



**VII Congresso
Novas Fronteiras
em Cardiologia**

Pulmonary valve diseases: What is new?

Structural Heart Disease Roundtable

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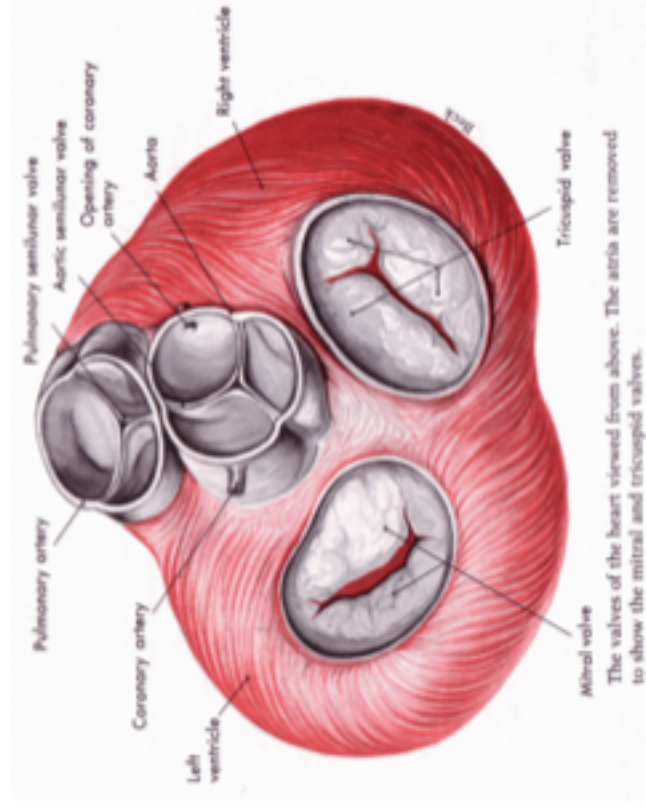
PULMONARY VALVE DISEASES

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- Conflict of interest:
 - Speaker fees: Abbott, Astra Zeneca, A. Menarini, Bayer, Boston Scientific

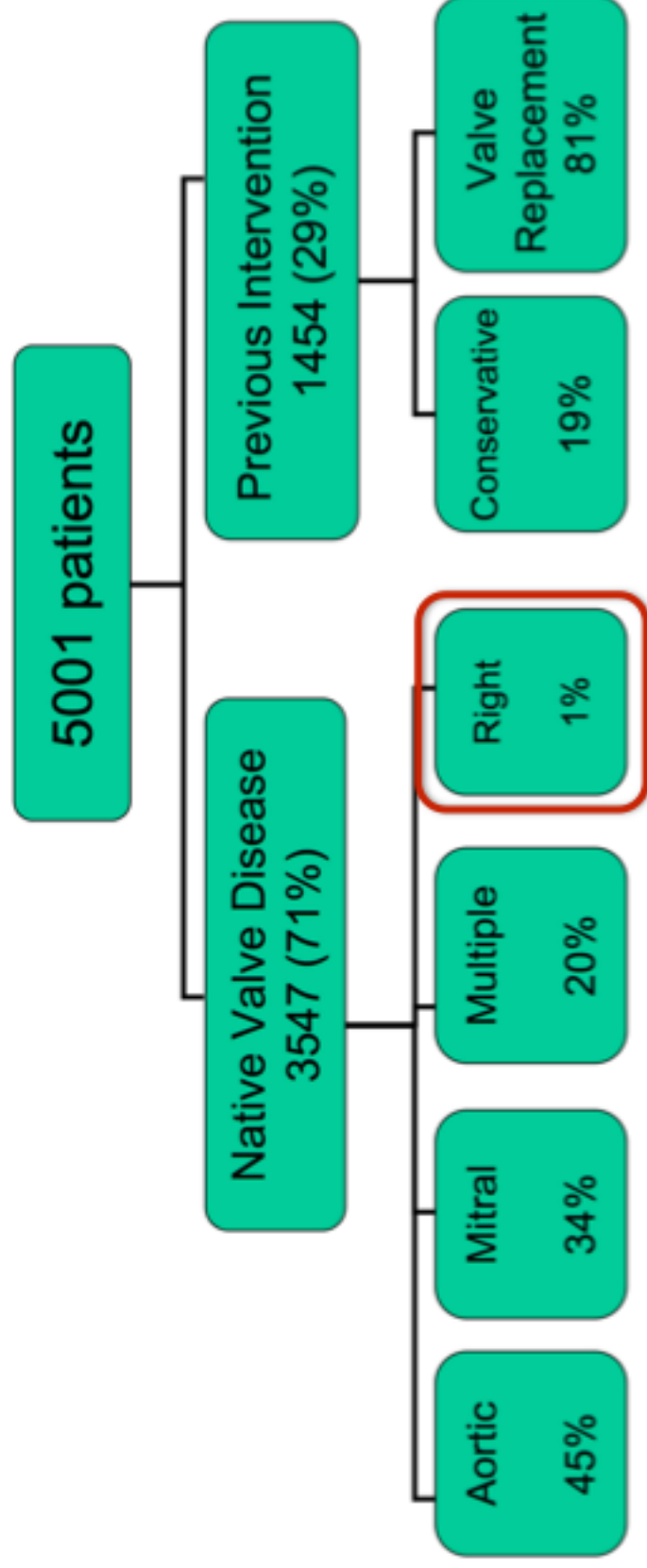
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- Background
- Pulmonary stenosis
- Pulmonary regurgitation
- RV-PA conduits
- What is new?
- Percutaneous intervention
- Balloon pulmonary valvuloplasty
- Percutaneous pulmonary valve implantation
- Clinical case
- Conclusions



- "The forgotten valve"

Type of VHD



- “The forgotten valve”

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• “The forgotten valve”



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ESC/EACTS GUIDELINES

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2.2 Contents of these guidelines

These guidelines focus on acquired VHD, are oriented towards management, and do not deal with endocarditis or congenital valve disease, including pulmonary valve disease, since recent guidelines have been produced by the ESC on these topics.^{10,11} Finally, these guidelines are not intended to include detailed information covered in ESC Guidelines on other topics, the ESC Association/Working Group's recommendations, position statements and expert consensus papers and the specific sections of the ESC Textbook of Cardiovascular Medicine.¹²

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ESC Guidelines for the management of grown-up congenital heart disease (new version 2010)

The Task Force on the Management of Grown-up Congenital Heart Disease of the European Society of Cardiology (ESC)

“The forgotten valve”

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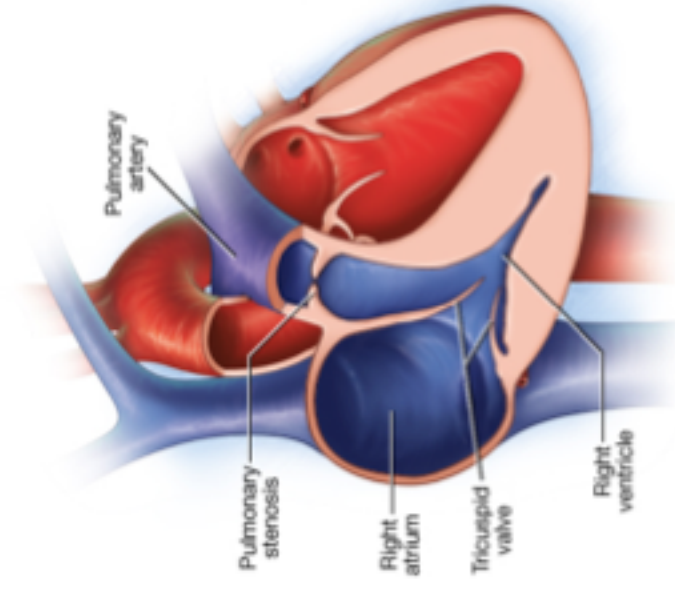
Table 13 Indications for intervention in right ventricular outflow tract obstruction

Indications	Class ^a	Level ^b
RVOTO at any level should be repaired regardless of symptoms when Doppler peak gradient is >64 mmHg (peak velocity >4m/s), provided that RV function is normal and no valve substitute is required	I	C
In valvular PS, balloon valvotomy should be the intervention of choice	I	C
In asymptomatic patients in whom balloon valvotomy is ineffective and surgical valve replacement is the only option, surgery should be performed in the presence of a systolic RVP >80 mmHg (TR velocity >4.3 m/s)	I	C
Intervention in patients with gradient <64 mmHg should be considered in the presence of: <ul style="list-style-type: none"> • symptoms related to PS or, • decreased RV function or, • double-chambered RV (which is usually progressive) or, • important arrhythmias or, • right-to-left shunting via an ASD or VSD. 	IIa	C
Peripheral PS, regardless of symptoms, should be considered for repair if >50% diameter narrowing and RV systolic pressure >50 mmHg and/or lung perfusion abnormalities are present	IIa	C

Table 20 Indications for intervention in patients with right ventricular to pulmonary artery conduits

Indications	Class ^a	Level ^b
Symptomatic patients with RV systolic pressure >60 mmHg (TR velocity >3.5 m/s; may be lower in case of reduced flow) and/or moderate/severe PR should undergo surgery	I	C
Asymptomatic patients with severe RVOTO and/or severe PR should be considered for surgery when at least one of the following criteria is present: <ul style="list-style-type: none"> • Decrease in exercise capacity (CPET) • Progressive RV dilation • Progressive RV systolic dysfunction • Progressive TR (at least moderate) • RV systolic pressure >80 mmHg (TR velocity >4.3 m/s) • Sustained atrial/ventricular arrhythmias 	IIa	C

- Location:
 - Valvular
 - Subvalvular / infundibular
 - Supravalvular
 - Pulmonary artery
- Etiology:
 - Congenital
 - Carcinoid
 - Rheumatic



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- Epidemiology:
 - 5 / 10.000 livebirths
 - ~7-12% of all congenital heart defects
 - 80-90% of all RVOT obstructions
 - Second only to VSD in prevalence
 - Usually an isolated lesion
 - May occur in up to 50% of patients with other CHD
 - Most cases are sporadic
 - Inheritance rate 1.7-3.6%
 - Autosomal dominant pedigrees have been reported

- Clinical presentation:
 - Mild to moderate: usually asymptomatic
 - Severe: dyspnea and reduced exercise capacity
- Diagnosis:
 - Echocardiography
 - Mild: peak gradient < 36 mmHg
 - Severe: peak gradient > 64 mmHg
 - Cardiac MRI and CT
 - Cardiac catheterisation
 - Mild: RVSP < 50 mmHg and gradient < 30 mmHg
 - Severe: Suprasystemic RVSP and gradient > 50 mmHg
- Management

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- Etiology:
 - Congenital
 - Pulmonary hypertension
 - Endocarditis
 - Rheumatic
 - Carcinoid
 - Connective tissue disease
- Epidemiology

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- Clinical presentation:
 - Right heart failure
- Diagnosis:
 - Echocardiography
 - Cardiac catheterisation
 - Cardiac MRI
- Management

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- Significant RVOT dysfunction is present in 20% of all patients with CHD
- Surgical PVR with valved conduits is used to treat RVOT dysfunction and is the most common mode of redo-operation in patients with CHD
- Conduits have a limited timespan (~10 years)
- Most patients have to undergo several surgeries

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- Since 2000, nothing...



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- Balloon pulmonary valvuloplasty
- Percutaneous pulmonary valve implantation (PPVI)

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- First performed by Kan and colleagues in 1982
- First-line treatment for valvular PS
- Procedure:
 - Transfemoral venous approach
 - UFH 50 IU/kg
 - Assessment of PA and RV pressures
 - RV angiography

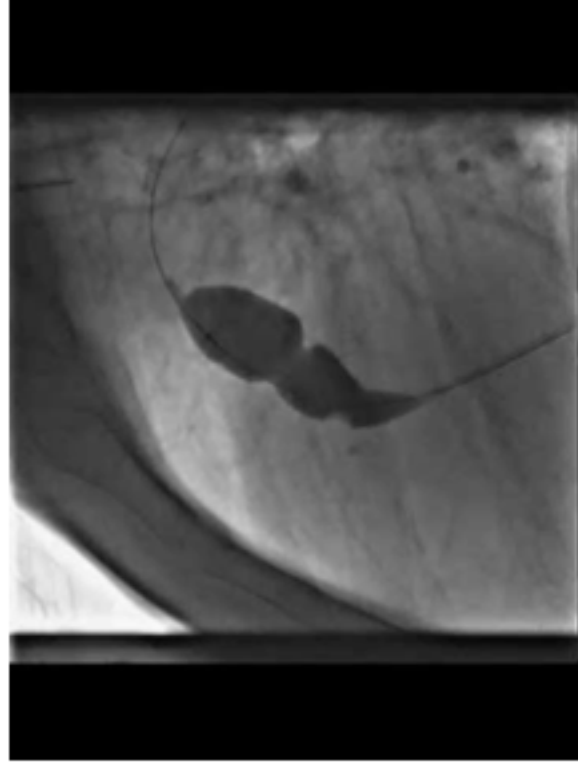
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Intervention in patients with gradient <64 mmHg should be considered in the presence of: <ul style="list-style-type: none"> • symptoms related to PS or, • decreased RV function or, • double-chambered RV (which is usually progressive) or, • important arrhythmias or, • right-to-left shunting via an ASD or VSD. 	IIa	C
Peripheral PS, regardless of symptoms, should be considered for repair if >50% diameter narrowing and RV systolic pressure >50 mmHg and/or lung perfusion abnormalities are present	IIa	C

2010 ESC Guidelines for the management of GUCH

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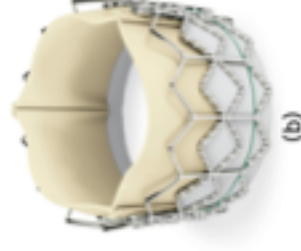
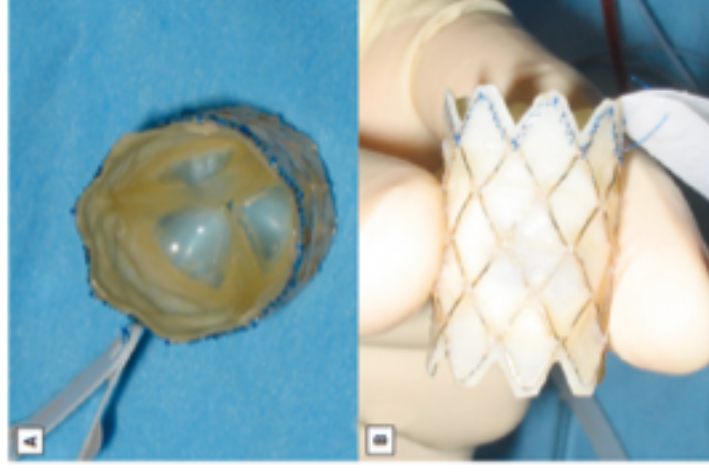
- Procedure:
 - Stiff exchange support wire (0.035-0.038")
 - Balloon:
 - Diameter: 110-120% of annular diameter
 - Length: 4 cm (> 1.5 x diameter)
 - Inflation: 10-15 seconds
 - Low pressure
 - 3-4 inflations
- If pulmonary annulus > 18-19 mm → double-balloon technique:
 - Two similar size balloons
 - Sum ~ 60% greater than the annulus



- Complications:
 - Rupture of the RVOT and cardiac tamponade
 - Injury to the tricuspid valve
 - Residual pulmonary regurgitation → PPVI
 - Dynamic infundibular obstruction
- Acute results:
 - Efficacy across all age groups
 - Final gradient < 30 mmHg
- Long-term follow-up:
 - Similar results to surgery
 - Re-intervention rate: 10-15% at 9 years

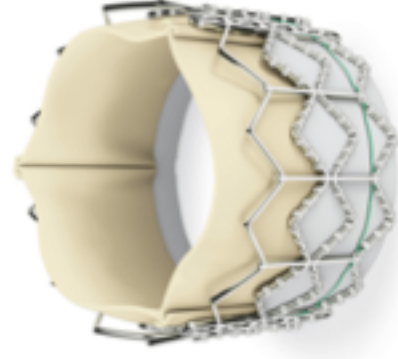
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- First described by Bonhoeffer in 2000
- > 8000 procedures performed worldwide
- Available devices:
 - Melody valve
 - Sapien valve
- Aims to prolong the lifespan of RV-PA conduits, postponing surgery
- Other (off-label) indications:
 - Native pulmonary regurgitation
 - RVOT with transannular patching
 - Pulmonary valve bioprosthesis



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	THE MELODY™ TRANSCATHETER VALVE	THE SAPIEN™ PULMONIC TRANSCATHETER HEART VALVE
Manufacturer	Medtronic Inc., MN, U.S.A	Edwards Lifesciences LLC, Irvine, CA, U.S.A.
Regulatory approval	CE 9/06 FDA 01/10	CE 5/2010 FDA 10/2012
[Tissue] characteristics	segment of bovine jugular vein with a central valve hand-sewn inside a stent	trileaflet bovine pericardial valve hand-sewn inside a stent
Stent type	Cheatham platinum stent (NuMED CP Stent CP8Z34) length 34 mm expandable up to 22 mm	stainless-steel stent length of 14 or 16mm
Available sizes	18, 20, 22 mm (depending on the favoured Ensemble™ delivery system)	23, 26, (XT 29#) mm
Delivery system	Ensemble™ (Medtronic, MN) with balloon in balloon (BiB) deployment design	Edwards Retroflex™ III containing a balloon catheter and a deflectable guiding catheter
Sheats for implantation	one-piece 22 Fr Teflon sheath	(18 Fr*) 22 Fr for 23 mm valves (19 Fr*) 24 Fr for 26 mm valves (16 Fr*) 24 Fr for 29 mm XT valves



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PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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- Indications:
 - RVSP > 65% of systemic pressure + symptoms
 - RVSP > 75% of systemic pressure, with no symptoms
- Adequate body size is required (> 20 kg)
- Pre-procedure assessment:
 - TTE
 - MRI
 - Coronary angiography
 - CPET (peak O₂ uptake <65% predicted)
 - ECG, Holter

Table 20 Indications for intervention in patients with right ventricular to pulmonary artery conduits

Indications	Class ^a	Level ^b
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Asymptomatic patients with severe RVOTO and/or severe PR should be considered for surgery when at least one of the following criteria is present: <ul style="list-style-type: none"> • Decrease in exercise capacity (CPET) • Progressive RV dilation • Progressive RV systolic dysfunction • Progressive TR (at least moderate) • RV systolic pressure >80 mmHg (TR velocity >4.3 m/s) • Sustained atrial/ventricular arrhythmias 	IIa	C

- Morphological criteria:
 - Melody: conduit diameter 16-22 mm
 - Implantation / post-dilatation with 24 mm balloons
 - Sapien: outflow tract diameter 18-26 (29) mm
- Novel approaches:
 - Implantation in PA branches
 - "Jailing" one of the main PA branches
 - Hybrid approach

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PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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- Procedure:
 - Surgical backup / ECMO
 - General anesthesia / conscious sedation
 - Venous access (femoral / jugular)
 - Arterial access
 - UFH 50-100 IU/kg
 - Broad-spectrum iv antibiotics

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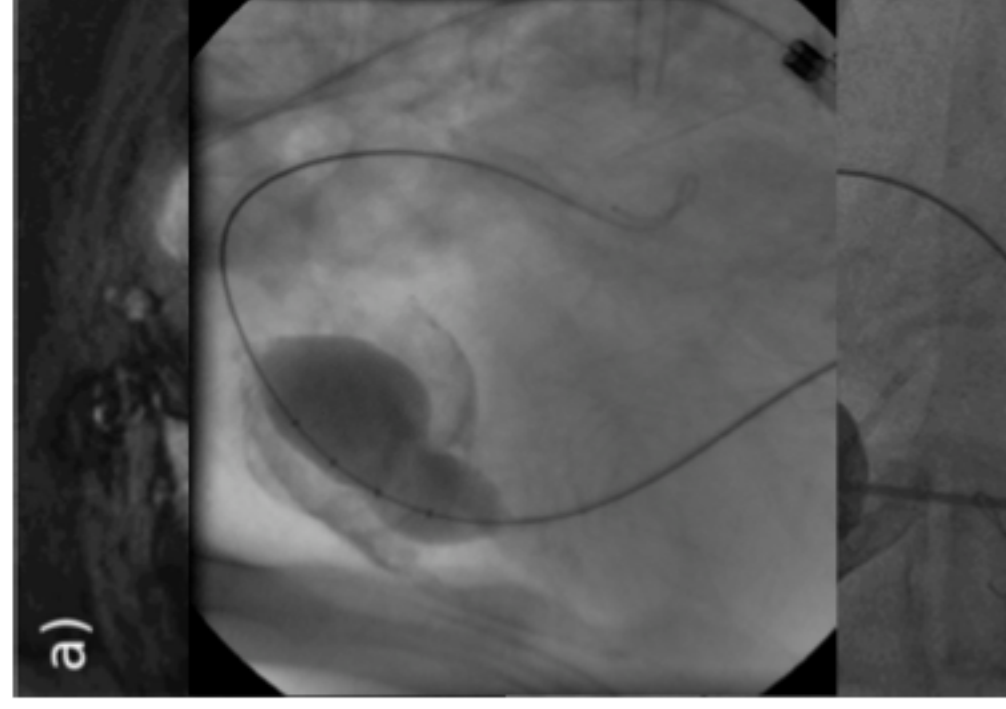
PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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• Procedure:

- L/RHC according to standard technique (RV, PA, aorta)
- Stiff 0.035" guidewire in a distal PA branch (balloon tipped floating catheter)
- Pre-dilatation ?
- Balloon sizing (patch-extended or native RVOT)
- Assessment for the risk of coronary artery compression
- Pre-stenting ? (balloon-expandable covered bare-metal stents)



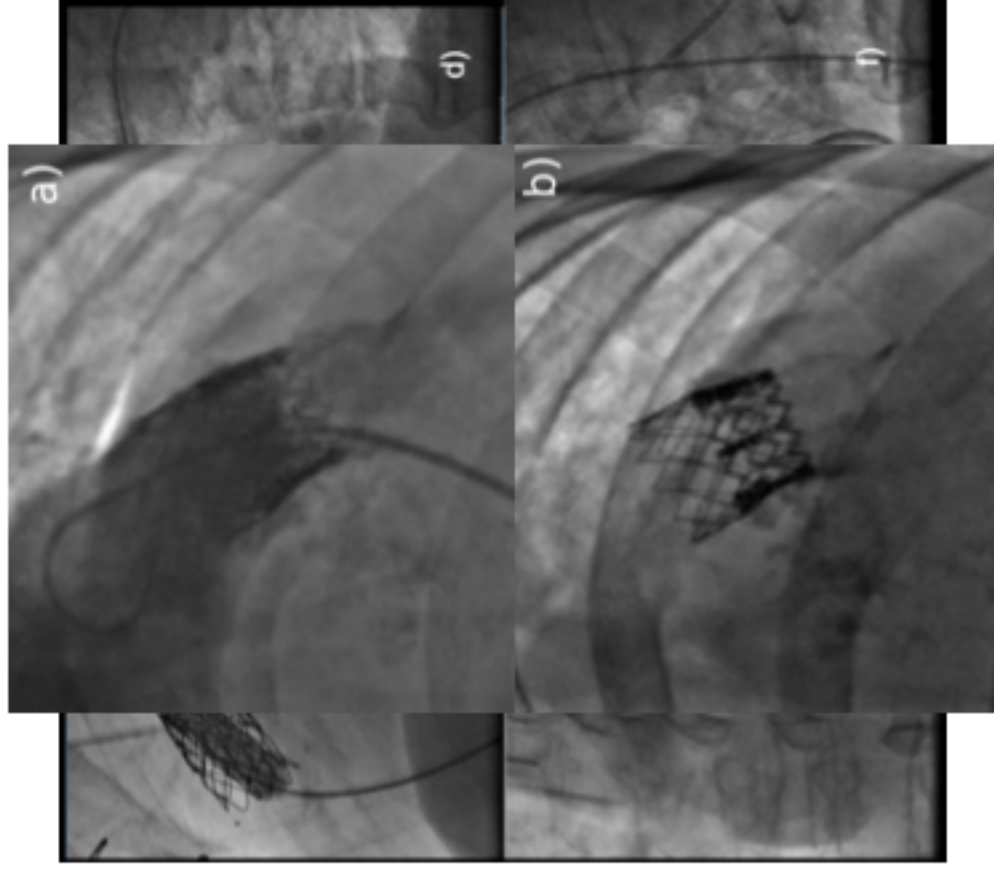
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- Procedure:
 - Deployment - Melody:
 - Retract outer sheath
 - Inflation of the inner balloon
 - Inflation of the outer balloon
 - Deployment - Sapien:
 - Positioning
 - Balloon inflation
 - Angiography and pressure measurements
 - Post-dilatation (residual gradient > 20 mmHg)



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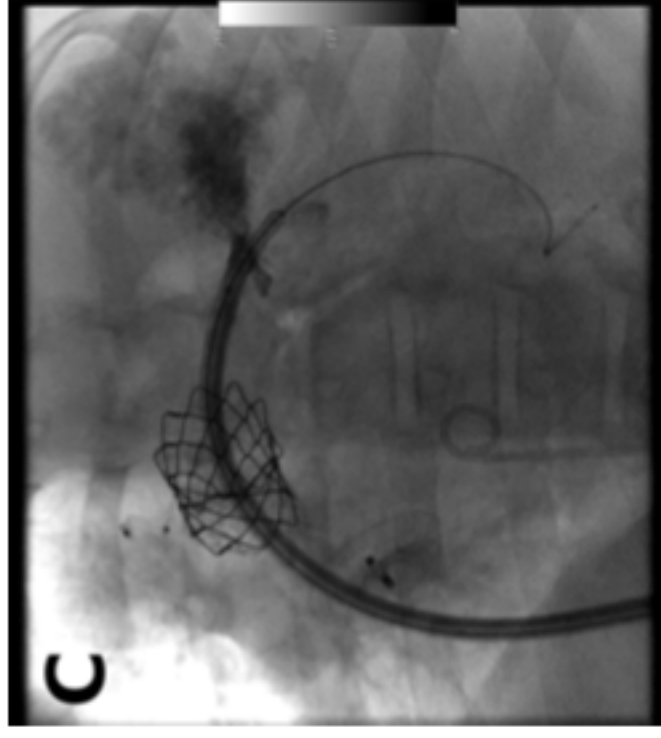
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- Complications:

- Complications:
 - Melody (n = 1003):
 - Major procedural complications 2.7%
 - Homograft rupture 2.2%
 - Perforation or guidewire injury of PA or PA branches 1.7%
 - Damage to tricuspid valve 1.6%
 - Device dislodgement 0.5%
 - Compression of coronary arteries 0.3%
 - Sapien (n = 34):
 - Successful deployment 97.1%
 - Adverse events 20.6%
 - Valve migration 8.8%
 - Stent embolization 2.9%
 - Pulmonary hemorrhage 5.9%
 - VF 2.9%



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- Acute hemodynamic outcome

parameter	US MELODY VALVE TRIAL (N=124)		LONDON MELODY EXPERIENCE (N=151)		MUNICH / BERLIN MELODY EXPERIENCE (N=102)		PHILADELPHIA MELODY EXPERIENCE (N=104)		EARLY EDWARDS EXPERIENCE (N=7)		LATER EDWARDS EXPERIENCE (N=36)		LATEST EDWARDS EXPERIENCE (N=25)	
	Pre	Post	Pre (mean)	Post (mean)	Pre (mean)	Post (mean)	Pre (mean)	Post (mean)	Pre (mean)	Post (mean)	Pre (mean)	Post (mean)	Pre (mean)	Post (mean)
RV systolic pressure, mm Hg	65	41*	63	45#	n.a.	n.a.	72	47#	n.a.	n.a.	55	42#	61	39#
Peak RV to PA gradient, mm Hg	37	12*	37	17#	37	14	39	11#	n.a.	n.a.	27	12#	39	9#
RV to systemic pressure, %	0.74	0.42*	0.69	0.45#	0.62#	0.36#	n.a.	n.a.	0.78	0.39#	0.60	0.40#	0.64	0.36#

Invasively measured pressures and gradients pre and post FPVI within the largest trials (n>100) on the Melody™ device (Lurz 2008) (McElhinney 2010) (Eicken 2011) (Gillespie 2012) and of Sapien™ implants (Boone 2010) (Kenny 2011) (Wilson 2015) in pulmonary position. In all studies, a profound improvement in RV to systemic pressure ratio in response to FPVI was seen (*p<0.001, # p<0.001, n.a. not available)

- Patients with significant RVOT regurgitation 49 → 1%
- Paravalvular leaks 2%

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- Long-term results:

- Overall mortality 0-5% (not related to the device)
- Functional class improvement
- Improvement on RVEF (in patients with obstruction)
- PR is rare and occurs only in the setting of endocarditis (1-5%; similar to surgery)
- Stent fracture leading to re-intervention 6.5-7.3% (Melody only)
- Association between high residual RVOT gradient and re-intervention
- Freedom from re-intervention:
 - 95.4% at 1 year
 - 87.6% at 2 years
 - 76% at 5 years

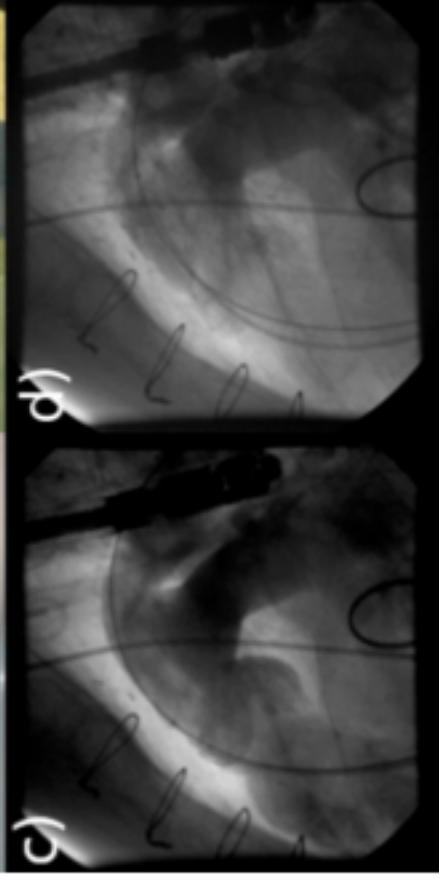
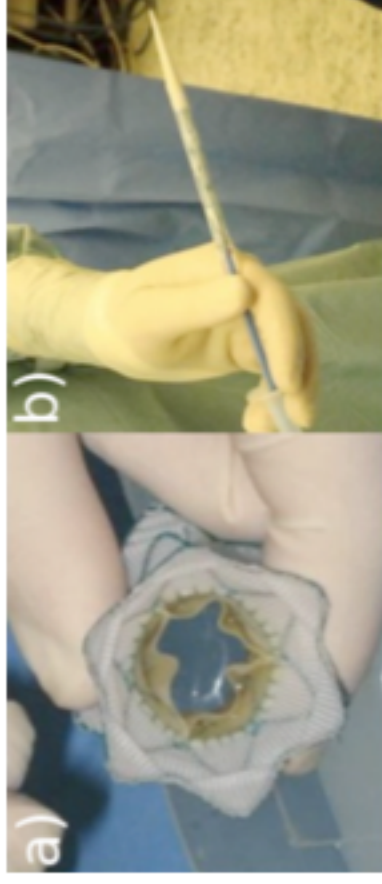
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- New devices:
 - Self-expanding valves:
 - Native Outflow Tract device
 - Venus P valve
 - Infundibular reducer devices
 - Low-profile valves:
 - Colibri Heart Valve



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CLINICAL CASE

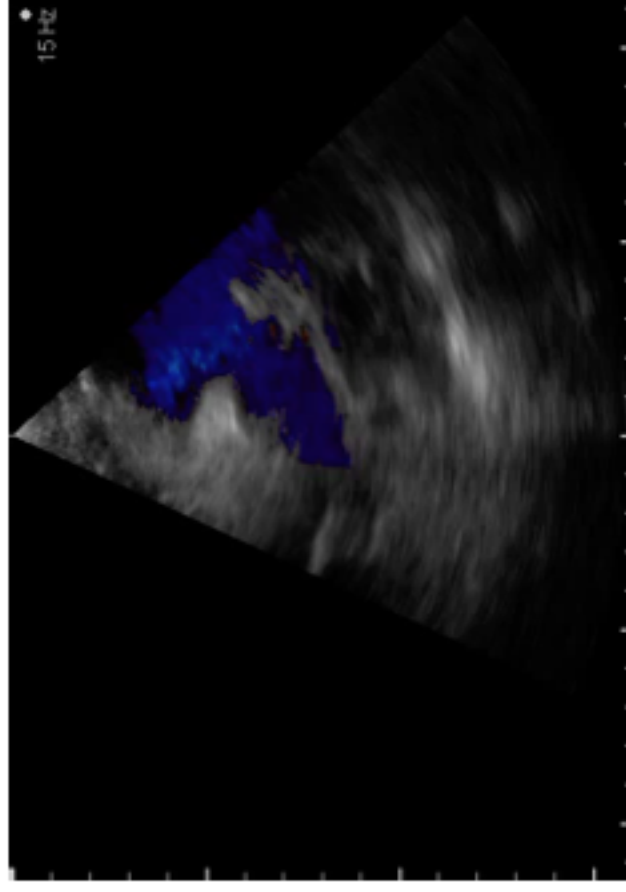
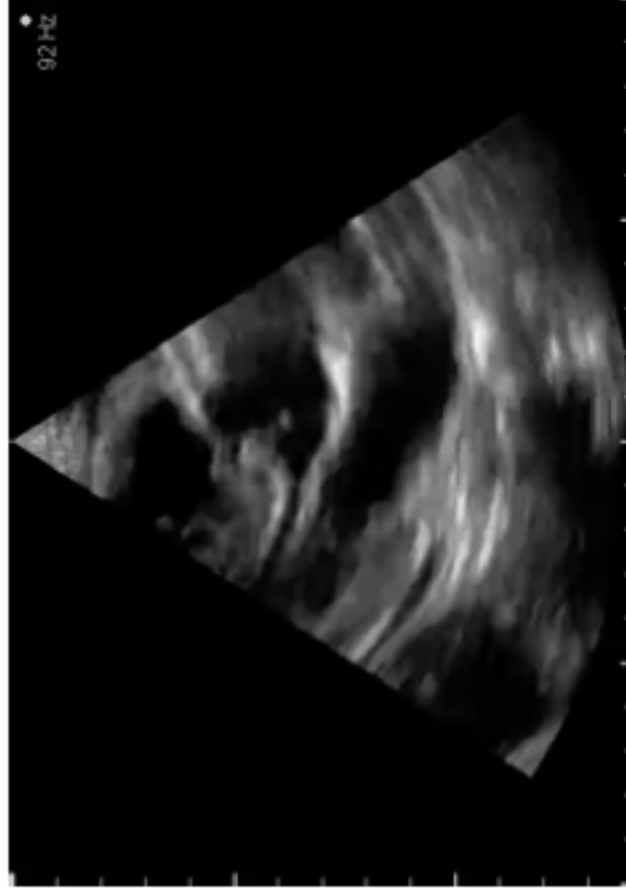
- ♀, 58 yo

- Admitted due to acute cholecystitis → urgent cholecystectomy, without complication
- Postoperative period:
 - Dyspnea on minimal exertion
 - Refractory hypoxemia (pO₂ = 60 mmHg on 100% supplemental oxygen)
 - Normotensive but tachycardic
 - III/VI systolic murmur, best heard at the LSE
 - Mild ankle edema
- Previous history:
 - Carcinoid tumour of the ileum with liver metastases
 - Treated with octreotide
- CT scan: bibasal pleural effusions; no pulmonary parenchymal lesions or thromboembolism

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CLINICAL CASE

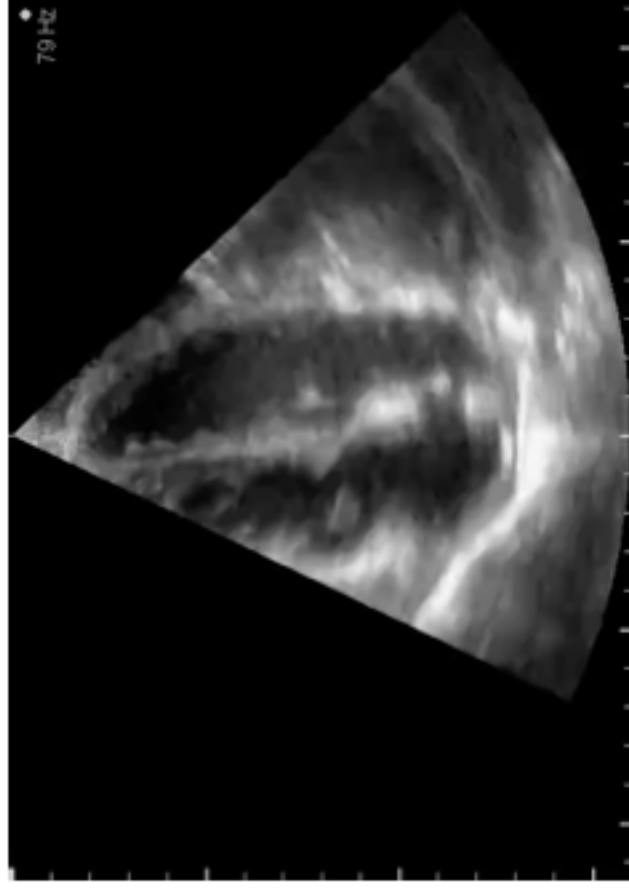
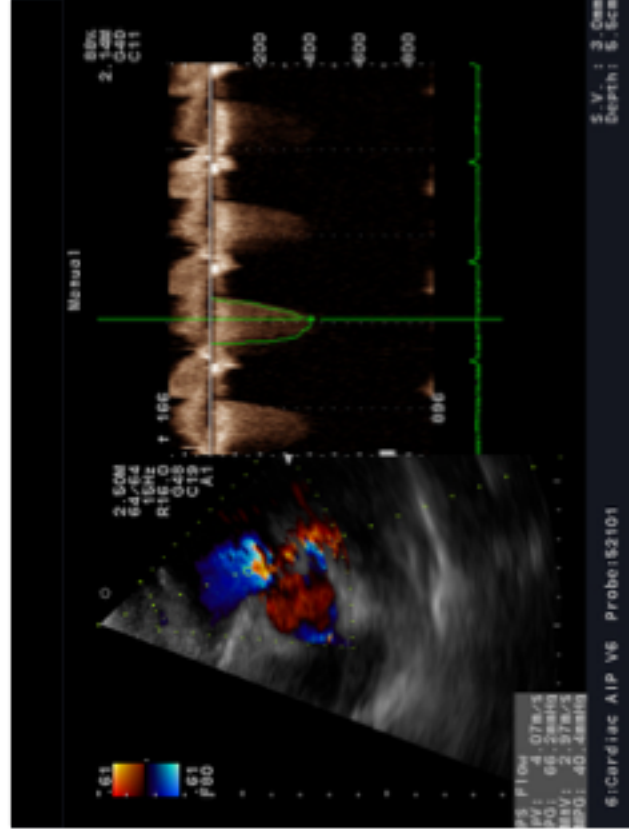
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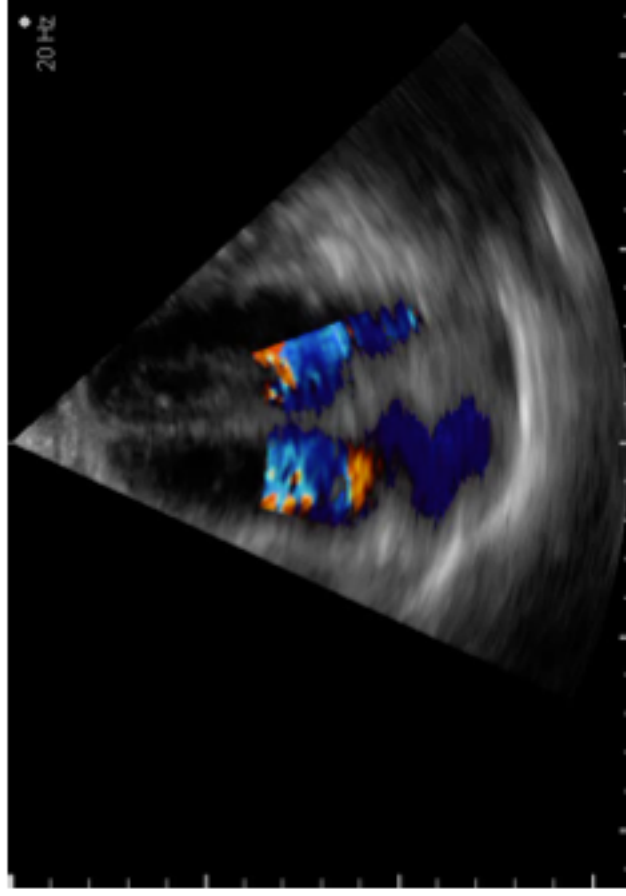


RV-PA gradient:
Maximum 66 mmHg
Mean 40 mmHg

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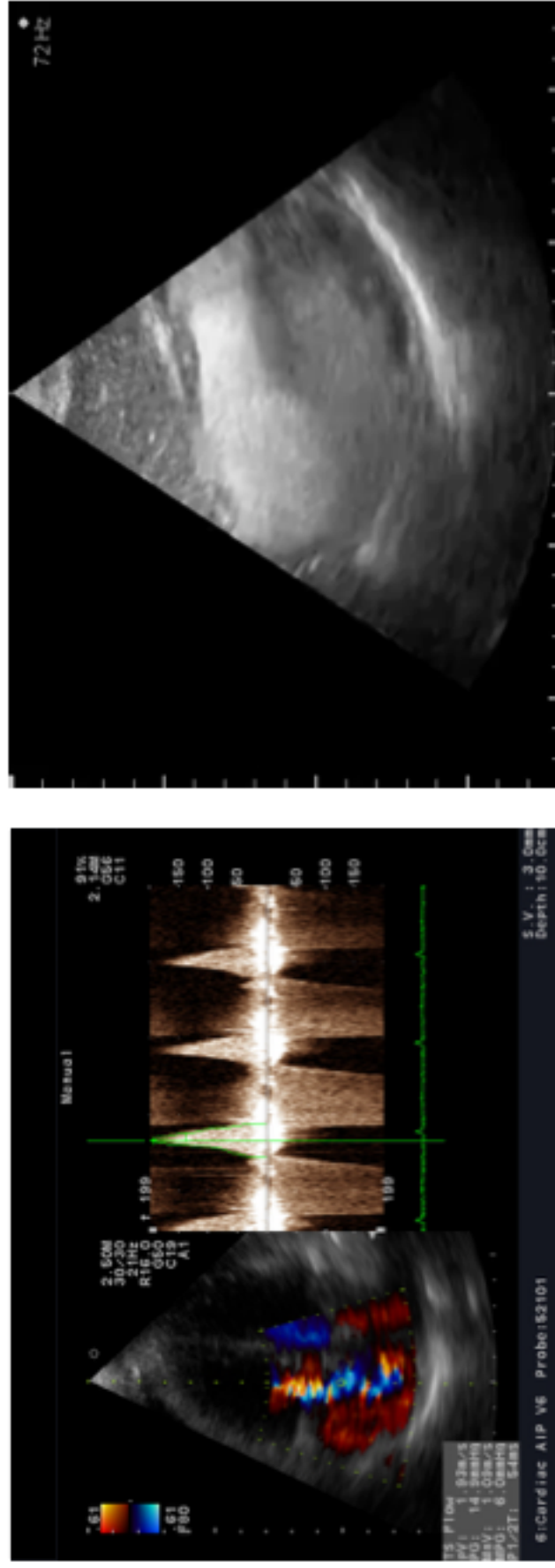


RV-RA gradient:
Maximum 104 mmHg

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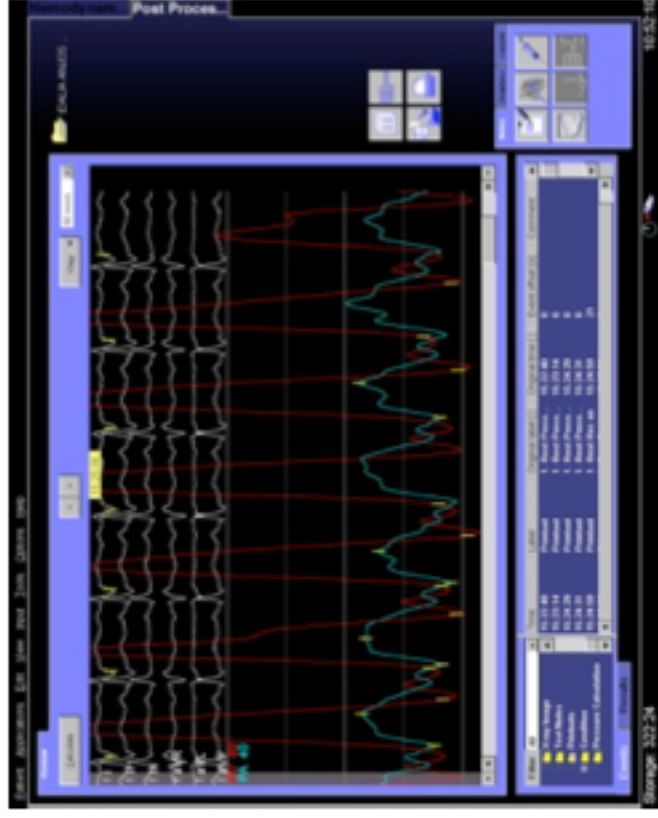


Mean tricuspid gradient 6 mmHg

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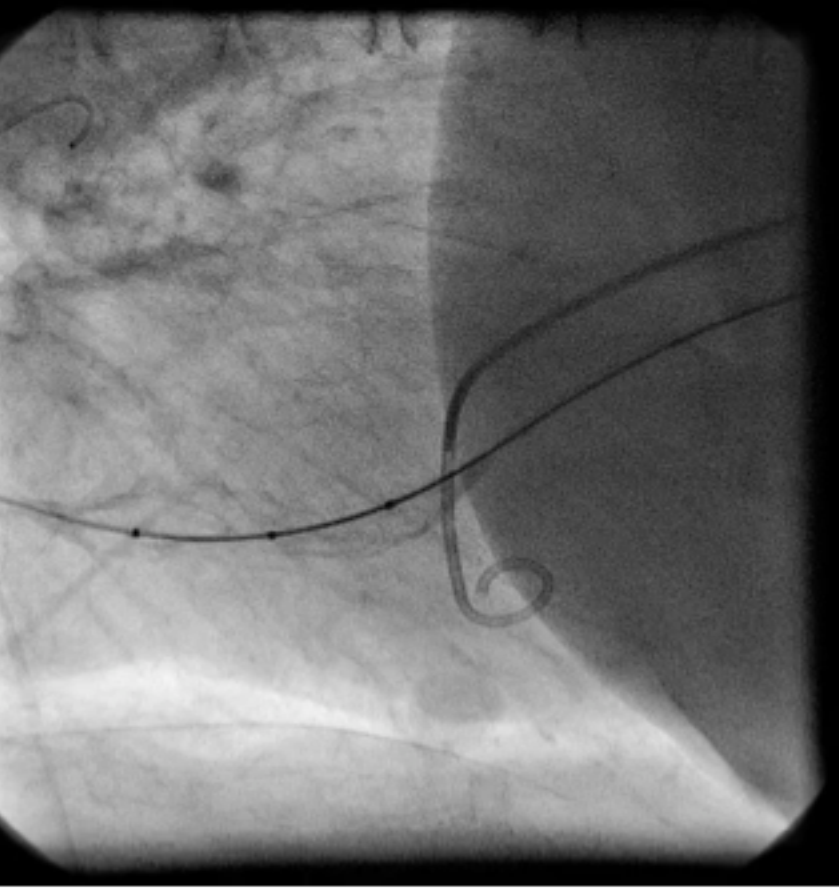
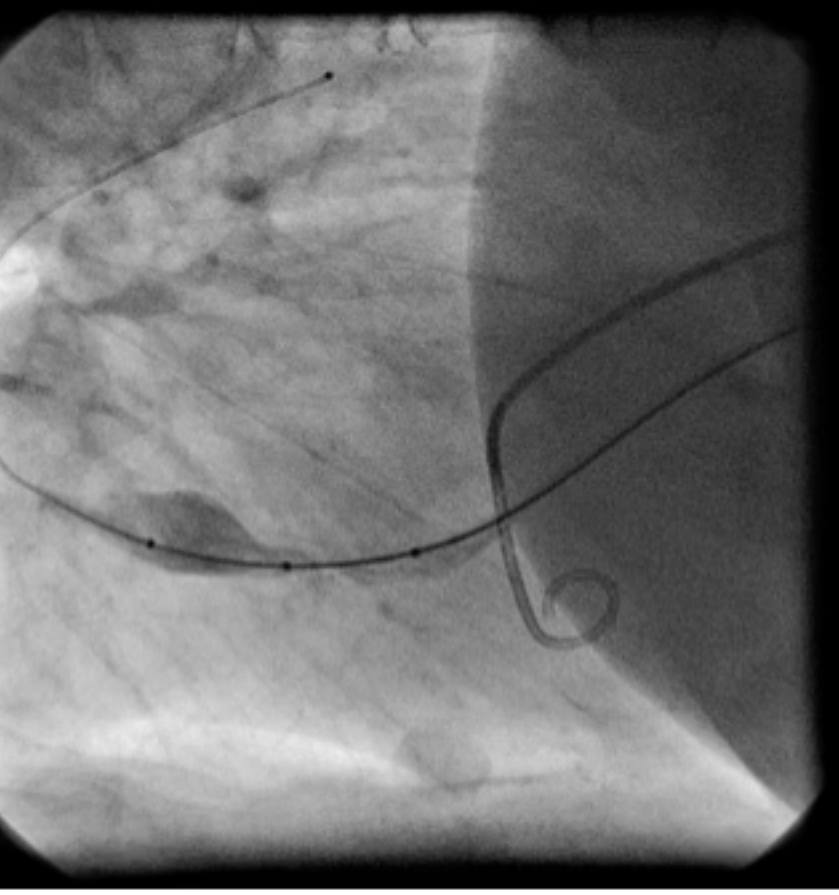
Peak gradient 55 mmHg

Pulmonary annulus diameter 19 mm

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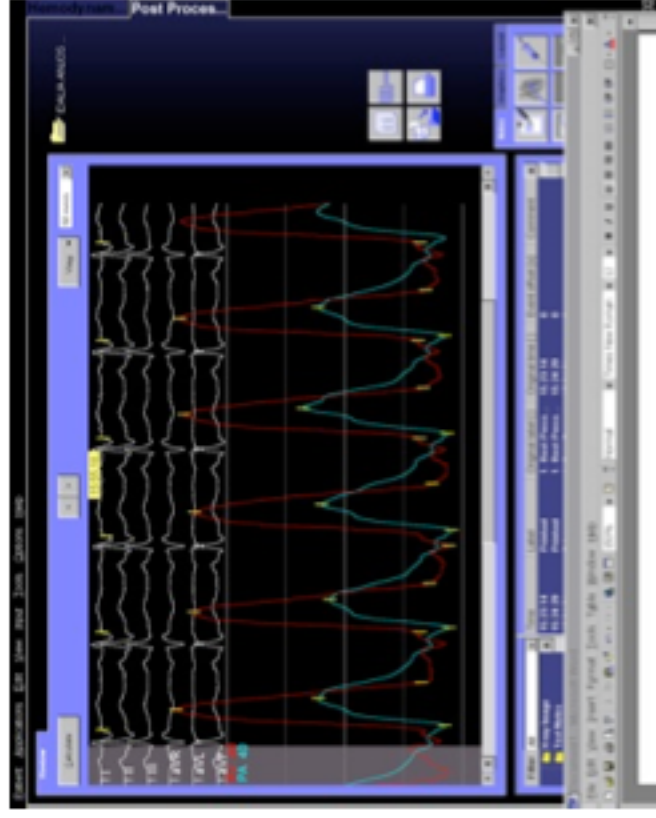
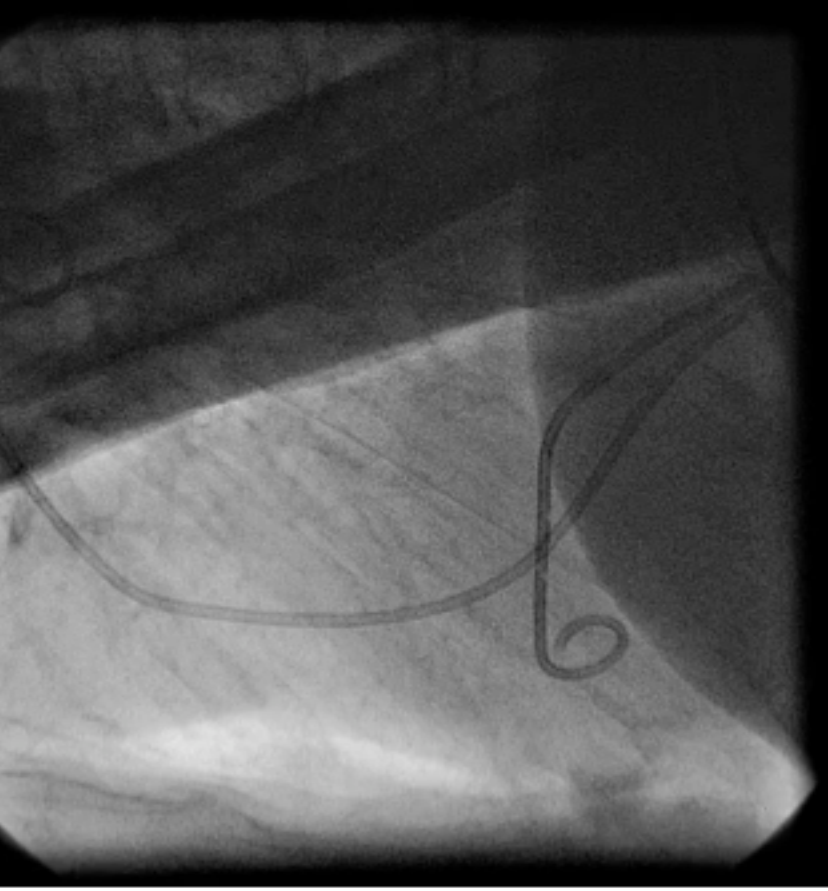


20 mm Numed Nucleus balloon

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Peak gradient 22 mmHg

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- Immediate clinical improvement ($pO_2 = 70$ mmHg, without supplemental oxygen)

- Discharge in stable condition after a few days
- Asymptomatic at 6 month follow-up
- Transthoracic echocardiogram:
 - Mild-to-moderate pulmonary stenosis (maximum velocity 2.90 m/s, mean gradient 20 mmHg) and regurgitation

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CONCLUSIONS

- The etiology of pulmonary valve disease is usually congenital

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- Commonly occurs in association with other CHD
- Balloon pulmonary valvuloplasty is the first-line treatment for valvular PS
- PPVI is typically used to prolong the lifespan of RV-PA conduits

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