

# Mitral Clip 2016: Indications, Clinical Data and Limitations

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**21st CardioVascular Summit-TCTAP 2016**

April 26- 29<sup>th</sup> 2016

COEX

Seoul, Korea

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## *Disclosure Information*

The following relationships exist:

*Grant support: Abbott, BSC, Cardiokinetics, Edwards, WL Gore*  
*Consultant: Abbott, BSC, Mitralign, WL Gore*

*Off label use of products and investigational devices  
will be discussed in this presentation*

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 14, 2011

VOL. 364 NO. 15

## Percutaneous Repair or Surgery for Mitral Regurgitation

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### BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

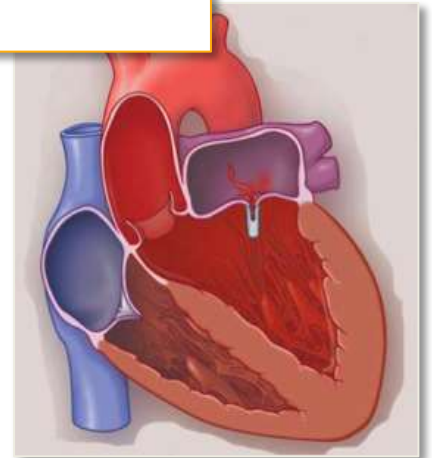
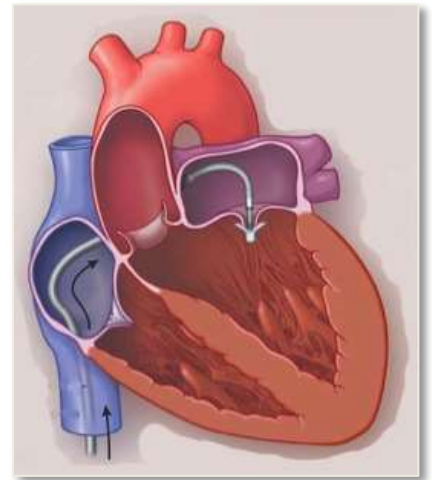
### CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

percutaneous-repair group and 73% in the surgery group ( $P=0.007$ ). The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ( $P<0.001$ ). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

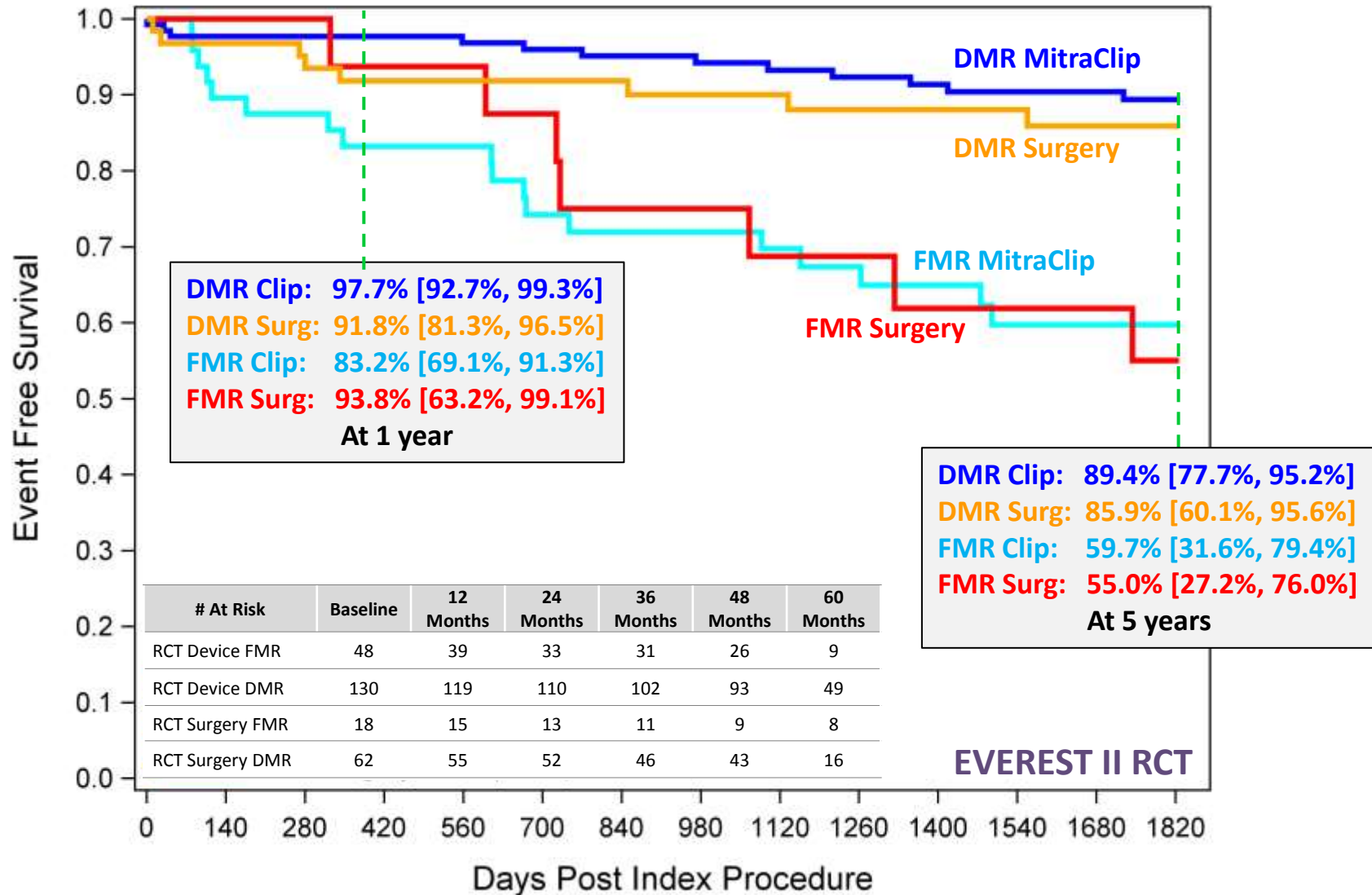
### CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)



New Engl J Med 364:1395-1406, 2011

# Freedom From Mortality & Reintervention



# MitraClip Clip Delivery System

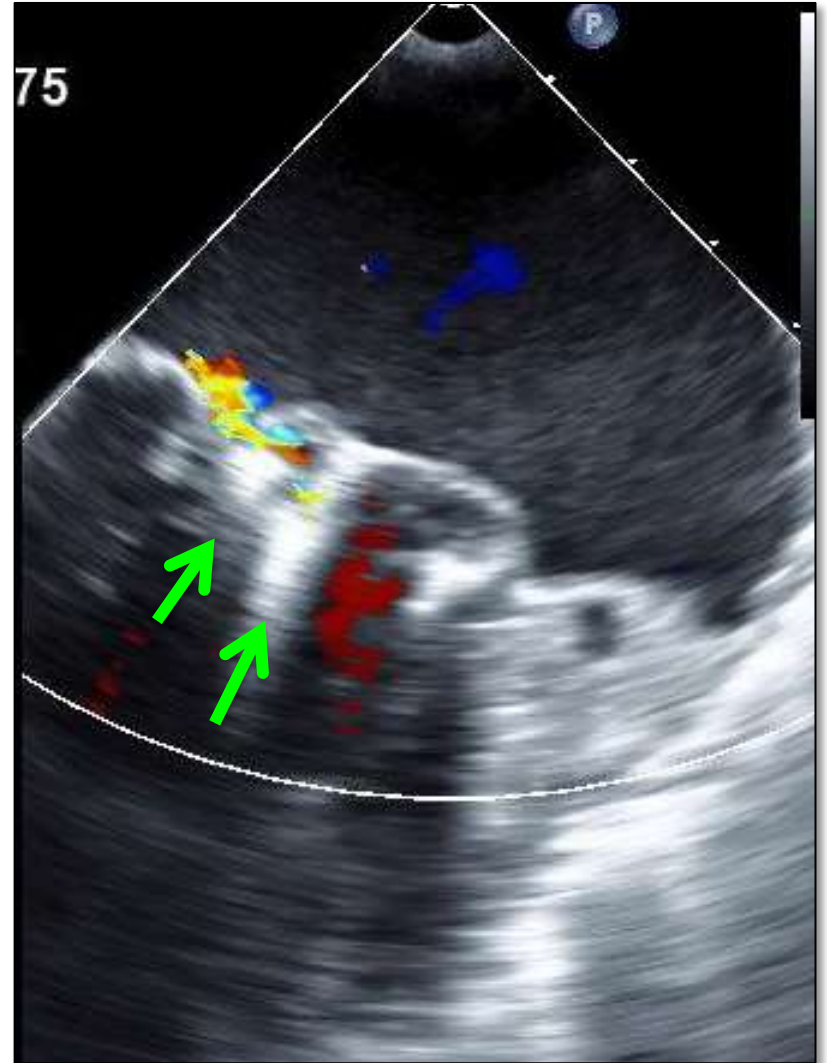
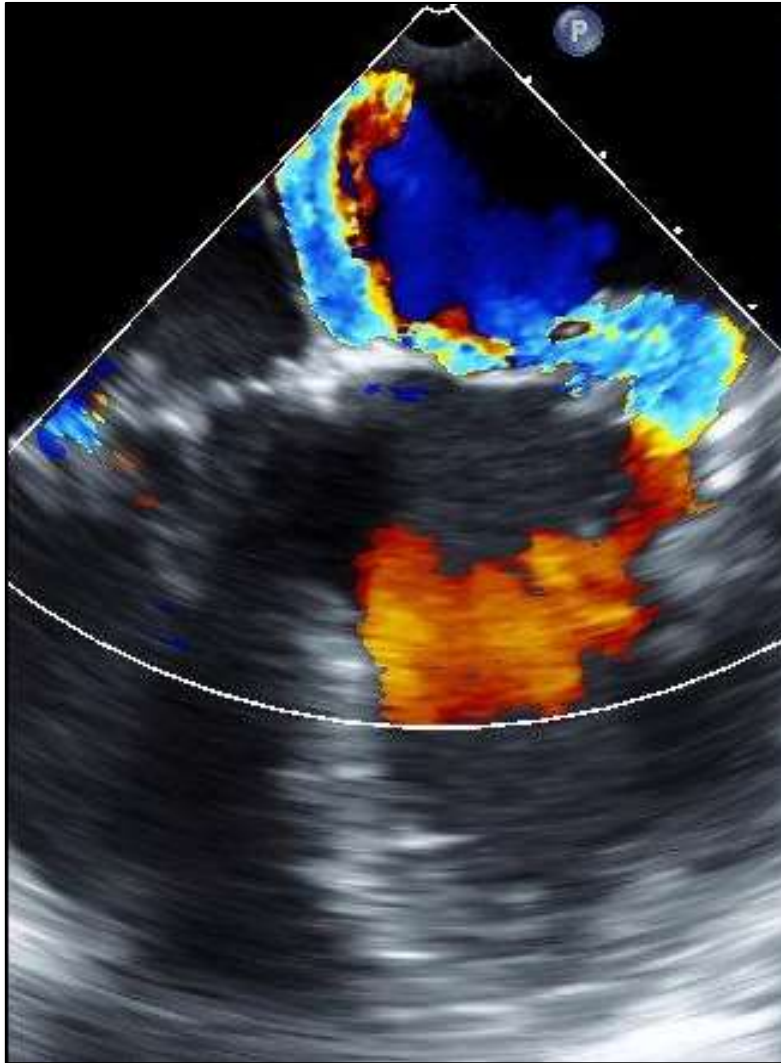
*Approved October 24, 2013*

## Indication for Use:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant **symptomatic** mitral regurgitation (MR  $\geq$  3+) due to primary abnormality of the mitral apparatus [**degenerative MR**] in patients who have been determined to be at **prohibitive risk for mitral valve surgery by a heart team**, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the **expected benefit** from reduction of the mitral regurgitation.



# DMR Pre vs Post 2 Clips



# Commercial MitraClip in the U.S.

## STS/ACC TVT Registry

n=564 commercial cases enrolled in TVT registry through August 31, 2014  
in-hospital & 30-day outcomes

N=564	%
Median age (% men)	83 yrs (56%)
HF hospitalization prior yr	51.8
Atrial fibrillation	62.6
Prior CVA	8.7
Diabetes	25
Prior CABG	32.4
Prior MI	24.6
O2 dependency	14.7
Median STS-PROM MV repair	7.9% (4.7, 12.2)
Median STS-PROM MV replacement	10.0% (6.3, 14.5)

*Paul Sorajja ACC 2015*

# Commercial MitraClip in the U.S.

*STS/ACC TVT Registry*

## **OUTCOMES**

<b>N=564</b>	<b>%</b>
Etiology DMR	86
Procedure success	91.8
Resultant MR ≤2+	93
Device-related adverse events	2.7
Procedure complications	7.8
Hospital mortality	2.3
30 day mortality	5.8
Length of stay (days)	3±1.6
Discharge home	81.9

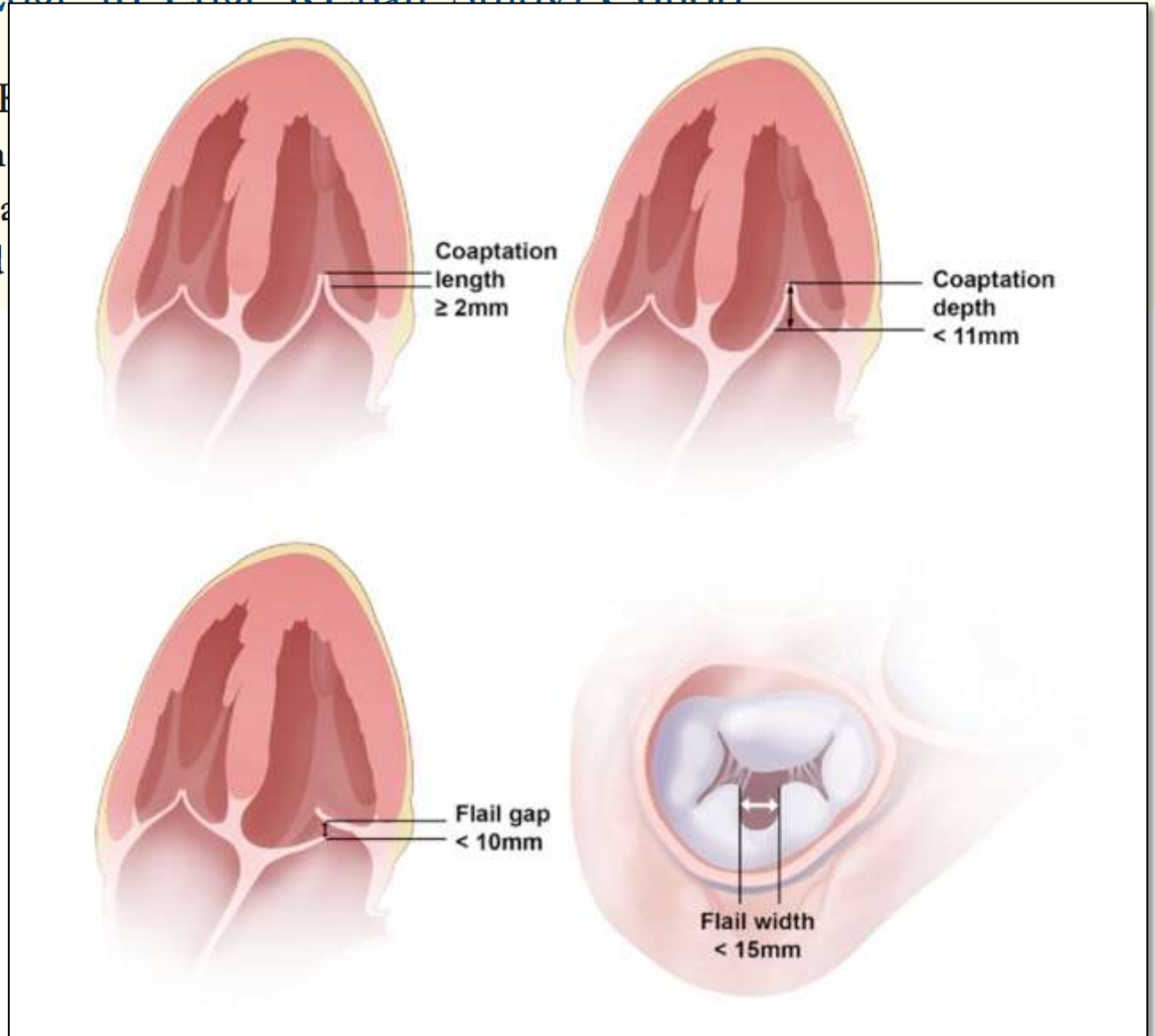


# Percutaneous Mitral Repair With the MitraClip System

## Safety and Midterm Durability in the Initial EVEREST (Endovascular Valve Edge-to-Edge REpair Study) Cohort

Ted Feldman, MD,\* Saibal P. Prasad, MD,||  
James Hermiller, MD,|| Richard C. Whitlatch, MD,||  
William Gray, MD,\*\* Regina D. Anderson, MD,||  
Elyse Foster, MD,||| Donald D. Glavind, MD,||

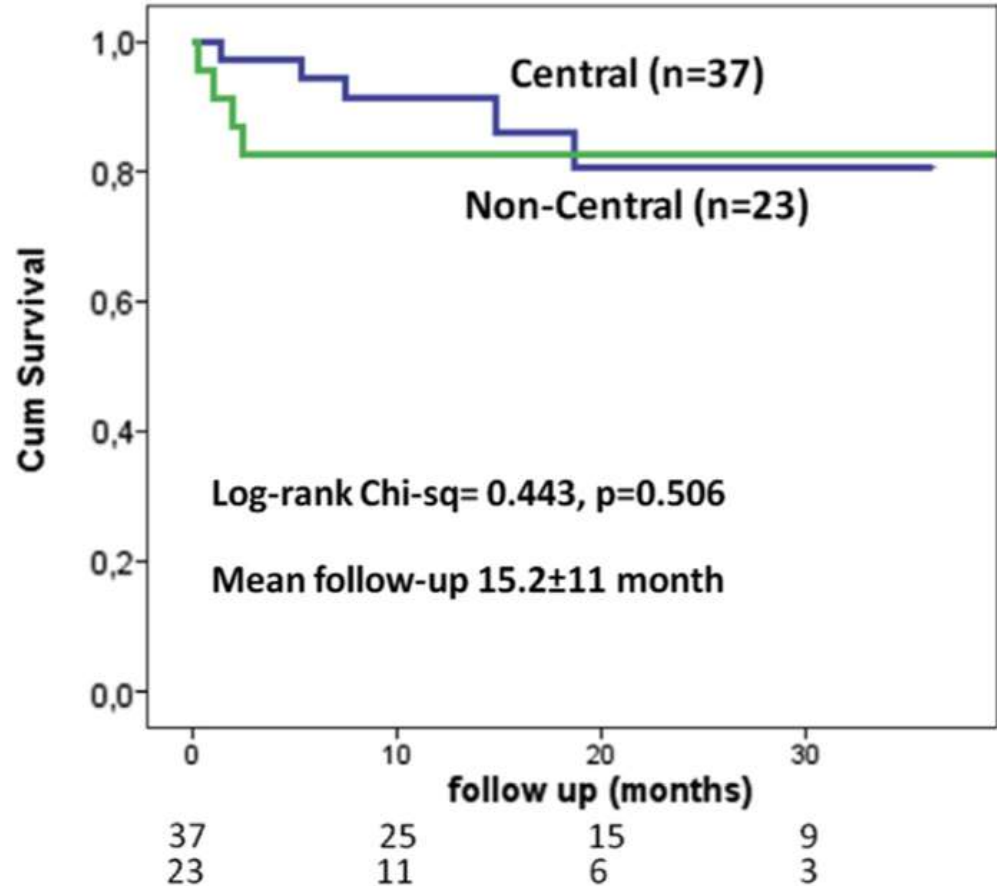
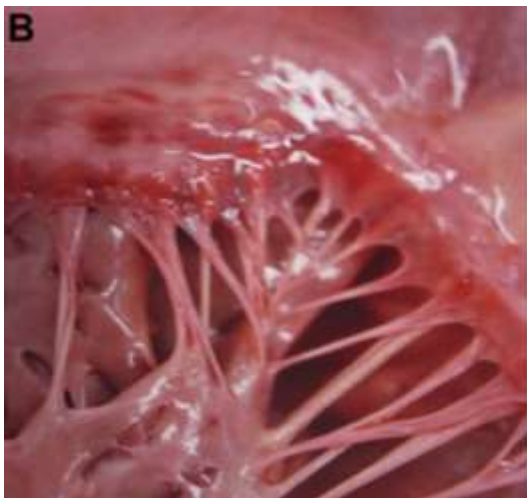
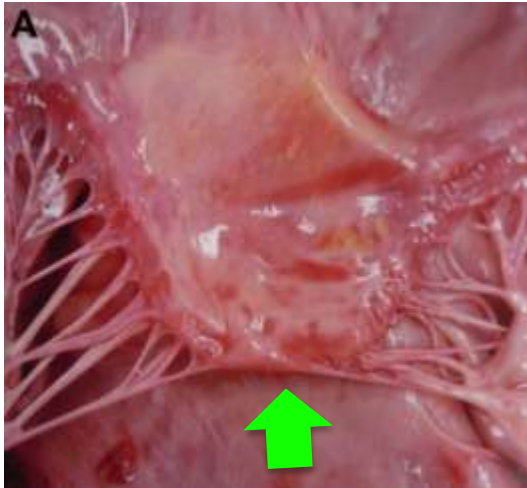
J Am Coll Cardiol 2009;54:686-94



# Anatomic predictors of procedural success with the MitraClip system

- 123 patients age  $77.5 \pm 8.0$  years with EuroScore  $29.8 \pm 21.5\%$
- failure (i.e., MR  $>2+$ , re-intervention, MV surgery, aborted procedure or leaflet detachment) in 16.8%
- Multivariable logistic regression identified
  - coaptation length  $<2.7$  mm
  - coaptation depth  $>6.3$  mm
  - distance between papillary muscles  $>32$  mm

# Central vs Noncentral Percutaneous Edge-to-Edge for DMR

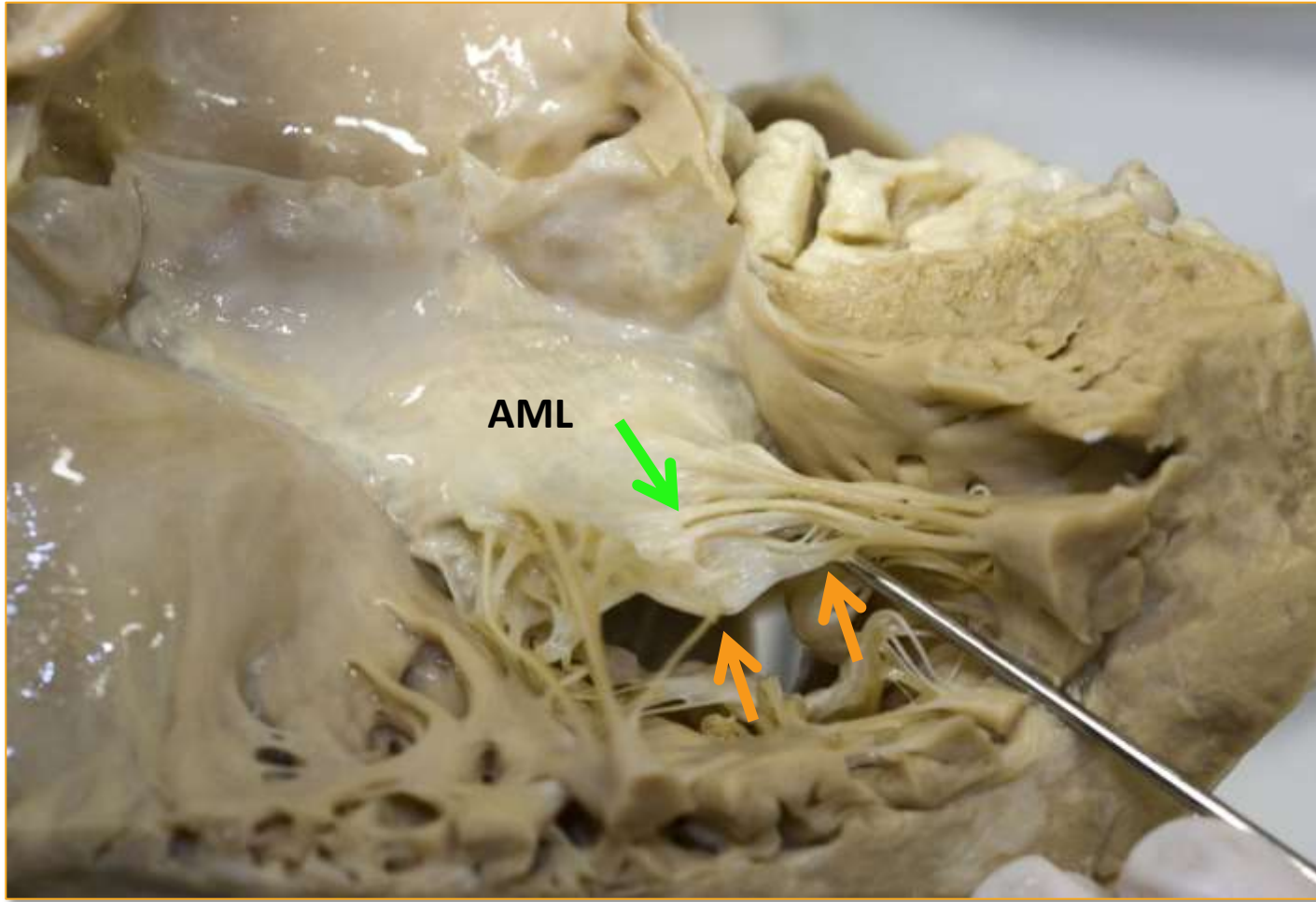


# Central vs Noncentral Percutaneous Edge-to-Edge for DMR

<b>Table 3 Periprocedural Adverse Events</b>				
	<b>Overall (N = 79)</b>	<b>Central (n = 49)</b>	<b>Non-Central (n = 30)</b>	<b>p Value</b>
Clip embolization	0 (0)	0 (0)	0 (0)	—
Partial clip detachment	2 (2.5)	1 (2)	1 (3.3)	1.000
Prolonged clip entanglement	0 (0)	0 (0)	0 (0)	1.000
Chordal rupture	1 (1.2)	1 (2)	0 (0)	1.000
Cardiac tamponade	1 (1.2)	1 (2)	0 (0)	1.000
Gastro-intestinal bleeding	2 (2.5)	1 (2)	1 (3.3)	1.000
Stroke	0 (0)	0 (0)	0 (0)	—
Transient AV block	1 (1.2)	1 (2)	0 (0)	1.000
Pneumonia	1 (1.2)	1 (2)	0 (0)	1.000
Mitral valve surgery	1 (1.2)	1 (2)	0 (0)	1.000
Death	1 (1.2)	0 (0)	1 (3.3)	1.000
<b>All complications</b>	<b>10 (12.6)</b>	<b>7 (14.3)</b>	<b>3 (10)</b>	<b>0.734</b>

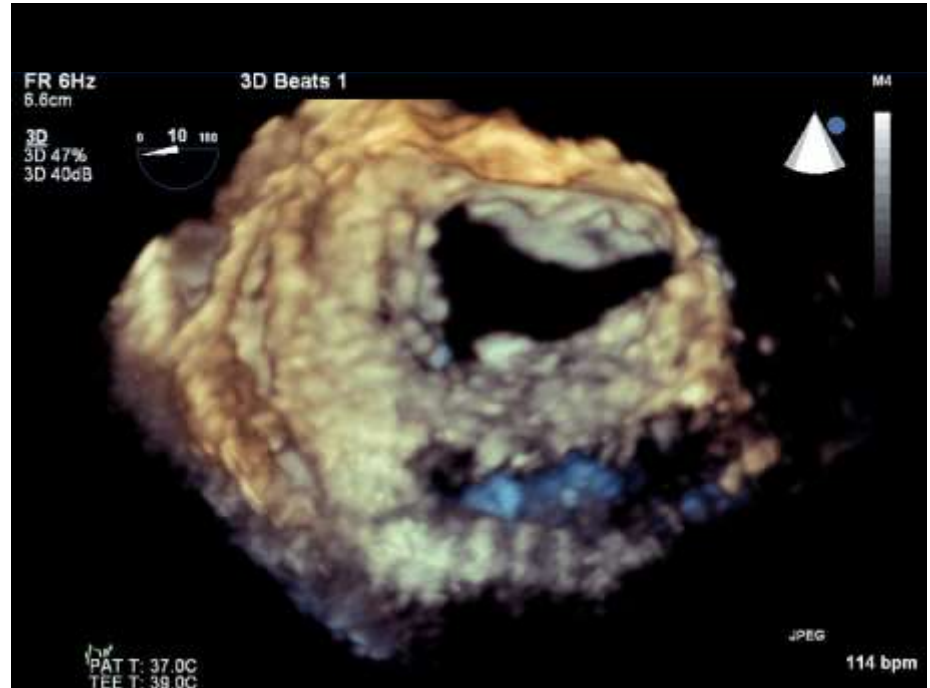
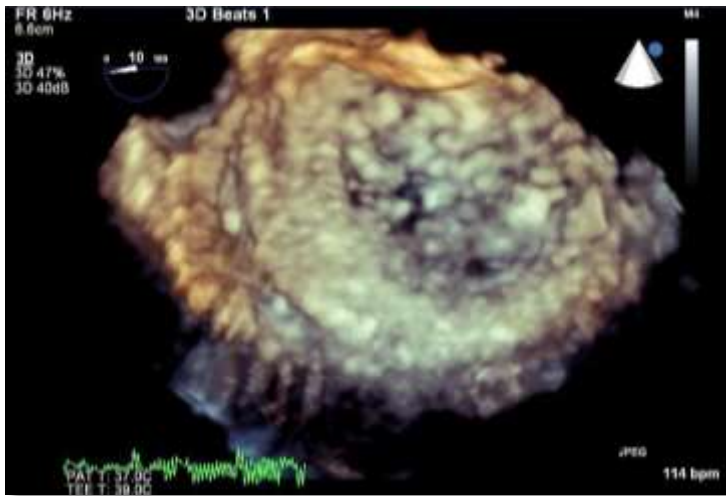


# Unsupported Leaflet





# Cleft



# Patient selection criteria and midterm clinical outcome for MitraClip therapy in patients with severe mitral regurgitation and severe congestive heart failure

Michael Neuss\*†, Thomas Schau†, Maren Schoepp, Martin Seifert, Frank Hölschermann, Jürgen Meyhöfer, and Christian Butter

**Table 4** Predictors of the combined event (primary endpoint: combination of all-cause mortality, left ventricular assist device implantation, mitral valve surgery, unsuccessful implantation) in univariate and multivariate analysis (Cox model)

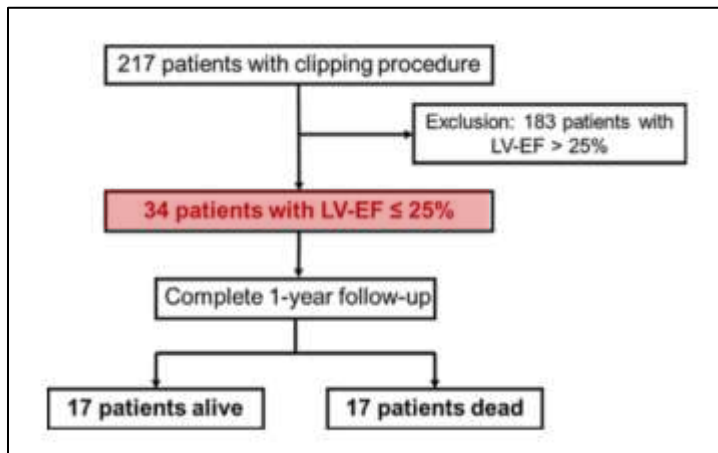
Parameter	Univariate analysis		Multivariate analysis: optimized model	
	HR (95% CI)	P-value	HR (95% CI)	P-value
NT-proBNP >10 000 pg/mL	4.6 (2.6–8.2)	<0.001	3.5 (1.9–6.7)	<0.001
Age >80 years	1.8 (1.0–3.3)	0.046	2.2 (1.2–4.2)	0.008
Serum creatinine >150 mmol/L	2.4 (1.4–4.3)	0.002		
NYHA class IV	2.1(1.2–3.7)	0.008	1.7(1.0–3.2)	0.049
TAPSE <15 mm	3.2 (1.8–5.6)	<0.001	1.9(1.0–3.6)	0.038
TR grade >2 +	2.0 (1.0–4.0)	0.052		

CI, confidence interval; HR, hazard ratio; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

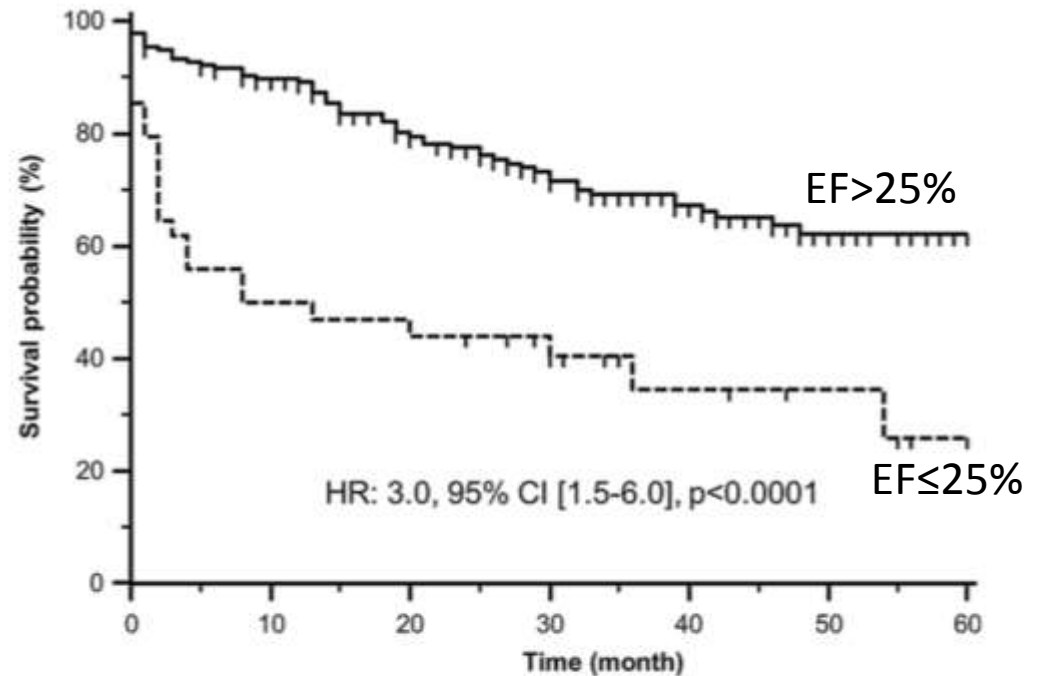


# Long-Term Outcome of Patients with Severe Biventricular Heart Failure after MitraClip

## *Predictive value of LVEF*



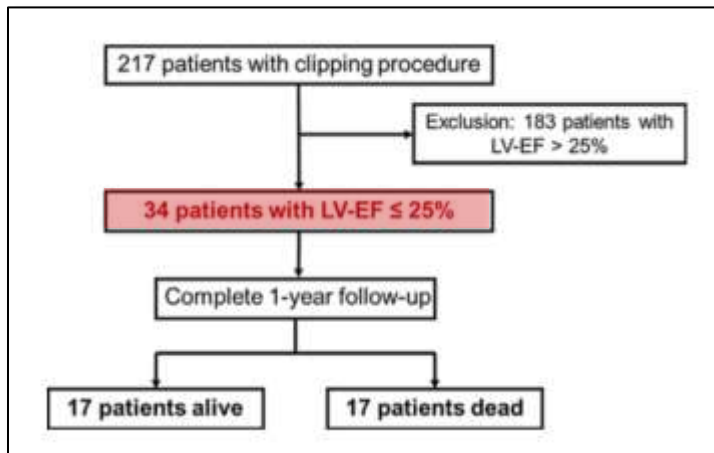
None of the patients met the inclusion criteria of EVEREST II



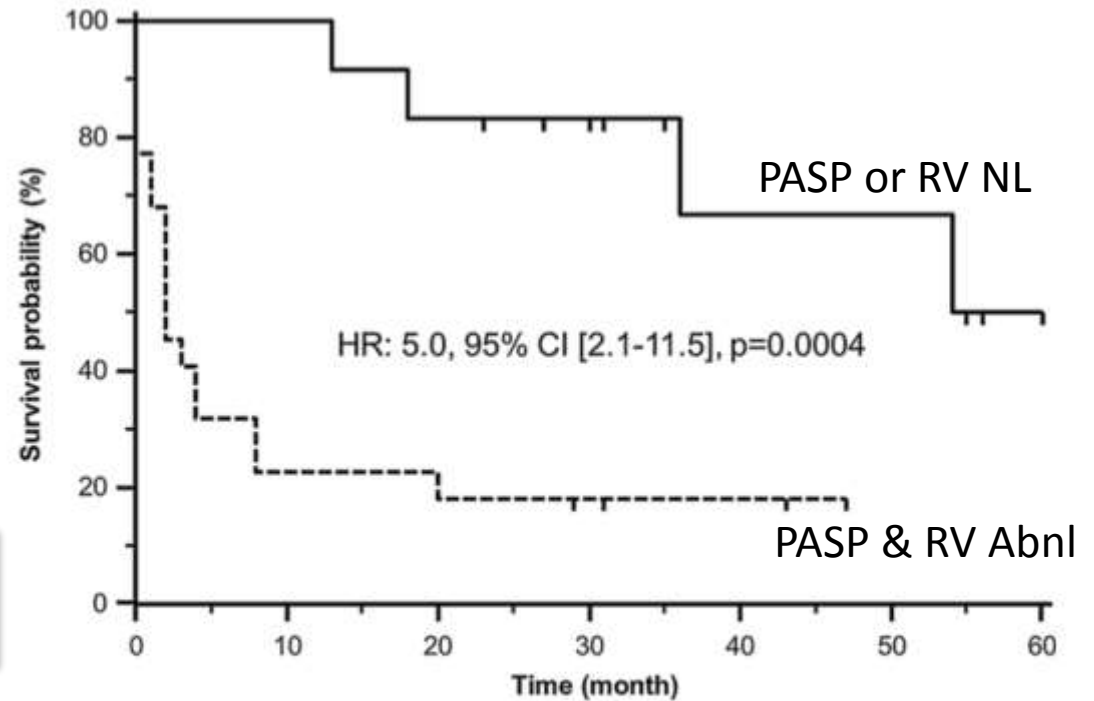
Number at risk		Time (month)						
		0	10	20	30	40	50	60
—	LV-EF > 25%	183	149	119	90	67	25	1
- - -	LV-EF ≤ 25%	34	17	15	10	6	4	1

# Long-Term Outcome of Patients with Severe Biventricular Heart Failure after MitraClip

## *Predictive value of PASP + RV function*



None of the patients met the inclusion criteria of EVEREST II



Number at risk

—	RVTG and RV-Function normal or one parameter abnormal	12	12	10	7	4	4	3
- - -	RVTG elevated and RV-Function impaired	22	5	4	3	2	0	0

# Registries

## *Prospective-Multicenter*

Study	n
REALISM US Continued Access	899
REALISM Compassionate/Emergency Use	66
ACCESS Europe Phase I	567
ACCESS Europe Phase II	286
German Transcatheter Mitral Valve Interventions (TRAMI)	1002
GRASP-It	304
MitraSwiss registry nationwide	265
Sentinel Registry EURObservational Research Programme ESC	628
MitraClip Asia-Pacific Registry (MARS)	145
ANZ MitraClip Registry	45

# Therapy for MR

	Degenerative	Functional
Low Surgical Risk	Surgical Mitral Repair	??
High Surgical Risk	Commercial MitraClip	COAPT

# Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for High Surgical Risk



~430 patients enrolled at up to 75 US sites

Significant FMR  $\geq 3+$  core lab; EF  $< 50\%$ ; CHF hospitalization or BNP  $> 300$

**High risk for mitral valve surgery- Local Heart Team**

Specific valve anatomic criteria

Randomize 1:1

MitraClip

Control group  
Standard of care

**Safety:** Composite death, stroke, worsening renal function, LVAD implant, heart transplant at 12 months

**Effectiveness:** Recurrent heart failure hospitalizations

# MitraClip RCTs in Functional MR

**1348 patients**

**Heart failure and FMR**

**MitraClip vs. GDMT or MV Surgery**

- **COAPT – 430**
- **MITRA-FR – 288**
- **RESHAPE-HF-2 – 420**
- **MATTERHORN (vs MVS) – 210**

# TVT Registry: Residual MR

