Get Ready for Percutaneous Mitral Valve Approaches

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HOPE – Unmet Need:
There are patients with severe MR who need something done and are too high risk for surgery

HYPE – Wall Street Mentality:
There are not millions of these patients, and we are not yet sure who benefits and who does not
Four Transcatheter Approaches

- Edge-to-edge clip (Alfieri-type) repair (MitraClip FDA approved)
- Annuloplasty
- Chordal replacement
- Mitral valve replacement (TMVR)

Transcatheter Mitral Valve Repair
MitraClip® System
MitraClip Worldwide Experience

- >52,000 Patients
- Implant Rate: 97%

Etiology
- FMR 64%
- DMR 22%
- Mixed 14%

MitraClip is Good but there are Issues

- Failure to eliminate MR
  - Is moderate (2+) good enough?
  - Residual severe (3-4+) in 5-10% of patients
- Late recurrence of MR
  - Reduces option for surgical repair
- Mitral stenosis
  - MPG < 5 mmHg in cath lab can be worse when patient is ambulatory
Transcatheter Annuloplasty
Carillon Device

Carillon Pivotal FDA IDE Trial

• 400 patient trial in 50 sites in US, Canada, Europe and Australia
• Blinded, sham-controlled
• 2:1 randomization
• Co-Primary Efficacy Endpoints
  • 1st Primary endpoint: Hierarchical Endpoint
    • Death, Heart Failure, 6 minute walk-test at 12 months
  • 2nd Co-Primary Efficacy Endpoint
    • Reduction in Regurgitant Volume at 12 months in treatment group compared to control group
Transcatheter Mitral Annuloplasty in Chronic Functional Mitral Regurgitation

6-Month Results With the Cardioband Percutaneous Mitral Repair System

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Cardioband is a Transfemoral Adjustable Ring

Surgery

Cardioband
Caveat: MR Recurrence after Complete Ring Annuloplasty in CTSN Severe MR Trial

Recurrence of Moderate or Severe MR

Secondary (functional) MR is a Disease of the LV; not the mitral annulus!

Chord Replacement
NeoChord Pivotal Trial

- 440 randomized pts, plus roll-in patients
- 20 sites
- Co-PIs – David Adams/Michael Borger
- Primary effectiveness endpoint – freedom from mod/sev MR at 1 year and freedom from mitral valve replacement or reintervention
- Primary safety endpoint – freedom from death, stroke, MAE (MVARC def) at 30 days
Severe MR

NeoChord Device - Grasp
Neochords Attached

Final Result
Chord Replacement: Caveats

- Still a thoracotomy; needs to become transfemoral, transseptal
- Benefit of off-pump not clear in CABG trials
- MVR often done minimally invasively now
- Early European results show late recurrence of MR (learning curve?)

Transcatheter Mitral Valve Replacement (TMVR)

- In light of CTSN trials, TMVR offers potentially lower risk option for valve replacement
- Technically more challenging than TAVR
  - Mitral annulus geometry
  - Larger orifice area
- Multiple devices under development
  - Transapical easier; EFS nearly done, pivotal startup
  - Transfemoral already starting
Anatomical Assessment for TMVI Eligibility and Device Sizing

**3D ANNULAR SEGMENTATION (CT/3D TEE)**

- Aortic cusps
- Aortomitral continuity
- Left atrial appendage
- Lateral trileg
- Medial trileg
- Posterior annulus
- AML
- PML

**Pertinent Annular Measurements**

- Annular area
- Perimeter
- SL-Distance
- IC-Distance

**Device Size**

**DEVICE SIMULATION FOR LVOT OBSTRUCTION PREDICTION (CT)**

- Embedded geometry in CT data set
- Trajectory determines device orientation
- Quantification of Neo-LVOT area
- Risk of LVOT Obstruction: low/high

Simulated device

**2D MA PLANE + MA TRAJECTORY (CT)**

- MA Plane
- MA Trajectory

**LANDING ZONE CHARACTERISTICS (CT/2D AND 3D TEE)**

- Annular calcification
- MVP/mitral annular disjunction
- Myocardial shelf
- Leaflet length
- Directly inserting papillary muscles

Adequate Landing Zone: yes/no

**FIGURE 10 Prediction of Neo-LVOT Dimensions**

- 3-chamber View
- Commisural View
- Short-axis LVOT View

A

B

C

D

E

F
Less invasive always wins!

TMVR Devices in Human Trials

- Tendyne
- Twelve
- CardiaQ
- Cephea
- Neovasc Tiara
- MValve
Different Designs for the Same Thing

Over time, TMVR devices will get smaller and better!

Finger at LV Apex
Wire in LUPV – Balloon to LA

32F Sheath in LA – What’s Wrong?
Device Extruding from Sheath

Device Rotated to Curtain
Device Seated

No PVL
Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation

A Global Feasibility Trial

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on behalf of the Terdyne Global Feasibility Trial Investigators

0/30 cardiovascular deaths at 30 days
1/3 (3.3%) noncardiovascular death (Hosp acq pneumonia)
0/30 strokes
0/30 acute MIs
Tendyne 30-Day Results

**Central Illustration**: Change in Mitral Regurgitation and LV Volumes After TMVR

- **A. Change in mitral regurgitation (MR) with TMVR**
  - MR severity
  - Baseline: 100%
  - 30 Days: 0%
  - $p<0.001$

- **B. Left ventricular end-diastolic volume index at baseline and after TMVR**
  - LV End-Diastolic Volume Index (mL/m²)
  - Baseline: 90.3
  - Day 30: 72.1
  - $p=0.0012$

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Device Thrombosis

- **One month post TMVR**
  - INR 1.1
  - Mean gradient 10 mmHg

- **Three months post TMVR**
  - INR 4.0
  - Mean gradient 2 mmHg
TMVR Devices

- Multiple device designs resemble surgical bioprosthetic valves
- Differences in leaflet tissue
  - Porcine vs bovine pericardium
- Differences in anchoring
  - Apical tether, annular fixation, leaflet clips, other
- First-in-human trials underway in Europe, Asia, United States

Profile Can Be Very Large
Challenges

- Mitral anatomy/function complex
- Mitral annular calcium
- Large device profiles
- Delivery systems large, mostly transapical
- LVOT obstruction / SAM
- Anchoring
- Paravalvular MR / hemolysis
- Device thrombosis
- Device-specific imaging needs

Multidisciplinary Mitral Valve Clinic
Thank you!