

Long-term experience with percutaneous pulmonary valve implantation (PPVI) Lessons we have learned

Andreas Eicken

Deutsches Herzzentrum München, Klinik für Kinderkardiologie und
angeborene Herzfehler, Technische Universität München

Kairo 2018





TAVI
2002, Cribier, Rouen




PPVI 2000
Bonhoeffer, Paris

Bonhoeffer P, Lancet. 2000 Oct 21;356(9239):1403-5
Cribier A, Circulation. 2002 Dec 10;106(24):3006-8

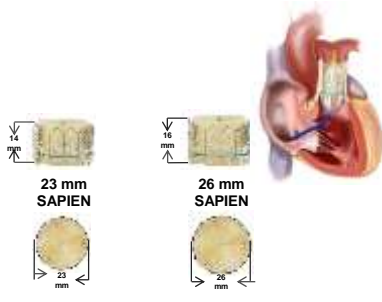
Kairo 2018


Percutaneous valves



18, 20, and 22 mm
double alloons





Melody TPV n >11.000



Edwards Sapien valves n >300




Kairo 2018



PPVI Melody valve


2000	1st percutaneous pulmonary valve Implantation, prototype
2003	1st PPVI with Melody in definite design
2005	1 st cohort for CE mark (59 Pat.), Khambadkone S.Circulation 2005;112(8):1189-97
2005	100. Patient
2006	CE-mark + approval in Canada 12/2006 1 st Patient in München
2010	FDA-approval

Kairo 2018




Indication for PPVI at DHM




- Severe RVOT obstruction with no or mild PR, and:
- Symptoms related to RVOT obstruction (<65% of expected or a significant decrease in exercise tolerance) plus a peak Doppler velocity at the tricuspid valve > 3,5 m/s or
- No symptoms + RV pressure > 4,3 m/s (measured at tricuspid regurgitation), > 2/3 systemic pressure in the right ventricle.
- Severe pulmonary regurgitation, with right ventricular end-diastolic volume index > 150 ml/m² by cMRI .
- Adequate RVOT conduit/vessel size to accommodate a valved stent.
- Adequate body size (no real lower limit, but usually > 20kg).

Kairo 2018





PPVI Experience DHM



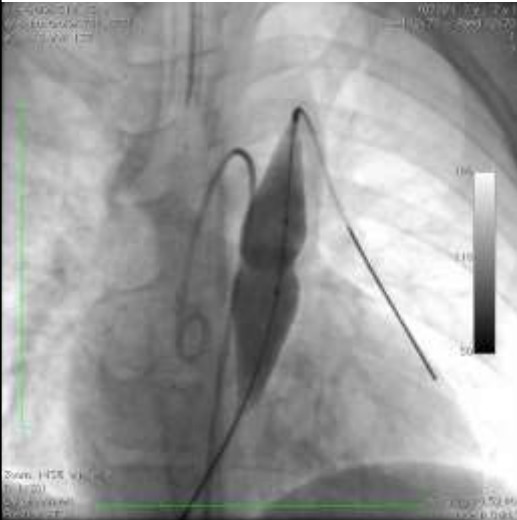


12/2006-02/2018 n = 243 patients
valve-in-valve n = 4

age median (y)	18.5 (4.1-78.9)
weight (kg)	59.0 (19 -176)
Gender	f = 85, m = 158
OP	2 (1-6)
diagnosis	TOF/PA 121, TAC 41, TGA 20, AoVS 28, other 33
conduit	Homograft 166, none 26, Hancock 7, Shelhigh 4, Matrix 1, Contegra 11, other 28
Valve position	PaV 243, (TrV 21, TCPC 1, other 1, MiV 1)
valve	Melody 226, Sapien 23 n = 4 Sapien 26 n = 9; Sapien 29 n = 4

Kairo 2018

		PPVI/PTVI			
247 valves/243 pts since 12/2006					
censored by OP (15), valve-in.valve (4) or death (6); 25/247 (10 %)					
Incidents:					
1.endocarditis	17 patients – 19 episodes of IE (7%)				
	medical				11
	OP				8
	total patient years up to now 922 years				
	Annual incidence of IE 1.9%/patient year				
2.Stenosis	11 (5%)				
Cath.	Re balloon dilatation with valve in valve				4
OP	outgrowth (all non dilatable conduits)				7
3.death	periprocedural 2/247 (0.8%)				
	coronary	1			
	Rvot rupture	1			
Heart failure	2				
SCD	2				
Kairo 2018					

		Coronary compression			
					
„positive“ balloontest after Ross-Konno OP					
„balloon interrogation“					
Kairo 2018					






RVOT rupture

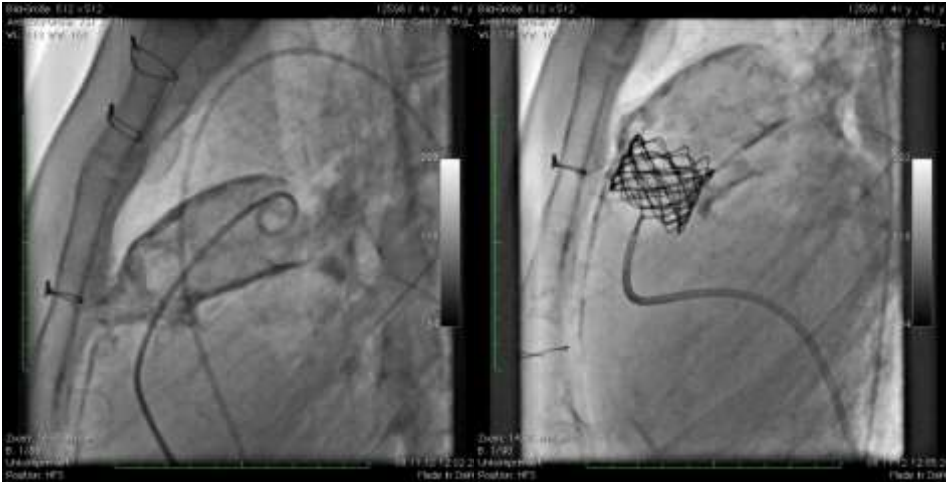
Aggressive ballooning of a calcified conduit may lead to severe, uncontrollable bleeding



Kairo 2018

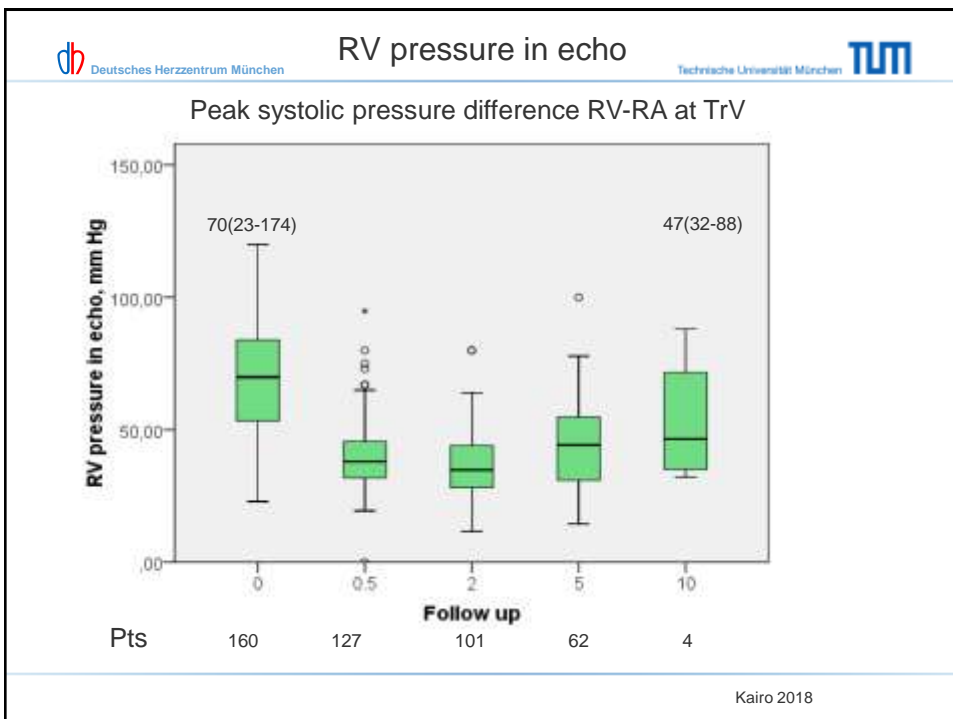



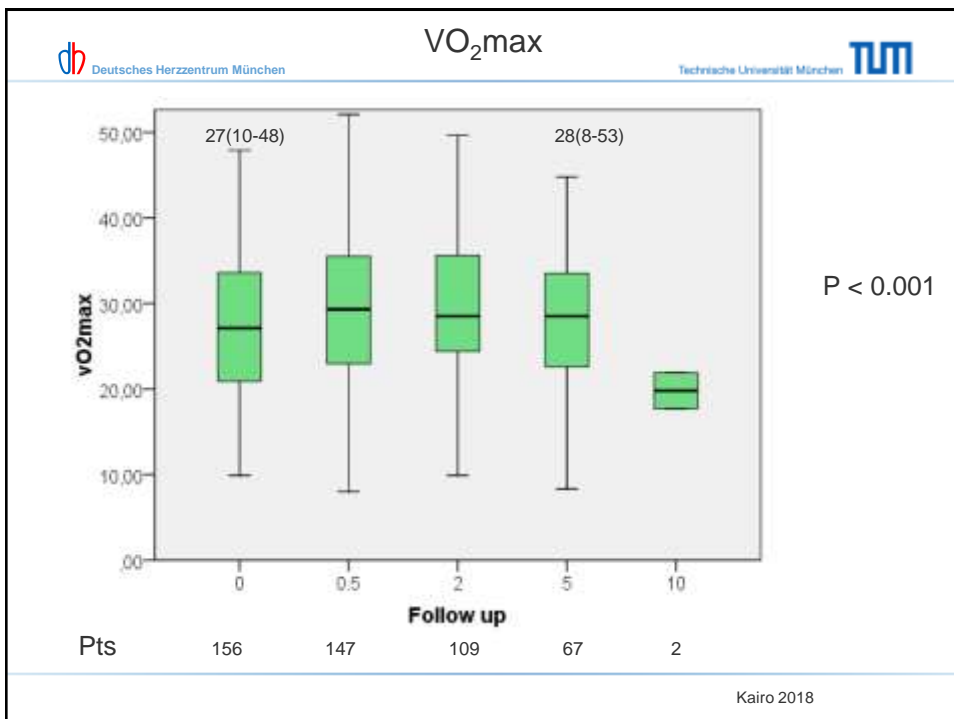
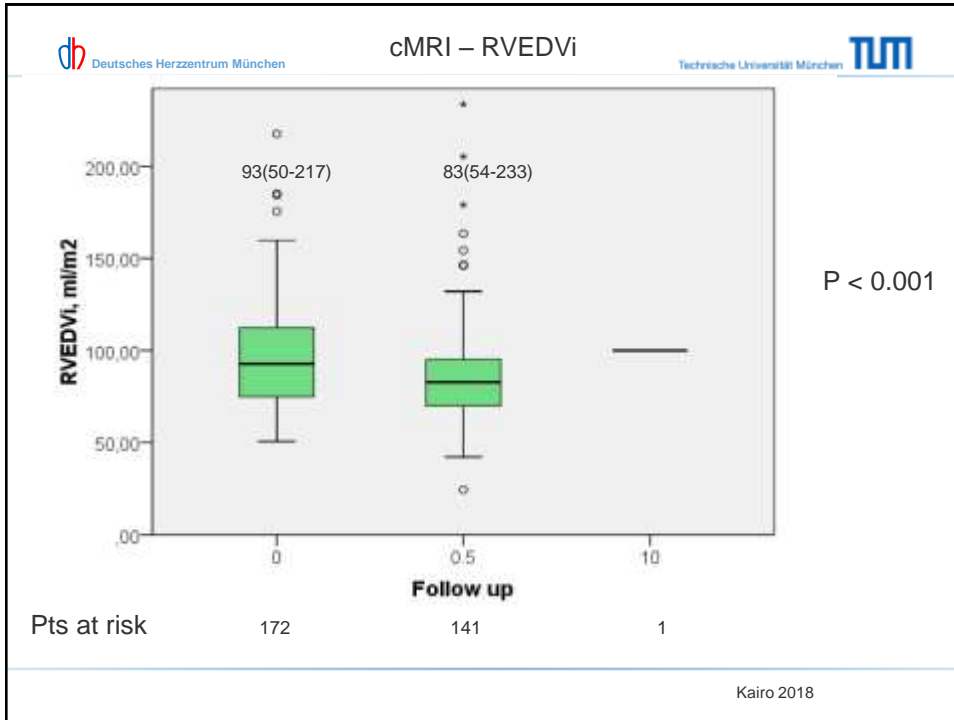
RVOT rupture

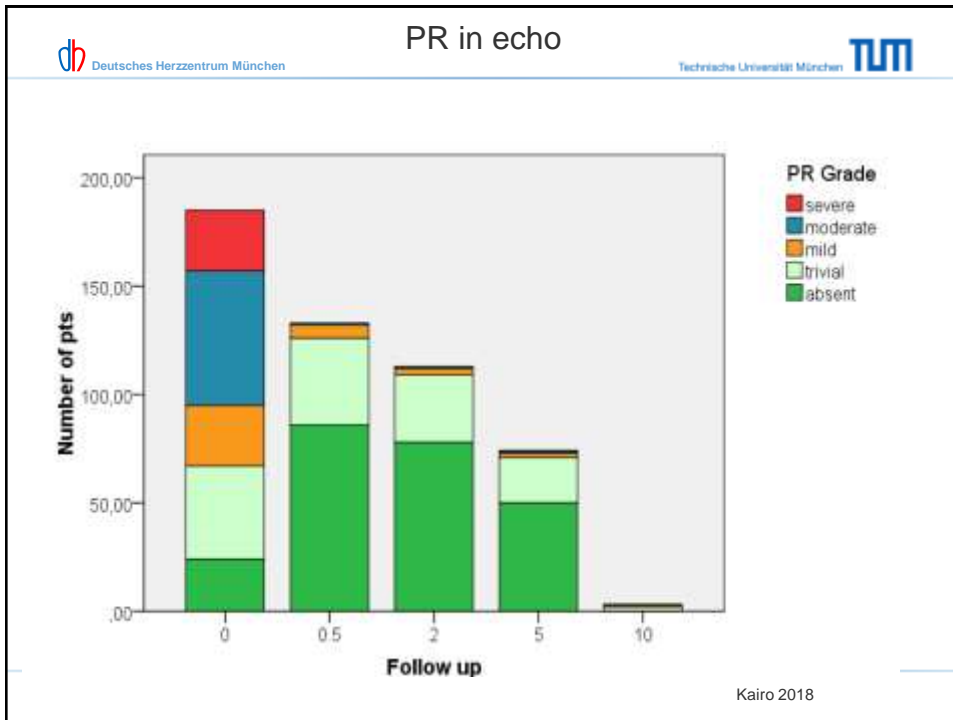


In severely calcified conduits completely cover the landing zone with covered stents before intending to break the calcified tube to avoid fatal rupture

Kairo 2018







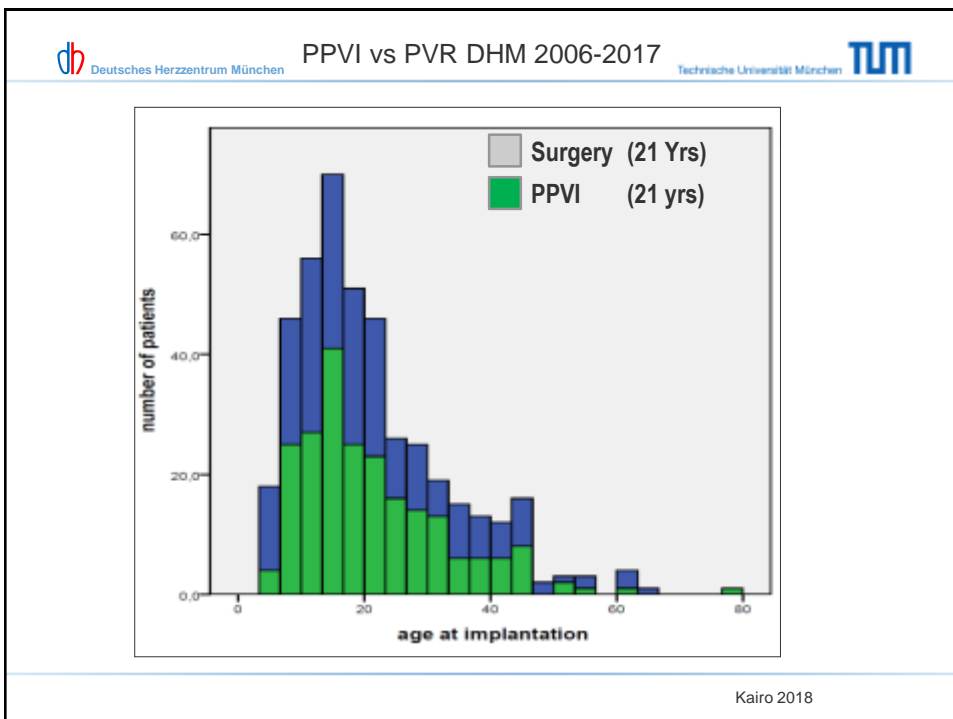
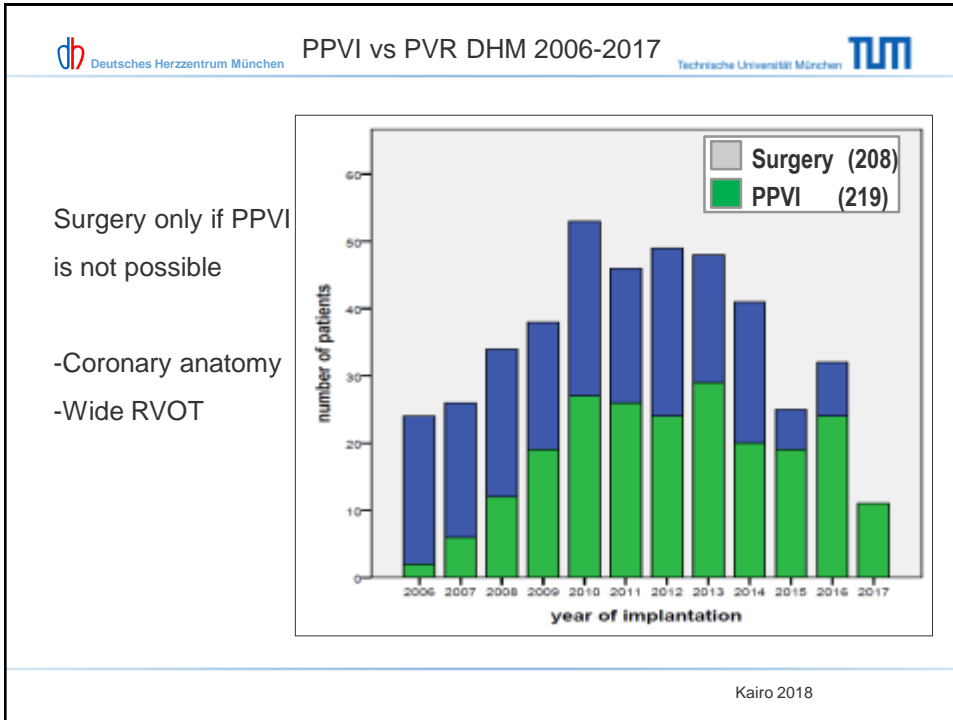
What we have learnt

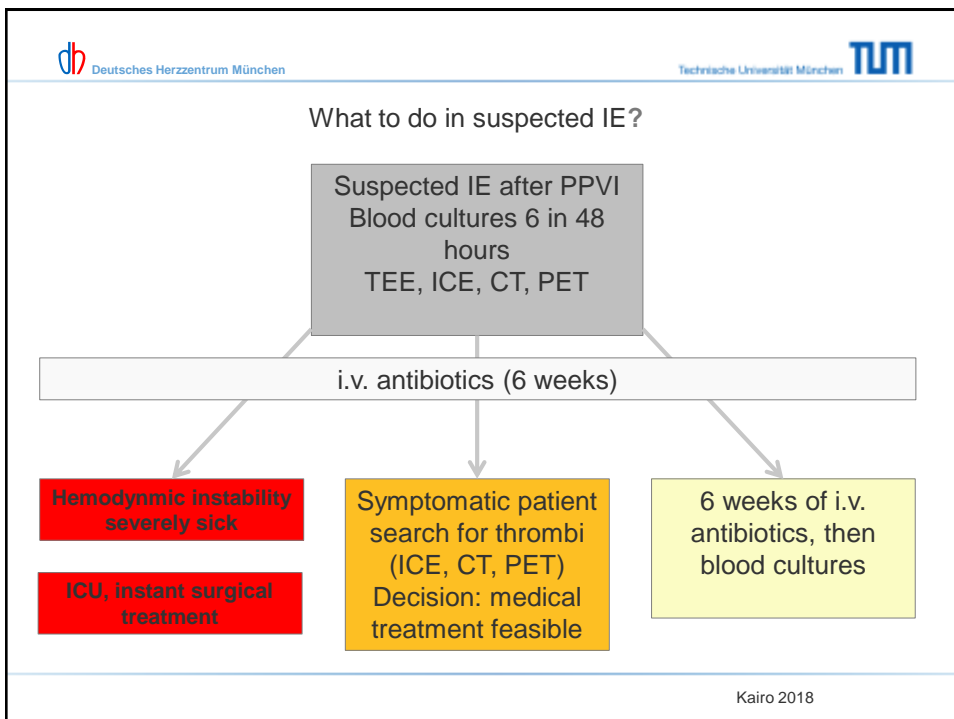
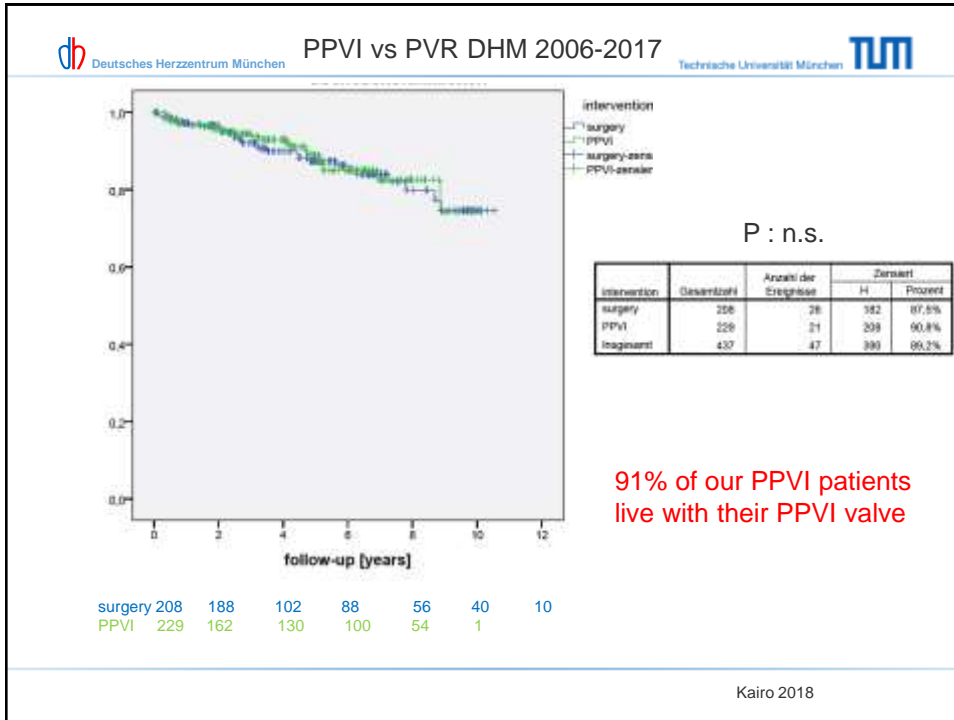
Deutsches Herzzentrum München Technische Universität München TUM



- balloontest (Z-Med or BiB) with aortogram and selective coronary depiction of both coronaries. Relation to RVOT must be clear. Risk – assessment: calcified homograft vs coronary testing with high pressure balloons, tissue compliance?
- High pressure testing indicated: 14 F long-Sheath
- After balloontest exclude rupture (dye through longsheat), sheath can be advanced rapidly to deliver cCP Stents or keep NuDEL available, Eicken et al. CTY 2017 6:1-4
- After pretesting, repeated selective coronary depiction pre final dilation
- „custom made“ 55 + 65 mm 8zcCP, or 10zcCP available

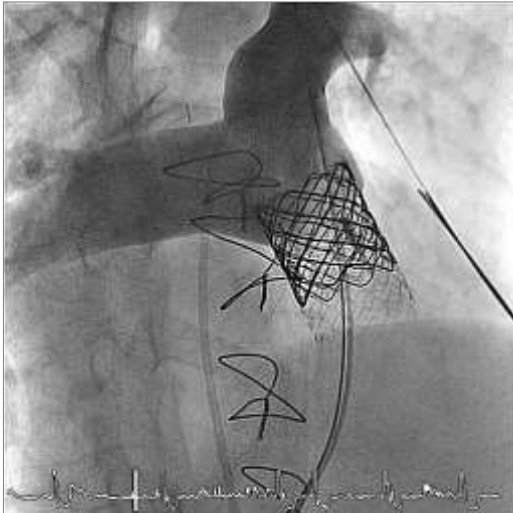
Balloon	8zig	10zig
22mm	25%	9%
24mm	35%	14%

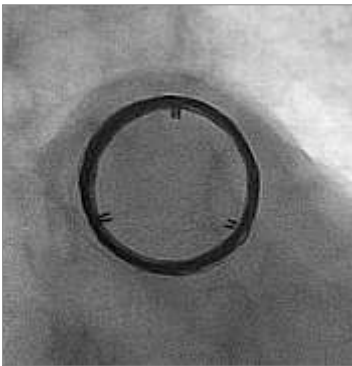
Kairo 2018








Extending the limits for PPVI






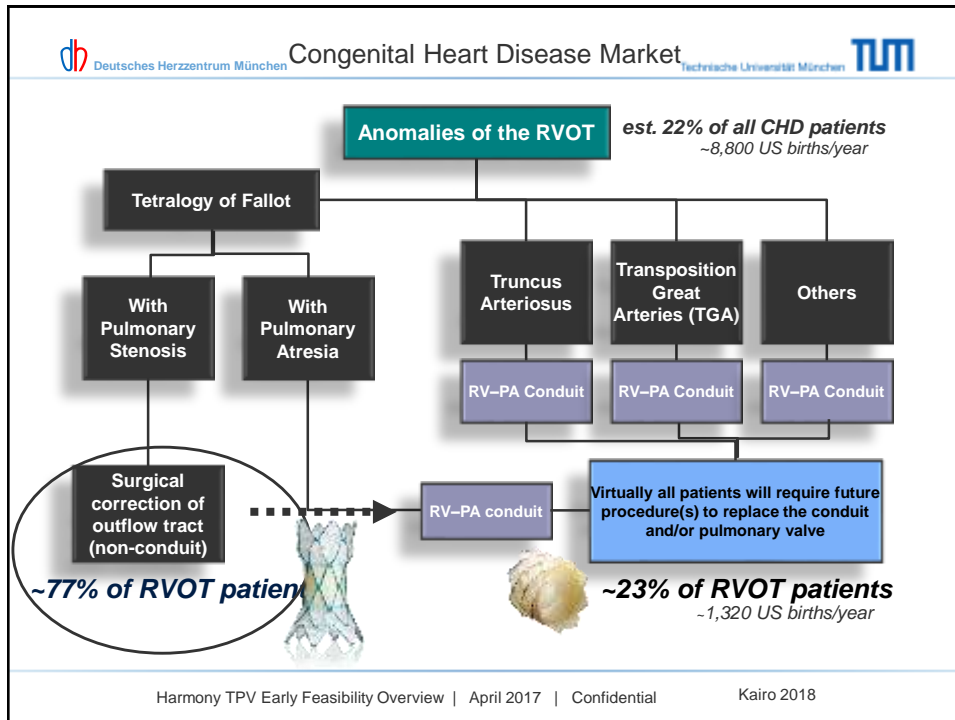
Ewert et al. 2010, *Clin Res Cardiol*
Sapien 29 in native RVOT

Kairo 2018


conclusion


- PPVI for RVOT dysfunction is the preferred treatment option in many centres
- Meticulous preparation of the landing zone results in optimal results (low residual gradient, less stent fractures)
- Coronary compression and conduit rupture are the hazards of PPVI. If coronary anatomy is „doubtful“ – no PPVI. Heavily calcified conduits („porcellan“) should be treated with cCP stents preceding PPVI
- Most patients have good valve function after PPVI at medium term follow – up. So far in 90% of our patients their first percutaneous valve is still performing well in pulmonic position (since 2006)
- If re-stenosis occurs a valve-in-valve procedure may be successful

Kairo 2018

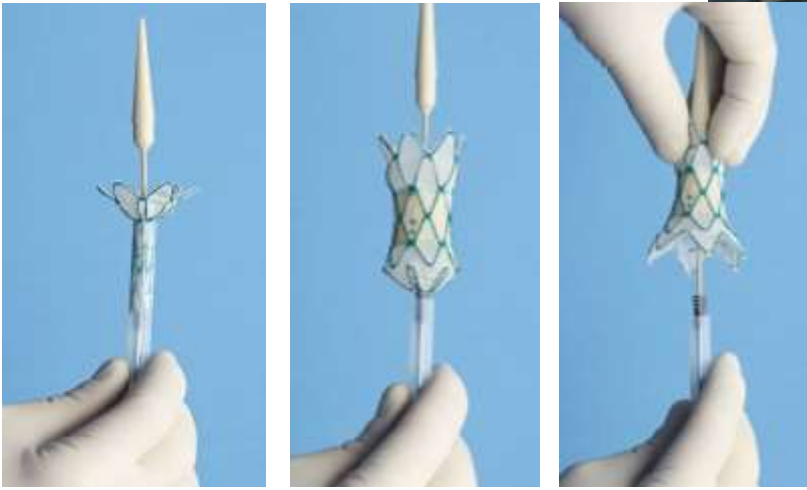


Deutsches Herzzentrum München **Early Feasibility Study Overview** Technische Universität München

- Prospective, Non-randomized
- First FDA approved Early Feasibility Study
- Primary Objective:
 - Obtain in vivo data to confirm assumptions on loading conditions for future in vitro frame evaluations
- Secondary Objectives:
 - Characterize procedural feasibility, safety & TPV performance
- 20 patients implanted for 5 year follow-up at 3 centers (May 2013 – May 2015)
 - The Hospital for Sick Children, Toronto Canada – Dr. Lee Benson
 - Nationwide Children’s Hospital, Columbus Ohio – Dr. John Cheatham
 - Boston Children’s Hospital, Boston, MA – Dr. Lisa Bergersen
- Screening Committee to review all potential candidates
- DSMB oversight of study

Kairo 2018

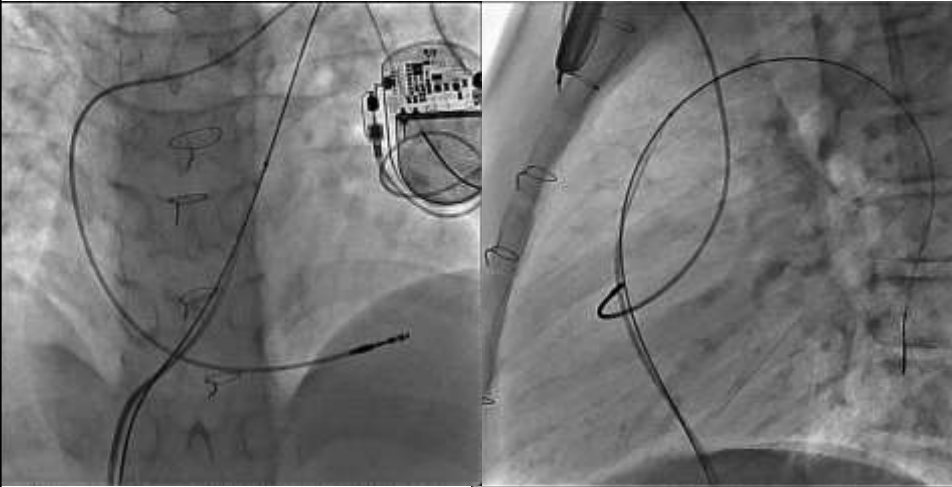
dh Deutsches Herzzentrum München Harmony valve Technische Universität München





Kairo 2018

dh Deutsches Herzzentrum München Technische Universität München TUM

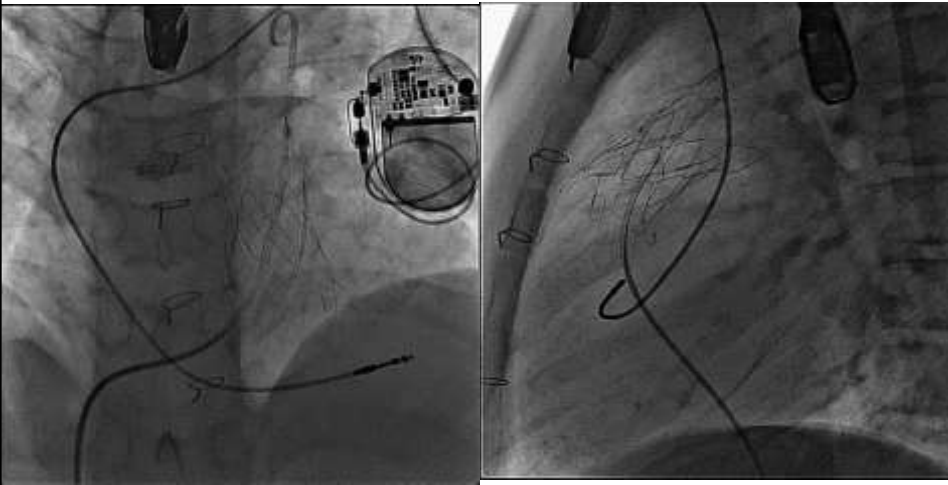
NCH Team Performed the FIM Implant of the new Native Outflow Tract TPV on May 30th, 2013





Pre p.a. Pre lat. Kairo 2018

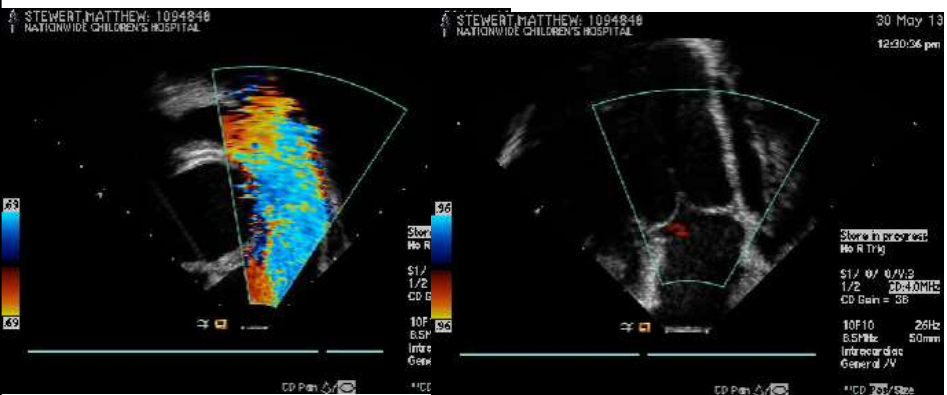
NCH Team Performed the FIM Implant of the new Native Outflow Tract TPV on May 30th, 2013



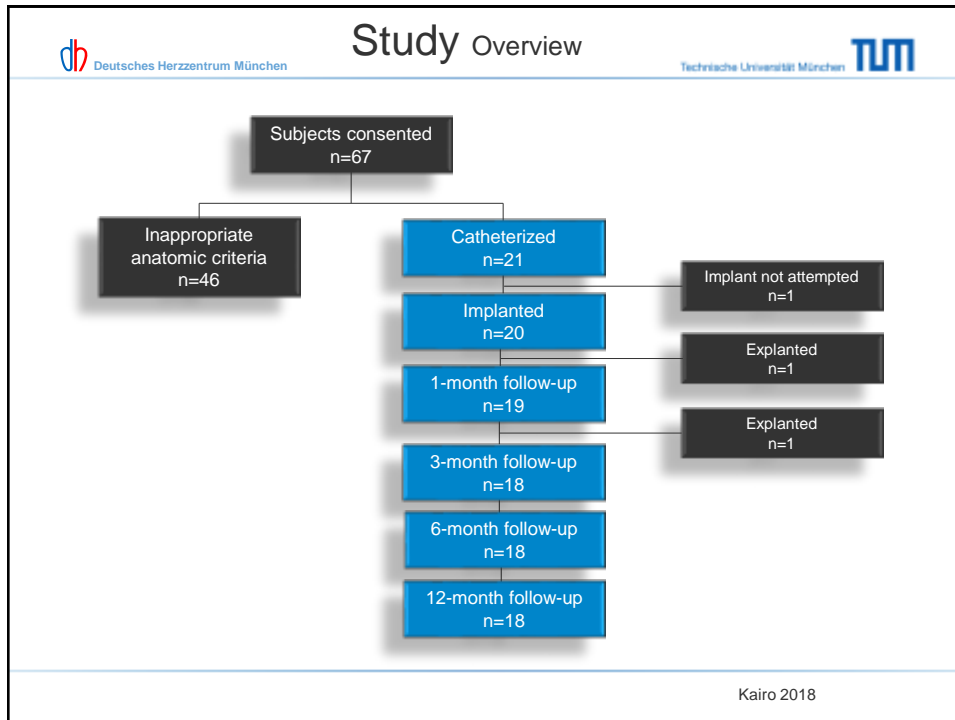
post p.a.
Post lat.
Kairo 2018

ICE pre and post implant



Courtesy John Cheatham
Kairo 2018

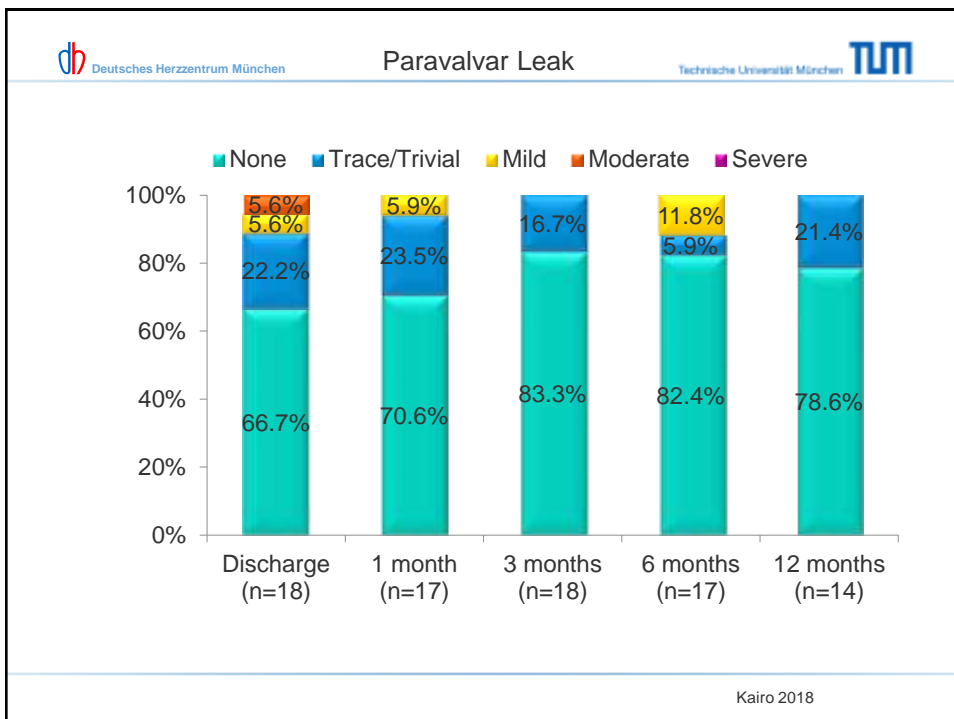
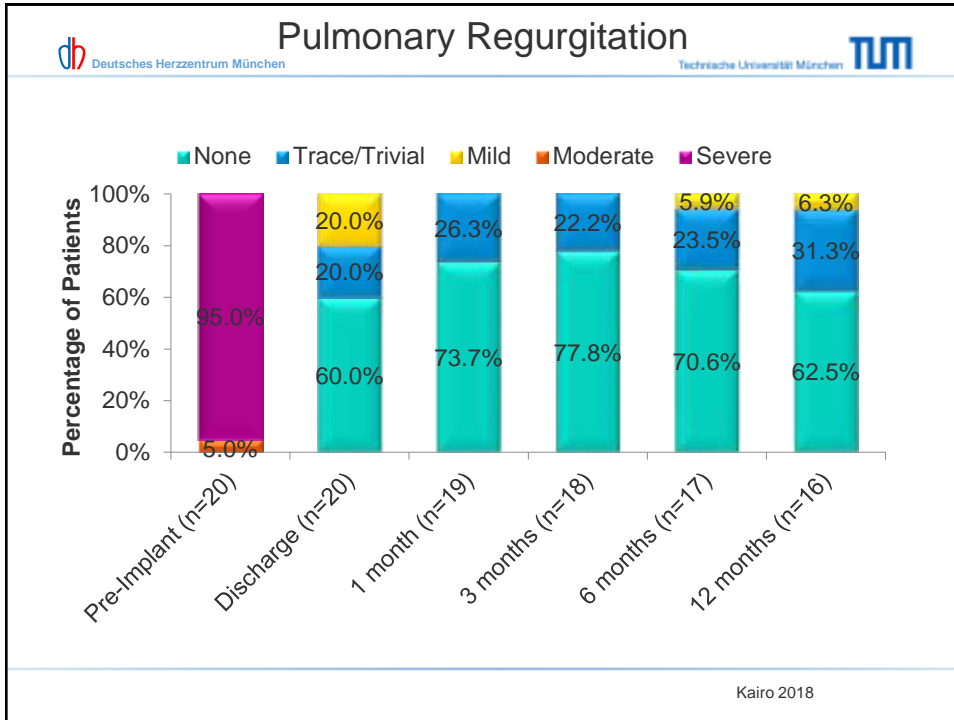


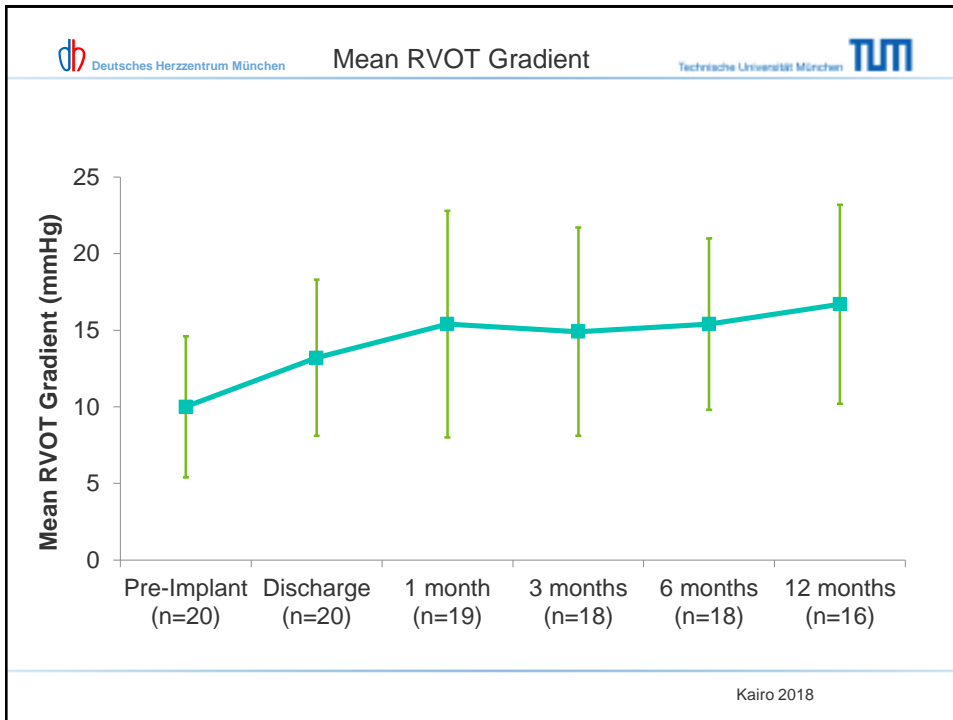
MRI Hemodynamics

Deutsches Herzzentrum München Technische Universität München **TUM**

Measurement	Pre-implant (n=12)	12-month (n=12)	P-value (pre-implant to 12 months)
RVEDV (ml)	280.4 ± 74.0	195.1 ± 57.9	0.001
RVEDVi (ml/m ²)	158.4 ± 35.5	106.7 ± 22.1	0.001
RVESV (ml)	140.1 ± 45.3	103.9 ± 40.1	0.001
AR (%)	2.1 ± 2.3 (n=10)	0.7 ± 2.2 (n=10)	0.16
RVEF (%)	50.8 ± 8.3	48.1 ± 9.5	0.34
PR (%)	48.9 ± 10.3 (n=11)	2.1 ± 3.4 (n=11)	0.001

Kairo 2018







dh Deutsches Herzzentrum München Reintervention & Reoperation Technische Universität München TUM



- 2 reoperations
 - Both involved TPV explant and surgical PVR and resolved without sequelae
 - 1: Stent fracture, valve dysfunction: stenosis, valve frame collapse – identified at 1 mo. Visit
 - 2: Migration, PVL (major & minor), “erosion” – identified at discharge
- No catheter reinterventions but 1 diagnostic catheterization

Kairo 2018



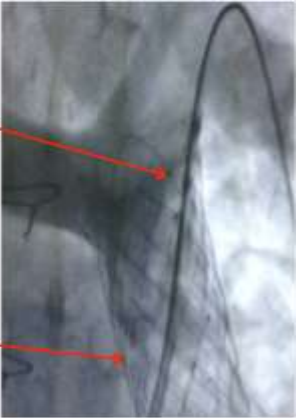

What is planned next?


- Continue 5 year follow up on EFS implanted patients
- Analyze an additional 160 CMRs to better understand the complex anatomy of the RVOT
- Leveraging engineering analysis and additional anatomical data for inputs into additional Harmony TPV sizes and optimized delivery system – development underway!
- Harmony TPV IDE approved Oct. 26th, 2016
 - 40 additional patients at 10 centers
 - Slightly modified screening process to be used
 - Slightly modified delivery system
 - Training course completed in November 2016
 - Actively enrolling - 1st implant March 2017

Kairo 2018


Deutsches Herzzentrum München


Venous P-valve
A New Self-Expandable Valve

Kairo 2018



Thank you!