Spectrum of Percutaneous Pulmonary Valves

& Future Perspectives

Shakeel A Qureshi

Evelina London Children's Hospital

London, UK

TCTAP Seoul, Korea 2015

Evelina London

Guy's and St Thomas' NHS
NHS Foundation Trust

Disclosures

Consultancy: NuMED Inc

Lifetech Inc

Venus Medtech

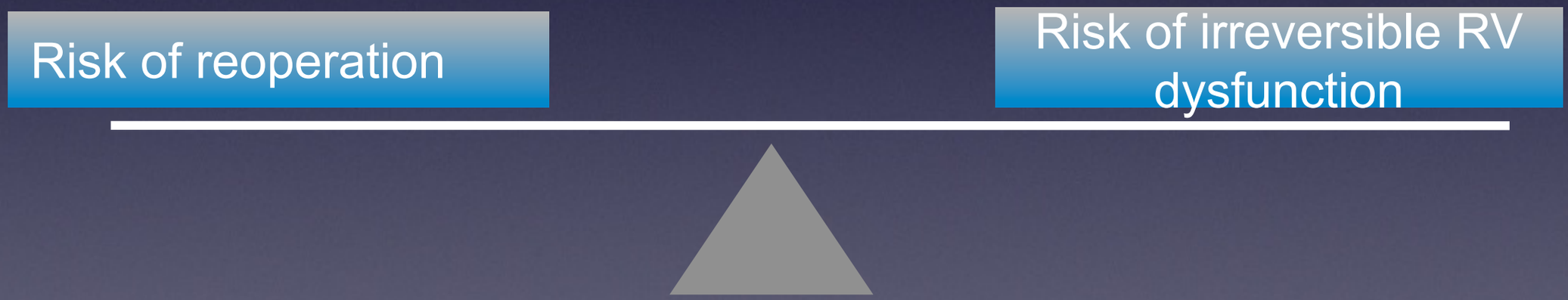
Proctor: Medtronic Inc

St Jude Medical

Indications for pulmonary valve replacement

- Pulmonary regurgitation is common after repair of tetralogy of Fallot with transannular patch
- Occurs also after degeneration of conduits between RVOT and PA e.g repair of pulmonary atresia/VSD, or TGA with pulmonary stenosis or common arterial trunk
- With conduits, the haemodynamic problem may be PR, PS or both
- These patients may require several repeat operations to have a competent valve
- Aggressive approach to PVR is needed nowadays
- If effort tolerance is deteriorating, with increasing cardiomegaly, pulmonary valve replacement is likely to produce useful improvement
- MRI has an important role in decision making. If RVEDV > 150 ml/m2, consider pulmonary valve replacement

Risk/benefit of dealing with RVOT dysfunction



Percutaneous pulmonary valve replacement

- Melody valve
- Sapien valve
- Venus P-valve

Pulmonary valve implantation

- For conduits, need to prepare a good landing zone
- With calcified conduits, there is a risk of rupture so covered stents are needed
- Often multiple stents are needed to reduce possibility of stent fractures
- Occasionally it is possible to enlarge small homografts from about 12-14 mm diameter to 20 mm diameter for a Melody valve

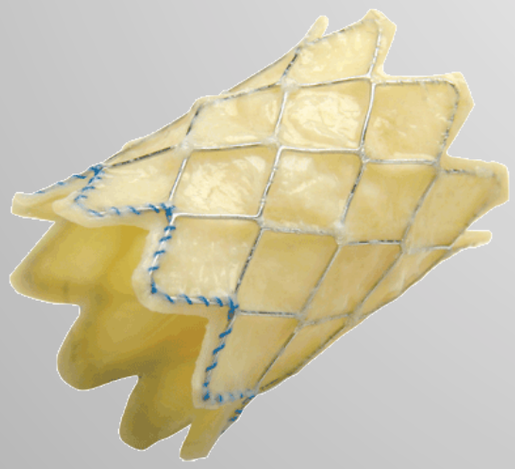
Indications & selection for percutaneous pulmonary valve replacement

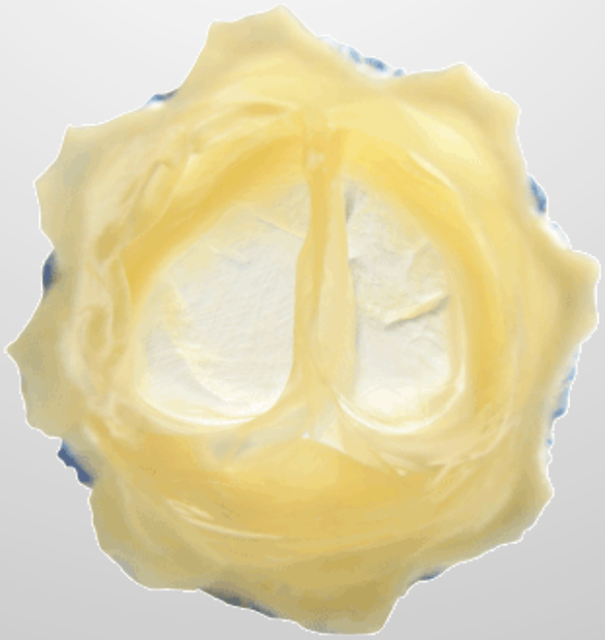
- Melody valve
  - Weight > 20 - 25 kg
  - Conduit stenosis or regurgitation
  - Severe pulmonary regurgitation
- Sapien valve
  - Weight > 20 - 25 kg
  - Conduit stenosis or regurgitation

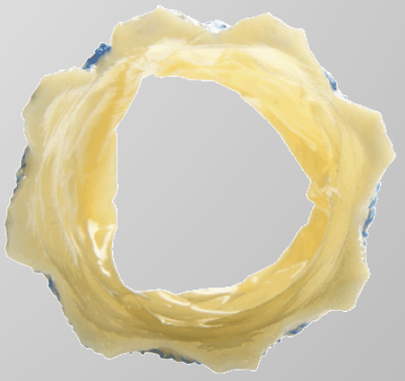
Guy's and St Thomas' NHS
NHS Foundation Trust

Medtronic Melody™ Transcatheter Pulmonary Valve

- 18mm modified Contegra® bovine jugular venous valve
- NuMed Platinum Iridium Stent
  - 28 mm length
  - Crimped to 6mm, expanded to 18 – 22 mm



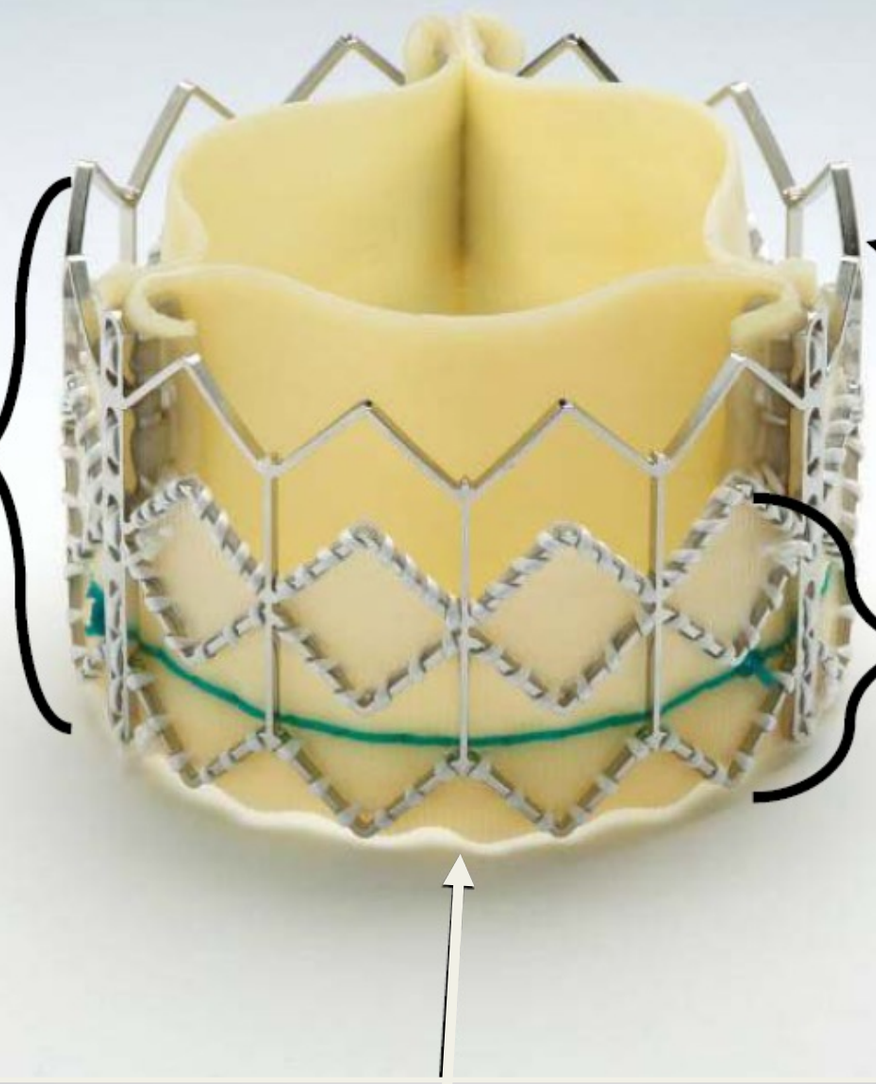




Guy's and St Thomas' NHS
NHS Foundation Trust

Edwards Sapien Pulmonic Valve

available in
23 and 26mm diameter



14-16mm
stent length

stainless steel
stent

PET-cover

Valve made from bovine pericardium,

Guy's and St Thomas' NHS
NHS Foundation Trust

Comparison of transcatheter pulmonary valves

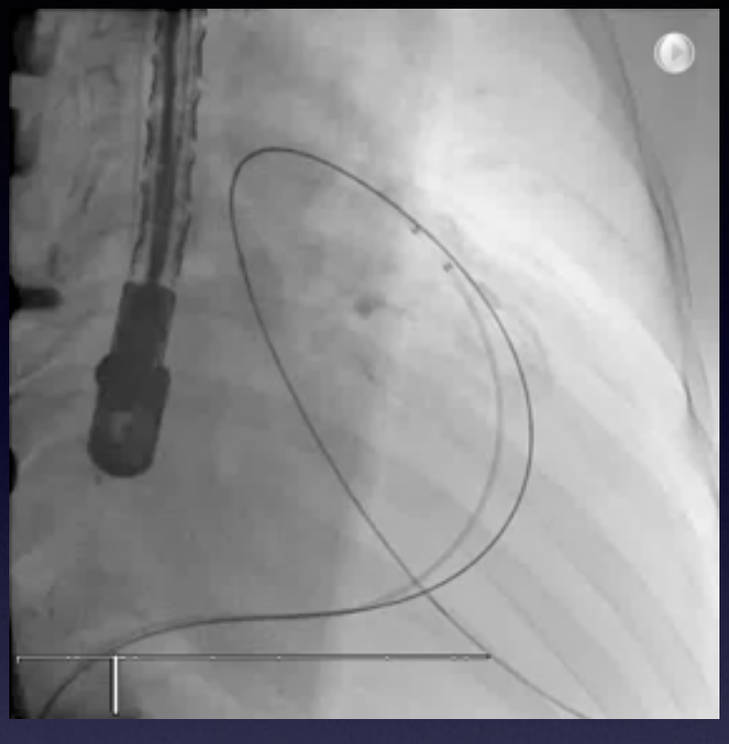
Medtronic Melody

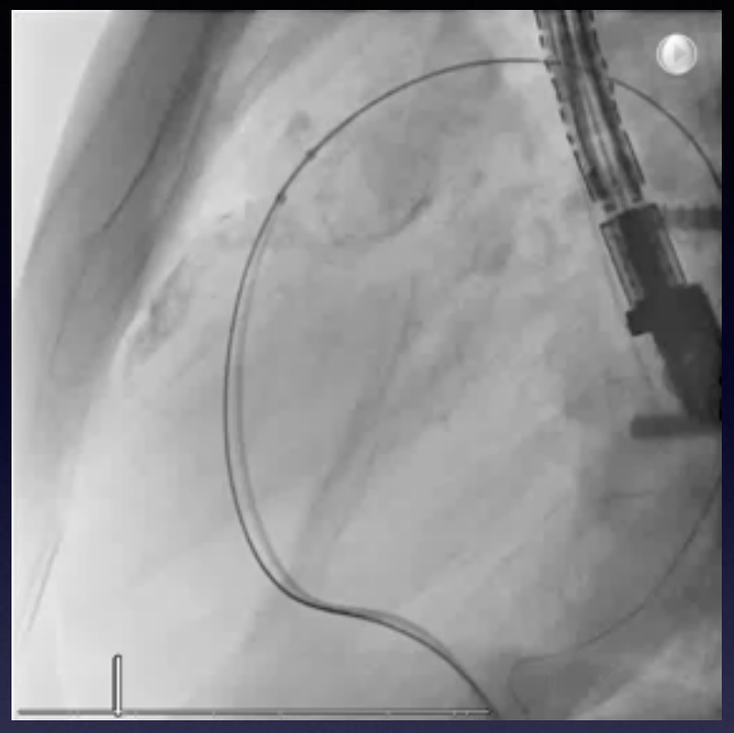
<18 mm – 24 mm

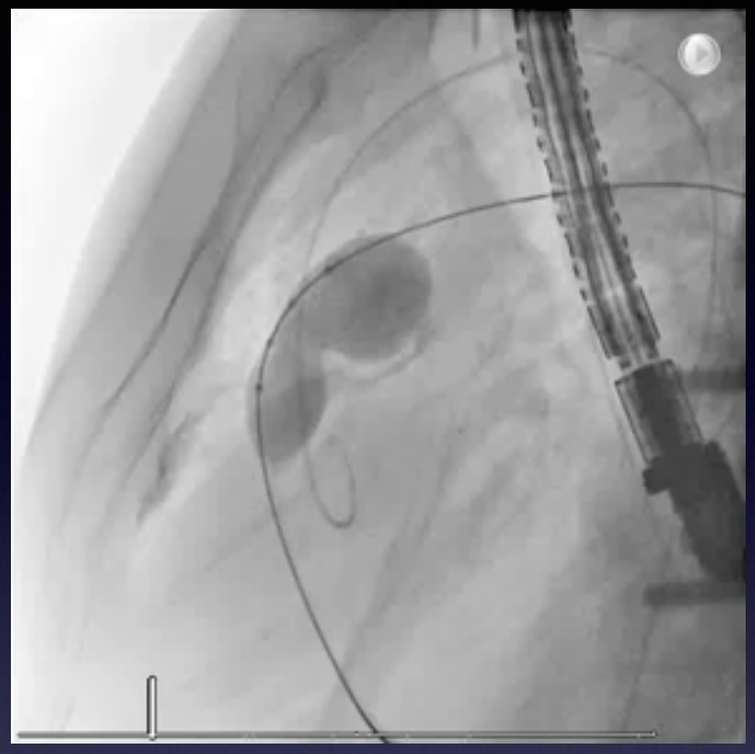
Edwards Sapien Pulmonic Valve

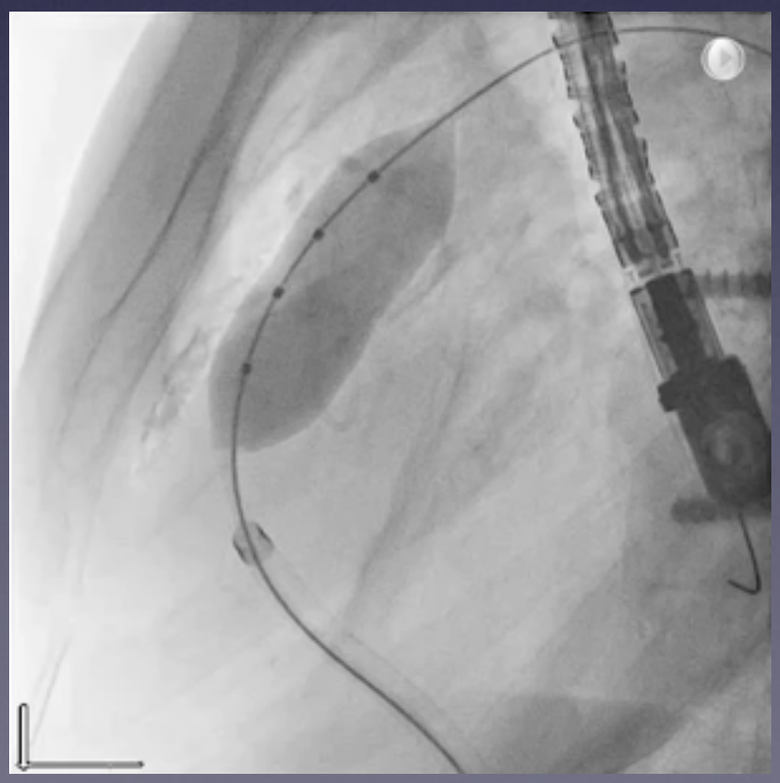
23 mm, 26 mm & 29 mm

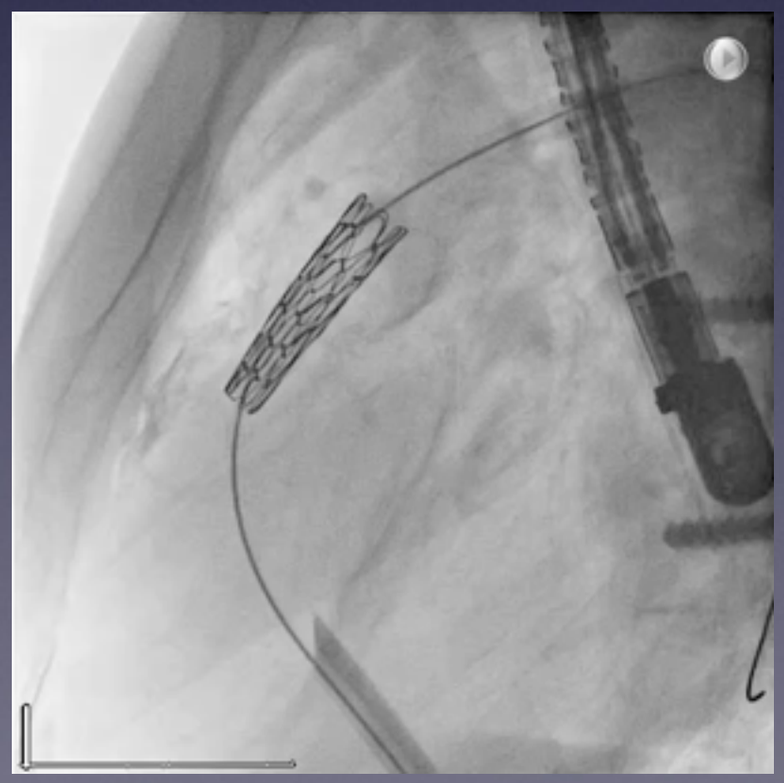
Melody valve implantation
Prestenting with covered CP stent in calcified RVOT

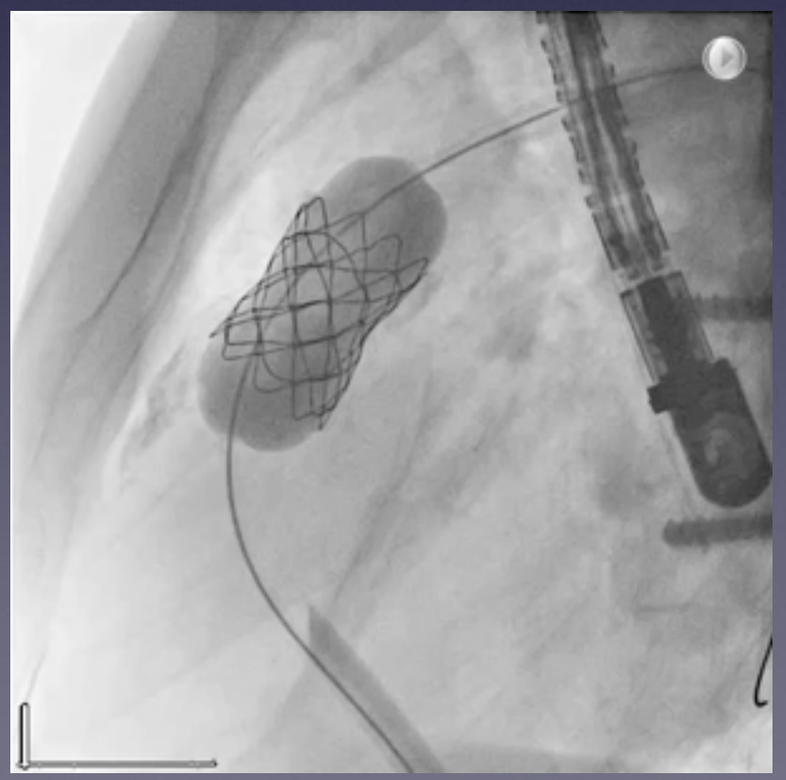




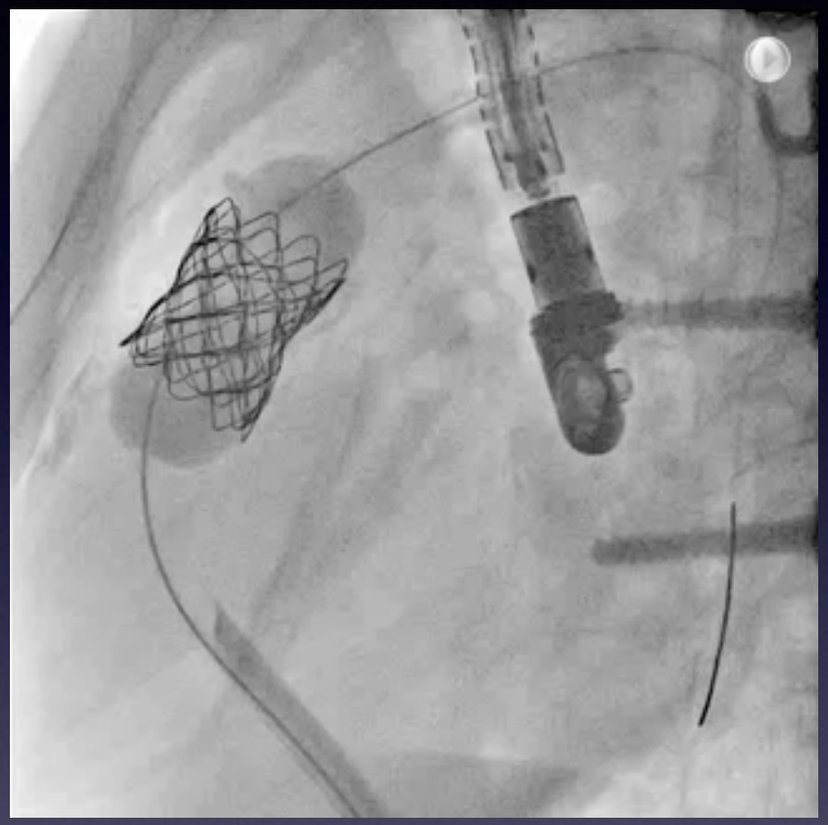


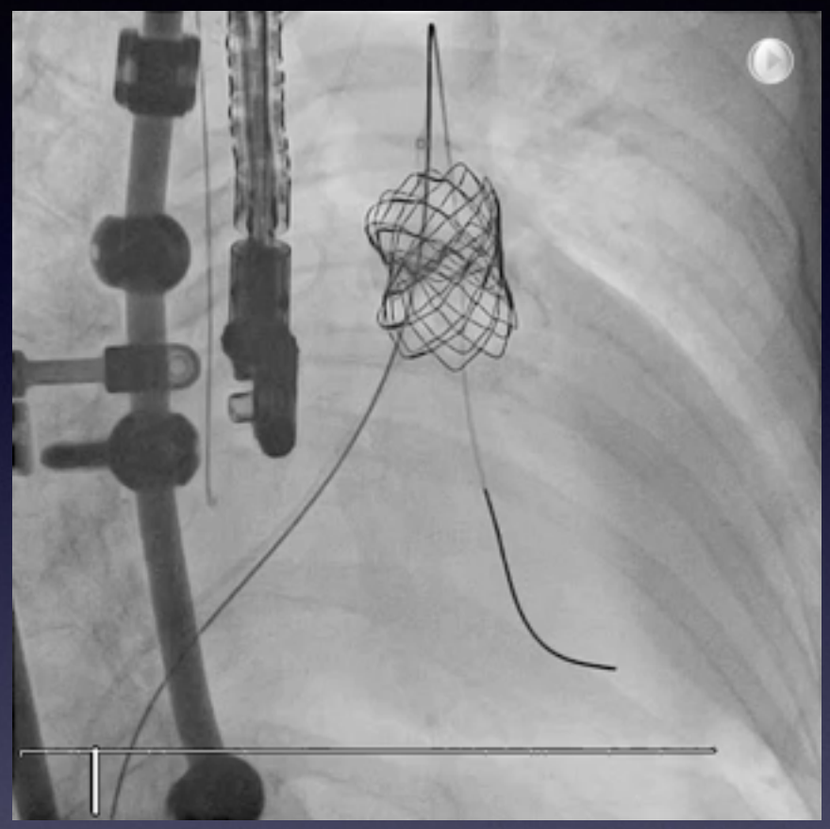


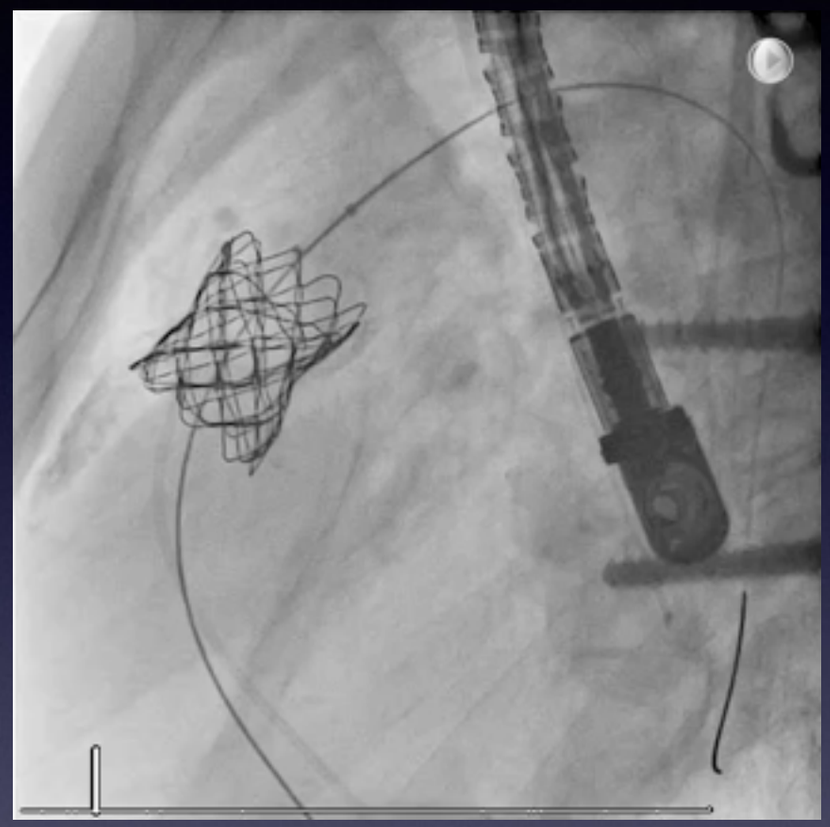




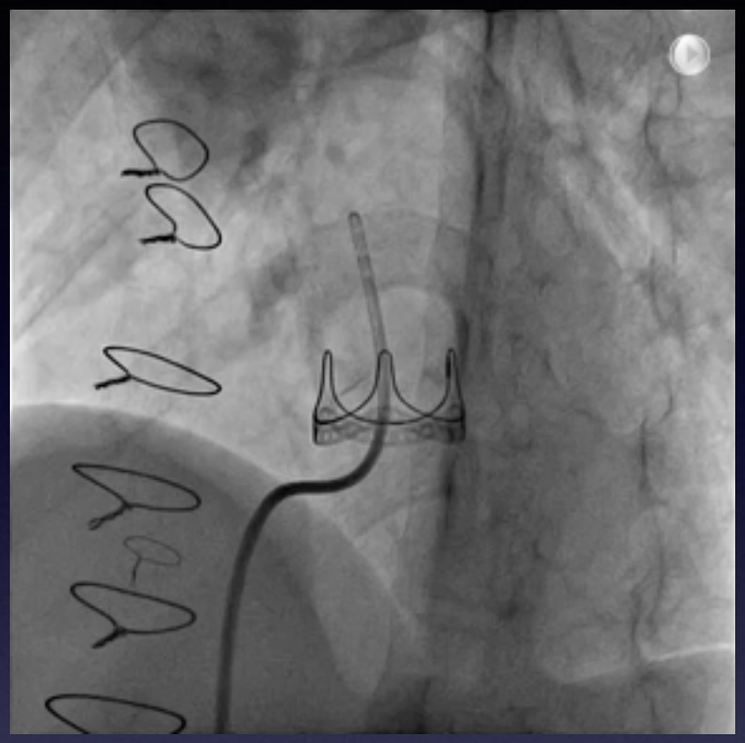
Melody valve implantation after prestenting with covered CP stent

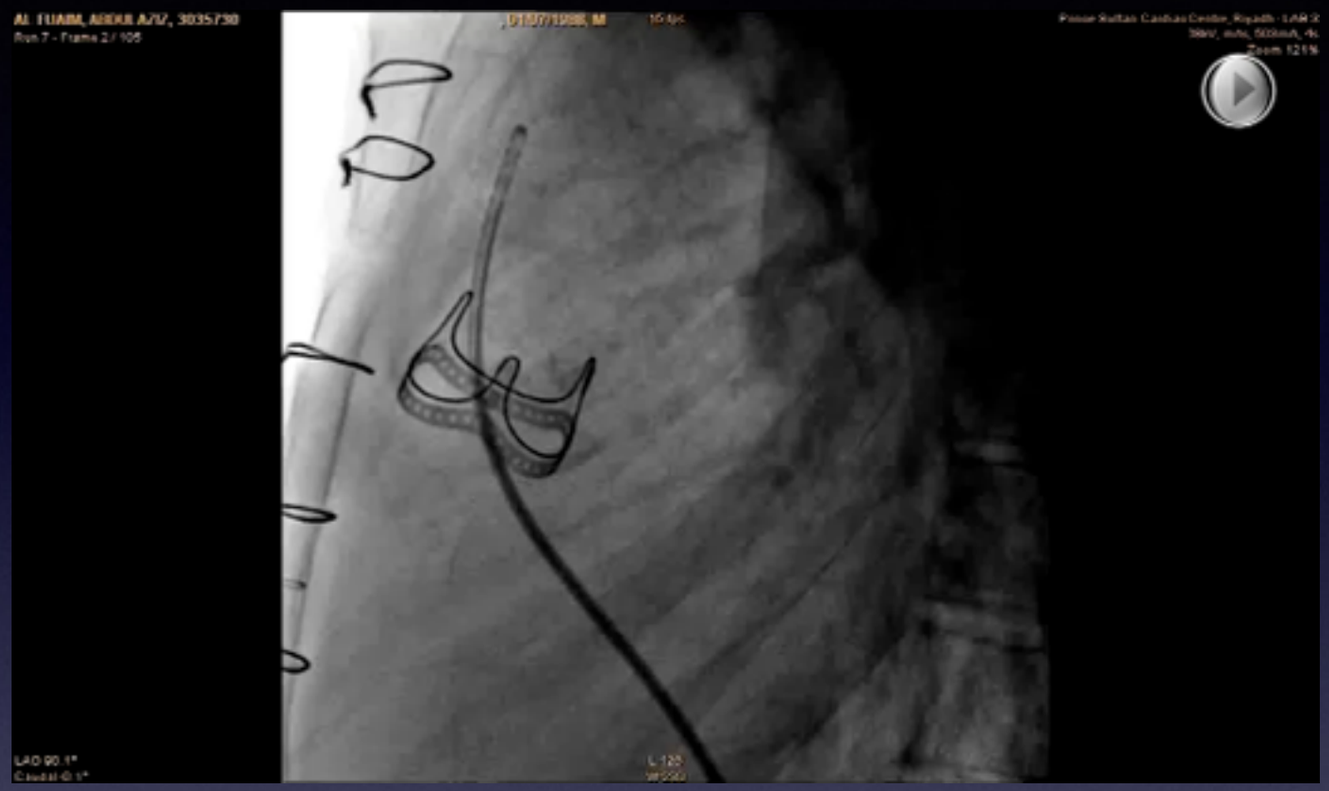


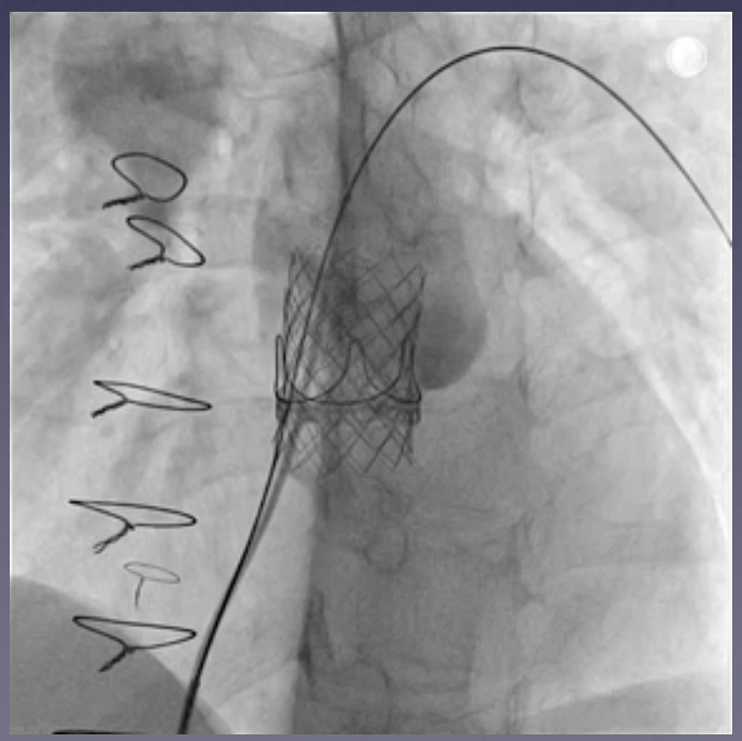


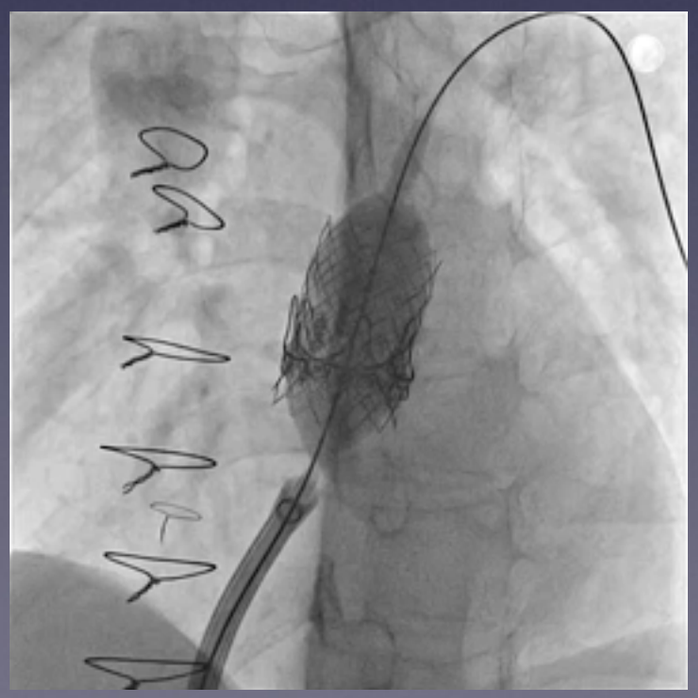


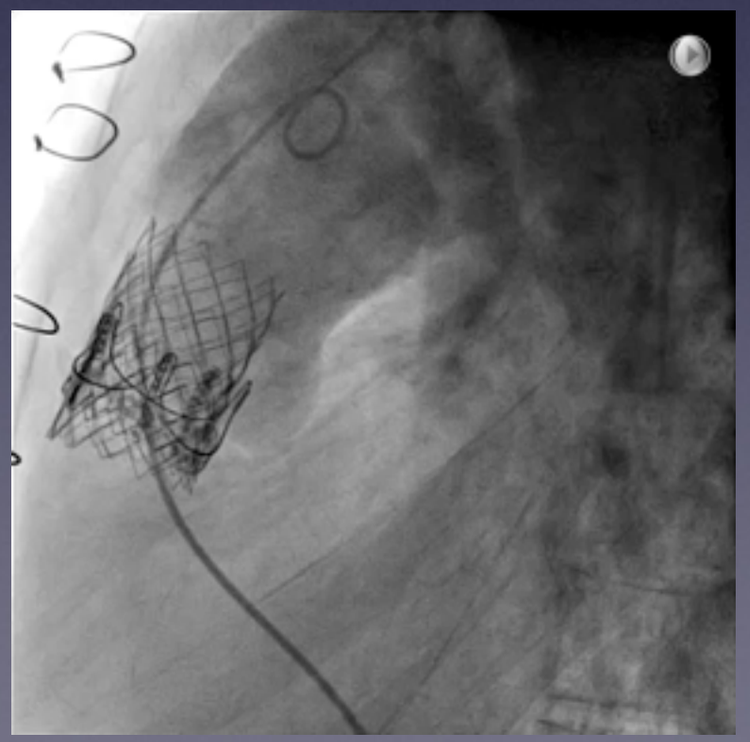
Sapien valve in pulmonary position
Prestenting in a tissue valve with 2 stents





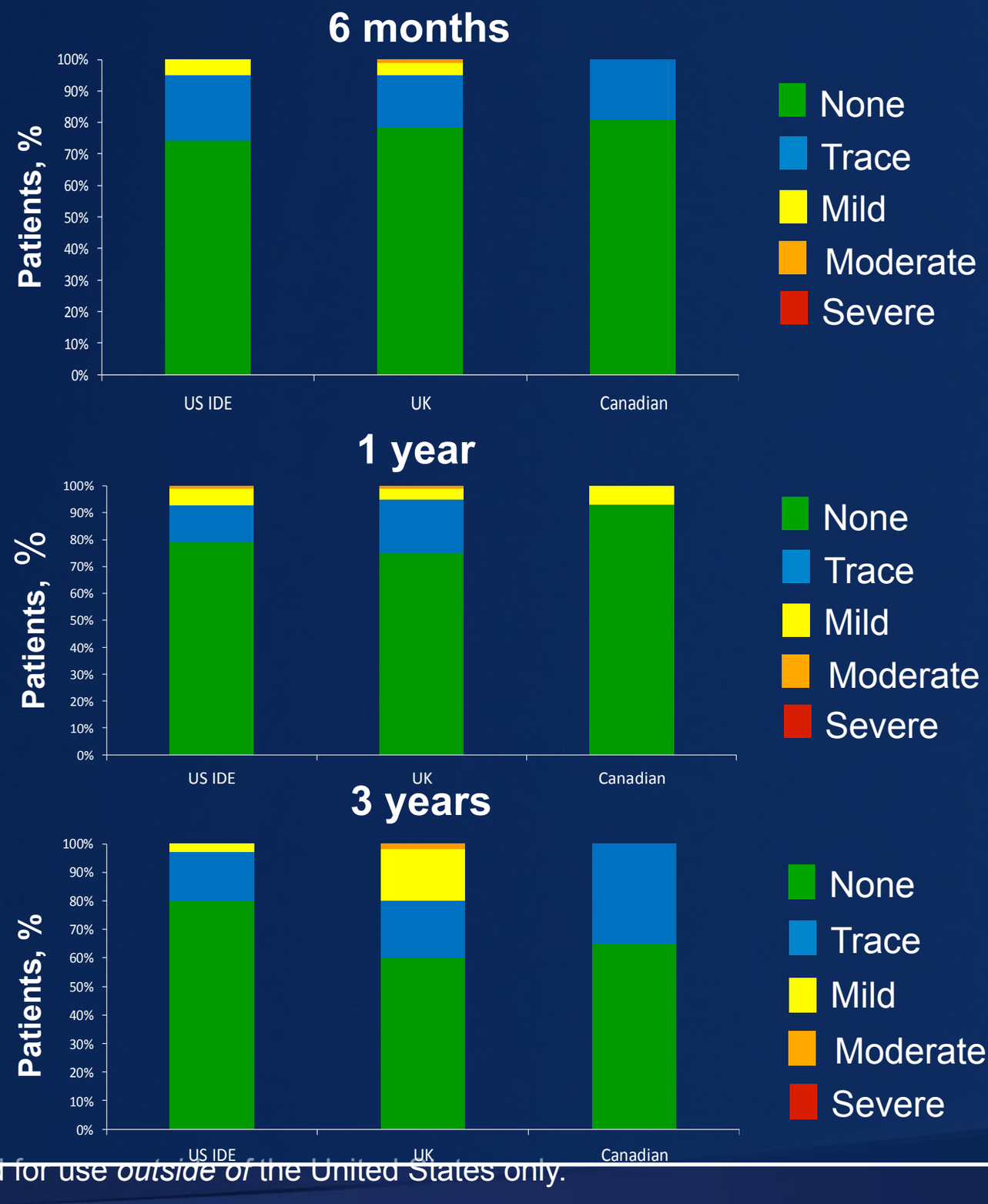




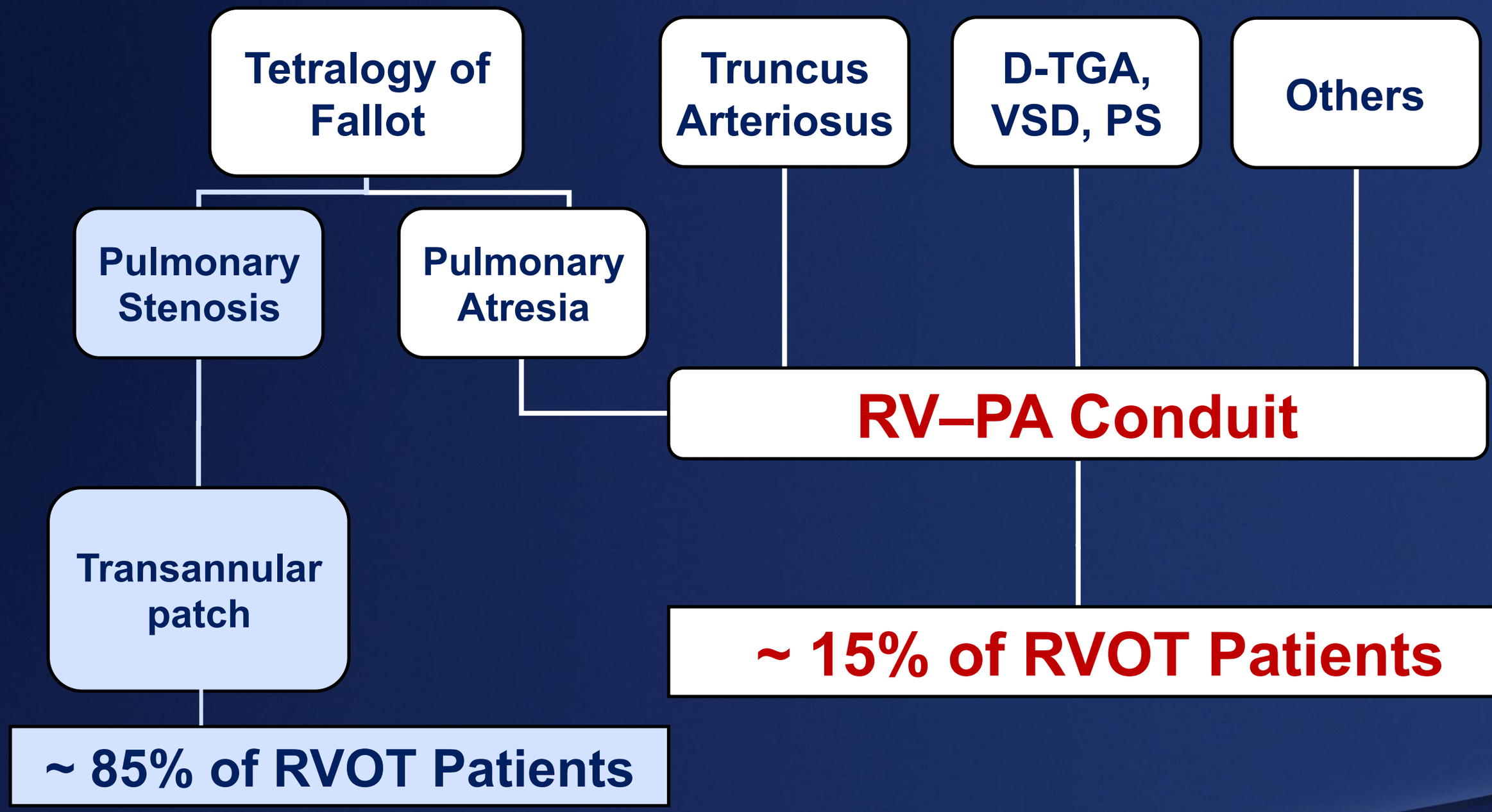


Long-term Outcomes

Pulmonary Valve Competence by Echocardiography



Congenital Heart Defects

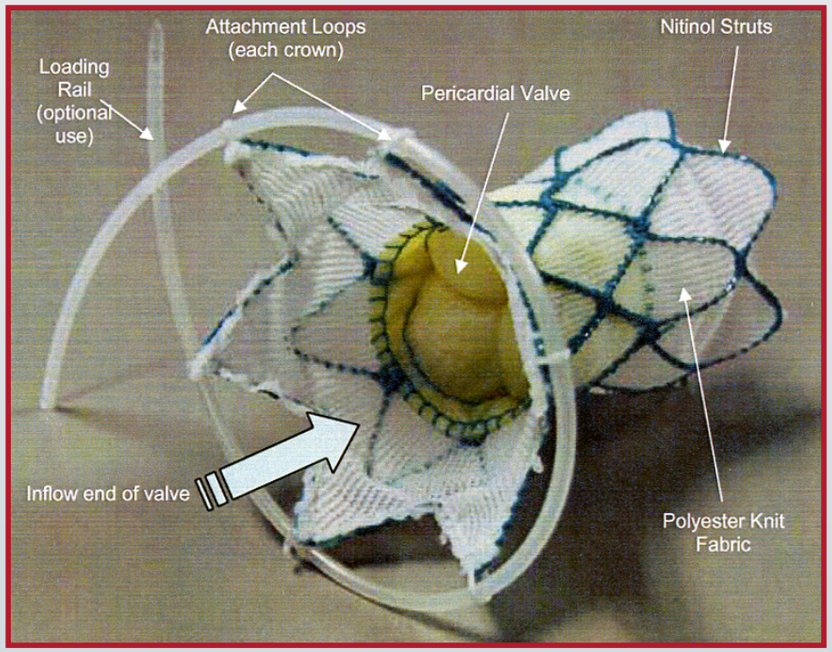


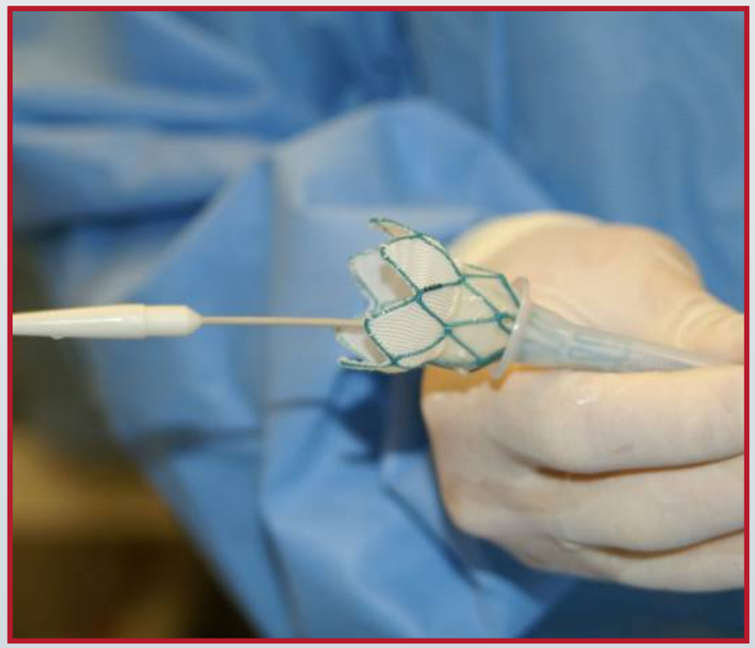
MELODY™ TPV
Post-Approval Study

Percutaneous pulmonary valve replacement

- Challenge is the dilated native RVOT and the landing zone
- Melody and Sapien can be used to complement each other
- Melody up to 22 mm diameter RVOT
- Sapien up to 26 - 27 mm diameter RVOT
- Larger RVOTs >28 mm remain a problem

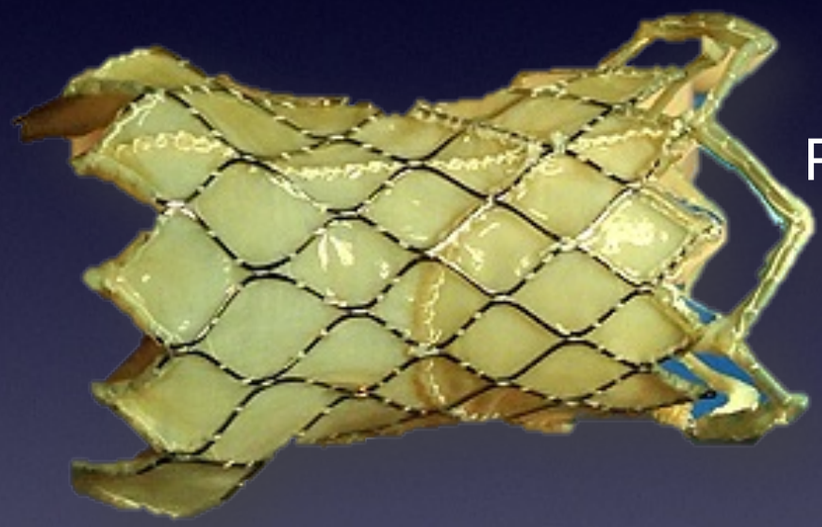
Native Outflow Tract Transcatheter Pulmonary Valve





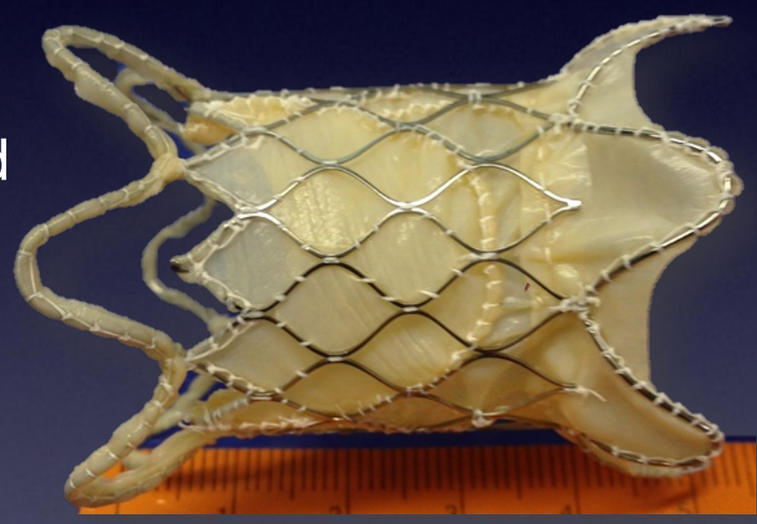
First-in-man-implantation of a novel percutaneous valve: a new approach to medical device development
Schievano S, Taylor AM, Capelli C, Coats L, Walker F, Lurz P, Nordmeyer J, Wright S, Khambadkone S, Tsang V, Carminati M, Bonhoeffer P.
EuroIntervention. 2010 Jan;5(6):745-50.

Percutaneous valve options: New arrival



Porcine pericardial tissue sutured

to the multilevel nitinol frame



Venus P-valve (Venus Medtech)

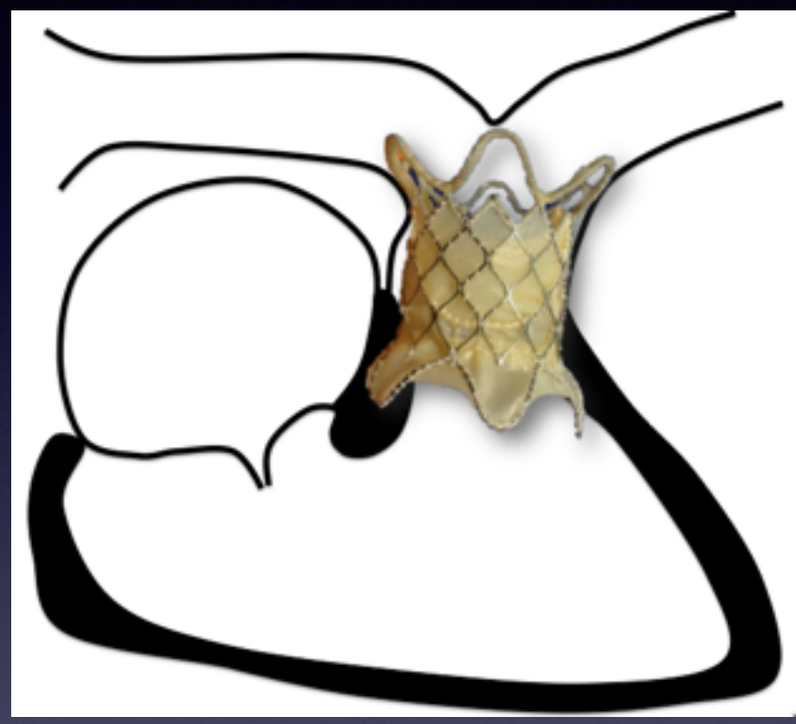
Evelina London

Guy's and St Thomas' NHS
NHS Foundation Trust

Venus P-valve

Patient selection

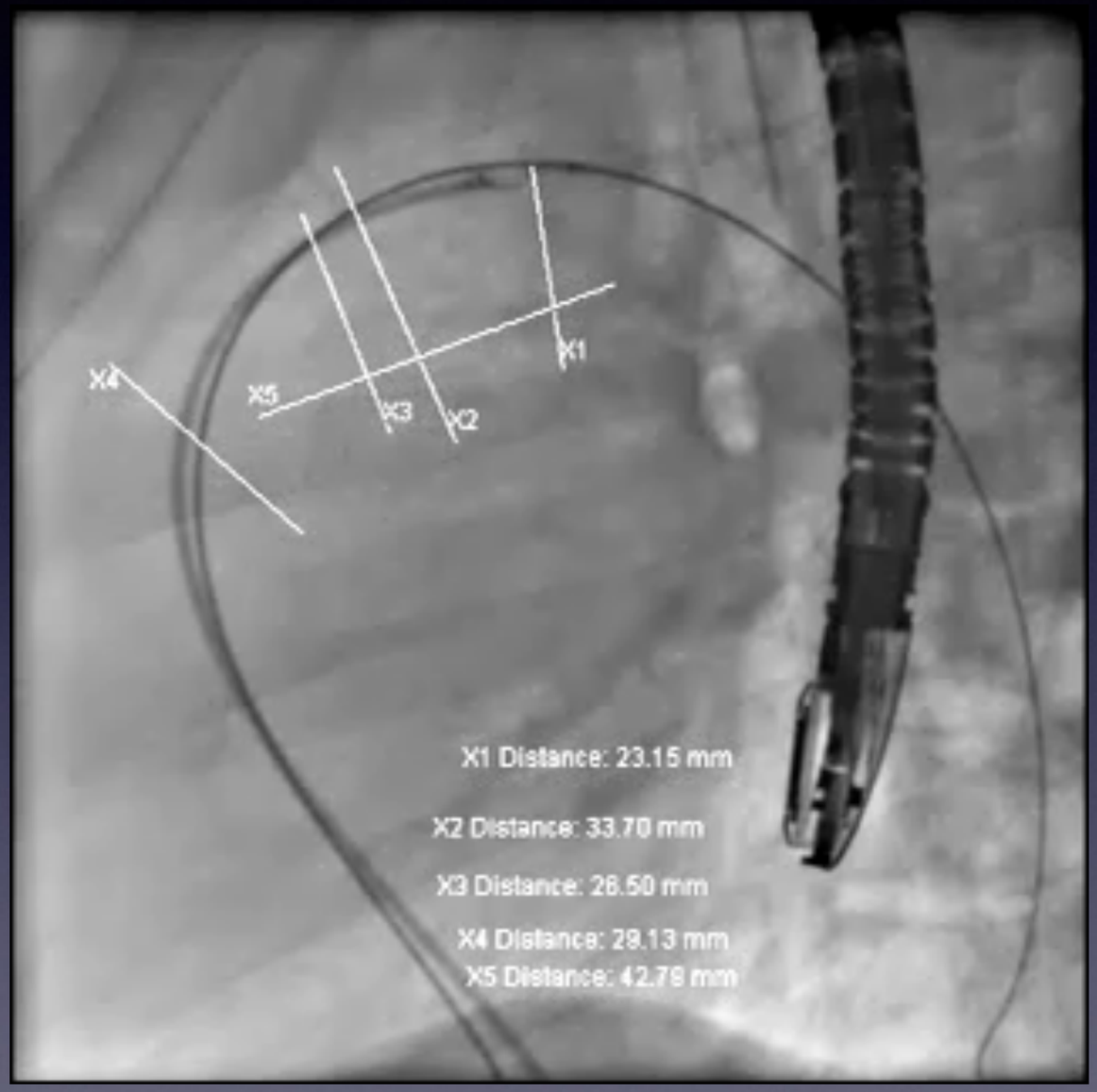
- Post tetralogy of Fallot repair
- Weight > 30 kg
- Symptoms related to pulmonary regurgitation
- Moderate to severe PR (MRI criteria for valve implantation)
- (RVEF < 45%, PRRF > 40%, RVEDV >150 ml/$m^{2)}$

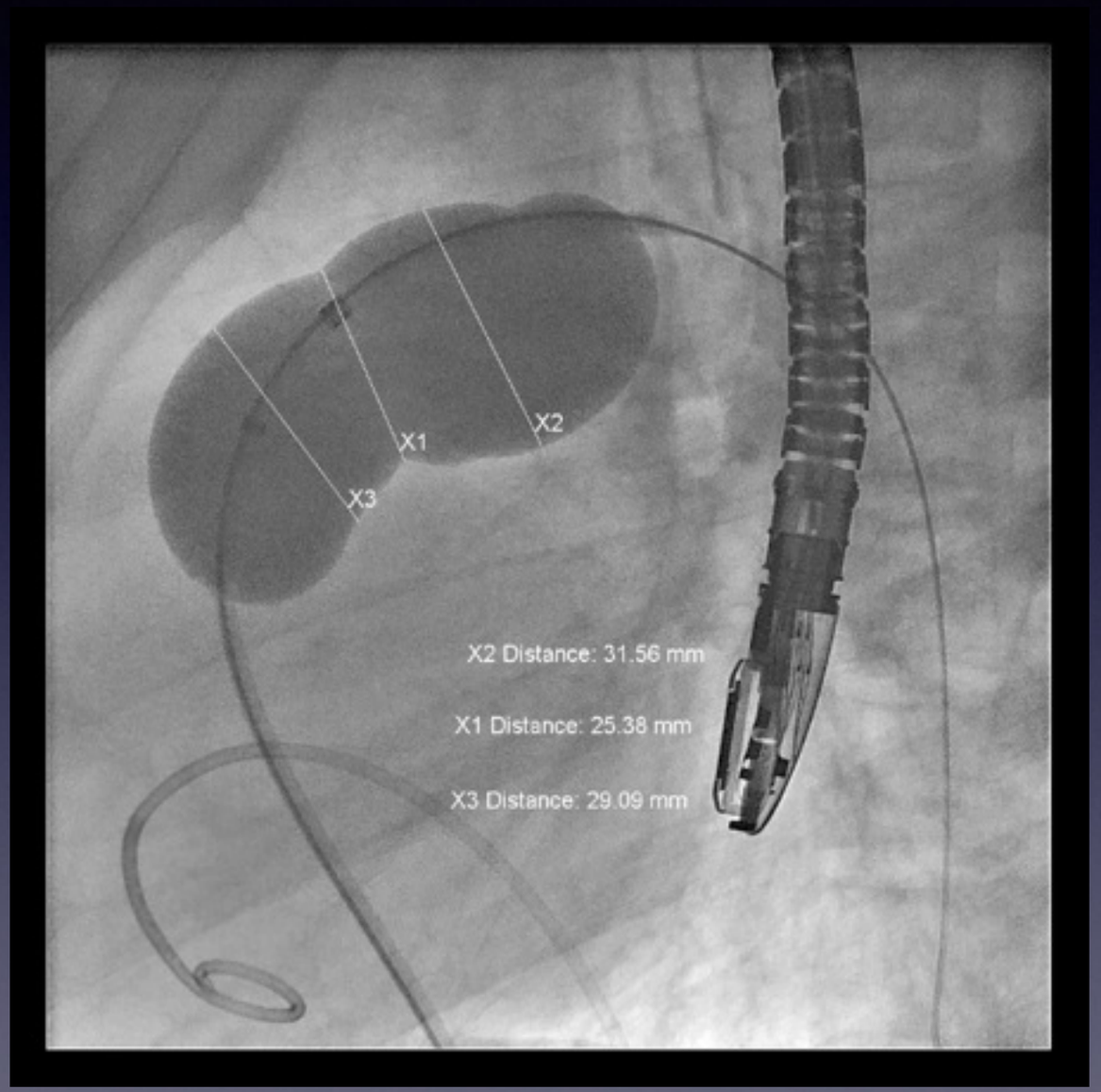


Evelina London

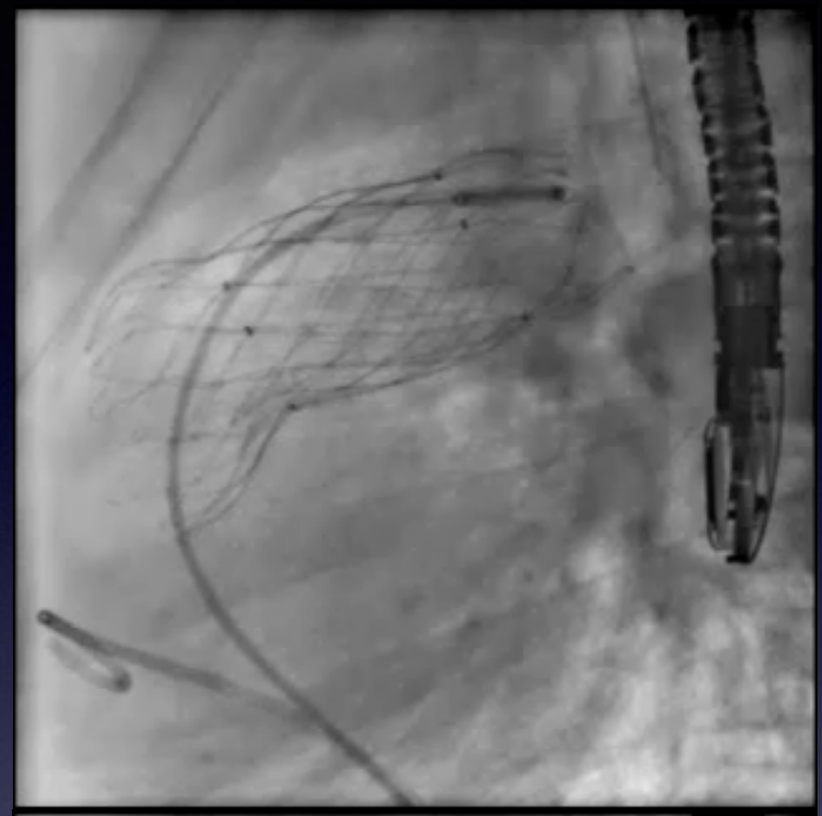
Guy's and St Thomas' NHS
NHS Foundation Trust

Venus P-valve implantation
Balloon interrogation





Venus P-valve implantation
Angiogram after implantation



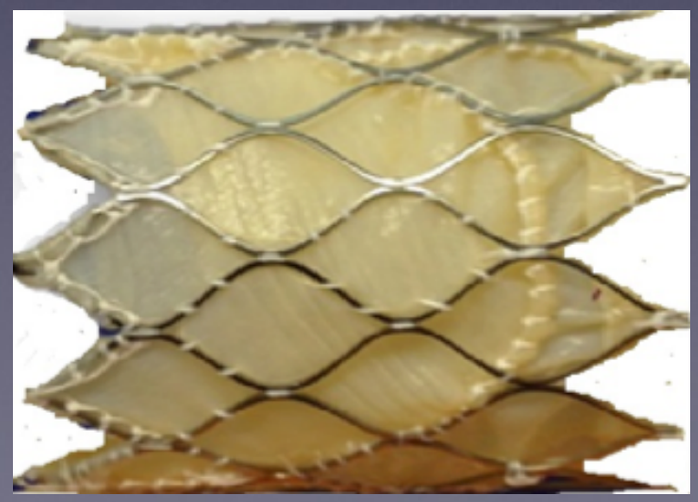
Venus P-valve

- Venus P-valve available up to 34 mm diameter (36 mm being evaluated)

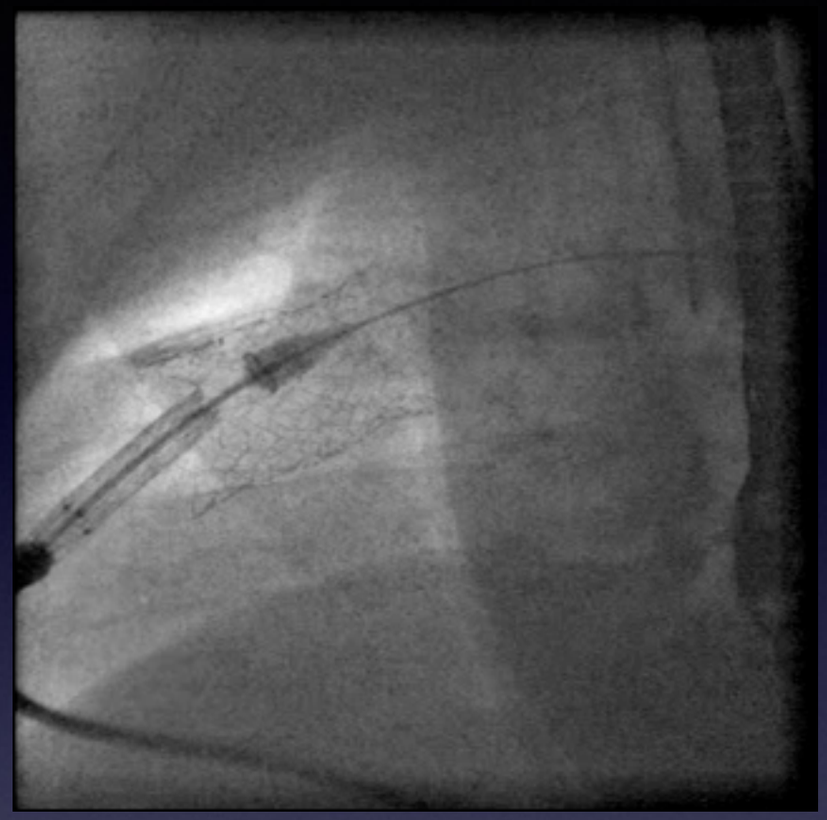
- Suitable for native RVOT/MPA up 31-32 mm diameter

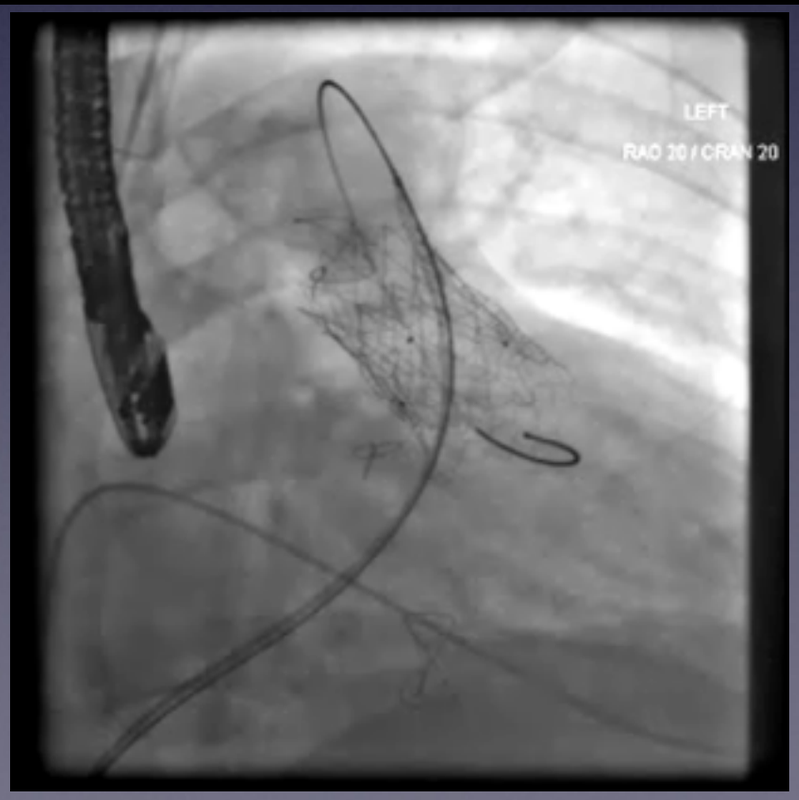
- What about pre-stented conduits?

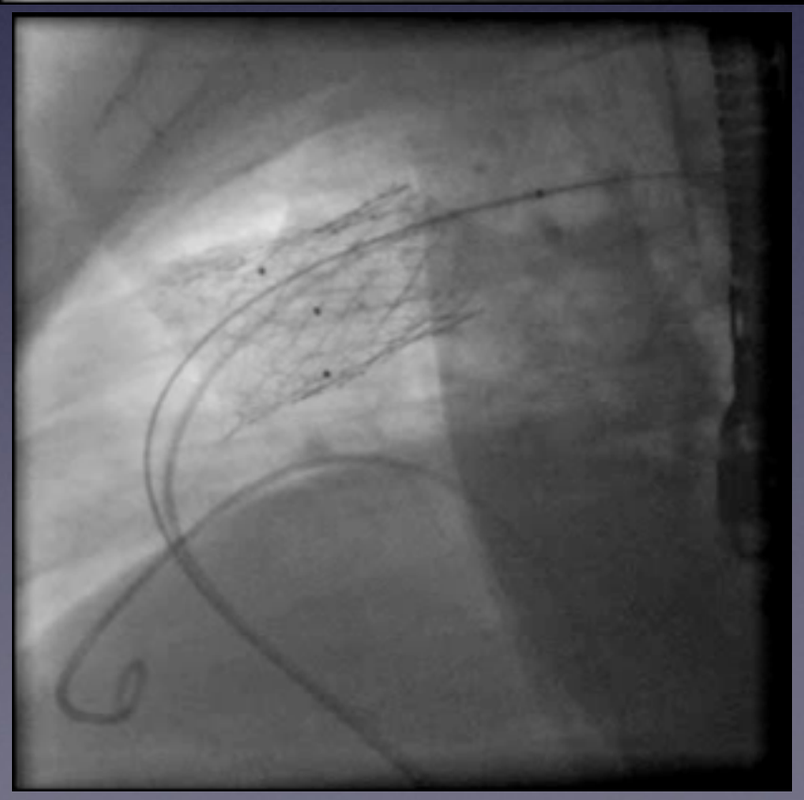
- With straight Venus P-valve, it is possible to implant in conduits



Pre-stented RVOT/MPA
28 mm mid and 30 mm proximal stent diameter







Venus P-valve experience
44 cases

City/Country	N	Hospital	Program Leader
Shanghai, China	10	Fudan University Zhongshan Hospital	Dr. Junbo Ge
Beijing, China	8	Fuwai Hospital	Dr. Shengshou Hu
Chengdu, China	3	West China Hospital, Sichuan University	Dr. Mao Chen
Shanghai, China	3	Shanghai Chest Hospital	Dr. Weiyi Fang
London, UK	3	Evelina Children's Hospital	Dr. Shakeel A Qureshi
Hanoi, Vietnam	1	Hanoi Medical University Hospital	Dr. Nguyen Lan Hieu
Bangkok, Thailannd	8	Queen Sirikit National Institute of Child Health	Dr. Worakan Promphan
Jakarta, Indonesia	1	Harapan Kita	Dr. Indriwanto Sakidjan
Kochi,India	2	Amrita Institute of Medical Sciences	Dr. Raman Krishna Kumar
Chennai, India	5	The Madras Medical Mission	Dr. K. Sivakumar

- 1 recent death of a patient 4 months after Venus valve in China. Cause unknown
- 1 sheath split (Bangkok). Needed surgery
- 1 proximal migration of borderline size valve (Cochin). Valve secured surgically
- 1 other proximal migration (Bangkok) - mild TR, managed conservatively

New Transcatheter Pulmonary Valve for native RVOT

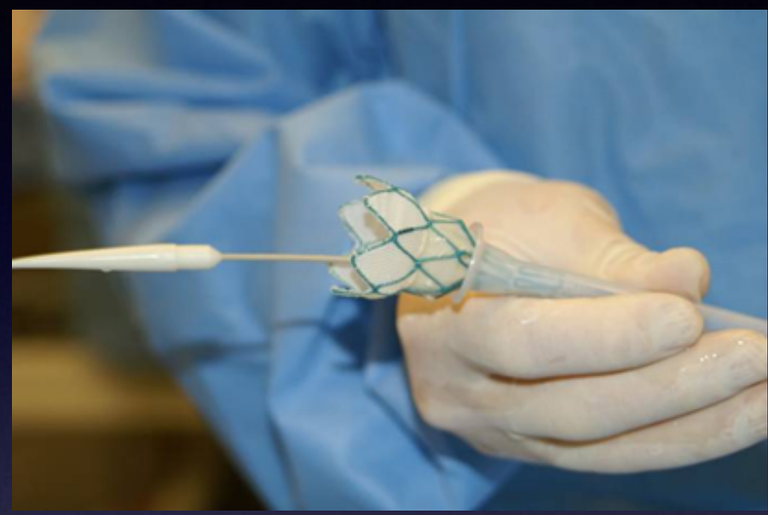
- Research clinical study underway in North America

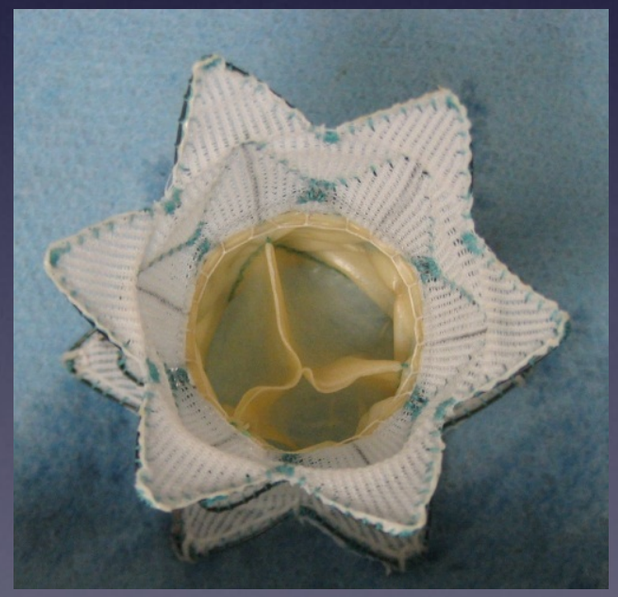
- Non-randomised feasibility study

- 20 pts planned and to be followed up for 5 years

- Valve made of porcine pericardium, valve mounted on self-expanding stent

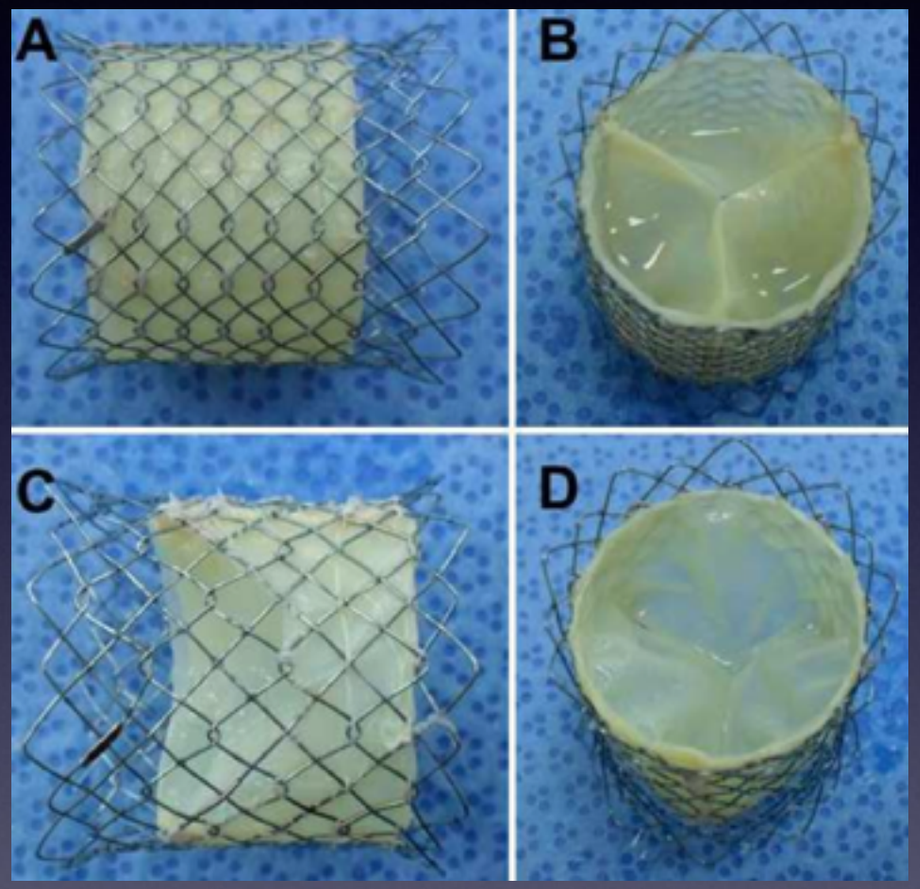
- 25 Fr profile





Future developments

- Experimental study of 12 sheep
- Valve made from nitinol stent and porcine pericardium
- Treated with alpha-galactosidase, glutaraldehyde, and glycine after decellularization
- Valve delivered through 18 Fr sheath
- Valve flared at each end, 4mm larger than the straight section



Gi Beom Kim et al,Seoul, 2014

Future developments

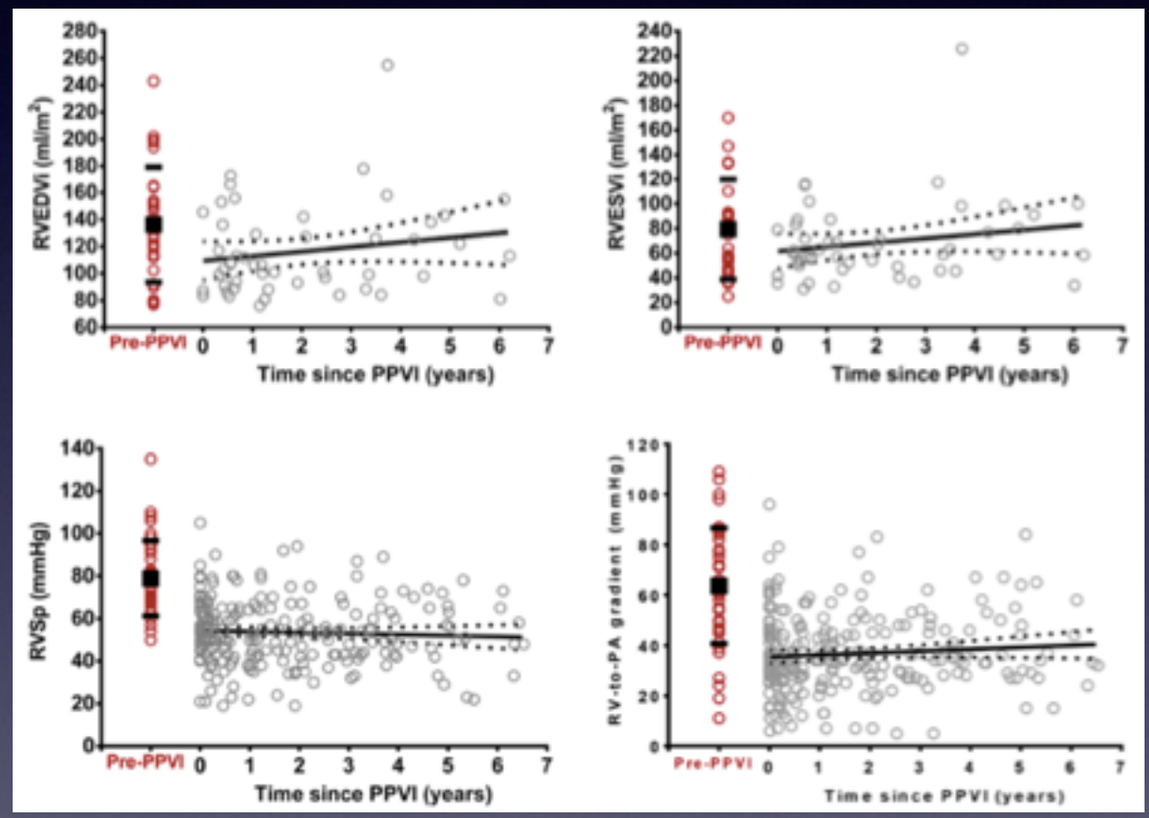
- 24mm valve in 7 sheep and 26mm in 5 sheep
- Valve in good position in 8/12 sheep 8 sheep were sacrificed after > 6months
- 5/6 had no PR on echo before sacrifice, 2 had trivial PR and 1 mild PR
- 5/6 sheep with optimal position of the valve showed well preserved valve and no calcification
- 1 sheep died at 3 months - valve endothelialised
- In 2 sheep valve was implanted in RVOT or MPA
- Valve malfunction with leaflets sticking to the stent
- Long term durability?

Gi Beom Kim et al,Seoul, 2014

Future developments

Early valve replacement

- 51 pts followed up for 0.9 - 7 years after Melody valve
- Freedom from any re-intervention was 87% at 3 yrs and 68% at 5 yrs
- Freedom from reoperation was 90% at 5 yrs
- Younger pts showed a trend towards reduction in RVEDVi/LVEDVi ratio and improvement in RVEF at 5 years, on MRI



Borik et al, 2015

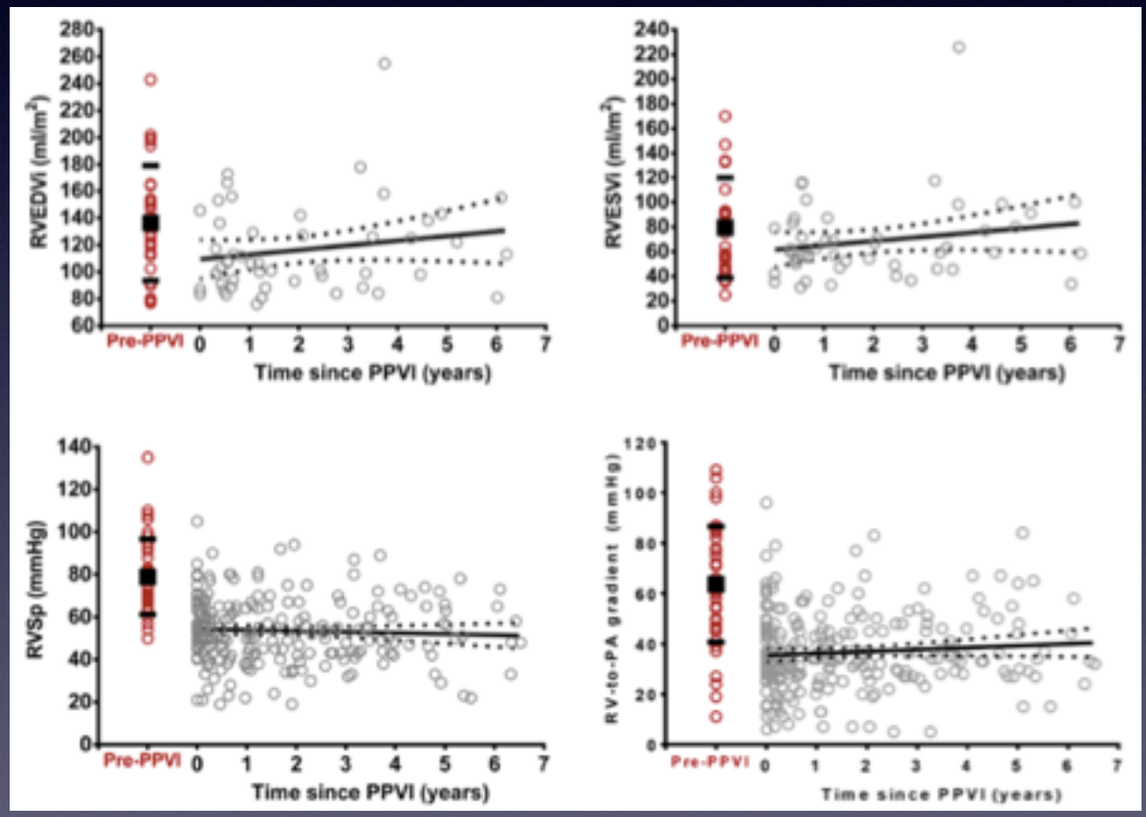
Future developments

Early valve replacement

- Younger pts showed a trend towards reduction in RVEDVi/LVEDVi ratio and improvement in RVEF at 5 years, on MRI

- Younger age at PPVI was associated with improved biventricular function and aerobic capacity and a lower RV size

- There is likely to be a trend towards considering PPVI well before RVEDVi has reached 150 ml/m2



Borik et al, 2015

Venus P-valve

- Venus P-valve is an important development for percutaneous pulmonary valve implantation

- It can deal with larger native RVOTs up to 30 - 32mm (with valves of up to 36 mm sizes)

- Early experience is encouraging

- European study is planned

- Other valves are being developed and tested in the near future

Venus P-valve

- Venus P-valve is an important development for percutaneous pulmonary valve implantation

- Self-expanding design makes it challenging to ensure accurate size is implanted

- It can deal with larger native RVOTs up to 30 - 32mm (with valves of up to 36 mm sizes)

- Early experience is encouraging

- European study is planned

Venus P-valve

- Venus P-valve has expanded the horizons for dealing with native RVOTs with pulmonary regurgitation

- Prestenting has been considered as a contraindication to Venus P-valve

- Straight Venus P-valve has been used in 5 cases (especially designed without distal or proximal flares)

- Has been effective in these patients

- Some of these patients would have been suitable for Melody or Sapien valves

- Manipulating the carrot through the prior stent may be difficult

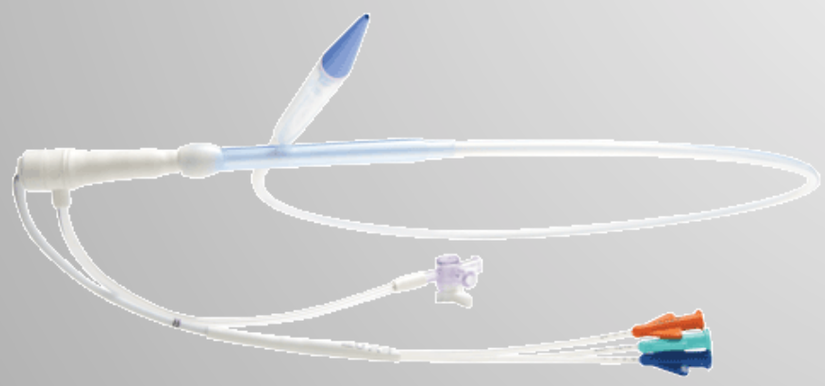
Disadvantages of Venus P-valve

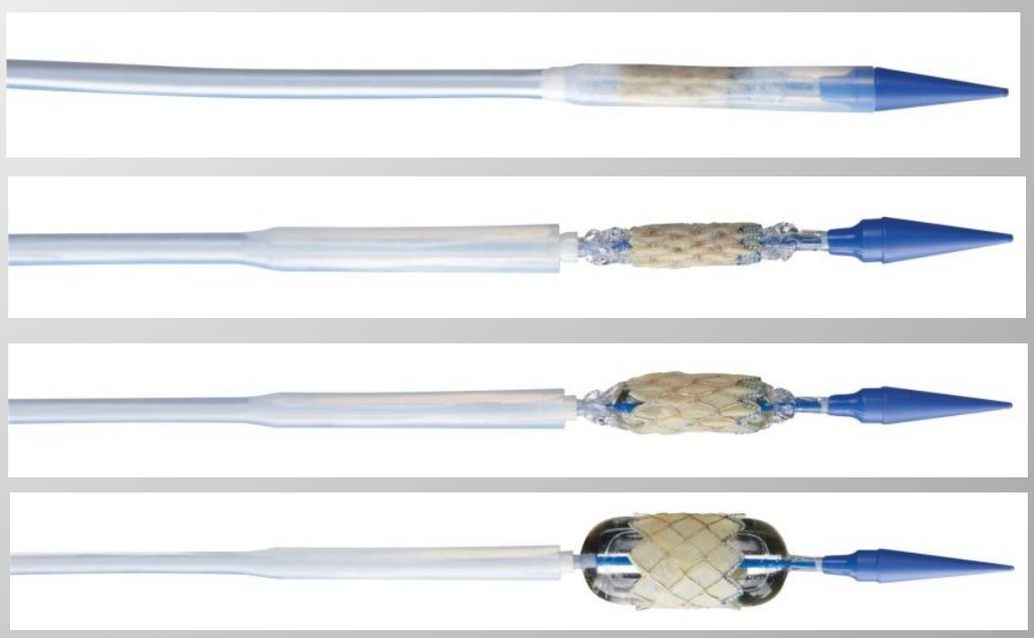
- Very early experimental and clinical study
- Small number of patients evaluated so far
- Stenosed calcified conduits are a problem but valve can be implanted in these potentially
- Short duration of follow up
- RVOT/MPA size of 31-32 mm currently
- Incidence of fractures, endocarditis and other complications unknown
- Valve function in longer term?

Guy's and St Thomas' NHS
NHS Foundation Trust

Medtronic Ensemble™ Delivery System

- Balloon-In-Balloon delivery system
- Protective sheath covers valve during delivery
- Three balloon sizes: 18, 20, 22mm
- 22Fr size and 100cm length

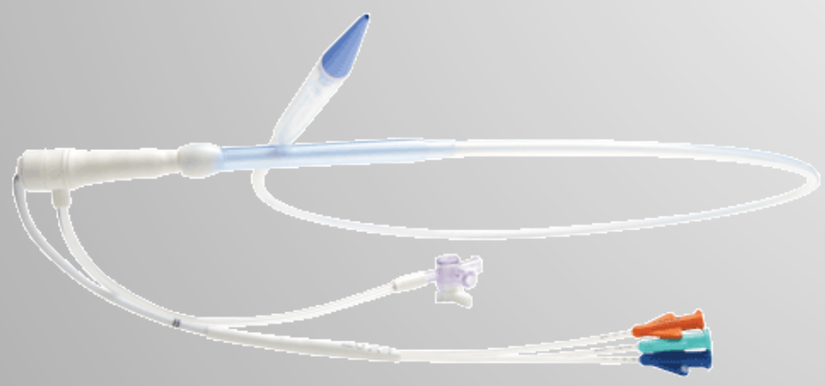


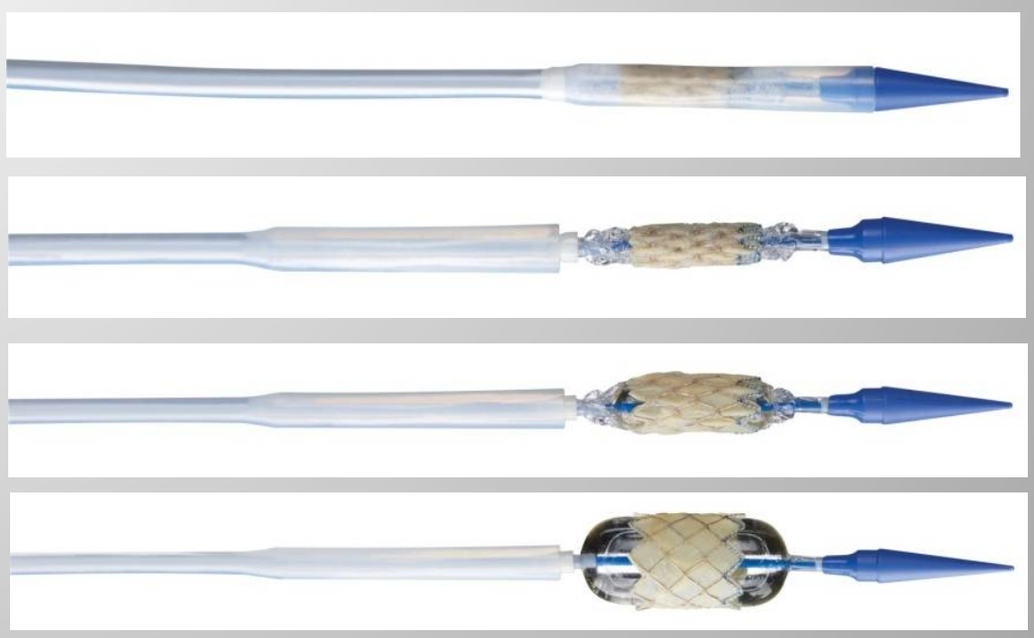


Guy's and St Thomas' NHS
NHS Foundation Trust

Medtronic Ensemble™ Delivery System

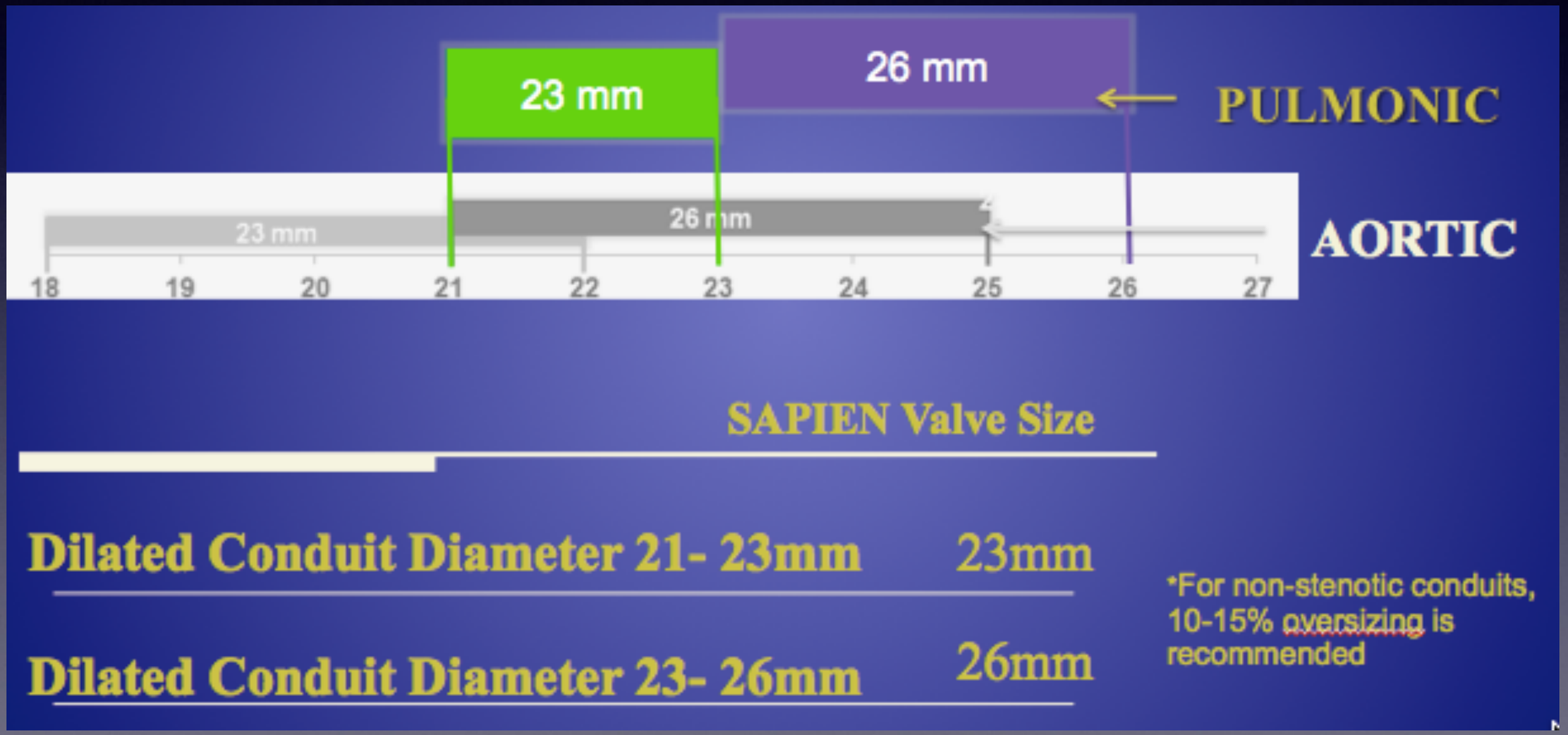
- Balloon-In-Balloon delivery system
- Protective sheath covers valve during delivery
- Three balloon sizes: 18, 20, 22mm
- 22Fr size and 100cm length



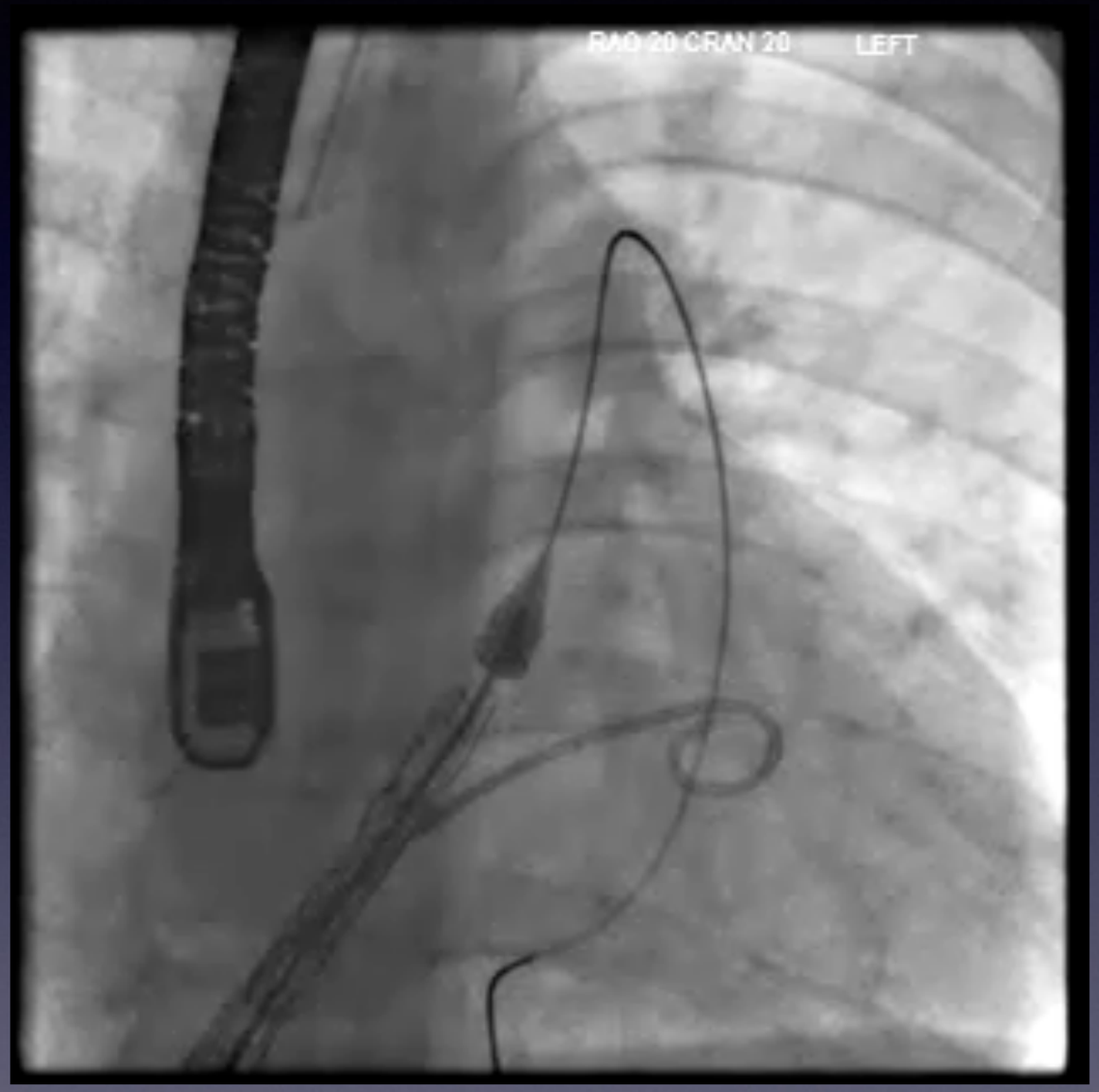


Sapien valve

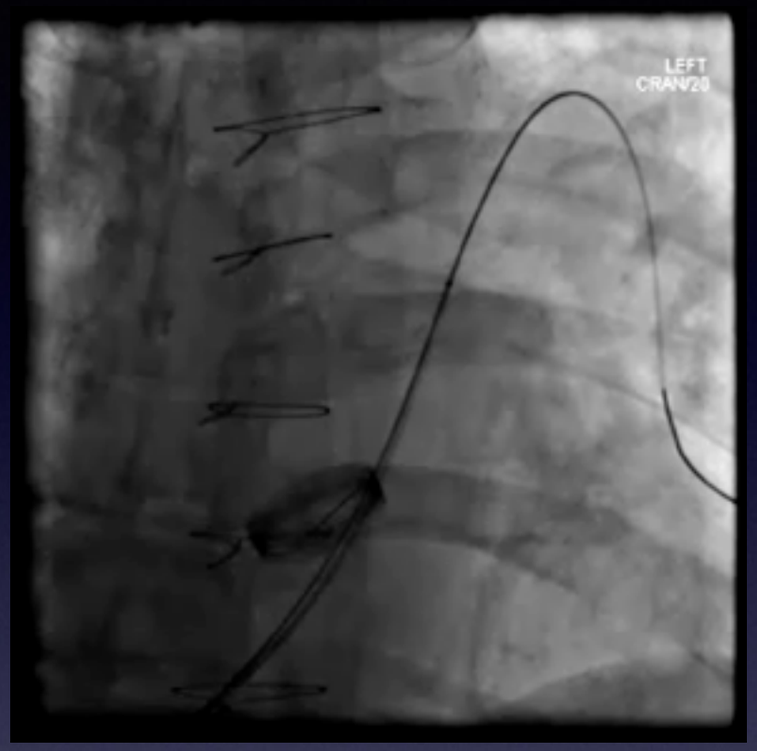
Sizing for Sapien valve

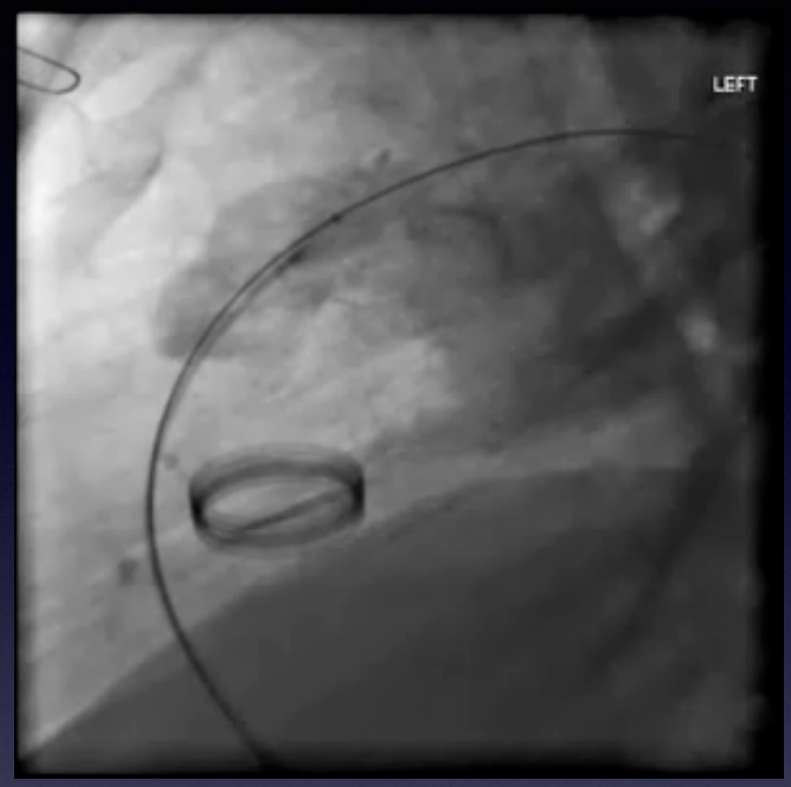


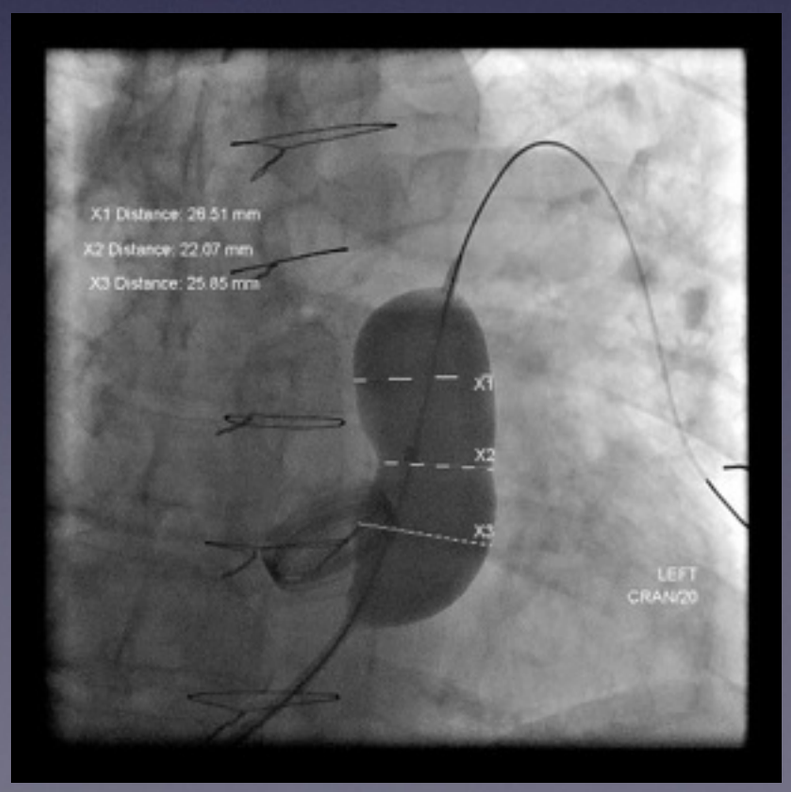
Venus P-valve implantation
Passage of Venus valve (32 mm diameter)



Venus P-valve implantation
ECH





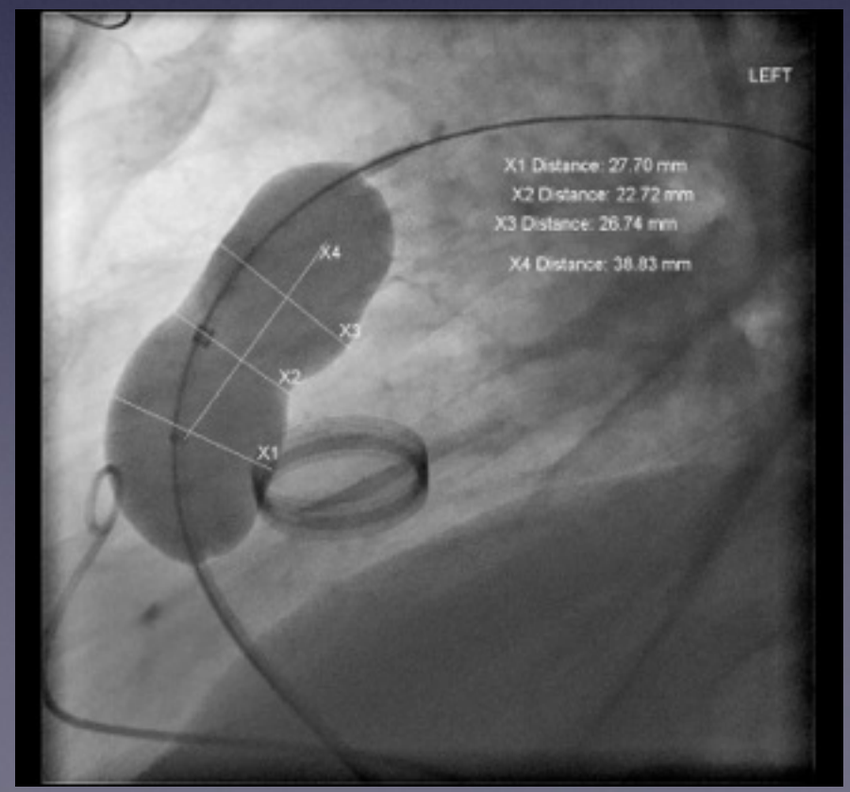


After MPA angio,

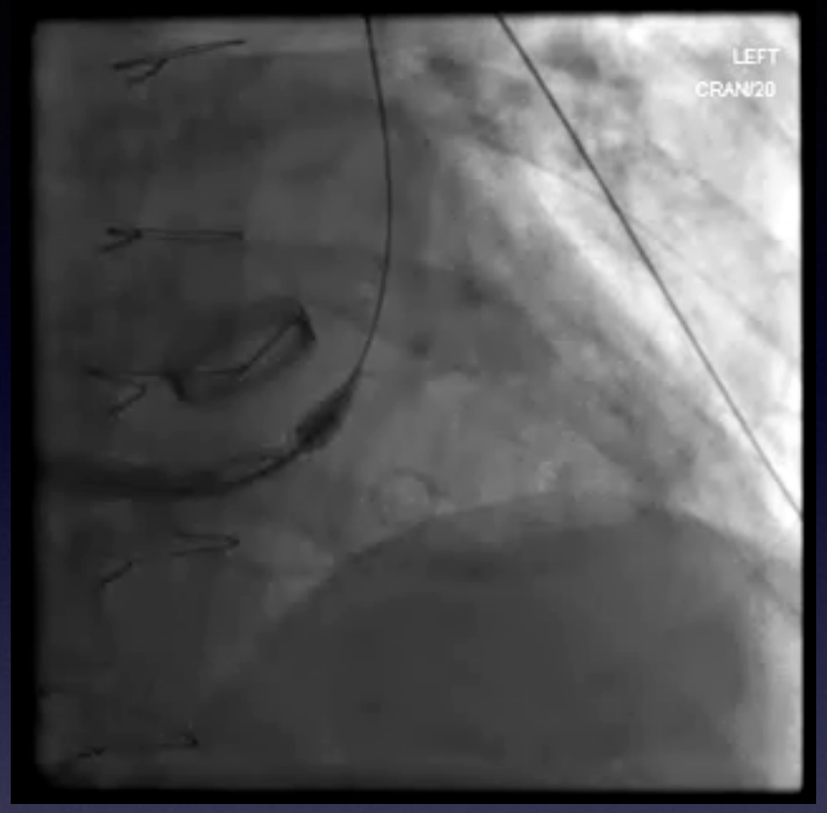
sizing balloon

performed to measure

RVOT/MPA



Venus P-valve implantation ECH

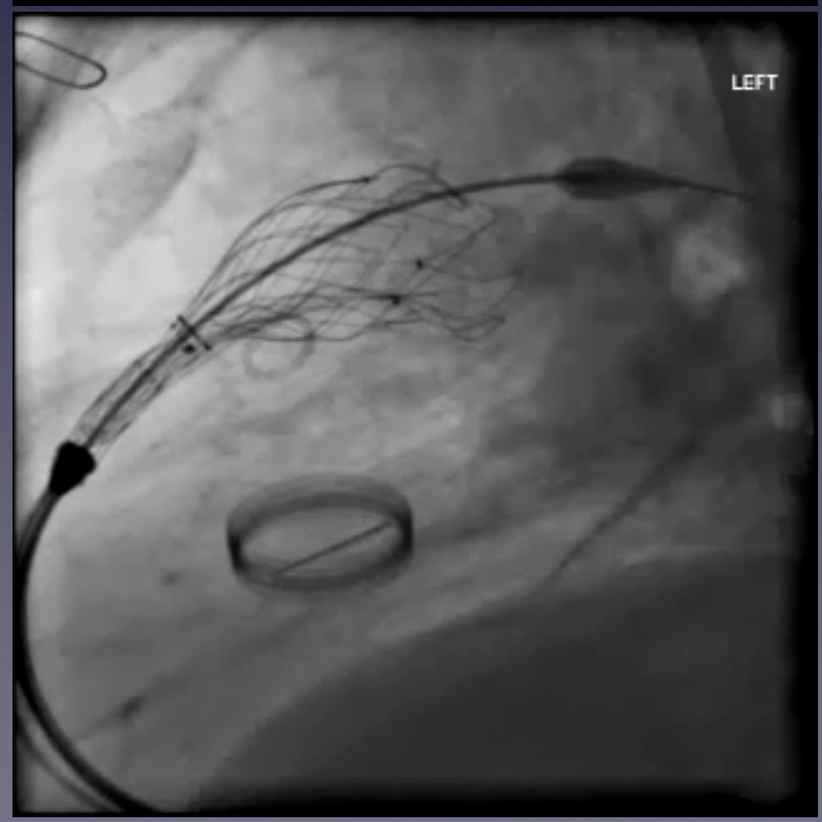


Passing the valve from

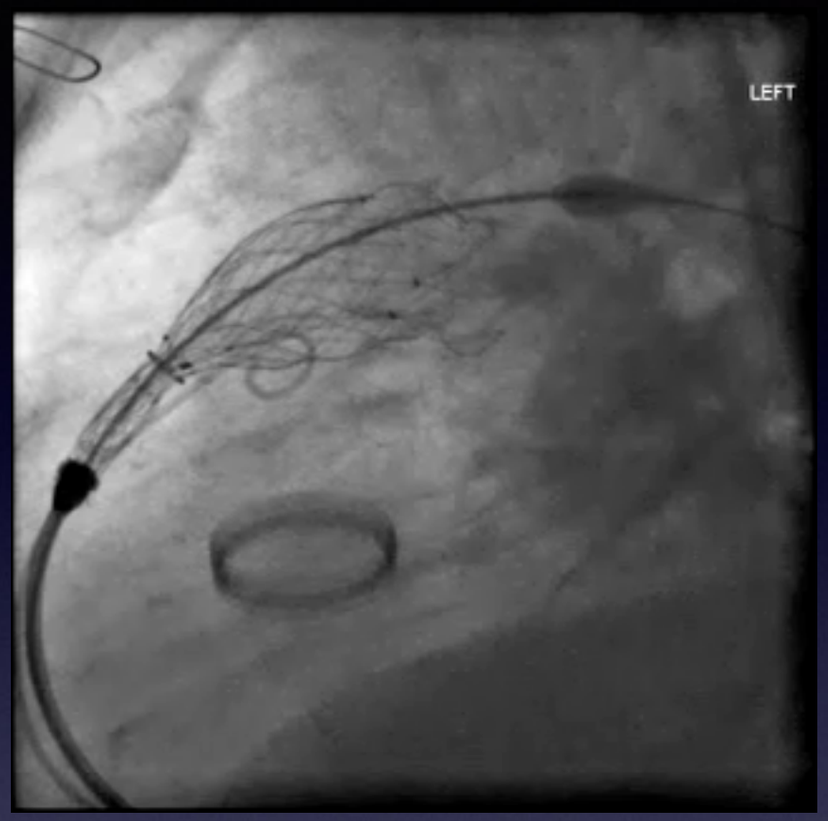
RV to PA can be difficult

Repeated angios needed

to check position of valve

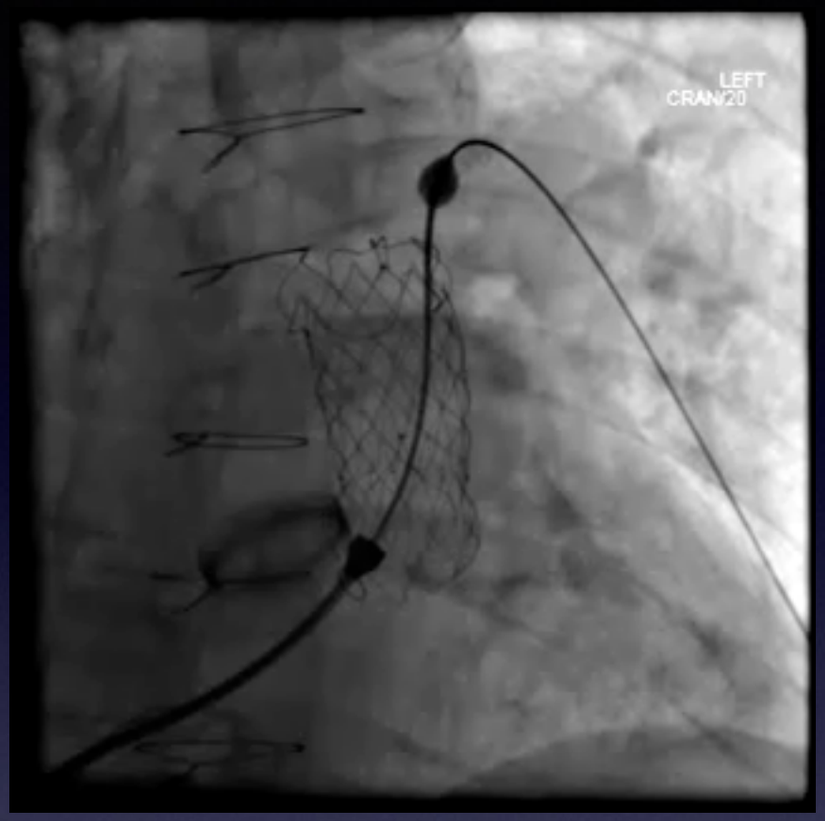


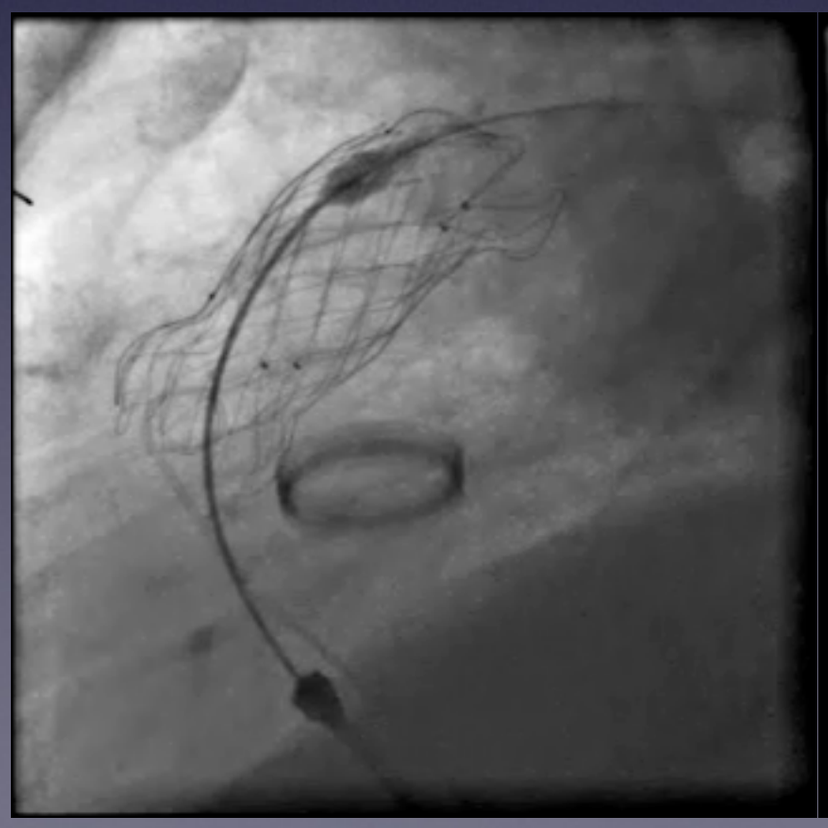
Venus P-valve implantation ECH

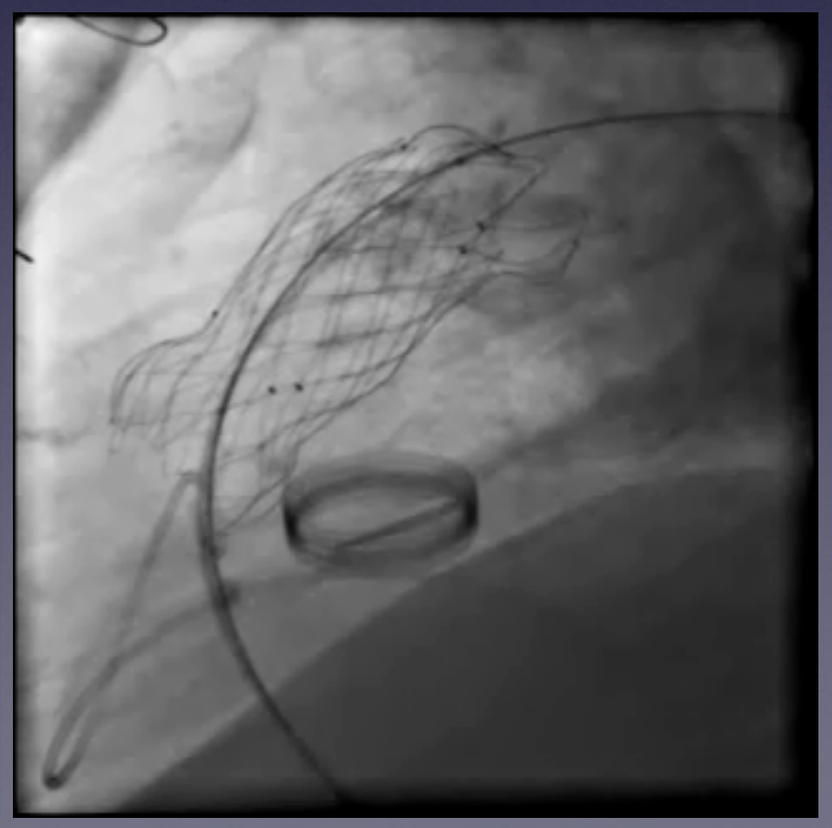


Venus valve full

deployment

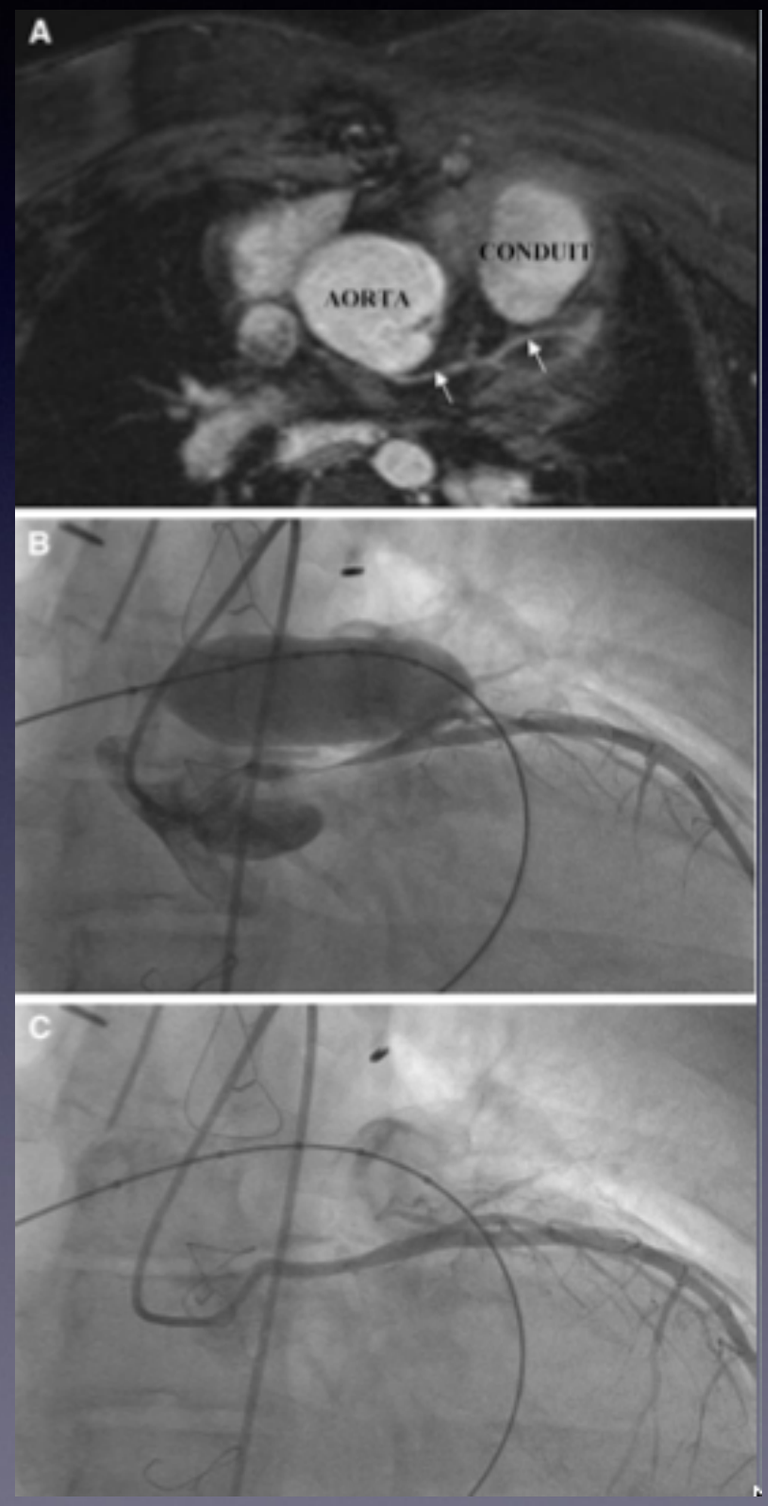






Coronary artery assessment

- This is essential
- Can obtain advanced information from CT or MRI scans also
- Still need to perform coronary angiography at same time as balloon dilation of RVOT



Pulmonary valve implantation

- 2000 - Philipp Bonhoeffer implanted the prototype Melody valve in a 12 year old boy
- 2006 - CE mark and approval in Canada for Melody valve
- 2010 - FDA approval for Melody valve

Conduit Dysfunction
Management

Current Options

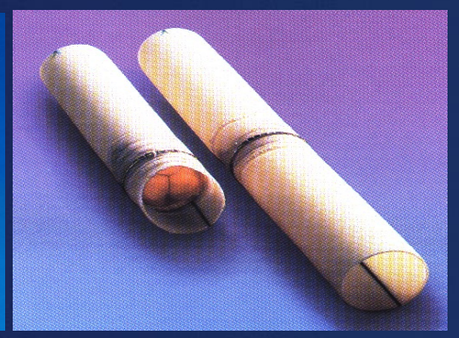
Surgical conduit replacement

- Valved conduits

Homografts

Xenografts

Contegra® PVC

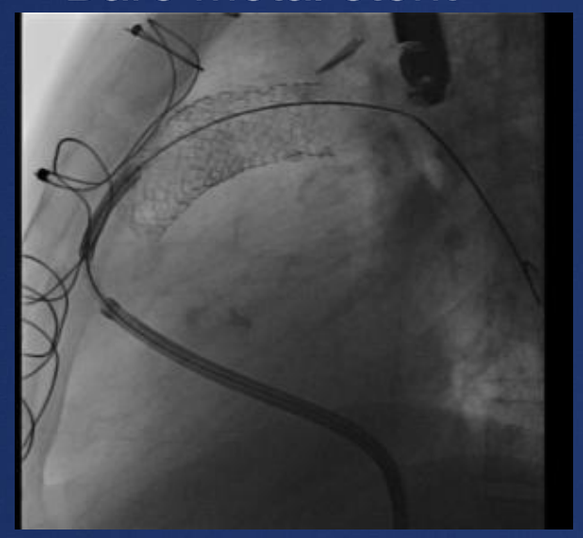


Hancock® Conduit

- Bioprostheses

Transcatheter

- Balloon angioplasty
- Bare metal stent



Pulmonary regurgitation

- Inevitable after transannular patching and pulmonary valvotomy
- Incidence of pulmonary regurgitation 60 – 90%
- Exercise performance reduced and may be related to pulmonary regurgitation
- Progressive RV dilatation
- Cardiomegaly on CXR
- Effort intolerance
- Arrhythmias
- ? Sudden death

Guy's and St Thomas' NHS
NHS Foundation Trust

Introducer sheaths for percutaneous pulmonary valves

Melody introducer:
22 Fr OD

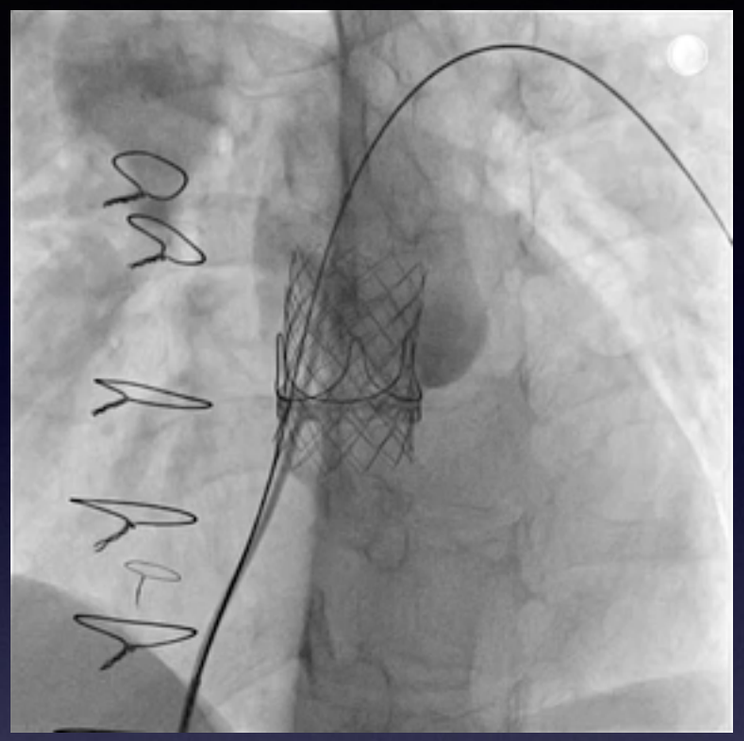
Sapien sheaths:
25 to 28 Fr OD

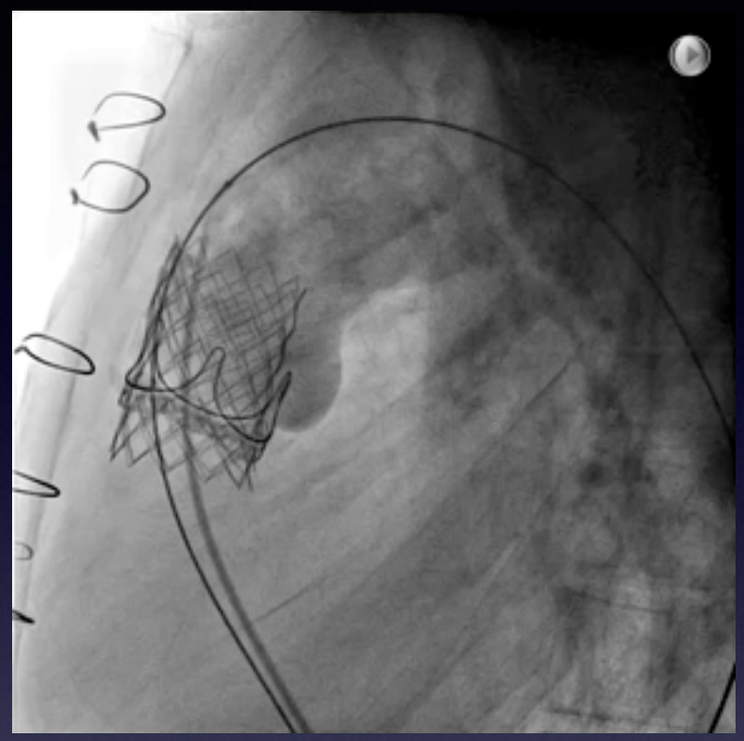
Sheath Set	Internal Diameter	Outside Diameter	Length
23 mm	**22F**	**8.4 mm**	**35 cm**
26 mm	**24F**	**9.2 mm**	**35 cm**

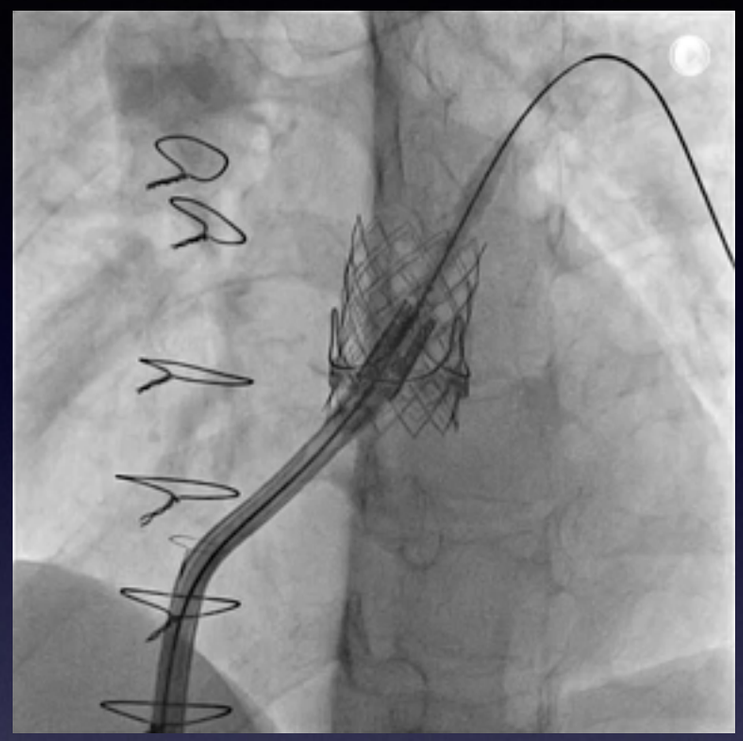
25 F

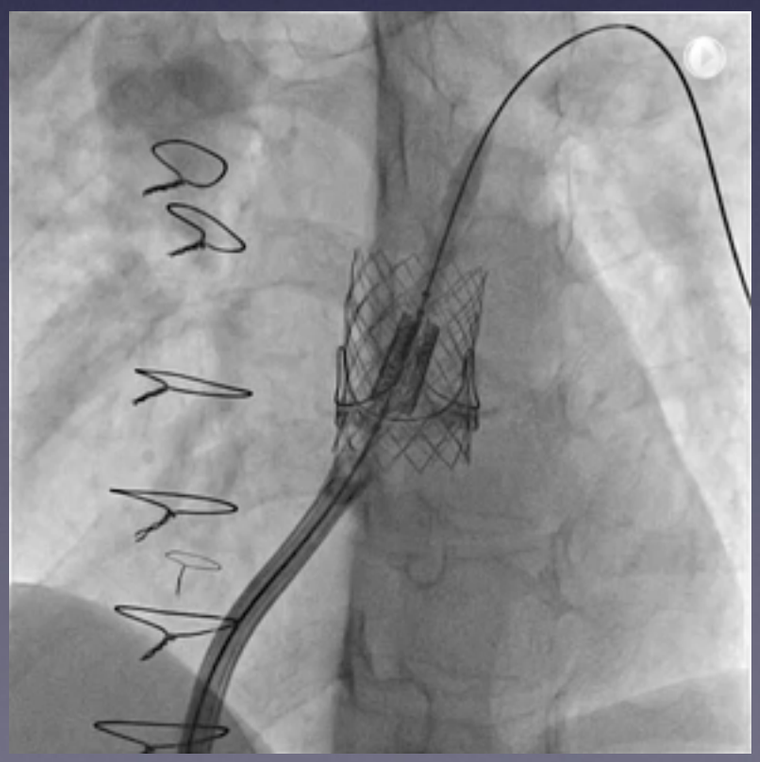
28 F

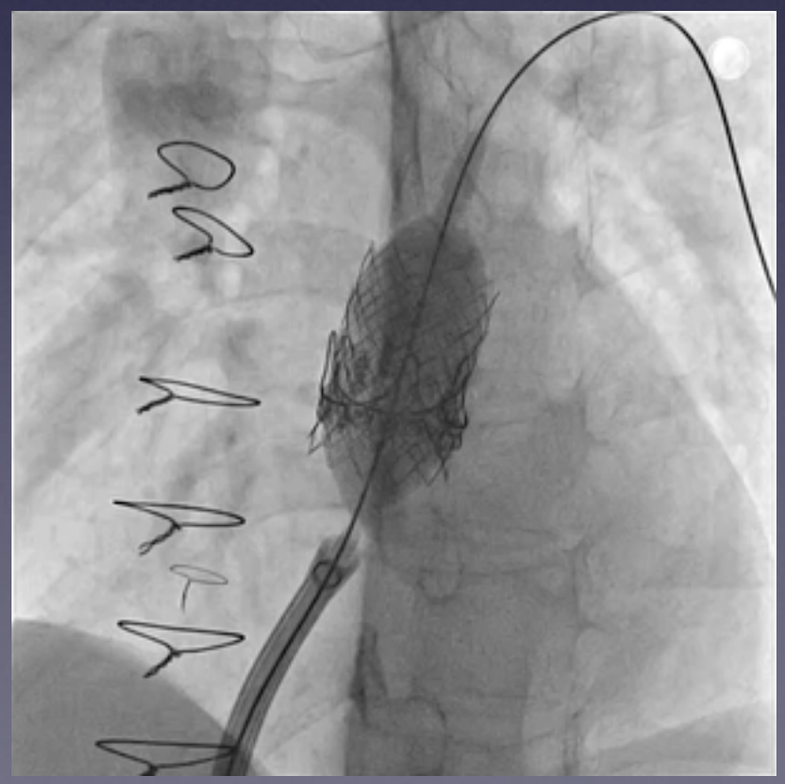
Sapien valve in pulmonary position
Prestenting in a tissue valve with 2 stents

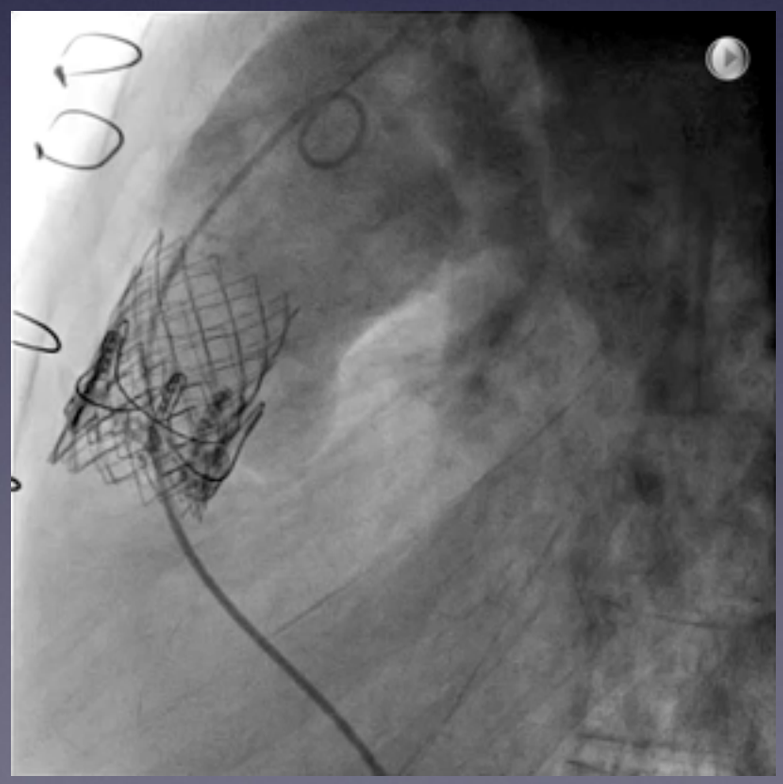




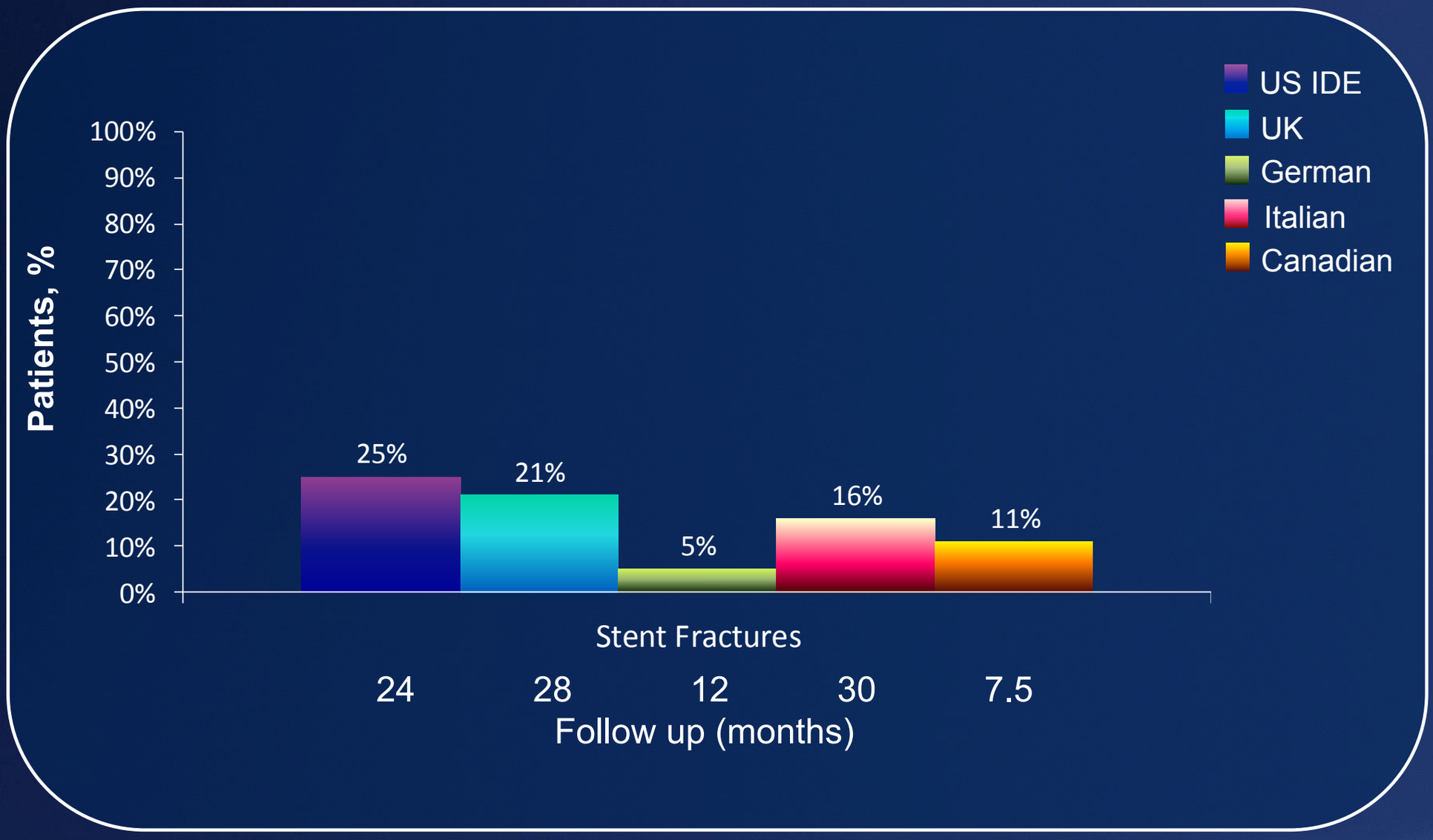








Complications
Stent Fractures (%)



This PowerPoint is intended for use *outside of* the United States only.

May 2014

Melody valve implantation

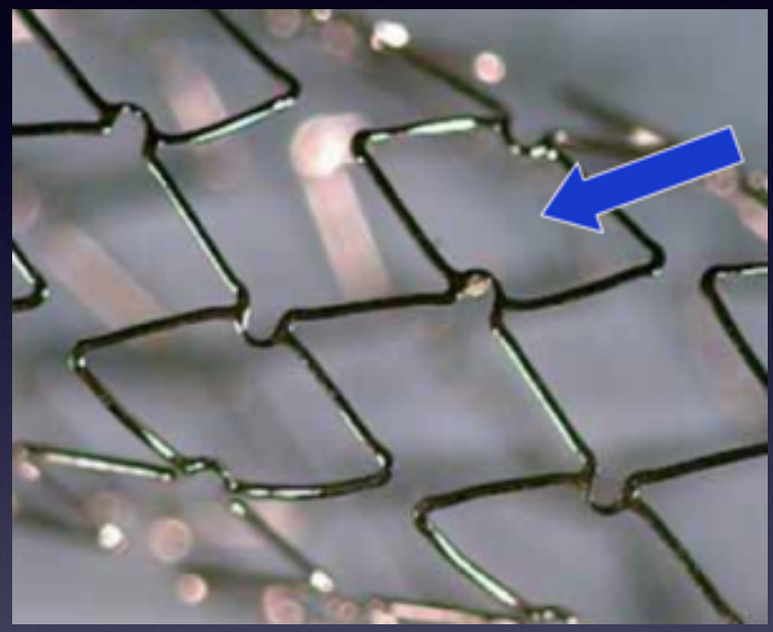
- Most re-interventions in these series were from recurrent RVOT obstruction and were almost always associated with stent fracture
- This highlights the importance of appropriate patient selection, adequate relief of obstruction at the time of Melody® valve implant and the need for measures to prevent or manage stent fractures

Concerns with current percutaneous valves

- Suitability for valves based on:
  - *Diameter of RVOT*
  - *Potential for coronary artery compression*
- Prestenting is essential
- Stent fractures - incidence of about 5-7%
- Incidence of endocarditis

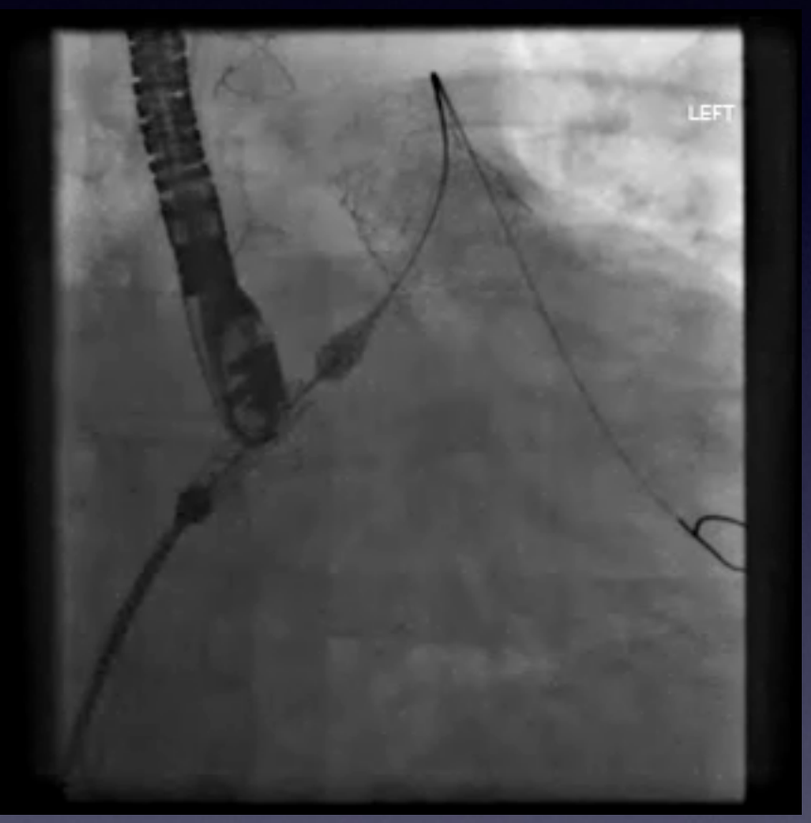
Pre-stented RVOT

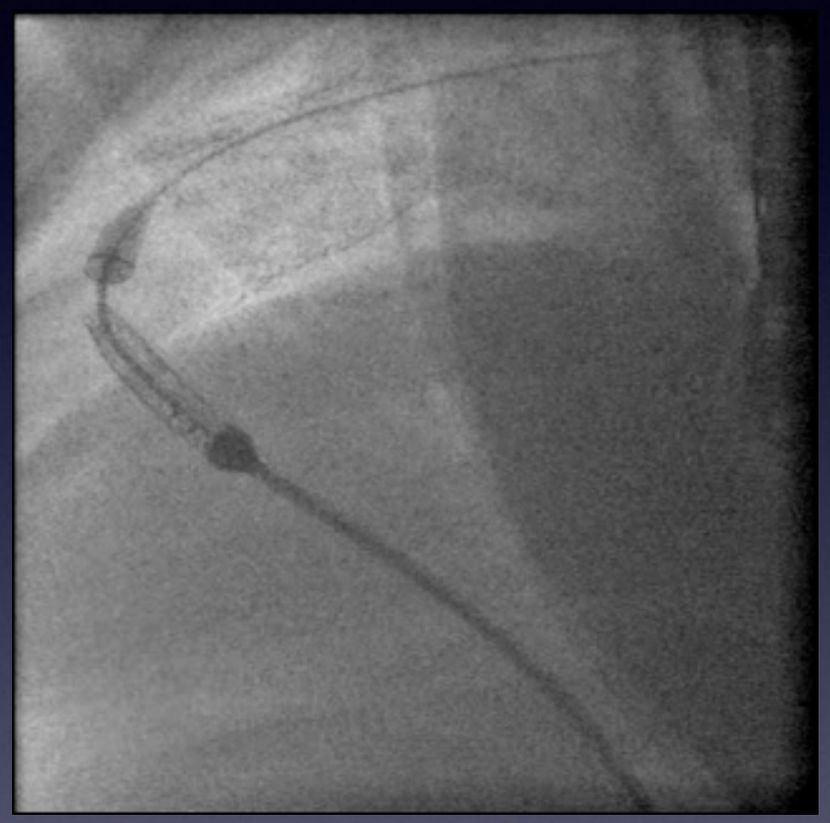
- 25 year old, 140 Kg, previous correction of tetralogy of Fallot
- Developed MPA stenosis near bifurcation
- No LPA or RPA stenosis
- Pre-stented with Andrastent XXL on 30 mm Z-Med
  - Made of cobalt-chromium
  - Hybrid closed and open cell design
  - Can be dilated to 32 mm
- Unsuitable for Edward Sapien XT valve

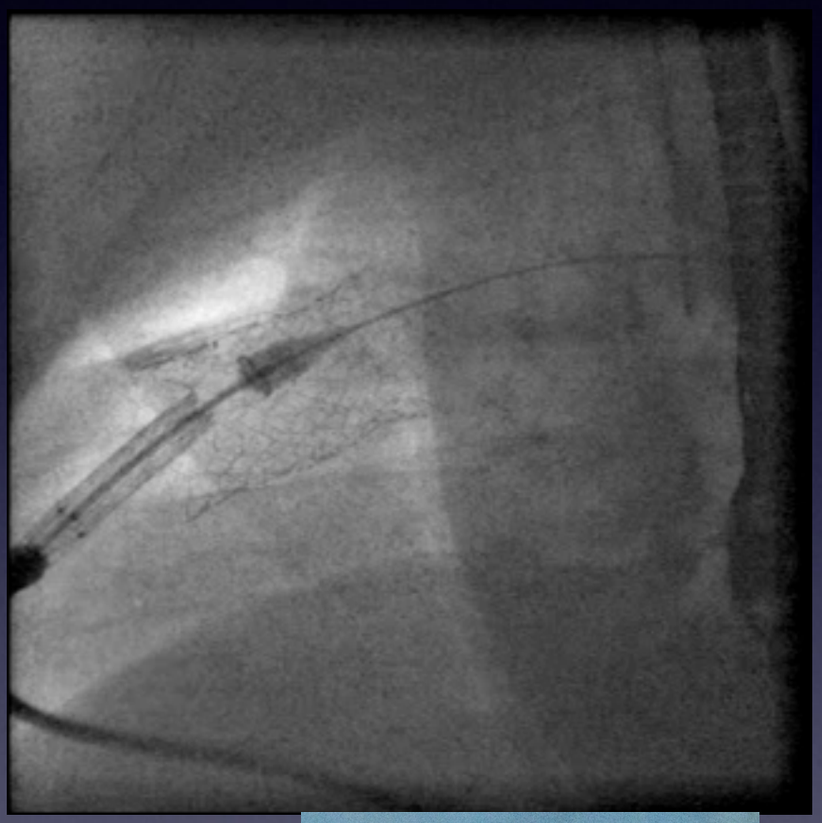


Pre-stented RVOT/MPA

Because of angles of RVOT, it may be difficult to manipulate the carrot of the assembly

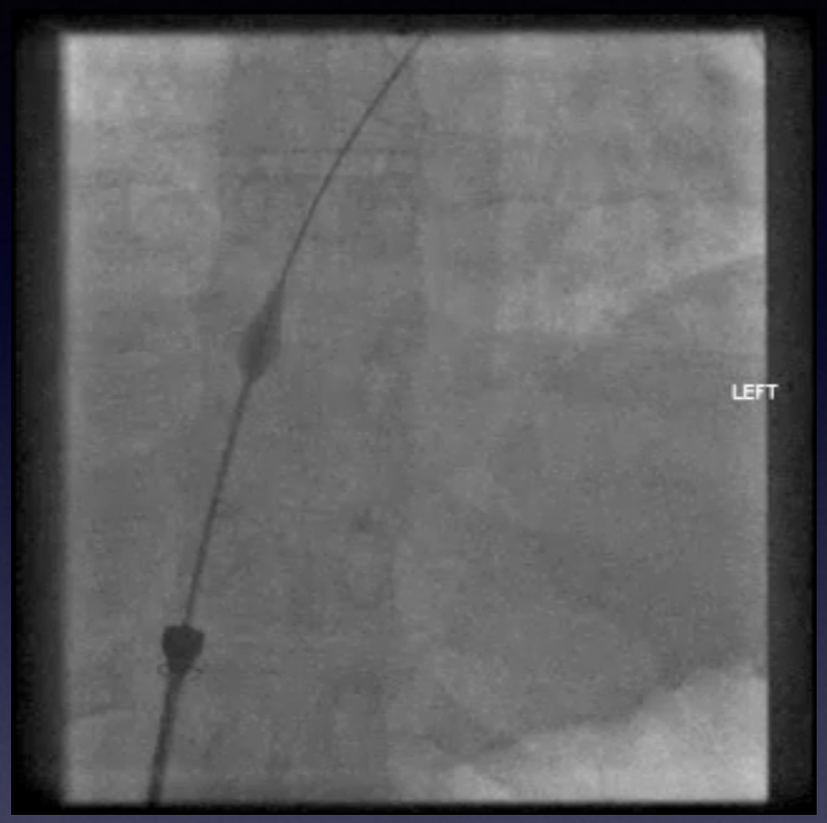


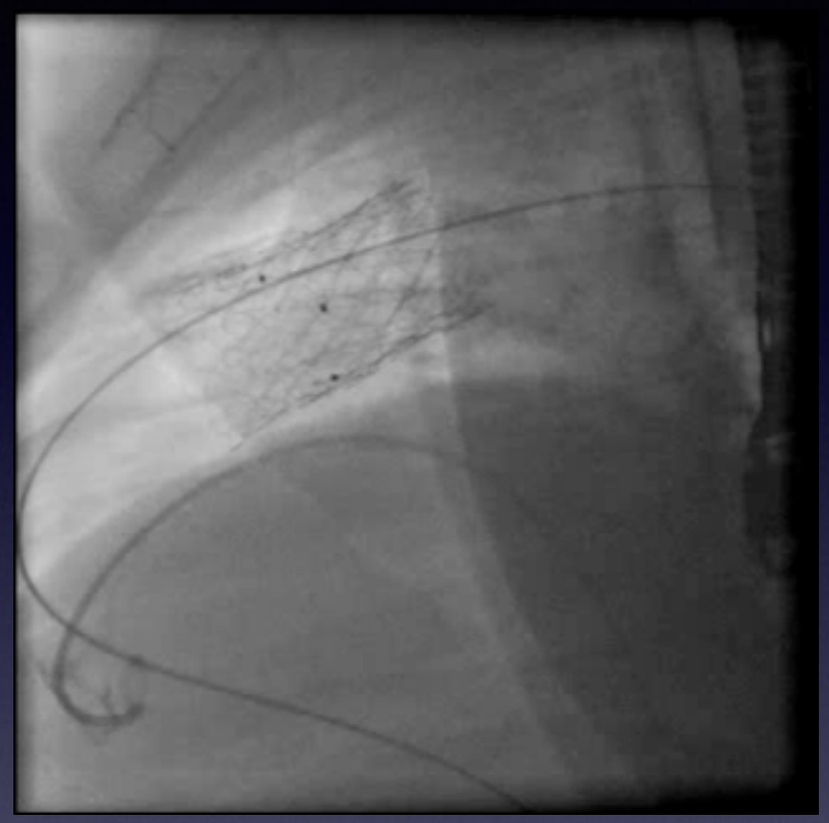




Pre-stented RVOT/MPA

Removal of carrot and delivery system

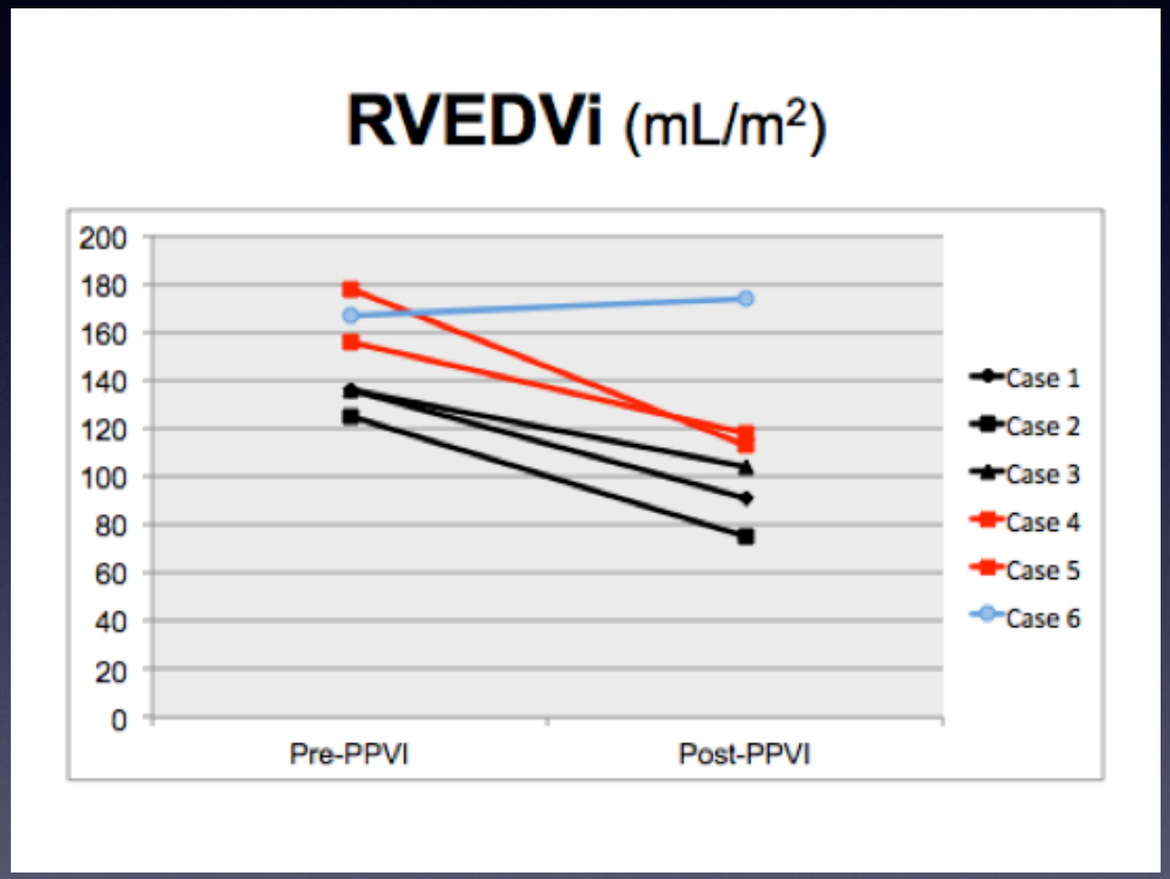


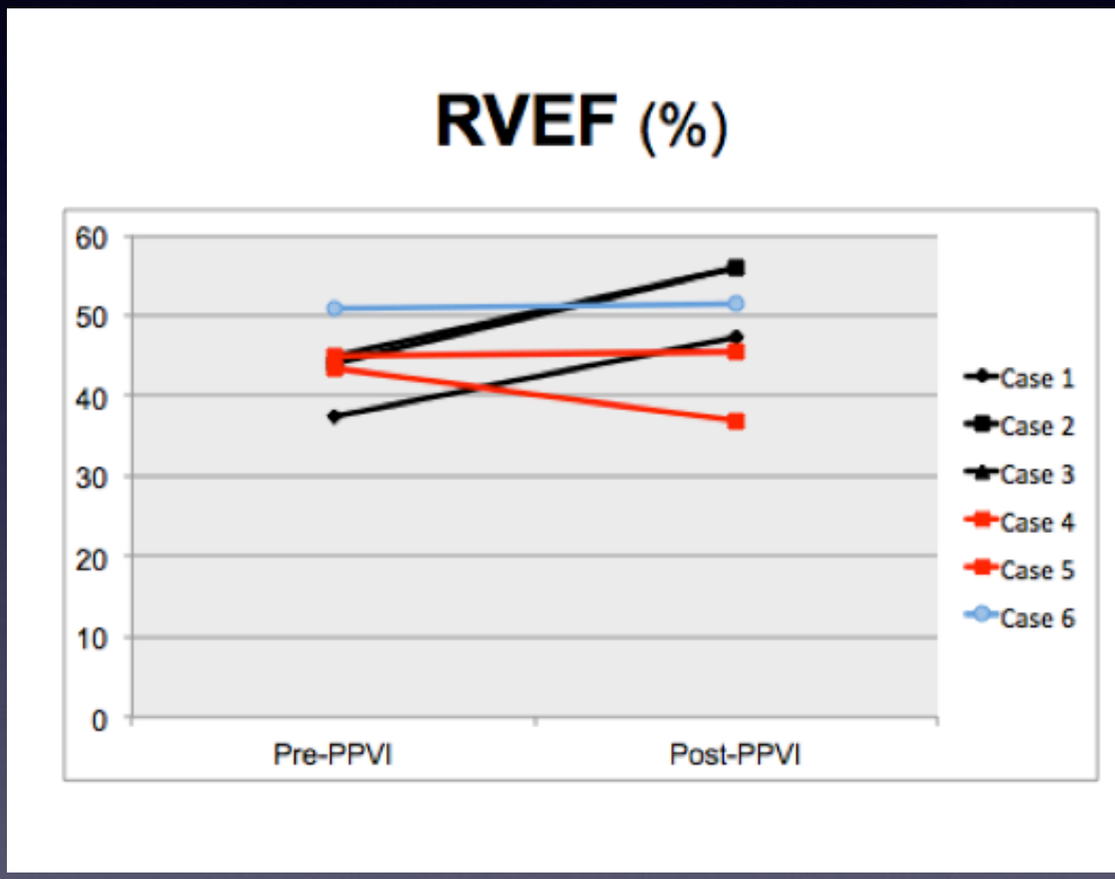


Venus P-valve in pre-stented RVOT/MPA

Final MPA angio

RVEDVi and RVEF before and 6 months after Venus valve

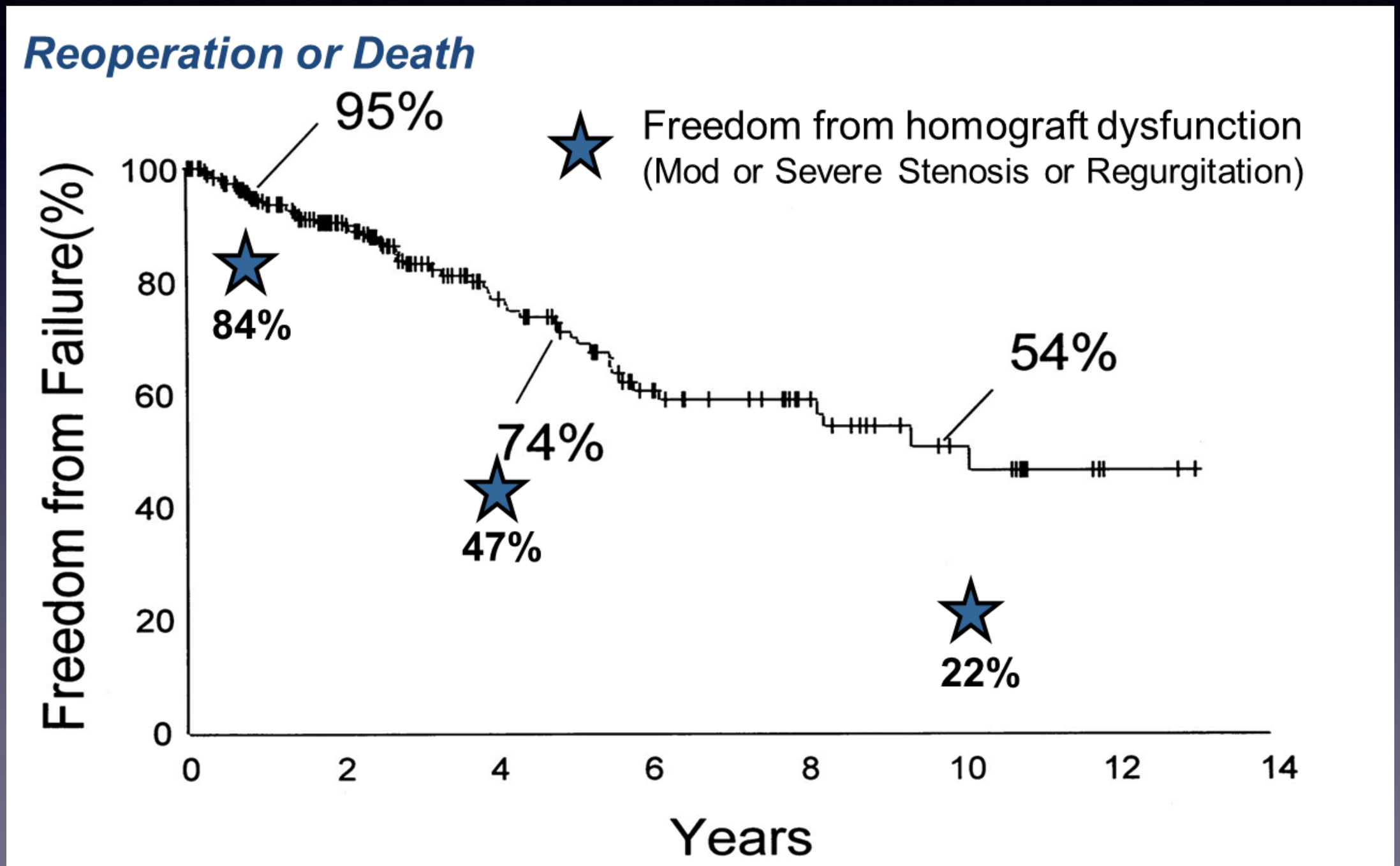




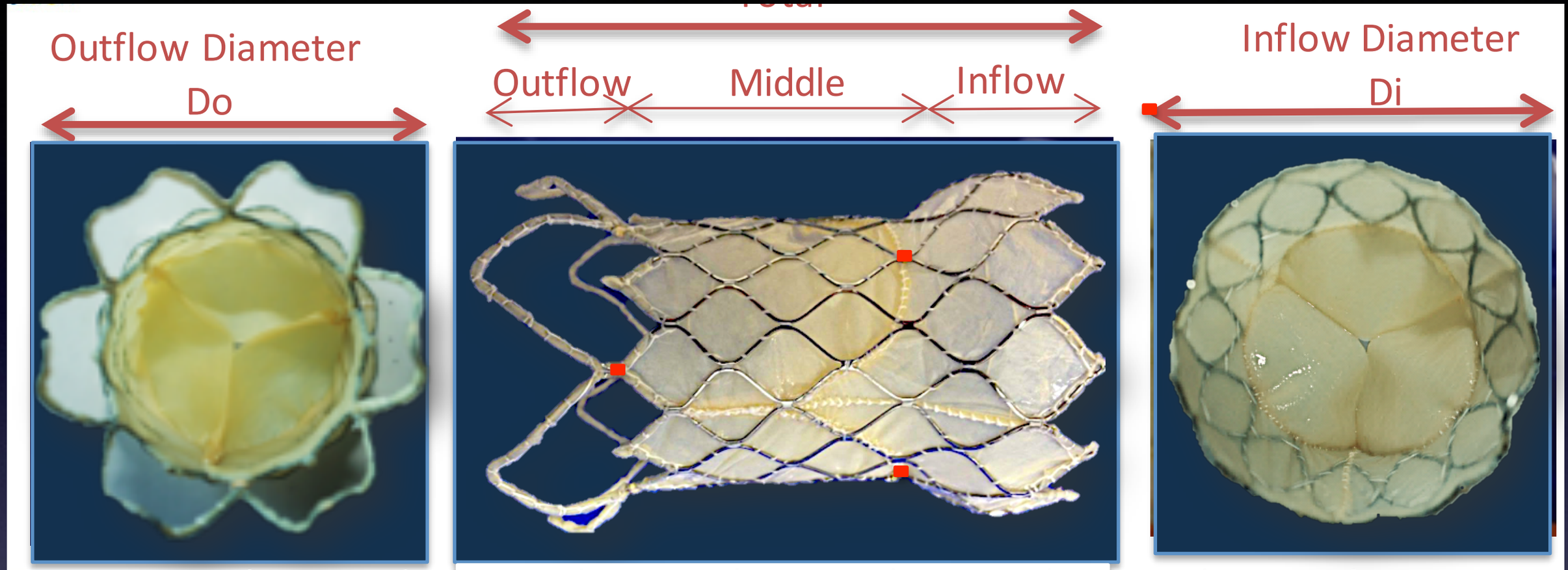
Pre-stented RVOT conduit

- Initially considered to be a contraindication to flared Venus P-valve
- With straight Venus P-valve, it is possible to implant in conduits

Durability of homografts



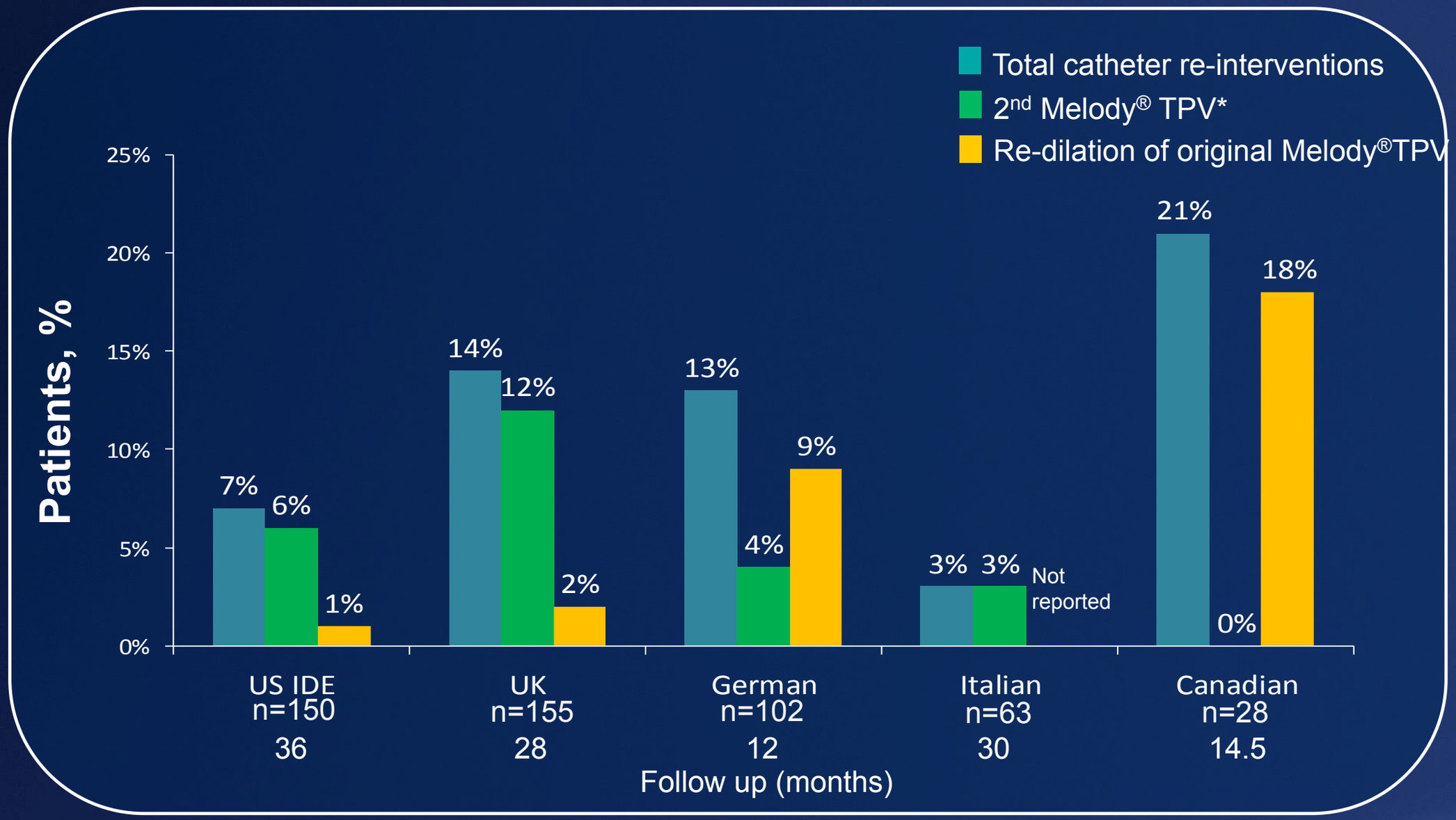
Venus P-valve



30 mm middle section	Expanded Length				Diameter			Loaded(mm)
	Outflow	Middle	Inflow	Total	Do	D	Di	Length
P32-30	13	30	18	61	42	32	42	77
P30-30	13	30	18	61	40	30	40	76
P28-30	13							
P26-30	12							
P24-30	12							
P22-30	12	30	14	56	32	22	32	74
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

Maximum diameter of 36 mm

Complications
Requiring Catheter Re-interventions



*Limited data are available on the clinical performance of re-implantation of another Melody TPV within the original Melody TPV.

This PowerPoint is intended for use *outside of* the United States only.

May 2014