Percutaneous Mitral Valve Repair

Khalil Fattouch, MD, PhD
Honored Guest's Address

Cardiac valve surgery—the “French correction”

Alain Carpentier, M.D., Paris, France

Mr. President, I would like to begin by expressing my gratitude to the Association for the privilege of presenting the Honored Guest Lecture at the Sixty-third Annual Meeting of The American Association for Thoracic Surgery. What surprises me the most in this meeting is my presence on this podium, since this honor is usually reserved for more senior and preeminent figures in thoracic surgery. I suppose that you wanted to distinguish a team rather than a man, so that I would like to share this honor with my co-workers who are present in this room: Drs. Deloche, Fabiani, Chauvaud, Reillard, Lessana, Lapayre, Mrs. Chauveau, Mrs. Menissier, Mrs. Veneziani, and with my wife, Sophie, who has participated in my laboratory work throughout the years. I also would like to pay special tribute to my respected teacher, Professor Charles Dubost, and to mention my two colleagues, Professors Bloudeau and Claude d’Allaines, who are unfortunately not with us today.

Members of the Association, in the past 14 years, I have attended the annual meeting of your Association 14 times with the privilege of having presented a paper 10 times. All through these years, wearing a pink identification badge, I observed with great admiration and respect the famous people wearing a white printed badge and seated in a carefully delineated area of reserved seats! Permit me to tell you how proud I am to enter your prestigious circle.

Guests, you are seated outside this circle, but only temporarily! I address you specifically, since you represent the future of thoracic surgery and the future of this august Association.

Members and guests, cardiac surgery has achieved remarkable progress in the past 10 years. Safer techniques of anesthesia and postoperative care, improved extracorporeal circulation and myocardial protection, and sophisticated surgical techniques are new tools which have been instrumental in reducing hospital mortality and increasing the efficiency of our operations. New surgical tools impose new surgical goals. Its not enough to save patients’ lives; we must also take into consideration the quality of life given to the patient and the socioeconomic impact of our surgical actions. There already have been some trends in this direction, such as operating for congenital malformations at an earlier stage and the development of reconstructive operations to replace palliative techniques. Reconstructive valve surgery may very well be considered another example of this nouvelle chirurgie which justifies making it the subject of today’s lecture.

Since everything we do in life has some visible or obscure relationship to the environment in which it
Very Long-Term Results (More Than 20 Years) of Valve Repair With Carpentier’s Techniques in Nonrheumatic Mitral Valve Insufficiency

E. Braunberger, MD; A. Deloche, MD; A. Berrebi, MD; F. Abdallah, MD; J.A Celestin, MD; P. Meimoun, MD; G. Chatellier, MD; S. Chauvaud, MD; J.N. Fabiani, MD; A. Carpentier, MD

Background—Mitral valve repair is considered the gold standard in surgery of degenerative mitral valve insufficiency (MVI), but the long-term results (>20 years) are unknown.

Methods and Results—We reviewed the first 162 consecutive patients who underwent mitral valve repair between 1970 and 1984 for MVI due to nonrheumatic disease. The cause of MVI was degenerative in 146 patients (90%) and bacterial endocarditis in 16 patients (10%). MVI was isolated or, in 18 cases, associated with tricuspid insufficiency. The mean age of the 162 patients (104 men and 58 women) was 56±10 years (age range 22 to 77 years). New York Heart Association functional class was I, II, III, and IV in 2%, 39%, 52%, and 7% of patients, respectively. The mean cardiothoracic ratio was 0.58±0.07 (0.4 to 0.8), and 72 (45%) patients had atrial fibrillation. Valve analysis showed that the main mechanism of MVI was type II Carpentier’s functional classification in 152 patients. The leaflet prolapse involved the posterior leaflet in 93 patients, the anterior leaflet in 28 patients, and both leaflets in 31 patients. Surgical technique included a Carpentier’s ring annuloplasty in all cases, a valve resection in 126 patients, and shortening or transposition of chordae in 49 patients. During the first postoperative month, there were 3 deaths (1.9%) and 3 reoperations (2 valve replacements and 1 repeat repair [1.9%]). Six patients were lost to follow-up. The remaining 151 patients with mitral valve repair were followed during a median of 17 years (range 1 to 29 years; 2273 patient-years). The 20-year Kaplan-Meier survival rate was 48% (95% CI 40% to 57%), which is similar to the survival rate for a normal population with the same age structure. The 20-year rates were 19.3% (95% CI 11% to 27%) for cardiac death and 26% (95% CI 17% to 35%) for cardiac morbidity/mortality (including death from a cardiac cause, stroke, and reoperation). During the 20 years of follow-up, 7 patients were underwent surgery at 3, 7, 7, 8, 8, 10, or 12 years after the initial operation. Valve replacement was carried out in 5 patients, and repeat repair was carried out in 2 patients. At the end of the study, 65 patients remained alive (median follow-up 19 years). Their median age was 76 years (age range 41 to 95 years). All except 1 were in New York Heart Association functional class I/II.

Conclusions—Mitral valve repair using Carpentier’s technique in patients with nonrheumatic MVI provides excellent long-term results with a mortality rate similar to that of the general population and a very low incidence of reoperation. (Circulation. 2001;104[suppl I]:I-8-I-11.)
Very Long-Term Survival and Durability of Mitral Valve Repair for Mitral Valve Prolapse

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

Background—Mitral regurgitation (MR) due to mitral valve prolapse (MVP) is often treatable by surgical repair. However, the very long-term (>10-year) durability of repair in both anterior leaflet prolapse (AL-MVP) and posterior leaflet prolapse (PL-MVP) is unknown.

Methods and Results—In 917 patients (aged 65±13 years, 68% male), surgical correction of severe isolated MR due to MVP (679 repairs and 238 replacements [MVRs]) was performed between 1980 and 1995. Survival after repair was better than survival after MVR for both PL-MVP (at 15 years, 41±5% versus 31±6%, respectively; \( P = 0.0003 \)) and AL-MVP (at 14 years, 42±8% versus 31±5%, respectively; \( P = 0.003 \)). In multivariate analysis adjusting for predictors of survival, repair was independently associated with lower mortality in PL-MVP (adjusted risk ratio [RR] 0.61, 95% CI 0.44 to 0.85; \( P = 0.0034 \)) and in AL-MVP (adjusted RR 0.67, 95% CI 0.47 to 0.96; \( P = 0.028 \)). The reoperation rate was not different after repair or MVR overall (at 19 years, 20±5% for repair versus 23±5% for MVR; \( P = 0.4 \)) or separately in PL-MVP (\( P = 0.3 \)) or AL-MVP (\( P = 0.3 \)). However, the reoperation rate was higher after repair of AL-MVP than after repair of PL-MVP (at 15 years, 28±7% versus 11±3%, respectively; \( P = 0.0006 \)). From the 1980s to the 1990s, the RR of reoperation after repair of AL-MVP versus PL-MVP did not change (RR 2.5 versus 2.7, respectively; \( P = 0.58 \)), but the absolute rate of reoperation decreased similarly in PL-MVP and AL-MVP (at 10 years, from 10±3% to 5±2% and from 24±6% to 10±2%, respectively; \( P = 0.04 \)).

Conclusions—In severe MR due to MVP, mitral valve repair compared with MVR provides improved very long-term survival after surgery for both AL-MVP and PL-MVP. Reoperation is similarly required after repair or replacement but is more frequent after repair of AL-MVP. Recent improvement in long-term durability of repair suggests that it should be the preferred mode of surgical correction of MVP whether it affects anterior or posterior leaflets and is an additional incentive for early surgery of severe MR due to MVP. (Circulation. 2001;104[suppl I]:I-1-I-7.)
Euro Heart Survey: 50% symptomatic patients with severe MR are denied surgery

Isolated MR (n=877)

No Severe MR (n=331)

Severe MR (n=546)

No Symptoms (n=144)

Symptoms (n=396)

No Intervention (n=193) 49%

Intervention (n=203) 51%

Mirabel et al, European Heart J 2007;28:1358-1365
Euro Heart Survey
Results: One-year survival

Operated (222 pts)
96.3 ± 1.3%

Non-operated (174 pts)
88.2 ± 2.5%

P = 0.003

Mirabel et al, European Heart J 2007; 28, 1358-1365
## Euro Heart Survey

Factors associated with the decision not to operate

<table>
<thead>
<tr>
<th>Pre-operative variables</th>
<th>Multivariate</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF (per 10% decrease)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Aetiology Non-ischaemic</td>
<td>0.0006</td>
</tr>
<tr>
<td>Age (per 10-years increase)</td>
<td>0.001</td>
</tr>
<tr>
<td>Charlson comorbidity index (per 1 point increase)</td>
<td>0.004</td>
</tr>
<tr>
<td>Degree of MR</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Mirabel et al, European Heart J 2007; 28, 1358-1365
Treatments tend to be under-used in the patients who have the highest risk profile

NEW TECHNOLOGY IN MR COULD HELP?

Mirabel et al, European Heart J 2007; 28, 1358-1365
Transcatheter mitral interventions

- Ballon commissurotomy
- Perivalvular leak closure
- **Annular repair**
- **Leaflet repair**
- Transcatheter MVR
Transcatheter Mitral Valve Repair

Opportunity

Minimizing the risks while preserving clinical efficacy of surgical repair and replacement

Challenges

Lack of evidence and limited clinical experience
1-Leaflet repair: Mitraclip

The Alfieri technique

- CE Mark approval in March 2008 for MITRA-CLIP
1-Leaflet repair: Mitraclip

Versatility

- Functional
- Degenerative
<table>
<thead>
<tr>
<th>Randomized Controlled trial, prospective, multicentered</th>
<th>2:1 randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mitraclip with standard cardiac surgery</strong></td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>279 patients (184 Mitraclip, 85 surgery)</td>
</tr>
<tr>
<td></td>
<td>Severe MR (73% degenerative, 27% functional)</td>
</tr>
<tr>
<td>Primary end point</td>
<td>MACE – death, stroke, MI, reoperation, transfusion</td>
</tr>
<tr>
<td>Secondary end point</td>
<td>Noinferiority compared to surgery</td>
</tr>
<tr>
<td>Study group</td>
<td>178 underwent treatment</td>
</tr>
<tr>
<td>APS</td>
<td>137 (77%)</td>
</tr>
<tr>
<td>At 30 days</td>
<td>1 end point – 9.6% (study group), (57% controls) (more transfusions)</td>
</tr>
<tr>
<td>At 12 months</td>
<td>Echo – positive LV remodelling (↓ LVEDD), 81% &lt;2+MR,</td>
</tr>
<tr>
<td></td>
<td>Symptoms – NYHA I or II – 97.6% vs 87.9%</td>
</tr>
<tr>
<td>Cross over</td>
<td>21%</td>
</tr>
<tr>
<td>No events in 136 patients who underwent Mitraclip placement</td>
<td></td>
</tr>
</tbody>
</table>

*Importance in functional MR also*

*Mitraclip is noninferior to surgery 72.4% vs 87.8%*
The EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation

Five-Year Results Stratified by Degenerative And Functional Etiologies

Saibal Kar, MD, FACC
Cedars-Sinai Medical Center, Los Angeles, CA USA

On behalf of the EVEREST II Investigators
Mitral Regurgitation Grade at 5 Years

DMR

- MitraClip (N=130)
  - BL 5 Years
    - 2+ 81%
    - 3+ 4%
    - 4+ 1%
  - BL 5 Years
    - 2+ 100%
    - 3+ 0%
    - 4+ 0%

- Surgery (N=62)
  - BL 5 Years
    - 2+ 0%
    - 3+ 1%
    - 4+ 3%

FMR

- MitraClip (N=48)
  - BL 5 Years
    - 2+ 86%
    - 3+ 16%
    - 4+ 8%

- Surgery (N=18)
  - BL 5 Years
    - 2+ 86%
    - 3+ 14%

Statistical significance:
- MitraClip vs Surgery: p<0.005
- FMR: p=0.82
NYHA Functional Class at 5 Years

DMR
MitraClip (N=130) p<0.005
Surgery (N=62) p<0.005

FMR
MitraClip (N=48) p<0.05
Surgery (N=18) p=0.68

Patients (%)

BL 5 Years
N=85

BL 5 Years
N=36

P values:
p<0.005
p<0.005
p<0.05
p=0.68

Survivors with paired data:
NYHA I = 95%
NYHA II = 97%

Changing demographics

**EVEREST II** (Randomized Controlled Trial)
- 73% Standard Risk
- 27% High Risk
- 10% DMR
- 90% FMR
- 178 patients
- Implant rate – 89%

**REALISM** (Continued Access Registry)
- 53% Standard Risk
- 47% High Risk
- 54% DMR
- 46% FMR
- 571 patients
- Implant rate – 94%

**Commercial** (Europe, Canada, Asia, Australia)
- 34% Standard Risk
- 66% High Risk
- 25% DMR
- 75% FMR
- 2,472 patients
- Implant rate – 95%
Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France), Ottavio Alfieri (Chairperson) (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

ESC Committee for Practice Guidelines (CPG): Jeroen J. Bax (Chairperson) (The Netherlands), Helmut Baumgartner (Germany), Claudio Ceconi (Italy), Veronica Dean (France), Christi Deaton (UK), Robert Fagard (Belgium), Christian Funck-Brentano (France), David Hasdai (Israel), Arno Hoes (The Netherlands), Paulus Kirchhof (United Kingdom), Juhani Knuuti (Finland), Philippe Kolh (Belgium), Theresa McDonagh (UK), Cyril Moulin (France), Bogdan A. Popescu (Romania), Željko Reiner (Croatia), Udo Sechtem (Germany), Per Anton Sirnes (Norway), Michal Tendera (Poland), Adam Torbicki (Poland), Alec Vahanian (France), Stephan Windecker (Switzerland)

Document Reviewers: Bogdan A. Popescu (ESC CPG Review Coordinator) (Romania), Ludwig Von Segesser (EACTS). Review Coordinator (Switzerland), Luigi P. Badano (Italy), Matjaž Bunc (Slovenia), Marc J. Claeyss (Belgium), Niksa Drinkovic (Croatia), Gerasimos Filippatos (Greece), Gilbert Habib (France), A. Pieter Kappetein (The Netherlands), Roland Kassab (Lebanon), Gregory Y.H. Lip (UK), Neil Moat (UK), Georg Nickenig (Germany), Catherine M. Otto (USA), John Pepper, (UK), Nicolo Piazza (Germany), Petronella G. Pieper (The Netherlands), Raphael Rosenehek (Austria), Naltin Shuka (Albania), Ehud Schwammenthal (Israel), Juerg, Schwitter (Switzerland), Pilar Tornos Mas (Spain), Pedro T. Trindade (Switzerland), Thomas Walther (Germany).
European guidelines recommendation for MitraClip in FMR and DMR (IIbC)

Indication for treating MR
- Symptomatic patients despite optimal medical therapy (incl CRT). Severe MR

High risk or inoperable
- The judgement is done by a TEAM. Life expectancy should be longer then 1 year

Anatomical eligibility
- No guidelines on anatomical eligibility (EVEREST criteria?)
American guidelines recommendation for MitraClip: inoperable or high risk pts with DMR (IIbB)

- Limited Value
- Optimum Value
- Surgical Risk
- Clinical Benefit

Increasing age, comorbidities, LV dyst.

- Poor value:
  - Patient
  - Purchaser
  - Physician
1-Leaflet repair: Mitraclip

Mitra clip: Limits

- Optimal indications
- Technique is complex
- Incomplete reduction of MR
- Only early results are available
  - No MV annulus stabilization

Feldman T et al., J Am Coll Cardiol 2009;54:686-94
Current indications for MitraClip

DMR
Surgery remains the gold standard
MitraClip is a palliative therapy for inoperable/high risk pts

FMR
MitraClip is becoming an option in symptomatic patients despite optimal medical therapy (including CRT).
2- Leaflets repair
cordhal adjustment -V-chordal

Beating-heart implantation of adjustable length mitral valve chordae: acute and chronic experience in an animal model

Francesco Maisano a,*, Micaela Cioni a, Joerg Seeburger b, Volkmar Falk c, Friedrich Wilhelm Mohr b, Michael J. Mack d, Ottavio Alfieri a, Hugo Vanermen e

V-Chordal

Respect rather than resect

- Vchordal is a sutureless device for adjustable chordal repair
  - Surgical
  - Percutaneous
3-Leaflets repair
Neochord implantation
Neochord implantation

**Pro**
- Off pump correction of prolapse
- Beating heart adjustable of chordae
- Minimally invasive approach

**Con**
- Limited applicability
- Apical attachment of the neochorda
- Need for annuloplasty??
4-Transcatheter annuloplasty

- Coronary sinus remodeling
- SL dimensions cinching
- RF/Ultrasound remodeling
- External compression
- Direct annuloplasty
Transcatheter annuloplasty
Coronary sinus remodeling
Transcatheter annuloplasty

Coronary sinus remodeling

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
<th>Trial details</th>
</tr>
</thead>
<tbody>
<tr>
<td>MONARC (Edwards Lifesciences LLC)</td>
<td>Two-anchor design with chronic reshaping (6 weeks) by a foreshortening bridge</td>
<td>EVOLUTION trial (69 pts enrolled)</td>
</tr>
<tr>
<td>CARILLON (Cardiac Dimensions Inc)</td>
<td>Acute reshaping device acting in P2P3, repositionable, retrievable</td>
<td>AMADEUS trial (43 pts enrolled)</td>
</tr>
<tr>
<td>PTMA (Viacor Inc)</td>
<td>Tri-lumen catheter, reshappable, possibility of multiple long term adjustment</td>
<td>PTOLEMY (24 pts enrolled)</td>
</tr>
</tbody>
</table>
MONARC (Edwards) System
## MONARC (Edwards) System

### EVOLUTION TRIAL

<table>
<thead>
<tr>
<th>Multicenter feasibility and safety study</th>
<th></th>
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<tbody>
<tr>
<td>Europe and Canada</td>
<td></td>
</tr>
<tr>
<td>Interim 2 year follow up of 72 patients</td>
<td></td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>2+ to 4+ functional MR</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>Severe LVSD(&lt;25%), organic mitral valve disease, severe MAC, coronary sinus pacing leads.</td>
</tr>
<tr>
<td>Device implantation</td>
<td>59 patients (82%)</td>
</tr>
<tr>
<td>Venous tortuosity or unfavorable size</td>
<td>13 patients</td>
</tr>
<tr>
<td>Safety from secondary end point</td>
<td>83% (6 months), 81% @ 1 yr, 72% @ 2 yrs.</td>
</tr>
<tr>
<td>NYHA class improvement</td>
<td>2.7 to 2.0 (p=0.002)</td>
</tr>
<tr>
<td>At 2 yrs MR improvement was significant</td>
<td></td>
</tr>
<tr>
<td>Device is moderately effective</td>
<td></td>
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</table>
Carillon Mitral Contour System
Carillon Mitral Contour System

- **AMADEUS TRIAL** (Am J Cardiol 2009, 565-570)

<table>
<thead>
<tr>
<th>Device</th>
<th>CARILLON XE device</th>
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<tbody>
<tr>
<td>No.</td>
<td>48 patients</td>
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<tr>
<td>Etiology</td>
<td>Functional MR, LV systolic dysfunction</td>
</tr>
<tr>
<td>Successful implantation</td>
<td>30 patients</td>
</tr>
<tr>
<td>6 month follow up</td>
<td></td>
</tr>
<tr>
<td>Decrease in mitral annular diameter</td>
<td>4.2 to 3.78 cm, 10%</td>
</tr>
<tr>
<td>MR reduction</td>
<td>23%</td>
</tr>
<tr>
<td>NYHA class</td>
<td>2.9 to 1.8</td>
</tr>
<tr>
<td>Quality of life score</td>
<td>improved</td>
</tr>
<tr>
<td>6 minute walk test</td>
<td>307-403 meters</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>18 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>13</td>
</tr>
<tr>
<td>complications</td>
</tr>
<tr>
<td></td>
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</tbody>
</table>
Carillon Mitral Contour System

- CE approval in Europe
- TITAN trial (Eur J Heart Fail 2012, 14; 931-938)

<table>
<thead>
<tr>
<th>No.</th>
<th>53 patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>country</td>
<td>8 centers in Europe</td>
</tr>
<tr>
<td>6 months interim report</td>
<td>68% successful implantation</td>
</tr>
<tr>
<td></td>
<td>15% transient coronary impingement</td>
</tr>
<tr>
<td>MACE rate</td>
<td>1.9%</td>
</tr>
<tr>
<td>6 month follow up</td>
<td>Reduction in MR was 35%.</td>
</tr>
<tr>
<td></td>
<td>1 grade reduction in NYHA class</td>
</tr>
<tr>
<td></td>
<td>100 meter improvement in 6 min walk distance</td>
</tr>
</tbody>
</table>
PTMA (Viacor) Device

Figure 5. Viacor Device

The Viacor (Viacor, Inc., Wilmington, Massachusetts) PTMA rods (top left), access to the coronary sinus (bottom left), introduction of the rods (top right), and after full implantation of the rods (bottom right) in the coronary sinus.
PTMA (Viacor) Device

- PTOLEMY trial

Percutaneous Transvenous Mitral Annuloplasty
The PTOLEMY I trial evaluated the feasibility and safety of the PTMA device in 27 symptomatic patients with moderate-severe functional mitral regurgitation. The device was successfully implanted in only 9 patients. In these patients, there was a reduction in the degree of mitral regurgitation and a reduction in the mitral annulus septal–lateral dimension (Sack et al., 2009).

PTOLEMY II trial since 2014
2-Transcatheter annuloplasty
Coronary sinus remodeling: Limits

CS to MA separation

Relation of LCX and CS
2-Transcatheter annuloplasty

Coronary sinus remodeling: Limits

- Limited clinical experience
- Coronary sinus is often superior to annulus
- Coronary sinus often overlies LCx artery, which can lead to acute MI
- Coronary sinus does not allow for complete ring annuloplasty
- Incomplete reduction of MR
Transcatheter anuloplasty
Direct Annuloplasty

- Mitralign Direct Annuloplasty System

- Based on the concept of direct suture annuloplasty.
- Three metal anchors connected by standard suture materials.
- Anchors are placed in the mitral annulus and suture cinched to perform the annuloplasty.
- Retrograde ventricular access
- Unique translation catheter with a two pronged “bi dent” design for device delivery.
- Magnetic guiding catheter placed in the coronary sinus
- Anchors placed from the ventricular side by imaging techniques.
- Positioned below the valve at the level of each posterior leaflet scallop – deployed – connected by suture material.
- Plicating the annulus by cinching the suture.
- In clinical testing

8/5/2015
Transcatheter annuloplasty
Direct Annuloplasty
Valtech cardioband
First-in-Man Transseptal Implantation of a “Surgical-Like” Mitral Valve Annuloplasty Device for Functional Mitral Regurgitation

Undersized annuloplasty is an established first-line therapy option for functional mitral regurgitation (MR) (1). Percutaneous direct annuloplasty as a stand-alone therapy, as well as in combination with other echocardiographic (TEE) guidance. Although fluoroscopy is fundamental for device handling, 3D echocardiography efficiently guides the intervention, providing the necessary information to proceed safely and effectively. In particular, 3D echocardiography is used to identify the commissures (Figure 1, Online Video 2) and to obtain images of the delivery system angulations related to the annulus, whereas 2D imaging (with X-plane functionality) is mostly used to confirm proper location and to rule out leaflet impingement. The transseptal puncture was performed under TEE guidance aiming for an inferior approach because this enables more accurate deployment of the Cardioband. Afterward, an extra support 0.035-inch guidewire was positioned in the upper left pulmonary vein, and this was used to advance a proprietary transseptal steerable sheath. The implant delivery system was then advanced inside the sheath.
Carillon
Monarc
PTMA

LA wall
Circumflex artery
Coronary sinus
Fibrous annulus
Posterior LV wall

Valtech
mitralign
gds
Conclusions

Surgery vs Percutaneous treatment

• Surgical mitral repair can provide excellent results in most patients
• Interventional MR repair is a great opportunity for expanding current treatment options
• Percutaneous treatment are complex procedure
• We need more data
  • Only mitra clip with follow-up
1-Leaflet repair: Mitraclip

The Alfieri technique

- The surgical “edge-to-edge” technique was first described in early 1990’s (Alfieri)
- Several data are reported in the literature
  - Safe, effective, durable
  - No occurrence of mitral stenosis
- Facilitates proper leaflet coaptation
  - Degenerative - anchor flail / prolapsing leaflets
  - Functional - Coapt tethered leaflets to reduce time and force required to close valve
- Creates tissue bridge
1-Leaflet repair: Mitraclip

EVEREST Trial: Anatomic eligibility

- Sufficient leaflet tissue for mechanical coaptation
- Non-rheumatic/endocarditic valve morphology
- Anatomic considerations
  - Flail gap <10mm
  - Flail width <15mm
  - Mitral Area > 4.0cm
  - Coaptation length > 2mm

Feldman T et al., J Am Coll Cardiol 2009;54:686-94
## EVEREST I
### Endovascular Valve Edge to Edge Repair Study I

<table>
<thead>
<tr>
<th>Year</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of study</td>
<td>Phase I, Prospective, multicenter safety and feasibility trial</td>
</tr>
<tr>
<td>No. of patients</td>
<td>27</td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>Moderate to severe MR, primary MR (93%), Ischemic MR (7%)</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>Rheumatic disease, severe MAC, severe LV systolic dysfunction, severe LV cavity dilation.</td>
</tr>
<tr>
<td>Primary end point</td>
<td>Acute safety at 30 days (freedom from death, cardiac tamponade, stroke, clip detachment, septicemia, cardiac surgery for failed clip).</td>
</tr>
<tr>
<td>MACE events</td>
<td>15% (3 clip detachments), 1 stroke (&lt;34.4% required on basis of comparison with surgical data).</td>
</tr>
<tr>
<td>Successful deployment</td>
<td>24 patients (89%)</td>
</tr>
<tr>
<td>Partial clip detachment</td>
<td>3 patients</td>
</tr>
<tr>
<td>30 day follow up</td>
<td>6 patients had ≥3+ MR</td>
</tr>
<tr>
<td>At 6 months follow up</td>
<td>13 patients (48%) MR ≤ 2+</td>
</tr>
<tr>
<td>2 years</td>
<td>Mild MR, positive LV remodelling noticed.</td>
</tr>
</tbody>
</table>

*(JACC 46:2134-2140, 2005)*
## EVEREST cohort follow up

<table>
<thead>
<tr>
<th>Patients</th>
<th>79% primary MR, 21% functional MR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute procedural success (APS)</td>
<td>79 patients (74%)</td>
</tr>
<tr>
<td>Priamry end point (MR &lt; 2+, freedom from surgery, death)</td>
<td>66% patients</td>
</tr>
<tr>
<td>At discharge MR</td>
<td>77% &lt; 2+MR</td>
</tr>
<tr>
<td>At 6 months follow up</td>
<td>50 of 76 patients (66%) &lt; 2 + MR</td>
</tr>
<tr>
<td>Mitral valve surgery</td>
<td>32 patients (23 had clip placement)</td>
</tr>
<tr>
<td>For clip detachment</td>
<td>10 patients</td>
</tr>
<tr>
<td>For &gt;2+MR</td>
<td>9 patients</td>
</tr>
<tr>
<td>MV replacement</td>
<td>4 patients</td>
</tr>
<tr>
<td>8/5/2015</td>
<td>Surgical repair is feasible for up to 18 months</td>
</tr>
</tbody>
</table>

MONARC (Edwards) System

- MONARC – delayed release system of nitinol and biodegradable specers – slowly dissolved over 3-6 weeks
- Shortening intended to induce a conformational change in the coronary sinus, extending to the mitral annulus.