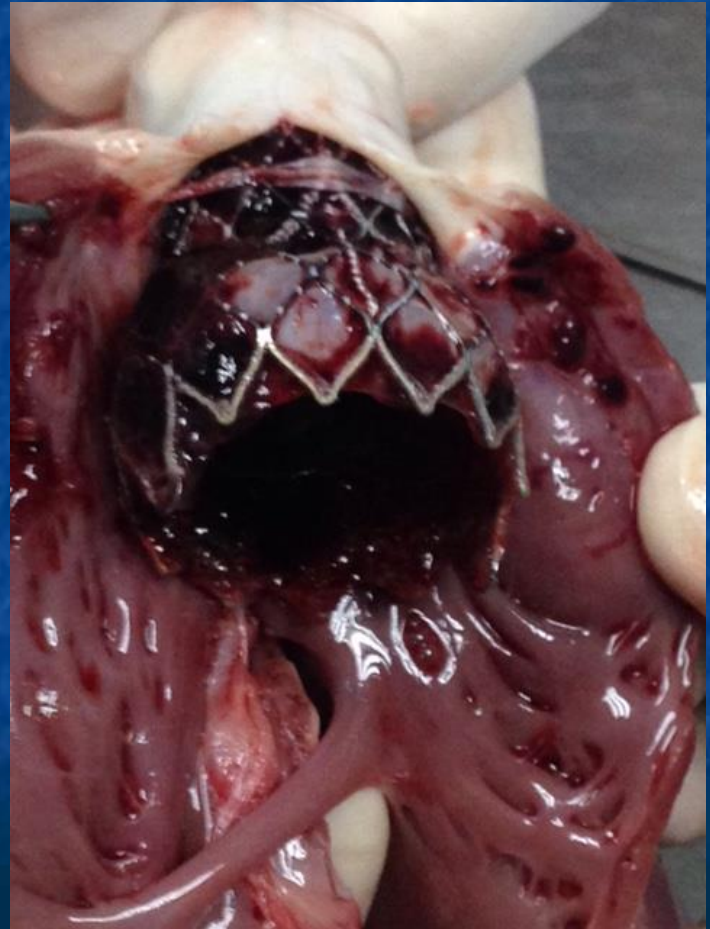
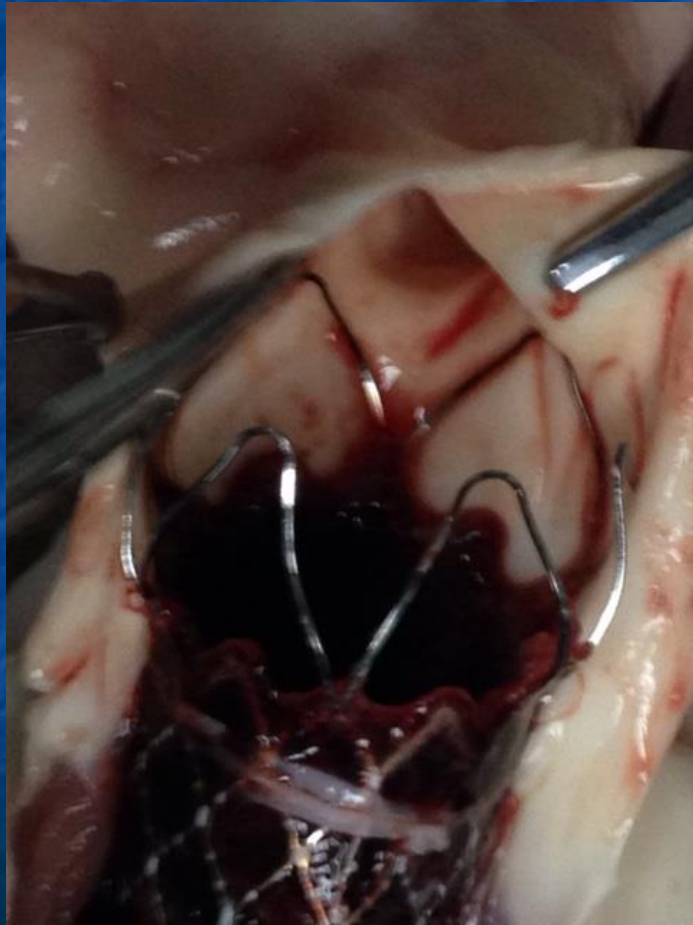
*Venus P-valve*

*Animal lab experience*



*Venus P-valve*

*Animal lab experience*





*Venus P-valve*

*Animal lab experience*



# *Background*

## **Early Clinical Experience With a Novel Self-Expanding Percutaneous Stent-Valve in the Native Right Ventricular Outflow Tract**

**Qi-Ling Cao,<sup>1</sup> MD, Damien Kenny,<sup>1</sup> MB, MD, Daxin Zhou,<sup>2</sup> MD, Wenzhi Pan,<sup>2</sup> MD, Lihua Guan,<sup>2</sup> MD, Junbo Ge,<sup>2</sup> MD, PhD, and Ziyad M. Hijazi,<sup>1\*</sup> MD, MPH**

*Catheterization and Cardiovascular Interventions 2014; 84: 1131–1137*

*5 pts*

*Median age 33 years*

*Mean body weight 54.8 kg*



# Outcomes

	Weight (kg)	Age (years)	QRSd (msec)	Minimum diameter (mm)	MPA diameter (mm)	RVEDV (ml/m <sup>2</sup> )	NYHA (class)
Patient 1	52	20	170	22	24	155	III
Patient 2	42	30	178	21	24	150	II
Patient 3	58	39	174	21	23	168.6	II
Patient 4	47	35	170	27	34	166.2	III
Patient 5	75	45	160	23	24	135	II

**Mean QRS duration**

**170.4 msec**

**Minimum annulus diameter**

**22.8 mm (21-27)**

**MPA diameter**

**25.8 mm (24-34)**

**Mean RVED volume**

**155.0 ± 16.6 ml/m<sup>2</sup>**

# Outcomes

- *NYHA functional class* **II (3p), III (2p)**
- *Mean PA diastolic pressure*  **$3 \pm 3.7$  mm Hg**
- *Valve diameter implanted (mm)* **26 (3 p), 30 (1 p), 32 (1 p)**
- *Valve length implanted (mm)* **30 (5 p)**
- *Procedure time*  **$136 \pm 26.8$  min**
- *Fluoroscopy time*  **$22.8 \pm 8.8$  min**
- *Paravalvular leak* **None**
- *Acute complications* **None**



# **Initial data:**

## *Original Article*

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### **Percutaneous pulmonary valve implantation with the Venus P-valve: clinical experience and early results**

Worakan Promphan,<sup>1</sup> Pimpak Prachasilchai,<sup>1</sup> Suvipaporn Siripornpitak,<sup>3</sup> Shakeel A. Qureshi,<sup>2</sup> Thanarat Layangool<sup>1</sup>

<sup>1</sup>*Pediatric Heart Center, Queen Sirikit National Institute of Child Health, College of Medicine, Rangsit University;*

<sup>2</sup>*Department of Radiology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand;*

<sup>3</sup>*Department of Paediatric Cardiology, Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom*

***Cardiology in the Young 2016; 26: 698-671***

**6 pts**

**Median age 18.5 years**

**Mean body weight 53.8 kg**

# Outcomes

- *Median time after last surgery* 13.5 y (10.7 – 15.3)
- *Angiographic MPA size* 23.8 ± 2.9 mm (21 – 28)
- *Balloon sizing MPA size* 25.7 ± 3.1 mm (21 – 30)
- *RVOT length* 30 ± 4.8 mm (23 – 26)
- *Difference MPA: MRI vs balloon sizing* -2 to 4.7 mm
- *Valve diameter implanted* 24 – 32 mm
- *Valve length implanted* 30 mm (5 p) – 20 mm (1 p)
- *Procedure time* 114 ± 14.6 min (94 – 130)
- *Fluoroscopy time* 29.8 ± 1.3 min (28.3 – 31.3)

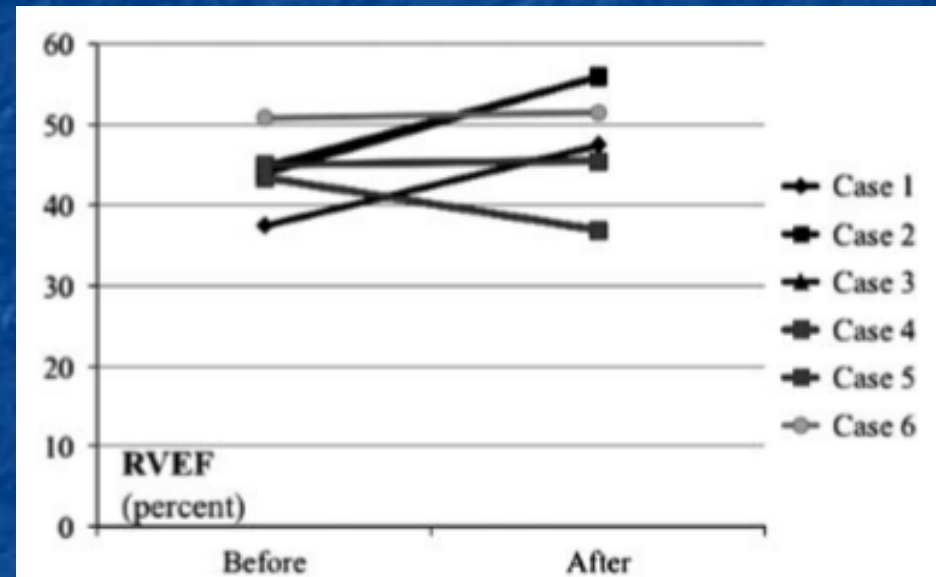
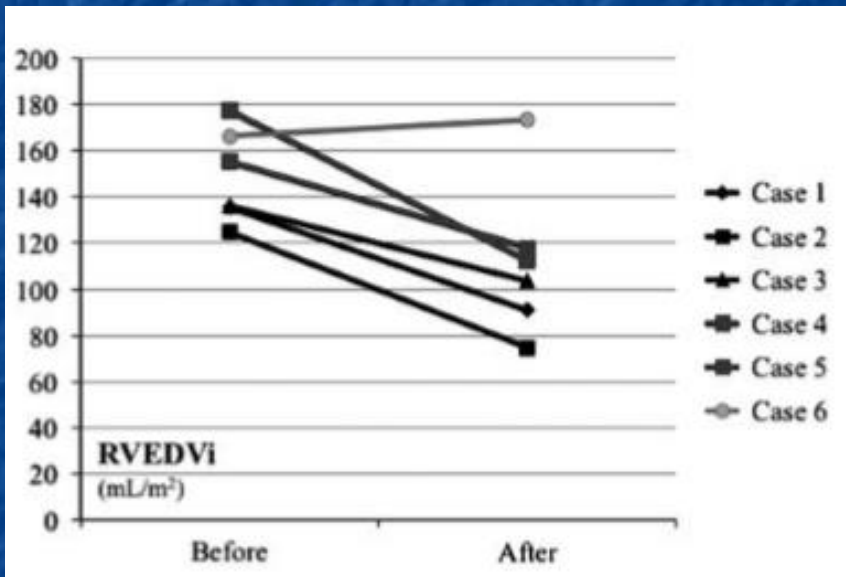


# Outcomes:

	<u>Before</u>	<u>@ 6 months</u>
<i>PR fraction</i>	42.15% (36 – 45)	2.45% (2.2 – 4.7)
<i>RV EF</i>	44.35% (42- 46)	49.45% (43 – 56)
<i>RV ED Vi</i>	145.7 ml/m <sup>2</sup> (132-169)	107.9 ml/m <sup>2</sup> (86 – 131)

## Venus P-Valve

# Outcomes: Cardiac MRI f/u data





## Venus P-Valve

# Outcomes: TTE f/u data

Patient	TR severity		PR severity (mmHg)		RVOT PG (mmHg)		Paravalvar leak 6 months
	Before	6 months	Before	6 months	Before	6 months	
1	Mild	Trivial	Severe	No	8	40	No
2	No	No	Severe	No	30	21	No
3	No	Mild	Severe	Trivial	8	25	No
4	Moderate	Mild	Severe	Trivial	6	10	No
5	Moderate	Mild	Severe	No	30	14	No
6	Trivial	Severe	Severe	No	5	4	Mild

*Pt # 6 had incomplete detachment of the “ear” of the valve at release with migration a few millimetres proximally into the RV during the retrieval of the delivery system causing severe TR due to tethering of the septal leaflet .*

*There was no RVOT pressure gradient after the procedure and an adequate PV competence. It was decided to continue observation of the pt.*

*Venus P-Valve*

# *Venus P- Valve China Clinical Trial*

*Updated April 2016.*

*Data provided by Dr. Z. Hijazi & Venus MedTech team.*



# Demographics

<b>Characteristics</b>	<b>N= 45</b>
<b>Age</b>	<b>29.1±12.0</b>
<b>Female Gender</b>	<b>73% (33)</b>
<b>Weight (kg)</b>	<b>53.7±8.2</b>
<b>Height (cm)</b>	<b>161.8±6.2</b>
<b>Age of 1<sup>st</sup> TOF repair (yrs)</b>	<b>14.0±11.6</b>
<b>Time from 1<sup>st</sup> TOF repair to PPVI.</b>	<b>15.1±8.7</b>
<b>NYHA Class III</b>	<b>20%</b>
<b>NYHA Class II</b>	<b>80%</b>
<b>PR grade 4 (severe)</b>	<b>64%</b>
<b>LV EF</b>	<b>60.8±10.8</b>

# Pre-Procedural data

<b>Characteristics</b>	<b>Value (N)</b>
<b>RVOT diameter , Mean± SD (mm)</b>	
<b>Echo</b>	<b>30.5±5.5 (36)</b>
<b>Annular Diameter , Mean± SD ( mm )</b>	
<b>Echo</b>	<b>23.3±4.9 (39)</b>
<b>CT</b>	<b>27.4±4.9 (42)</b>
<b>Mid-MPA diameter , Mean± SD (mm)</b>	
<b>Echo</b>	<b>24.1±4.1 (44)</b>
<b>Narrow -MPA diameter , Mean± SD (mm)</b>	
<b>CT</b>	<b>24.7±3.4 (30)</b>
<b>RPA Diameter , Mean± SD (mm)</b>	
<b>CT</b>	<b>19.7±5.3 (39)</b>
<b>LPA Diameter , Mean± SD (mm)</b>	
<b>CT</b>	<b>17.7±4.6 (39)</b>



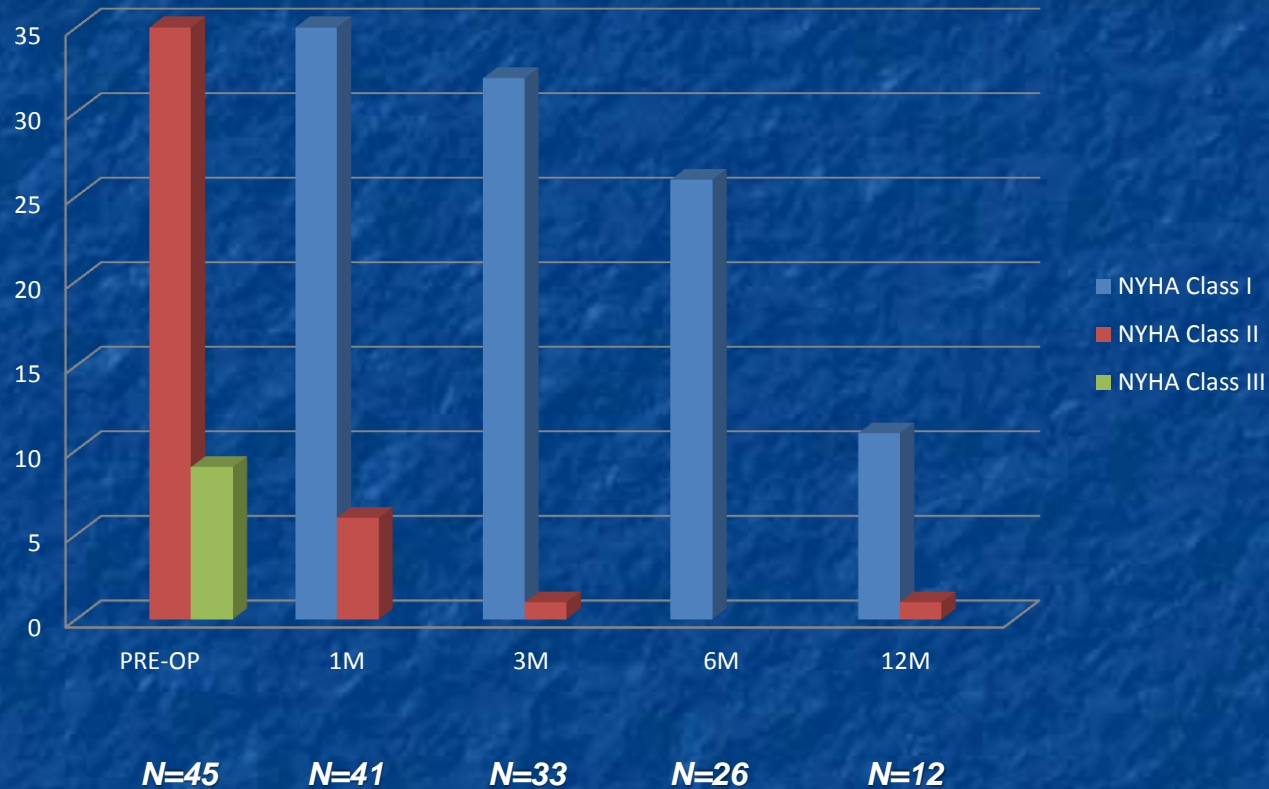
# Implanted Venus P-Valve

<i>Valve implanted</i>	<i>N° of pts</i>	<i>Annular diameter ( mm)</i>
26 - 25mm	2	21
28 - 25mm	1	25
30 - 25mm	2	25
26 - 30mm	8	23.2±2.3
24 - 30mm	1	21
28 - 30mm	8	24.9±1.7
30 - 30mm	6	25.9±0.5
32 - 25mm	1	26
32 - 30mm	15	26.5±1.3
30 - 35mm	1	24

**Fluoroscopy time (min): 22.5 ± 6.8**

	<i>Pre ( N=41 )</i>			<i>Post ( N=40 )</i>		
<i>PA pressure (mmHg)</i>	28	7	14	32	14	19
<i>RV pressure (mmHg)</i>	36	4	13	37	5	14

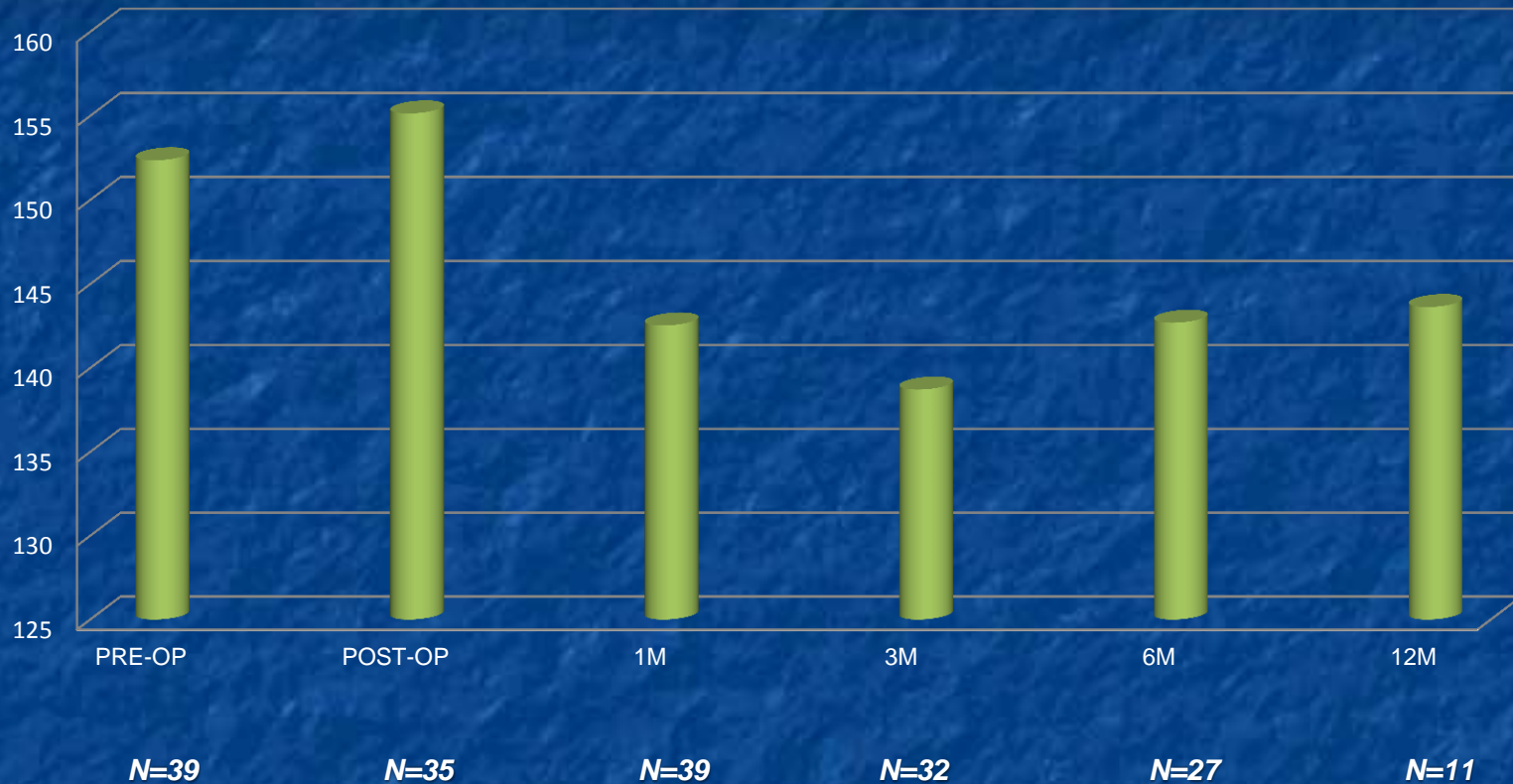
# NYHA Functional Class



*In 26 pts their NYHA class improved from class III to class II or I during the 6m follow-up*

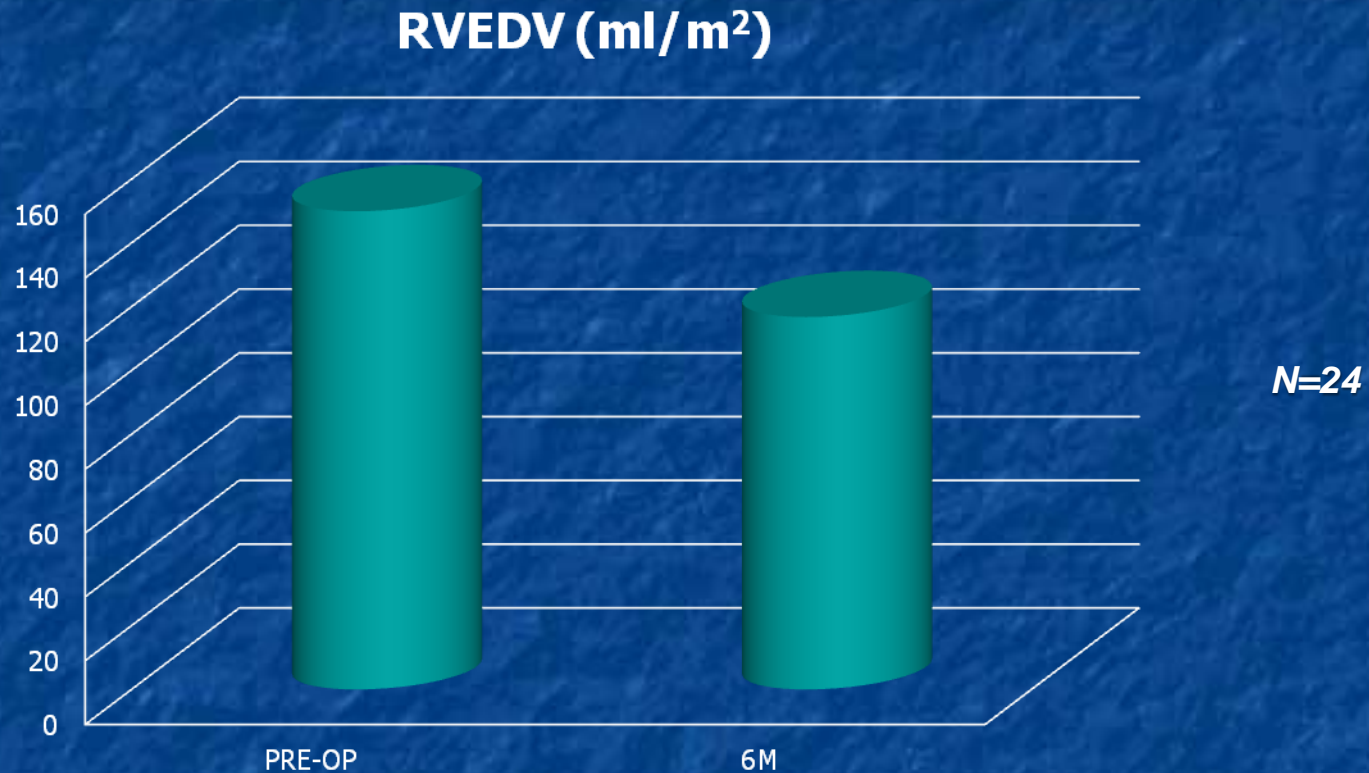


# ***EKG - QRS duration (msec)***



***QRS wave duration narrowed down by 5.3% for 26 pts during 6m follow-up***

# Primary End Point

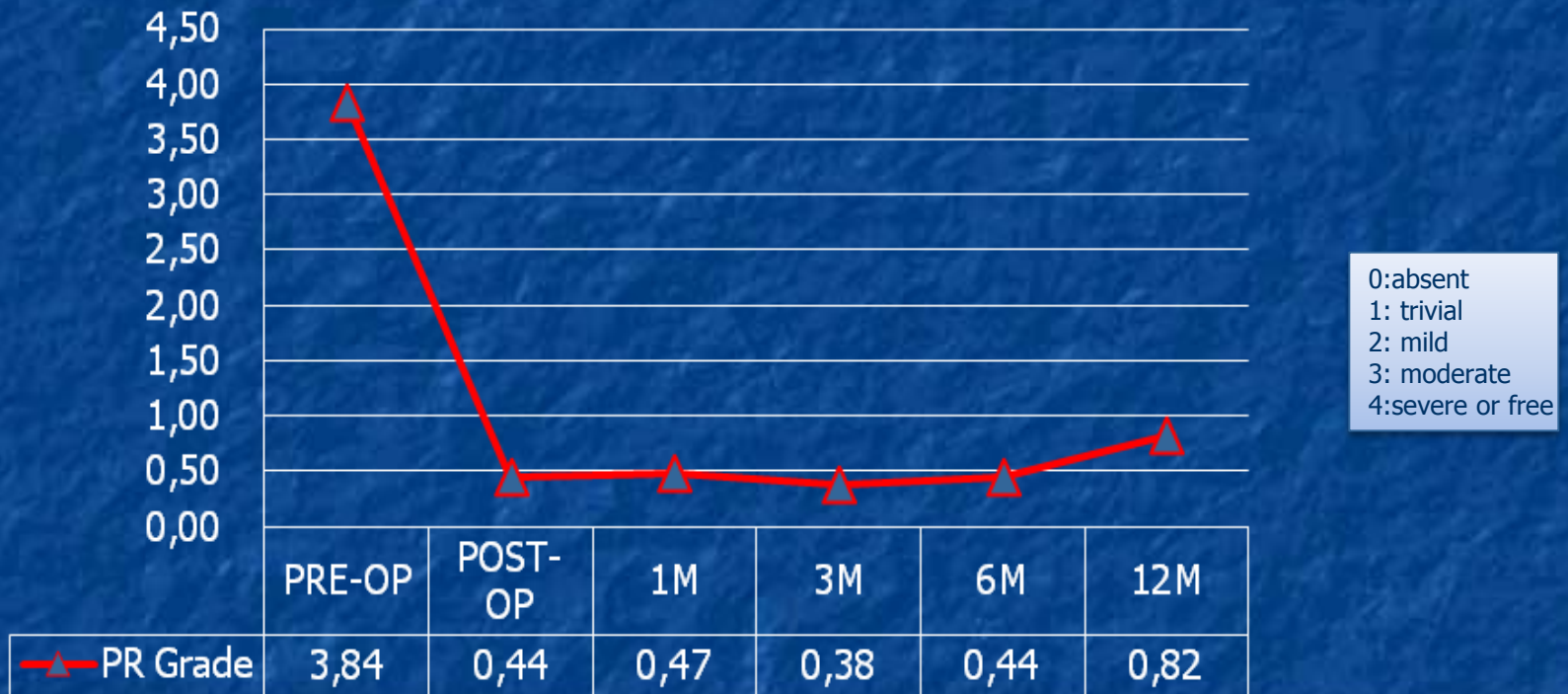


***RVEDVI has significantly decreased in 24 patients during 6m follow-up (RVEDV: 150  $\pm$  37 vs 117  $\pm$  31,  $p < 0.01$ )***



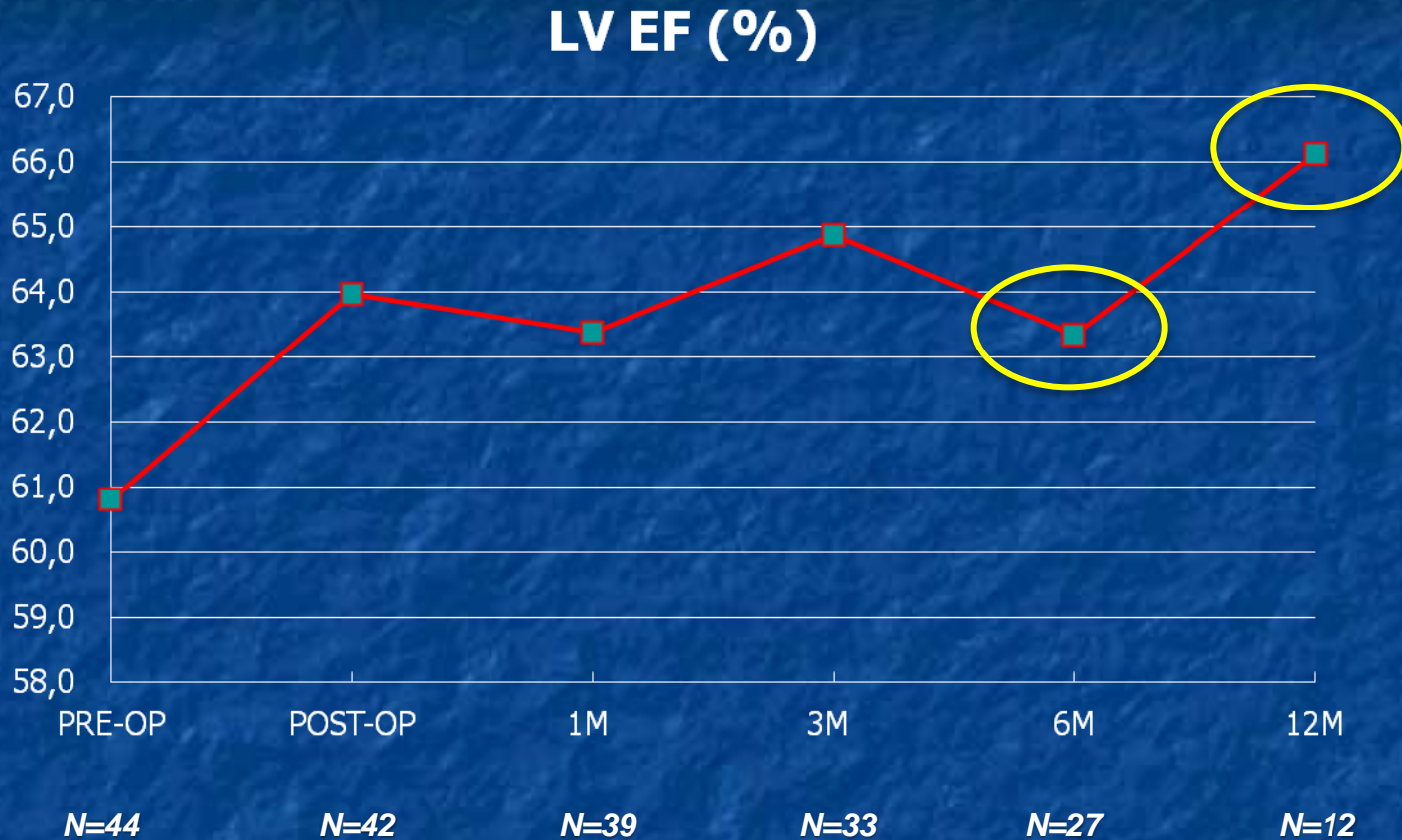
# Pulmonary valve regurgitation (grade)

## Pulmonary Regurgitation



**27 pts showed mild or none PR during 6m follow up  
(mild # 12, none # 15)**

# TT Doppler Echocardiography

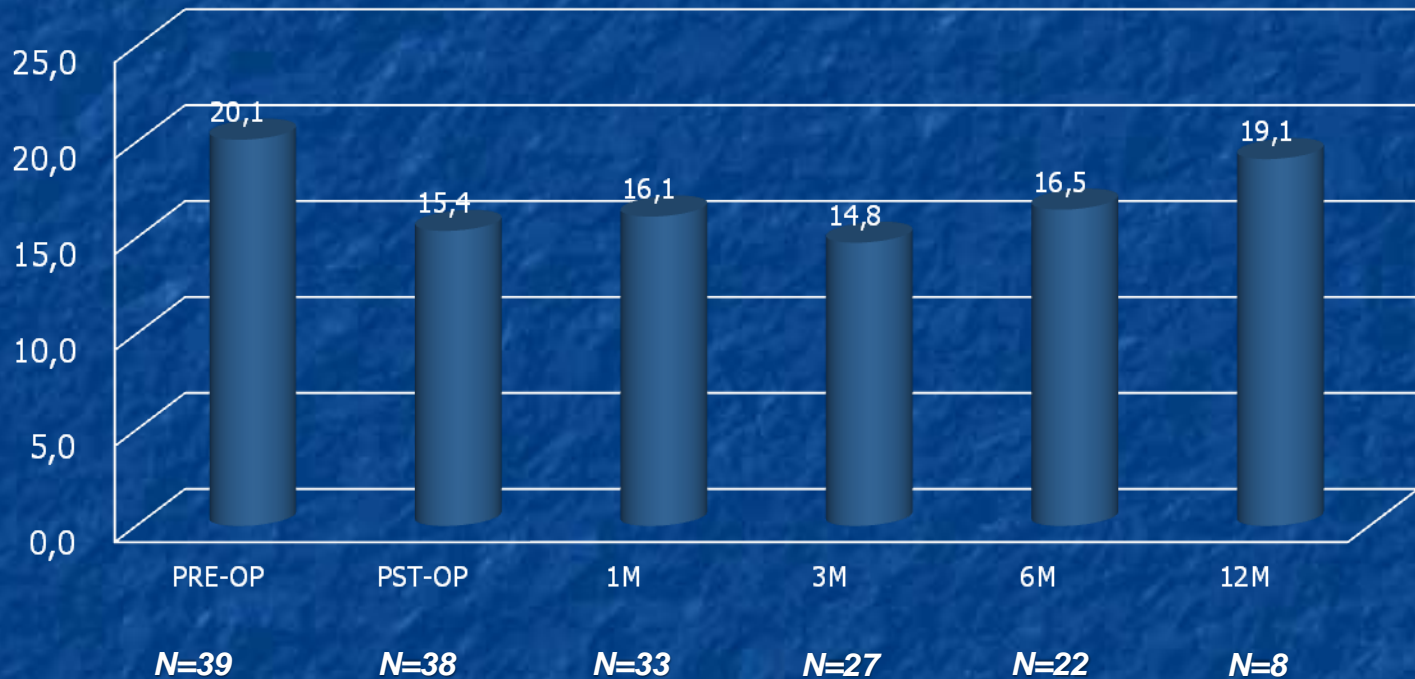


***LVEF increased by 6.9% in 27 pts during 6m follow-up and improved by 10.4% in 12 pts during 12m follow-up***



# TT Doppler Echocardiography

## Transvalvular Gradients (mmHg)



***RVOT gradient decreased by 14% for 22 pts at 6m follow-up and decreased by 4% for 8 pts during 12m follow-up***

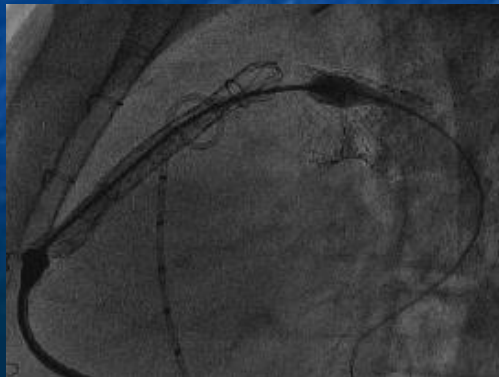
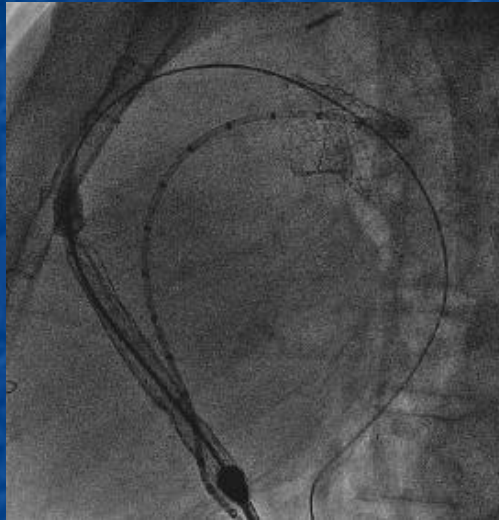
# Sudden Adverse Events

<b>SAE</b>	<b>Cases</b>	<b>Treatment</b>	<b>Outcome</b>
<i>Death</i>	<i>1</i>	<i>-</i>	<i>1 month after intervention. Transit accident.</i>
<i>Endocarditis</i>	<i>1</i>	<i>Antibiotic and surgical removal</i>	<i>Healed without sequence</i>
<i>Fever</i>	<i>2</i>	<i>Antibiotic</i>	<i>Healed without sequence</i>
<i>Migration</i>	<i>1</i>	<i>Surgical intervention for fixation</i>	<i>Healed without sequence</i>
<i>Arrhythmia</i>	<i>1</i>	<i>Electrical conversion</i>	<i>Healed without sequence</i>



# *Delivery system malfunction:*

*Aborted case. Breaking of the capsule*

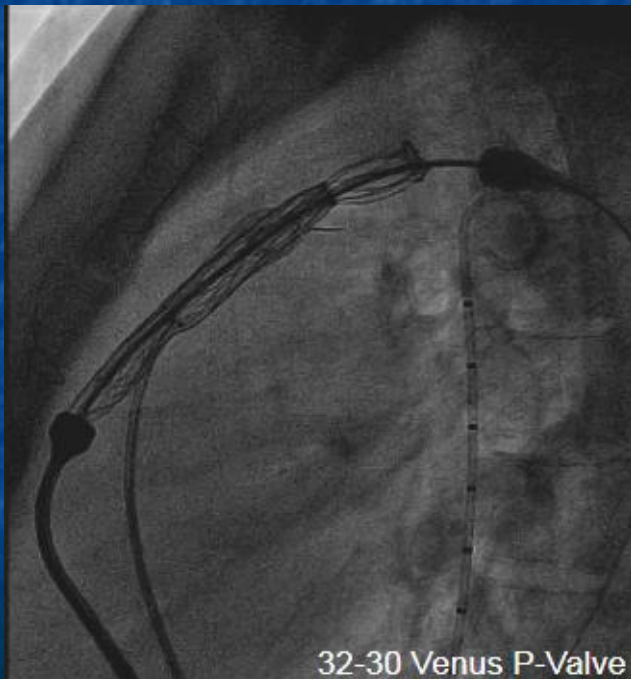




## Venus P-valve

# Delivery system malfunction:

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



# *Delivery system and valve modifications:*



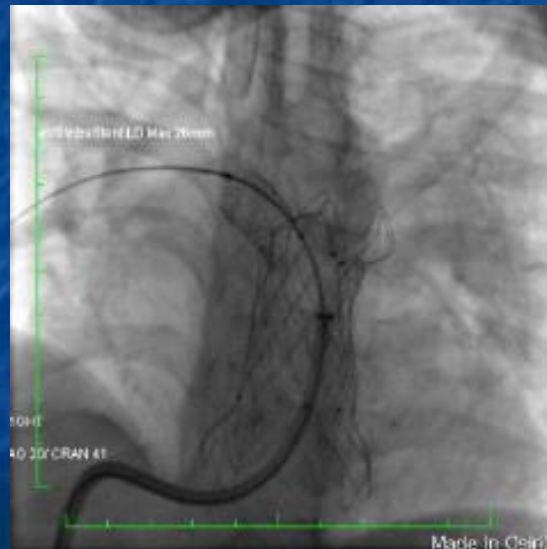
## **Delivery system modifications**

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

## Venus P-valve

# Valve complication: RPA occlusion

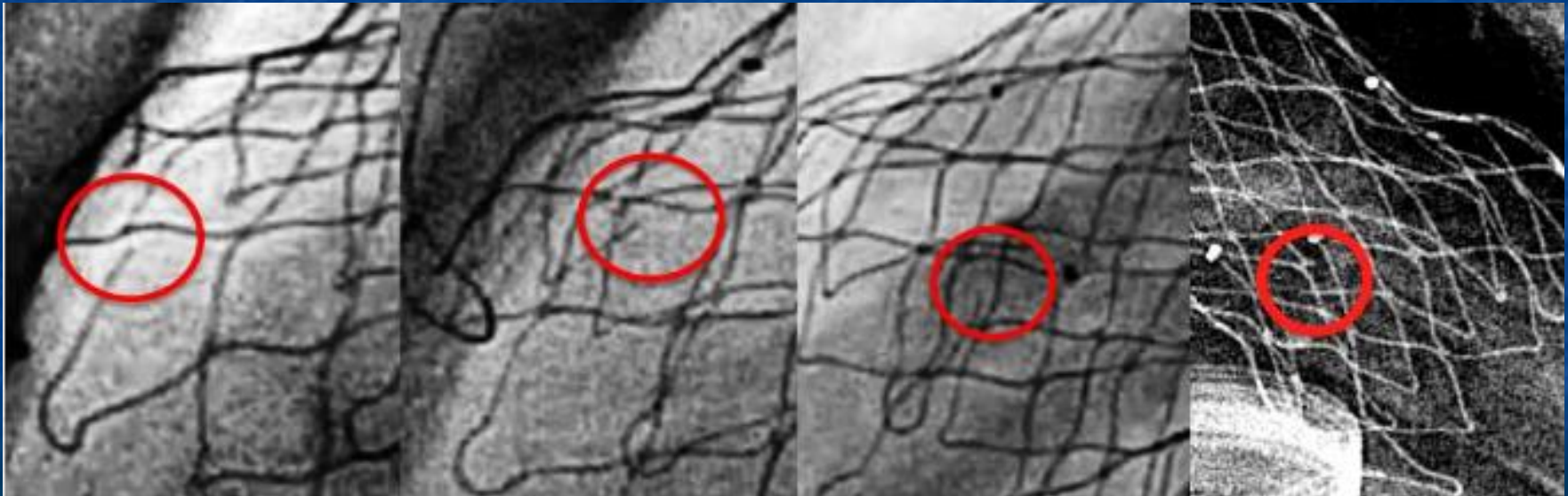
**Prior RPA stenosis occluded by Venus P-valve needing stenting (Max LD 26 mm in length on a 15 x 30 mm Crystal balloon)**





# Fluroscopy follow-up:

*Single wire fracture 4 cases (earliest @ 3 months)  
w/o hemodynamic consequences*

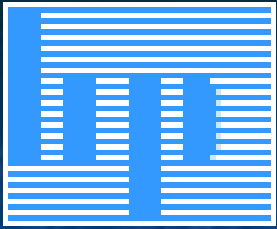


## Venus P-Valve

# Worldwide experience: 36 pts

Global Compassionate Implantation, As of March, 2016			
City/Country	Case No.	Hospital	Program Leader
London, UK	8	<u>Evelina</u> Children's Hospital	Dr. <u>Shakeel A Qureshi</u>
Dublin, Ireland	1		Dr. Kevin Walsh
Hanoi, Vietnam	1	Hanoi Medical University Hospital	Dr. Nguyen <u>Lan Hieu</u>
Bangkok, Thailand	13	Queen <u>Sirikit</u> National Institute of Child Health	Dr. <u>Worakan Promphan</u>
Jakarta, Indonesia	1	Harapan Kita National Cardiovascular Center	Dr. <u>Indriwanto Atmosudigdo</u>
Kochi, India	2	Amrita Institute of Medical Sciences	Dr. Raman Krishna Kumar
Chennai, India	6	The MADRAS MEDICAL MISSION	Dr. K. <u>Sivakumar</u>
Hyderabad, India	1	Care Hospital	Dr. <u>Nageswara Rao</u>
Santiago, Chile	3	<u>Pontificia</u> Universidad <u>Católica</u> de Chile	Dr. Francisco <u>Garay</u>

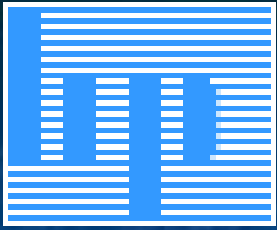




## **Conclusions:**

- ***The Venus P-Valve can be implanted successfully and effectively in pts with severe PR and a large RVOT after transannular patch surgery.***
- ***The valve restores early, sustained pulmonary competence with RV remodeling and improvement in clinical symptoms.***
  - ***Early results with this valve are encouraging.***
- ***More extensive clinical trials are in progress and will likely provide more robust longer-term data on the valve functionality and durability.***





Venus P-Valve



# Acknowledgments



**Gracias!**

# Background

- *Clinical experience to date with transcatheter PVR has been limited to two balloon expandable systems: **Melody Valve** (Medtronic Inc, Minneapolis, MN) **SAPIEN valve** (Edwards Lifesciences, Irvine, CA).*
- *Both have undergone clinical trials with good medium-term valve durability.*
- *Limitations to the extended application of these valves have generally centered on the maximum diameter of the RVOT and native outflow tracts.*
- *In the majority of pts requiring PVR, these balloon expandable systems are not large enough to maintain stable valve position within the dilated native RVOT.*
- *Therefore more recent efforts have concentrated on a self-expanding system to provide valve competence despite significant dilation of the native RVOT adapting to the wide variety of post-operative anatomical variants.*



## **The valve:**

### **The Venus P-Valve<sup>®</sup> 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



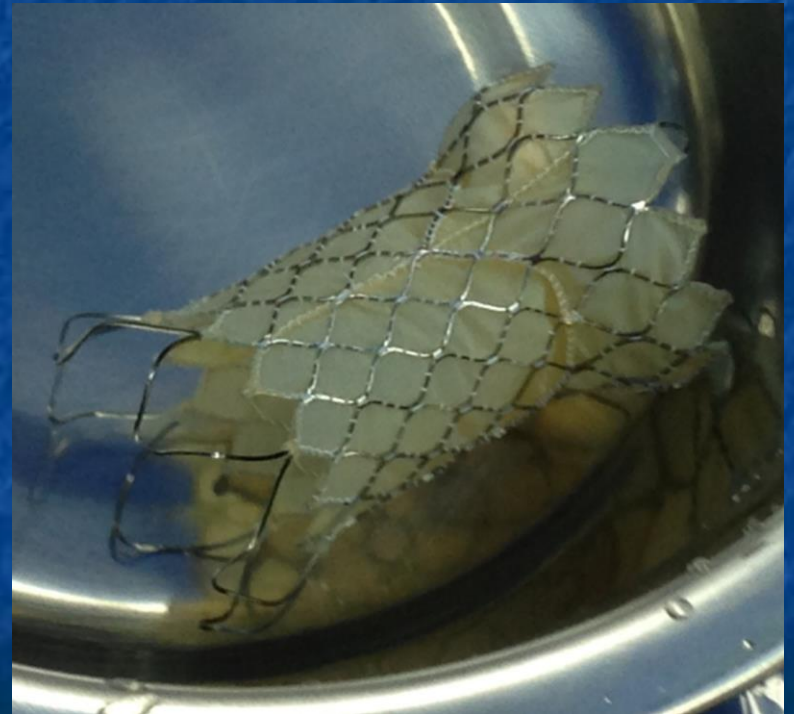
#### **Venus P Valve<sup>®</sup>**

Straight body for  
pre-stented conduit  
Max diameter 30 mm



*Venus P-valve*

*The valve:*



## Venus P-valve

### *The procedure:*

