TMVR and TMVRepair
Competition or Synergy?

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☑ I have the following potential conflicts of interest to report:

: Consultant: Edwards Lifesciences
         Medtronic Inc
         Abbott
         4Tech
         4C
         Cephea
Burden of MV disease and options

- 10% of individuals over 75 years
- Life expectancy is on rise
- Open heart surgery (repair or replacement) – <30%
- Majority managed as heart failure
Types of MV disease

- Primary MR: Spectrum
- Secondary MR
Primary MR

- Surgery is gold standard
- Some pathologies have very bulky leaflets
Secondary MR

- Disease of the ventricle
- Surgery has higher mortality
- Replacement better than Repair?
- We do not know if correcting MR in these patients improves prognosis
Two Philosophies

Repair

Replacement
## Strength and weakness

### Replacement:
- Easy to perform
- Valve sparing option
- Mechanical and Tissue option
- Future VIV option
- Negative effect on LV function
- Anticoagulation
- Longevity
- Risk of IE

### Repair:
- Skill set required
- Logevity
- Remodels LV
- Superior for degenerative MR
- Longer operation
- Durability?
- VIR option
• Transcatheter repair techniques focus on one element only:
  – annuloplasty (Internal or external)
  – Chrodae
  – Leaflets
Transcatheter Repair

1. Annulus
2. Chordae
3. Leaflet
4. Ventricle
Chordae Replacements

NeoChord (NeoChord DS1000)
Chordal repair

V-Chordal-Off Pump (Valtech)
Chordal repair

Challenges
1. Indication
2. Efficacy
3. Technical
Annular Stabilisation

1. Indication
2. Efficacy
3. Technical

Mitralign Bident (Mitralign)
Direct annuloplasty

Cardioband TF (Valtech)
Direct annuloplasty

Millipede Ring (Millipede)
Direct annuloplasty
Coronary sinus based

CARILLON (Cardiac Dimensions)
Indirect Annuloplasty

PS3 (MVRx)
Annuloplasty

Challenges
1. Indication
2. Efficacy
3. Technical
Mitraclip® (Abbott)
Evolution of Mitraclip

• History of development
  – Surgical Concept 1990
  – Transcatheter concept 1998
  – Early efforts: discontinued due to poor results
  – It has taken > 10 years to understand in which patients it may be useful

• Evidence
  – Slow to evolve
  – Yard stick: unclear i.e. how much MR reduction will be good for a given patient
  – Not without complication
  – Excludes TMVR if fails and may even exclude surgical repair

Edge to edge repair surgical

<15% of cases with complex repairs and need for quick surgery
Real world: used in L< 1-2% of cases
Challenges for repair technology

Primary MR
• Complex***
• Two technologies or more
• Cost
• Durability
• Competition: surgery

Secondary MR
• Durability
• Competition: TMVR
Conclusions TMVRepair

- Safety profile is best
- Increasing experience will help identify best indication
- Reduction vs elimination: unclear
- Combination of technologies vs single
- Can we perform additional procedures if it fails?
Design Goals for TMVR

- Complete elimination of MR
- Minimize risk of LVOT obstruction
- Minimize risk of paravalvular leak
- Address wide range of patient sizes
- Durability

- Ease of implant
- Trans-septal
Mitral Valve Anatomy
Anatomically & Physiologically Challenging

Highly mobile over cardiac cycle
Very little to “hold on to”
LVOT sensitive to obstruction
High closing pressures
It’s not one disease
Challenges with designing a TMVR device

• Device: Complex and large structure
• Leaflets: material, performance
• Frame
  – Multiple components
  – Effect of crimping
  – Mitral annular and LV pressure loops
  – Interaction with blood elements
TMVR landscape

- Braile Biomedica
- Braile Biomedica
- CardiAQ 1st G
- CardiAQ Edwards
- Cephea
- Direct Flow Medical
- Twelve Medtronic
- M-Valve
- Edwards Fortis
- HighLife
- Navigate
- Neovasc Tiara
- PermaValve MID
- Sinomed
- Tendyne Abbott

Others: MitraHeal, Mitrassist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo
TMVR timeline – First in Man

- Neovasc Tiara (February)
- CardiAQ (May)
- Twelve (November)
- CardiAQ (June)
- Caisson (June)

- 2012
- 2014
- 2015
- 2016

- CardiAQ (June)
- Edwards Fortis (March)
- Tendyne (October)
- Navigate (November)
- HighLife (January)
Edwards CardiAQ

MULTIPLE ACCESS ROUTE
  TA or TF

POSITIONING & CONTROL
  Sits higher in the atrium
  Minimal LVOTO

ANCHORING
  • Unique frame designed for annular attachment without radial force
  • Preserves chords and uses native leaflets
NeoVasc - Tiara Valve

“D” shape Design
1. Help minimize PVL,
2. Avoid LVOT obstruction and
3. Avoid impingement on the aortic valve
The Edwards Fortis TMVR

- Bovine pericardial tissue
- Anti-calcification - GLX
- Self-expanding
- Unique anchoring
- At present one size – 29
Tendyne

Tendyne Device
- D-Shaped
- Self-Expanding Nitinol Frame
- Porcine Pericardial Tri-Leaflet Valve
- Left Ventricular Tether to Apex
- Fully Repositionable and Retrievable Mitral Valve
- Multiple sizes
Highlife
Caisson: 2 steps
Patient background

- 63 yo female, 172 cm, 75 kg
- FMR, grade 4+
- NYHA Class III
- LVEF: 23%

Cardiac history
- Prior aortic valve replacement (19mm Perimount) with moderate stenosis
- Porcelain aorta
- CABG
- Moderate tricuspid regurgitation

Medical history
- Hypertension
- STS score: 2.5% mortality
- Euroscore II: 9.1%
1. Conformable Outer Stent engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy
2. Circular Inner Stent houses a 27 mm tricuspid bovine pericardium valve
Medtronic Intrepid TMVR
Hydraulic Deployment of Self-Expanding Stent

Step 1. Advance across valve
Step 2. Deploy brim
Step 3. Retract to desired position
Step 4. Expand fixation ring
Step 5. Release
Annulus sizing

• 50 mm implant
• 25% diameter oversizing
  – 22% perimeter oversizing
  – 13% CC compression
• Patent LVOT
LVOT & LV assessment
Deployment
Result

- Accurate placement
- Good valve function
  
  Trace tripoint leak
  
  Mean MV gradient: 3 mmHg
- Good paravalvular sealing
Result

- Implant conformed to the anatomy
• Patent LVOT
  – Mean LVOT gradient: 2 mmHg
Procedure Time

• Apical access (puncture to closure): 23 min
• Placement (insertion to final deployment): 12 min
• Rapid pacing for full deployment: 30 sec
• Skin-to-skin: 114 min
One year

- Stable position
- Good valve function
  - Mean MV gradient: 7 mmHg
- No paravalvular leak
Long-Term Survival (n=50)

Blue = surviving patients
Gray = deceased (n=11)

Days Post Index Procedure
1-Year Survival

- Survival rate: 76.5% (61.4 – 86.3)
- Number at risk: 50, 41, 21, 10

Graph showing the survival rate over 12 months after TMVR.
New York Heart Association Classification

- Baseline (n=50):
  - NYHA I: 16.0%
  - NYHA II: 70.0%
  - NYHA III: 14.0%
- 30 Days (n=42):
  - NYHA I: 2.4%
  - NYHA II: 54.8%
  - NYHA III: 21.4%
- Last Follow-Up (n=43, Median 173 days):
  - NYHA I: 20.9%
  - NYHA II: 34.9%
  - NYHA III: 44.2%

79% NYHA I or II in follow-up
Data Summary (n=50)

- Device implant success in 48/49 (98%)
- 30-day mortality = 14%
  - 3 from apical bleeding, 3 from CHF, 1 from malposition
- One-year survival = 77%
  - 3 SCDs in patients with low EF and no ICDs
  - No death after 180 days
- No device malfunction, hemolysis, or thrombosis
- No or mild MR in all survivors
- 79% of patients in NYHA class I or II in follow-up
Screen failures

LV cavity size
Apical thickness

Thinned out Apex
< 5mm
Left Atrial Thrombus
TMVR lessons learnt

• High screen failure rate
• Mortality is higher than repair options
• Trans-apical
• Anticoagulation is must
• More than one device design may be required to address spectrum of pathologies
Technology vs Technique

• One for all vs Many for one

• Skill levels required for single vs multiple technologies

• Procedure duration

• Cost
TMVR and TMVr are Complimentary

Choice

- Pathology
- Safety Profile
- Expertise
- Life expectancy