Update On Transcatheter Pulmonary Valve Replacement

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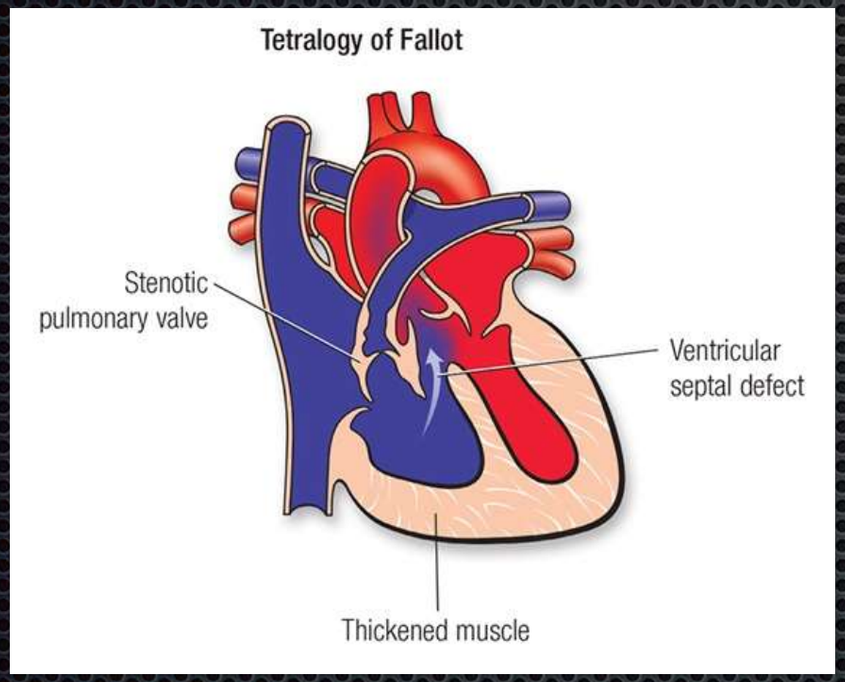
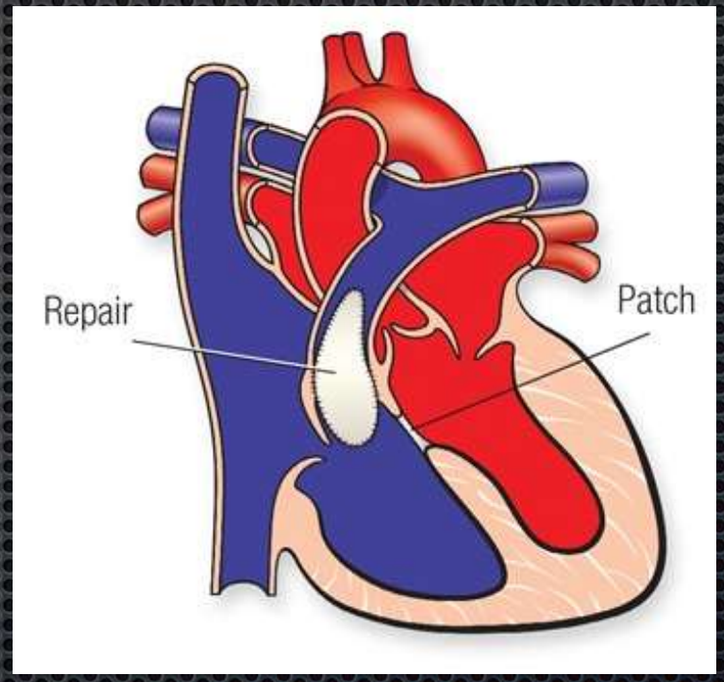
Disclosures

None

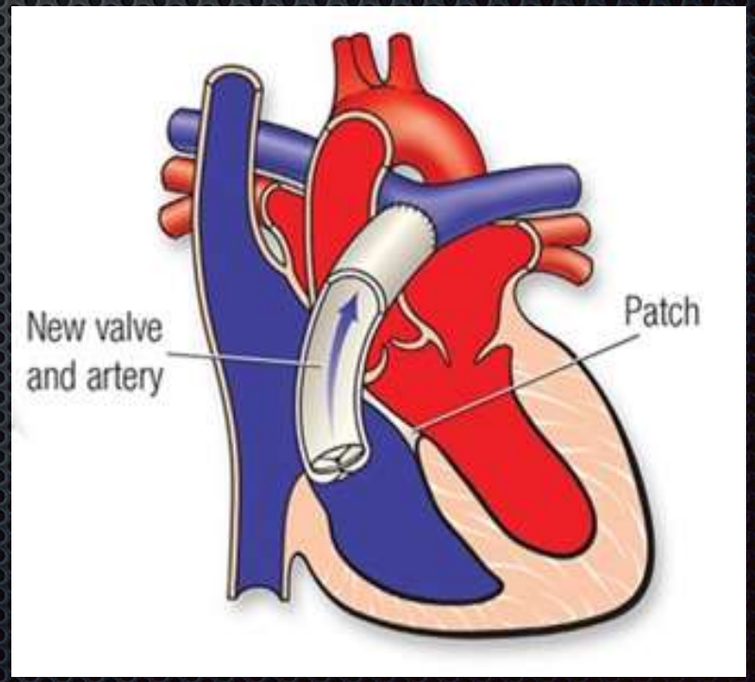
Pulmonary Regurgitation

- 23% of Congenital Heart Disease has abnormality of the RVOT (usually stenosis) relieved by surgical patch or conduit between the right ventricle and pulmonary artery Eg: Tetralogy of Fallot, Truncus Arteriosus, Transposition of Great Arteries with VSD





Patch



Conduit

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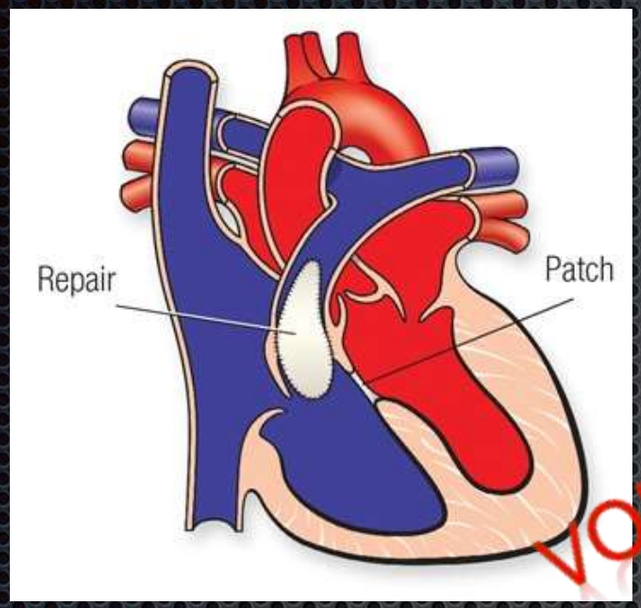
Long Term Sequale of Patch vs. Conduit Repairs

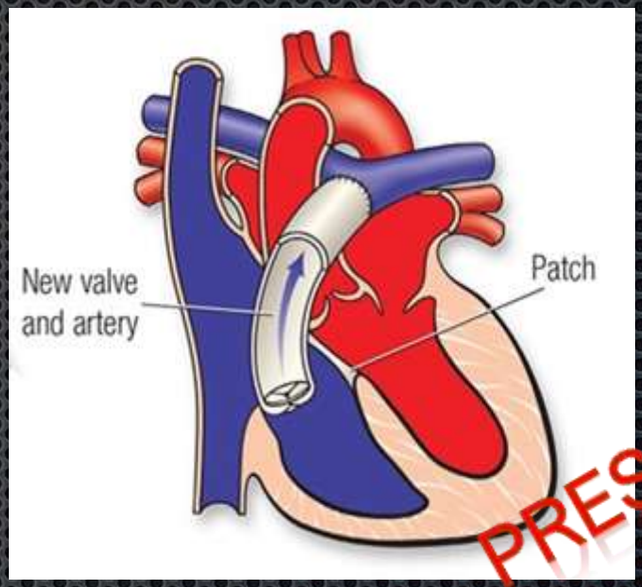
Patch



REGURGITATION

- RV dilation
- Systolic and Diastolic Dysfunction
- Arrhythmias

Conduit



STENOSIS
(and regurgitation)

- RV hypertrophy
- Diastolic Dysfunction
- Arrhythmias

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Surgical Pulmonary Valve Replacement

- Patients can be treated surgically for conduit / pulmonary valve replacement but risks and difficulties of repeated surgeries
- Boston Children's 2003 paper
  - 254 surgical pulmonary valve replacements
  - Patient age 10-21 years
  - Early Mortality 0.7%
  - Periop Strokes 2%
  - Early reoperation (bleeding) 3%
  - Overall SAE 7.9%

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Transcatheter Pulmonary Valve Replacement - History

- In 2000, Philipp Bonhoeffer in Paris, France reported the first-in-man replacement of a pulmonary valve in a regurgitant conduit using a catheter-based system
- The original design has undergone a few revisions, and the work purchased by Medtronic
- The valve is now called Melody and the delivery system Ensemble
- HDE approval was granted for the Melody valve in conduits December 2010 - first FDA approved transcatheter valve!
- Valve-in-valve FDA approval March 2017

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Melody Valve and Ensemble Delivery System

- Bovine interval jugular vein valve mounted on platinum-iridium stent
- Balloon-in-Balloon stent delivery catheter with “carrot” and protective outer sheath to allow single-pass delivery
- 3 sizes 18, 20, 22mm balloons

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Transcatheter Pulmonary Valve Replacement - History

- March 2016 Edwards Sapien XT valve FDA approved for pulmonary conduits
- 20 23 26 29 mm sizes
- NB: Sapien S3 valve being used “off-label”

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TPVR vs. TAVR

	Aortic	Pulmonary
Indication	Stenosis	Regurg and Stenosis
Disease	Degenerative	Congenital
Etiology	Degenerative	Iatrogenic!
Age	Older adult	Children - Adult
Annulus compliance	Non compliant	Very compliant
Pre-stenting	No	Always
Access	Artery	Vein

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Melody vs. Sapien

	Melody	Sapien
Sheath	22Fr	“18"Fr
Delivery system	covers valve	valve “bare”
Ease of delivery	easy	can be hard
Bailout	easy	can be hard
Size range	16mm-22mm	20mm-29mm
Stent rigidity	soft	rigid
Durability	good	good
Late SBE	higher	lower

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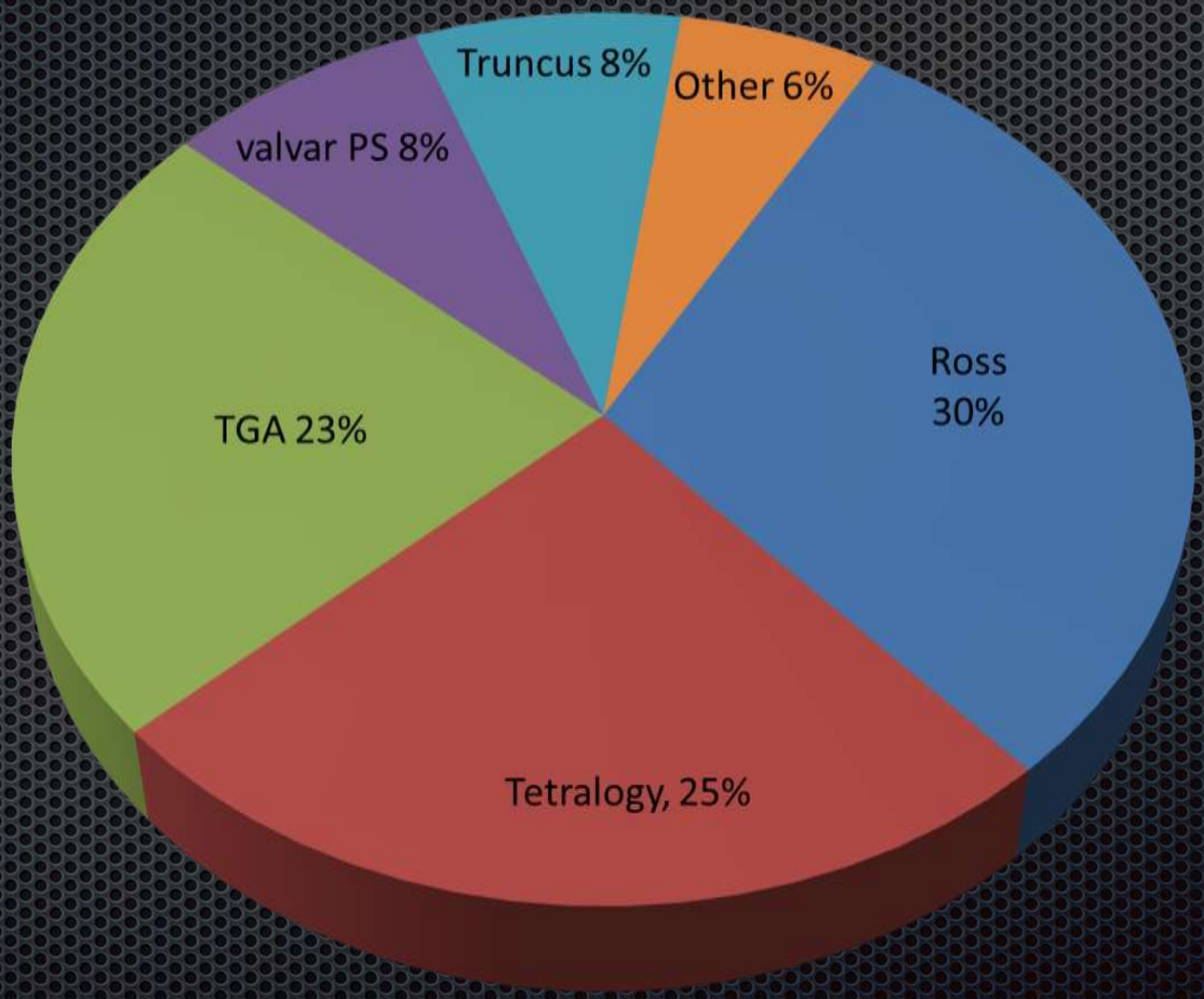
Underlying Disease Needing TPVR - Mount Sinai Experience



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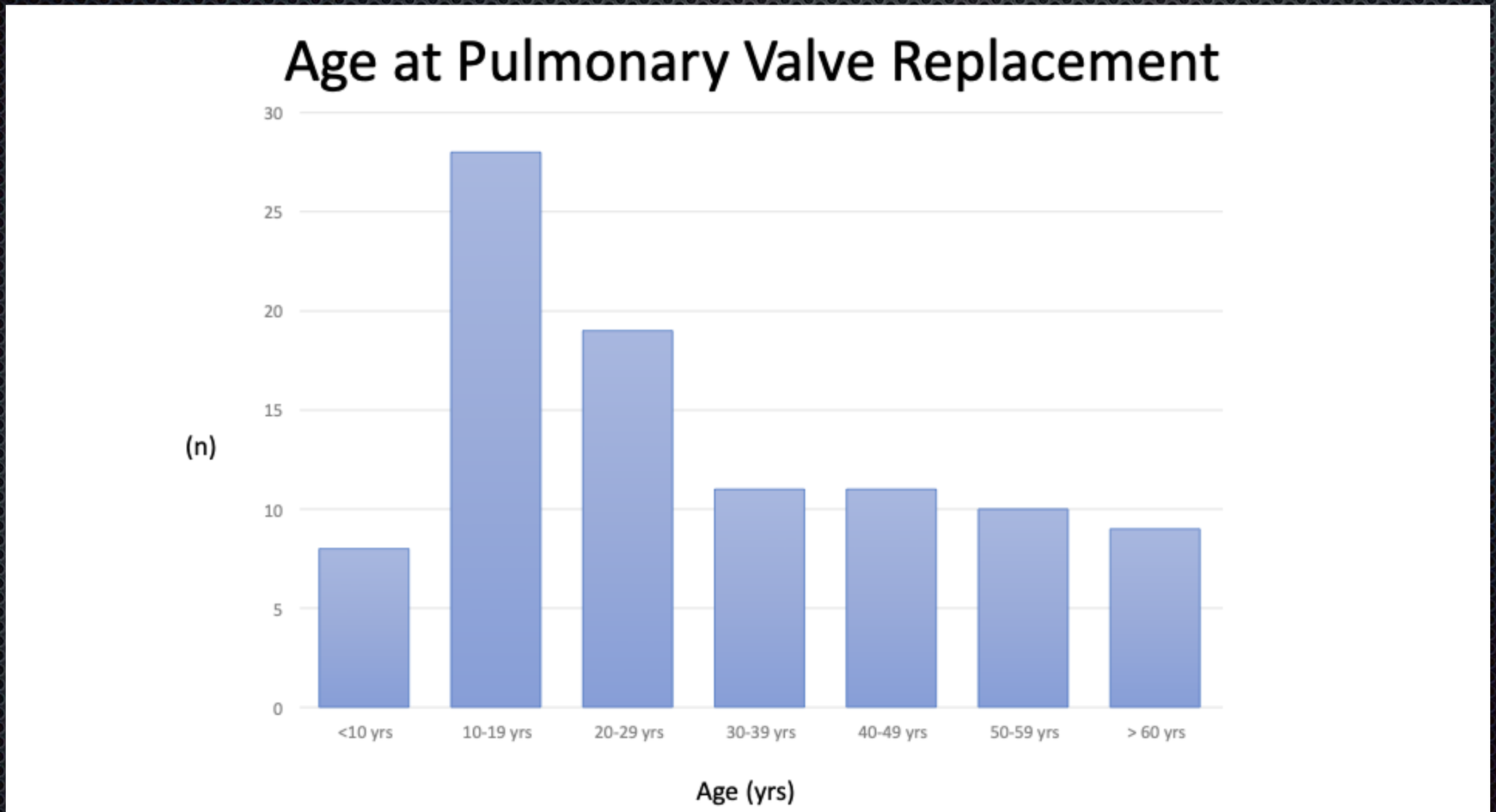
Age at TPVR - Mount Sinai Experience



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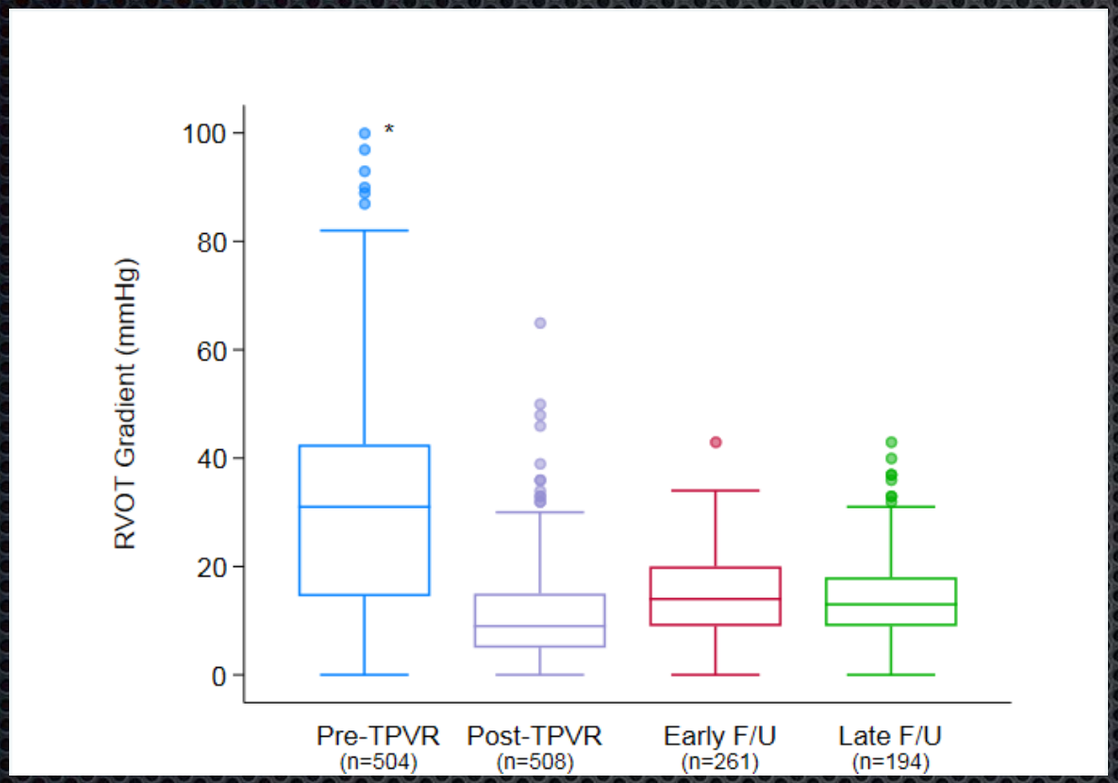
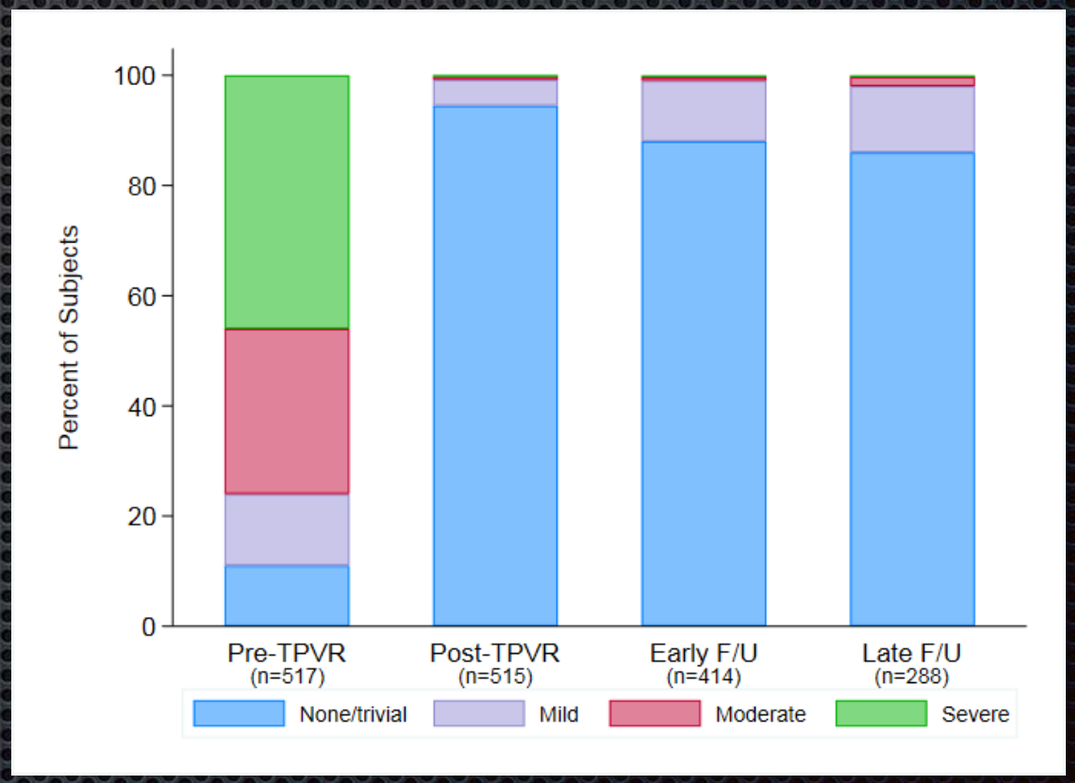
Acute Outcomes

- Multicenter (17 site) registry of 530 TPVR implants over 3 years 2014-16
- Melody 88% Sapien 12%
- SAE 9%





- Adverse Events, Radiation Dose and Reinterventions Following Transcatheter Pulmonary Valve Replacement: A Multicenter C3PO-QI Report. Goldstein et el. JACC (in-press)

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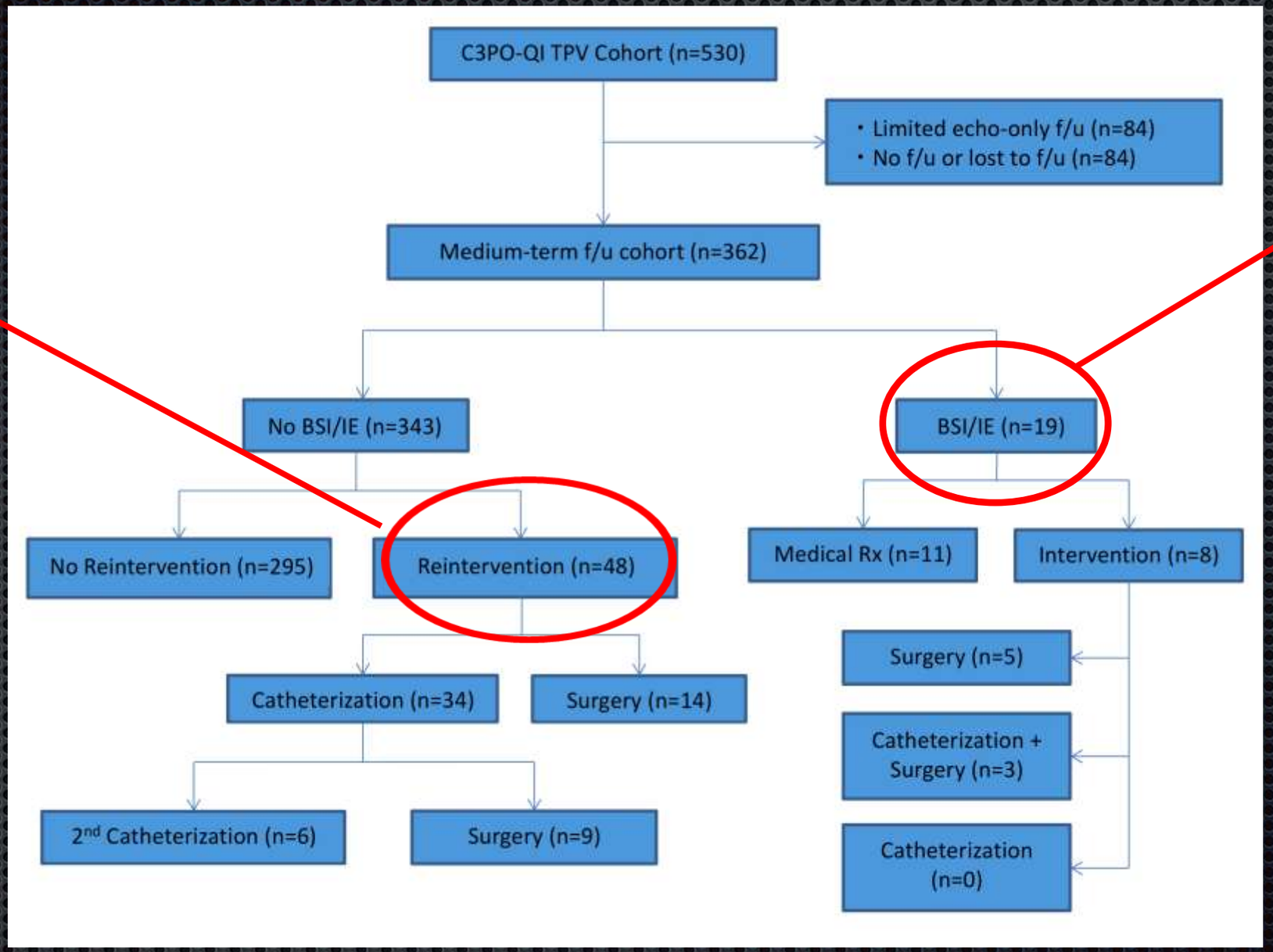
Medium-Term Outcomes

13% Reinterventions
But only 6%
Unplanned for PV

5% SBE



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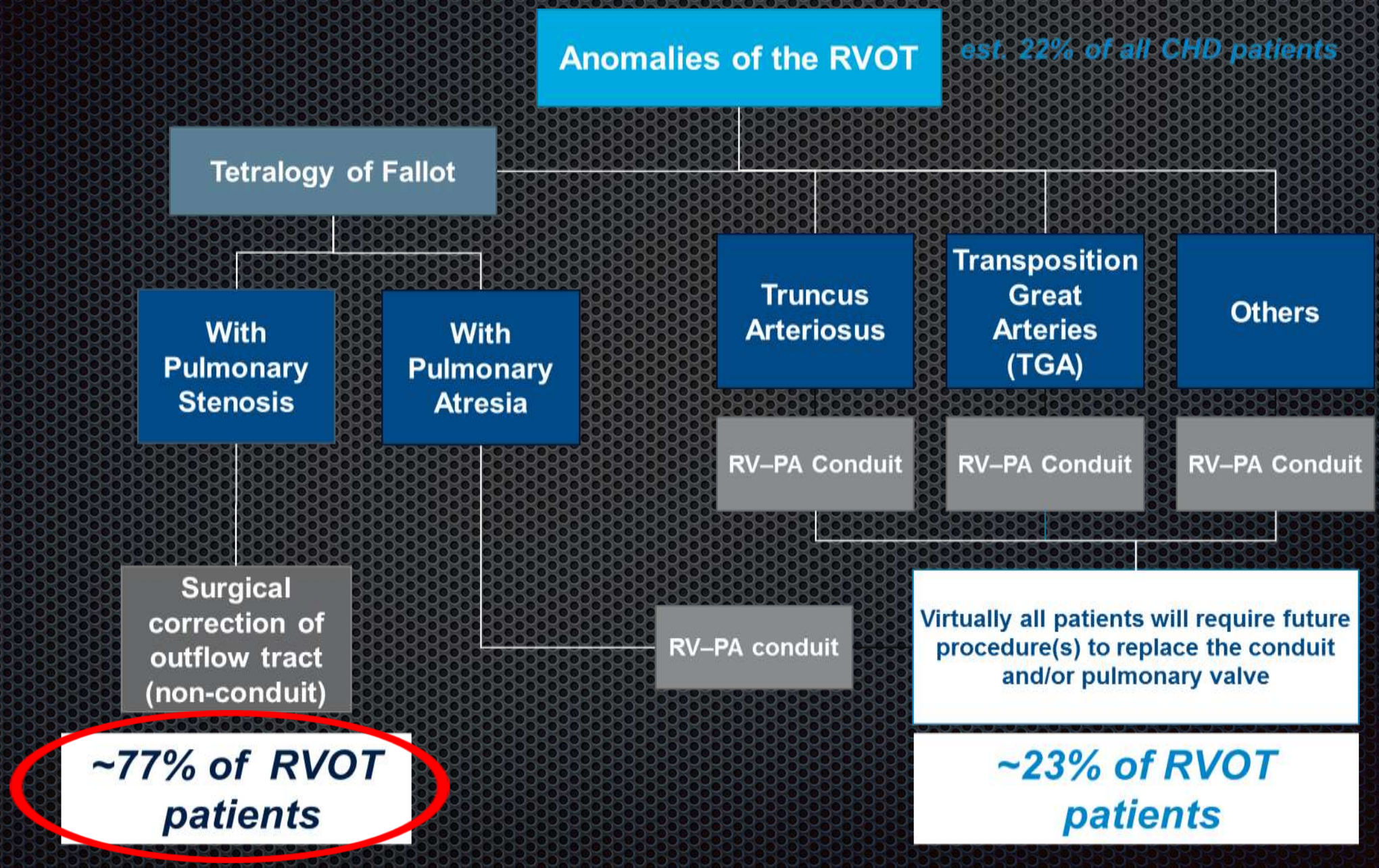
The Future



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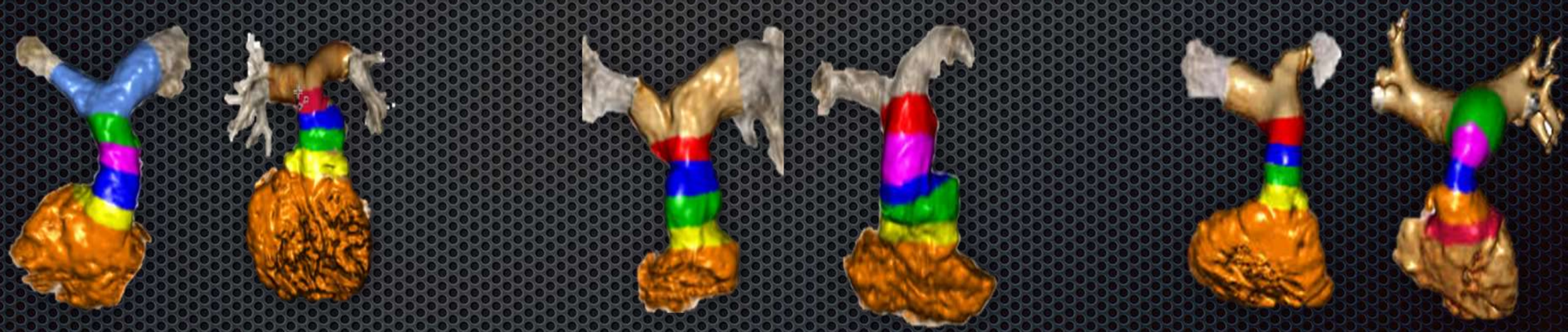
Challenges of Native RVOT

- Highly variable
- Large
- Compliant anatomy



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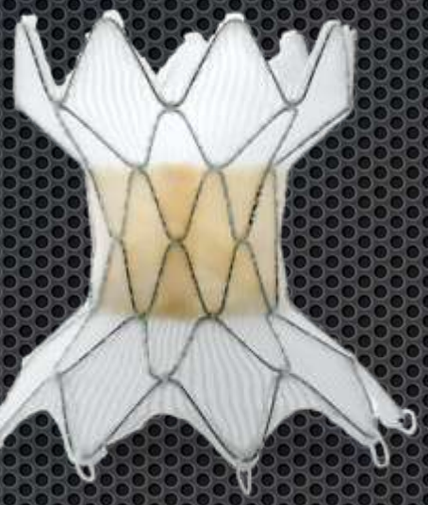
Clinical Studies

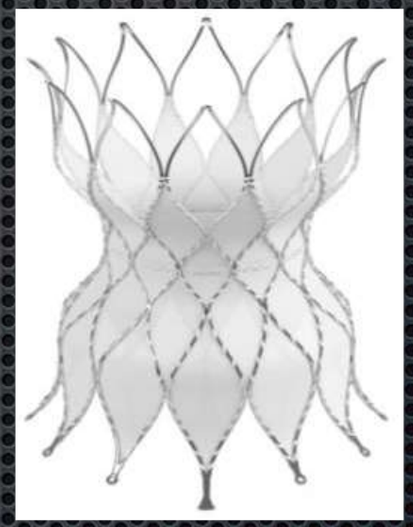
- Medtronic Harmony

Harmony TPV 22



Harmony TPV 25

- Edwards Alterra



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