Transcutaneous Aortic Valve Implantation (TAVI)
Percutaneous Aortic Valve Replacement (PAVR)

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Plan

1. Current treatment of Severe Calcific Aortic Stenosis

2. How CoreValve works, and some patient presentations

3. Mercy results for Core Valve TAVI in patients unsuitable for conventional surgery

   37 cases no stroke and only one death by 30d
   Entirely percutaneous.
   First in Asia Pacific at Mercy

5. MitraClip- percutaneous treatment of Mitral Regurgitation- Efficacy is non-inferior to conventional surgery and Complications much fewer
   Plan to be first in Asia Pacific
Normal and calcific aortic valves
Of patients with severe aortic stenosis who have symptoms, and who do not have valve replacement, between 50 and 80% will be dead in two years.

The standard of care for severe symptomatic aortic stenosis is surgical valve replacement.

There are many patients who are not suitable or are very high risk for surgical replacement because of comorbidities eg:

- advanced age
- renal problems
- respiratory problems
- cerebrovascular disease
- LV dysfunction
- previous heart surgery
Patients who are high risk or unsuitable for Surgical Aortic Valve Replacement have been offered balloon aortic valvuloplasty (BAV) or managed medically.
Balloon valvuloplasty
Balloon aortic valvuloplasty

- Can produce early symptomatic improvement
- Serious acute complications (10%)
- Restenosis and clinical deterioration occur in most patients within 6-12 months
  - 1-yr survival in the order of 55%
  - 3-yr survival - 23%
  
  Otto et al., Circulation 1994;89:642

- There is no medical therapy that prolongs life and only limited medical therapies to alleviate symptoms

Bonow et al. Circulation 2006;114:e84
The Purpose of Percutaneous Aortic Valve Replacement

- Implant an aortic valve in patients at high risk or unsuitable for surgical aortic valve replacement (SAVR)
- Less invasive and recovery is more rapid than SAVR
- Aim is to relieve symptoms, to improve quality of life and improve duration of life.
CoreValve

Nitinol self expanding frame
Leaflets made from porcine pericardium
18F (6mm) delivery
Can be repositioned before final deployment
Percutaneous (unless cut down to eg subclavian)
Sapien Edwards percutaneous aortic valve

- Stainless steel balloon expandable
- Leaflets made from bovine pericardium
- Rapid pacing needed during delivery
- 24F (8mm-becoming less)
- No repositioning during deployment
- Cutdown usually – femoral or apical
- Surgical closure usually
For those with Ilio-femoral artery disease---

1. Edwards- Trans-apical mini-thoracotomy for Edwards

2. CoreValve- Surgical cutdown to L subclavian artery
1. The downstream or ascending aortic zone orientates and secures the valve in the ascending aorta.

2. The zone with the smallest dimension holds leaflets away from coronary arteries to preserve coronary blood flow. Coronary angiography and PCI are possible.

3. Flared intra-annular zone adapts to a range of annulus sizes preventing/limiting aortic regurgitation.
CoreValve

The leaflets are made from porcine pericardium
CoreValve percutaneous aortic valve delivery system

Rotation "withdraws" sheath

6mm diameter end constrains the self-expanding valve

4 mm Shaft
With the device across the diseased valve, the sheath is withdrawn (black arrow) so that the self-expanding frame is no longer constrained and can open up (white arrow).
CoreValve percutaneous aortic valve

As of May 2010 there have now been > 10,000 CoreValve Implants world wide!

When we began <2 yrs ago there had been 1500

Growth is exponential
FiCoreValve patients at Mercy Hospital

Supported by the Auckland Heart Group Charitable Trust
Mercy Registry Cases – High risk or unsuitable for surgical AVR

- August 08- May 10, 35 patients (+2 not registry eligible)
- Mean age 85 years (44-96 yr)
- Symptomatic Class III/IV 33/35
- Mean Logistic Euroscore 23.46% (7.42-52.33)
Mercy Experience- Echo Characteristics

► Severe AS –
  - peak aortic velocity: 4.5 ± 1 m/s (3.8-5.5)
  - peak gradient: 83 ± 49 mmHg (38-132)
  - mean gradient: 51 ± 34 mmHg (31-85)

► AVA: 0.6± 0.7 cm² (0.4-1.3)

► LV EF: 53% (range 30-75%)
<table>
<thead>
<tr>
<th>Mercy Procedural Data</th>
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<tbody>
<tr>
<td>• Light General Anaesthesia</td>
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<tr>
<td>• Percutaneous closure</td>
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<tr>
<td>• Post-procedural gradient</td>
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<tr>
<td>• Post-procedural AR ( \leq ) grade 2</td>
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<tr>
<td>• Procedure time, mins, mean (range)</td>
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<td>• ICU</td>
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<td>• Post-procedural days in hospital</td>
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Mercy Experience- Morbidity

- Transfusion: 16/35 (46%)
- Stroke/TIA: NIL
- Renal function deterioration: Nil
- Pacemaker after: 9/35 (26%)
Mercy Experience Mortality

• Death by 30 days __________________ 1/37

• Significant symptomatic improvement ___31/35

• Discharge medication includes
  aspirin (and clopidogrel)
  warfarin if in atrial fibrillation
Mrs JM 89 yo female First PAVR in Asia Pacific

Critical AS
Recent heart failure
Previous CVA
Not frail
Mild bilateral carotid stenoses
Did not want surgery.
Euroscore 32

Multidisciplinary meeting minutes

“JM 89 yo female
Recent heart failure, critical AS. Previous CVA. Mild bilateral carotid stenoses. Does not want surgery.
Euroscore 32
Unanimous agreement - percutaneous AVR appropriate”
Balloon valvuloplasty before CoreValve insertion
CoreValve advances up descending thoracic aorta
CoreValve advances across native aortic valve
Aortogram to check position
Sheath withdrawal begins and inflow portion of nitinol frame begins to expand.
Further sheath withdrawal with further frame expansion
Gradient across the aortic valve before and after CoreValve implantation

Before P-P gradient 70 mm Hg

After P-P gradient 0 mm Hg
This patient was the first in Asia Pacific to have a percutaneous aortic valve replacement. She has had a dramatic improvement in symptoms.
Ms O’C
Ms O’C

- 76 yr old
- In 2000, she had surgical replacement of her calcified stenotic native aortic valve with a size 21 Carpentier Edwards bovine pericardial prosthesis
- Fragile aorta and pericardial patch to aortotomy site
- COPD FEV1/FVC 0.73/1.32
- 2008 progressively more breathless. NT-ProBNP 145mol/L (N <35)
- Serial echo increasing AS and AR – valve area 0.8 and mod AR
- EF fell from 53% to 38%
- Euroscore 31% and STS 40%
Ms O’C. CoreValve across failed Carpentier Edwards surgical valve

- Flotation pacemaker from Jugular
- Superstiff wire looped in LV
Not fully released
Trivial AR on final angio
The gradient across the aortic valve is abolished.
1. This was 76 yr old small woman with a deteriorating Carpentier-Edwards bovine pericardial prosthesis

2. The surgeon noted a fragile aorta that needed a pericardial patch to aortotomy site at the time of initial AVR

3. COPD FEV1/FVC 0.73/1.32

4. Euroscore 31% and STS

5. PAVR was successful in-
Choice of aortic valve prosthesis may change in the future

1. Currently mechanical surgical valves are chosen for younger patients because of the risk of leaflet deterioration in surgical bioprostheses

2. A disadvantage of mechanical valves is the need for warfarin

3. The potential for replacement of a surgical bioprostheses with transcatheter valve means that some surgeons are selecting bioprostheses for younger patients when there are potential issues with eg warfarin therapy
Conclusion

- Percutaneous AVR has been introduced with good short term results in patients very high risk or unsuitable for surgery

- Only 1 death and no stroke by 30 days in 37 patients

- High incidence of pacemaker requirement

- No surgical scars, no cardiopulmonary bypass

- The procedure is expensive because valve costs nearly $40,000
Percutaneous treatment of mitral regurgitation
There is a current surgical edge-to-edge technique called the Alfieri stitch

Over 900 reported
Outcomes equivalent to standard of care surgical therapy
Applicable to both
- Structural (Degenerative) MR
- Functional MR
The anterior and posterior leaflets can be joined by a MitraClip mimicking the surgical suture.
Catheter-Based Mitral Valve Repair
MitraClip® System
The Everest II randomized trial of surgery vs MitraClip for mitral regurgitation showed that the MitraClip was

1. Non-inferior for efficacy

2. Highly significant reduction in complications

Feldman ACC 2010
The randomized trial results (Everest II) are very promising for MitraClip.

We are working at Mercy this year toward the first MitraClip in Asia Pacific.