Rehabilitation Management of Transcatheter Heart Procedures
Disclosures

• None
Objectives

• Discuss Current State of Transcatheter Procedures
• Review Evidence and Future Studies
• Describe Rehabilitative Management across the Continuum of Care
Heart Valve Disease Incidence

![Graph showing prevalence of heart valve disease by age group.

- All valve disease: 14%
- Mitral valve disease: 12%
- Aortic valve disease: 8%

Age groups are: <45, 45-54, 55-64, 65-74, 75+ years.](image)
Heart Valve Disease Incidence

Canadian Journal of Cardiology 30 (2014) 962-970
Valve Anatomy
Advances in Technology, Technique, and Imaging
Projected Growth
Aortic Stenosis (AS)

<table>
<thead>
<tr>
<th>Congenital Abnormality</th>
<th>Rheumatic Fever</th>
<th>Infection</th>
<th>Age-Related Calcific Aortic Stenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>less common</td>
<td>Adults who have had rheumatic fever may also be at risk for aortic stenosis.</td>
<td>Aortic stenosis can be caused by various infections.</td>
<td>Aortic stenosis in patients over the age of 65 is usually caused by calcific (calcium) deposits associated with aging.</td>
</tr>
</tbody>
</table>

In some cases adults may develop aortic stenosis resulting from a congenital abnormality.
Aortic Valve Disease Incidence

- ≤0.2% before 65 years of age
- 1.3% between 65 and 74 years
- 2.8% after 75 years

Canadian Journal of Cardiology 30 (2014) 962-970
Epidemiology

AT THE HEART OF AORTIC STENOSIS

Aortic Stenosis is a narrowed aortic valve, commonly due to calcium build-up, that limits its ability to open and close properly, which reduces blood flow to the rest of the body.

33% of these patients are deemed too high risk for open heart surgery.

100k people in the U.S. are diagnosed with severe aortic stenosis each year.

50% of patients at extreme risk for open-heart surgery will die from severe aortic stenosis within one year if left untreated.

Prognosis

After the onset of symptoms, patients with severe aortic stenosis have a survival rate as low as 50% at 2 yrs without aortic valve replacement.¹
Evidence: Timeline of TAVR Evolution

- **1989**: First porcine implant by H. Andersen

- **1994**: Post-mortem studies of intra-valvular stenting

- **1999**: PVT prototype
  - PVT animal implantations
  - 1st Percutaneous valve implant (RV to PA conduit) by P. Bonhoeffer

- **2002**: 1st TF-TAVI by J.G. Webb
  - 1st Self-expanding THV (CoreValve) by E. Grube

- **2004-2005**: 1st TA-TAVI by F. Mohr

- **2007-2008**: CE Mark Edwards and CoreValve

- **2010**: FDA Approval
  - High-risk patients

- **2011**: NOTION RCT
  - Low-risk patients

- **2014**: FDA Approval
  - Inoperable patients

- **2015**: CoreValve U.S. RCT
  - High-risk patients

- **2016-2017**: ACC/AHA YHD Focused Update Guidelines
  - I-A (inoperable-risk)
  - I-A (high-risk)
  - Ila-B (intermediate-risk)
  - SURTAVI RCT
    - Intermediate-risk patients

- **2016**: CE Mark and FDA Approval
  - Intermediate-risk patients

- **2017**: ESC VHD Guidelines
  - I-B (inoperable)
  - Ila-B (high-risk)

- **2018**: 1st Repositionable THV (Lotus) by E. Grube
  - 1st Consensus Document TAVI EACTS-ESC-EAPCI

- **2019**: PARTNER A RCT
  - High-risk

- **2020**: FDA Approval
  - Inoperable patients

- **2021**: PARTNER 2 RCT
  - Intermediate-risk patients

- **2022**: FDA approves low-risk RCTs
  - PARTNER 3 and Evolut R Low-risk

**2016 EuroIntervention**
• Partner A&B, II
• Corevalve, SurTavi
TAVI Trials: Impact on Clinical Practice
SAVR vs TAVR: Current Guidelines

**Figure 1.** Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS

- **Severe AS Symptomatic (stage D)**
  - Low surgical risk
    - Surgical AVR (Class I)
  - Intermediate surgical risk
    - Surgical AVR (Class I)
    - TAVR (Class Ia)
  - High surgical risk
    - Surgical AVR or TAVR (Class I)
  - Prohibitive surgical risk
    - TAVR (Class I)

AS indicates aortic stenosis; AVR, aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

Figure 1. American Heart Association/American College of Cardiology guidelines recommendations for TAVR versus surgical aortic valve replacement in severe AS. Adapted from Nishimura RA et al. and reprinted with permission from the Journal of the American College of Cardiology; Publisher: Elsevier. Abbreviations: AS, aortic stenosis; AVR, aortic valve replacement; TAVR, transcatheter aortic valve replacement.
TAVR: Valve Systems

Sapien 3 Valve

Evolut Pro Valve
Device Evolution
TAVR: Evolut Pro
TAVR: Sapien 3

**Initial Positioning**
- Positioning

**Deployment**
- Inflation

**Final Placement**
- Placement
Mortality Rates

30-Day Mortality Rates with SAPIEN Valves in PARTNER I and II trials

Vahl et al. JACC 2016
Stroke Rates

30-Day Stroke Rates with SAPIEN Valves in PARTNER I and II trials

Vahl et al. JACC 2016
Comparison of major clinical outcomes between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR).

Siemieniuk RA et al. BMJ 2016
Mitral Valve Anatomy

Normal MITRAL valve area in adult humans is roughly the size of a US quarter.

4-6 cm²

Normal AORTIC valve in adult humans is roughly the size of a US nickel or dime.

2-4 cm²

Normal TRICUSPID valve in adult humans is roughly the size of a US half-dollar coin.

6-8 cm²
## Mitral Valve Disease

<table>
<thead>
<tr>
<th>Mitral Stenosis</th>
<th>Acute Mitral Regurgitation</th>
<th>Chronic Mitral Regurgitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Rheumatic - Majority</td>
<td>• Infective endocarditis</td>
<td>• Ischemic Heart disease</td>
</tr>
<tr>
<td>• Congenital</td>
<td>• Ischemic Heart disease</td>
<td>• Papillary ms dysfunction</td>
</tr>
<tr>
<td>• Prosthetic valve stenosis</td>
<td>• Mitral valve prolapse</td>
<td>• Inferior &amp; posterior MI</td>
</tr>
<tr>
<td>• Mitral Annular Calcification</td>
<td>• Chordal rupture</td>
<td>• Mitral Valve prolapse</td>
</tr>
<tr>
<td>• Left Atrial Myxoma</td>
<td>• Papillary muscle rupture</td>
<td>• Infective endocarditis</td>
</tr>
<tr>
<td></td>
<td>• Chest trauma</td>
<td>• Rheumatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Prosthetic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Mitral annular calcification</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cardiomyopathy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LV dilatation</td>
</tr>
</tbody>
</table>
Mitral Valve Disease Incidence

- MR most common
- MS rare with estimates of 0.1%
- Increased risk with normal aging

Canadian Journal of Cardiology 30 (2014) 962-970
NORMAL MITRAL VALVE VS. RHEUMATIC MITRAL STENOSIS

Mitral valve seen from left ventricular perspective

Normal mitral valve

Severe mitral stenosis
Percutaneous Mitral Balloon Valvuloplasty

The balloon is reinforced with a nylon micromesh. Its shape changes in 3 stages, depending on the extent of inflation.

Fluoroscopic guidance of PMBV.
Mitral Regurgitation Incidence

Mitral regurgitation (MR) is the most frequent valve disease in the United States. Nearly 1 in 10 people age 75 and older has moderate or severe MR. In comparison, 1 in 20 is affected by aortic valve disease.

Figure: Prevalence of isolated moderate to severe MR according to age and sex.
## Transcatheter Mitral Valve Repair Technologies

<table>
<thead>
<tr>
<th>Company</th>
<th>Abbott</th>
<th>NeoChord</th>
<th>Cardiac Dimensions</th>
<th>Valtech Cardio</th>
<th>Mitralign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>MitraClip</td>
<td>DS1000</td>
<td>Carillon*</td>
<td>Cardioband</td>
<td>Bident</td>
</tr>
<tr>
<td>Description</td>
<td>Edge-to-edge technique</td>
<td>Implantation through TA access</td>
<td>Coronary sinus cinching</td>
<td>Transcatheter surgical-like annuloplasty</td>
<td>Plication device</td>
</tr>
<tr>
<td>Strengths</td>
<td>Versatility (DMR and FMR)</td>
<td>Solid surgical background</td>
<td>Simplicity</td>
<td>Solid surgical background</td>
<td>Simpler than other direct annuloplasty</td>
</tr>
<tr>
<td>Weaknesses</td>
<td>Lack of annuloplasty</td>
<td>TA access</td>
<td>Limited efficacy, unpredictable results</td>
<td>Complexity, advanced imaging</td>
<td>Limited efficacy</td>
</tr>
<tr>
<td>MR etiology</td>
<td>DMR and FMR</td>
<td>DMR</td>
<td>FMR</td>
<td>FMR</td>
<td>FMR</td>
</tr>
<tr>
<td>Status</td>
<td>About 40,000 patients worldwide</td>
<td>About 300 patients</td>
<td>About 500 patients</td>
<td>About 100 patients</td>
<td>About 100 patients</td>
</tr>
</tbody>
</table>

DMR: degenerative mitral regurgitation; FMR: functional mitral regurgitation. * Carillon® Mitral Contour System®; Cardiac Dimensions Inc., Kirkland, WA, USA
3D TEE GUIDANCE OF MITRAL CLIP PROCEDURE

1. Femoral venous access
2. Trans-septal puncture
3. Mitral Clip Deployment
CLIP POSITION

Clip being positioned: note flail segment

Clip released: no more flail segment
# Transcatheter Mitral Valve Replacement (TMVR)

<table>
<thead>
<tr>
<th>Company</th>
<th>Abbott</th>
<th>Edwards</th>
<th>Edwards</th>
<th>Medtronic</th>
<th>Neovasc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Tendyne</td>
<td>CardiAQ</td>
<td>Fortis</td>
<td>Twelve</td>
<td>Tiara</td>
</tr>
<tr>
<td>Patients treated</td>
<td>31</td>
<td>12</td>
<td>23</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>First implant</td>
<td>October 2014</td>
<td>June 2012</td>
<td>February 2014</td>
<td>September 2014</td>
<td>January 2014</td>
</tr>
<tr>
<td>Functional aetiology</td>
<td>86%</td>
<td>64%</td>
<td>100%</td>
<td>73%</td>
<td>54%</td>
</tr>
<tr>
<td>Successful deployment</td>
<td>21/23 (91%)</td>
<td>9/11 (82%)</td>
<td>10/13 (77%)</td>
<td>14/15 (93%)</td>
<td>9/11 (82%)</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>1/23 (4%)</td>
<td>5/11 (45%)</td>
<td>5/13 (38%)</td>
<td>2/15 (13%)</td>
<td>3/11 (27%)</td>
</tr>
<tr>
<td>MR grade 0 at follow-up</td>
<td>19/19 (100%)</td>
<td>na</td>
<td>8/9 (89%)</td>
<td>13/14 (93%)</td>
<td>na</td>
</tr>
</tbody>
</table>

INTREPID – TMVR System

- Conformable Outer Stent engages annulus and leaflets providing fixation and sealing while isolating the inner stent from the dynamic anatomy
- Circular Inner Stent houses a tricuspid bovine pericardium valve
- Flexible Brim
Intrepid Transapical Valve Program
CAISSON Transcatheter MVR

ANCHOR + VALVE = VALVE IN ANCHOR
Heart Surgery without the Surgery

Here’s how a team at NYU Langone implanted one of the first artificial mitral valves without leaving a single stitch.

Placed atop the worn-out mitral valve, the replacement valve regulates the flow of oxygenated blood from the lungs.
Final Deployment
Rehabilitative Management Across the Continuum

Phase I: Acute Hospital

Phase II & III: Outpatient Rehabilitation

- Home Care/TeleRehabilitation
- Subacute Rehabilitation
- Inpatient Rehabilitation
- Community
Rehabilitation Considerations

Where does your patient fit…

- Inoperable, High Risk, Intermediate, Low Risk???
- Society of Thoracic Surgeons (STS) score:
  - Low Risk
  - Intermediate Risk
  - High Risk
- Comorbid Conditions
- Frailty Score
- How long have they been monitoring (Degree of deconditioning)
- Functional Status
Rehabilitation Considerations

Major Complications

- Bleeding
- Stroke
- Arrhythmia: AF, High Degree AV Blocks, BBB, PPM
- Paravalvular Leak (PVL)
- Thrombosis
Outcomes

• Frailty Tests
  – Grip strength
  – Essential Frailty Tool
  – Katz Index, Barthel Index
  – Timed Up and Go (TUG)

• Functional Testing
  – 5 meter walk speed
  – 6 minute walk test (6MWT)
  – Exercise Tolerance Test (ETT)
  – Cardiopulmonary Exercise Test (CPET)

• Questionnaires
  – KCCQ

Frailty in Older Adults Undergoing Aortic Valve Replacement. JACC 2017
Signs and Symptoms

- Subjective: SOB, fatigue, palpitations, Incisional discomfort, Dizzy/lightheaded
- Observation:
  - Edema, Increased RR, JVD
- Examination:
  - Resting Vitals: HR, BP, Spo2
  - Auscultation: rales
  - ECG: Irregular heart beat (palpitations)
  - Incisional location

Assess hemodynamics with self care, transfers, ambulation

Decreased exercise tolerance and work capacity
Acute: Post-op Rehab Guidelines

• Patient will be on bed rest for 3.0 hours post-op
• Therapist evaluates patient 3.0 hours post-op, once hemostasis achieved at catheter access sites and patient’s HR and BP stable
• OOB/Ambulation as tolerated with vital signs monitored with each new position change (supine > semifowlers > long sitting > sitting EOB > standing > walking)
• Therapist to make mobility recommendations
  – Activity order based on therapist recommendations
  – Nursing/PCT to follow therapy recommendations
    • Therapy continue to make recommendations daily as patient progresses
Acute: Post-op Therapy Guidelines

- Plan of Care (LOS 2 days)
  - PT Provided (Monday-Sunday)
    - POD #0: 1x
    - POD # 1-2: 1x/discharged

- OT (Monday-Friday, Weekends for Evals only, follow up sessions as need to ensure safe discharge)
  - POD # 1-2: 1x daily
Acute: Post-op Therapy Guidelines

• Precautions
  – Patients who are in complete heart block or have an extremely slow rhythm (<50bpm) and are TVP dependent should remain on bedrest. Some TVP dependent patients may be allowed OOB to chair for meals (case by case basis)
  – If patient cleared for OOB/ambulation with TVP, activity order must be present stating ‘patient cleared for OOB/ambulation with TVP’
  – Avoid shoulder ROM to side where TVP present
  – Ensure TVP stabilized with two anchors prior to mobilizing patient - consult NP/PA/RN to reinforce TVP
  – Once TVP removed, continue to carefully monitor VS response to activity
Phase II CR Literature

Transcatheter Aortic Valve Replacement: Optimizing Outcomes for Health Recovery.

Table 3

Benefits and Adverse Events of Cardiac Rehabilitation After Transcatheter Aortic Valve Replacement

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved 6-min walk distance</td>
<td>41, 42, 45, 47, 48</td>
</tr>
<tr>
<td>Improved peak oxygen uptake</td>
<td>46, 48</td>
</tr>
<tr>
<td>Improved muscular strength, rowing, pull down, and leg press</td>
<td>46</td>
</tr>
<tr>
<td>Improved Barthel Index</td>
<td>42, 45, 47</td>
</tr>
<tr>
<td>Improved quality of life</td>
<td>46</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Reference Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>No major complications were directly associated with the exercise training</td>
<td>42, 47, 49</td>
</tr>
</tbody>
</table>

*Barthel index is a validated scale (0 = total dependence, 100 = total independence) of independence in activities of daily living.*

References @ JCRP 2018, 38:1-7
Phase II Systematic Review

- started cardiac rehabilitation early after TAVR (mean: 26 d)
- improvement in 6-min walk distance from 186 m to 257 m (odds ratio = 0.69; 95% CI, 0.47-0.91; \( P < .001 \)).
- significant increase (3.7 mL/min/kg) in peak oxygen uptake on a cardiopulmonary exercise test, improved muscular strength, better quality of life, and reduced symptom burden.
- safe and is associated with marked improvements in exercise capacity, functional independence, and frailty parameters, and should be encouraged in all patients.

Outpatient: Rehabilitation Management

Considerations

• Know your patient (comorbidities, STS, Frailty, etc.)
• Emphasis on Function Assessment
  – History of Falls, Balance, Transfers, Gait
• Cardiac Rehabilitation Session
  – Safety, choice the right modalities
• Monitor vitals closely
  – Establish baseline; HR, BP, ECG.
  – Determine if appropriate response to Activity
• Post-discharge recommendations:
  – Ensure post program plan is established
Outpatient: Rehabilitation Management

Exercise Prescription

• Driven by Outcomes: Exercise Stress Test, CPET, 6MWT
  – Frequency: 2-3x/week
  – Intensity: THR, RPE, MET level for work load
  – Type: TM, RB, UBE, NuStep, Elliptical, Free Weights
  – Time: 60 min/session

• Home Exercise Program: Walking Program

• Patient and Family Education

<table>
<thead>
<tr>
<th></th>
<th>Pre-Rehab</th>
<th>Post-Rehab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>01/24/2018</td>
<td>07/12/2018</td>
</tr>
<tr>
<td>Place</td>
<td>AGC 16</td>
<td>AGC 45</td>
</tr>
<tr>
<td>Protocol</td>
<td>naughton</td>
<td>naughton</td>
</tr>
<tr>
<td>Duration</td>
<td>2:01</td>
<td>11:01</td>
</tr>
<tr>
<td>MET Level</td>
<td>1.7</td>
<td>6.3</td>
</tr>
<tr>
<td>Rest HR</td>
<td>90</td>
<td>70</td>
</tr>
<tr>
<td>Max HR</td>
<td>111</td>
<td>130</td>
</tr>
<tr>
<td>Rest BP</td>
<td>180/100</td>
<td>144/68</td>
</tr>
<tr>
<td>Max ex BP</td>
<td>190/100</td>
<td>138/80</td>
</tr>
<tr>
<td>RPP</td>
<td>21090</td>
<td>17940</td>
</tr>
<tr>
<td>ST Changes</td>
<td>none</td>
<td>BLA, likely no significant changes</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Max HR achieved</td>
<td>Max HR achieved</td>
</tr>
<tr>
<td>Comments</td>
<td>negative</td>
<td>Likely negative maximal EST for ischemia.</td>
</tr>
</tbody>
</table>

Exercise Test Percentage Improvement: 270%

Exercise Prescription:
- THR: 90-100
- THR Changes: none
- Starting MET Level: 1
- RPE: 12-13
- Predicted DC MET Goal: 3

Exercise Class Progress:
- Avg. Starting MET: 3.5
- Avg. Recent MET: 4.5
- % Improvement: 29%

Percent of DC MET Goal Achieved:
- Predicted MET: 3
- Actual Met: 4.5
- % Achieved: 150%

Exit Ex. Prescriptions:
- THR: 110-120
- RPE: 11-14
Conclusion

• Percutaneous valve repair/replacement is a rapidly evolving field
• Numerous research trials evaluating new devices and lower risk patients
• Cardiac Rehab - need more supportive evidence
  – Standardize approach: Outcomes, Scales, Questionnaires
• Rehabilitation is safe and effective
  – Exercise Capacity: Improved 6MWT distance, Peak VO$_2$, MET Level
  – Improved Muscle Strength
  – Functional Independence
  – Frailty: Improved tests (Barthel, Katz, etc.)
  – Improved QOL
• Use rehabilitation evidence to help guide medical care
Resources

- Transcatheter Aortic Valve Replacement: Optimizing Outcomes for Health Recovery. JCRP 2018, 38:1-7
- TMVR: Continuing the Paradigm Shift in Valvular Heart Disease Therapy. JACC 2015, 66:9 1020-1022