



Interventional Therapies For Congenital & Structural Heart Disease



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Doha-Qatar



Interventional Therapies For Congenital & Structural Heart Disease



Disclosure

Consultant to the following companies:

Occlutech: ASD & PFO Closure devices

NuMED Inc: Balloon Angioplasty/Valvuloplasty Catheters

Colibri Heart Valve: aortic and pulmonic valves

Venus Medtech: Pulmonic valve



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Scope of the Problem!

1. CHD: Currently, there are more than one million adult patients with congenital heart disease (un-repaired, repaired, and palliated) in the US
2. SHD: AS patients; MR patients; Afib Patients; etc!
Millions of patients.



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The Team

- 1. Interventional Adult Cardiologist-Expertise in CHD**
- 2. Interventional Pediatric Cardiologist**
- 3. Cardiac Surgeon-Expertise in CHD & Valve disease**
- 4. Echocardiographer-Expertise in CHD**
- 5. Anesthesia-Expertise in CHD/SHD**
- 6. Nurses/Techs/Perfusionists/etc**



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CHD: Based on Physiology

- A. **Left-to-right shunting lesions.**
- B. Right-to-left shunting lesions.
- C. Right heart obstructive lesions.
- D. **Left heart obstructive lesions.**
- E. Post Fontan operation.
- F. **Post Tetralogy repair patients.**
- G. **Miscellaneous**



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SHD: Based on Anatomy

- A. Aortic Valve Stenosis**
- B. Mitral Valve Regurgitation/Stenosis**
- C. LAA in Afib Patients**
- D. Pulmonary Valve Regurgitation/Stenosis**
- E. Paravalvar leaks**
- F. Other conditions**



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Left-to-right shunting lesions

1. Secundum Atrial Septal Defects

2. Patent Foramen Ovale

TIA/Stroke

Orthodeoxia/Platypnea

3. Patent Ductus Arteriosus

4. Coronary AV Fistulas

5. Congenital muscular VSDs

6. Post infarct VSDs



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Secundum ASD

Benefits of Closure

Pre-selection of Patients

Closure Device

Closure Protocol

Results

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Benefits of Closure

Most patients with hemodynamically significant ASD are asymptomatic during the 1st decade of life.

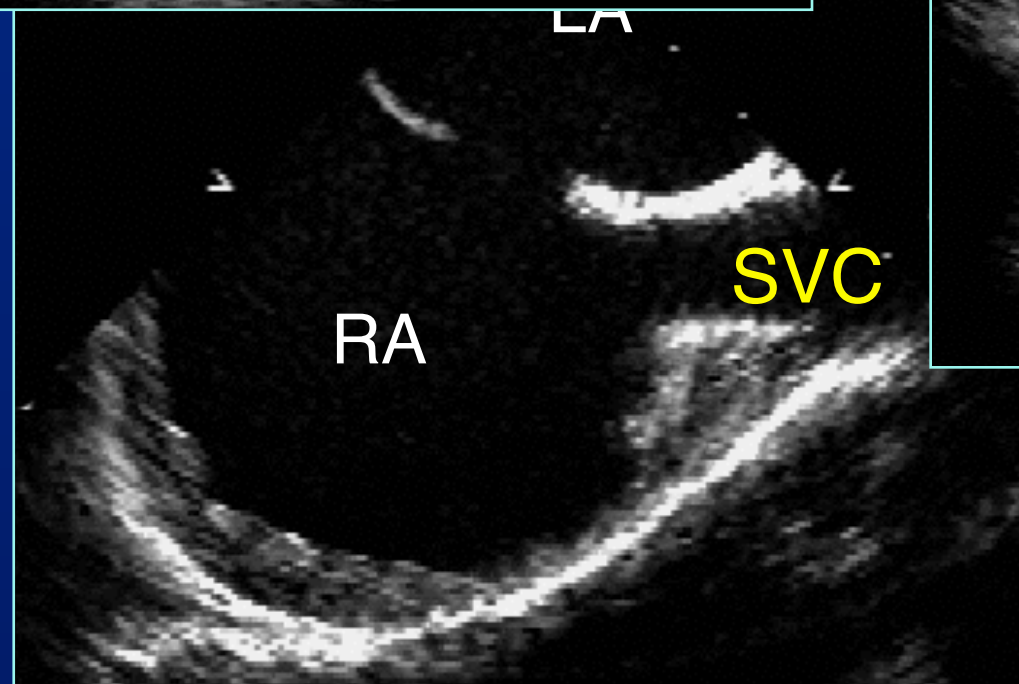
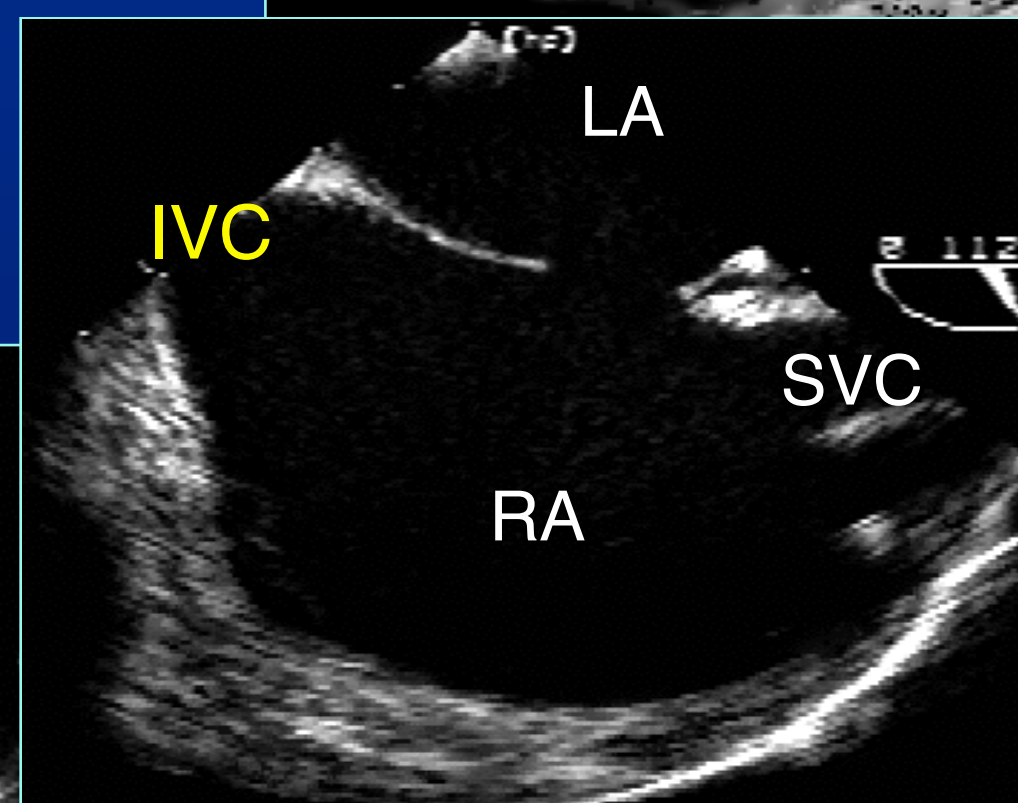
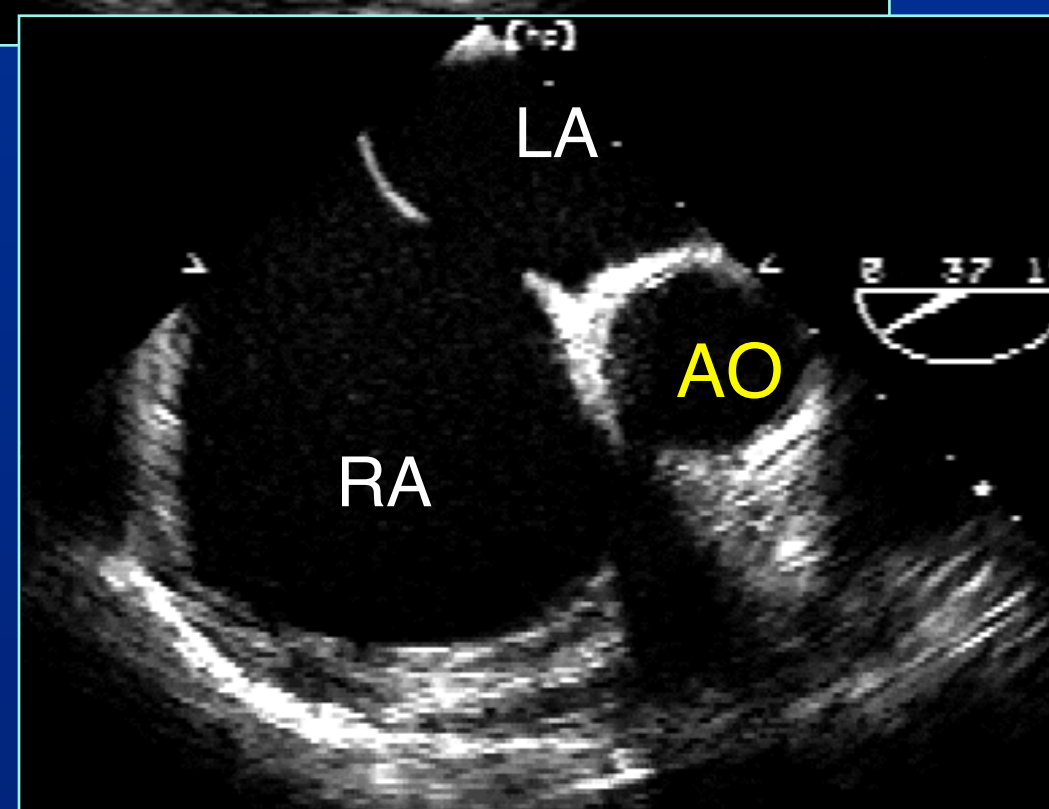
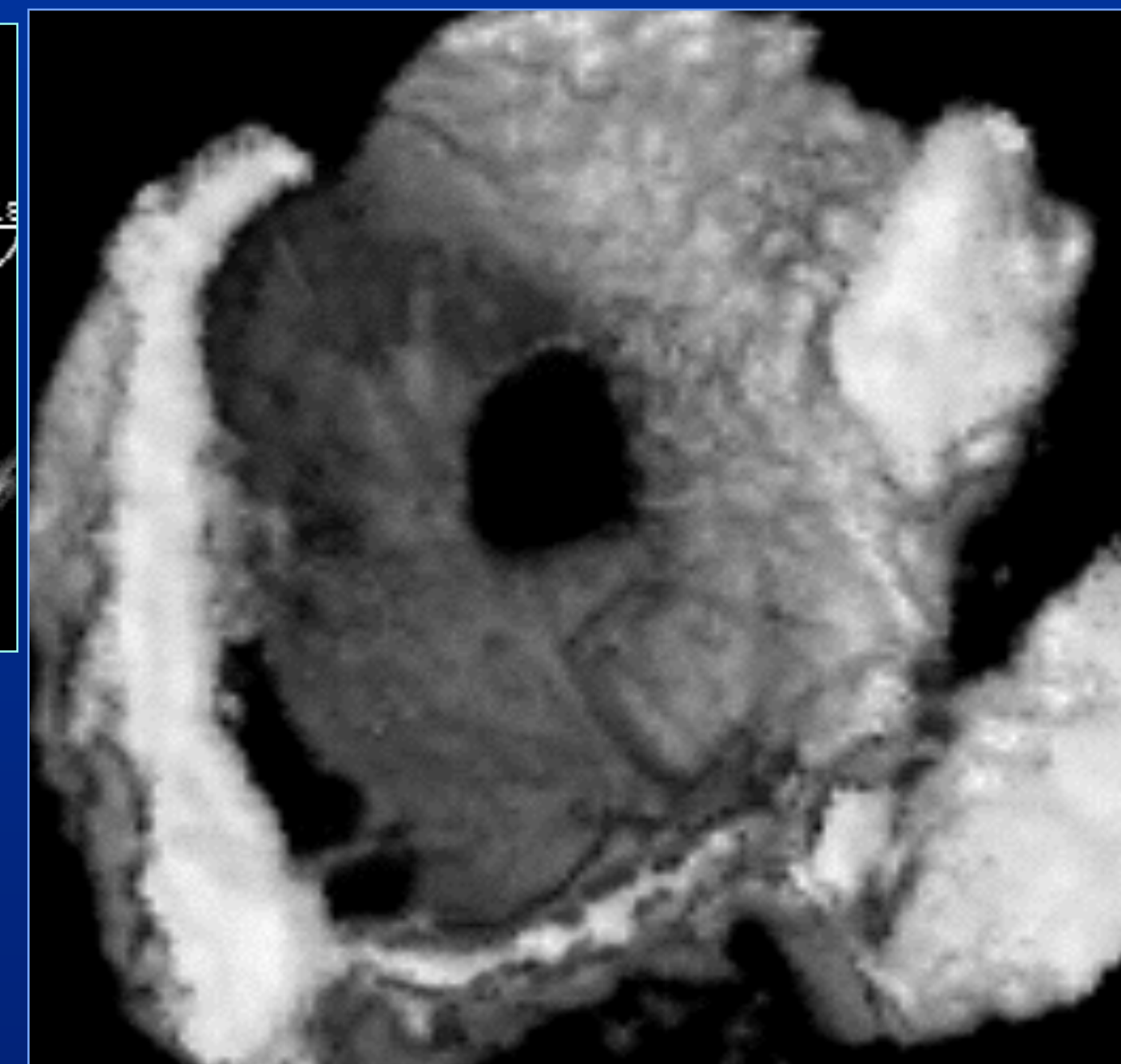
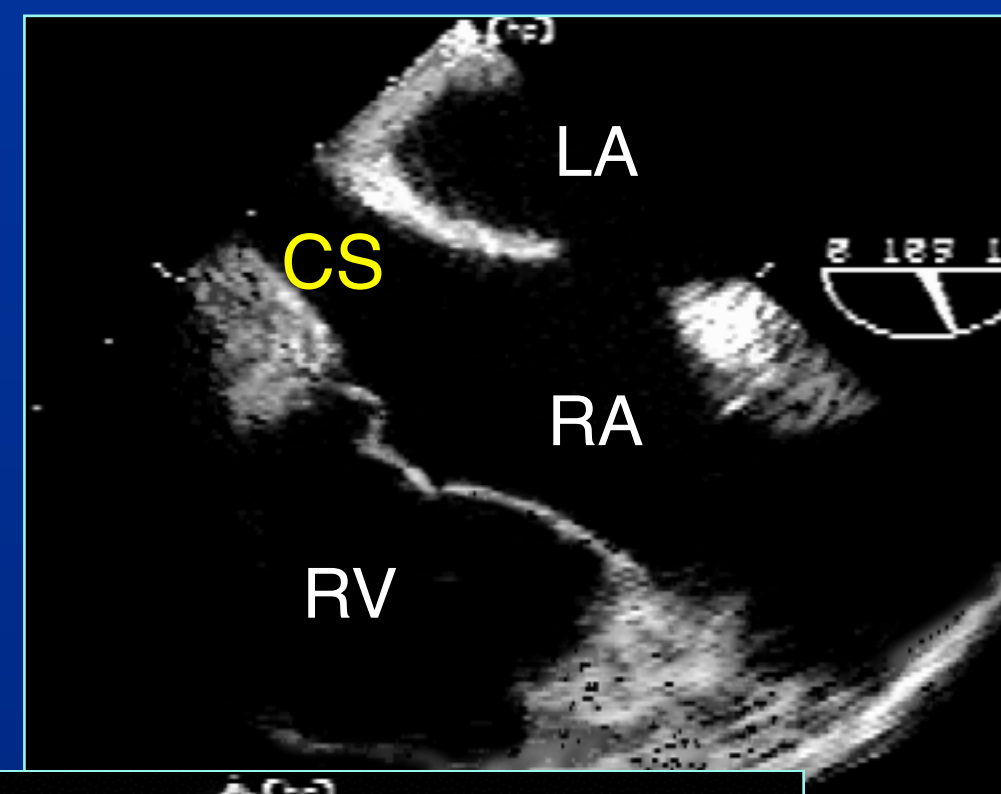
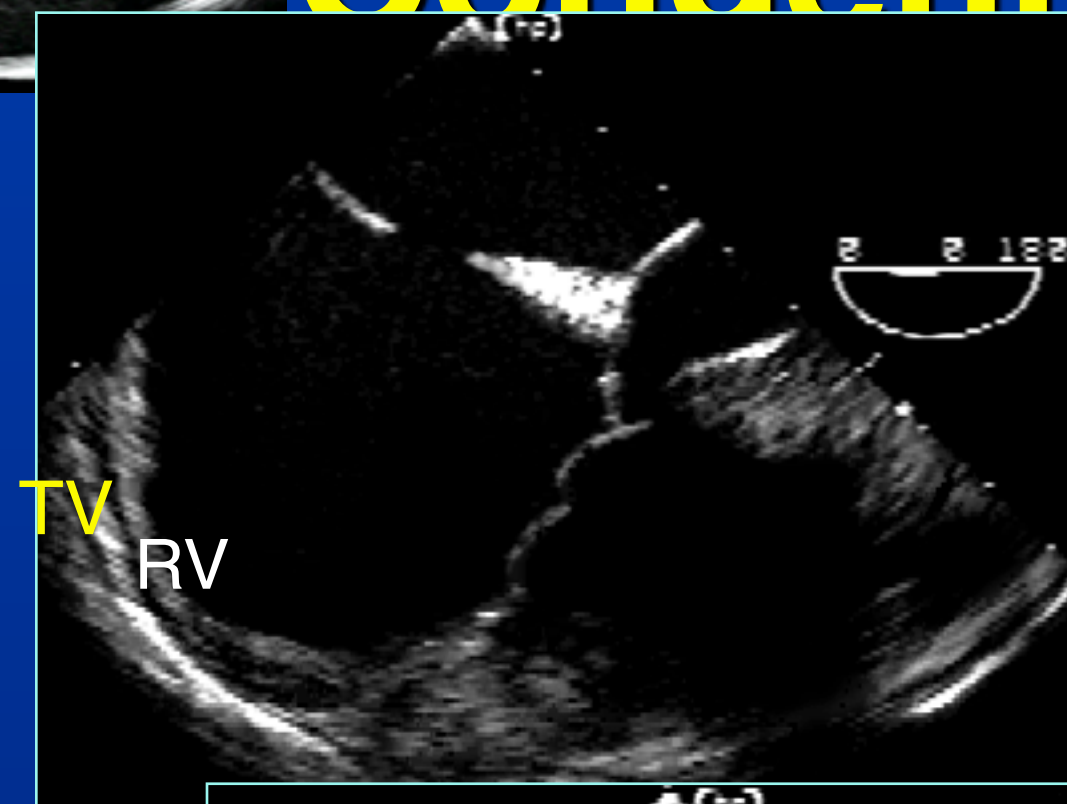
By 20y/o, 50% will c/o exertional dyspnea ; 90% by 60y/o.

If uncorrected until after 50 y/o, there is a 75% mortality.

High rate of atrial flutter/fibrillation with increasing age.

Correction at an appropriate age avoids CHF, pulmonary hypertension, thromboembolic complications, and atrial arrhythmias.

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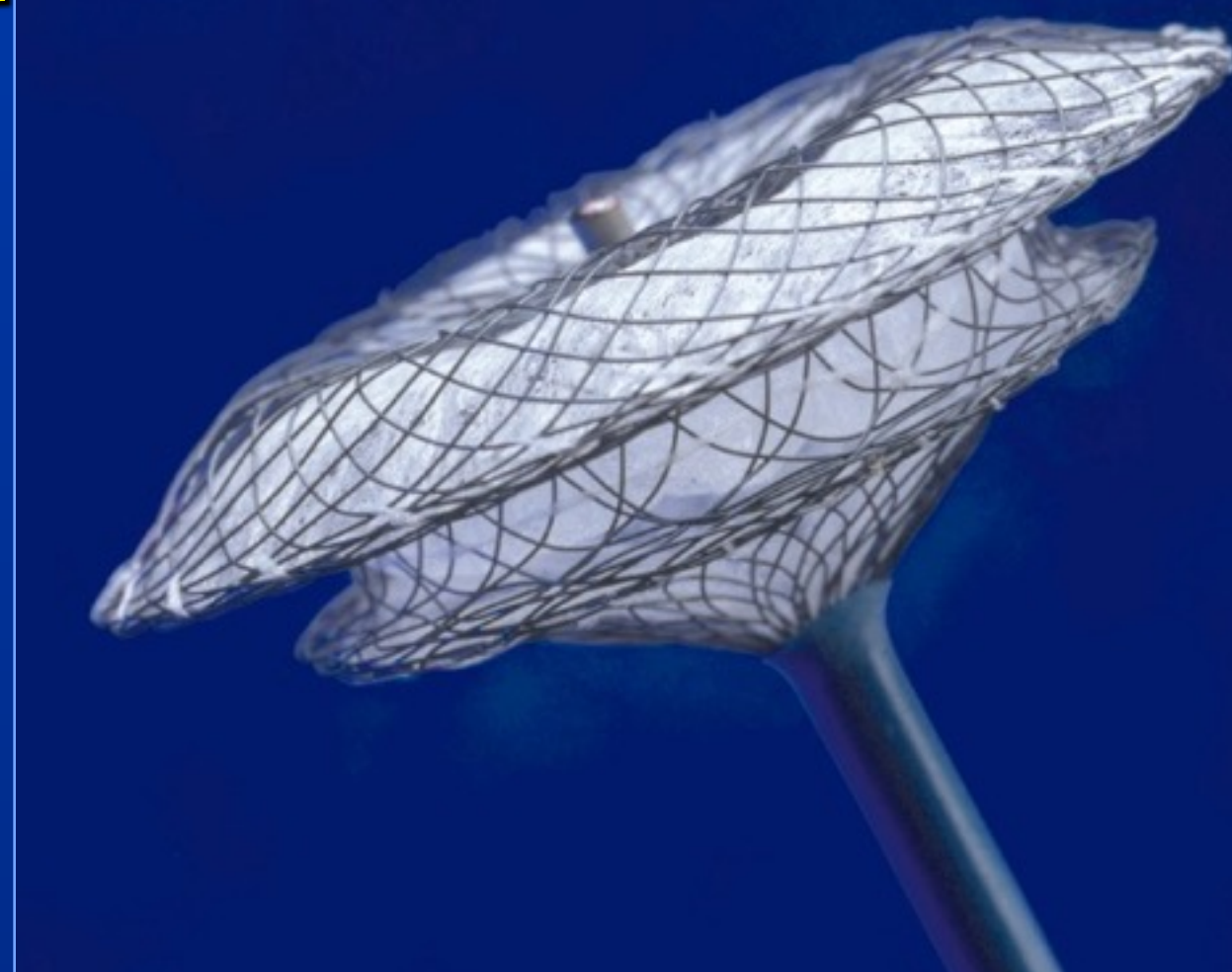


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Devices

1. Amplatzer Septal Occluder
2. Gore Devices
3. CardioSeal/StarFlex
4. Cardia Intrasept
5. Occlutech-Figulla Flex II
6. Solysafe
7. Patch Sideris
8. Others



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Closure Protocol

Local anesthesia with ICE

R & L Heart Catheterization

RUPV Angiogram (LAO/Cr)

Balloon Sizing

Closure

ICE/Angiogram (RA/PA)

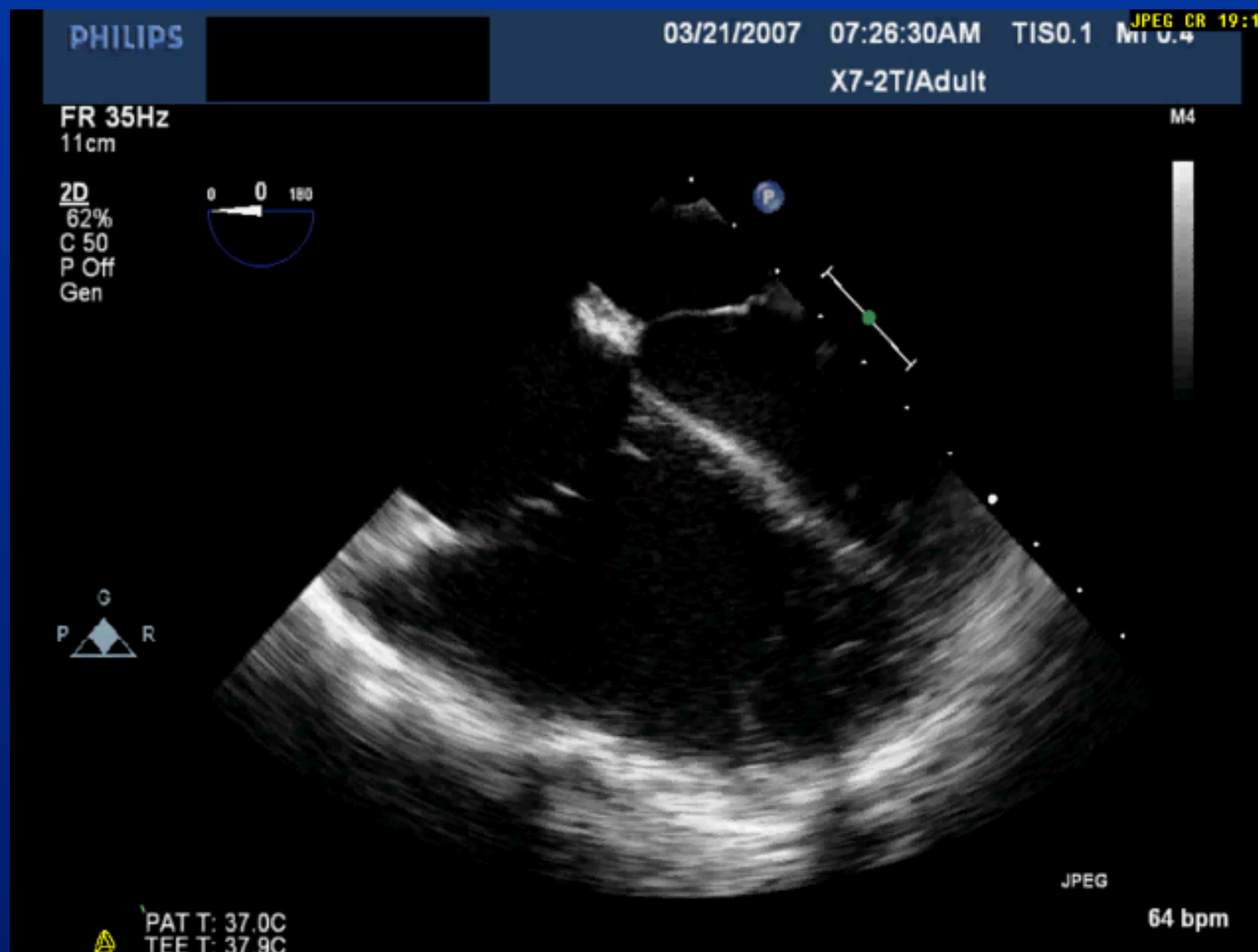


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Possible Complications of ASD Closure

- Embolization
- Arrhythmias/CHB
- Thrombus formation
- Air Embolism
- TIA/Stroke
- SBE
- Cobra formation
- Headaches/Migraines
- Erosions/PE/Tamponade/Death

Comparison Between Transcatheter and Surgical Closure of Secundum Atrial Septal Defect in Children and Adults

Results of a Multicenter Nonrandomized Trial

Zhong-Dong Du, MD,* Ziyad M. Hijazi, MD, MPH, FACC,* Charles S. Kleinman, MD, FACC,† Norman H. Silverman, MD, FACC,‡ Kinley Larntz, PhD,¶ for the Amplatzer Investigators

Chicago, Illinois; Orlando, Florida; San Francisco, California; and Minneapolis, Minnesota

OBJECTIVES This study sought to compare the safety, efficacy and clinical utility of the Amplatzer septal occluder (ASO) for closure of secundum atrial septal defect (ASD) with surgical closure.

BACKGROUND The clinical utility of a device such as the ASO can only be judged against the results of contemporaneous surgery.

METHODS A multicenter, nonrandomized concurrent study was performed in 29 pediatric cardiology centers from March 1998 to March 2000. The patients were assigned to either the device or surgical closure group according to the patients' option. Baseline physical exams and echocardiography were performed preprocedure and at follow-up (6 and 12 months for device group, 12 months for surgical group).

RESULTS A total of 442 patients were in the group undergoing device closure, whereas 154 patients were in the surgical group. The median age was 9.8 years for the device group and 4.1 years for the surgical group ($p < 0.001$). In the device group, 395 (89.4%) patients had a single ASD; in the surgical group, 124 (80.5%) ($p = 0.008$) had a single ASD. The size of the primary ASD was 13.3 ± 5.4 mm for the device group and 14.2 ± 6.3 mm for the surgery group ($p = 0.099$). The procedural attempt success rate was 95.7% for the device group and 100% for the surgical group ($p = 0.006$). The early, primary and secondary efficacy success rates were 94.8%, 98.5% and 91.6%, respectively, for the device group, and 96.1%, 100% and 89.0% for the surgical group (all $p > 0.05$). The complication rate was 7.2% for the device group and 24% for the surgical group ($p < 0.001$). The median length of hospital stay was 1.0 ± 0.3 day for the device group and 3.4 ± 1.2 days for the surgical group ($p < 0.001$). Quality of life was similar in both groups.

CONCLUSIONS The early, primary and secondary efficacy success rates for surgical versus device closure of ASD were not statistically different; however, the complication rate was lower and the length of hospital stay was shorter for device closure than for surgical repair. Appropriate patient selection is an important factor for successful device closure. Transcatheter closure of secundum ASD using the ASO is a safe and effective alternative to surgical repair. (J Am Coll Cardiol 2002;39:1836–44) © 2002 by the American College of Cardiology Foundation

Complication rate was 7.2% for the device Group and 24% for the surgical group ($P < 0.001$)



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Left heart obstructive lesions

Aortic Valve Stenosis

Mitral Valve Stenosis (Rheumatic)

Coarctation of The Aorta



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Prevalence & Associations

6-8% of CHD

Males more than females

Turner syndrome

Cardiac: BAV; VSD; AS; PDA; Mitral valve disease.

Non Cardiac: Intracerebral aneurysm



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Pathogenesis

Reduced anterograde intrauterine flow

Extension of ductal tissue into thoracic aorta

Pathology: medial thickening and intimal hyperplasia forming a ridge. Rarely, inflammation.

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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

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Indications For Intervention

CLASS I

1. Intervention for coarctation is recommended in the following circumstances:
 - a. Peak-to-peak coarctation gradient greater than or equal to 20 mm Hg. (*Level of Evidence: C*)
 - b. Peak-to-peak coarctation gradient less than 20 mm Hg in the presence of anatomic imaging evidence of significant coarctation with radiological evidence of significant collateral flow. (*Level of Evidence: C*)

ACC/AHA 2008 Guidelines for the management of adults with CHD. JACC 2008;52:e143-263



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2. Choice of percutaneous catheter intervention versus surgical repair of native discrete coarctation should be determined by consultation with a team of ACHD cardiologists, intervention-
alists, and surgeons at an ACHD center. (*Level of Evidence: C*)
3. Percutaneous catheter intervention is indicated for recurrent,
discrete coarctation and a peak-to-peak gradient of at least
20 mm Hg. (*Level of Evidence: B*)
4. Surgeons with training and expertise in CHD should perform
operations for previously repaired coarctation and the following
indications:
 - a. Long recoarctation segment. (*Level of Evidence: B*)
 - b. Concomitant hypoplasia of the aortic arch. (*Level of Evi-
dence: B*)

CLASS IIb

1. Stent placement for long-segment coarctation may be consid-
ered, but the usefulness is not well established, and the
long-term efficacy and safety are unknown. (*Level of Evi-
dence: C*)



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Treatment Options

1. Surgical Repair
2. Balloon Angioplasty
3. Stent Implantation



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Surgical Repair

1. E-E Anastomosis
2. Patch Aortoplasty
3. **Subclavian Flap!!! Not in the adults!**



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Outcome of Surgical Repair

1. Very good.
2. Thoracotomy!
3. Complications!



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Balloon Angioplasty

1. Very good option.
2. Not good for long segment coarctation!
3. Results: about 85% success
4. Complications: dissection, aneurysm formation and rupture!



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Stents

Over 20+ years of experience, very good results!

But, technically challenging!



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Protocol

GEA

Access from RFA/RFV

Hemodynamics

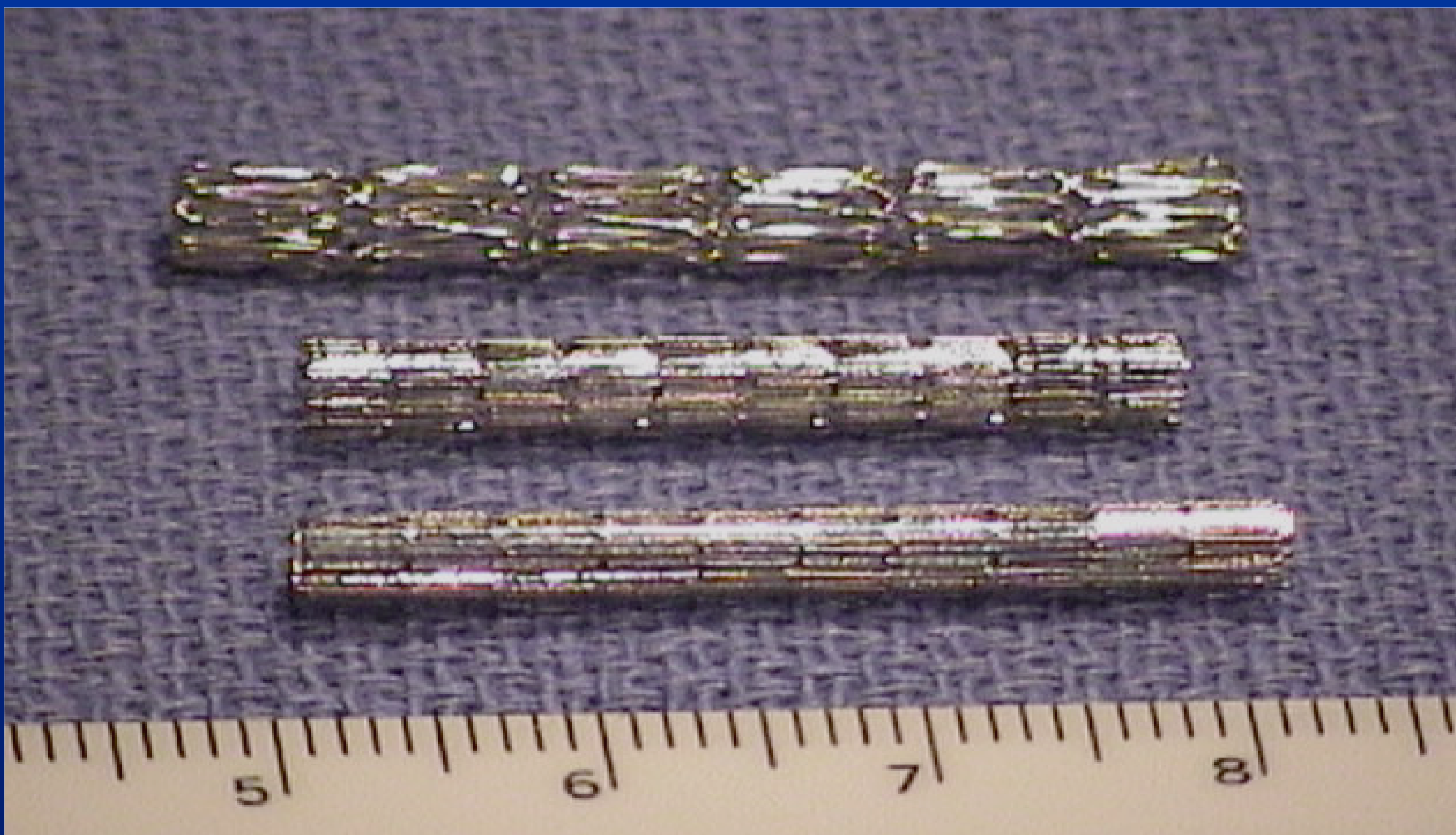
Angiography

Stent Deployment....RV rapid pacing vs BIB

Assessment of result

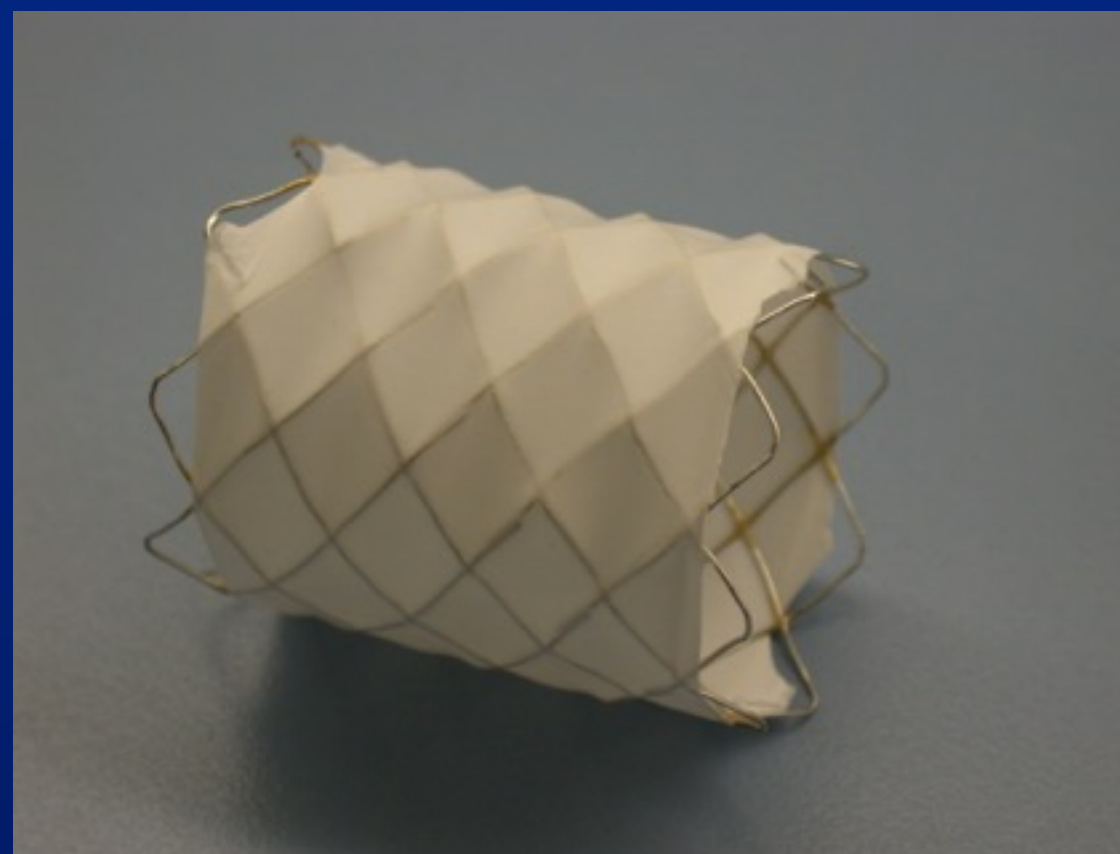


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**Congenital Cardiovascular Interventional
Study Consortium**



Con

Interventional Therapies For

Procedural Results and Acute Complications in Stenting Native and Recurrent Coarctation of the Aorta in Patients Over 4 Years of Age: A Multi-Institutional Study

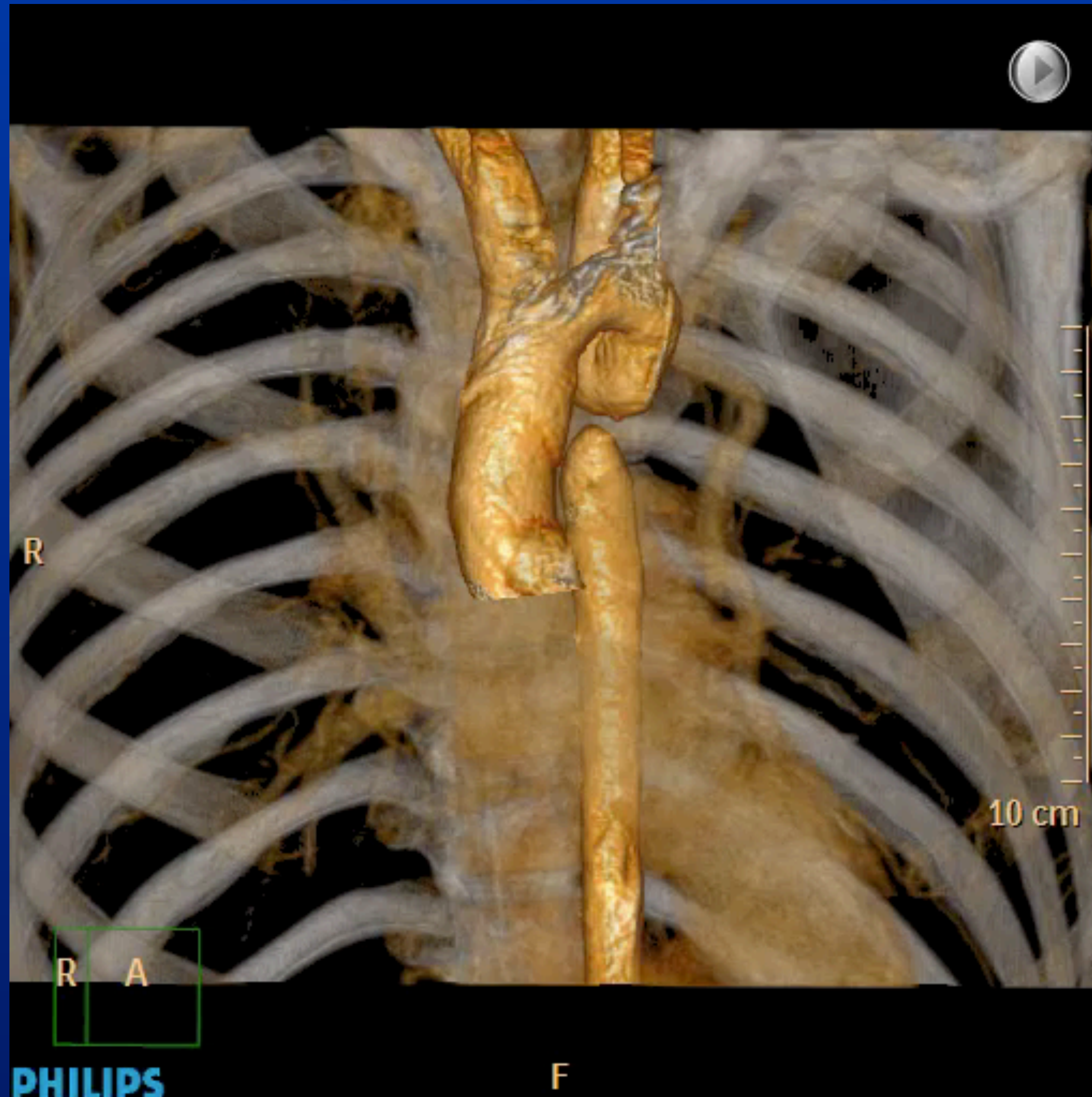
ease



Thomas J. Forbes,^{1*} MD, Swati Garekar,¹ MD, Zahid Amin,² MD, Evan M. Zahn,³ MD, David Nykanen,³ MD, Phillip Moore,⁴ MD, Shakeel A. Qureshi,⁵ MD, John P. Cheatham,⁶ MD, Makram R. Ebeid,⁷ MD, Ziyad M. Hijazi,⁸ MD, Satinder Sandhu,⁸ MD, Donald J. Hagler,⁹ MD, Horst Sievert,¹⁰ MD, Thomas E. Fagan,¹¹ MD, Jeremy Ringewald,¹² MD, Wei Du,¹ PhD, Liwen Tang,¹ MD, MS, David F. Wax,¹³ MD, John Rhodes,¹⁴ MD, Troy A. Johnston,¹⁵ MD, Thomas K. Jones,¹⁵ MD, Daniel R. Turner,¹ MD, Carlos A.C. Pedra,¹⁶ MD, and William E. Hellenbrand,¹⁷ MD, Congenital Cardiovascular Interventional Study Consortium (CCISC)

Background: We report a multi-institutional experience with intravascular stenting (IS) for treatment of coarctation of the aorta. **Methods and Results:** Data was collected retrospectively by review of medical records from 17 institutions. The data was broken down to prior to 2002 and after 2002 for further analysis. A total of 565 procedures were performed with a median age of 15 years (mean = 18.1 years). Successful reduction in the post stent gradient (<20 mm Hg) or increase in post stent coarctation to descending aorta (DAo) ratio of >0.8 was achieved in 97.9% of procedures. There was significant improvement ($P < 0.01$) in pre versus post stent coarctation dimensions ($7.4 \text{ mm} \pm 3.0 \text{ mm}$ vs. $14.3 \pm 3.2 \text{ mm}$), systolic gradient ($31.6 \text{ mm Hg} \pm 16.0 \text{ mm Hg}$ vs. $2.7 \text{ mm Hg} \pm 4.2 \text{ mm Hg}$) and ratio of the coarctation segment to the DAo (0.43 ± 0.17 vs. 0.85 ± 0.15). Acute complications were encountered in 81/565 (14.3%) procedures. There were two procedure related deaths. Aortic wall complications included: aneurysm formation ($n = 6$), intimal tears ($n = 8$), and dissections ($n = 9$). The risk of aortic dissection increased significantly in patients over the age of 40 years. Technical complications included stent migration ($n = 28$), and balloon rupture ($n = 13$). Peripheral vascular complications included cerebral vascular accidents (CVA) ($n = 4$), peripheral emboli ($n = 1$), and significant access arterial injury ($n = 13$). Older age was significantly associated with occurrence of CVAs. A significant decrease in the technical complication rate from 16.3% to 6.1% ($P < 0.001$) was observed in procedures performed after January 2002. **Conclusions:** Stent placement for coarctation of aorta is an effective treatment option, though it remains a technically challenging procedure. Technical and aortic complications have decreased over the past 3 years due to, in part, improvement in balloon and stent design. Improvement in our ability to assess aortic wall compliance is essential prior to placement of ISs in older patients with coarctation of the aorta. © 2007 Wiley-Liss, Inc.

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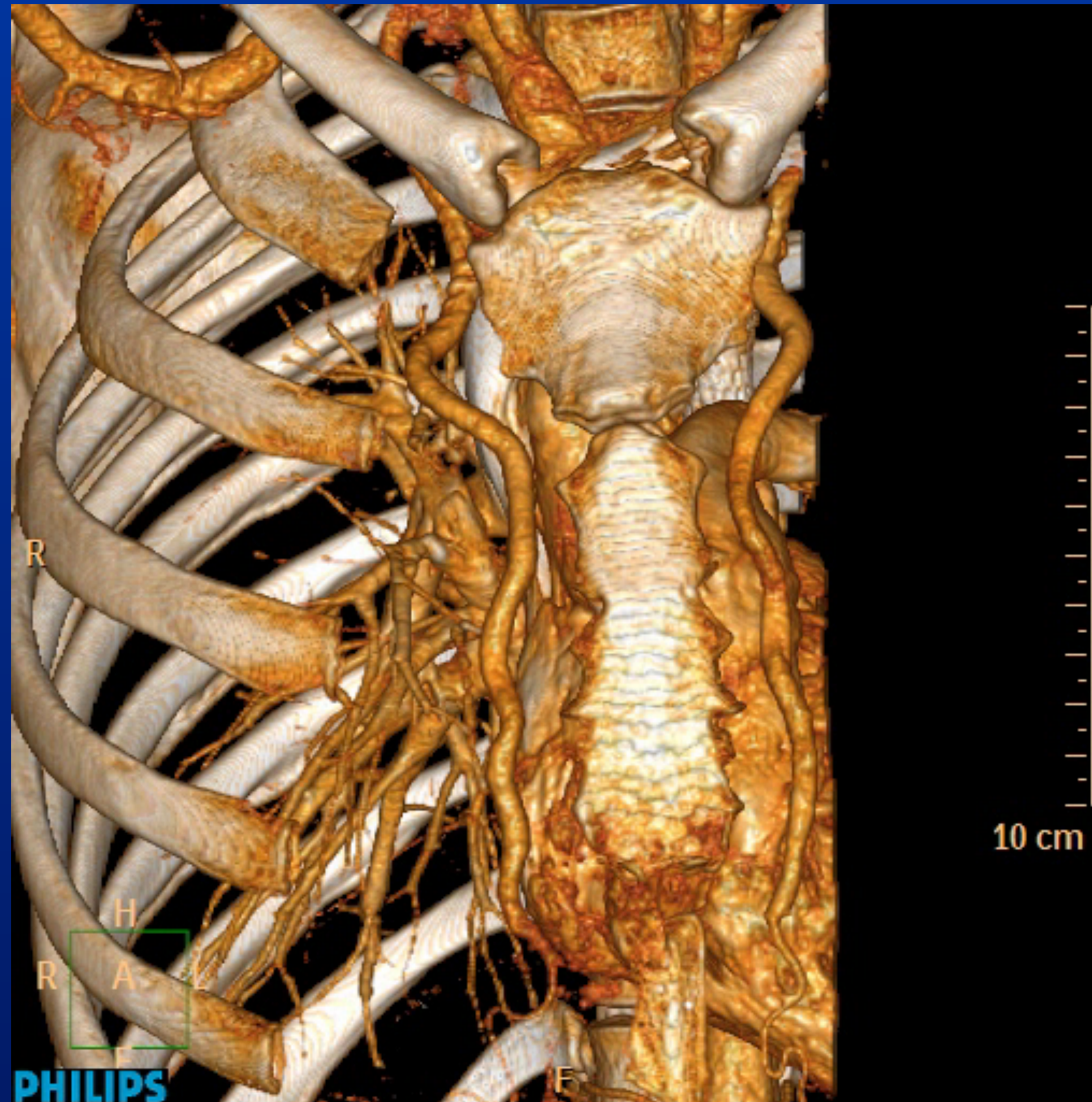




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Post Tetralogy Repair Patients

PA abnormalities

Lung Perfusion Scans

Residual Intracardiac Defects

ASD/VSD

AP Collaterals

Pulmonary Insufficiency “PPV”.



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Percutaneous Valve Insertion/Repair

1. Aortic Valve
2. **Pulmonic Valve**
3. Mitral Valve
4. Tricuspid Valve



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All patients born with
Congenital Heart Defects
1.6 M Worldwide

**RVOT (22%)
352,000**

*Pulmonary Stenosis
Tetralogy of Fallot
Truncus Arteriosus
Transposition of the Great Arteries
Double Outlet Right Ventricle (DORV)
Pulmonary Atresia*

**Non-conduit
Patients**

**Conduit Pt (30%)
105,600**



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Disorder	Annual Potential Candidates
Transcatheter Pulmonic Valve Replacement	5,000 – 6,000
Patent Ductus Arteriosus (PDA)*	5,000 – 7,000
Atrial Septal Defect (ASD)*	8,000 – 10,000
Ventricular Septal Defect (VSD)*	5,000 – 8,000
Patent Foramen Ovale (PFO)*	75,000 – 150,000



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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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Unmet Clinical Need

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

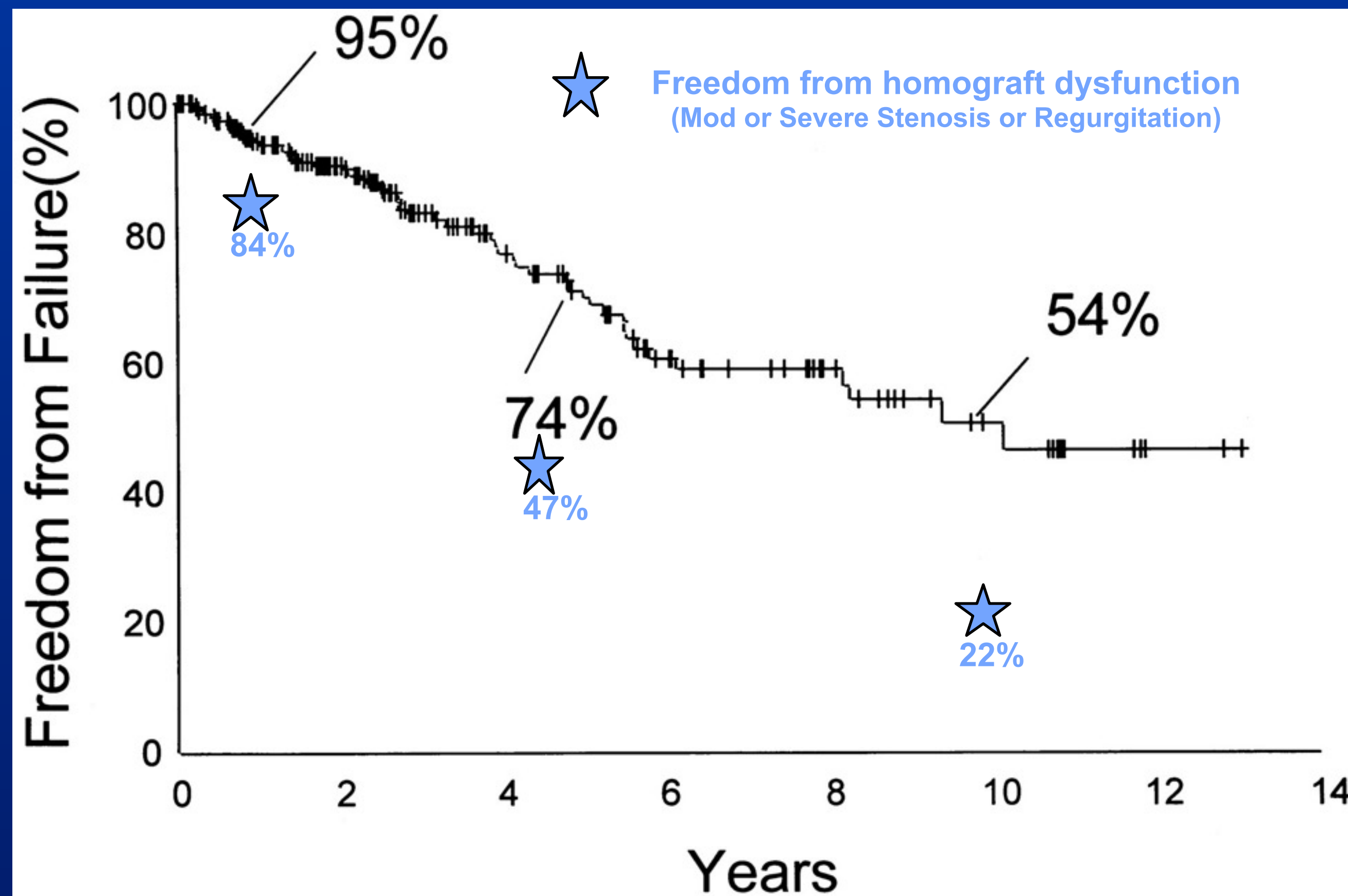
- Mean time to reoperation*:
 - 10.3 years for xenografts
 - 16 years for homografts
- Reoperations associated with increasing mortality**:
 - 4% mortality rate on initial procedure
 - 7% mortality rate on first re-operation
 - 11% mortality rate on second re-operation
 - 13% mortality rate on additional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

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



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Indications For PVR

Severe PR in patients with NYHA class II or III symptoms

If Asymptomatic: Regurgitant fraction $>35\%$; RVEDV >150 ml/m²; RV EF $<40\%$; QRS duration >180 msec

Bonow R et al: ACC/AHA 2006 guidelines for the management of patients with valvular heart disease. JACC 2006;48:e1-e148



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The Melody Valve





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The Melody Valve

- **Bonhoeffer Was the 1st in the world to implant a percutaneous valve in a human! Pediatric Cardiologist!!!!**
- **Implanted in >8000 patients in the Pulmonic position.**
- **Bovine jugular vein valve sutured onto a platinum iridium stent**
- **Using balloon in balloon from NuMED**
- **Hand crimping stent onto balloons**
- **Requires 22 Fr delivery sheath.**



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The Edwards Sapien THV

- Three bovine pericardial valve leaflets
- Stainless steel initially, then cobalt chromium stent frame
- Now available in 20, 23, 26 and 29 mm diameters.
- Height 14-19mm long
- E-sheath: 18-20 Fr

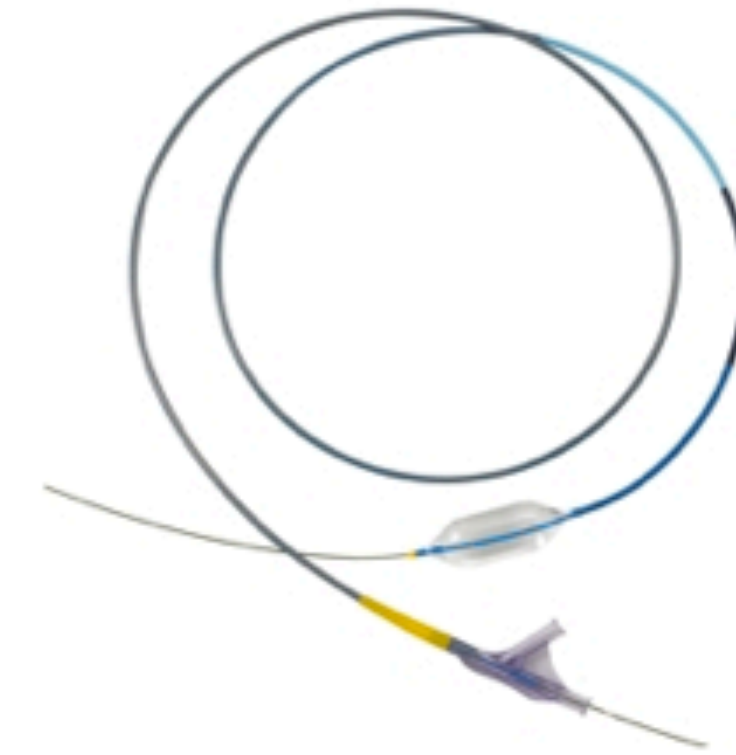
Interventional Therapies For



Edwards SAPIEN THV



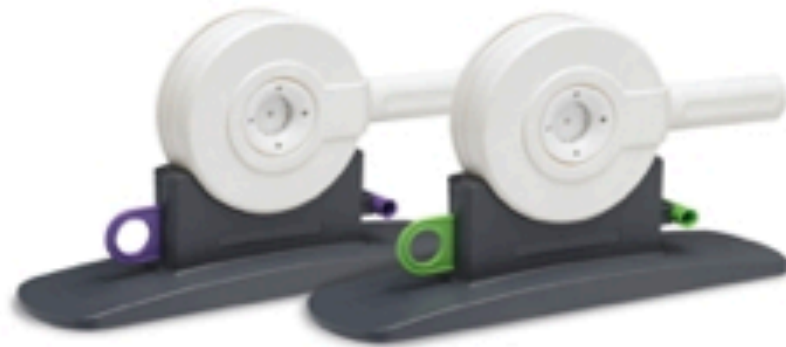
RetroFlex 3 Delivery System



RetroFlex Balloon Catheter



RetroFlex 3 introducer Sheath Set



Crimper



RetroFlex Dilator Kit



**Atrion
Inflation Device**



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Study Background

Significant pulmonary valve regurgitation (PR) results in:

- Progressive RV dilation & development of ventricular arrhythmias
- RV dysfunction and sudden death

Pulmonic valve implantation at an appropriate age may restore RV function and improve the symptoms

Early clinical experiences show that transcatheter implantation of bioprosthetic valves may be safely achieved in the pulmonic position.



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The COMPASSION Study

Congenital Multicenter trial of Pulmonic vAlve regurgitation
Studying the SAPIEN™ InterventOnal 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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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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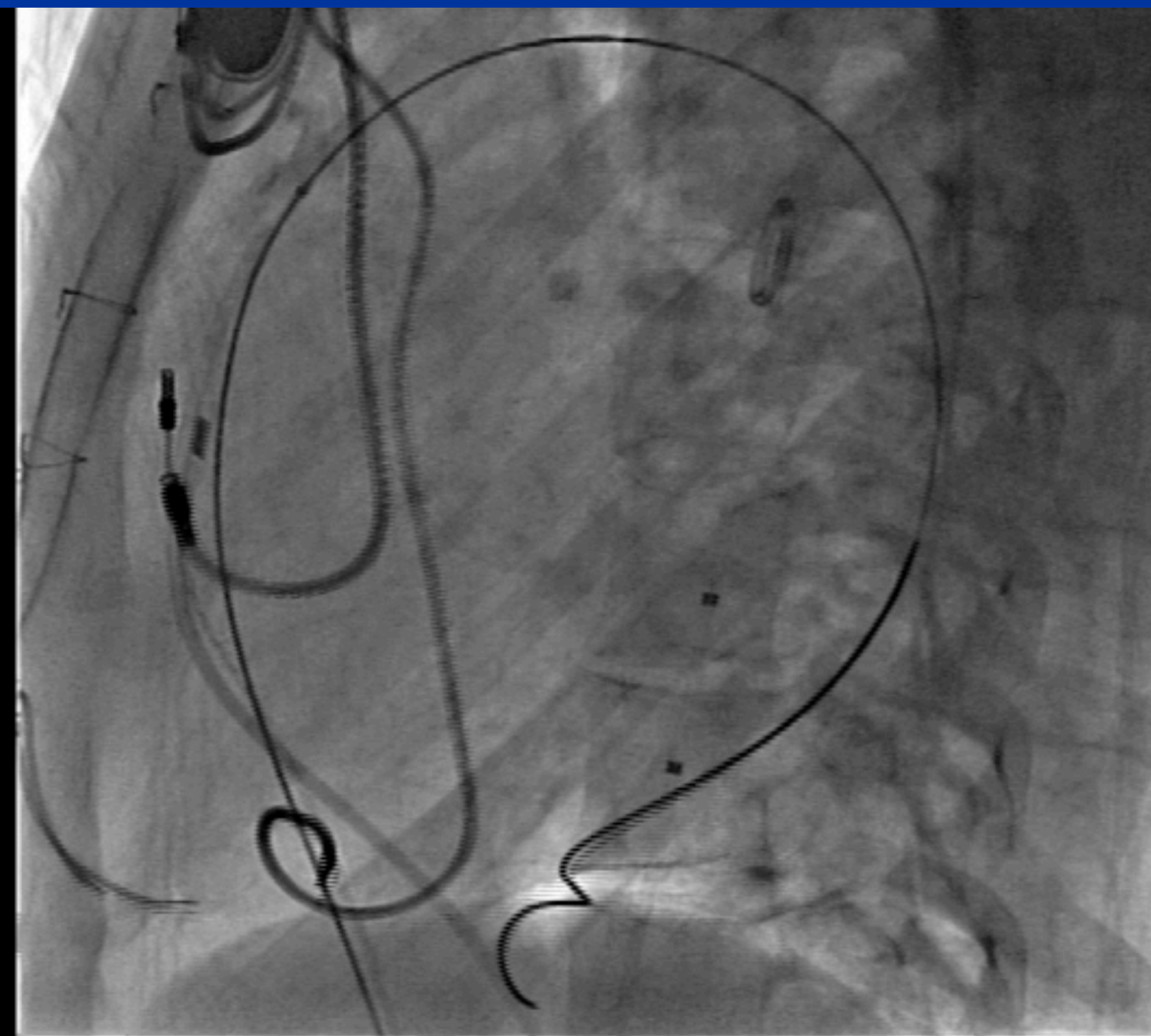


Exclusion Criteria

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



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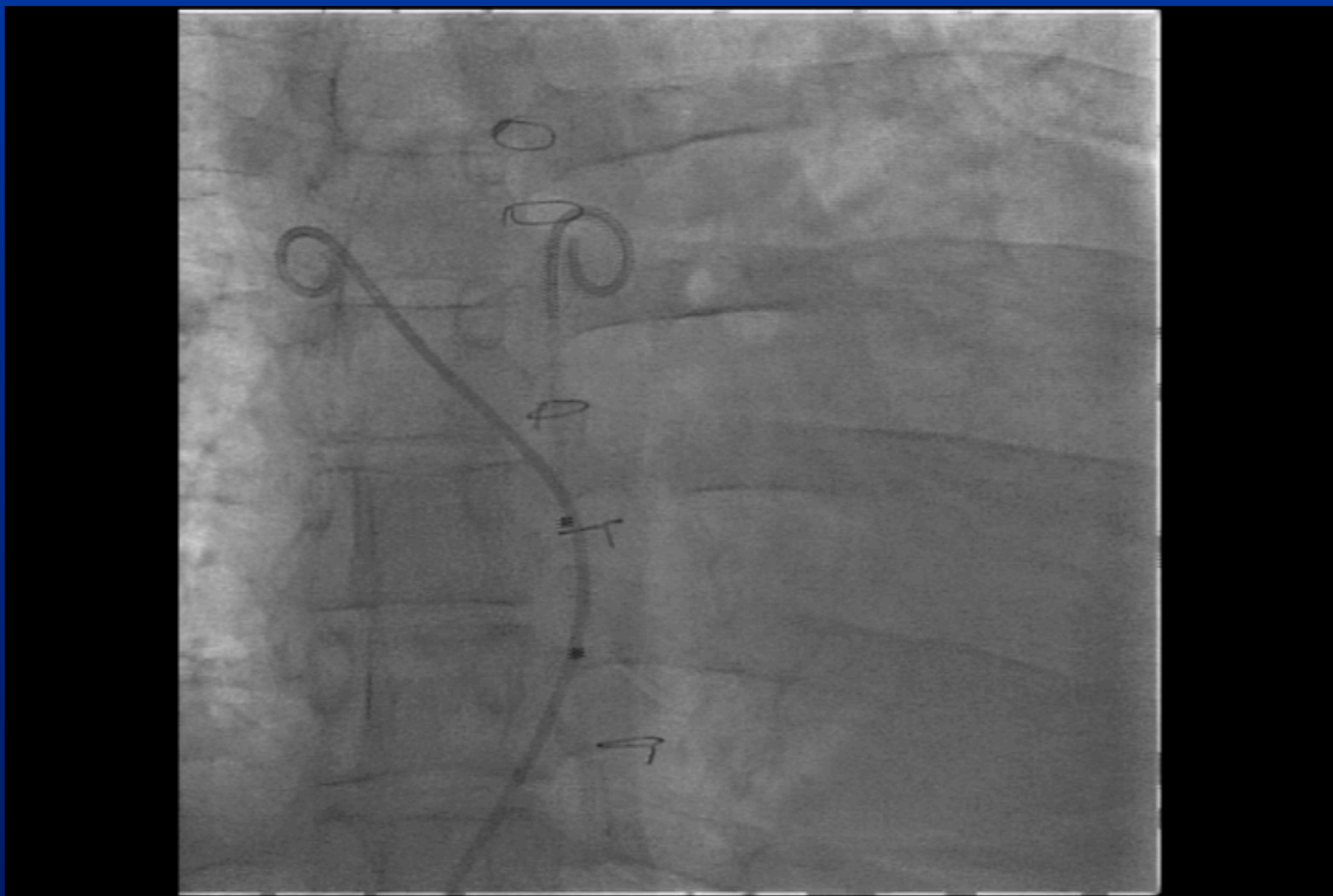


Miscellaneous

Post Mustard/Senning Operation
Post Arterial Switch Patients.
Systemic Veins Obstruction.
Conduits (RV-PA) Obstructions.
Aortic pseudo aneurysms



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SHD



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Calcific AS

Indications for Surgical AVR

- Symptomatic patients with severe AS

Why is surgical AVR so great?

- Patients with severe AS undergoing CABG

(Class I-A)

- Patients with severe AS undergoing AVR

Because our patients...

- Patients with severe AS undergoing AVR
 - Patients with severe AS undergoing AVR
 - Patients with severe AS undergoing AVR
1. Live longer
 2. Feel better (marked Sx benefit)
 3. Have improved LV function

- Patients with severe AS undergoing AVR

or

(Class IIa-B)



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Rules of Engagement





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Indications for Transcatheter AVR

- **Symptomatic patients with severe AS who are**
 - ❖ **high risk for surgery**
 - ❖ **Inoperable**
- **? Class IIa - B**



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Who Are The High Risk Patients?

- Octogenarians with multiple co-morbidities (COPD, diabetes, ↑creatinine, PVD, ↓LVEF, previous cardiac surgery, and others)
- STS Predicted Risk >10%, ~ Logistic EuroSCORE >30% (~15% operative risk @ 30 days)
- Requires close surgical consultation (significant inter-site variability)

There is no perfect formula-Requires quantitative risk algorithm + thoughtful surgeon/cardiologist



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Who is The inoperable Patient?

- Radiation chest wall/heart disease
- Chest wall deformities (severe)
- End-stage COPD
- Cirrhosis with portal hypertension
- Porcelain aorta (CT proven)
- Degenerative neurocognitive dysfunction
- High “frailty” index (qualitative assessment)
- >50% chance of mortality or never leaving a chronic care facility

Even less perfect formula-Surgeon as a
gatekeeper



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NOT Indicated for Transcatheter AVR

- **Low or normal risk patients based on...**
 - ❖ patient preference
 - ❖ referring MD preference
- **CAVEAT: There is a subtle middle ground of intermediate risk AS patients (5-15% operative mortality) who may be appropriate candidates based on other factors**
- **AS with endocarditis or bicuspid valves (?) or requiring Ao repair**



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The potential AS patients that require treatment

	2004 Population	AS Prevalence	Severe AS	Severe AS 50% with Sx
18-44	125,841,694	0.10%	41,947	20,974
45-54	41,618,805	0.20%	27,746	13,873
55-64	29,078,924	0.60%	58,158	29,079
65-74	18,463,472	1.40%	86,163	43,081
>75	17,830,513	4.60%	273,401	136,701
Total	232,833,408	—	487,415	243,708

Based upon the Olmsted County AS prevalence data and US population statistics; **more than half of the severe AS patients are >75 years old!**



Interventional Therapies For Congenital & Structural Heart Disease

The potential AS patients that require treatment

	2004 Population	AS Prevalence	Severe AS	Severe AS 50% with Sx
18-44	125,841,694	0.10%	41,947	20,974
45-54	41,618,805	0.20%	27,746	13,873
55-64	29,078,924	0.60%	58,158	29,079
65-74	18,463,472	1.40%	86,163	43,081
>75	17,830,513	4.60%	273,401	136,701
Total	232,833,408	—	487,415	243,708

Based upon the Olmsted County AS prevalence data and US population statistics; *the potential AS treatment cohort could exceed 250,000 patients!*

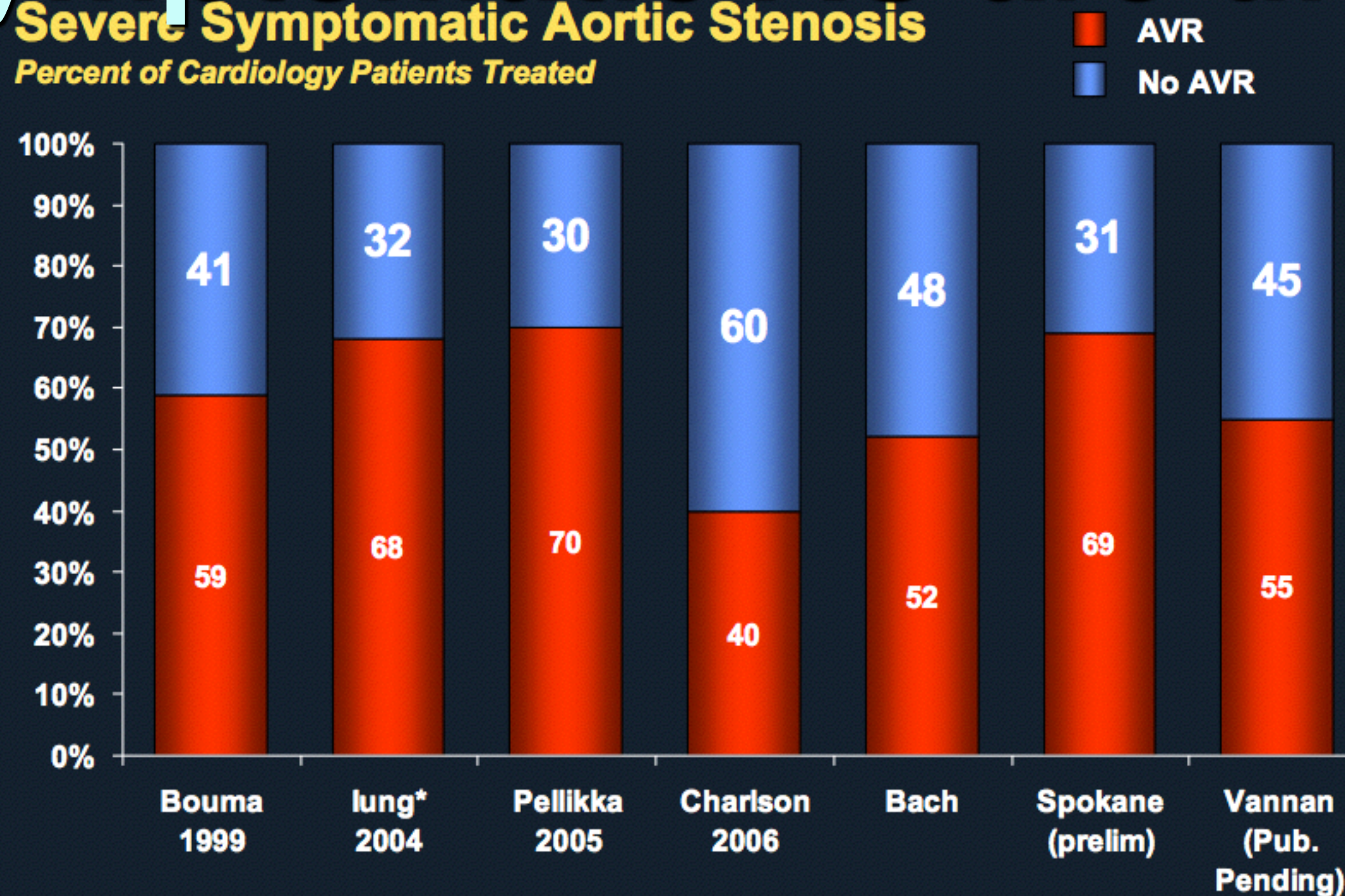


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At least 30% of patients with severe symptomatic AS are untreated!

Severe Symptomatic Aortic Stenosis
Percent of Cardiology Patients Treated



Under-treatment
especially
prevalent among
patients
managed by
Primary Care
physicians

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. lung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis 2006;15:312-321



Interventional Therapies For Congenital & Structural Heart Disease



Transcatheter Aortic Valve Systems- 1st Generation

- **Edwards Aortic Bioprosthesis**
 - Balloon expandable stainless steel bioprosthesis
 - Equine → Bovine pericardial valve
 - Unsheathed and sheathed (RetroFlex)
 - Antegrade, retrograde, or trans-apical approach
- **CoreValve Revalving™ System**
 - Self-expanding nitinol cage bioprosthesis
 - Porcine pericardial valve
 - Sheathed system (21 Fr and 18 Fr)
 - Retrograde (trans-apical) approach



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Alain Cribier



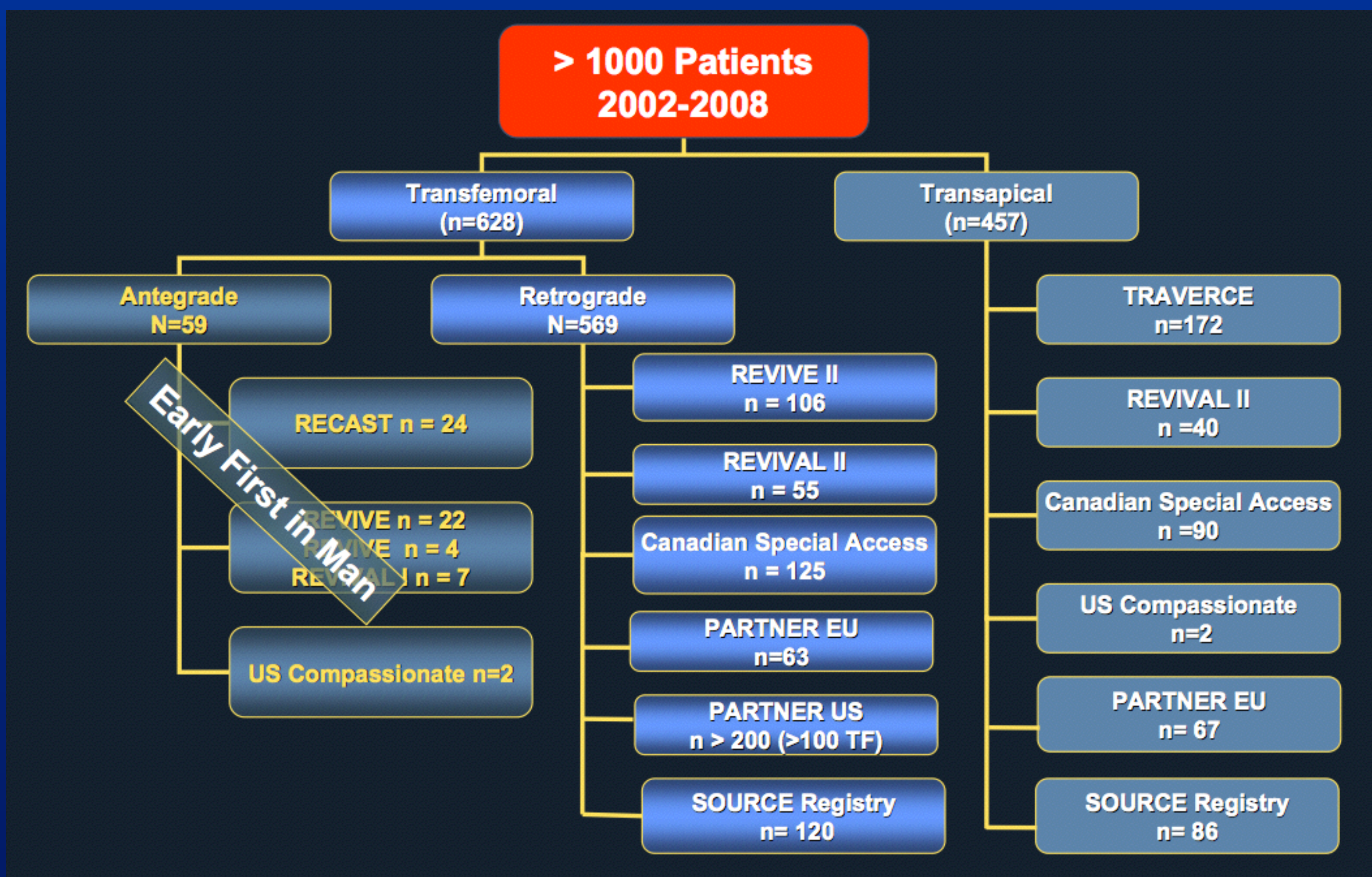
April 16, 2002



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Edwards THV Clinical Trial Program

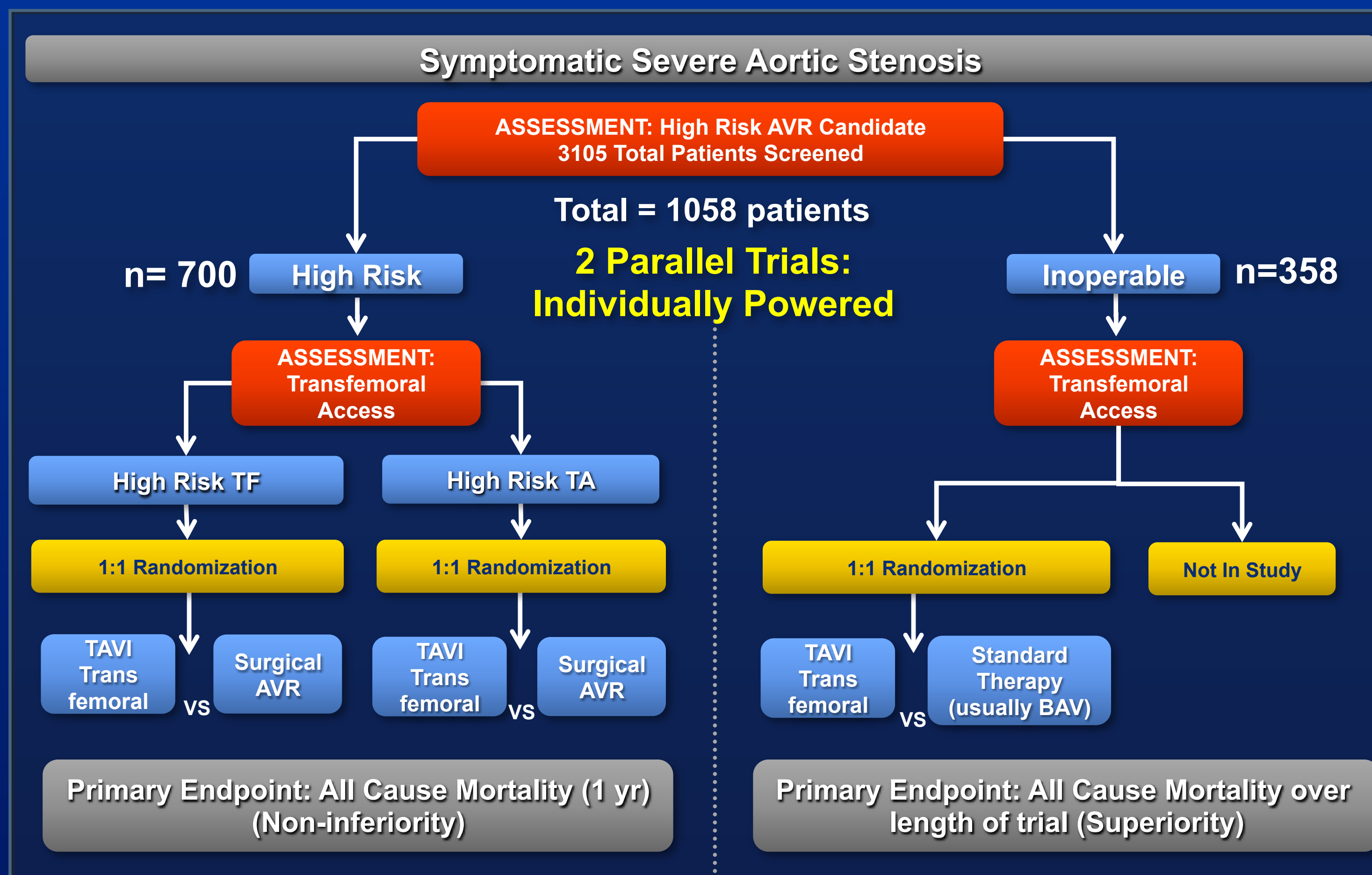




Interventional Therapies For Congenital & Structural Heart Disease



PARTNER Study Design



Interventional Therapies For Congenital & Structural Heart Disease

The NEW ENGLAND JOURNAL *of* MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D.,
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

Presented & published September 2010 at TCT



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PARTNER Endpoints

Primary Endpoint:

Cohort A: Freedom from death at one year (non-inferiority)

Cohort B: Freedom from death (superiority)

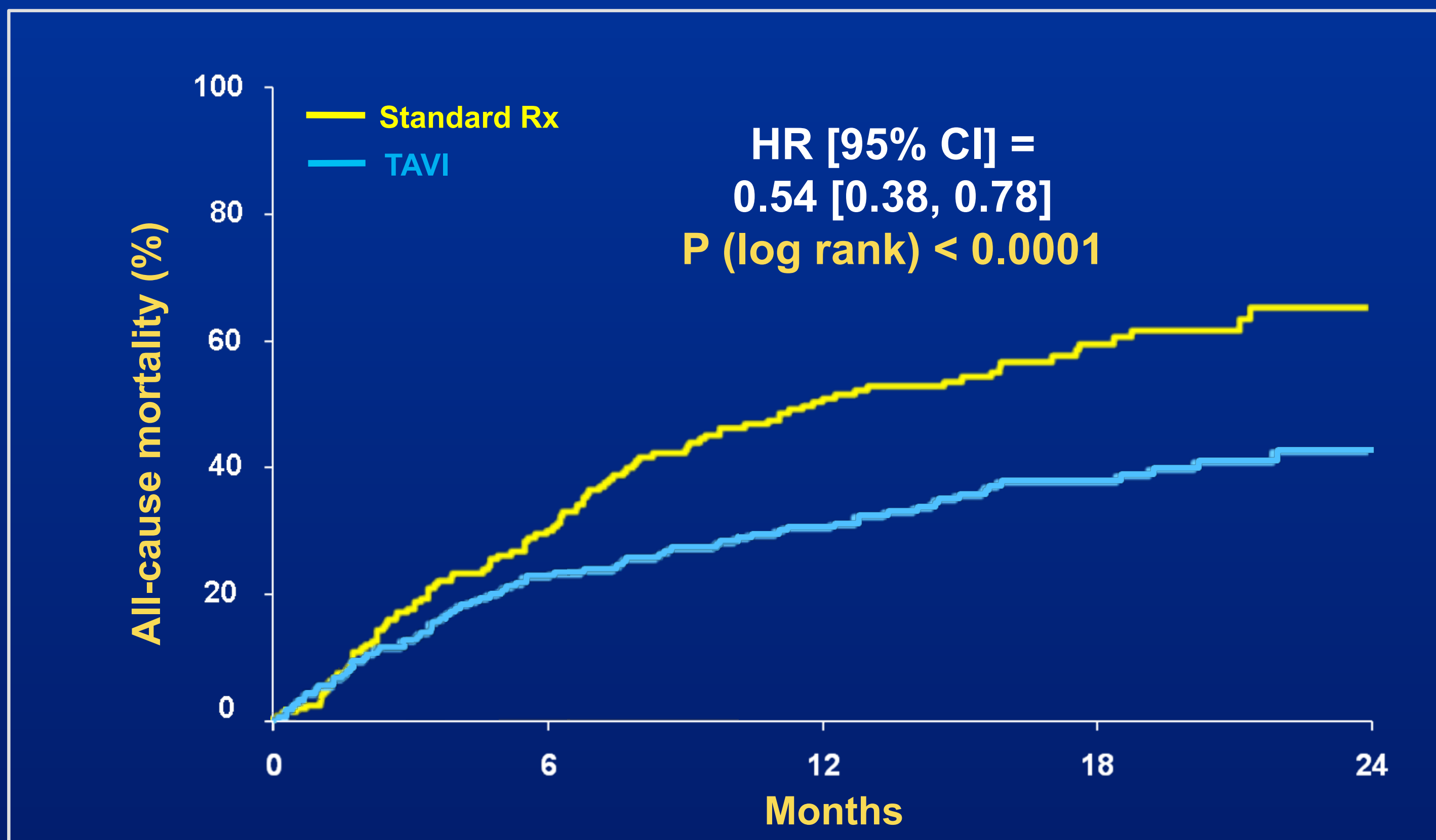
Key Secondary Endpoints:

- Freedom from MACCE (death, MI, stroke, aortic valve re-intervention at 1, 6, and 12 months)
- Echo assessment of valve function at 1, 6, and 12 months
- Clinical improvement (NYHA functional class and 6 min walk test) at 1, 6, and 12 months



Interventional Therapies For Congenital & Structural Heart Disease

All Cause Mortality



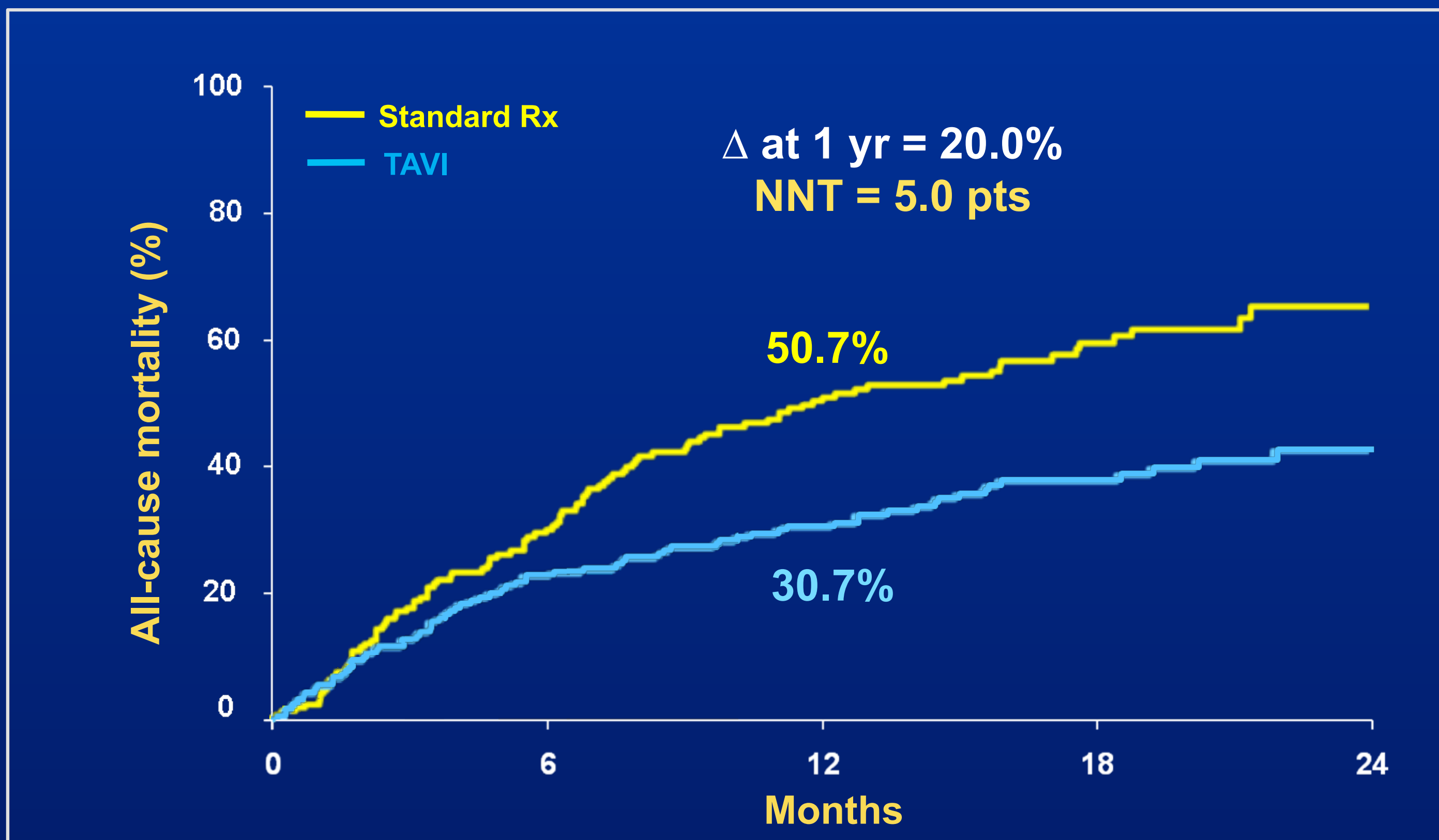
Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12



Interventional Therapies For Congenital & Structural Heart Disease



All Cause Mortality

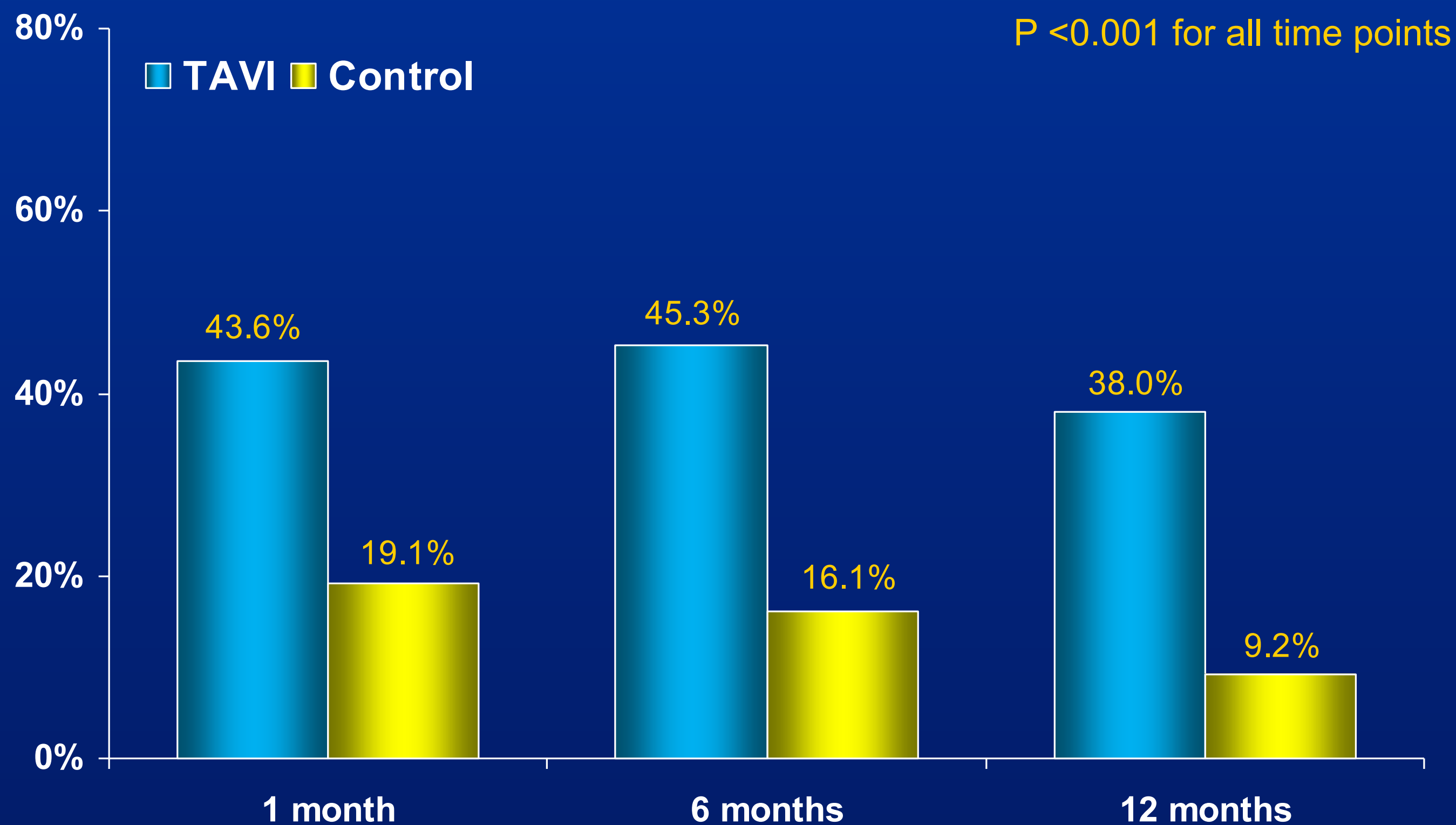


Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12



Interventional Therapies For Congenital & Structural Heart Disease

KCCQ-Summary: Excellent Outcome *



* Excellent Outcome = Alive and KCCQ-Summary Score improved ≥ 20 points vs. baseline



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions - 1

In patients with severe AS and symptoms, who are not suitable candidates for surgery...

- Standard therapy (including BAV in 83.8% of pts) did not alter the dismal natural history of AS; all-cause and cardiovascular mortality at 1 year was 50.7% and 44.6% respectively
- Transfemoral balloon-expandable tAVR, despite limited operator experience and an early version of the system, was associated with acceptable 30-day survival (5% after randomization in the intention-to-treat population)



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions - 2

- **tAVR was superior to standard therapy, markedly reducing the rate of...**
 - **all-cause mortality by 46%, $P < 0.0001$, NNT = 5.0 pts**
 - **cardiovascular mortality by 61%, $P < 0.0001$, NNT = 4.1 pts**
 - **all-cause mortality and repeat hospitalization**
 - **hierarchical (FS method), $P < 0.0001$**
 - **non-hierarchical (KM analysis) by 54%, $P < 0.0001$, NNT = 3.4 pts**



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions - 3

- tAVR improved cardiac symptoms (NYHA class, $P < 0.0001$) and six minute walking distance ($P = 0.002$), after 1-year follow-up
- tAVR resulted in more frequent complications at 30 days, including...
 - major vascular complications, 16.2% vs. 1.1%, $P < 0.0001$
 - major bleeding episodes, 16.8% vs. 3.9%, $P < 0.0001$
 - major strokes, 5.0% vs. 1.1%, $P = 0.06$



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions - 4

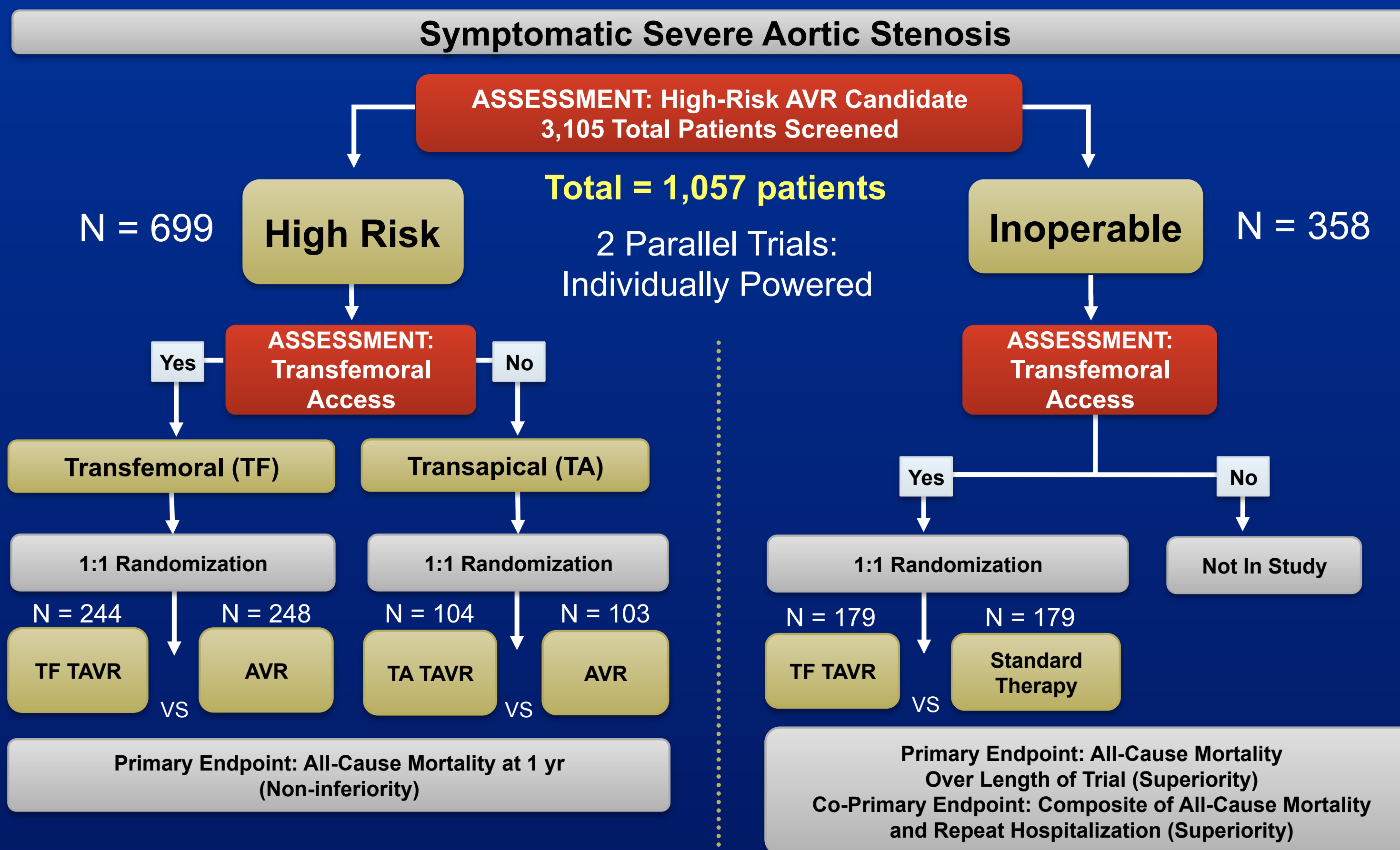
- Serial echocardiograms in tAVR patients indicated...
 - reduced mean gradients ($P < 0.0001$) which were unchanged during 1-year FU
 - frequent paravalvular AR, which was usually trace or mild (~90%), remained stable during 1-year FU, and rarely required further Rx.



Interventional Therapies For Congenital & Structural Heart Disease



PARTNER Study Design

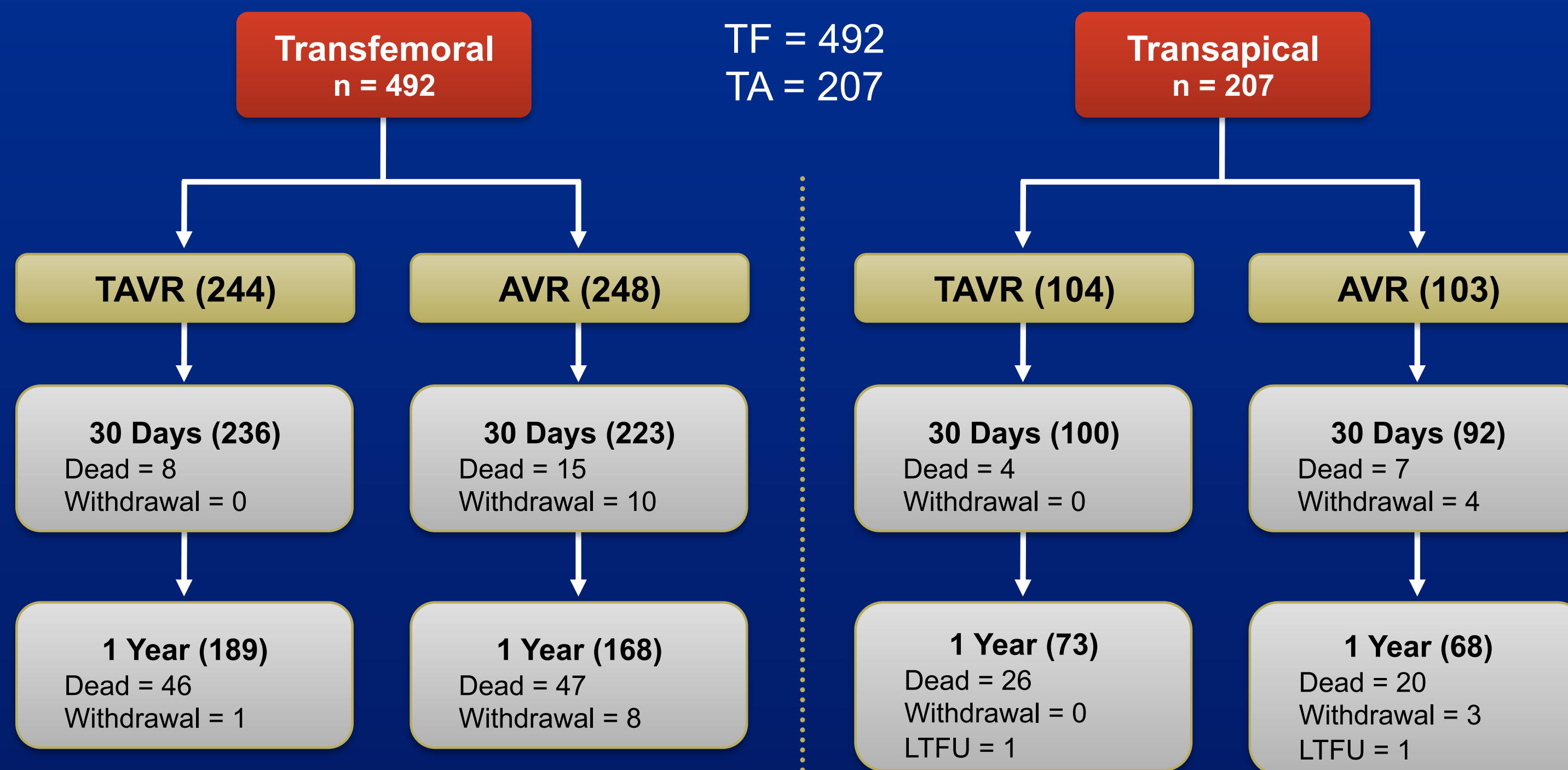




Interventional Therapies For Congenital & Structural Heart Disease

Study Flow

Randomized = 699 patients

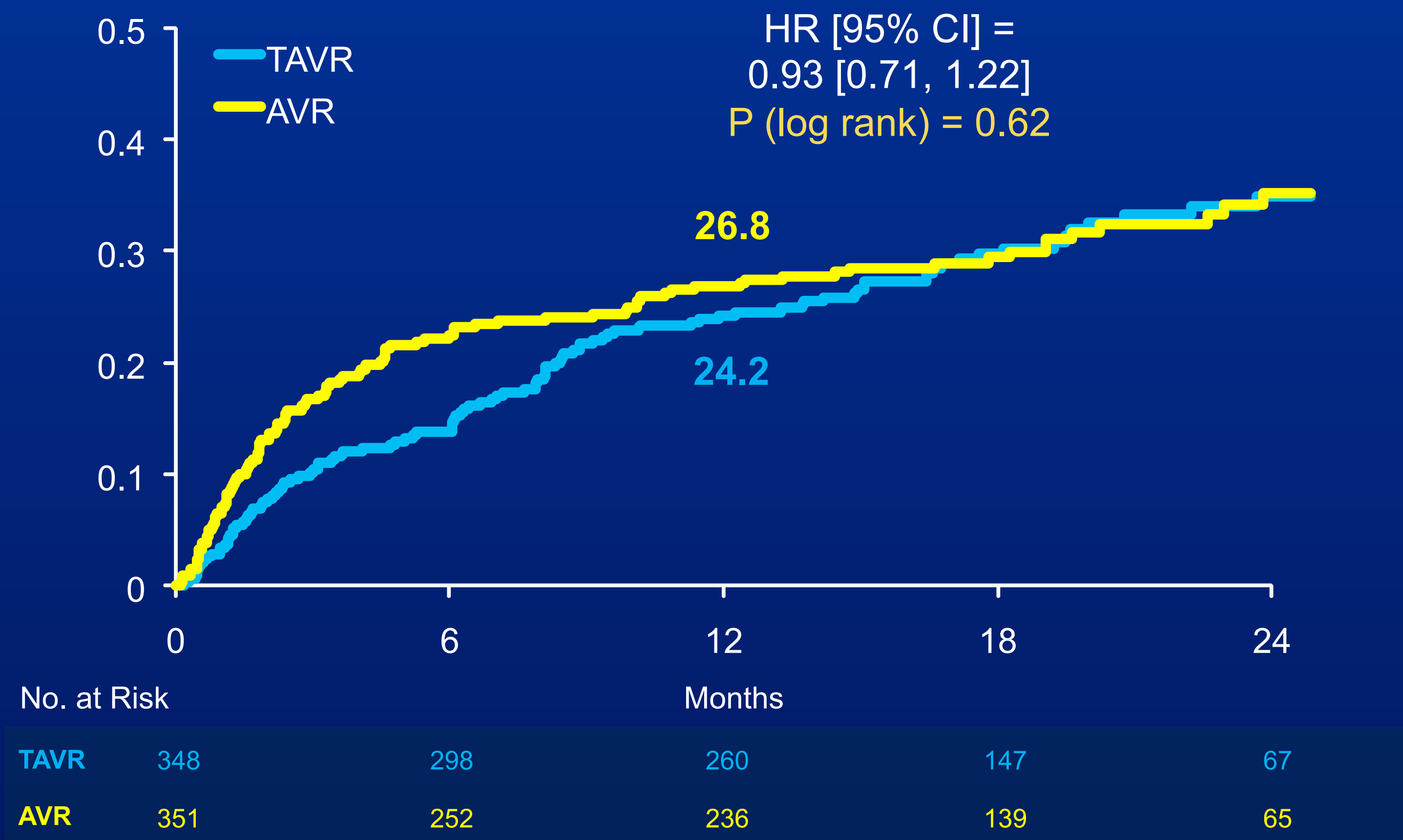




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**Primary Endpoint:
All-Cause Mortality at 1 Year**

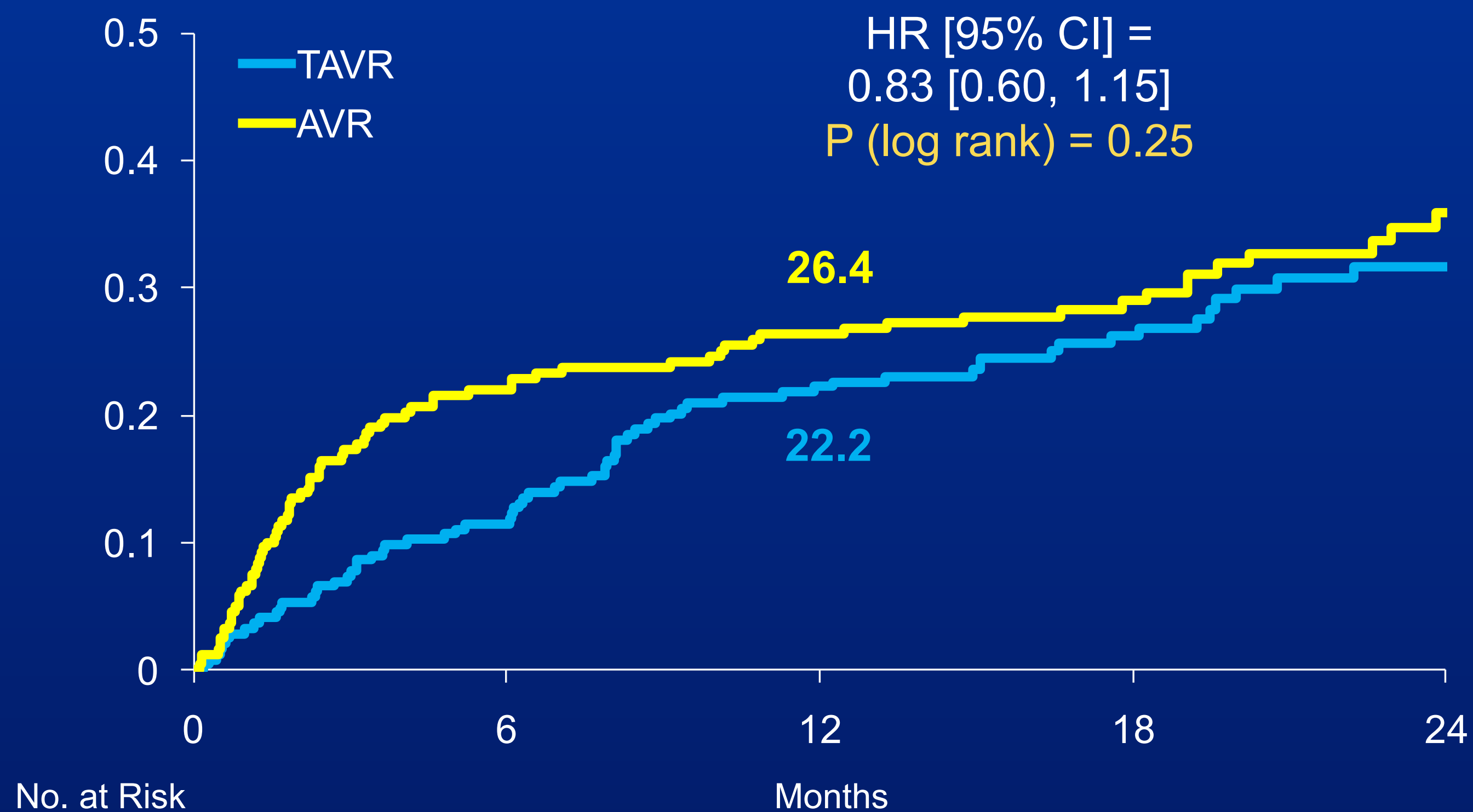




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All-Cause Mortality Transfemoral (N=492)



TAVR	244	215	188	119	59
AVR	248	180	168	109	56



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions (1)

- The primary endpoint of the trial was met:
 - In patients with aortic stenosis at high risk for operation, TAVR was non-inferior to AVR for all-cause mortality at 1 year (24.2% vs. 26.8%, $p=0.001$ for non inferiority)
 - Transfemoral TAVR subgroup was also non-inferior to AVR ($p=0.002$ for non-inferiority)
- Death at 30 days was lower than expected in both arms of the trial:
 - TAVR mortality (3.4%) was the lowest reported in any series, despite an early generation device and limited previous operator experience
 - AVR mortality (6.5%) was lower than the expected operative mortality (11.8%)



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions (2)

- Both TAVR and AVR were associated with important but different peri-procedural hazards:
 - Major strokes at 30 days (3.8 vs. 2.1%, $p=0.20$) and one year (5.1% vs. 2.4%, $p=0.07$) and major vascular complications were more frequent with TAVR (11.0% vs. 3.2%, $p<0.001$)
 - Major bleeding (9.3% vs. 19.5%, $p<0.001$) and new onset atrial fibrillation (8.6% vs. 16.0%, $p<0.001$) were more frequent with AVR
- TAVR and AVR are both acceptable therapies in these high-risk patients; differing peri-procedural hazards should influence case-based decision-making



Interventional Therapies For Congenital & Structural Heart Disease



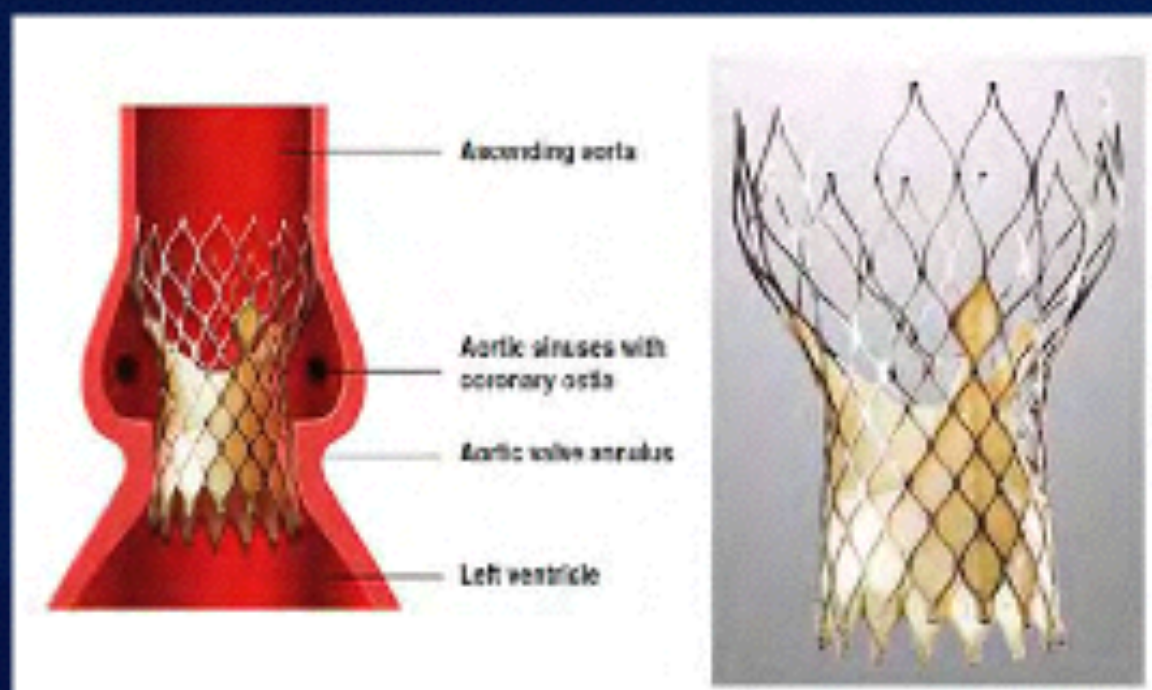
Conclusions (3)

- Symptom improvement (NYHA class and 6-min walk distance) favored TAVR at 30 days and was similar to AVR at one year
- Echo findings indicate:
 - Small hemodynamic benefit with TAVR vs. AVR at 1 year (mean gradient $p=0.008$, AVA $p=0.002$)
 - Increased para-valvular regurgitation associated with TAVR ($p<0.001$)
- Preliminary subgroup analyses should be interpreted cautiously:
 - Possible TAVR benefit in women and patients without prior CABG



Interventional Therapies For Congenital & Structural Heart Disease

CoreValve



CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results

Jeffrey J. Popma, MD

On Behalf of the CoreValve US Clinical Investigators



Interventional Therapies For Congenital & Structural Heart Disease



Other Valves

1. Direct Flow
2. Portico
3. Lotus
4. Others



Interventional Therapies For Congenital & Structural Heart Disease



Mitral Paravalvular Leaks



Interventional Therapies For Congenital & Structural Heart Disease



Background

1. Uncommon! 1%/patient-year.
2. Most commonly the mitral valve
3. Multifactorial etiology
4. Clinical significance: heart failure & hemolysis
5. Medical therapy: transfusions
6. Surgery
7. Device closure



Interventional Therapies For Congenital & Structural Heart Disease



Surgery

1. Operative mortality 6.6%! Repeat operations mortality 13%, 15%, 37% for 1st, 2nd, and 3rd operations.
2. Stroke risk of 5.1%
3. Actuarial survival at 10 yrs 30%
4. Recurrence 22%



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Device Closure

1. Success (mild or no residual regurgitation) 81% in 16 patients. No mortality, but stroke, perforation, embolization, arrhythmias
2. Devices used: PDA devices, ASD/VSD/vascular plugs/coils



Interventional Therapies For Congenital & Structural Heart Disease Devices

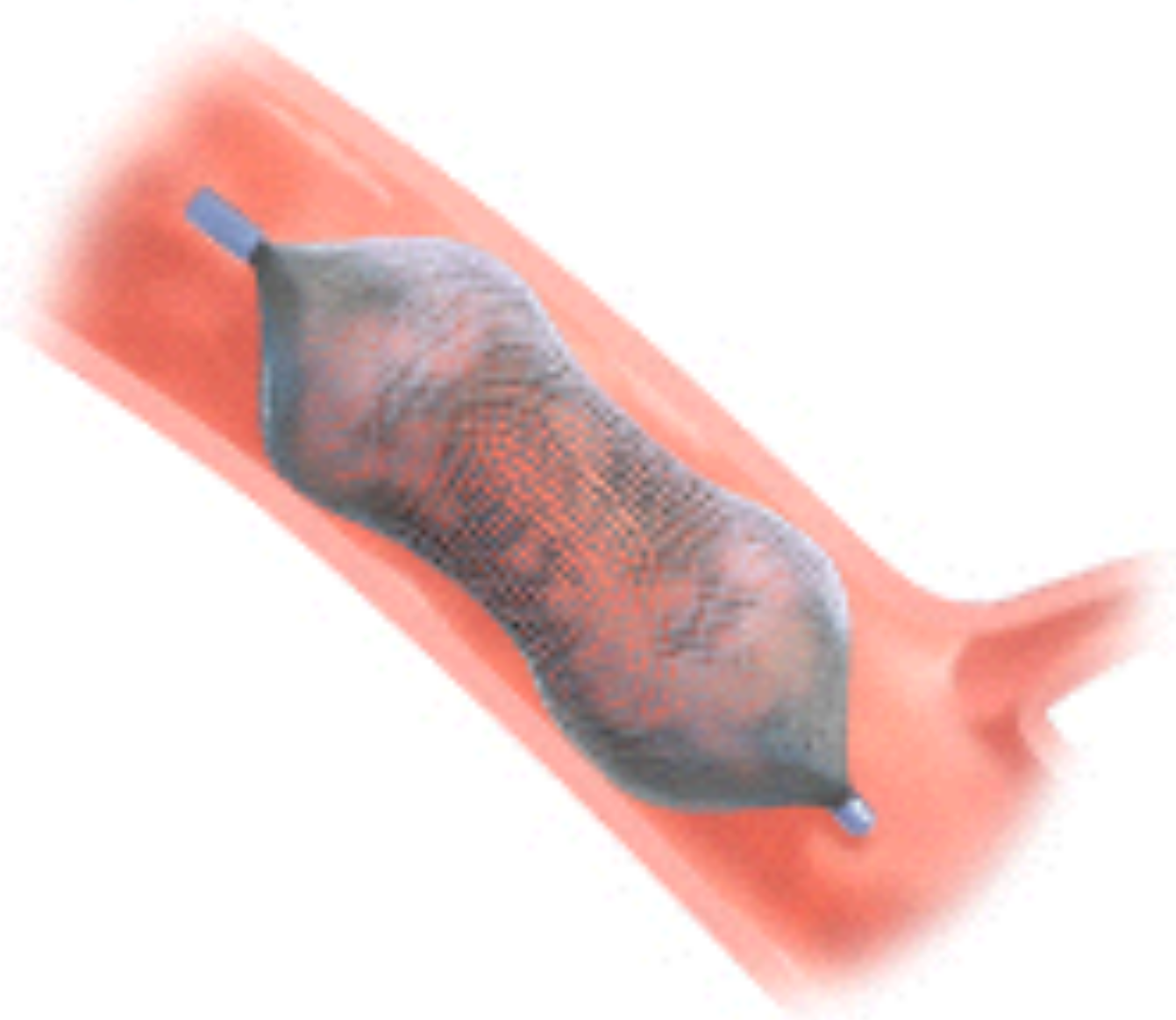


Interventional Therapies For

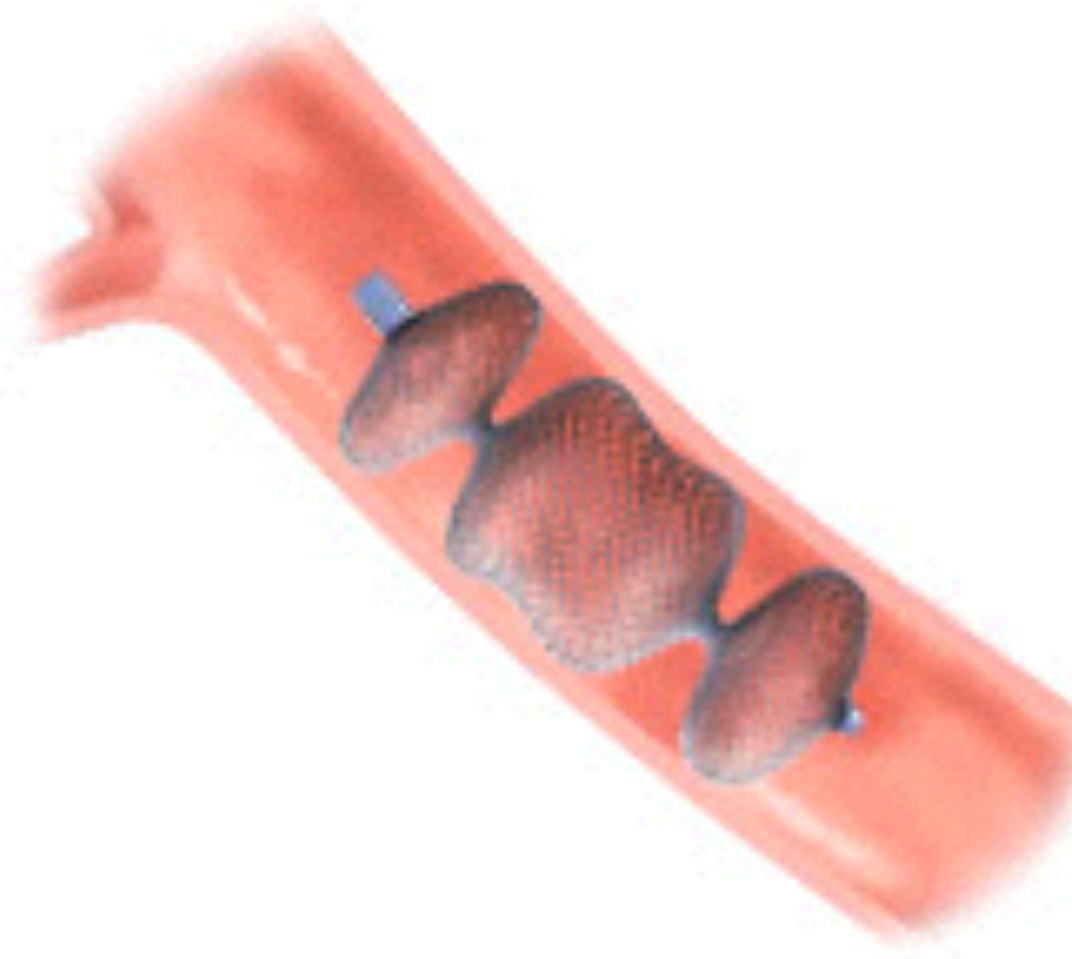
Co

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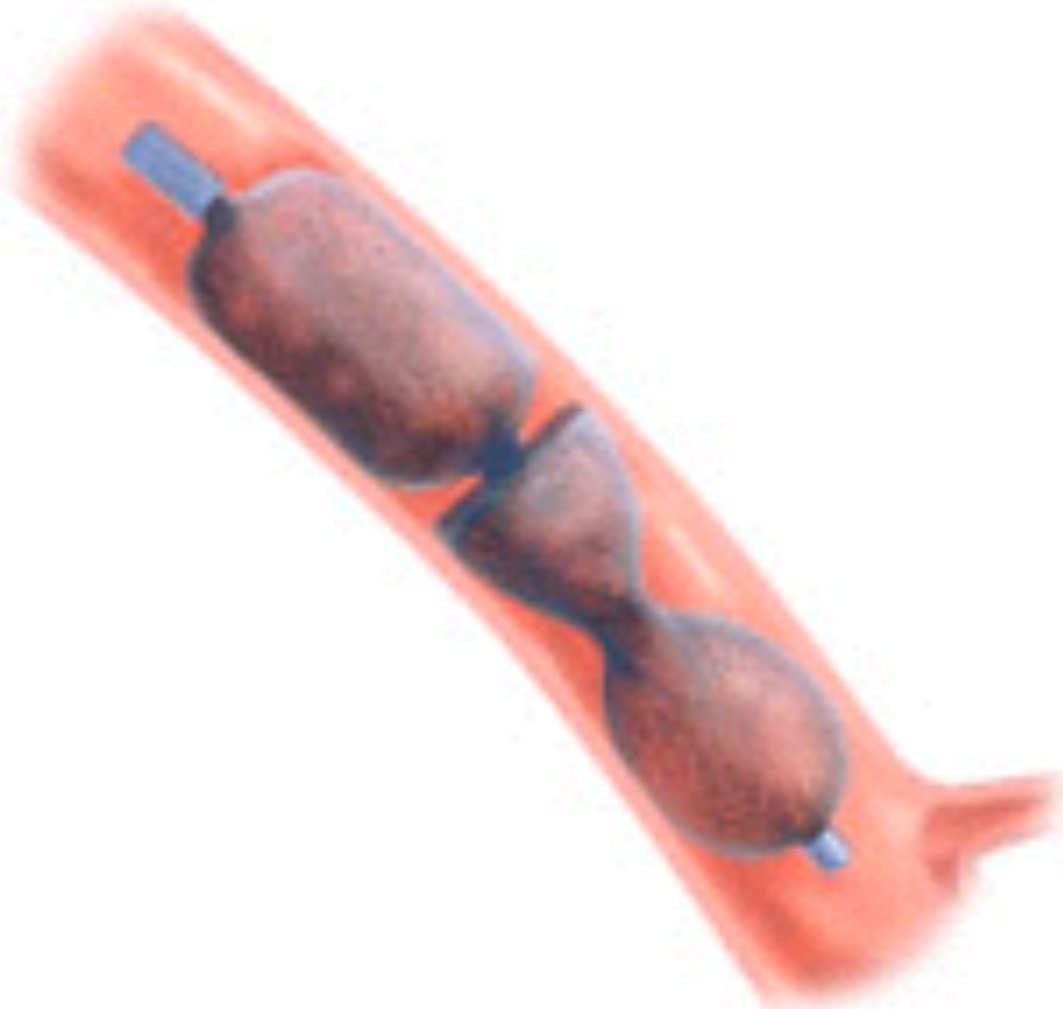
AMPLATZER Vascular Plug



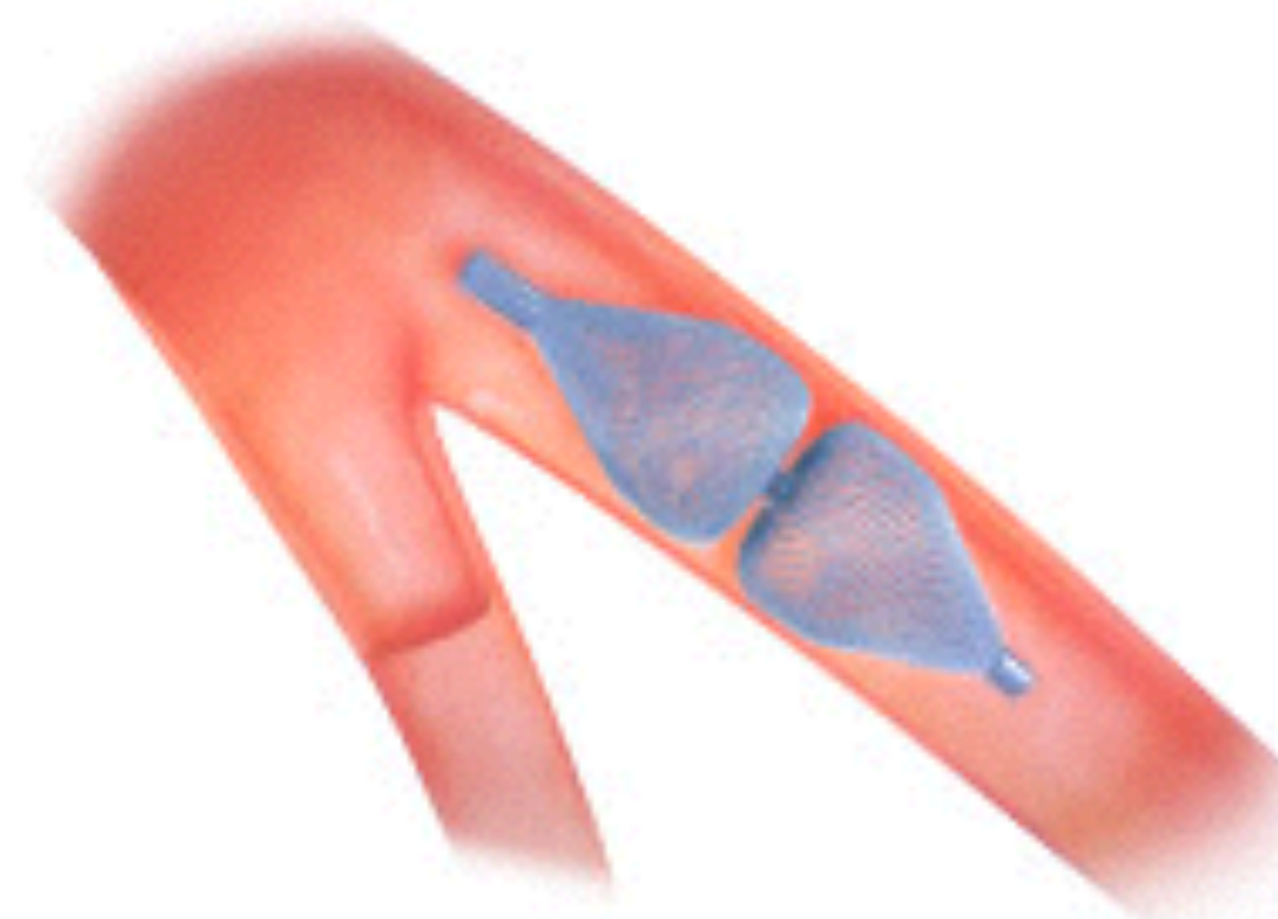
AMPLATZER Vascular Plug II



AMPLATZER Vascular Plug III



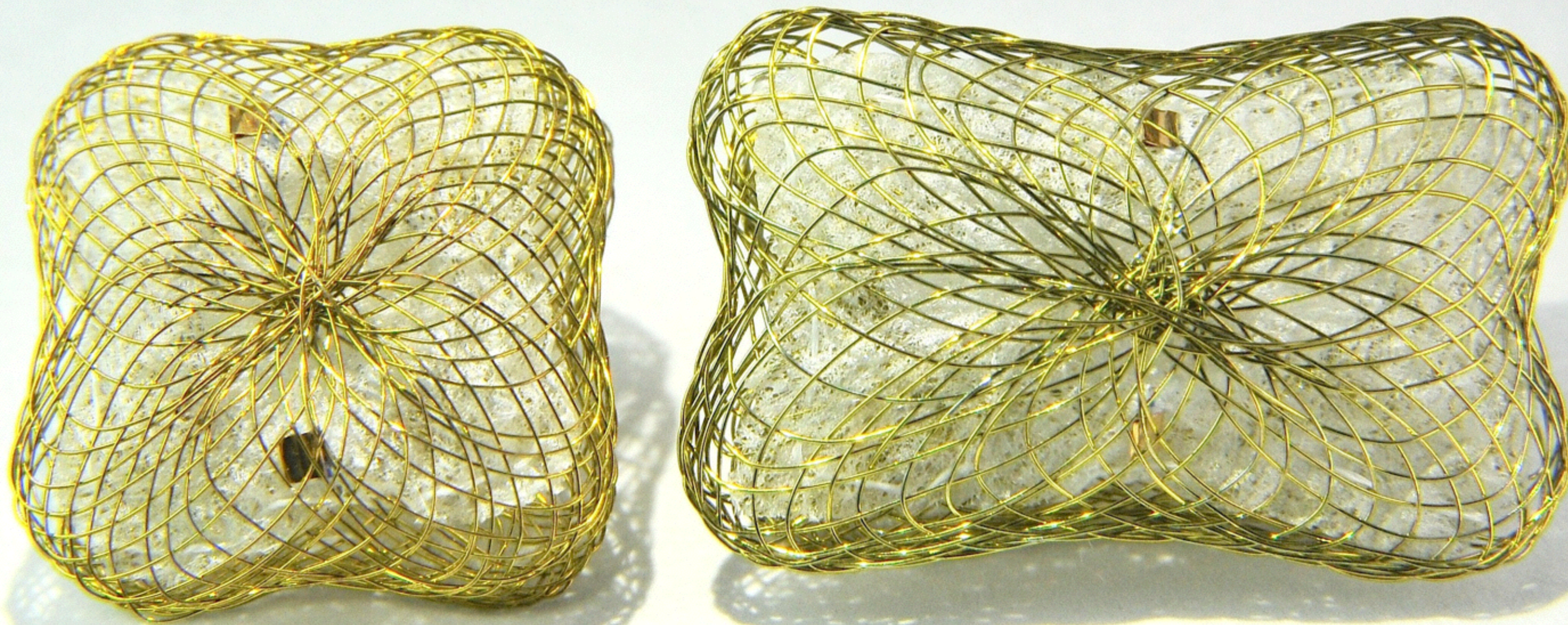
AMPLATZER Vascular Plug 4





Interventional Therapies For Congenital & Structural Heart Disease

Occlutech PVL Devices





Interventional Therapies For Congenital & Structural Heart Disease

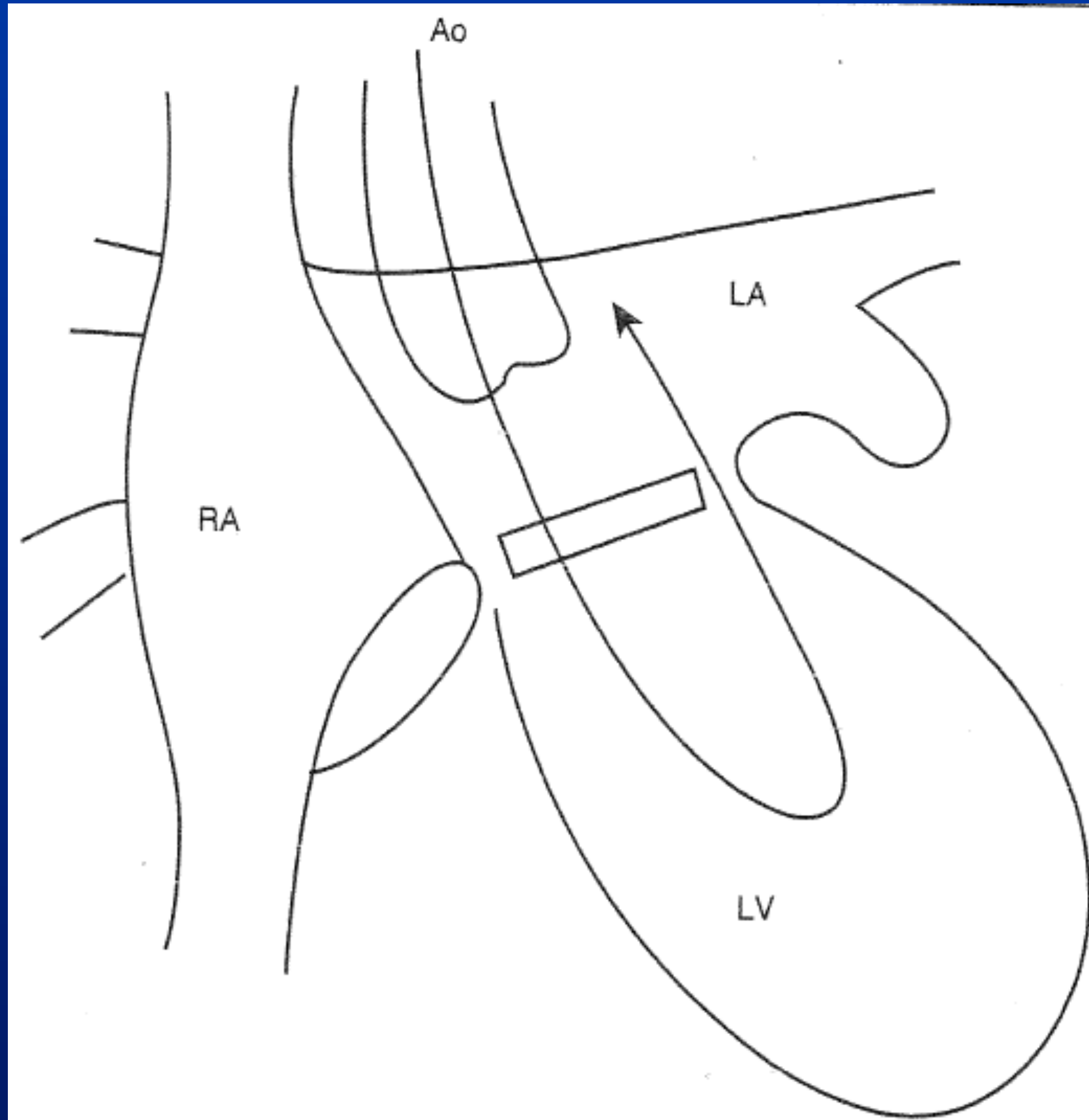


Treatment of Paravalvular Mitral Leaks

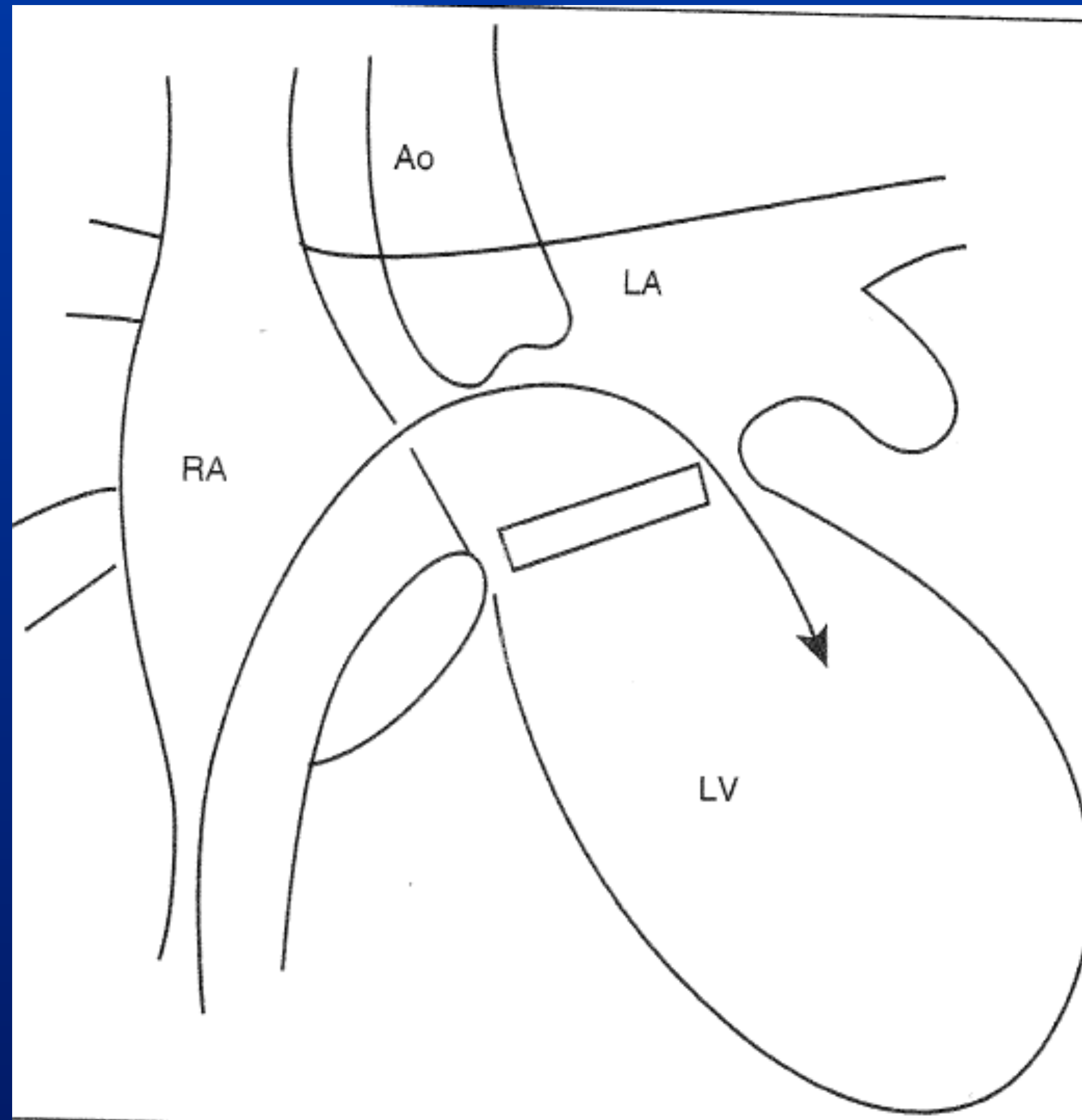
1. Retrograde approach.
2. Anterograde approach
3. Trans-apical



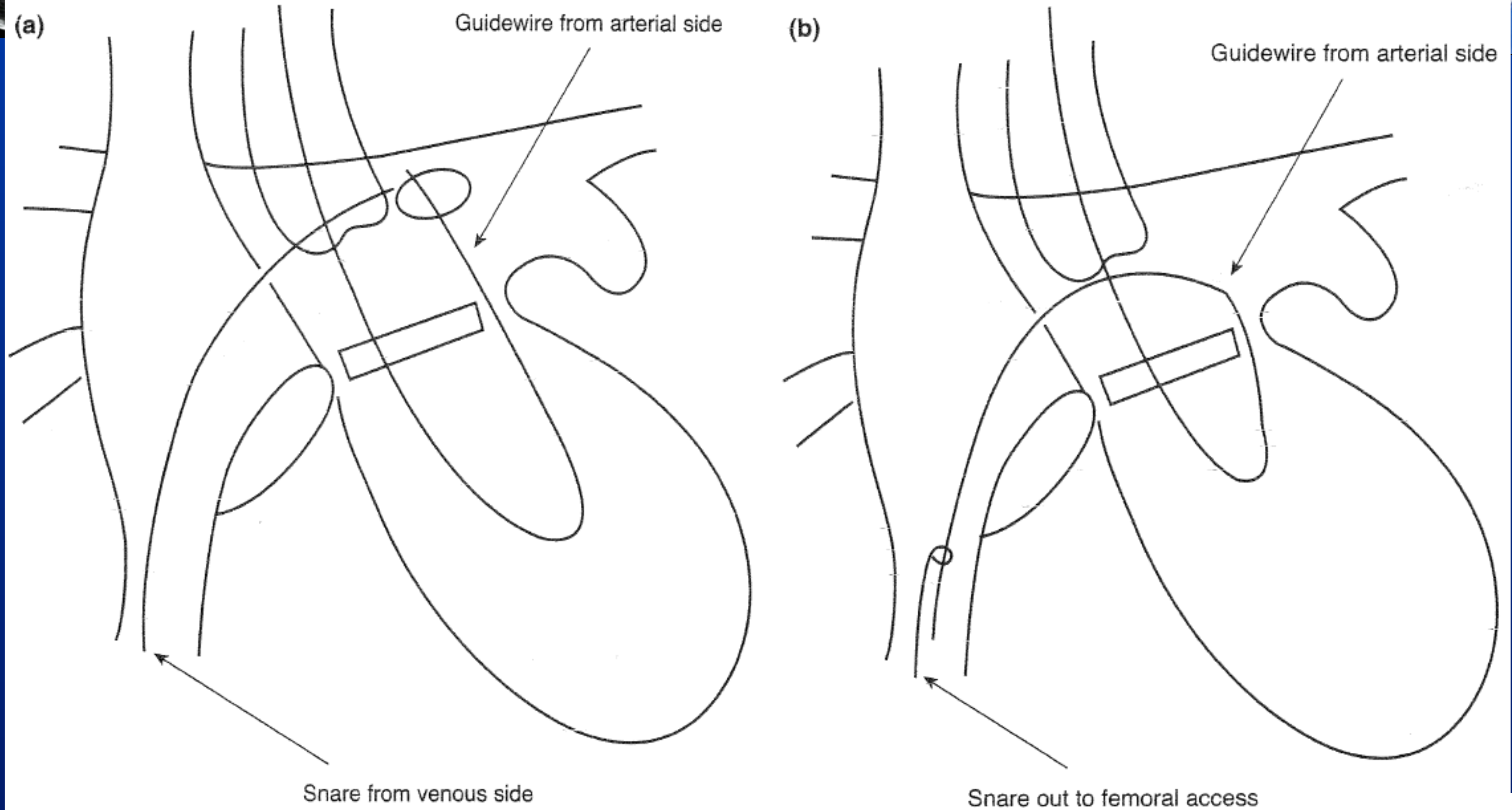
Interventional Therapies For Congenital & Structural Heart Disease



Interventional Therapies For Congenital & Structural Heart Disease

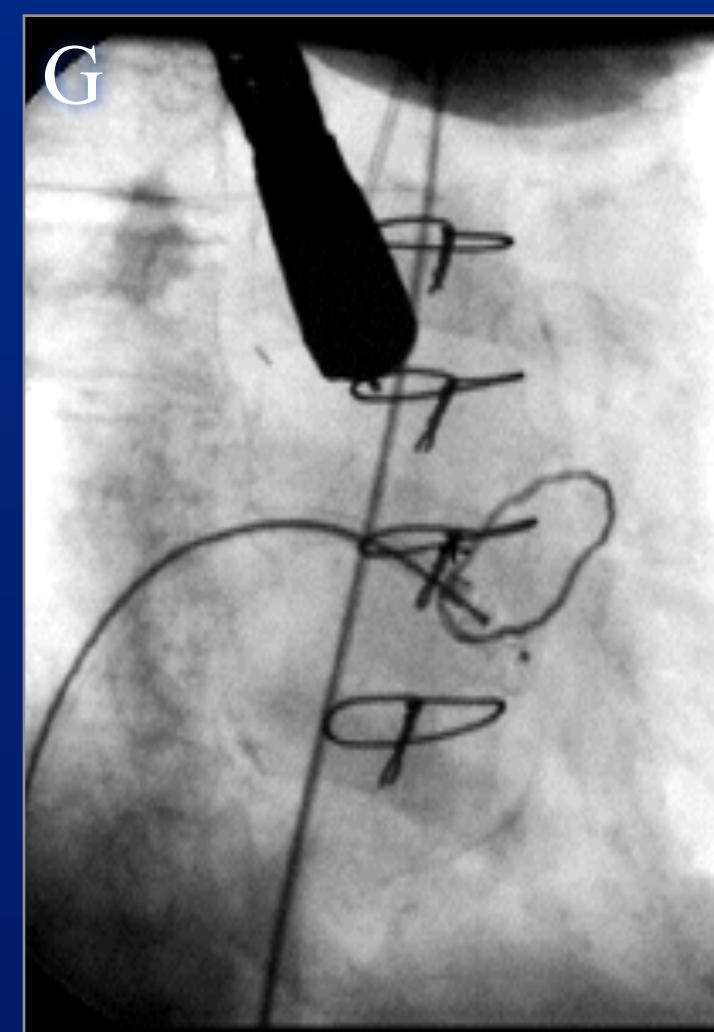
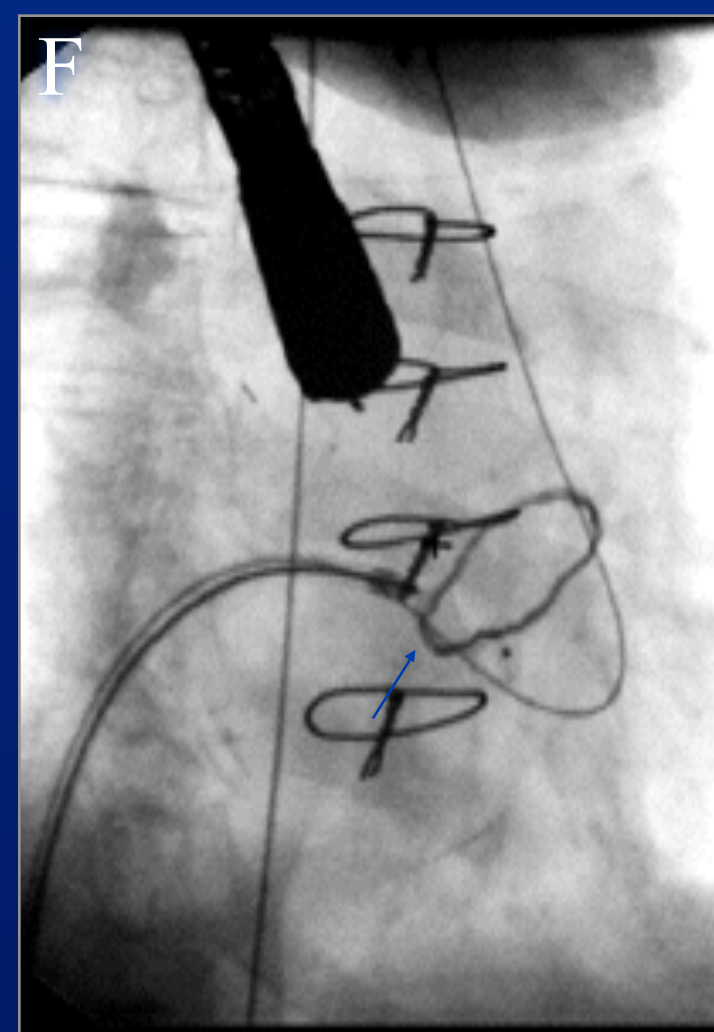
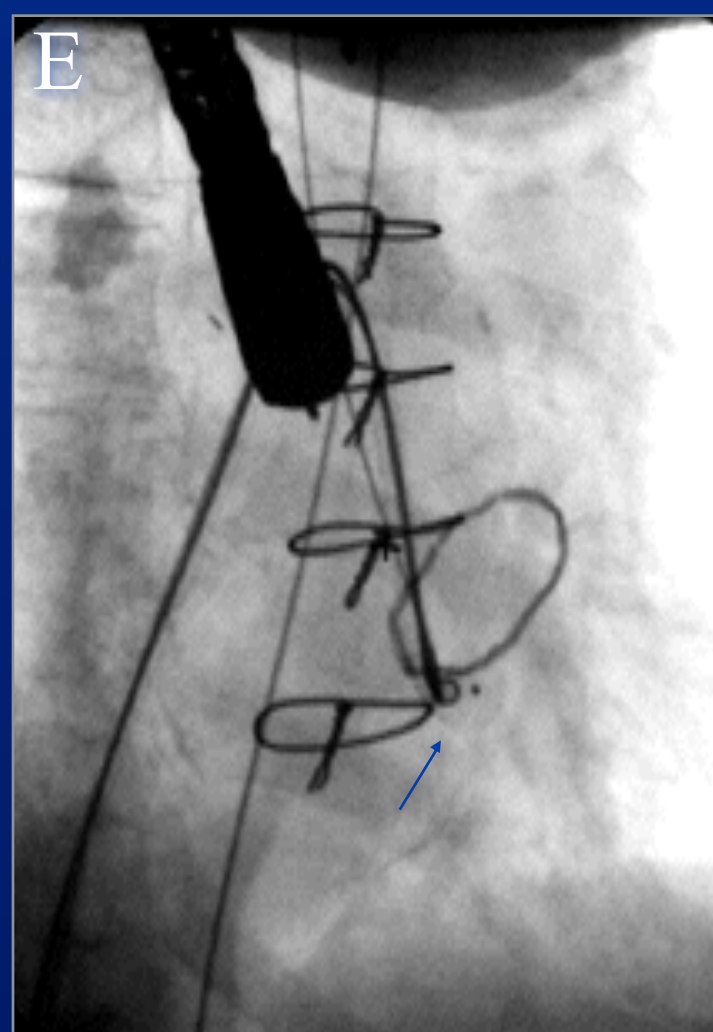
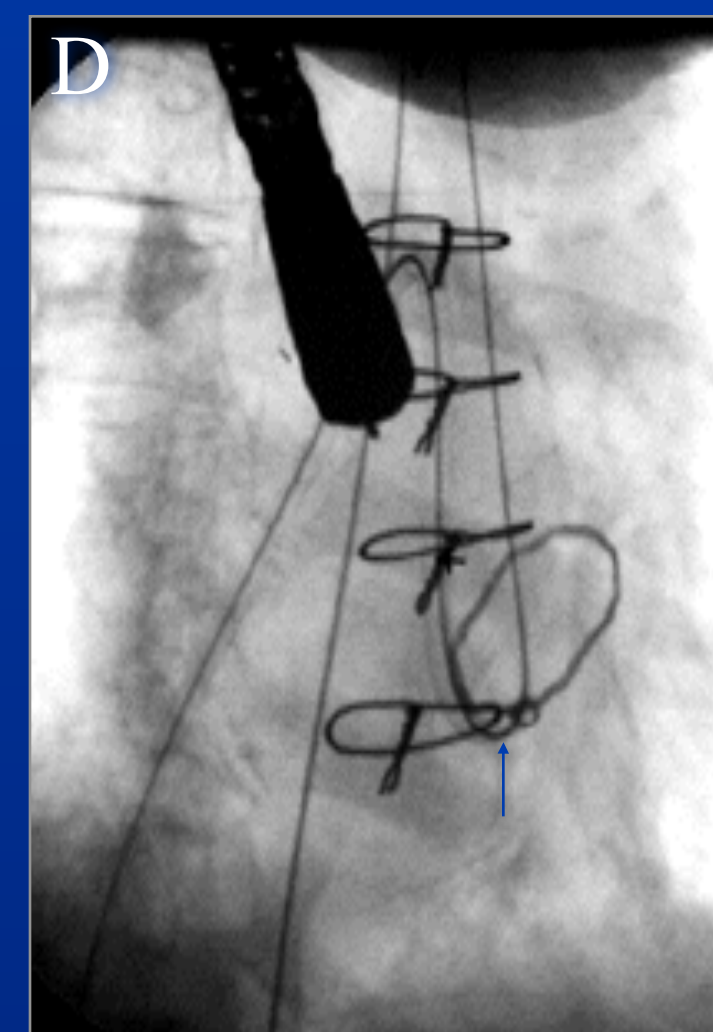
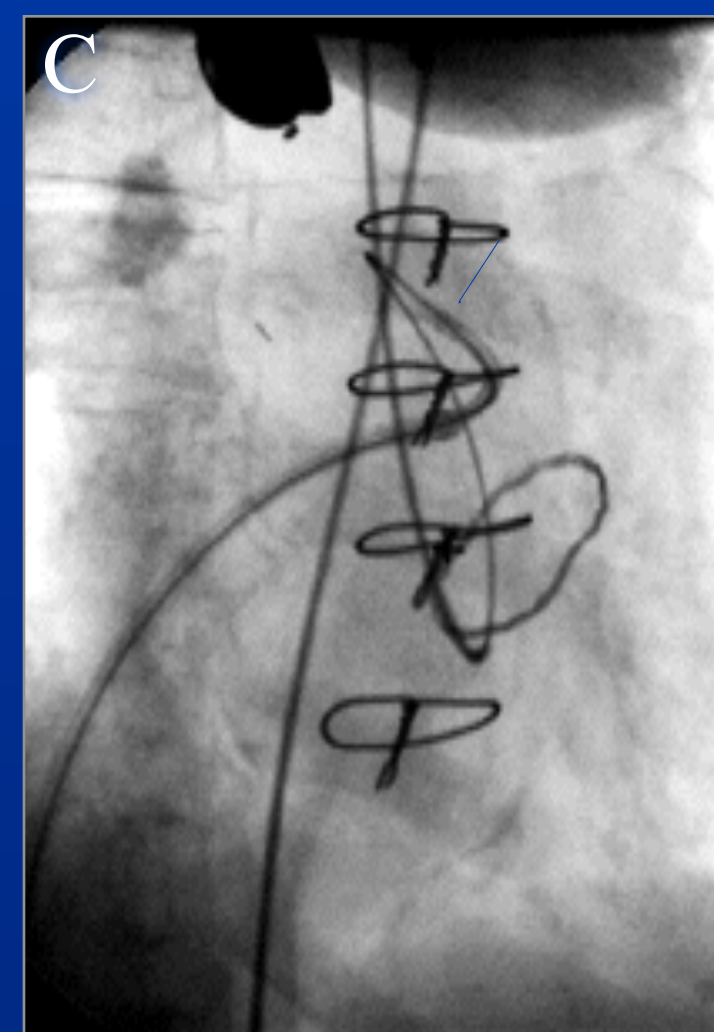
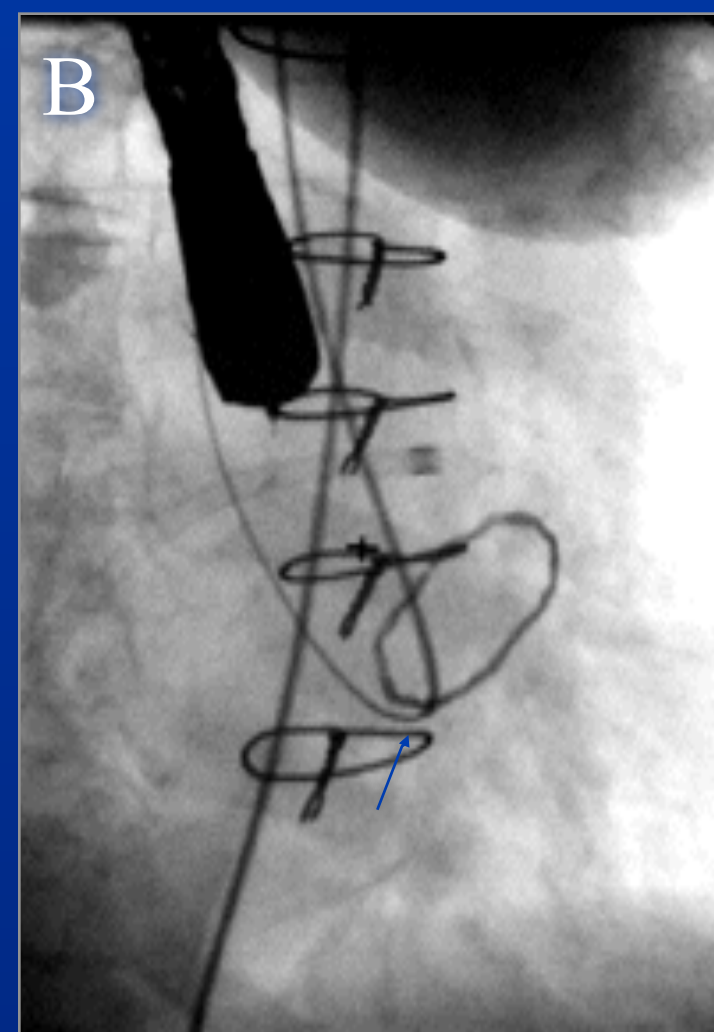
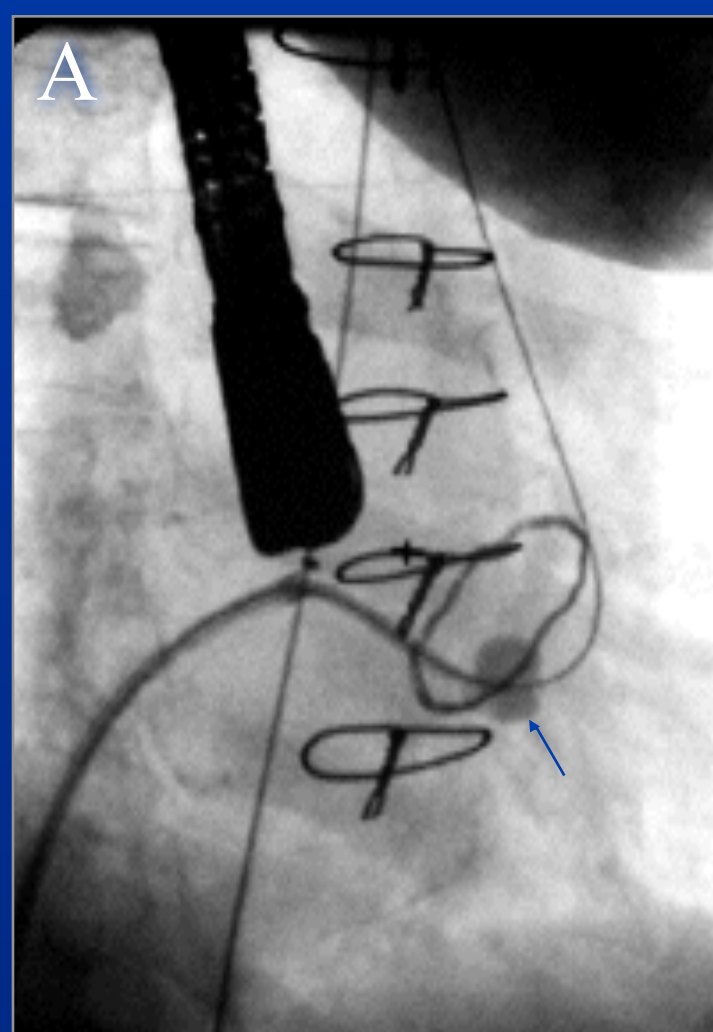


Interventional Therapies For Congenital & Structural Heart Disease

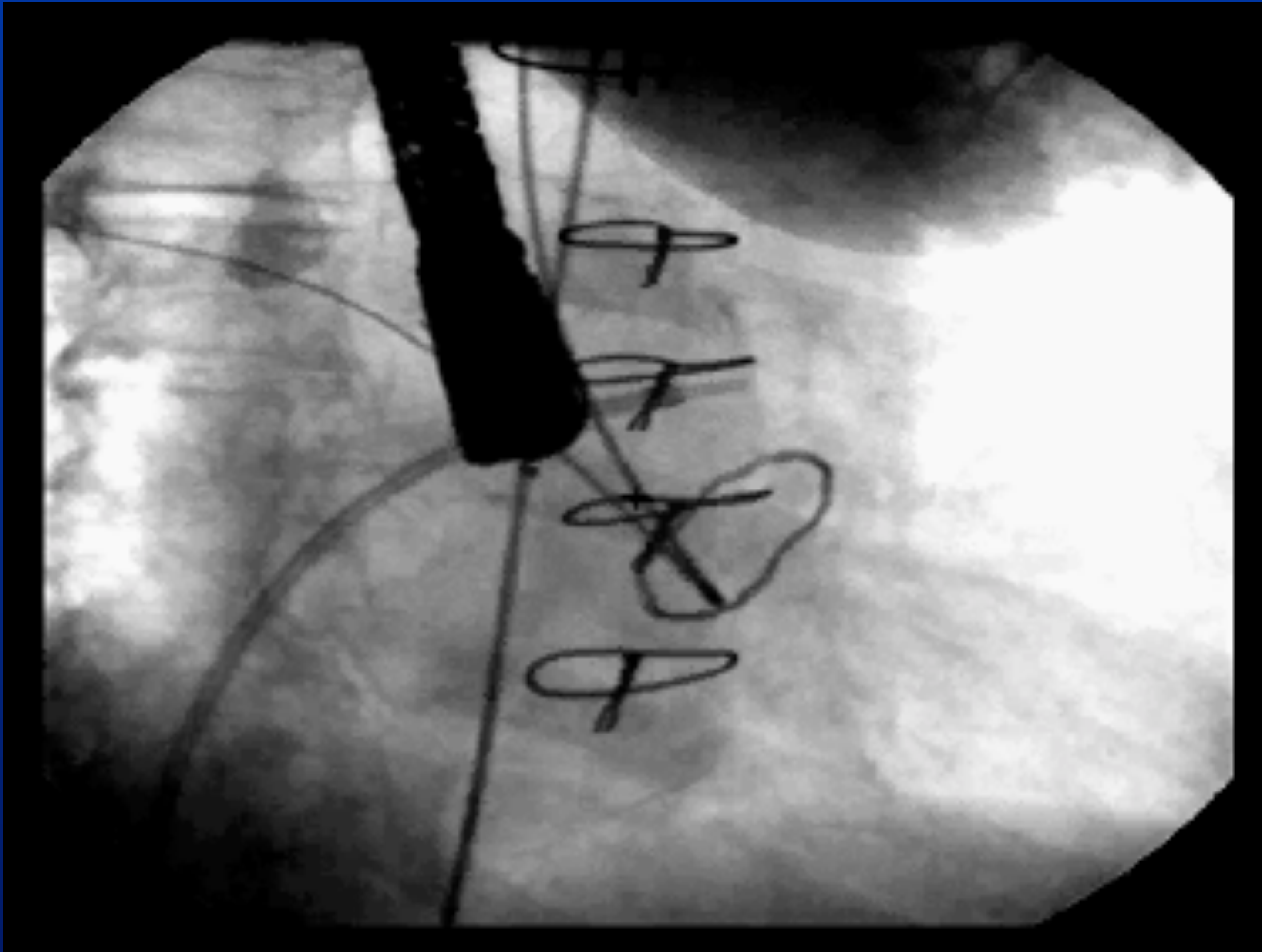




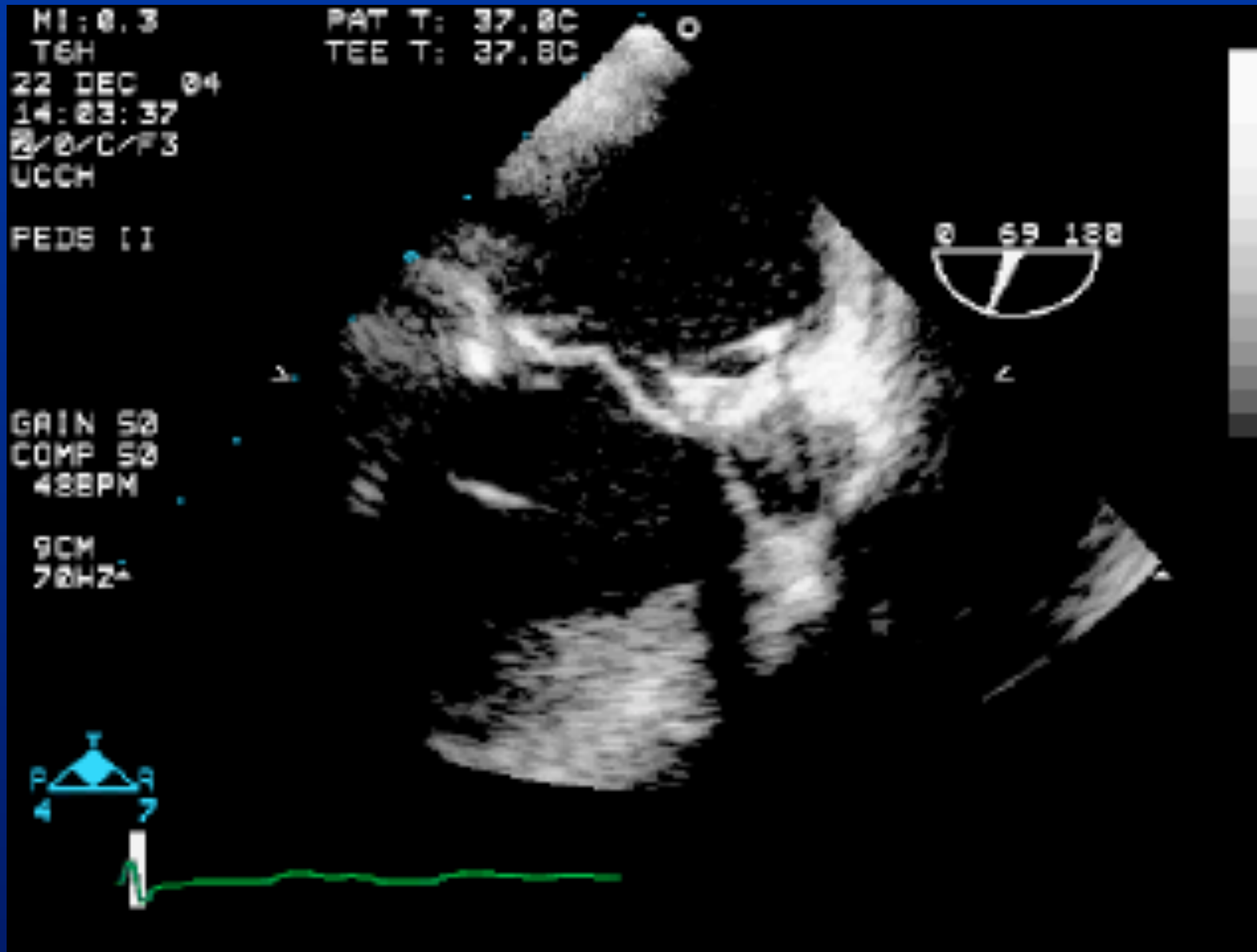
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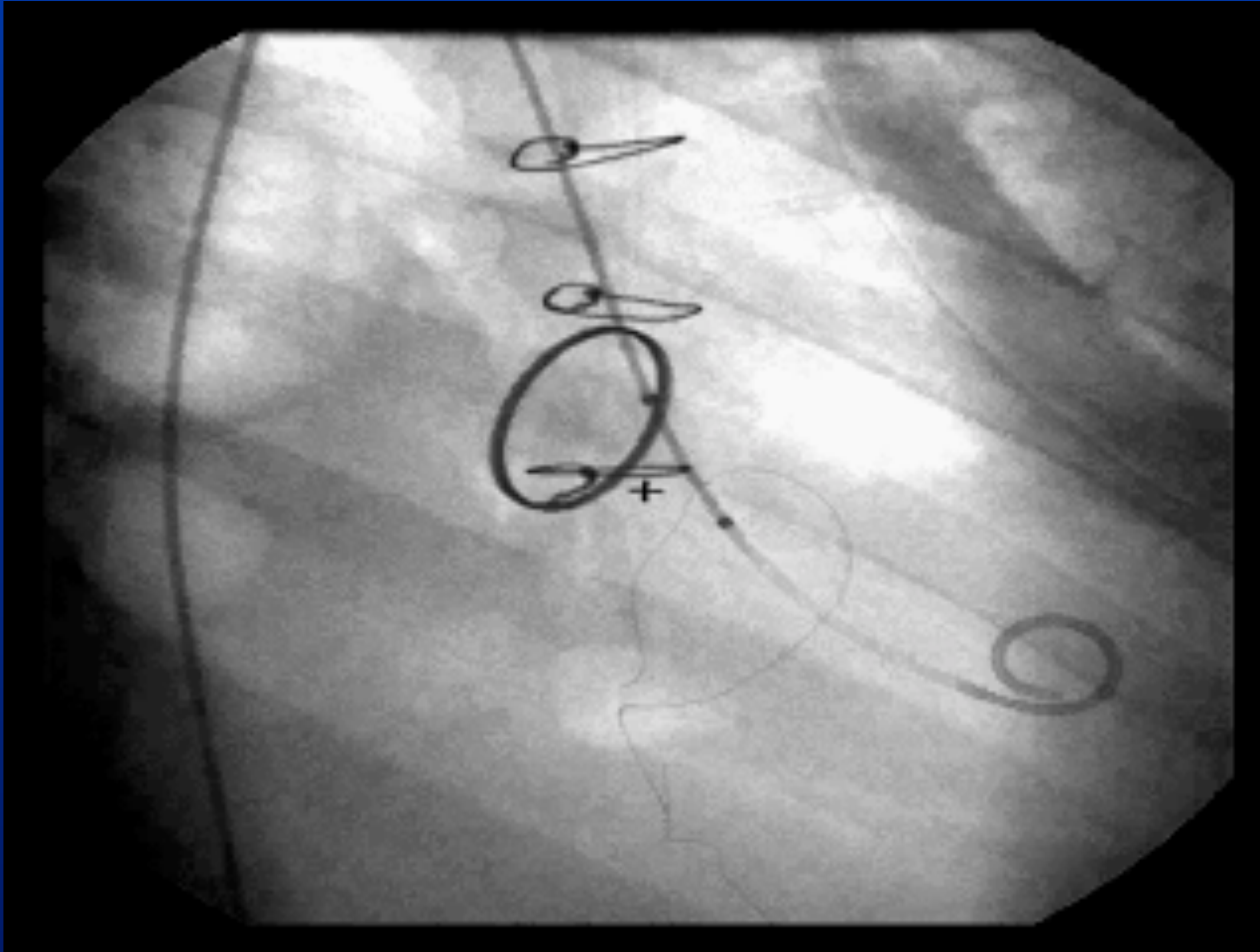
Interventional Therapies For Congenital & Structural Heart Disease



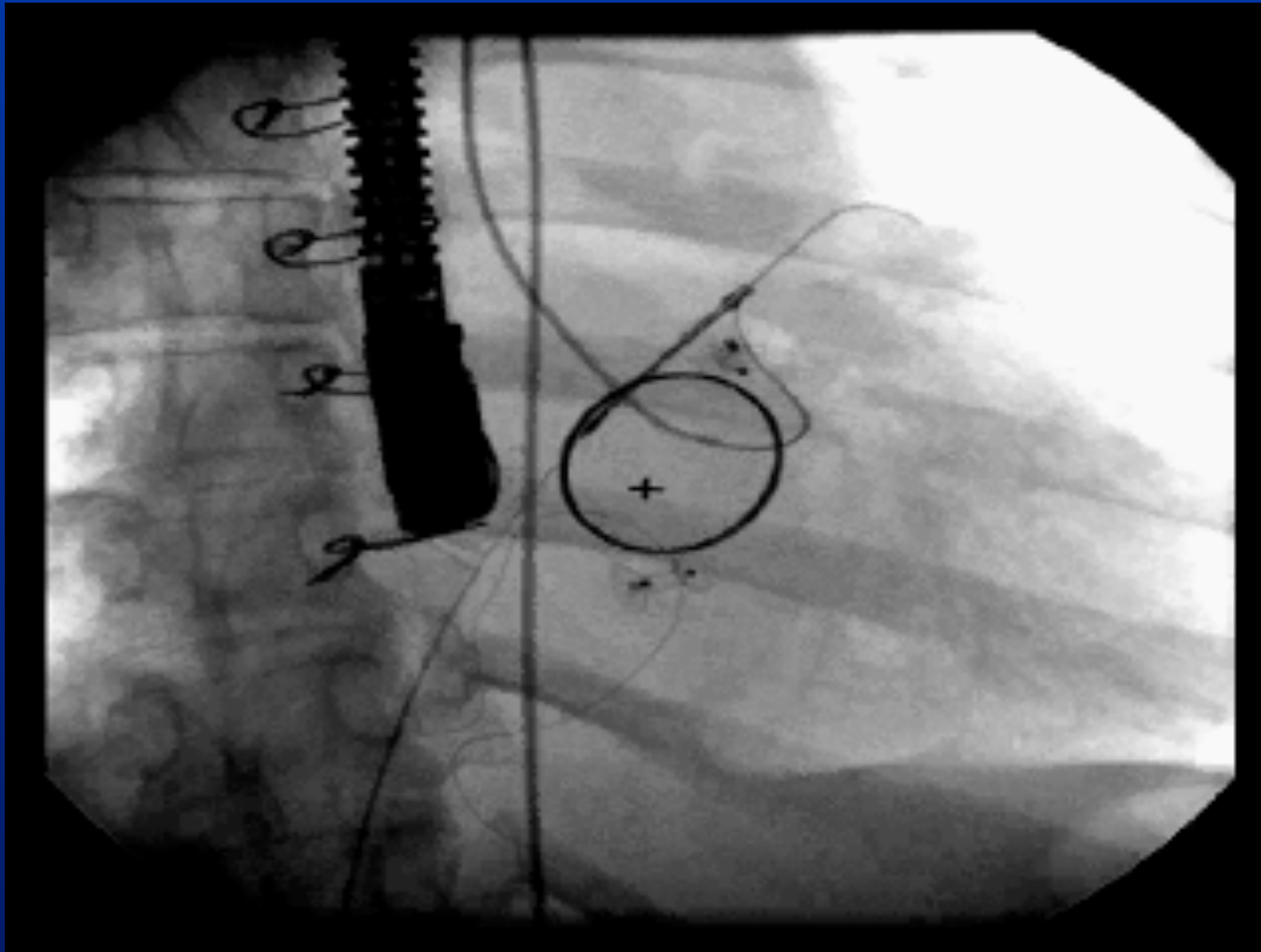
Interventional Therapies For Congenital & Structural Heart Disease



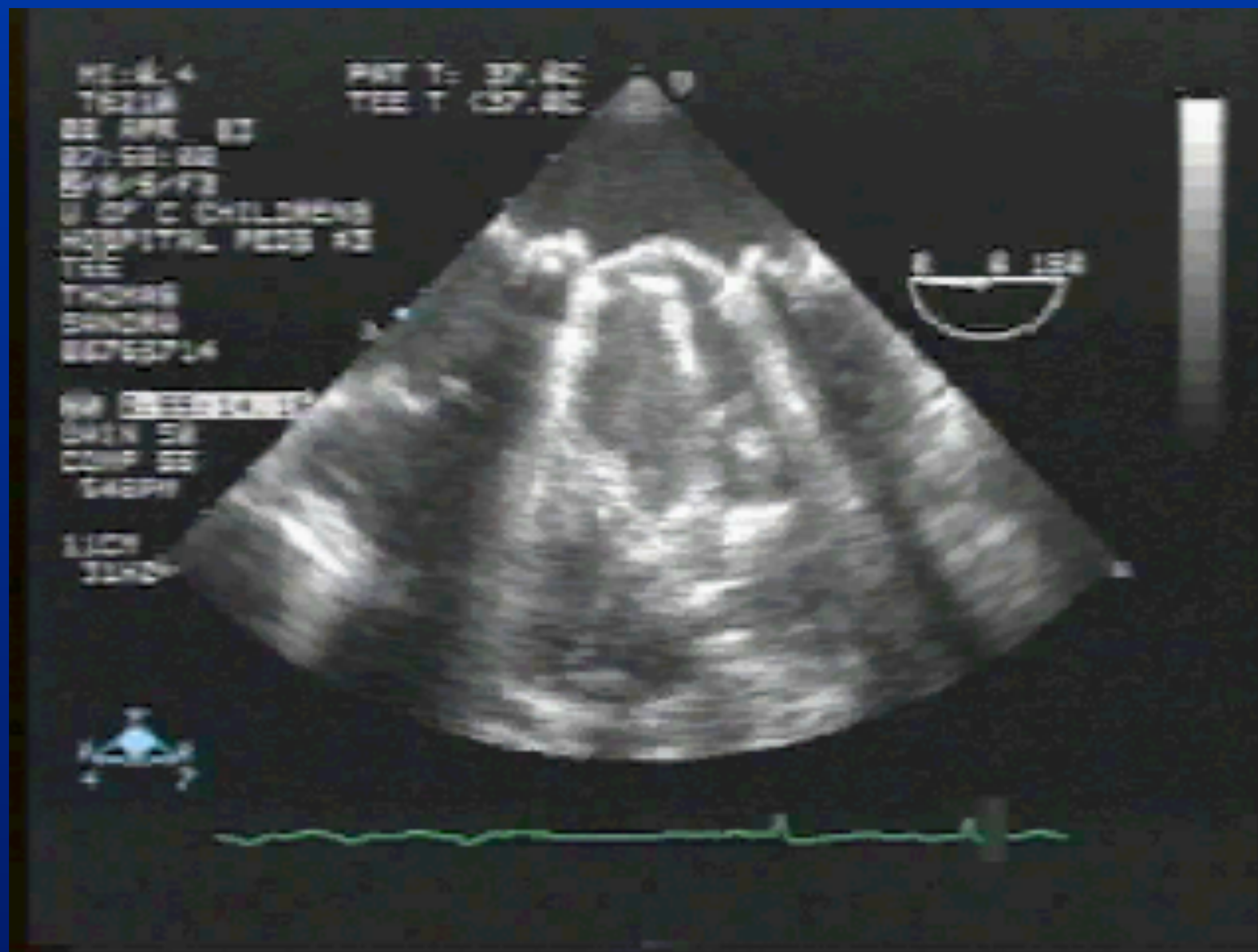
Interventional Therapies For Congenital & Structural Heart Disease



Interventional Therapies For Congenital & Structural Heart Disease

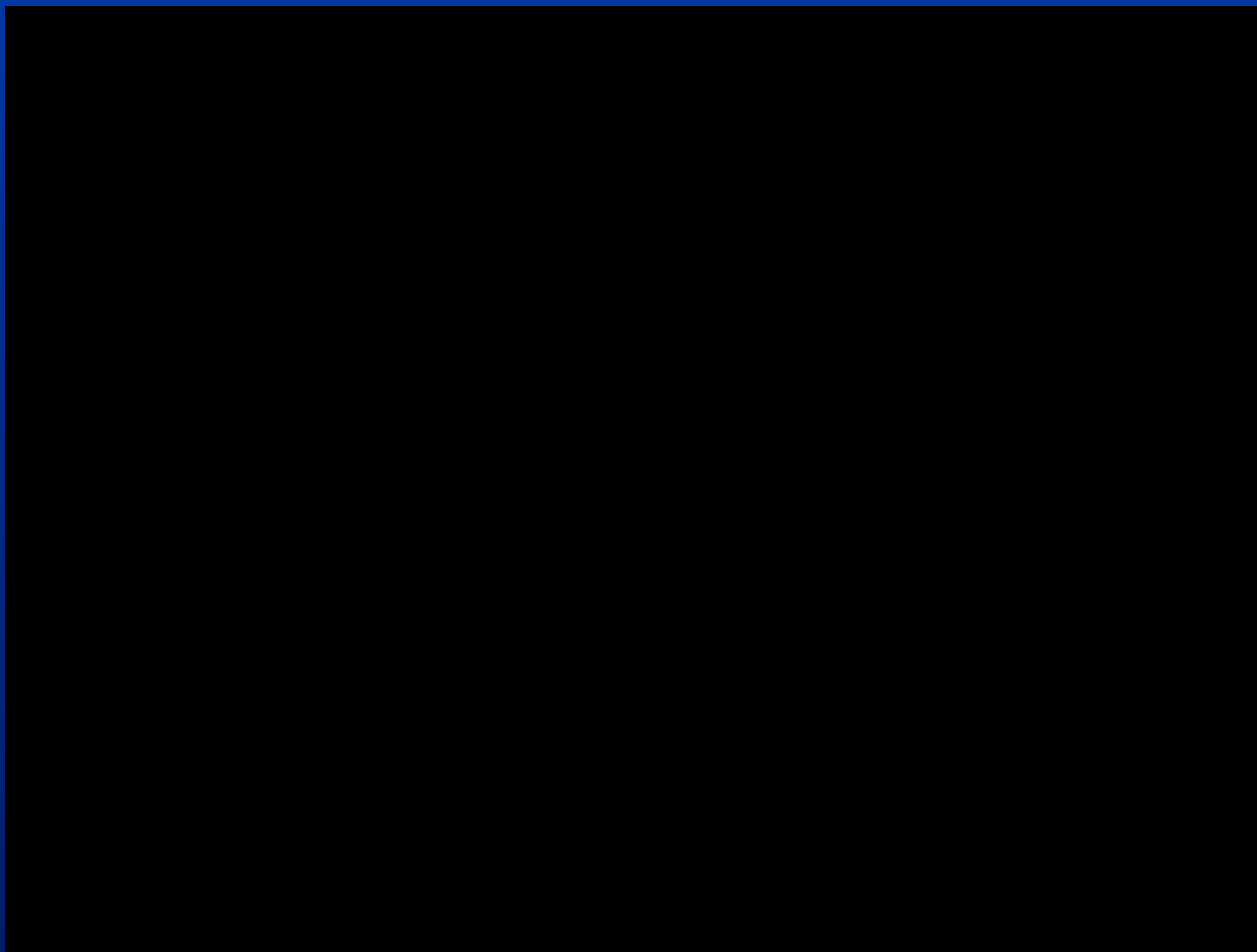


Interventional Therapies For Congenital & Structural Heart Disease





Interventional Therapies For Congenital & Structural Heart Disease





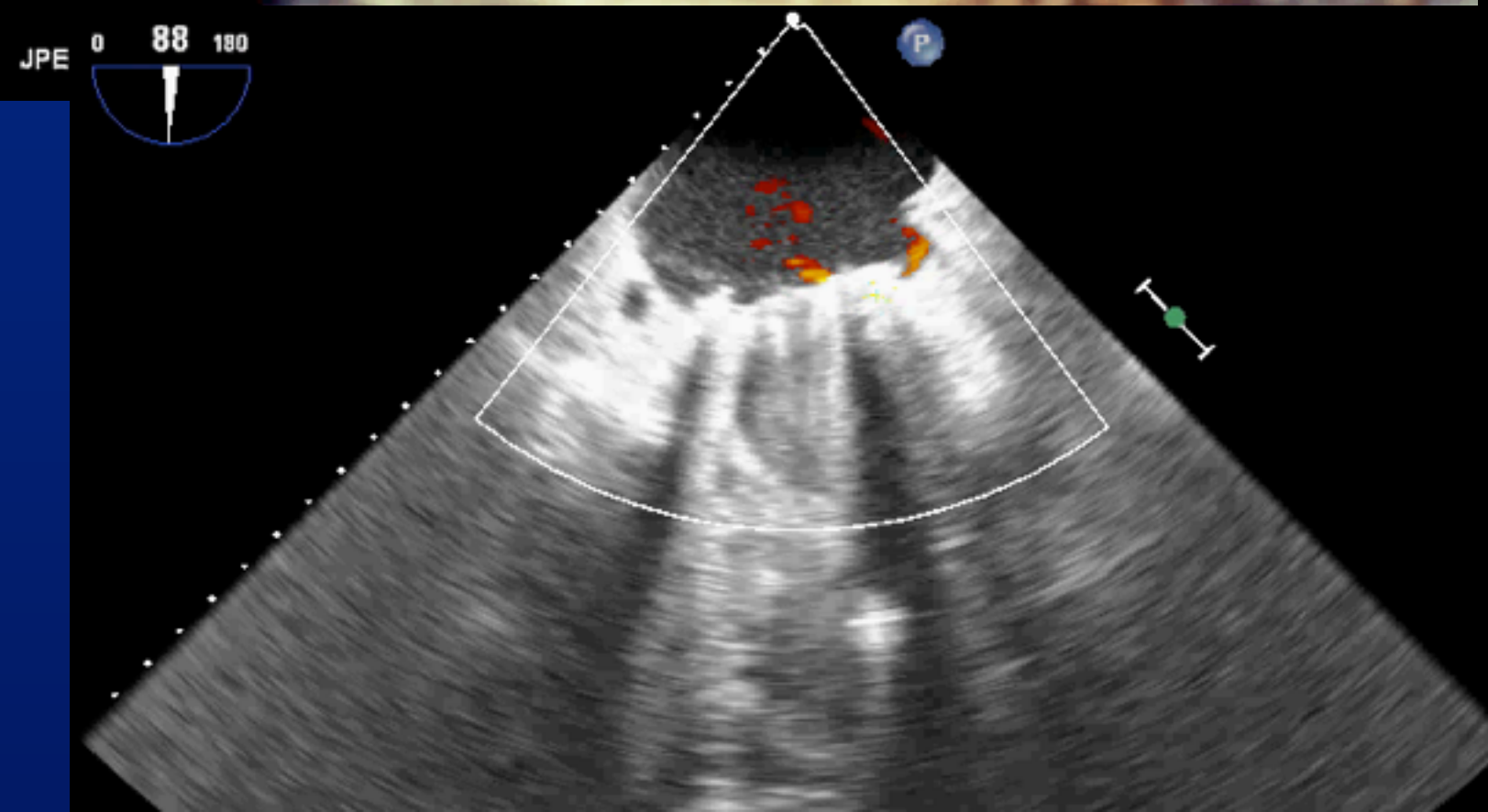
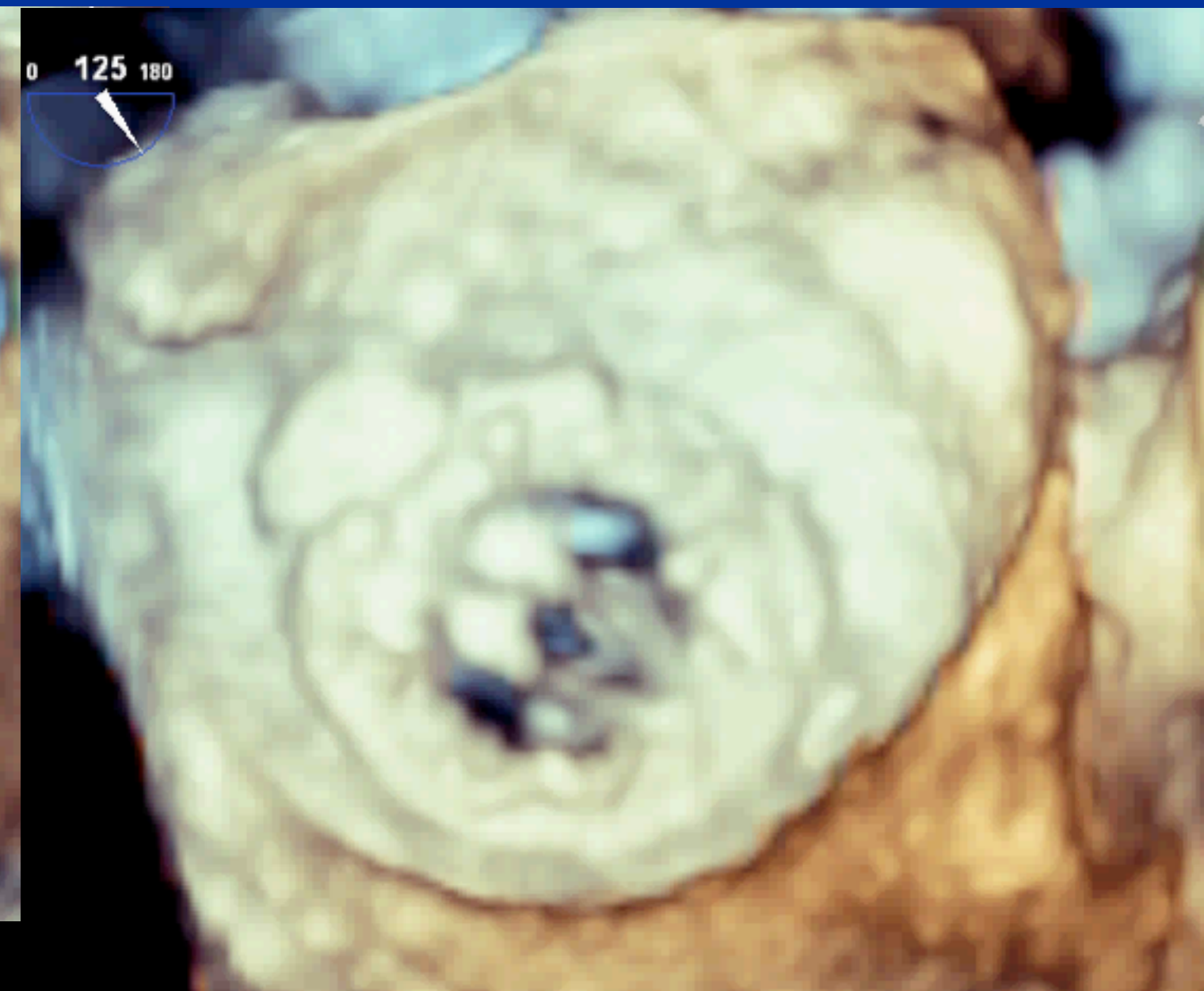
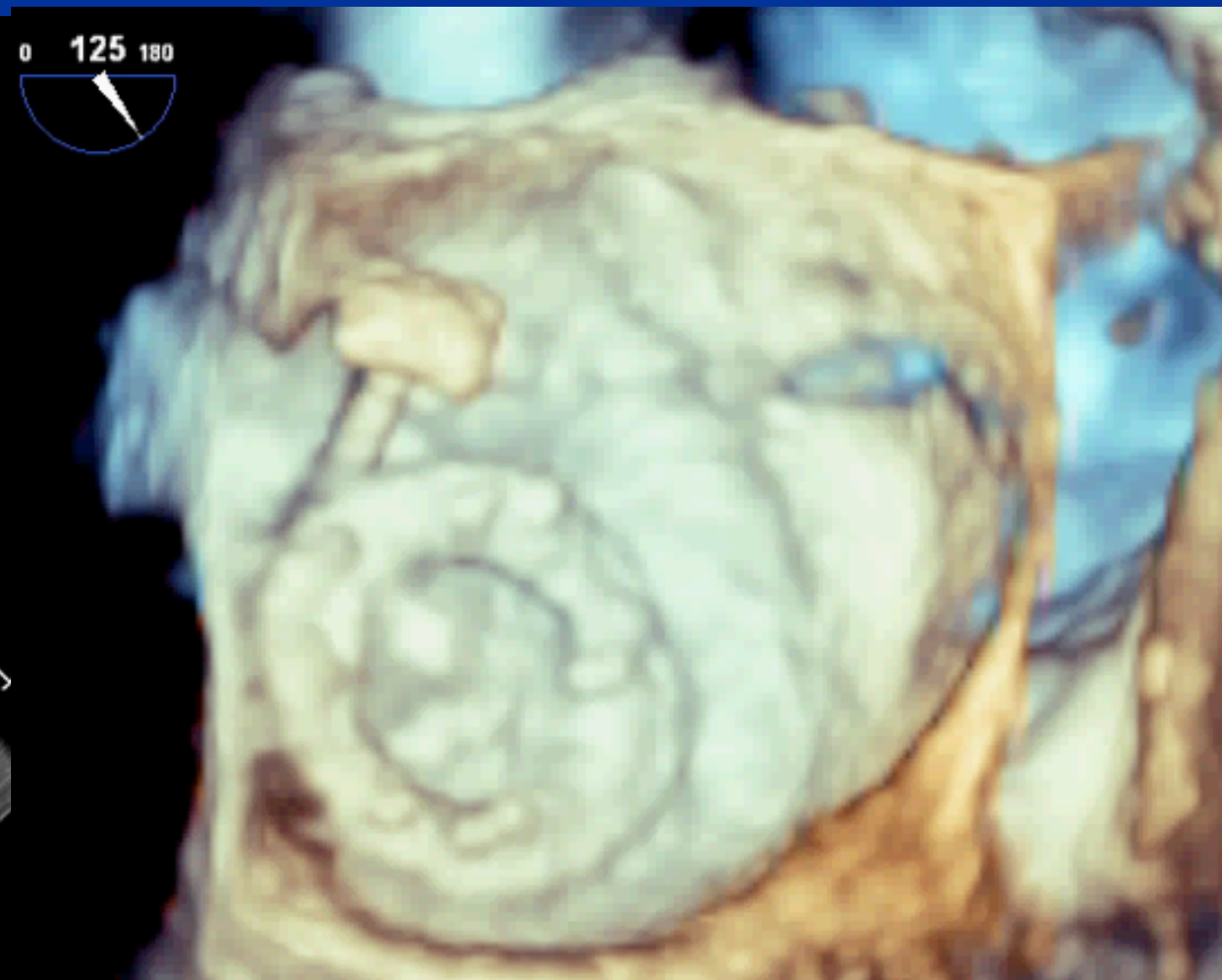
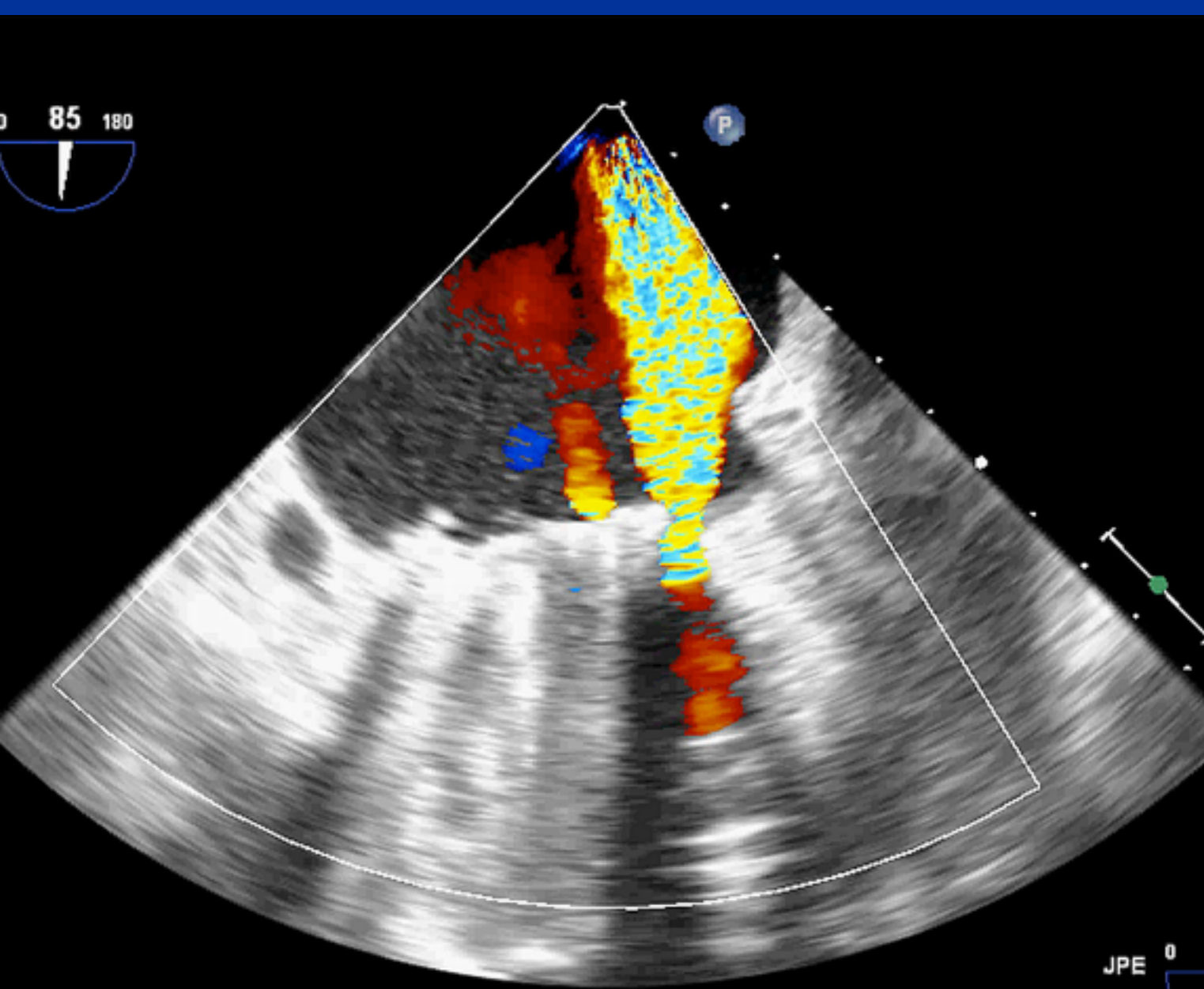
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Trans-Apical

Interventional Therapies For Congenital & Structural Heart Disease

Case-Occlutech Mitral PVL





Interventional Therapies For Congenital & Structural Heart Disease



Conclusions

Mitral paravalvar leak can be done percutaneously via endovascular technique or via trans-apical approach. New devices [lesion-specific] (Amplatzer vascular plug-III) and (Occlutech PVL devices) have increased the closure rates.



Interventional Therapies For Congenital & Structural Heart Disease



Conclusions

Currently, there are more adults than children in the US living with CHD. Such patients have various needs.

SHD Intervention can be carried out for various conditions with low risk and very high success rate. The future is very promising for percutaneous valve insertion/repair.



Int Conger



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