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Congenital Heart Diseases
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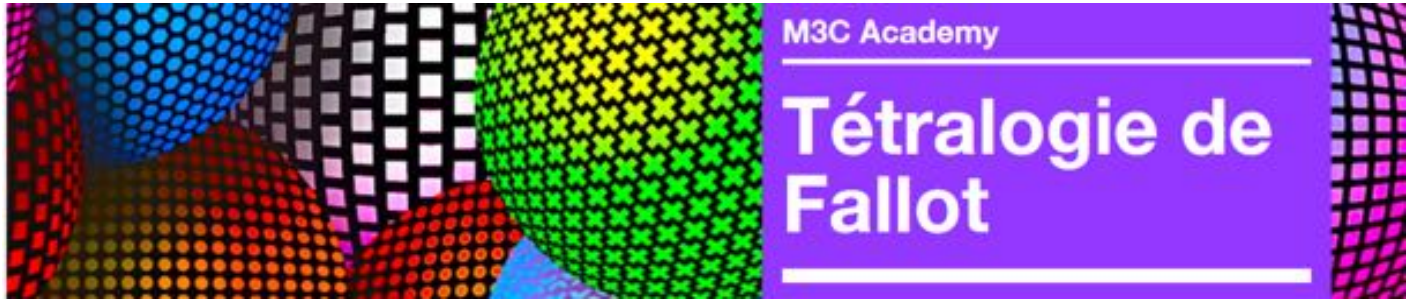
06 72 64 10 18

Pulmonary valve replacement: indications



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Clinical research priorities in adult congenital heart disease☆,☆☆

Timothy Cotts [a,b,*], Paul Khairy [c], Alexander R. Opotowsky [d,e], Anitha S. John [f], Anne Marie Valente [d,e], Ali N. Zaidi [g,h,i], Stephen C. Cook [j], Jamil Aboulhosn [k], Jennifer Grando Ting [l], Michelle Gurvitz [d,e], Michael J. Landzberg [d,e], Amy Verstappen [m], Joseph Kay [n,o], Michael Earing [p,q], Wayne Franklin [r,s], Brian Kogon [t], Craig S. Broberg [u], for the Alliance for Adult Research in Congenital Cardiology (AARCC)

ABSTRACT

Background: Adult congenital heart disease (ACHD) clinicians are hampered by the paucity of data to inform clinical decision-making. The objective of this study was to identify priorities for clinical research in ACHD.

Methods: A list of 45 research questions was developed by the Alliance for Adult Research in Congenital Cardiology (AARCC), compiled into a survey, and administered to ACHD providers. Patient input was sought via the Adult Congenital Heart Association at community meetings and online forums. The 25 top questions were sent to ACHD providers worldwide via an online survey. Each question was ranked based on perceived priority and weighted based on time spent in ACHD care. The top 10 topics identified are presented and discussed.

Results: The final online survey yielded 139 responses. Top priority questions related to tetralogy of Fallot (timing of pulmonary valve replacement and criteria for primary prevention ICDs), patients with systemic right ventricles (determining the optimal echocardiographic techniques for measuring right ventricular function, and indications for tricuspid valve replacement and primary prevention ICDs), and single ventricle/Fontan patients (role of pul-


GUIDE
GUIDE

Why considering PVR ?


OLYMPIC

Cuypers, circulation 2014

natural evolution

Survival 72% at 40 yo

- Heart Failure

- Ventricular Fibrillation

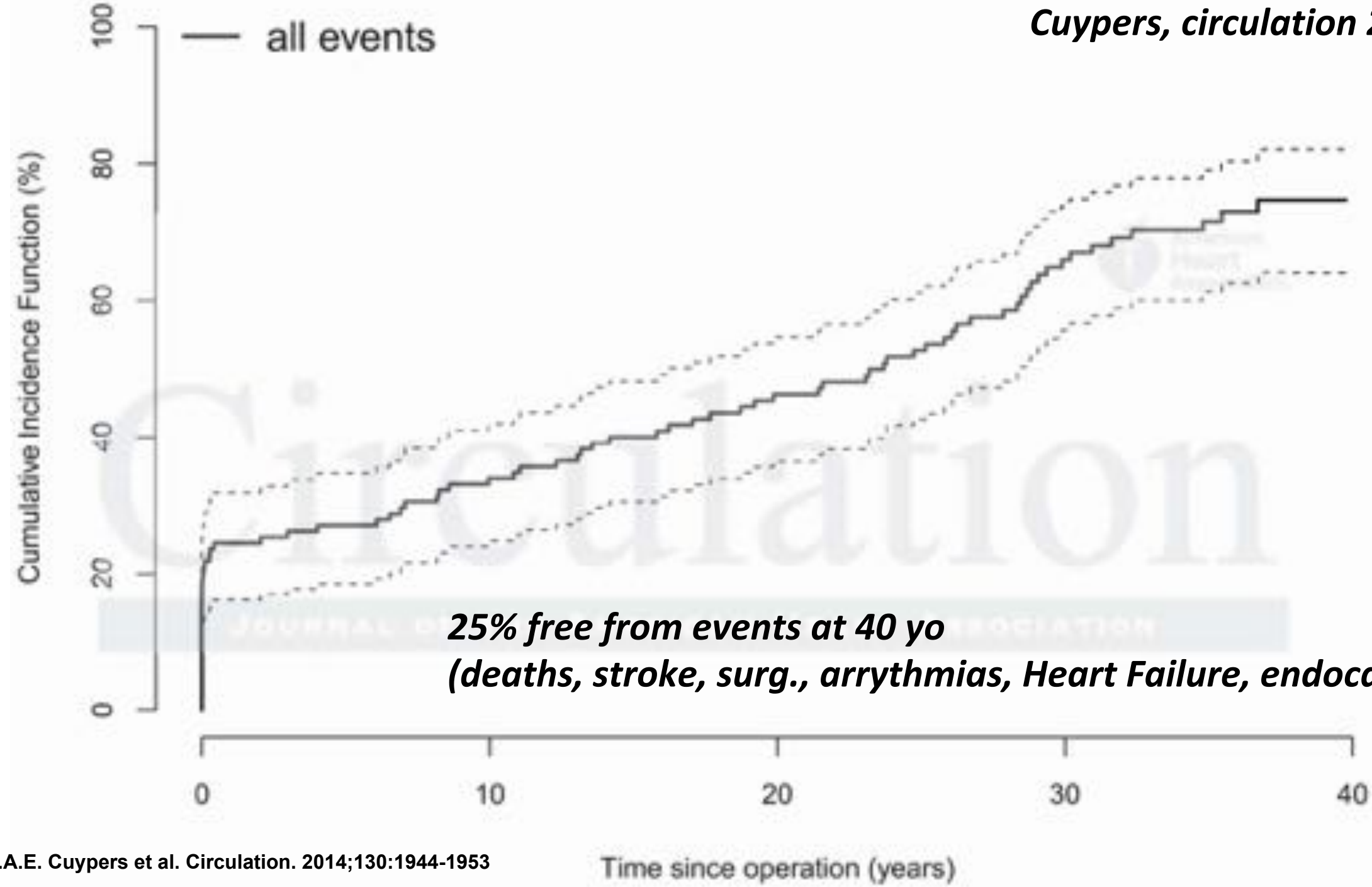
After excluding 3Od mortality, cum. Surv.:

- **96% at 20 y**

- 86% at 40 y

Judith A.A.E. Cuypers et al. Circulation. 2014;130:1944-1953

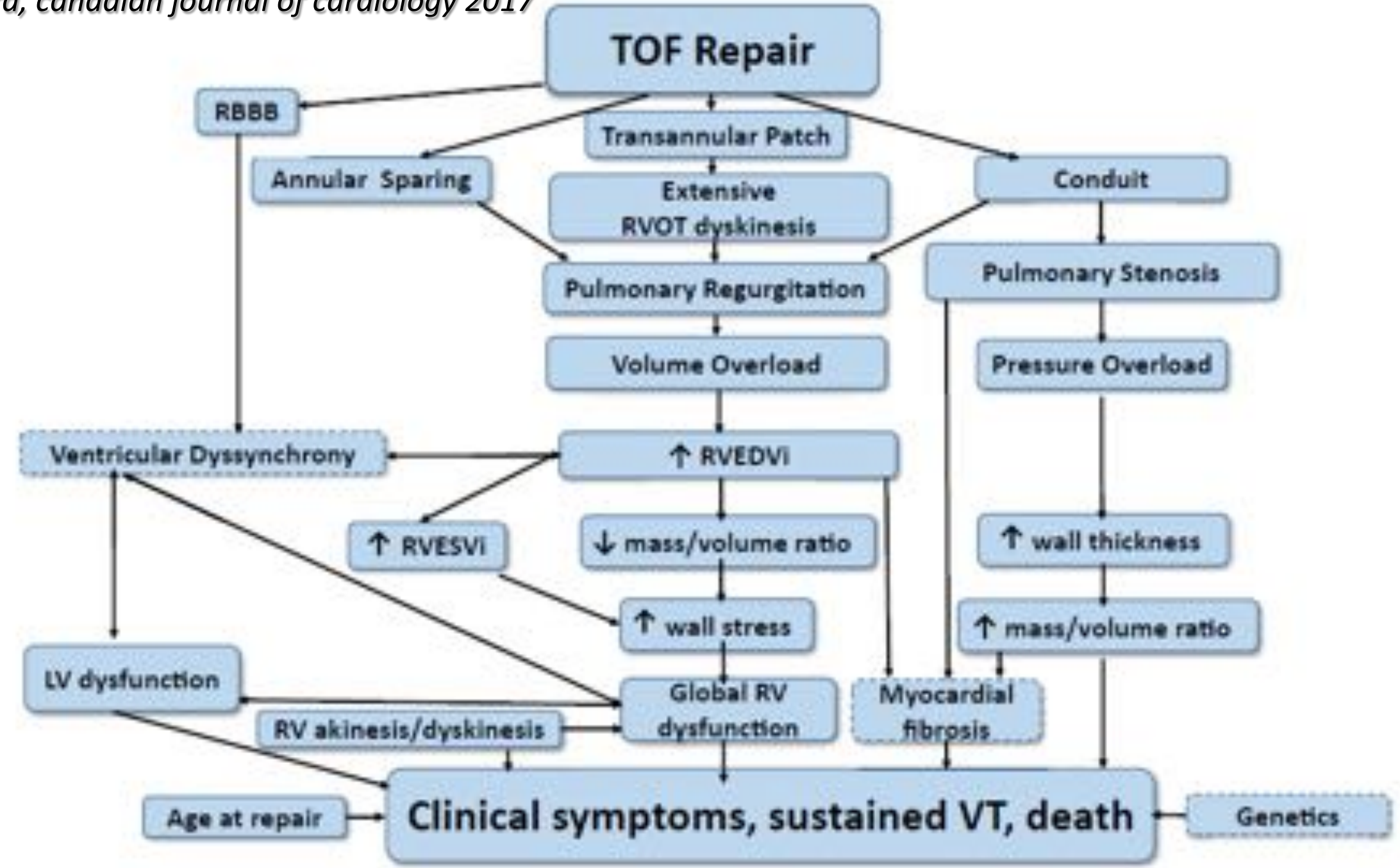
Cuypers, circulation 2014



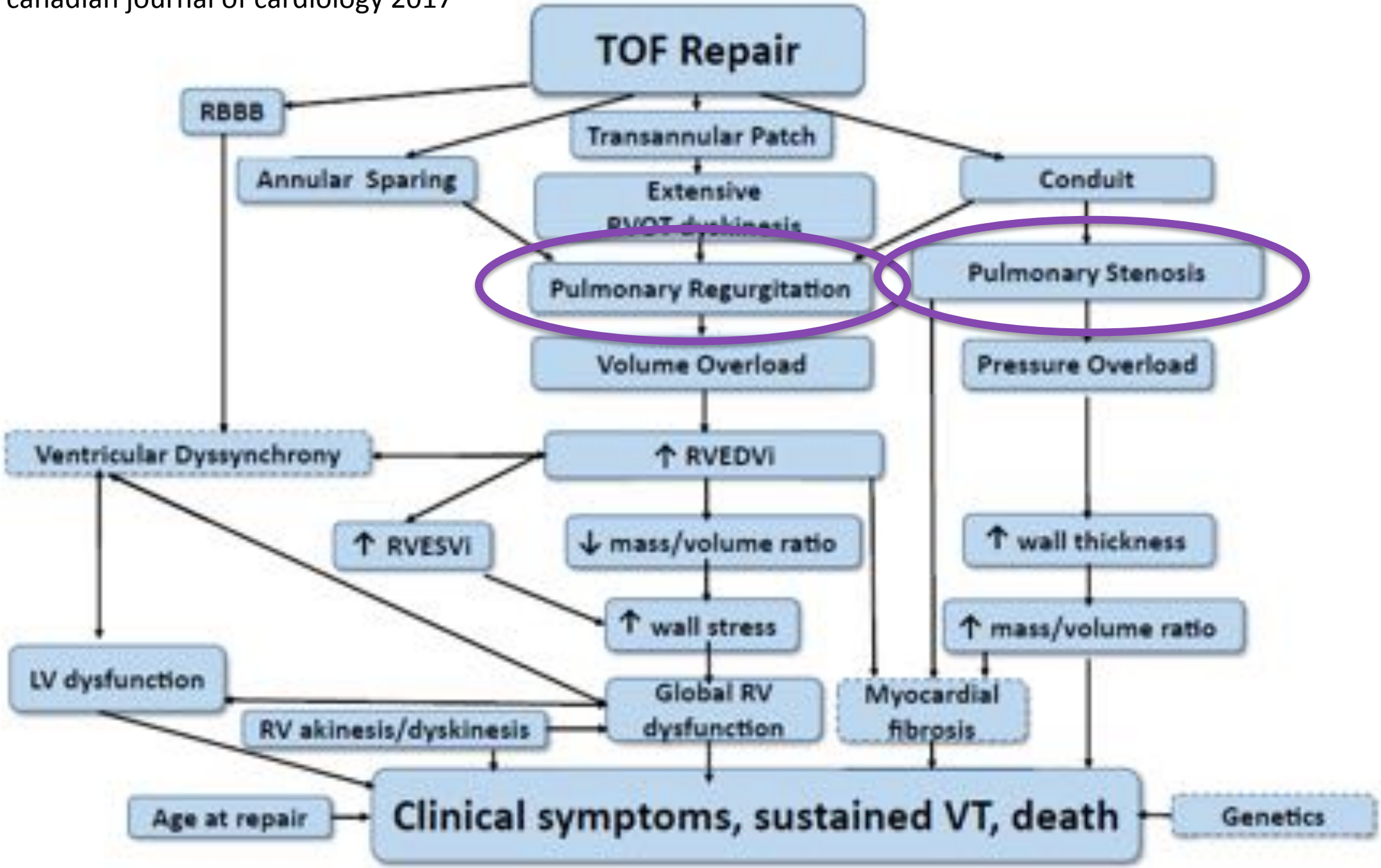
25% free from events at 40 yo
(deaths, stroke, surg., arrythmias, Heart Failure, endocarditis)

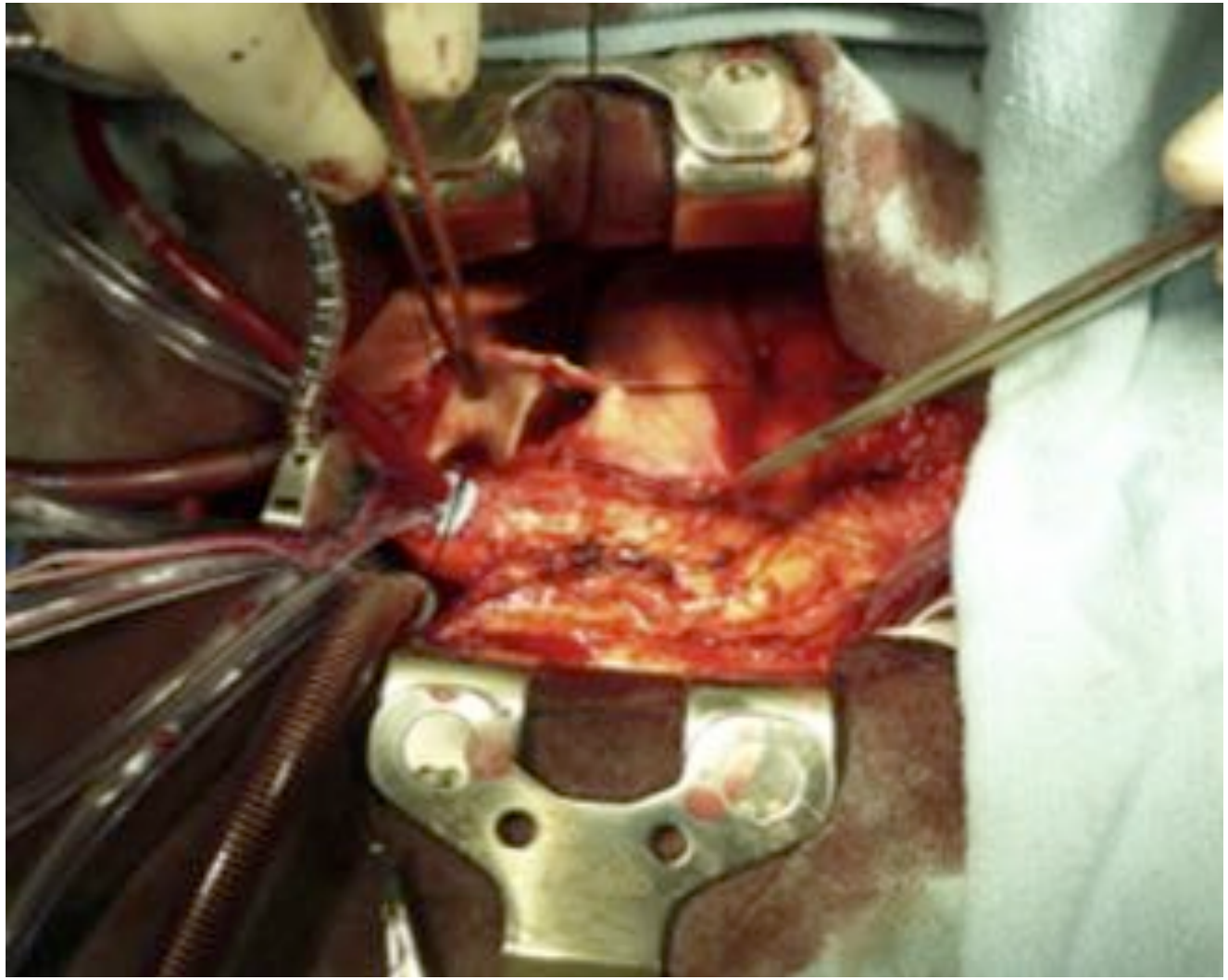
Judith A.A.E. Cuypers et al. Circulation. 2014;130:1944-1953

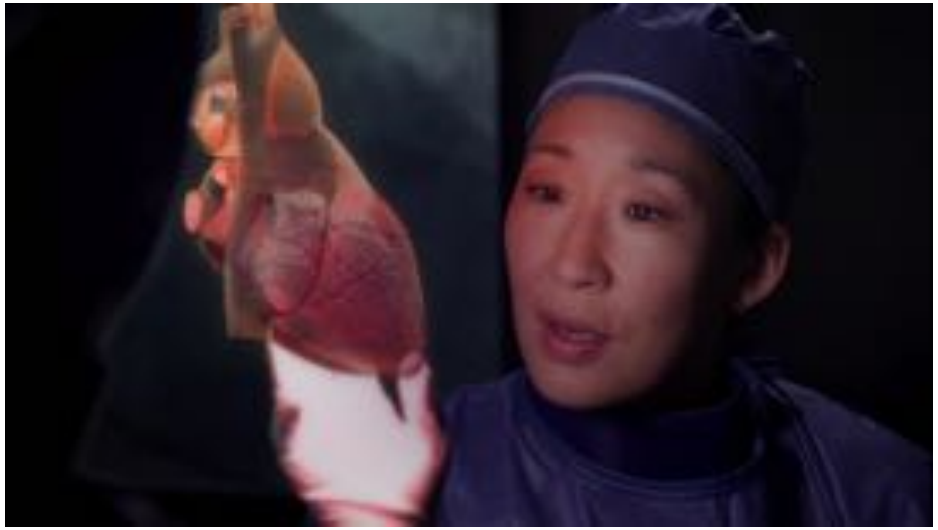
Bhagra, canadian journal of cardiology 2017



Bhagra, canadian journal of cardiology 2017







Early report

Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction

Philipp Bonhoeffer, Younes Boudjemline, Zakria Saliba, Jacques Merckx, Yacine Aggoun, Damien Bonnet, Philippe Acar, Jérôme Le Bidois, Daniel Sidi, Jean Kachaner

Summary

Background Valved conduits from the right ventricle to the pulmonary artery are frequently used in paediatric cardiac surgery. However, stenosis and insufficiency of the conduit usually occur in the follow-up and lead to reoperations. Conduit stenting can delay surgical replacement, but it aggravates pulmonary insufficiency. We developed an innovative system for percutaneous stent implantation combined with valve replacement.

Methods A 12-year-old boy with stenosis and insufficiency of a prosthetic conduit from the right ventricle to the pulmonary artery underwent percutaneous implantation of a bovine jugular valve in the conduit.

Findings Angiography, haemodynamic assessment, and echocardiography after the procedure showed no insufficiency of the implanted valve, and partial relief of the conduit stenosis. There were no complications after 1 month of follow-up, and the patient is presently in good physical condition.

Interpretation We have shown that percutaneous valve replacement in the pulmonary position is possible. With further technical improvements, this new technique might also be used for valve replacement in other cardiac and non-cardiac positions.

Lancet 2000; **356**: 1403–05

Introduction

The treatment of congenital heart disease has become increasingly interventional as the armamentarium of tools grows. The most important advancements in interventional cardiology are the development of devices for closure of septal defects, and stents with or without covering.[1]

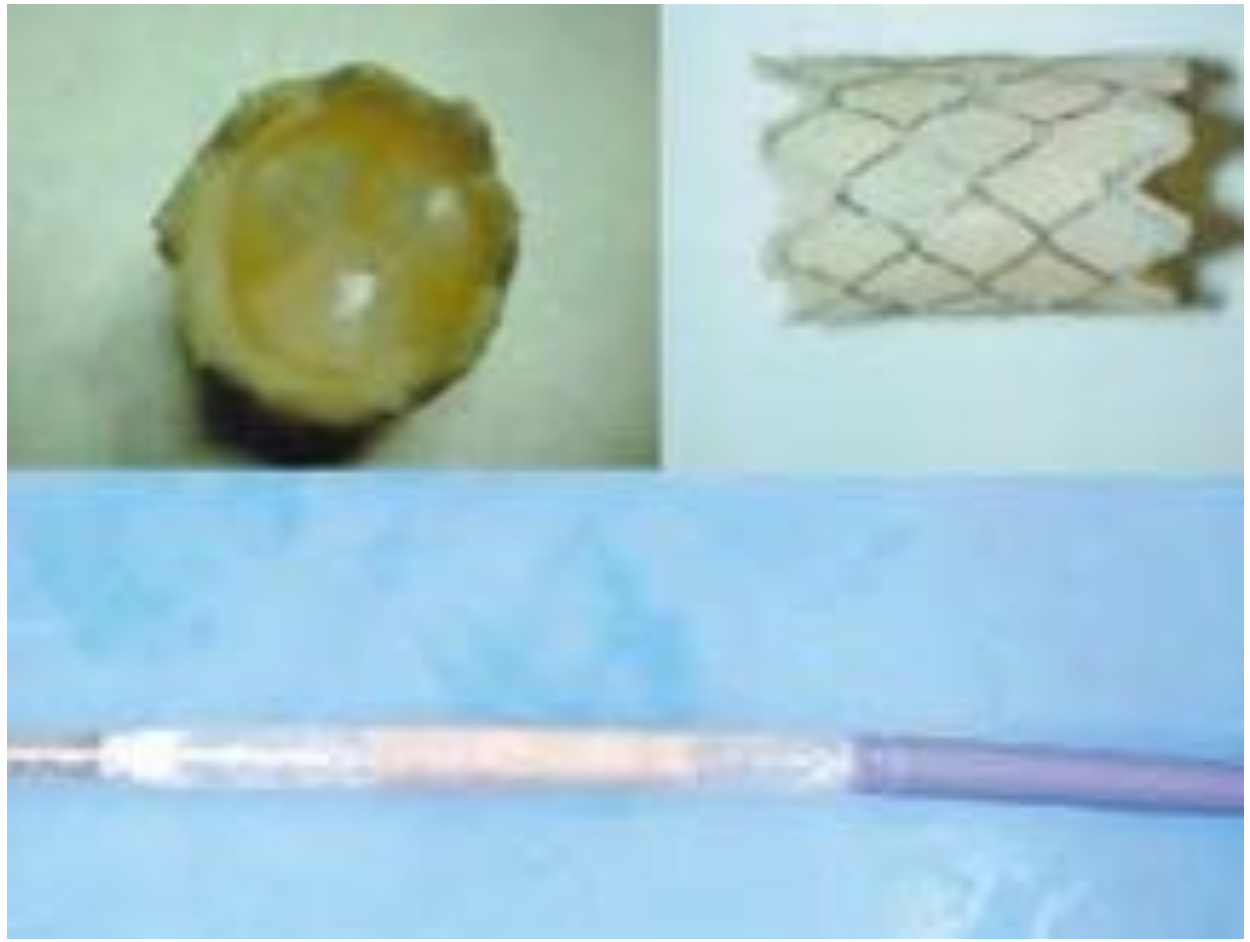
The development of extracardiac conduits for the establishment of right-ventricular to pulmonary-artery continuity has been one of the major advances in paediatric cardiac surgery. Conduits have permitted repair of previously uncorrectable congenital heart defects, and facilitated the treatment of other complex diseases. The prosthetic conduits are either valveless,[2] or use xenograft,[3,4] pericardial,[5] or homograft valves.[6–8] However, conduit failure inevitably occurs after a period that largely depends on the type of valve mounted in the conduit. Progressive obstruction of the conduit secondary to calcific stenosis of the heterograft valve or accumulation of fibrous peel within the conduit necessitates its surgical replacement. In addition, somatic growth, infection, and conduit incompetence can also indicate a surgical substitution.[9] Conduits with porcine valves require replacement about 7·4 years (range 1·1–17·7) after implantation.[9] However, long-term results seem to be more encouraging with autologous pericardial valves.[6,7] Conduits made with bovine jugular valves have recently become popular in surgery, but their long-term performance in the clinical setting still remains to be established.

Conduit stenting during percutaneous catheterisation has emerged as an efficient technique to reopen the conduit narrowing, thereby delaying the need for surgery.[10–12] However, this technique is not entirely satisfactory because the valve in the conduit has to be sacrificed, which then leads to pulmonary insufficiency. Pulmonary regurgitation chronically overloads the right ventricle, compromising its long-term function.[13] Despite the rare but possible complications of stent placement,[14,15] a non-surgical technique to correct the conduit obstruction without compromising the competence of the valve is therefore attractive. By preserving adequate long-term right-ventricular function, this option potentially diminishes the number of surgical interventions in patients who need numerous open-heart operations during their life.

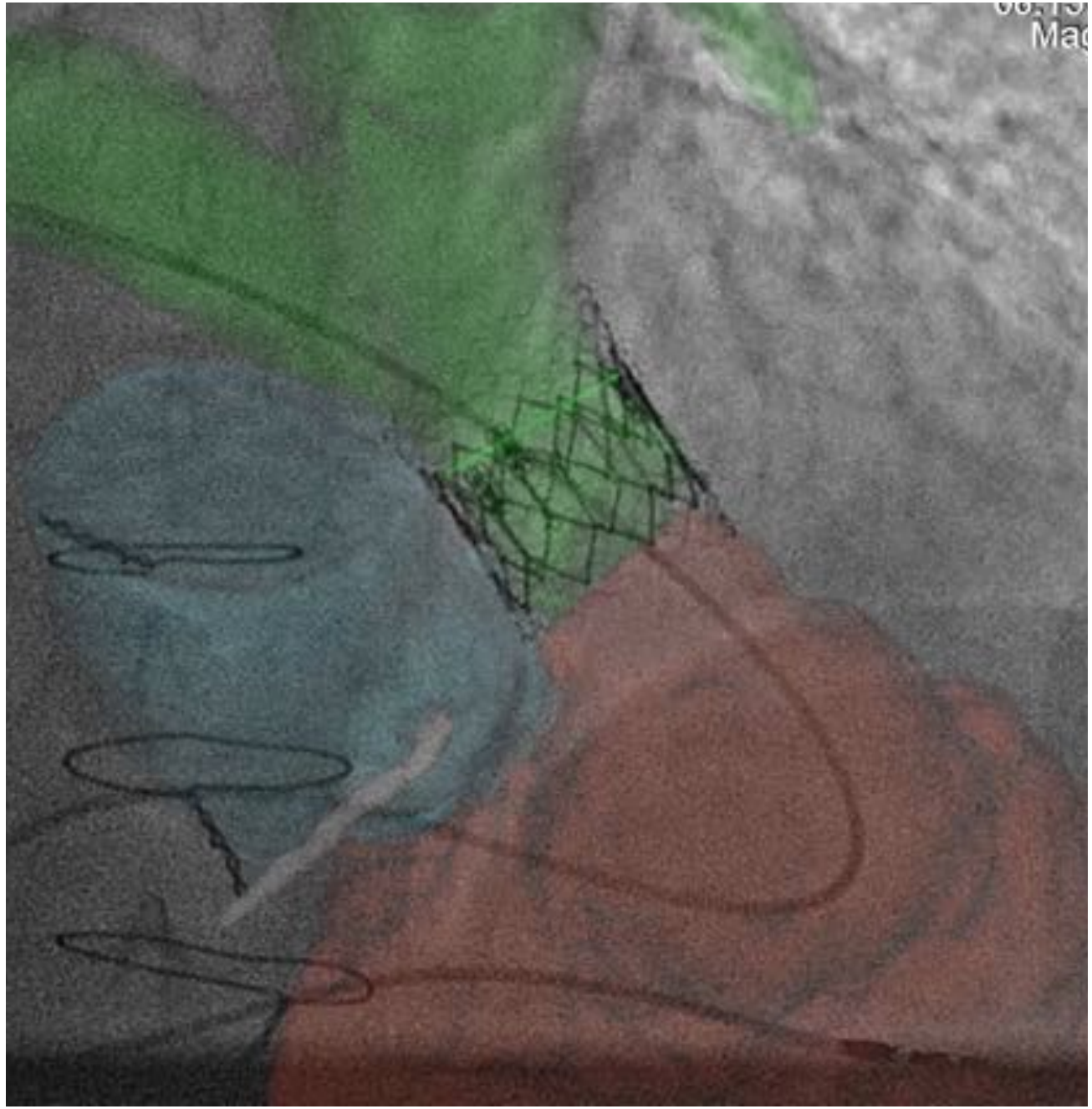
In an animal study, we reported having done a percutaneous pulmonary valve replacement using a valve from a bovine jugular vein mounted inside an expandable stent.[16] The experiment showed that valve function was good after mounting of the device. We succeeded in implanting a valved stent in seven of 11 animals; the valve remained functional after 2 months in

Service de Cardiologie Pédiatrique (P Bonhoeffer MD, Y Boudjemline MD, Z Saliba MD, Y Aggoun MD, D Bonnet MD, P Acar MD, J Le Bidois MD, Prof D Sidi MD, Prof J Kachaner MD), **and Département d'Anesthésie** (J Merckx MD), **Hôpital Necker-Enfants-Malades, 75743 Paris Cedex 15, France**
Correspondence to: Dr Philipp Bonhoeffer
(e-mail: philipp.bonhoeffer@nck.ap-hop-paris.fr)

Lancet 2000



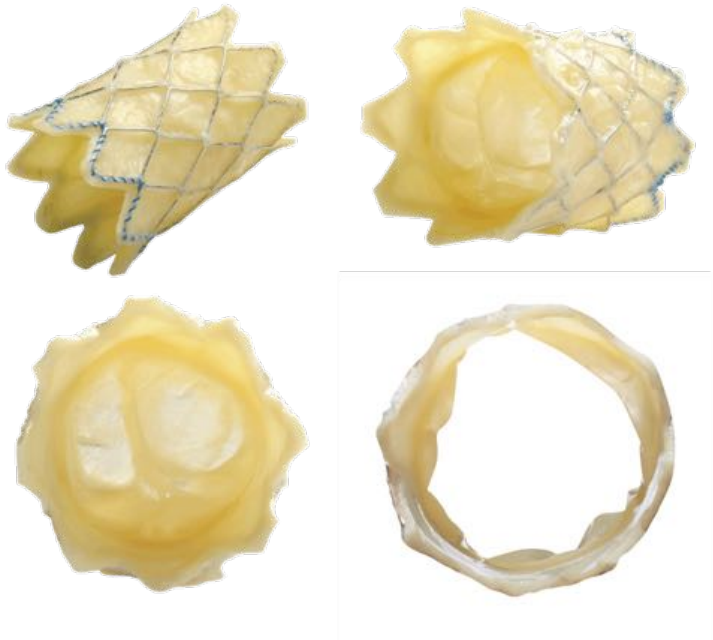
Bonhoeffer et al., Melody valve.



Melody Valve

1st implant 2000
CE 2006
FDA 2010

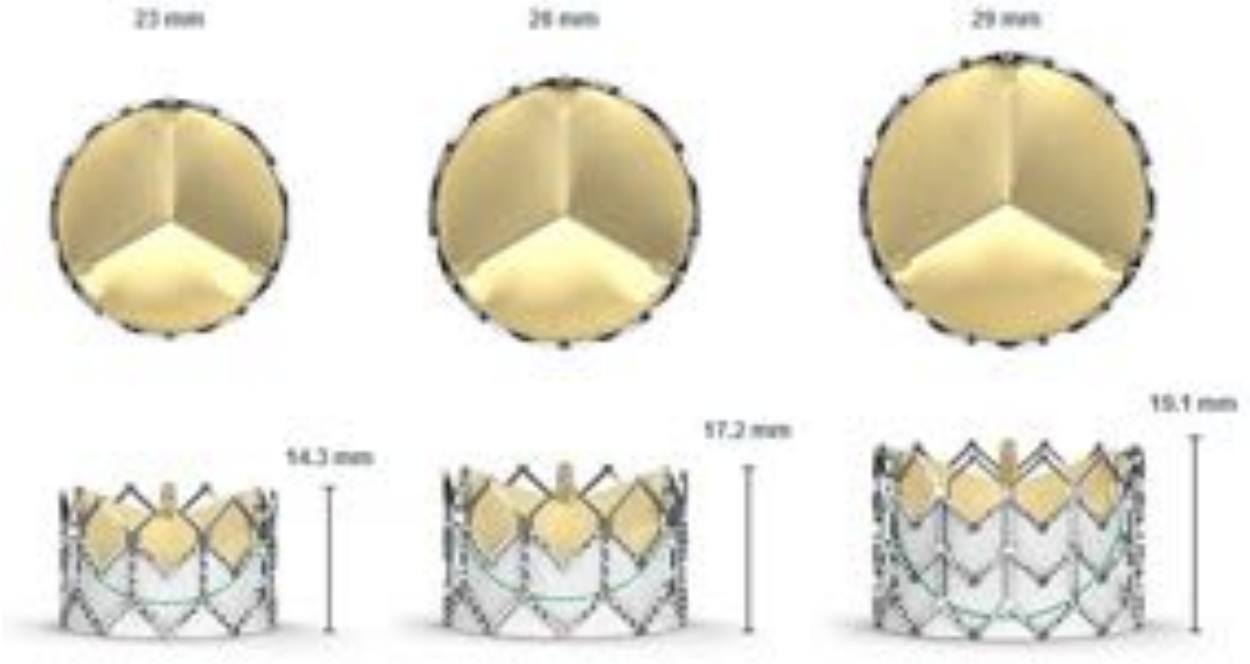
16-18-20-22 mm



Sapien Valve

CE 2010
FDA 2016

20-23-26-29 mm



PVR:
how considering indications?

indications

Patient: event-free good quality of life for 8 decades

PVR

versus

Natural evolution

Niveaux de preuve

PVR effects?

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Congenital Heart Disease

Pulmonary Valve Replacement After Operative Repair of Tetralogy of Fallot

Meta-Analysis and Meta-Regression of 3,118 Patients From 48 Studies

Paulo Ernando Ferraz Cavalcanti, MD, MSc,*†‡ Michel Pompeu Barros Oliveira Sá, MD, MSc,*†‡ Cecília Andrade Santos, MD,† Isaac Melo Esmeraldo, MD,† Rodrigo Renda de Escobar, MD,*† Alexandre Motta de Menezes, MD,*† Orlando Morais de Azevedo, Jr, MD,*† Frederico Pires de Vasconcelos Silva, MD,*† Ricardo Felipe de Albuquerque Lins, MD, MSc,*† Ricardo de Carvalho Lima, MD, MSc, PhD, ChM*†‡

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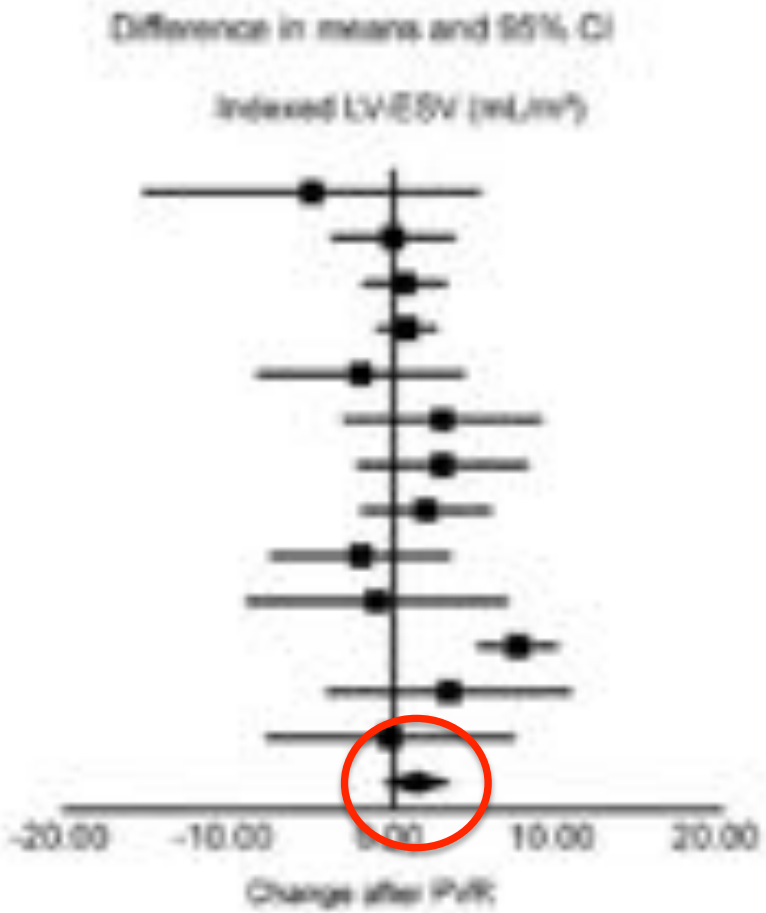
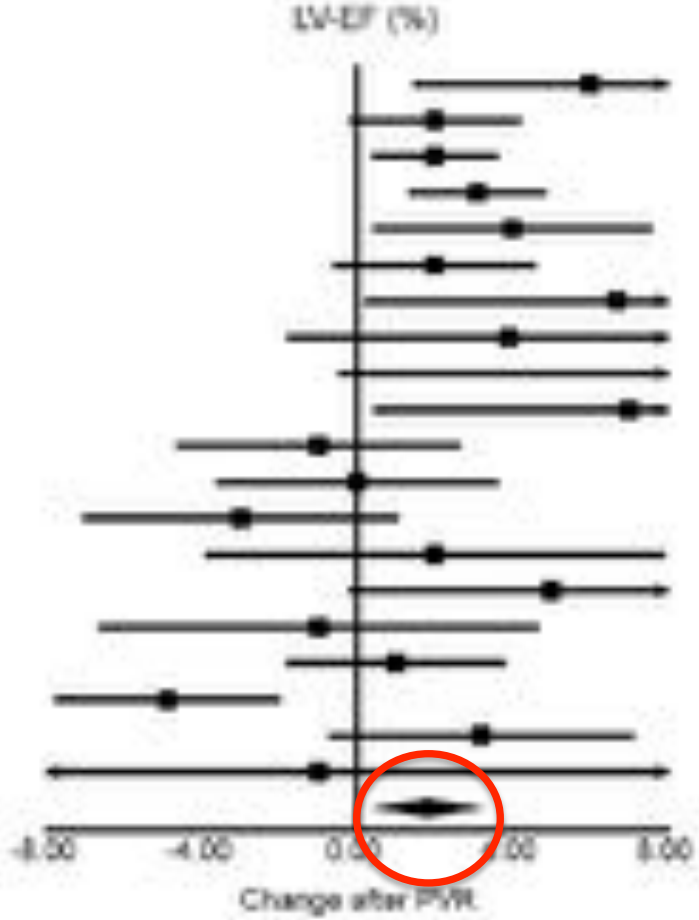
Recife, Pernambuco, Brazil

Left ventricle





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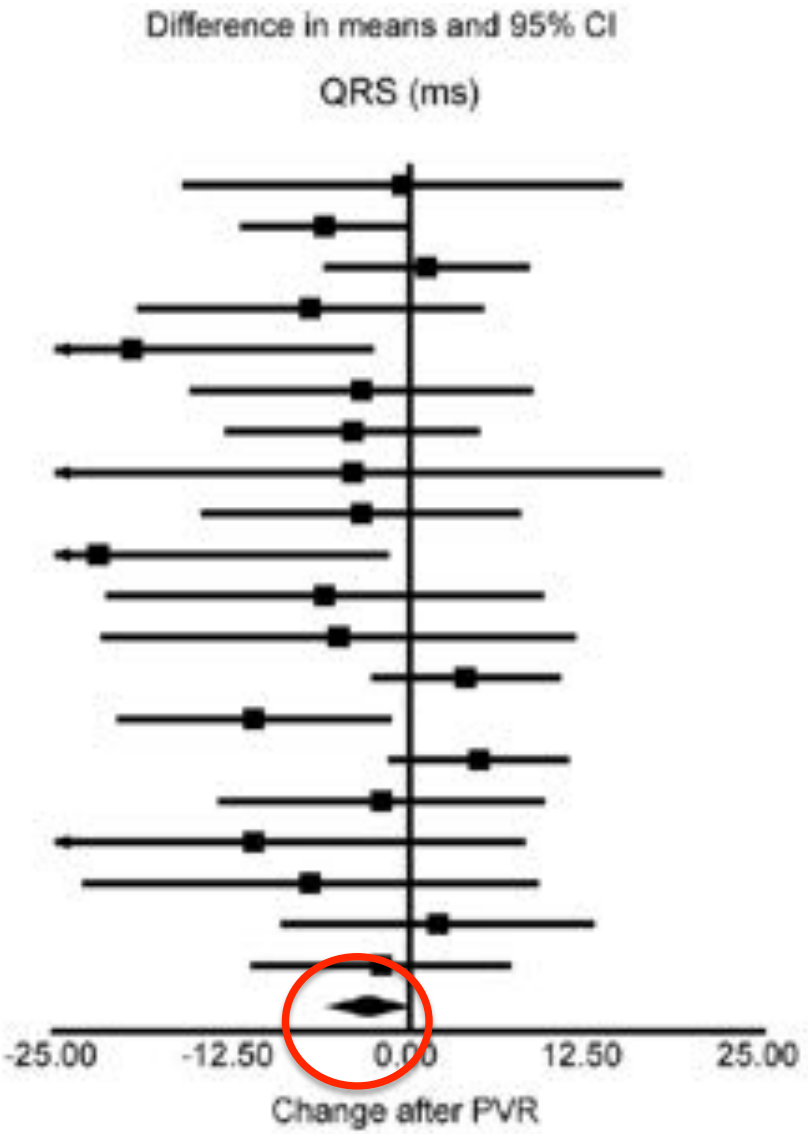
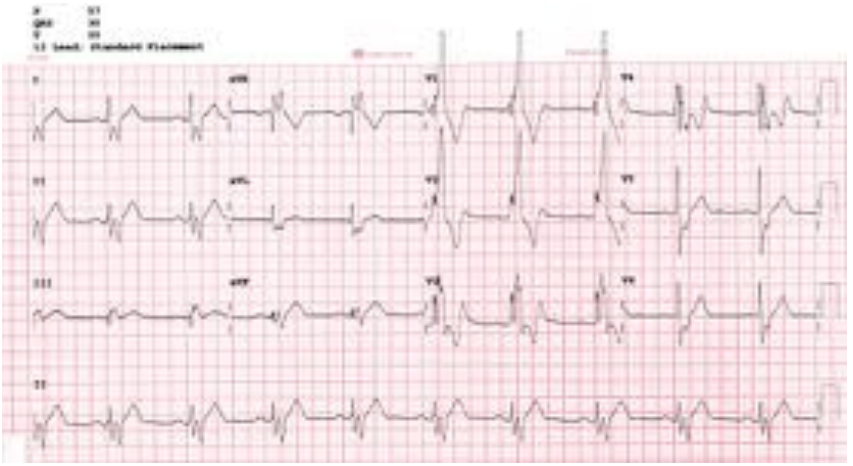
Recife, Pernambuco, Brazil

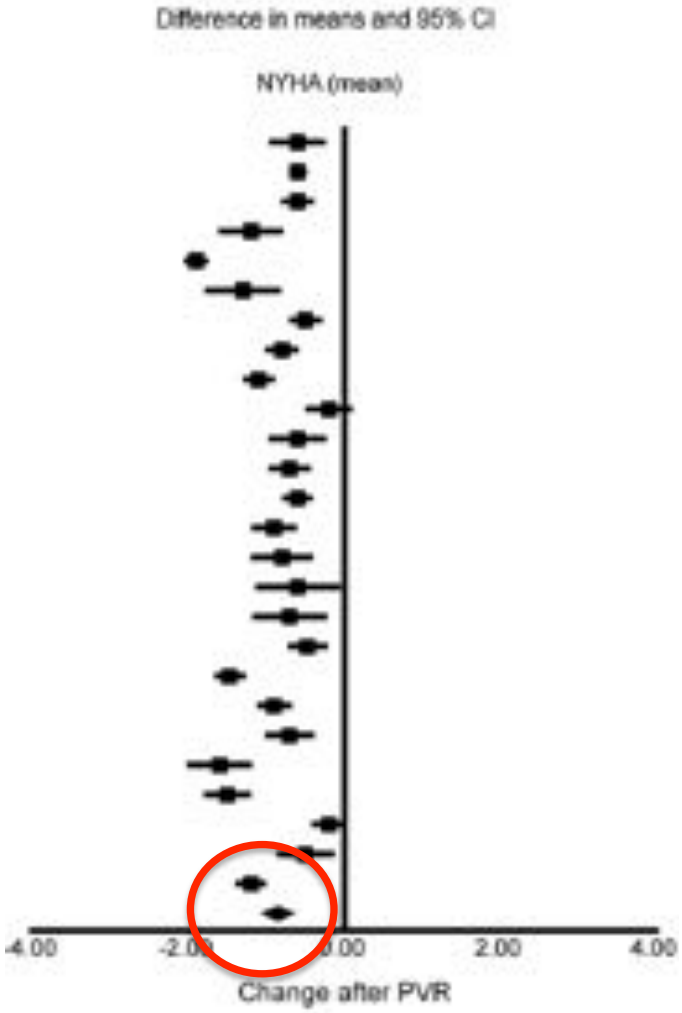
QRS duration





NYHA

- Essentiellement des études avec patients symptomatiques

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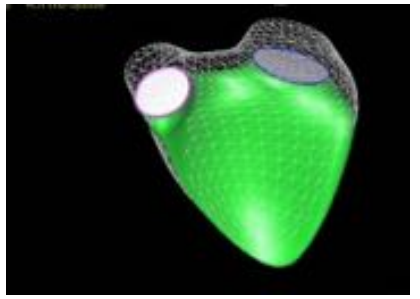
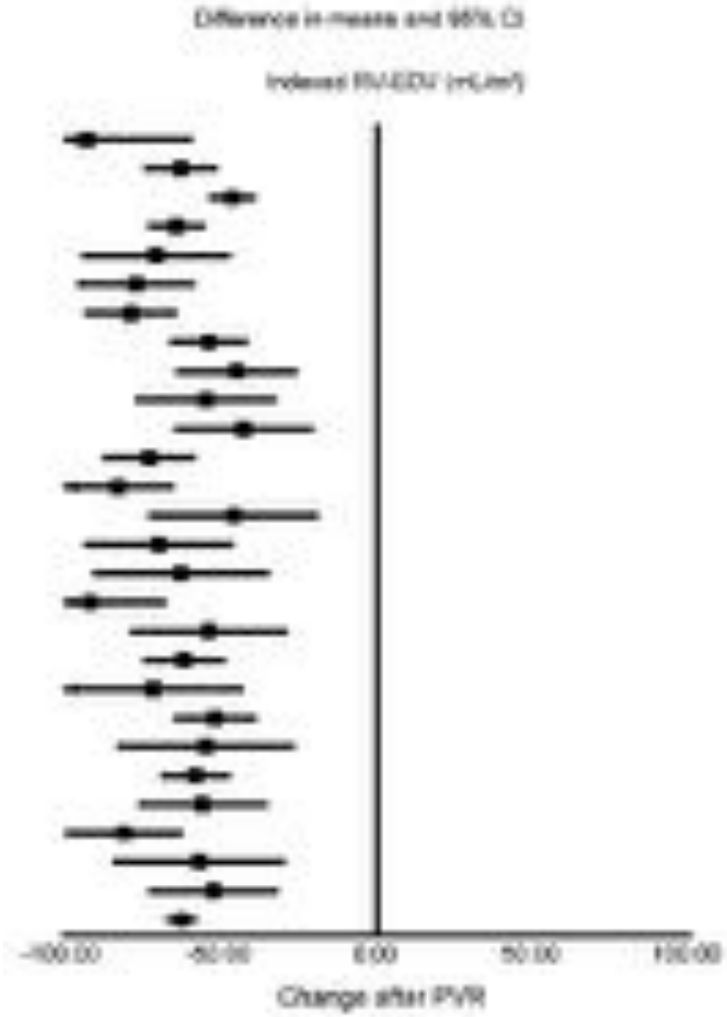
Recife, Pernambuco, Brazil

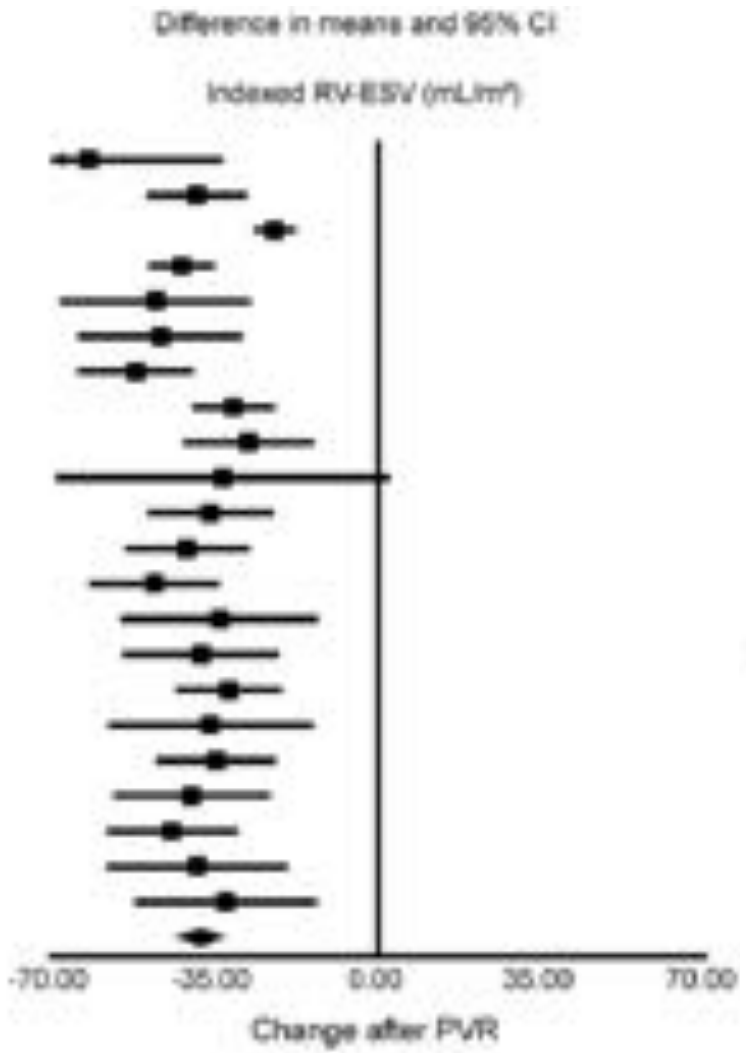
Right ventricle



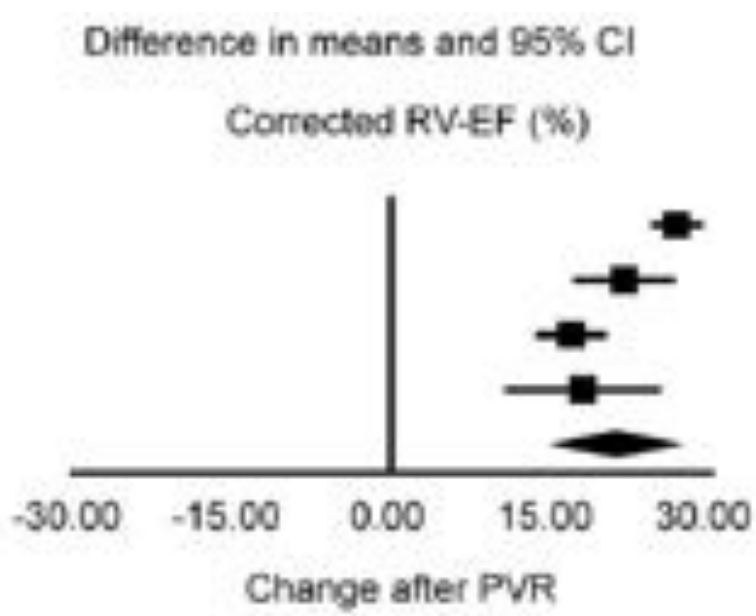
↘ RV-EDV



↘ RV-ESV



↗ RVEF



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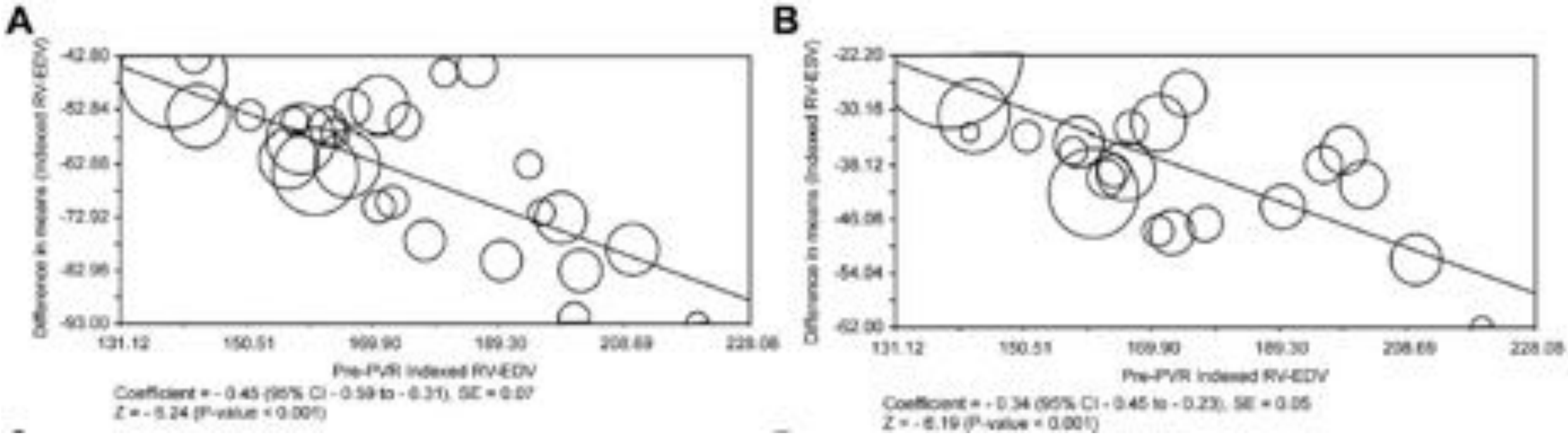
RV remodeling



RV remodeling

Heterogeneity among patients and studies

- RV EDV 150 à 170 ml/m²
- RV ESV 80 à 90 ml/m²
- RVEF 45%

Limits: MRI variability

Therrien AJC 2005, Alfakih JMRI 2003, Geva circulation 2010, Buechel Eur Heart J 2005, Oosterhof Circulation 2007, Bokma EHJ 2016, Lee JACC 2012

RV remodeling and outcome

- RV ESV<80 ml/m² => good outcome
- RV EDV >95 ml/m² α deaths/Heart failure/ Ventricular Tachycardia

Bokma EHJ 2016

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Recife, Pernambuco, Brazil

Mortality

"Our meta-analysis identified reduction of QRS duration and LVEF improvement after PVR, which in combination might mean reduction of long-term mortality. Obviously, the latter statement is a mere speculation, and specific studies are required to confirm it."

Reco USA (ACC/AHA JACC 2008)

CLASS IB: Free PR and symptoms or altered functional status

CLASS Iia: Free PR and:

- RV dysfunction (*Level of Evidence: B*)
- RV dilation (*Level of Evidence: B*)
- Arrythmias A or V (*Level of Evidence: C*)
- TR (*Level of Evidence: C*)

Stenosis and :

- max gradient > 50 mm Hg (*Level of Evidence: C*)
- SRVP >70% systemic level (*Level of Evidence: C*)
- RV dysfunction (*Level of Evidence: C*)

Reco canada 2009 (CJC 2010)

Classe IIa – C

- Free PR and RV EDV > 170 mL/m2 or RV dysfunction or TR or atrial arrhythmias / symptoms, altered functional status

- Stenosis and SRVP > 2/3 systemic level

Reco europe (EHJ 2010)

PVRep should be performed in symptomatic patients with severe PR and/or stenosis (RV systolic pressure >60 mmHg, TR velocity >3.5 m/s)	I	C
PVRep should be considered in asymptomatic patients with severe PR and/or PS when at least one of the following criteria is present: • Decrease in objective exercise capacity • Progressive RV dilation • Progressive RV systolic dysfunction • Progressive TR (at least moderate) • RVOTO with RV systolic pressure >80 mmHg (TR velocity >4.3 m/s) • Sustained atrial/ventricular arrhythmias	IIa	C

Treat associated lesions: branches stenosis…

Criteria	AHA [13]	ESC [11]	CCS [12]
RVEDVi	≥Moderate	>160 mL/m^2	>170 mL/m^2
RVESVi	Not specified	Not specified	Not specified
RV function	≥Moderate RV dysfunction	Progressive RV dysfunction	≥Moderate RV dysfunction
RVOT obstruction[a]	PIG ≥50 mm Hg or RV/LV pressure ratio ≥0.7	PIG ≥80 mm Hg (4.3 m/s)	RV systolic pressure ≥2/3 systemic pressure
PR[a]	Severe	Severe	Free
TR	≥Moderate	≥Moderate	"Important"
QRS duration	Not specified	>180 msec	Not specified
Arrhythmia	Symptomatic or sustained AT or VT	Sustained AT or VT	AT or VT
Exercise cardiopulmonary function	Not specified	Objective decrease	Not specified
Other considerations	Significant residual VSD or AR	Not specified	Significant residual VSD

Tretter 2016 IJC

but …

INDICATOR

873 patients

Valente Heart 2014

PR and RV volumes not correlated with outcome

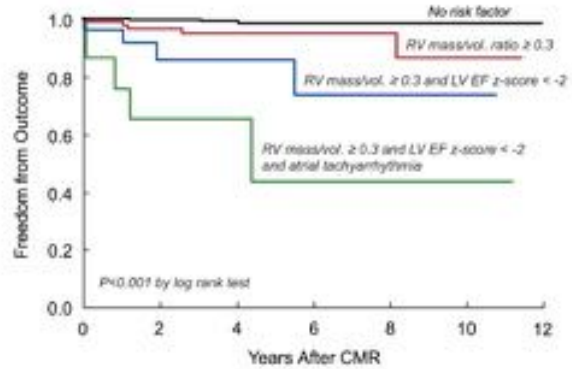


Table 4 Multivariable predictors of outcome

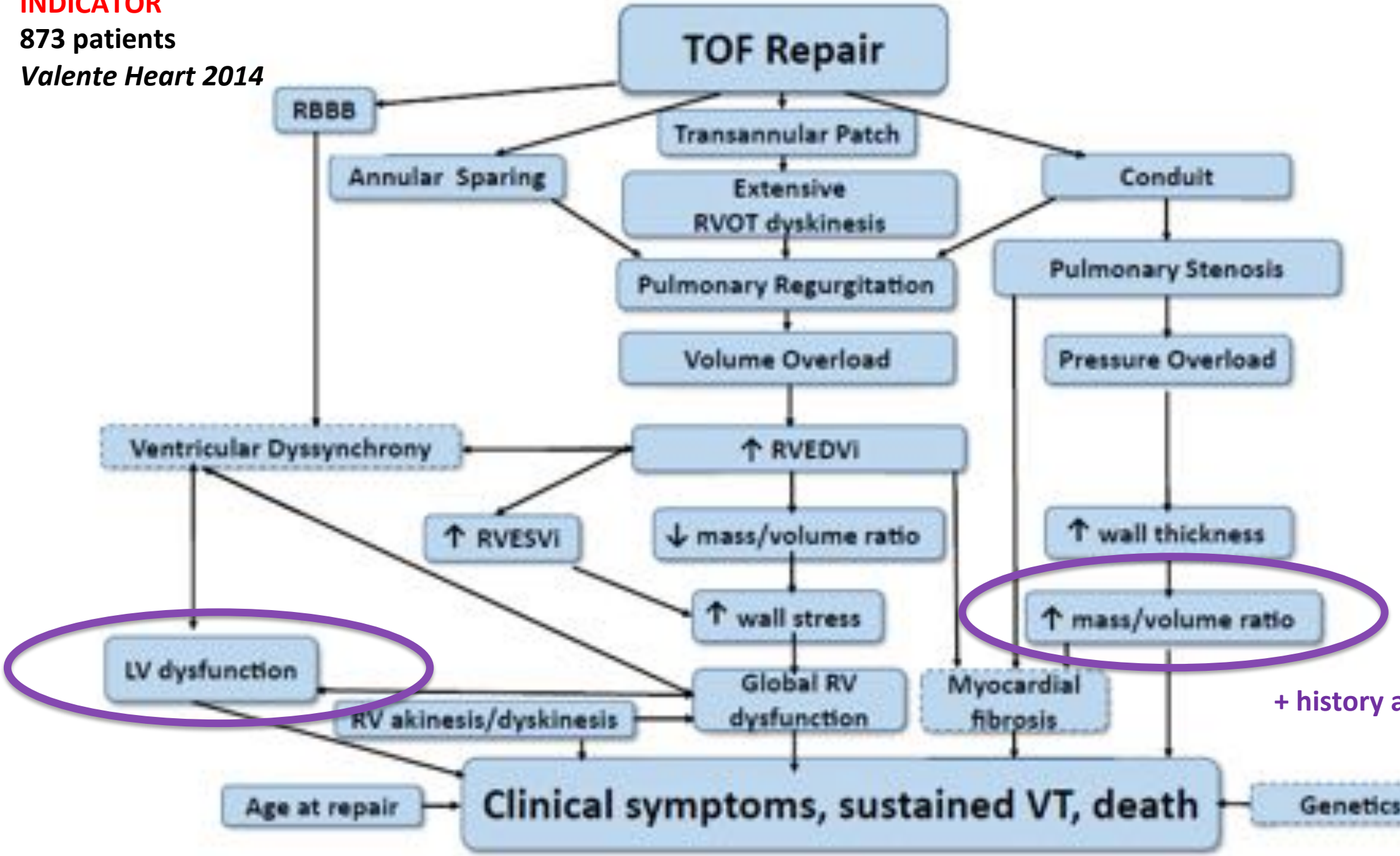
	HR	95% CI	p Value	C index	R^2
All subjects (N=873; 32 outcomes)					
Model 1					
RV mass/volume ratio ≥0.30 (g/mL)	5.04	(2.30 to 11.0)	<0.001	0.832	0.246
LV EF z score <−2.0	3.34	(1.59 to 7.01)	0.001		
History of atrial arrhythmia	3.65	(1.75 to 7.62)	0.001		
Model 2					
RV mass/volume ratio ≥0.30 (g/mL)	4.17	(1.96 to 8.86)	<0.001	0.781	0.215
RV EF z score <−2.0	2.59	(1.19 to 5.64)	0.02		
History of atrial arrhythmia	3.61	(1.77 to 7.34)	<0.001		
Subjects without RV-PA conduits (N=724; 19 outcomes)					
RV mass/volume ratio ≥0.30 (g/mL)	5.58	(1.99 to 15.7)	0.001	0.848	0.278
LV EF z score <−2.0	5.48	(1.96 to 15.4)	0.001		
History of atrial arrhythmia	6.14	(2.36 to 16.0)	<0.001		
Subjects with RV-PA conduits (N=149; 13 outcomes)					
RV mass/volume ratio ≥0.50 (g/mL)	9.31	(2.74 to 31.6)	<0.001	0.799	0.292
LV end-systolic volume index ≥35 (mL/m^2)	5.79	(1.50 to 22.3)	0.01		
Subjects with Doppler data (N=315; 22 outcomes)					
RV mass z score (↑1)	1.08	(1.02 to 1.14)	0.008	0.864	0.362
LV EF z score (↓1)	1.52	(1.19 to 1.94)	0.001		
RV pressure by Doppler (↑10 mm Hg)	1.39	(1.19 to 1.62)	<0.001		

PA, pulmonary artery.

INDICATOR

873 patients

Valente Heart 2014



+ history a. arrhythmias

ORIGINAL RESEARCH ARTICLE

Preoperative Predictors of Death and Sustained Ventricular Tachycardia After Pulmonary Valve Replacement in Patients With Repaired Tetralogy of Fallot Enrolled in the INDICATOR Cohort

Editorial, see p 2116

Tal Geva, MD
Barbara Mulder, MD
Kimberlee Gauvreau, ScD
Sonya V. Babu-Narayan, MBBS
Rachel M. Wald, MD
Kelsey Hickey, BA
Andrew J. Powell, MD
Michael A. Gatzoulis, MD
Anne Marie Valente, MD

BACKGROUND: Risk factors for adverse clinical outcomes have been identified in patients with repaired tetralogy of Fallot before pulmonary valve replacement (PVR). However, pre-PVR predictors for post-PVR sustained ventricular tachycardia and death have not been identified.

METHODS: Patients with repaired tetralogy of Fallot enrolled in the INDICATOR cohort (International Multicenter TOF Registry), a 4-center international cohort study, who had a comprehensive preoperative evaluation and subsequently underwent PVR were included. Preprocedural clinical, ECG, cardiovascular magnetic resonance, and postoperative outcome data were analyzed. Cox proportional hazards multivariable regression analysis was used to evaluate factors associated with time from pre-PVR cardiovascular magnetic resonance until the primary outcome: death, aborted sudden cardiac death, or sustained ventricular tachycardia.

RESULTS: Of the 452 eligible patients (median age at PVR, 25.8 years), 36 (8%) reached the primary outcome (27 deaths, 2 resuscitated death, and 7 sustained ventricular tachycardia) at a median time after PVR of 6.5 years. Cox proportional hazards regression identified pre-PVR right ventricular ejection fraction <40% (hazard ratio, 2.39; 95% CI, 1.18–4.85; P=0.02), right ventricular mass-to-volume ratio ≥0.45 g/mL (hazard ratio, 4.08; 95% CI, 1.57–10.6; P=0.004), and age at PVR ≥28 years (hazard ratio, 3.10; 95% CI, 1.42–6.78; P=0.005) as outcome predictors. In a subgroup analysis of 230 patients with Doppler data, predicted right ventricular systolic pressure ≥40 mm Hg was associated with the primary outcome (hazard ratio, 3.42; 95% CI, 1.09–10.7; P=0.04). Preoperative predictors of a composite secondary outcome, postoperative arrhythmias and heart failure, included older age at PVR, pre-PVR atrial tachyarrhythmias, and a higher left ventricular end-systolic volume index.

CONCLUSIONS: In this observational investigation of patients with repaired tetralogy of Fallot, an older age at PVR and pre-PVR right ventricular hypertrophy and dysfunction were predictive of a shorter time to postoperative death and sustained ventricular tachycardia. These findings may inform the timing of PVR if confirmed by prospective clinical trials.

Key Words: hypertrophy, right ventricular ■ pulmonary valve ■ risk factors ■ tachycardia, ventricular ■ tetralogy of Fallot ■ treatment outcome

Sources of Funding, see page 2114

https://www.ahajournals.org/journal/circ

452 patients

Predictive markers of mort. and Vent. Arrhymtmias after PVR

- **Age at PVR (>= 28 y)**
- **RVEF < 40%**
- **RV Mass /volume >= 0.45g/ml**

What Are the Clinical Implications?

- Indications for pulmonary valve replacement in repaired tetralogy of Fallot have relied on markers of postoperative right ventricular remodeling, with a paucity of information regarding predictors of clinical outcomes.
- This study identified preoperative demographic predictors and imaging biomarkers associated with poor clinical outcomes after pulmonary valve replacement that may be useful for guiding clinical recommendations for valve implantation in this population.

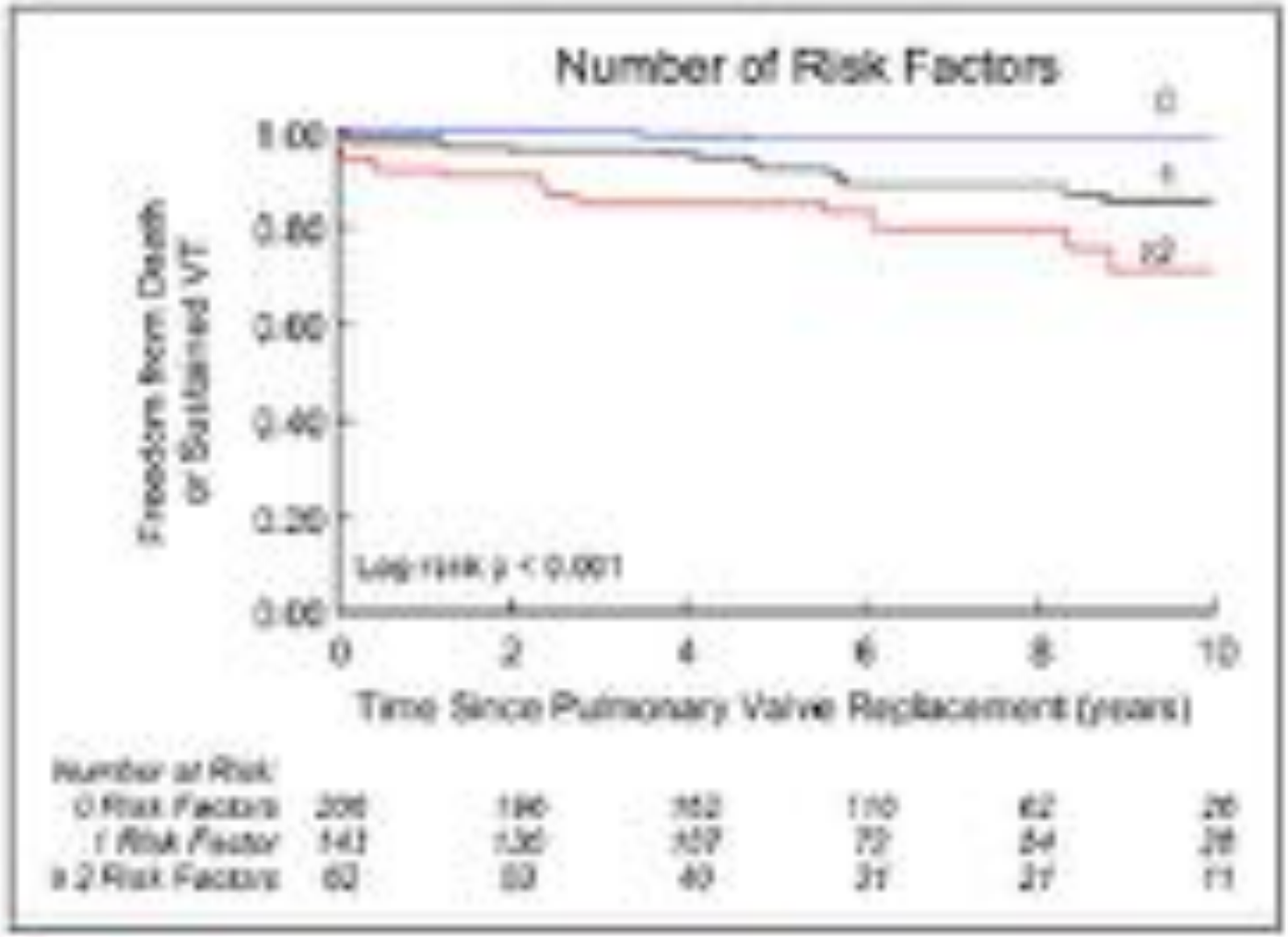


Figure 2. Kaplan-Meier analysis of freedom from death or sustained VT stratified by number of risk factors summed for each patient.

The 3 risk factors for the primary outcome identified by multivariable analysis included RV ejection fraction <40%, RV mass-to-volume ratio ≥45 g/mL, and age at PVR ≥28 years. PVR indicates pulmonary valve replacement; RV, right ventricle; and VT, ventricular tachycardia.

European Heart Journal
doi:10.1093/eurheartj/ehv634

EDITORIAL

Tetralogy of Fallot, pulmonary valve replacement, and right ventricular volumes: are we chasing the right target?

Matthias Greutmann*

Adult Congenital Heart Disease Program, University Heart Center, Zurich, Switzerland

PVR and mortality?

Surgical PVR

- Mortality 0.87% 30d
- 2.2% at 5 y
- 4.9% at 5 y redo PVR

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Congenital Heart Disease

Pulmonary Valve Replacement After Operative Repair of Tetralogy of Fallot

Meta-Analysis and Meta-Regression of 3,118 Patients From 48 Studies

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Cecília Andrade Santos, MD,† Isaac Melo Esmeraldo, MD,† Rodrigo Renda de Escobar, MD,*†
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Recife, Pernambuco, Brazil

Published in final edited form as:
Circulation. 2009 January 27; 119(3): 445–451. doi:10.1161/CIRCULATIONAHA.108.775221.

Pulmonary Valve Replacement in Tetralogy of Fallot: Impact on Survival and Ventricular Tachycardia

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Abstract

Background—Pulmonary valve replacement (PVR) in repaired tetralogy of Fallot (TOF) reduces pulmonary regurgitation and decreases right ventricular (RV) dilation, but its long-term impact on ventricular tachycardia (VT) and mortality is unknown. This study aimed to determine the incidence of death and VT in TOF following PVR and test the hypothesis that PVR leads to improvement in these outcomes.

Methods and Results—A total of 98 patients with TOF and late PVR for RV dilation were identified. Matched controls were identified for 77 of these; controls had TOF with RV dilation but no PVR. Matching was done by age (±2y) and baseline QRS duration (±30msec). There were no significant differences in age, QRS duration, type or decade of initial repair, age at TOF repair, or presence of pre-PVR VT between the two groups; limited echocardiographic and MRI data showed no difference in left ventricular function but more RV dilation among PVR patients than controls. In the PVR group, there were 13 events over 272 patient-years. There was no significant change in QRS duration for any group. Overall 5- and 10-year freedom from death and/or VT was 89% and 41%. In the matched comparison, there were no significant differences seen in VT, death, or combined VT and/or death; $p = 0.32$, 0.06 (nearly favoring controls), 0.21.

Conclusions—This cohort experienced either VT or death every 20 patient-years. In a matched comparison with a similar TOF group, late PVR for symptomatic PR/RV dilation did not reduce the incidence of VT or death.

Keywords

Tetralogy of Fallot; Survival; Arrhythmia; Pulmonary Valve Replacement

What add percutaneous PVR?

SYSTEMATIC REVIEW AND META-ANALYSIS

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

Devenir après RVP percut. Melody

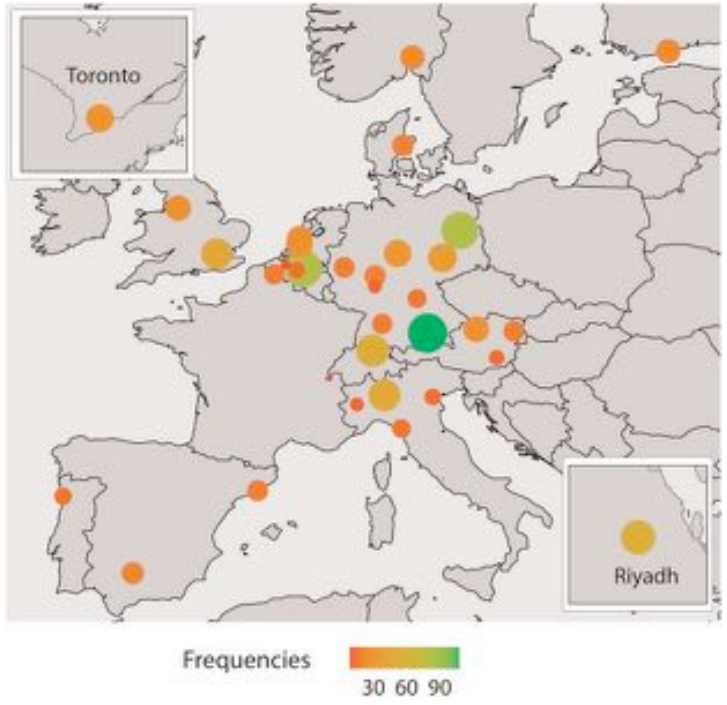
ESC European Society of Cardiology
European Heart Journal (2019) 0, 1–10
doi:10.1093/eurheartj/ehz201

CLINICAL RESEARCH
Congenital heart disease

Acute and midterm outcomes of the post-approval MELODY Registry: a multicentre registry of transcatheter pulmonary valve implantation

Johannes Nordmeyer[1]*, Peter Ewert[2,3,4], Marc Gewillig[5], Mansour AlJufan[6], Mario Carminati[7], Oliver Kretschmar[8], Anselm Uebing[9], Ingo Dähnert[10], Robert Röhle[11], Heike Schneider[12], Maarten Witsenburg[13], Lee Benson[14], Roland Gitter[15], Regina Bökenkamp[16], Vaikom Mahadevan[17], and Felix Berger[1,18,19]; on behalf of the MELODY Registry investigators

845 patients
suivi médian 5.9 ans (0-11 ans)



Melody

Death reoperation
4.2% / patient y

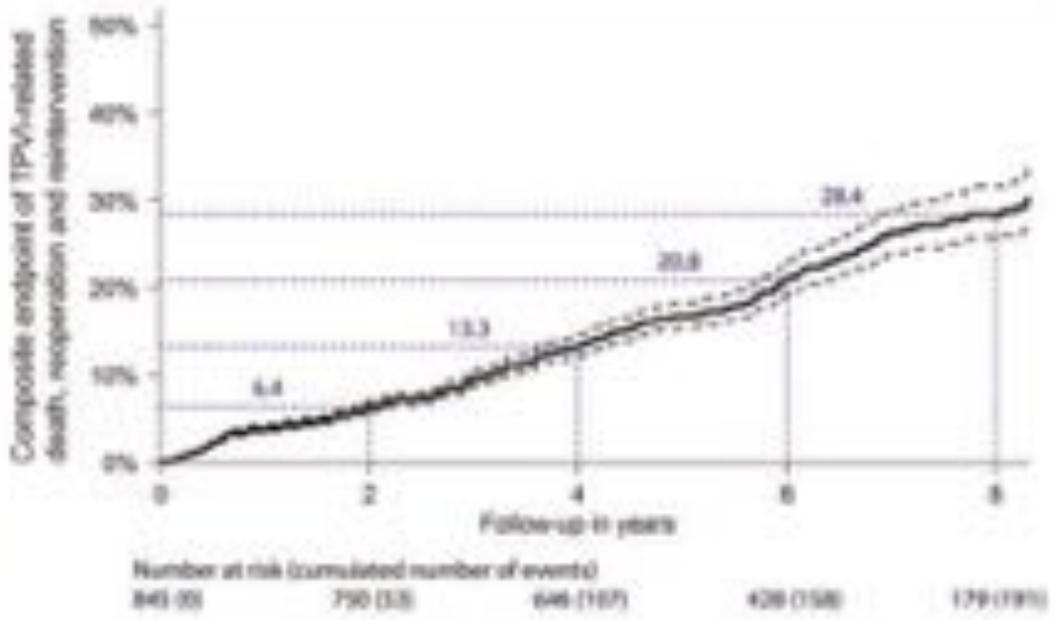


Figure 2 Cumulative incidence plots for the composite endpoint of transcatheter pulmonary valve implantation-related death, reoperation, and reintervention. At 6 years, the cumulative incidence of the composite endpoint was 20.8% (95% confidence interval 19.1–22.8), and at 8 years, the cumulative incidence of the composite endpoint was 28.4% (95% confidence interval 25.6–31.4).

endocarditis
2.3% / patient y

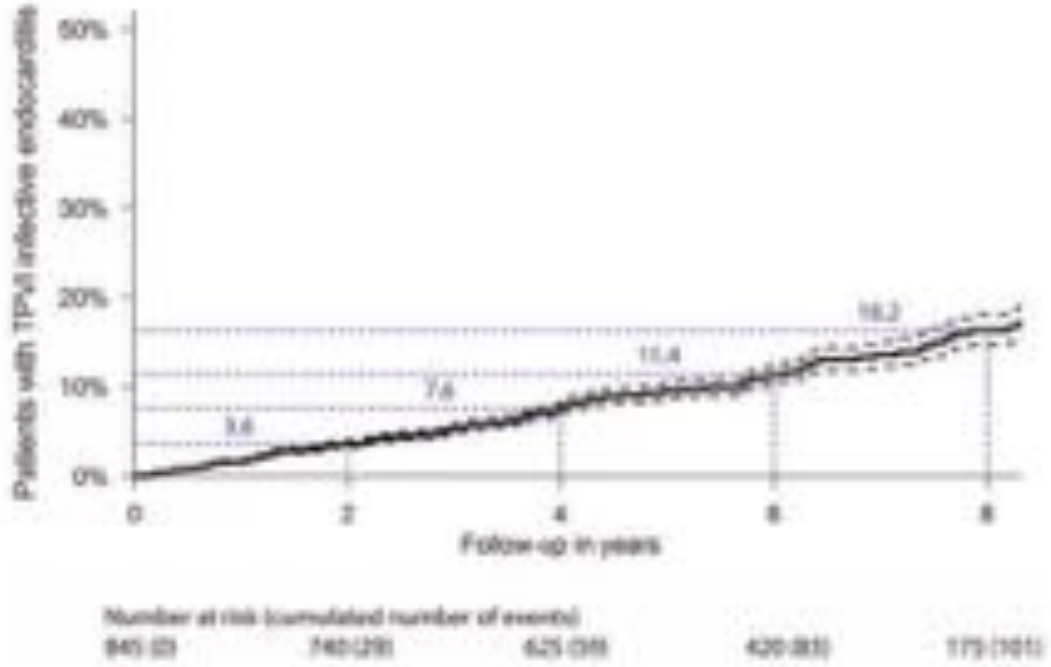


Figure 3 Cumulative incidence plots for transcatheter pulmonary valve implantation infective endocarditis. At 6 years, the cumulative incidence of transcatheter pulmonary valve implantation infective endocarditis was 11.4% (95% confidence interval 10.3–12.5), and at 8 years, the cumulative incidence of transcatheter pulmonary valve implantation infective endocarditis was 16.2% (95% confidence interval 14.6–18.1).

Melody

Table 3 Cox regression model related to the composite endpoint of TPVI-related death, reoperation, and reintervention

Variables	Coefficient	Standard error	Hazard ratio, exp (coefficient)	95% confidence interval		P-value
Calendar year of TPVI procedure*	-0.10	0.05	0.91	0.82	1.01	0.062
Patient age (years)	-0.04	0.01	**0.96**	**0.95**	**0.98**	**0.0001**
Patient gender: female (vs. male)	-0.40	0.16	**0.67**	**0.49**	**0.93**	**0.015**
Lesion: predominant PR (vs. predominant PS)	0.15	0.20	1.16	0.78	1.72	0.453
Lesion: mixed (vs. predominant PS)	-0.05	0.18	0.95	0.67	1.34	0.765
Prestenting: yes (vs. no)	-0.31	0.19	0.73	0.50	1.07	0.104
Size of delivery system: 20 mm (vs. 18 mm)	-0.29	0.20	0.75	0.51	1.10	0.141
Size of delivery system: 22 mm (vs. 18 mm)	-0.52	0.19	**0.59**	**0.41**	**0.86**	**0.006**
Residual RV-to-PA pressure gradient (per 5 mmHg)	0.19	0.04	**1.21**	**1.12**	**1.30**	**<0.0001**

Test for proportional hazard assumption: $P = 0.088$.
Test for goodness-of-fit: $P = 0.416$.
Significant differences in bold.
*2006–2013.

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AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

3-Year Outcomes of the Edwards SAPIEN Transcatheter Heart Valve for Conduit Failure in the Pulmonary Position From the COMPASSION Multicenter Clinical Trial

Damien Kenny, MD, MPH,[a] John F. Rhodes, MD,[b,c] Gregory A. Fleming, MD,[a] Sahil Kar, MD,[a] Evan M. Zahn, MD,[a] Julie Vincent, MD,[a] Girish S. Shirali, MBBS,[a] Jeremy Gurdick, PhD,[a] Mark A. Fogel, MD,[a] John T. Fahey, MD,[a] Dennis W. Kim, MD, PhD,[a] Vasile C. Balaban, MD,[a] Aimee K. Armstrong, MD,[a] Ziyad M. Hijazi, MD, MPH[a]

ABSTRACT

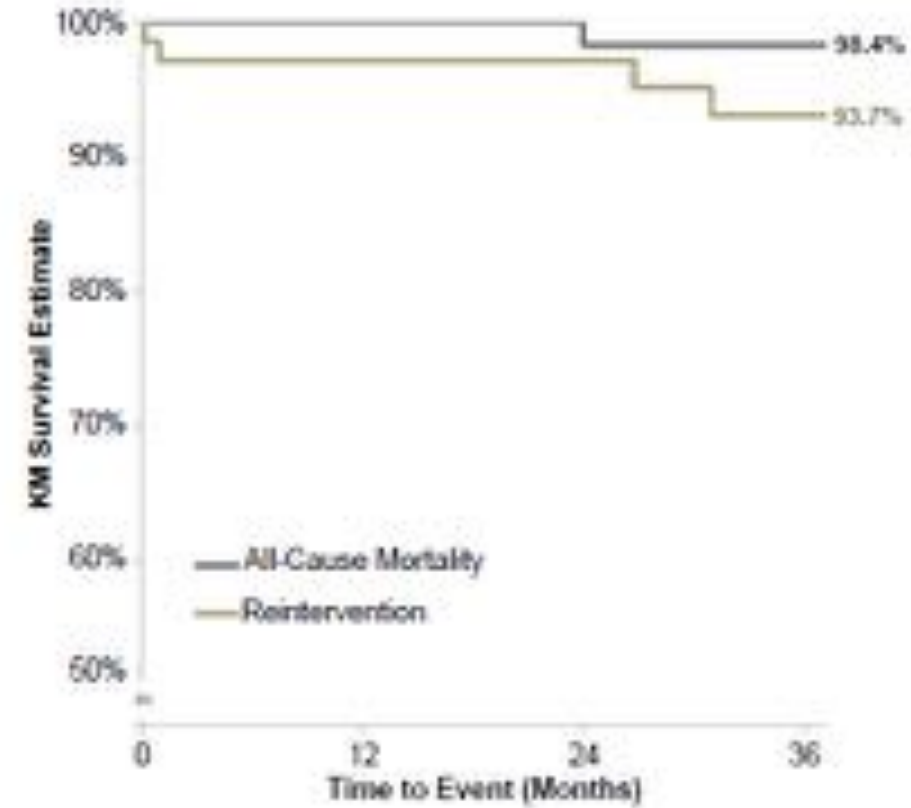
OBJECTIVES This study provides the 3-year follow-up results of the COMPASSION (Congenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the SAPIEN Transcatheter Heart Valve) trial. Patients with moderate to severe pulmonary regurgitation and/or right ventricular outflow tract conduit obstruction were implanted with the SAPIEN transcatheter heart valve (THV).

BACKGROUND Early safety and efficacy of the Edwards SAPIEN THV in the pulmonary position have been established through a multicenter clinical trial.

METHODS Eligible patients were included if body weight was ≥35 kg and in situ conduit diameter was ≥16 and ≤24 mm. Adverse events were adjudicated by an independent clinical events committee. Three-year clinical and echocardiographic outcomes were evaluated in these patients.

RESULTS Fifty-seven of the 63 eligible patients were accounted for at the 3-year follow-up visit from a total of 69 implantations in 87 enrolled patients. THV implantation was indicated for pulmonary stenosis (7.6%), regurgitation (12.7%), or both (79.7%). Twenty-two patients (37.9%) underwent implantation of 26-mm valves, and 47 patients received 23-mm valves. Functional improvement in New York Heart Association functional class was observed in 90.5% of patients. Mean peak conduit gradient decreased from 37.5 ± 20.4 to 17.8 ± 12.4 mm Hg ($p < 0.001$), and mean right ventricular systolic pressure decreased from 59.6 ± 17.7 to 42.9 ± 13.6 mm Hg ($p < 0.001$). Pulmonary regurgitation was mild or less in 91.7% of patients. Freedom from all-cause mortality at 3 years was 98.4%. Freedom from reintervention was 96.7% and from endocarditis was 97.1% at 3 years. There were no observed stent fractures.

CONCLUSIONS Transcatheter pulmonary valve replacement using the Edwards SAPIEN THV demonstrates excellent valve function and clinical outcomes at 3-year follow-up. (J Am Coll Cardiol Intv 2018;11:1820–30)



Expert Review of Medical Devices

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Intermediate outcomes of transcatheter pulmonary valve replacement with the Edwards Sapien 3 valve – German experience

Anja Lehner, Tsvetina Dashkalova, Sarah Ulrich, Silvia Fernandez Rodrigue, Guido Mandilaras, Andre Jakob, Robert Dalla-Pozza, Marcus Fischer, Heike Schneider, Gleb Tarusinov, Christoph Kampmann, Michael Hofbeck, Ingo Dähnert, Majed Kanaan & Nikolaus A. Haas

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE
CLINICAL RESEARCH

Special feature: Percutaneous Pulmonary Valve Implantation

Early outcomes of percutaneous pulmonary valve implantation using the Edwards SAPIEN 3 transcatheter heart valve system

Sebastien Hascoet[1], MD; Robert Dalla Pozza[2], MD; Jamie Bentham[3], MD; Ronald Giacomo Carere[4], MD; Majed Kanaan[5], MD; Peter Ewert[6], MD; Elzbieta Katarzyna Biernacka[7], MD; Oliver Kretschmar[8], MD; Cornelia Deutsch[9], MD; Florence Leroi[10], MD; Anja Lehner[2], MD; Marianos Kantzis[3], MD; Jana Kupusova[3,4], MD; Martin Thoenes[11], MD; Peter Bramlage[1], MD; Nikolaus A. Haas[6*], MD

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WILEY

ORIGINAL STUDIES

Initial results from the off-label use of the SAPIEN S3 valve for percutaneous transcatheter pulmonary valve replacement: A multi-institutional experience

Sanjay Sinha MD[1] | Jamil Aboulhosn MD[1,2] | Jeremy Asnes MD[3] | Martin Bocks MD[4] | Evan Zahn MD[5] | Bryan H. Goldstein MD[6] | Jeffrey Zampi MD[7] | William Hellenbrand MD[3] | Morris Salem MD[8] | Daniel Levi MD[1,2]

SYSTEMATIC REVIEW AND META-ANALYSIS

American Heart Association | American Stroke Association

Infective Endocarditis After Melody Valve Implantation in the Pulmonary Position: A Systematic Review

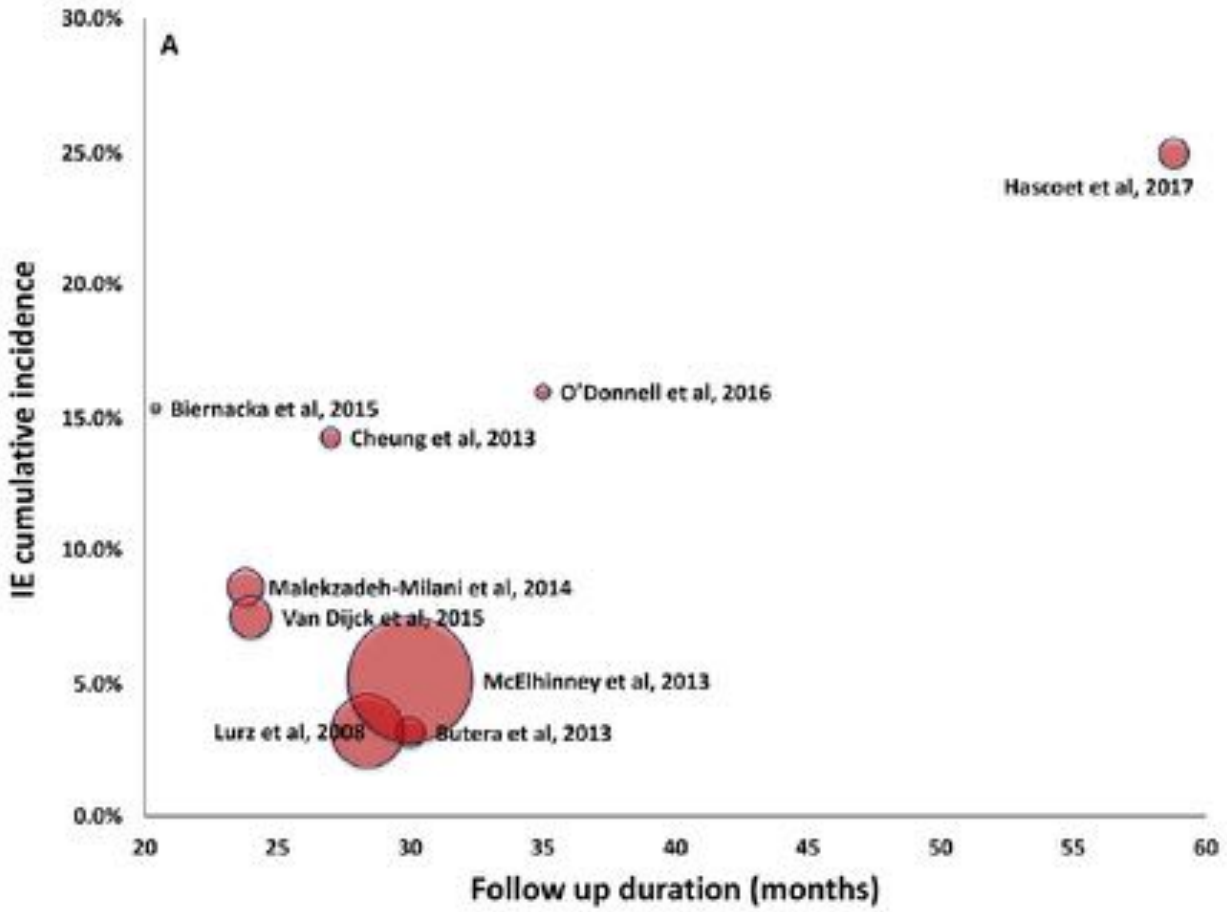
Mohammad Abdelghani, MD; Martina Nassif, MD; Nico A. Blom, MD, PhD; Martijn S. Van Mourik, MSc; Bart Straver, MD, PhD; David R. Koolbergen, MD, PhD; Jolanda Kluin, MD, PhD; Jan G. Tijssen, PhD; Barbara J. M. Mulder, MD, PhD; Berto J. Bouma, MD, PhD; Robbert J. de Winter, MD, PhD

Background—Infective endocarditis (IE) after transcatheter pulmonary valve implantation (TPVI) in dysfunctioning right ventricular outflow tract conduits has evoked growing concerns. We aimed to investigate the incidence and the natural history of IE after TPVI with the Melody valve through a systematic review of published data.

Methods and Results—PubMed, EMBASE, and Web of Science databases were systematically searched for articles published until March 2017, reporting on IE after TPVI with the Melody valve. Nine studies (including 851 patients and 2060 patient-years of follow-up) were included in the analysis of the incidence of IE. The cumulative incidence of IE ranged from 3.2% to 25.0%, whereas the annualized incidence rate ranged from 1.3% to 9.1% per patient-year. The median (interquartile range) time from TPVI to the onset of IE was 18.0 (9.0–30.4) months (range, 1.0–72.0 months). The most common findings were positive blood culture (93%), fever (89%), and new, significant, and/or progressive right ventricular outflow tract obstruction (79%); vegetations were detectable on echocardiography in only 34% of cases. Of 69 patients with IE after TPVI, 6 (8.7%) died and 35 (52%) underwent surgical and/or transcatheter reintervention. Death or reintervention was more common in patients with new/significant right ventricular outflow tract obstruction (69% versus 33%; P=0.042) and in patients with non-streptococcal IE (73% versus 30%; P=0.001).

Conclusions—The incidence of IE after implantation of a Melody valve is significant, at least over the first 3 years after TPVI, and varies considerably between the studies. Although surgical/percutaneous reintervention is a common consequence, some patients can be managed medically, especially those with streptococcal infection and no right ventricular outflow tract obstruction. **(*J Am Heart Assoc.* 2018;7:e008163. DOI: 10.1161/JAHA.117.008163.)**

SYSTEMATIC REVIEW AND META-ANALYSIS



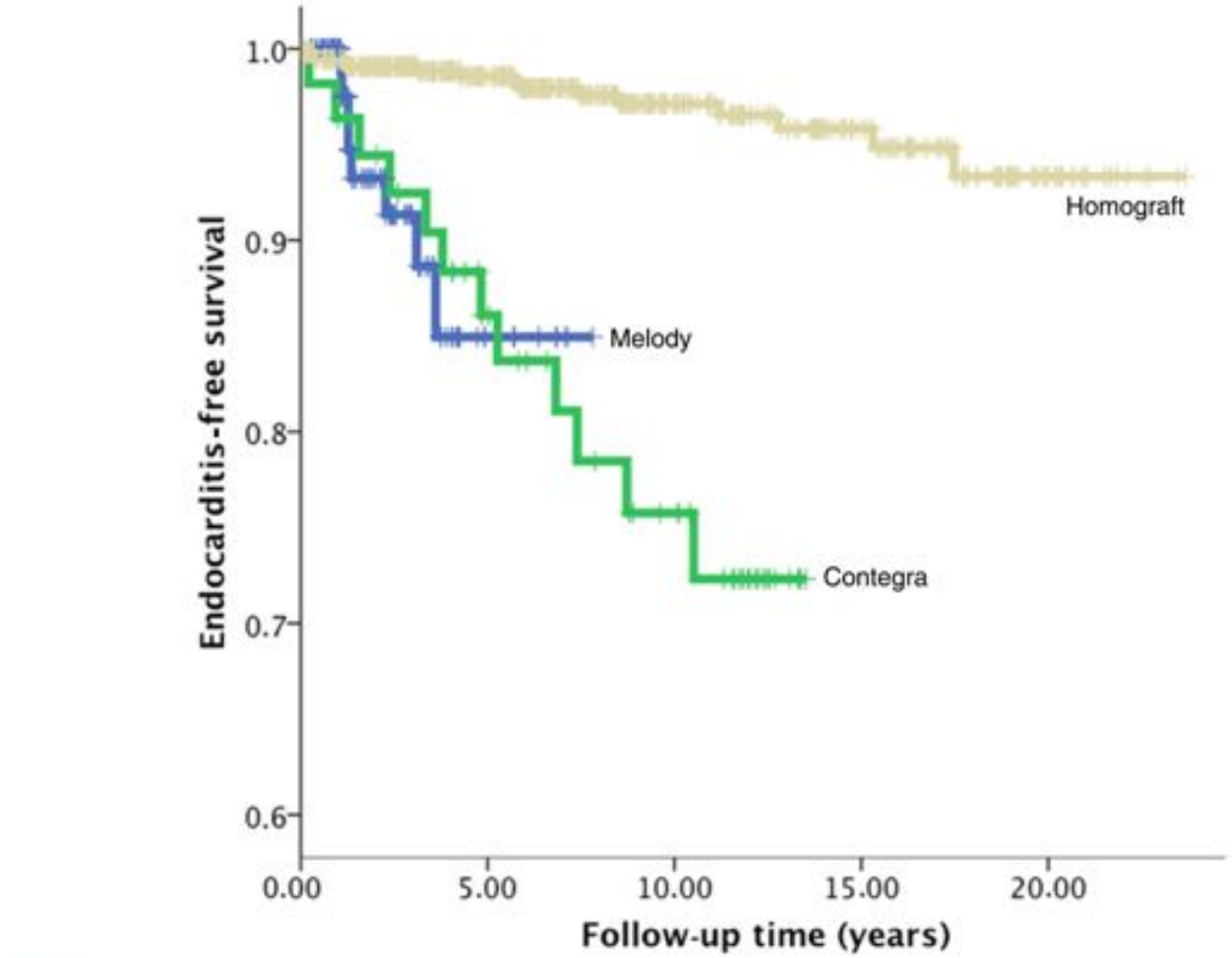
Clinical Perspective

What Is New?

- The risk of infective endocarditis after implantation of the Melody valve is significant, extending at least over the first 3 years after the procedure.
- The diagnosis is challenging, and the modified Duke criteria have a modest diagnostic yield in this setting.
- Approximately 52% of patients require reintervention, either surgically or percutaneously.
- The outcome is favorable when streptococci are the causative organism and the right ventricular outflow tract is not obstructed.

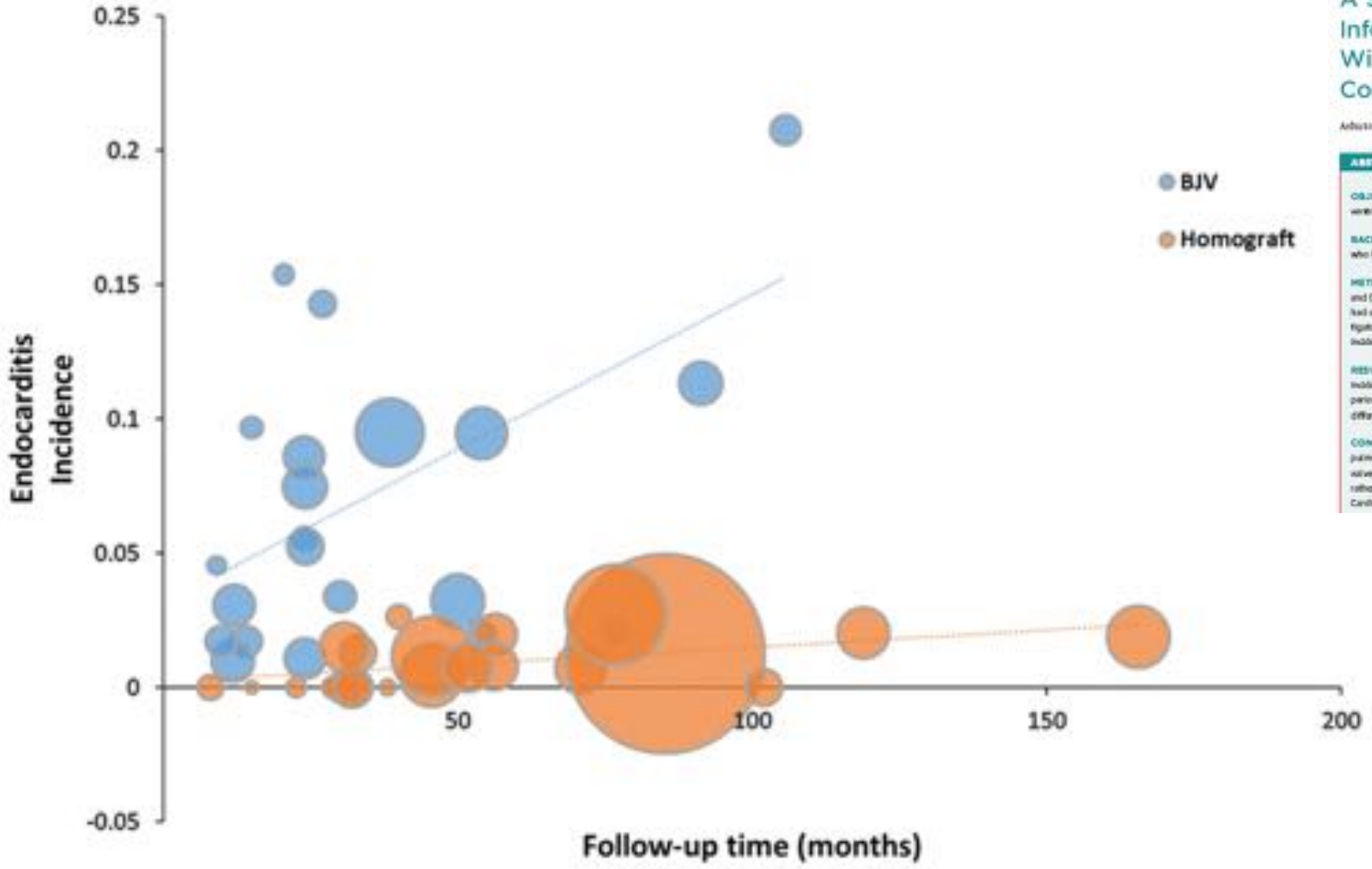
What Are the Clinical Implications?

- More attention should be paid to prevent and early detect infective endocarditis in patients who receive Melody valve implantation.
- Documentation of valvular involvement on echocardiography is challenging, and failure to visualize vegetations should not exclude the diagnosis of infective endocarditis when the clinical suspicion is high.
- The causative organism and the pressure gradient across the valve can be used for risk stratification of the patients.



Homograft	AR	577	342	180	101	27
	IE	0	6	10	12	14
Contegra	AR	54	37	25		
	IE	0	6	10		
Melody	AR	106	11			
	IE	0	8			

Van Dijck, Heart 2015



JACC: CARDIOVASCULAR INTERVENTIONS
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A Systematic Review of Infective Endocarditis in Patients With Bovine Jugular Vein Valves Compared With Other Valve Types

Ashutosh Sharma, BSc,* Alicia T. Cote, PhD,*†‡ Martin C.K. Honking, MD,*† Kevin C. Harris, MD*†

ABSTRACT

OBJECTIVES The aim of this study was to systematically evaluate the incidence of infective endocarditis (IE) in right ventricle-to-pulmonary artery conduits and valves, comparing bovine jugular vein (BJV) valves with all others.

BACKGROUND Recent evidence suggests that the incidence of IE is higher in patients with congenital heart disease who have undergone implantation of BJV valves in the pulmonary position compared with other valves.

METHODS Systematic searches of published research were conducted using electronic databases (MEDLINE, Embase, and CINAHL) and citations cross-referenced current to April 2016. Included studies met the following criteria: patients had undergone right ventricle-to-pulmonary artery conduit or percutaneous pulmonary valve implantation, and investigators reported on the type of conduit or valve implanted, method of intervention (surgery or catheter based), IE incidence, and follow-up time.

RESULTS Fifty studies (Levels of Evidence: 2 to 4) were identified involving 7,063 patients. The median cumulative incidence of IE was higher for BJV compared with other valves (5.4% vs. 1.2%; p < 0.0001) during a median follow-up period of 24.0 and 36.5 months, respectively (p = 0.03). For patients with BJV valves, the incidence of IE was not different between surgical and catheter-based valve implantation (p = 0.82).

CONCLUSIONS There was a higher incidence of endocarditis with BJV valves than other types of right ventricle-to-pulmonary artery conduits. There was no difference in the incidence of endocarditis between catheter-based bovine valves and surgically implanted bovine valves, suggesting that the substrate for future infection is related to the tissue rather than the method of implantation. (J Am Coll Cardiol Intv 2017;10:449–58) © 2017 by the American College of Cardiology Foundation.

Sharma JACC CI 2017

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Review

The risk of infective endocarditis following interventional pulmonary valve implantation: A meta-analysis

Anja Lehner (MD), Nikolaus A. Haas (MD, PhD), Markus Dietl (MSc, PhD)*, Andre Jakob (MD), Ingram Schulze-Neick (MD, PhD), Robert Dalla Pozza (MD, PhD), Silvia Fernandez Rodriguez (MD), Marcus Fischer (MD)

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ABSTRACT

Background: Interventional percutaneous pulmonary valve implantation (PPVI) was first reported in 2000. Today, two different valves are certified for this procedure (i.e. Medtronic Melody® valve (Medtronic, Dublin, Ireland) and Edwards Sapien™ valve (Edwards Lifesciences, Irvine, CA, USA)). For a decade, studies have reported an increasing risk of infective endocarditis (IE) after PPVI; as patients for PPVI are usually younger, even a low annual incidence of IE is important. However, the overall incidence and potential differences between the valves remain unclear.

Methods: A systematic literature search was performed in the databases Medline, Cochrane Library and Embase including the clinical trials register. The aim was to summarize and compare the cumulative incidence of IE after PPVI. Using a sensitivity analysis we set the incidence rates of the two valve types in ratio with a normal population.

Results: A total of 987 publications were identified searching for "pulmonary valve implantation," "PPVI," and 67 publications were used for final analysis. A total 3616 patients with Melody® valves and 501 with Sapien™ valves were included. IE after PPVI occurred in 214 patients with Melody® valves and in 5 patients only with Sapien™ valves. The pooled incidence for Melody® and Sapien™ valves was 4.9% (95% CI: 3.6–6.2) and 1.3% (95% CI: 0.3–2.3), respectively. Chi-square test was significant. The sensitivity analysis showed that the incidence rate ratio was 213.3 (95% CI: 187.6–338.6) for Melody® valves and for Sapien™ valves 2.7 (95% CI: 0.8–8.2).

Conclusions: At present, there is an important difference for the risk of IE after PPVI. To reduce the risk of post PPVI endocarditis, a careful valve selection in favor of the Sapien™ valves seems to be beneficial.

	Melody (n = 3616)	Sapien (n = 501)
Mean age	21 ± 6	23 ± 5
Mean Follow up	35 ± 22 months	23 ± 16 months
IE events (cumulative incidence)	214 (4.9%)	5 (1.3%)
	n = 155	n = 2
Time to IE	20 ± 16 months	2 ± 0 months
Severity stage of IE patients	n = 176	n = 5
Only antibiotic treatment	43%	60%
Cardiac catheterization	15%	–
Explantation by surgery	34%	40%
Death	8%	–
Types of bacteria	n = 141	n = 4
Staphylococcus aureus	28%	25%
Other Staphylococcus	18%	50%
Streptococcus	31%	–
HACEK	7%	25%
Other Gram-positive bacteria	11%	–
Other Gram-negative bacteria	5%	–

IE, infective endocarditis.

3616 melody – 214 IE

Incidence 4.9% (95% CI: 3.6-6.2)

501 Sapien – 5 IE

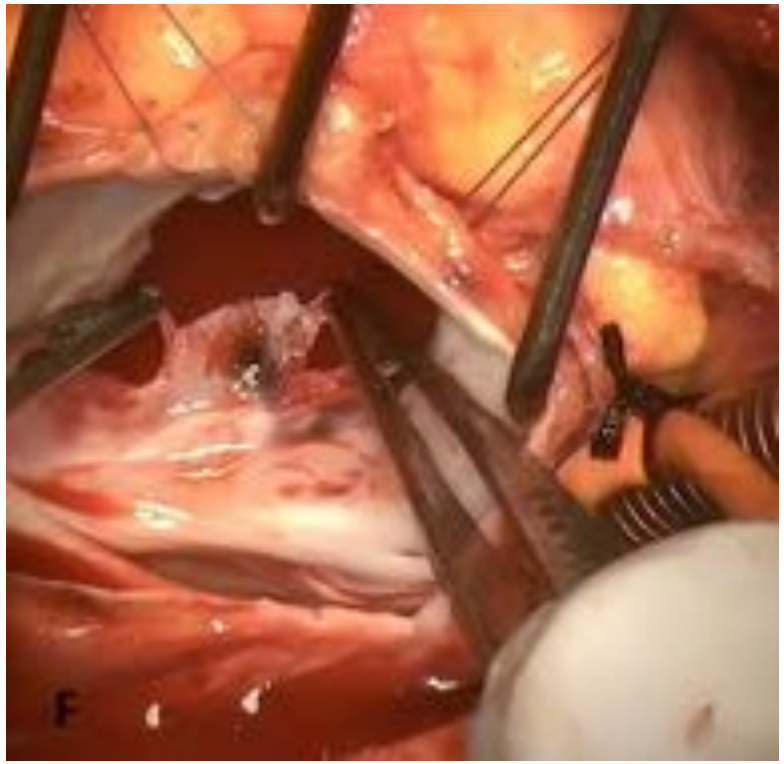
Incidence 1.3% (95% CI: 0.3-2.3)

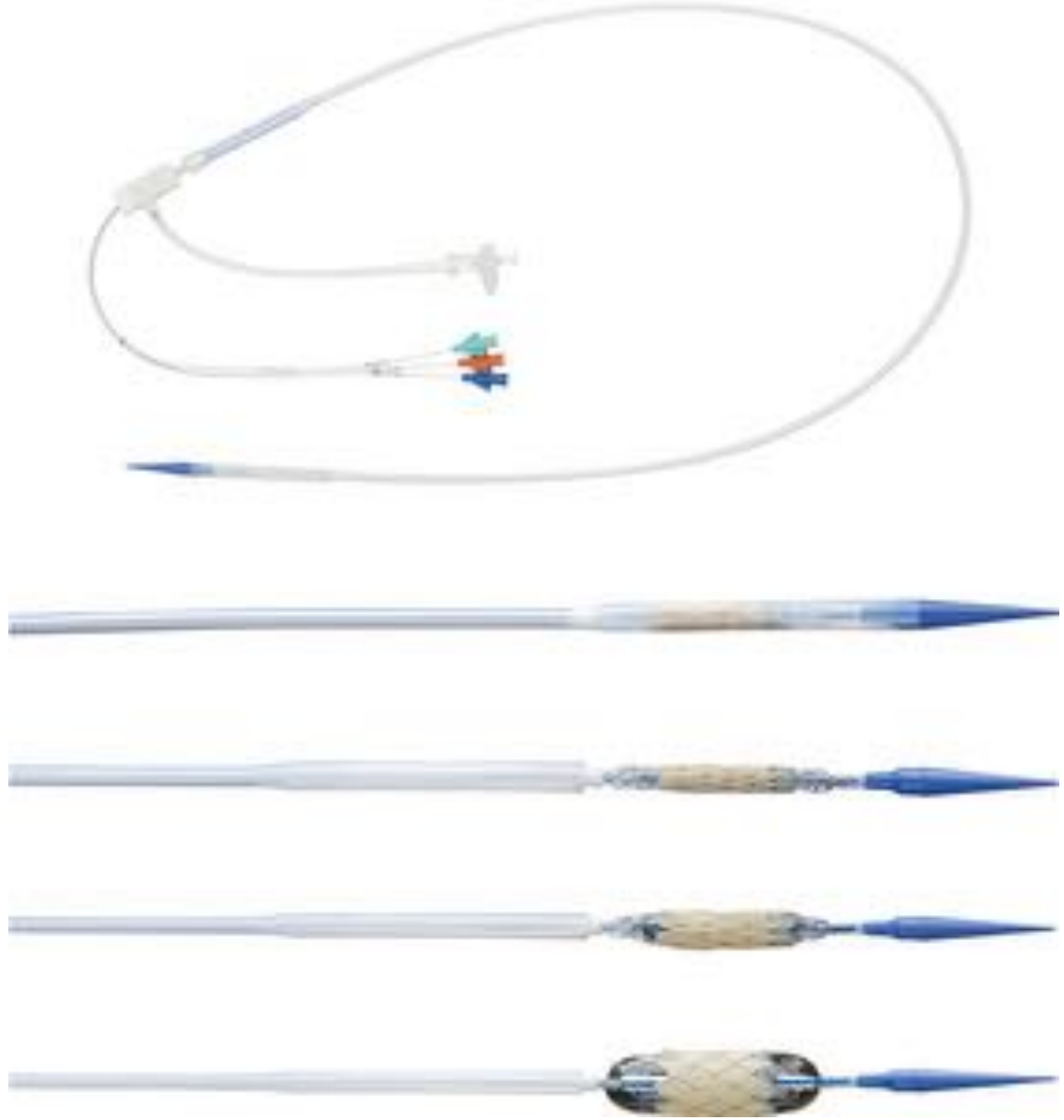
CASE REPORT

WILEY

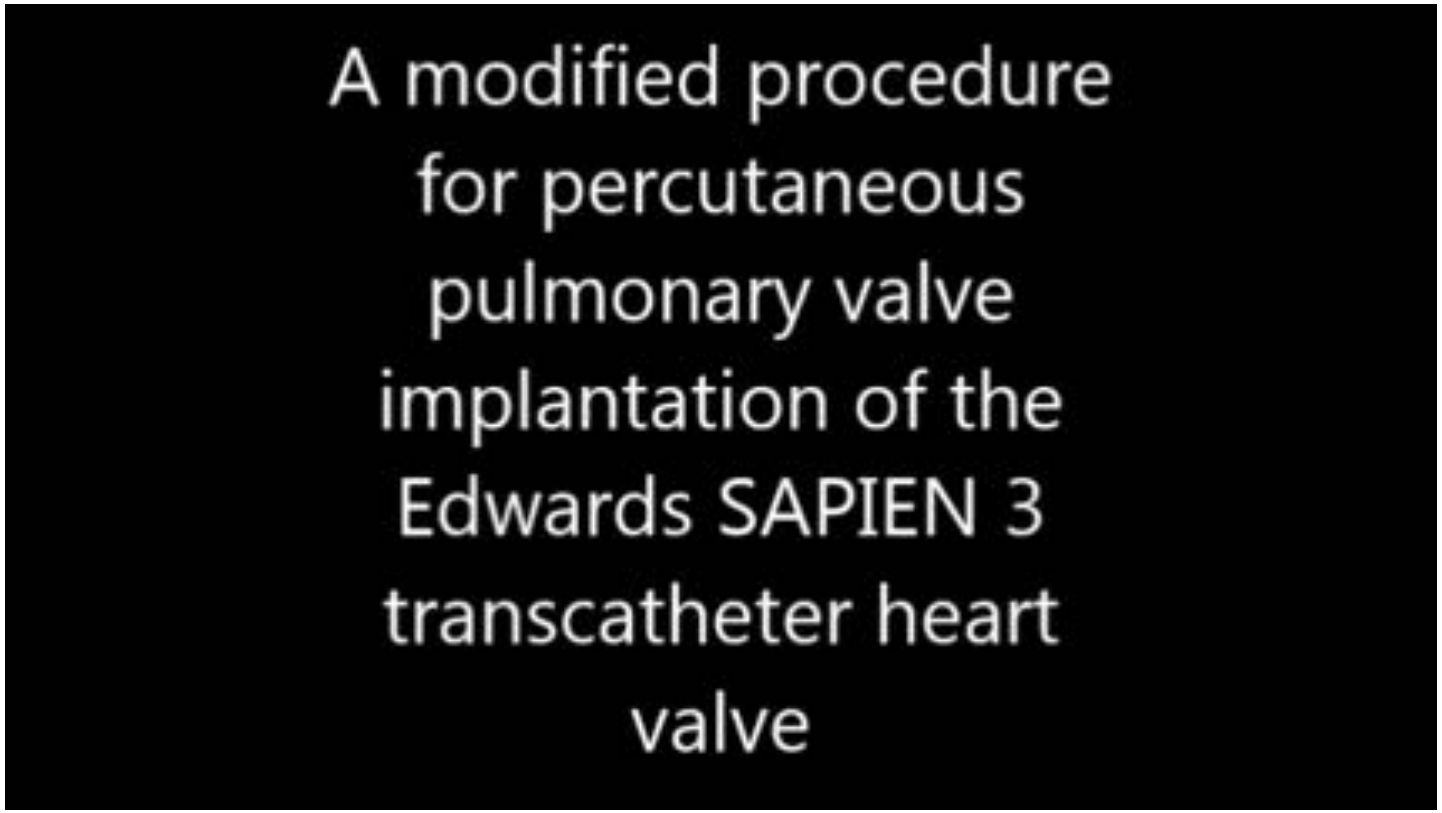
Tricuspid regurgitation as a complication of Edwards Sapien XT valve implantation in pulmonary position a problem to deal with

Alessia Faccini, MD | Gianfranco Butera, MD





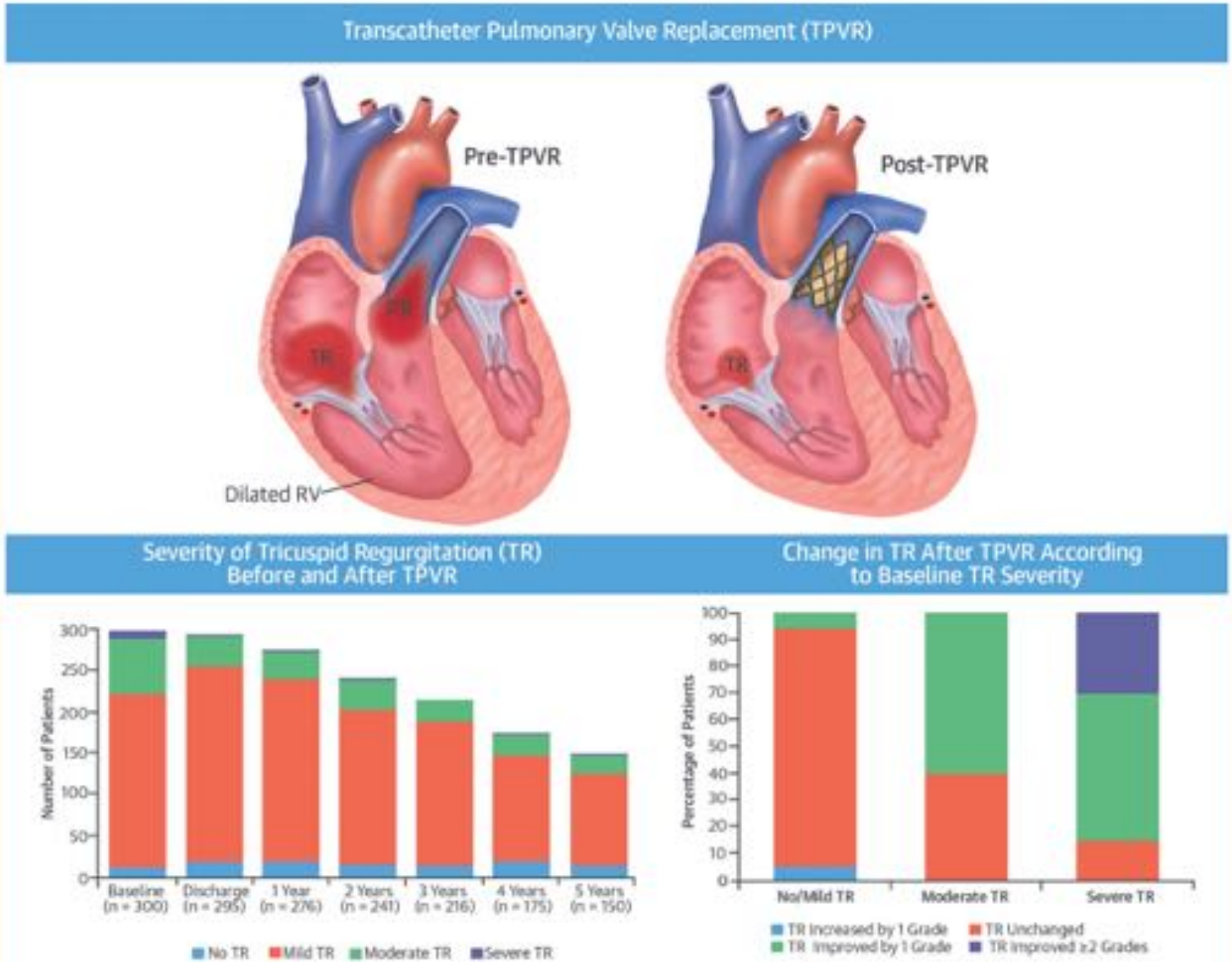
Technique modifiée



Hascoet eurointervention 2019

Tricuspid valve and PVR?

CENTRAL ILLUSTRATION: Impact of Transcatheter Pulmonary Valve Replacement in Tricuspid Regurgitation



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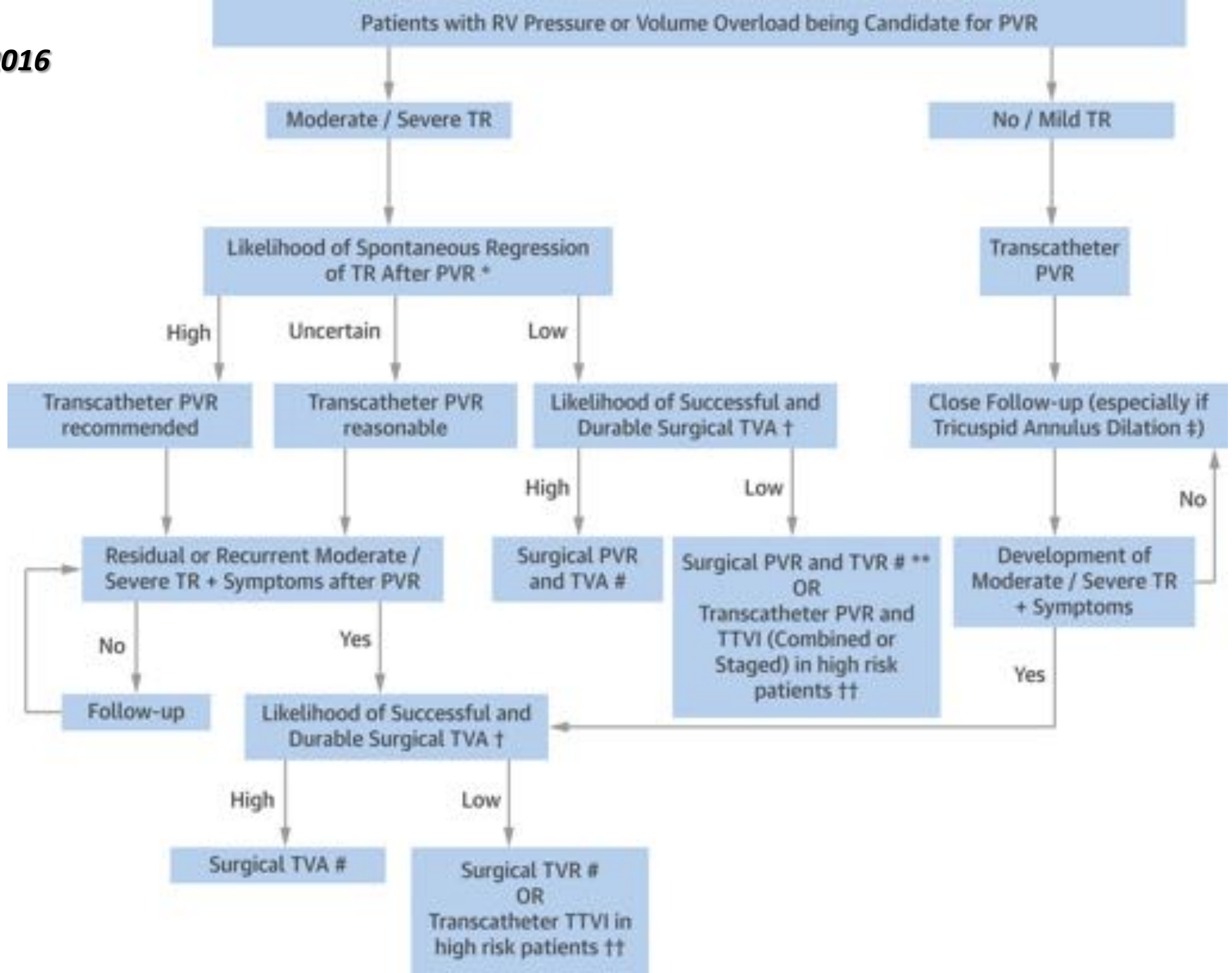
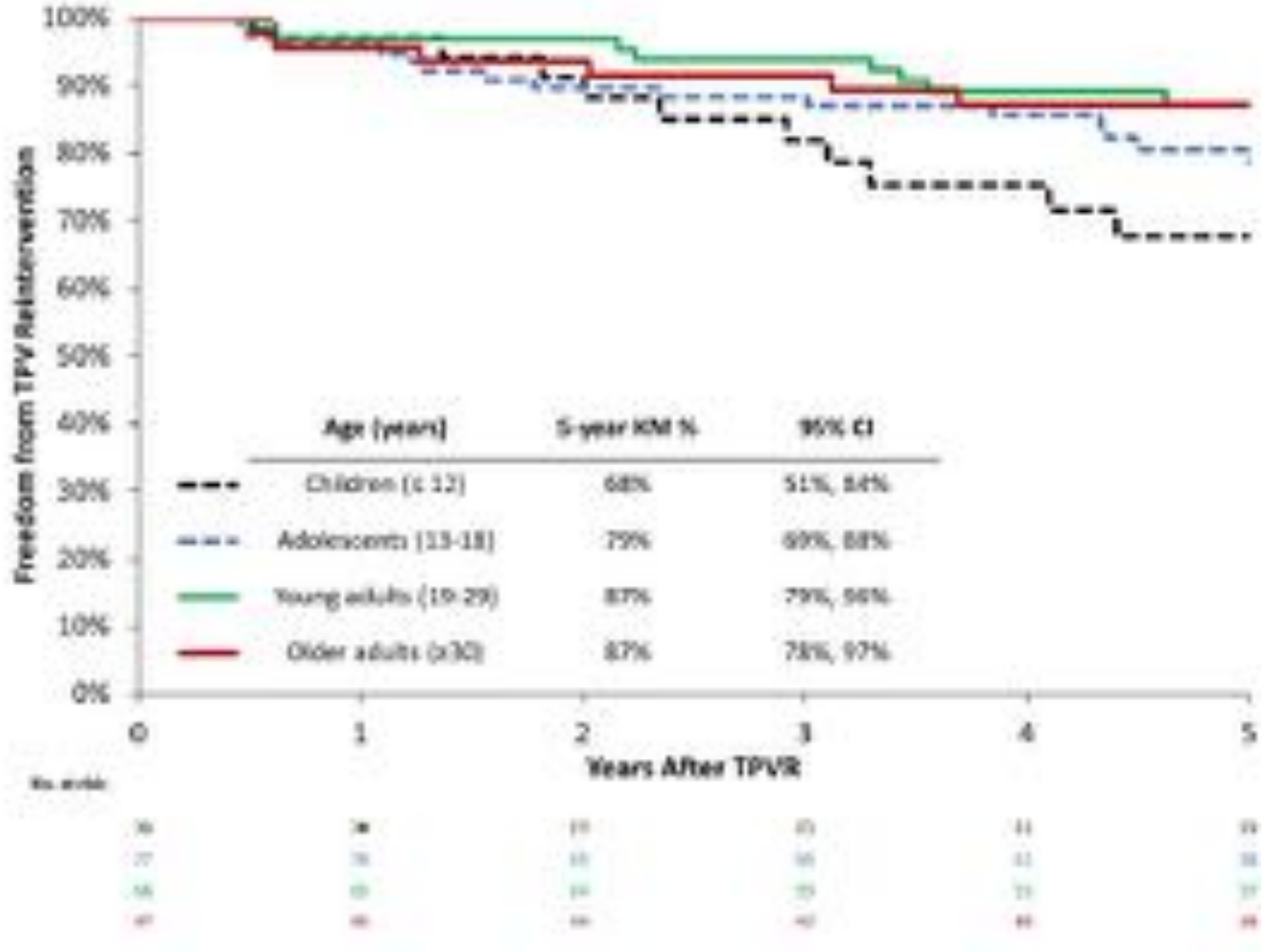


Age at PVR ?



Association between patient age at implant and outcomes after transcatheter pulmonary valve replacement in the multicenter Melody valve trials

Aimee K. Armstrong et al., catheterization and cardiovascular interventions, may 2019

Interactive CardioVascular and Thoracic Surgery (2017) 1–7
doi:10.1093/icvts/ivx118

ORIGINAL ARTICLE

Cite this article as: Dobbels B, Herregods M-C, Troost E, Van De Bruaene A, Rega F, Budts W et al. Early versus late pulmonary valve replacement in patients with transannular patch-repaired tetralogy of Fallot. Interact CardioVasc Thorac Surg 2017; doi:10.1093/icvts/ivx118.

Early versus late pulmonary valve replacement in patients with transannular patch-repaired tetralogy of Fallot

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Abstract

OBJECTIVES: Although the effects of pulmonary regurgitation after tetralogy of Fallot repair are detrimental, timing of pulmonary valve replacement (PVR) is unclear. Our goal was to evaluate the midterm efficacy and safety of early PVR.

METHODS: Patients with tetralogy of Fallot who underwent repair from 1962 to 2015 were included from the local database. Statistical analyses compared patients who underwent early PVR (age ≤16 years), late PVR and no PVR. The timing of the intervention was compared for efficacy—all-cause mortality and the combined end-point of all-cause mortality, ventricular tachycardia and defibrillator implantation—and for safety—the combined end-point of 1-year postoperative mortality after PVR, endocarditis and reintervention. Echocardiographic and electrocardiographic data at the last follow-up examination were compared across the 3 groups.

RESULTS: Two hundred seventy-three patients (age 21 ±5 years; 52% female) were included. The mean follow-up was 24 (95% confidence interval 22.7–26.2) years; the observed median was 21 years (interquartile range 11–31). No significant difference in survival was found between the early PVR ($n = 106$; 39%), the late PVR ($n = 47$; 17%) and the no PVR groups ($n = 120$; 44%) ($P = 0.990$). No significant difference in the combined efficacy end-point was noted between patients who underwent early PVR compared with patients who underwent late PVR ($P = 0.247$). Worse event-free survival for the 3-point safety end-point was observed after early PVR ($P < 0.001$). Right ventricular morphology ($P < 0.001$) and function ($P < 0.001$) were better preserved in the patient group that underwent PVR before the age of 16 years.

CONCLUSIONS: As expected, PVR-related morbidity was higher in patients who underwent early PVR but the midterm outcome was similar. Nevertheless, better preservation of right ventricular morphology and function in the early PVR group might result in better long-term survival.

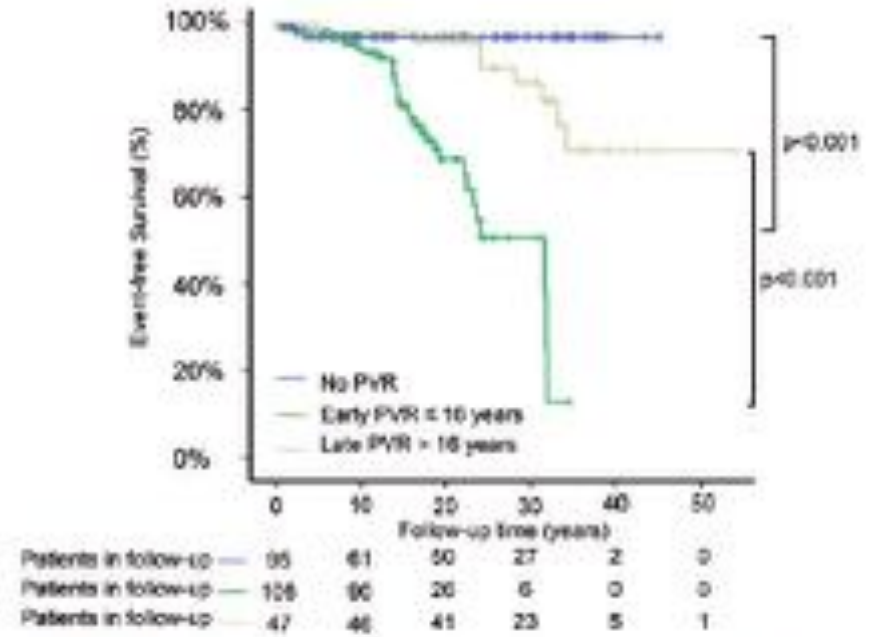

Figure 4: Kaplan–Meier event-free survival curve for the combined safety end-point of 1-year mortality after pulmonary valve replacement (PVR), endocarditis and redo pulmonary valve replacement.

Original Studies

Right Ventricular Remodelling after Transcatheter Pulmonary Valve Implantation: Time Matters!

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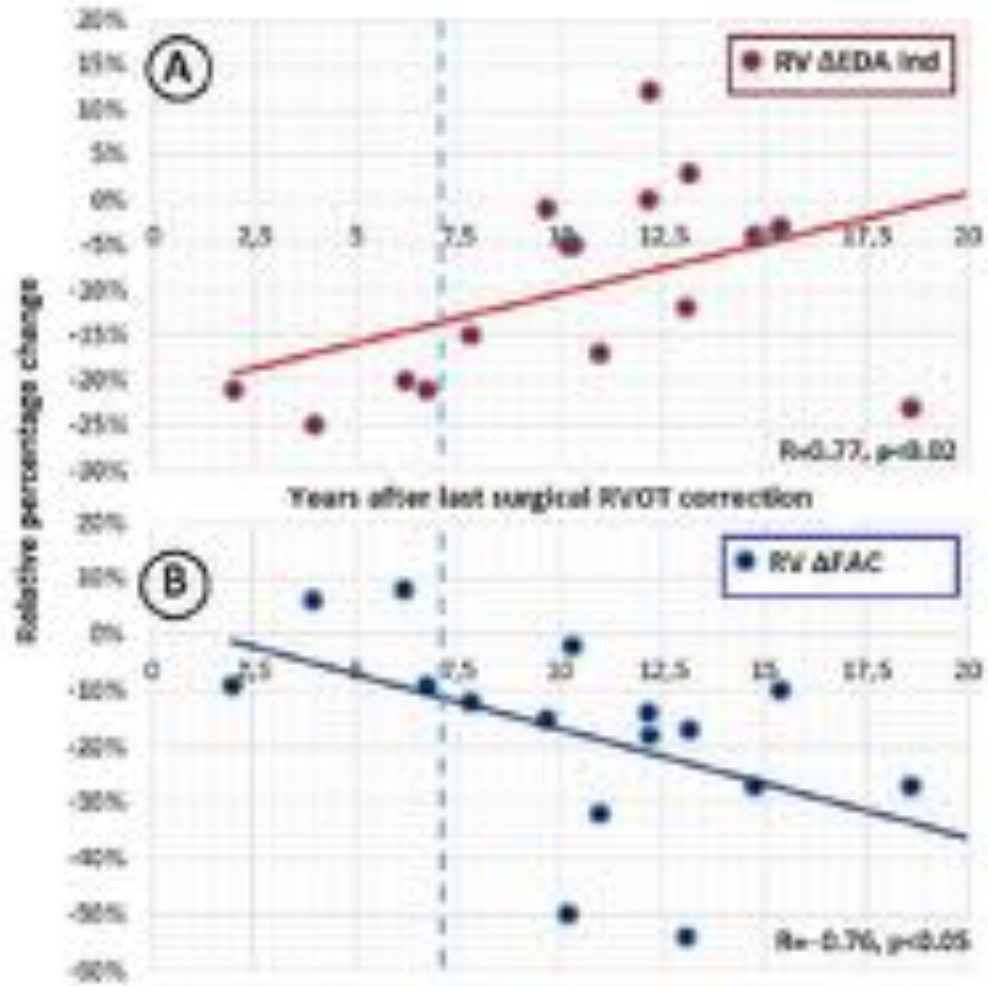
Objectives: To define the optimal timing for percutaneous pulmonary valve implantation (PPVI) in patients with severe pulmonary regurgitation (PR) after Fallot's Tetralogy (ToF) correction. Background: PPVI among the aforementioned patients is mainly driven by symptoms or by severe right ventricular (RV) dilatation/dysfunction. The optimal timing for PPVI is still disputed. Methods: Twenty patients [age 13.8 ± 9.2 years, (range 4.3–44.9), male 70%] with severe PR (≥3 grade) secondary to previous correction of ToF, underwent Melody valve (Medtronic, Minneapolis, MN) implantation, after a pre-stent placement. Full echocardiographic assessment (traditional and deformation analysis) and cardiovascular magnetic resonance evaluation were performed before and at 3 months after the intervention. 'Favorable remodelling' was considered the upper quartile of RV size decrease (>20% in 3 months). Results: After PPVI, indexed RV effective stroke volume increased from 38.4 ± 9.5 to 51.4 ± 10.7 mL/m², ($P = 0.000$), while RV end-diastolic volume and strain indices decreased (123.1 ± 24.1–101.5 ± 18.3 mL/m², $P = 0.000$ and −23.5 ± 2.5 to −21 ± 2.2%, $P = 0.002$, respectively). After inserting pre-PPVI clinical, RV volumetric and deformation parameters in a multiple regression model, only time after last surgical correction causing PR remained as significant regressor of RV remodelling ($R^2 = 0.60$, beta = 0.397, 95%CI(0.07–0.7), $P = 0.019$). Volume reduction and functional improvement were more pronounced in patients treated with PPVI earlier than 7 years after last RV outflow tract (RVOT) correction, reaching close-to-normal values. Conclusions: Early PPVI (<7 years after last RVOT operation) is associated with a more favorable RV reverse remodelling toward normal range and should be considered, before symptoms or RV damage become apparent.

Key words: transcatheter valve implantation; right ventricular function; imaging TEE/TTE; imaging cardiac magnetic resonance imaging; congenital heart disease adults



ORIGINAL RESEARCH ARTICLE

Preoperative Predictors of Death and Sustained Ventricular Tachycardia After Pulmonary Valve Replacement in Patients With Repaired Tetralogy of Fallot Enrolled in the INDICATOR Cohort

Editorial, see p 2116

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Barbara Mulder, MD
Kimberlee Gauvreau, ScD
Sonya V. Babu-Narayan, MBBS
Rachel M. Wald, MD
Kelsey Hickey, BA
Andrew J. Powell, MD
Michael A. Gatzoulis, MD
Anne Marie Valente, MD

BACKGROUND: Risk factors for adverse clinical outcomes have been identified in patients with repaired tetralogy of Fallot before pulmonary valve replacement (PVR). However, pre-PVR predictors for post-PVR sustained ventricular tachycardia and death have not been identified.

METHODS: Patients with repaired tetralogy of Fallot enrolled in the INDICATOR cohort (International Multicenter TOF Registry), a 4-center international cohort study, who had a comprehensive preoperative evaluation and subsequently underwent PVR were included. Preprocedural clinical, ECG, cardiovascular magnetic resonance, and postoperative outcome data were analyzed. Cox proportional hazards multivariable regression analysis was used to evaluate factors associated with time from pre-PVR cardiovascular magnetic resonance until the primary outcome: death, aborted sudden cardiac death, or sustained ventricular tachycardia.

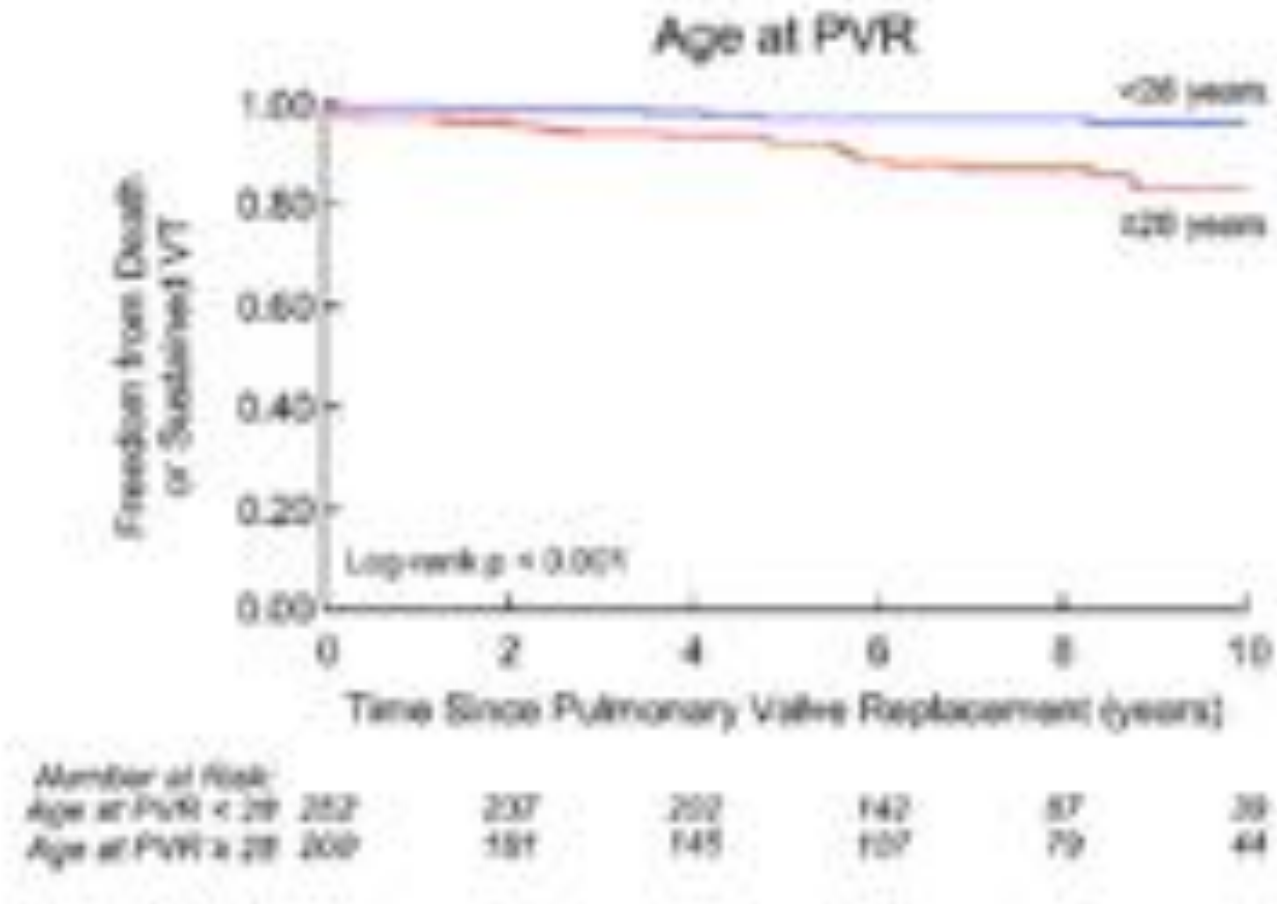
RESULTS: Of the 452 eligible patients (median age at PVR, 25.8 years), 36 (8%) reached the primary outcome (27 deaths, 2 resuscitated death, and 7 sustained ventricular tachycardia) at a median time after PVR of 6.5 years. Cox proportional hazards regression identified pre-PVR right ventricular ejection fraction <40% (hazard ratio, 2.39; 95% CI, 1.18–4.85; P=0.02), right ventricular mass-to-volume ratio ≥0.45 g/mL (hazard ratio, 4.08; 95% CI, 1.57–10.6; P=0.004), and age at PVR ≥28 years (hazard ratio, 3.10; 95% CI, 1.42–6.78; P=0.005) as outcome predictors. In a subgroup analysis of 230 patients with Doppler data, predicted right ventricular systolic pressure ≥40 mm Hg was associated with the primary outcome (hazard ratio, 3.42; 95% CI, 1.09–10.7; P=0.04). Preoperative predictors of a composite secondary outcome, postoperative arrhythmias and heart failure, included older age at PVR, pre-PVR atrial tachyarrhythmias, and a higher left ventricular end-systolic volume index.

CONCLUSIONS: In this observational investigation of patients with repaired tetralogy of Fallot, an older age at PVR and pre-PVR right ventricular hypertrophy and dysfunction were predictive of a shorter time to postoperative death and sustained ventricular tachycardia. These findings may inform the timing of PVR if confirmed by prospective clinical trials.

Key Words: hypertrophy, right ventricular ■ pulmonary valve ■ risk factors ■ tachycardia, ventricular ■ tetralogy of Fallot ■ treatment outcome

Sources of Funding, see page 2114

https://www.ahajournals.org/journal/circ



Circulation. 2018;138:2106–2115. DOI: 10.1161/CIRCULATIONAHA.118.034740

Conclusion : PVR timing

- **not too late:**
  - **Exercise intolerance**
  - **Arrhythmia V & A**
  - **Irreversible Ventricular damage**
  - **Premature death**
- **not too early:**
  - **Procedural risk**
  - **Events due to conduit: dysfunction, IE**
  - **Repeated replacements due to limited longevity: •δ n°/lifetime ?**

Synthèse: propositions d'indications….
À débattre

- Patients symptomatiques
- Patients « faussement » asymptomatiques / altération EE – VO2
- Patients asymptomatiques avec fuite pulmonaire libre et
  - VTDVD> 150 mL/m² / RVESVi > 80 mL/m² avec notion d'évolutivité
  - FEVD< 45% ou dysfunction VG
  - IT
  - Arythmies soutenues
  - Sténoses de branche
- Patients asymptomatiques avec Élévation PVDS > 80 mmHg ou 2/3 pression systémique

Éléments modulateurs

- Âge (environ 16-28 ans)
- Diamètre voie pulmonaire : valve de taille adulte - 23 mm
- Faisabilité de la revalvulation pulmonaire percutanée

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Remplacement valvulaire pulmonaire : indications.