Transcatheter Aortic Valve Replacement: Current and Future Devices: How do They Work, Eligibility, Review of Data

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Disclosures

• Edwards LifeSciences

Current and Future Devices
Transcatheter Aortic Valve Replacement

- Anderson et al, 1992
  - Swine model
- Bonhoeffer et al, 2000
  - First human use of stent mounted bioprosthesis for pulmonary valve regurgitation
- Cribier et al, 2002
  - First-in-man percutaneous aortic valve implantation
  - Antegrade transvenous delivery
- Webb et al, 2006
  - Retrograde via femoral artery
  - Also transapical LV delivery

Transcatheter Valve Technology

- April 23, 2002
- First Heart Valve Replacement Without Open Heart Surgery.
- SOURCE: Percutaneous Valve Technologies, Inc. (PVT)
- Experimental Device Developed By Percutaneous Valve Technologies May Provide Alternative to Open Heart Surgery In the United States
- “The 57 year old male patient that received the aortic valve procedure had a failing heart and was refused for surgery by three surgical teams because of his deteriorating condition and complicated vascular disease,” said Dr. Alain Cribier. “Lacking any other clinical solution for this patient, the PVT valve was a life saving technology. We are pleased to be the world’s first clinical site to utilize this device.”

SAPIEN Transcatheter Heart Valve

- Top left: Before percutaneous heart procedure
- Top right: After implantation
- Bottom: Expandable stainless steel stent for aortic valve replacement
Percutaneous Aortic Valve Implantation Via Antegrade Approach

Balloon valvuloplasty followed by stented valve deployment during rapid ventricular pacing

Cribier et al. JACC 2004;43:698-703

Transfemoral Retrograde Approach for Transcatheter Aortic Valve Replacement

Percutaneous Aortic Valve Implantation Retrograde From the Femoral Artery

Webb et al. Circulation 2006; 113:842-850

Alternative Mode of Transcatheter Deployment: Transapical Antegrade Approach
Direct Aortic Approach

Sapien THV and Delivery Systems

Edwards SAPIEN THV
23 and 26 mm valves

RetroFlex
22 and 24 F sheaths

Ascendra
24 and 26 F sheaths

The Next Generation: SAPIEN XT THV
CoreValve

Emerging Transcatheter Heart Valves

Who is Eligible?

- Medical Eligibility
- Anatomic Eligibility
PARTNER Study Design

PARTNER Study Design: Inoperable Patients

Inclusion Criteria: Inoperable Group

- **Severe Aortic Stenosis**: Echo-derived AVA < 0.8 cm² (or AVA index < 0.5 cm²/m²) and mean AVG > 40 mm Hg or peak jet velocity > 4.0 m/sec.
- **Cardiac Symptoms**: NYHA Functional Class II or greater
- **Inoperable**: Predicted risk of death or serious irreversible morbidity must exceed 50%
Transfemoral Delivery

All Cause Mortality (ITT)

FDA Approval

Edwards SAPIEN THV via Transfemoral Delivery approved by FDA for inoperable patients
Who is Eligible?

- Medical Eligibility
  - Symptomatic Severe Calcific Aortic Stenosis
  - Inoperable in estimation of two cardiac surgeons
  - Implantation route via FDA labeling

PARTNER Study Design: High Risk Surgical Group

Inclusion Criteria: High-Risk Surgical Group

- **Severe Aortic Stenosis**: Echo-derived AVA < 0.8 cm² (or AVA index < 0.5 cm²/m²) and mean AVG > 40 mm Hg or peak jet velocity > 4.0 m/sec.
- **Cardiac Symptoms**: NYHA Functional Class II or greater
- **High Surgical Risk**: Predicted risk of operative mortality ≥ 15% (determined by site surgeon and cardiologist); guideline = STS score ≥ 10
TAVR: Transfemoral or Transapical Delivery

ACC 2012: All-Cause Mortality at 2 Years

Who is Eligible?

- Medical Eligibility
  - Symptomatic Severe Aortic Stenosis
  - Inoperable in estimation of two cardiac surgeons
  - Implantation route via FDA labeling
  - **High risk surgical candidates** soon to come?
  - Meets eligibility for ongoing clinical trial (PARTNER II, CoreValve U.S. Pivotal)

Medical Eligibility: Contraindications and Cautions

- Non-calcified aortic valve
- Bicuspid aortic valve
- Severe aortic regurgitation
- Severe mitral regurgitation
- Poor prognosis from non-cardiac disease (advanced malignancy, very severe COPD)

Transcatheter Aortic Valve Replacement: Outcomes of Patients With Moderate or Severe Mitral Regurgitation

Source XT: Improvement in Mitral Regurgitation
Medical Eligibility: Areas of Uncertainty

- Understanding Frailty
- Mild or Moderate Dementia
- End-Stage Renal Disease
- Low-gradient Aortic Stenosis (without contractile reserve)
- Very Low Ejection Fraction

Anatomic Eligibility

- Aortic valve morphology
- Annulus size
- Determining route of vascular access for implantation
  - Not always about vessel size
  - Minimize risk of stroke and vascular complications
- LVOT and aortic root anatomy/pathology
  - HOCM
  - Narrowed and circumferentially calcified STJ

Relation of Paravalvular Aortic Regurgitation to All-Cause Mortality in the TAVR As-Treated Population.

How to Assess Eligibility

- Comprehensive medical evaluation
- Echocardiogram
- CTA
- Cardiac catheterization
- Transesophageal echocardiography

THANK YOU!