Which is the best treatment option for mitral regurgitation : surgical or percutaneous ?

Claudio Moretti

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ADVANCES IN CARDIAC ARRHYTHMIAS and **GREAT INNOVATIONS IN CARDIOLOGY**
XXVII GIORNATE CARDIOLOGICHE TORINESI

European Heart Journal (2003) 24, 1231–1243

ELSEVIER

EUROPEAN SOCIETY OF CARDIOLOGY

A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

Table 2 Type of valvular heart disease

	Total population *n*=5001		Patients with intervention *n*=1269	
Native valve disease (%)	71.9		87.0	
Aortic (% native)	44.3		57.4	
Aortic stenosis (%)		33.9		46.6
Aortic regurgitation (%)		10.4		10.8
Mitral (% native)	34.3		24.3	
Mitral stenosis (%)		9.5		10.2
Mitral regurgitation (%)		24.8		14.1
Multiple (% native)	20.2		16.8	
Right (% native)	1.2		1.5	
Previous intervention (%)	28.1		13.0	
Conservative surgery (%)	18.4		28.7	
Valve replacement (%)	81.6		71.3	

ESC/EACTS GUIDELINES

SEVERE PRIMARY MITRAL REGURGITATION: INDICATIONS FOR SURGERY

	Class [a]	Level [b]	Ref [c]
Mitral valve repair should be the preferred technique when it is expected to be durable.	I	C	
Surgery is indicated in symptomatic patients with LVEF >30% and LVESD <55 mm.	I	B	127, 128
Surgery is indicated in asymptomatic patients with LV dysfunction (LVESD ≥45 mm and/or LVEF ≤60%).	I	C	
Surgery should be considered in asymptomatic patients with preserved LV function and new onset of atrial fibrillation or pulmonary hypertension (systolic pulmonary pressure at rest >50 mmHg).	IIa	C	
Surgery should be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk and flail leaflet and LVESD ≥40 mm.	IIa	C	
Surgery should be considered in patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy with high likelihood of durable repair and low comorbidity.	IIa	C	
Surgery may be considered in patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy with low likelihood of durable repair and low comorbidity.	IIb	C	
Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and: • left atrial dilatation (volume index ≥60 ml/m² BSA) and sinus rhythm, or • pulmonary hypertension on exercise (SPAP ≥60 mmHg at exercise).	IIb	C	

SEVERE PRIMARY MITRAL REGURGITATION: STRENGHT OF EVIDENCE

1536

JACC Vol. 24, No. 6
November 15, 1994:1536–43

VALVULAR HEART DISEASE

Echocardiographic Prediction of Left Ventricular Function After Correction of Mitral Regurgitation: Results and Clinical Implications

MAURICE ENRIQUEZ-SARANO, MD, FACC, A. JAMIL TAJIK, MD, FACC, HARTZELL V. SCHAFF, MD, THOMAS A. ORSZULAK, MD, MICHAEL D. McGOON, MD, FACC, KENT R. BAILEY, PhD, ROBERT L. FRYE, MD, FACC

Rochester, Minnesota

Methods. **In 266 patients undergoing correction of mitral regurgitation between 1980 and 1989, left ventricular function was echocardiographically assessed preoperatively (within 6 months) and postoperatively (within 1 year).**

Selecting Patients With Mitral Regurgitation and Left Ventricular Dysfunction for Isolated Mitral Valve Surgery

Constance K. Haan, MD, Cristina I. Cabral, MD, Donald A. Conetta, MD, Laura P. Coombs, PhD, and Fred H. Edwards, MD

Divisions of Cardiothoracic Surgery and Cardiology, University of Florida, Jacksonville, Florida, and The Outcomes Research and Assessment Group, Duke Clinical Research Institute, Durham, North Carolina

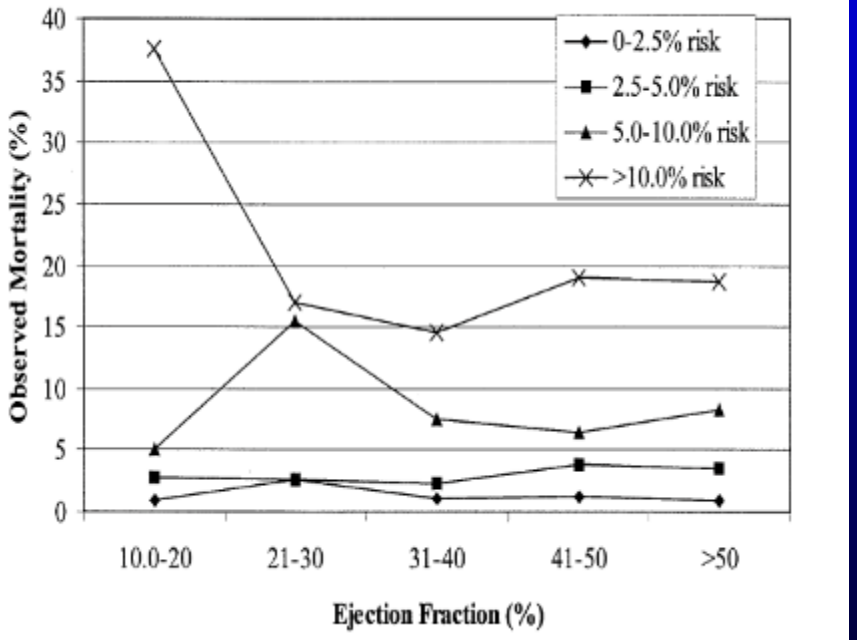
Methods. We queried the Society of Thoracic Surgeons (STS) National Database to identify patients who had isolated mitral valve replacement or repair for MR between 1998 and 2001. Mortality and morbidity outcomes were compared by EF category (≤ 30% vs > 30%), and observed mortality compared by EF group, stratified by predicted risk for mortality. A classification and regres-

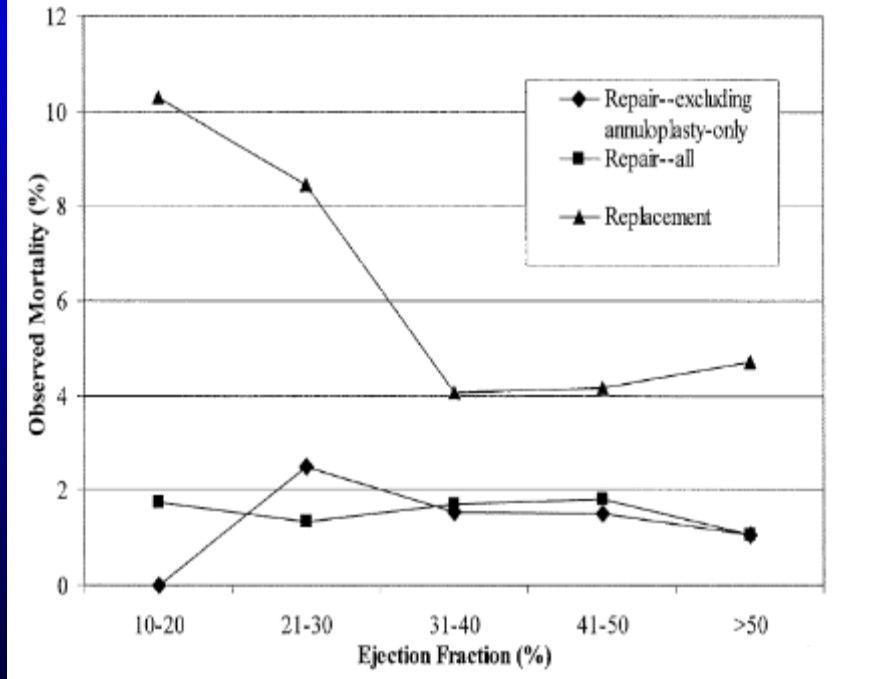
Selecting Patients With Mitral Regurgitation and Left Ventricular Dysfunction for Isolated Mitral Valve Surgery

Constance K. Haan, MD, Cristina I. Cabral, MD, Donald A. Conetta, MD, Laura P. Coombs, PhD, and Fred H. Edwards, MD

Divisions of Cardiothoracic Surgery and Cardiology, University of Florida, Ja
Assessment Group, Duke Clinical Research Institute, Durham, North Carolir

(Ann Thorac Surg 2004;78:820–5)





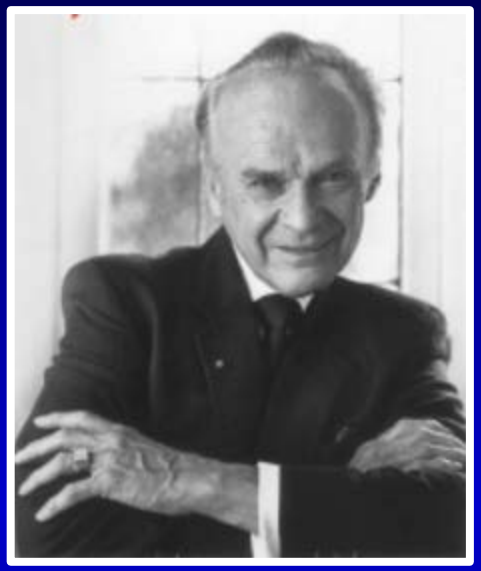
CLINICAL OUTCOME OF ORGANIC MITRAL REGURGITATION UNDER MEDICAL MANAGEMENT

	Number of patients	Symptoms	MR cause	MR severity	Age (years)	LV diameter (mm)	Study specifics	Yearly mortality	Yearly cardiac events
Enriquez-Sarano, et al[9*†]	129	0	Organic	Moderate (ERO area 20–39 mm^2)	65	56	Quantitative; prospective	3%‡	8%
Rosenhek, et al[81*]	132	0	Degenerative	Moderate to severe	55	56	Referral centre; prospective	1%	6%
Avierinos, et al[83*]	153	0	MVP	Moderate to severe	60	58	Community based	6%	14%
Ling, et al[84§]	229	19%	Flail leaflets	Severe	66	64	Cause specific	6·3% overall; 4·1% without symptoms	10–11%
Grigioni, et al[67§]	360	19%	Degenerative in SR	Severe	65	60	Cause specific	6%	10–11%
Rosen, et al[80§]	31	0	Organic	Severe	52	65	Prospective with exercise	..	10%
Enriquez-Sarano, et al[9§†]	198	0	Organic	Severe (ERO area ≥40 mm^2)	61	61	Quantitative; prospective	9%	15%

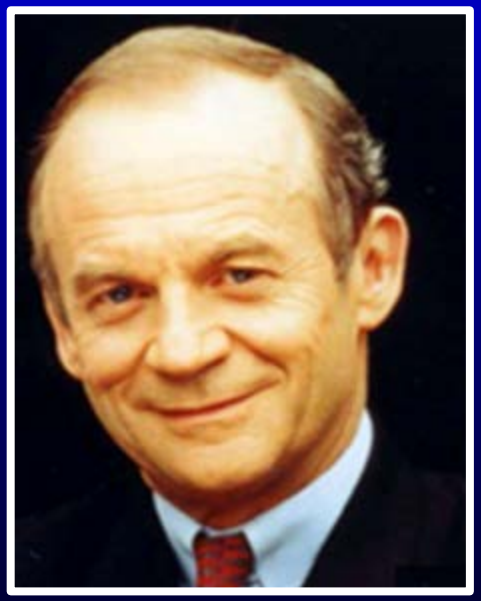
MITRAL VALVE SURGERY: OUTCOME DATA

	EACTS (2010)	STS (2010)	UK (2004–2008)	Germany (2009)
Mitral valve repair, no CABG (%)	2.1 (3231)	1.6 (7293)	2 (3283)	2 (3335)
Mitral valve replacement, no CABG (%)	4.3 (6838)	6.0 (5448)	6.1 (3614)	7.8 (1855)
Mitral valve repair/replacement +CABG (%)	6.8/11.4 (2515/1612)	4.6/11.1 (4721/2427)	8.3/11.1 (2021/1337)	6.5/14.5 (1785/837)

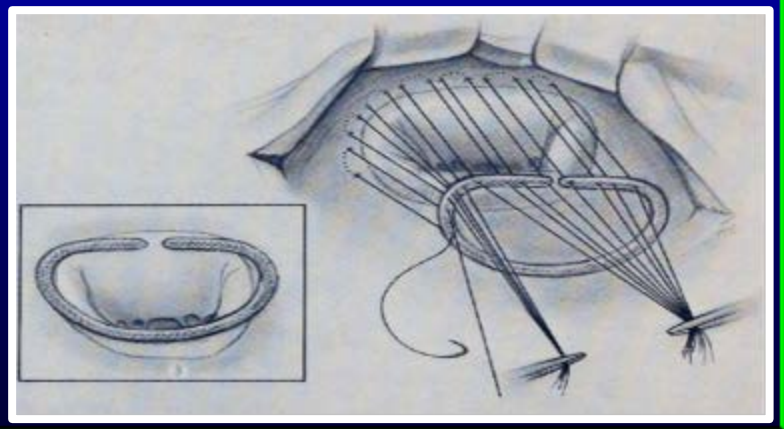
MITRAL VALVE SURGERY



1956 FIRST MITRAL VALVE REPAIR , W. Lillehei



1968 REMODELING ANNULOPLASTY, A. Carpentier



1983 - The “French correction”

Reprinted from THE JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY
St. Louis
Vol. 86, No. 3, pp. 323-337, September, 1983 (Printed in the U.S.A.)
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Volume 86 Number 3 September 1983

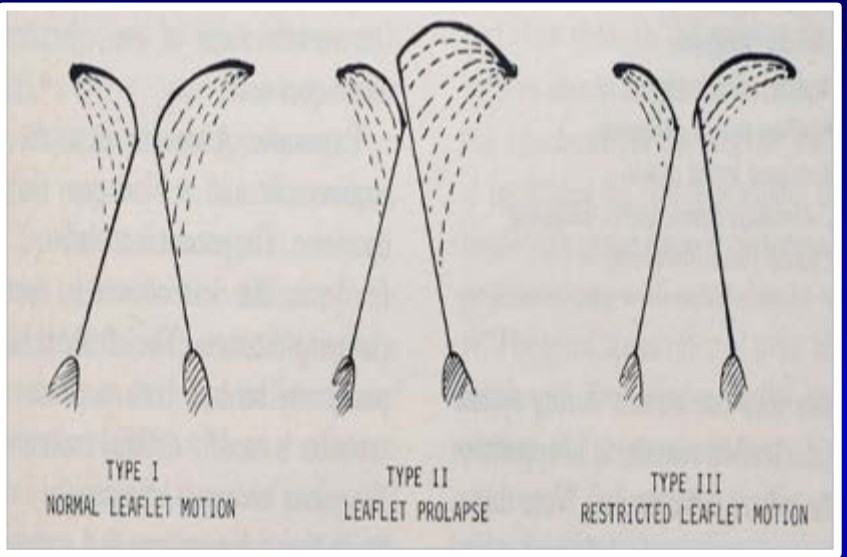
The Journal of THORACIC AND CARDIOVASCULAR SURGERY

J THORAC CARDIOVASC SURG 86:323-337, 1983

Honored Guest's Address

Cardiac valve surgery—the “French correction”

Alain Carpentier, M.D., *Paris, France*



« Surgeons are not basically concerned withlesions. We care more about function. Therefore one may define the aim of a valve reconstuction as restoring normal leaflet function rather than normal valve anatomy »

A. Carpentier, the French Correction 1984

TYPE I M.R.– TECHNICAL EVOLUTION

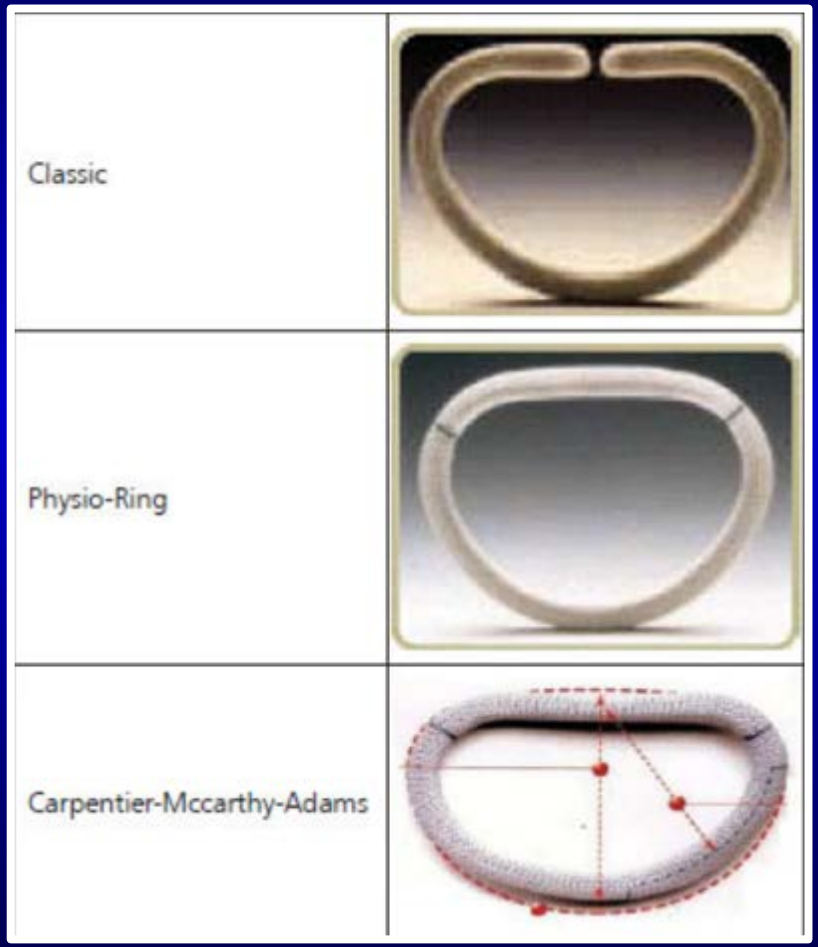
ANNULAR DILATATION

Semi-rigid prosthetic D-shape ring (Carpentier)

Complete flexible ring (Duran)

Physio-Ring (Edwards)

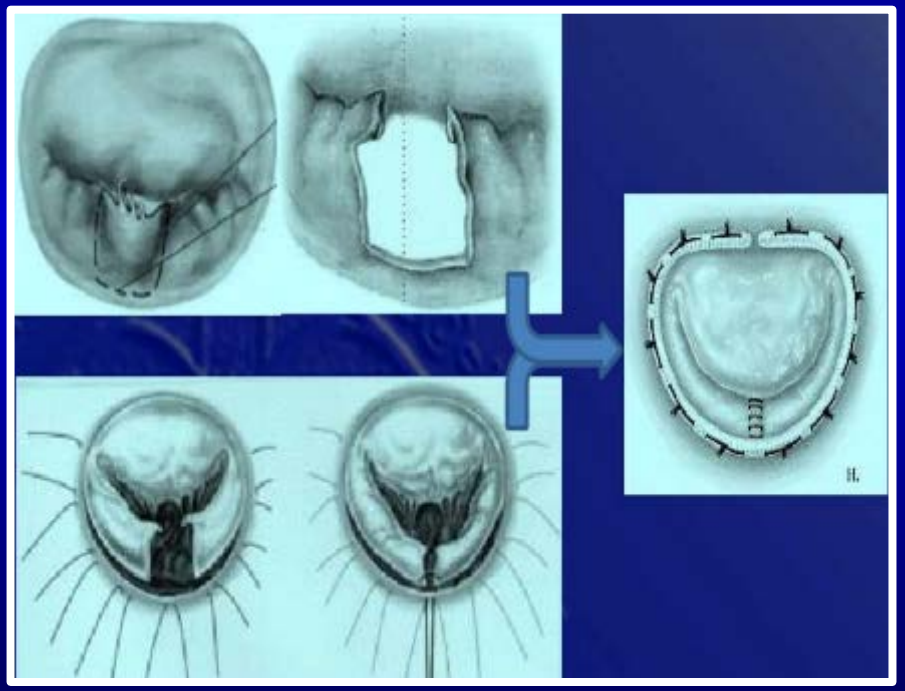
Restrictive annuloplasty with a flexible ring

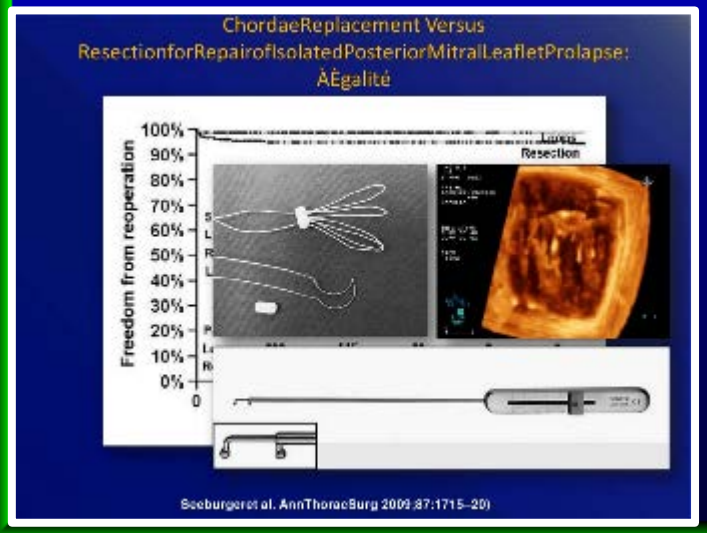


TYPE II M.R.– TECHNICAL EVOLUTION

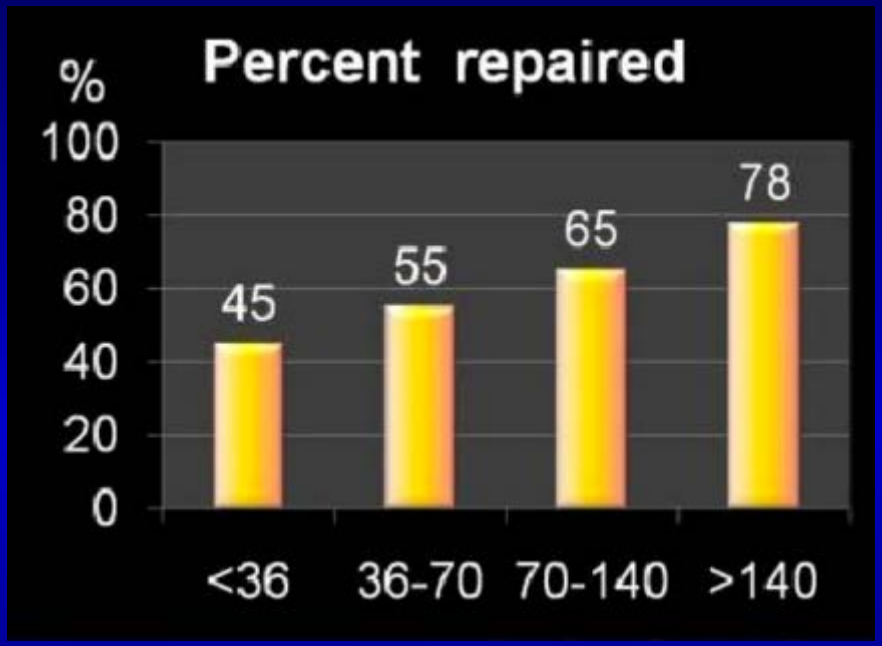
Partial annular plication (Gerbode)
Resection (triangular /quadrangolar) of prolapsed leaflet segment (Carpentier)
Chordal transposition
Leaflet fixation on secondary chordae
Papillary muscle plasty (Dreyfus)
Edge-to-edge approximation (Alfieri)
Artificial chords implantation

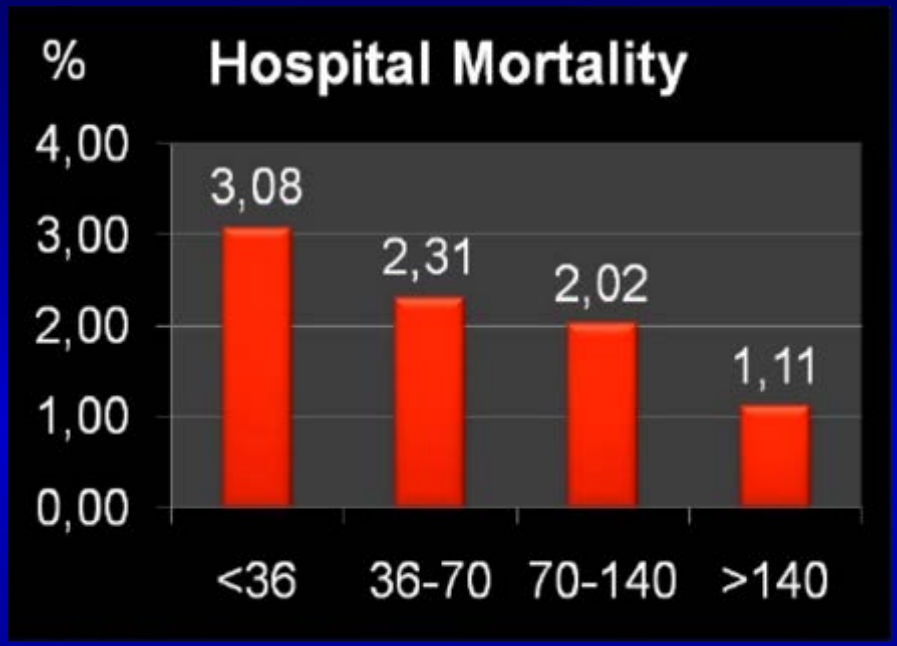
“Respect rather than resect” concept (Perier)





HOSPITAL VOLUMES vs REPAIR PREVALENCE AND RISK





13.614 pts having elective isolated MR surgery between 2000 And 2003 in 575 US centers partecipating in the STS National Cardiac Database.

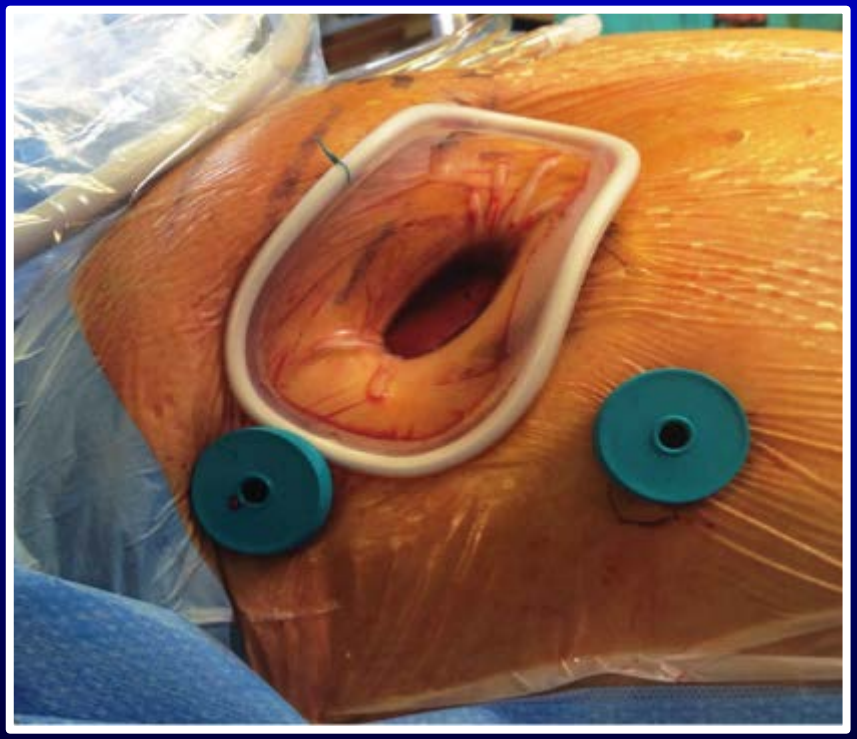
Gamie et al. Circulation 2007;115:881-887

SEVERE PRIMARY MITRAL REGURGITATION
SURGERY IS A NEVER ENDING STORY…

Minimally invasive MV surgical approach
Right mini thoracotomy / lower ministernotomy

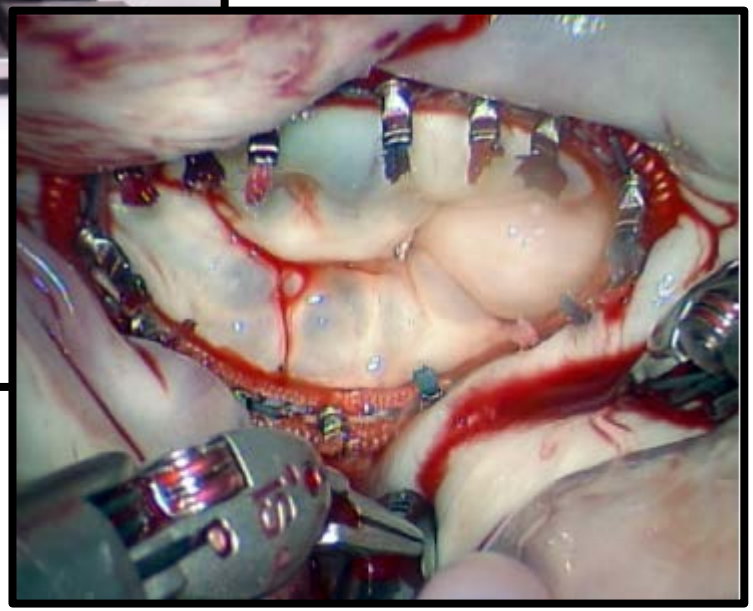
LESS SURGICAL TRAUMA
LESS BLEEDING
LESS STERNAL WOUND INFECTION
LESS POST-OP PAIN
BETTER RESPIRATORY FUNCTION
BETTER COSMESIS
FASTER RECOVERY

with the same quality, safety, efficacy.



Da Vinci

Robotic cardiac surgery



- Remotely controlled servo / 3D visualization
- Human wrist activity emulation / ambidexterity
- Tremor filtration
- Avoidance of of the fulcrum effect associated with long-shafted endoscopic instruments
- Port incision of 1 cm

Minimally invasive mitral valve surgery: "The Leipzig experience"

Piroze M. Davierwala, Joerg Seeburger, Bettina Pfannmueller, Jens Garbade, Martin Misfeld, Michael A. Borger, Friedrich W. Mohr

Department of Cardiac Surgery, Heart Center, University of Leipzig, Leipzig, Germany

Annals of cardiothoracic surgery, Vol 2, No 6 November 2013

n =3,438 MIMVS (1999 to 2010)

Table 1 Distribution of preoperative and intraoperative variables

Preoperative variables	
Age in years	60.3±13
Male	1,733 (61.3)
Body-mass index (kg/m^2)	25.6±3.9
Preoperative cerebrovascular accident	90 (3.2)
Left ventricular ejection fraction (%)	56.8±18.9
Prior cardiac surgery	152 (5.4)
Active endocarditis	36 (1.3)
Timing of surgery	
Elective	2,632 (93)
Urgent/emergent	197 (7)
Log EuroSCORE (%)	4.9±6

Outcomes	n (%)
30-day mortality	23 (0.8)
Low output syndrome	31 (1.1)
Failed mitral valve repair	45 (1.6)
Re-exploration for bleeding	198 (7)
Myocardial infarction	18 (0.6)
Sepsis	24 (0.8)
Stroke	57 (2)
Postoperative new dialysis	87 (3.1)
Postoperative symptomatic neuropsychotic syndrome	71 (2.5)
Hospital stay, days	12.2±9.4

Aortic cannulation system for minimally invasive mitral valve surgery

The Journal of Thoracic and Cardiovascular Surgery, 2015

Cristina Barbero, MD, Davide Ricci, MD, PhD, Suad El Qarra, MD, Giovanni Marchetto, MD, PhD, Massimo Boffini, MD, and Mauro Rinaldi, MD, Torino, Italy

Age (y, mean ± SD)	68.7 ± 9.5
Female sex (no.)	14 (21.5%)
Body mass index (kg/m^2, mean ± SD)	25.0 ± 3.7
Hypertension (no.)	43 (66.1%)
Diabetes (no.)	4 (6.1%)
Chronic obstructive pulmonary disease (no.)	6 (9.2%)
Atrial fibrillation (no.)	19 (29.2%)
Peripheral vascular disease (no.)	40 (61.6%)
Abdominal aortic aneurism (no.)	6 (9.2%)
Aortoiliac-femoral high tortuosity (no.)	19 (29.2%)
Ischemic MR (no.)	14 (21.5%)
Degenerative MR (no.)	37 (56.9%)
Logistic euroSCORE (mean ± SD)	9.7 ± 13.1
Ejection fraction (%, mean ± SD)	55.9 ± 13.2
PAPs (mm Hg, mean ± SD)	45.9 ± 12.7
Previous cardiac surgery (no.)	17 (26.1%)
MV replacement (no.)	12 (18.5%)
Mitral prosthesis replacement (no.)	5 (7.7%)
MV repair (no.)	48 (73.8%)
Conversion to sternotomy (no.)	1 (1.5%)
Ventilation (h, mean ± SD)	17.7 ± 29.7
Intensive care unit stay (d, mean ± SD)	2.2 ± 2.4
Reoperation for bleeding (no.)	3 (4.6%)
Acute renal failure (no.)	3 (4.6%)
Stroke (no.)	0 (0%)
30-d mortality (no.)	1 (1.5%)

N = 65

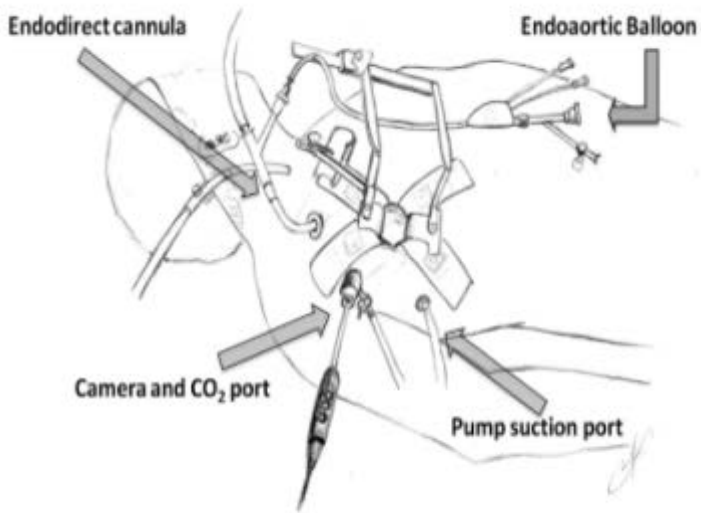


FIGURE 2. Patient's positioning and port and incision placements.

Minimally invasive mitral valve repair in Barlow's disease: Early and long-term results

J Thorac Cardiovasc Surg 2014; 148:1379-85

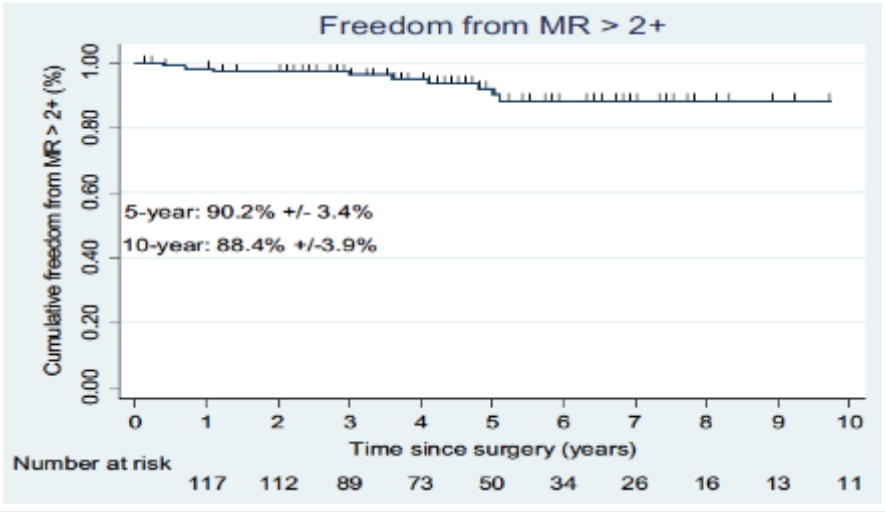
Michael A. Borger, MD, PhD, Anna F. Kaeding, MD, Joerg Seeburger, MD, PhD,
Serguei Melnitchouk, MD, Michael Hoebartner, MD, Michael Winkfein, MD,
Martin Misfeld, MD, PhD, and Friedrich W. Mohr, MD, PhD

TABLE 2. Intraoperative data of 145 patients with Barlow's disease (repair techniques are not mutually exclusive)

Operative data	
Total duration of surgery, min (mean ± SD)	200 ± 44
CPB time, min (mean ± SD)	153 ± 47
Aortic crossclamp time, min (mean ± SD)	99 ± 33
Surgical techniques	
MV replacement	8 (5.5%)
MV repair	137 (94.5%)
Neochordae formation with the loop technique	104 (71.7%)
Neochordae AML	90 (62.1%)
Neochordae PML	87 (60.0%)
Resection PML	41 (28.3%)
Resection AML	10 (6.9%)
Sliding annuloplasty PML	12 (8.3%)
Alfieri technique	25 (17.2%)
Chordal transfer	13 (9.0%)
Commissural plication	13 (9.0%)
Cleft closure	7 (4.8%)
Complete annuloplasty ring	110 (75.9%)
Partial annuloplasty ring	26 (17.9%)
Mean ring size, mm	35.7 ± 2.8
Concomitant procedures	
Tricuspid valve repair	8 (5.5%)
Cryoablation	41 (28.3%)
ASD/PFO closure	17 (11.7%)

TABLE 3. Perioperative complications (n = 145)

	Patients (n)
Rethoracotomy for bleeding	6 (4.1%)
LCOS	2 (1.4%)
IABP	2 (1.4%)
ECMO	2 (1.4%)
Postoperative atrial fibrillation	41 (28.3%)
Respiratory failure	3 (2.1%)
CVA	2 (1.4%)
Sepsis	2 (1.4%)
Renal failure	1 (0.7%)
30-d mortality	1.4%



Outcomes of Minimally Invasive Valve Surgery Versus Median Sternotomy in Patients Age 75 Years or Greater

Ann Thorac Surg 2011; 91:79-84

Joseph Lamelas, MD, Alejandro Sarria, MD, Orlando Santana, MD, Andres M. Pineda, MD, and Gervasio A. Lamas, MD

Division of Cardiothoracic Surgery and Columbia University Division of Cardiology, Mount Sinai Medical Center and Heart Institute, Miami Beach, Florida

Characteristics	Median Sternotomy (n = 84)	Right Minithoracotomy (n = 119)
Patient characteristics:		
Age, years (median, IQR)	80 (78–84)	79 (77–83)
Males (%)	37 (44)	47 (39)
Body mass index (IQR)	26.2 (23.9–29.2)	26.5 (23.1–29.7)
Preoperative creatinine (IQR)	1.02 (0.87–1.3)	1.02 (0.86–1.25)
Ejection fraction (median, IQR)	0.55 (0.46–0.60)	0.58 (0.50–0.63)
Diabetes mellitus (%)	20 (23.8)	32 (26.9)
Hypertension (%)	80 (95.2)	109 (91.6)
Peripheral vascular disease (%)	8 (9.5)	7 (5.9)
Cerebrovascular disease (%)	9 (10.7)	19 (16)
Prior coronary bypass graft surgery (%)	10 (11.9)	12 (10.1)
Prior valve surgery (%)	8 (9.5)	8 (6.7)
Prior heart failure (%)	47 (56)	43 (36.1)
Procedural characteristics:		
Mitral valve surgery	49%	51%
Aortic valve surgery	51%	49%

Outcomes	Median Sternotomy	Right Minithoracotomy	*p* Value
Postoperative complications (%)	38 (45)	25 (21)	<0.001
In-hospital death (%)	8 (9.5)	2 (1.7)	0.01
Stroke (%)	4 (4.8)	4 (3.4)	0.61
Reoperation for bleeding (%)	5 (6)	8 (6.7)	0.83
Prolonged ventilation (%)	32 (38)	23 (19)	0.003
Renal failure (%)	14 (16.7%)	1 (0.8%)	<0.001
Wound infection (%)	5 (6%)	1 (0.8%)	0.03
Intensive care unit length of stay hours (IQR)	119 (57–193)	52 (44–93)	<0.001
Total hospital length of stay days (IQR)	12 (9–20)	7 (6–10)	<0.001

Minimally invasive right thoracotomy approach for mitral valve surgery in patients with previous sternotomy: A single institution experience with 173 patients

Michele Murzi, MD, Antonio Miceli, MD, PhD, Gioia Di Stefano, MD, Alfredo G. Cerillo, MD, Pierandrea Farneti, MD, Marco Solinas, MD, and Mattia Glauber, MD

Complication	Number	%
30-d mortality	7	4.1
Stroke	11	6.3
Transient	9	81.8
Permanent	2	18.2
Delirium	20	11.5
Postoperative AMI	0	0
Pulmonary complications	20	11.5
Renal failure	20	11.5
New-onset dialysis	4	2.3
Reoperation for bleeding	11	6.3
Atrioventricular block	6	3.4
Postoperative AF	54	31.2

Outcomes of Minimally Invasive Mitral Valve Surgery in Patients With an Ejection Fraction of 35% or Less

Innovations 2013;8:1-5

Orlando Santana, MD, Javier Reyna, MD,* Andres M. Pineda, MD,* Christos G. Mihos, DO,* Lior U. Elkayam, MD,* Gervasio A. Lamas, MD,* and Joseph Lamelas, MD**

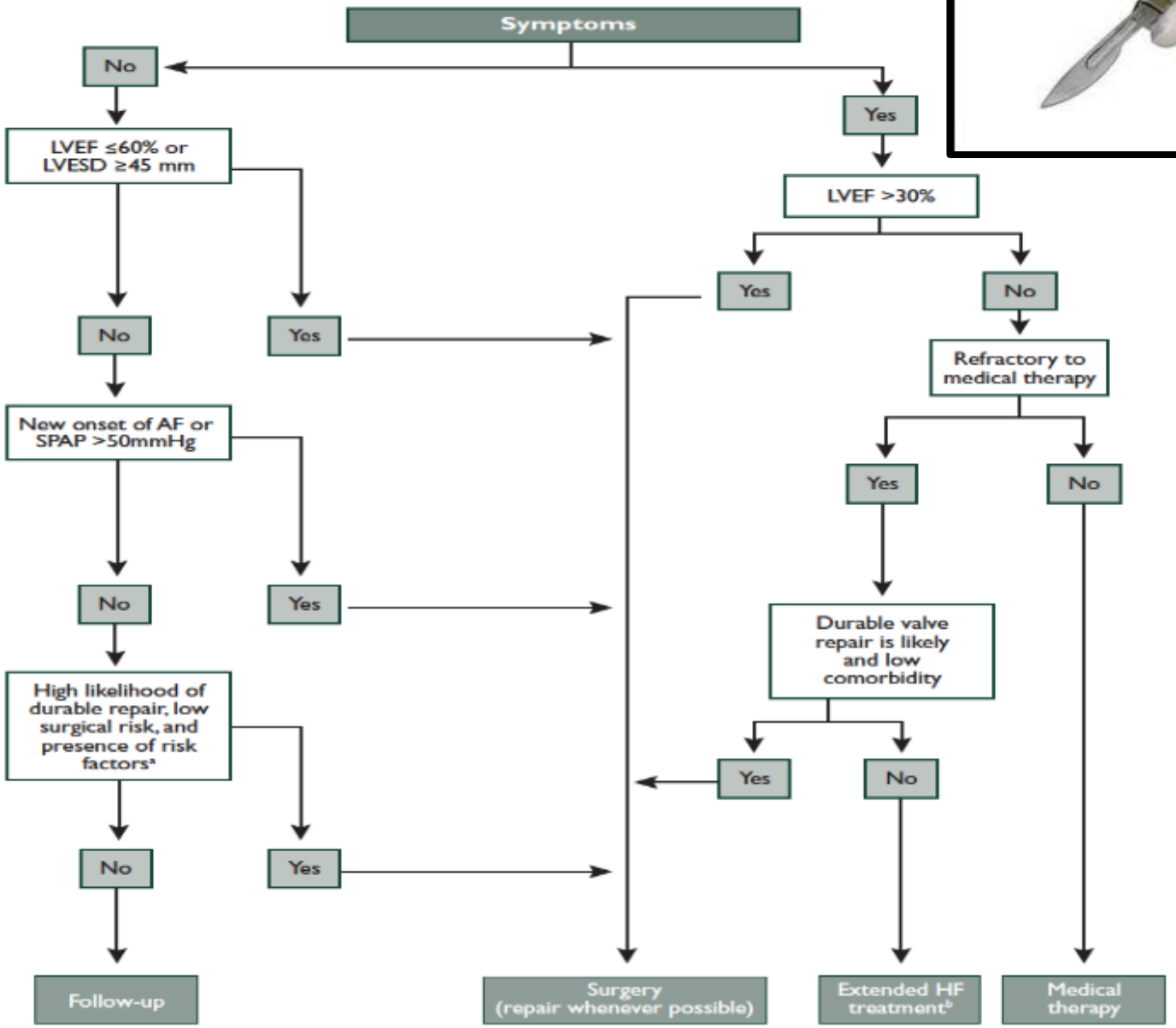
TABLE 1. Patient Baseline Characteristics

Variables	Minimally Invasive (N = 71)
Age, mean ± SD, y	67 ± 10
Men, n (%)	44 (62)
Hypertension, n (%)	67 (94)
Diabetes mellitus, n (%)	23 (32)
Dyslipidemia, n (%)	51 (72)
Ejection fraction, mean ± SD, %	27 ± 6
Previous coronary bypass graft surgery, n (%)	19 (27)
Previous aortic valve replacement, n (%)	9 (13)
History of cerebrovascular accident, n (%)	6 (9)
History of atrial fibrillation, n (%)	32 (45)
Chronic obstructive pulmonary disease, n (%)	24 (34)
Preoperative creatinine, mean ± SD, mg/dL	1.2 ± 0.5
Ischemic cardiomyopathy, n (%)	37 (52)
Nonischemic cardiomyopathy, n (%)	34 (48)
New York Heart Association functional class III or IV, n (%)	71 (100)

TABLE 3. Postoperative Complications

Variables	Minimal Invasive (N = 71)
Morbidity and mortality	13 (18.3)
30-d mortality	2 (2.8)
Reoperation for bleeding	0
Renal failure	5 (7)
Prolonged intubation	10 (14)
Reintubation	5 (7)
Sternal deep wound infection	0
Cerebrovascular accident	1 (1.4)
Atrial fibrillation	7 (10)

ESC/EACTS GUIDELINES

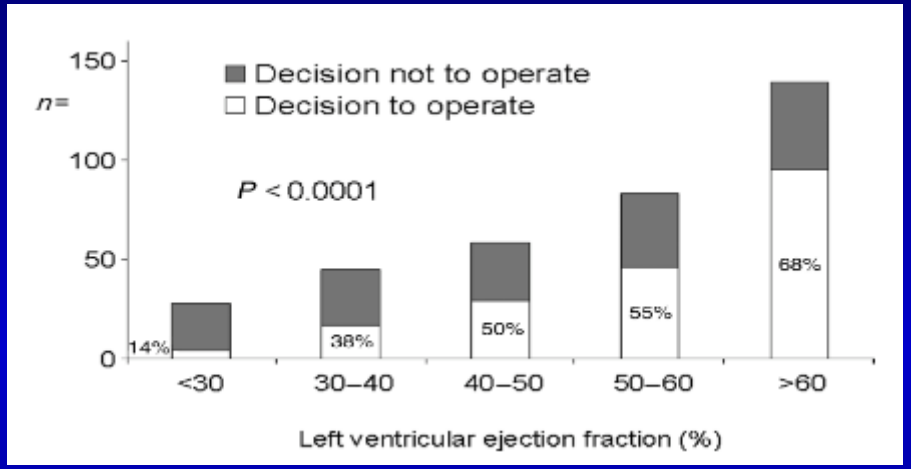


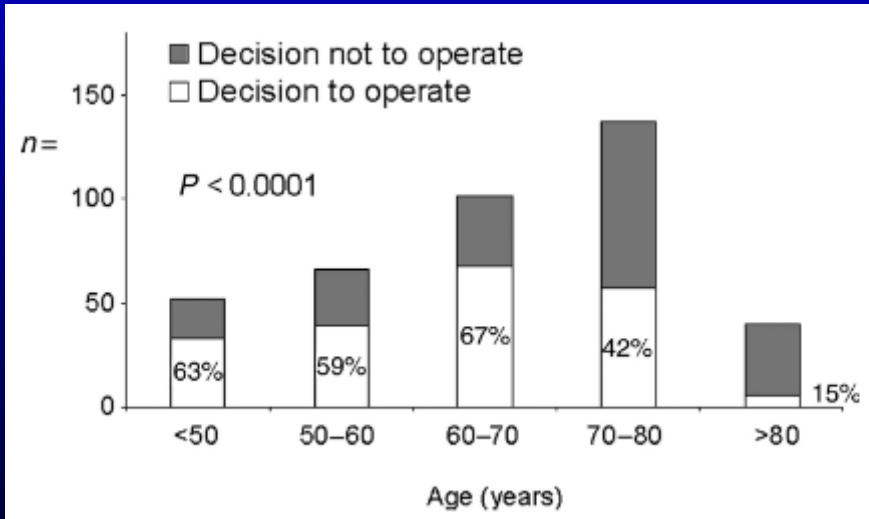
SEVERE SYMPTOMATIC MITRAL REGURGITATION. PATIENTS WHO ARE DENIED SURGERY

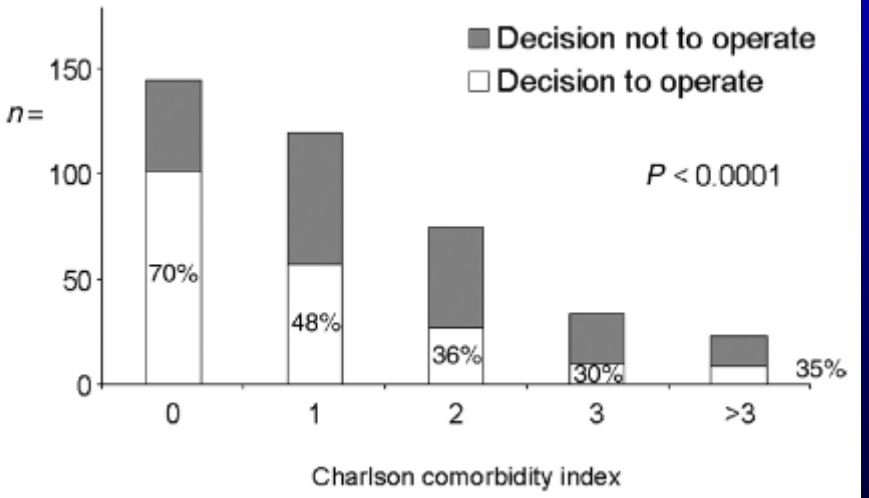
EURO HEART SURVEY on valvular heart disease – Mirabel et al. EHJ (2007) 28, 1358-65.

Table 3 Factors associated with a decision not to operate. Multivariable analysis

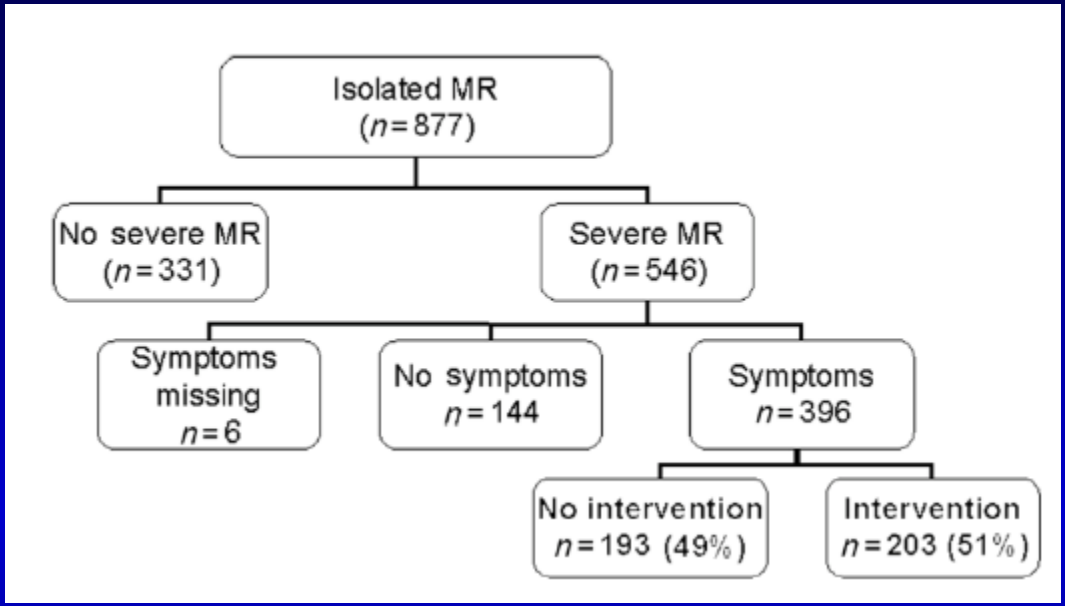
	P	Odds ratio	95% CI
LVEF (per 10% decrease)	0.0002	1.39	(1.17–1.66)
Aetiology	0.0006		
Ischaemic		1	
Non-ischaemic		4.44	(1.96–10.76)
Age (per 10-year increase)	0.001	1.40	(1.15–1.72)
Charlson comorbidity index (per 1 point increase)	0.004	1.38	(1.12–1.72)
Degree of MR	0.005		
Grade 4/4		1	
Grade 3/4		2.23	(1.28–3.29)







EURO HEART SURVEY on valvular heart disease – Mirabel et al. EHJ (2007) 28, 1358-65.



- 49% pts were denied surgery
- Reasons advocated: resolution of symptoms unter Tx (45%), comorbidity (37%), advanced age (28%), pt refusal (23%), terminal HF (18%)
- One-year survival was lower in Med Tx (89% vs 96%)

In multivariable analysis, older age and higher comorbidity index were predictive of a 1-year mortality while therapeutic decision WAS NOT.

Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair

The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study

Table 1 Baseline Characteristics

Characteristic	High-Risk Group (n = 78)	Concurrent Comparator Group (n = 36)	p Value
Age, yrs	76.7 ± 9.8	77.2 ± 13.0	0.85
>75 yrs	61.5	63.9	0.84
Male	62.8	50.0	0.22
Comorbidities			
≥5 comorbidities	88.5	77.8	0.16
Coronary artery disease	84.2	71.4	0.13
History of congestive heart failure	100.0	83.3	0.0007
Chronic pulmonary disease	34.6	33.3	0.95
Moderate to severe renal disease	23.1	31.4	0.36
History of diabetes	41.0	41.7	>0.999
History of cerebrovascular disease	17.9	22.2	0.62
History of peripheral vascular disease	18.2	22.9	0.61
Myocardial infarction	55.8	36.4	0.10
Atrial fibrillation	61.6	52.8	0.41
Previous cardiovascular surgery	62.8	72.2	0.40
Pacemaker or ICD implant	35.1	13.9	0.02
Percutaneous coronary intervention	38.5	30.6	0.53
NYHA functional class III or IV	89.7	83.9	0.20
LV ejection fraction	54.4 ± 13.7	55.2 ± 18.1	0.82
LV internal diameter, systole, cm*	3.9 ± 1.1	3.8 ± 1.1	0.46
MR etiology			
Degenerative	41.0	36.1	0.49
Functional	59.0	63.9	
Predicted surgical mortality rate (STS risk score and/or surgeon estimated risk), %†	18.2 ± 8.0	17.4 ± 7.4	0.42
Predicted surgical mortality rate (STS calculated risk score only), %‡	14.2 ± 8.2	14.9 ± 8.5	0.68

Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair

The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study

Table 2 Nonhierarchical Major Adverse Events

Description of Major Adverse Event*	Procedure Through 30 Days		Procedure Through 12 Months	
	Patients	No. of Events	Patients	No. of Events
Death	7.7 (6/78)	6	24.4 (19/78)	19
Myocardial infarction	2.6 (2/78)	2	5.1 (4/78)	5
Reoperation for failed MV surgical repair or replacement	0.0 (0/78)	0	0.0 (0/78)	0
Urgent or emergent cardiovascular surgery for adverse event	0.0 (0/78)	0	0.0 (0/78)	0
Major stroke	2.6 (2/78)	2	2.6 (2/78)	2
Renal failure	3.8 (3/78)	3	6.4 (5/78)	5
Deep wound infection	0.0 (0/78)	0	0.0 (0/78)	0
Mechanical ventilation >48 h	2.6 (2/78)	2	2.6 (2/78)	2
GI complication requiring surgery	1.3 (1/78)	1	3.8 (3/78)	3
New onset of permanent AF	0.0 (0/78)	0	0.0 (0/78)	0
Septicemia	0.0 (0/78)	0	3.8 (3/78)	3
Transfusion of ≥2 U of blood	17.9 (14/78)	22	24.4 (19/78)	31
Total†	26.9 (21/78)	38	42.3 (33/78)	69

A systematic review on the safety and efficacy of percutaneous edge-to-edge mitral valve repair with the MitraClip system for high surgical risk candidates

Munkholm-Larsen S, *et al*. *Heart* 2014;**100**:473–478

Table 1 Summary of baseline patient characteristics in high risk patients undergoing mitral valve repair using MitraClip

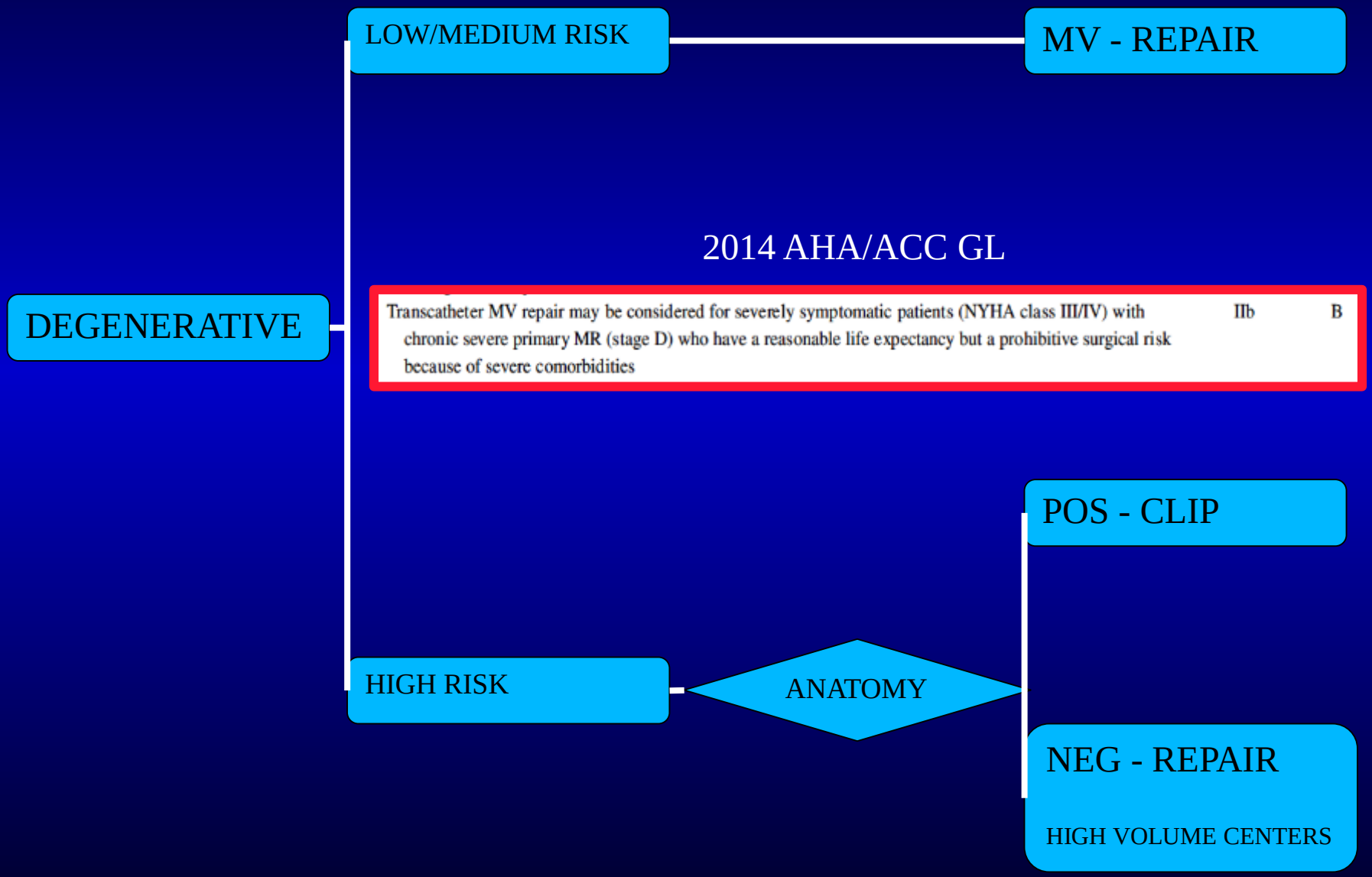
Author	n	Level of evidence	Follow-up period (months)	Age (years)	Male (%)	Logistic EuroSCORE (%)	STS score (%)	Mitral valve pathology (%)		Grade of severity of MR (%)			Previous cardiac surgery (%)
								Functional	Degenerative	2	3	4	
Altiok[12]	39	Level 4	6	73±9	62	18±12	–	100	0	0	74	26	–
Treede[15]	202	Level 4	12	75±9	63	36 (21–54)*	–	65	35†	2	53	46	35
Pleger[18]	36	Level 4	1	76±13	61	41±7	24±4	63	36	12	88	0	39
Schillinger[19]	75	Level 4	12	73±2	69	29±4	11±2	65	35	1	33	65	37
Paranskaya[20]	85	Level 4	12	78±6	56	24±12	12±7	57	44†	–	–	–	27
Grasso[25]	117	Level 4	12	72±10	67	12±14	–	76	24	2	60	39	19
Ihlemann[29]	16	Level 4	3	77±9	–	22±10	–	–	–	–	–	–	44
Chan[30]	27	Level 4	12	74±12	63	27±12	14±9	44	56	–	–	–	–
Van den Branden[31]	52	Level 4	6	73±10	69	27±17	10±8	90	10	–	46	54	–
Sürder[34]	100	Level 4	6	77	67	17 (19)‡	–	62	38	0	30	70	–
Auricchio[35]	51	Level 4	14	70±9	86	30±19	14±14	100	0	–	–	–	8
Whitlow[48]	78	Level 4	12	77±10	63	–	14±8	59	41	–	–	–	63

A systematic review on the safety and efficacy of percutaneous edge-to-edge mitral valve repair with the MitraClip system for high surgical risk candidates

Munkholm-Larsen S, *et al*. *Heart* 2014;**100**:473–478

Author	30 day mortality (%)	Acute procedural success (%)	Successful clip implantation (%)	Number of clips implanted (%)			Early need for surgery (%)	Clip related chordal rupture (%)	Transseptal complication (%)	Partial clip detachment (%)	Transfusion of ≥2 units (%)	Median length of hospital stay (days)
				1	2	3 or more						
Altiok[12]	–	97	100	77	23	0	–	–	–	–	–	–
Treede[15]	3.5	92	97	62	32	4	5.4	–	–	–	–	12±10*
Pleger[18]	0	–	92	73	27	0	–	–	–	–	2.8	–
Schillinger[19]	2.7	84	99	–	–	–	0	–	–	5.3	0	–
Paranskaya[20]	4.7	97	–	17	55	28	1.2	–	–	2.4	–	–
Grasso[25]	0.9	100	–	59	40	1	0	–	–	0	0.9	
Ihlemann[29]	6.2	100	–	75	25	0	6.2	6.2	–	12.5	–	6±3*
Chan[30]	0	93	–	41	52	–	–	–	–	–	–	–
Van den Branden[31]	3.6	–	96	84	11	2	1.8	–	1.8	3.6	3.6	5
Sürder[34]	1.0	85	–	54	40	4	3.0	2.0	3.0	5.0	–	7
Auricchio[35]	7.8	95	–	51	49	0	2.0	2.0	–	–	9.8	–
Whitlow[48]	7.7	72†	96	–	–	–	0	–	1.2	–	17.9	–
Weighted mean	3.3	91	97.5	57	37	5	2.3	2.4	2.17	6.2	5.7	NA

SEVERE PRIMARY MITRAL REGURGITATION FLOW - CHART



Background in the Management (Moderate-Severe) Secondary MR

1. Operative mortality is higher than in primary MR
2. Long-term prognosis is worse (comorbidities)
3. No evidence that surgery prolongs life (5-yrs death 50%)
    1. CABG alone does not correct MR in most patients
    2. Untreated MR is associated with recurrent HF and death
    3. Functional improvement uniformly reported after MVS
4. Persistence and high recurrence rate of MR after MV repair

Non randomized observational trials for most

Retrospective trials

One randomized study not powered to evaluate the outcome has compared CABG with CABG/MVRepair in moderate ischemic MR

→ Improvement in class/LV function

Fattouch JTCVS 2009

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Impact of Mitral Valve Annuloplasty on Mortality Risk in Patients With Mitral Regurgitation and Left Ventricular Systolic Dysfunction

Audrey H. Wu, MD, MPH,* Keith D. Aaronson, MD, MS,* Steven F. Bolling, MD, FACC,†
Francis D. Pagani, MD, PHD, FACC,† Kathy Welch, MS, MPH,‡ Todd M. Koelling, MD, FACC*
Ann Arbor, Michigan

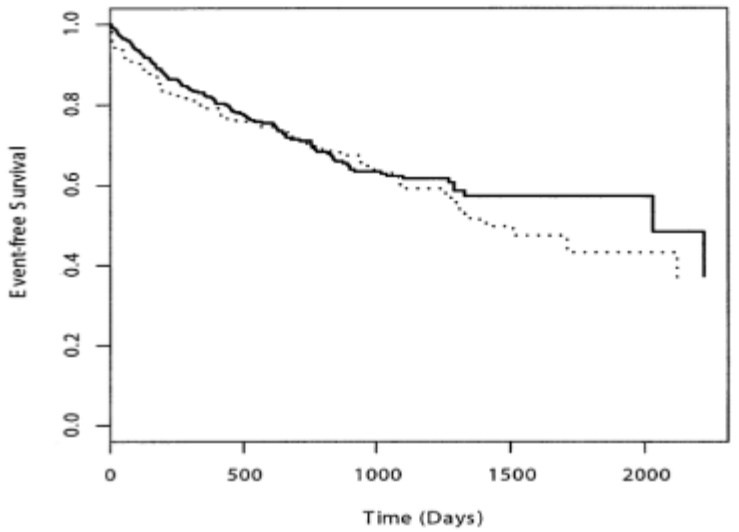

Figure 1. Event-free survival for non-mitral-valve annuloplasty (MVA) group **(solid line)** and MVA group **(dotted line)**.

"…retrospective analysis of this large cohort of patients with LV disfunction and significant MR demonstrates no mortality benefit conferred by undergoing MVA. (…)MVA was not associated with the combined endpoint of death, LV assist device implantation, or UNOS status 1 heart transplantation".

Indications for mitral valve surgery in secondary mitral regurgitation

	Class	Level
Surgery is indicated in patients with severe MR undergoing CABG, and LVEF > 30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG (Exercise echo is recommended to identify dyspnea, increase in severity of MR and in SPAP).	IIa	C
Surgery should be considered in symptomatic patients with severe MR, LVEF < 30%, option for revascularization, and evidence of viability.	IIa	C
Surgery may be considered in patients with severe MR, LVEF > 30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.	IIb	C

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ORIGINAL ARTICLE

Mitraclip therapy and surgical mitral repair in patients with moderate to severe left ventricular failure causing functional mitral regurgitation: a single-centre experience†

Maurizio Taramasso[a], Paolo Denti[a], Nicola Buzzatti[a], Michele De Bonis[a], Giovanni La Canna[a], Antonio Colombo[b], Ottavio Alfieri[a] and Francesco Maisano[a,*]

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Table 1: Preoperative clinical features

	Surgery (*n* = 91)	MitraClip (*n* = 52)	*P*-value*
Age (years)	64.9 ± 9.8	68.4 ± 9.2	0.04
Female gender, *n* (%)	21 (23.1)	9 (17.3)	0.4
Previous AMI, *n* (%)	34 (37.4)	31 (59.6)	0.01
Log EuroSCORE, *n* (%)	10.2 ± 7.4	21.9 ± 4.8	<0.0001
Previous cardiac surgery, *n* (%)	9 (9.9)	12 (23.1)	0.03
Coronary artery disease, *n* (%)	44 (48.3)	37 (71.2)	0.03
Atrial fibrillation, *n* (%)	29 (32)	37 (17.3)	0.01
Chronic renal failure, *n* (%)	16 (17.6)	30 (57.7)	<0.0001
COPD, *n* (%)	3 (3.3)	11 (21.2)	0.0005
Cerebrovascular disease, *n* (%)	6 (6.6)	5 (9.6)	0.5
Diabetes, *n* (%)	9 (9.9)	14 (26.9)	0.007
NYHA functional class, *n* (%)			
I	4 (4.4)	0	0.1
II	26 (28.6)	8 (15.4)	
III	47 (51.6)	35 (63.3)	
IV	14 (15.4)	9 (17.3)	

AMI: acute myocardial infarction; COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association.
*Student's unpaired *t*-test for continuous data; Chi-square test for categorical data.

Table 3: Perioperative results

	Surgery (*n* = 91)	MitraClip (*n* = 52)	*P*-value*
In-hospital mortality, *n* (%)	6 (6.6)	0	0.01
Acute kidney injury, *n* (%)	28 (30.7)	16 (30.7)	1
Need for CVVH, *n* (%)	2 (2.2)	3 (5.8)	0.2
LCOS, *n* (%)	3 (3.3)	4 (7.7)	0.2
Major infection/sepsis, *n* (%)	15 (16.5)	3 (3.8)	0.02
Stroke, *n* (%)	2 (2.2)	0	0.2
AMI, *n* (%)	0	0	Na
Discharge MR ≥ 3+, *n* (%)	0	5 (9.6)	0.002

CVVH: continuous veno-venous haemofiltration; LCOS: low cardiac output syndrome; AMI: acute myocardial infarction; MR: mitral regurgitation.
*Chi-square test.

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Mitraclip therapy and surgical mitral repair in patients with moderate to severe left ventricular failure causing functional mitral regurgitation: a single-centre experience†

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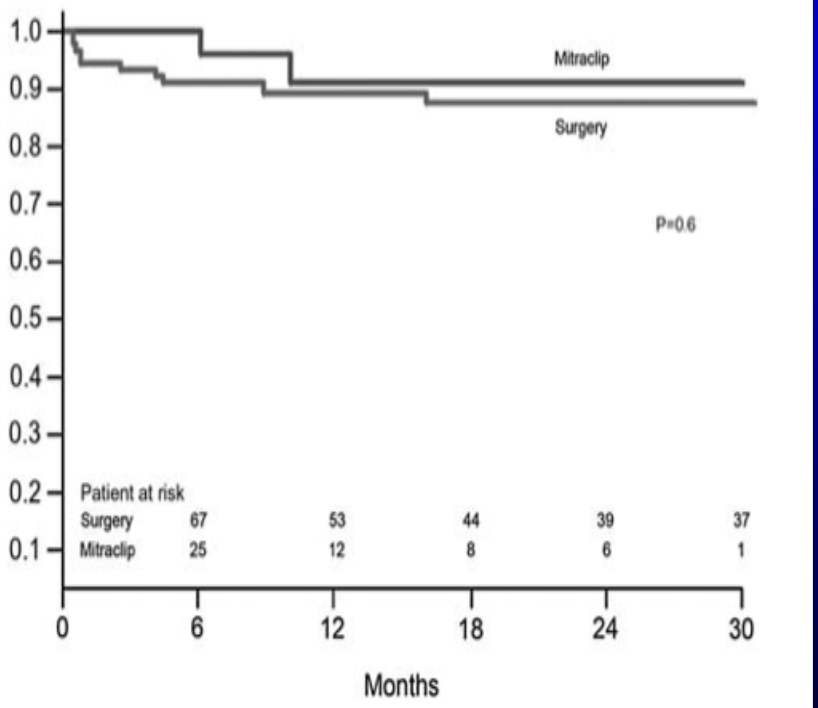

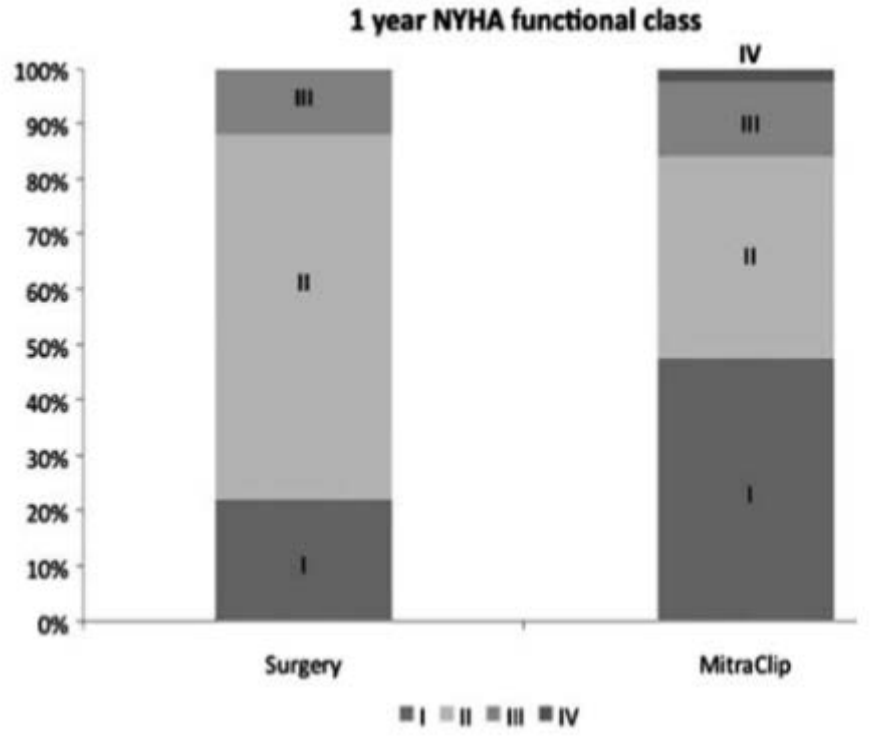

Mitral valve pathology in severely impaired left ventricles can be successfully managed using a right-sided minimally invasive surgical approach†

Jens Garbade*, Joerg Seeburger, Denis R. Merk, Bettina Pfannmüller, Marcel Vollroth, Markus J. Barten, Michael A. Borger and Friedrich-Wilhelm Mohr

Department of Cardiac Surgery, Heart Center, University of Leipzig, Leipzig, Germany

European Journal of Cardio-Thoracic Surgery 44 (2013)

Table 1: Baseline clinical characteristics in patients undergoing Mini-MV with an LVEF < 30%

Variable	Mini-MV *n* = 177 patients
Study period	1999–2010
Demographics	
Age (years)	67 ± 11
Sex (male)	110 (63%)
Weight (kg)	75.3 ± 13.3
BMI	25.8 ± 3.6
LVEF (%)	23.9 ± 5.8
LVEDD (mm)	69 ± 11
NYHA class	3.1 ± 0.8
Comorbidities	
Previous cardiac surgery	32 (18.3%)
Primary ICM	22 (12.4%)
Primary DCM	155 (87.6%)
COPD	9 (5.4%)
Renal insufficiency	45 (25%)
Stroke	2 (1.1%)
Hypertention	35 (19.8%)
Diabetes	51 (28.8%)
EuroSCORE (%)	14.7 ± 13.6
Indication for surgery	
MV insufficiency	172 (97.2%)
MV stenosis/insufficiency	5 (2.8%)
Concomitant indications	
TV insufficiency	27 (15.4%)
Atrial fibrillation	61 (34.5%)
ASD/PFO	10 (5.6%)

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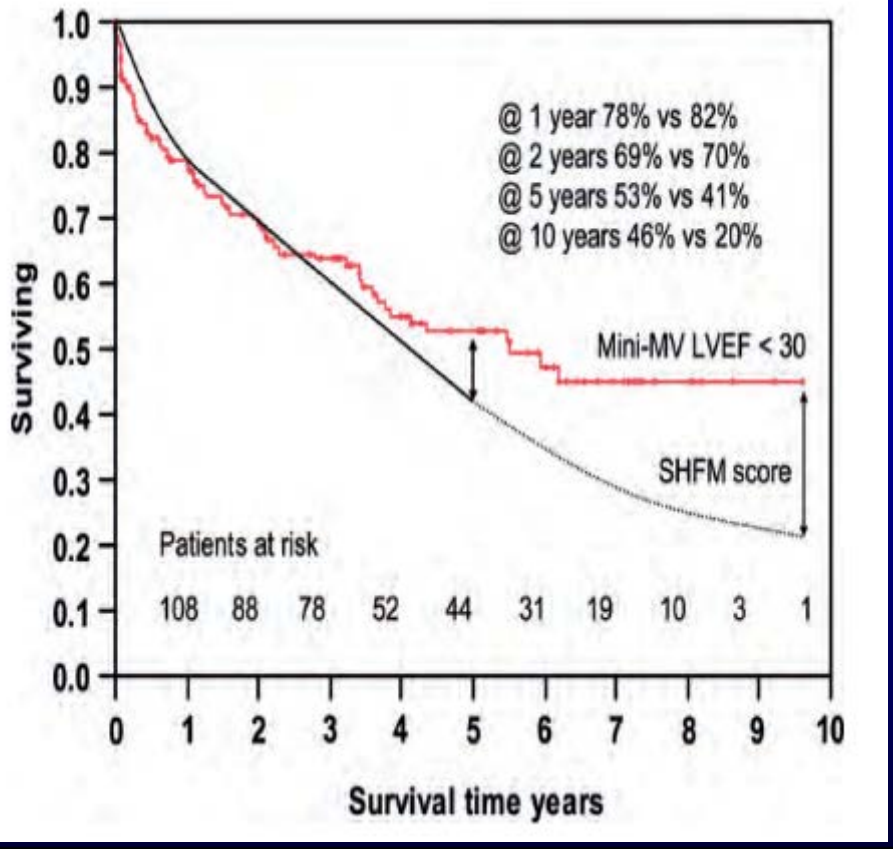
Table 4: Outcomes, complications and reinterventions in patients undergoing Mini-MV with LVEF < 30%

Variable	Mini-MV $n = 177$
Early postoperative course	
30-day mortality	14 (7.9%)
Inotropic support	132 (74%)
Low cardiac output syndrome requiring mechanical circulatory support	15 (8.5%)
IABP	9 (5%)
ECMO	6 (3.8%)
Bleeding, requiring surgery within 24 h	12 (6.9%)
Sepsis	14 (7.9%)
Acute renal failure/haemodialysis	12 (6.7%)
Respiratory failure	7 (4.0%)
CVE (transient or persistent)	4 (2.7%)
Intensive care time > 24 h	129 (72.8%)
Hospital stay (days)	17 ± 12
Long-term follow-up	
Heart transplantation	10 (5.7%) 3–47 months after Mini-MV
LVAD implantation	3 (1.7%) 4–8 months after Mini-MV
Reoperation on MV during the follow-up	7 (4.0%)

IABP: intra-aortic ballon pump; ECMO: extracorporeal membrane oxygenation; CVE: cerebrovascular event; LVAD: left ventricular assist device.



Percutaneous Mitral Valve Edge-to-Edge Repair

In-Hospital Results and 1-Year Follow-Up of 628 Patients of the 2011–2012 Pilot European Sentinel Registry

TABLE 1 Baseline Clinical Characteristics

	Overall (n = 628)	Mixed/ Other (n = 17)	Functional MR (n = 452)	Degenerative MR (n = 143)	p Value*
Age, yrs	74.2 ± 9.7	78.0 ± 8.4	72.8 ± 9.8	78.3 ± 8.5	<0.001
Male	63.1	41.2	67.7	52.5	<0.001
Diabetes mellitus	27.9	11.8	33.1	12.6	<0.001
Hypertension	75.9	88.2	77.6	69.0	0.038
COPD	19.3	11.8	19.8	20.3	0.905
Previous stroke	14.4	17.7	12.8	18.2	0.109
Significant CAD	30.9	29.4	31.9	25.9	0.659
Previous MI	31.2	25.5	37.6	13.3	<0.001
Previous PCI†	15.5	11.8	16.4	14.1	0.515
Previous CABG	32.3	35.3	34.9	21.7	<0.003
Previous valve surgery	10.4	5.9	9.7	11.9	0.459
NYHA functional class					0.004
I	1.6	0.0	1.1	3.5	
II	12.9	23.5	10.4	19.6	
III	68.7	52.9	70.3	63.6	
IV	16.8	23.5	18.2	13.3	
AFib/flutter	31.7	18.8	27.2	50.0	<0.001
LVEF <30%	32.8	12.5	42.0	2.8	<0.001
Baseline SCr, µmol/l	132.0 ± 80.5	115.7 ± 37.2	137.7 ± 88.0	112.6 ± 45.8	0.002
CKD	30.5	17.7	32.8	24.1	0.051
Hemodialysis	9.2	0.0	9.3	10.5	0.634
EuroSCORE	20.4 ± 16.7	15.5 ± 11.2	21.9 ± 17.6	16.3 ± 13.7	0.003

Percutaneous Mitral Valve Edge-to-Edge Repair

In-Hospital Results and 1-Year Follow-Up of 628 Patients of the 2011–2012 Pilot European Sentinel Registry

TABLE 2 Procedural/In-Hospital Clinical Outcomes

	Overall* (n = 628)	Functional MR (n = 452)	Degenerative MR (n = 143)	p Value†
Death	2.9	2.0	4.9	0.075
Tamponade	1.1	0.7	1.8	0.298
Stroke	0.2	0.0	0.7	0.241
Severe bleeding	1.1	0.9	2.1	0.368
Transfusion	10.1	9.7	12.4	0.406
Vascular complication requiring intervention	0.7	1.0	0.0	0.581
New-onset atrial fibrillation	11.7	12.6	10.2	0.599
Acute procedural success	95.4	95.8	93.7	0.304
Clip embolization	0.7	0.5	0.9	0.521
Inability to reduce MR	3.5	3.0	4.4	0.387
Implant ≥2 clips	37.5	36.5	44.3	0.098
Procedure duration, min	138.3 ± 67.9	137.2 ± 68.2	132.1 ± 65.6	0.463
Median hospital stay (IQR), d	5 (3–7)	5 (4–7)	5 (3–7)	0.348

One- and Twelve-Month Safety and Efficacy Outcomes of Patients Undergoing Edge-to-Edge Percutaneous Mitral Valve Repair (from the GRASP Registry)

Carmelo Grasso, MD[a], Davide Capodanno, MD, PhD[a,b,*], Salvatore Scandura, MD[a], Stefano Cannata, MD[a], Sebastiano Immè, MD[a], Sarah Mangiafico, MD[a], Anna Pistritto, MD[a], Margherita Ministeri, MD[a], Marco Barbanti, MD[a], Anna Caggegi, MD[a], Marta Chiarandà, MD[a], Fabio Dipasqua, MD[a], Sandra Giaquinta, MD[a], Michele Occhipinti, MD[a], Gianpaolo Ussia, MD[a], and Corrado Tamburino, MD, PhD[a,b]

Major adverse events at 30 days

Outcome	Overall (n = 117)	Degenerative (n = 28)	Functional (n = 89)
Any MAE	4 (3.4%)	0	4 (4.5%)
Death	1 (0.9%)	0	1 (1.1%)
Myocardial infarction	0	0	0
Reoperation for failed surgical repair or replacement	0	0	0
Urgent or emergency cardiovascular surgery for adverse event	0	0	0
Major stroke	1 (0.9%)	0	1 (1.1%)
Renal failure	0	0	0
Deep wound infection	0	0	0
Mechanical ventilation for >48 h	0	0	0
Gastrointestinal complication requiring surgery	0	0	0
New onset of permanent atrial fibrillation	1 (0.9%)	0	1 (1.1%)
Septicemia	0	0	0
Transfusion of ≥2 U of blood	1 (0.9%)	0	1 (1.1%)

SEVERE FUNCTIONAL MITRAL REGURGITATION FLOW - CHART

FUNCTIONAL

MEDIUM RISK

ANATOMY

POS – SURGERY/ **CLIP**

NEG – SURGERY (MVR)
CLIP *OFF LABEL*

HIGH RISK

ANATOMY

POS - **CLIP**

NEG – MED TX/
CLIP *OFF LABEL*

MITRAL REGURGITATION: SURGICAL OR PERCUTANEOUS ?

HEART TEAM APPROACH IS **MANDATORY**

- Is valvular heart disease severe ?
- Does the patient have symptoms ?
- Are symptoms related to valvular disease ?
- What are pt life expectancy and quality of life ?
- Do the benefits outweight the risks ?
- What are the patient's wishes ?
- Are local resources optimal for planned intervention ?