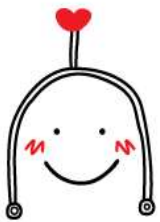


Perspective of Percutaneous Pulmonary Valve Implantation in the future

Gi Beom Kim

Department of Pediatrics

Seoul National University Children's Hospital



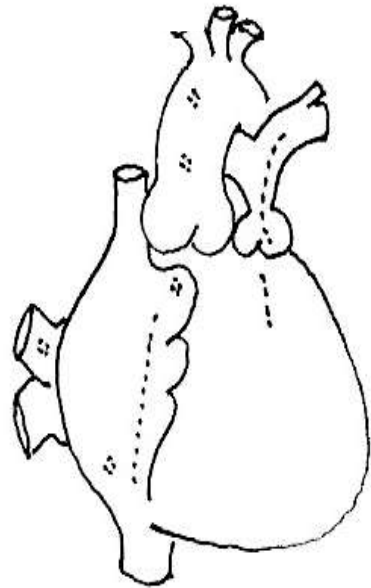
서울대학교 병원

어린이병원 심장센터



SNUH
SEOUL NATIONAL UNIVERSITY
CHILDREN'S HOSPITAL

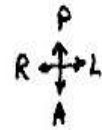
Tetralogy of Fallot Operation Record



TOF

- VSD (low MO)
- PS (combined)

PFO

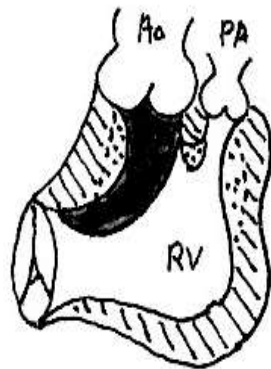


Pul. valve : bicuspid



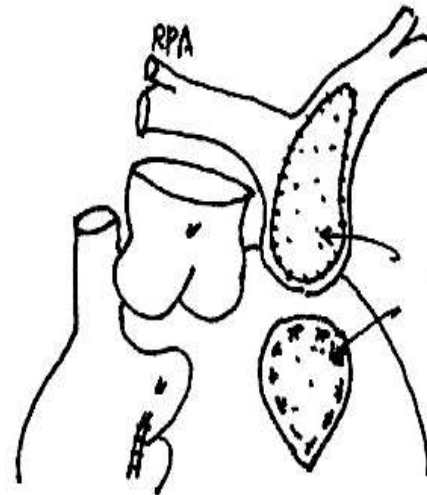
bilat.
commissurotomy

Post. leaflet : thick, small



Total repair

1. Pul. valve preserved
2. VSD patch baffling via RA
3. RV infundibular muscle resection & patch widening
4. MPA & LPA patch angioplasty



PFO primary closure

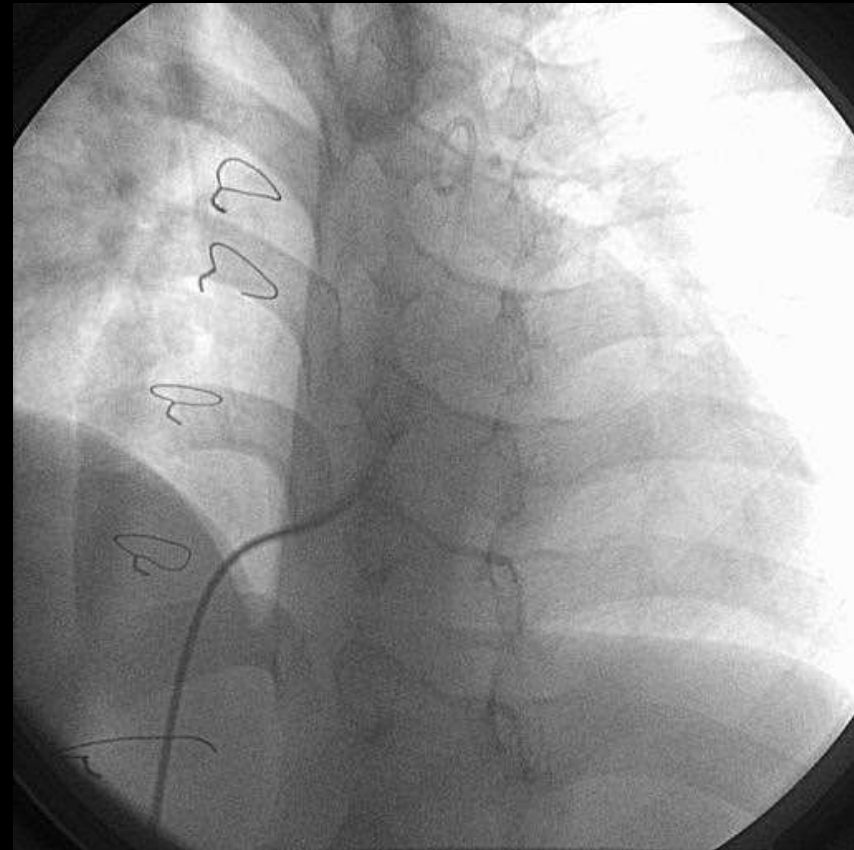
GA-fixed
auto-pericardium

Extensive plastic surgery in RVOT !

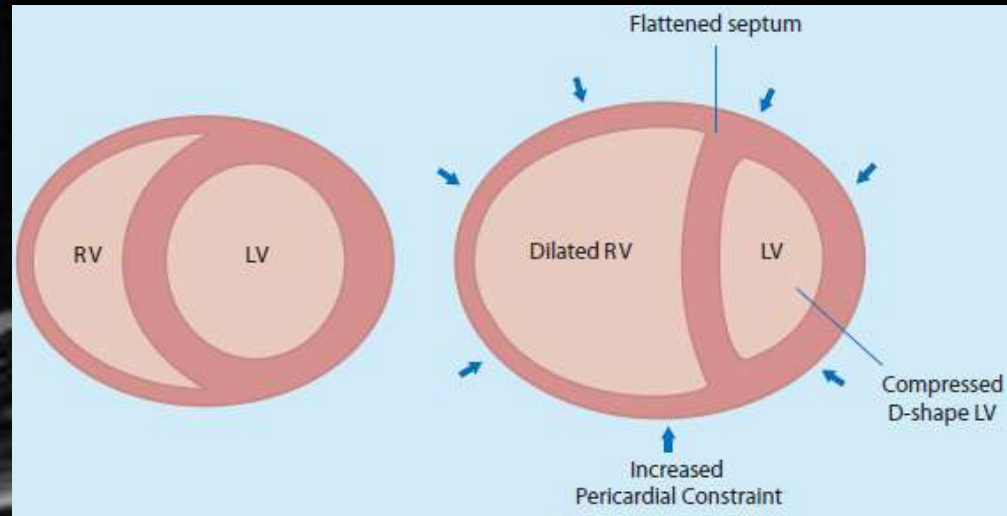
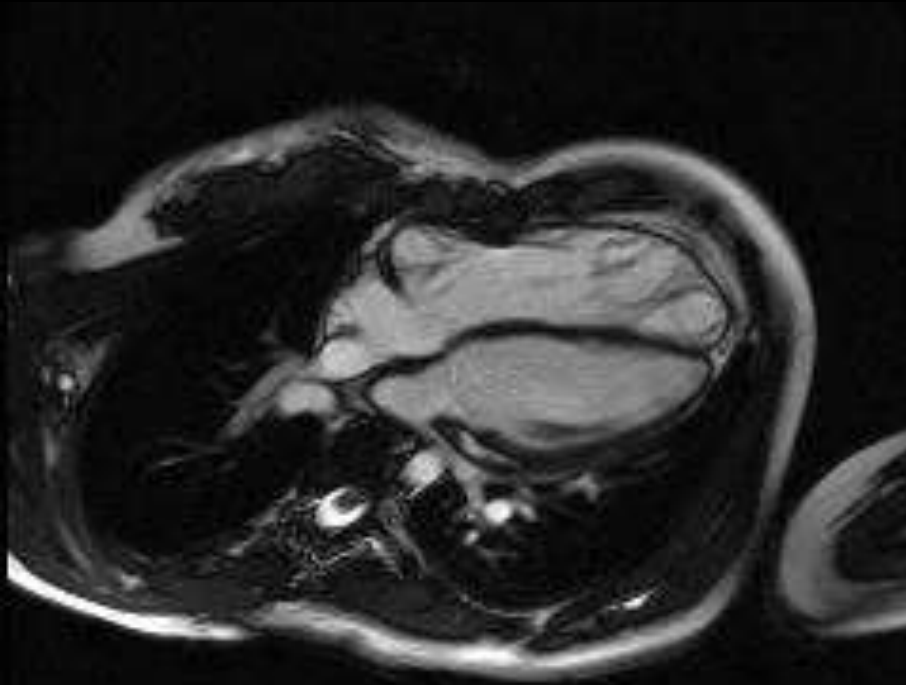
Progressive PR in TOF

● 이오희 (M/ 13Yr)

- TOF total correction (1996.1)
- **Severe PR with RV volume overloading**



The **effect** of **chronic PR** on **RV**

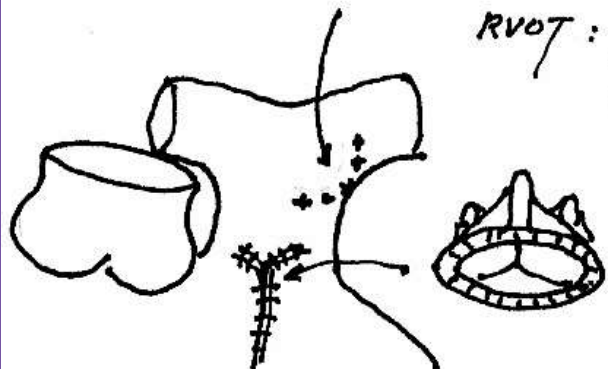


(Hadhad F et al. 2008 Circulation)

Surgical PVR

LPA origin angioplasty

RVOT : primary closure



A

Bovine bioprosthetic valve



CE Perimount



CE Perimount
Magna



CE Perimount
Magna Ease



Sorin Mitroflow

B

Porcine bioprosthetic valve



Medtronic
Hancock II



Medtronic Mosaic



CE Porcine SAV



Biocor

C

Stentless bioprosthetic valve



Edwards Prima
Plus



Medtronic
Freestyle



St. Jude Toronto
SPV

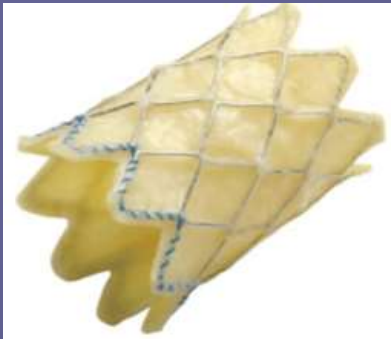


Sorin Freedom

Available percutaneous pulmonic valve

Melody valve

by Medtronic Company



Melody* Transcatheter Pulmonary Valve

Order Number	Description
PB1018	<ul style="list-style-type: none"> • A bovine jugular vein valve sutured within a platinum iridium stent. • One size valve (18 mm) that is crimped to 6 mm and re-expanded from 18 mm to 22 mm. • Thin, compliant leaflets open fully and close readily with a minimum of pressure. • Preservation in a proprietary sterilant of glutaraldehyde and alcohol.

Torque Wrench

Order Number	Description
01-0055	Reusable jar opener

Ensemble* Transcatheter Delivery System

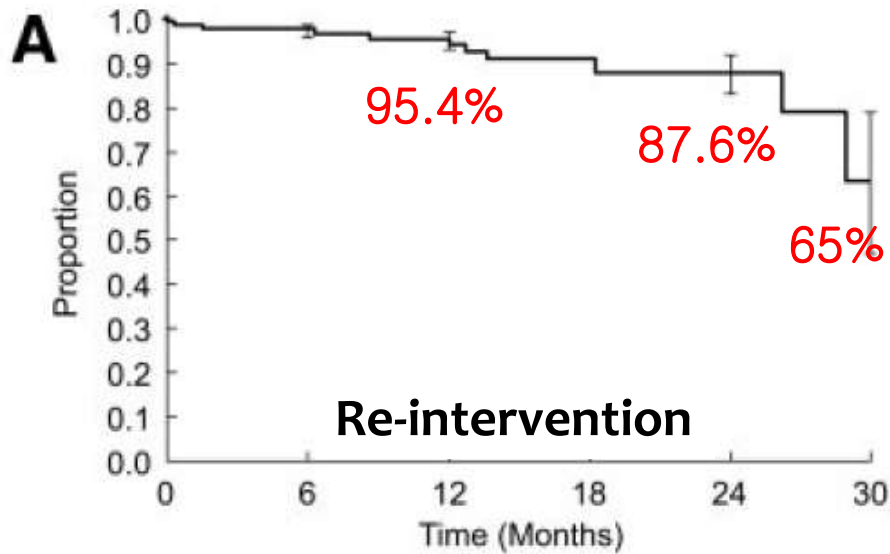
Order Number	Balloon Size	French Size	Overall Length
NU1018	18 mm	22	100 cm
NU1020	20 mm	22	100 cm
NU1022	22 mm	22	100 cm

Description

- Balloon-in-balloon catheter delivery system with a retractable polytetrafluoroethylene (PTFE) sheath covering.
- Nylon inner and outer balloons available in three sizes: 18 mm, 20 mm and 22 mm. At inflation, the inner balloon is half the diameter of the outer balloon.
- Sheath with side port for flushing the system and a hemostatic sleeve to minimize bleeding at the insertion site.

US Melody valve trial

- 2007.1~2009.8
- 5 centers in USA, 136 patients (median: 19 years, range: 7~53 years)



At risk: 124

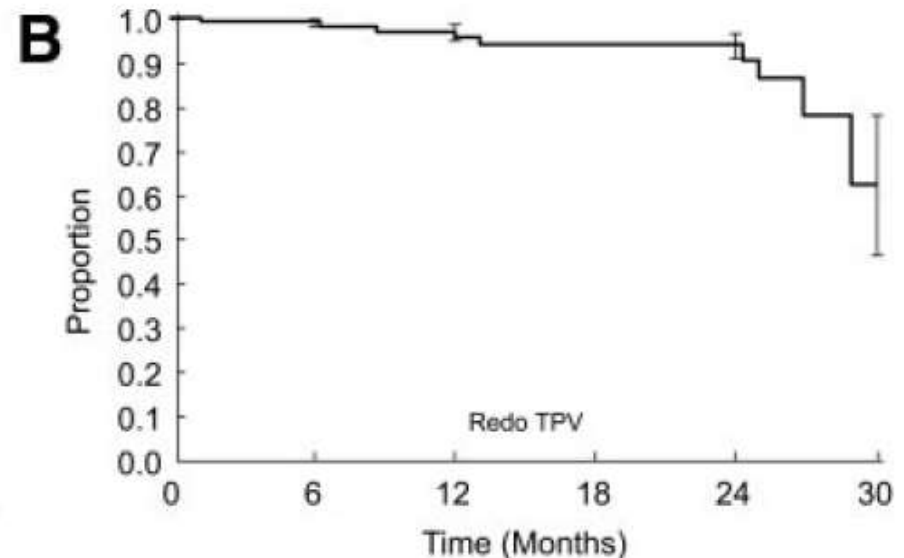
106

70

38

24

3



At risk: 123

106

70

39

26

3

Freedom from Melody valve dysfunction or reintervention

: 93.5% at 1 year, 87.6% at 2 years

(McElhinney et al, 2010 Circulation)

Clinical and hemodynamic outcomes **up to 7 years** after transcatheter pulmonary valve replacement in the **US melody valve investigational device exemption trial**.

- **148 patients**, median follow-up duration: **4.5 years** (range, 0.4-7 years)
- **32 patients**: underwent right ventricular outflow tract **reintervention** due to
 - obstruction (n=27, with stent fracture in 22)
 - endocarditis (n=3, 2 with stenosis and 1 with pulmonary regurgitation)
 - right ventricular dysfunction (n=2).
- 11 patients: TPV explanted as an initial or second reintervention.
- **5-year freedom from reintervention and explantation: $76 \pm 4\%$ and $92 \pm 3\%$**
- **113 patients** who were alive and reintervention free
 - follow-up gradient (median, 4.5 years after implantation) was unchanged from early post-TPV replacement
 - all but 1 patient had mild or less pulmonary regurgitation.
 - Almost all patients were in New York Heart Association class I or II.
- The main cause of TPV dysfunction was stenosis related to **stent fracture**, which was uncommon once prestenting became more widely adopted.

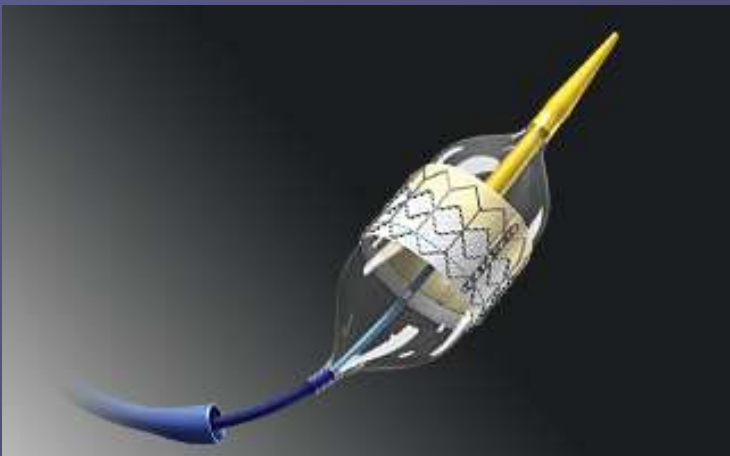
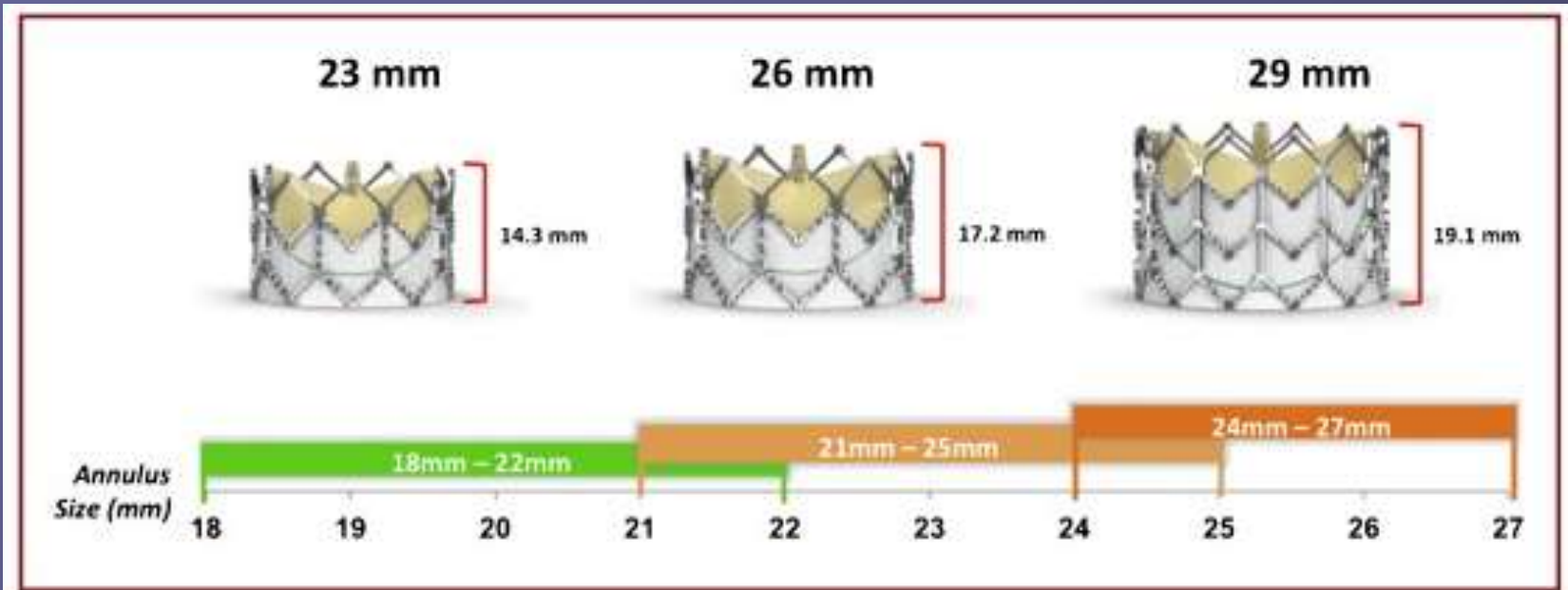
Indication of balloon-expandable PVR

- Indication (by FDA) for **Melody valve**
 - Existence of a **full (circumferential) RV outlet tract conduit**
 - equal to or **greater than 16 mm** in diameter when originally implanted
 - **Dysfunctional RVOT conduits** with a clinical indication and either:
 - regurgitation: **\geq moderate** regurgitation, or
 - stenosis: **mean RVOT gradient \geq 35 mmHg**



Available percutaneous pulmonic valve

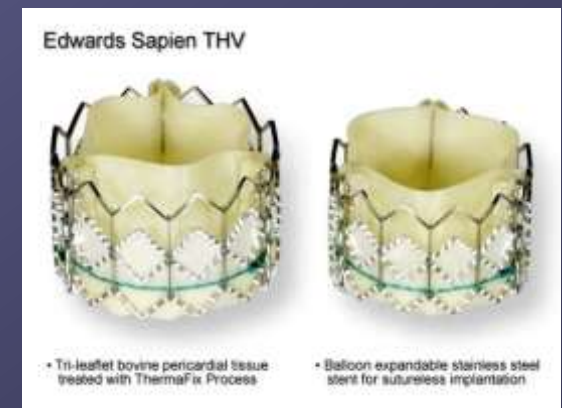
Edwards SAPIEN by Edwards Company



- **three bovine pericardial leaflets** hand-sewn to a tubular, slotted, stainless steel, stent with fabric sealing cuff covering the lower portion of the stent.

COMPASSION study – long term result

- 76 patients recruited from 4 centers, 2008.4 ~2015
- Mean age: 28.3 ± 14 year-old
- Successful implantation: 66 patient
- Valve migration: 3 patients, before 2009
- No mortality
- 97% of patients free from MACCE at 6 months and one year
- 100% freedom from fractures
- 97% freedom from endocarditis at one year



(Hijazi ZM et al. PICS-AP 2015)

Limitation of Melody and Edwards valve

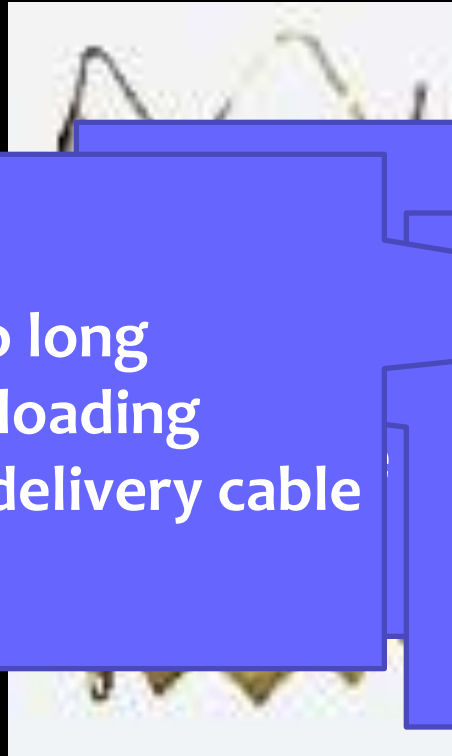
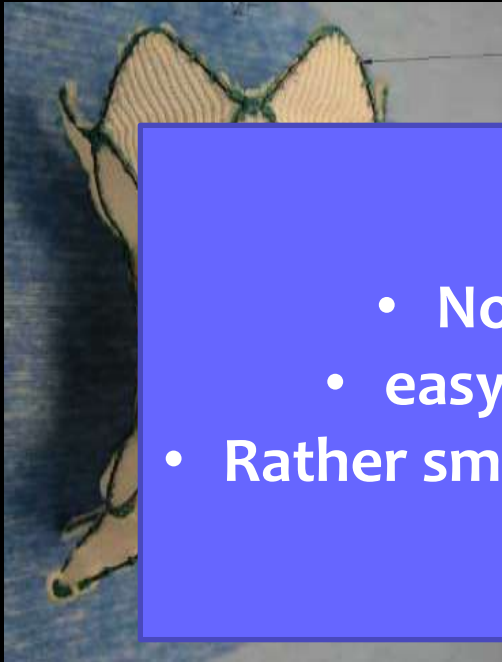


- **Melody** valve and **Edwards** valve
 - **fit for** patients with a **conduit** or a **bioprosthetic valve** in RVOT
 - post-op patient with **RVOT lesions**: indicate only **15-20%**



Most post-op **TOF** patients : **Native** RV Outflow Tract Valve!

New self-expandable pulmonic valved-stent



- Not too long
- easy to loading
- Rather small delivery cable

- Too long and bulky
- Difficult to loading
- Rather large delivery cable

**Native Outflow Tract
Transcatheter Pulmonary
Valve, Medtronic, USA**

**Venous P Valve,
Medtech, China**

**Transcatheter Pulmonary
Valve, SNUCH, South Korea**

Valve diameter: **22 mm**
25 Fr. delivery cable

Valve diameter: **16-32 mm**
14-22 Fr. delivery cable

Valve diameter: **18-28 mm**
18 Fr. delivery cable

New self-expandable valved stent in SNUCH

- Stent using **Nitinol-wire backbone**
 - **self-expandable**
- Tissue valve using **porcine pericardium**
 - **multiple steps for tissue preservation**



Disclosure

- **TaeWoong Medical Co., Ltd.:** technical support

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TaeWoong
MEDICAL

COMPANY PRODUCT NEWS ROOM CAREER

HOME > COMPANY > About Taewoong > **History**

History

Waiting for Question!

About Taewoong

- History
- Timeline
- Qualified Innovation
- CEO Message

The screenshot shows a website layout with a dark blue background. On the left, there is a light blue sidebar containing the TaeWoong Medical logo and a 'COMPANY' section with a list of links: 'About Taewoong', 'History', 'Timeline', 'Qualified Innovation', and 'CEO Message'. The main content area has a white background with a navigation bar at the top containing 'COMPANY', 'PRODUCT', 'NEWS ROOM', and 'CAREER'. Below the navigation bar, there is a breadcrumb trail: 'HOME > COMPANY > About Taewoong > History'. The main heading is 'History'. At the bottom of the main content area, there is a black and white illustration of a city skyline reflected in water. On the right side of the main content area, there is a green circular button with a speech bubble icon and the text 'Waiting for Question!'.

Tissue preservation for porcine pericardium

1. **Decellularization** with 0.25% SDS (sodium dodecyl sulfate)
2. 0.1 units/mL **alpha-galactosidase treatment**
(for **reduction of immunogenicity**)
3. **Space filler** with PEG (polyethylene glycol)
4. 0.5 % **GA fixation** with solvent (75% ethanol + 5% octanol)
5. **Detoxification** with 0.1M glycine

J Heart Valve Dis. 2012;21:387-97.

Eur J Cardiothorac Surg. 2012;41:383-90.

Int J Cardiol. 2014;173: 74-79.

In Vitro valve motion test

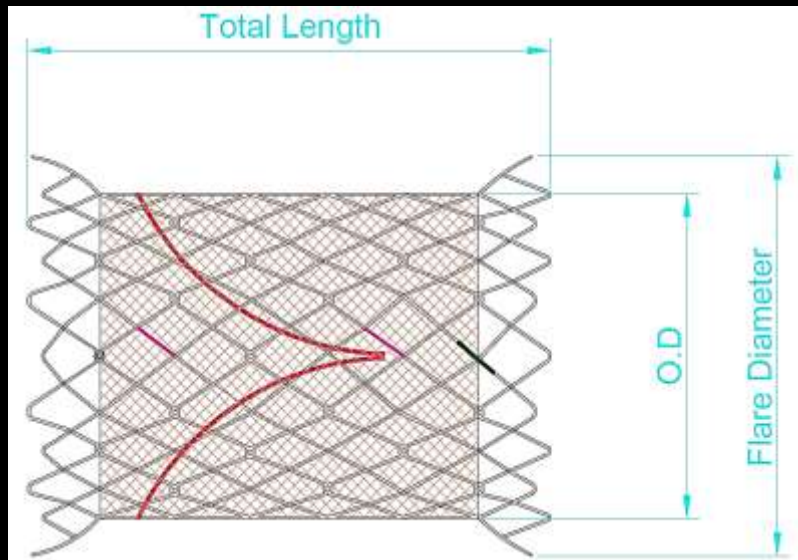


In normal valve model



In diseased valve model
: 22 mm valve in 19 mm porcine Ao. valve

Pulmonary valved-stent shape

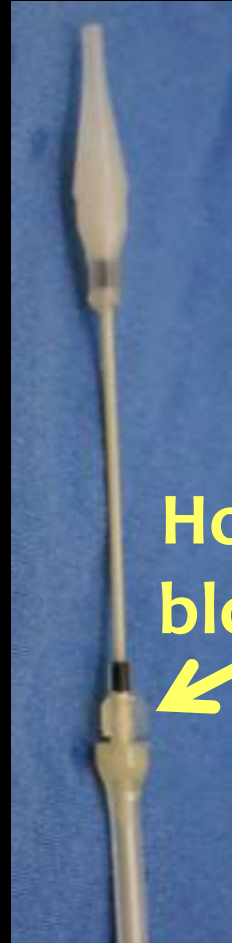


	Outer Diameter (mm)	Total Length (mm)	Flare Diameter (mm)	Expansion Force (gf)	Compression Force (gf)
TPV18	Ø18	28 ± 1.4	Ø22	628	1707
TPV20	Ø20		Ø24	630	1758
TPV22	Ø22	31 ± 1.55	Ø26	448	1468
TPV24	Ø24		Ø28	452	1540
TPV26	Ø26	33 ± 1.65	Ø30	473	1713
TPV28	Ø28		Ø32	453	1725

Trans-catheter delivery system



long delivery catheter
- Usuable length: 110 cm



Hook
block

Head



Handle



18Fr.
(5.9 mm)

12Fr. shaft

Stent loading

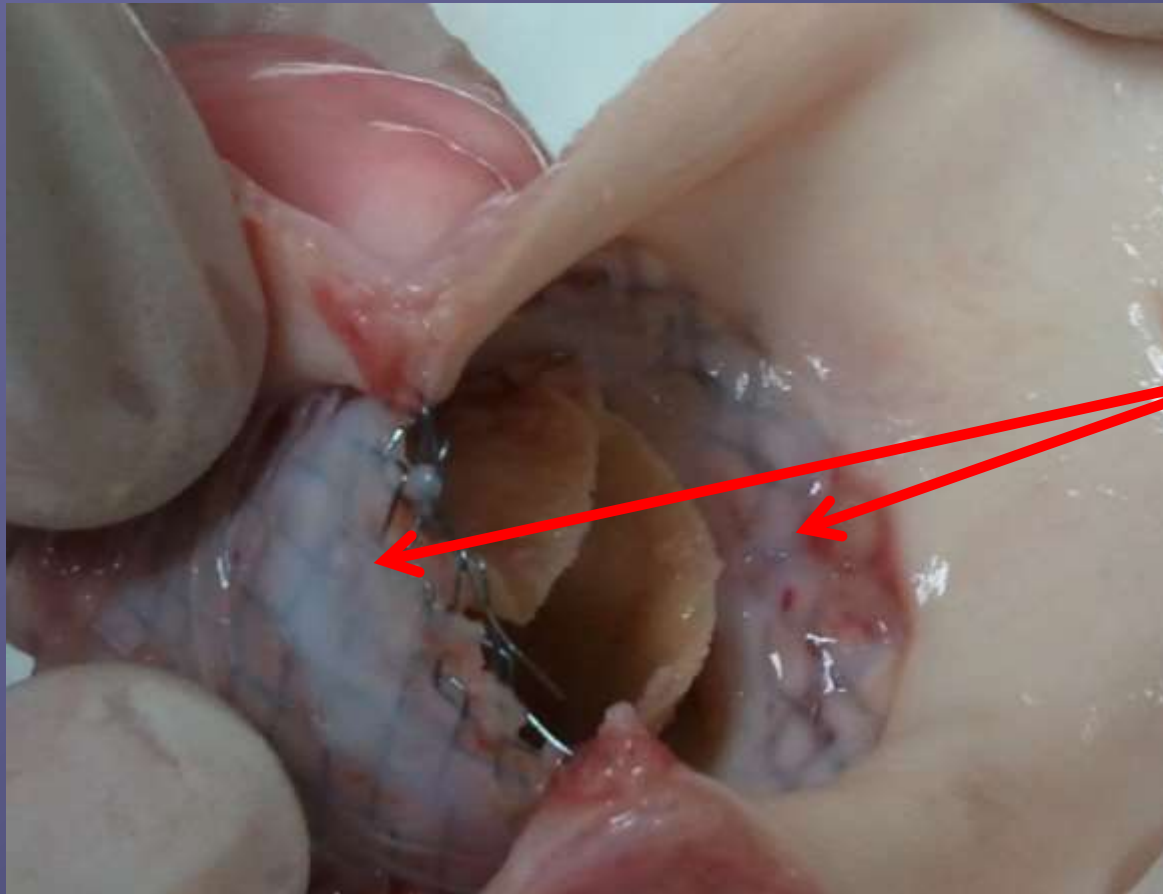


Animal study of percutaneous PVR

- About 6 Month-old
- 40- 50 kg

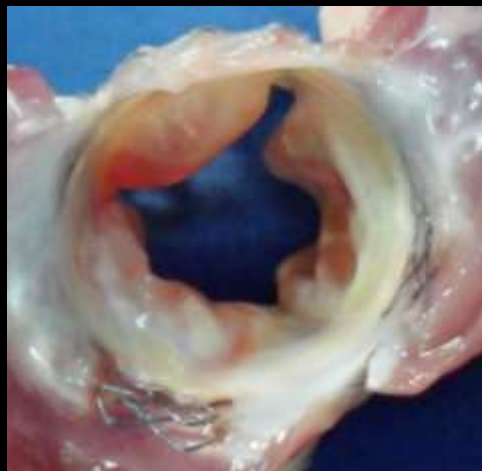
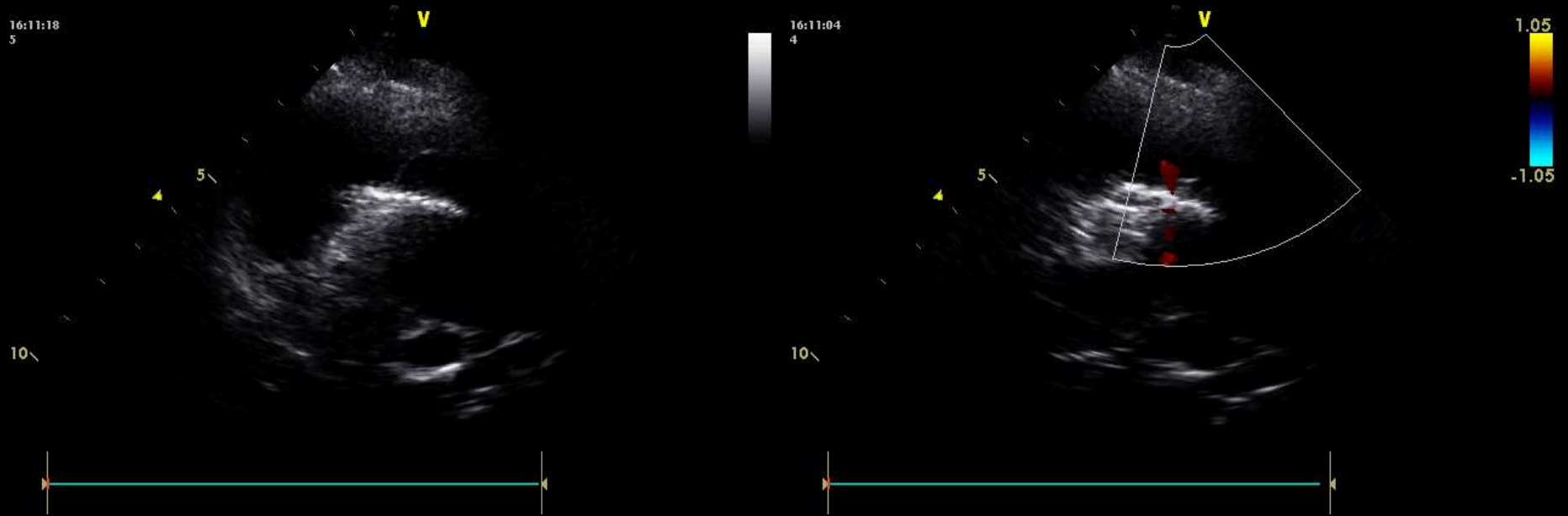


Endothelization



**Full endothelization
after 3 months**


6 Month F/U



A feasibility study to evaluate the safety and short-term effectiveness of implantation of 'Transcatheter Pulmonary Valve (TPV)' for the treatment of Congenital heart disease with Pulmonary valve disease

- Acquired **SNUH IRB** and **Korean FDA** approval
 - A **feasibility** study: **10** patients
 - : **primary outcome**
 - Procedure success
 - Procedural / Device related serious adverse events at 6month
 - Hemodynamic functional improvement rate at 6month

Transcatheter Self-expandable Pulmonary Valve

Transcatheter Pulmonary Valve	Size	Pulmonary Annulus Diameter
	18 mm	15 mm ~ 16.9 mm
	20 mm	17 mm ~ 18.9 mm
	22 mm	19 mm ~ 20.9 mm
	24 mm	21 mm ~ 22.9 mm
	26 mm	23 mm ~ 24.9 mm
	28 mm	25 mm ~ 26.9 mm

TPV Delivery System	Diameter	Usable Length
	18Fr (5.9 mm)	110 cm

A feasibility study

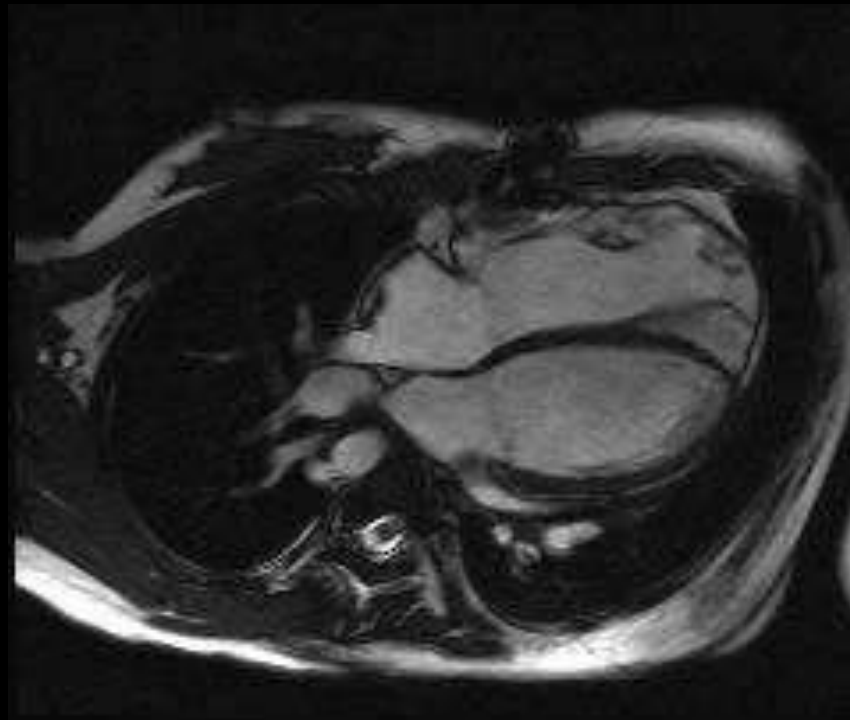
Study Procedure	Screening	Procedure	Follow-up				
			F/U (Short-term)				F/U (Long-term)
	Visit1	Visit2	Visit3	Visit4	Visit5	Visit 6	Visit 7~11
	Baseline	Day1	Discharge	1mon ±1week	3mon ±2week	6mon ±4week	Annually ±8week
OPD/Adm.	Adm.	Adm.	OPD	OPD	OPD	OPD	
Consent	√						
Demographic data	√						
Vital sign	√	√	√	√	√	√	√
physical exam.	√		√	√	√	√	√
History/Allergy	√						
Blood test	√	√	√	√	√	√	√
12-Lead ECG	√		√	√	√	√	√
Cardiac MRI	√					√	
X-ray	√	√	√	√	√	√	√
Echocardiography	√		√	√	√	√	√
Cardiac catheterization with Angiography		√				√	
TPV procedure		√					
Procedural success evaluation			√				
Clinical evaluation							
NYHA classification	√		√	√	√	√	√
Concomitant med.	√	√	√	√	√	√	√
Adverse event/SAE		√	√	√	√	√	√

First patient – 2016.2.25.

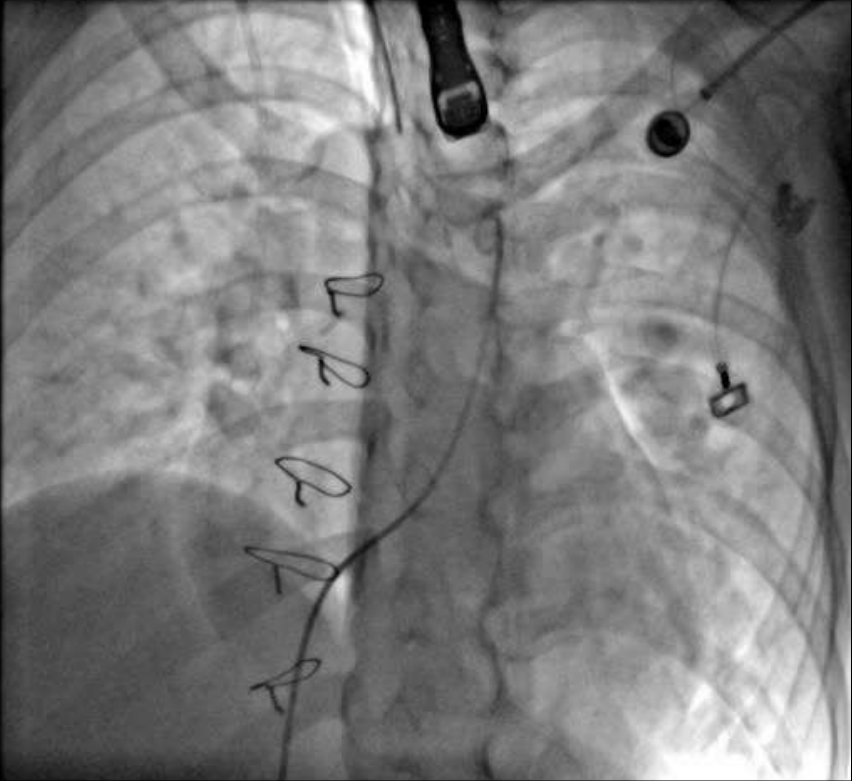
- Female/20 years with Tetralogy of Fallot
- Two times of open heart surgery
 - 2 months old: TOF total repair
 - 14 years old: pulmonary valvuloplasty for severe pulmonary regurgitation
- NYHA: III
- **Max VO_2 : 14.9 mL/kg/min**

First patient – 2016.2.25.

- Before procedure
 - Severe pulmonary regurgitation, **PR fraction: 38.4%**
 - Enlarged Rt. Ventricle: **End-diastolic volume – 181.7 mL/m²**
End-systolic volume – 89.9 mL/m², EF- 50.5%



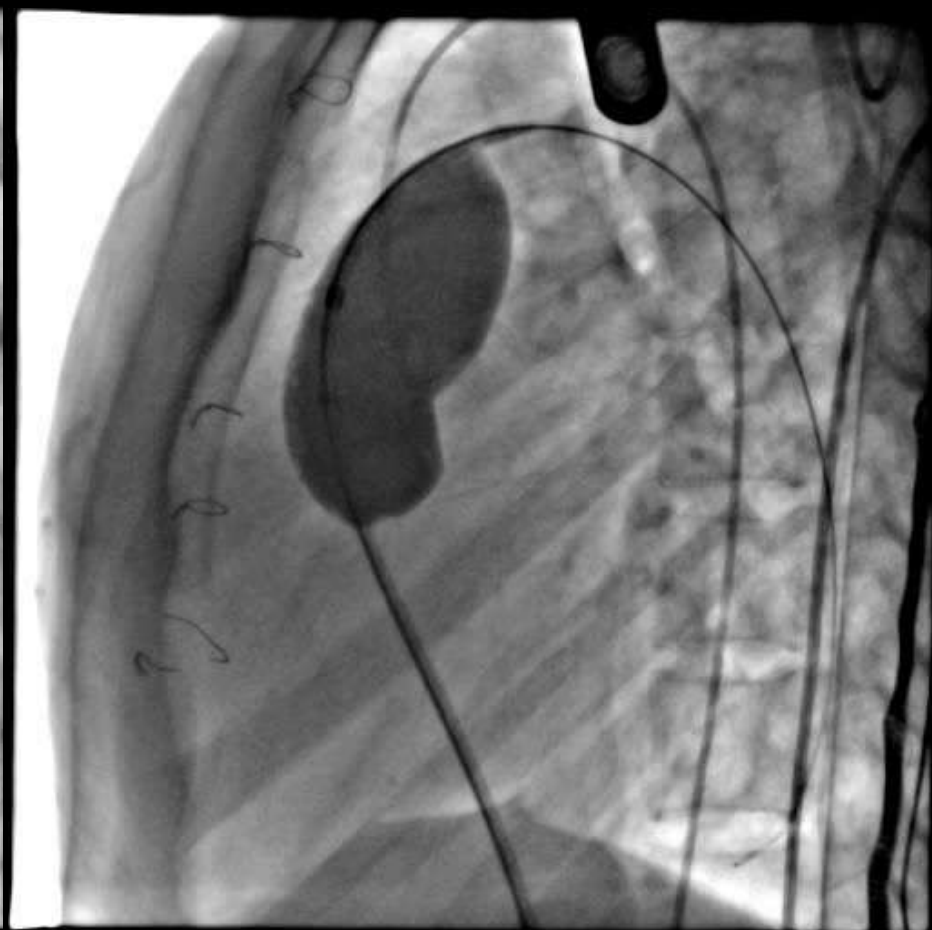
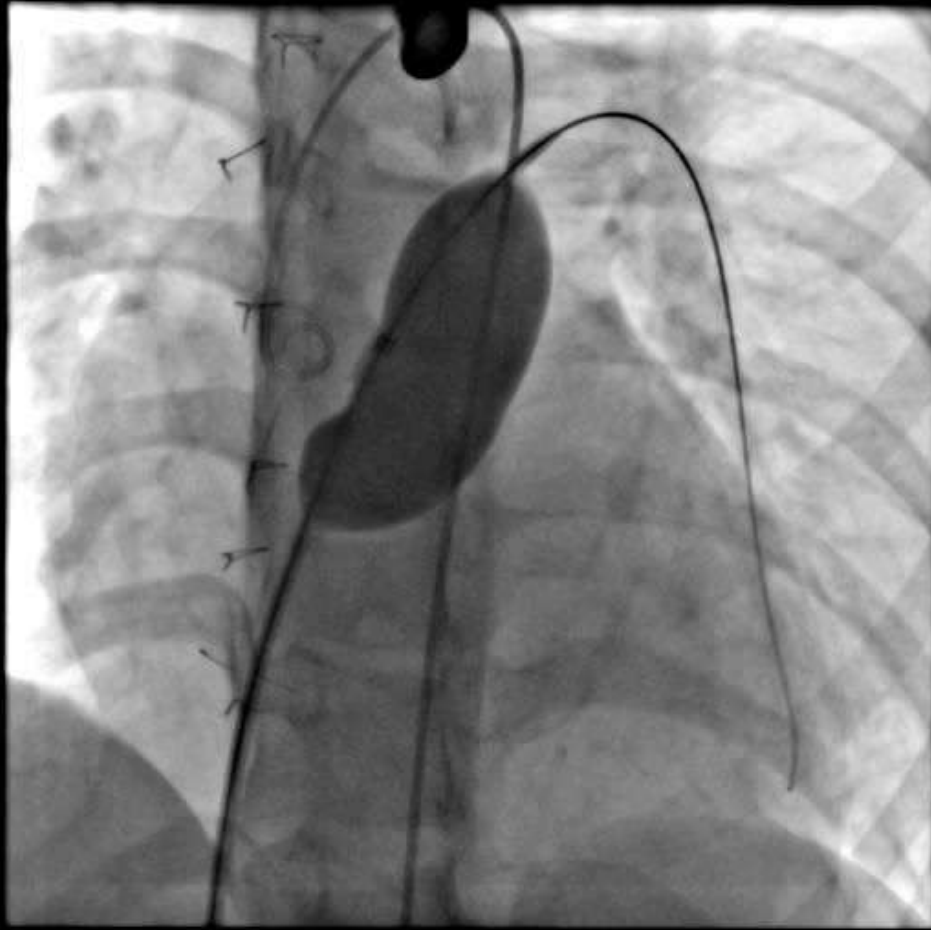
Hemodynamic study before PPVR



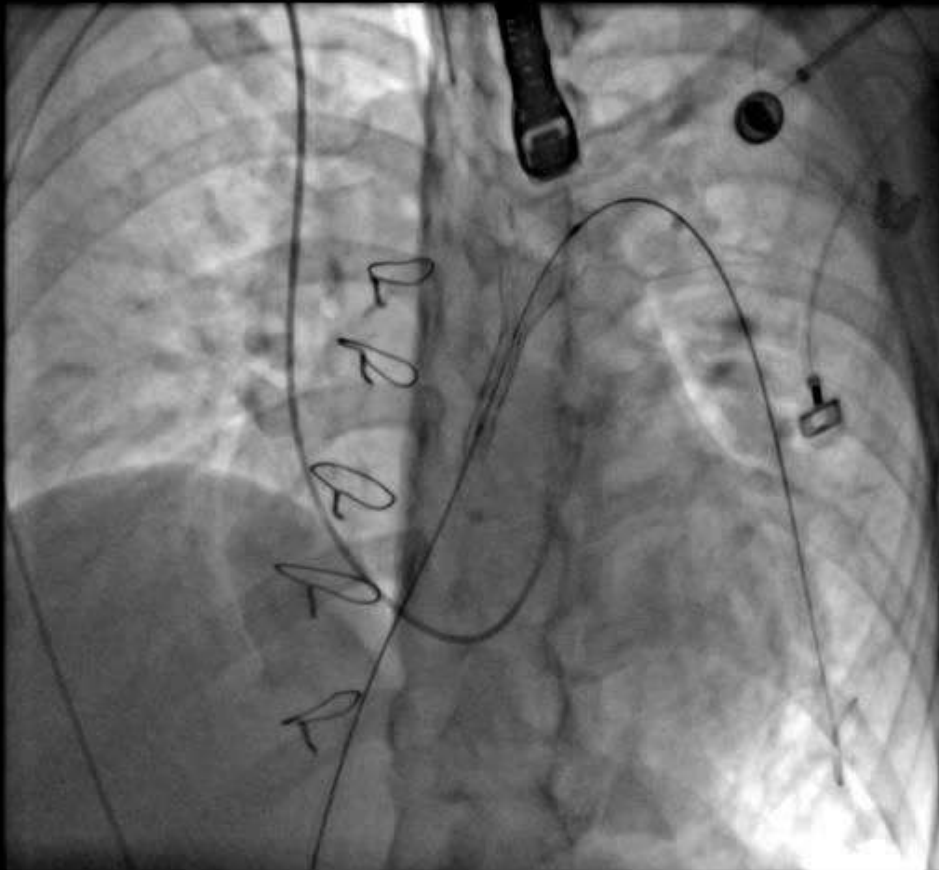
Transesophageal
echocardiography

MPA angiogram

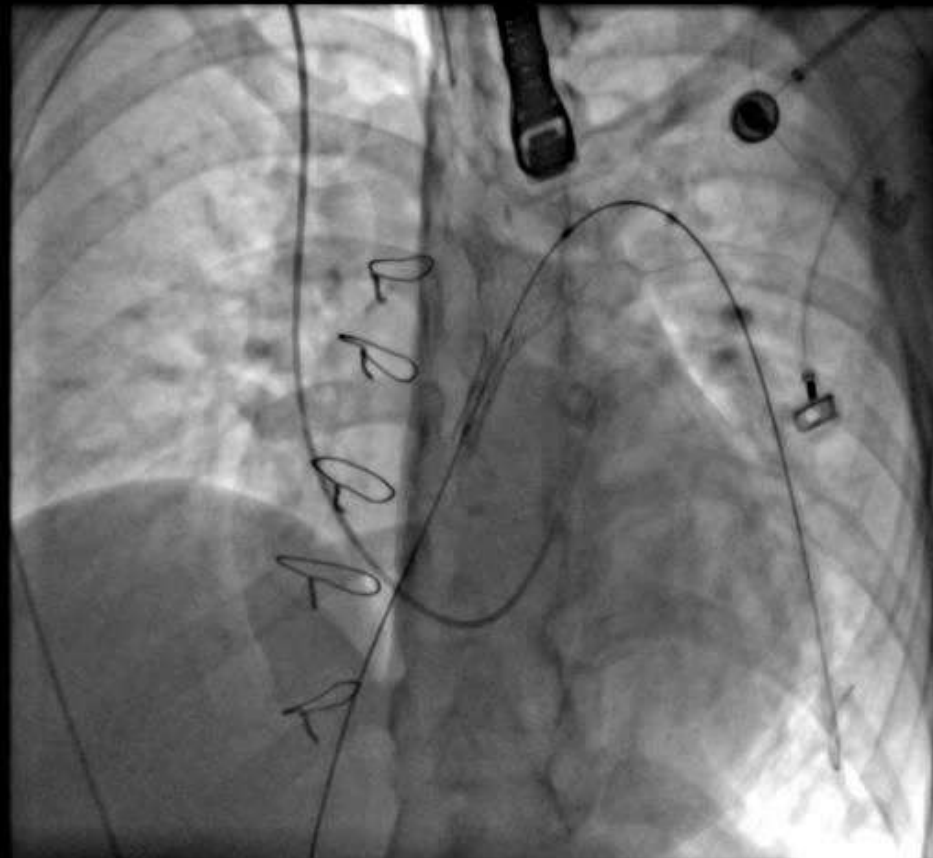
Balloon sizing of main PA and coronary angiography



Deployment of valved-stent

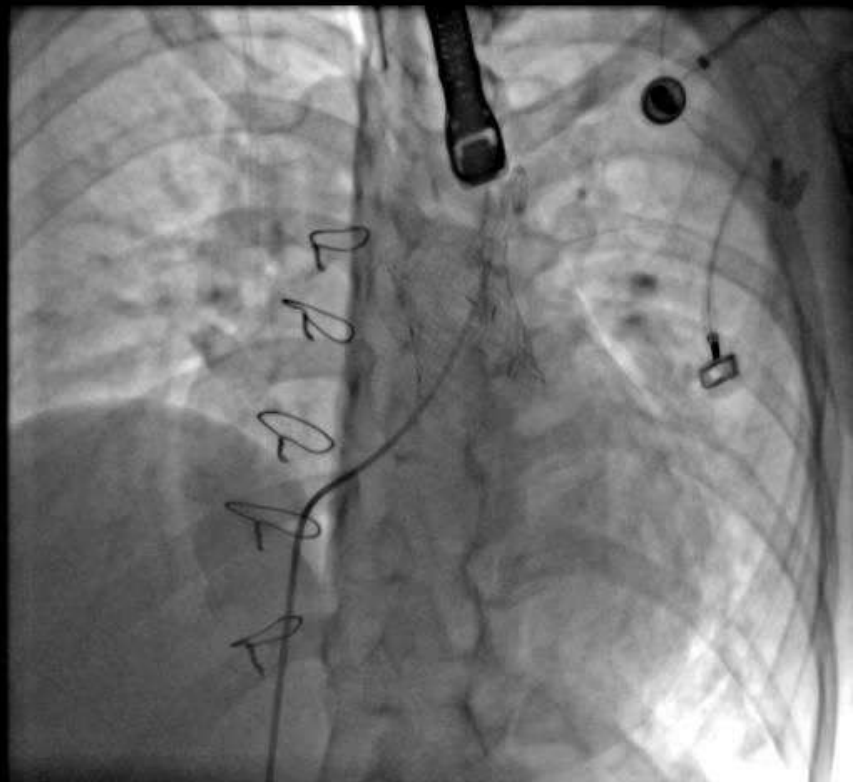
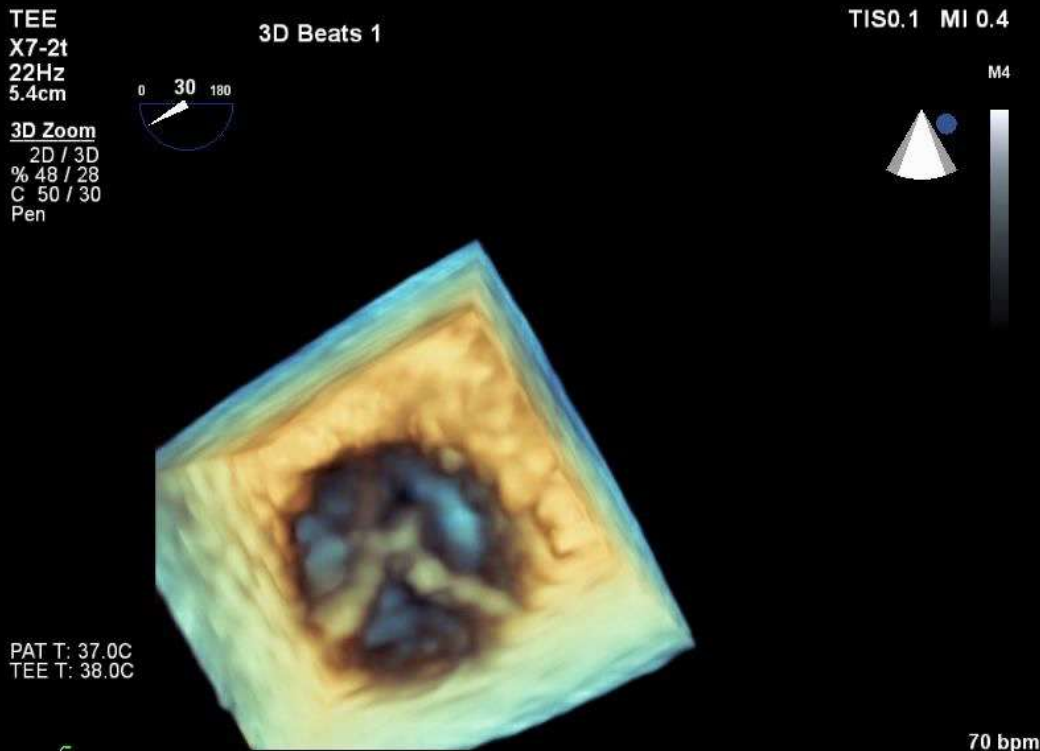


**Partial deployment
and positioning**



Full deployment

Hemodynamic study before PPVR



3D valve motion from TEE

MPA angiogram

Chest PA change – 1st case



Pre- procedure
CT ratio: **54.3%**

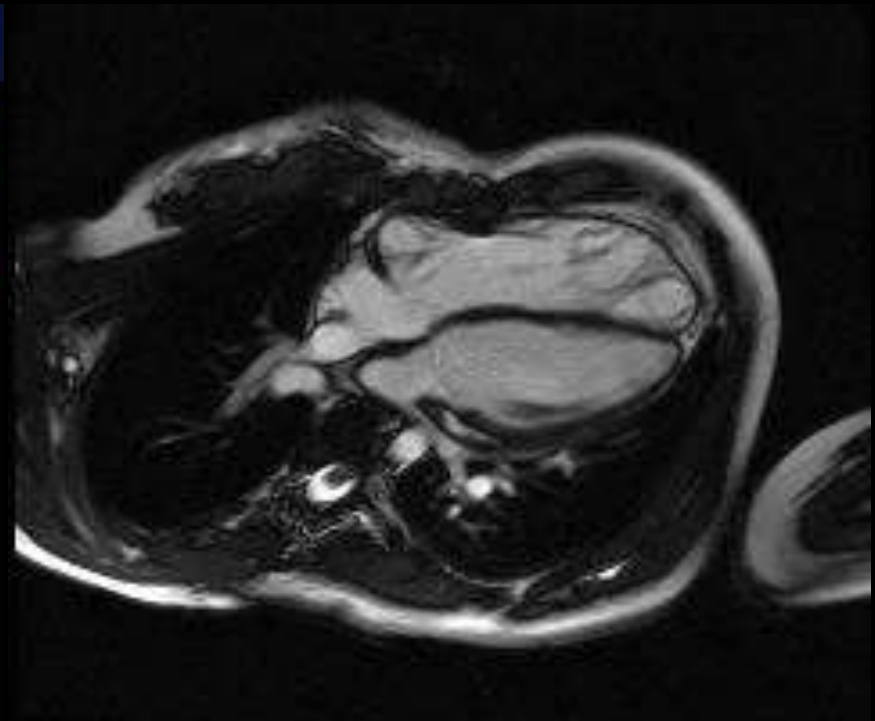


1 Mo. After
CT ratio: **52.1%**

Second patient – 2016.4.7.

- Before procedure
 - Severe pulmonary regurgitation, **PR fraction: 56%**
 - Enlarged Rt. Ventricle: **End-diastolic volume – 167.5 mL/m²**

End-systolic volume – 81.5 mL/m², EF- 51.4%



Chest PA change – 2nd case, 19 yr-old female

- NYHA: III
- Max V_{O2}: 16.9 mL/kg/min

- NYHA: I ~ II



Pre- procedure
CT ratio: **51.2%**

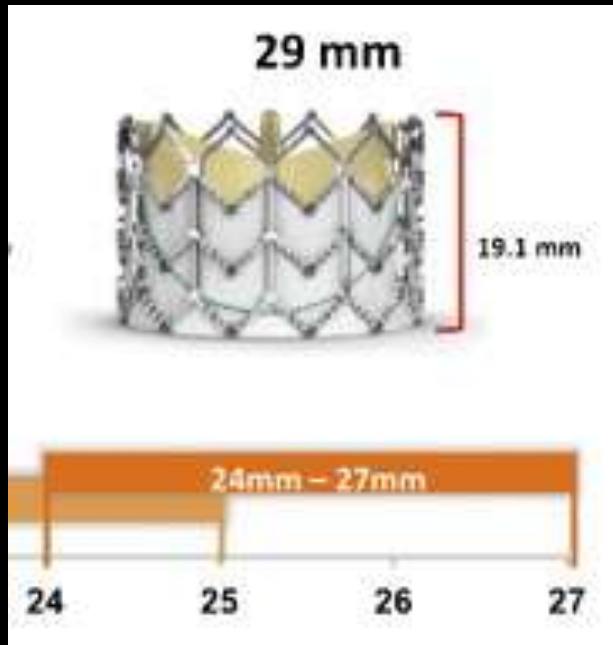


10 days After
CT ratio: **42.1%**

Next Plan !

- Completion of clinical trial in this year
- Expansion of PVR candidate
 - Larger size stent: up to **34 mm**
 - Age **≥ 10 year-old**, Body weight **≥ 30 kg**
- Global cooperation

Now available pulmonic valved-stent for native RVOT lesions



**Edwards - Sapien
Valve,**
Need pre-stenting



Venous P Valve,
Medtech, China

Valve diameter: **16-32 mm**
14-22 Fr. delivery cable



**Transcatheter Pulmonary
Valve,** SNUCH, South Korea

Valve diameter: **18-28 mm**
18 Fr. delivery cable

Ideal valved-stent !

- **long durability** with good valve function
- **good stability**
 - good position without migration
- **high radial strength**
- **easy feasibility** for stent implantation
- **low guiding sheath profile**

Conclusions

- **Balloon-expandable Melody and Edwards valve** for RVOT conduit shows good clinical outcome in US and Europe.
- **New Nitinol-based self-expandable valved stent** for RVOT lesions is on the clinical trial in US, China, and Korea.

Thank You for Attention !