

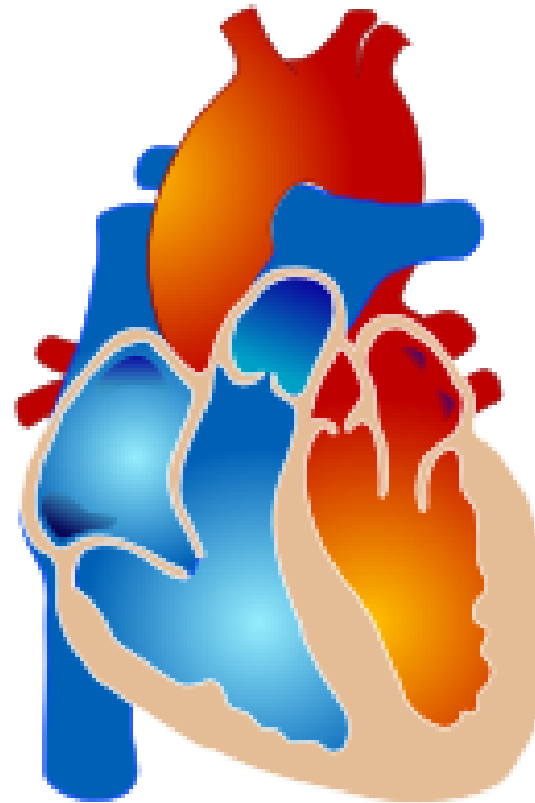
Percutaneous
pulmonary valve
implantation in
congenital heart
disease - Beyond the
Melody valve

Michael Rahbek Schmidt,
PhD, DMSc

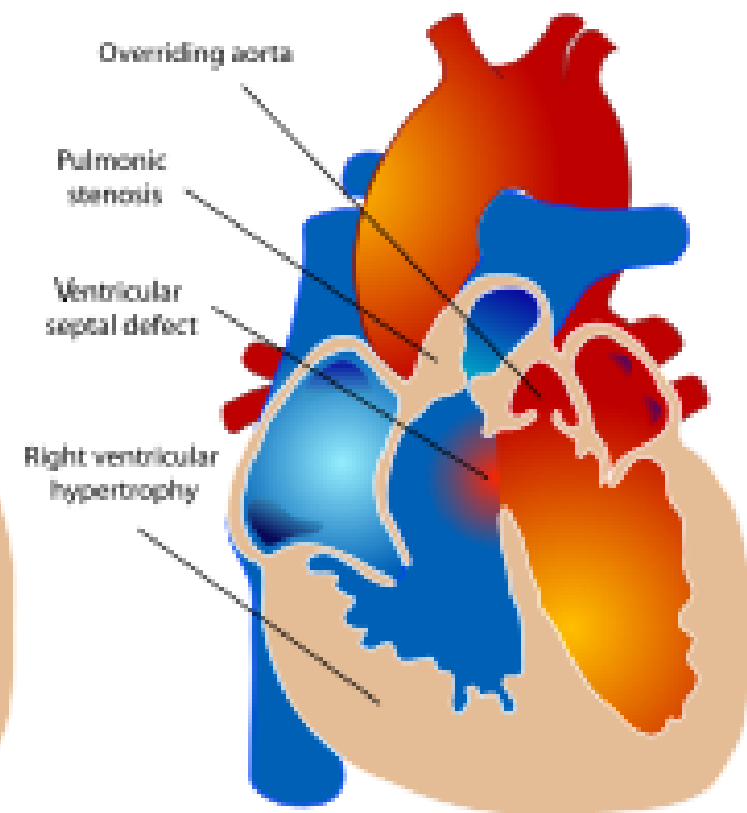
Rigshospitalet, Copenhagen
Denmark

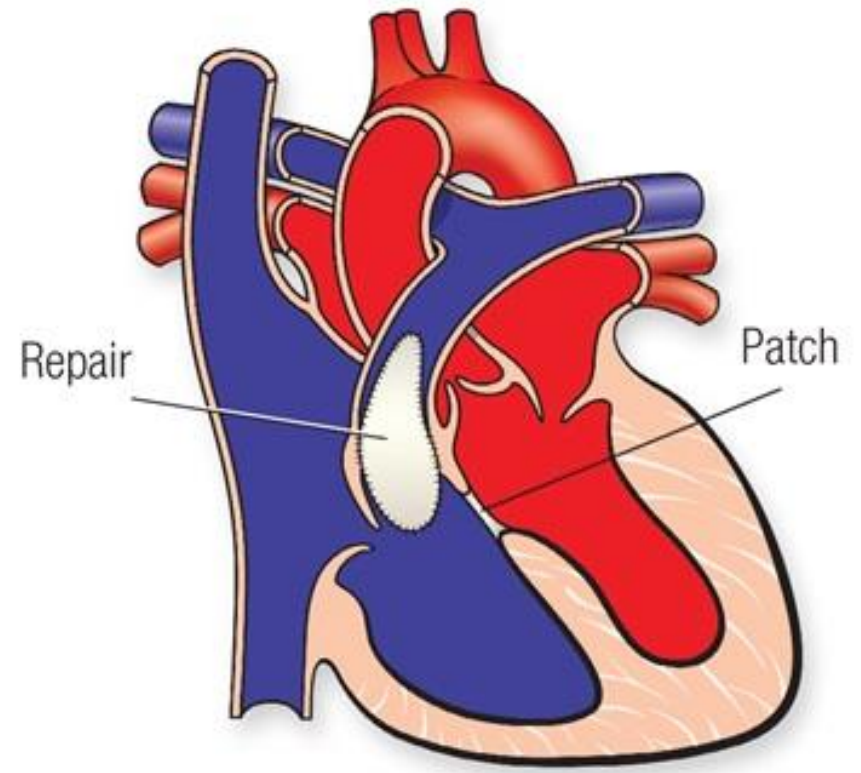
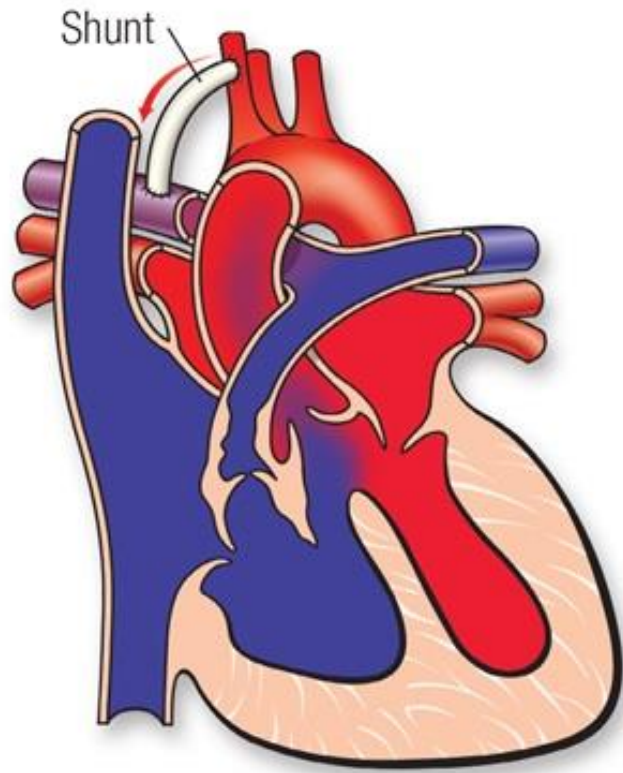
Tetralogy of Fallot

Normal heart



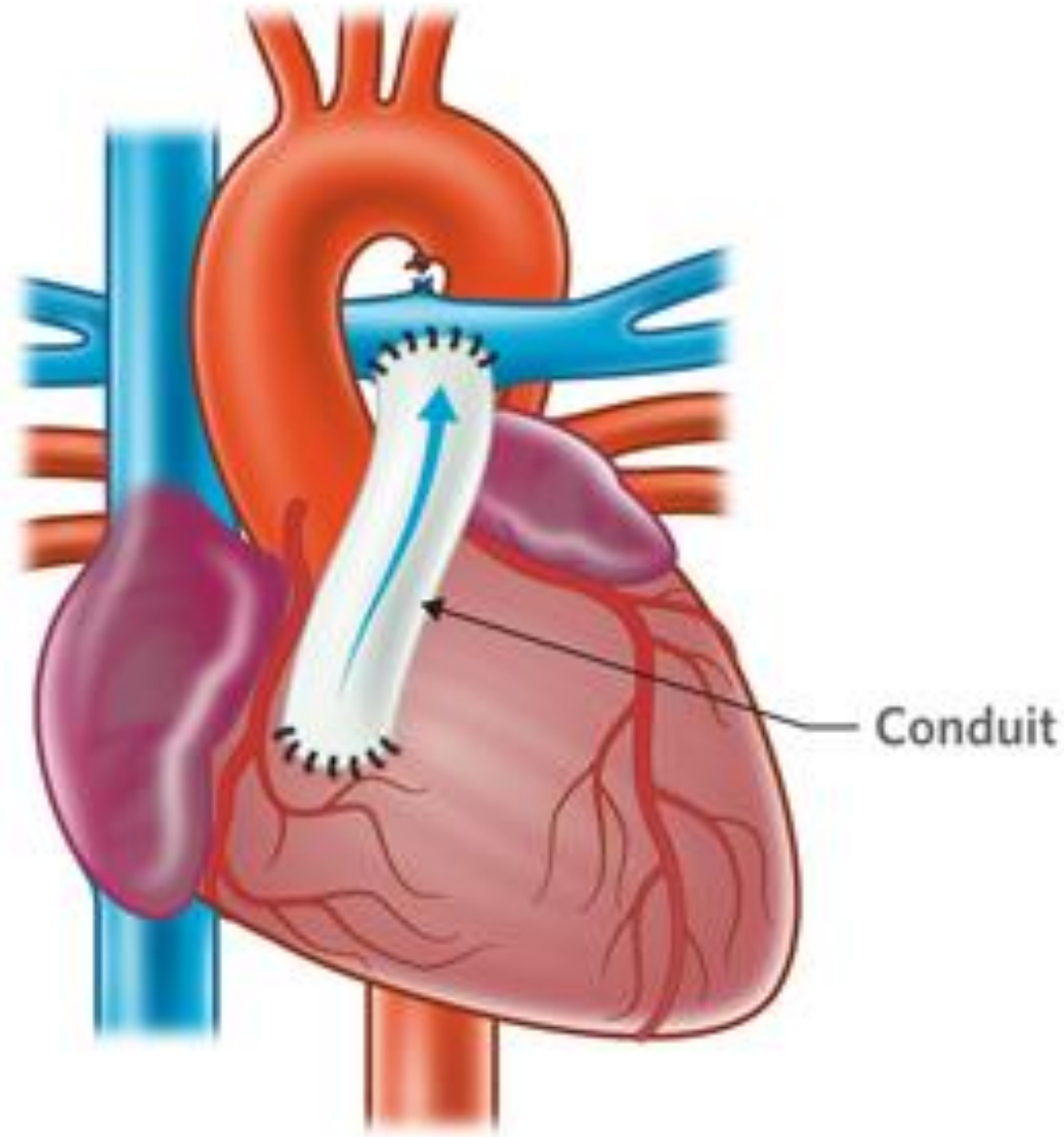
Tetralogy of Fallot



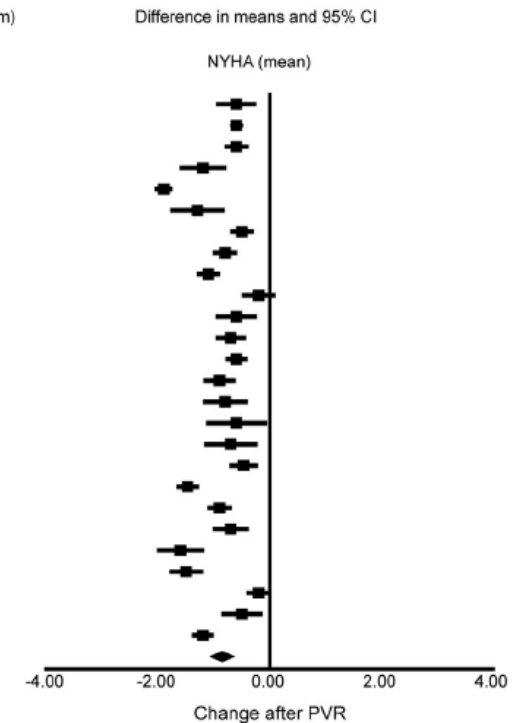
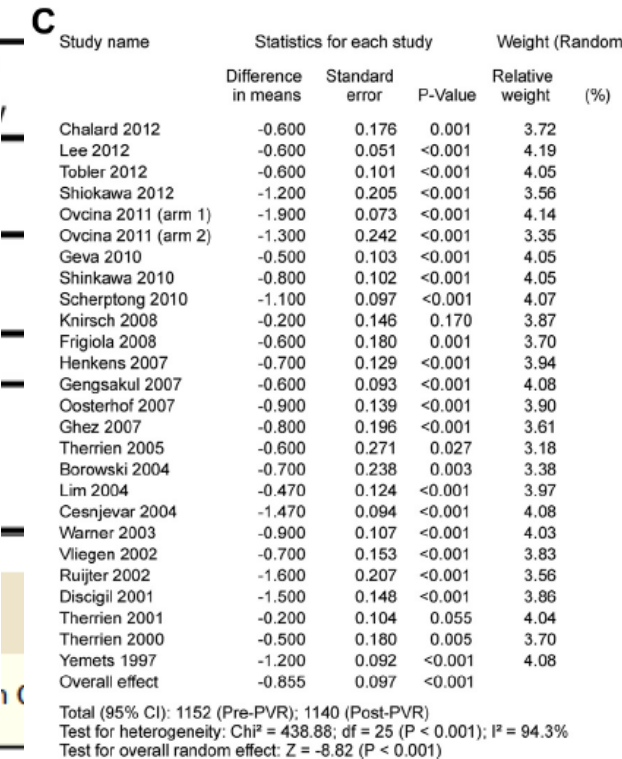
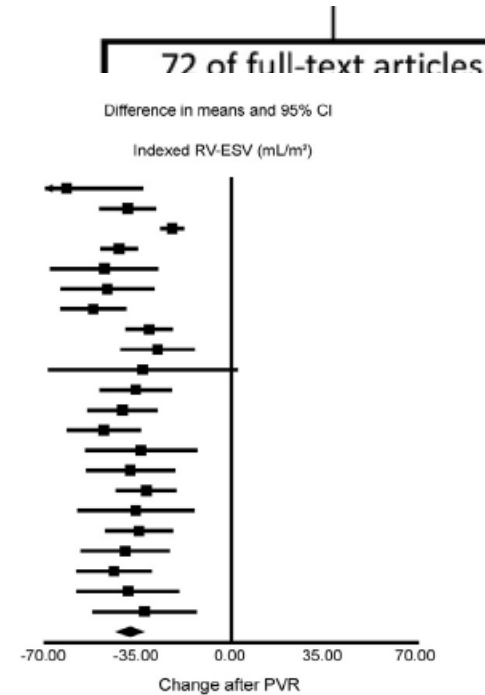
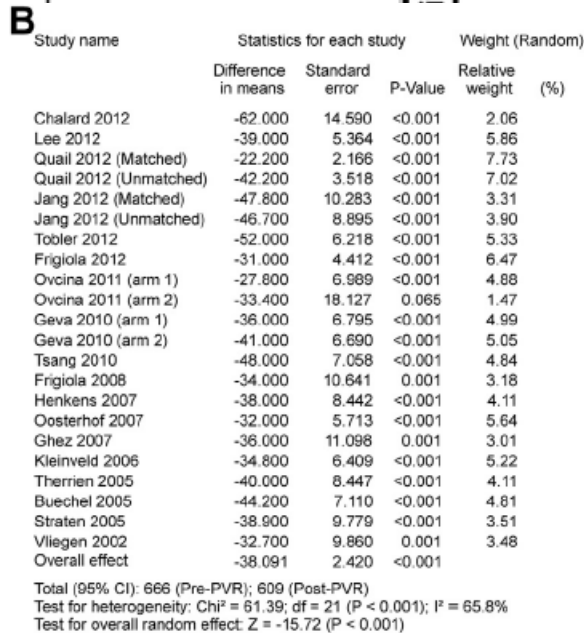
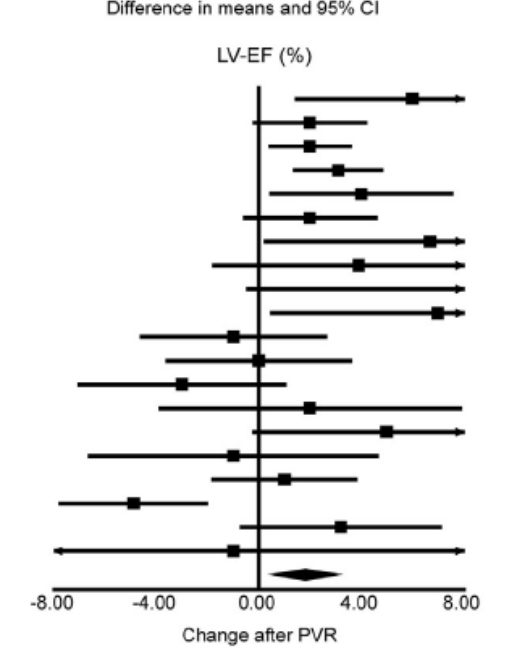
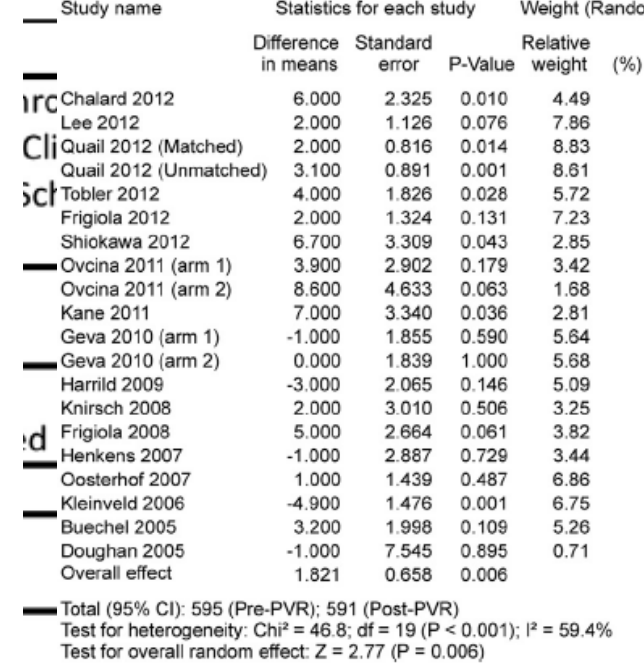
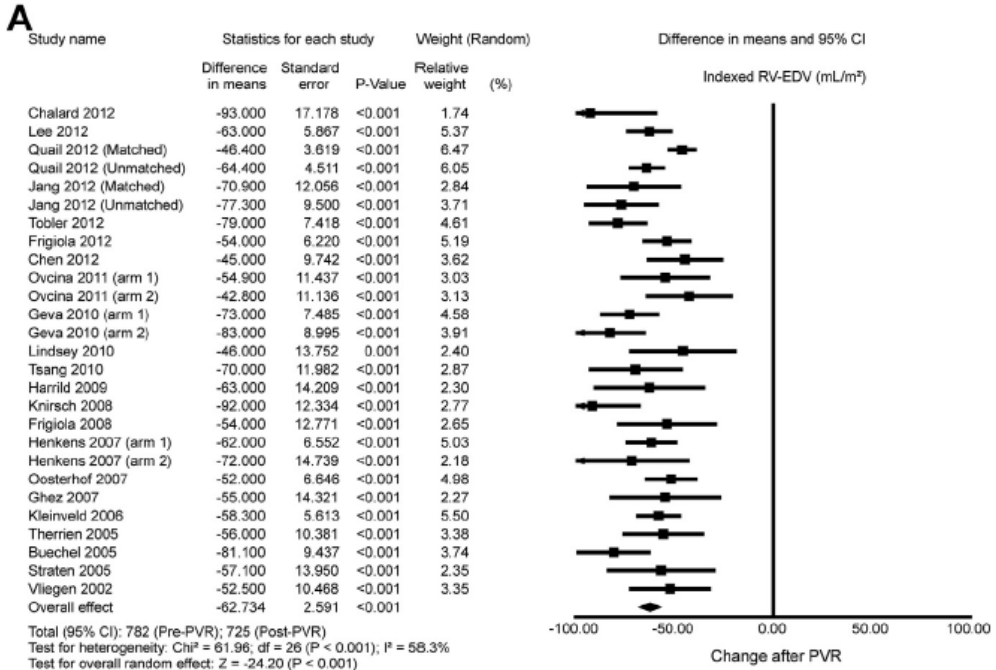


Tetralogy of Fallot – early intervention

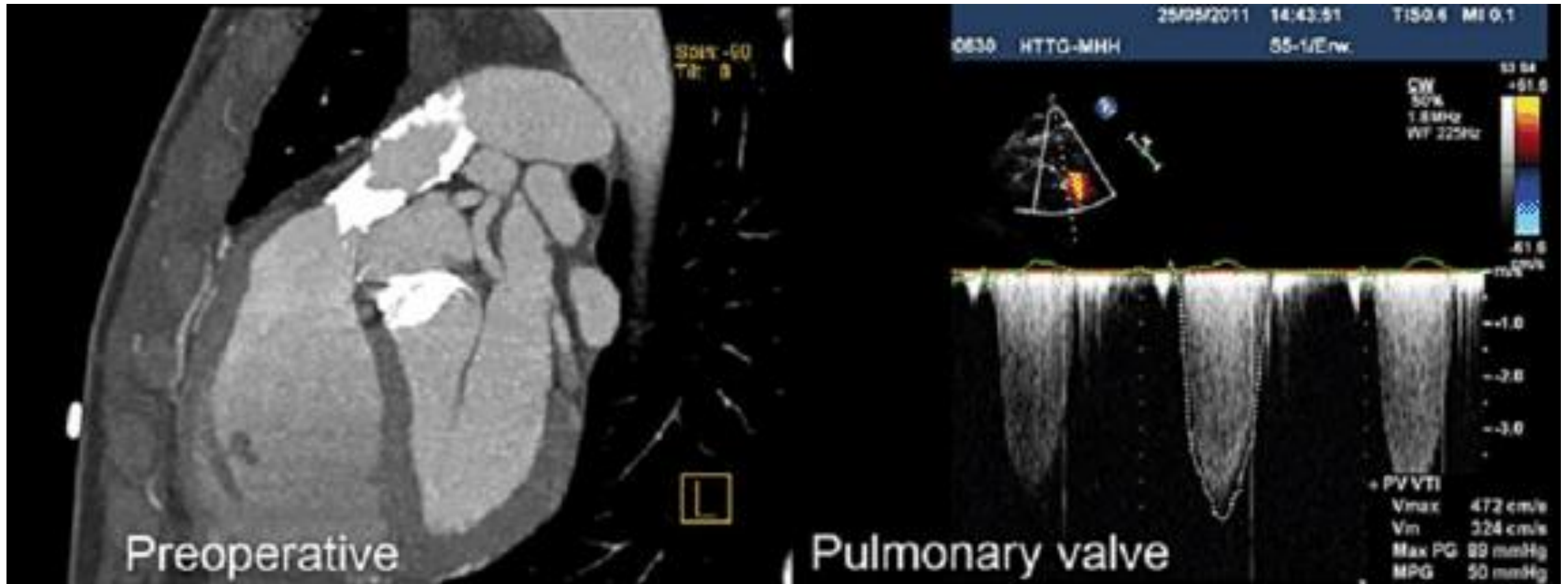
Fallot – later
repair



Similar conduits used in Ross procedures, Truncus arteriosus repair, and Rastelli



Conduits don't last



First use in
man 2000

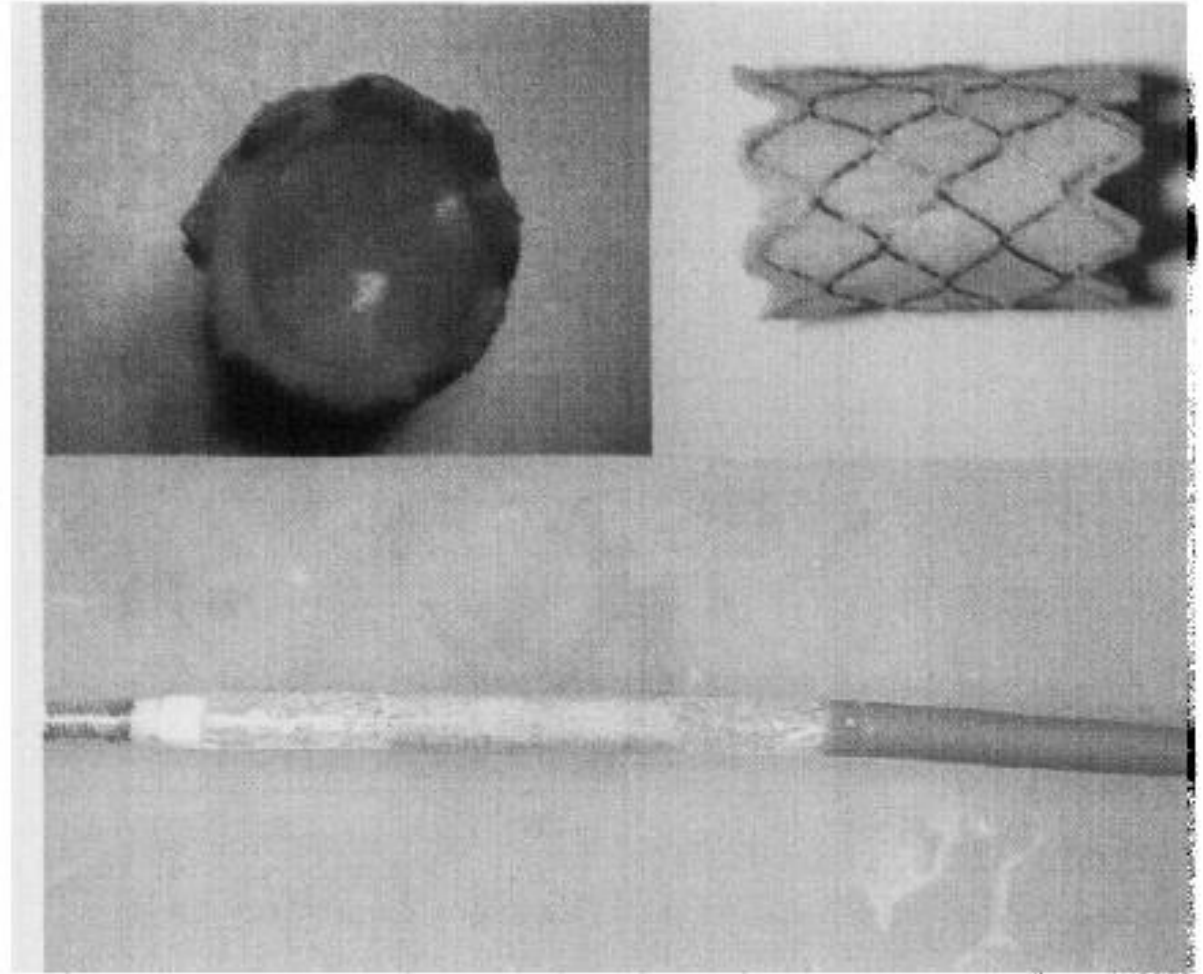


Figure 1: Valved stent

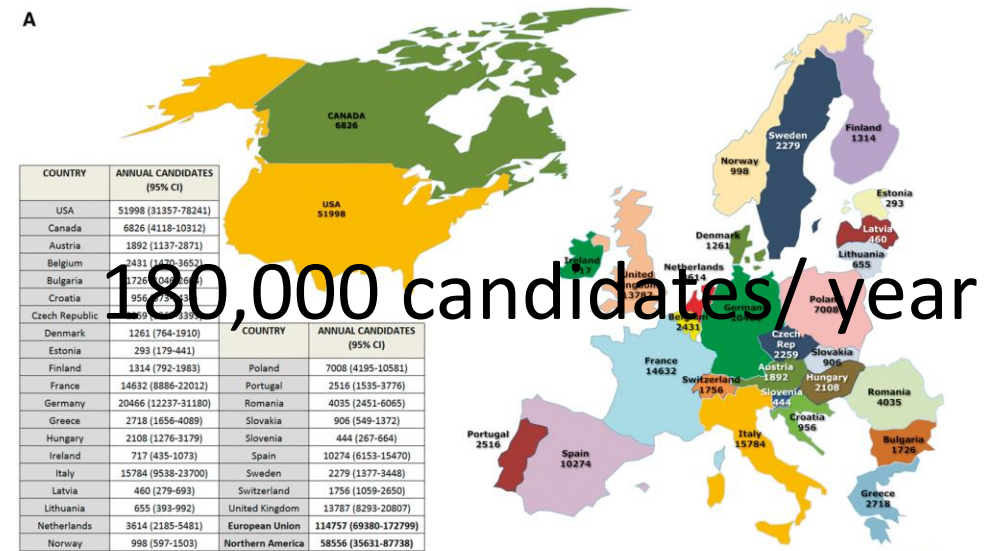
Upper left: closed valve mounted in the stent. Upper right: profile of the valved stent before compression. Below: valved stent in the delivery system.

TPVI

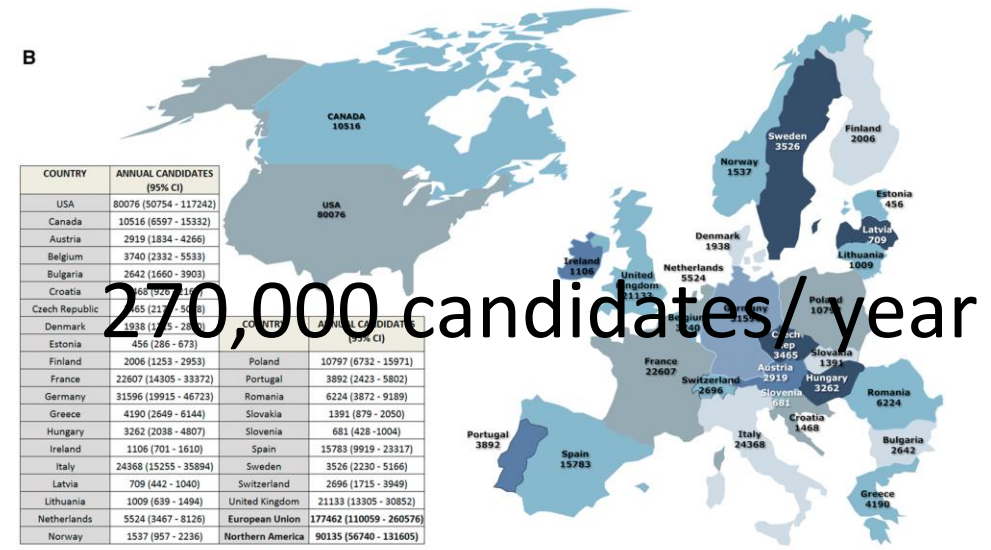
- First implant 2000
- CE mark in 2006
- FDA approval 2010
- Approx. 11,000 implanted totally

TAVI

A



B



The Melody[®] valve

- Initial indication – strictly RV-PA conduits
- Developed specifically to be positioned in a tube
- Not durable enough for moving/contracting surroundings
- Intended to postpone need for re-operation



Longevity of the Melody valve

Fig. 1 Graft survival : freedom from explant or redo PPVI

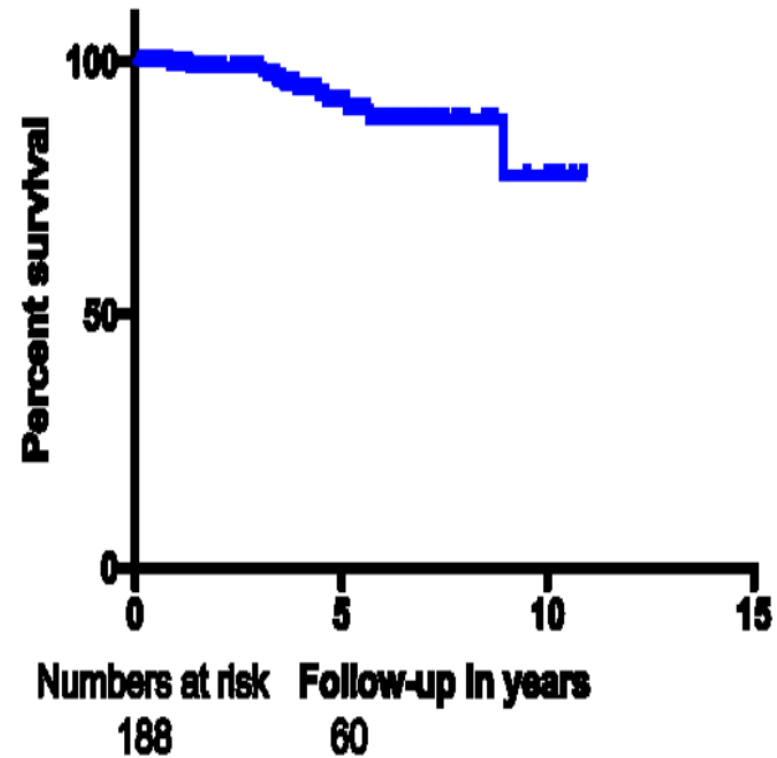
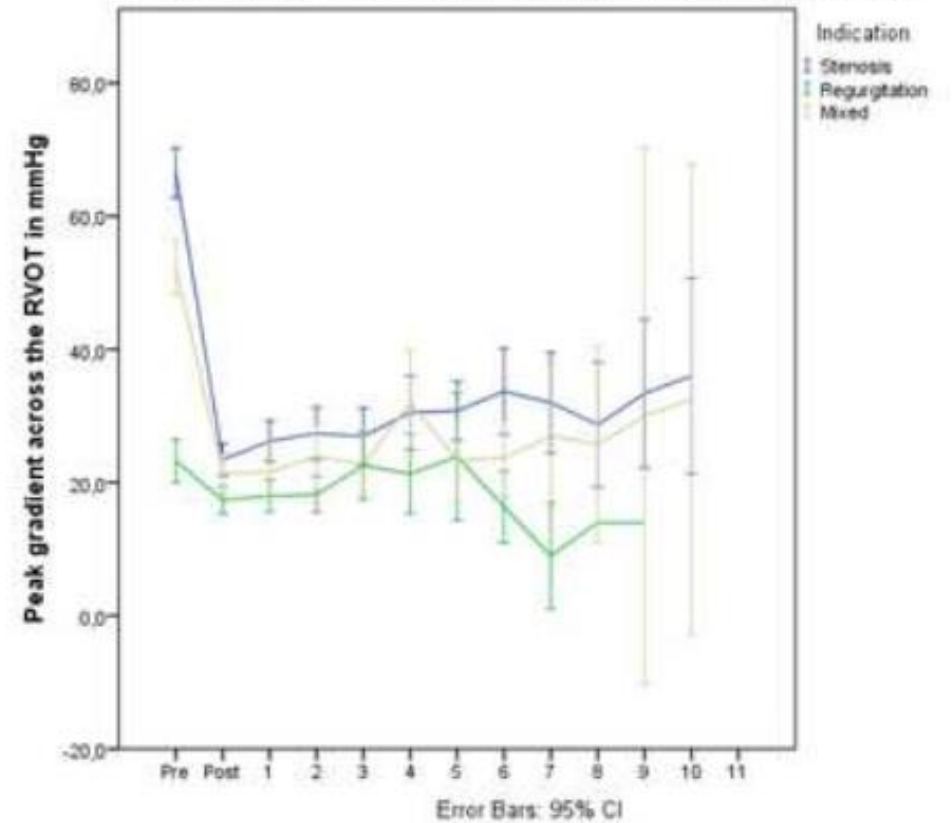
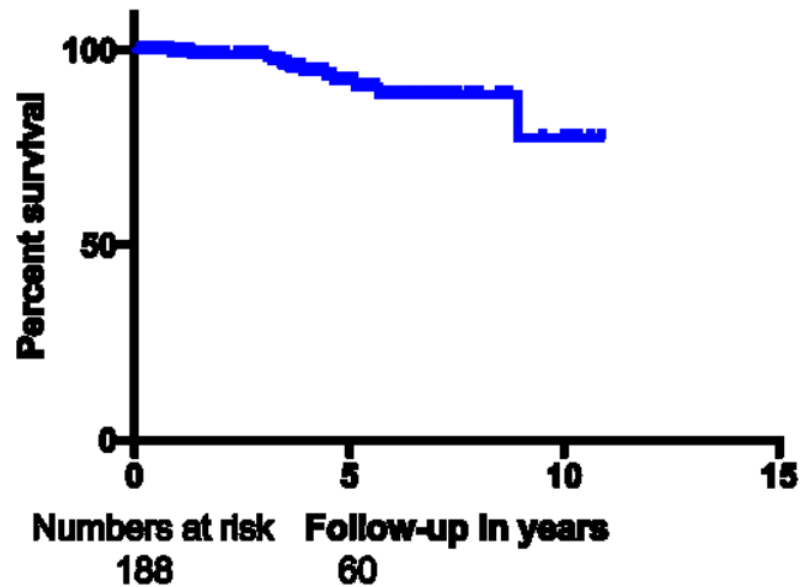


Fig2. Evolution of peak gradient across the RVOT after PPVI



Also feasible in non-conduit RVOTs.....

Fig. 1 Graft survival : freedom from explant or redo PPVI



conduit type	native or patch	61
	homograft	98
	Contegra [®]	23
	Hancock [®]	1.0
	Freestyle [®]	3

But still limited to size of 18-22mm...

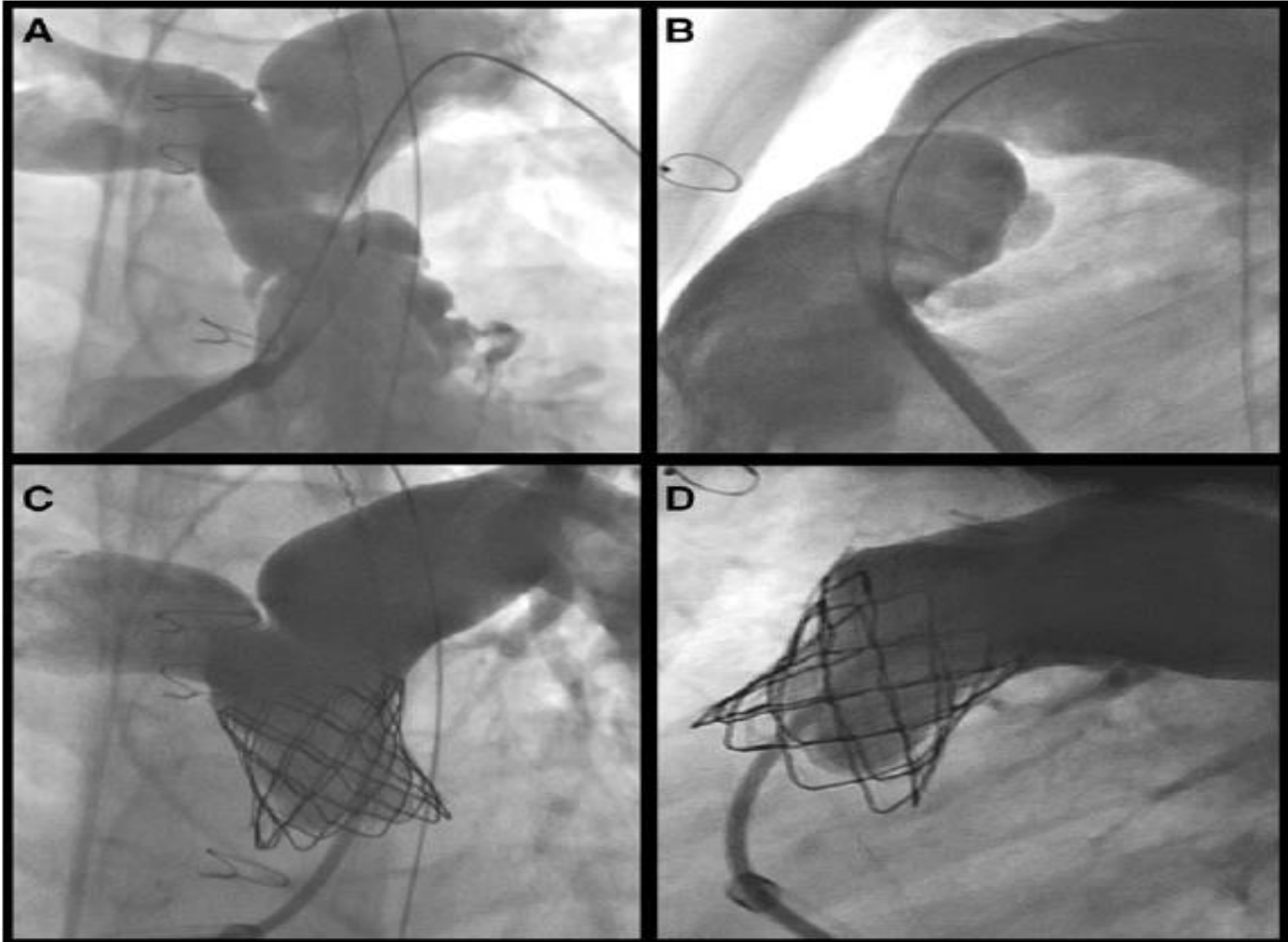
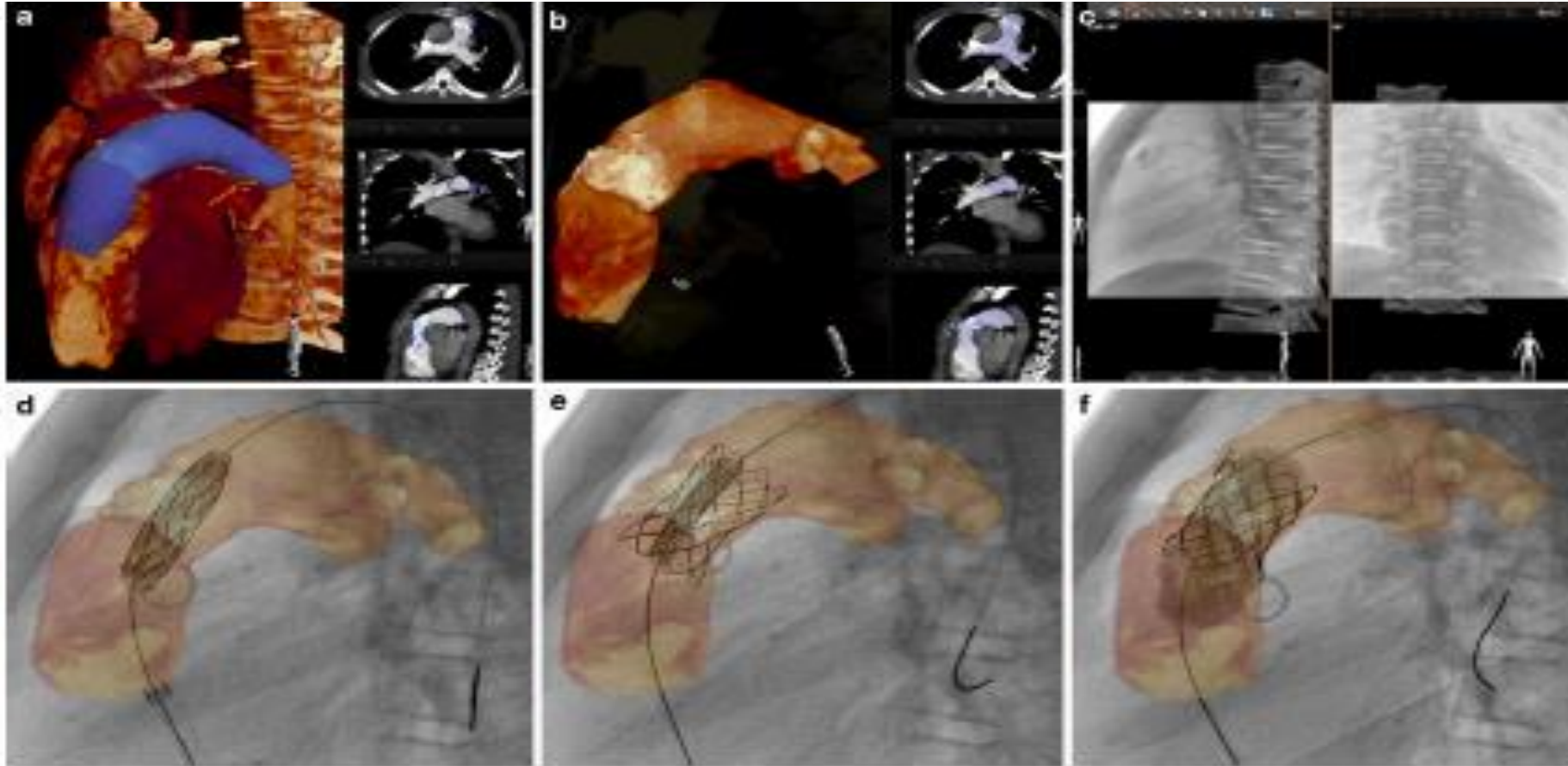


Table 1. Procedural Characteristics

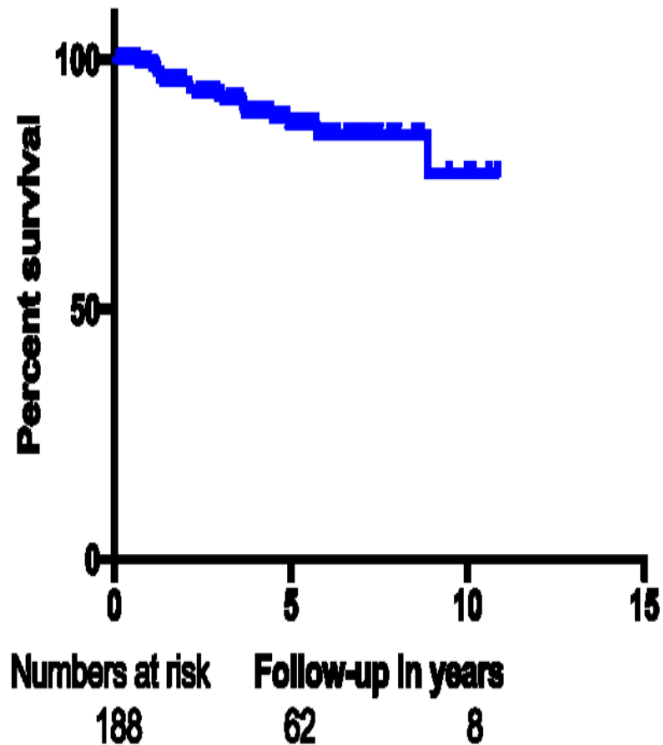
Balloon sizing prior to TPV implant	30/31	97%
RVOT pretest placed prior to TPV implant	22/31	71%
Pretest type		
Palmaz	19/22	86.5%
Genesis XD	1/22	4.5%
EV3	1/22	4.5%
CCPS+Palmaz	1/22	4.5%
TPV deployment balloon delivery size		
18 mm	1	3%
20 mm	5	16%
22 mm	24	77%
24 mm*	1	3%
Postdilation performed	5/31	16%
Postdilation balloon size	22–24 mm	

Advanced fusion imaging helps



Endocarditis

Fig. 5 Freedom from endocarditis



Cools et al, Eurointervention 2018

	Cools et al ¹	Hascoet et al ³	McElhinney et al ^{***4}	Malekzadeh-Milani et al ⁵
Number of patients	185	32	311	85
Patient age	19.4±13.2	19.8 (15.8-28.9)	N/A	23.3±10.5
Study period	2006-2017	2008-2016	2007-2012	2009-2012
Median follow-up time (years)	Mean 4.4, up to 11	4.9	2.5	2
Systolic RV-PA gradient post implantation (mmHg)	23.4±11.1	N/A	N/A	12.4±7.4
Proportion of patched/native RVOT (%)	32.8	16.5	0	0
Proportion of patients on aspirin post implantation (%)	0	100 (6 mo)	N/A	91
Endocarditis in Melody valves (%/person years)	2.3*	5.7 (2.9-11.4)**	2.4	3
Repeat pulmonary valve replacement during follow-up (%)	22 after 10 years	15.5 after 3.4 years	N/A	N/A

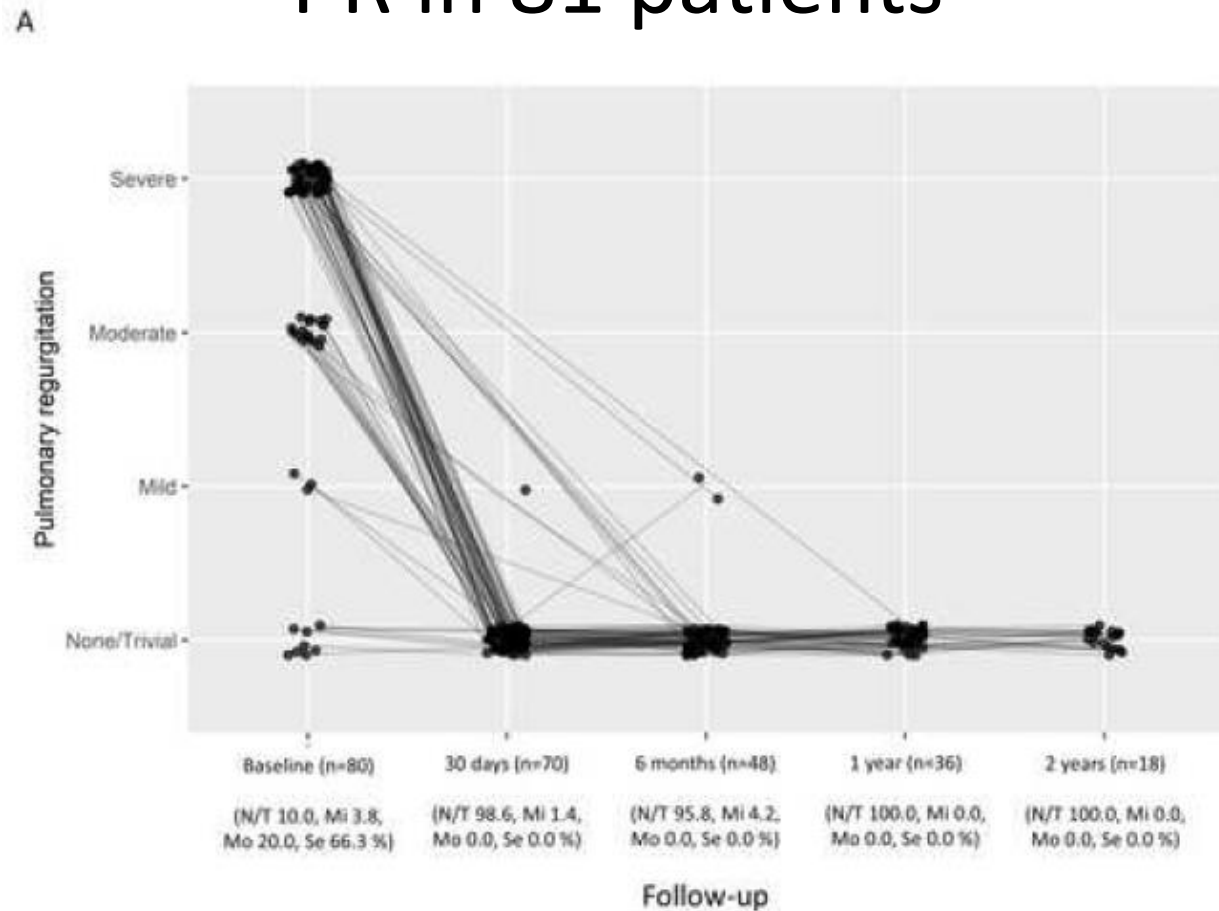
* Declined to <1% after introduction of strict prophylaxis. ** 7.8% before and 2% after April 2010. *** Pooled data from 3 studies.

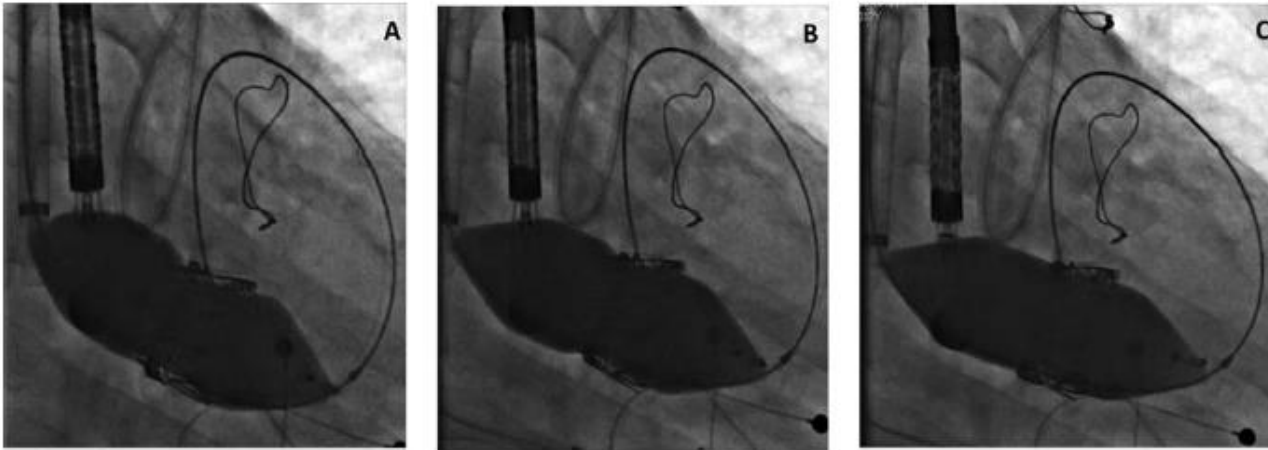
Schmidt, Eurointervention 2018

Sapien® valves allow for TPVI in large RVOTs

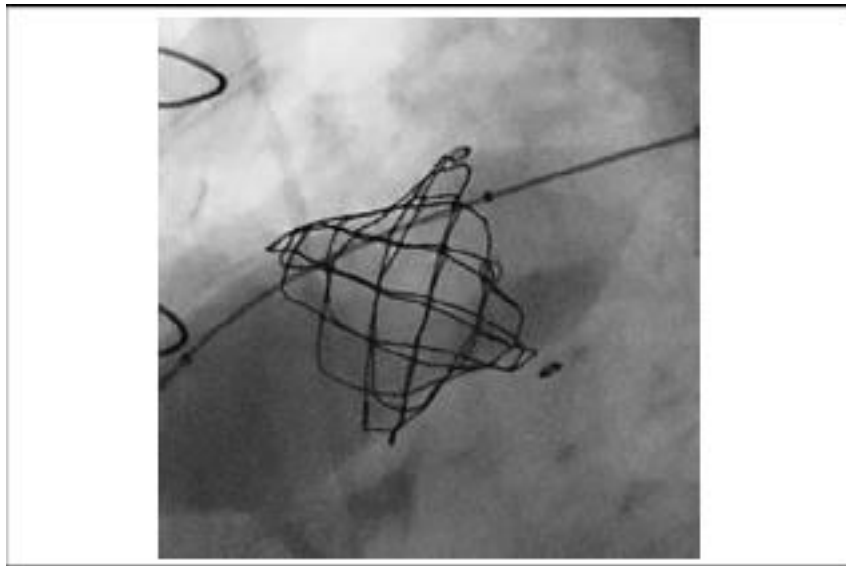
- Approved for TPVI (XT)
- Sizes 23mm, 26mm, and 29mm (Sapien 3)
- More complications?
- Advanced through RV uncovered
- Lower endocarditis risk?

PR in 81 patients





Brown Cath and cardiovasc interv 2016



Cabalka J Thorac Cardiovasc Surg 2018

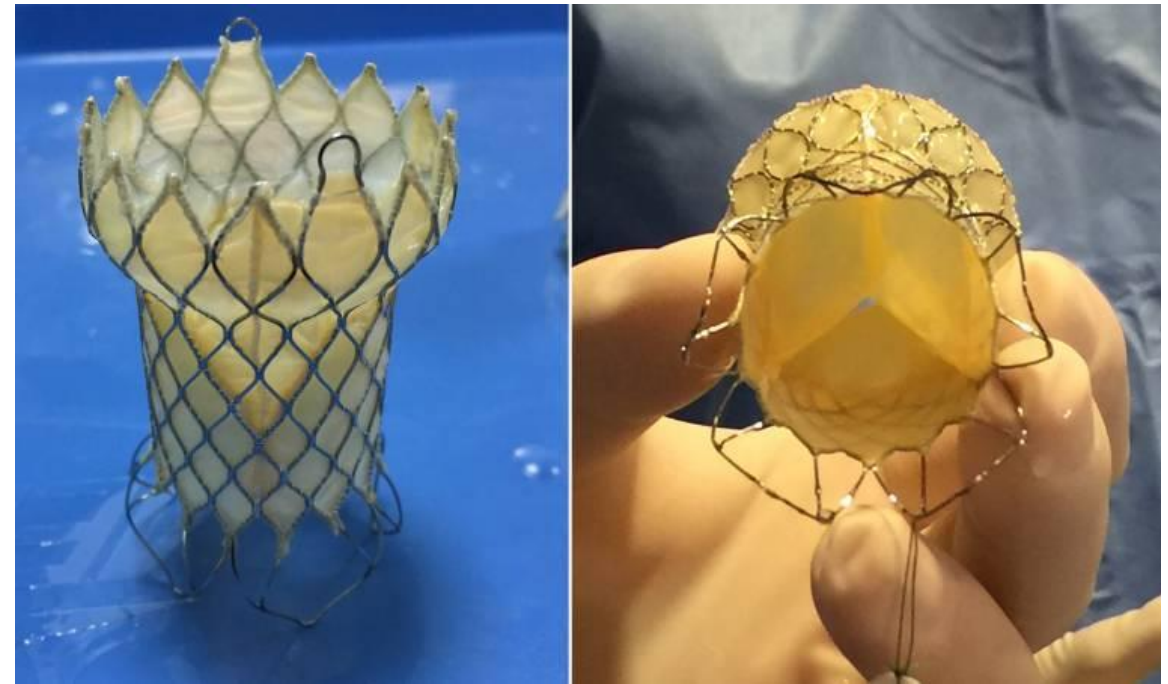
Advanced implantation techniques

- Cracking bioprosthetic valves takes 22-25 ATM
- Anchoring in stent in LPA
- Folding of MELODY valve
- In smaller children:
 - EDVi 150->130ml/m²
 - ESVi 90->80ml/m²
 - Jugular acces in patients <30
 - Sapien in patients <30kg very risky
- Long sheath for Sapien Valves
- Surgical and hybrid procedures

New valves



Harmony® (Medtronic)



Venus P-valve® (Venus Medtech)



Harmony valve

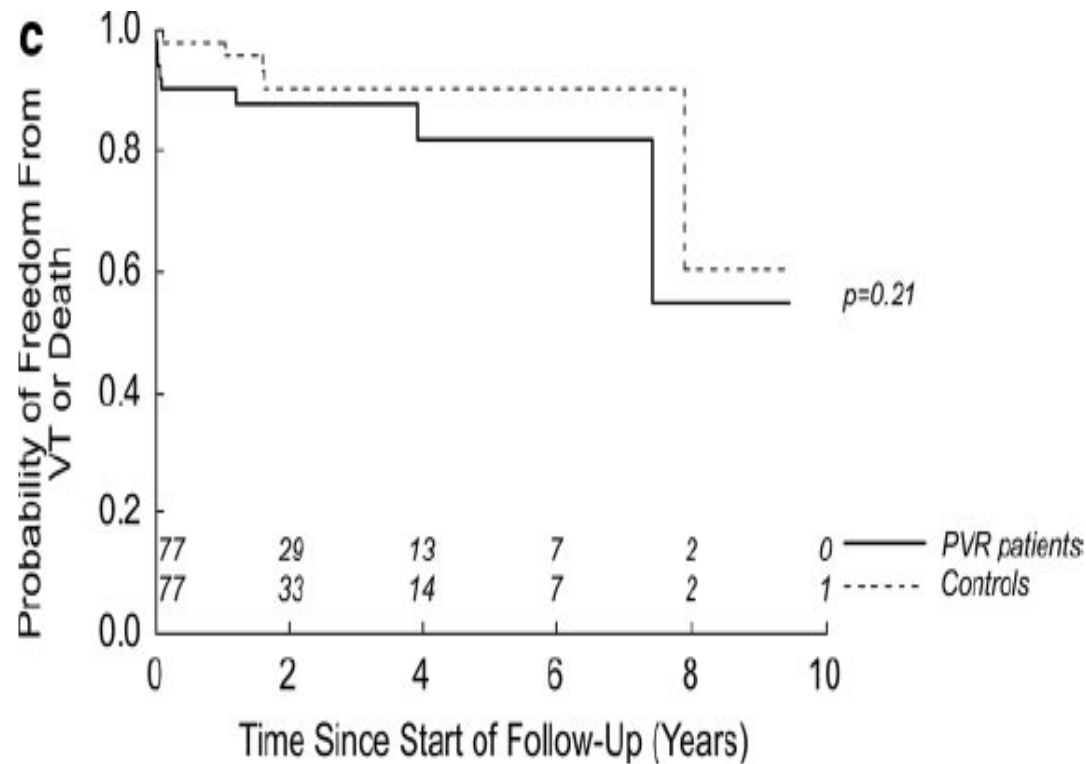
- Porcine pericardial tissue valve mounted on a self-expanding nitinol frame
- Expands 23.5 mm at valved section
- Pre-procdural CT important
- First feasibility studies promising
- More than 100 valves implanted
- Easier than TPVI with Melody?



Venus P valve

- **Porcine pericardial tissue valve mounted on a self-expanding nitinol frame**
- **Diameter 18-34 and length 20-35mm of straight segment**
- **For use in RVOT up to 32mm**
- **Pre-procdural CT important**
- **First feasibility studies promising**
- **More than 100 valves implanted**

Optimal timing of re-valving



- Uncertain effect in older patients
- RV remodelling may be irreversible
- RV fibrosis increasing with long-lasting PT

Earlier re-valving?

Pros	Cons
Prevention of ventricular remodelling	Need for multiple interventions during life-time
Less exercise intolerance, arrhythmias and sudden cardiac death	Procedural risk
Potential mortality benefit	Endocarditis and stent fractures
Transcatheter pulmonary valve implantation may be possible (initial and/or later)	

Summary

- TPVI has become a standard procedure for revalving in stenotic/incompetent RV-PA conduits
- The Melody[®] and Sapien[®] valves have also been successfully used in native and patch-augmented RVOTs, in bioprosthetic valves and in smaller children down to 30kg
- Stent valves can be used in in surgical and hybrid procedures, also in AV-valve position
- New valves allow for use in large RVOTs

Time for earlier pulmonary
valve replacement?
