AMLI
ATHENS MEDICAL LEADERSHIP + INNOVATION CONFERENCE

ATHENS MEDICAL GROUP
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32 YEARS OF EXCELLENCE

23-25 September 2016
Megaron Athens International Conference Center
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Thank you!

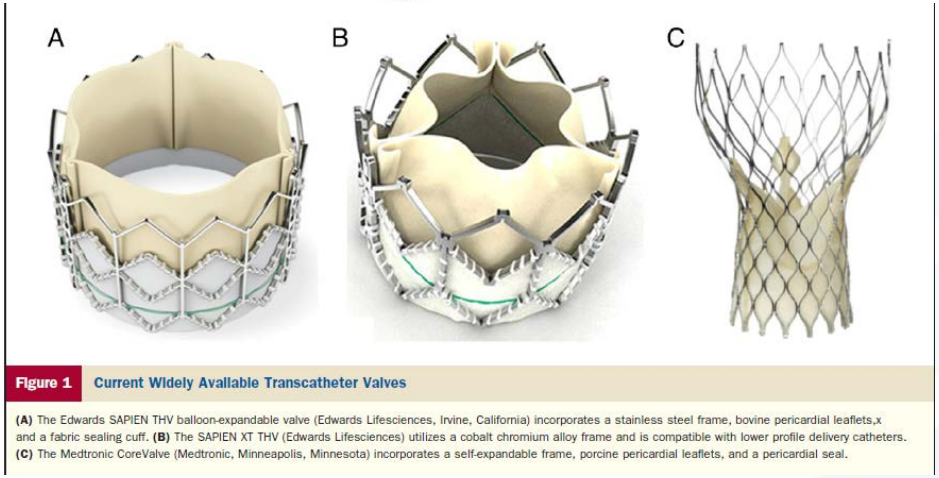

Figure 1 Current Widely Available Transcatheter Valves

(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets,x and a fabric sealing cuff. **(B)** The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. **(C)** The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal.

Interventional Cardiology and Structural Heart Disease

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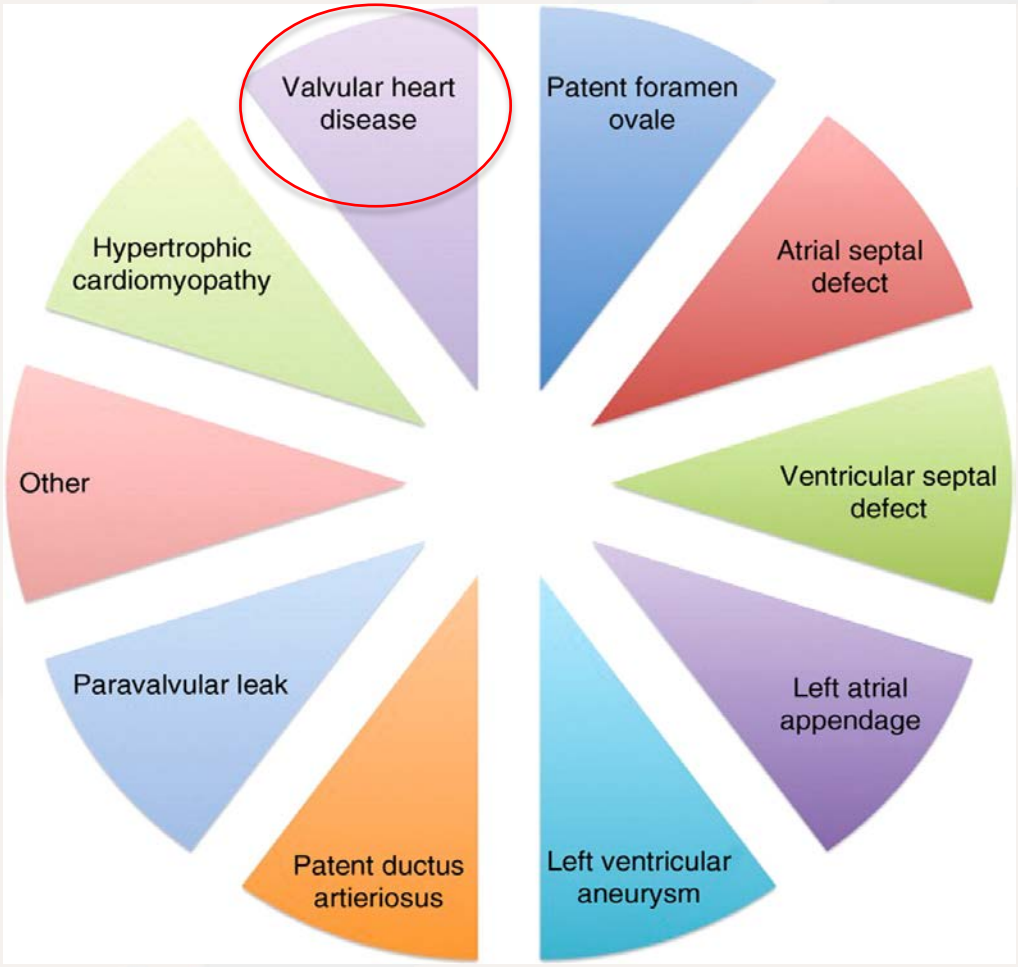
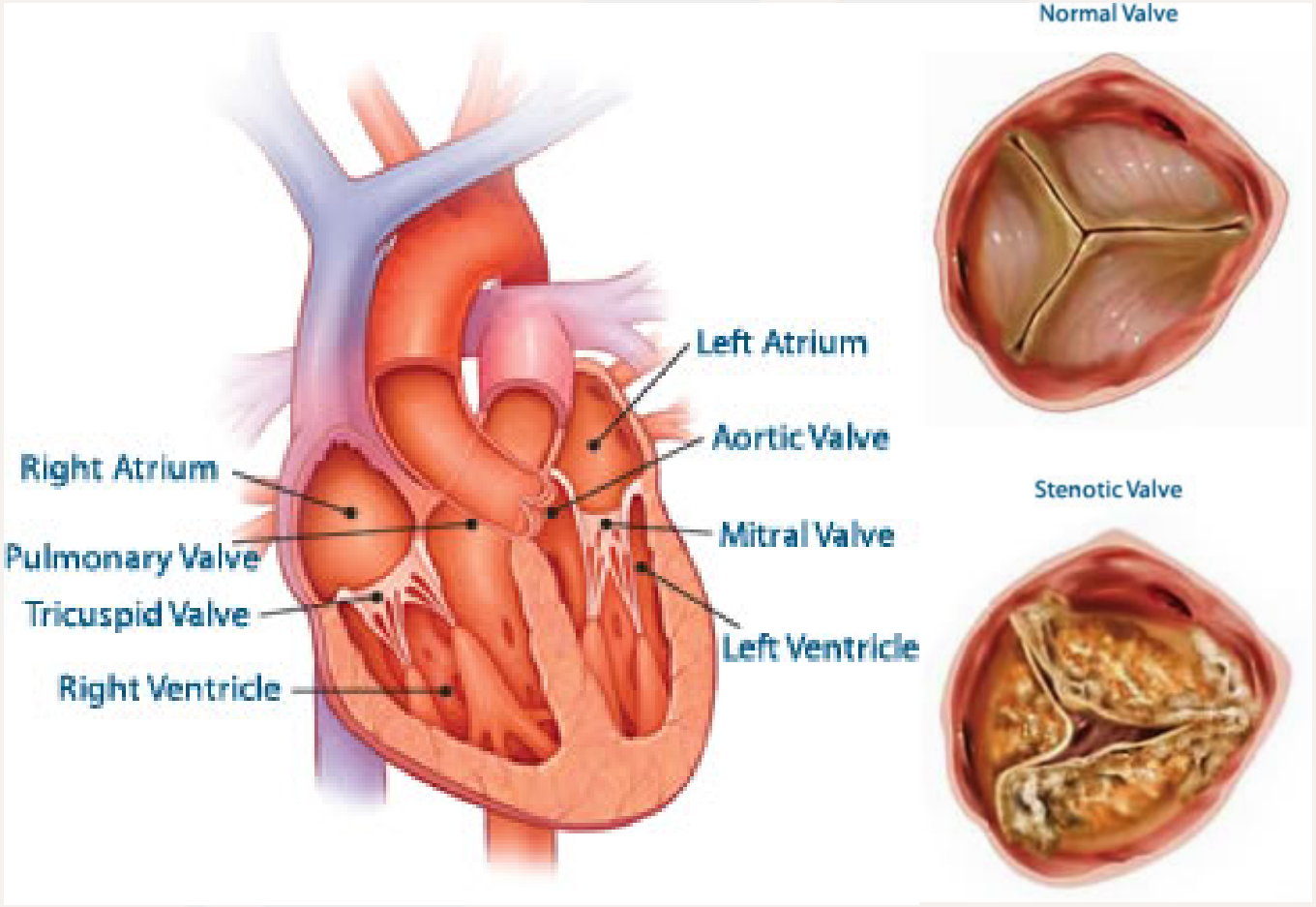
25/9/2016

In collaboration with: Research Institute for Longevity and Prevention of Geriatric Diseases

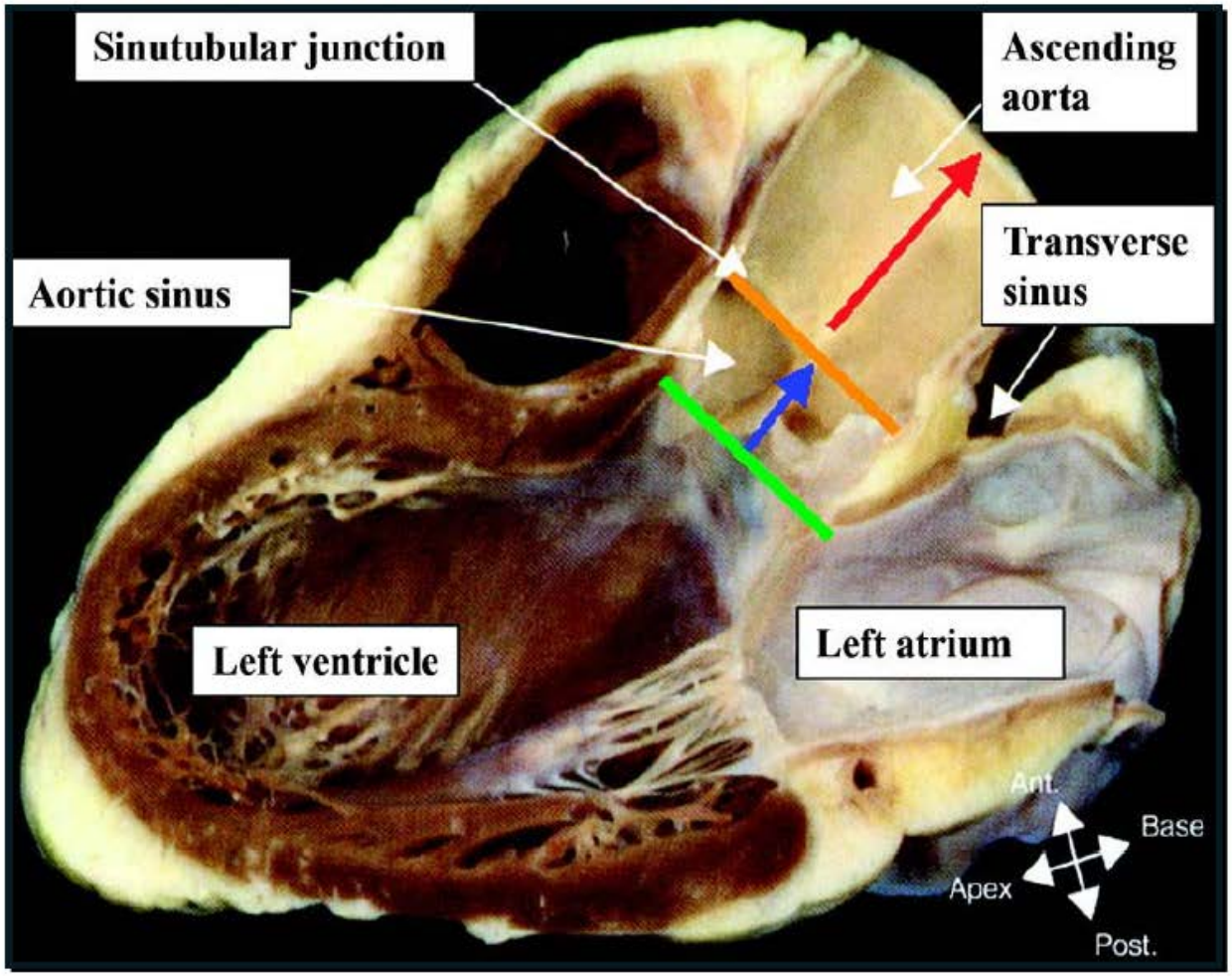
Adult Structural Heart Disease



Aortic Valve Anatomy



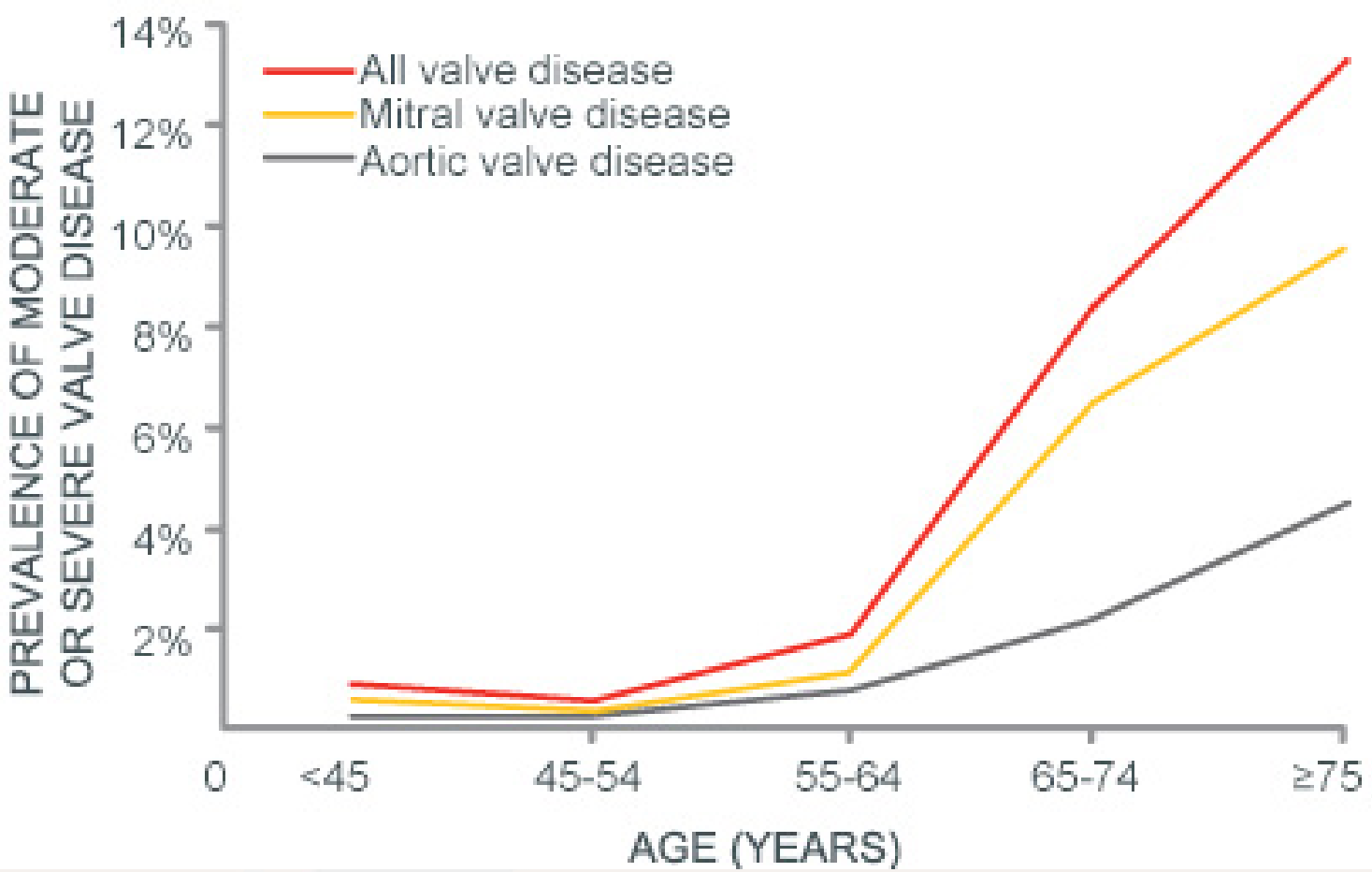
Aortic Root Anatomic Overview



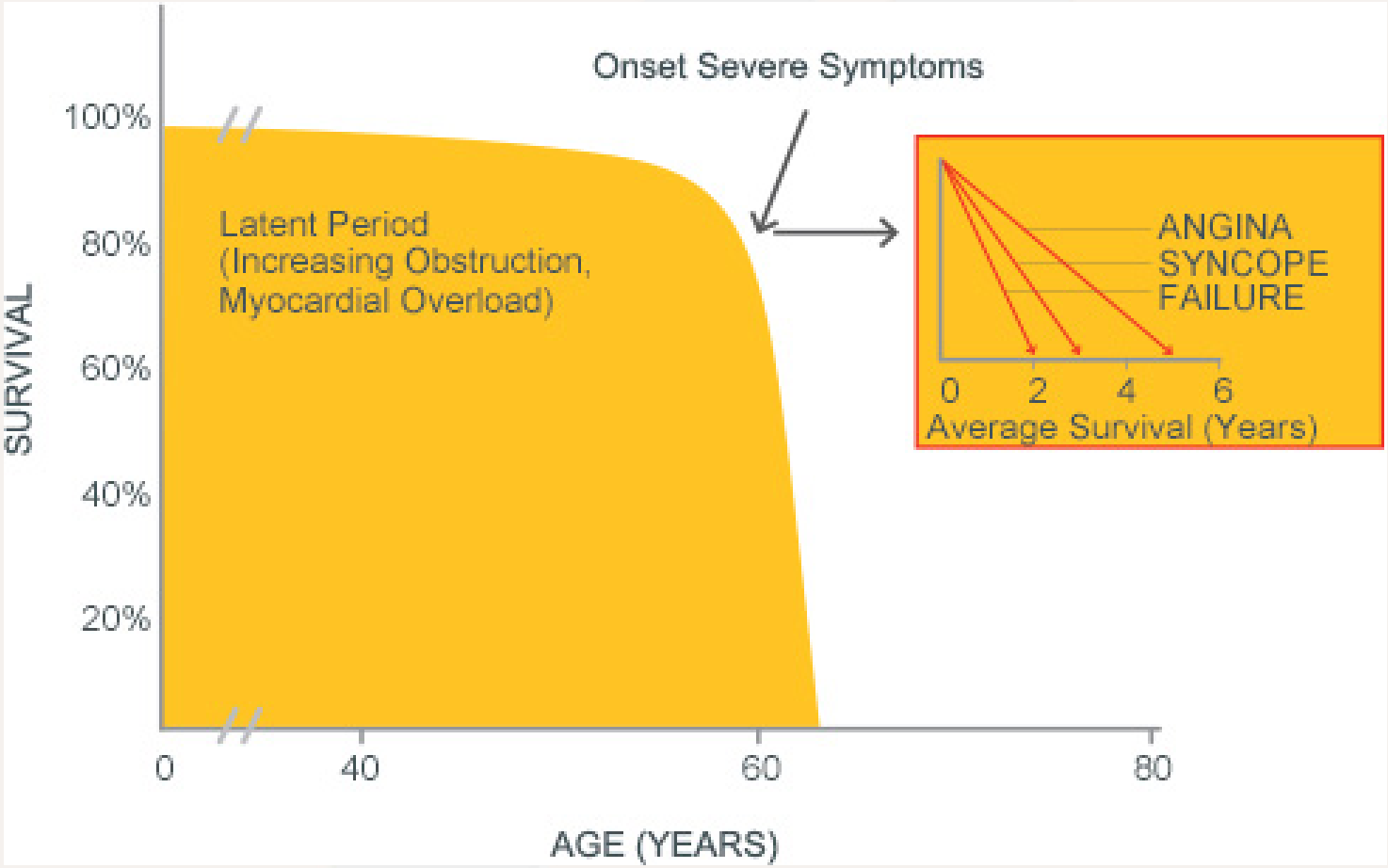
Causes of Aortic Stenosis

- Age related-Annular Calcification
- History of Rheumatic Fever
- Congenital Anomalies (Bicuspid Valve)
- History of Chest Radiation
- Autoimmune Diseases
- Congenital Hypercholesterolemia
- End-stage Renal Disease

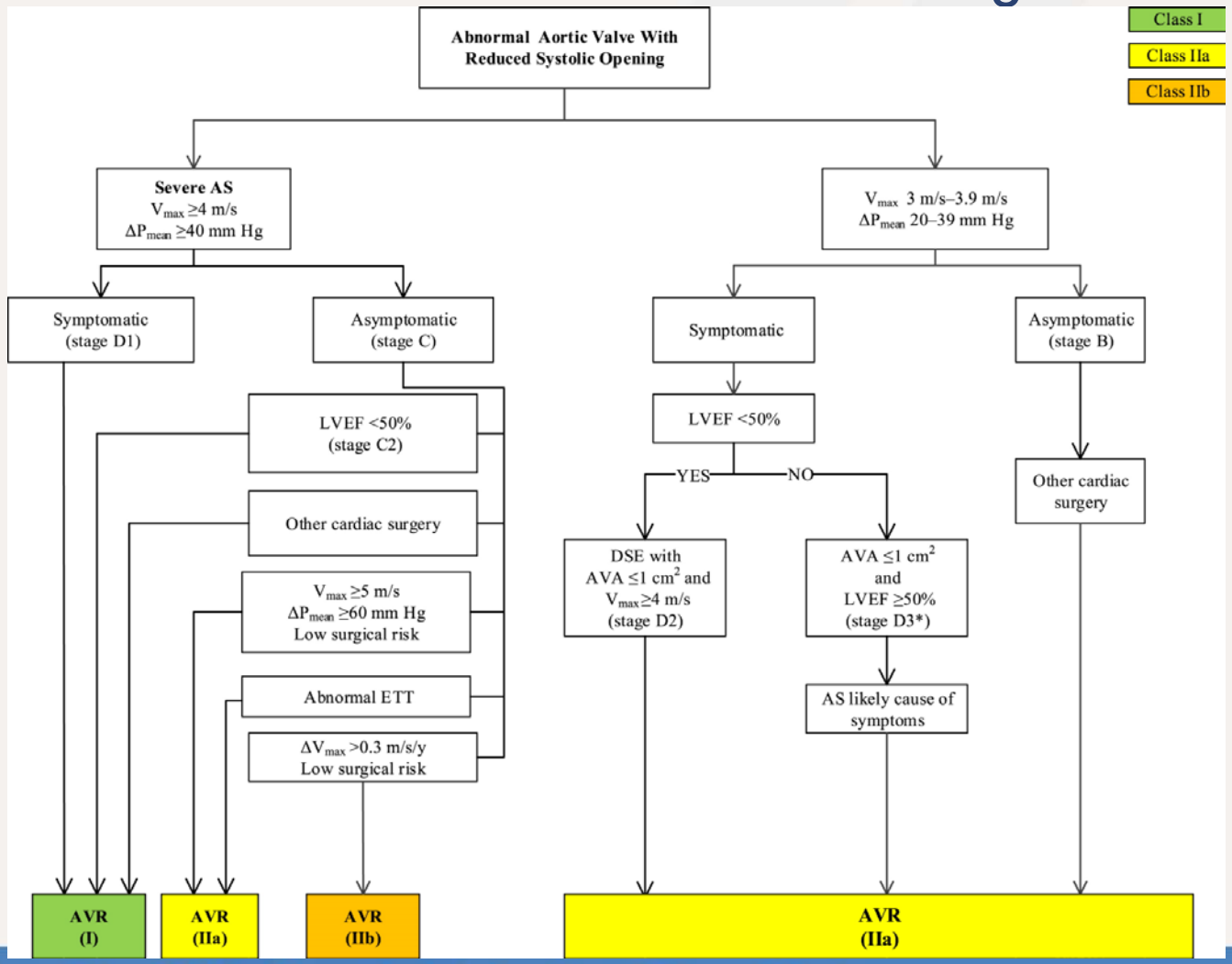
Incidence of Aortic and Mitral Valve Disease



Natural History and Symptoms of Aortic Stenosis



Aortic Stenosis Treatment Algorithm



Choice of Surgival or Transcatheter Treatment of AS

Recommendations	Class	LOE
Surgical AVR in low or intermediate risk patients	I	A
TAVI or high-risk Surgery should be performed under Heart Team Guidance	I	C
TAVI for extremely high-risk patients + post TAVI predicted survival > 12 months	I	B
TAVI alternative to SAVR for high-risk patients	IIa	B
BAV as a bridge to TAVI or SAVR	IIb	C
TAVI not recommended in patients with comorbidities which preclude benefit	III	B

PARTNER 1B-Extremely High Risk Pts

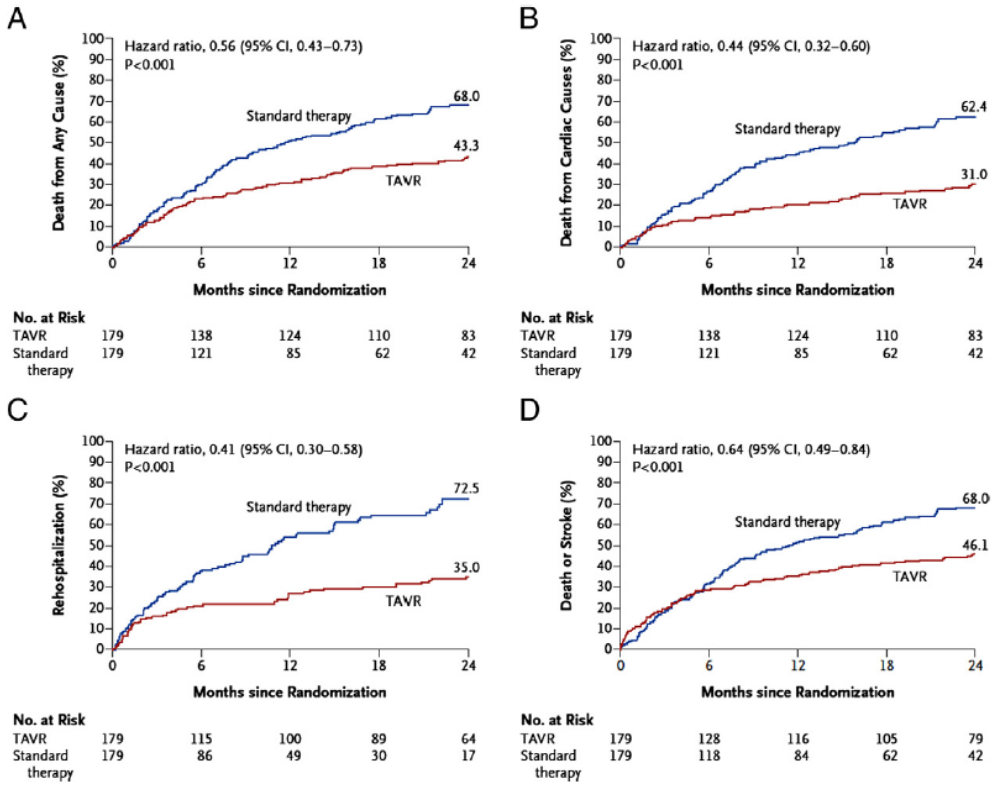
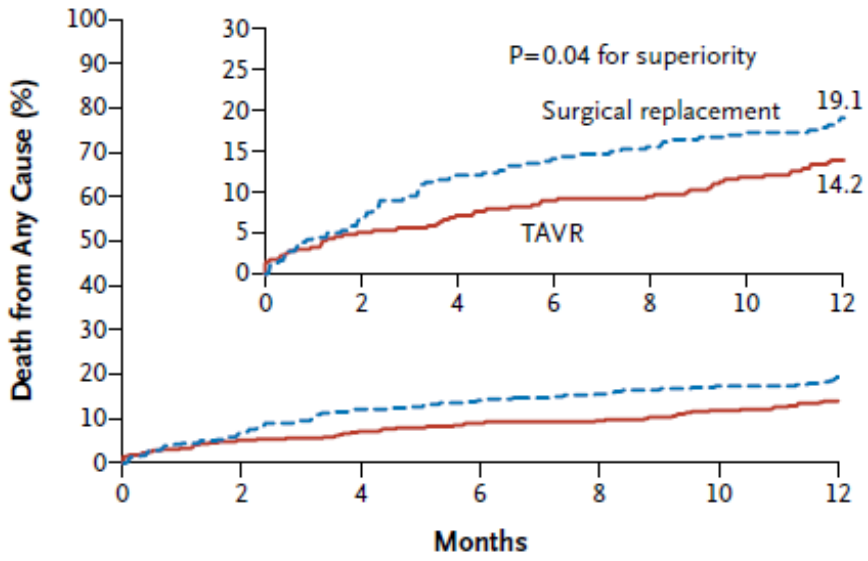


Figure 6 The PARTNER 1B Trial Compared Transarterial TAVR to Medical Management in Extremely High-Risk (Inoperable) Patients

Time to event analyses of death **(A)**, death due to cardiac causes **(B)**, rehospitalization **(C)**, and the combined endpoint of death or stroke **(D)**. Redrawn from Leon MR, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607, with information from Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortc-valve replacement for inoperable severe aortic stenosis. N Engl J Med 2012;366:1696–704, with permission from the Massachusetts Medical Society. PARTNER = Placement of AoRTic TraNscathetER Valve; TAVR = transcatheter aortic valve replacement.

US CoreValve Trial



No. at Risk				
TAVR	390	377	353	329
Surgical replacement	357	341	297	274

Figure 2. Kaplan–Meier Cumulative Frequency of Death from Any Cause.

The rate of death from any cause in the TAVR group was noninferior to that in the surgical group (P<0.001). A subsequent test for superiority at 1 year showed that TAVR was superior to surgical replacement (P=0.04). The inset shows the same data on an enlarged y axis.

TAVI Candidates

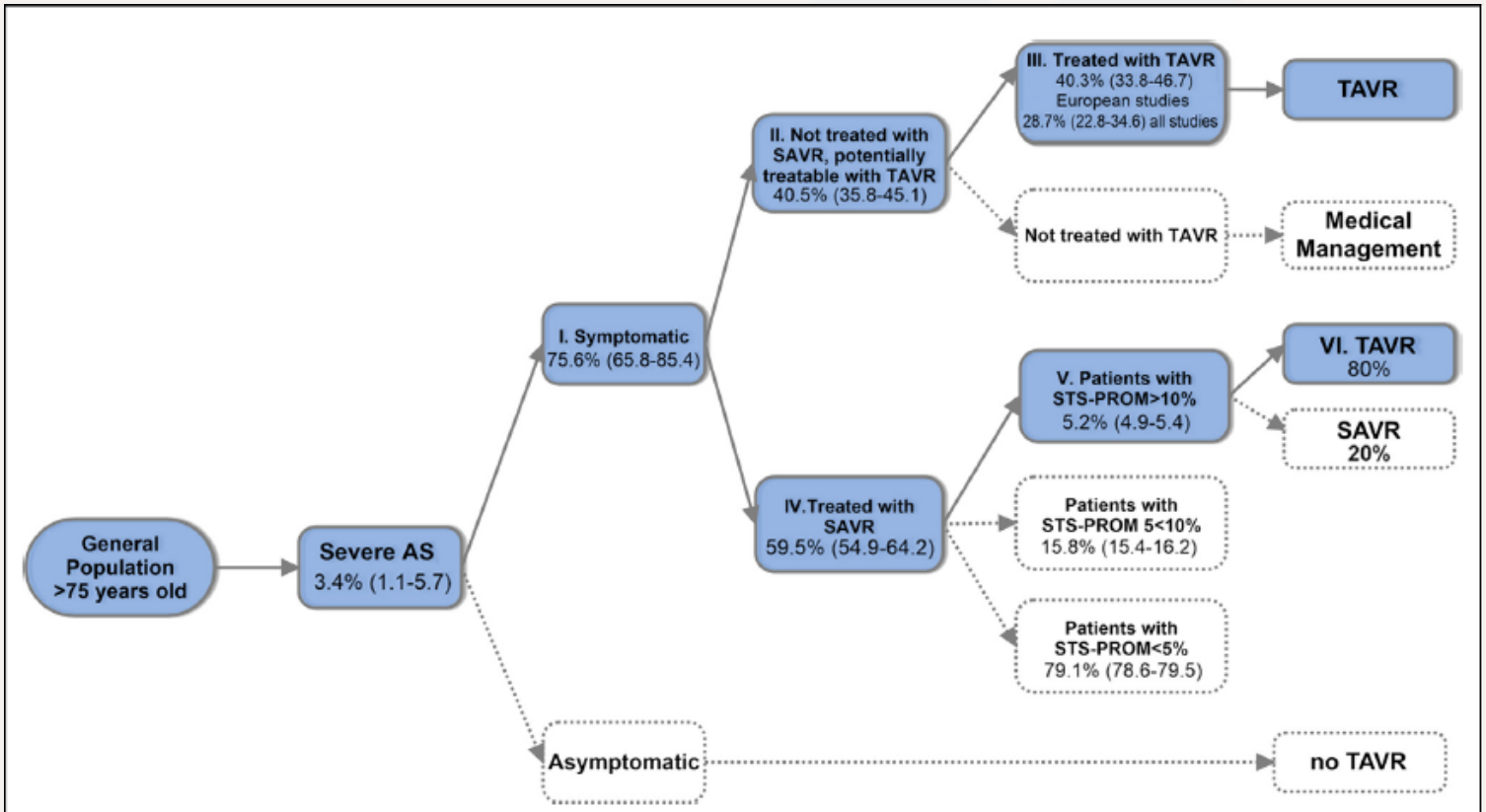


Figure 3 Model for the Estimation of TAVR Candidates Among the Elderly

AS = aortic stenosis; SAVR = surgical aortic valve replacement; STS-PROM = The Society of Thoracic Surgery Predicted Risk of Mortality; TAVR = transcatheter aortic valve replacement.

Worldwide TAVI Candidates

Total number of TAVR candidates	
Country	**Candidates (95%CI)**
Austria	3,250 (1,389-5,947)
Belgium	4,603 (1,964-8,409)
Czech Republic	3,336 (1,433-6,160)
Denmark	1,885 (805-3,448)
Finland	2,100 (898-3,856)
France	28,026 (11,992-51,266)
Germany	36,220 (15,388-66,610)
Greece	5,174 (2,258-9,493)
Italy	29,597 (12,596-54,471)
Ireland	1,100 (467-2,003)
Luxembourg	162 (69-298)
Norway	1,705 (731-3,103)
Poland	11,896 (5,162-22,051)
Portugal	4,670 (1,990-8,538)
Spain	19,436 (8,265-35,713)
Sweden	3,854 (1,633-7,083)
Switzerland	3,020 (1,280-5,554)
The Netherlands	5,631 (2,379-10,379)
The United Kingdom	23,838 (10,554-43,461)
Total 19 European countries	**189,836 (80,281-347,372)***
The United States	91,227 (38,885-165,875)
Canada	10,958 (4,688-19,995)
Total North America	**102,558 (43,612-187,002)***

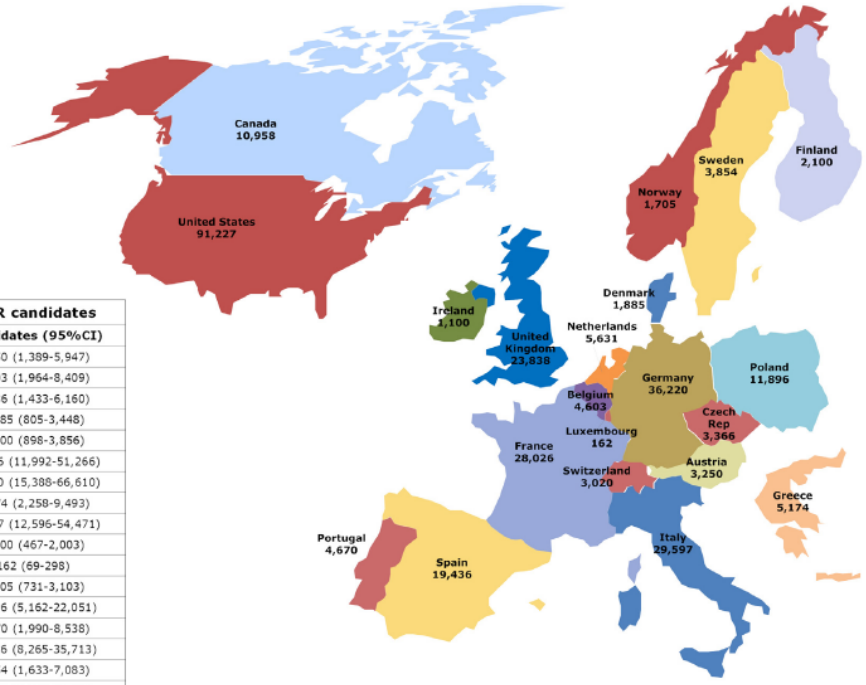
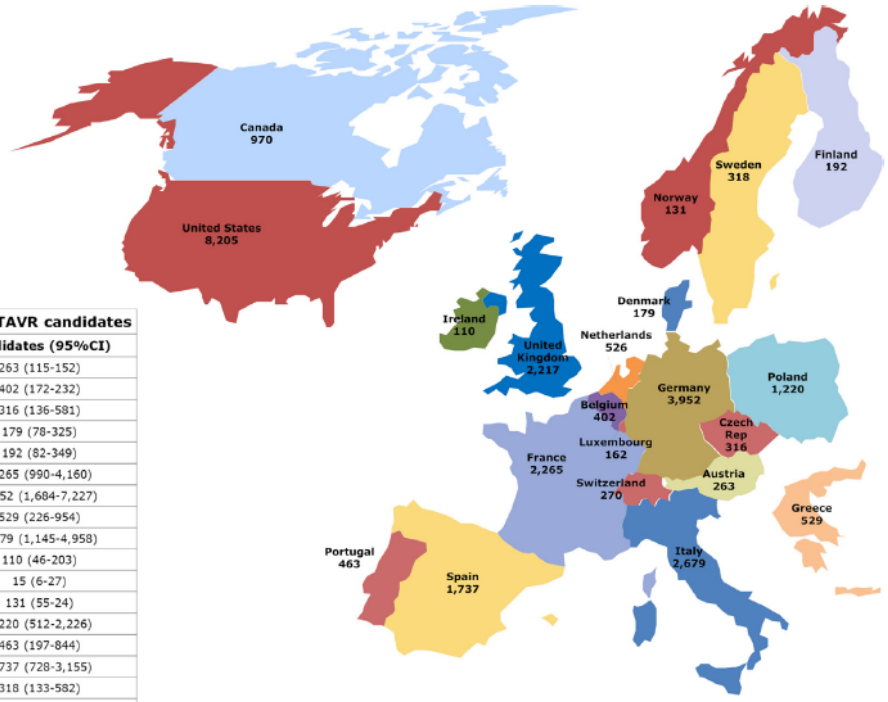


Figure 5 Total of TAVR Candidates in Different Countries Under Current Treatment Indications

*Due to the simulation process, the totals are not exactly the same as the sum of the individual countries. CI = confidence interval; TAVR = transcatheter aortic valve replacement.

Wordwide TAVI Incidence Candidates



Annual number of new TAVR candidates	
Country	**Candidates (95%CI)**
Austria	263 (115-152)
Belgium	402 (172-232)
Czech Republic	316 (136-581)
Denmark	179 (78-325)
Finland	192 (82-349)
France	2,265 (990-4,160)
Germany	3,952 (1,684-7,227)
Greece	529 (226-954)
Italy	2,679 (1,145-4,958)
Ireland	110 (46-203)
Luxembourg	15 (6-27)
Norway	131 (55-24)
Poland	1,220 (512-2,226)
Portugal	463 (197-844)
Spain	1,737 (728-3,155)
Sweden	318 (133-582)
Switzerland	270 (115-495)
The Netherlands	526 (224-965)
The United Kingdom	2,217 (896-3,904)
Total 19 European countries	**17,712 (7,590-32,691)***
The United States	8,205 (3,470-15,139)
Canada	970 (408-1,777)
Total North America	**9,189 (3,898-16,682)***

Figure 6 Annual Number of TAVR Candidates in Different Countries Under Current Treatment Indications

*Due to the simulation process, the totals are not exactly the same as the sum of the individual countries. CI = confidence interval; TAVR = transcatheter aortic valve replacement.

Edwards-Sapien XT Valve

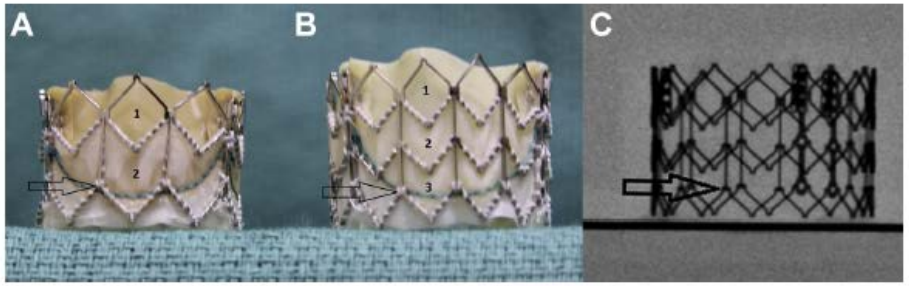


Figure 2. Sapien XT Valve Features

(A) Size 26 Sapien XT made of 2 rows of metal cells (1 and 2). **(B)** Size 29 Sapien XT made of 3 rows of metal cells (1, 2, and 3). **(C)** Sapien XT size 29 under fluoroscopy. **Arrows** point to the level of the nadir of the leaflets. Row 1 is not covered by the fabric across all sizes.

Figure 1 Profile of the Edwards SAPIEN Transcatheter Heart Valve

The Edwards SAPIEN transcatheter aortic prosthesis is mounted on a balloon-expandable stainless steel stent that is placed in the subcoronary position. The trileaflet bovine pericardial prosthesis is attached to the stent and treated with an anticalcification treatment. The stent has a polyethylene terephthalate fabric skirt that decreases perivalvular leaks.

CoreValve

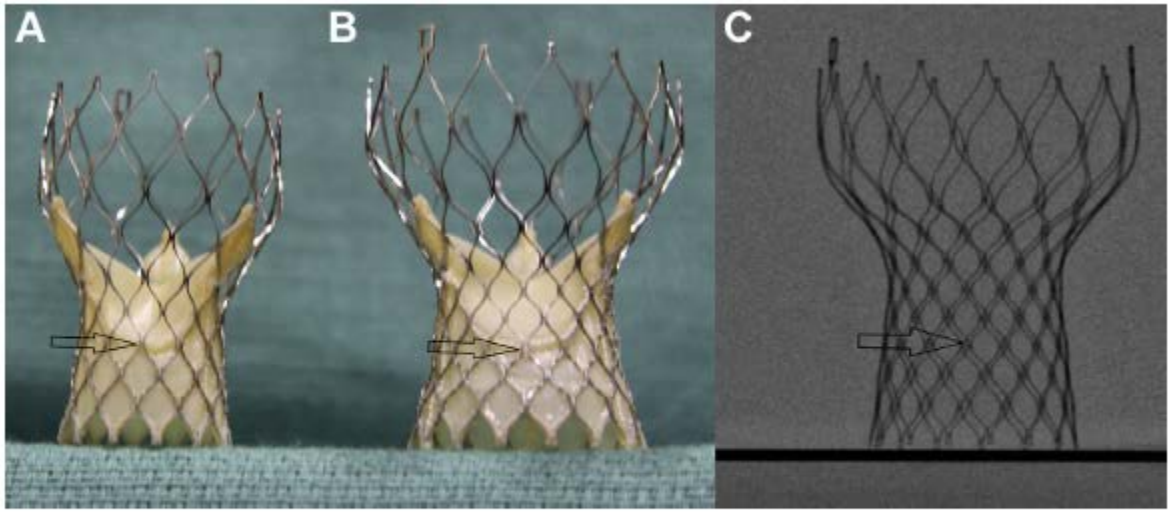


Figure 3. Evolute and CoreValve Features

(A) Evolute size 23; **(B)** CoreValve size 29; and **(C)** CoreValve size 29 under fluoroscopy. The **arrows** point to the third node, which corresponds to the nadir of the pericardial leaflets.

Emerging Valves

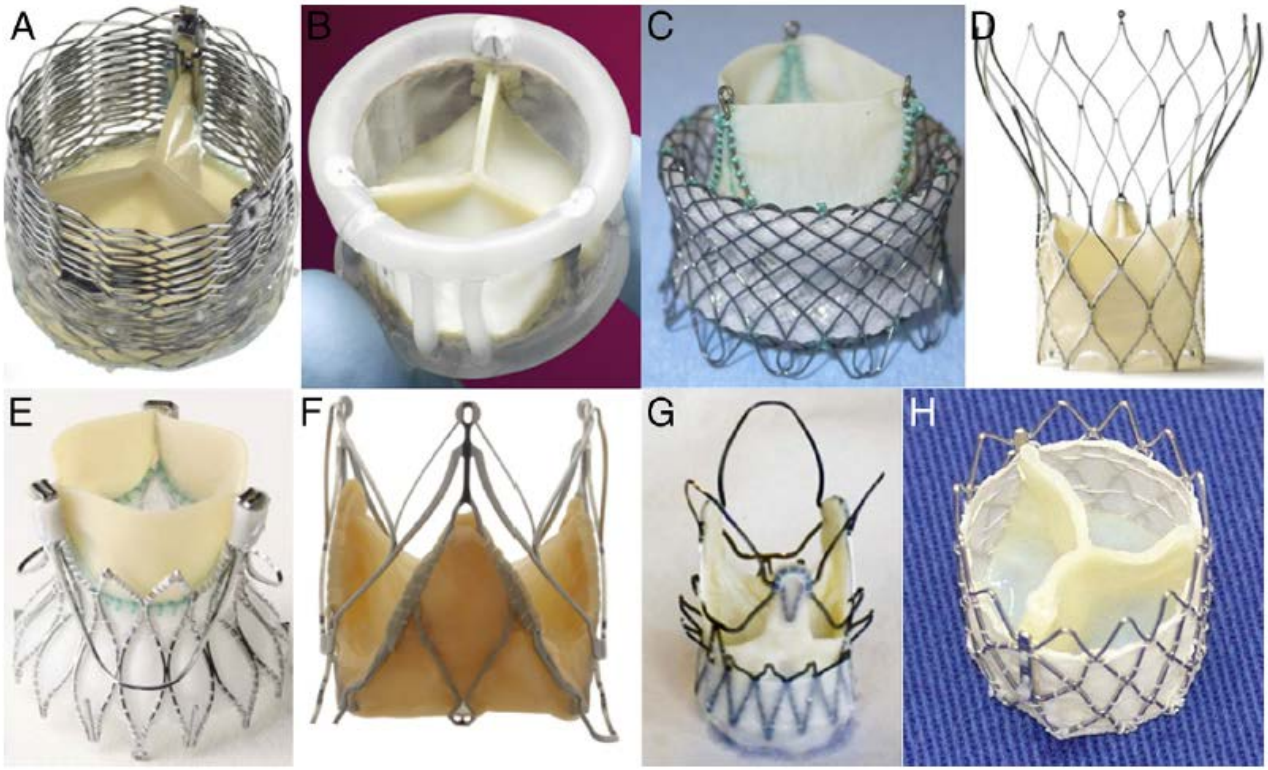
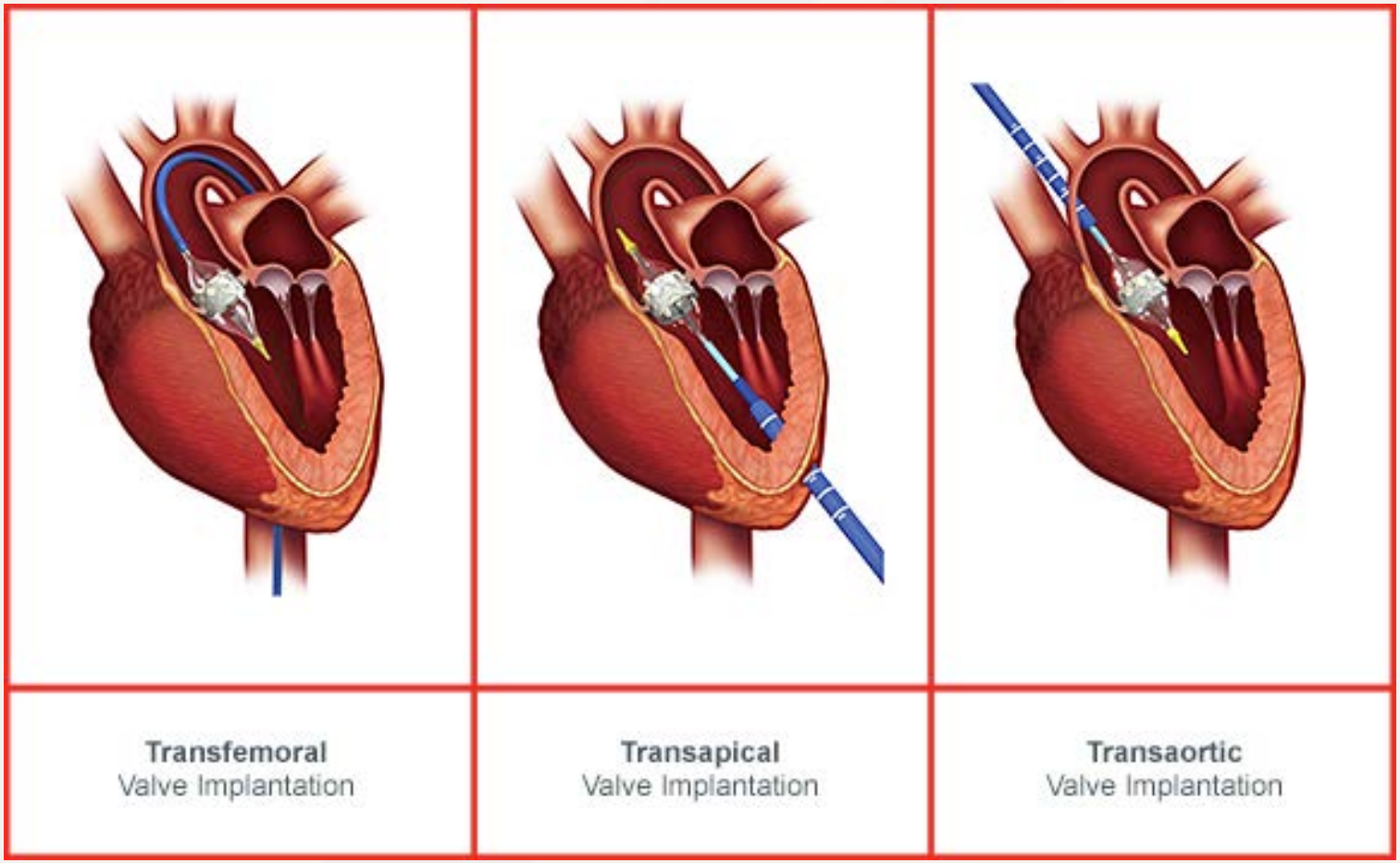


Figure 4 **Valves Undergoing Early Evaluation**

(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), **(B)** Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), **(C)** HLT (Bracco Inc., Princeton, New Jersey), **(D)** Portico (St. Jude Medical Inc., St. Paul, Minnesota), **(E)** Engager (Medtronic Inc., Minneapolis Minnesota), **(F)** JenaClip (JenaValve Inc., Munich, Germany), **(G)** Acurate valve (Symetis Inc., Ecublens, Switzerland), and **(H)** Inovare (Braile Biomedica Inc., São José do Rio Preto, Brazil) valves.

TAVI Route


Transfemoral
Valve Implantation
Transapical
Valve Implantation
Transaortic
Valve Implantation

Preclose technique

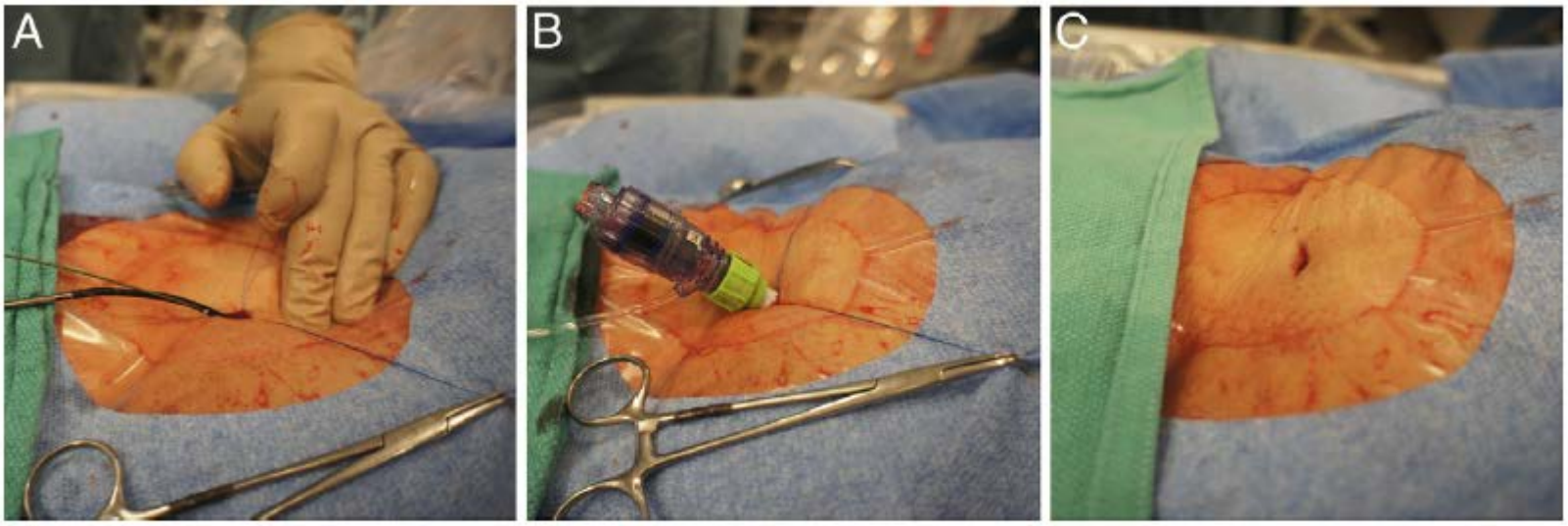


Figure 5 **Percutaneous Access and Closure**

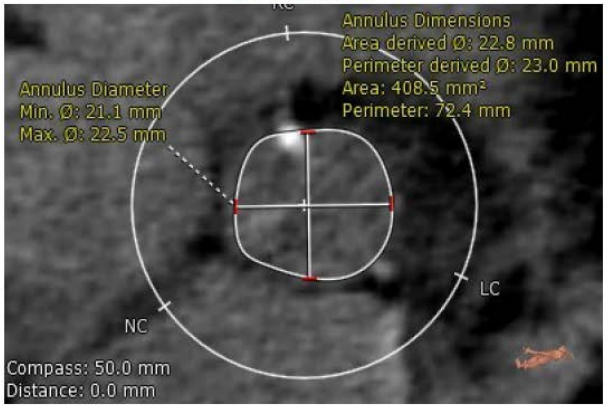
(A) The femoral artery is punctured and a guidewire placed within the artery. Percutaneous sutures are placed using a "pre-closure" device. **(B)** The large vascular access sheath is inserted. **(C)** Following sheath removal the sutures are tightened.

TAVI Screening

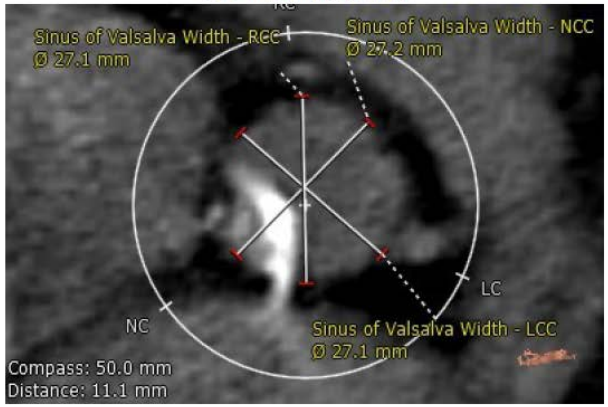
- Euroscore > 20%
- STS Score > 10%
- Echocardiogram
- Coronary Angiography
- CT Angiography (Aorta & Peripherals)

CT Angiography (LVOT-Annulus-SOV-Aorta)

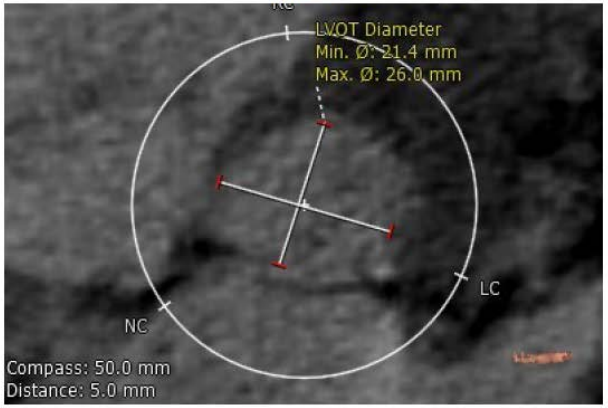
ANNULUS



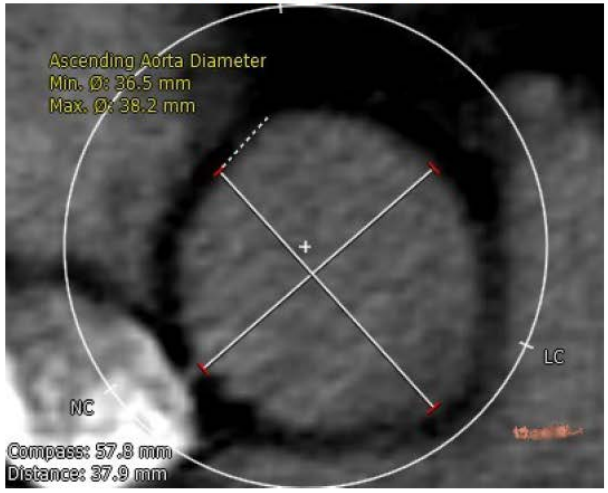
SOV DIAMETER



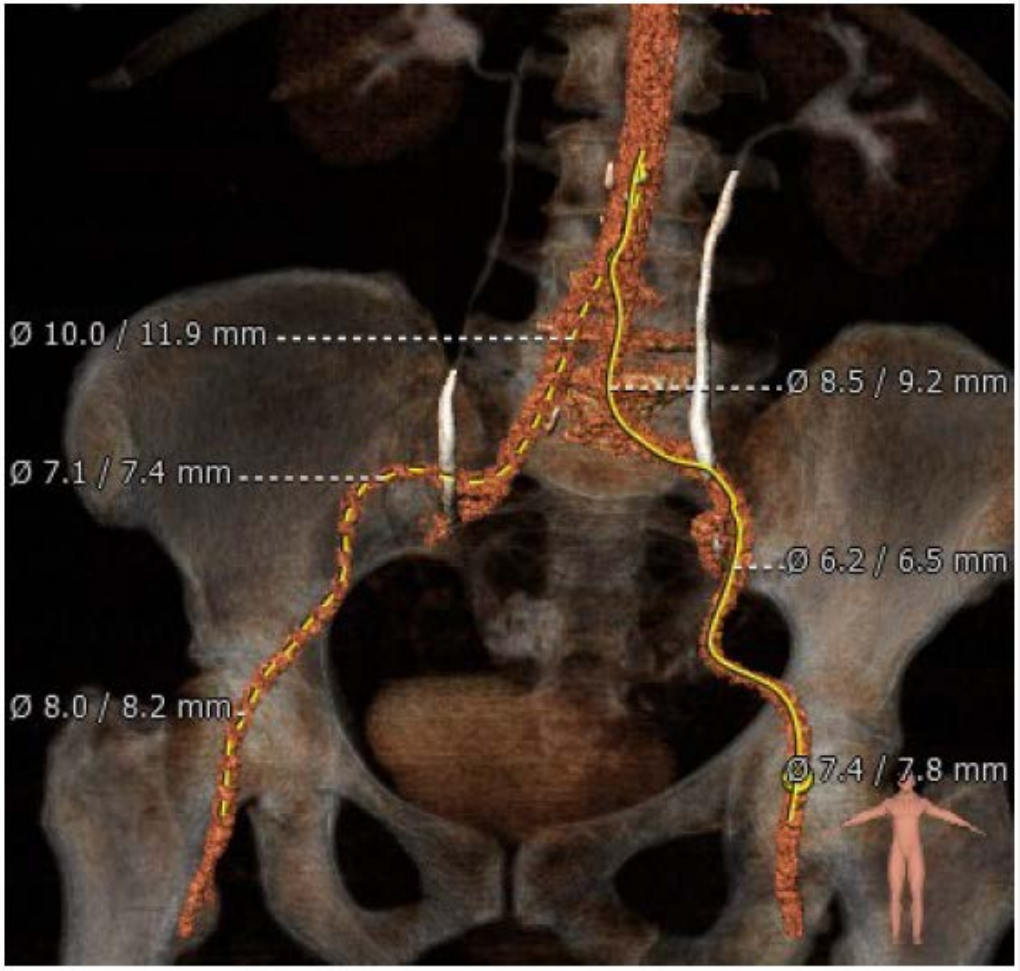
LVOT



ASCENDING AORTA



CT Angiography (Peripherals)



Screening Report

Max Ascending Aorta Diameter (mm): 38.2

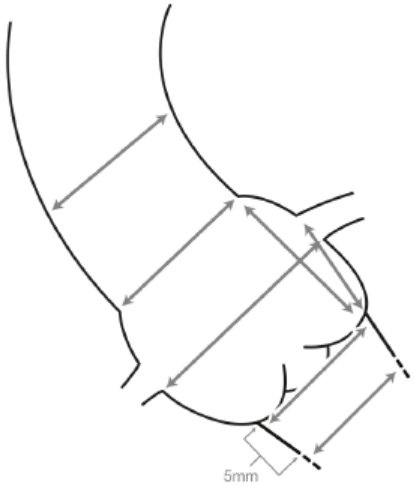
Sinotubular Junction Diameter (mm): 29.6 (Min) x 30.0 (Max)

ANNULUS

Diameter (mm): 21.1 (Min) x 22.5 (Max), 21.8 mm (Mean)

Perimeter (mm): 72.4, 23.0 (Derived Diameter)

Area: 408.5 mm², 22.8 mm (Derived Diameter)



Sinus of Valsalva Diameter (mm): 27.1 (LCC), 27.1 (RCC), 27.2 (NCC)

Sinus of Valsalva Height (mm): 17.7 (LCC), 20.0 (RCC), 19.3 (NCC)

Coronary Ostia Height (mm): 10.4 (Left), 13.2 (Right)

LVOT Diameter (mm): 21.4 (Min) x 26.0 (Max)

RIGHT

CIA Min Diameter (mm): 10.0 x 11.9

EIA Min Diameter (mm): 7.1 x 7.4

Femoral Min Diameter (mm): 8.0 x 8.2

LEFT

CIA Min Diameter (mm): 8.5 x 9.2

EIA Min Diameter (mm): 6.2 x 6.5

Femoral Min Diameter (mm): 7.4 x 7.8

RIGHT

Subclavian Min Diameter (mm): x

Annular Angulation:

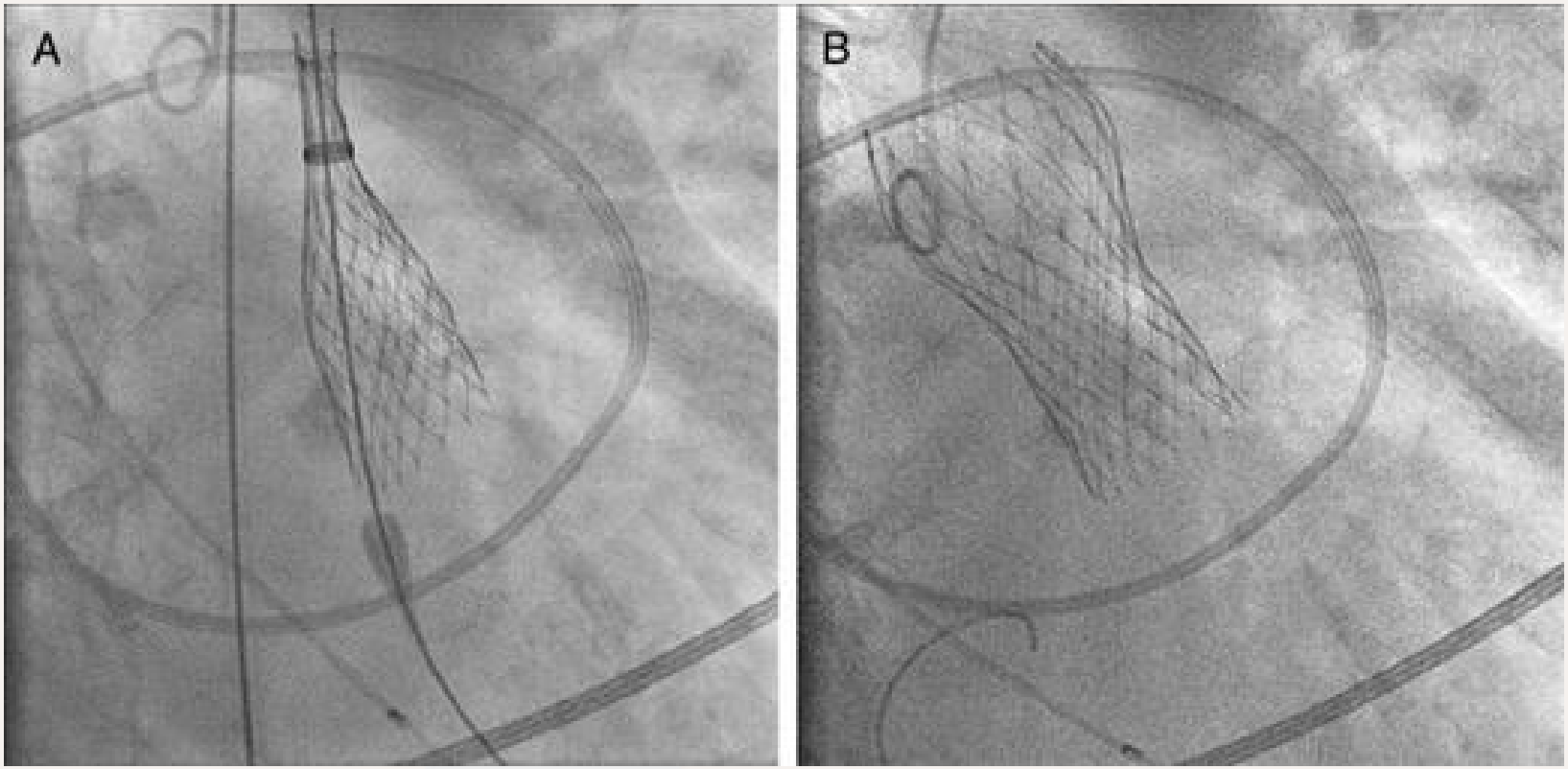
LEFT

Subclavian Min Diameter (mm): x

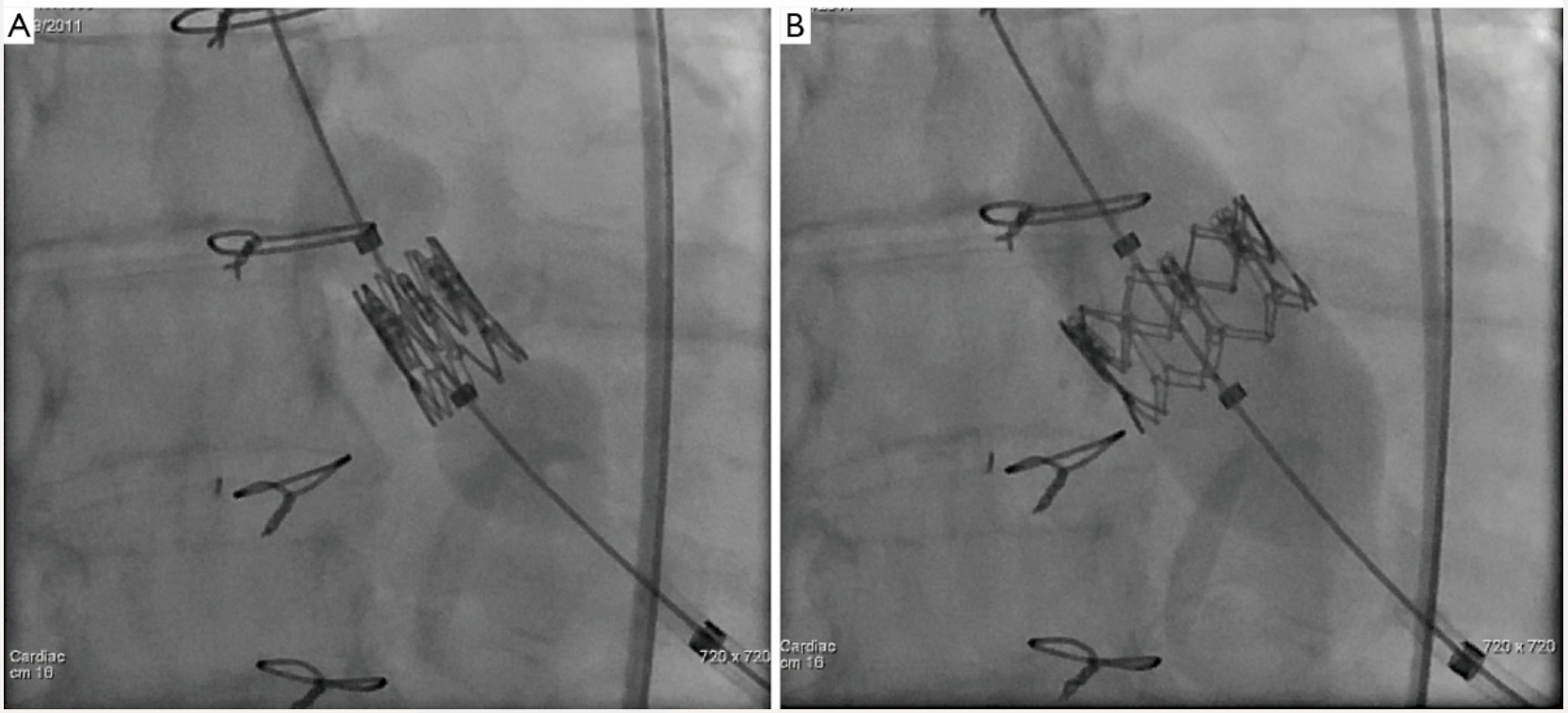
Please review imaged for direct aortic evaluation.

Calcium: Mild ☑ Moderate ☐ Severe ☐

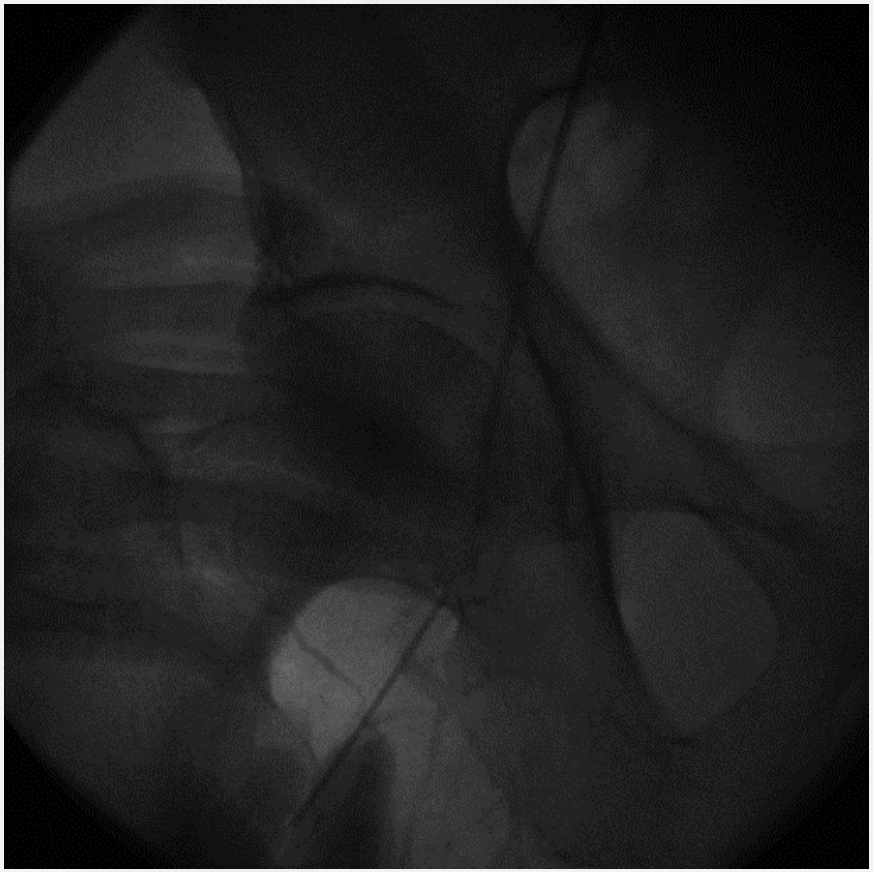
Fluroscopic Image of Valve Release (CoreValve)



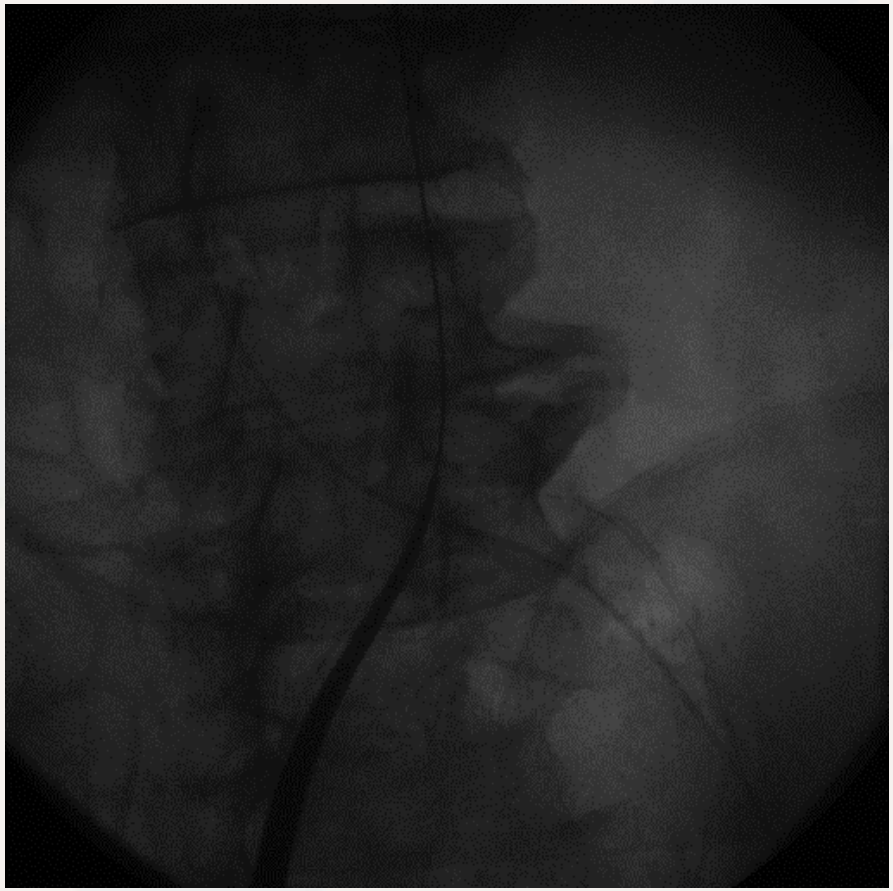
Fluroscopic Image of Valve Release (Edwards-Sapien)



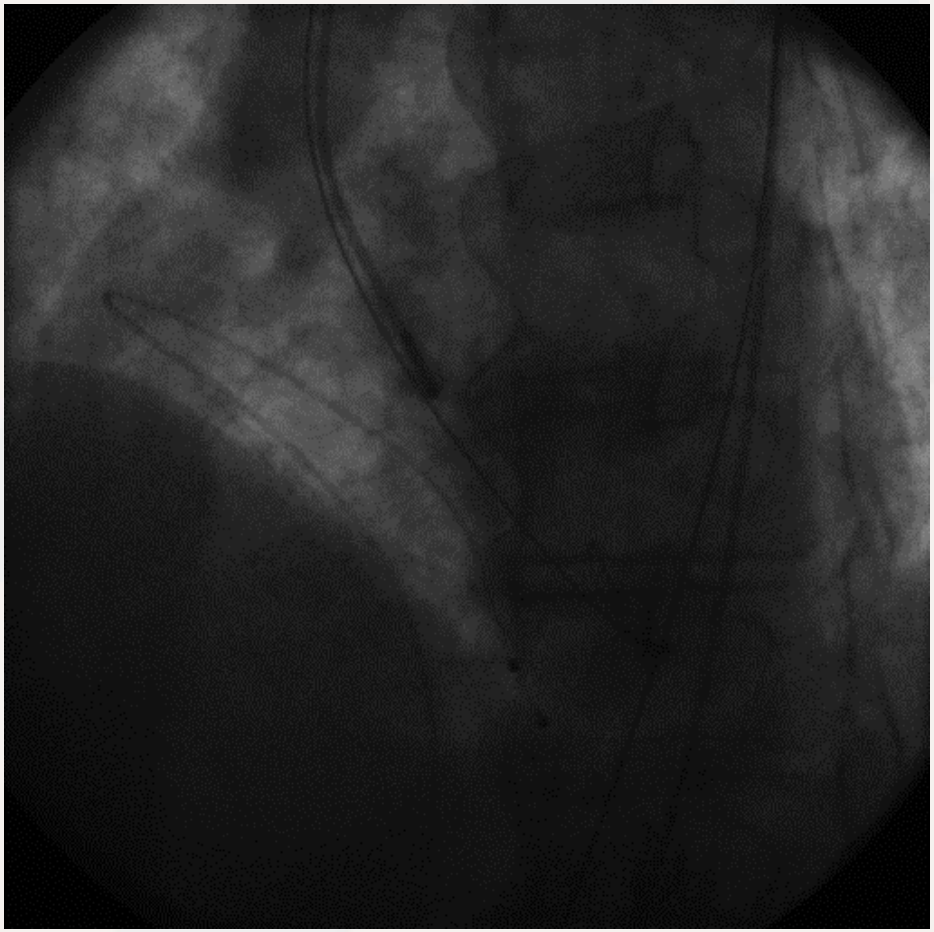
Femoral Arterial Puncture



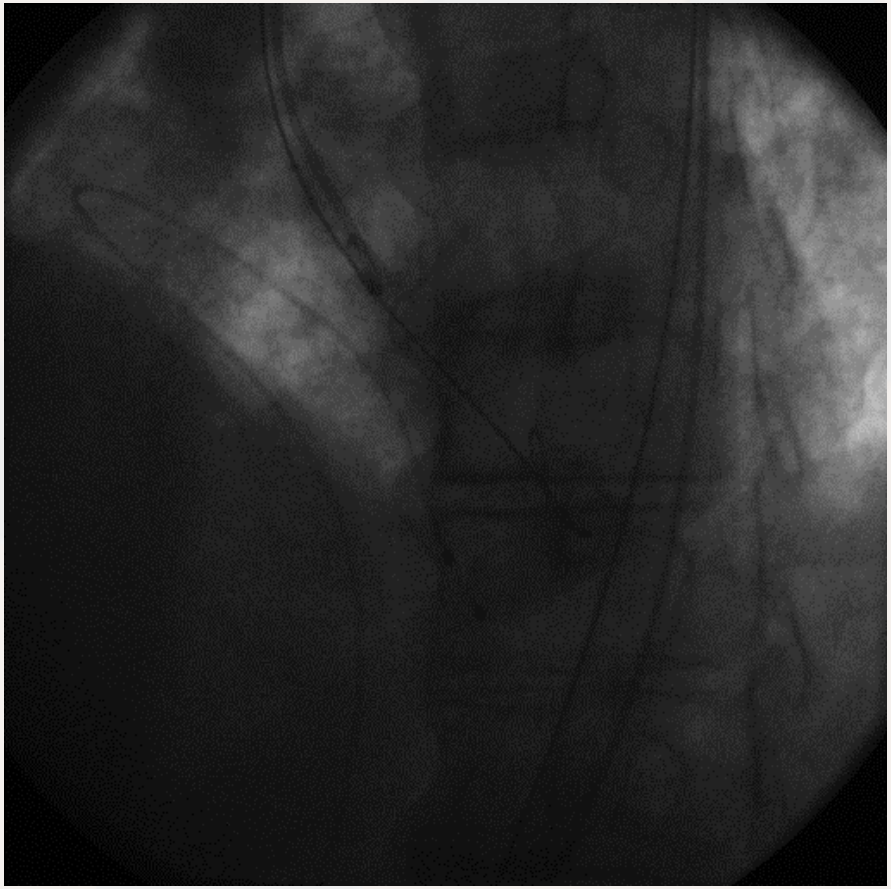
Sheath Insertion (14-22 F)



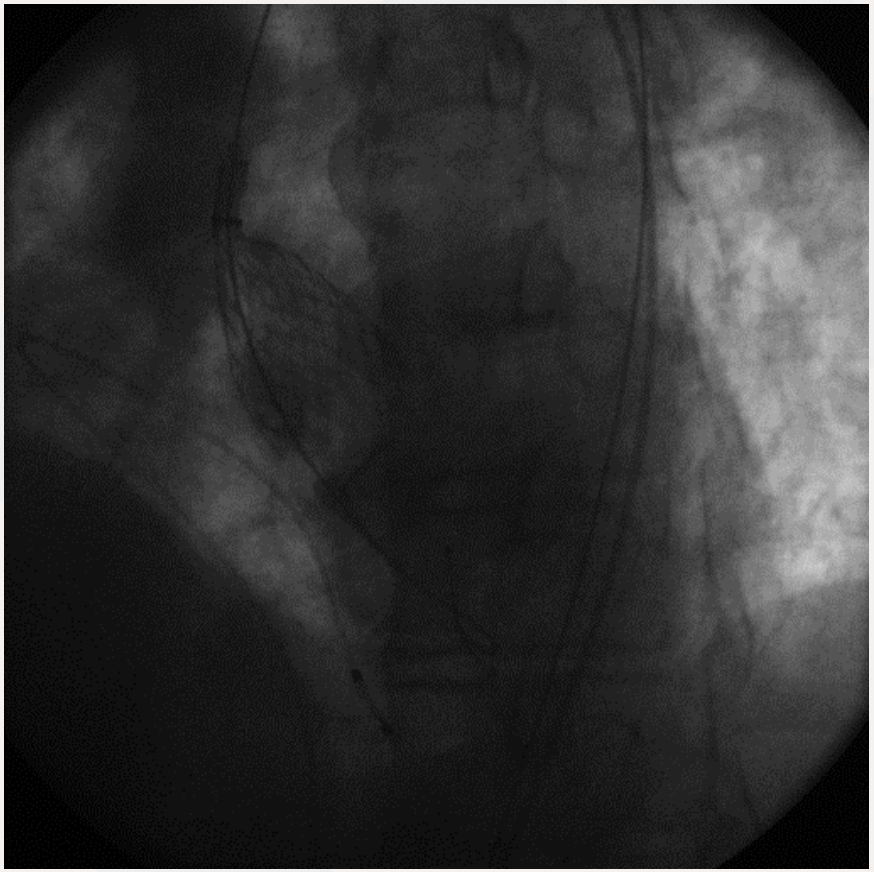
Baseline Aortography



Aortic Valvuloplasty

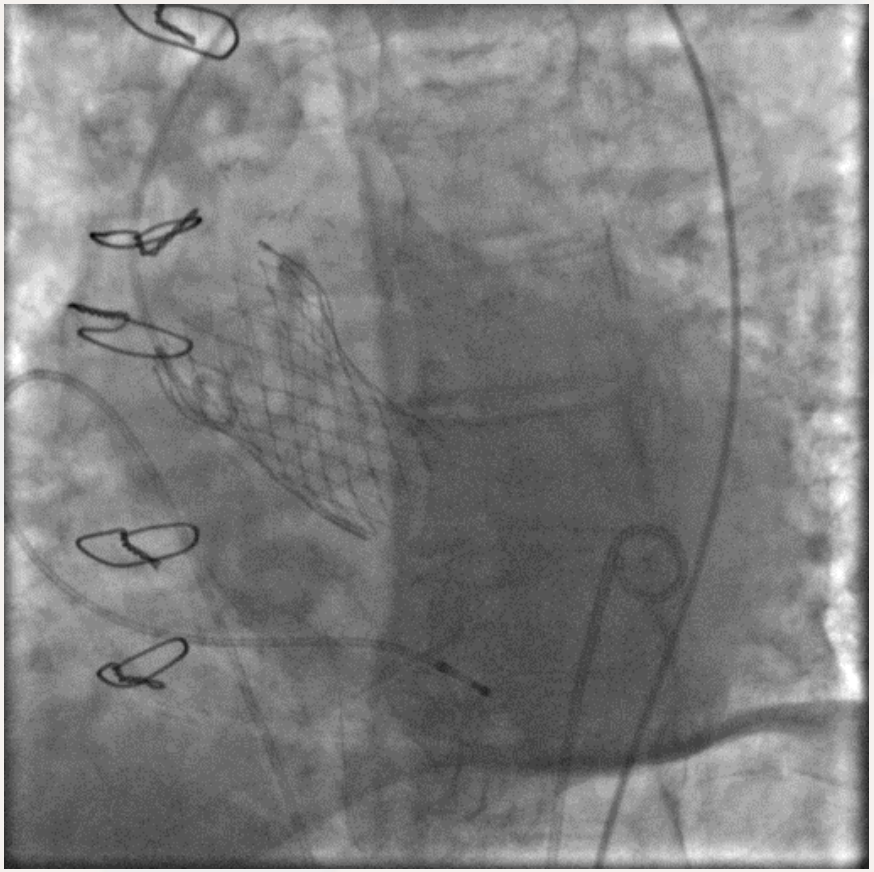


Final Valve Release (CoreValve)



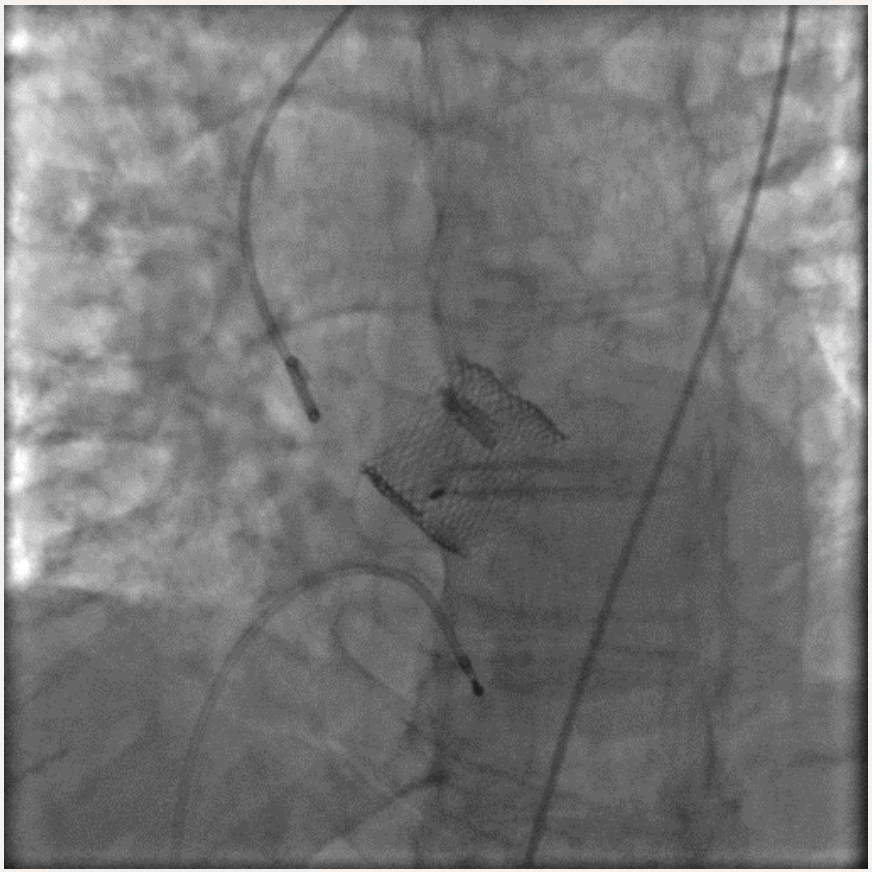
TAVI through Aortic Stent Graft

Final Evolut R Placement



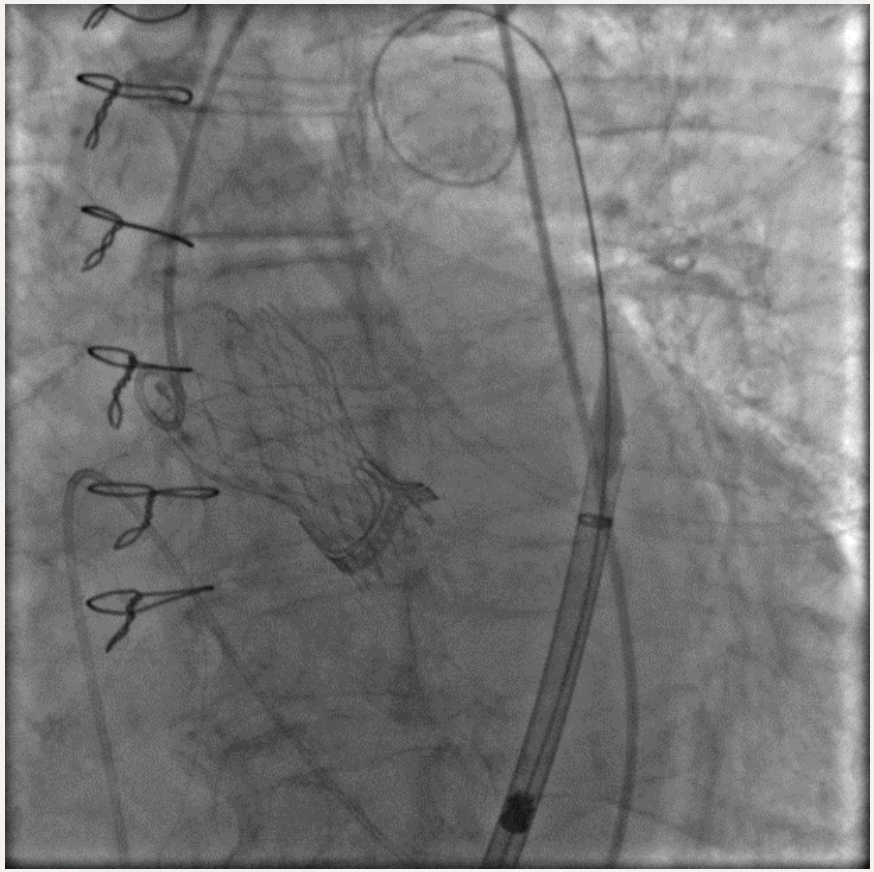
AS - Lotus Valve - Aortography

Final Placement of Lotus Valve



Valve in Valve CE Magna 21

Valve in Valve Evolut R



TAVI Vascular Arterial Complications

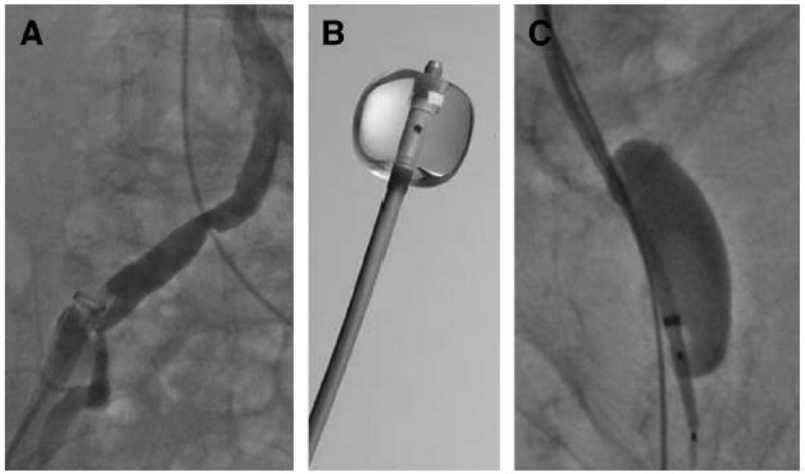


Figure 1. Vascular Injury

(A) Dissection of the right iliac artery. **(B)** Occlusion balloon (Occlusion Catheter, Boston Scientific, Natick, Massachusetts). **(C)** Occlusion balloon (Coda Occlusion Balloon Catheter, Cook Medical, Inc., Bloomington, Indiana) inflated in the left iliac artery.

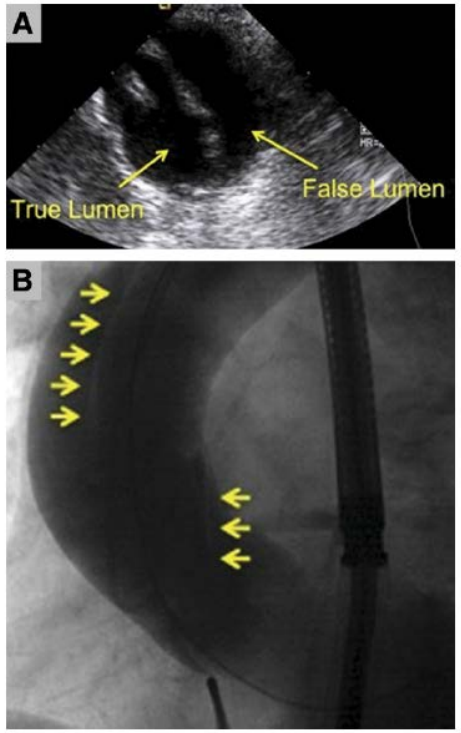


Figure 2. Dissection of the Ascending Aorta

(A) Cross-sectional transesophageal echocardiographic and **(B)** angiographic images (**yellow arrows** delineate the spiral dissection).

TAVI Mitral Valve Injury

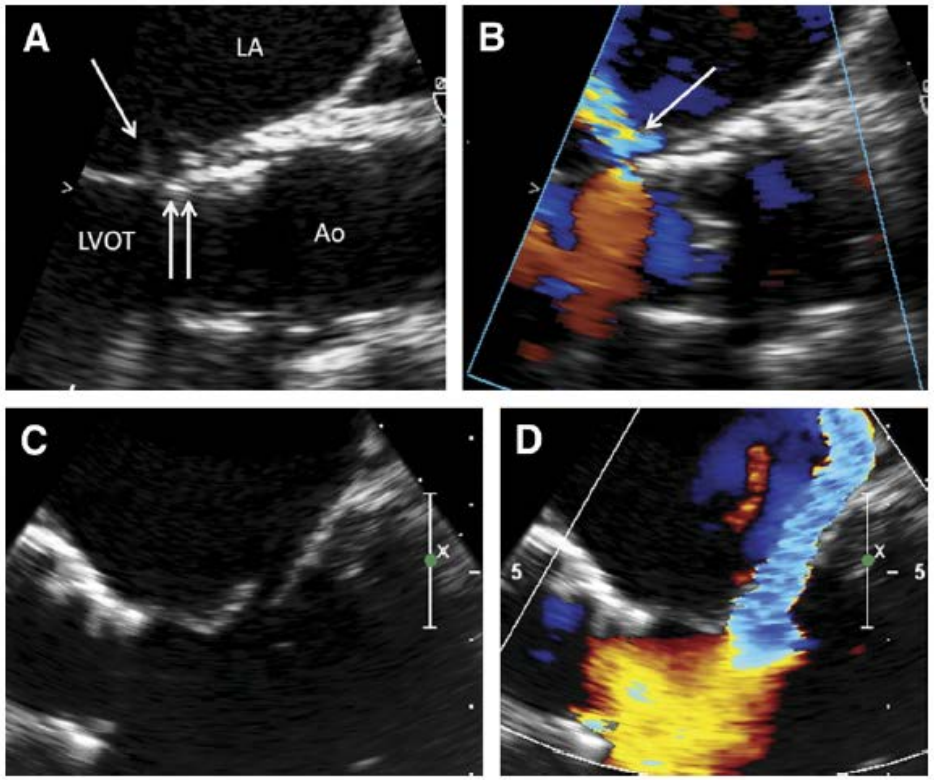


Figure 8. Delayed Mitral Valve Injury

(A) The stent **(double arrow)** is in contact with the anterior mitral leaflet. Prosthetic valve endocarditis 1 year after implantation associated with perforation of the mitral leaflet at the point of contact **(single arrow)**. **(B)** Ensuing severe mitral regurgitation. **(C)** In a second patient, prolapse of the anterior mitral leaflet secondary to chordeal rupture created **(D)** severe mitral regurgitation several months after the procedure. Ao = aorta; LA = left atrium; LVOT = left ventricular outflow tract.

TAVI Paravalvular Regurgitation

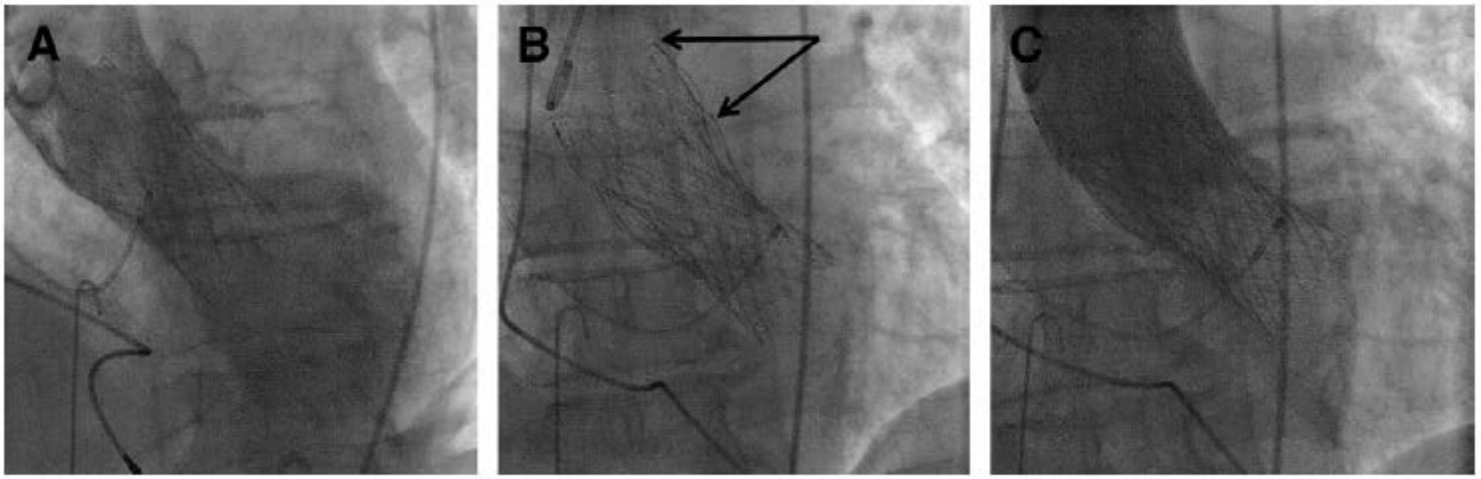


Figure 9. Paravalvular Regurgitation

(A) Self-expanding valve implanted too low, resulting in severe paravalvular regurgitation. **(B)** A second prosthesis was implanted in the correct position (**arrows** indicate the distal edge of both prostheses). **(C)** Mild residual paravalvular leak.

TAVI Annulus Rupture

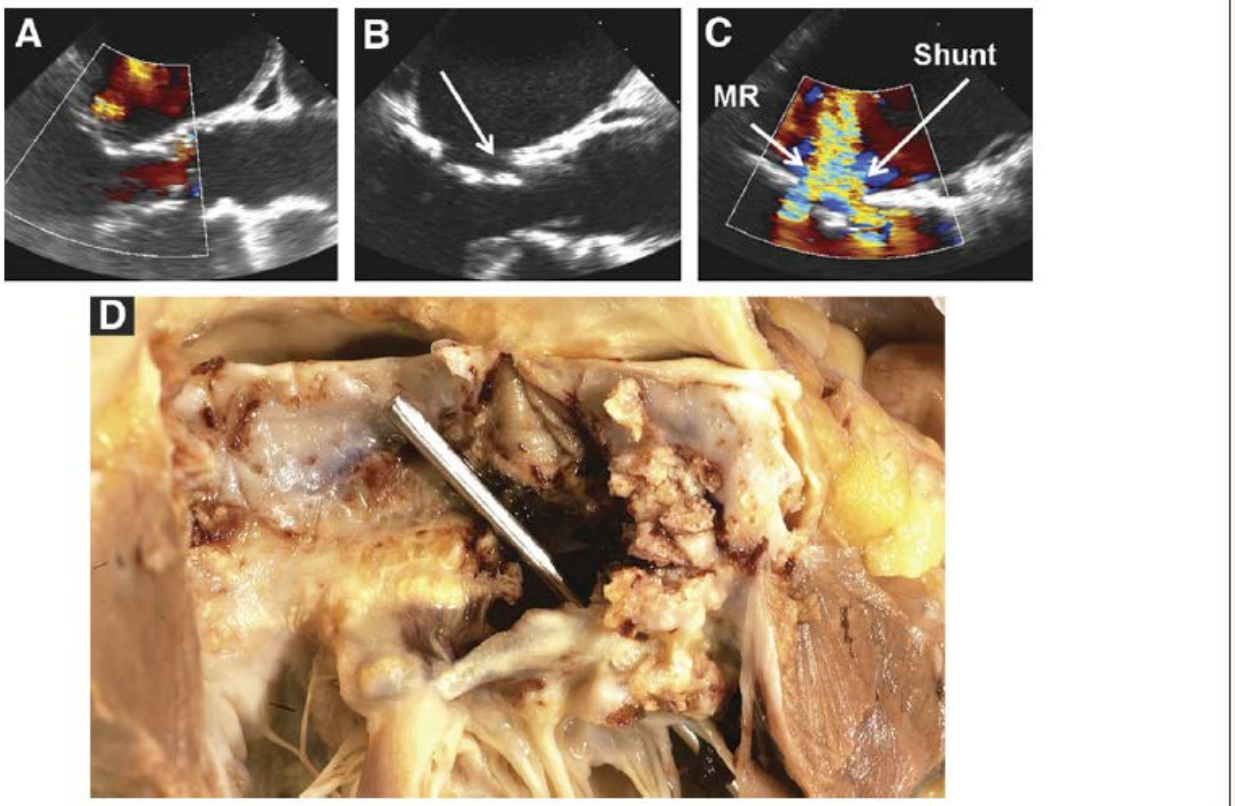


Figure 11. Annulus Rupture

(A) Pre-implantation significant mitral regurgitation (MR) and severe calcification of the aortic annulus and subvalvular tissues. **(B and C)** After valve implantation, a tear **(arrows)** is visible at the ventricular edge of the stent, connecting the left ventricular outflow tract and left atrium, with large left ventricular to left atrial shunt. **(D)** Autopsy proven tear of the anterior mitral curtain.

TAVI Coronary Obstruction

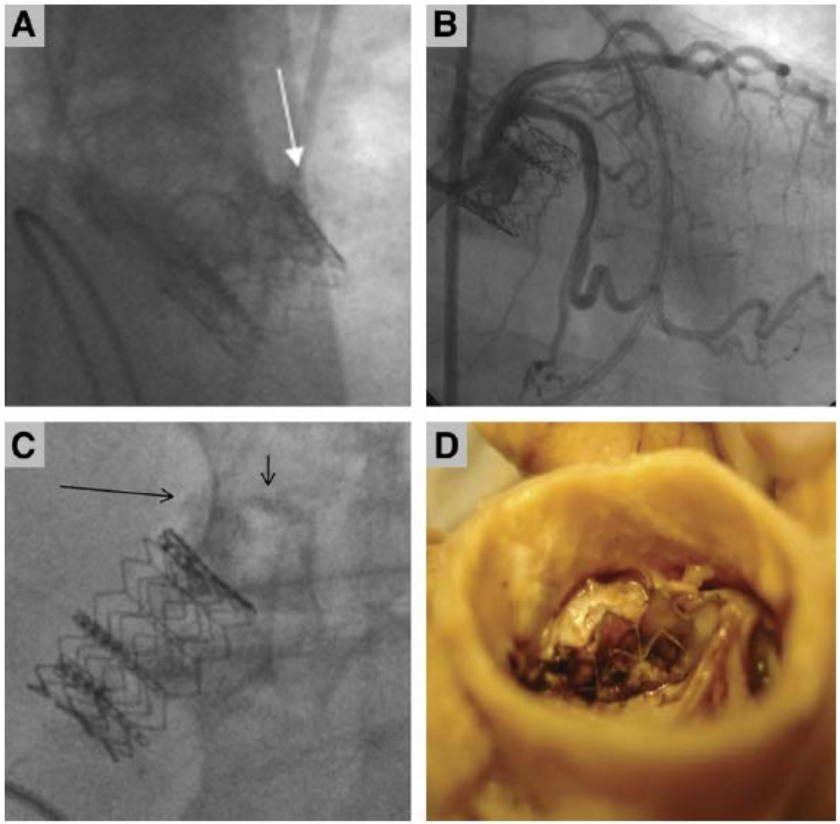
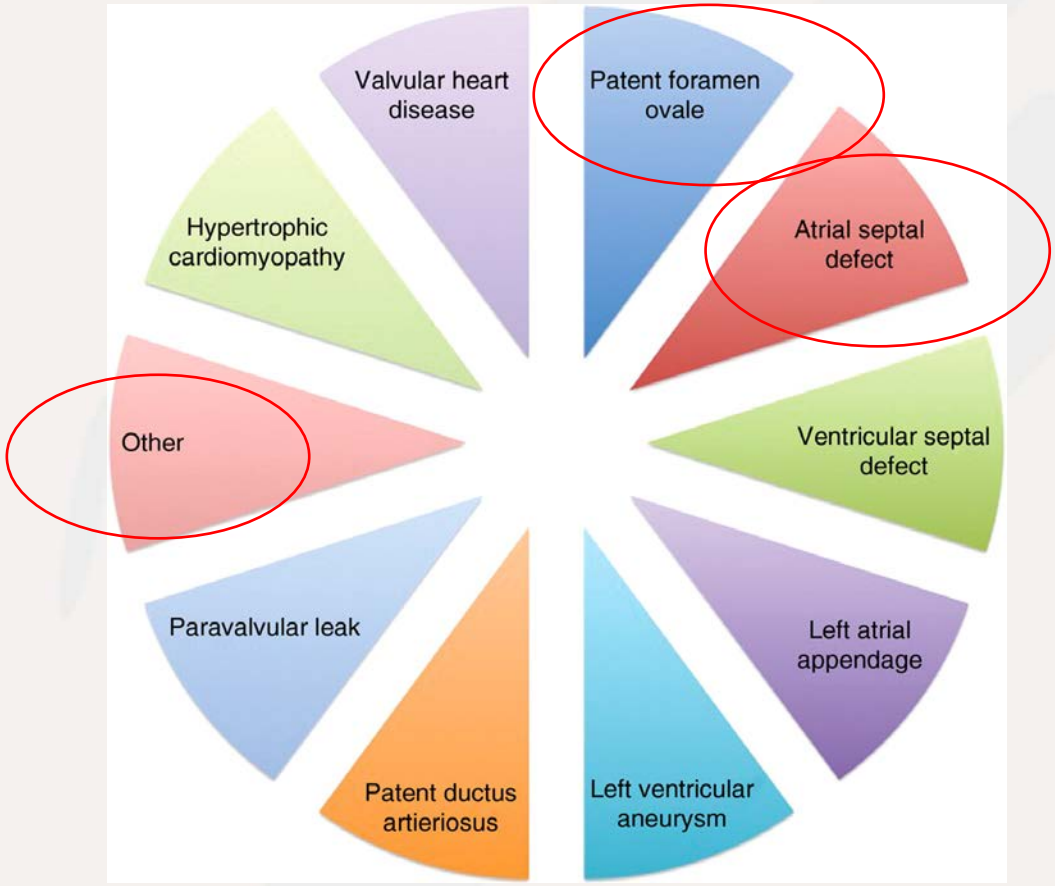


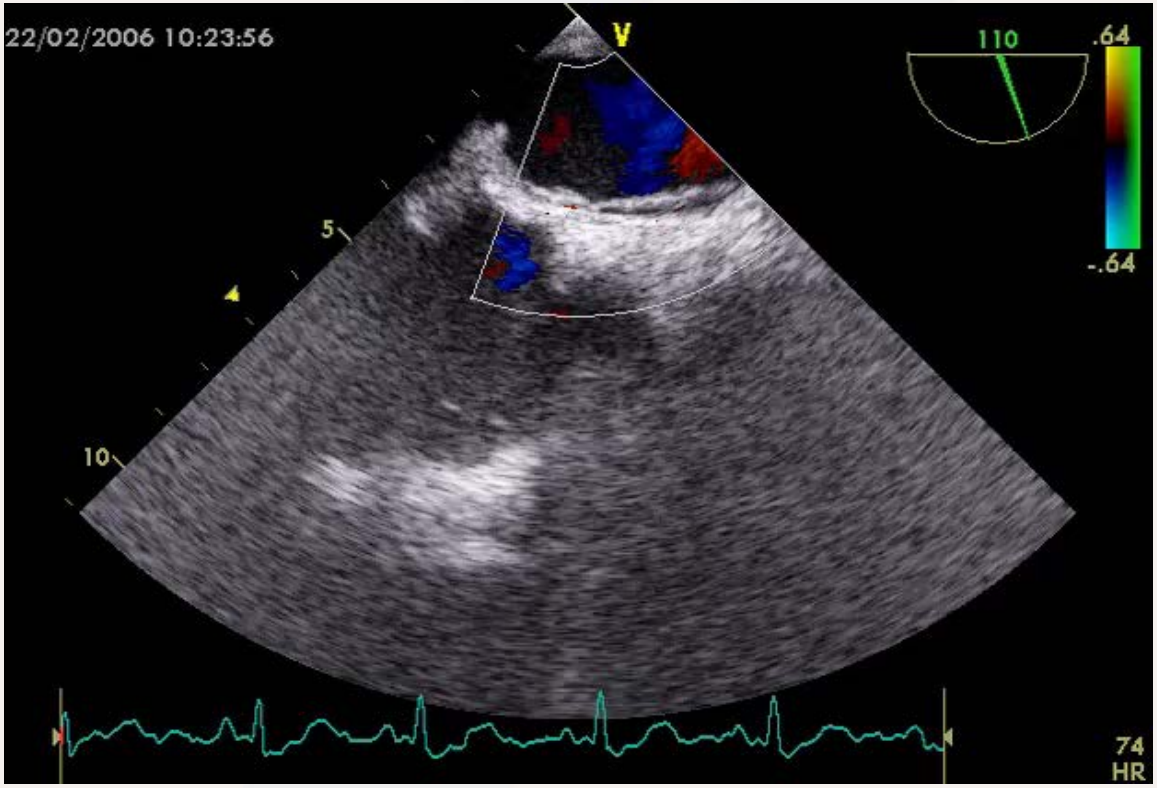
Figure 7. Left Main Obstruction

(A) Left main coronary artery occlusion resulting from a bulky leaflet displaced over the ostium. **(B)** Successful percutaneous intervention restored left coronary flow. **(C)** In a second patient, calcifications from the native aortic leaflet and left main **(arrows)** are approximated after valve implantation. **(D)** At autopsy, the leaflet (not the stent itself) seemed to obstruct the ostium.

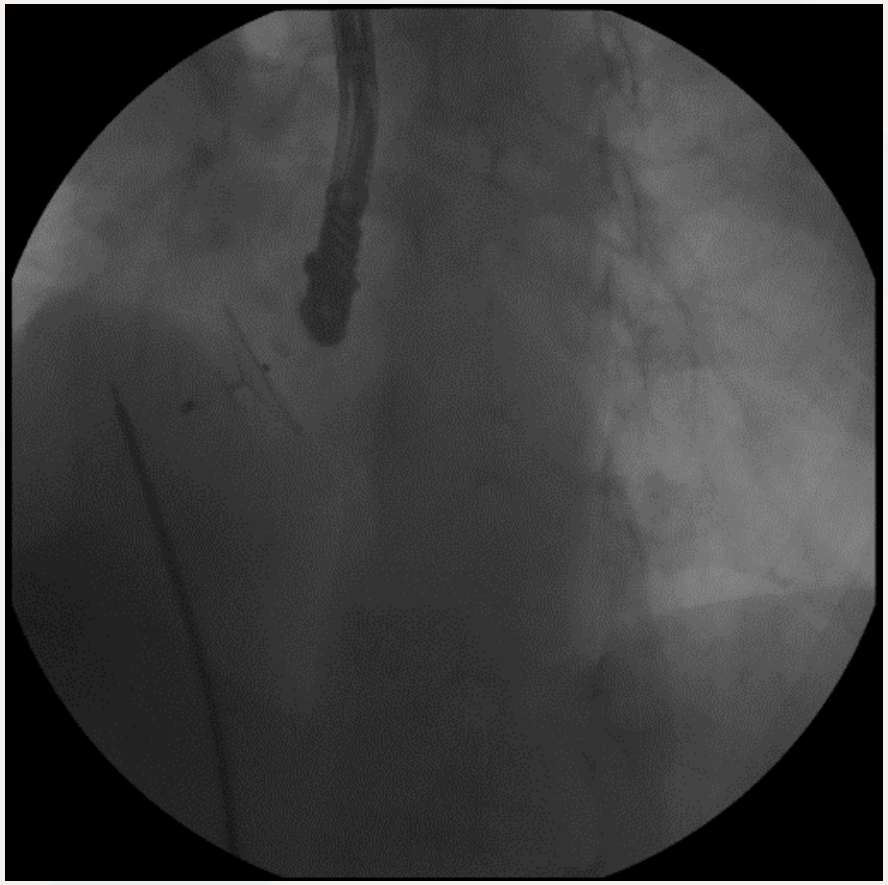
Adult Structural Heart Disease



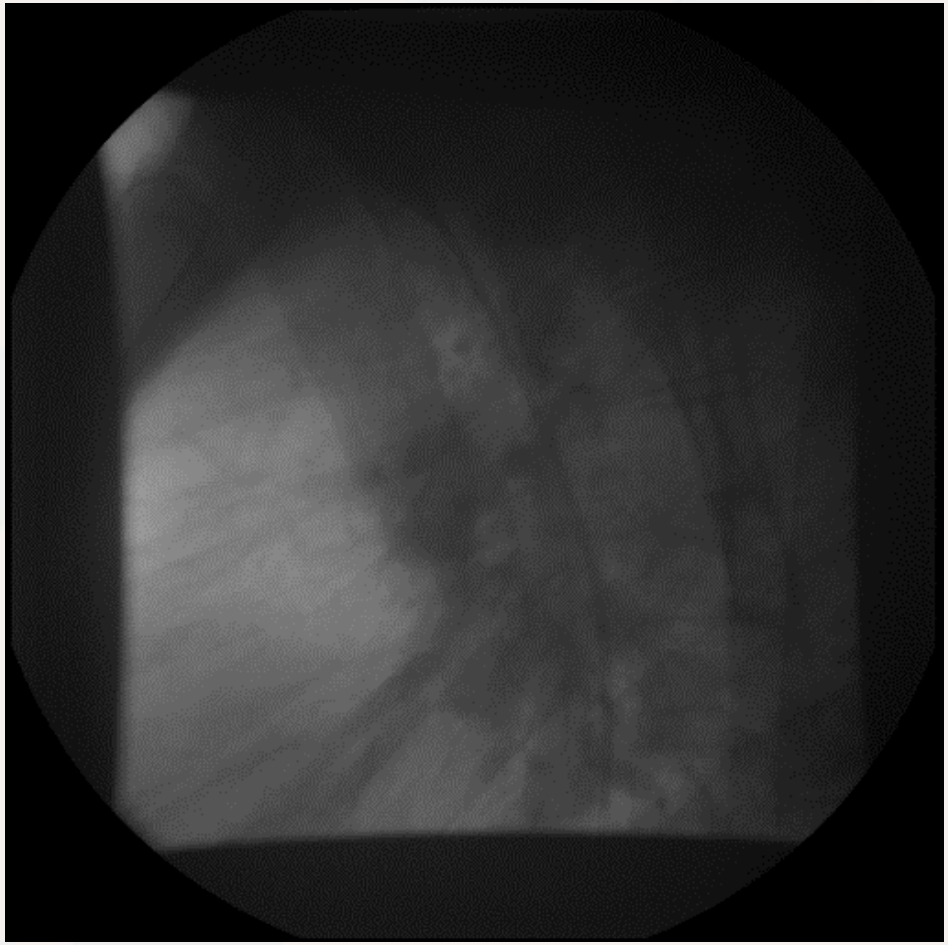
PFO & Cryptogenic Stroke



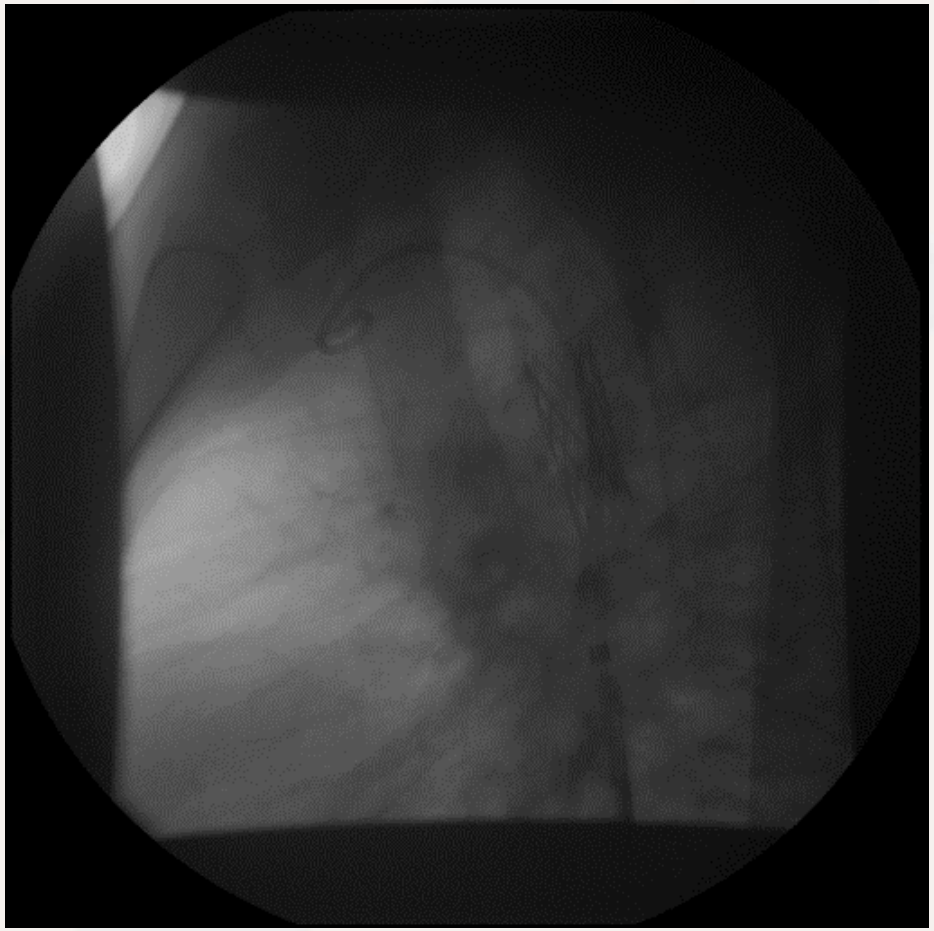
PFO Closure (Amplatzer)



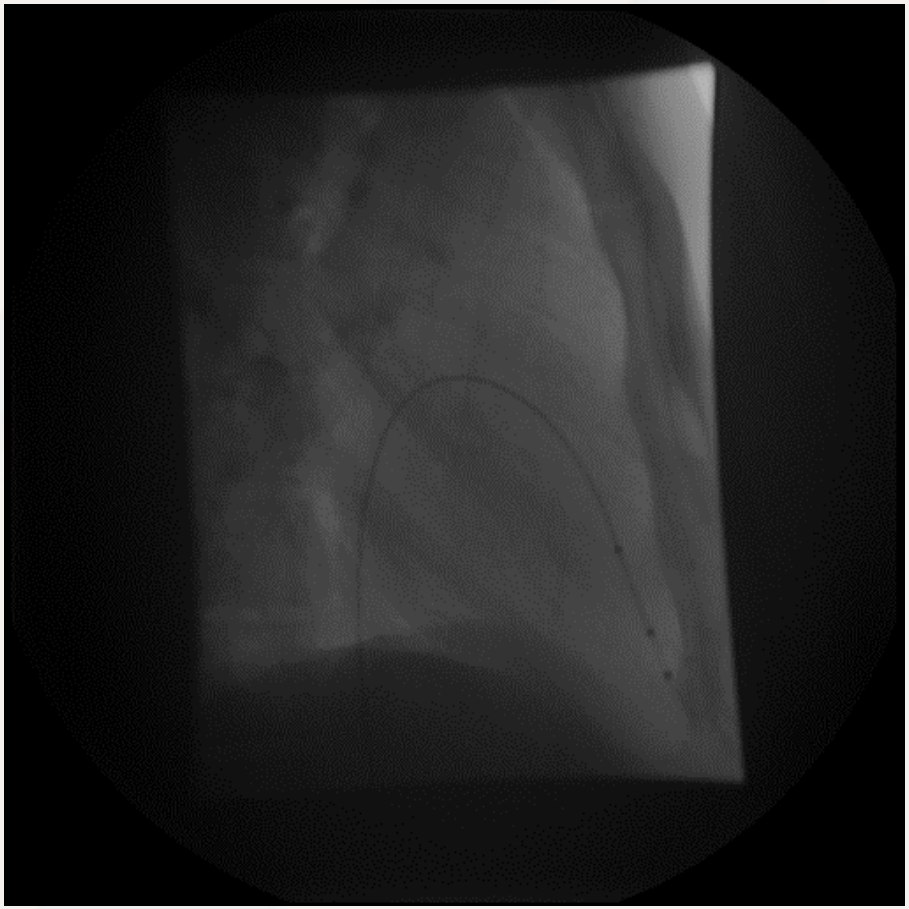
Coarctation - Angiography



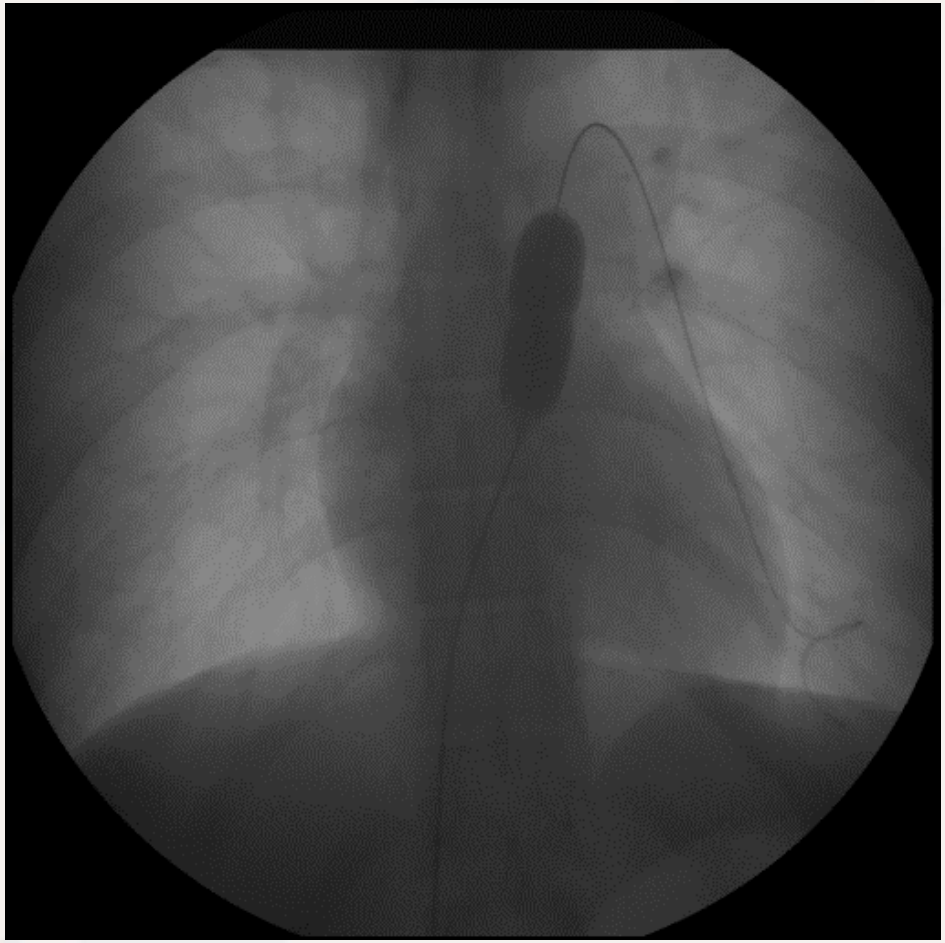
Coarctation - Stent Placement



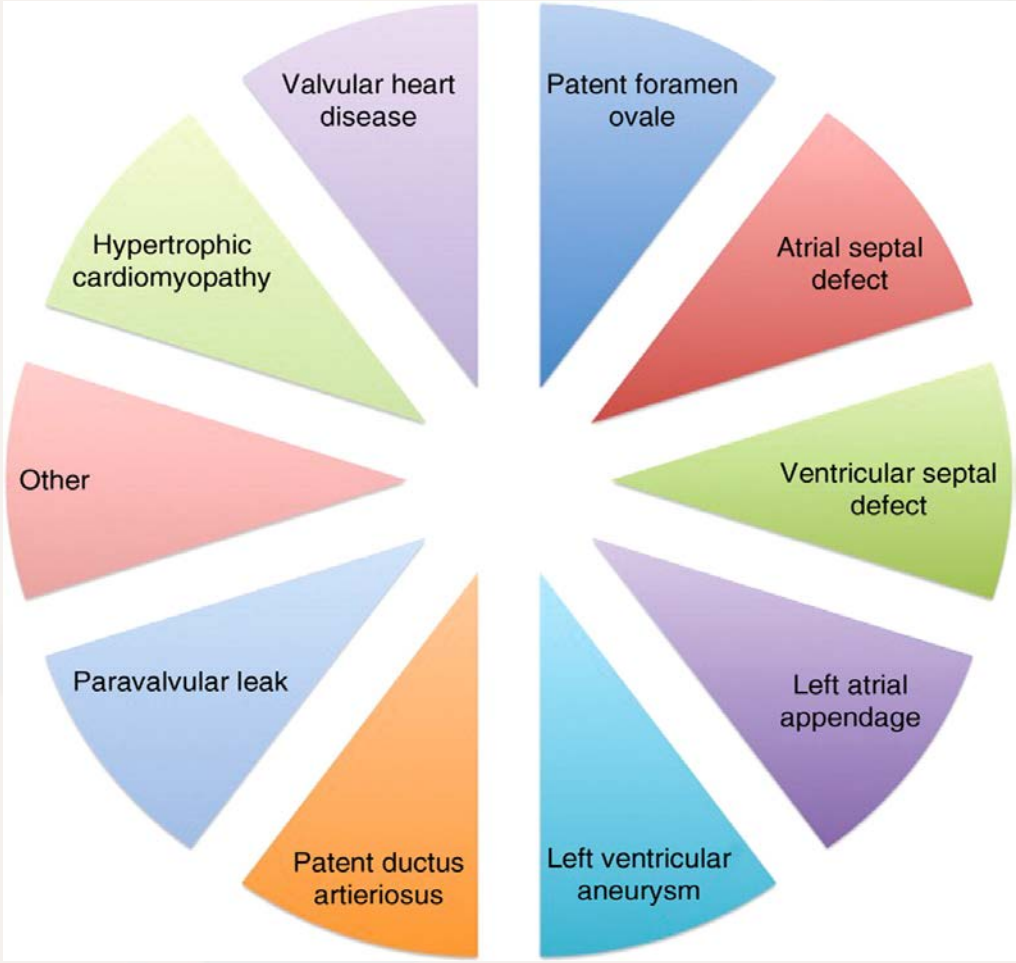
Pulmonic Valve stenosis



Pulmonic Valve Angioplasty



Adult Structural Heart Disease



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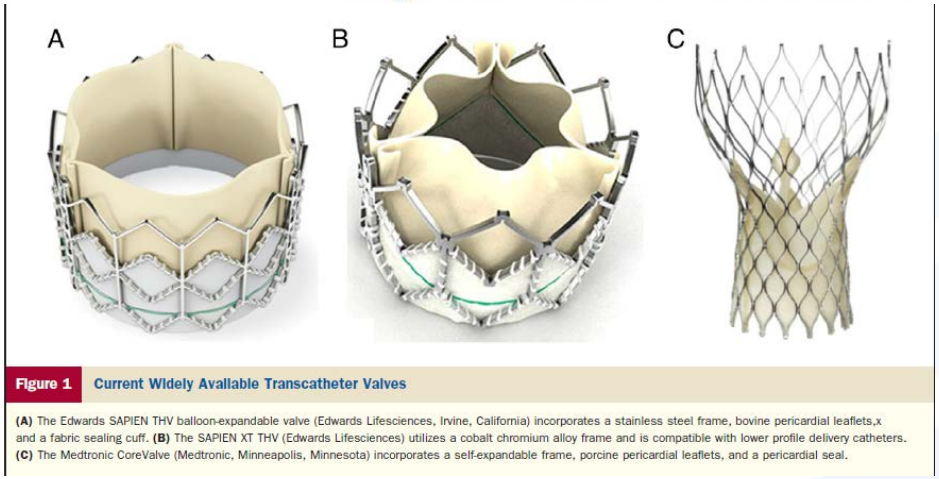

Figure 1 Current Widely Available Transcatheter Valves

(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets,x and a fabric sealing cuff. **(B)** The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. **(C)** The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal.

Interventional Cardiology and Structural Heart Disease

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In collaboration with: Research Institute for Longevity and Prevention of Geriatric Diseases