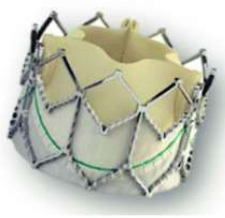


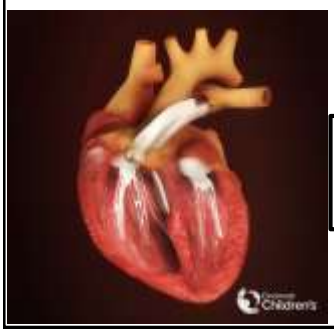
Pulmonary Valve Implantation , current indications, what is new

EgSC
EGYPTIAN SOCIETY OF CARDIOLOGY

REDA ABUELATTA, MD,FSCAI, FACC
Consultant interventional cardiologist
Madinah Cardiac Center SA
National Heart Institute EG
Cardio-Egypt
February 2018

Congenital Cardiac Diagnoses

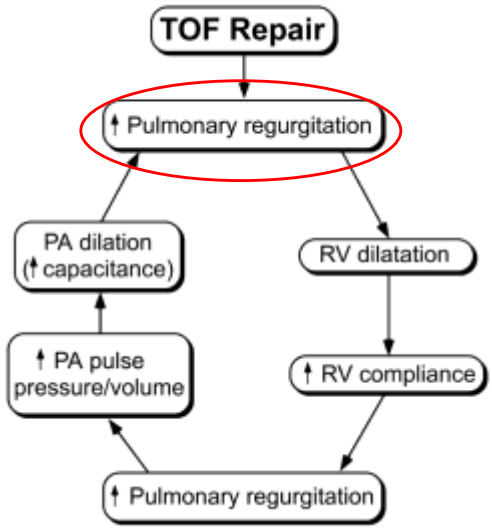
>20% of CHD lesions affect the RVOT



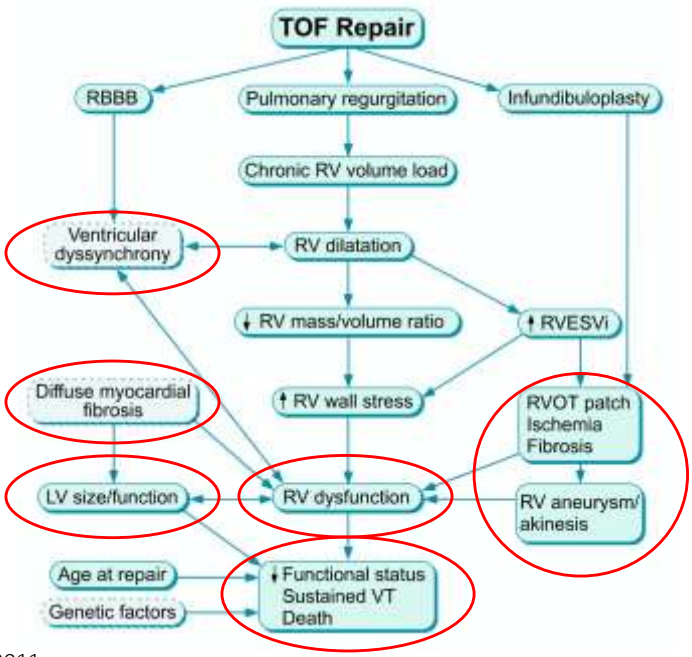
~20% repaired with conduit*

~80% repaired without conduit

Residual Lesions in TOF



Geva T. J Cardiovasc Mag Res 2011.



Geva T. J Cardiovasc Mag Res 2011.

The Bottom Line

Risks > Benefits

Risks ≈ Benefits

Risks < Benefits

Indications for conduit replacement (RVOT dysfunction)

- No formal guidelines regarding timing of sub-pulmonary conduit replacement
- Class IIa (LOE B):
  - It is reasonable to consider trans-catheter pulmonary valve replacement (TPVR) in the patient with ≥ moderate PR or PS provided the patient meets TPV IFU criteria

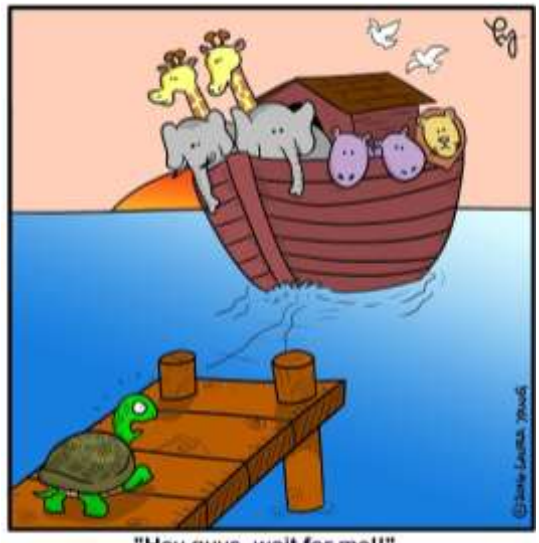
Feltes T et al. Circulation 2011;123:2607-2652.

Indications for Surgical PVR in TOF

- Class I: Severe symptomatic PR or PS
  - Exercise intolerance otherwise not explained
  - Signs/Symptoms of heart failure
  - Syncope attributable to arrhythmia

Irreversible RV dysfunction is *generally* present by the time symptoms develop

Geva T. J Cardiovasc Mag Res 2011.



Criteria	AHA	ESC	CCS	Geva
RVEDVi	≥Moderate	>160mL/m2	>170mL/m2	>150mL/m2 or Z-score >4 or RV/LV end-diastolic volume ratio >2
RVESVi	Not specified	Not specified	Not specified	>80mL/m2
RV function	≥Moderate RV dysfunction	Progressive RV dysfunction	≥Moderate RV dysfunction	RV EF <47%
RVOT obstruction	PIG ≥50mmHg or RV/LV pressure ratio ≥0.7	PIG ≥80mmHg (4.3m/s)	RV systolic pressure ≥2/3 systemic pressure	RV systolic pressure ≥2/3 systemic pressure
PR	Severe	Severe	Free	≥Moderate (PRF≥25%)
TR	≥Moderate	≥Moderate	"Important"	≥Moderate
QRS duration	Not specified	>180msec	Not specified	>140msec
Arrhythmia	Symptomatic or sustained AT or VT	Sustained AT or VT	AT or VT	Sustained tachyarrhythmia
Surgical considerations	Significant residual VSD or AR	Not specified	Significant residual VSD	LV EF <55%, large RVOT aneurysm, severe branch pulmonary artery stenosis, significant residual left-to-right shunt, severe AR or aortic dilation

What is the real value of PPVI

SYSTEMATIC REVIEW AND META-ANALYSIS

American Heart Association | American Stroke Association

Transcatheter Pulmonary Valve Implantation: A Comprehensive Systematic Review and Meta-Analyses of Observational Studies

Arka Chatterjee, MD; Navkaranbir S. Bajaj, MD, MPH; William S. McMahon, MD; Marc G. Cribbs, MD; Jeremy S. White, MD; Amrita Mukherjee, BDS, MPH; Mark A. Law, MD

Background—Transcatheter pulmonary valve implantation is approved for the treatment of dysfunctional right ventricle to pulmonary artery conduits. However, the literature is limited because of a small patient population, and it does not reflect changing procedural practice patterns over the last decade.

Methods and Results—A comprehensive search of Medline and Scopus databases from inception through August 31, 2016 was conducted using predefined criteria. We included studies reporting transcatheter pulmonary valve implantation in at least 5 patients with a follow-up duration of 6 months or more. In 19 eligible studies, 1044 patients underwent transcatheter pulmonary valve implantation with a pooled follow-up of 2271 person-years. Procedural success rate was 96.2% (95% confidence intervals [CI], 94.6–97.4) with a conduit rupture rate of 4.1% (95% CI, 2.5–6.8) and coronary complication rate of 1.3% (95% CI, 0.7–2.3). Incidence of reintervention was 4.4 per 100 person-years overall (95% CI, 3.0–5.9) with a marked reduction in studies reporting ≥75% prestenting (2.9 per 100 person-years [95% CI, 1.5–4.3] versus 6.5/100 person-years [95% CI, 4.6–8.5]; $P<0.01$). Pooled endocarditis rate was 1.4 per 100 person-years (95% CI, 0.9–2.0).

Conclusions—Our study provides favorable updated estimates of procedural and follow-up outcomes after transcatheter pulmonary valve implantation. Widespread adoption of prestenting has improved longer-term outcomes in these patients.
(*J Am Heart Assoc.* 2017;6:e006432. DOI: 10.1161/JAHA.117.006432.)

Key Words: endocarditis • Melody valve • reintervention • transcatheter pulmonary valve

Transcatheter pulmonary valve implantation: valve technology and procedural outcome

Parameter	No. of Studies	Events/ 100 PY	Lower CI	Upper CI	I^2	*P* Value
Death	19	0.6	0.3	0.9	0.0	0.95
Stent fracture	14	4.4	2.4	6.3	79.7	0.00
Type 2/3 stent fracture	15	1.3	0.5	2.0	53.3	<0.01
Patients requiring reintervention	19	4.4	3.0	5.9	51.4	<0.01
Catheter re-interventions	19	2.7	1.7	3.7	44.7	0.02
Surgical reintervention	19	1.7	1.2	2.2	0.0	0.56
Endocarditis	19	1.4	0.9	2.0	11.9	0.31
TPV specific endocarditis	19	0.6	0.3	0.9	0.0	0.70
Endocarditis requiring explantation/ death/reintervention	19	0.6	0.3	0.9	0.0	0.88
Effect of prestenting						
Stent fracture						<0.01*
≥75% prestenting	8	2.3	0.8	3.7	57.7	0.02
<75% prestenting	5	7.2	5.0	9.3	26.9	0.24
Type 2/3 stent fracture						0.01*
≥75% prestenting	9	0.6	0	1.2	0.0	0.91
≤75% prestenting	5	2.3	1.4	3.2	60.5	0.04
Patients requiring reintervention						<0.01*
≥75% prestenting	12	2.9	1.5	4.3	0	0.46
<75% prestenting	6	6.5	4.6	8.5	56.5	0.04
Catheter reinterventions						<0.01*
≥75% prestenting	12	1.5	0.7	2.3	1.5	0.43
<75% prestenting	6	4.4	3.3	5.5	0.0	0.56
Surgical reinterventions						<0.01*
≥75% prestenting	12	1.3	0.5	2.0	0.0	0.81
<75% prestenting	6	2.2	1.4	3.0	35.7	0.17

Systematic review and meta-analyses pooling studies reporting TPVI outcomes on conduit as well as non-conduit RVOTs with Melody and Edwards THV systems

- TPVI was found to have an outstanding procedural success rate with an acceptable complication profile and low need for surgical conversion.
- lower rates of infective endocarditis and TPV-related endocarditis
- More experience needs to be gained with non-conduit RVOT TPVI procedures as well as with using the newer generations of Edwards Sapien XT and Sapien 3 systems to draw concrete conclusions about the same

Journal of the American Heart Association. 2017;6:e006432
Originally published August 4, 2017

Indications for Melody TPVR

- Presence of circumferential RVOT conduit ≥ 16 mm < 24 mm at implantation and RVOT dysfunction
- Pulmonary regurgitation
  - ≥ Moderate PR
- Pulmonary stenosis
  - RVOT mean gradient (echo) ≥ 35 mmHg
- Mixed PR/PS:
  - One criteria from each category

McElhinney. Circulation 2010;122:507-516.

Indications for Sapien XT/3 TPVR

- RVOT conduit > 18 mm/ < 32 mm
- Presence of a dysfunctional non-compliant RVOT conduit
- Pulmonary regurgitation
  - ≥ moderate PR
- Pulmonary stenosis
  - Mean RVOT gradient (echo) ≥ 35 mmHg

Kenny D et al. J Am Coll Cardiol 2011;58:2248-2256.

Melody™

Transcatheter Pulmonary Valve (TPV)

Designed specifically for pulmonic

- Natural Bovine Jugular Vein Valve
  - Indicated for re-expansion from 18mm to 22mm
- Platinum Iridium Frame
  - 28mm length when expanded to 18mm
  - Crimped down to 6mm on delivery system

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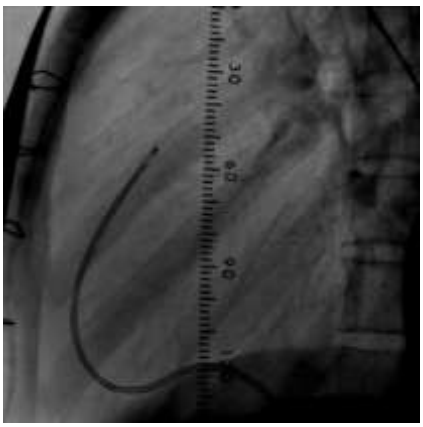
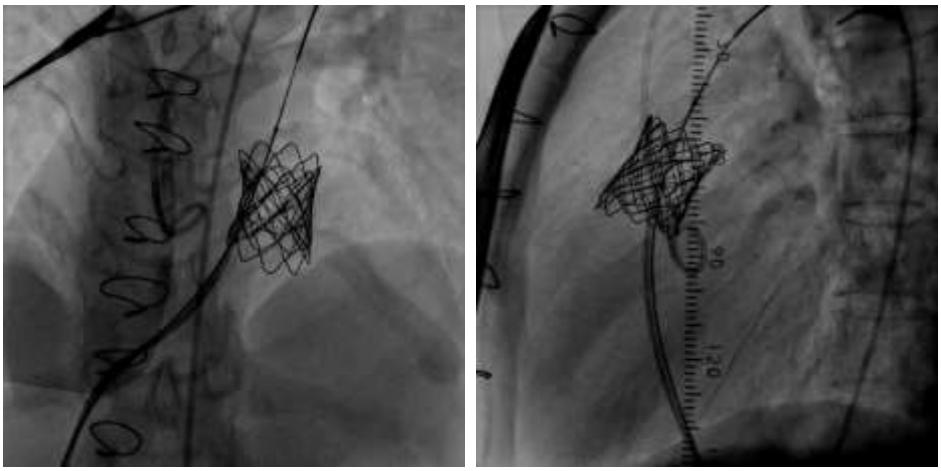
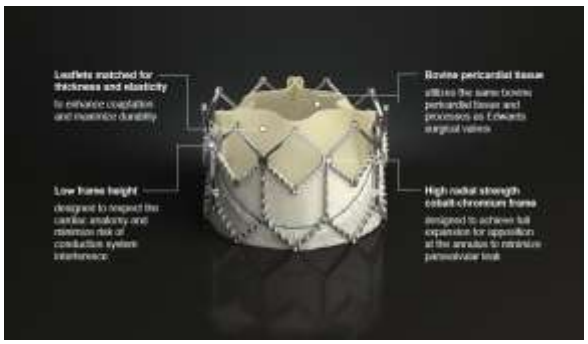
BASELINE VENTRICULOGRAPHY



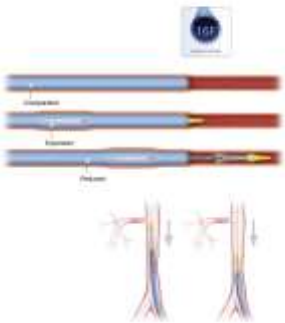
POST IMPLANTATION PULMONARY ANGIOGRAPHY



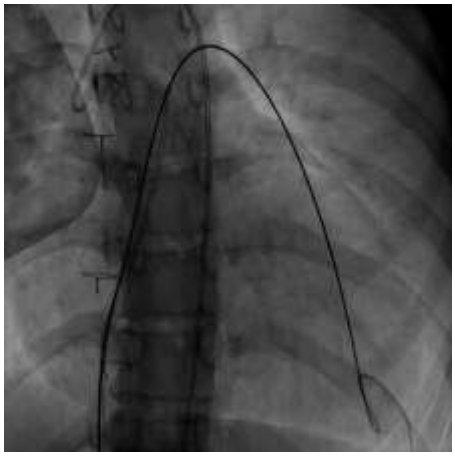
Sapien XT

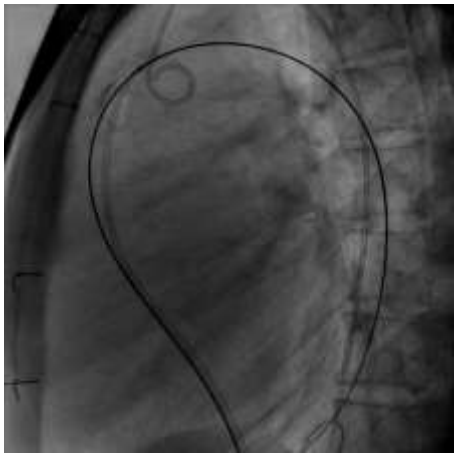


Sapien 3

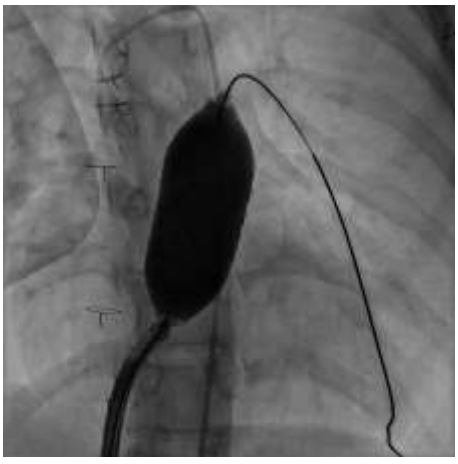


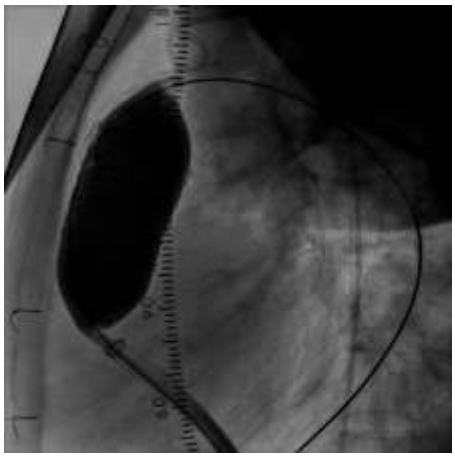
Baseline Pulmonary Angiography



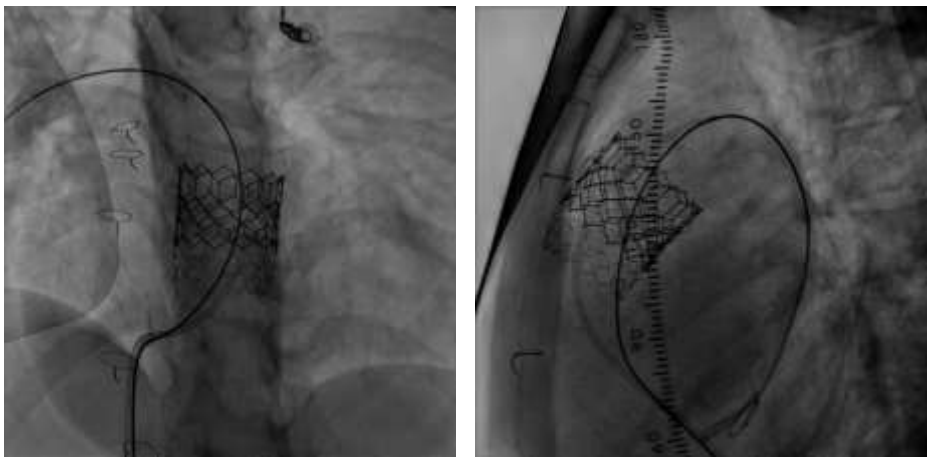


Why we do this step





Final pulmonary angiography



Indications for TPV Therapy Clinical Scenarios in Patients with PR

- Meets threshold for surgical PVR, needs a valve
  - Good candidate for TPV
  - Poor candidate for surgery ???
-
- Does not meet threshold for surgical PVR
  - Symptomatic
  - Asymptomatic
    - Silent symptoms
    - Asymptomatic with RV dysfunction
      - At rest
      - With exercise/pharmacologic stress
    - Prophylactic (protect RV) ???

Take home message

- RV-PA conduit and “native” RVOT repairs are distinct
- Different anatomy and pathophysiology
  - “Native” RVOT: Predominant PR
  - RV-PA Conduit: Predominant PS or Mixed
- Guidelines specific to TPVR are lacking
- Timing of PVR may be a moving target
- Very good outcome of PPVI by available valves and waiting for more

THANK YOU FOR YOUR ATTENTION