Choosing the Right Treatment for Primary Mitral Regurgitation

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Mitral Regurgitation

• Very common disease
• Variety of etiologies (degenerative, ischemic/functional, rheumatic, endocarditis etc)
• Many therapies available
Too Many Choices!!
What is the **Ideal** Treatment?

- Improves Survival / Life Expectancy
- Improves Quality of Life and Symptoms
- Durable Repair – Doesn’t require re-repair in future
- ZERO residual mitral regurgitation
- Can treat a variety of pathologies
- Minimal Procedural Complications
- LONG-TERM DATA AVAILABLE
One Size Fits All?
Or “Sur Mesure” / Custom-Made?
Therapies We Will Discuss:

- Surgical Mitral Repair (Sternotomy or Thoracoscopic)
- Mitraclip
- Neochord device
- Transcatheter Repair Devices (in Development)
- Transcatheter Replacement (in Development)
Surgical Mitral Repair
Surgical Mitral Repair – Improved Survival

- AL-MVP: 87±2% Repair, 63±5% Replacement
- PL-MVP: 85±2% Repair, 70±3% Replacement

Survival (%) vs. Years after surgery

Repair: 251, 161, 36, 5, 428, 304, 106, 22
MVR: 150, 103, 55, 15

Surgery for Valvular Heart Disease

Very Long-Term Survival and Durability of Mitral Valve Repair for Mitral Valve Prolapse

Dania Mohy, MD; Thomas A. Orszulak, MD; Hartzell V. Schaff, MD; Jean-Francois Avierinos, MD; Jamil A. Tajik, MD; Maurice Enriquez-Sarano, MD

(Circulation 2001 104[suppl I]:I-1-I-7.)
Surgical Mitral Repair – Improves Quality of Life

Psychoemotional and Quality of Life Response to Mitral Operations in Patients With Mitral Regurgitation: A Prospective Study

Tali Bayer-Topilsky, PhD, Rakesh M. Suri, MD, DPhil, Yan Topilsky, MD, Yariv N. Marmor, PhD, Max R. Trenerry, PhD, Ryan M. Antiel, MD, Douglas W. Mahoney, MS, Hartzell V. Schaff, MD, and Maurice Enriquez-Sarano, MD
Surgical Mitral Repair – A Durable Repair

ADAMS DH, JTCVS, 2012
Surgical Mitral Repair – Treats a Variety of Pathologies

Possible Techniques Surgeons Can Use:

- Triangular Resection, Quadrangular Resection, Cleft Closure
- Annuloplasty Ring, Commisuroplasty, Neochordae
- Papillary muscle sliding plasty, Papillary muscle shortening
- Chordal Transposition, Chordal Shortening
Surgical Mitral Repair – Minimal Procedural Complications

- 0.8% Mortality
- 0.5% Stroke
- 0.7% Renal Failure
- 0.9% Re-exploration for Bleeding
- 1.1% Infection
Surgical Mitral Repair – Long Term Data Available?

From 1958 through 1980, 131 patients had repair of ruptured chordae tendineae of the mitral valve; 62% were men. Ages ranged from 5 to 70 years (median 57). Chordae to the anterior mitral leaflet were ruptured in 44 patients (34%), to the posterior mitral leaflet in 85 (65%), and to both leaflets in two patients (1%). The mitral valve was repaired by leaflet plication without resection in 116 patients, plication after wedge resection of the unsupported leaflet in six, Ivalon sponge buttress of the posterior leaflet in three, resuspension of chordae in two, and annuloplasty alone in the remaining four. Mitral valve annuloplasty was performed in addition to leaflet repair in 115 patients (88%). Operative (less than 30 days) mortality was 6.1%. Survival rate of patients dismissed from the hospital was 92% at 5 years and 73% at 10 years. There were no differences in late survival or risk of reoperation for recurrent or residual mitral insufficiency between patients with ruptured chordae to the anterior leaflet and those with ruptured chordae to the posterior leaflet. Survival was significantly better for the group with repair than it was for a group that underwent mitral valve replacement for ruptured chordae during this same time interval (5 year survival rate, 92% versus 72%, p less than 0.003). The incidence of thromboembolism after repair was 1.8 episodes/100 patient-years compared with 8.0 episodes/100 patient-years after replacement. Our data indicate that valvuloplasty is the procedure of choice for most patients with mitral regurgitation owing to ruptured chordae tendineae, including selected patients with ruptured chordae to the anterior leaflet.
Thoracoscopic Mitral Repair
Thoracoscopic Mitral Repair – Compared to Open Surgery

- No difference in mortality rate at 9-year follow-up
- Slightly less bleeding, afib, return to work time
- Slightly more stroke (2.1% vs 1.2%), groin infection (2% vs 0%), CPB time, Procedure Time
- Surgeon-dependent for outcomes! Both Sternotomy and Thoracoscopic can provide good results in the right hands.
MitraClip
MitraClip – Improved Survival?

From the Abbott Company website “No benefit on how long a patient survives following MitraClip therapy has been demonstrated.”
MitraClip – Durable Repair?

C. Freedom From MV Surgery or Reoperation

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation
5-Year Results of EVEREST II
MitraClip – Procedural Complications

Initial Experience With Commercial Transcatheter Mitral Valve Repair in the United States

Paul Sorajja, MD, Michael Mack, MD, Sreekanth Vemulapalli, MD, David R. Holmes, Jr, MD, Amanda Stebbins, MS, Saibal Kar, MD, D. Scott Lim, MD, Vinod Thourani, MD, Patrick McCarthy, MD, Samir Kapadia, MD, Paul Grayburn, MD, Wesley A. Pedersen, MD, Gorav Ailawadi, MD
MitraClip – Can It Treat a Variety of Pathologies?

• No! In major series there is around a 10% failure to implant rate, even when the case has been preselected to be a “Good” case.
MitraClip – New Data Emerging

- COAPT: SHOWED A BENEFIT
- MITRA-FR: SHOWED NO BENEFIT
- RESHAPE: COMING OUT SOON
Neochord Device
Neochord Simulator
Neochord Device

- The largest series so far, 213 patients from year 2013-2016
- Only one year of follow-up available
- Patients who had to have Sternotomy Mitral Surgery: 4 at time of surgery, 1 before discharge, 3 more at 30 days, 7 more at 6 months, 5 more at 1 year (total of 20/213 = 9.3%).
25% of patients have 2+ or more regurgitation by the 12 month period!
Neochord Device – Useful For All Types of Mitral Pathology?

- **No!** From the Company: Only for patients with ISOLATED posterior leaflet prolapse and NO annular dilation.
Does Neochord Device Seem Ideal?

• Improves Survival / Life Expectancy: NO!
• Improves Quality of Life and Symptoms: Yes
• Durable Repair –Doesn’t require re-repair in future: NO!
• ZERO residual mitral regurgitation: NO!
• Can treat a variety of pathologies: NO!
• Minimal Procedural Complications: Yes
• Long-Term Data Available: NO!
Transcatheter Mitral Repair Devices – In Development

Transcatheter MV Repair: Device Landscape 2018

Edge-to-edge
- Abbott MitraClip
- Edwards Pascal
- MitraFlex

Direct and indirect annuloplasty
- CDI Carillon
- Mitralign TAMR
- Edwards Cardioband
- Ancora Heart Accucinch
- Millipede IRIS
- MVRx Arto
- Mardil VenTouch
- Mitraspan TASRA
- Valcare Amend
- Micra enCor
- MitraLoop Cerclage
- Cardiac Implants RDS
- QuantumCor (RF)
- Valfix

MV replacement
- Edwards CardiAQ
- Edwards Fortis
- Neovasc Tiara
- Abbott Tendyne
- Medtronic Intrepid
- HighLife
- Caisson
- NCSI NaviGate
- MValve
- Mitraltech CardioValve
- Cephea
- St. Jude
- Micro Interventional
- ValveXchange
- MitrAssist
- Braile Quattro
- Direct Flow
- Sinomed AccuFit
- Valcare Corona

MV replacement (cont)
- MitralHeal
- HT Consultant Saturn
- Lutter valve
- Transcatheter Technologies
- Tresillo
- Venus
- Verso
- Transmural Systems
- Saturn (InnovaxHeart)
- 4C Medical TMVR
- Other approaches
- NeoChord DS 1000
- Harpoon neochoords
- Babic chords
- Middle Peak Medical
- St. Jude leaflet plication
- Cardiosolutions Mitra-Spacer
- Mitralix
- Mitraltech Vchordal
- Coramae Mitramaze

*In patients *CE mark *FDA approved
TRANSCATHETER REPAIR
Transcatheter Mitral Replacement
Medtronic Intrepid
Medtronic Intrepid TMVR
Early Experience With New Transcatheter Mitral Valve Replacement

Vinayak Bapat, MBBS, MS, MCh, Vivek Rajagopal, MD, Christopher Meduri, MD, MPH, R. Saeid Farivar, MD, Antony Walton, MD, Stephen J. Duffy, MBBS, PhD, Robert Gooley, MBBS, PhD, Aubrey Almeida, MD, Michael J. Reardon, MD, Neal S. Kleiman, MD, Konstantinos Spargias, MD, Stratis Pattakos, MD, Martin K. Ng, MBBS, PhD, Michael Wilson, MD, David H. Adams, MD, Martin Leon, MD, Michael J. Mack, MD, Sharla Chenoweth, MS, Paul Sorajja, MD, for the Intrepid Global Pilot Study Investigators
• Radial interference, small cleats, frictional elements & tissue ingrowth
• Excellent healing response in longer term porcine and ovine studies
1. Advance into LA

2. Expand brim & align with annulus target

3. Retract to target & deploy

MEDTRONIC INTREPID™ TMVI
HYDRAULIC DEPLOYMENT OF SELF-EXPANDING STENT

Working length
~32.9cm

OD≤11.7mm / 35Fr

~19.1cm

CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE. These tests may not be indicative of clinical performance. These statements have not been evaluated by the FDA and are not intended to represent claims of human clinical performance or serve as a substitute for medical judgment.
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Today’s Conclusion