Percutaneous Mitral Therapies

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Transcatheter therapy in pts with MR..... REALLY?

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AHA
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Disclosure

• Research Support/Grants: Edwards Lifesciences

• Consulting / Employment: Medtronic

• Stock Equity or Options: Direct Flow Medical

• Other Relationships: Proctor for Edwards Lifesciences
COI

- Medtronic: consultant
- DirectFlow Medical: consultant; equity
- QuantumCor; SAB
- Edwards Lifesciences; PARTNER site
A rose is a rose, is a rose

But..........

MR is not MR is not MR
(structural / ischemic / cardiomyopathic)
Structural MR (prolapse) — a valvar problem

Ischemic & Cardiomyopathy MR — a ventricular problem
Survival at 10 yrs --92% 
Freedom from reoperation - 93%
Freedom from recurrent moderate or severe MR at 10 yrs 80%
15-year survival 76%, superior to the age- and sex-matched US population.
Hospital deaths (0.07%)
10 yr freedom from mitral reoperation --97% --
77% had no or 1+ MR; 11% had 3+ or 4+
Surgery Sets a High Bar for Structural (prolapse) Disease Outcomes
BUT WHAT ABOUT ISCHEMIC AND FUNCTIONAL MR?
How Good is Surgery for Ischemic MR?

Operative mortality — ~7-15%

3 yr survival ~ 60-80%

Recurrent MR in at least 1/3 of pts.

Recurrent MR and poor LVEF predict poor outcome
More answers coming soon:

Two current NIH surgical trials: both for ISCHEMIC MR

1. Moderate Ischemic MR Trial
   CABG vs MV repair + CABG
   end point 1 yr (F/U not done)

   Does MVR with CABG make a difference? (Prob not but pts feel better)

2. Severe Ischemic MR trial
   MV repair +/- CABG vs MVR
   enrollment complete (?AHA results)

   Is MV repair with CABG better than MVR? (prob no difference)
Moving on to transcatheter possibilities

Micardia

Valtech

Accucinch

enCor

Mitralign
The somewhat mixed EVEREST II message

MitraClip is safer than surgery
MR reduction not as good
Long term outcomes
...........still unknown
So...........
Where does that leave the MitraClip?
EVEREST was designed for pts with mitral valve prolapse but also included……..

Patients with pre-existing LV Dysfunction and Functional Mitral Regurgitation (FMR)
MitraClip Decreases Hospital Admissions for CHF

Clip Improves NYHA and QOL

Clip Reverses LV Remodeling

MR

EVEREST Functional MR High Risk Registry

Summary

Maybe reduction of MR to 2+ or less is enough to improve outcomes in selected pts

Based on this MitraClip gets FDA approval for high risk pts
Given the data available, & now with FDA approval -------------- which patients are best treated with the MitraClip?

The Real (European) World of Mitral Repair
Clinical outcomes of Mitraclip therapy in pts not amenable to surgery
Rudolph ; JACC 2011(German experience)
Take Home Message
For perc repair MR:

- Mitraclip helps selected pts with structural MR……and some with functional MR
- LOTS of pts with functional MR might benefit with Clip treatment…………

We need a trial.
COAPT
North American trial

420 high risk CHF pts with FMR
Randomized to medical Rx
Primary endpoint – HF hospitalization rate
Who will be chosen???
Functional MR 3-4+ (central A2-P2) in symptomatic pts at surgical risk STS>8, on OMT, EF>20, or high stroke/op risk
RESHAPE-HF European Trial

Commercial post market
80 FMR pts with severe CHF
Randomized to medical Rx
Primary endpoint = HF hospitalization and death (composite)
Enrollment beginning
But wait...... There's more!

Forecasting what is & might be hot (or cold)
CS approaches

growing ... growing ...

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<th>Monarc:</th>
<th>Viacor:</th>
<th>Carillon:</th>
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<tbody>
<tr>
<td>Implanted</td>
<td>59/69(86%) pts implanted</td>
<td>21/26(84%) pts implanted</td>
<td>24/29 (83%) pts implanted</td>
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<tr>
<td>Reduced MR</td>
<td>60% have reduced MR</td>
<td>44% able to reduce MR</td>
<td>63% able to reduce MR</td>
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Summary: about 80% of pts chosen can be implanted: of those about ½ get a 1-1.5+ reduction of MR
Innovation is alive and well in 2013

Leaflet Solutions
Evalve
Neochord
Cardiosolutions
Middle Peak

Annular Solutions
Mitralign
Guided Delivery Systems
QuantumCor
Valtech
Millipede
Accucinch
NeoChord successful live case performed at EACTS. Nov. 5, 2013

TACT Trial
(Transapical Artificial Chordae Tendinae)

Success Rate by Neochords Deployed

TACT Trial: 12 Mo. Results
MR ≤ 2+

Unsuccessful
Successful

Patients 1 - 15
Patients 16 - 30
Summary: TACT Trial
(Transapical, off-pump artificial chordae)

Acute procedural success 47/52 = 90%

30 Day MR <2+ 74% of acute successes

MR @ 1 yr similar to 30 day results

Average procedure time ~ 2 hrs
Helping vets save pets

MitraSpacer: collaborative effort between Colorado State Univ. and Avalon Medical.

“Finishing research in experimental animals...”
Posterior annuloplasty devices
(Mitralign, Accucinch, Micardia Valtech, et al.)

Will they succeed? — surgical experience (-)
“Those who do not read history are bound…”
Innovation is alive and well in 2013.

**Leaflet Solutions**
- Evalve
- Neochord
- Cardiosolutions
- Middle Peak

**Annular Solutions**
- Mitralign
- Guided Delivery Systems
- QuantumCor
- Valtech
- Millipede
- Accucinch
Valtech
Transseptal mitral cinching ring

Cases (~15) already underway in Europe

Promising results short term so far
..& if it does not work long term?

Tissue ingrowth = inflammation
= Ca++ =

a great landing zone for TMVR
Adjustable Posterior ventricular support device (At CABG)

The “BACE” Concept
Do I see MVR?
Mitral valve is larger.
Ao diameter ~ 23-29mm: mitral ~ 40mm.
Implications for delivery (more material to compress, larger catheter sizes) and durability (larger valve means greater sheer stresses and higher pressure differentials).

Access more complicated (requiring either a venous/transseptal approach or a TA or transatrial approach)
But it boils down to anchoring

No Ca++ to secure the valve: need anchor

ALSO:
Aortic valve tends to be circular with an annular plane
mitral valve saddle-shaped annulus with an irregular, D-shaped orifice.

PVL is not tolerated on the mitral side.

Must be low profile to prevent
a) interaction with the aortic valve (AS or AR)
b) damaging the subvalvar apparatus.
CardiAQ prosthesis (CardiAQ Valve Technologies, Winchester, MA). 1st in man June 2012

Device implanted “on pump”

Pt death: day 3 (?cirrhosis /multi-organ failure/ bowel infarct?)

No further implant to date: Gen 2 in place
Tendyne Valve

- Nitinol Stent Frame with porcine pericardium
- Left ventricular apical tether
- Controlled deployment
- Requires no rapid pacing or CPB support
- Fully retrievable and repositionable

Human Implant

Ventriculogram Post Procedure

Baseline

Post Tendyne
Mitral Valved Stent

- bioprosthetic valve
- ventricular body
- atrial crown

Transapical implantation: off-pump

- Ao
- MV
- LVOT
- LV
Transseptal Endo valve
Currently “on hold”: animal studies to be cont’d as company prioritizes
81% of test animals successfully implanted. Procedure times ranging from 17 to 26 min. No obstruction of LV outflow tract, No transvalvular gradients. No significant paravalvular leak. Echo at 3 mos after implant demonstrated continuing good function and integrity of the valve. Chronic animal studies are ongoing.
Lutter valve
nitinol self-expandable
valved stent

Lutter valve in swine : JTCVS2010

Trileaflet bioprosthesis contains atrial and ventricular fixation systems.

Eight pigs underwent TEE-guided transapical implantation through a mini-sternotomy.

Gradient across LVOT was not affected.

Average animal survival was 7.3 days (8 hours to 29 days).

Animals that died before 1 week (n = 4) had valved stent malpositioning. Animals that survived 1 week or more had accurate deployment and only trace post-deployment paravalvular leak. The causes of death in this latter group were endocarditis (n = 1), failure of atrial fixation (n = 2), and failure of ventricular fixation (n = 1). There was no valve embolization in any of the animals.
Medtronic Transcatheter Mitral Valve Replacement

- Design Priorities & Status:
  - Preserve native mitral apparatus
  - Self expanding Nitinol scaffold
  - Bovine pericardium
  - Valve with 3 cusps
  - Large, flexible inlet conforms to anatomy
  - Support arms capture and cover native leaflets, preventing LVOT obstruction
  - Minimal extension into LV
  - Acute animals complete. Chronic animals ongoing.
What TMVR must do:

Deliver implant transseptally or transapically
Deploy implant in proper position
Securely anchor implant
Ensure proper hemodynamics
Avoid LVOT obstruction
Avoid conduction system issues
Preserve subvalvar apparatus
Have no PVL/residual MR

4 keys: delivery, fixation, residual MR, SAM
The step by step path to Transcatheter Mitral Valve Replacement
Here & Now….. or Here and Not Now?

1931 → 1937
TMVR

Not quite here........

But stay tuned