# Pulmonary Valve Regurgitation


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# Pulmonary Valve Regurgitation

## DISCLOSURE

- Consultant to Edwards Lifesciences
- Advisory Board of JenaValve
- Consultant, stock option Colibri Heart Valve

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# Pulmonary Valve Regurgitation

## Physiology of PR

- The size of the regurgitant orifice
- Pulmonary Artery Anatomy
- Pulmonary vascular resistance
- Right ventricle compliance
- Left ventricle function

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# Pulmonary Valve Regurgitation

## Symptoms

- Asymptomatic, if not challenged
- Diminished exercise tolerance
- R & L ventricle failure
- Increased risk of arrhythmias, leading to syncope and sudden death

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# Pulmonary Valve Regurgitation

## How To Assess PR?

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# Pulmonary Valve Regurgitation

## Physical Examination

1. Prominent parasternal heave
2. Single S2; S3 sometime present.
3. Diastolic decrescendo murmur.
4. Systolic ejection murmur is usually present.
5. Signs of right sided CHF.
6. If there is PFO, cyanosis may appear.

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# Pulmonary Valve Regurgitation

## EKG

1. RVH.
2. ST-T wave abnormalities if right ventricle wall stress is increased.
3. CRBBB
4. Increased QRS duration. Change of QRS duration overtime & risk of sudden death.

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# Pulmonary Valve Regurgitation

## Echocardiography

1. Quite challenging.
2. Semi-quantitative:
3. Ratio of the width of regurgitant jet color flow: annulus.
4. Holo-diastolic retrograde flow in the distal pulmonary artery.
5. Doppler estimates of regurgitant fraction.
6. RV EF & volume (2D, M-Mode, 3D, MPI, d*p*/d*t).*
7. LV function.
8. Estimation of the RV pressure.
9. Localization of obstruction.
10. Doppler tissue imaging.

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# Pulmonary Valve Regurgitation

## Echocardiography

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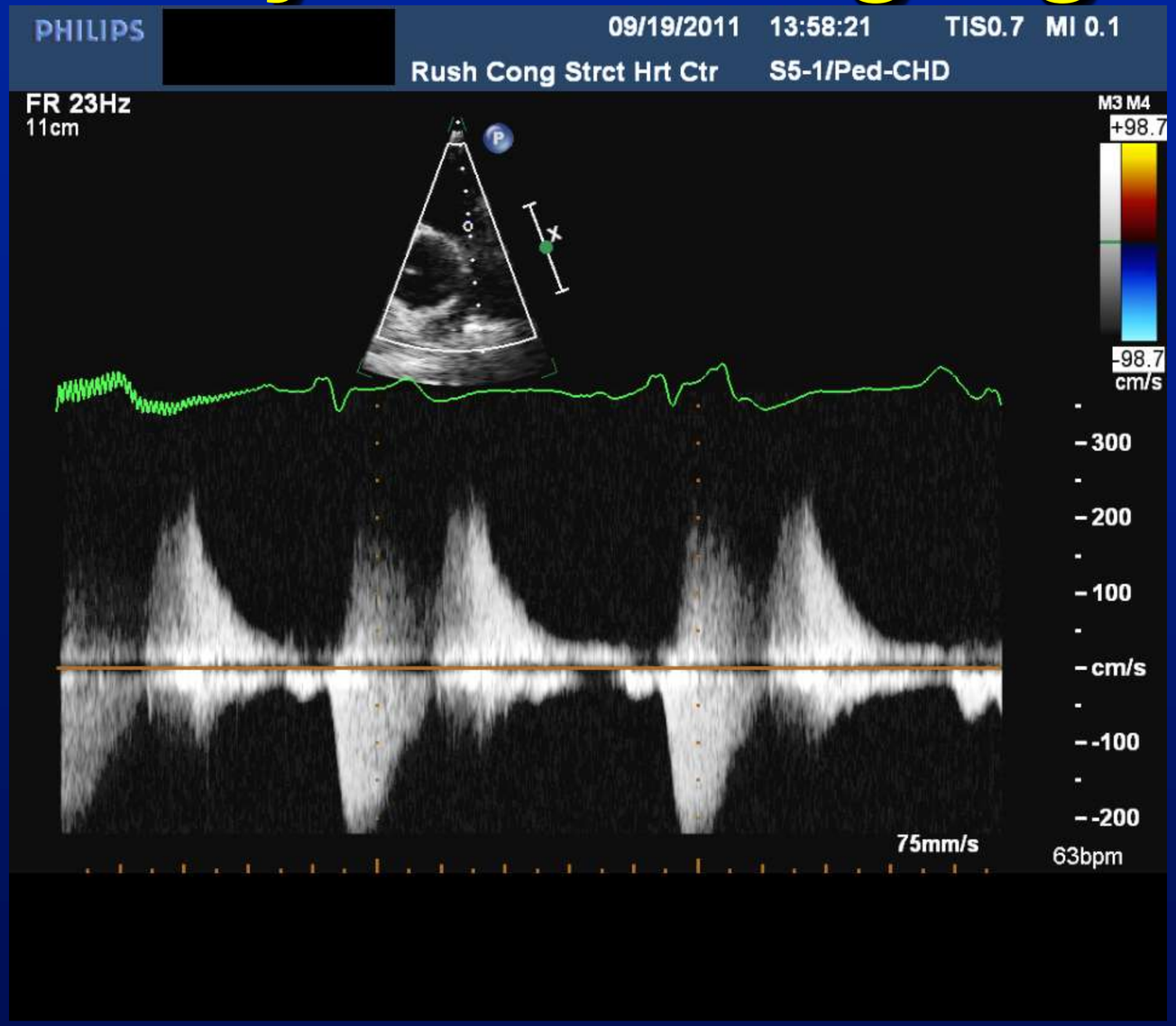


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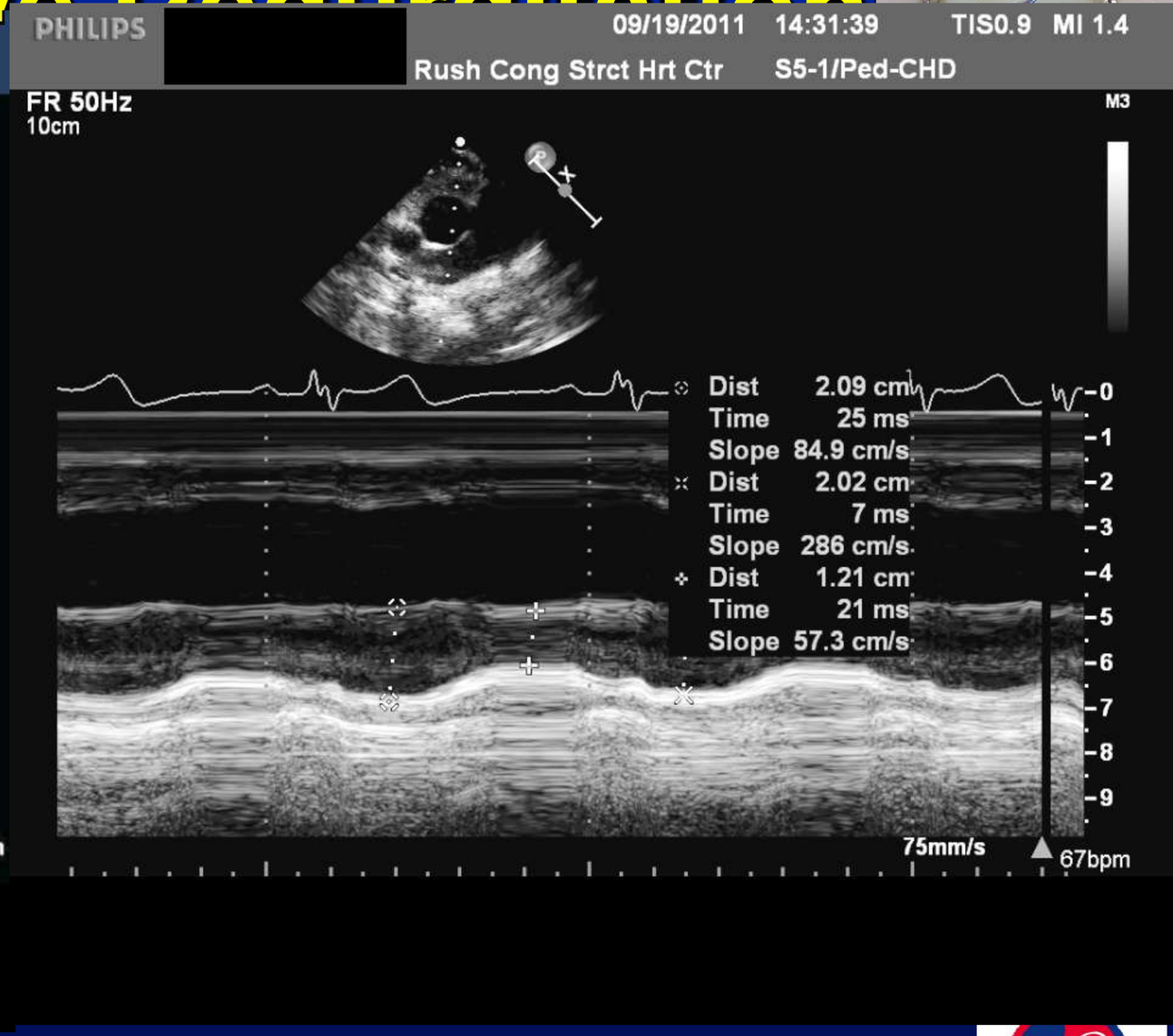


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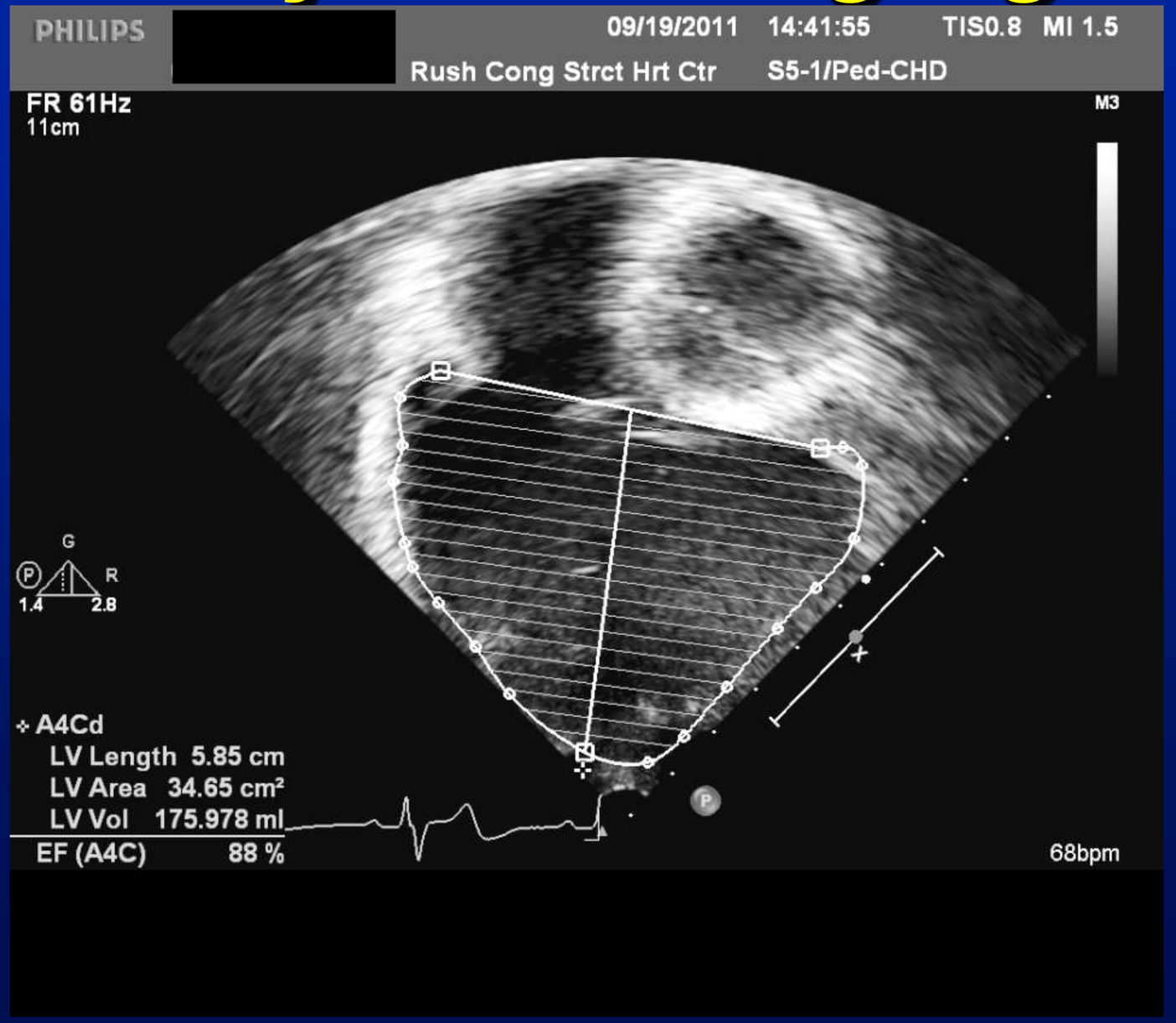
# Pulmonary Valve Regurgitation

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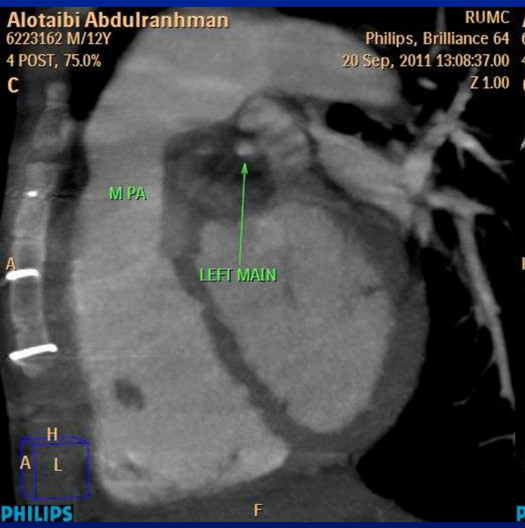
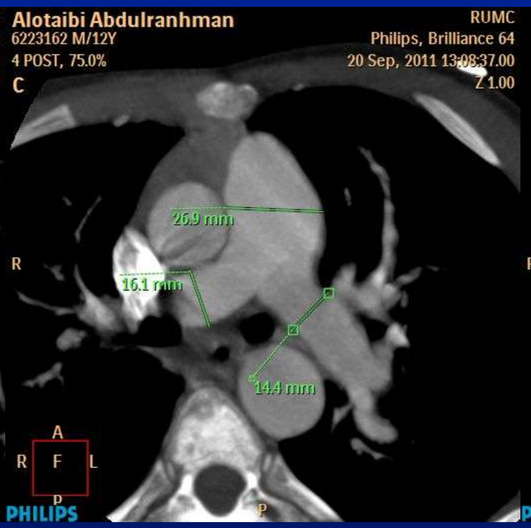
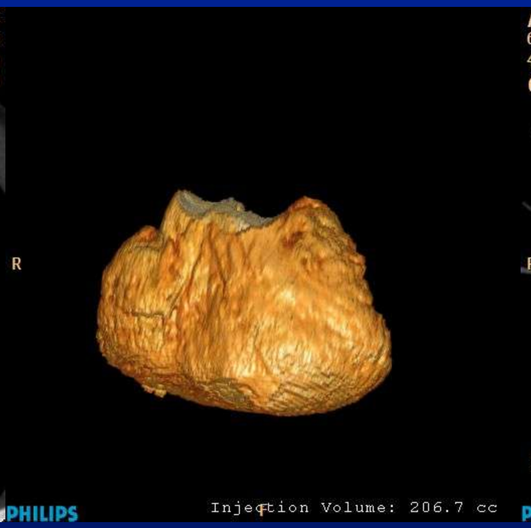
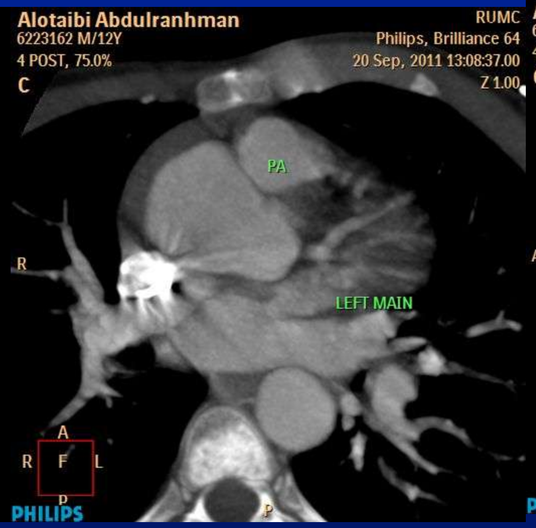
# Pulmonary Valve Regurgitation

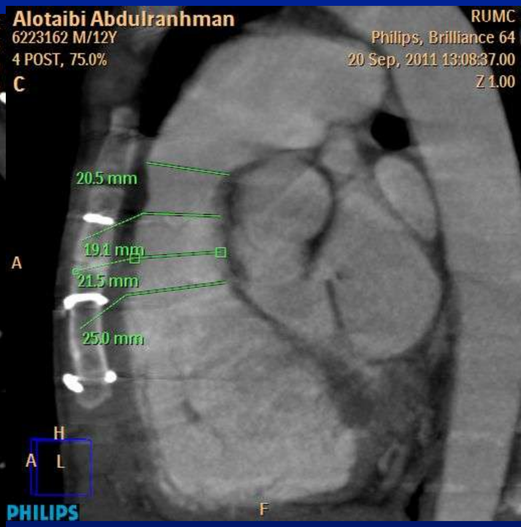
## Cardiac CT

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# Pulmonary Valve Regurgitation

## Cardiac MRI

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# Pulmonary Valve Regurgitation

## Cardiac Catheterization

1. CO
2. RV pressure: DAO
3. MPA/RPA/LPA pressure tracings and gradient
4. R-L shunt
5. Regurgitant fraction (pressure-volume loops)
6. Angiography in RV, MPA, branches

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# Pulmonary Valve Regurgitation


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# Pulmonary Valve Regurgitation

## Conduit Types

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

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# Pulmonary Valve Regurgitation

## 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


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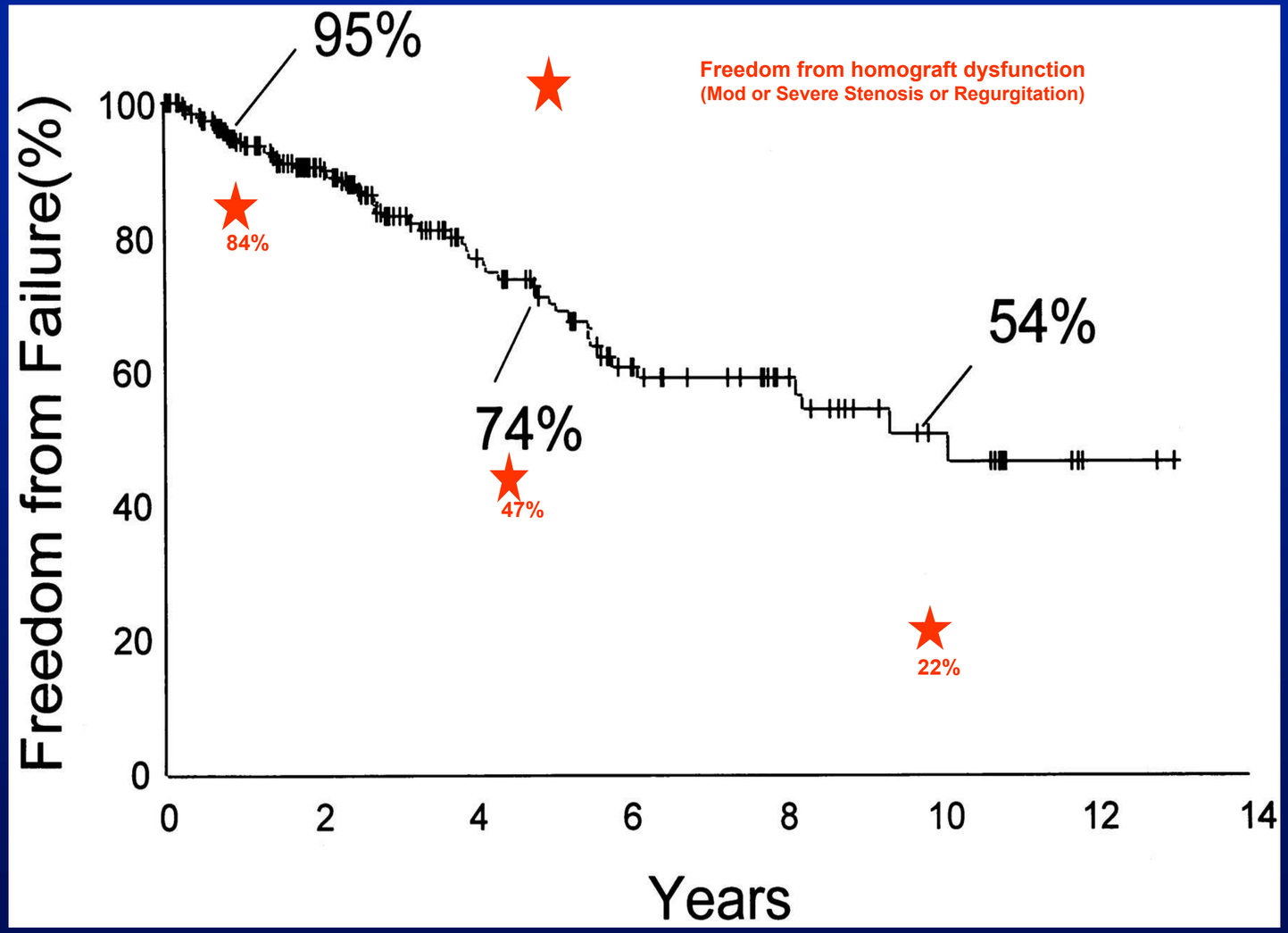
# Pulmonary Valve Regurgitation




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

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# Pulmonary Valve Regurgitation

**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

# 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*

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# Pulmonary Valve Regurgitation

## 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

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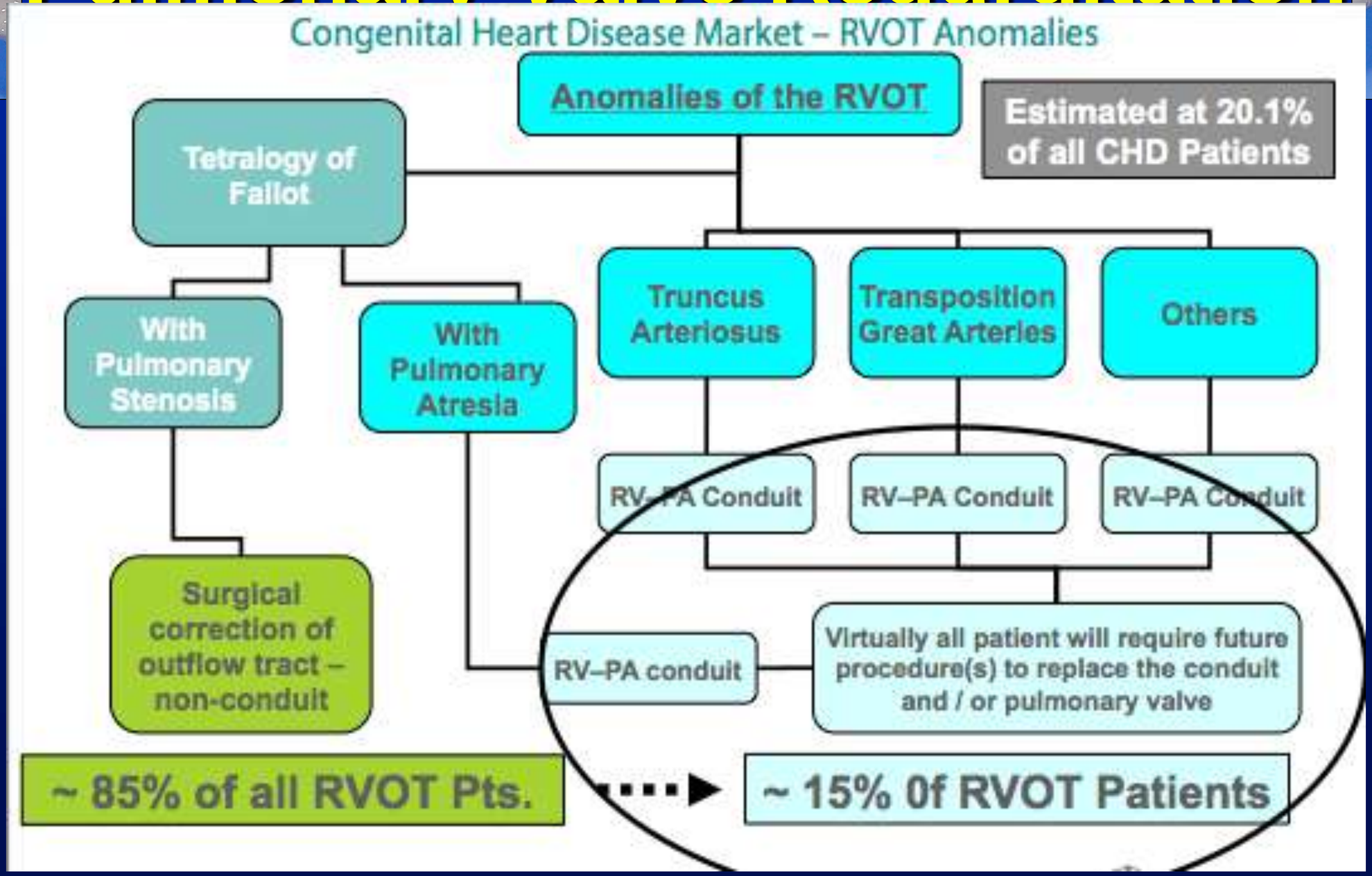
# Pulmonary Valve Regurgitation

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# Pulmonary Valve Regurgitation

## The Melody Valve

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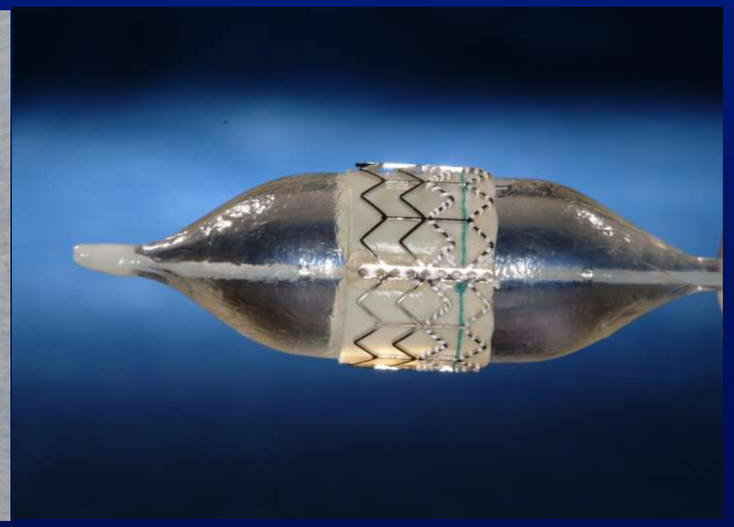
# Pulmonary Valve Regurgitation

## 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



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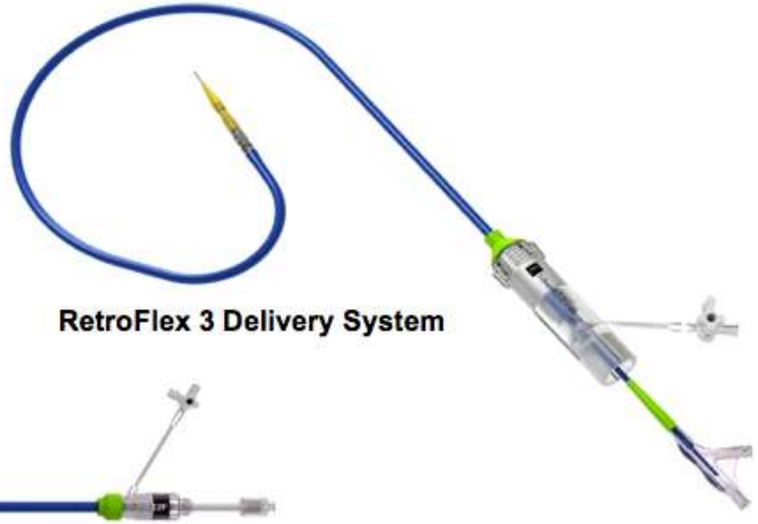
# Percutaneous Pulmonary Valve Replacement
# Current Status

Edwards SAPIEN THV



RetroFlex 3 Delivery System

RetroFlex Balloon Catheter

RetroFlex 3 introducer Sheath Set

Atrion
Inflation Device

Crimper

RetroFlex Dilator Kit

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# Percutaneous Pulmonary Valve Replacement Current Status

## 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

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# Percutaneous Pulmonary Valve Replacement Current Status

## 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

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# Percutaneous Pulmonary Valve Replacement Current Status

## 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)

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# Percutaneous Pulmonary Valve Replacement

## Medical history
### (including conduit size at time of implant)

COMPASSION

- **21 Yr Female**
- **- TOF/PA/small confluent PA's & MAPCA's**
  **- Left aortic arch**
- **Surgical Hx**
  - 3 mo (1990) - LMBT shunt and ligation of 2 MAPCA via left lateral thoracotomy
  - 23 mo (1991) - VSD closure via right ventriculotomy, LPA angioplasty, placement of 23 mm pulmonary homograft, ligation of LBTS and right sided MAPCA's, PFO closure

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# Percutaneous Pulmonary Valve Replacement

## Comprehensive transthoracic 2D Echo

(≤ 30 days before procedure)

COMPASSION

- 7-28-11
- Free PI
- No residual PS
- Moderate RV dilation
- Qualitatively good biventricular funtion

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Cardiac MRI

(≤ 60 days before procedure) per Core Lab Protocol

COMPASSION

**7/28/2011**

| | | |
|---|---|---|
| Volumetric data | Moderate – severe PR | |
| | PR fraction | 37% |
| | **RV EDV** | **121.2 ml/m2** |
| | **RV EF** | **56.3 %** |
| | **LV EF** | **61.9 %** |
| | **QpR:QpL** | **56%:44%** |

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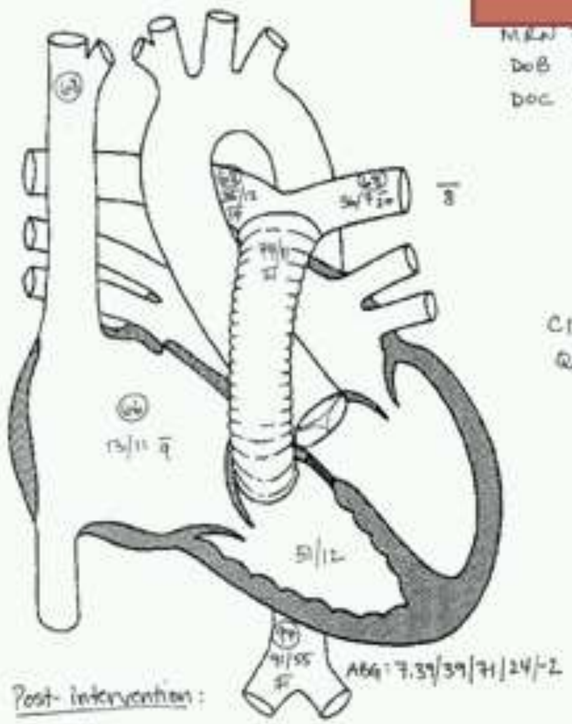
# PROCEDURE
# Cath data 8-12-11

COMPASSION



[redacted]
MRN 3576195
DoB 1/5/90
DoC 8/12/11

Wt = 68.3 kg
Hgb = 14.1
$FiO_2$ 21%

CI = 2.0 L/min/m²
Qp:Qs = 1

ABG: 7.39/39/71/24/-2

Post-intervention:
RV 34/7
PA 30/9 17
LPA 26/14 22
PCWP 12
d Ao 95/55 72

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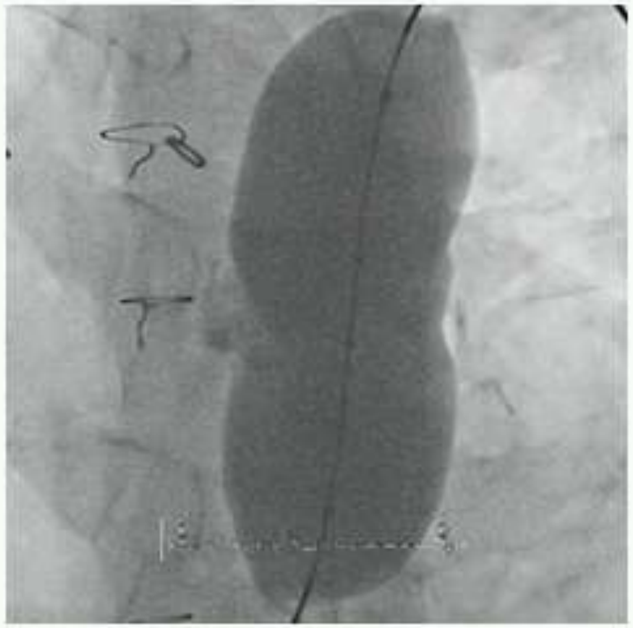
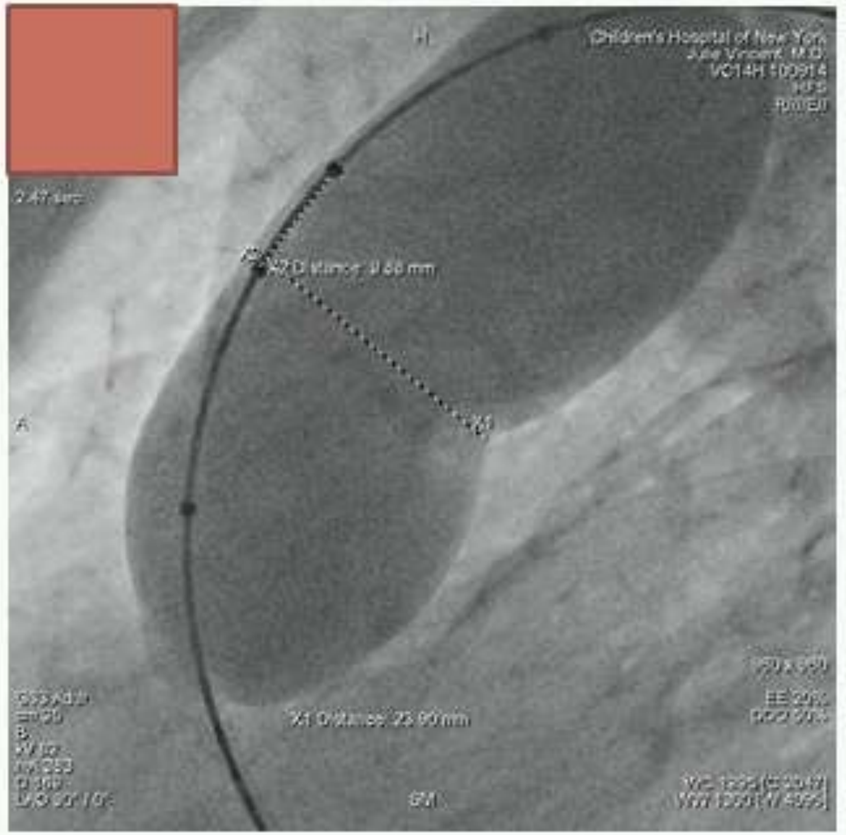
# PROCEDURE (8-12-11)
## Balloon sizing

COMPASSION



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# Current Status

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# Percutaneous Pulmonary Valve Replacement
# Current Status

Perc ment

# Percutaneous Implantation of the Edwards SAPIEN Transcatheter Heart Valve for Conduit Failure in the Pulmonary Position

## Early Phase 1 Results From an International Multicenter Clinical Trial

Damien Kenny, MD,* Ziyad M. Hijazi, MD, MPH,* Saibal Kar, MD,† John Rhodes, MD,‡ Michael Mullen, MD,§ Raj Makkar, MD,† Girish Shirali, MD,‖ Mark Fogel, MD,¶ John Fahey, MD,# Mary G. Heitschmidt, RN,* Christopher Cain, RN, MBA**

*Chicago, Illinois; Los Angeles and Irvine, California; Durham, North Carolina; London, United Kingdom; Charleston, South Carolina; Philadelphia, Pennsylvania; and New Haven, Connecticut*

**Objectives** The purpose of this study was to evaluate the safety and effectiveness of the Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences LLC, Irvine, California) in the pulmonary position in patients with moderate to severe pulmonary regurgitation with or without stenosis.

**Background** Transcatheter pulmonary valve replacement is evolving, but to date, experience has been limited to the Melody valve (Medtronic Inc., Minneapolis, Minnesota).

**Methods** Eligible patients with dysfunctional right ventricle-to-pulmonary artery conduits were screened if body weight was ≥35 kg and the in situ conduit diameter was ≥16 mm and ≤24 mm. Standardized implantation and follow-up protocols were used.

**Results** Thirty-six patients from 4 centers were recruited between April 2008 and May 2010. Mean body weight was 73.4 ± 22.9 kg. Successful valve deployment was achieved in 33 of 34 attempts (97.1%). Valve migration occurred in 3 patients, with 2 requiring surgical retrieval; however, 1 patient underwent successful perventricular valve implantation. Further intraprocedure complications included pulmonary hemorrhage (n = 2), ventricular fibrillation (n = 1), and stent migration (n = 1). Pullback gradient across the conduit decreased from 26.8 ± 18.4 mm Hg to 11.7 ± 8.0 mm Hg ($p < 0.001$). The right ventricular/aortic pressure ratio decreased from 0.6 ± 0.2 to 0.4 ± 0.1 ($p < 0.001$). Peak Doppler gradient across the right ventricular outflow tract decreased from 41.9 ± 27.9 mm Hg to 19.1 ± 13.3 mm Hg ($p < 0.001$). At 6-month follow-up, all patients were alive. The number of patients with New York Heart Association functional class I increased from 5 at baseline to 27 at follow-up. Pulmonary regurgitation was ≤2+ in 97% of patients. Freedom from reintervention was 97% with 1 patient undergoing elective placement of a second valve due to conduit-induced distortion of the initial implant.

**Conclusions** Transcatheter pulmonary valve replacement using the Edwards SAPIEN transcatheter heart valve is safe and effective in patients with dysfunctional right ventricle-to-pulmonary artery conduits. (J Am Coll Cardiol 2011; 58:2248–56) 

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# Percutaneous Pulmonary Valve Replacement
# Current Status

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# Percutaneous Pulmonary Valve Replacement Current Status

## 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 | ☆ | | | ☆ | ☆ | ☆ |

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# Percutaneous Pulmonary Valve Replacement Current Status

## 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
    - – symptoms assessed by NYHA classification
    - –exercise tolerance as assessed by CPET

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Procedure

- Accurate conduit sizing ⟶ angiography
- Coronary assessment
- Pre-stenting with BMS in all cases
- Stenotic Conduits:
  - *23mm THV if dilated conduit 21-23mm*
  - *26mm THV if dilated conduit 23-26mm*
- Conduits without stenosis
  - *23mm THV if conduit 19-21mm*
  - *26mm THV if conduit 21-23mm*

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Patients – 36 (4 Centers)

| | |
|---|---|
| **Age (years)** | 30.3±15.1 |
| **Weight (kgs)** | 73.4±22.9 |
| **Sex** | 24M:12F |
| **Diagnosis** | *Tetralogy of Fallot* (16) |
| | *Ross Procedure* (11) |
| | *Others* (8) |
| **Open Heart Surgeries** | 1.94 (1-5) |
| **RVOT Conduit Types** | *Homograft* (29) |
| **Original RVOT Conduit Size (mm)** | 23.4±3.9 |
| **Primary Indication** | *Stenosis* (15) |
| | *Regurgitation* (19) |
| | *Mixed* (2) |
| **RVOT Pre-Stenting** | Stent placed at time of procedure (24) |
| | Stent placed before day of procedure(12) |

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Statistics

- Core laboratories
- Device success → THV delivery and PR≤2+
- TTE/MRI and CPET → THV implanted
- Data → Mean±SD
- Wilcoxon rank test: Baseline → 6 months

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Results

- Successful SAPIEN implant in 33/34 attempts
  - *Conduit Too Small*
  - *Stent Migration - Surgery*
  - *THV Migration – Surgery*
- THV migration in 3 patients
  - *Surgical retrieval (n=2) – Perventricular*
  - *Deployment in IVC (n=1)*
- Device success: 31/36 pts (86.1%)

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# Percutaneous Pulmonary Valve Replacement Current Status

## Results (2)

***Intra procedural Hemodynamics***

| | Pre-Implant | Post-Implant | p Value |
|---|---|---|---|
| RV systolic pressure (mmHg) | 55.3±18.2 | 42±13.2 | <0.001 |
| RV diastolic pressure (mmHg) | 10.5±4.0 | 9.2±4.3 | 0.036 |
| Mean PA pressure (mmHg) | 16.0±5.2 | 30±8.2 | 0.001 |
| Diastolic PA pressure (mmHg) | 9.3±3.1 | 12.4±5.5 | <0.001 |
| RV-PA pressure gradient (mmHg) | 26.8±18.4 | 11.7±8.0 | <0.001 |
| RV/Aortic pressure (mmHg) | 0.6±0.2 | 0.4±0.1 | <0.001 |

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Results (3)

***Transthoracic Echocardiography***

| | Baseline | 6 Months | P value |
|---|---|---|---|
| Conduit Peak Gradient (mmHg) | 41.9±26.2 | 19.1±13.3 | p<0.001 |
| Conduit Mean Gradient (mmHg) | 24±15.0 | 12±8.8 | p<0.001 |
| Estimated RV Pressure (mmHg) | 67.3±20.6 | 49.3±11.1 | p=0.005 |

***Magnetic Resonance Imaging****

| | Baseline | 6 Months | P value |
|---|---|---|---|
| Pulmonary regurgitant fraction (%) | 28.64 ± 18.0 | 3.47 ± 5.40 | p<0.001 |
| RV end-diastolic volume (mls.m$^{-2}$) | 130.9 ± 62.6 | 86.9 ± 19.6 | p=0.02 |

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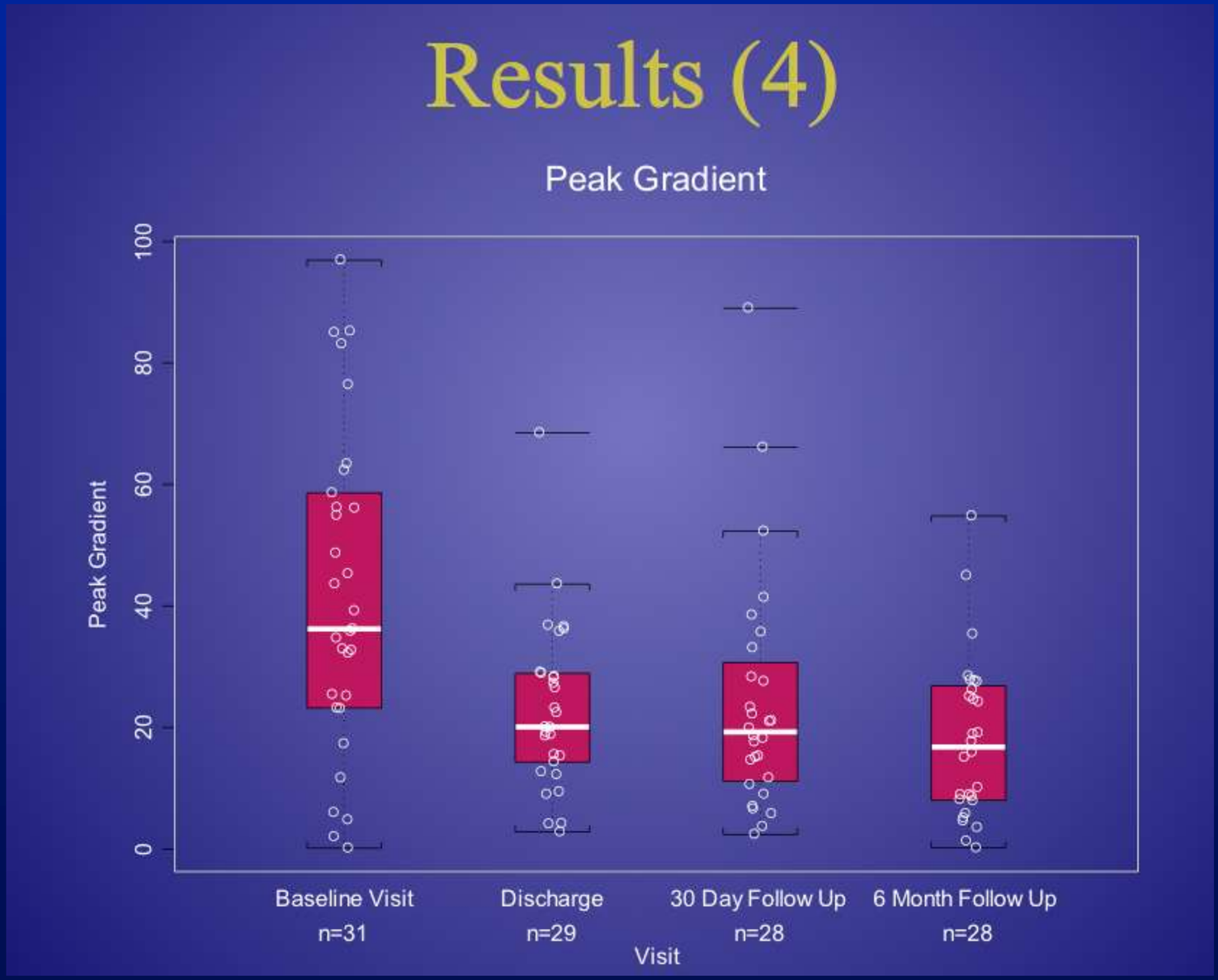
# Percutaneous Pulmonary Valve Replacement
# Current Status

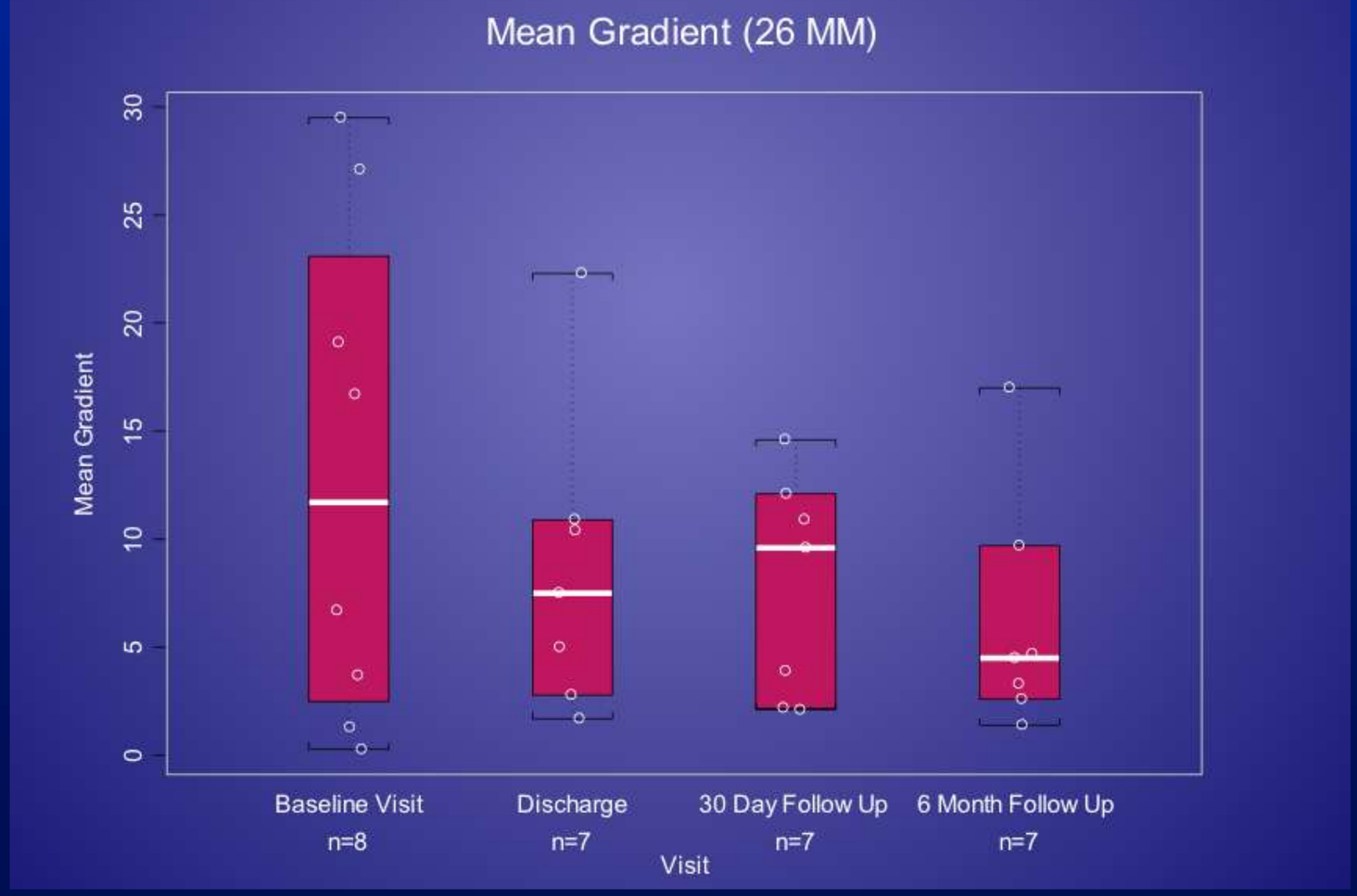
## Results (4)




Rush Center for Congenital and Structural Heart Disease

# Percutaneous Pulmonary Valve Replacement
# Current Status

## Results (5)

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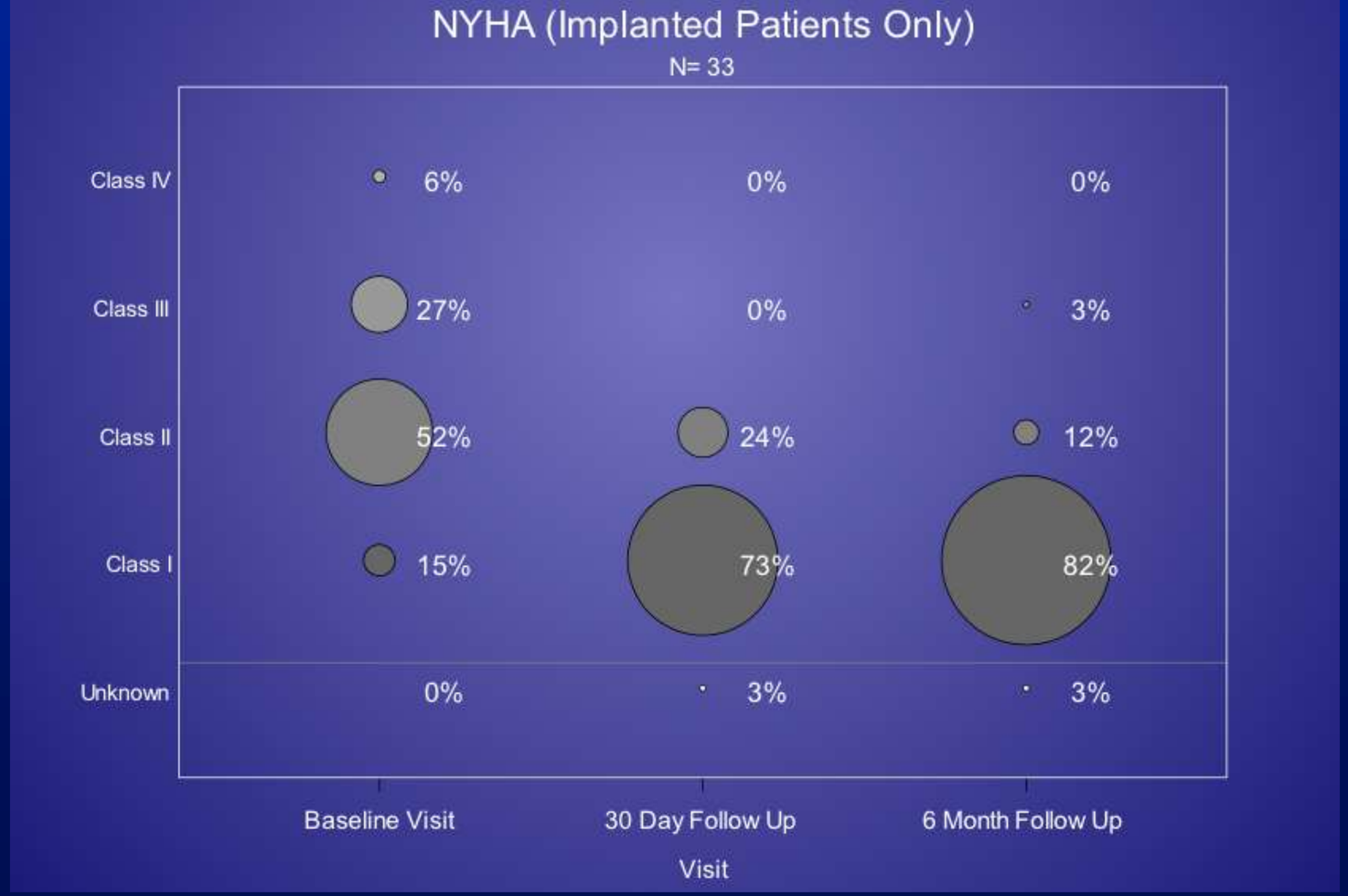
# Percutaneous Pulmonary Valve Replacement
# Current Status

## Results (6)

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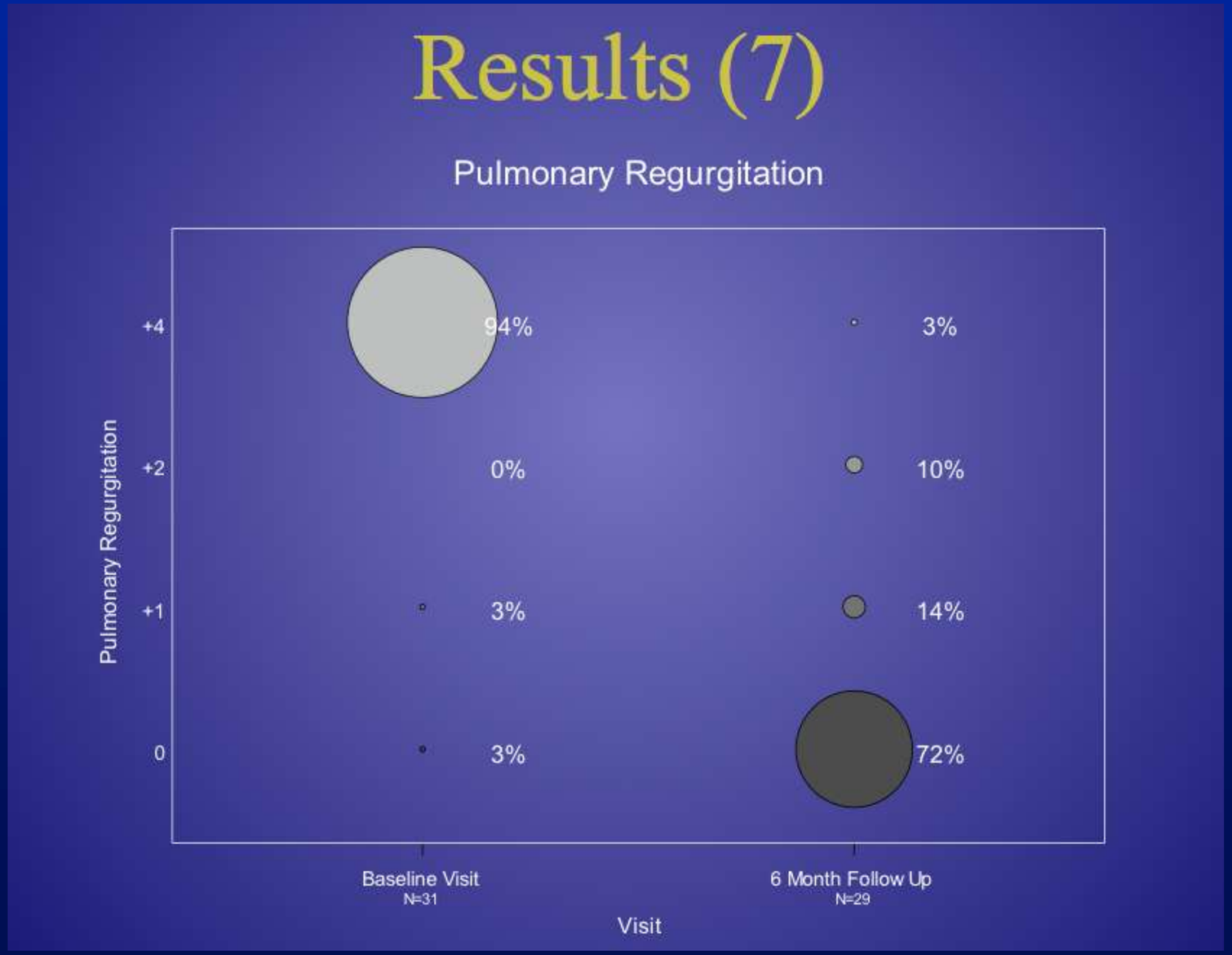
# Percutaneous Pulmonary Valve Replacement
# Current Status

## Results (7)

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Intra-Procedural A/E's

- N=7
  - THV migration → Surgical removal and PVR
  - THV migration → Surgical removal and TA delivery 26mm THV
  - THV migration → Deployment in IVC
  - Stent migration → Surgical removal and PVR
  - Pulmonary hemorrhage (n=2) → Spontaneous resolution
  - Ventricular fibrillation → DC Cardioversion

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Follow-up

- No stent fractures (CXR or CT)
- Further↓ in RVOT gradient on TTE
- No difference in CPET data
- Repeat THV required in 1 patient

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## Summary

- Edwards SAPIEN THV → Safe and Effective
- Significant sustained improvements:
  - RVOT gradients
  - PR
  - Symptoms
- Extended follow-up required

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# Percutaneous Pulmonary Valve Replacement
# Current Status






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# Percutaneous Pulmonary Valve Replacement
# Current Status

Colibri
Heart Valve

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## The Valve

1. Uniquely processed, ultra-thin, folded biological membrane leaflet assembley.
2. Custom engineered stent frame
3. Integrated pre-packaged delivery system-lowest profile available!

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# Percutaneous Pulmonary Valve Replacement Current Status

## The Valve

1. Thin-100micrometer, maximum pliability, resistant to calcification
2. Resistant to surface fracture and fraying.
3. Very low mass-can accelerateto high speed bpm with competent function.
4. Natural opening gradient of 5 mmHg.
5. Very low packing volume-lowest available catheter delivery profile.

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# Percutaneous Pulmonary Valve Replacement
# Current Status

## The Valve

1. Balloon expandable
2. Valve premounted in a delivery system in a dry state
3. Diameters:

20-22mm: 12Fr
23-26mm: 14Fr
27-30mm: 16Fr

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# Percutaneous Pulmonary Valve Replacement Current Status

## The Valve

1. Dry tissue has 30% of the mass of a wet membrane
2. Does not require storage and transport in solution
3. Dry valve can be mounted on delivery catheter at manufacturer, allows for pre package and sterilization of integrated delivery system.
4. Dry valve does not require rinising, rehydration or mounting in the cath lab

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# Percutaneous Pulmonary Valve Replacement
# Current Status

QuickTime?and a
Cinepak decompressor
are needed to see this picture.

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# Percutaneous Pulmonary Valve Replacement
## Current Status

# Conclusions

- PR previously thought to be harmless disease.
- Patients with severe PR die prematurely due to right heart failure, arrhythmias and sudden death.
- Resurrection of a competent pulmonary valve hopefully improves outcome

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# Percutaneous Pulmonary Valve Replacement
## Current Status

# Conclusions

- Results of Medtronic Melody valve and Edwards Sapien THV are very encouraging, with low risk of complications and good mid-term results.
- COMPASSION Trial: Expansion of trial to include 7 more centers in the US is underway
- New valve (Colibri) is under study-lowest profile possible!

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