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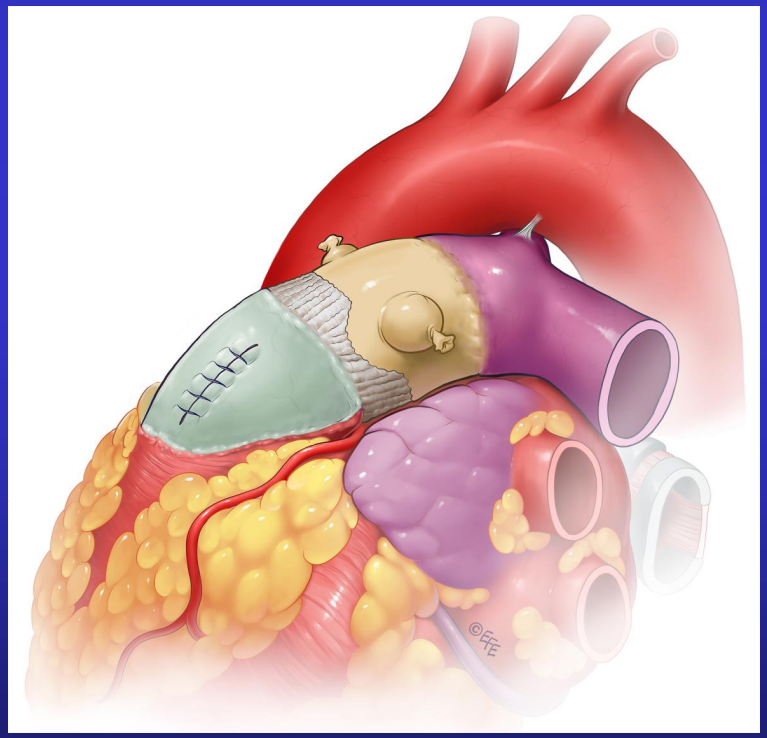
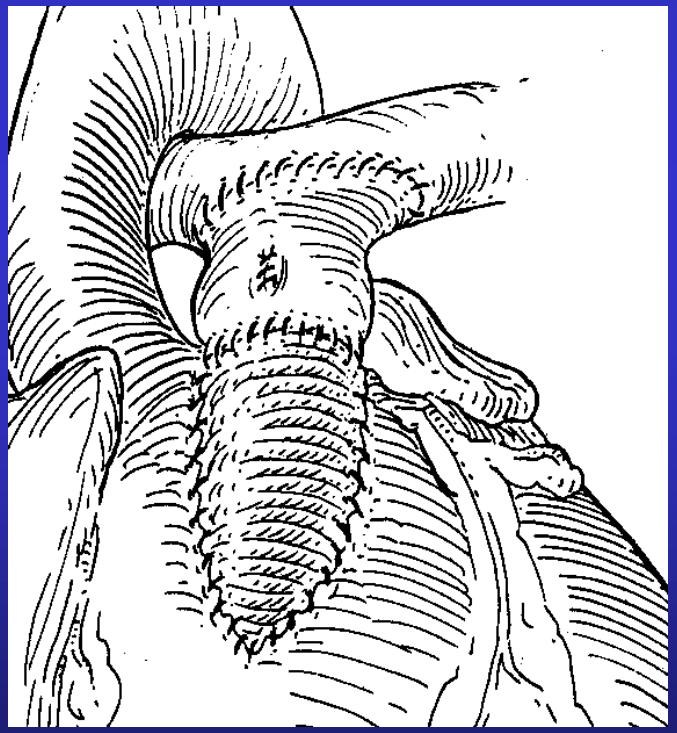
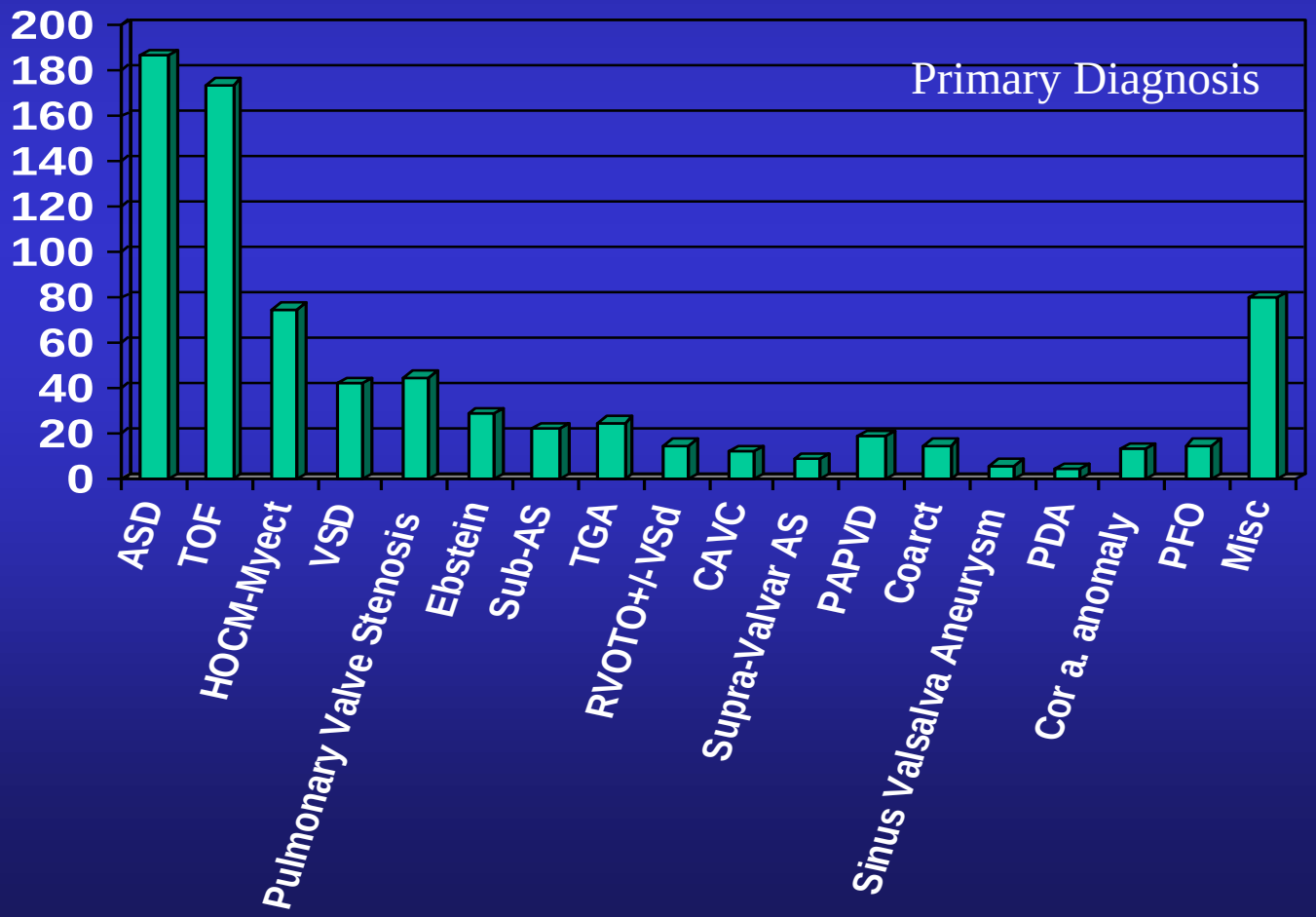
RV- PA Surgical Valve Choices **in Adults** –longevity and risks



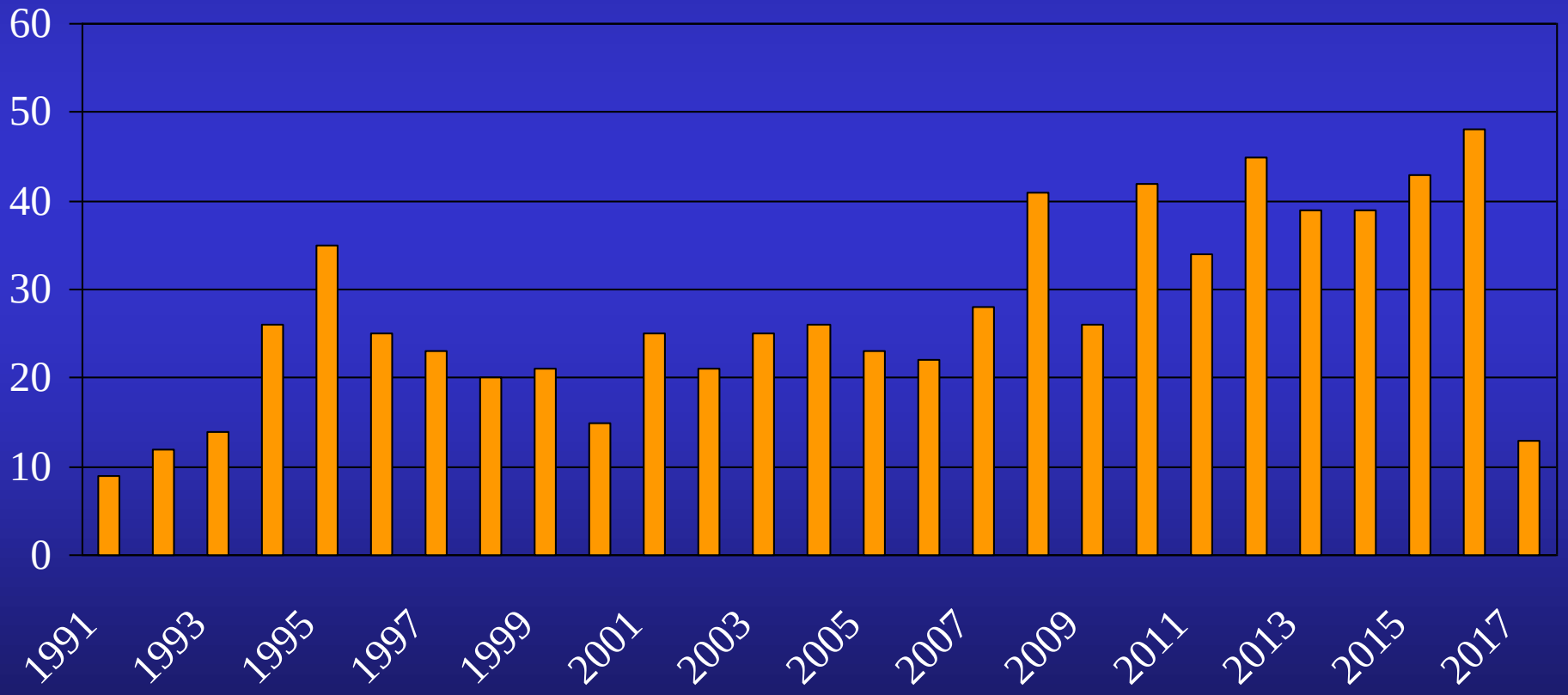


ACHD, Queenstown, 2017

Adult Congenital Heart Surgery
1991 – 8/3/2017
Total = 751 Patients



Surgery For Adult CHD 1991 – Feb 2017 (N=751)



PVR with RV – PA conduit insertion (pul. Allograft or porcine) Oct 1991 – Feb 2017

- TOF: re-operation conduit (incl. PA/VSD) 168
  - 1*complete correction 3
- other congenital:- pul. valve. stenosis 38
  - TGA/PS/ VSD 8
  - P. atresia / IVS 7
  - Truncus Arteriosus 7
  - Miscellaneous 11 242
- Ross procedure – exclusive pul. Allo 429

TOTAL 668

*EM = 1

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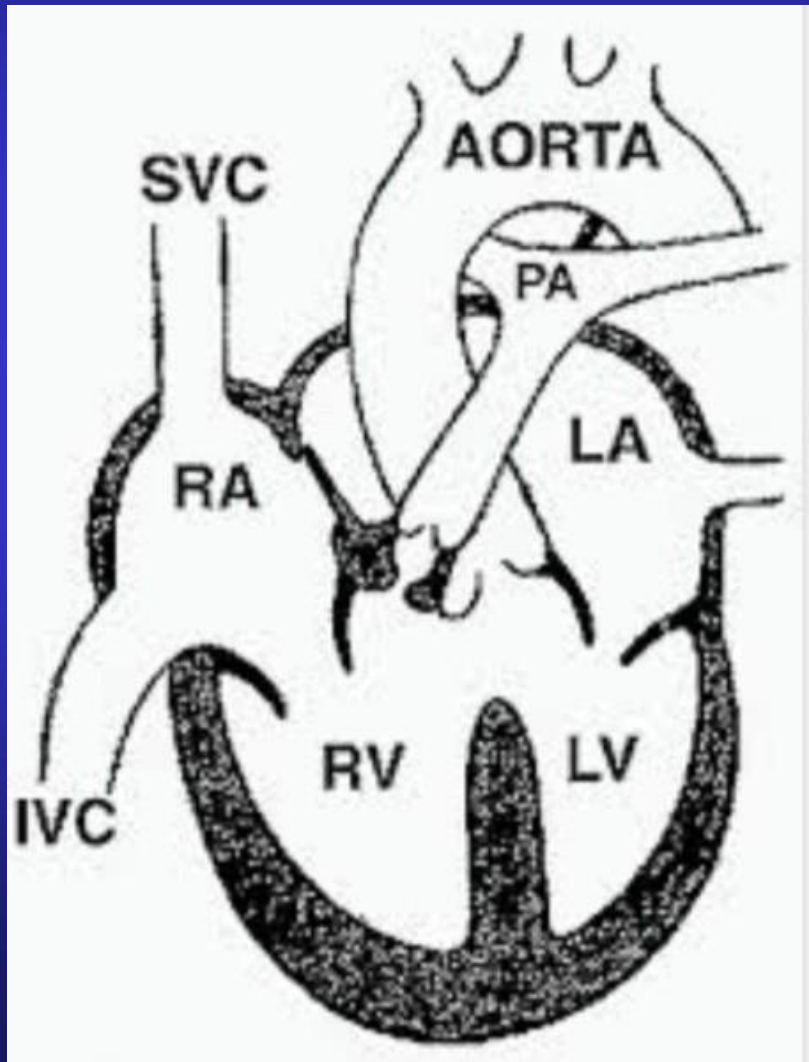
Tetralogy of Fallot (TOF)

- Malalignment VSD
- Overriding aorta
- RV hypertrophy
- Pulmonary stenosis (variable) – infundibulum
  - pul. Valve
  - pul. arteries



TOF - Late problems requiring Surgical intervention

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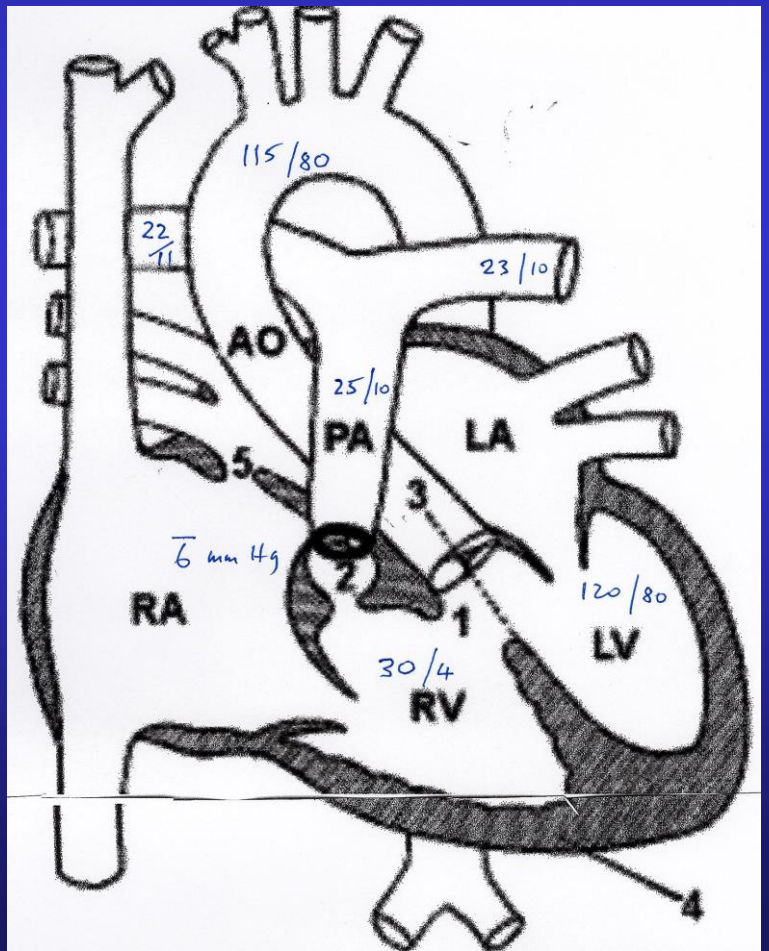
- Pulmonary Valve Replacement (severe PR)
- Residual pulmonary stenosis (all levels)
- Residual VSD
- RVOT aneurysm
- Aortic enlargement
- Other uncorrected or overlooked problems

Indications for PVR - all patients have severe PR

The Royal Melbourne Hospital

- Severe PR with symptoms (20-40%)
- RV enlargement or reduced contractility
  - RVEDVI > 150mls/ sq m (BSA)
  - RV > double LV EDV **(MRI*)**
- Reduced RVEF , no increase with exercise
- Severe PR with Ventricular arryhthmias
- PS/PR

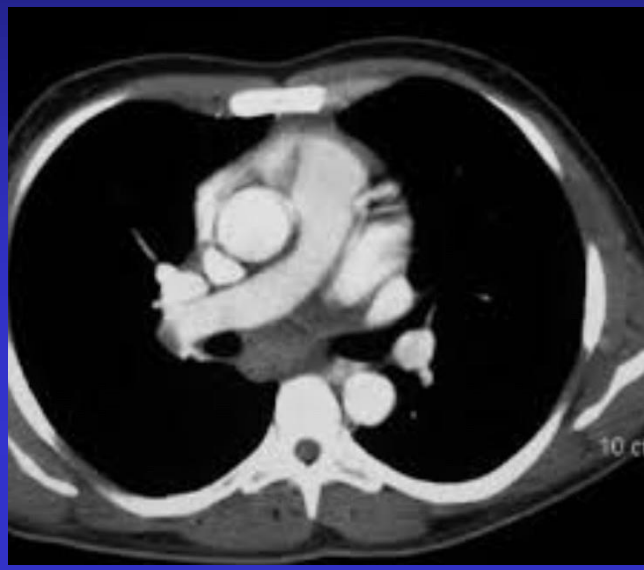
Preop Workup Echo + Right Heart Cardiac Catheterization



- MRI
- CT (non contrast)
- CTCA? (if no C. Cath)

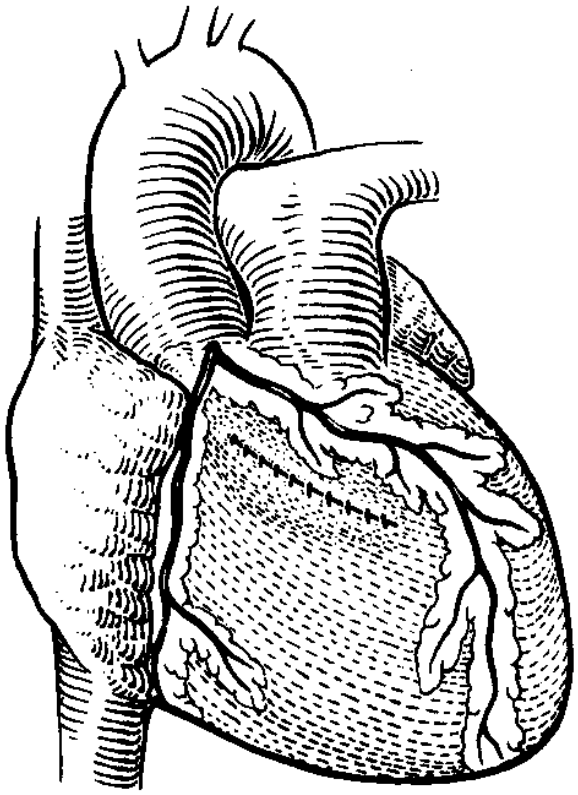
Preop CT Thorax

- ensure safe sternotomy*
- other pathology (LSVC)
- MRI good for RVEDVI, quantification PR, pul. stenoses



Why study CA's? - Anomalous LAD arising off RCA

- Courses across RVOT
- 3% of TOF cases
- Op note possibly lost
- Potential for damage at reoperation



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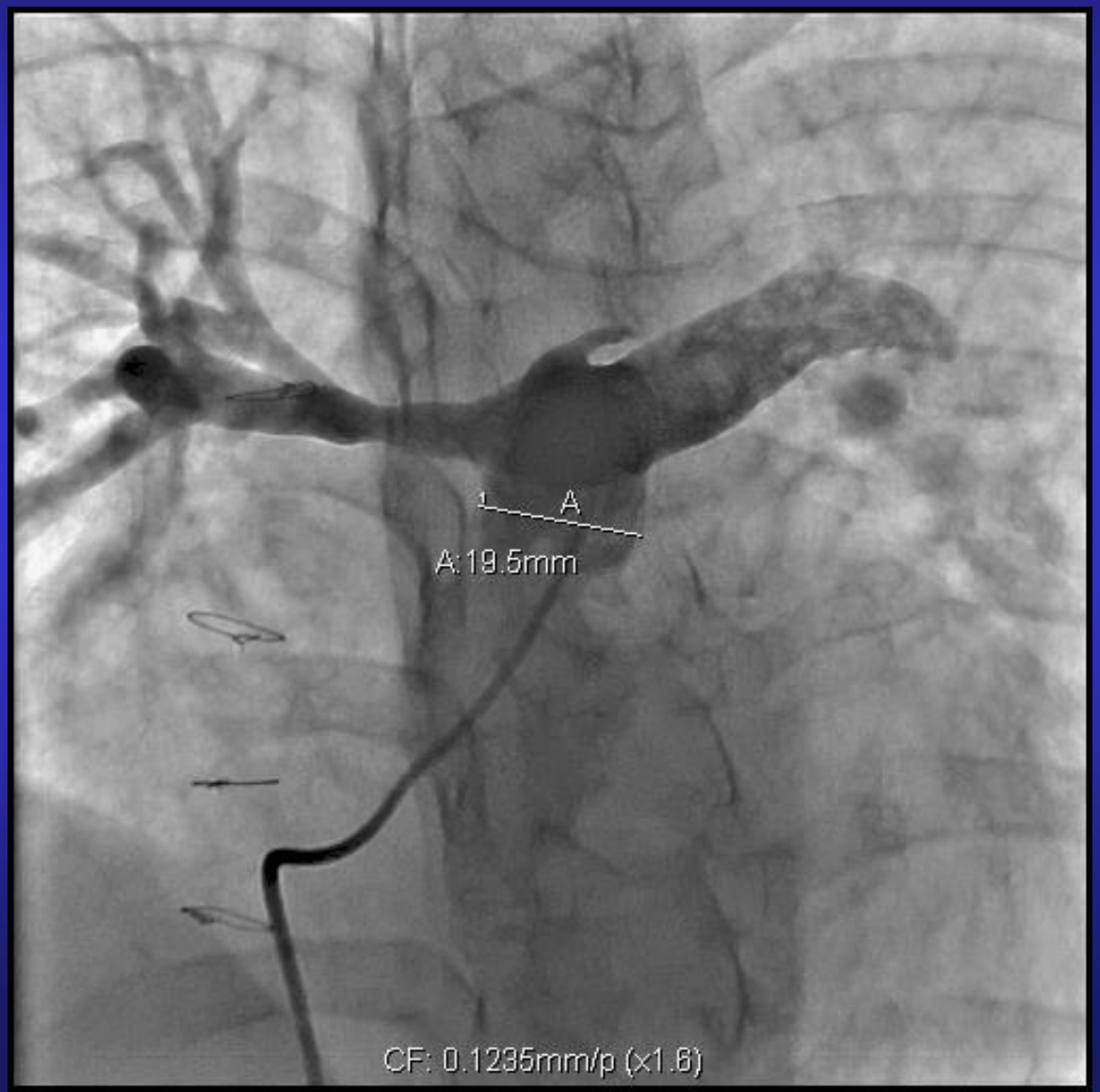
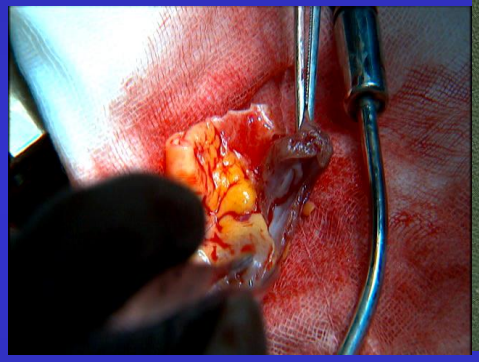
RPA stenosis



Options for PVR

- **Pulmonary** or aortic allograft valve (tissue bank)



- Bioprosthetic valve
  - Medtronic “Freestyle” porcine

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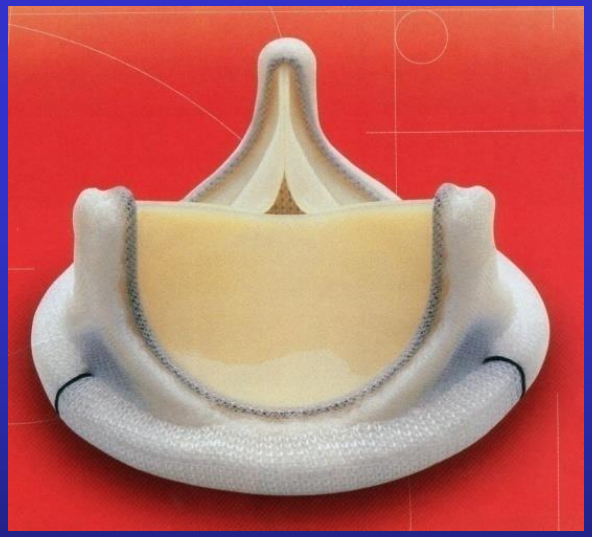
Aortic Allografts, and Stented Bioprostheses



Reason: poor haemodynamics

poor durability, Ca++

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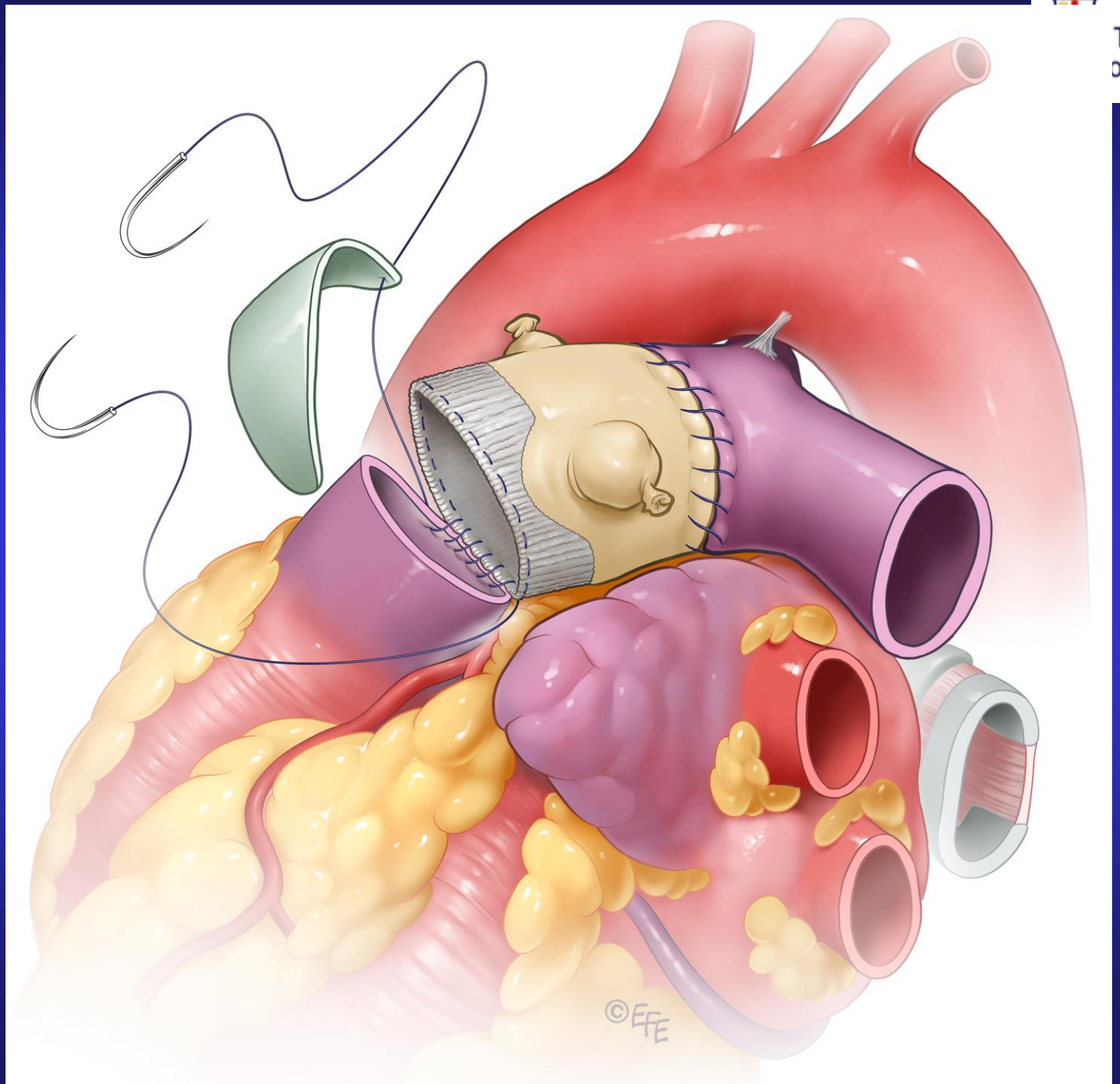
Contegra Bovine Jugular Valved Conduit (Medtronic)

- used in paediatric patients
- available in small sizes
- high stenosis rate in small sizes
  - 83% for 12mm graft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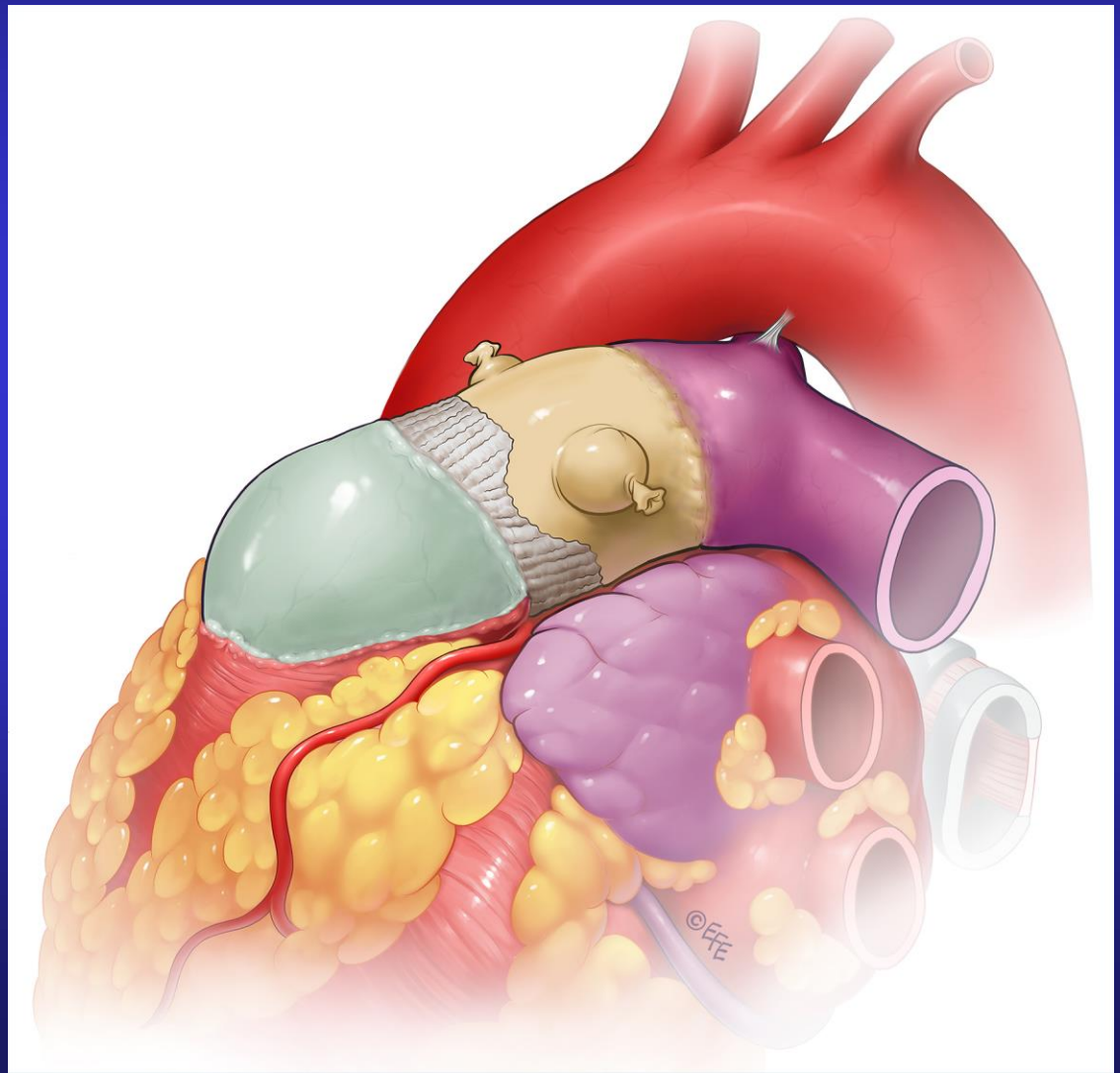
RVOT Augmentation



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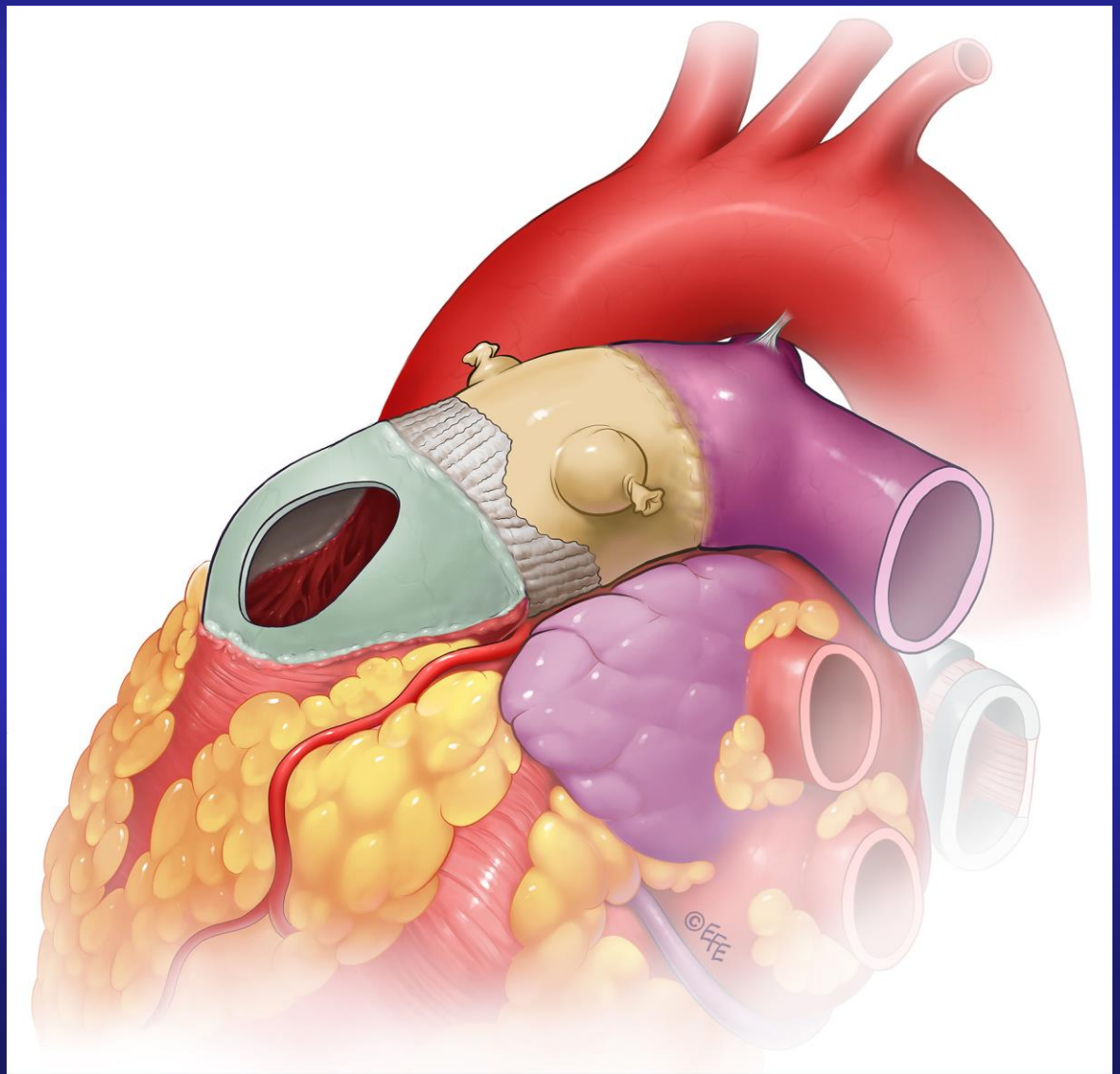
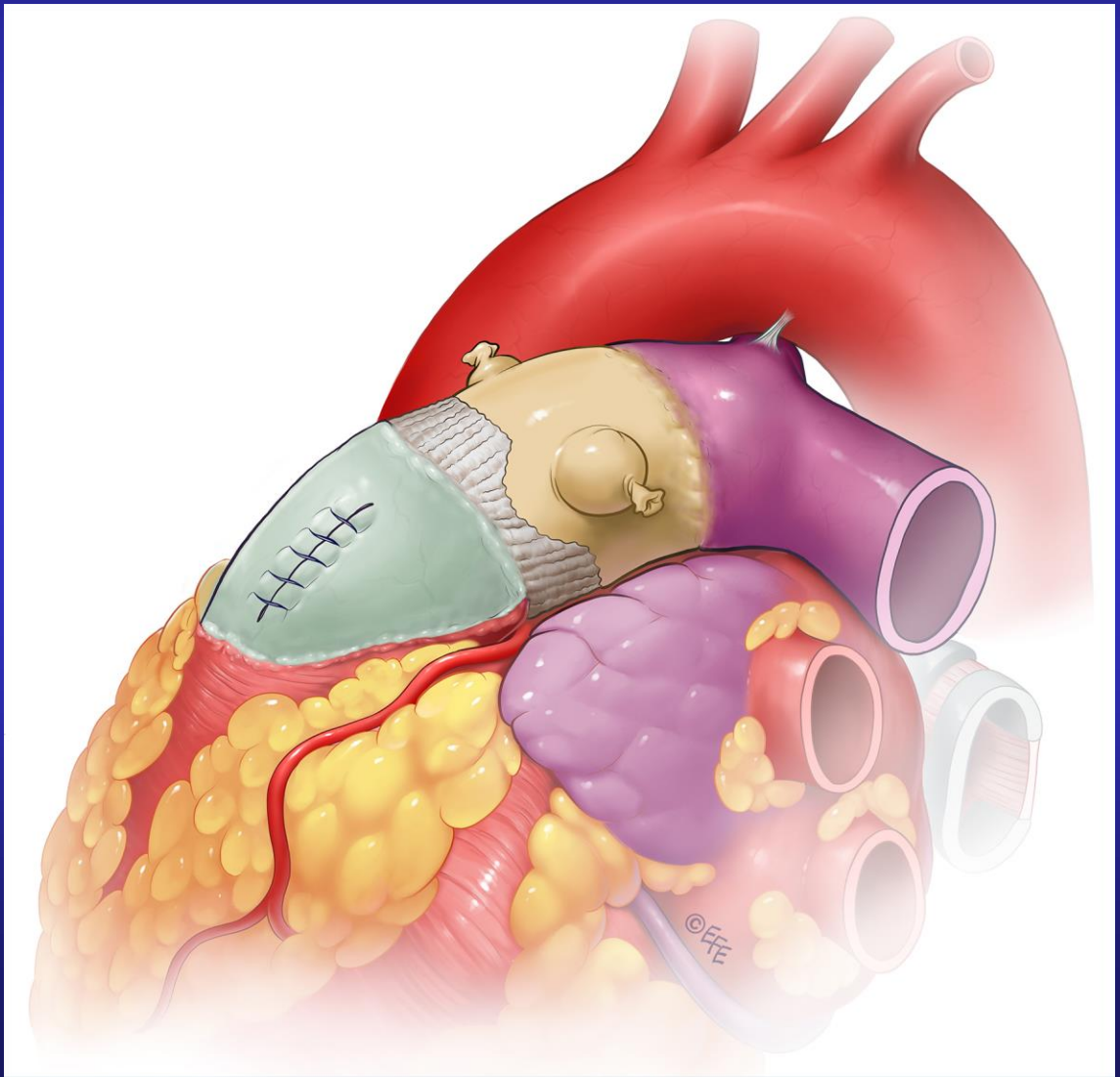
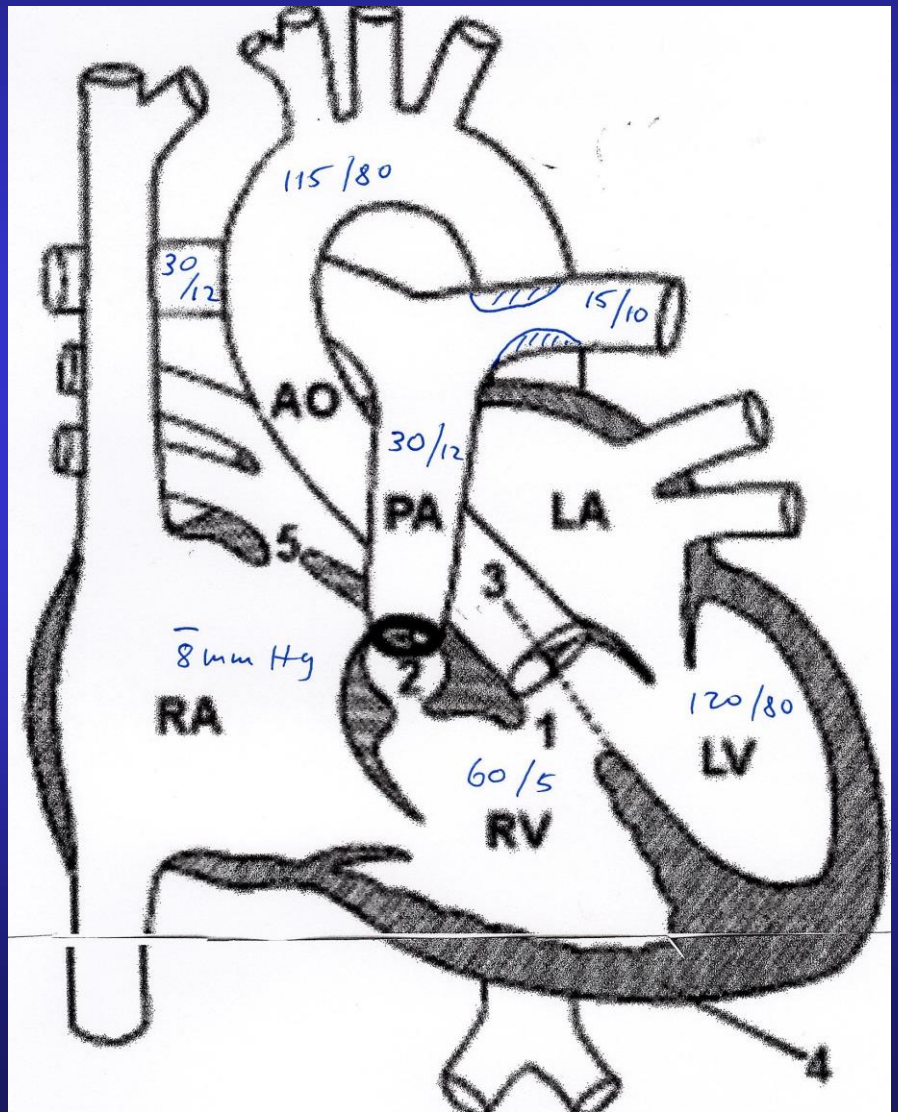
Exc. RVOT Aneurysm



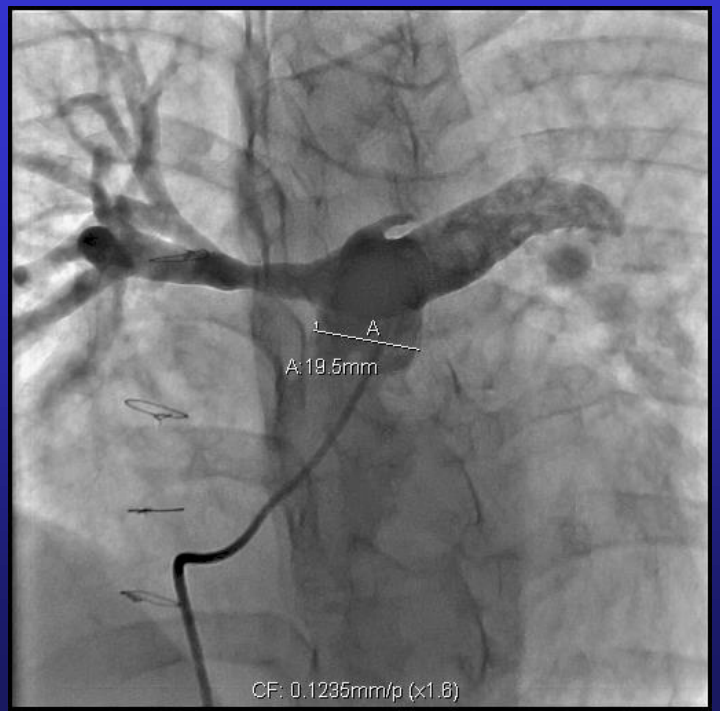
Longitudinal Repair RVOT An.



PR/PS and LPA stenosis



RPA stenosis



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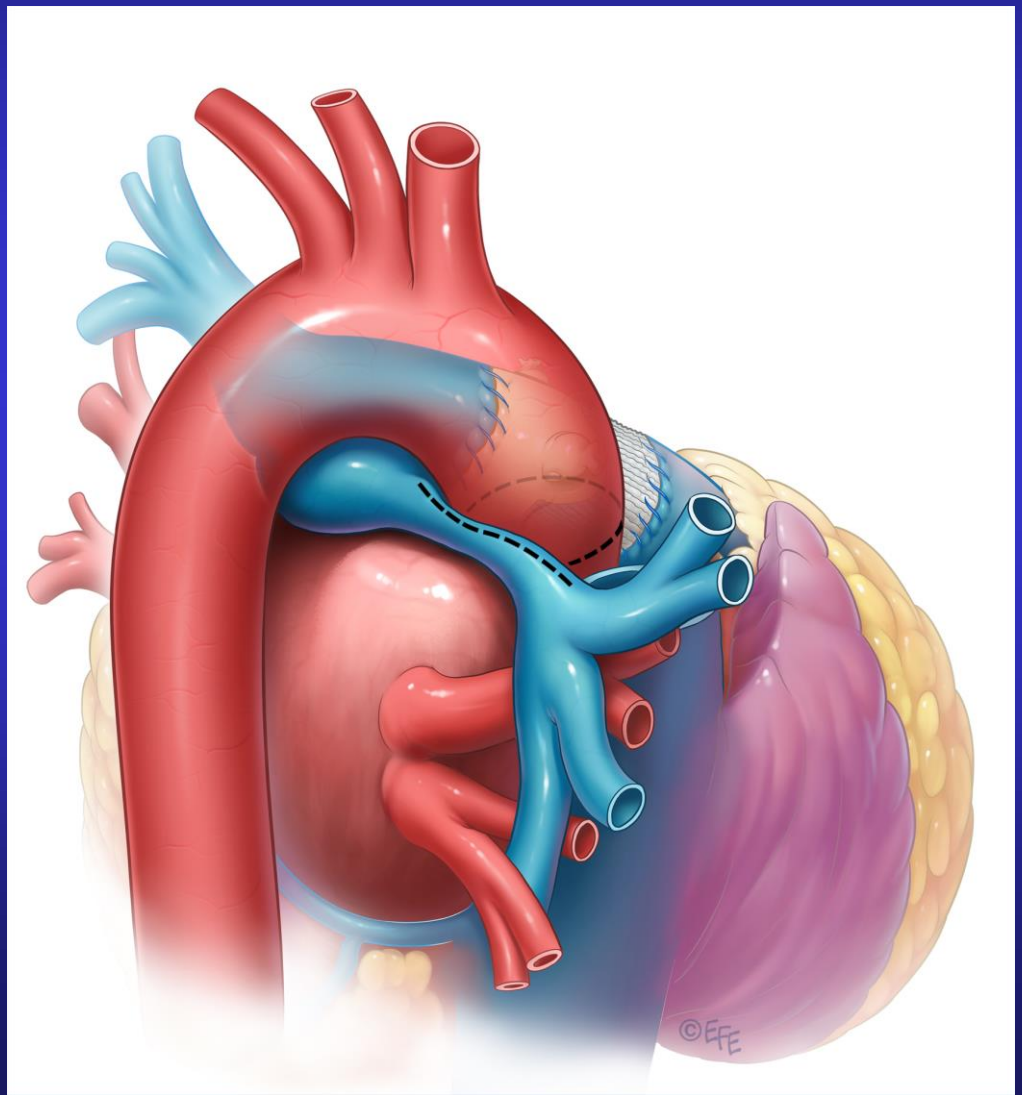
Diffuse RPA stenosis



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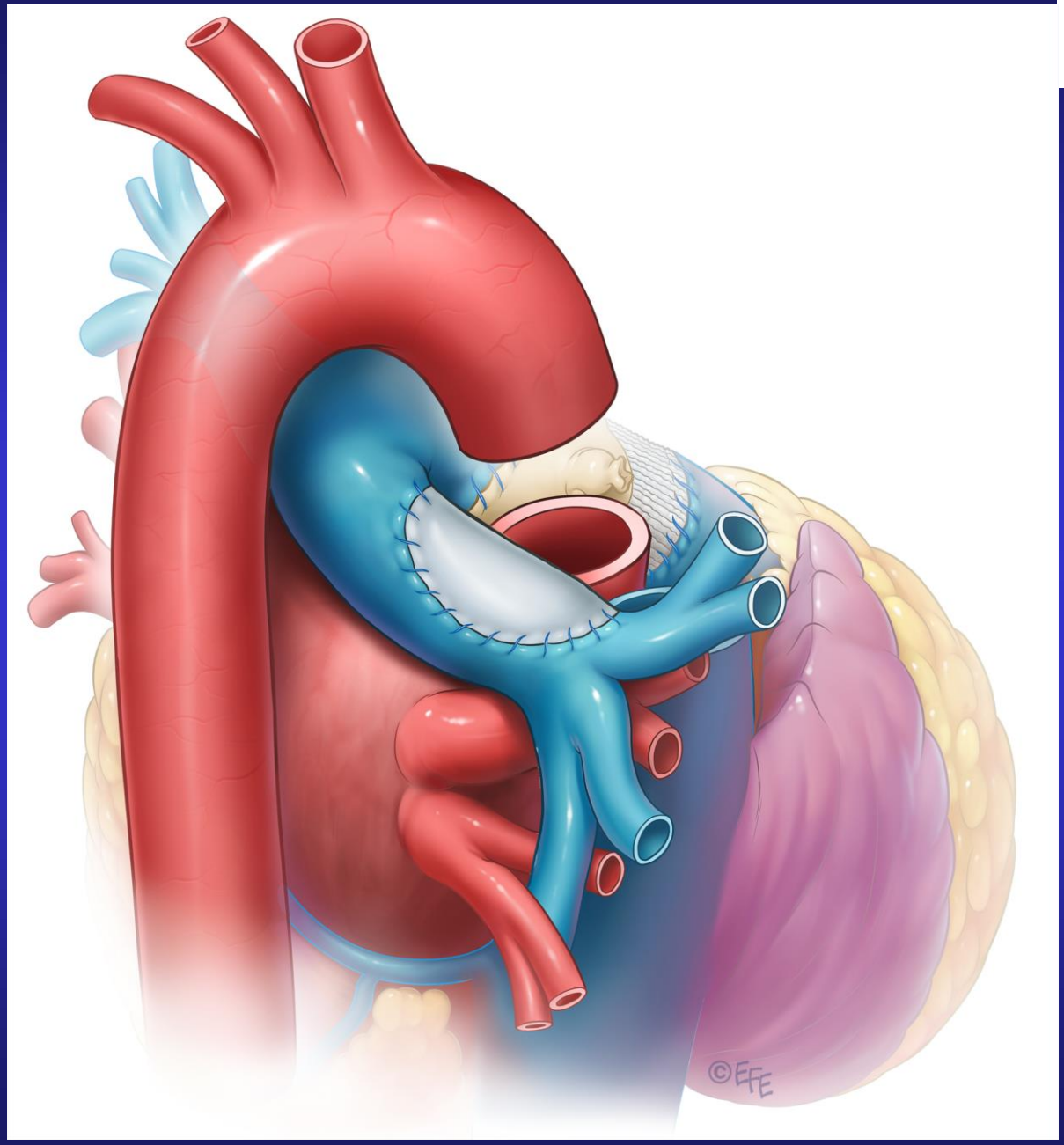

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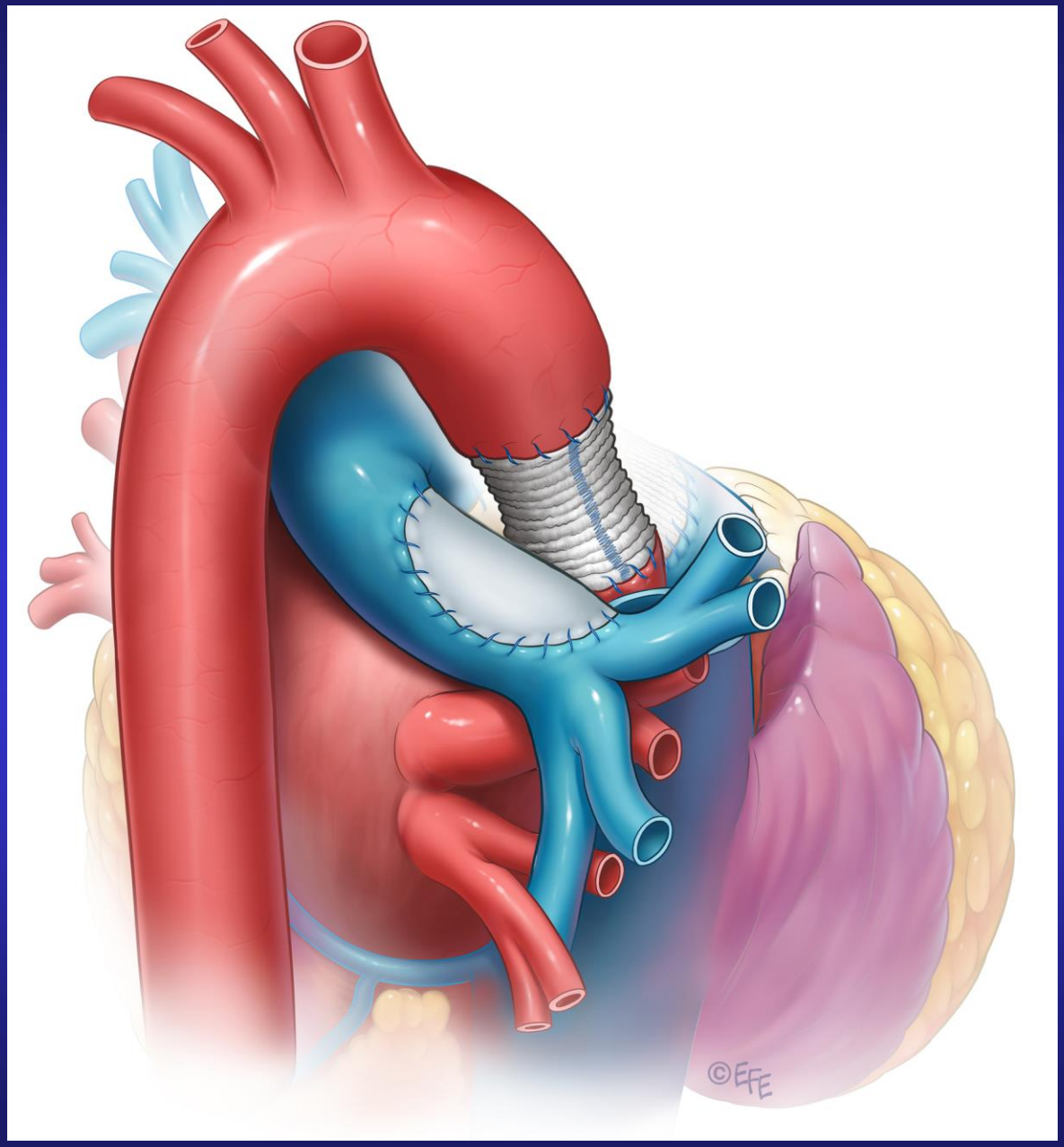
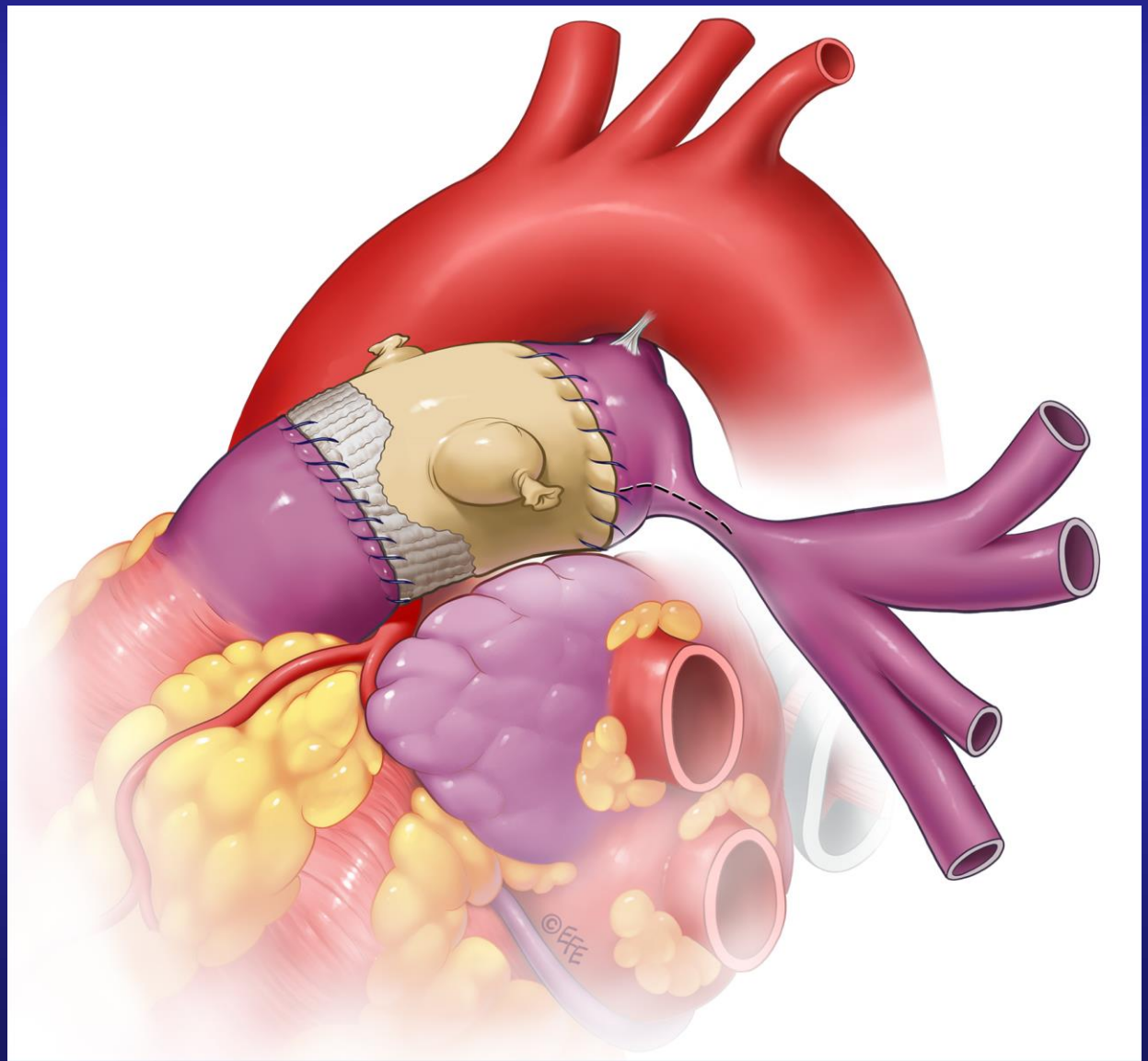


LPA Stenosis



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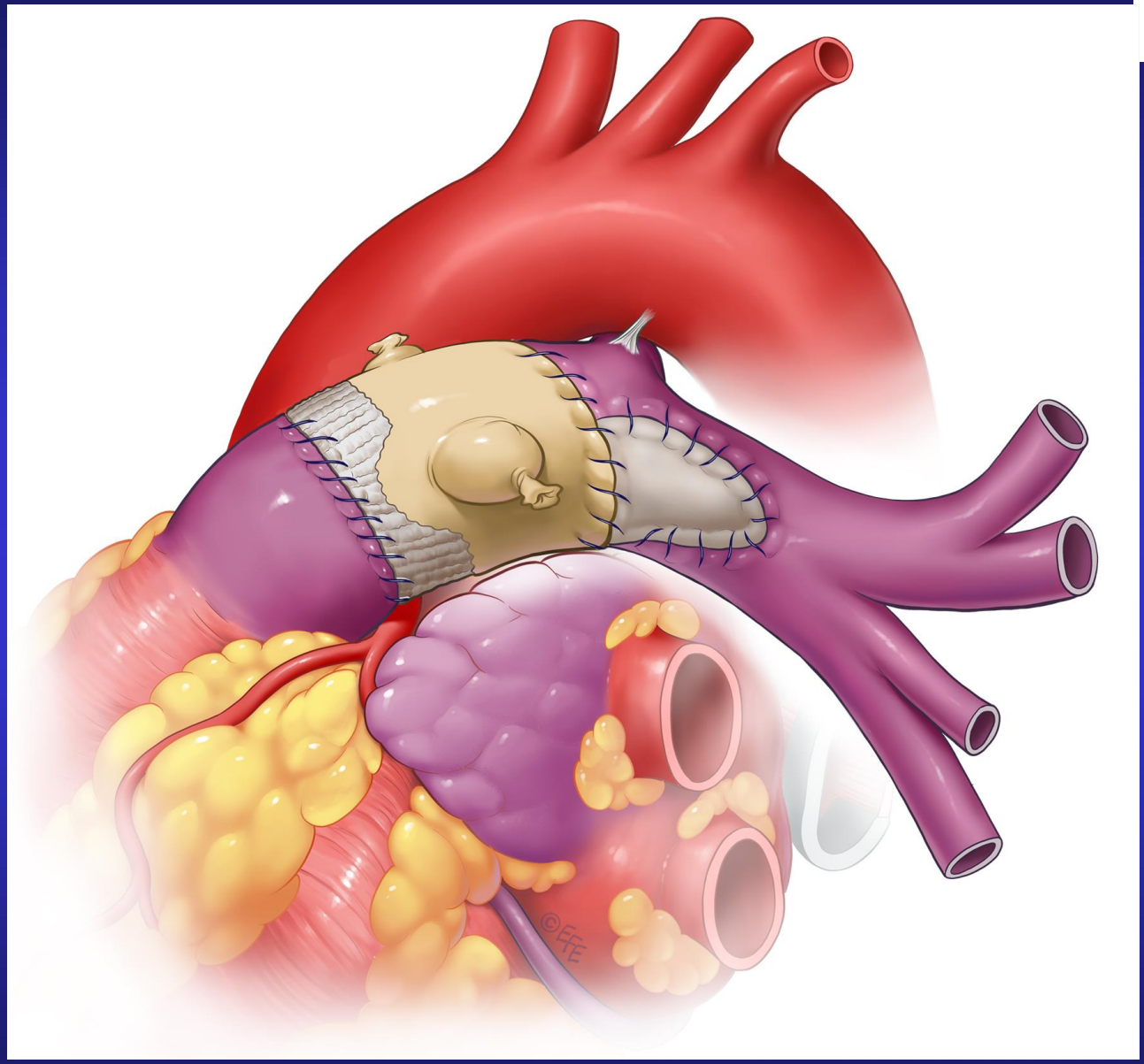

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Risks - minimal

- Safe operation, often multiple previous sternotomy
- 1991- 2007; 222pts, zero mortality (0%)
- Few major early complications
- CVA x 2 (0.9%) – both full recovery
- AF (10%), sternal infection x1, bleeding x 3
- Sternotomy, heart beating, only stop heart if intracardiac shunt (PFO, ASD, VSD)

Pulmonary Allograft Pros and Cons

The Royal Melbourne Hospital

- Easy insertion, soft and pliable tissue
- Difficult procurement – tissue banks, sizing etc
- Durability variable – mostly good, 7% mild- mod stenosis
- Occasional early regurgitation (PR)
- Some fail early, most still good at 20yrs
- Tendency to calcify – variable
- Shrinkage – “valve in valve” difficult

Homograft failure

(mod-sev PR OR RVSP >40)

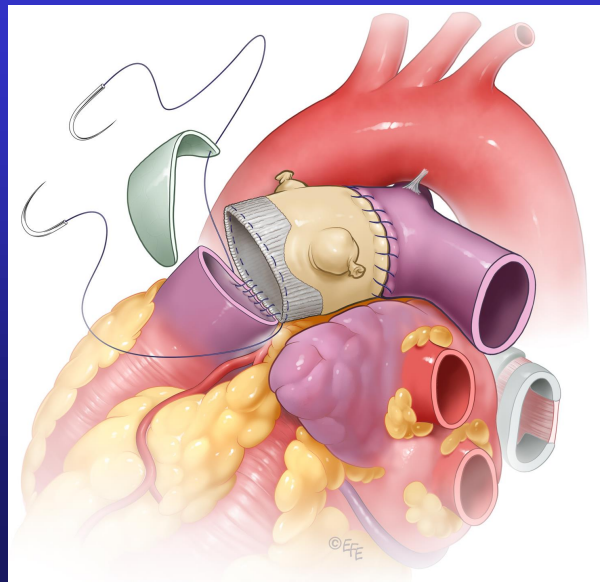
- Factors associated with homograft dysfunction[1]
  - Younger recipient
  - Aortic homograft
  - Small size
  - Age of donor?
  - Tissue type disparity
  - ?Immune mediated reaction
  - ? Pannus, excessive fibrosis – keloid analogy

[1]*Sievers et al Circulation 2010*

Medtronic “Freestyle” Porcine Root

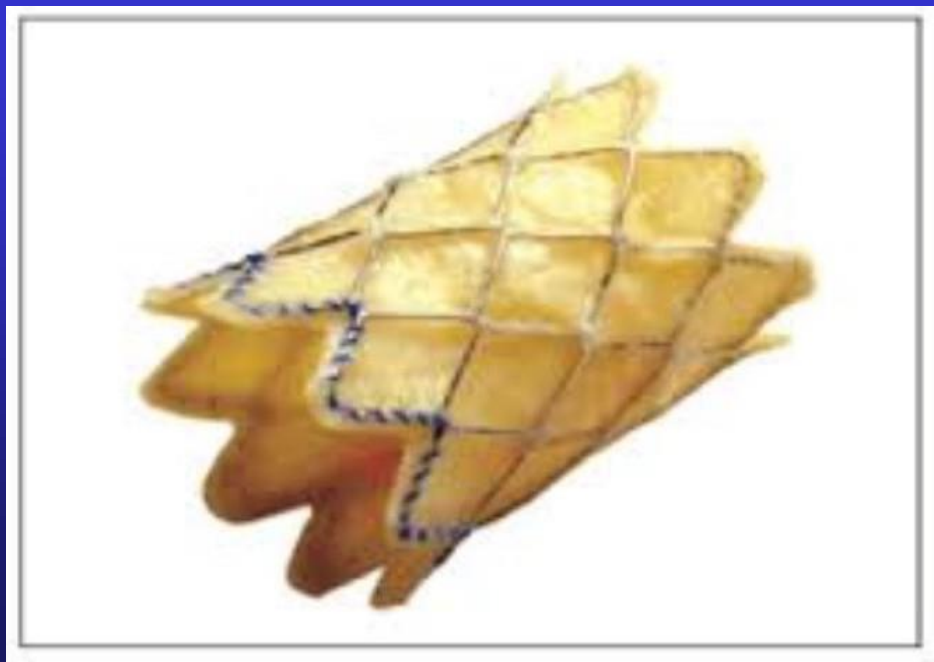
The Royal Melbourne Hospital

- Easy to procure - on the shelf
- More difficult to insert – conduit stiff and non pliable
- Need RVOT patch usually
- Higher gradients
- no regurgitation
- Unknown long term durability -? 20 yrs
- Should be good “V in V” candidates



Aim is to set patient up for "Valve in Valve"

- Because of severe PR, annulus too big
- Current strategy for next procedure



RV to PA Conduit use

The Royal Melbourne Hospital

Pulmonary Allograft
1991 – 2017

81 pts

Mean age 33.0yrs

(range 17-61)

Medtronic "Freestyle"
2008 – 2017

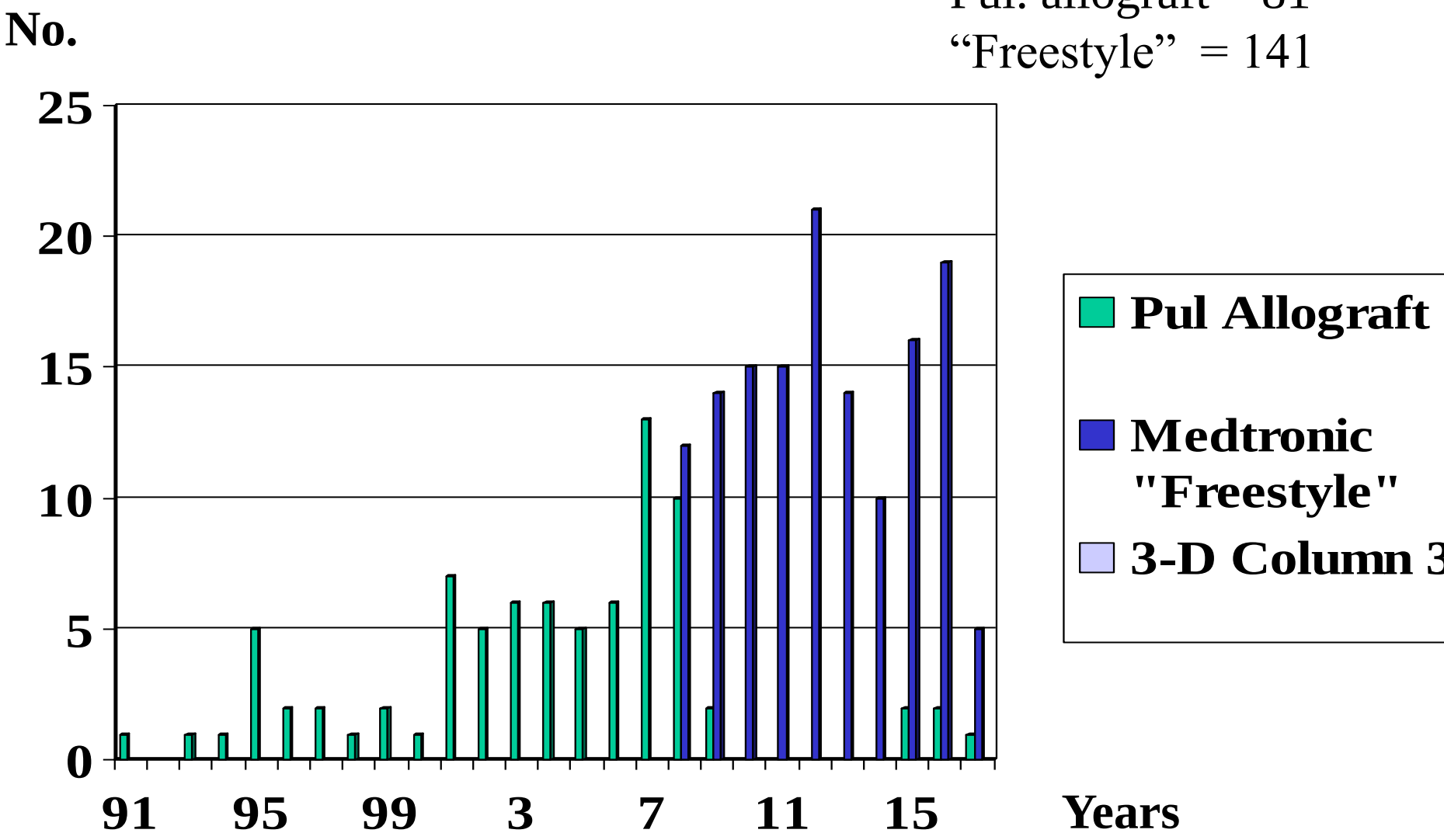
141

34.5

(19-80)

RV-PA Conduit use 1991-2017

Pul. allograft = 81
"Freestyle" = 141



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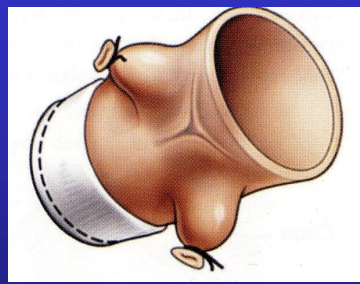
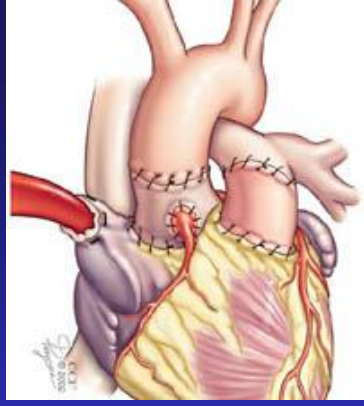
Reoperations

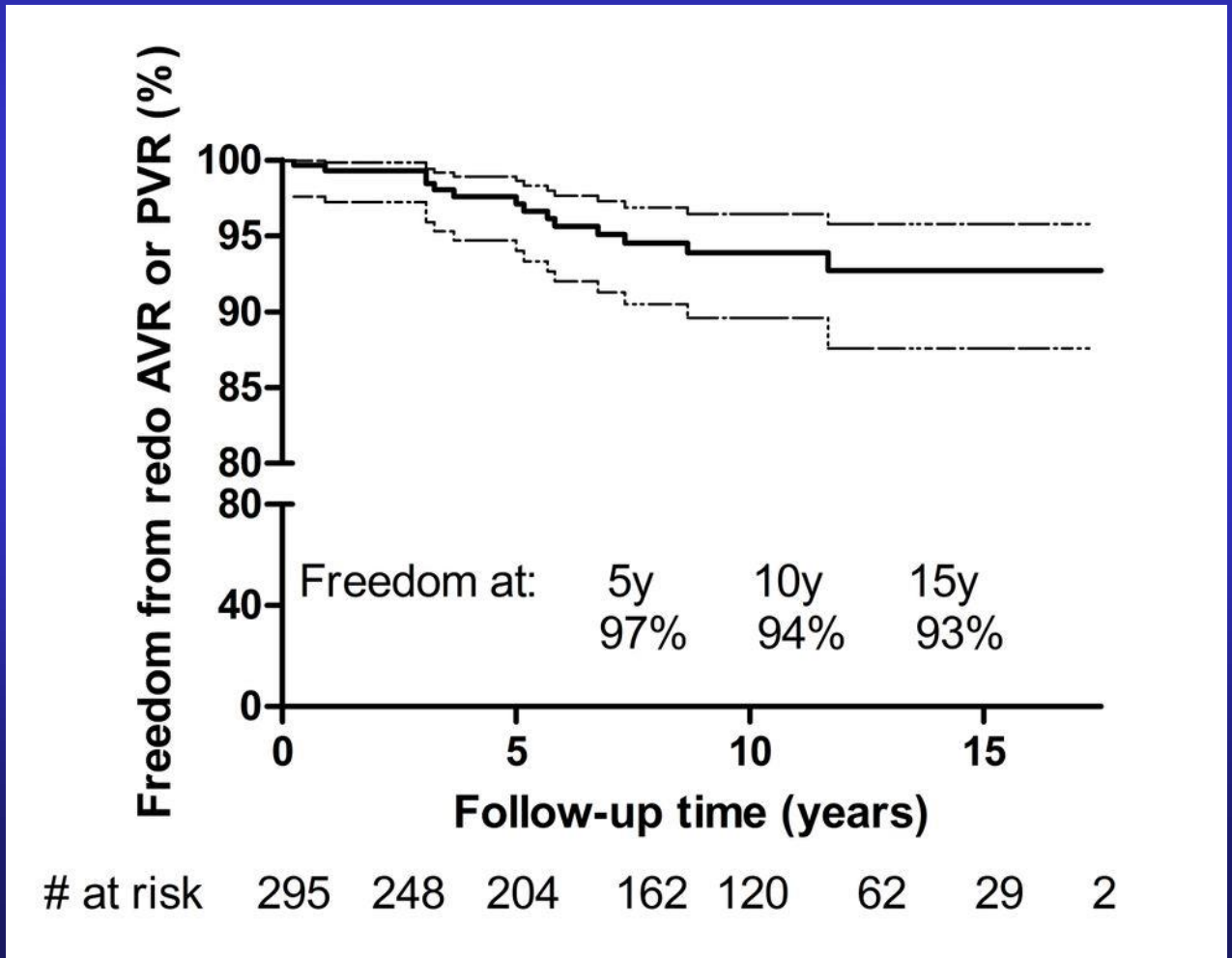
	No	Freedom reop
Pulmonary Allograft (5, 9, and 15yrs)	3	96% at 15yrs
Medtronic "Freestyle" (4yrs – small conduit)	1	99% at 5yrs



* Now only insert 25,27 or 29mm diameter size valves

Freedom from redo AVR and/or PVR (n=300) after Ross – exclusively use Pulmonary Allo.





15 patients

11 AVR only

3 PVR only

1 AVR &PVR

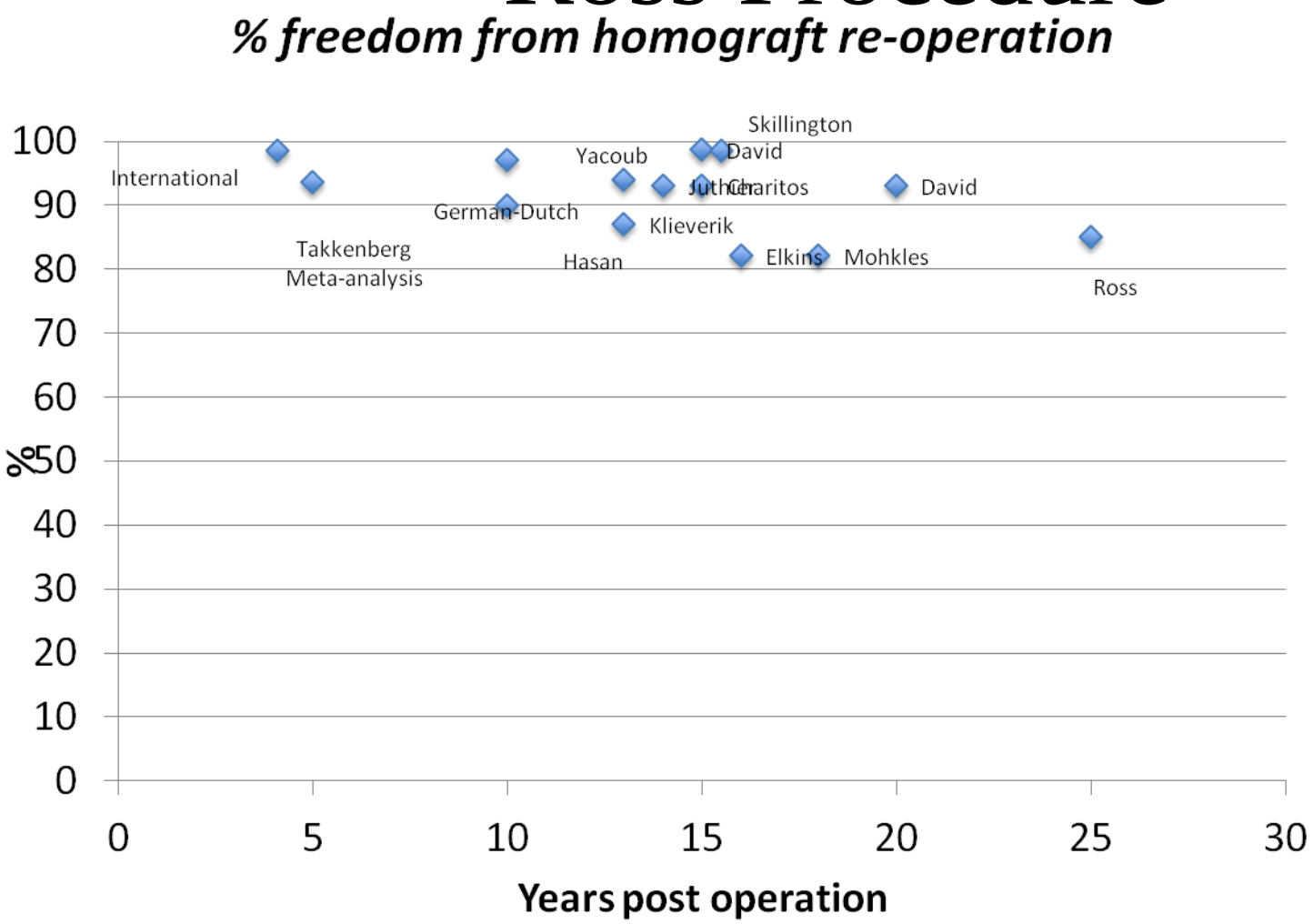
*** 20yr Freedom Reop 97%***

Skillington et al Ann Thorac Surg 2013

Echo Results

• Valve	Pulmonary Allograft	Medtronic “Freestyle”
• Time period	1991-2017	2008-2017
• No. patients	81	141
• Echo available	49 (60%)	119 (84%)
• Echo last 2yrs	26 (53%)	115 (97%)
• Mean gradient (mmHG)	11.2 (2-38)	16.6 (2-43)
• Pulm. Regurg.	Nil/trivial 33 Mild 12 Mod 4	Nil/trivial 118 Mild 1 Mod 0

Homograft re-operation after Ross Procedure



German-Dutch registry:
0.3% per patient year

Meta-analysis:
0.55% per patient year

Pulmonary-Valve Replacement in Adults: Results With the Medtronic Freestyle Valve

Sowmya Ramanan, MRCSEd, MCh, Nicolas Doll, MD, Dietmar Boethig, MD, PhD, Nadir Tafer, MD, Alexander Horke, MD, Xavier Roques, MD, PhD, Wolfgang Bruno Hemmer, MD, and François Roubertie, MD

Departments of Cardiovascular Surgery, and Cardiac Anesthesiology, Bordeaux Heart University Hospital, University of Bordeaux II, Bordeaux, France; Department of Cardiac Surgery, Sana Cardiac Surgery Stuttgart GmbH, Stuttgart, Germany; and Department of Cardiothoracic, Transplantation, and Vascular Surgery, Hannover Medical School, Hannover, Germany

Background. We used the Medtronic Freestyle valve (Medtronic, Minneapolis, MN) as an orthotopic conduit in pulmonary valve replacement in repaired tetralogy of Fallot and as part of the Ross procedure. Midterm outcomes and hemodynamic status of this conduit were analyzed and performances in both subgroups were compared.

Methods. From February 2002 to July 2012, 115 Freestyle valves were implanted in 52 patients with tetralogy of Fallot and 63 patients within the Ross procedure. Preoperative and perioperative data were reviewed retrospectively in this bicentric study.

Results. Mean age at valve surgery was 37 ± 13 years. Median implanted valve size was 27 mm (21 to 29). Early postoperative mortality was 3.48%. There was 100% follow-up for the survivors at a mean of 4.38 ± 2.52 years. There was 1 case of thromboembolism (0.89%), 6 endocarditis (5.4%), and 9 (7.8%) conduit re-interventions. Echocardiography at discharge and last follow-up showed average peak systolic transvalvular gradients of 12.4 ± 5.1 and 18.7 ± 8.8 mm Hg, respectively. Ten patients had significant proximal anastomotic gradients of greater than 50 mm Hg and 4 moderate conduit regurgitations. Survival was 96.52%. No valve degeneration was seen in 87.82% at 5 years. The only risk factor identified for valve re-intervention was conduit implantation without infundibular hood ($p = 0.01$ in multivariate analysis).

Conclusions. Mid-term data show that Freestyle valves are well suited for pulmonary valve replacement in adults in both categories. The surgical technique used in valve implantation is important to ensure conduit durability. These results and accessibility to the Freestyle valve make this an acceptable alternative to homografts.

(Ann Thorac Surg 2015;100:1047–53)

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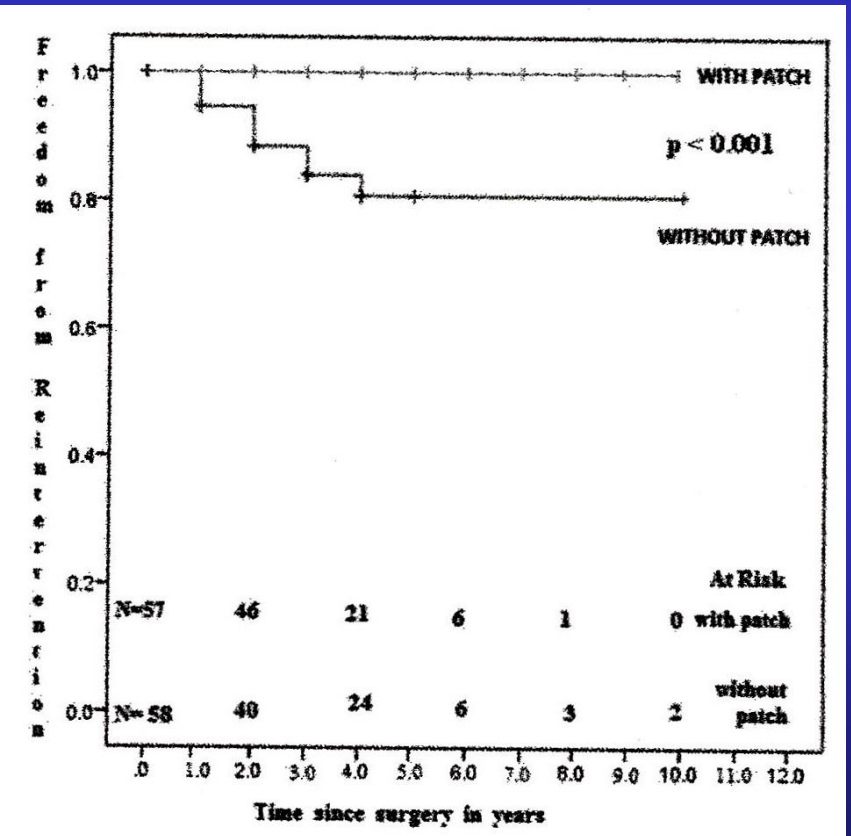
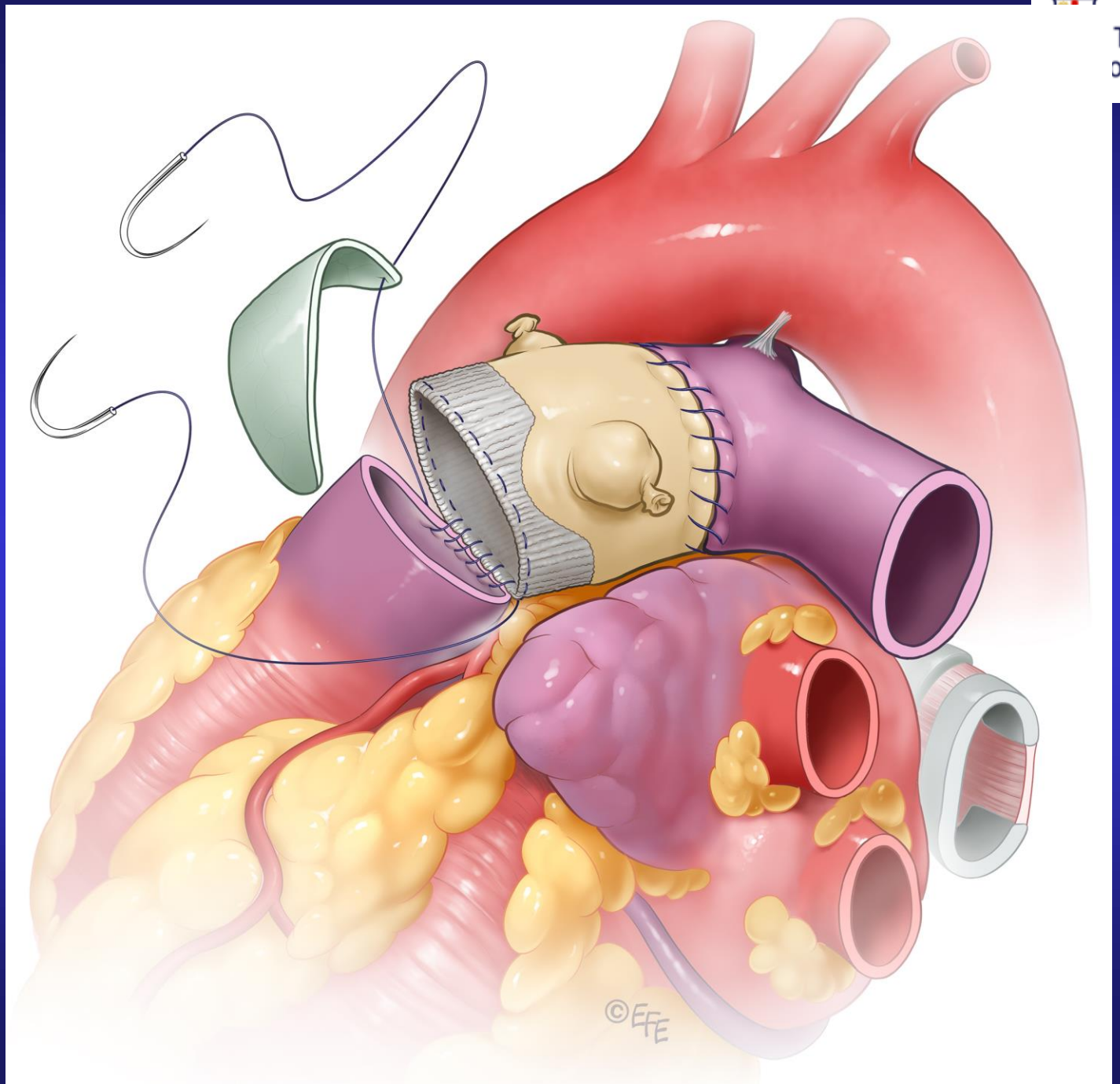


Fig 4. Freedom from Freestyle valve re-intervention in the with, and without, infundibular patch groups.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Australian Experience with "Freestyle valve" - WA

The Royal Melbourne Hospital

Medium-term outcomes after pulmonary valve replacement with the Freestyle valve for congenital heart disease: a case series

Ben Dunne[a,*], Elizabeth Suthers[a], Peter Xiao[a], Jianguo Xiao[b], Edward Litton[a,c,d] and David Andrews[a,e]

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eceived 13 October 2015; received in revised form 18 December 2015; accepted 29 December 2015

European J.of Cardiothoracic Surgery

Feb, 2016

Abstract

OBJECTIVES: The Freestyle valve may be used for pulmonary valve replacement (PVR). Whether its stentless design and anticalcification treatment improve durability relative to alternative bioprostheses, however, is unknown and long-term data are lacking.

METHODS: We performed a retrospective review of all Freestyle PVRs performed by a single surgeon in two institutions. All patients were contacted for follow-up to establish survival, New York Heart Association class and reintervention. Up to date, echocardiography was obtained to assess valve function. Perioperative factors associated with structural valve dysfunction (SVD) were assessed using Cox regression.

RESULTS: Between 2000 and 2014, PVR with a Freestyle valve was performed in 114 patients with congenital heart disease. There were 70 males and 44 females. The median age was 21 years (interquartile range 11–35 years). The median clinical and echocardiographic follow-up was 62 months (interquartile range 35–115 months, $n = 110$) and 58 months (interquartile range 30–93 months, $n = 107$), respectively. Follow-up was complete for 107 of 114 patients (94%). The survival rate was 95% at 5 years and 91% at 10 years. The rate of freedom from SVD at 5 years was 82%, and at 10 years was 61%. The reintervention-free survival rate was 85% at 5 years, and 71% at 10 years.

CONCLUSION: The Freestyle valve in the pulmonary position in a congenital population is associated with low medium-term incidences of SVD and reintervention. It performs equally well to the homograft when a conduit is required and can be considered a valid alternative to stented bioprostheses when PVR alone is required.

Keywords: Pulmonary valve • Right ventricle • CHD • Tetralogy of Fallot • Valve

Freedom from SVD
Mean age 21yrs (11 – 50)

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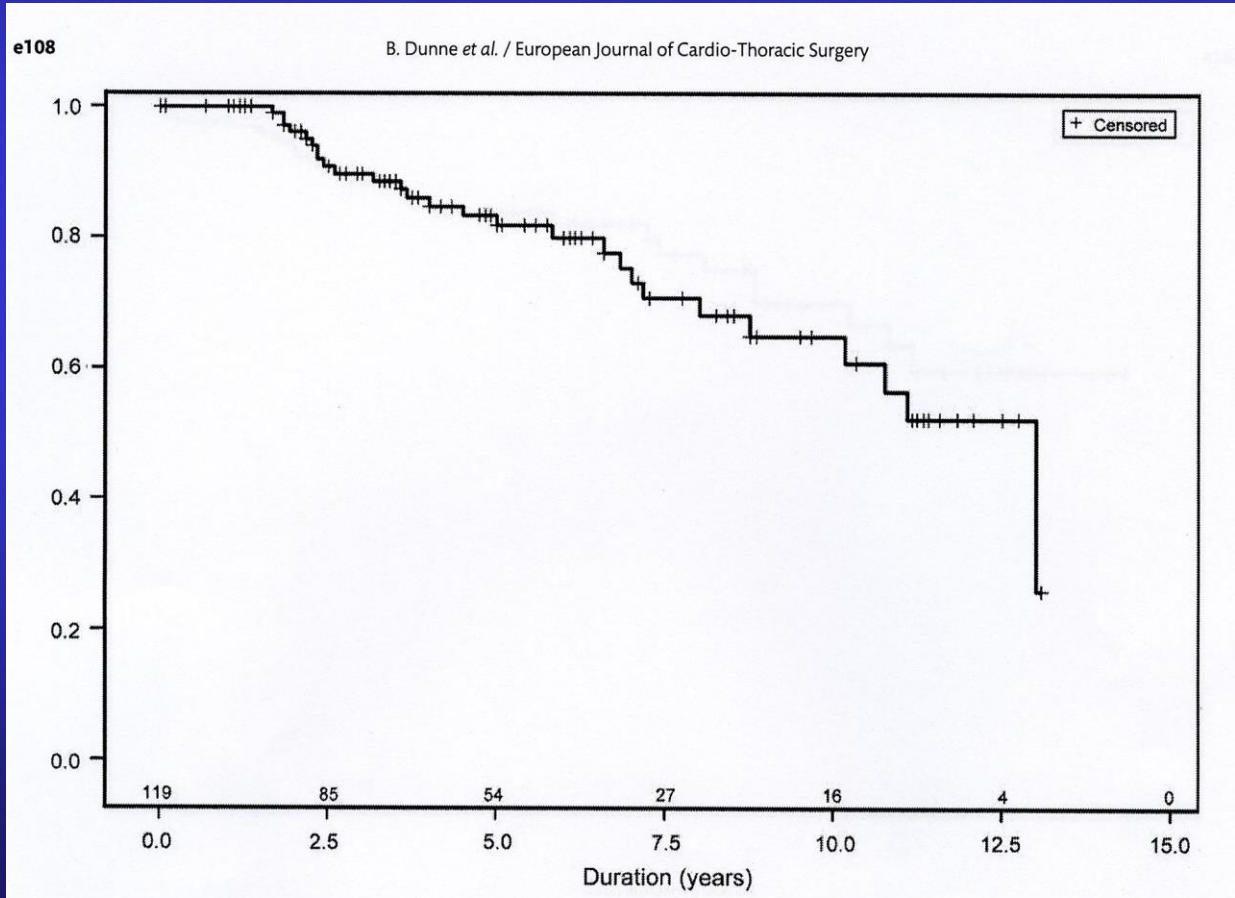
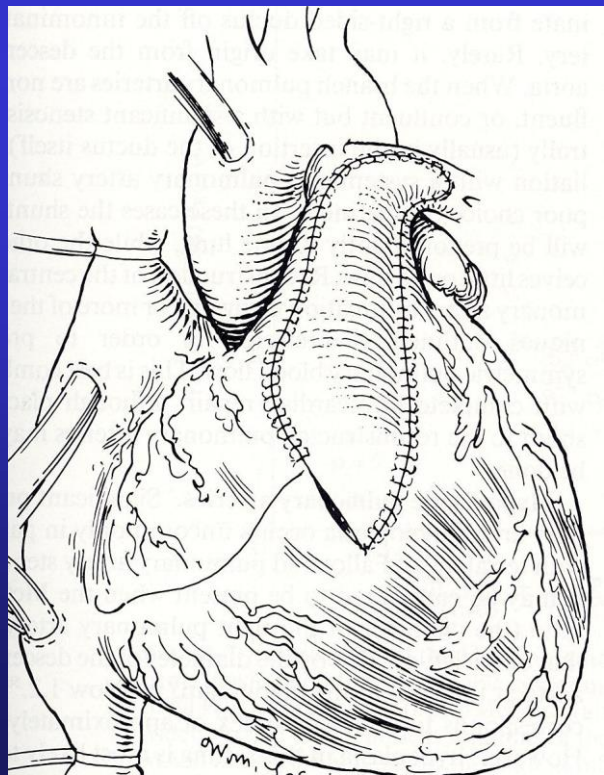


Figure 3: Kaplan–Meier curve of structural valve deterioration (months).

The Royal Melbourne Hospital

Influence of 1st operation on late results in TOF

- Longer interval if RA/PA approach
- Minimal trans annular patch
- Old RV approach led to earlier PVR (worse RV, PR)
- Mean age 34yrs, interval 30yrs
- RPA, LPA problems dealt with leads to later reop



Conclusions

- Safe surgery – zero mortality
- Beating heart surgery improves recovery
- Better durability of all RV – PA conduits in adults cf children
- Deal with concomitant lesions: RPA, LPA stenoses most challenging; others straight forward (VSD, RVOTO, RVOT aneurysm)
- Operate before severe TR occurs

Conclusions (cont)

- RVOT augmentation patch important especially for more rigid prostheses eg ‘Freestyle”

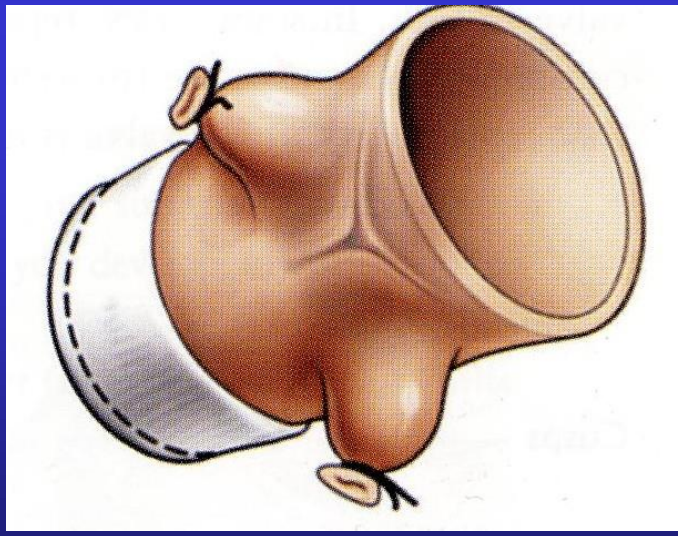
- Pulmonary allograft capable of very good long term durability beyond 20yrs, but occasionally fails early, calcifies and shrinks in 7-10%, availability limited

- Medtronic “Freestyle” – only 9yrs experience
  - on the shelf – availability+
  - sl. more difficult insertion
  - higher gradients, **no** regurg.
  - ? better “valve in valve”

The Royal Melbourne Hospital

The Royal Melbourne Hospital

The Royal Melbourne Hospital



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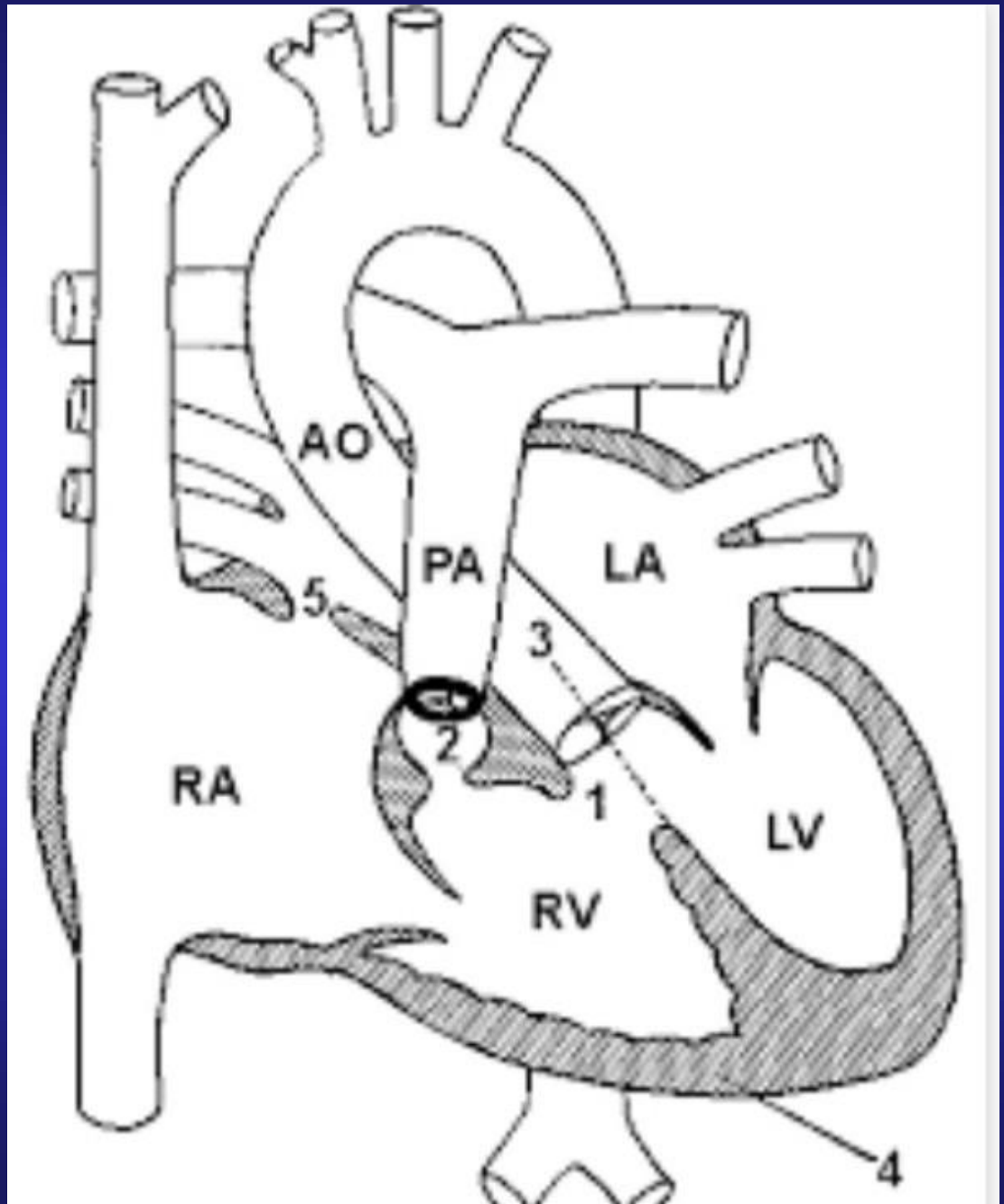

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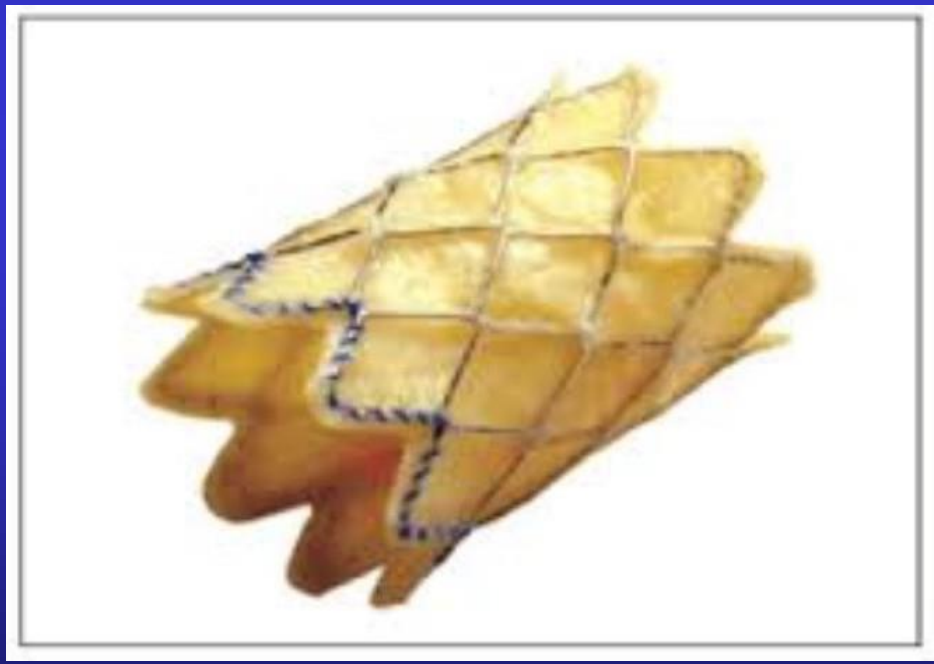

Epworth HealthCare

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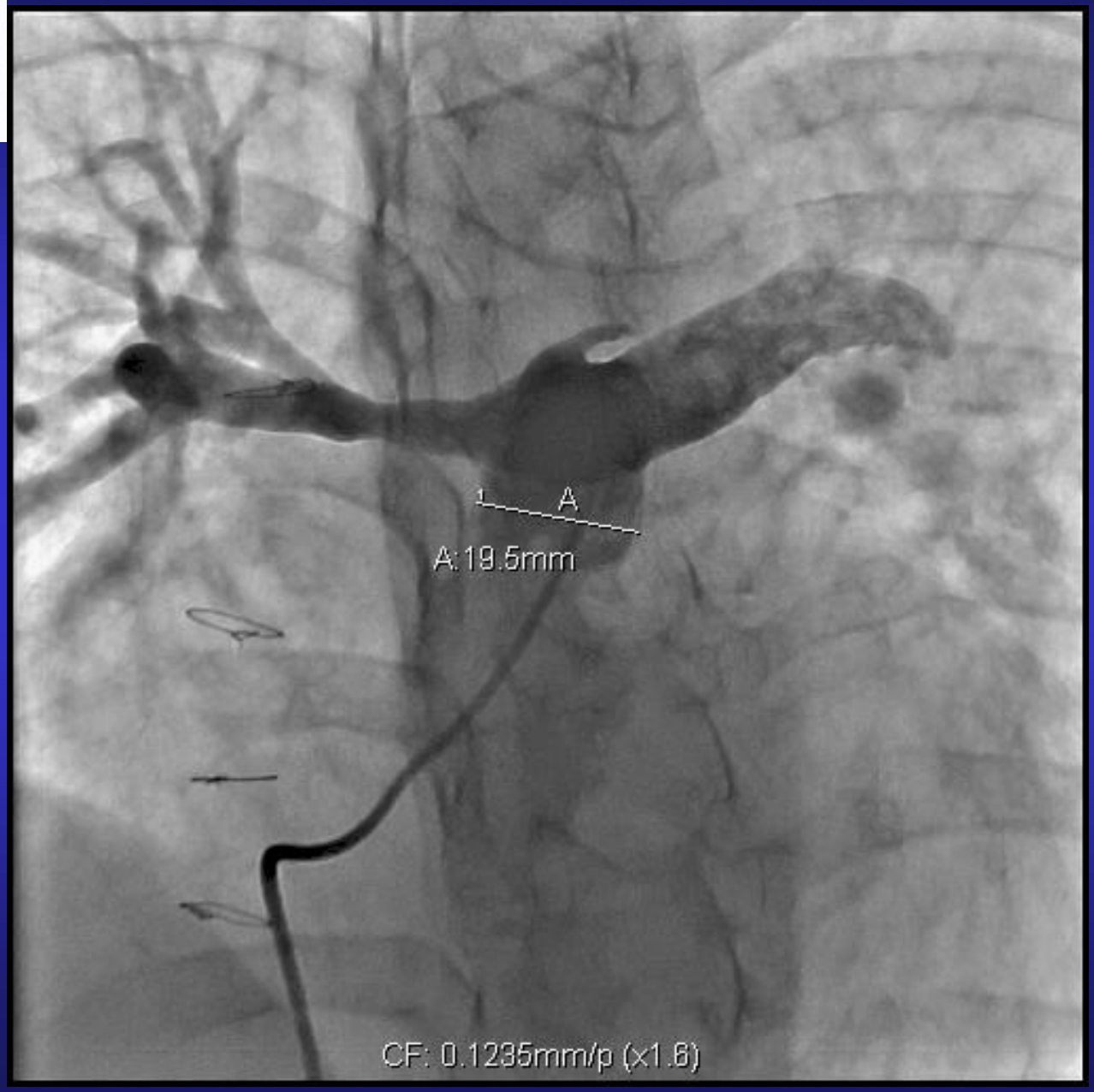

The Royal Melbourne Hospital

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Late Pulmonary Valve Reoperations – Ross 2013

- Endocarditis : 3,7,9yrs 3
- Tubular Stenosis : 11yrs 1

Mean Pulmonary Valve Gradient

- 11mmHg at 15 yrs

Epworth HealthCare

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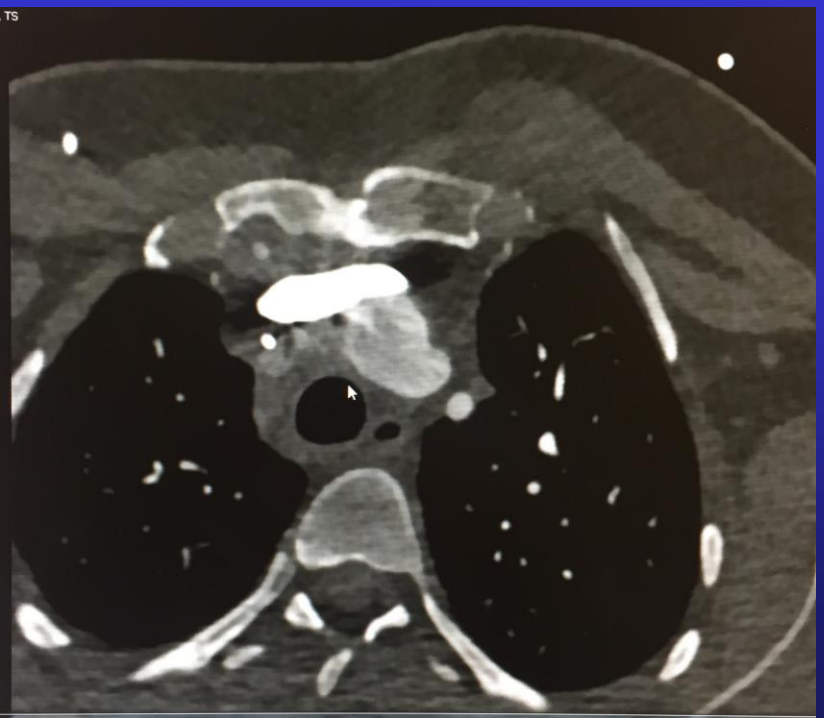
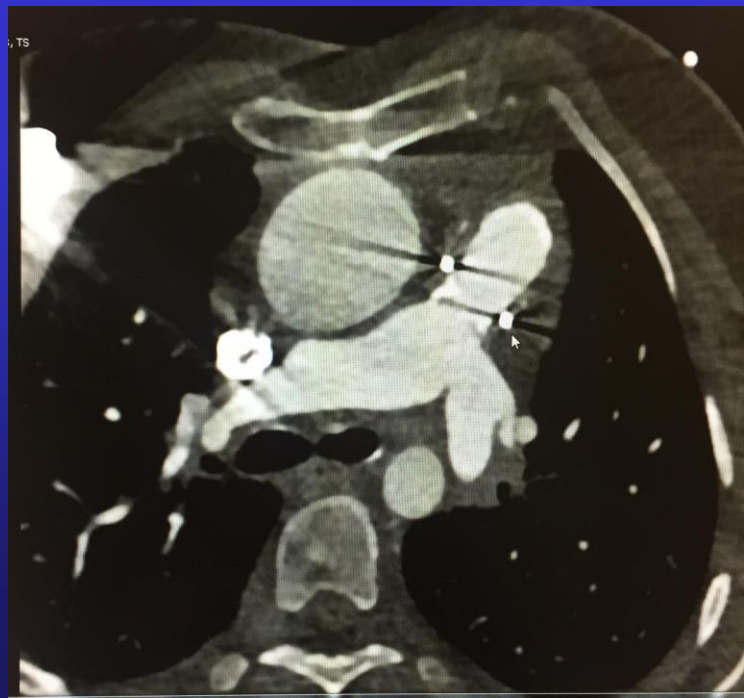
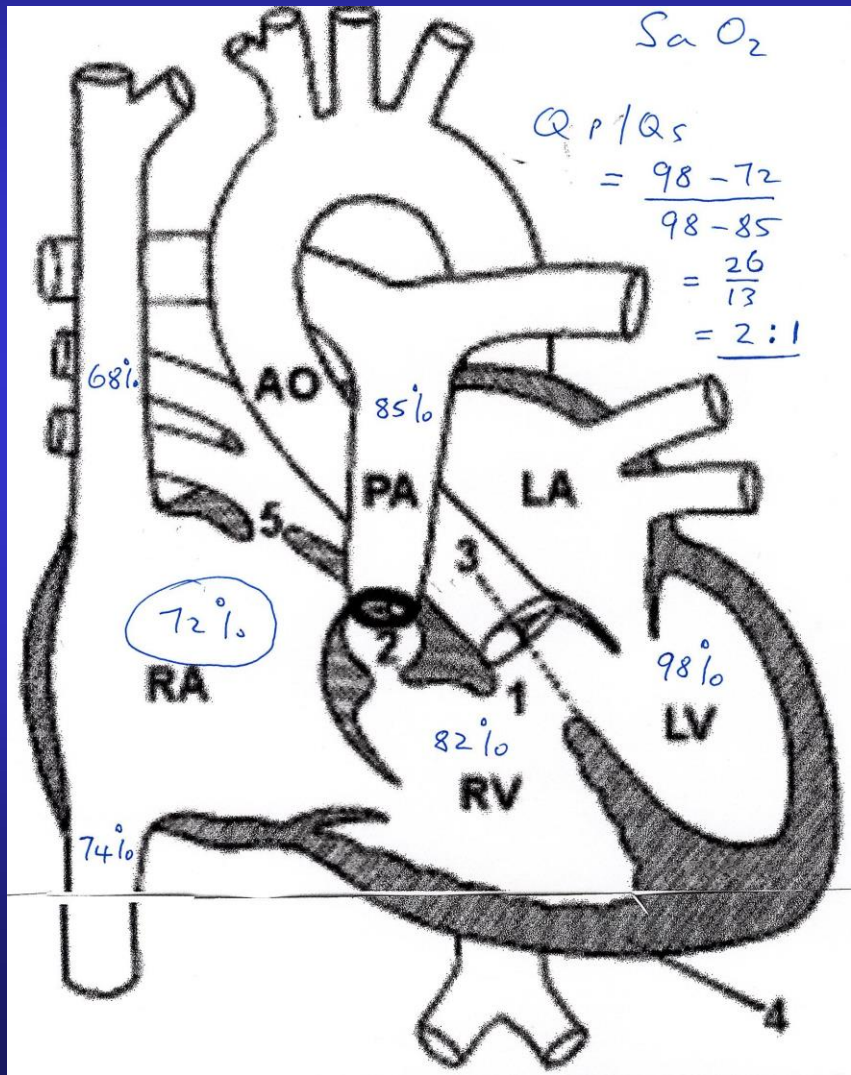
Proximity of L. Innominate v., Asc. Aorta and enlarged RV to sternum





•Residual VSD

- Usually small, peri-patch
- may or may not show on echo
- Step up in Oxygen saturation on RH c. cath



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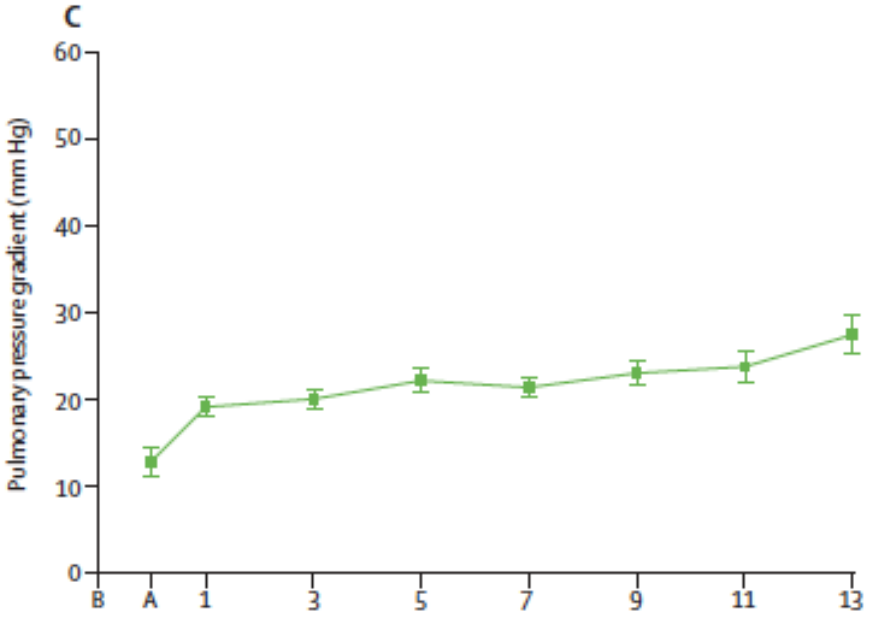
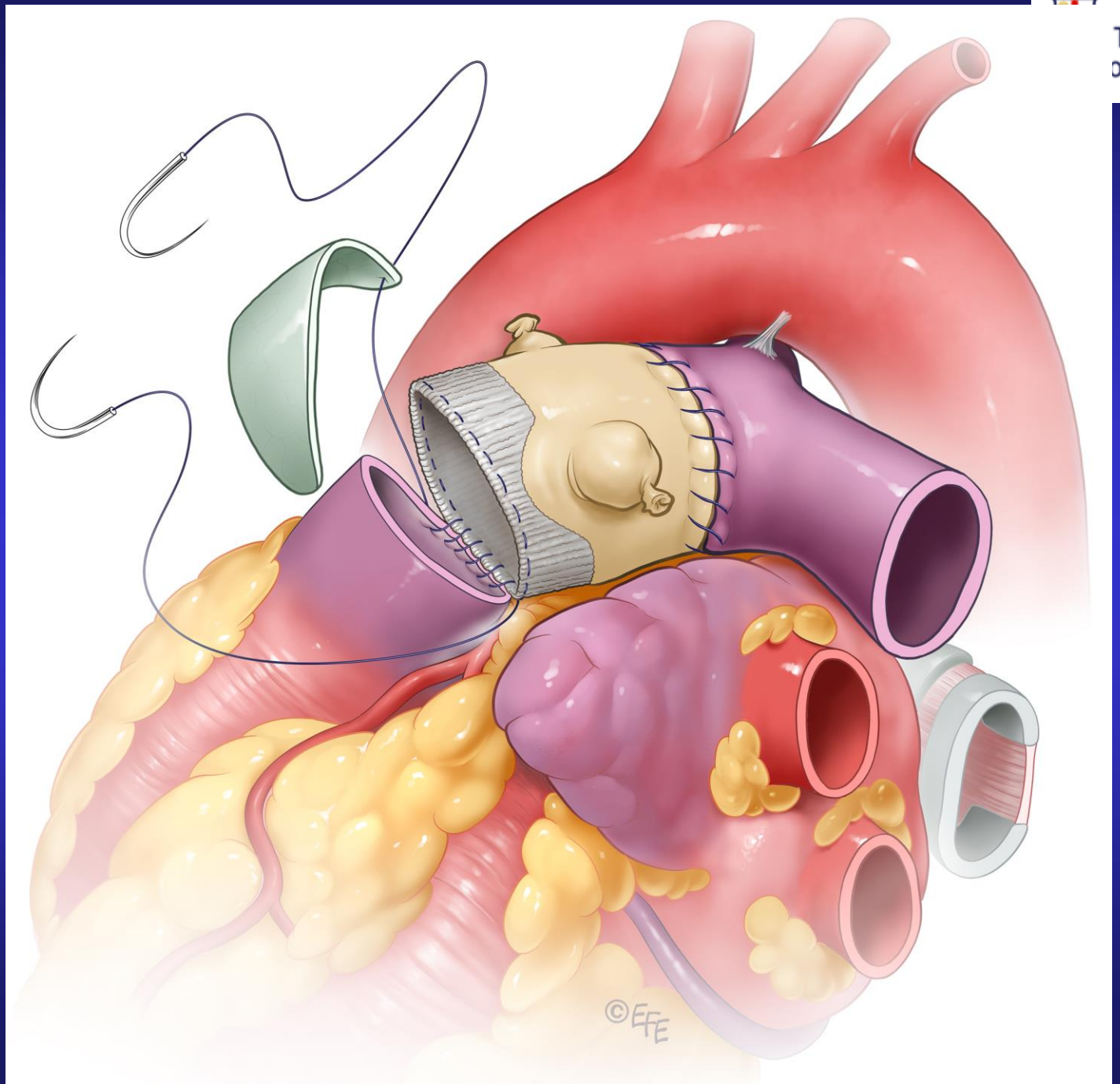
Fate of homograft?

- Homograft subject to calcific degeneration
  - Common to shrinkage and Ca++ at inflow
  - Rise in gradients seen in first 2 years then stabilises
- Greater longevity than when used for RVOT repair in congenital heart disease
  - Orthotopic position
  - Normal pulmonary pressures



El Hamamsy Lancet 2010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R. Heart Catheterization -Pt with PR and additional PS