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Percutaneous Mitral Valve Repair

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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 priviledge of presenting the Honorod 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 proeminent figures in thoracic surgery. I suppose that you wanted to distinguish a team rather than a man, so that I would Eke to share this honor with my co-workers who are present in this room: Drs. Deloche, Fabiani, Chauvaud, Relland, Lessana, Lapeyre, 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 Blondeau 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 priviledge of having presented a paper 10 times. All through these years, wearing a pink

From Höpstul Broussais, Paris, France.

- Read at the Nixty-third Annual Moeting of The American Association for Thoracic Surgery, Atlanta, Ga., April 25-27, 1983
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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 natient 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 can very well be considered another example of this nouvelle chirargie 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

J Thorac Cardiovasc Surg 1983;86:323-37

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 (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-I-I-7.)

Euro Heart Survey: 50% symptomatic patients with severe MR are denied surgery



Mirabel et al, European Heart J 2007;28:1358-1365

Euro Heart Survey Results:One-year survival



96.3± 1.3%

Non-operated (174 pts)

88.2± 2.5%



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

Euro Heart Survey

Factors associated with the decision not to operate

Pre-operative variables	Multivariate
	р
LVEF (per 10% decrease)	0,0002
Aetiology Non-ischaemic	0,0006
Age (per 10-years increase)	0,001
Charlson comorbidity index (per 1 point increase)	0,004
Degree of MR	0,005

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

Euro Heart Survey Conclusions

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





EVEREST trial II

Randomized Controlled	trial, prospective, multicentered	2:1 randomization
	Mitraclip with standard cardiac s	urgery
No.	279 patients(184 Mitraclip,85 surgery)	
	Severe MR (73% degenerative,27%	functional)
Priamry end point	MACE - death, stroke, MI, reoperation, transfusion	
Secondary end point	Noinferiority compared to surgery	
Study group	178 underwent treatment	
APS	137 (77%)	
At 30 days	1 end point - 9.6%(study group),(57% controls)(more transfusions)	
At 12 months	Echo – positive LV remodelling (\downarrow LVEDD),81% <2+MR,	
	Symptoms - NYHA I or II - 97.6%	vs 87.9%
Cross over	21%	
No events in 136 patien	ts who underwent Mitraclip placement	
Importance in function	al MR also	
Mitraclip is noninferior	r to surgery 72.4% vs 87.8%	36

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

FMR



NYHA Functional Class at 5 Years





Changing demographics





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 lung (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)

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European guidelines reccommendation for MitraClip in FMR and DMR (IIbC)

Indication for treating MR

 Symptomatic patients despite optimal medical therapy (incl CRT). Severe MR



 The judgement is done by a TEAM. Life expectancy should be longer then 1 year

Anatomical eligibility No guidelines on anatomical eligibility (EVEREST criteria?)





2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

Circulation. published online March 3, 2014; Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231 Copyright © 2014 American Heart Association, Inc. All rights reserved. Print ISSN: 0009-7322. Online ISSN: 1524-4539 American guidelines recommendation for MitraClip : inoperable or high risk pts with DMR (IIbB)



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 chordal adjustment -V-chordal



EUROPEAN JOERNAL OF CARDIO-THORACIC SURGERY

European Journal of Cardio-thoracic Surgery 40 (2011) 840-847

www.elsevier.com/locate/ejcts

Beating-heart implantation of adjustable length mitral valve chordae: acute and chronic experience in an animal model $^{\Rightarrow,\pm\pm}$

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



3-Leaflets repair Neochord implantation



of Real Property lies







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



Transcatheter annuloplasty Coronary sinus remodeling



Transcatheter annuloplasty Coronary sinus remodeling

AV N	MONARC (Edwards Lifesciences LLC)	Two-anchor design with chronic reshaping (6weeks) by a foreshortening bridge	EVOLUTION trial (69 pts enrolled)
AN	CARILLON (Cardiac Dimensions Inc)	Acute reshaping device acting in P2P3, repositionable, retrievable	AMADEUS trial (43 pts enrolled)
Quidewire Multisumen PTMA Delivery Catheter PTMA device	PTMA (Viacor Inc)	Tri-lumen catheter, reshapable, possibility of multiple long term adjustment	PTOLEMY (24 pts enrolled)

MONARC (Edwards) System







MONARC (Edwards) System

EVOLUTION TRIAL

Multicenter feasibility and safety study	
Europe and Canada	
Interim 2 year follow up of 72 patients	
Inclusion criteria	2+ to 4+ functional MR
Exclusion criteria	Severe LVSD(<25%),organic mitral valve disease,severe MAC,coronary sinus pacing leads.
Device implantation	59 patients (82%)
Venous tortuoisity or unfavorable size	13 patients
Safety from secondary end point	83% (6 months),81% @ 1 yr,72%@ 2 yrs.
NYHA class improvement	2.7 to 2.0(p=0.002)
At 2 yrs MR improvement was significant	
Device is moderately effective	577

Carillon Mitral Contour System



Carillon Mitral Contour System

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

Device	CARILLON XE device
No.	48 patients
Etiology	Functional MR,LV systolic dysfunction
Successful implantation	30 patients
6 month follow up	
Decrease in mitral annular diameter	4.2 to 3.78 cm,10%
MR reduction	23%
NYHA class	2.9 to 1.8
Quality of life score	improved
6 minute walk test	307-403 meters
18 patients	
5	Coronary sinus related complications(n=3) Fluoroscopic equipment failure(n=2)
13	Retrieval of device after implantation (inadequate reduction in MR or coronary compromise.
complications	6 patients within 30 days of procedure
One multiorgan failure,3 MI,3 corona	ary dissection /perforation 52

Carillon Mitral Contour System

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

No.	53 patients
country	8 centers in Europe
6 months interim report	68% successful implantation
	15% transient coronary impingement
MACE rate	1.9%
6 month follow up	Reduction in MR was 35%.
	1 grade reduction in NYHA class
	100 meter improvement in 6 min walk distance

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 annuloplasty 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





Letters

TO THE EDITOR

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 standalone 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.



Circumflex artery

Carillon Monarc PTMA

Coronary sinus

Fibrous annulus

Posterior LV wall

mitralign

obs

Valtech



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
 - <u>Degenerative</u> anchor flail / prolapsing leaflets
 - <u>Functional</u> Coapt tethered leaflets to reduce time and force required to close valve
- Creates tissue bridge







1-Leaflet repair: Mitraclip EVEREST Trial: <u>Anatomic elegibility</u>

- Sufficient leaflet tissue for mechanical coaptation
- Non-rheumatic/endocarditic valve morphology
- Anatomic considerations
 - Flail gap <10mm</p>
 - Flail width <15mm</p>
 - Mitral Area <u>></u> 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

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

JACC 46:2134-2140,2005.

EVEREST cohort follow up

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

JACC 54(8):686-694,2009.

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.