Transcatheter Aortic Valve Replacement

Rachel Kile, PharmD
PGY1 Pharmacy Resident
Memorial Health Care System
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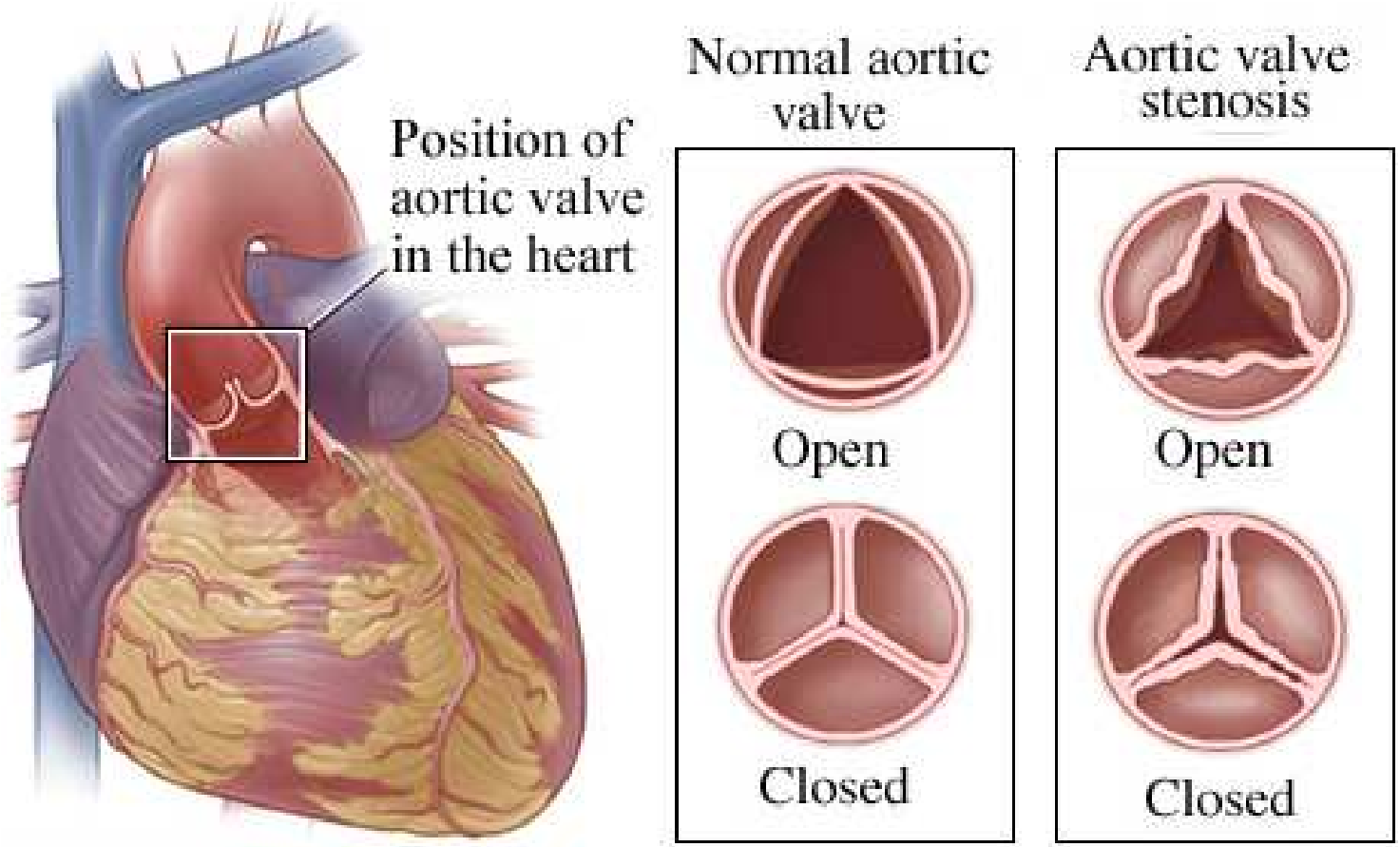
Objectives

- Identify signs and symptoms of aortic stenosis
- Recognize patients who may qualify for transcatheter aortic valve replacement (TAVR)
- Briefly summarize the TAVR procedure
- List benefits and risks of the TAVR procedure
- Formulate a plan for peri and post-TAVR antithrombotic therapy

Aortic Stenosis

- Narrowing of aortic valve
  - Improper functioning
  - Impaired blood flow from left ventricle through aorta
  - Improper blood flow from pulmonary veins to heart
- Aging population
- Decreased quality of life



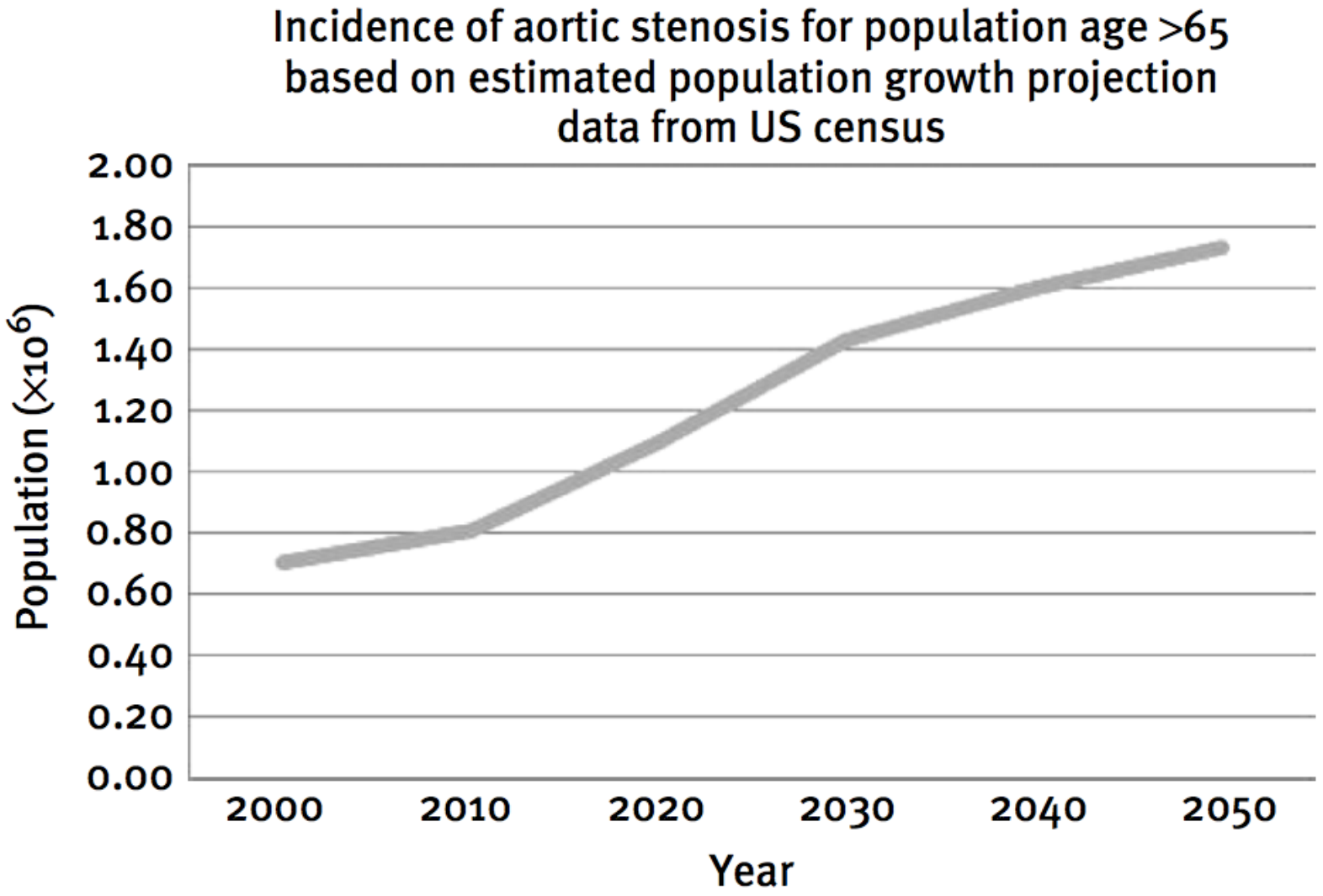


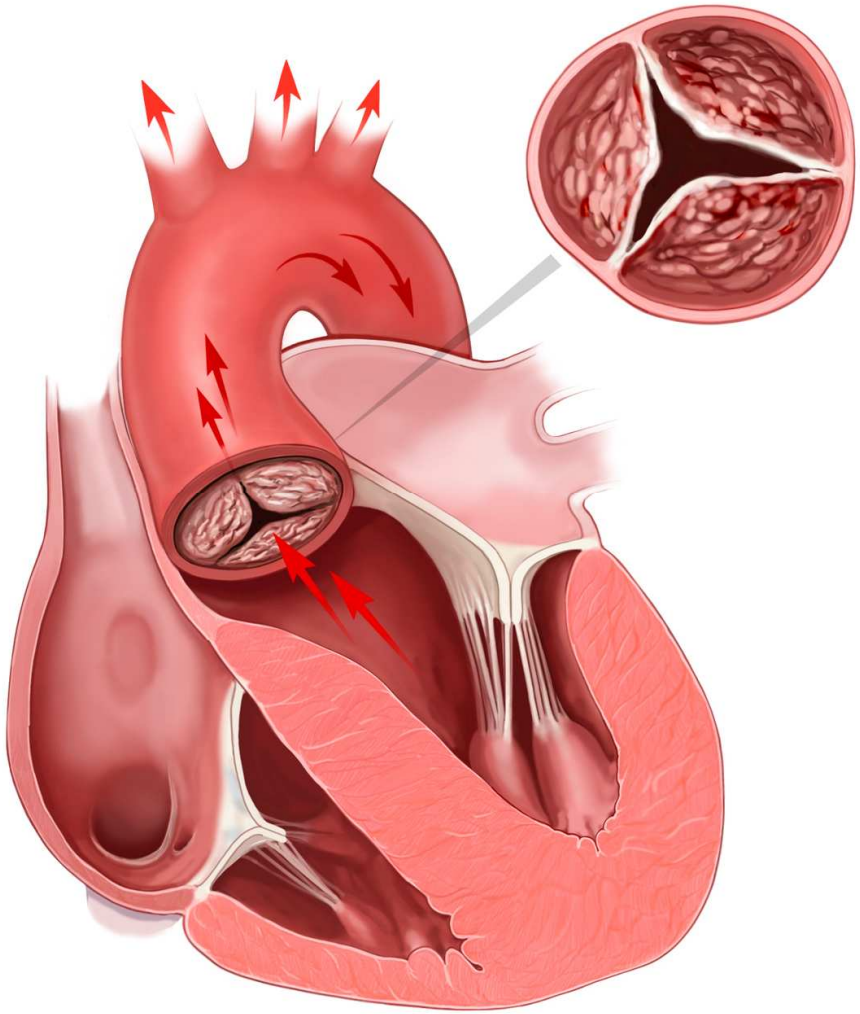
Figure 1. Incidence of aortic stenosis for population age >65 based on estimated population growth projection data from US Census assuming that 2% of the population age >65 have aortic stenosis.[1–3]

Aortic Stenosis

- Signs/Symptoms
  - SOB
  - Chest pain
  - Syncope
  - Dizziness
  - Fatigue
  - Palpitations
  - Murmur
  - Weak pulse

Aortic Stenosis

- "Senile" aortic stenosis
  - Calcified aortic valve
  - Severity correlates with calcification
- Poor survival rates without surgery
  - Symptomatic
  - 50% mortality after 2 years



SAVR

- Surgical aortic valve replacement (SAVR)
- Sternotomy (open heart surgery)
- Low operative mortality
- Improved survival in otherwise healthy patients
- Typical exclusions
  - Severe, symptomatic aortic stenosis
    - Elderly
    - Left ventricular dysfunction
    - Multiple co-morbidities

SAVR Excluded Patients

- Standard Treatments
  - Balloon valvuloplasty
  - Medical treatment
- No improved mortality provided

Transcatheter Aortic Valve Replacement (TAVR)

- Minimally invasive surgical procedure
- Circulation 2002- first human report
- “Senile” aortic stenosis
  - Severe, symptomatic and inoperable
  - High risk operable (elderly, co-morbidities)

TAVR Procedure

- Catheter inserted into heart
- New valve surrounds inflatable balloon inserted through sheath via catheter
- Balloon expands, expanding and implanting new valve over native valve

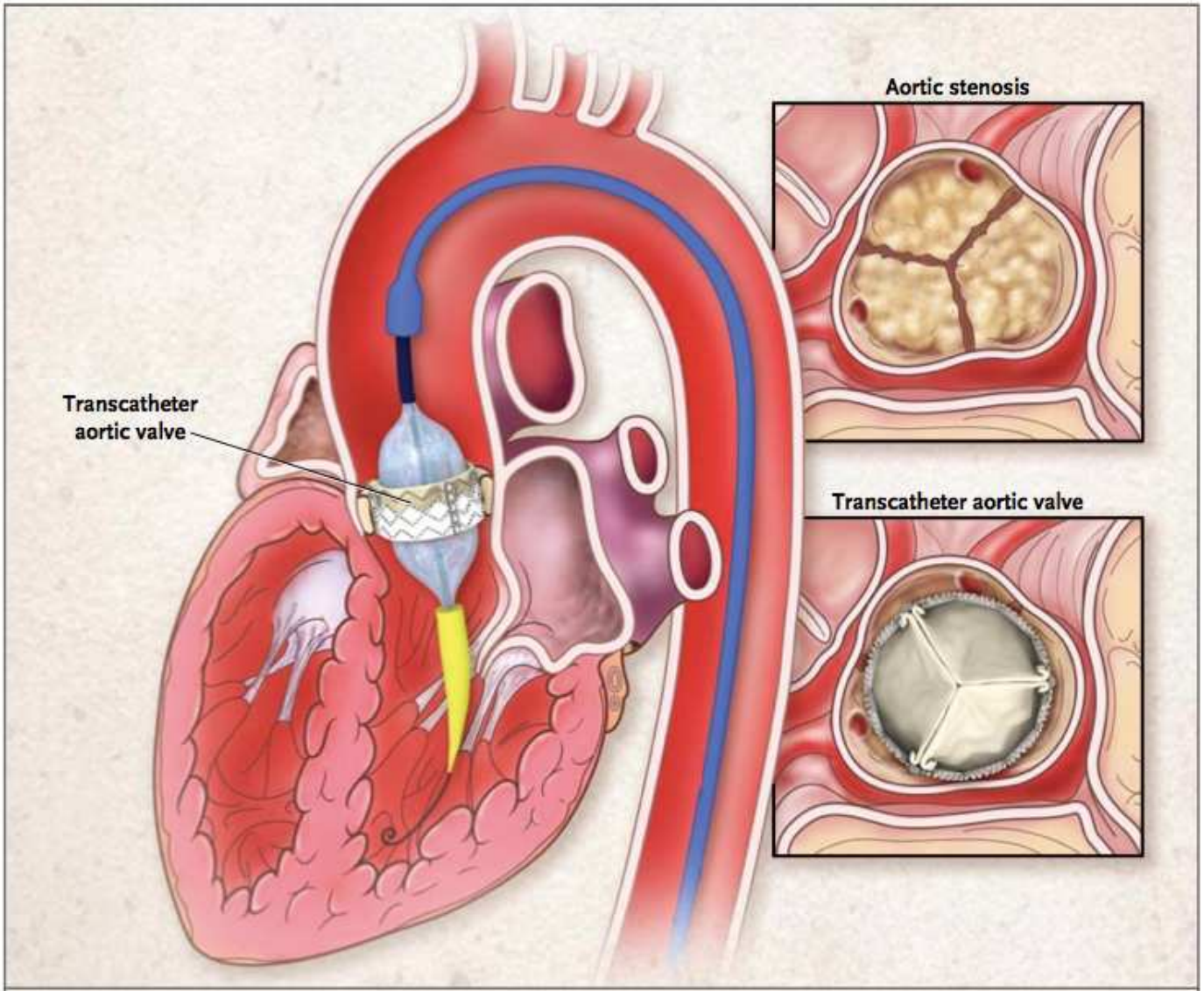


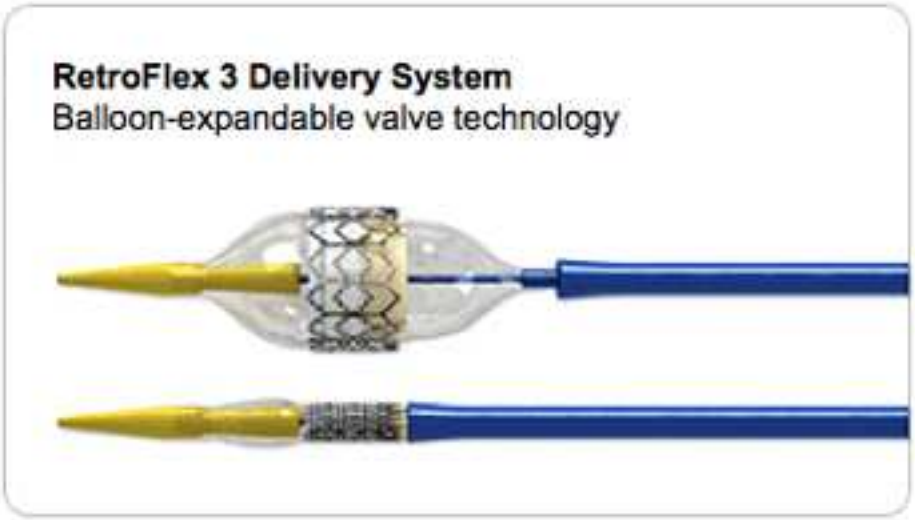
Figure 1. Transcatheter Aortic-Valve Replacement.

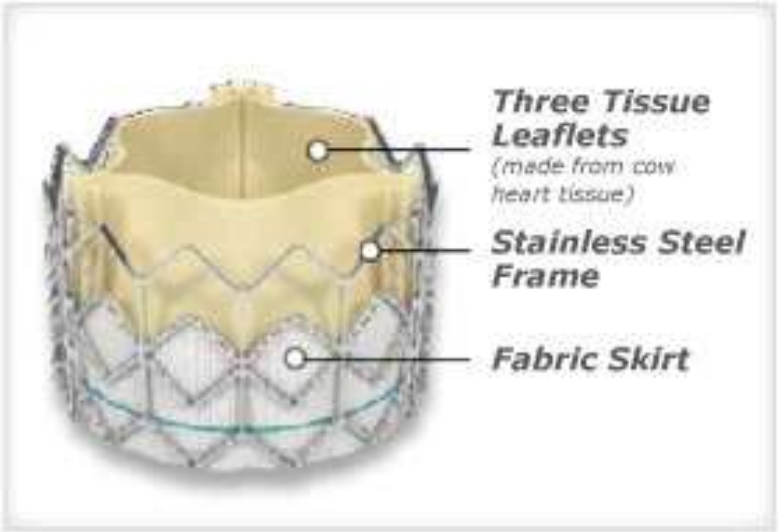
The transcatheter valve is positioned at the level of the native aortic valve during the final step of valve replacement, when the balloon is inflated within the native valve during a brief period of rapid ventricular pacing. The delivery system is shown after it has traversed the aorta retrograde over a guidewire from its point of insertion in the femoral artery (transfemoral placement). Before balloon inflation, the valve and balloon are collapsed on the catheter (dark blue) and fit within the sheath (blue). After balloon inflation, the calcified native valve (upper panel) is replaced by the expanded transcatheter valve (lower panel, shown in short-axis view from the aortic side of the valve).

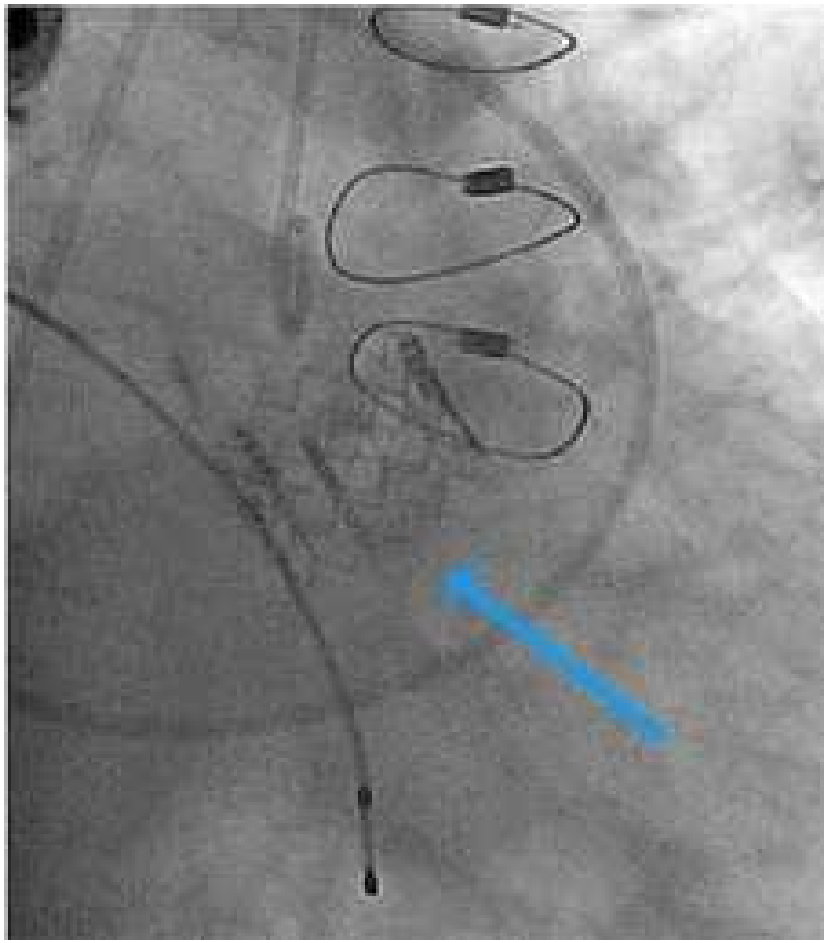
TAVR Procedure

FDA Approved Valve/Device

- Edwards Lifesciences SAPIEN device
  - Balloon expandable
  - Bovine pericardium valve (bioprosthetic)
    - Stainless steel balloon-expandable stent







TAVR

- Techniques
  - Transfemoral
  - Transapical
    - More invasive

- Challenges
  - Catheter size
    - Arterial dissection
    - Arterial perforation
    - Thrombosis
  - Valve
    - Positioning
    - Sizing
      - Paravalvular leak
      - Embolization

TAVR Complications

- Embolic vs. bleeding events
  - 3.5% thirty day embolic stroke risk
    - 66-86% new ischemic defects peri-procedurally
    - 3% clinically apparent stroke
    - Atrial arrhythmias also increase risk
  - 10% thirty day major bleeding/vascular complications
    - Mechanical (i.e. large catheter size)
    - Anemia

Antithrombotic Therapy

- Procedural
  - Unfractionated heparin
    - Bolus to ACT goals
      - >250 per PARTNER trials
      - >300 per expert consensus
    - Protamine reversal for closure
    - Angiomax?

Antithrombotic Therapy

Table 4 Current Recommendations for Antithrombotic Agents and Strategies for TAVI

	PARTNER Trial (17,18)	ACC/STS Recommendations (58)	CCS Statement (59)
Pre-procedural	Aspirin 80 mg Clopidogrel 300 mg	—	—
Procedural	Unfractionated heparin Goal ACT: 250 s Reversal with protamine optional Bivalirudin—not allowed?	Unfractionated heparin Goal ACT: 300 s Reversal with protamine recommended Bivalirudin—not mentioned	—
Post-procedural (first 30 days)	Aspirin 81 mg/day indefinitely + Clopidogrel 75 mg/day × 90 days	Aspirin 81 mg/day indefinitely + Clopidogrel 75 mg/day × 3–6 months If warfarin indicated (AF), then no clopidogrel	Indefinite low-dose aspirin generally recommended + Thienopyridine × 1–3 months If oral anticoagulant indicated (AF), avoid triple therapy unless definite indication exists

ACC = American College of Cardiology; ACT = activated clotting time; AF = atrial fibrillation; CCS = Canadian Cardiovascular Society; STS = The Society for Thoracic Surgeons; TAVI = transcatheter aortic valve implantation.

Antithrombotic Therapy

- Considerations
  - 30% of TAVR patients have chronic atrial fibrillation
    - Variable antithrombotic regimens
    - Rate of afib increases post-TAVR
  - Further research required
    - Platelet vs thrombin-based thromboembolic events
    - ARTE Trial

The PARTNER Trial

- Placement of AoRTicTraNscathetER Valve Trial
- April 2007-March 2017
- Higher rate of cerebrovascular events with TAVR vs standard therapy
- Higher rate of major bleeding with TAVR vs standard therapy
  - Lower rate vs SAVR

TAVR Outcomes

- vs Standard Therapy
  - Standard Therapy = medical treatment or balloon valvuloplasty
  - 20% absolute reduction in all-cause mortality at 1 year (PARTNER trial)
  - Improved quality of life at 1 year
  - 30 dayshigher incidence of major strokes and major vascular complications
- vs SAVR
  - No difference in all-cause mortality at 1 year in high-risk operable patients

TAVR Registry

- The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry
  - "STS/ACC TVT Registry"
  - https://www.ncdr.com/TVT/Home/Default.aspx
- "Benchmarking tool developed to track patient safety and real-world outcomes related to TAVR"
- CMS approved (meets CMS conditions for coverage)

TAVR Registry

- JAMA 2013
  - "Outcomes Following Transcatheter Aortic Valve Replacement in the United States"
  - 7710 patients, 224 STS/ACC TVT registry sites
  - Median age 84
  - 92% device implantation success
  - 5.5% overall in-hospital mortality rate
  - 2% stroke rate

Memorial Health Care System

- Heart Valve Program
  - Cardiovascular surgeons
  - Interventional cardiologists
  - Imaging cardiologists
- Third implant in the nation
- Post-op heart surgery orders

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Questions?