*ACC Middle East Conference 2016, Jeddah, Saudi Arabia, October 2016*


# Adults with repaired TOF: Is the Culprit PV or RV? Indications for PV Implantation; Catheter Lab or Surgery? Arrhythmia and SCD Management

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Royal Brompton Hospital
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# *Congenital Heart Disease (including TET):*

## *Determinants of long-term outcome*

- Anatomy
- Age at surgery
- Type of surgery
- Residual lesions *

- *FU and surveillance (including pregnancy)*
- *Re-operations (timing/increasing complexity)*
- *Arrhythmia and sudden cardiac death*
- *Life style issues and functional aspects of care*

- *Acquired cardiovascular and other disease*

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# *Residual Lesions*/Common Problems Late After Tetralogy Repair*

- RVOT lesions (PR, PS, PA stenosis)
- RV/LV dysfunction
- Aortopathy
- Exercise intolerance
- Atrial flutter/fibrillation
- Sustained VT
- Premature death (SCD)

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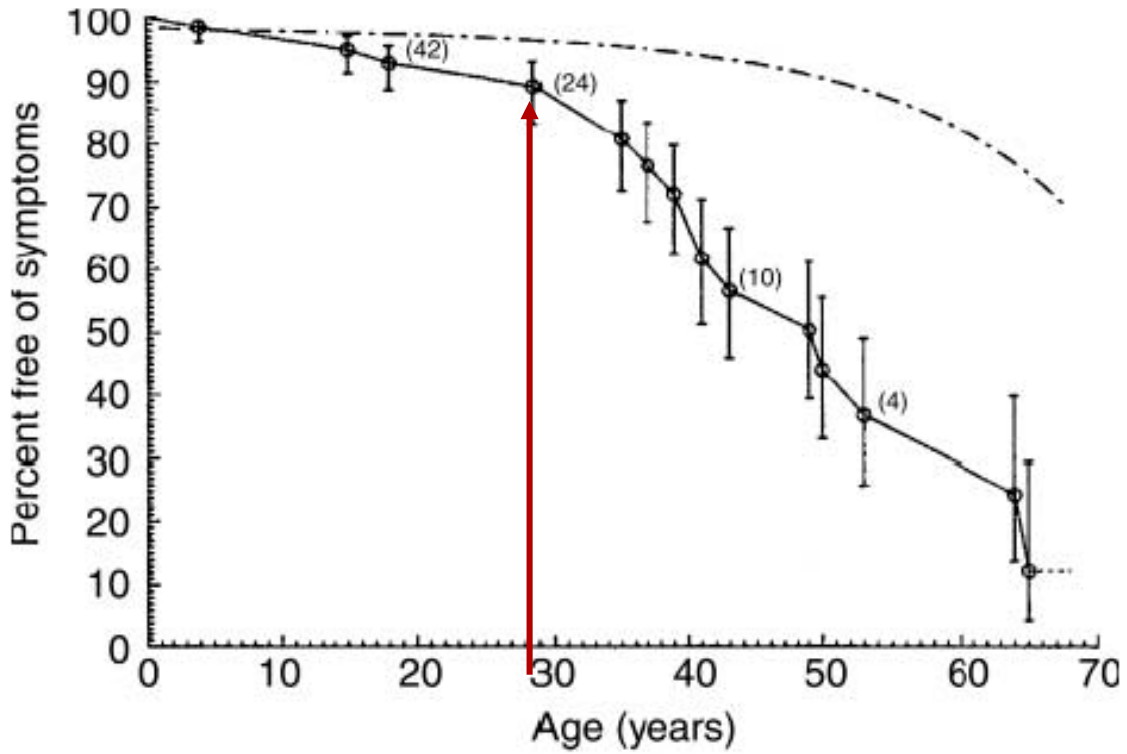
# Natural history of isolated congenital PR

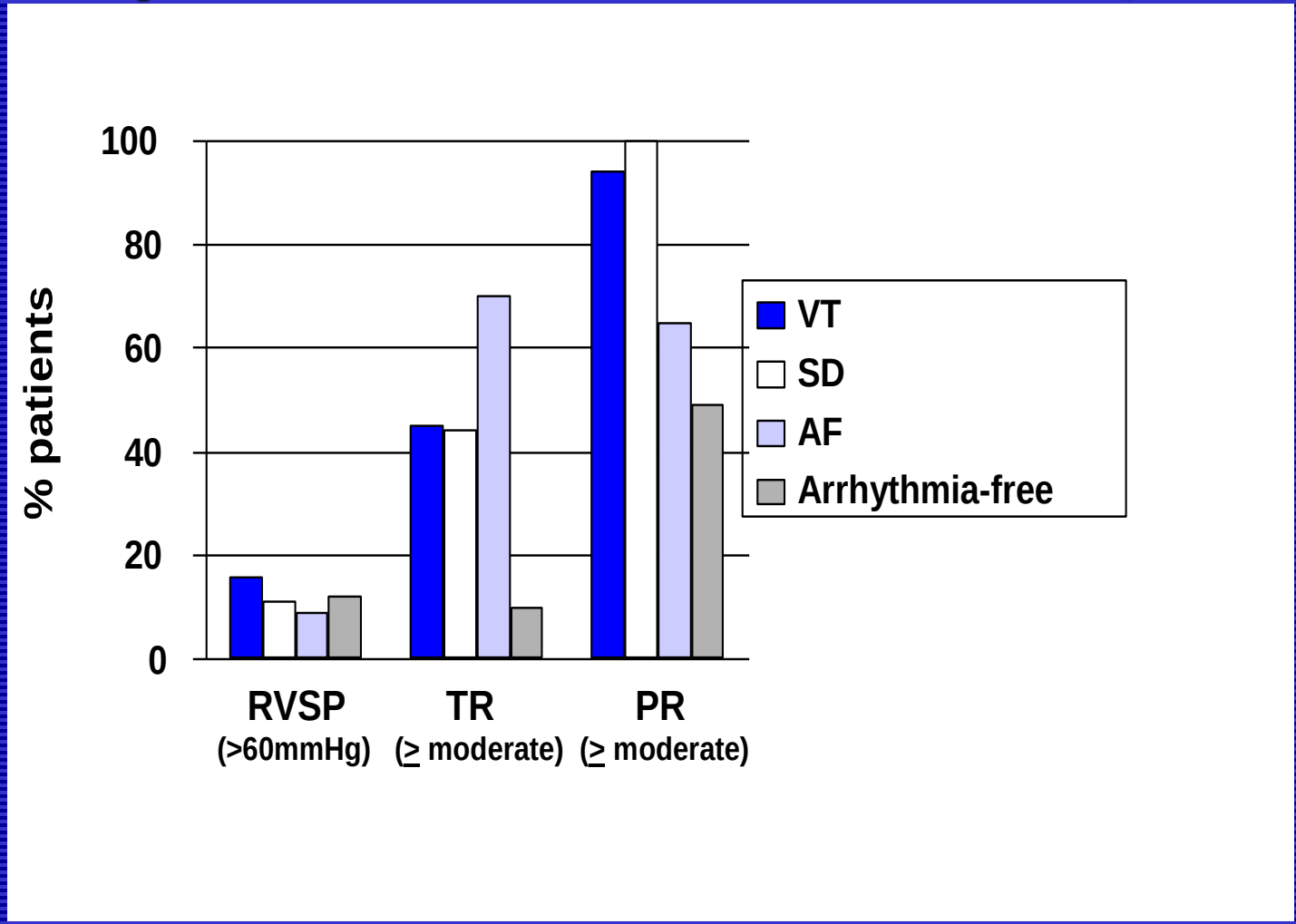



- Effort intolerance
- Dyspnoea
- Oedema
- Sudden death

**Shimazaki *et al*., Thorac Cardiovasc Surg 1984**

# PR after Tetralogy Repair

## Arrhythmia and sudden cardiac death *(n=793)*




*Gatzoulis et al Lancet 2000*

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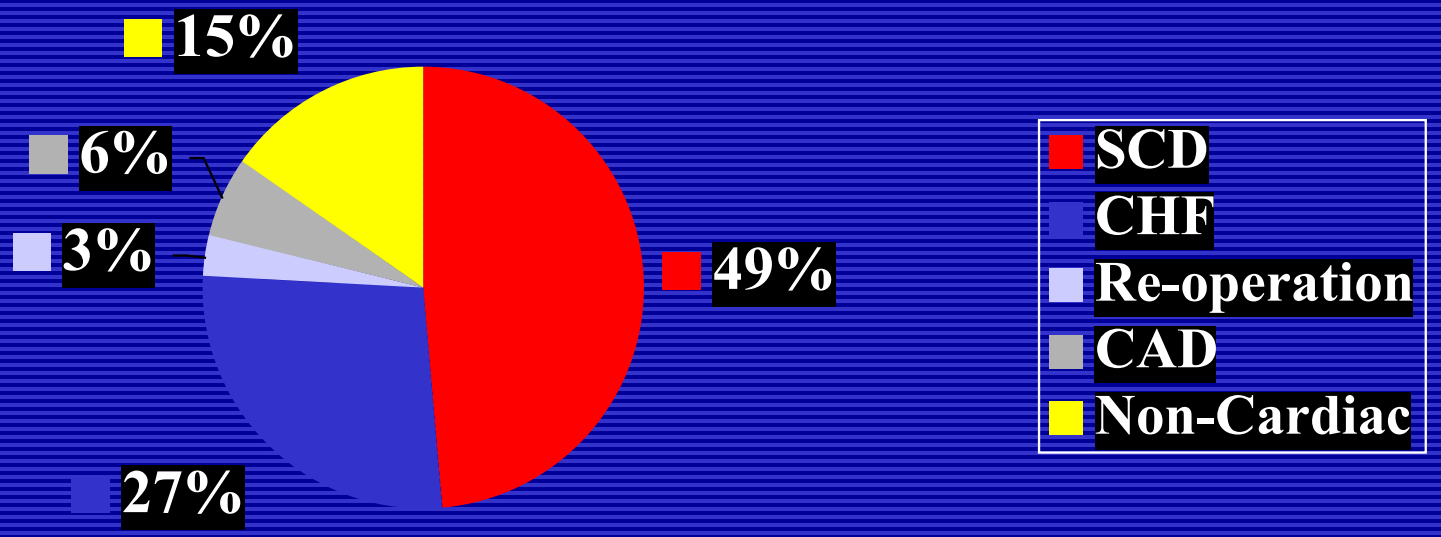
# Late Death in Repaired Tetralogy

*793 adult pts (1985-95)*
*33 pts died (4.2% mortality)*




*Gatzoulis et al Lancet 2000*

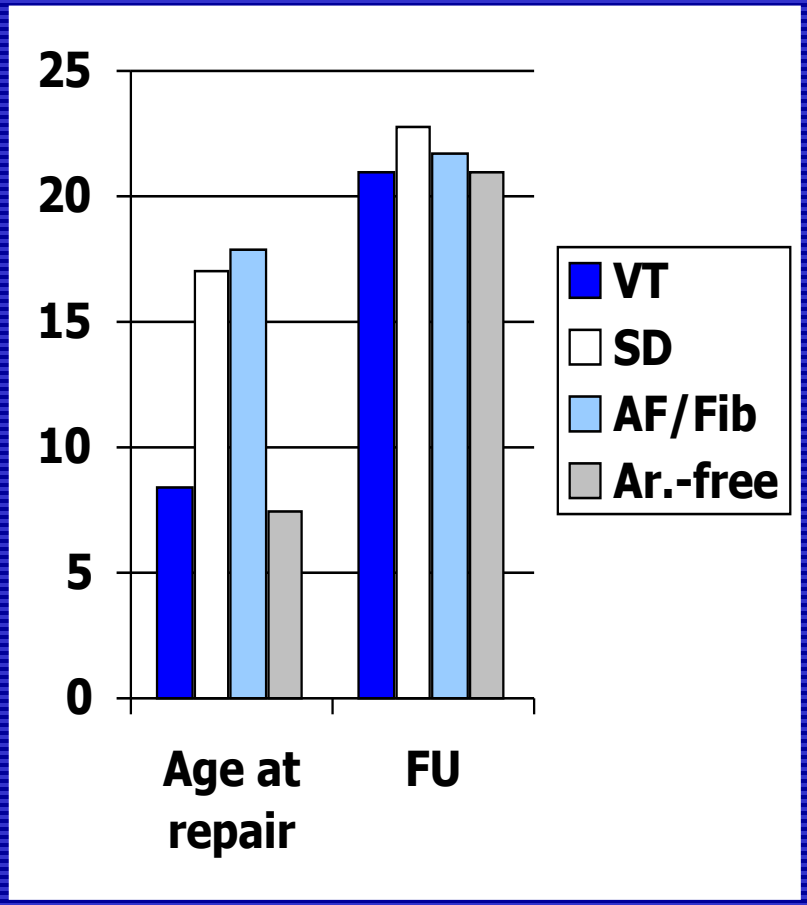
Royal Brompton

## *TET Multi-Centre Study*

(793 pts, 1985-95)

- 33 pts sustained VT
- 16 sudden deaths
- *29 pts AF/Fib*
- 715 pts arrhythmia-free

*4pts with AF ⇒ VT,*
*1 of them ⇒ SCD*




*Lancet 2000*

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| *Variable* | *Predictors* | *Effect (b)* | *95% CI* | *P .* |
|---|---|---|---|---|
| **PRF** | *TAP* | +16% | 8 to 25 | <0.001 |
| **RVEDVi** | *RVOTa/a* | +24% | 6 to 42 | 0.008 |
| | **PRF** | +1.5ml/% | 1.1 to 1.9 | <0.001 |
| **RVESVi** | *RVOTa/a* | +19% | 7.2 to 31 | 0.002 |
| | *RVEDVi* | +0.53ml/ml | 0.43 to 0.63 | <0.001 |
| | *RVMi* | +0.28ml/g | 0.04 to 0.52 | 0.025 |
| **RVEF** | *RVOTa/a* | -5.3% | -9.8 to -0.8 | 0.021 |
| | *RVMi* | -0.26%/g | -0.4 to -0.1 | *<0.00* |
| **LVEF** | **RVEF** | +0.6%/% | 0.42 to 0.78 | 0.001 |
| | **ARF** | -0.46%/% | -0.8 to -0.1 | 0.013 |

*Davlouros et al JACC 2002*

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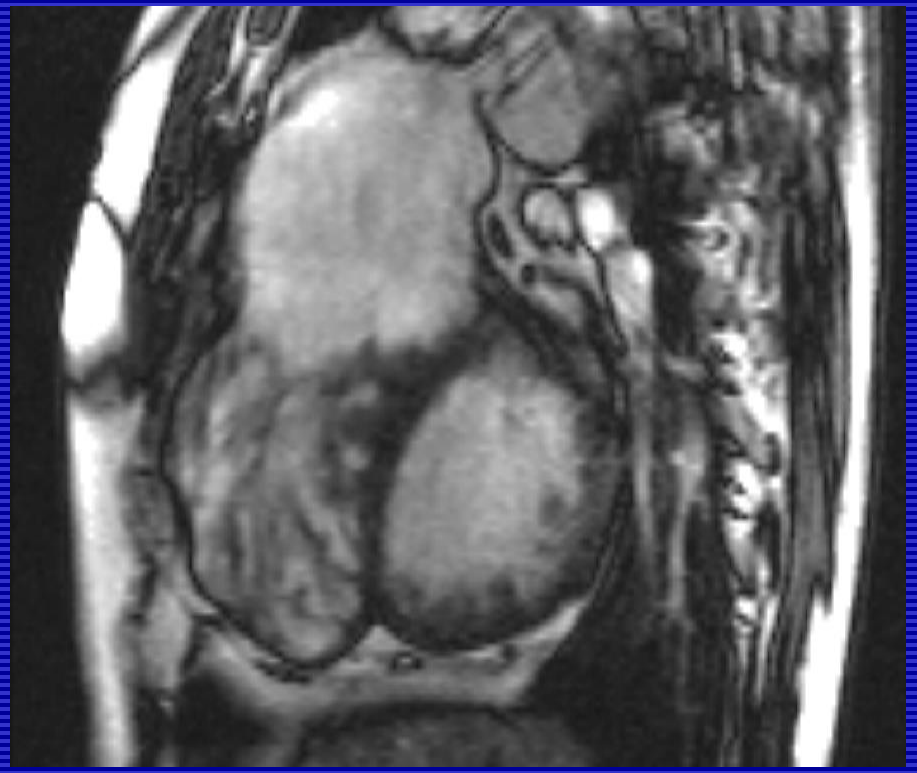
# RVOT aneurysms and akinesia



- RVOT aneurisms and akinesia common
- Not always related to RVOT or transannular patching
- Contributory to RF dysfunction
- VT focus

*Davlouros et al JACC 2002*

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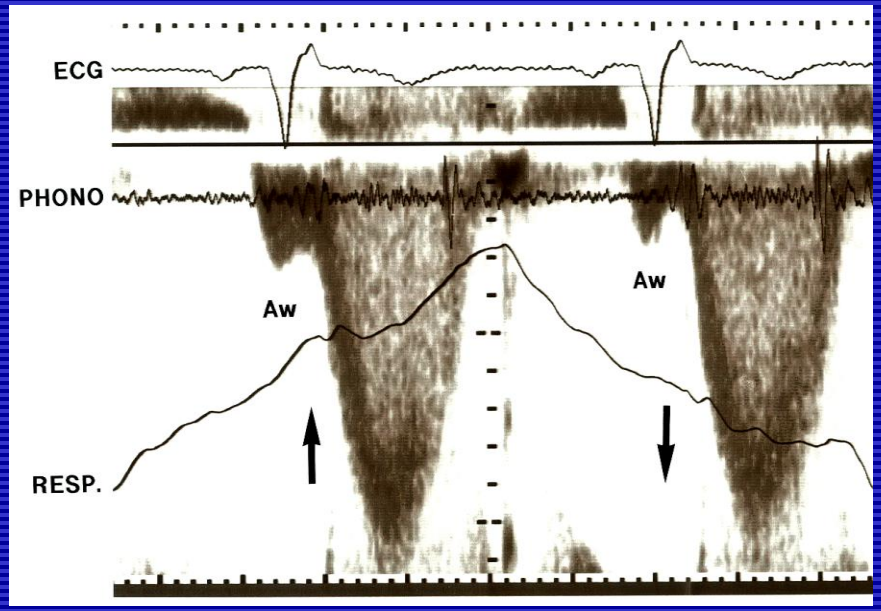
# Assessing the RV after TET Repair: Diastolic function





- Common in adults with TET repair *(amongst pts with preserved PV annulus)*
- Counteracts chronic effects of PR
- Restrictive pts had smaller RVs and better exercise performance

*Gatzoulis et al Circulation 1995*

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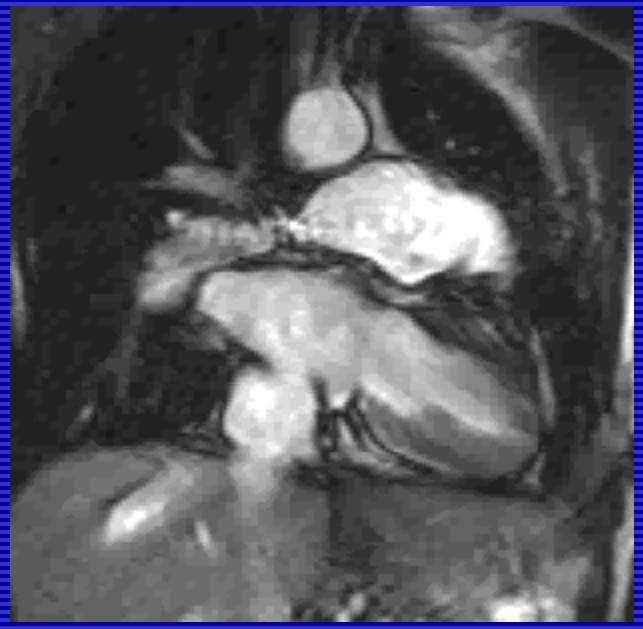
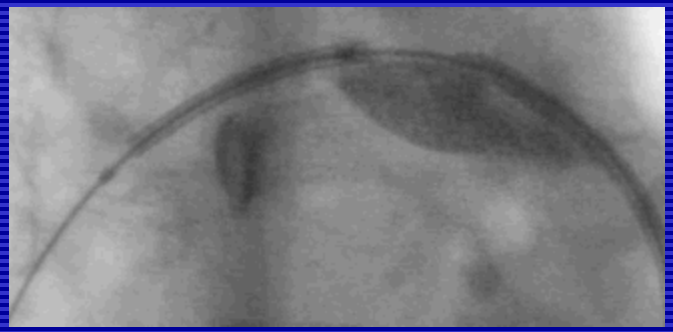
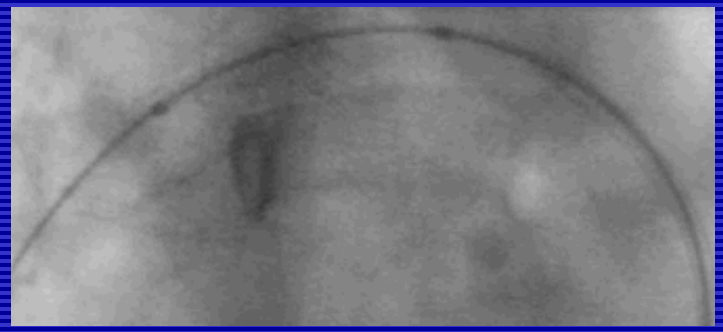
# Peripheral PS augments PR after TET repair







*Chatuverdi et al Circulation 1997*

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# Preoperative Thresholds for Pulmonary Valve Replacement in Patients With Corrected Tetralogy of Fallot Using Cardiovascular Magnetic Resonance

Thomas Oosterhof, MD, PhD; Alexander van Straten, MD; Hubert W. Vliegen, MD, PhD; Folkert J. Meijboom, MD, PhD; Arie P.J. van Dijk, MD, PhD; Anje M. Spijkerboer, MD, PhD; Berto J. Bouma, MD, PhD; Aeilko H. Zwinderman, PhD; Mark G. Hazekamp, MD, PhD; Albert de Roos, MD, PhD; Barbara J.M. Mulder, MD, PhD

- 101 TOF pts; prospective; multi-centre; MRI(baseline & 9 months post PVR)
- Indications for PVR: *reviewed in next slide*
- **Results**
- RV volumes decreased (mean of 28%)
- RVEF did no change (42 vs 43%)
- Concomitant RVOT aneurysm reduction ⇒ 25% greater RV reduction
- Higher pre-op RV volumes associated with higher post-op RV volumes
- Receiver operator characteristic analysis ⇒ cut off value of <160 ml/m² for normalisatation of RVEDV and <82 ml/m² for RVESV

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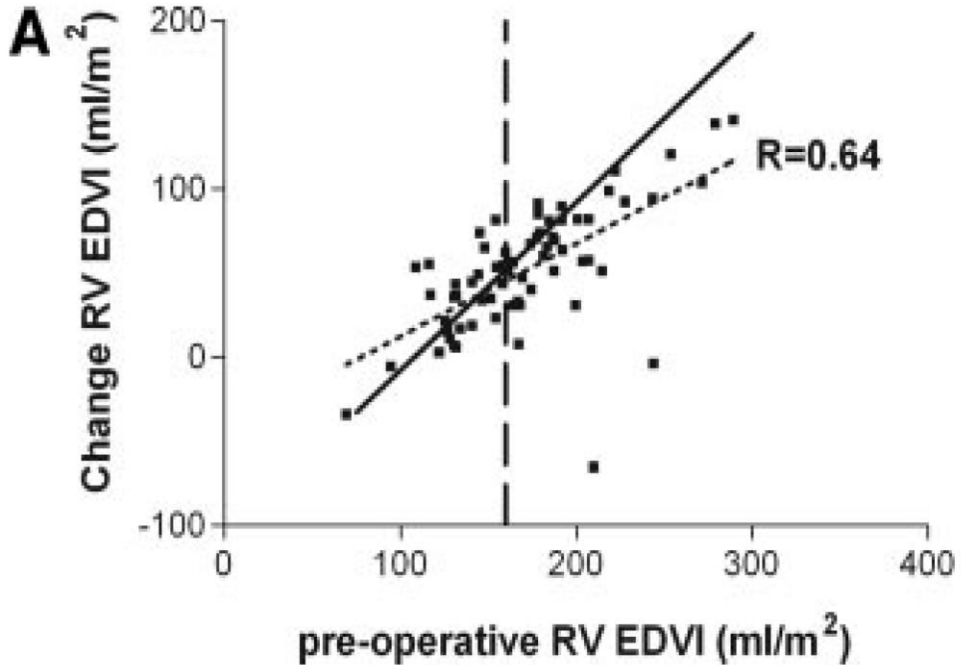
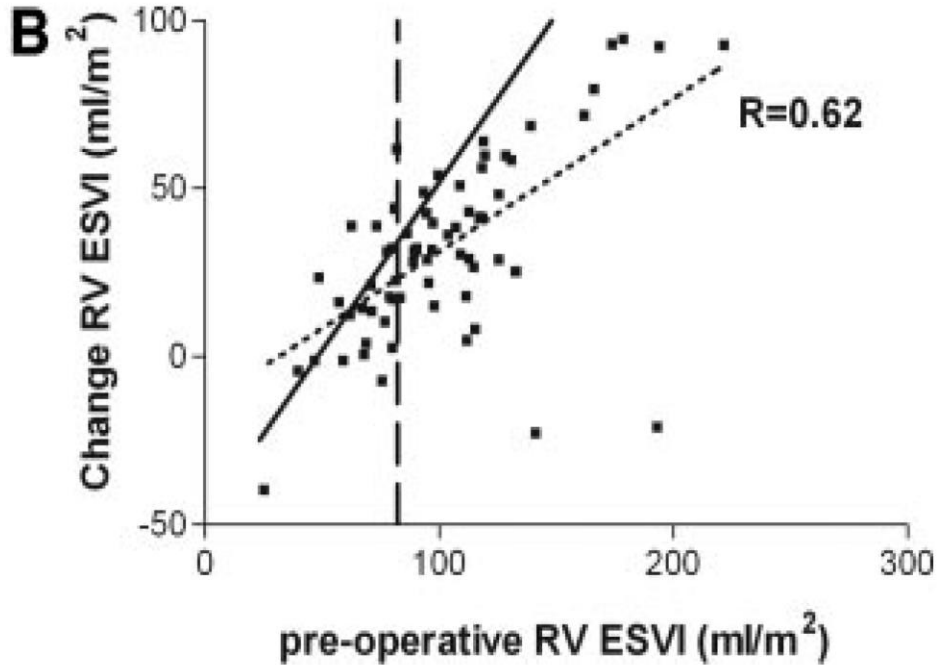
*Circulation 2007*

| | |
|---|---|
| Indications for PVR (all patients had moderate to severe pulmonary regurgitation) | |
| Symptomatic | 71 |
| Asymptomatic with progressive RV dilatation | 24 |
| Ventricular arrhythmias or QRS >180 ms | 15 |
| Progressive tricuspid regurgitation | 4 |
| Age at PVR, y, median (IQR) | 29 (23 to 37) |
| Previous PVR | 6 |
| Diameter homograft, mm, mean±SD | 25±1.7 |
| Type of graft for RVOT reconstruction | |
| Pulmonary homograft | 96 |
| Contegra conduit | 3 |
| Aorta homograft | 1 |
| Concomitant procedures | |
| Tricuspid valve plasty or ring | 24 |
| RV reduction plasty | 18 |
| Pulmonary artery angioplasty | 15 |
| Ventricular septal defect closure | 4 |

## TABLE 2. Hemodynamic Changes After Surgery

| Variable | Before Surgery | After Surgery |
|---|---|---|
| RV EDVI, mL/m$^2$ | 171±44 | 119±34* |
| RV ESVI, mL/m$^2$ | 102±38 | 70±29* |
| RV SV index, mL/m$^2$ | 70±16 | 49±10* |
| RV EF, % | 42±10 | 43±10 |
| RV corrected EF, % | 24±8.1 | 41±11* |
| LV EDVI, mL/m$^2$ | 85±22 | 94±20* |
| LV EF, % | 52±9 | 53±8 |
| Pulmonary regurgitant fraction, % | 44±13 | 5±9* |
| Net forward flow, mL/m$^2$ | 38±16 | 46±12* |
| Tricuspid regurgitation grade ≥2, % | 26 | 19 |
| QRS duration, ms | 155±29 | 144±29* |
| NYHA class ≥II, % | 53 | 11* |




*Circulation 2007*

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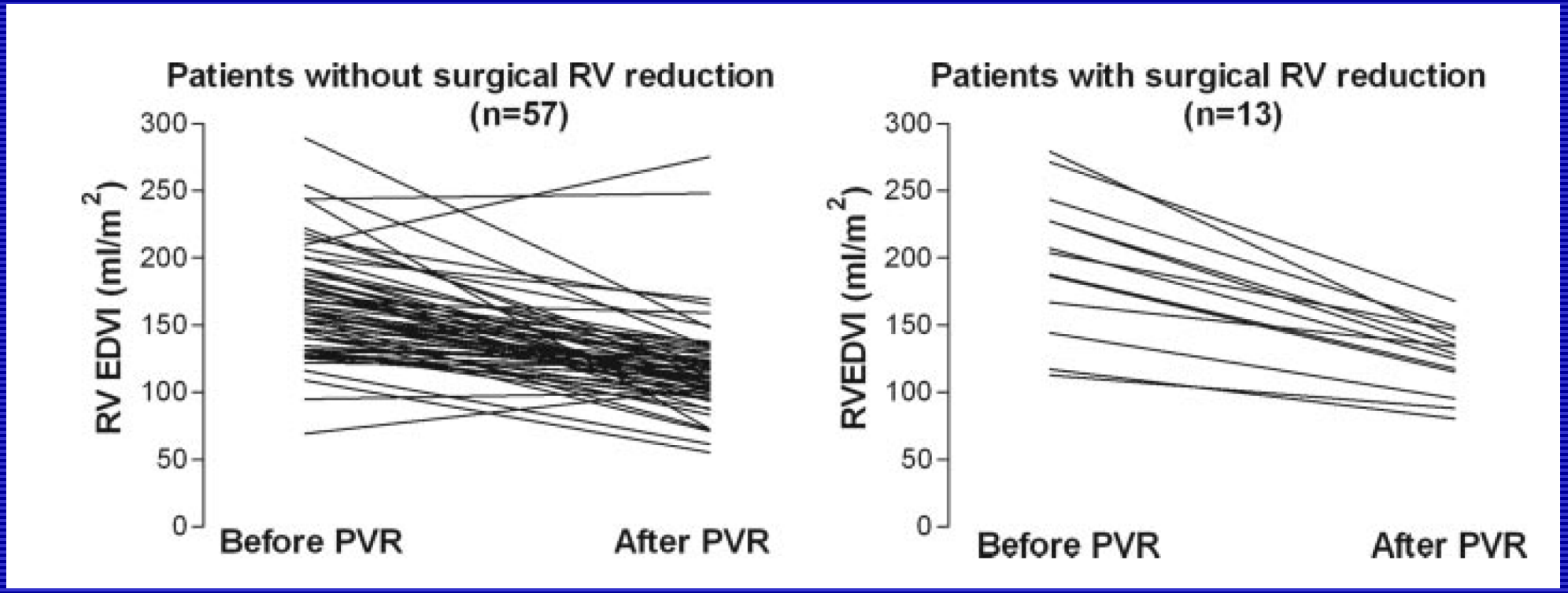


*Circulation 2007*

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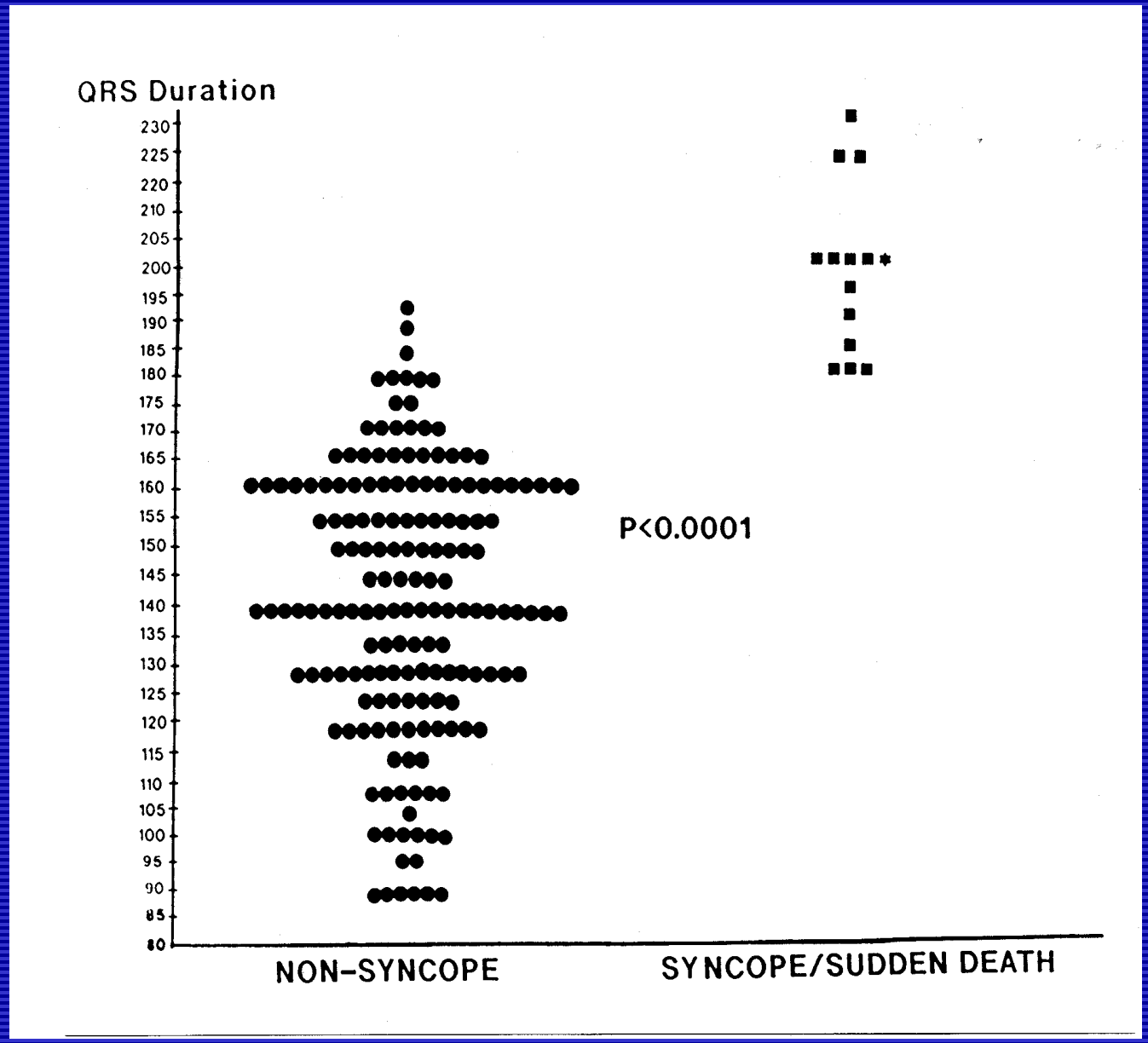


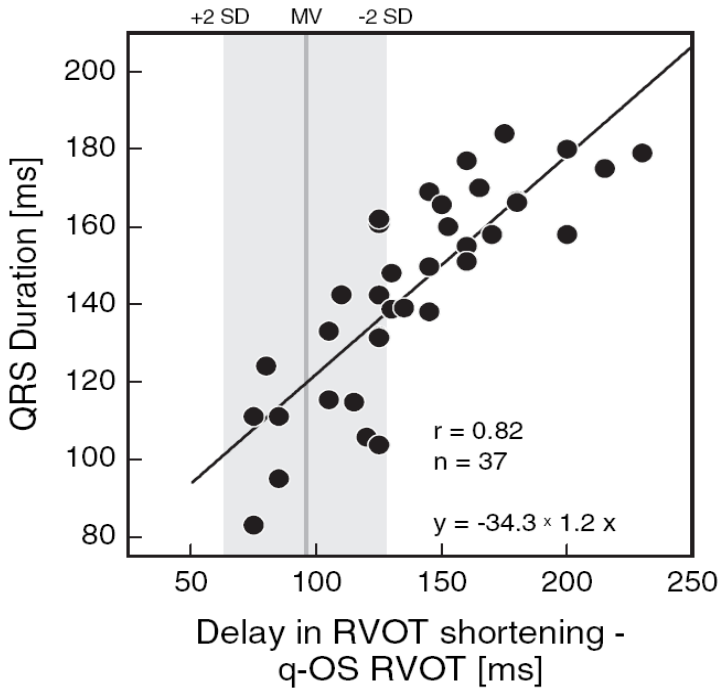

*Gatzoulis et al Circulation 1995*

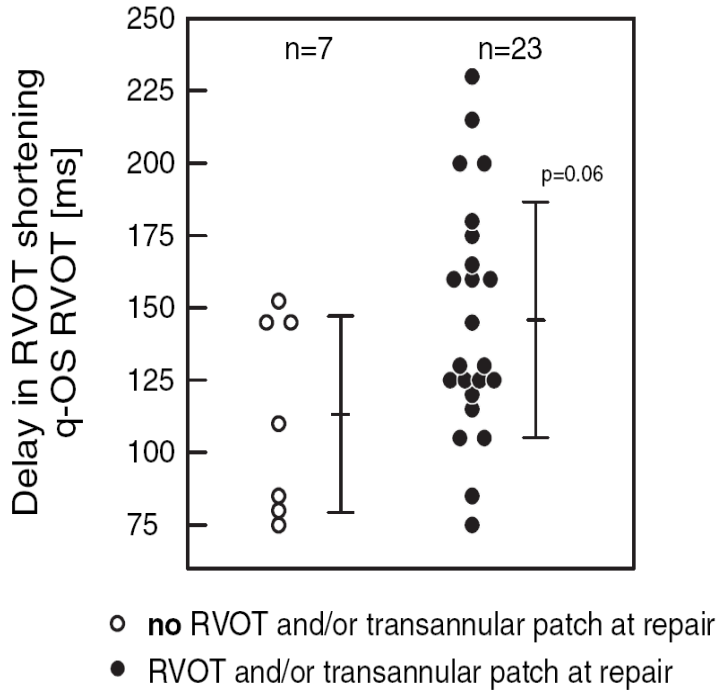
Royal Brompton

# Right Ventricular Mechanics and QRS Duration in Patients With Repaired Tetralogy of Fallot

## Implications of Infundibular Disease

Anselm Uebing, MD; Derek G. Gibson, MB, FRCP; Sonya V. Babu-Narayan, BSc, MRCP; Gerhard P. Diller, MD; Konstantinos Dimopoulos, MSc, MD; Omer Goktekin, MD; Mark S. Spence, MD, MRCP; Kai Andersen, MD, PhD; Michael Y. Henein, MD, PhD; Michael A. Gatzoulis, MD, PhD; Wei Li, MD, PhD




*Uebing et al Circulation 2007*

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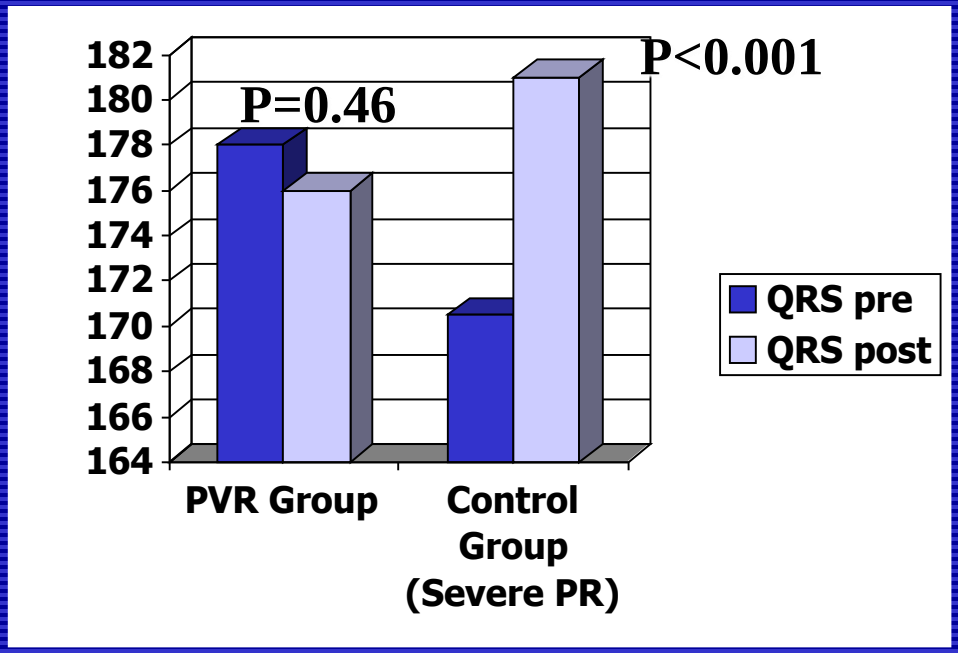
# Impact of PVR on Arrhythmia Markers
## QRS Duration




*70 adults with repaired TET*
*Undergoing redo surgery PVR*

**3 (4%) peri-operative mortality**
***All 3 had marked RV dysfunction***

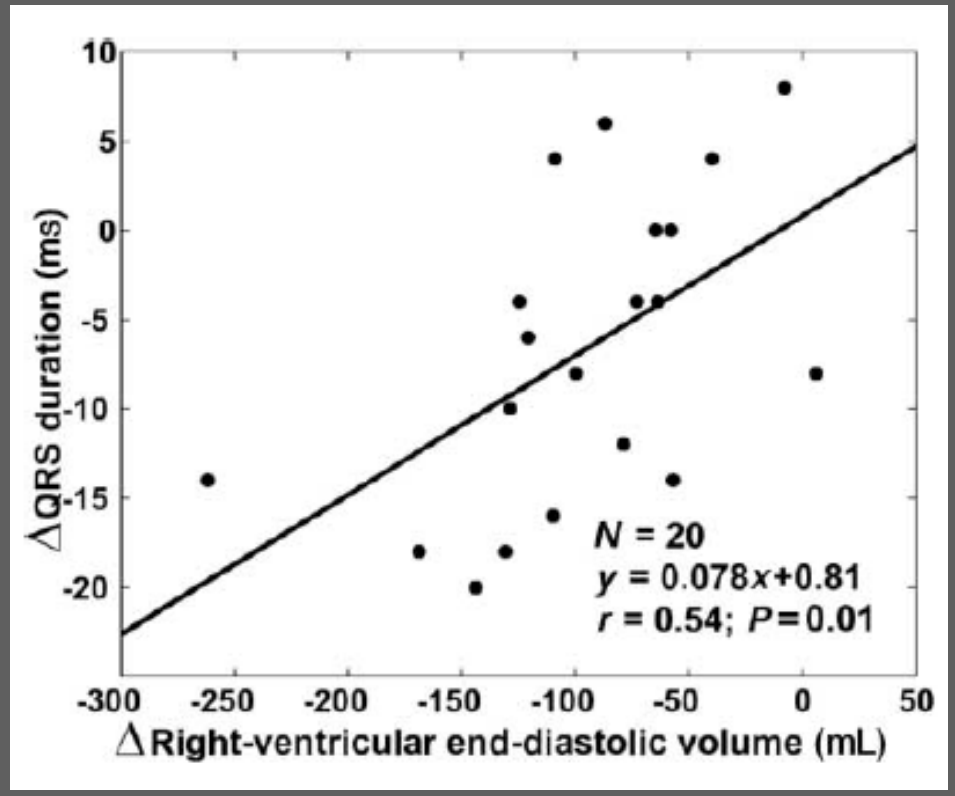
***FU time 4.7 yrs (from PVR)***

University of Toronto Congenital Cardiac Center for Adults
Montreal Heart Institute, Canada
Chiba Cardiovascular Center, Japan
Kardiocentrum, Prague, Czech Republic

*Therrien et al Circulation 2001*

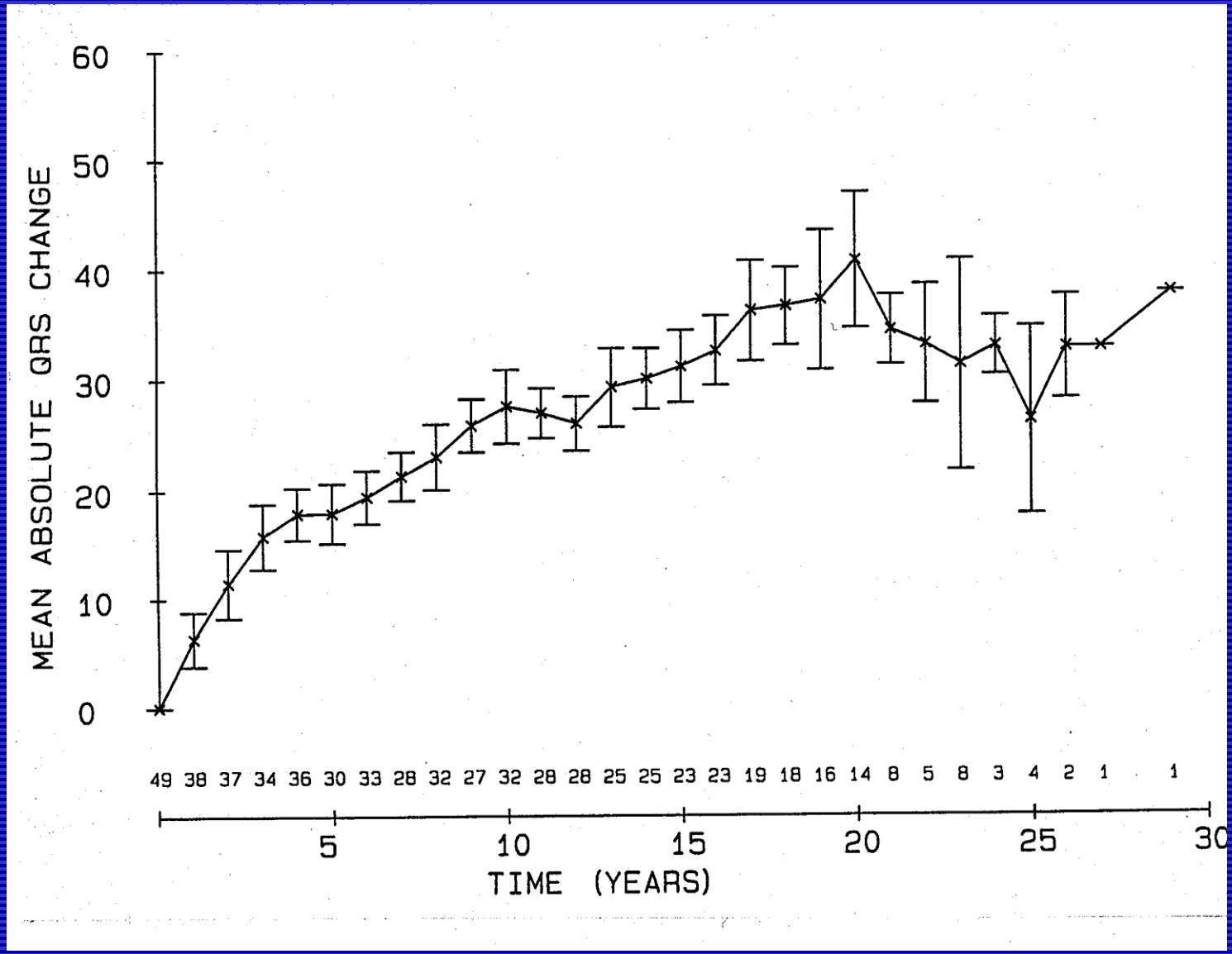
Royal Brompton

# Decreased QRSd after PVR




RV volume and QRS duration pre and post PVR

van Huysduynen *et al,* Eur Heart J 2005




*Till et al, Circulation (suppl) 1995*

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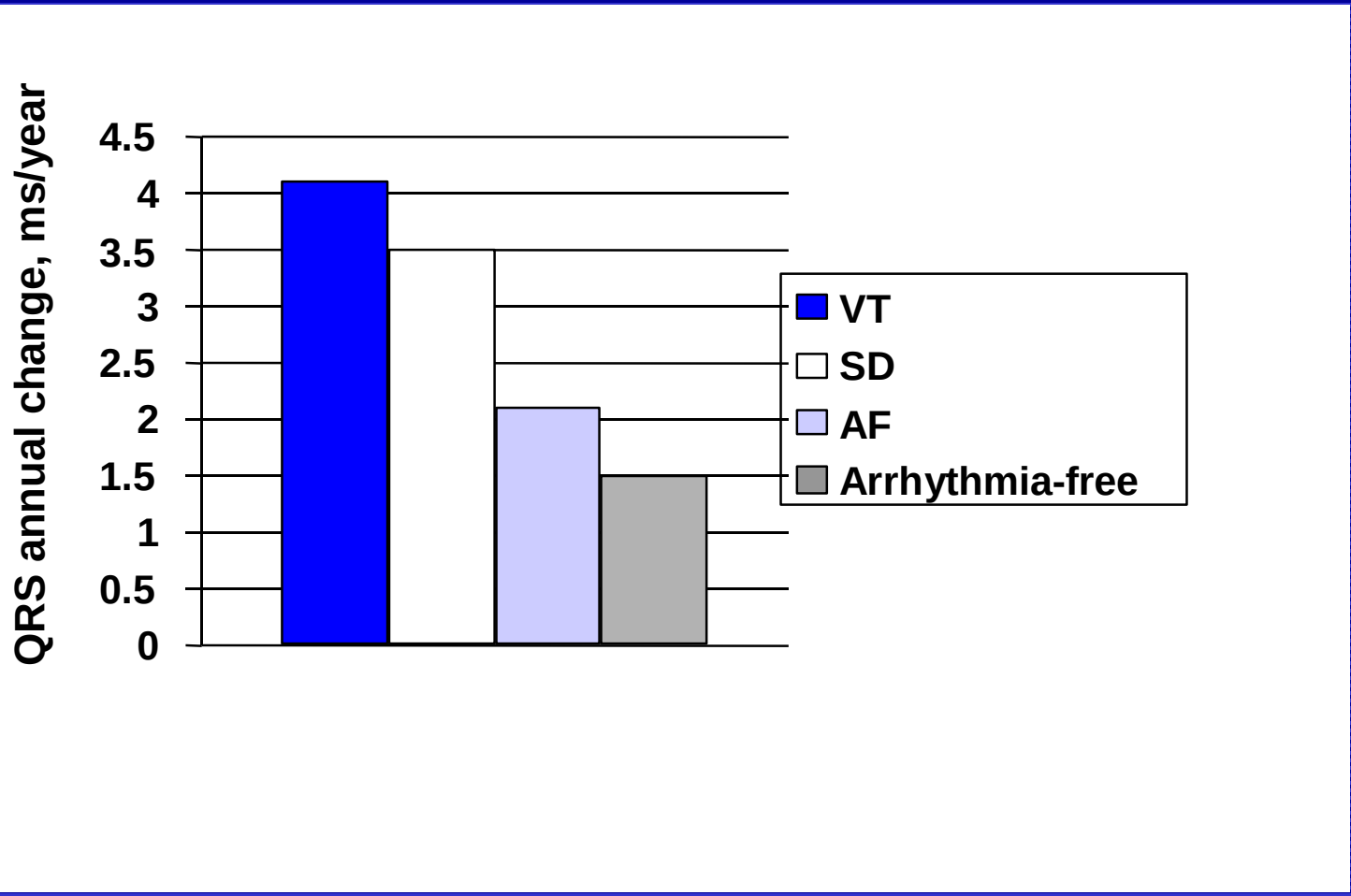


*Gatzoulis et al Lancet 2000*

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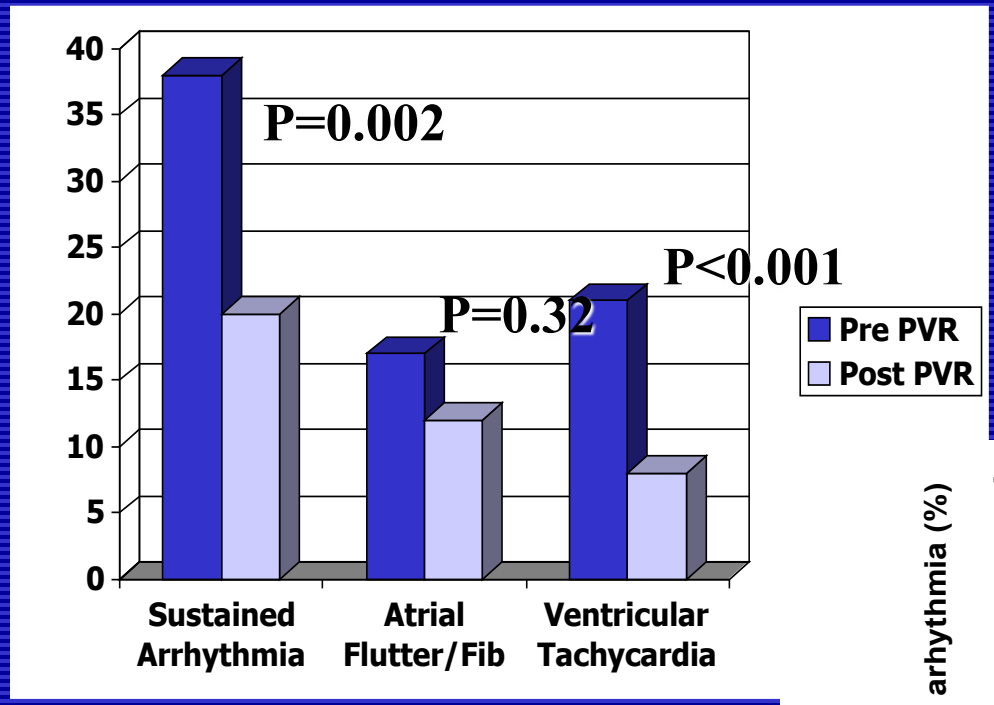
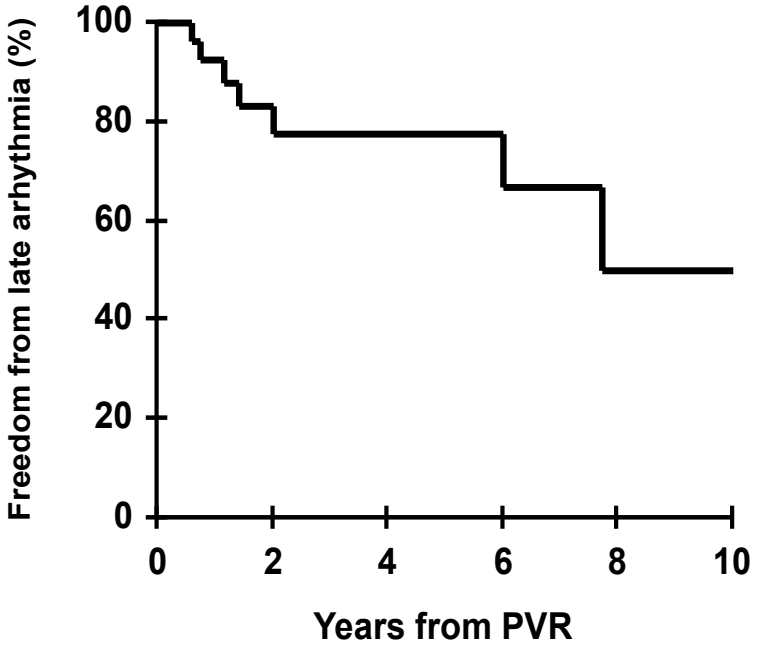
# Impact of PVR on Arrhythmia Recurrence




*Circulation 2001*

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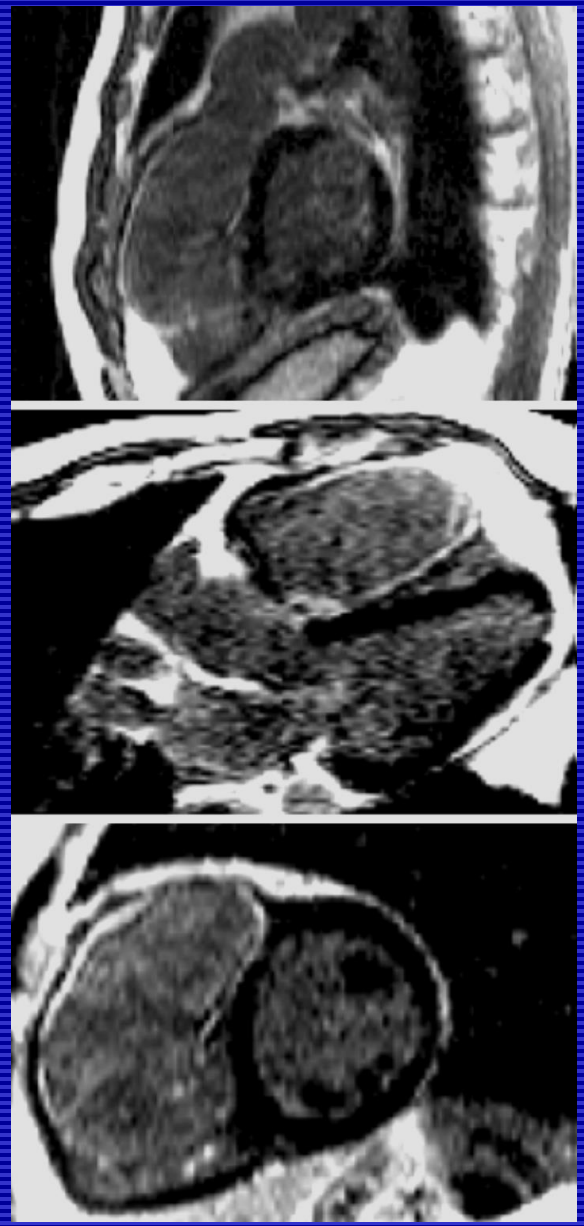

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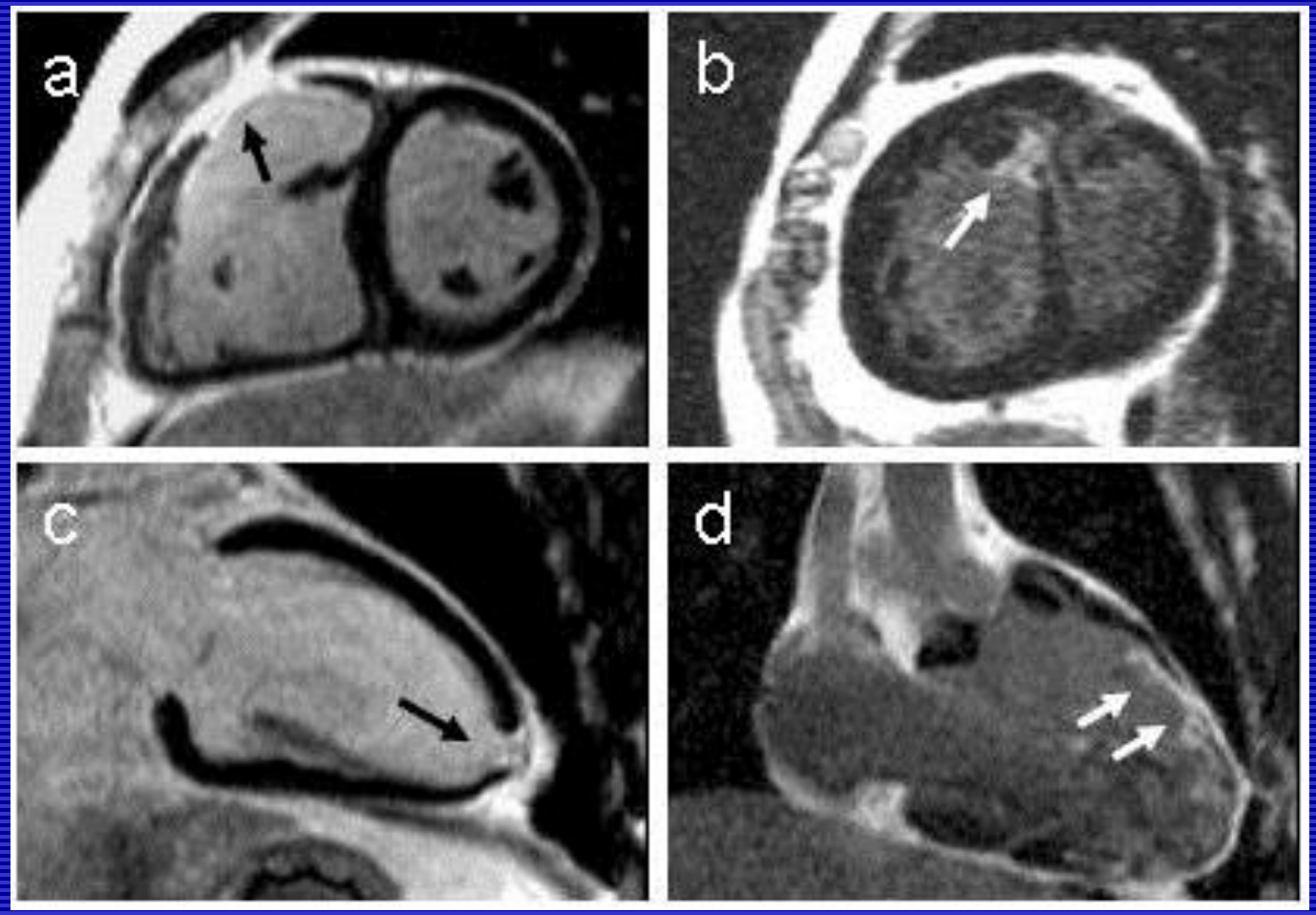
# Tetralogy and Gadolinium enhancement




*Babu-Narayan et al Circulation, 2005*

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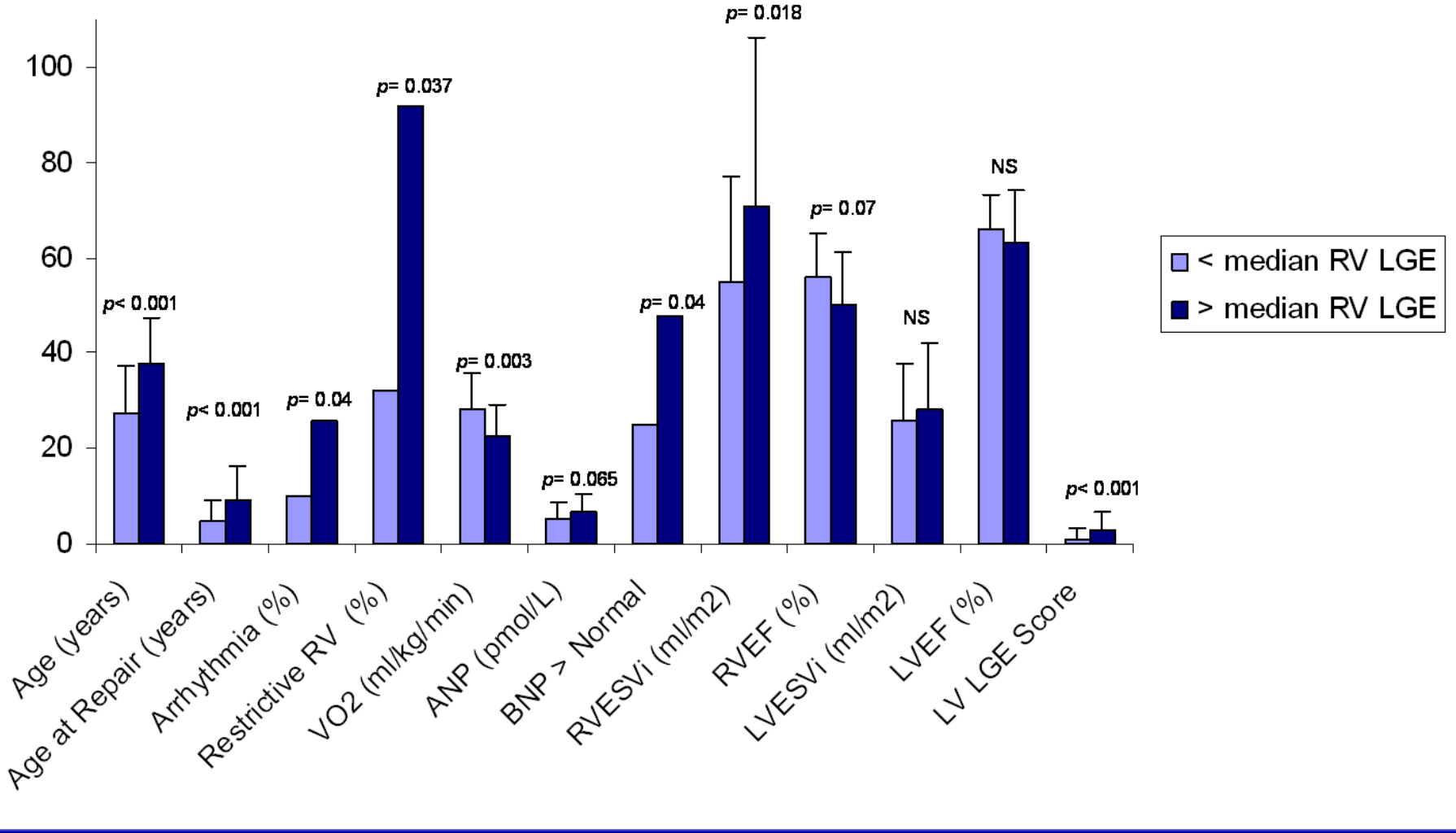
# MRI Gadolinium enhancement
## Myocardial fibrosis in repaired TET




*Babu-Narayan et al Circulation 2005*

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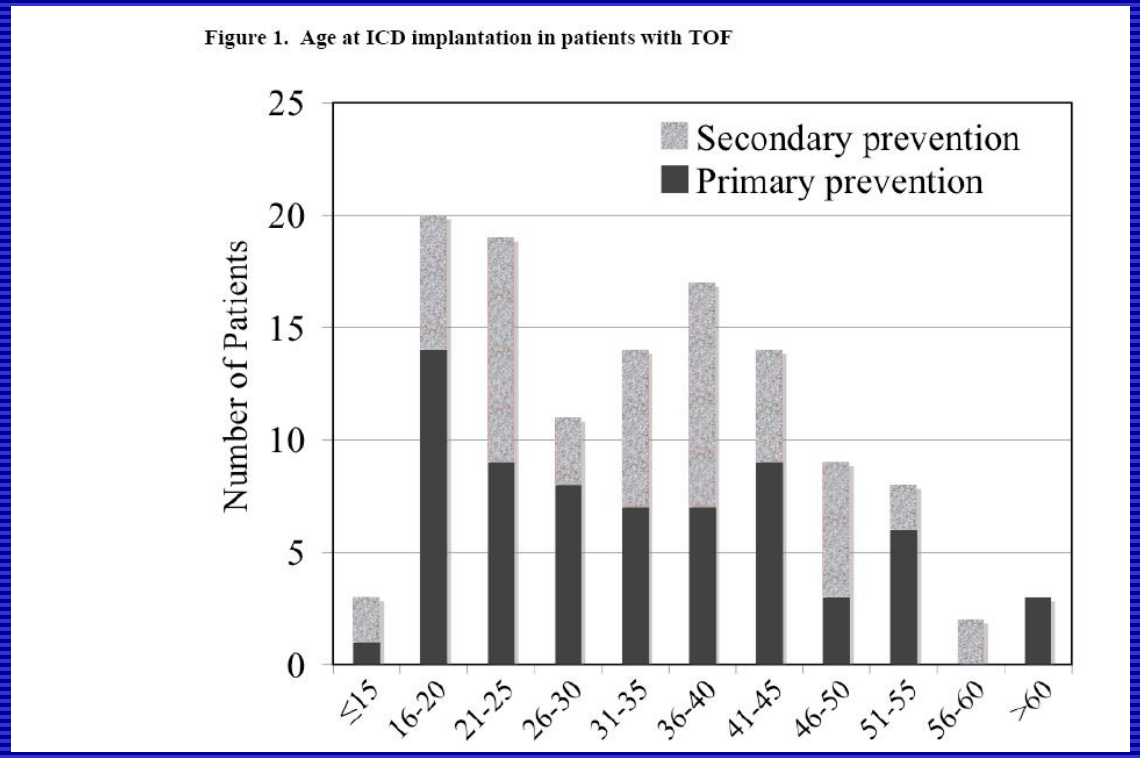
# Tetralogy: AICDs (Tetralogy n=121)
## Secondary vs Primary Prevention




From the *Canadian Adult Congenital Heart (CACH) Network; †Alliance for Congenital heart Quebec Interinstitutional REsearch (ACQUIRE); ‡Leeds General Hospital, UK; §Royal Brompton Hospital, UK; and ¶Children's Hospital, Boston

*Khairy et al Ciruclation 2008*

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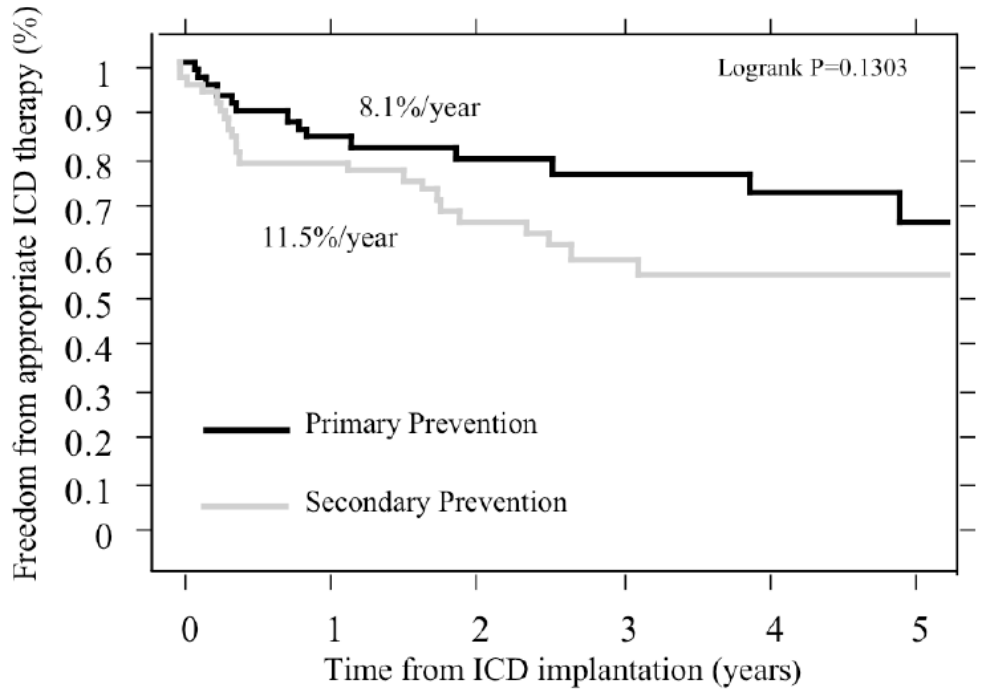
**Figure 2. Appropriate ICD therapy in primary and secondary prevention**




*Khairy et al Circulation 2008*

Royal Brompton

# ICDs in ACHD and appropriate therapies

**Circ 2008** Congenital Heart Disease

## Implantable Cardioverter-Defibrillators in Tetralogy of Fallot

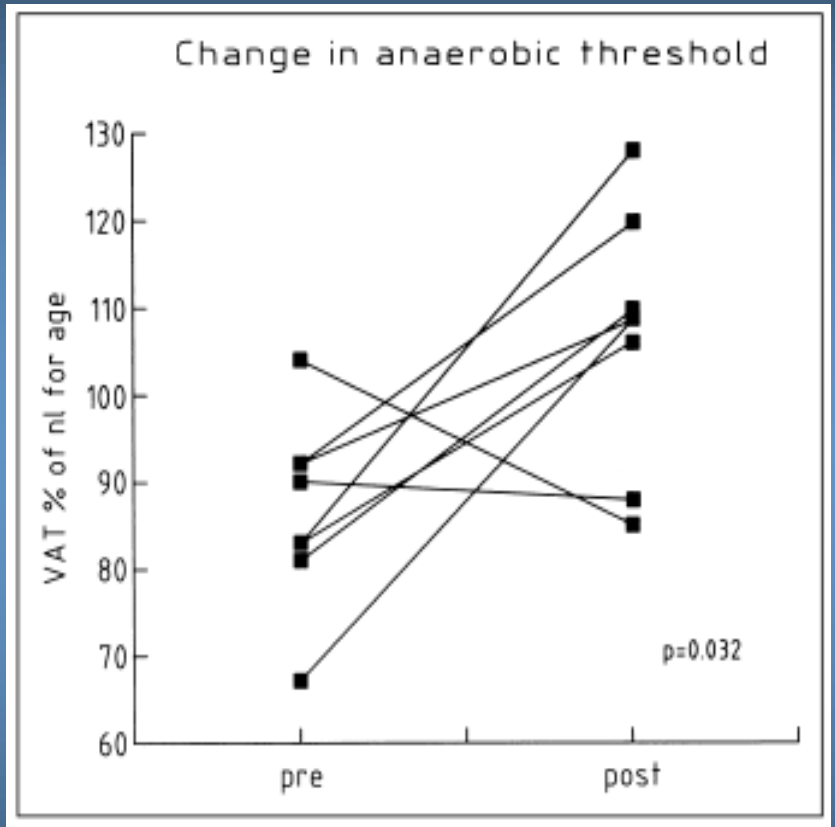
Paul Khairy, MD, PhD; Louise Harris, MD; Michael J. Landzberg, MD; Sangeetha Viswanathan, MRCPCH; Amanda Barlow, MD; Michael A. Gatzoulis, MD; Susan M. Fernandes, MHP, PA-C; Luc Beauchesne, MD; Judith Therrien, MD; Philippe Chetaille, MD; Elaine Gordon, MD; Isabelle Vonder Muhll, MD; Frank Cecchin, MD

**Table 3. Risk Score for Appropriate ICD Shocks in Primary Prevention**

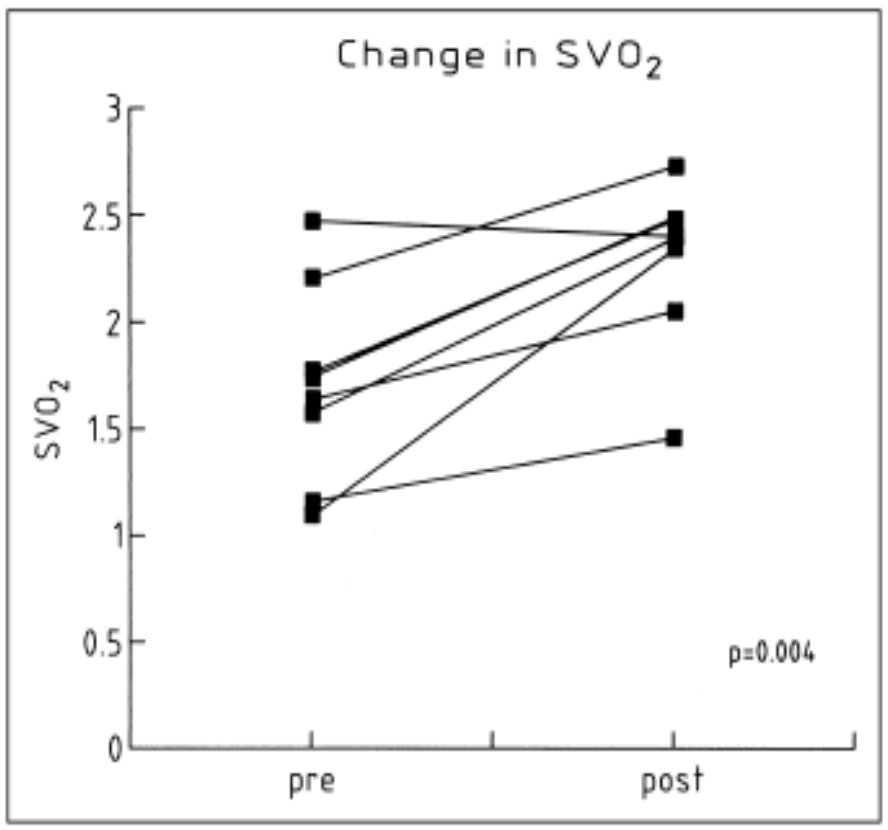
| Variable | Exp(β) | Points Attributed |
|---|---|---|
| Prior palliative shunt | 3.2 | 2 |
| Inducible sustained ventricular tachycardia | 2.6 | 2 |
| QRS duration ≥180 ms | 1.4 | 1 |
| Ventriculotomy incision | 3.4 | 2 |
| Nonsustained ventricular tachycardia | 3.7 | 2 |
| LVEDP ≥12 mm Hg | 4.9 | 3 |
| Total points | . . . | 0–12 |

**>6 high risk**
**3-5 intermediate risk**
**< 2 low risk**

# Effects of Pulmonary valve implantation: ↑ exercise performance post PVI

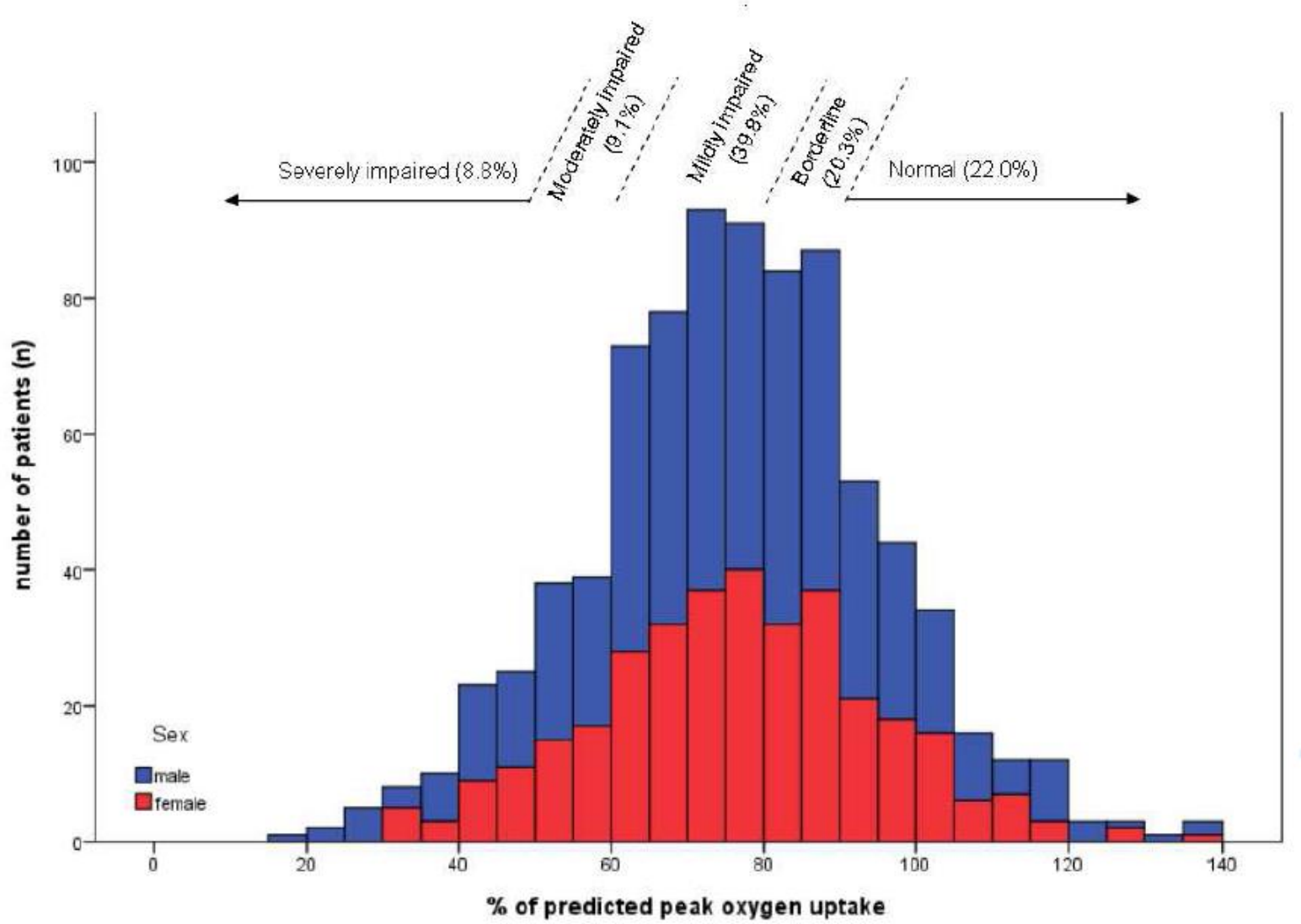



n = 11



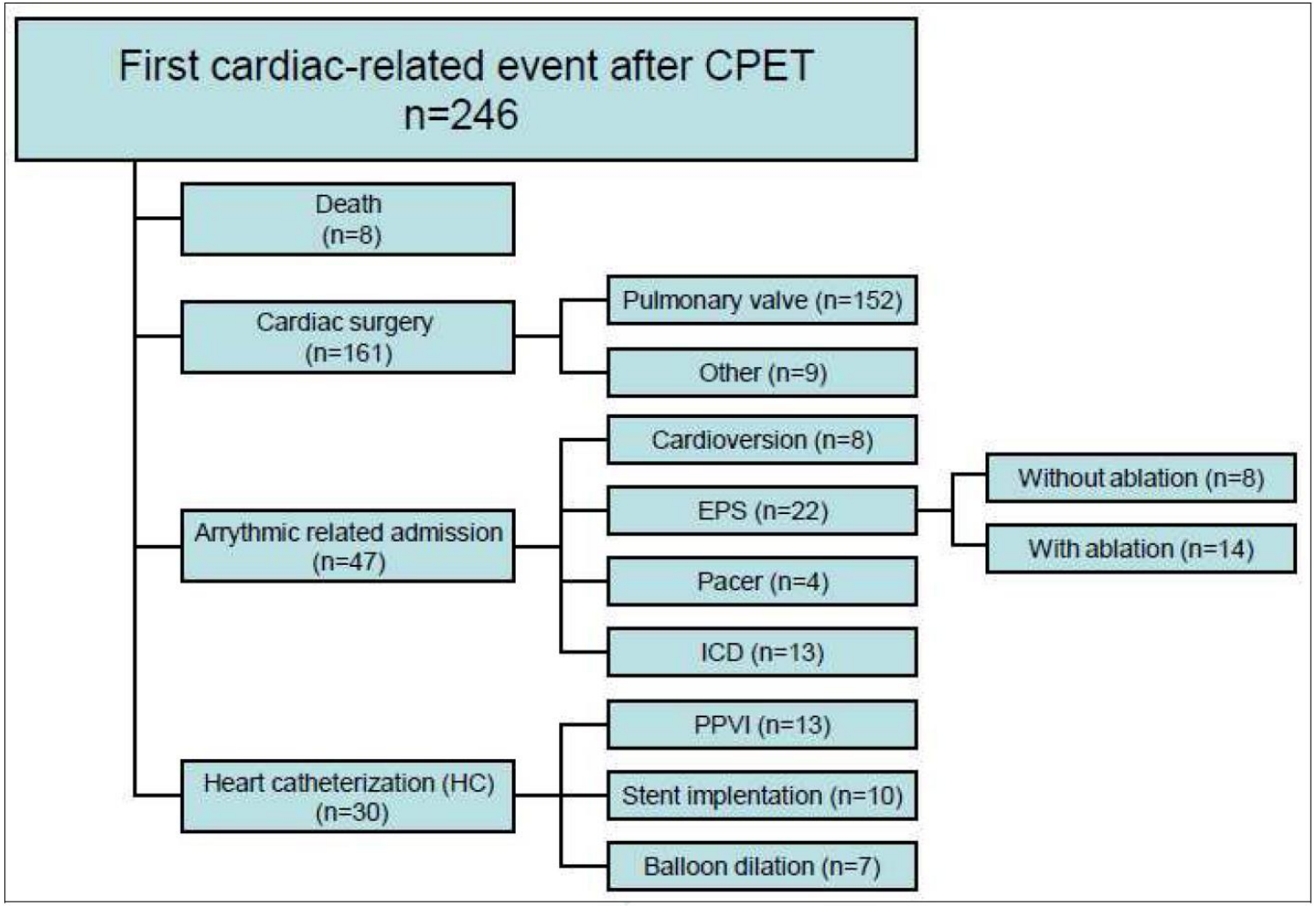

Eyskens *et al.*, Am J Cardiol 2000

Figure 1: Peak oxygen uptake in percentage of predicted in 842 patients with Tetralogy of Fallot.




*Muller et al, Int J Cardiol 2015*

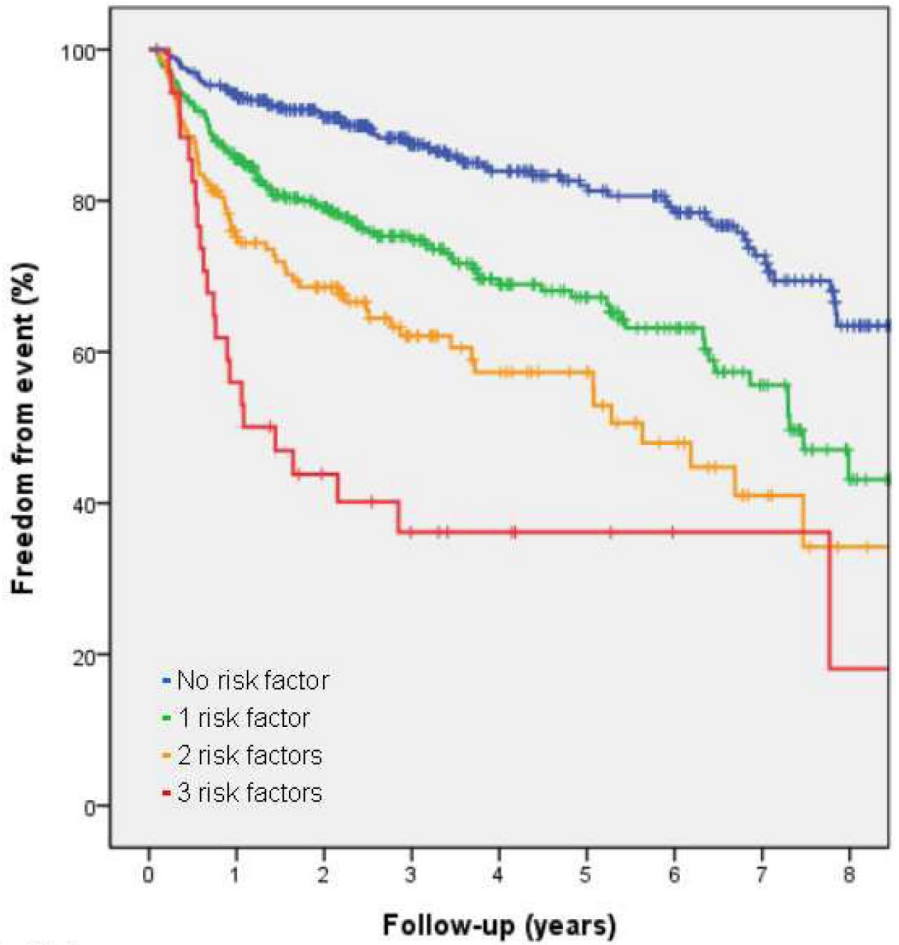
Figure 3: Flow chart of the first cardiac related event after cardiopulmonary exercise testing (CPET)




EPS: Intracardiac electrophysiology study, ICD: Implantable Cardioverter/Defibrillator, PPVI: Percutaneous Pulmonary Valve Implantation

*Muller et al, Int J Cardiol 2015*

Figure 4: Kaplan-Meier curve for event free survival according to the numbers of risk factors (peak $\dot{V}O_2$ ≤65% predicted, $\dot{V}_E/\dot{V}_{CO_2}$ slope ≥31, resting QRS duration ≥170ms) depicting that risk is increasing for every additional factor.




| Patients at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| No risk factor | 361 | 327 | 265 | 197 | 149 | 121 | 105 | 69 | 38 |
| 1 risk factor | 307 | 251 | 186 | 133 | 93 | 73 | 50 | 30 | 9 |
| 2 risk factors | 139 | 94 | 77 | 47 | 34 | 26 | 16 | 7 | 2 |
| 3 risk factors | 35 | 18 | 11 | 10 | 7 | 5 | 3 | 2 | 1 |

Muller et al, Int J Cardiol 2015

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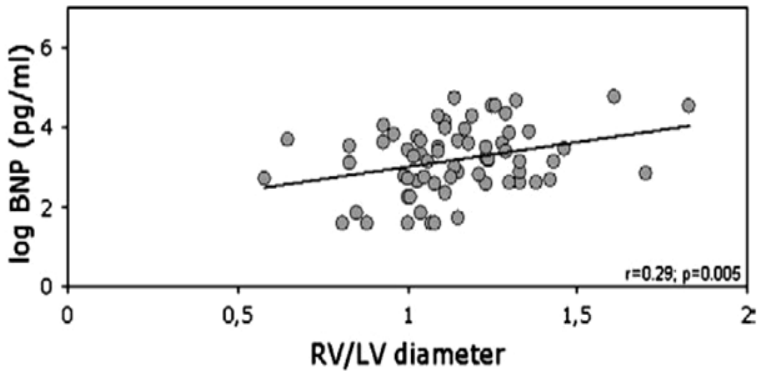
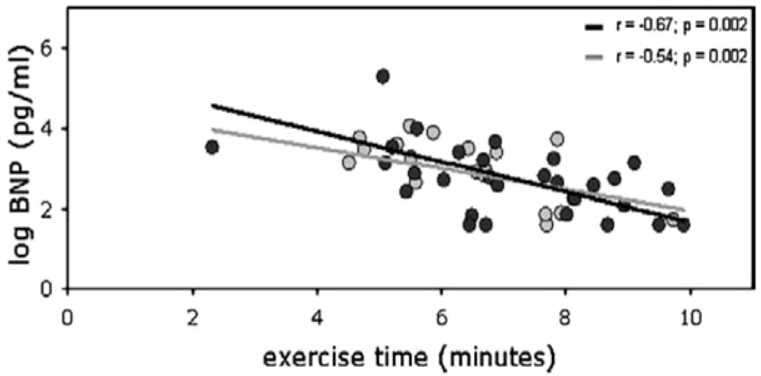
# Biomarkers in TET: BNP






- 130 pts with repaired TET, 16+/-7 years of age
- Serial BNP levels
- Echo and exercise assessment at baseline

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# Biomarkers in TET: BNP

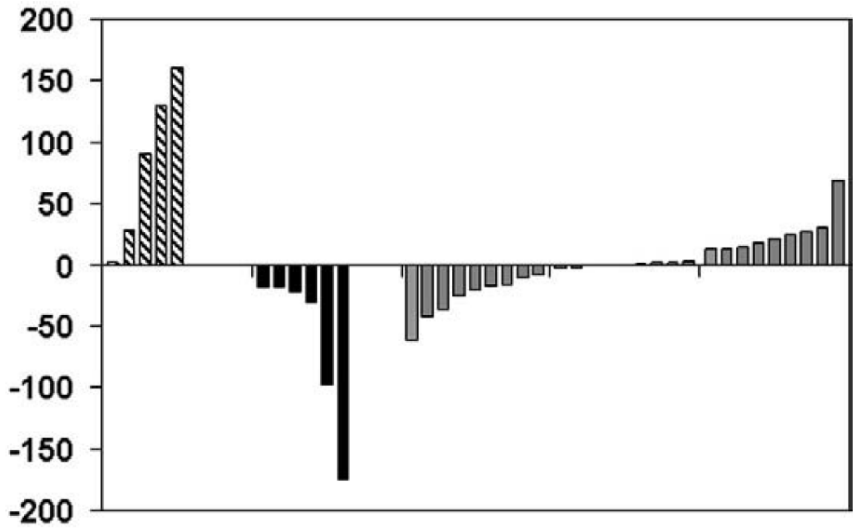


Fig. 4. Longitudinal evaluation of BNP in 38 patients. Bars represent the differences between second and first BNP level. Time interval between the two measurements was mean 2.3+1.2 years. Patients classified to need pulmonary valve replacement: shaded symbols, patients with measurement of BNP before and after pulmonary replacement: black symbols, patients with no need of surgery: grey symbols.

*Koch et al Int J Card 2010*

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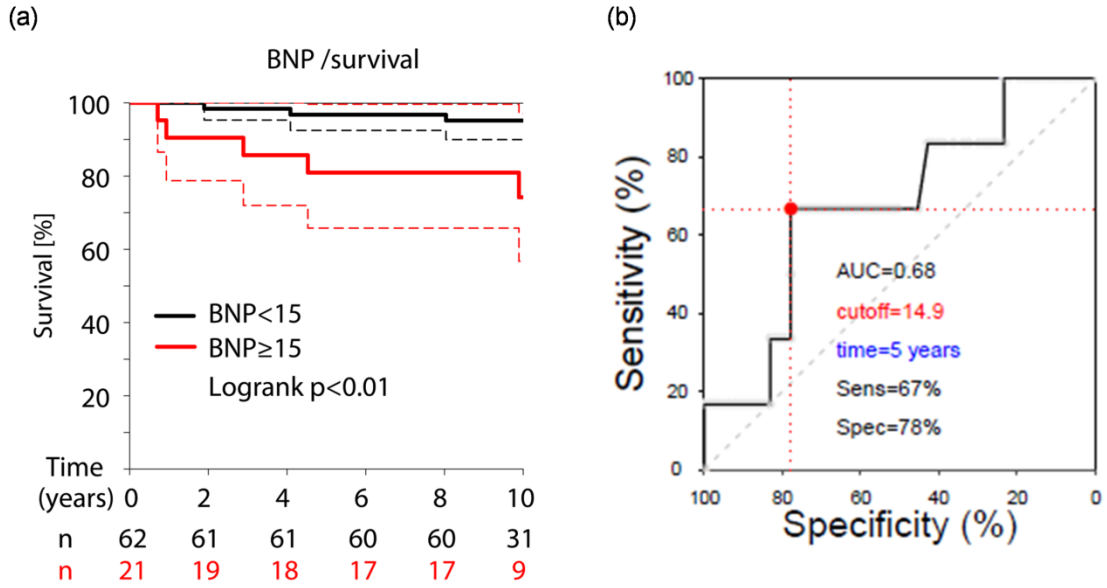
# BNP predicts mortality in Fallot – n=90




BNP elevated compared with controls
BNP elevated in asymptomatic patients
BNP≥15pmol/L associated with five-fold increased risk of death.
Absolute risk of death at 5 years 19% for BNP≥15pmol/L vs 3% in patients with BNP≤15pmol/L
BNP was also a predictor of sustained tachyarrhythmia

**Heng et al, Heart 2015**

# *A*CE inhibitors for *P*otential *PR*evention *O*f the deleterious effects of *P*ulmonary *R*egurgitation *I*n *A*dults with *TE*tralogy of Fallot Repair
# - The APPROPRIATE Study

## A Randomised, Double-Blinded, Parallel Group, Placebo-Controlled Trial In Adults with Congenital Heart Disease

International Standard Randomised Controlled Trial Number 97515585

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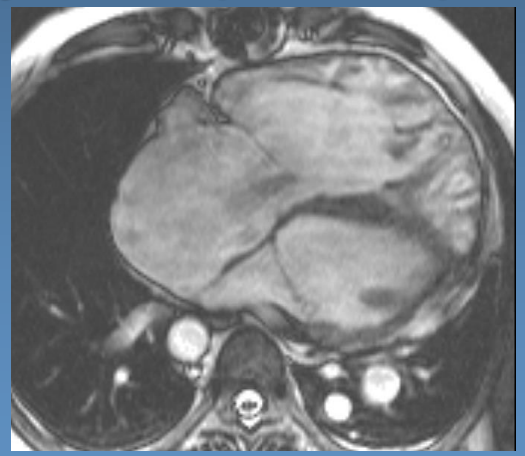
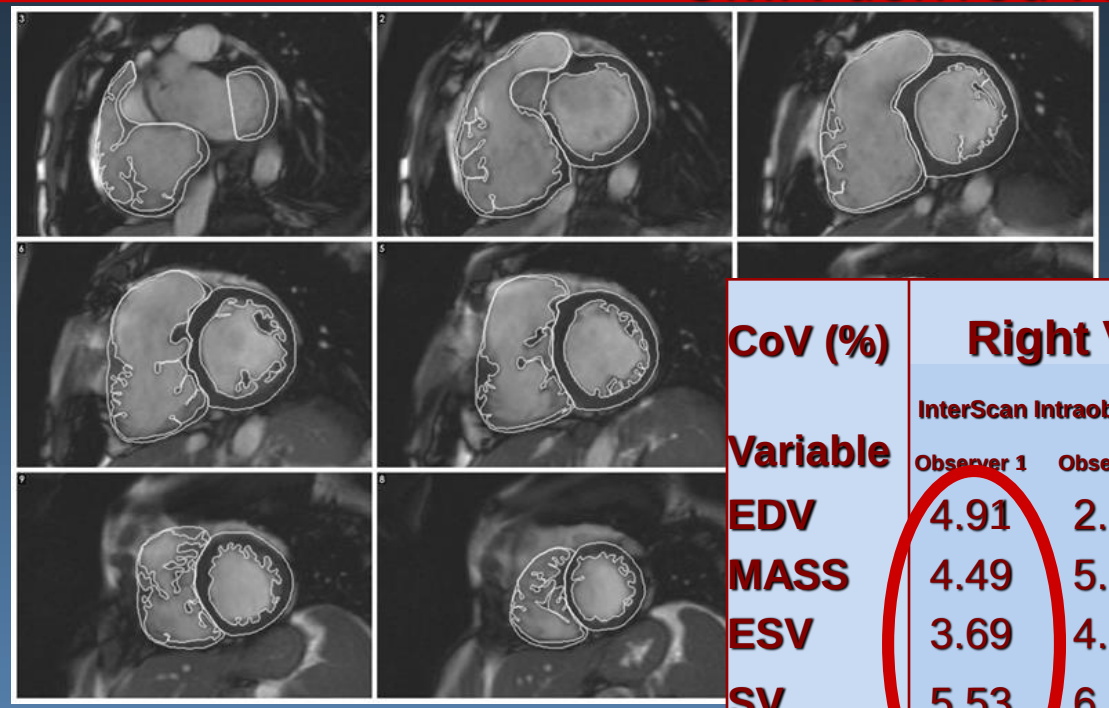
Royal Brompton Hospital

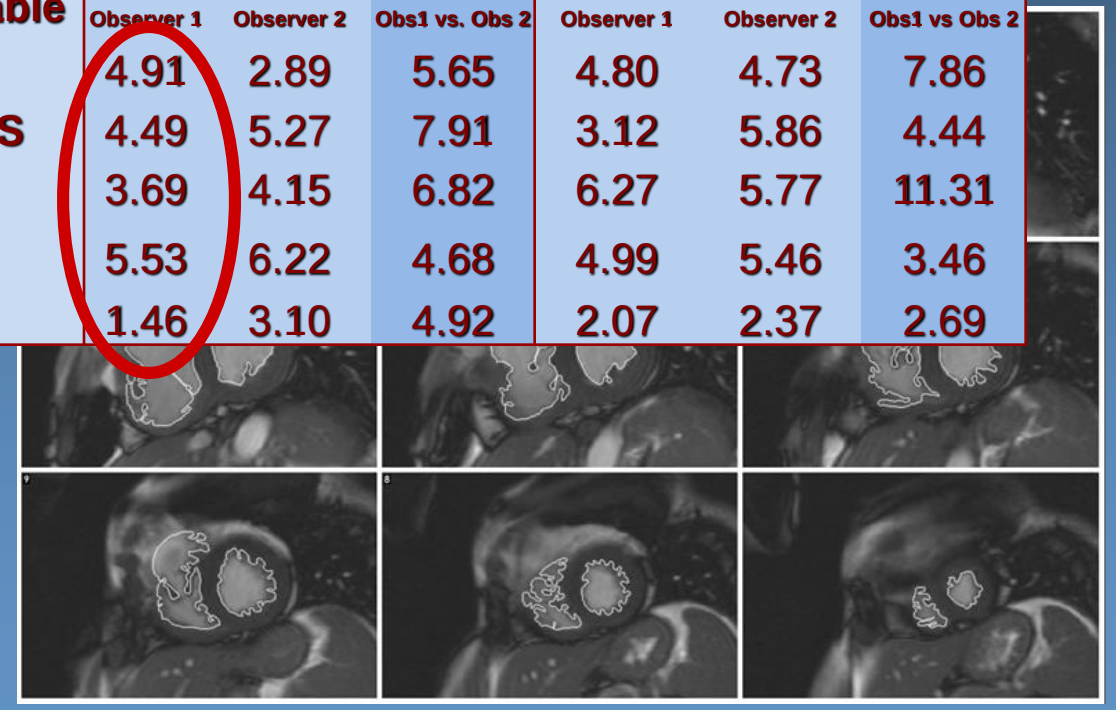


*Supported by the British Heart Foundation

# The APPROPRIATE Study/Primary endpoint: CMR derived RVEF



| CoV (%) | Right Ventricle | | | Left Ventricle | | |
|---|---|---|---|---|---|---|
| | InterScan | Intraobserver | Interoberver | InterScan | Intraobserver | Interoberver |
| Variable | Observer 1 | Observer 2 | Obs1 vs. Obs 2 | Observer 1 | Observer 2 | Obs1 vs Obs 2 |
| EDV | 4.91 | 2.89 | 5.65 | 4.80 | 4.73 | 7.86 |
| MASS | 4.49 | 5.27 | 7.91 | 3.12 | 5.86 | 4.44 |
| ESV | 3.69 | 4.15 | 6.82 | 6.27 | 5.77 | 11.31 |
| SV | 5.53 | 6.22 | 4.68 | 4.99 | 5.46 | 3.46 |
| EF | 1.46 | 3.10 | 4.92 | 2.07 | 2.37 | 2.69 |



Babu-Narayan, Bouzas et al, JCMR 2005; 7: S-153 – S-153

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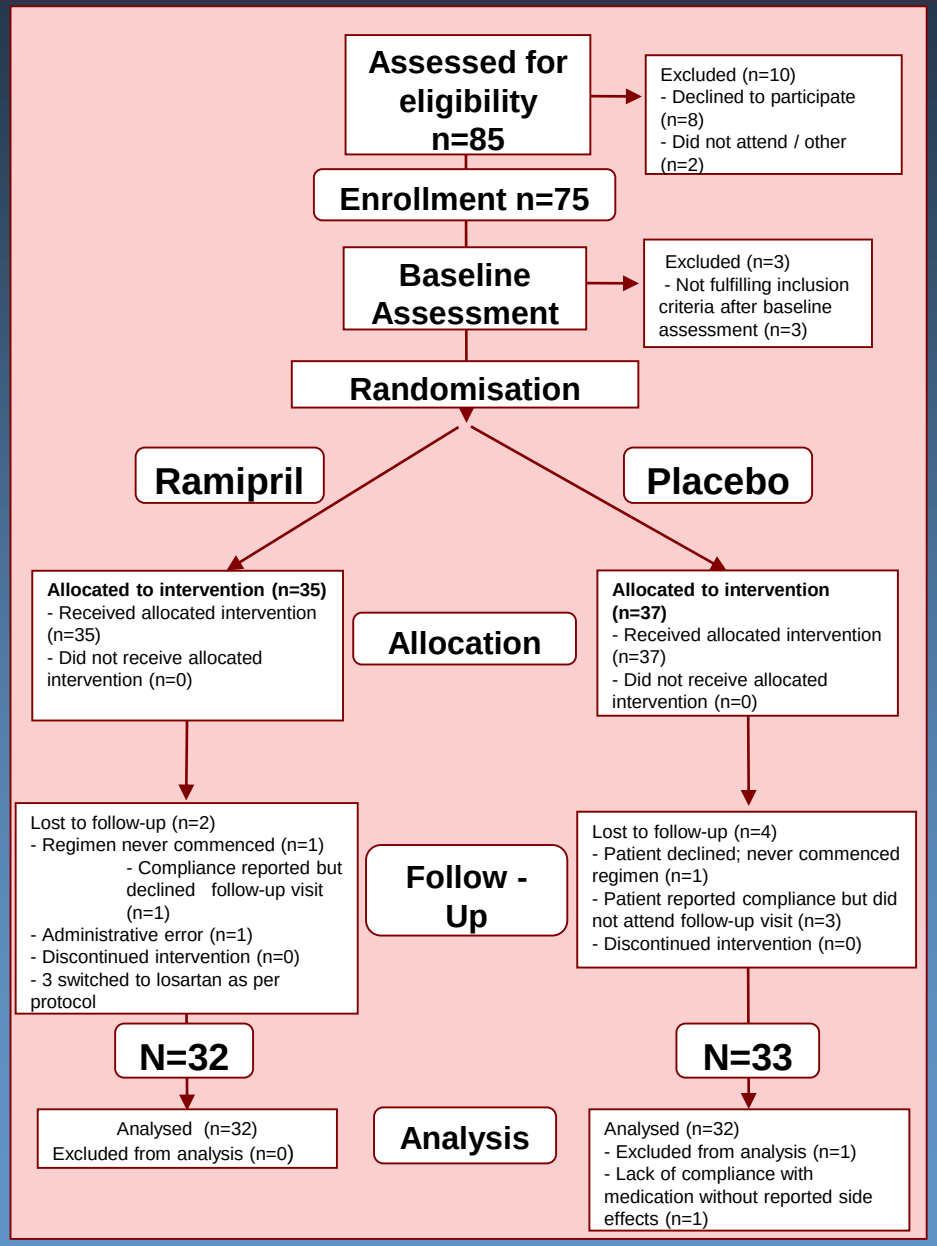
# Study Population

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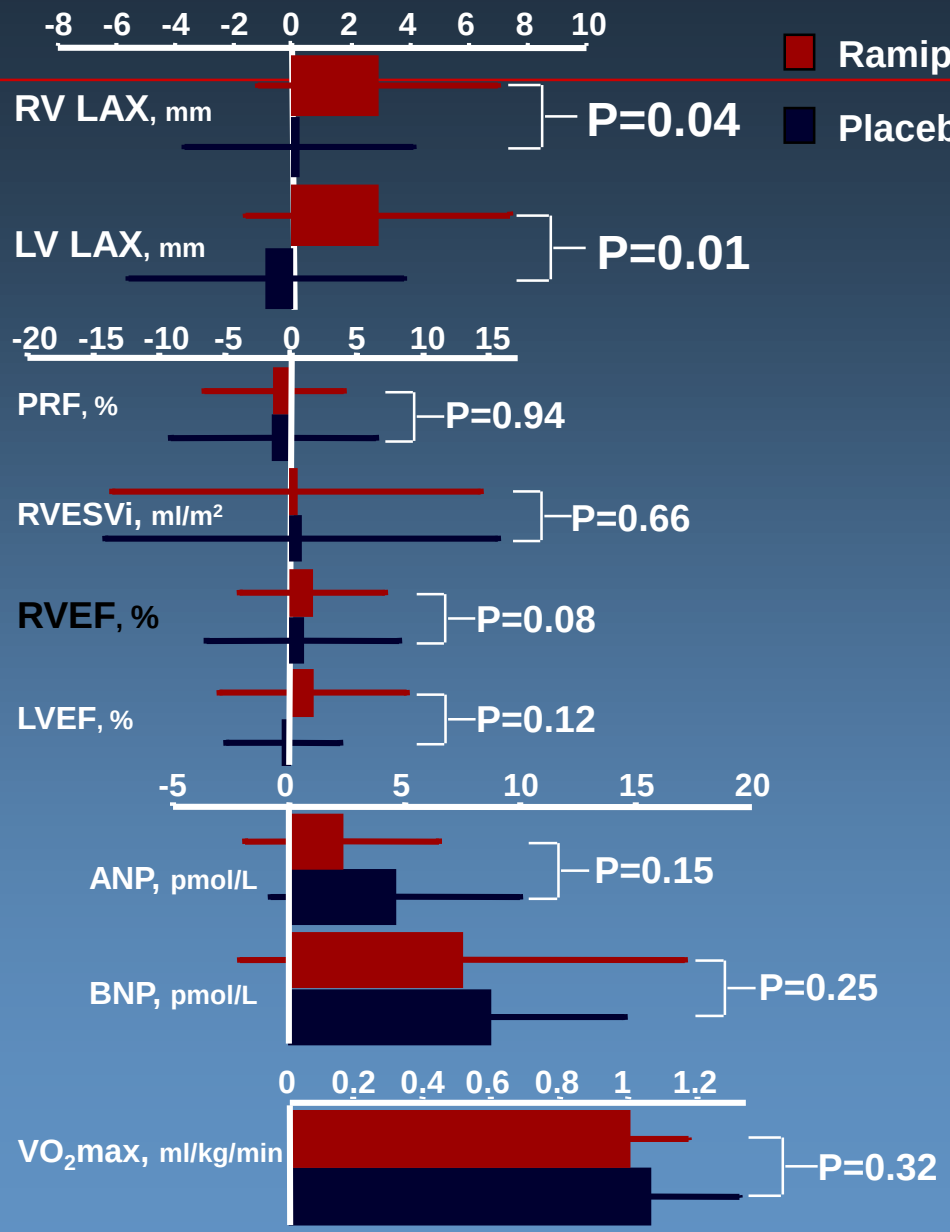


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Babu-Narayan et al Int J Card 2011

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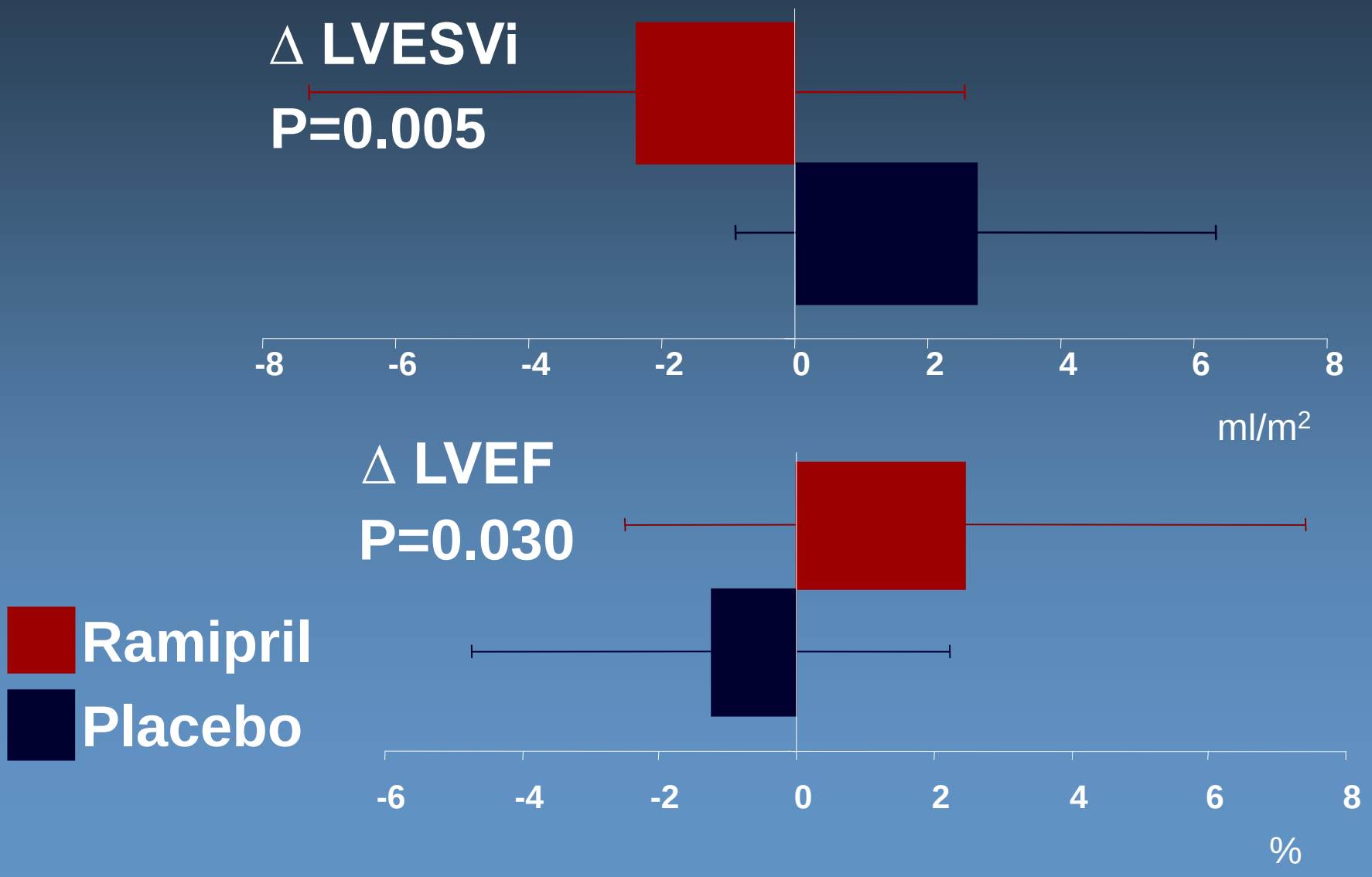
# Subgroup analysis: Patients with RV restrictive physiology
## Changes in LV systolic function after 6 months

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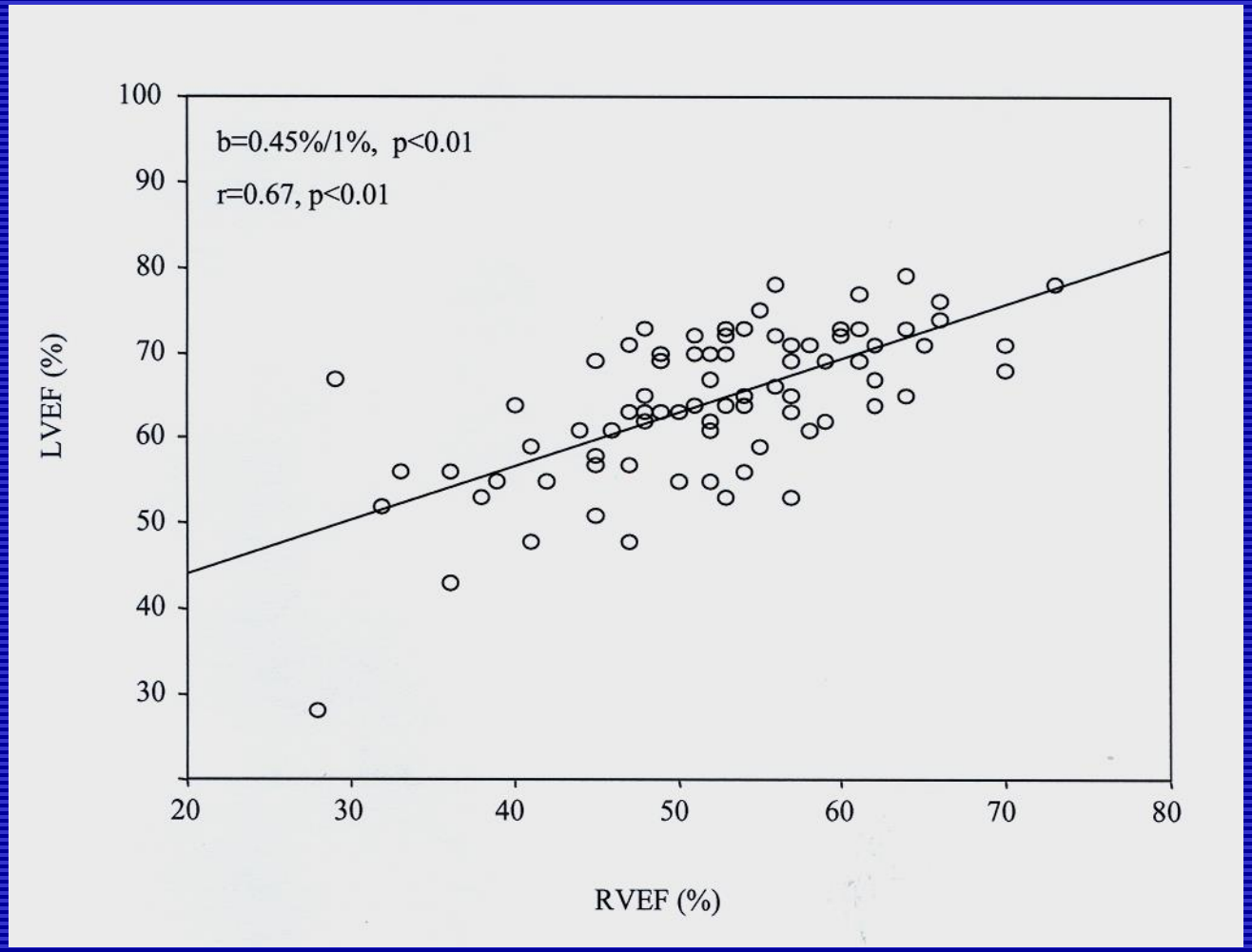
# Right / Left ventricular interaction




*Davlouros et al JACC 2002*

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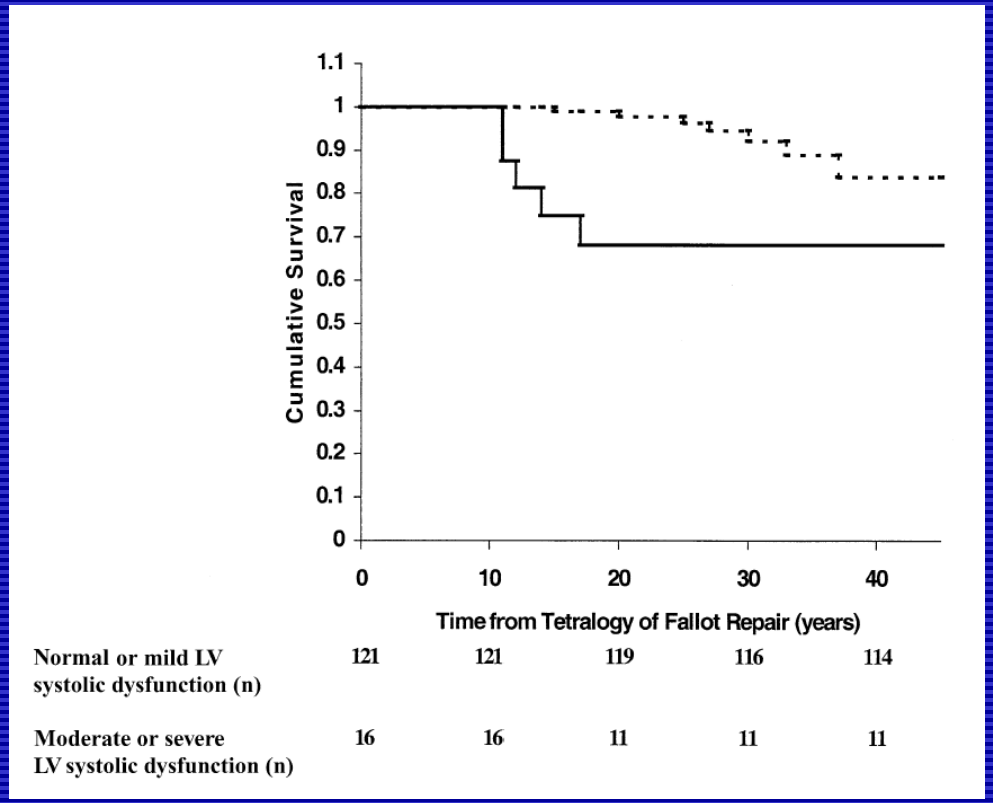
# *LV dysfunction and SCD*
## *Echo*




Moderate/Severe LV dysfunction is common late after TET repair (12.4%)

LV dysfunction Risk factor for SCD *(predictive values)*

| | +ve | -ve |
|---|---|---|
| LV dysfunction alone | 29% | 94% |
| *with QRS ≥180ms* | *66%* | *93%* |

*Ghai et al JACC 2002*

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# EPS inducible sustained VT

**Table 4. Predictors of inducible sustained VT**

| Variable | Odds Ratio | 95% Confidence Interval | P-Value |
|---|---|---|---|
| Multivariate Analysis | | | |
| Age at EP study ≥18 years | 3.32 | 1.05,10.54 | 0.0416 |
| Palpitations | 2.80 | 1.15,6.81 | 0.0234 |
| Prior palliative surgery | 3.09 | 1.23,7.58 | 0.0163 |
| Modified Lown ≥2 | 5.57 | 1.01,30.86 | 0.0493 |
| Cardiothoracic ratio ≥0.60 | 3.26 | 1.20,8.83 | 0.0200 |

EP denotes electrophysiologic; AF, atrial flutter; RV, right ventricle; PR, pulmonary regurgitation; TR, tricuspid regurgitation

**N=252**

*Khairy et al Circulation 2004*

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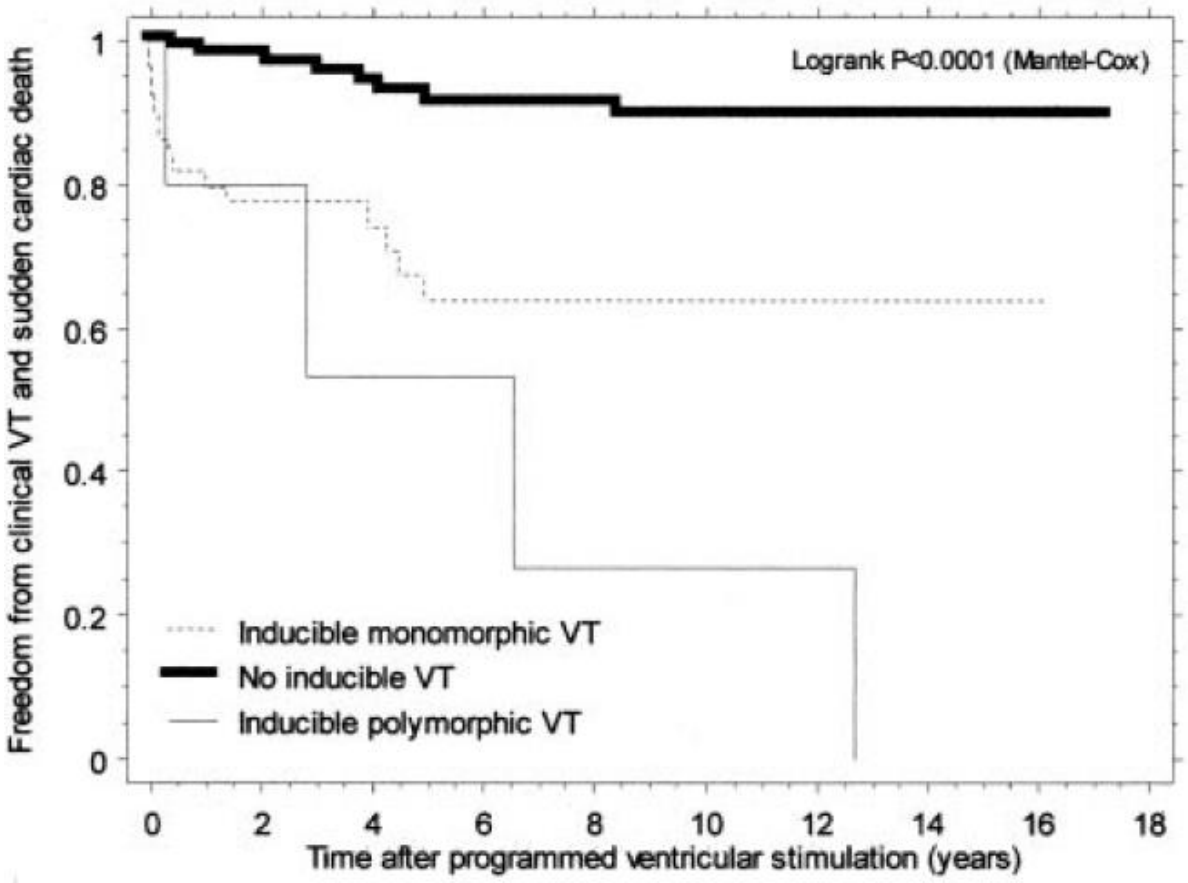
# Inducible VT at EPS predicts clinical VT/SCD




**Khairy *et al*, Circulation 2004**

# Predictors of EP catheter inducible VT: Myocardial fibrosis (MRI/LGE)

| | (+) VA | (-) VA | |
|---|---|---|---|
| (+) Scar | 11 | 8 | Positive Predictive Value = 58% |
| (-) Scar | 1 | 25 | Negative Predictive Value = 96% |
| | Sensitivity = 92% | Specificity = 76% | |

Figure 2. Sensitivity, specificity, and predictive values of fibrosis/scar with late postgadolinium imaging for inducibility of VA.

*Tsai et al Am J Card 2010*

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# INDICATOR multicentre study of 873 adult Fallot

- Outcome: death (n=28) or sustained VT (n=4) in FU
- Freedom from Death/VT 98% at 5 years and 98% at 10 years if none of these predictors

**Table 4. Multivariable Predictors of Outcome**

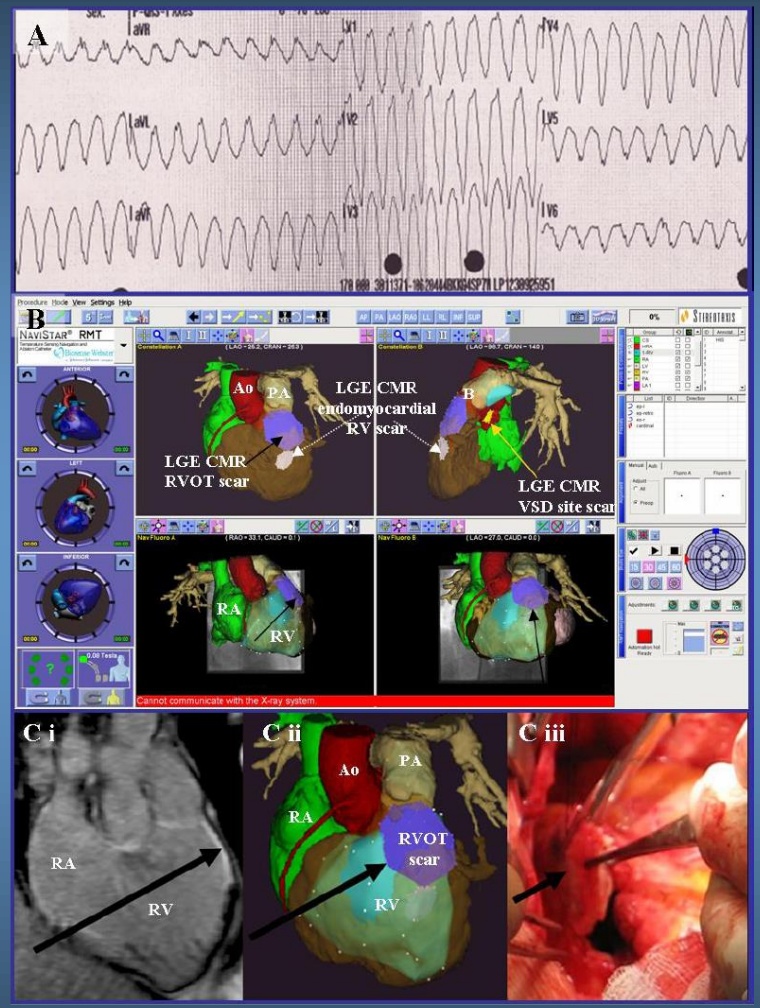
| | HR | 95% CI | *P* value | C index | $R^2$ |
|---|---|---|---|---|---|
| All subjects (N = 873) | | | | | |
| Model 1 | | | | | |
| RV mass/volume ratio ≥ 0.30 (g/mL) | 5.04 | (2.30, 11.0) | < 0.001 | 0.832 | 0.246 |
| LV ejection fraction z-score < -2.0 | 3.34 | (1.59, 7.01) | 0.001 | | |
| History of atrial arrhythmia | 3.65 | (1.75, 7.62) | 0.001 | | |
| Model 2 | | | | | |
| RV mass/volume ratio ≥ 0.30 (g/mL) | 4.17 | (1.96, 8.86) | < 0.001 | 0.781 | 0.215 |
| RV ejection fraction z-score < -2.0 | 2.59 | (1.19, 5.64) | 0.02 | | |
| History of atrial arrhythmia | 3.61 | (1.77, 7.34) | < 0.001 | | |

- RVH, ventricular dysfunction and atrial tachyarrhythmias predict death or sustained VT

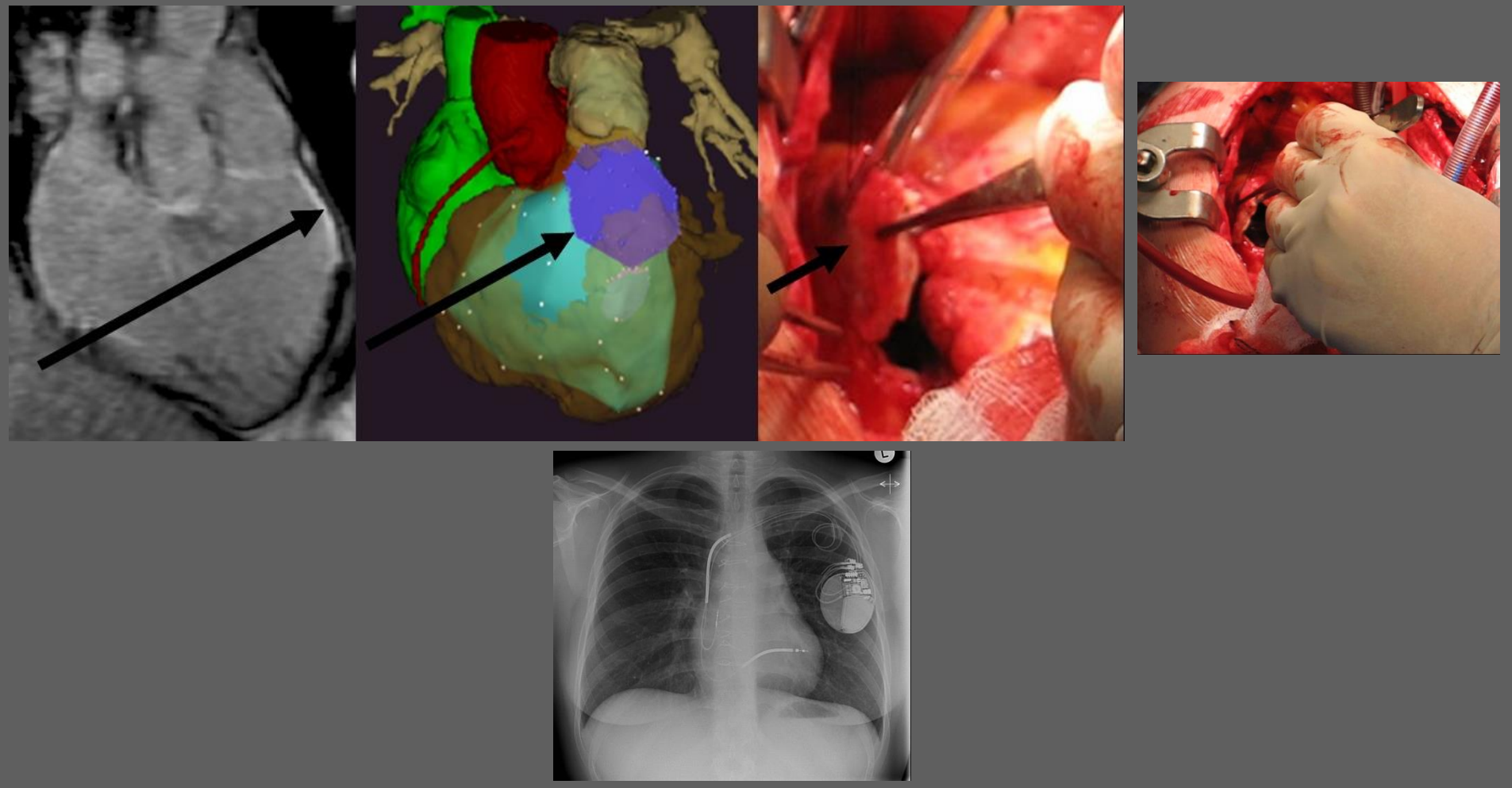
Valente AM et al, Heart 2014

# Emerging Image Merge possibilities

| Use of ventricular stimulation studies in risk stratification of repaired tetralogy of Fallot | |
|---|---|
| **Ventricular stimulation study useful** | **At least 1 criteria from list below** |
| | Clinically documented sustained VT or VF |
| | History of cardiac syncope |
| | At atrial ablation procedures* |
| **Ventricular stimulation study potentially useful** | **At least 2 criteria from list below** |
| | QRS duration >180ms |
| | Rapid QRS prolongation during follow-up |
| | LV dysfunction in addition to significant pulmonary regurgitation |
| | **Non-apical vent LV fibrosis suggested by late gadolinium CMR |
| | Extensive RV fibrosis suggested by late gadolinium CMR |
| | Severe RV dysfunction |
| | Patient considered at risk of perioperative VT |
| | Holter recorded arrhythmia in patients assessed/ investigated for VT/ SCD |



# VT from RVOT scar treated with image integration VT ablation, surgical scar resection and PVR and or secondary prevention AICD

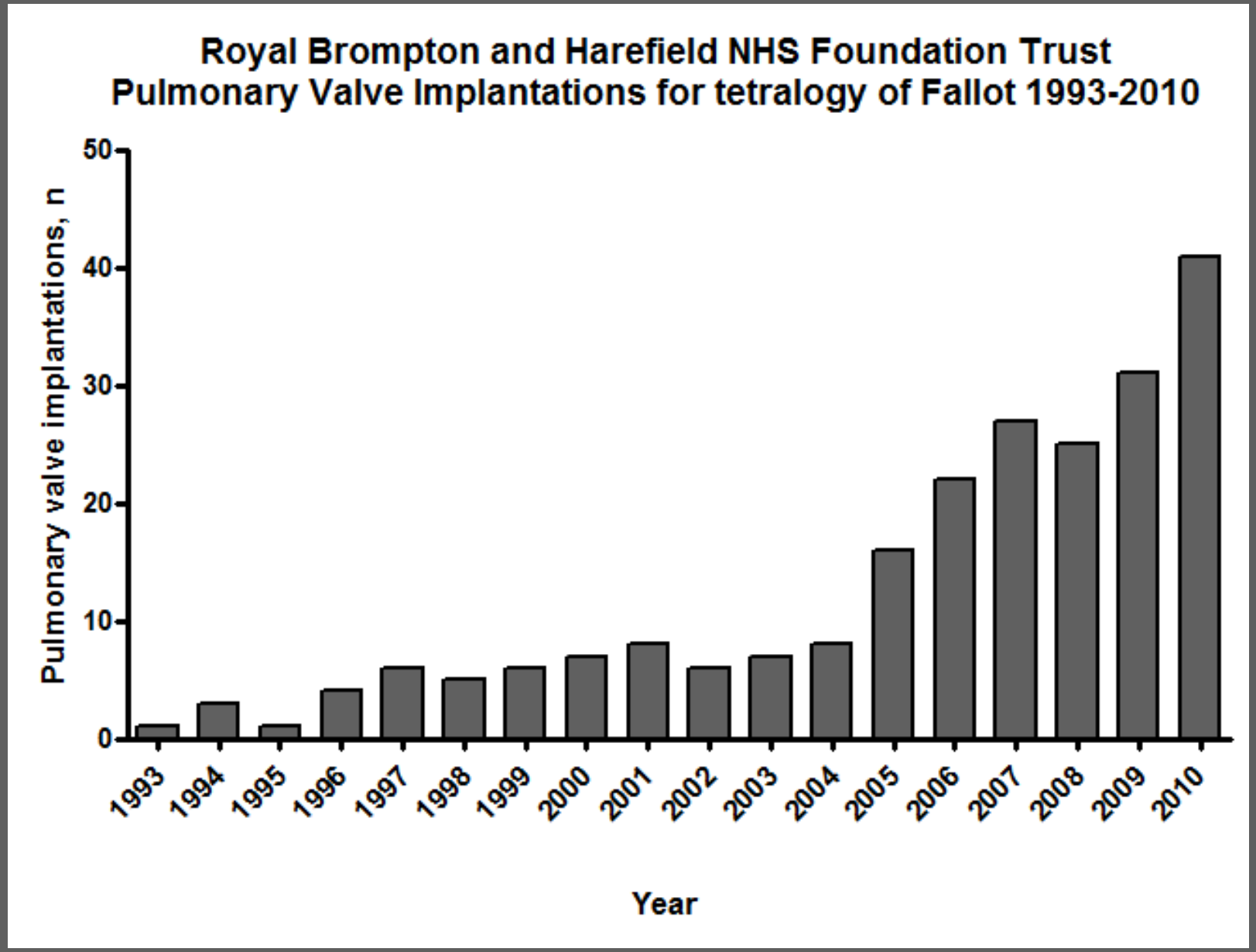


from Tetralogy of Fallot in Diagnosis and Management of ACHD, Gatzoulis, Daubeney and Webb, 3rd edition 2017

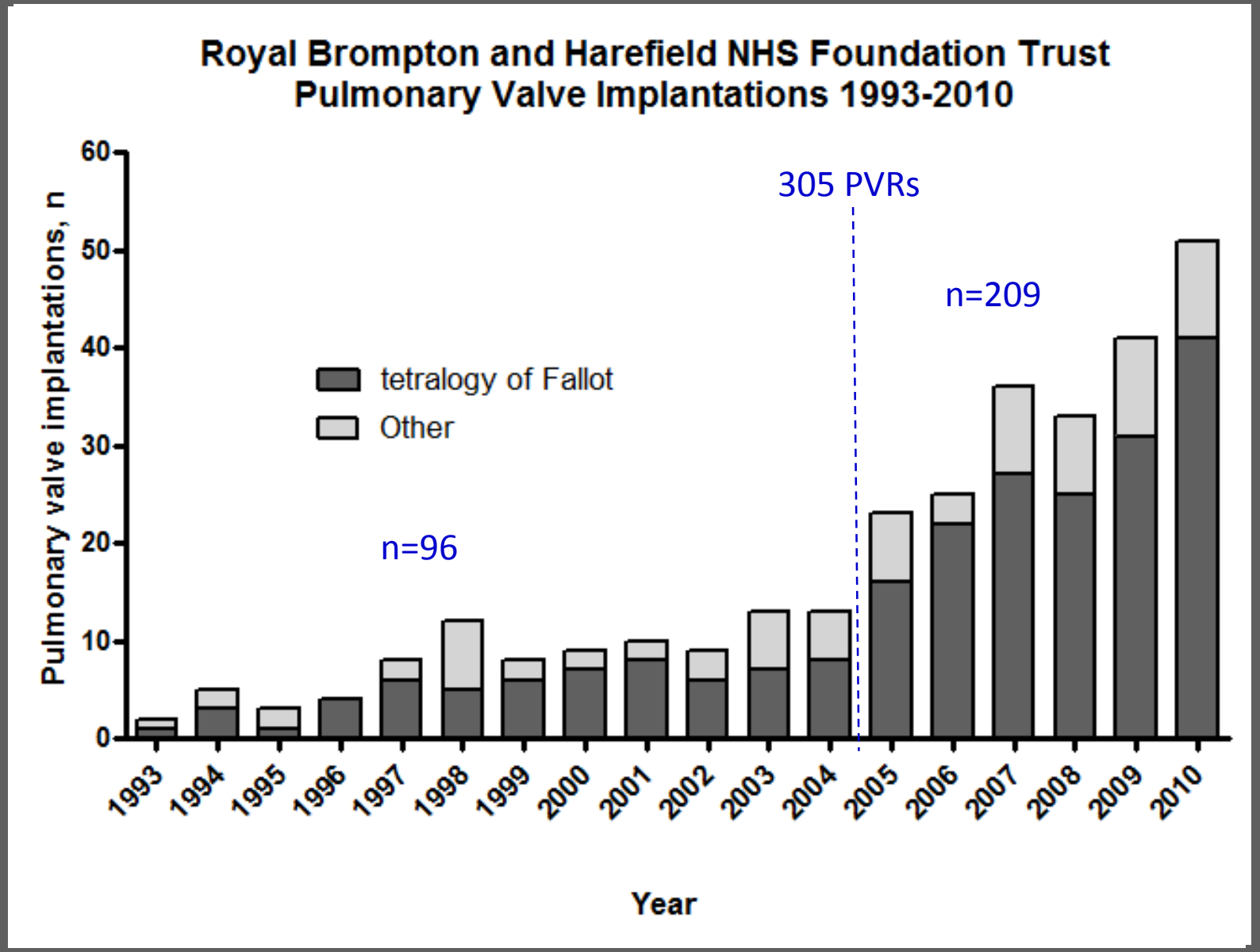
# *PVR after Tetralogy Repair (and timing)*

***Criteria for PV replacement (evolving)***

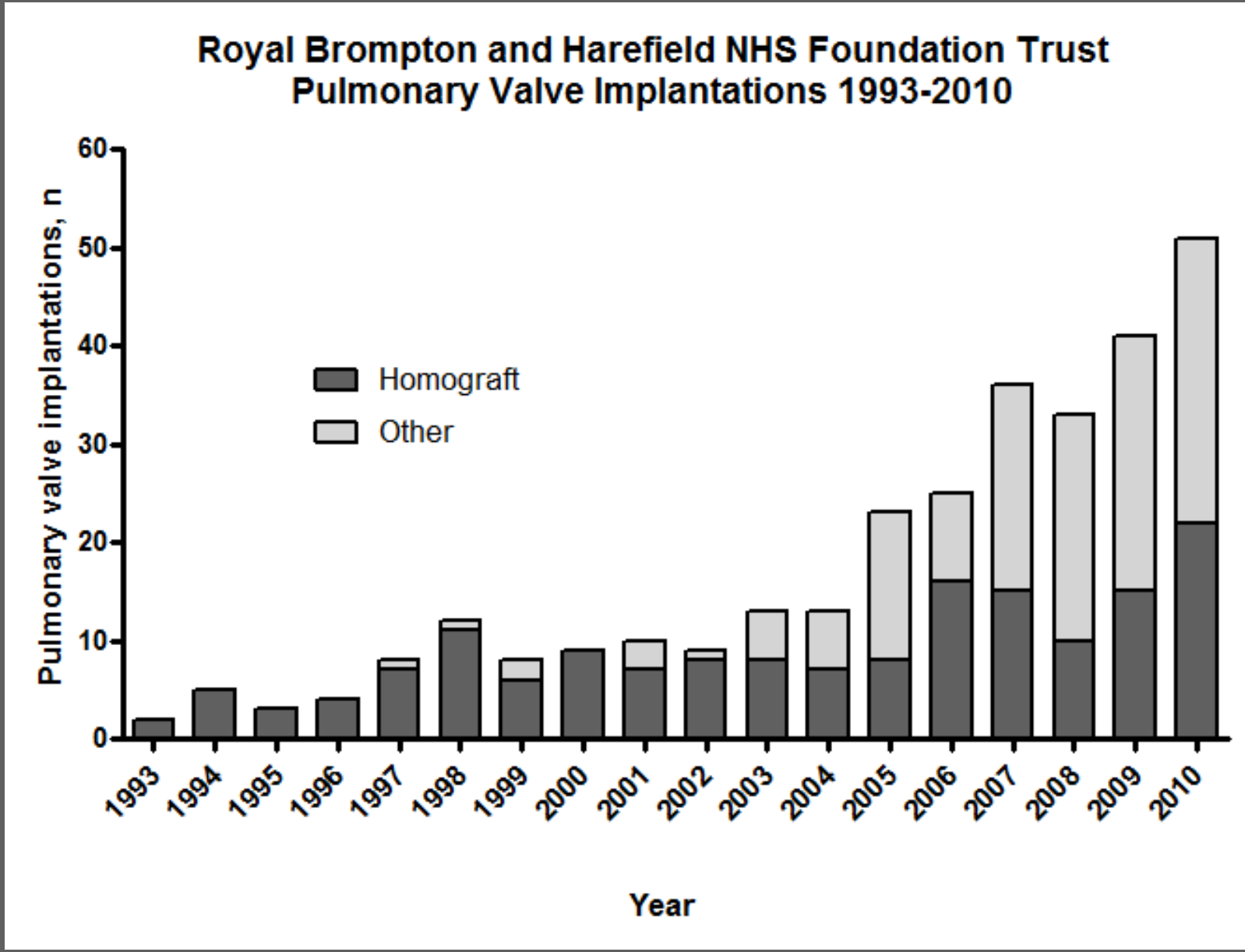
- CTR >50%
- QRS prolongation
- RVESV/RVEDV ⇑ with moderate/severe PR (respectively 82/160 ml/m$^{2)}$
- Drop in MVO2
- Symptoms (SOB, fatigue, arrhythmia)



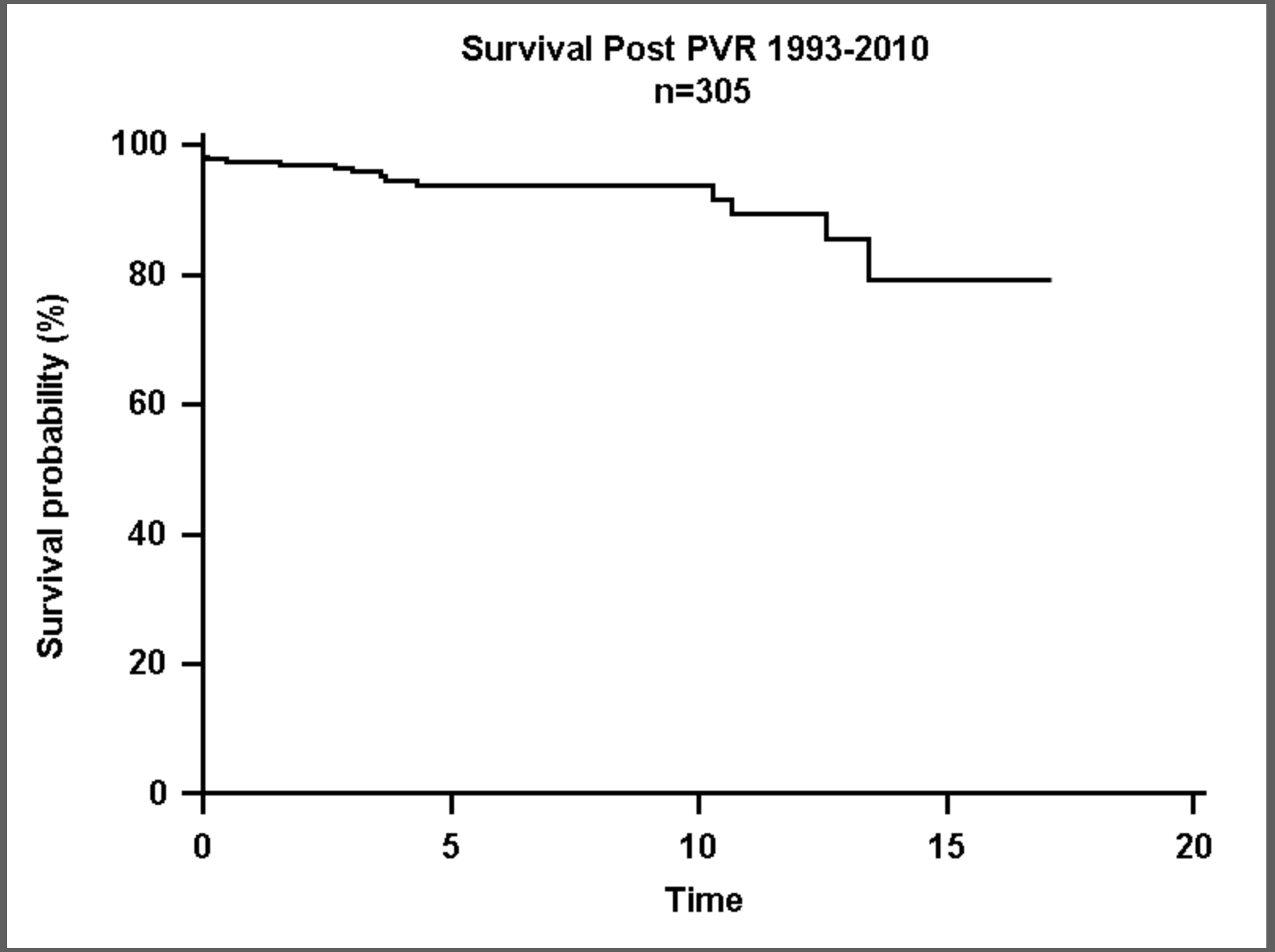

Babu-Narayan et al., Circulation 2014



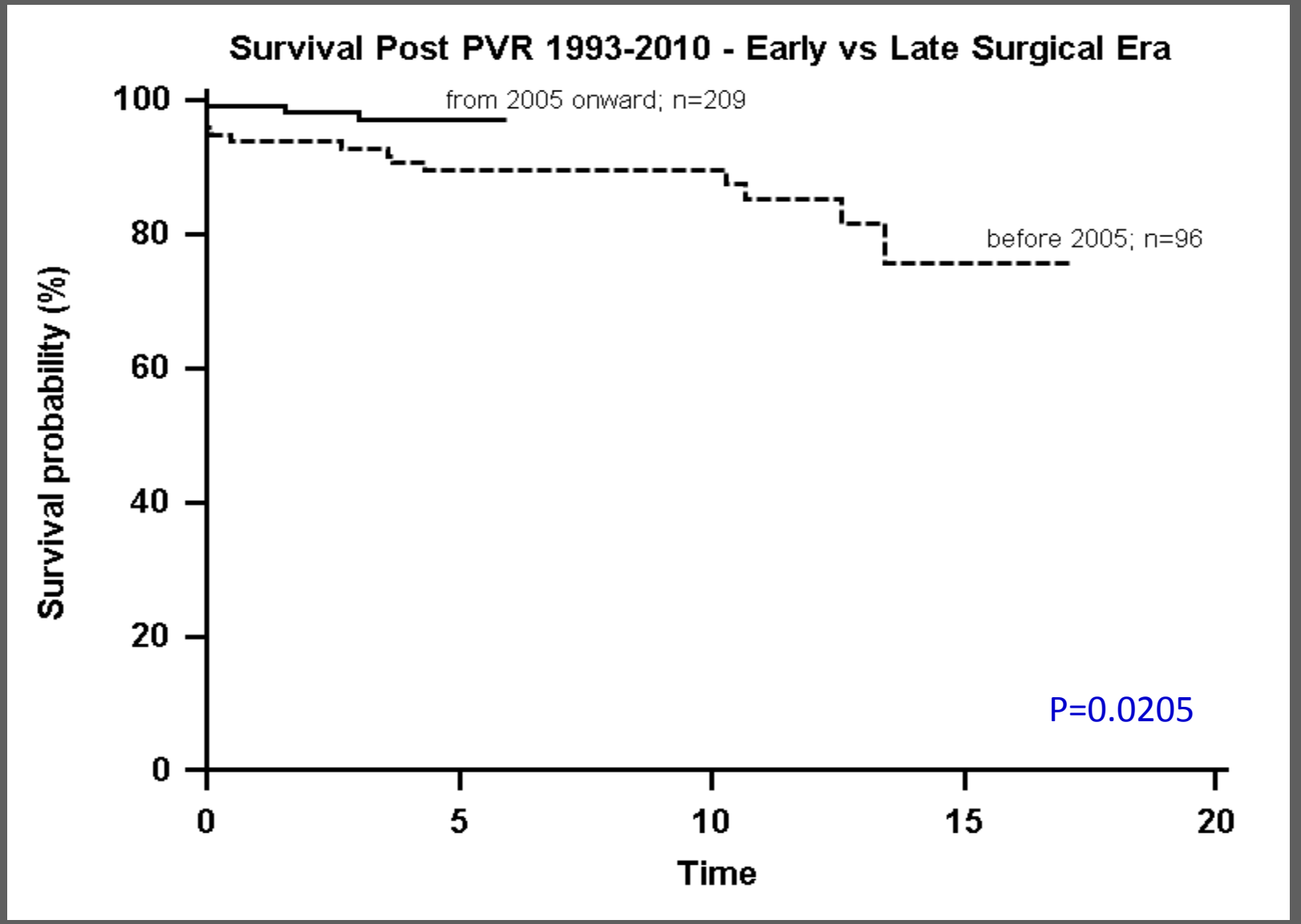

Babu-Narayan et al., Circulation 2014



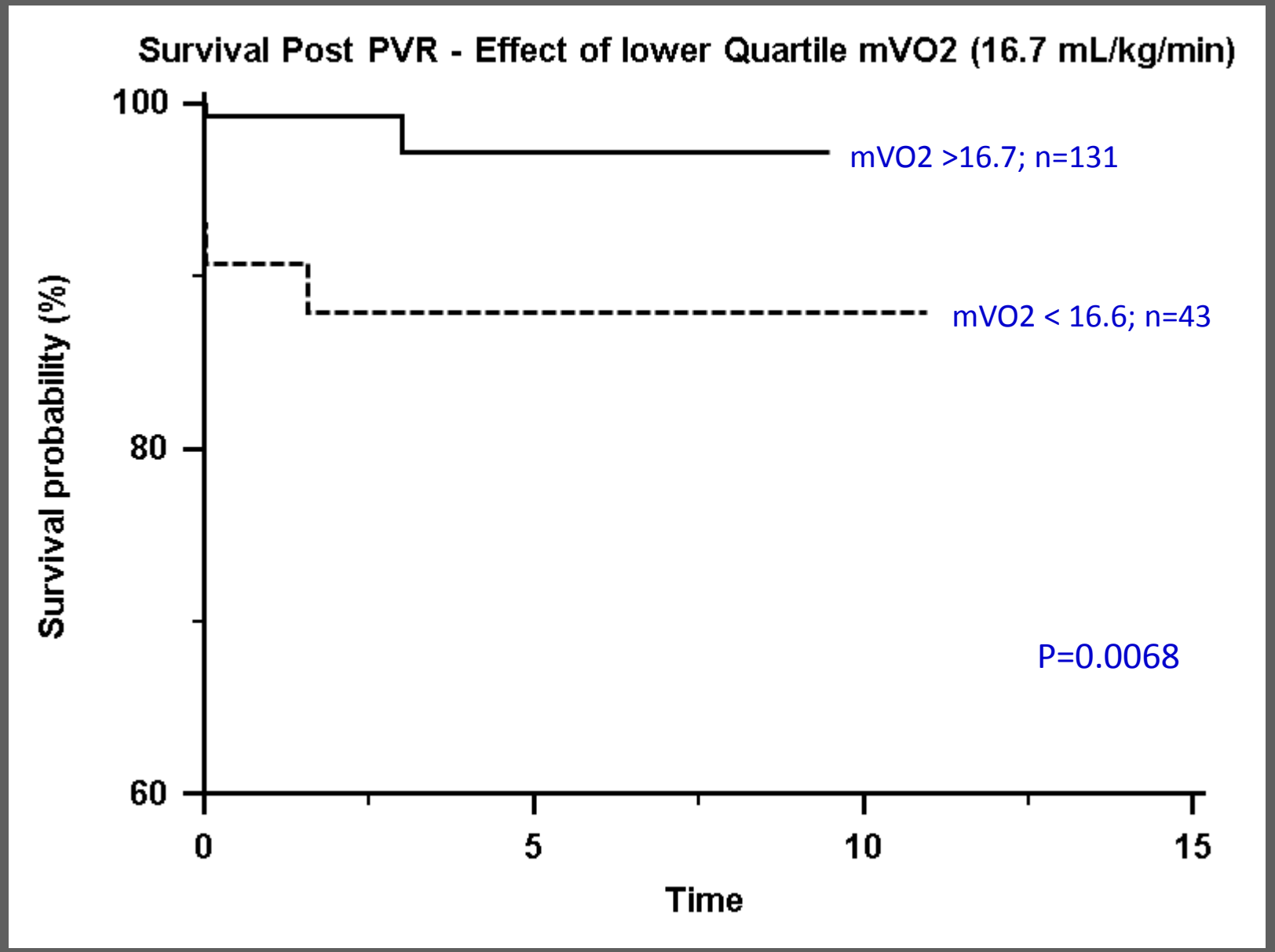

Babu-Narayan et al., Circulation 2014



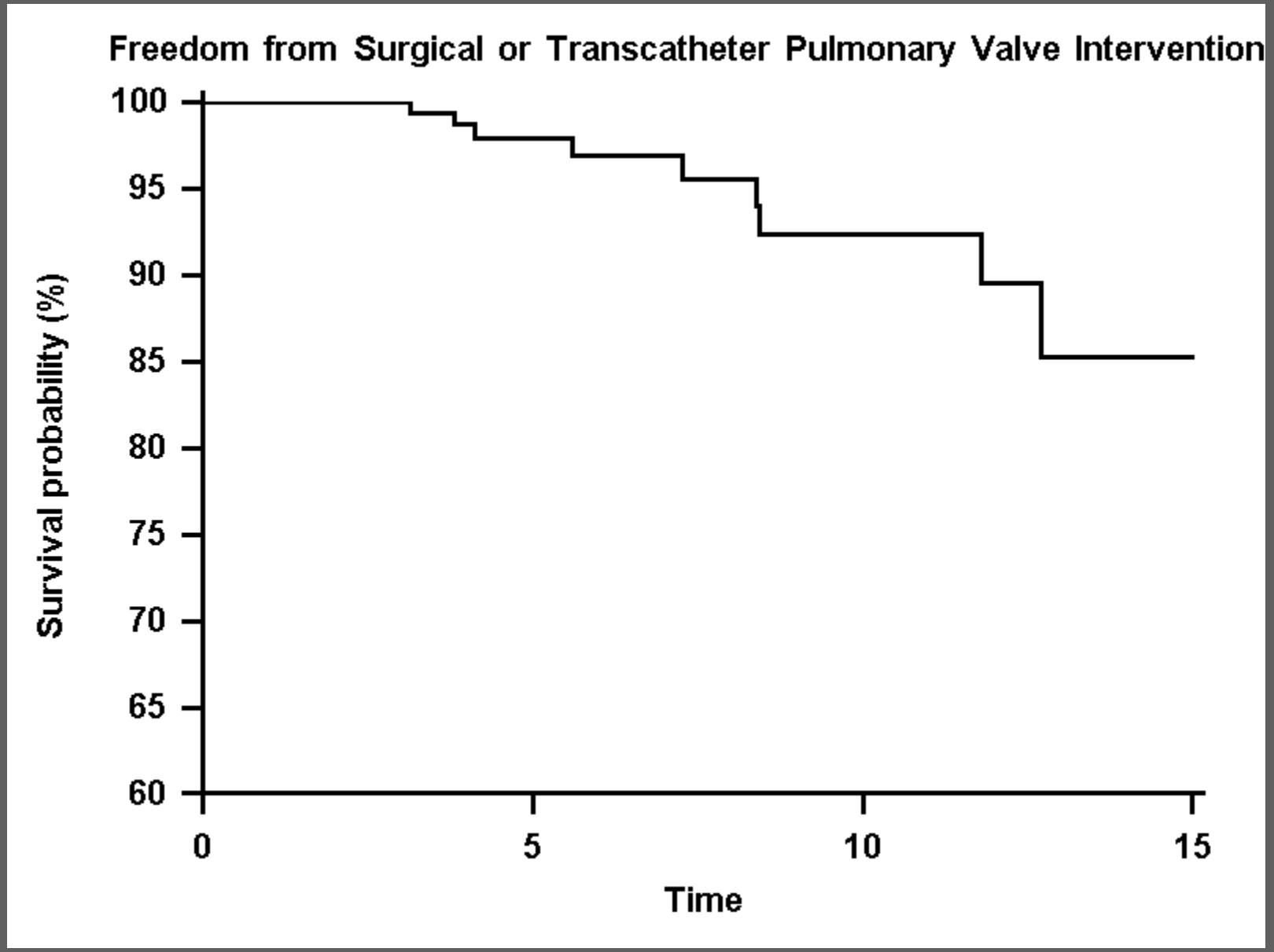

Overall survival was 97.3% at 1 year, 95.8 % at 3 years and 93.7% at 10 years.




Babu-Narayan et al., Circulation 2014

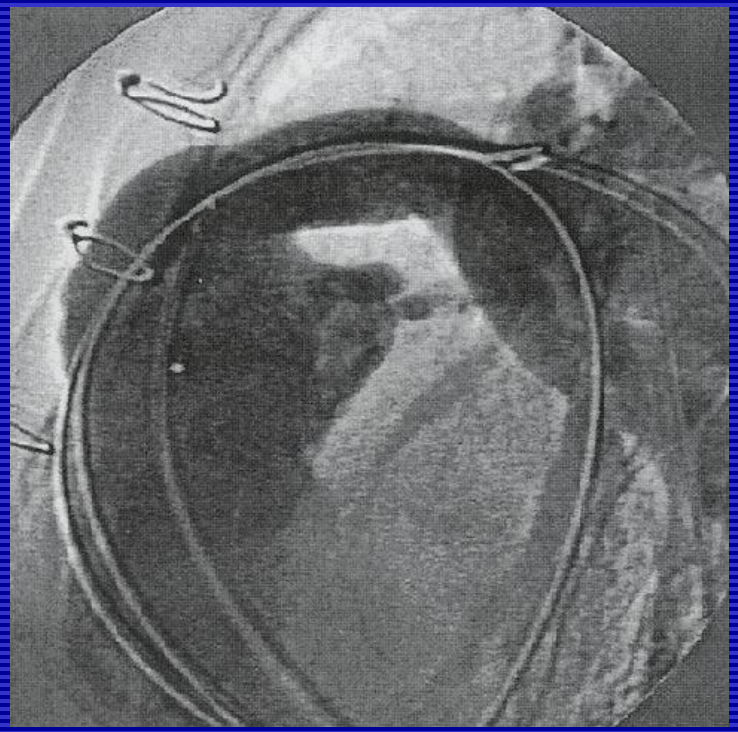


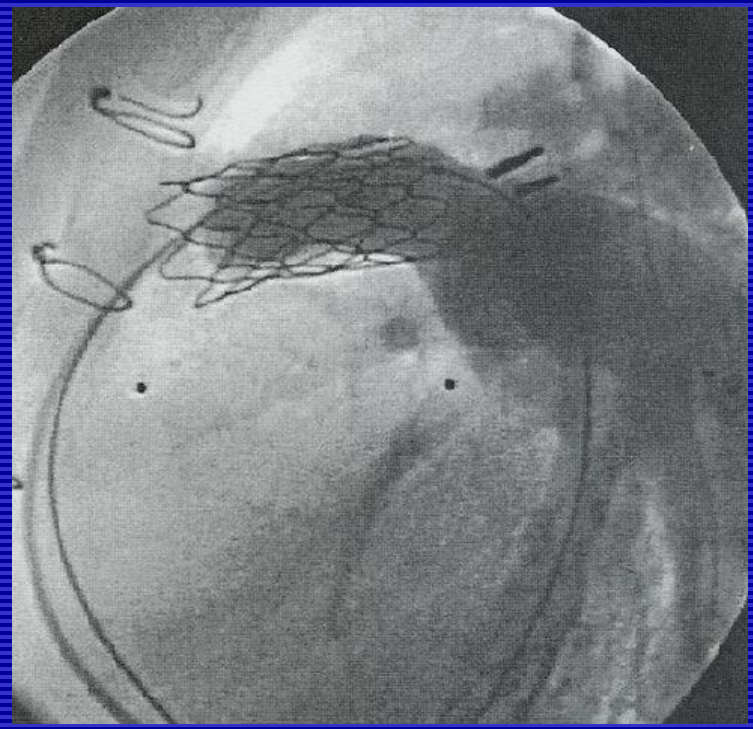

Babu-Narayan et al., Circulation 2014




Freedom from reintervention was 100% at 1 year, 96.9% at 5 years, 85.3% at 12 years.
No deaths occurred in reintervention patients.

# PVR late after repair of Tetralogy
## Transcatheter PV implantation

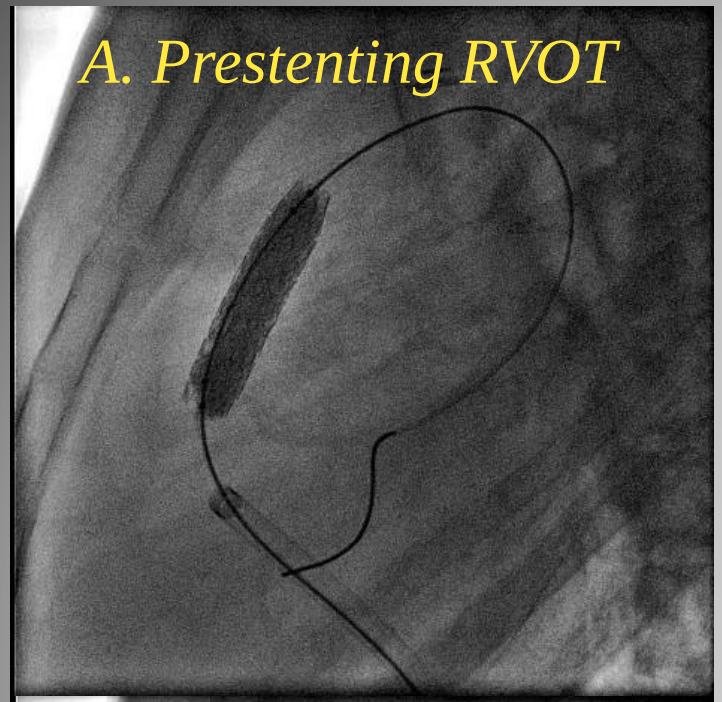


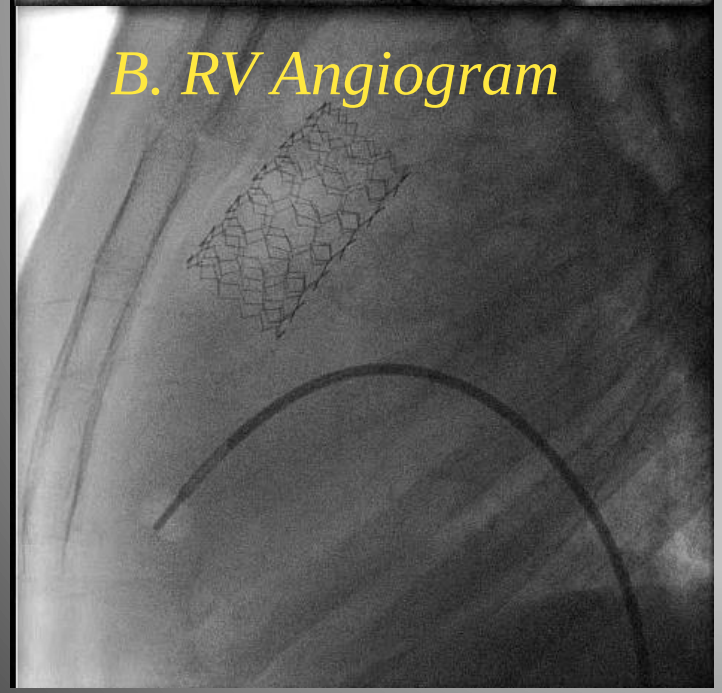


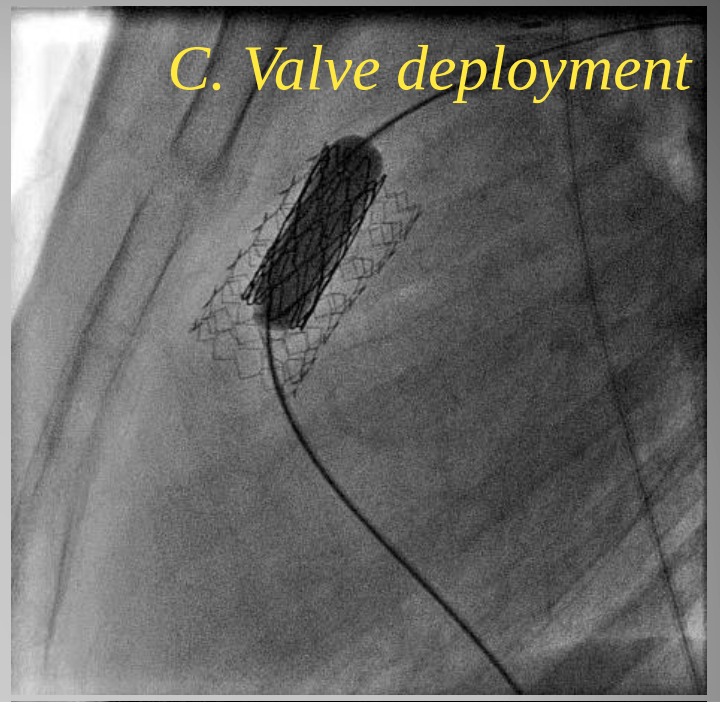
*Major advance*
*Native PV "annulus" is a problem for patients with non-conduit repair*
*We take percutaneous PVR into account, when planning surgical PVR*

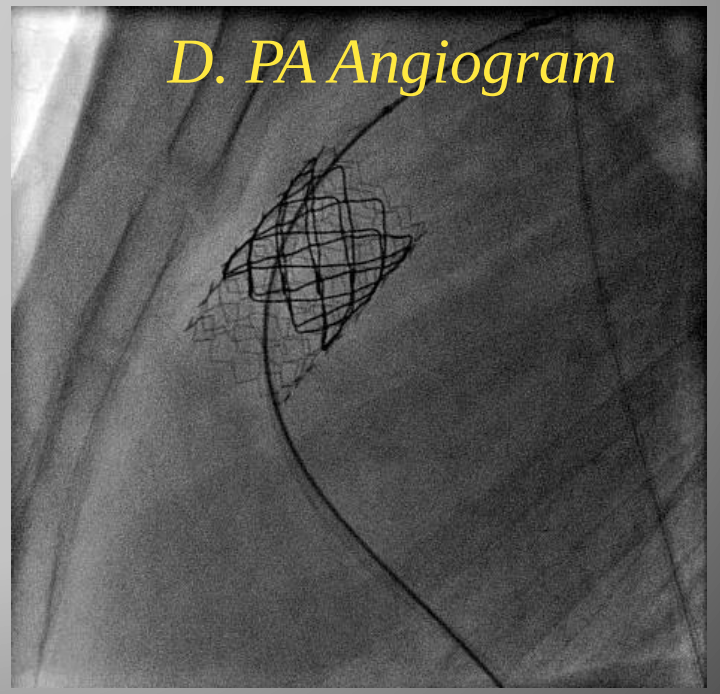
*Bonhoeffer et al, JACC 2002*

Royal Brompton


A. Prestenting RVOT

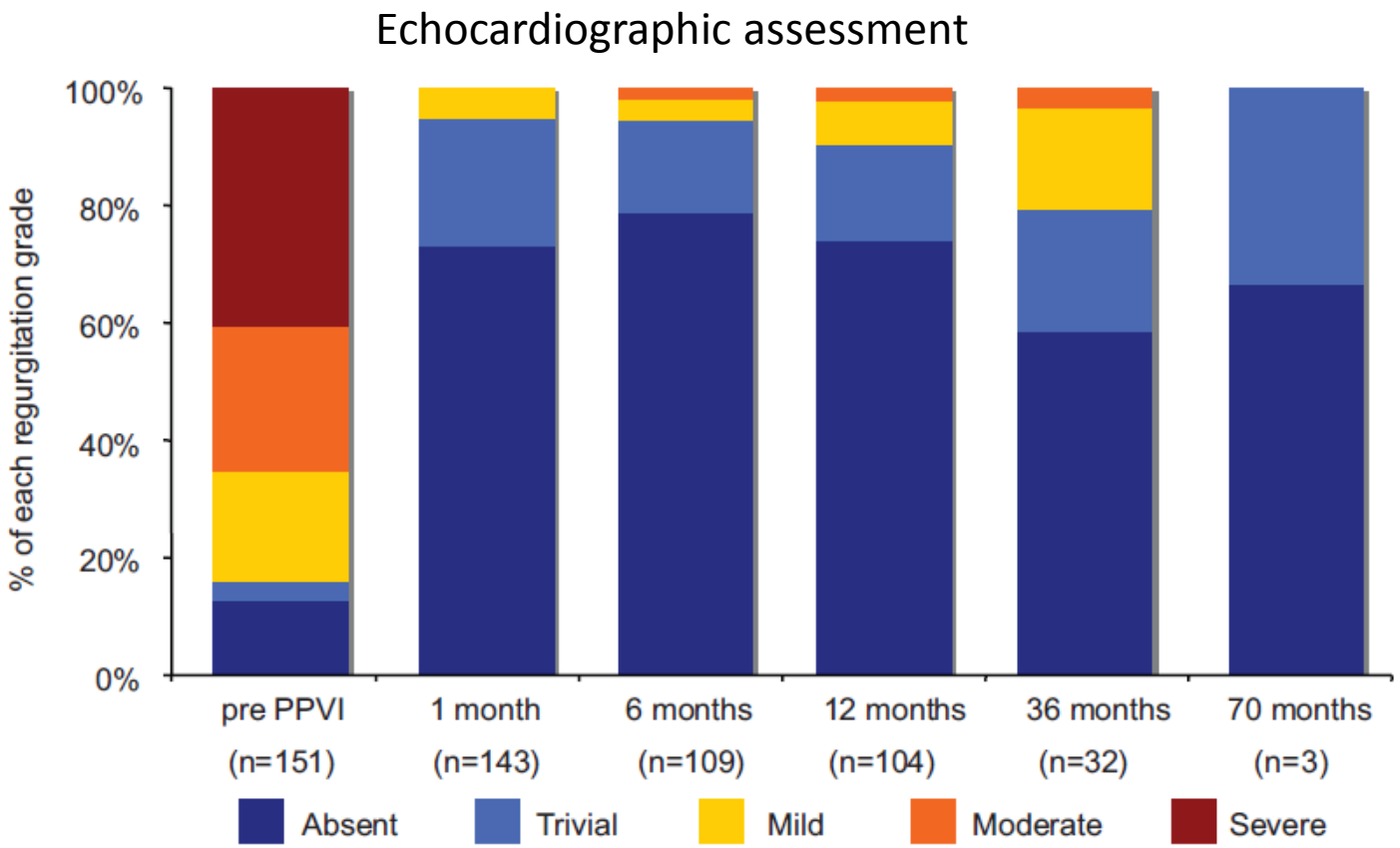

B. RV Angiogram


C. Valve deployment


D. PA Angiogram

# PPVI – Results

## Pulmonary Regurgitation




Lurz et al., Circulation 2008

# PPVI – Results

## Pulmonary Stenosis

**Table 3. Pressures at Catheterization**

| | Total Population (n=151) | | | Predominantly Stenosis (n=61) | | |
|---|---|---|---|---|---|---|
| Parameter | Pre | Post | *P* | Pre | Post | *P* |
| RV systolic pressure, mm Hg | 63±18 | 45±13 | <0.001 | 72±16 | 46±13 | <0.001 |
| RV end-diastolic pressure, mm Hg | 12±4 | 10±5 | <0.001 | 12±4 | 9±4 | <0.001 |
| PA systolic pressure, mm Hg | 27±11 | 29±12 | 0.056 | 25±11 | 26±9 | 0.373 |
| PA diastolic pressure, mm Hg | 10±4 | 14±9 | <0.001 | 10±4 | 12±4 | 0.003 |
| RV-to-PA gradient, mm Hg | 37±20 | 17±10 | <0.001 | 48±18 | 19±12 | <0.001 |
| Aortic systolic pressure, mm Hg | 94±15 | 101±16 | <0.001 | 92±15 | 98±14 | 0.004 |
| Aortic diastolic pressure, mm Hg | 54±10 | 58±10 | <0.001 | 54±9 | 57±10 | 0.021 |
| RV-to-systemic pressure, % | 69±19 | 45±14 | <0.001 | 81±16 | 47±12 | <0.001 |

Lurz et al., Circulation 2008

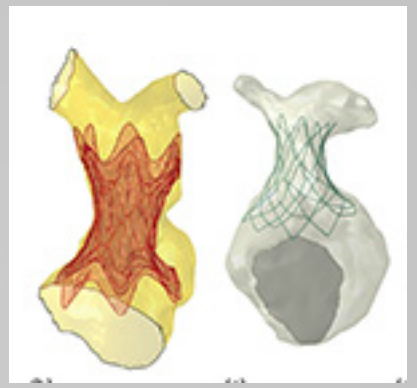
## *RVOT aneurysms and akinesia*

- RVOT aneurisms and akinesia common
- Not always related to RVOT or transannular patching
- Contributory to RF dysfunction
- VT focus

*Davlouros et al JACC 2002*

# *Extending Current Procedures*

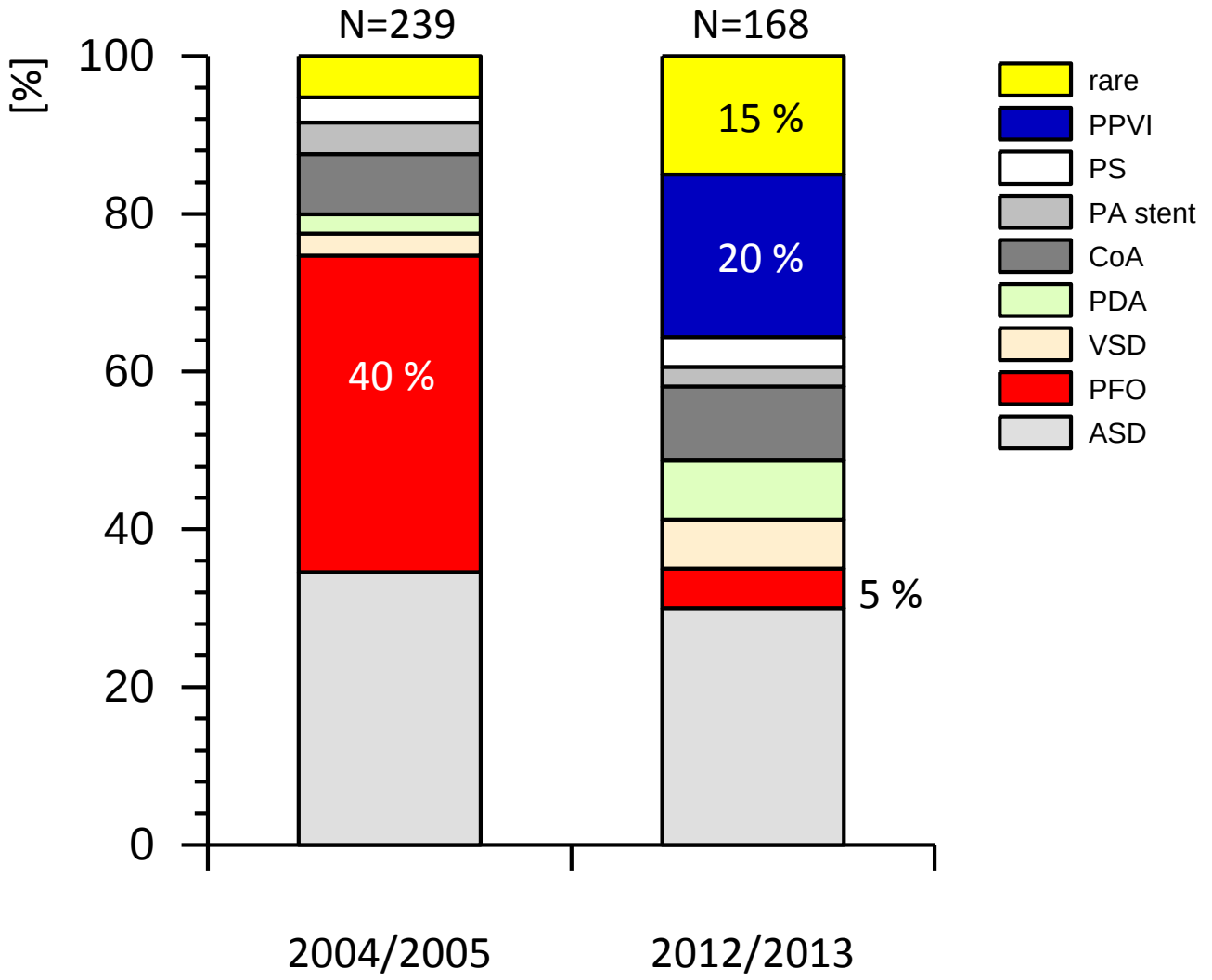
- *Percutaneous Stented Tissue Valves matched to aneurysmal RVOT*



- *Percutaneous Decellularised  Homografts/Allografts*

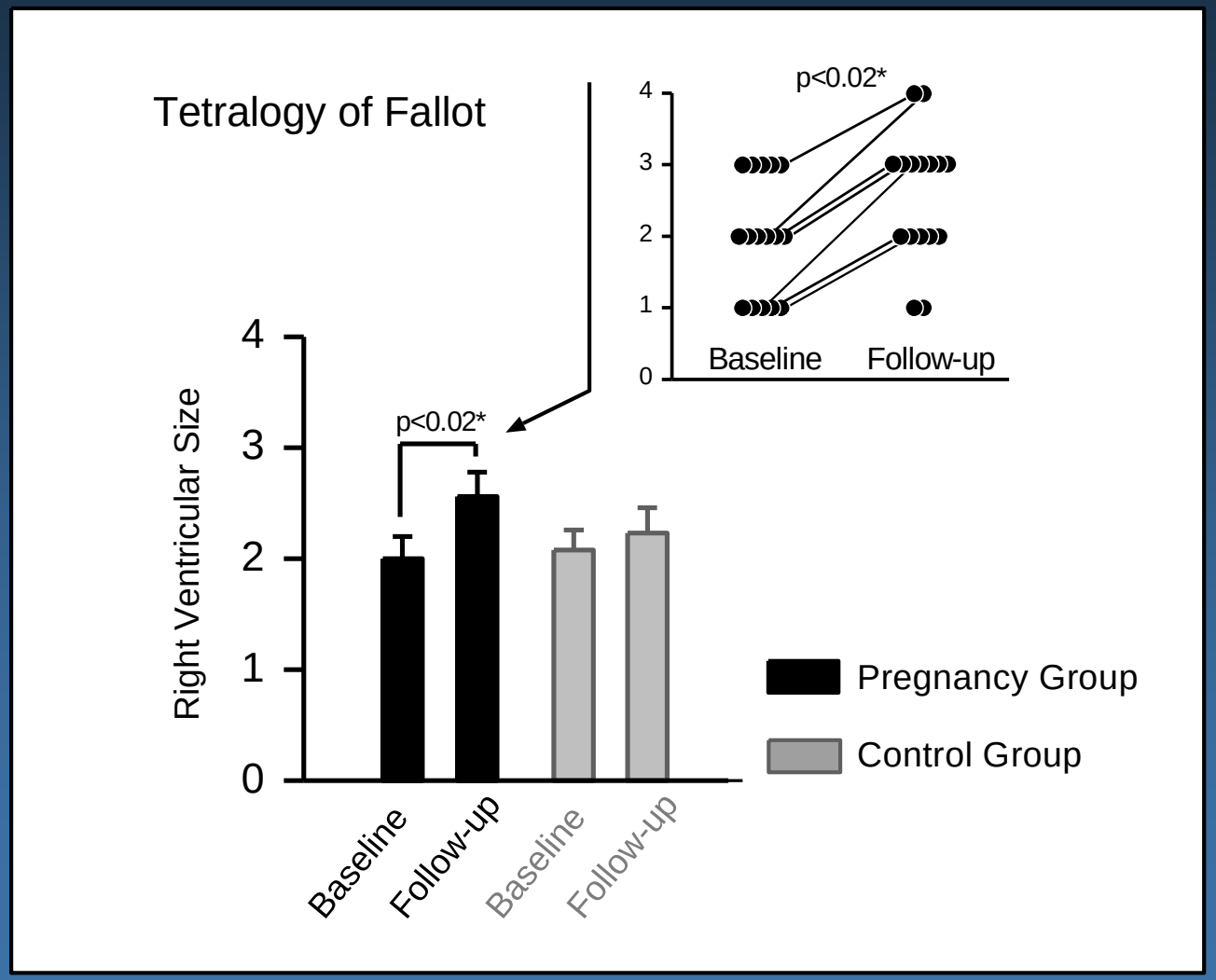
*Does merely covering the aneurysmal outflow prevent Ventricular arrhythmias ??*

# ACHD Catheter Interventions
# Royal Brompton




Slide courtesy of Anselm Uebing

# Pulmonary Regurgitation & Pregnancy: Adverse long-term Impact on RV ?




Uebing et al, IJC 2008

# *Pulmonary Valve Replacement:*
## *Rationale and Timing*

- To maintain RV function
- Reduce overall heart size, neurohormonal activation and objective exercise capacity and thus potentially improve survival.
- To improve quality of life and functional capacity
- In paralel risk stratification for VT and SCD is clearly required. Non-invasive and invasive tools (EP) should all be taken into account and an individualized decision/approach needs to be taken (always in conjunction with the patient)
- A combination of surgical PVR, this point in time with percutaneous PVR next time round, in conjunction with arrhythmia targeting intervention is likely in a significant number of patients
- Contemplating pregnancy may bring forward this cycle

Royal Brompton