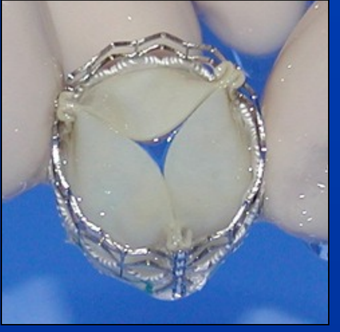


Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

Ziyad M. Hijazi, MD, FSCAI, FACC

James A. Hunter, University Chair

Professor

Of Pediatrics & Internal Medicine

Rush Center For Congenital & Structural Heart Disease

Rush University Medical Center

Chicago, IL

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

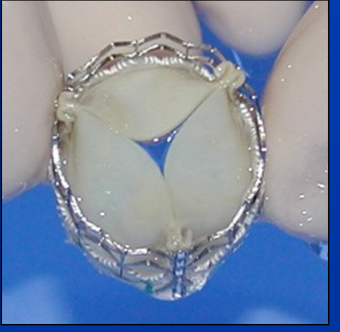
Disclosure: None Related to this

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

Pulmonary Regurgitation

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

Significant PR results in:

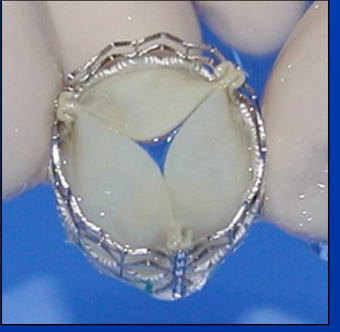
Progressive RV dilation & development of ventricular arrhythmias.

RV dysfunction & sudden death.

Pulmonary valve replacement at an appropriate age may restore RV function and improve the symptoms.

Early clinical exprience with transcatheter pulmonary valve replacement is safe and very encouraging.

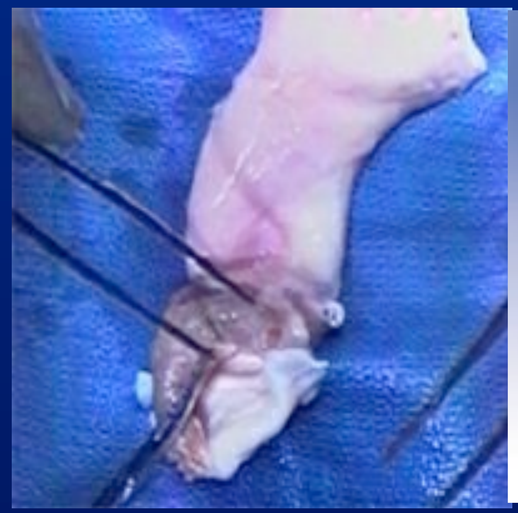
Rush Center for Congenital and Structural Heart Disease



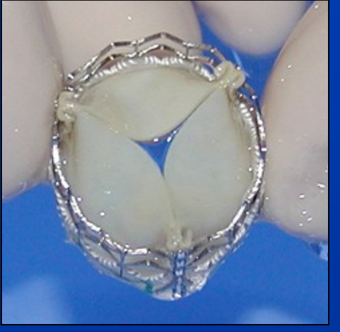
Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

Conduit Types

Homograft
Cloth tube conduit – porcine valve mounted into polyester tube
Medtronic Contegra – bovine jugular vein
- **Conduit/valve stenosis is primary failure mode**



Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Unmet Clinical Need

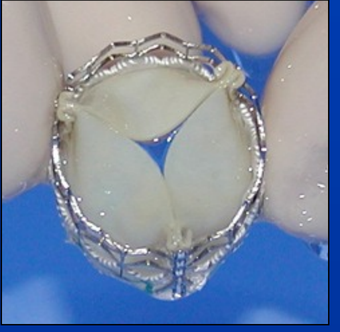
Conduit durability is often limited by resulting stenosis, thrombosis and calcification of the valve causing clinical deterioration and requiring reoperation.

- **Mean time to reoperation*:**
  - **10.3 years for xenografts**
  - **16 years for homografts**
- **Reoperations associated with increasing mortality**:**
  - **4% mortality rate on initial procedure**
  - **7% mortality rate on first re-operation**
  - **11% mortality rate on second re-operation**
  - **13% mortality rate on additional operations**

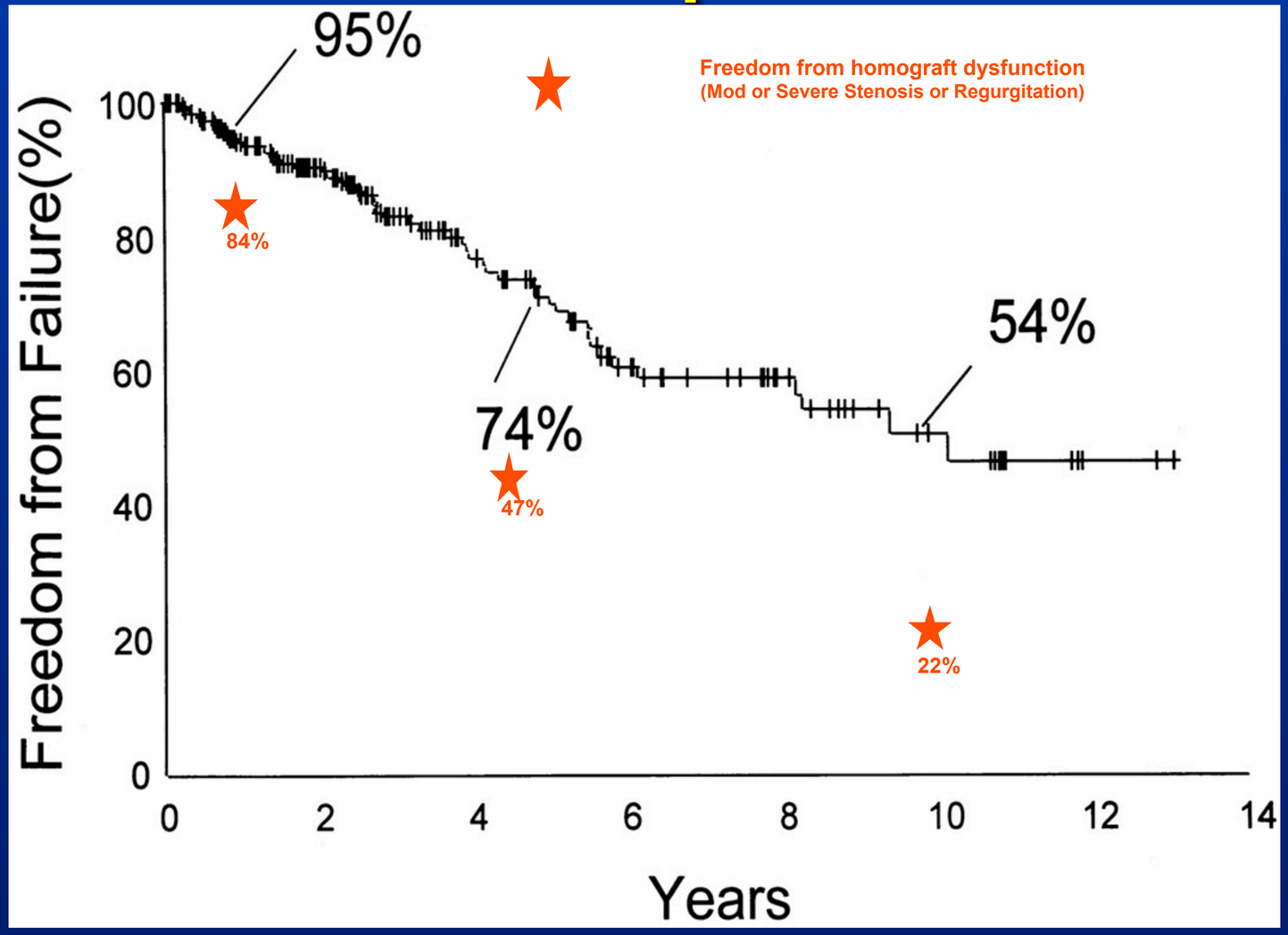
*Tweddell et al. Factors affecting longevity of homograft valves used in RVOT reconstruction for CHDCirc 2000;102:(Suppl):III-130-III-135 and Homann M, et al. Reconstruction of the RVOT with valved biological conduits: 25 years experience with allografts and xenografts. EurJCardioThorac Surg 2000; 17:624-30

**Dore A et al. Cardiac Surgery for Grown-Up Congenital heart patients: Survey of 307 Consecutive Operations from 1991-1994 Am J Cardiol 1997; 80:906-13 and Somerville J. Grown-up congenital heart disease - medical demands look back, forward 2000. Thorac Cardiovasc Surg 2001; 49(1); 21-6

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve



Tweddell et al. Factors affecting longevity of homograft valves used in RVOT reconstruction for CHD Circ 2000;102:(Suppl):III-130-III-135.

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease) Developed in Collaboration With the Society of Cardiovascular Anesthesiologists Endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons

Robert O. Bonow, Blase A. Carabello, Kanu Chatterjee, Antonio C. de Leon, Jr, David P. Faxon, Michael D. Freed, William H. Gaasch, Bruce Whitney Lytle, Rick A. Nishimura, Patrick T. O'Gara, Robert A. O'Rourke, Catherine M. Otto, Pravin M. Shah, Jack S. Shanewise, Sidney C. Smith, Jr, Alice K. Jacobs, Cynthia D. Adams, Jeffrey L. Anderson, Elliott M. Antman, David P. Faxon, Valentin Fuster, Jonathan L. Halperin, Loren F. Hiratzka, Sharon A. Hunt, Bruce W. Lytle, Rick Nishimura, Richard L. Page, and Barbara Riegel

J. Am. Coll. Cardiol. 2006;48;e1-e148
doi:10.1016/j.jacc.2006.05.021

Percutaneous Pulmonary Valve Implantation

PRACTICE GUIDELINE: FULL TEXT

ACC/AHA 2008 Guidelines for the Management of Adults With Congenital Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Develop Guidelines on the Management of Adults With Congenital Heart Disease)

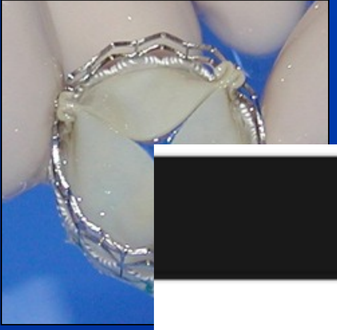
Developed in Collaboration With the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

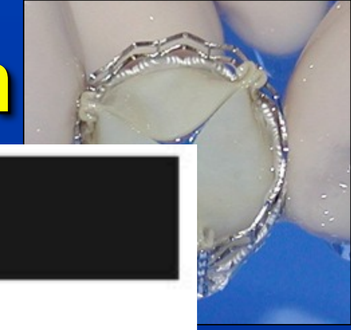
WRITING COMMITTEE MEMBERS

Carole A. Warnes, MD, FRCP, FACC, FAHA, Co-Chair; Roberta G. Williams, MD, MACC, FAHA, Co-Chair; Thomas M. Bashore, MD, FACC; John S. Child, MD, FACC, FAHA; Heidi M. Connolly, MD, FACC; Joseph A. Dearani, MD, FACC*; Pedro del Nido, MD; James W. Fasules, MD, FACC; Thomas P. Graham, Jr, MD, FACC†; Ziyad M. Hijazi, MBBS, MPH, FACC, FSCAI‡; Sharon A. Hunt, MD, FACC, FAHA; Mary Etta King, MD, FACC, FASE§; Michael J. Landzberg, MD, FACC; Pamela D. Miner, RN, MN, NP; Martha J. Radford, MD, FACC; Edward P. Walsh, MD, FACC‖; Gary D. Webb, MD, FACC¶

ter for Congenital
tural Heart Disease

Percutaneous Pulmonary Valve Implantation





AHA Scientific Statement

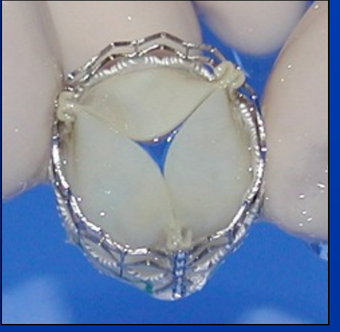
Indications for Cardiac Catheterization and Intervention in Pediatric Cardiac Disease

A Scientific Statement From the American Heart Association

Endorsed by the American Academy of Pediatrics and Society for Cardiovascular Angiography and Intervention

Timothy F. Feltes, MD, FAHA, Chair; Emile Bacha, MD; Robert H. Beekman III, MD, FAHA; John P. Cheatham, MD; Jeffrey A. Feinstein, MD, MPH; Antoinette S. Gomes, MD, FAHA; Ziyad M. Hijazi, MD, MPH, FAHA; Frank F. Ing, MD; Michael de Moor, MBBCh; W. Robert Morrow, MD; Charles E. Mullins, MD, FAHA; Kathryn A. Taubert, PhD, FAHA; Evan M. Zahn, MD; on behalf of the American Heart Association Congenital Cardiac Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Clinical Cardiology, and Council on Cardiovascular Radiology and Intervention

Rush Center for Congenital and Structural Heart Disease



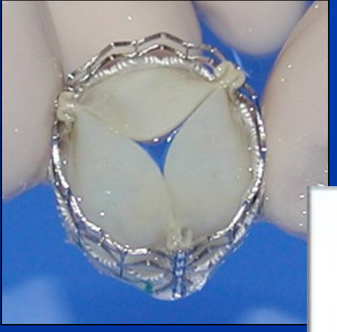
Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

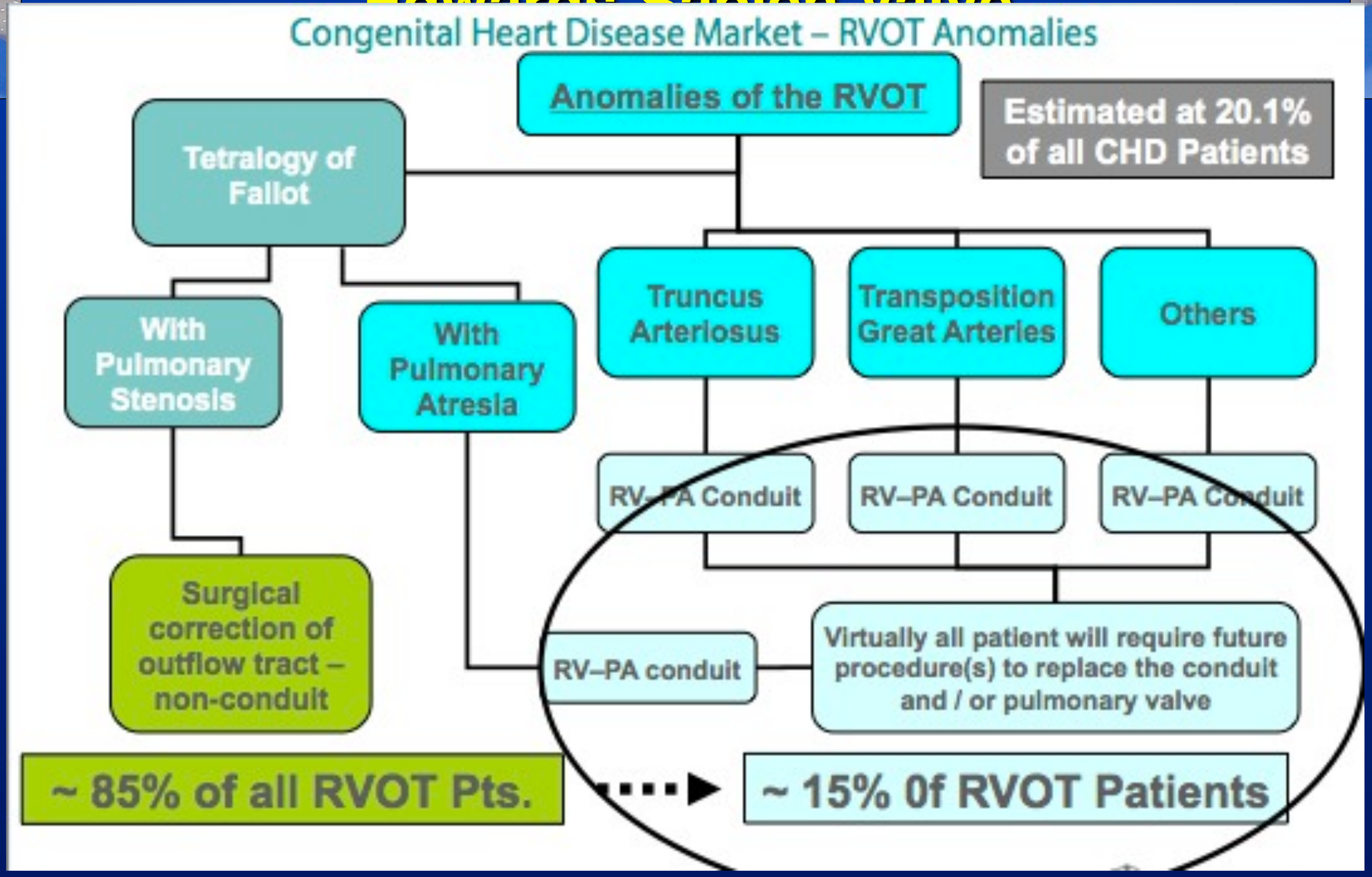
Indications to Replace PV

- Symptomatic patients with severe PR-NYHA Class II-III
- Asymptomatic patients: Regurgitant fraction >40%; RVEDV>150 ml/m2; RF EF<40%; QRS>180 msec

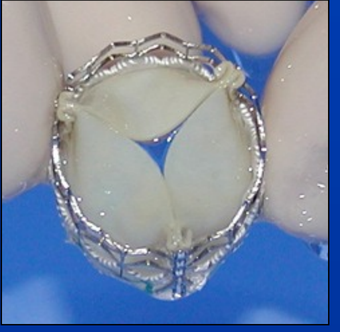
Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation
Edwards Sapien Valve





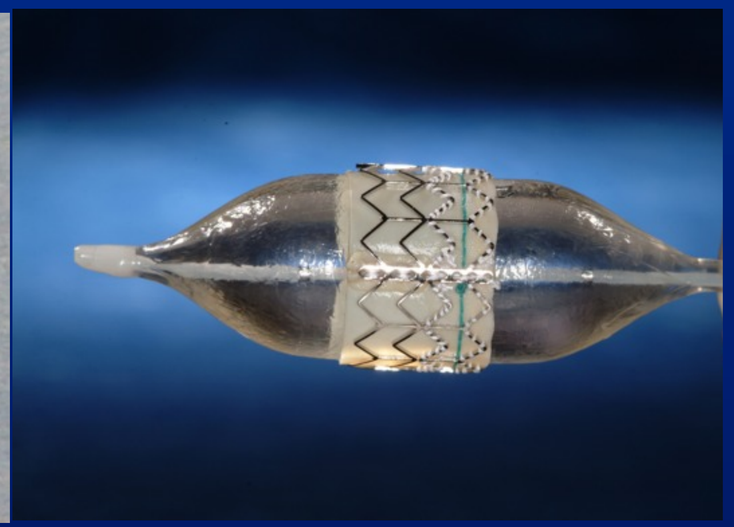
Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

The Edwards Sapien THV™

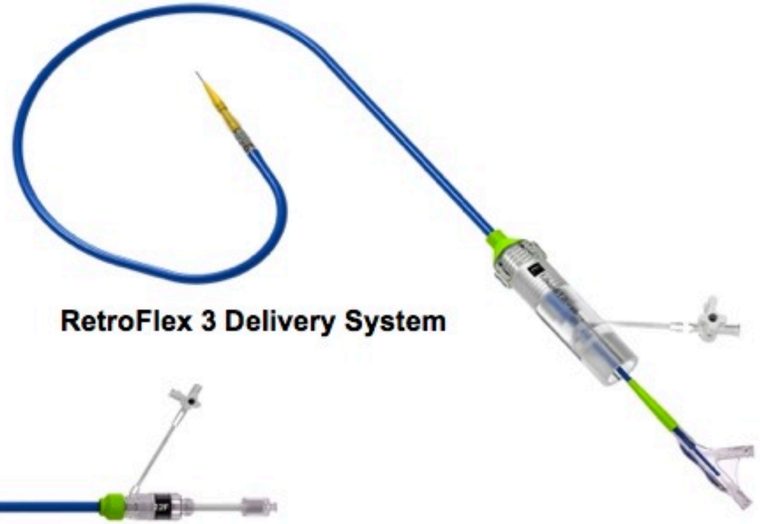
- Made of three Bovine pericardial leaflets
- Stent: stainless steel, 14 mm long, maximal diameter is 23-26mm.
- Requires 22-24 Fr sheath for delivery



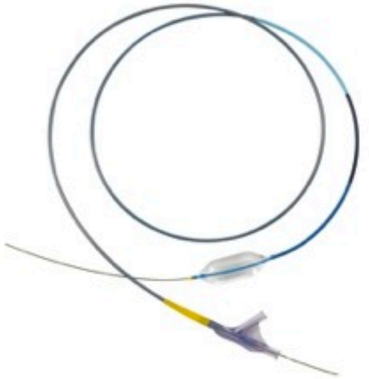
Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

Edwards SAPIEN THV



RetroFlex 3 Delivery System



RetroFlex Balloon Catheter

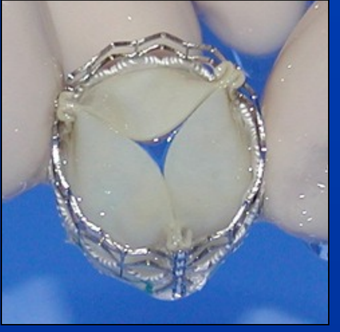
RetroFlex 3 introducer Sheath Set

Atrion
Inflation Device

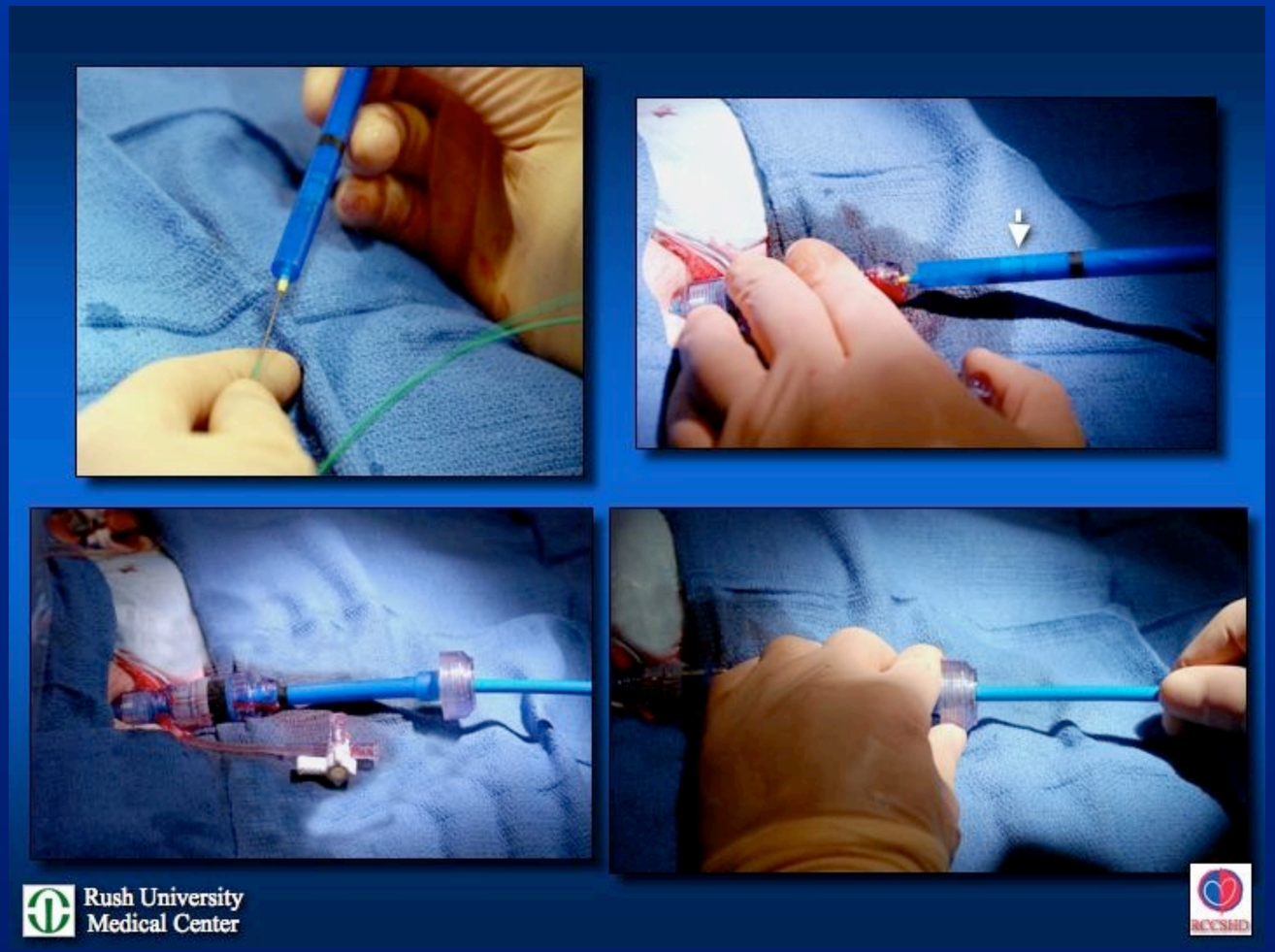
Crimper

RetroFlex Dilator Kit

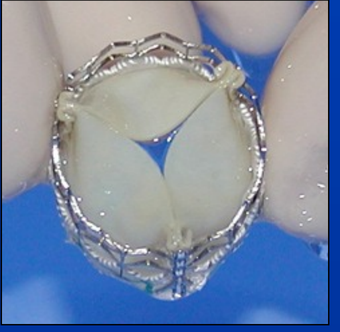
Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve



Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

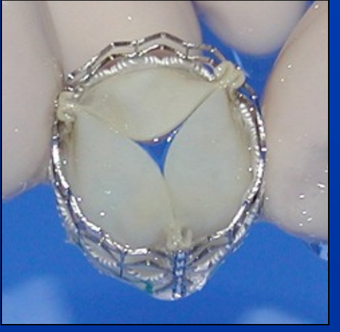
The COMPASSION Study

COngenital Multicenter trial of Pulmonic vAlve regurgitation Studying the SAPIEN™ InterventIONal THV

Inclusion Criteria

- 1. Weight>35 kg
- 2. Conduit >16mm & <24mm
- 3. Severe PR >3+ or >40% regurgitant fraction and or severe PS
- 4. Subject is symptomatic as evidenced by CP exercise testing
- 5. Must comply with F/U
- 6. Subject agrees to come back for F/U
- 7. Catheterization is feasible

Rush Center for Congenital and Structural Heart Disease

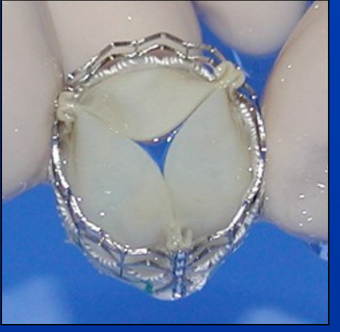


Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Exclusion Criteria

- 1. Active Infection
- 2. Previously enrolled in this study
- 3. Subject has prosthetic heart valve
- 4. Severe Chest wall deformity
- 5. Leukopenia (<3000)
- 6. Acute or chronic anemia (<9 gm%)
- 7. Platelet count <100,000
- 8. Echo evidence of intracardiac mass/ thrombus
- 9. History of or active endocarditis
- 10. Hypersensitivity to aspirin or heparin
- 11. Life expectancy <1 year

Rush Center for Congenital and Structural Heart Disease

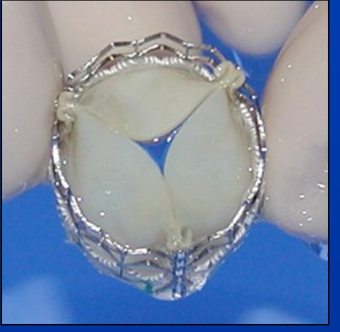


Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Exclusion Criteria

- 12. Obstruction of the central veins
- 13. Positive pregnancy test
- 14. RVOT aneurysm
- 15. Ileofemoral vessel that would preclude 22-24F
- 16. Contraindication to MRI
- 17. Need for concomitant interventional procedure (ASD/ VSD)

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

24 y/o Female, Wt: 46 Kg

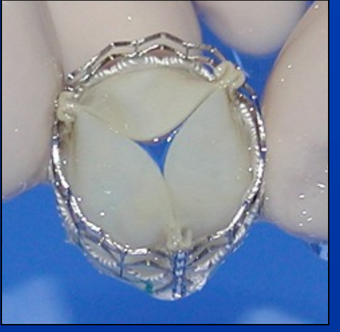
Dx: Subaortic obstruction. Age 2yr: resection.
Age 5 yr: Modified Kono, resulted in CHB & AR.
Age 7 yr: Ross Operation, 21 mm Homograft.
NYHA-II

Age 24: cath: RV:DAO 62:97.

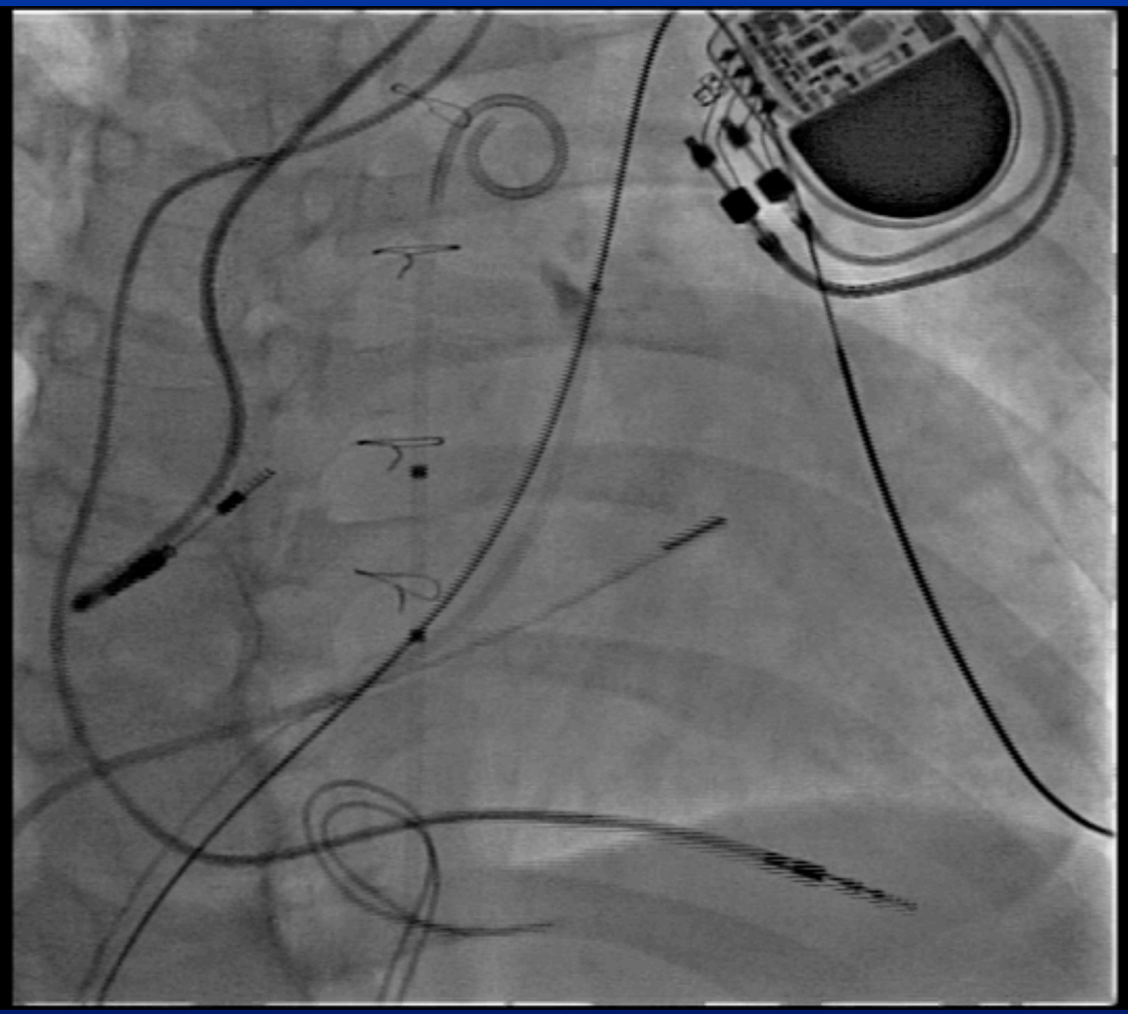
Post P3110 stent on 20mm BiB: RV:DAO 42:97.

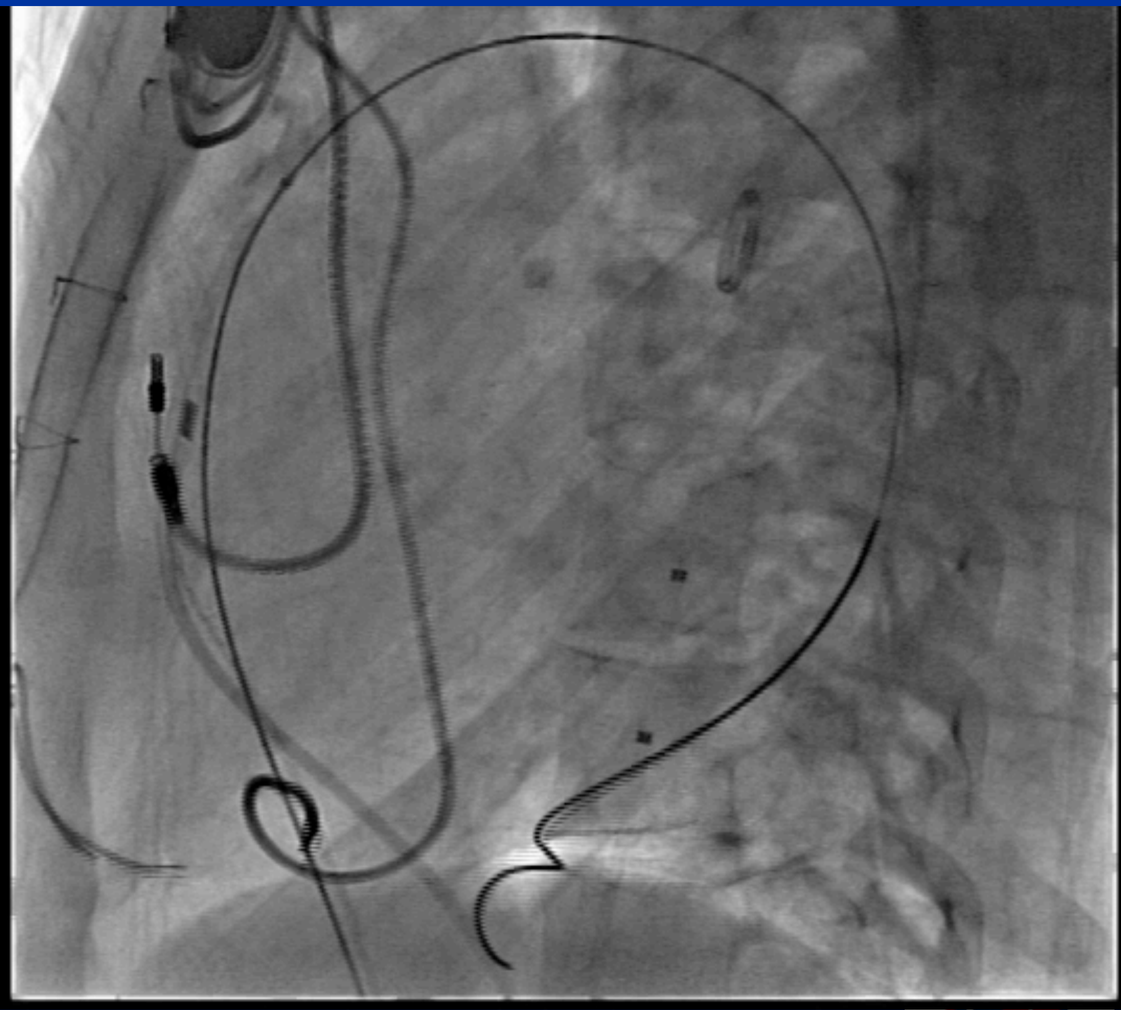
Post 23mm Sapien RV:DAO 25:117

Rush Center for Congenital and Structural Heart Disease

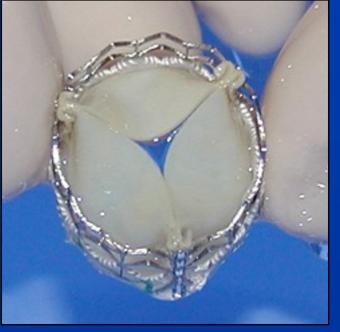


Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve





Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Take Home Messages

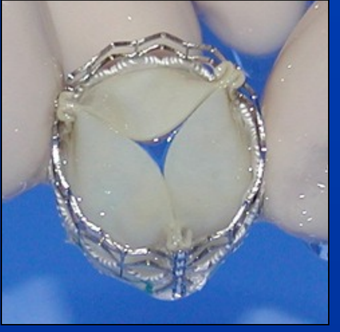
- 1. tPVR is available option for patients with dysfunctional conduits
- 2. Pre-stenting of conduits
- 3. Very high pressure balloons are needed
- 4. Evaluation of coronary artery proximity to the conduit

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Interim Analysis

Rush Center for Congenital and Structural Heart Disease



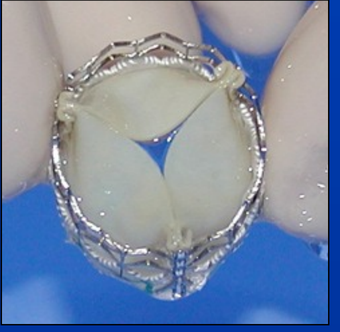
Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Methods - Criteria

- Dysfunctional RV-PA conduit:
  - ≥3+ PR by TTE or PRF ≥40% by cardiac MRI ± stenosis
  - body weight was ≥35kgs
  - *In situ* conduit diameter was ≥ 16mm and ≤ 24mm
- Schedule of Events:* *includes NYHA*

	Baseline	D/c	30/7	6/12	12/12	Annual
Physical*	☆	☆	☆	☆	☆	☆
AEA		☆	☆	☆	☆	☆
CXR/TTE	☆	☆	☆	☆	☆	☆
CPET	☆			☆	☆	☆
MRI	☆			☆		
CTA	☆			☆	☆	☆

Rush Center for Congenital and Structural Heart Disease



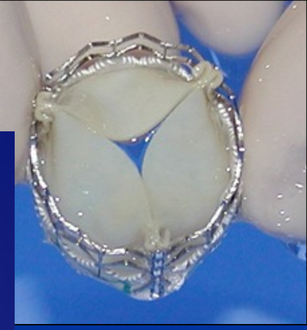
Percutaneous Pulmonary Valve Implantation Edwards-Sapien Valve

Outcomes

- **Primary Outcome:**
  - *Freedom from device failure or procedure related death and/or reoperation at 1 year*
- **Secondary Outcomes:**
  - *Freedom from major adverse cardiac and cerebral events at 6 months*
  - *evidence of functional improvement assessed by improvement in:*
    - –degree of pulmonary regurgitation and stenosis on TTE
    - –pulmonary regurgitation on MRI

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation



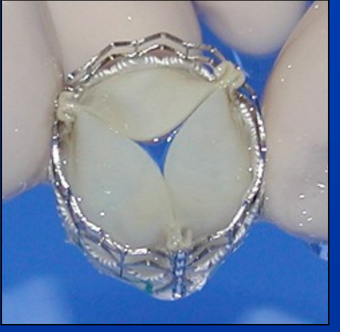
Edwards SAPIEN THV Sizing

SAPIEN Valve Size

Dilated Conduit Diameter 21- 23mm	23mm
Dilated Conduit Diameter 23- 26mm	26mm

*For non-stenotic conduits, 10-15% oversizing is recommended

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

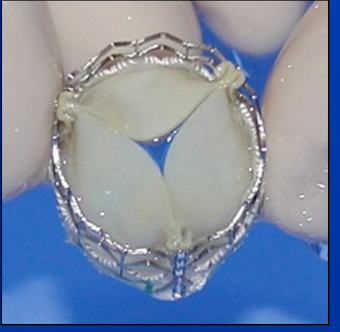
RUSH UNIVERSITY MEDICAL CENTER

COMPASSION Patient Summary

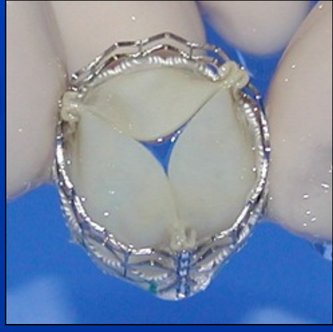
• Patients (AT)	n = 50
• Age	28.7 ± 15.0 years (10 – 72)
• Sex	31M:19F
• Weight	72.8 ± 24.5kgs
• Diagnosis	
ToF	40%
Ross Procedure	36%
• Open Heart Surgeries	2.1 (1-4)
• RVOT Conduit Type	96% homograft
• Original RVOT Conduit Size	24 ± 3mm (18 – 29mm)
• Indication	
• Mixed	64%
• Regurgitation	18%
•RVOT Pre-stenting	100%

COMPASSION

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation

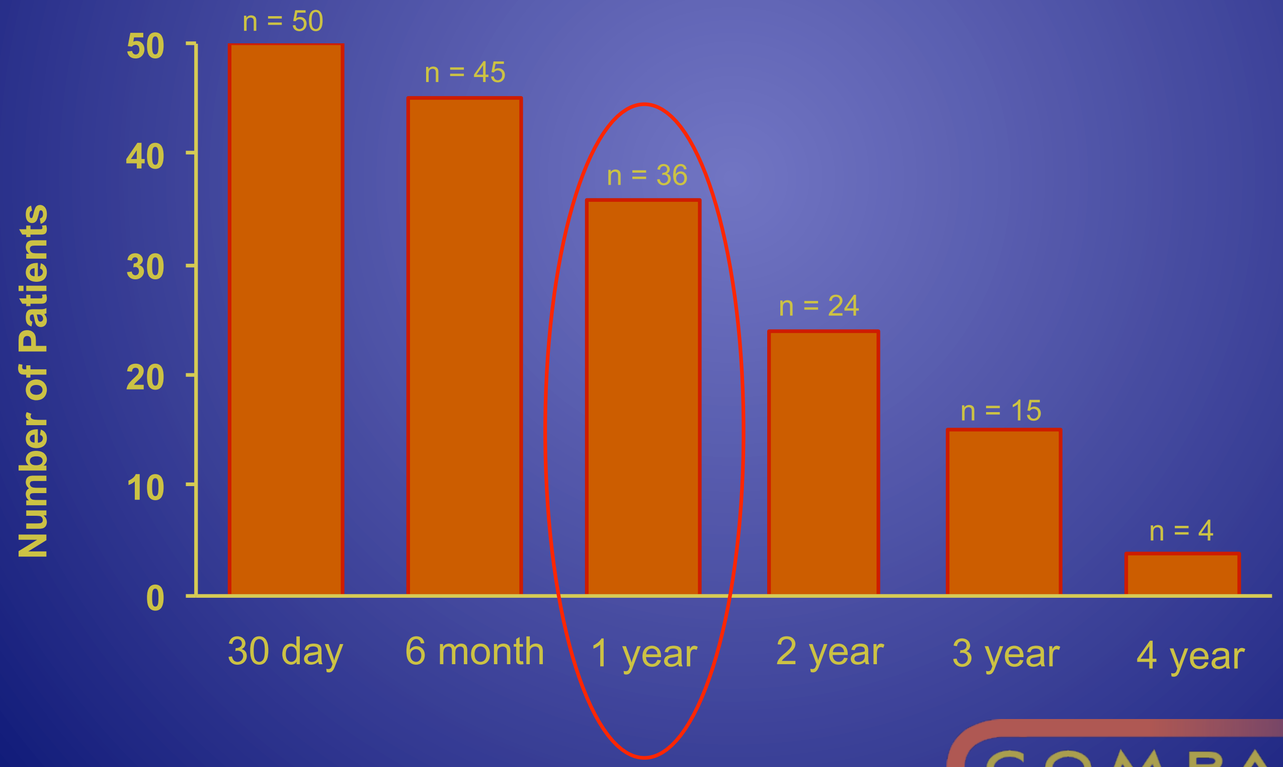


PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

RUSH UNIVERSITY MEDICAL CENTER

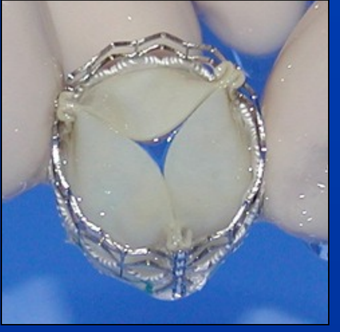
Patient Follow-up

- **50 implants, 5 centers (26mm valve, n=15)**
- **87.9 total patient years, mean = 1.76 ± 1.2 year**



COMPASSION

Rush Center for Congenital and Structural Heart Disease

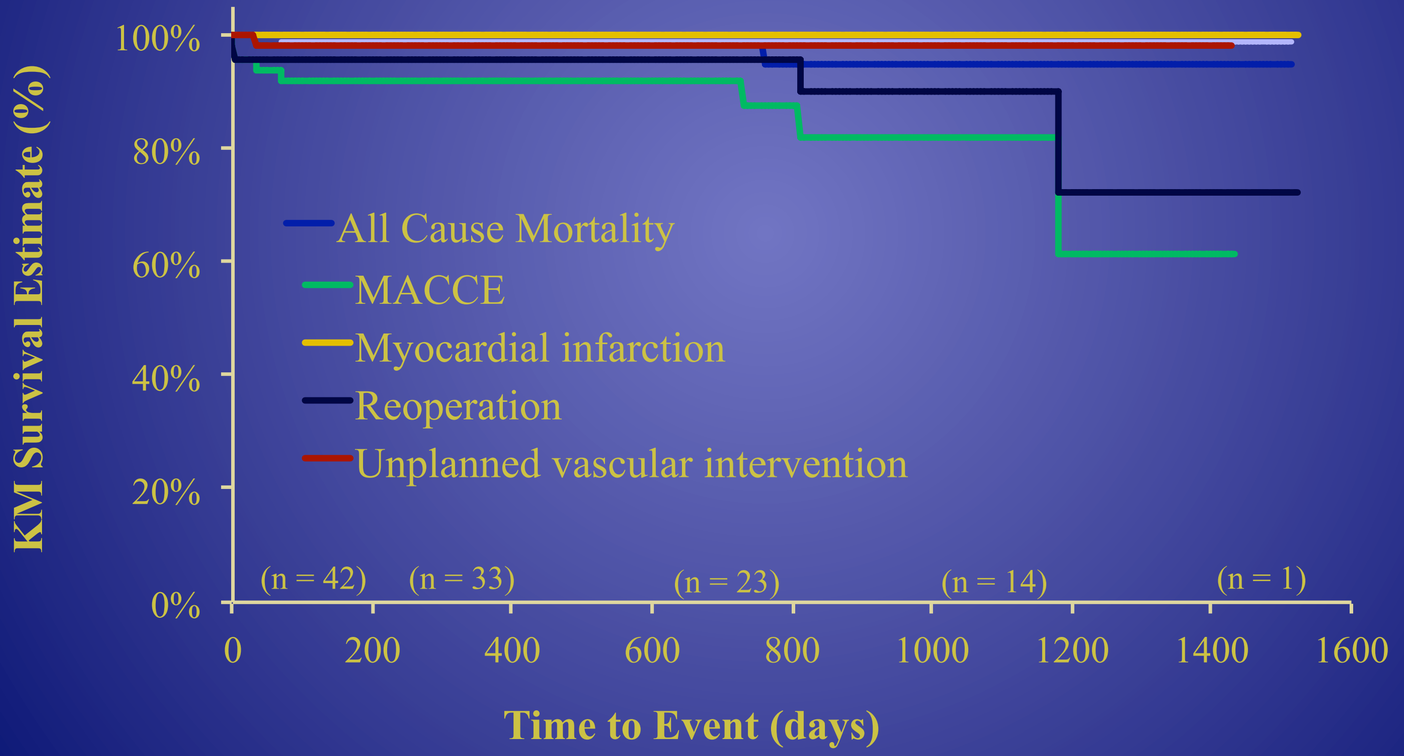


Percutaneous Pulmonary Valve Implantation

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

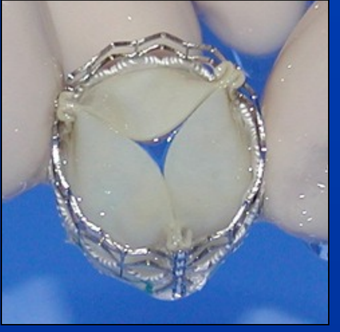
RUSH UNIVERSITY MEDICAL CENTER

- 96% Freedom from death or reoperation at 1 year
- 94% Freedom from MACCE at 6 months and 1 year



COMPASSION

Rush Center for Congenital and Structural Heart Disease

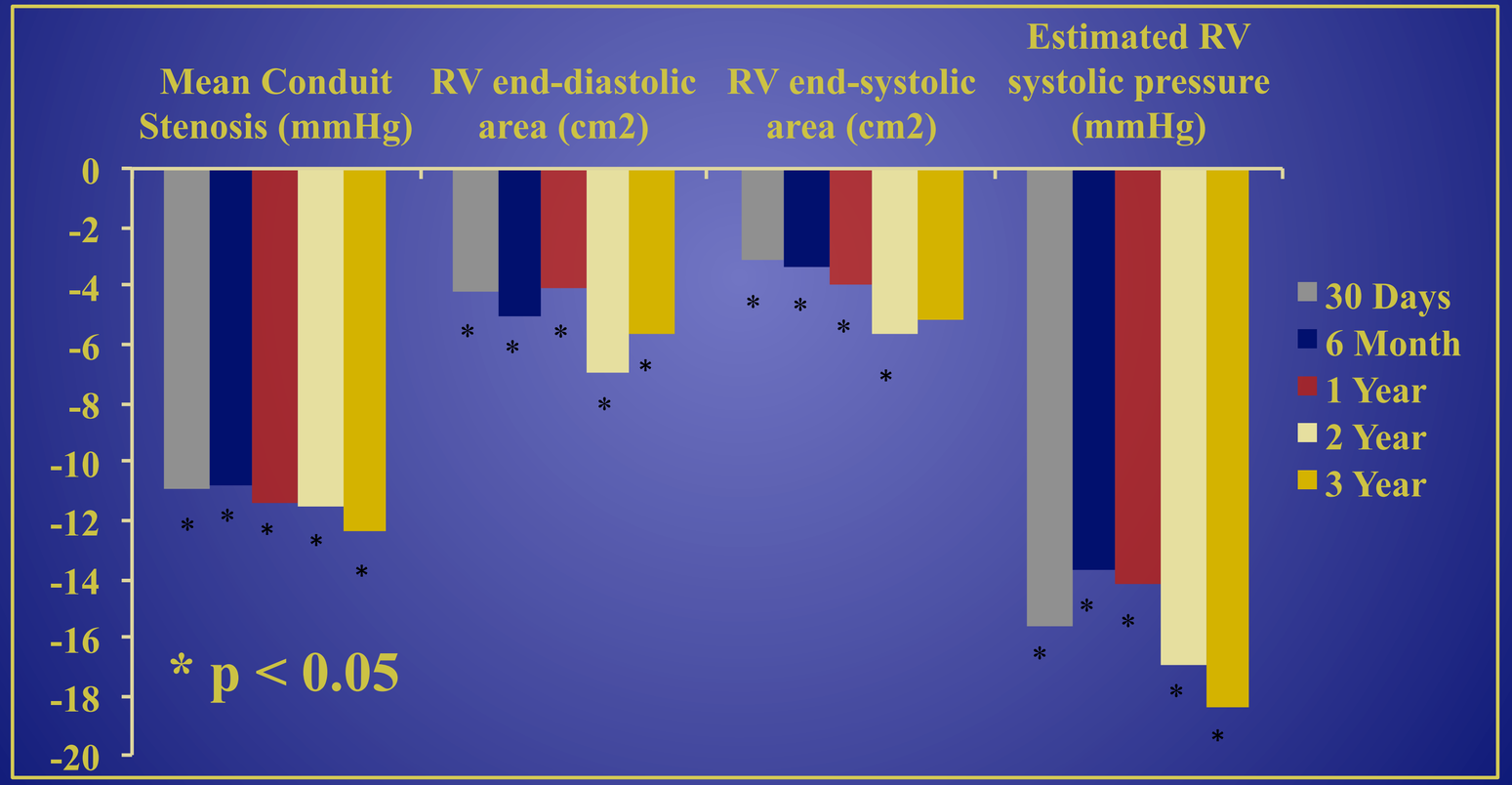


Percutaneous Pulmonary Valve Implantation

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

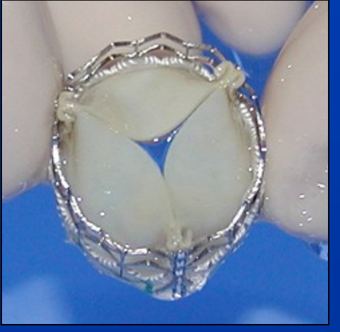
RUSH UNIVERSITY MEDICAL CENTER

Echocardiographic Changes from Baseline

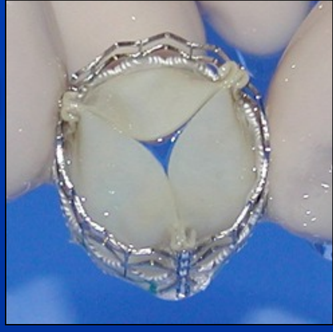


COMPASSION

Rush Center for Congenital and Structural Heart Disease



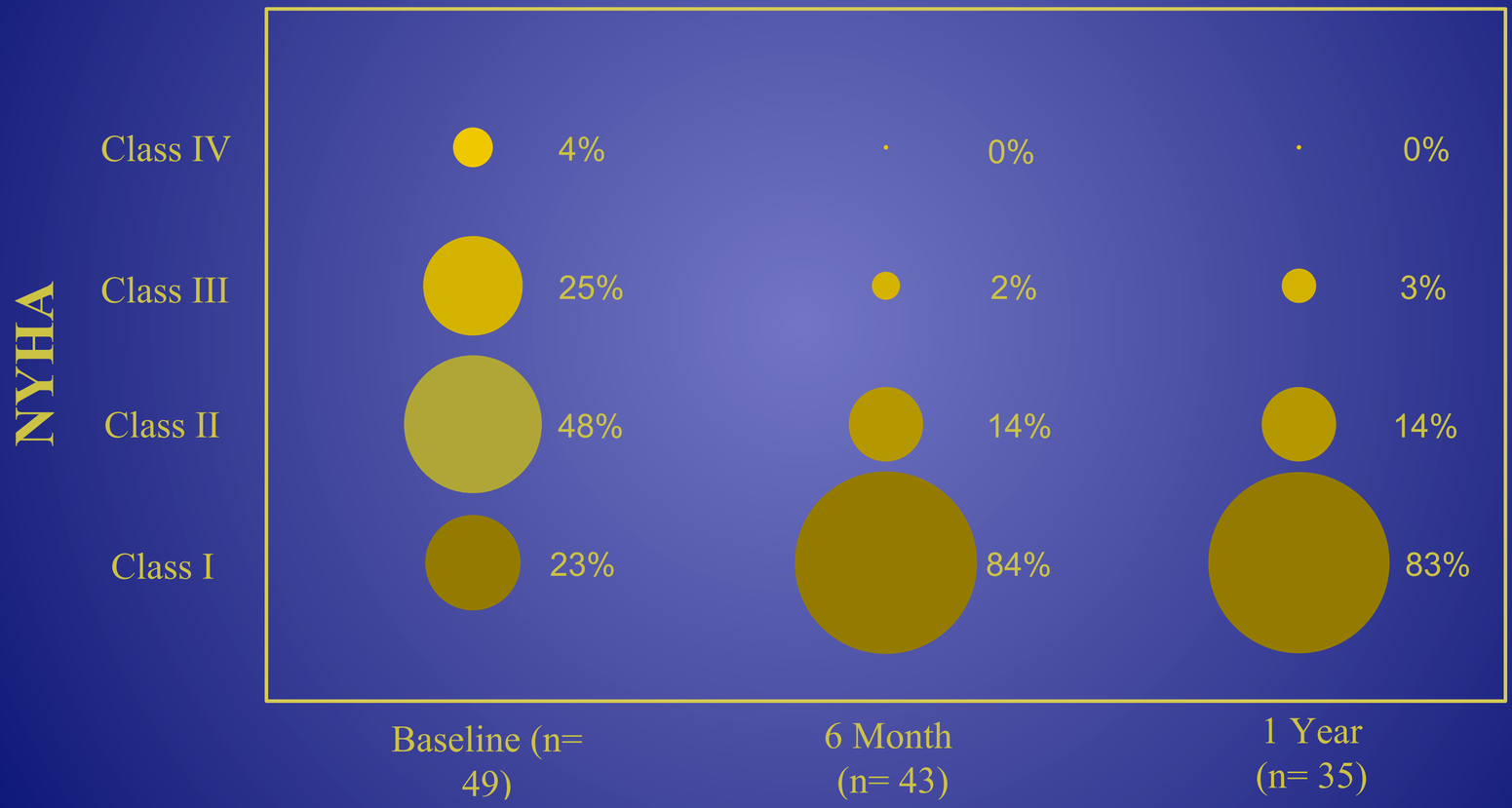
Percutaneous Pulmonary Valve Implantation



PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

RUSH UNIVERSITY MEDICAL CENTER

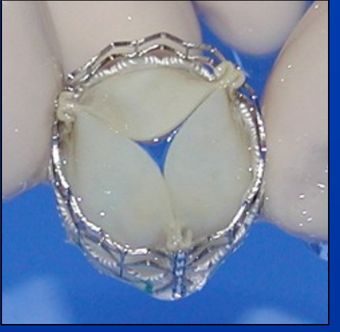
- **77% improvement in NYHA of at least 1 class at 1 year ***



* Overall improvement for patients with NYHA ≥ Class II

COMPASSION

Rush Center for Congenital and Structural Heart Disease

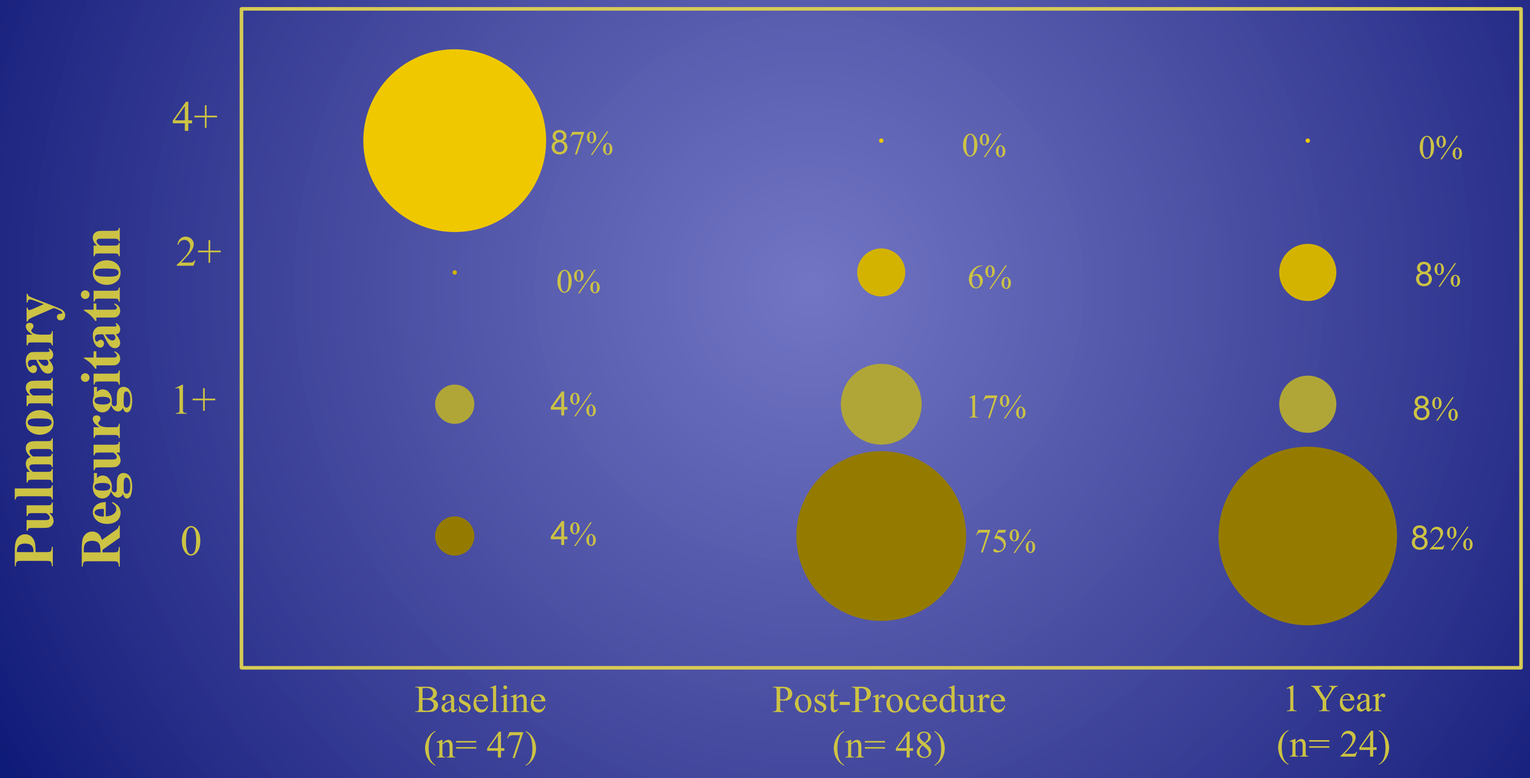


Percutaneous Pulmonary Valve Implantation

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

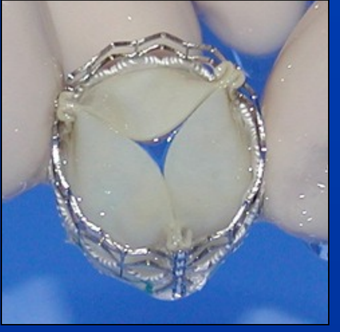
RUSH UNIVERSITY MEDICAL CENTER

- **100% Improvement (≥ 1 grade) in PR at 1 year**



COMPASSION

Rush Center for Congenital and Structural Heart Disease

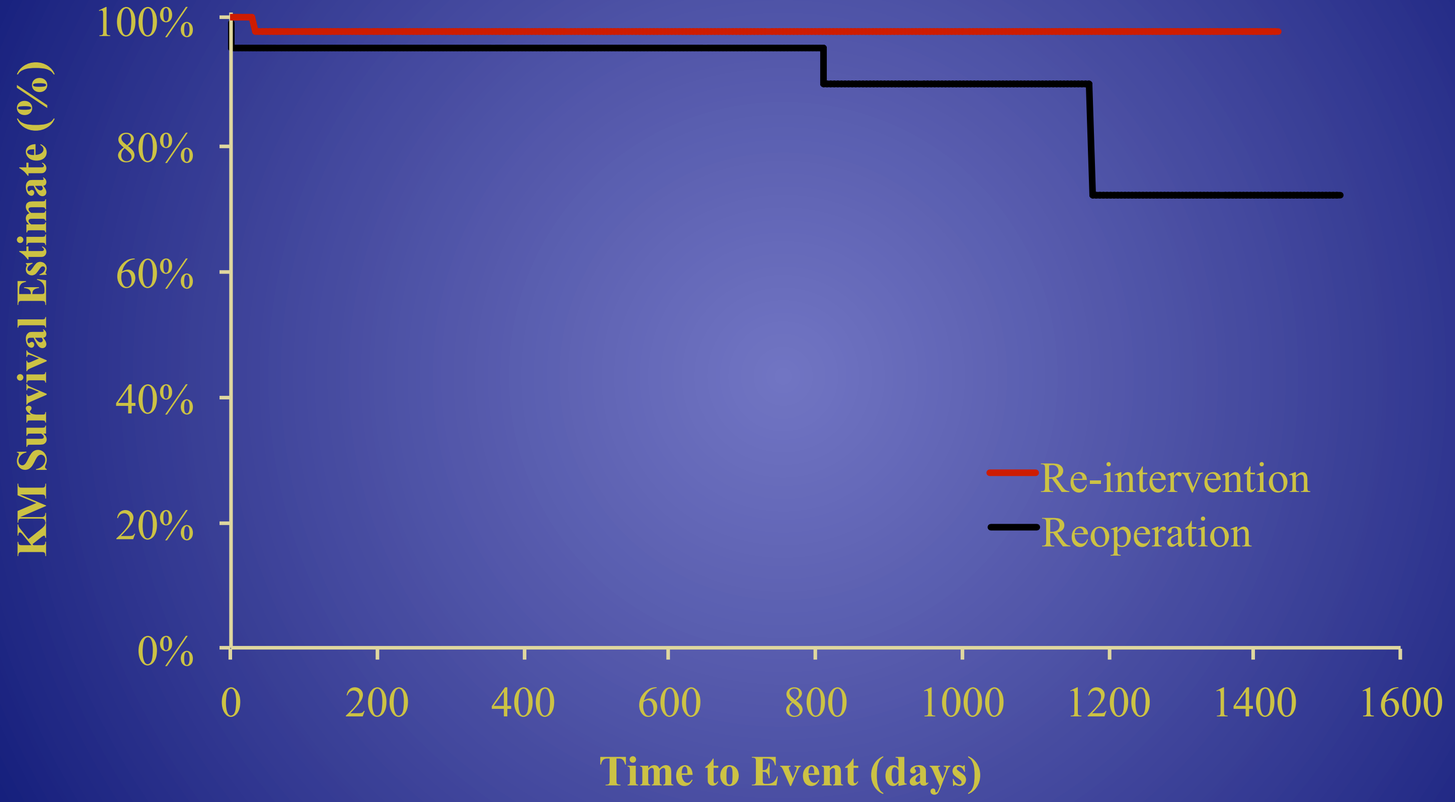


Percutaneous Pulmonary Valve Implantation

PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

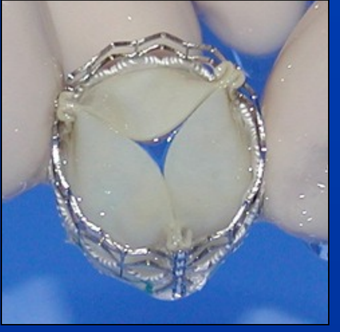
RUSH UNIVERSITY MEDICAL CENTER

Results

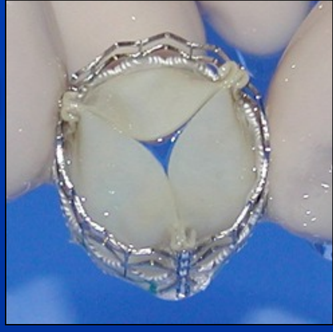


COMPASSION 14

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation

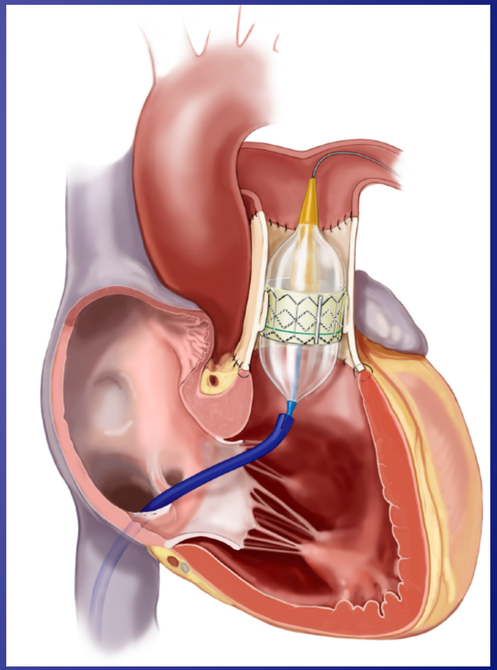


PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium

RUSH UNIVERSITY MEDICAL CENTER

Summary

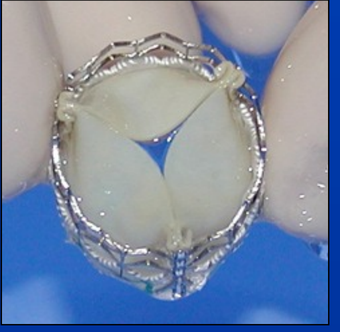
- COMPASSION enrollment and extended follow-up ongoing
- 50 patients, 5 centers
  - 36 patients with 1 year follow-up
  - 87.9 total patient years, mean = 1.76 ± 1.2 year
- Outcomes, latest data extract:
  - 96% Freedom from death or reoperation at 1 year
  - 94% Freedom from MACCE at 6 months and 1 year
  - 77% Improvement (≥ 1 class) in NYHA at 1 year *
  - 100% Improvement (≥ 1 grade) in PR at 1 year
  - *Other functional improvements currently under analysis*
  - No SAPIEN fractures
  - No endocarditis in implanted population



* Overall improvement for patients with NYHA ≥ Class II

COMPASSION

Rush Center for Congenital and Structural Heart Disease



Percutaneous Pulmonary Valve Implantation
Edwards-Sapien Valve

CONCLUSIONS

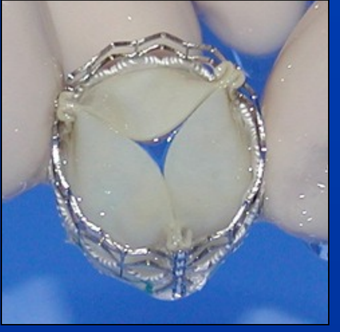
Transcatheter Pulmonary valve replacement (tPVR) therapy is safe and effective in patients with a dysfunctional conduit between the RV-PA.

The COMPASSION trial has been expanded to include 10 US sites.

tPVR is a game changer!

Rush Center for Congenital and Structural Heart Disease

Percutaneous Pulmonary Valve Implantation

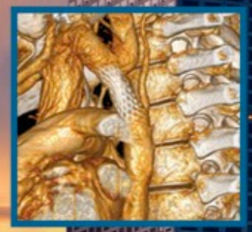


PICS-AICS

Pediatric and Adult Interventional Cardiac Symposium

SAVE THE DATE
JUNE 7-10, 2014

MARRIOTT CHICAGO DOWNTOWN



CHICAGO

LIVE CASE DEMONSTRATIONS | ABSTRACT SESSIONS
HOT DEBATES | "MY NIGHTMARE CASE IN THE CATH LAB" | WORKSHOPS | SMALLER BREAKOUT SESSIONS

www.picsymposium.com

RUSH UNIVERSITY MEDICAL CENTER

Rush Center for Congenital and Structural Heart Disease