Clinical Results of MitraClip in Degenerative MR

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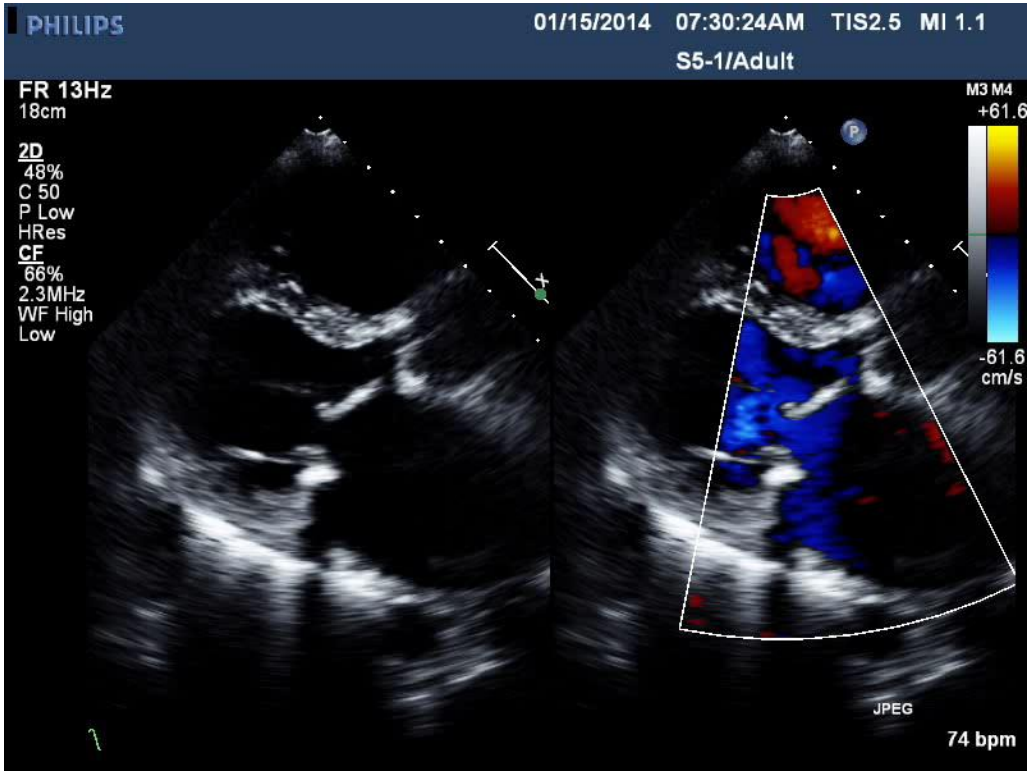
Disclosures

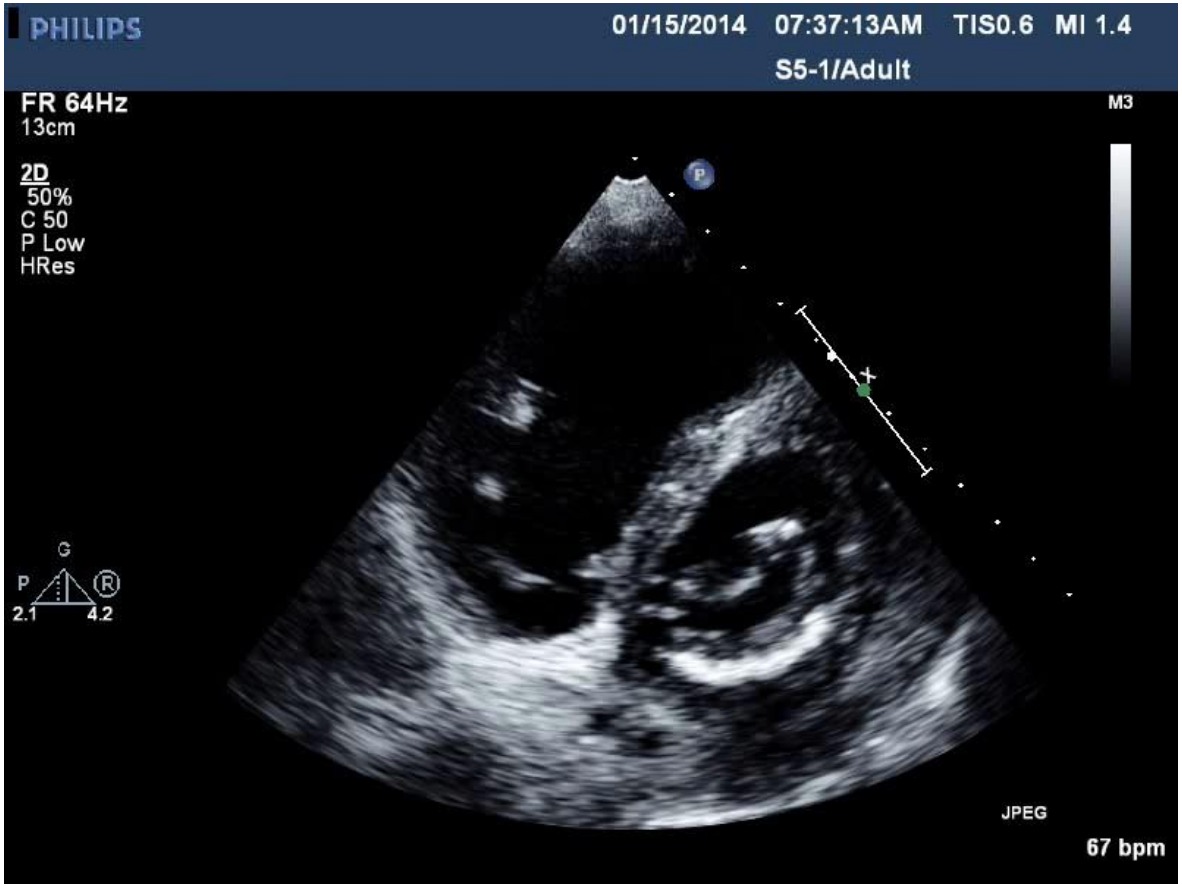
- **No financial conflict**
- **Steering Committee**
  - **Mitraclip (COAPT)**

Case Presentation

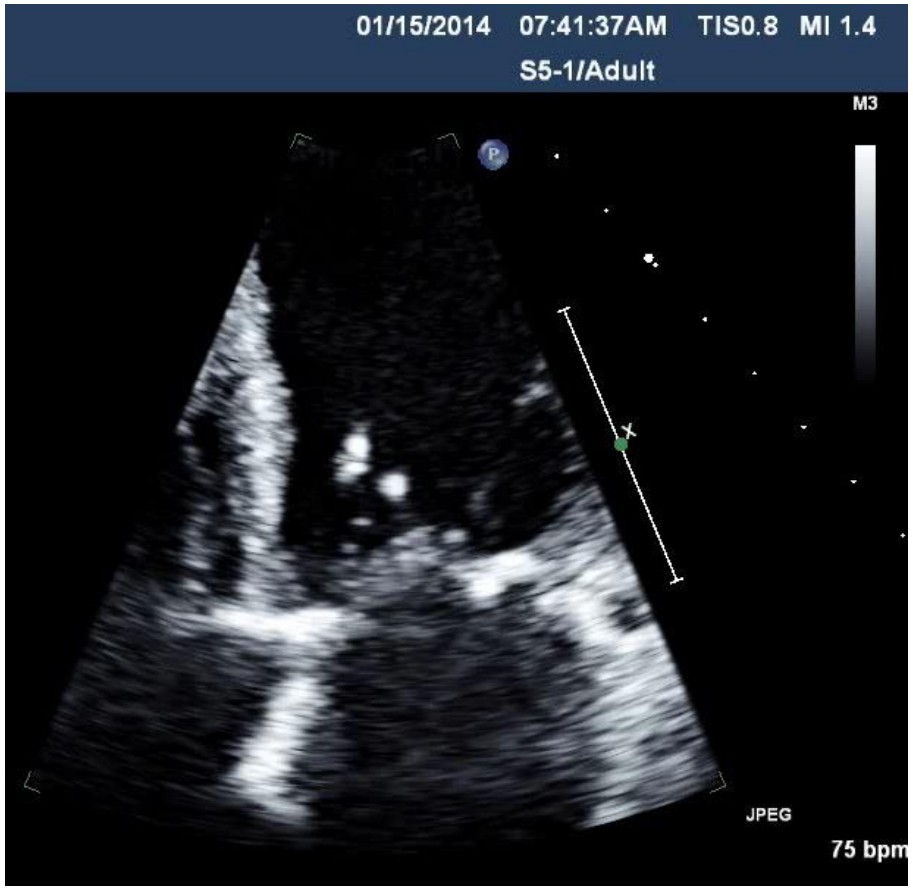
90 year old patient with prior CABG 2002, now with CHF
3 admissions in 3 months, mother of a surgeon
4++ MR and normal LV, PHTN with RVSP 70 mm Hg
Cr 1.8, no recent cath, no CP

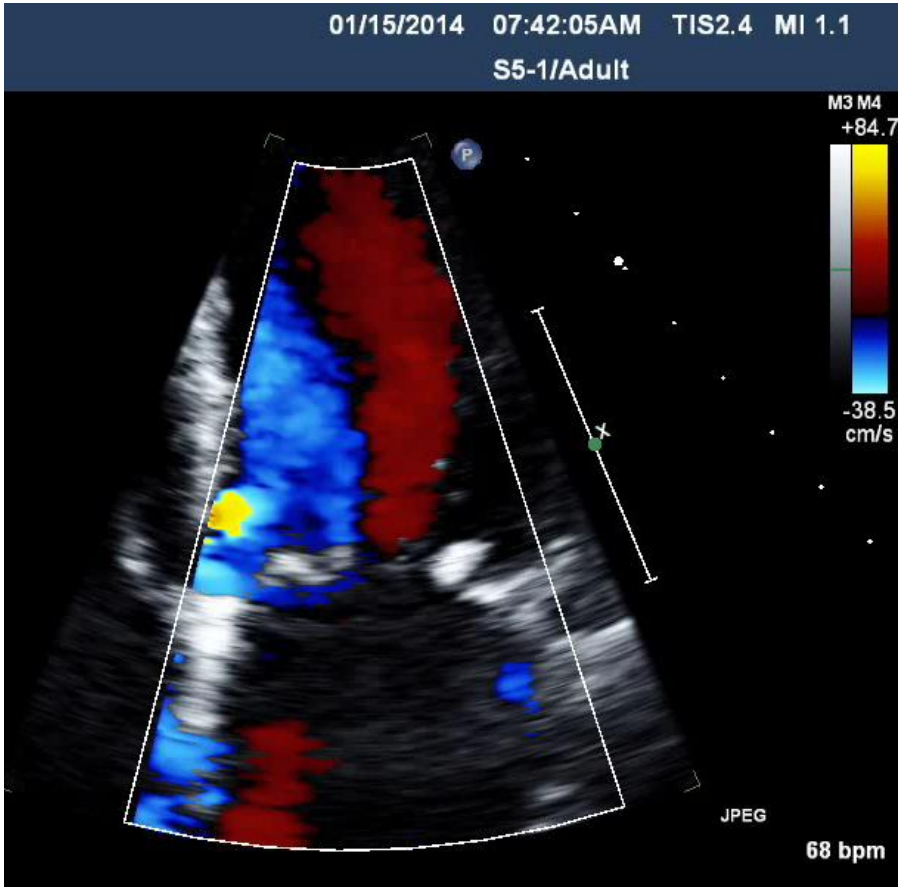


Severe MAC with MVA 3.5 cm^2

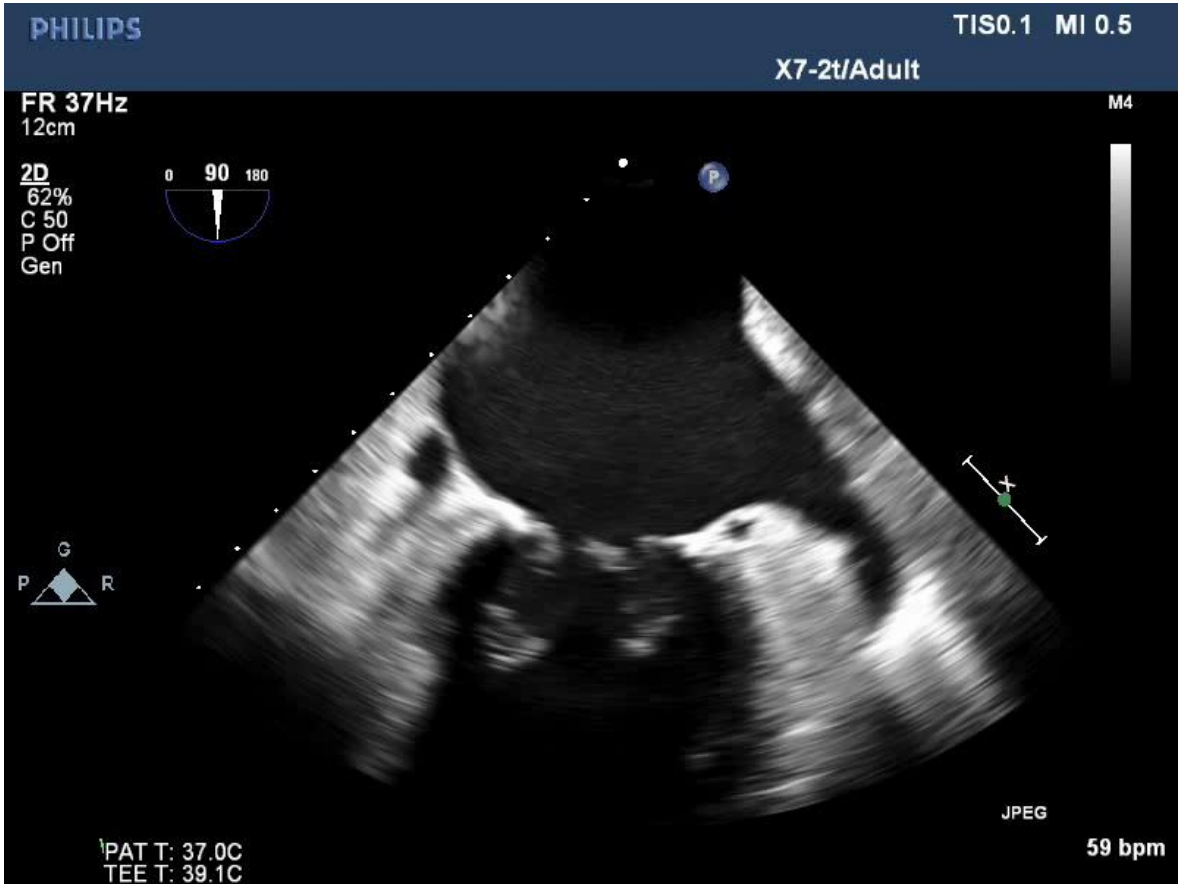


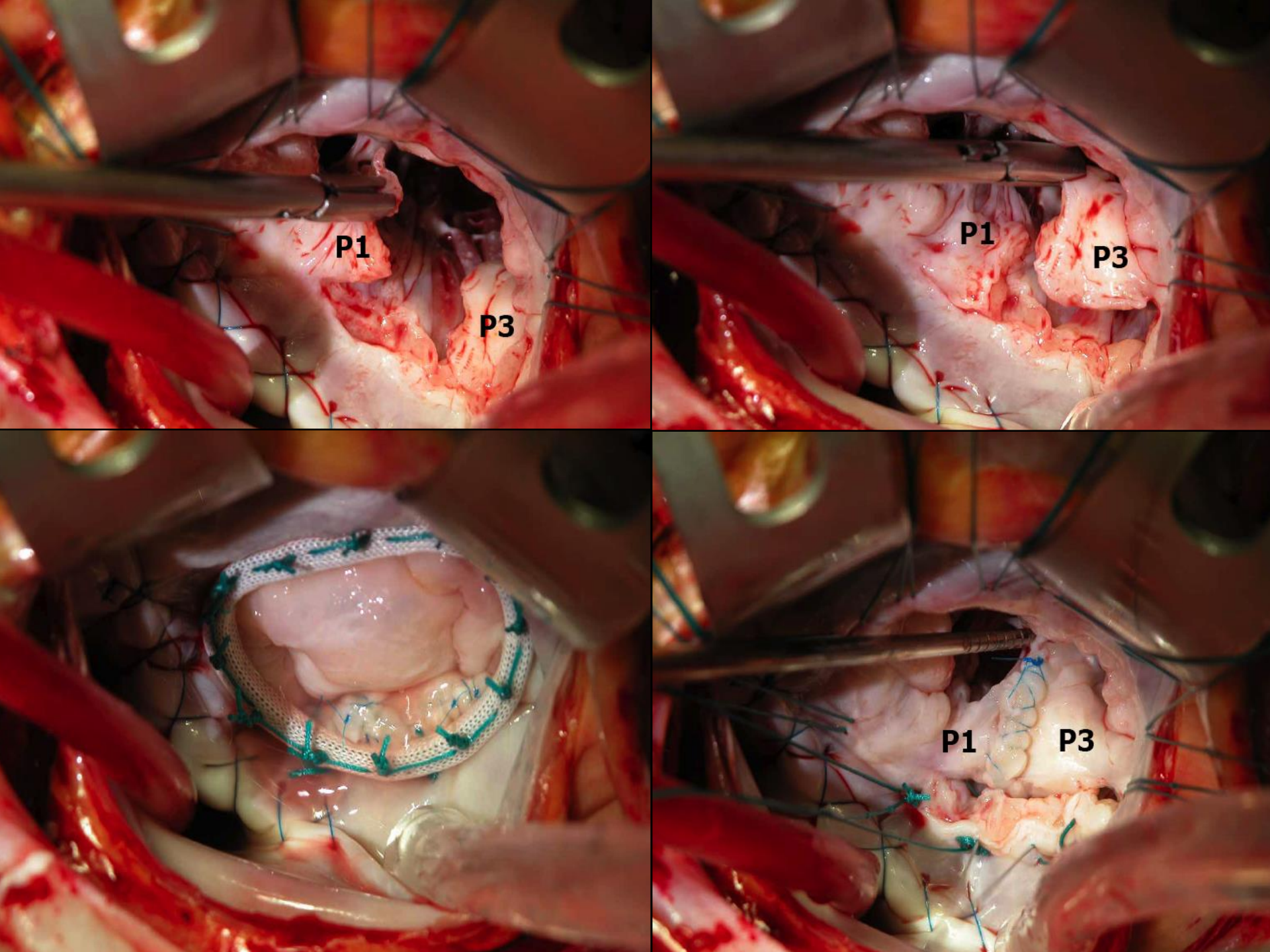
Mechanism appears to anterior flail





Confirm Flail on TEE

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P3
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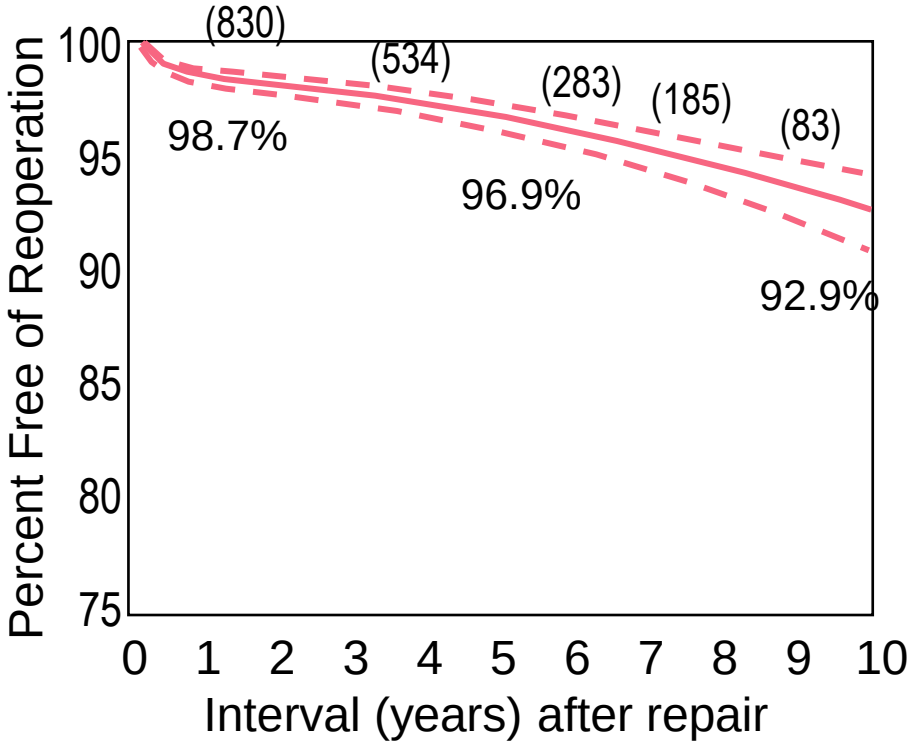
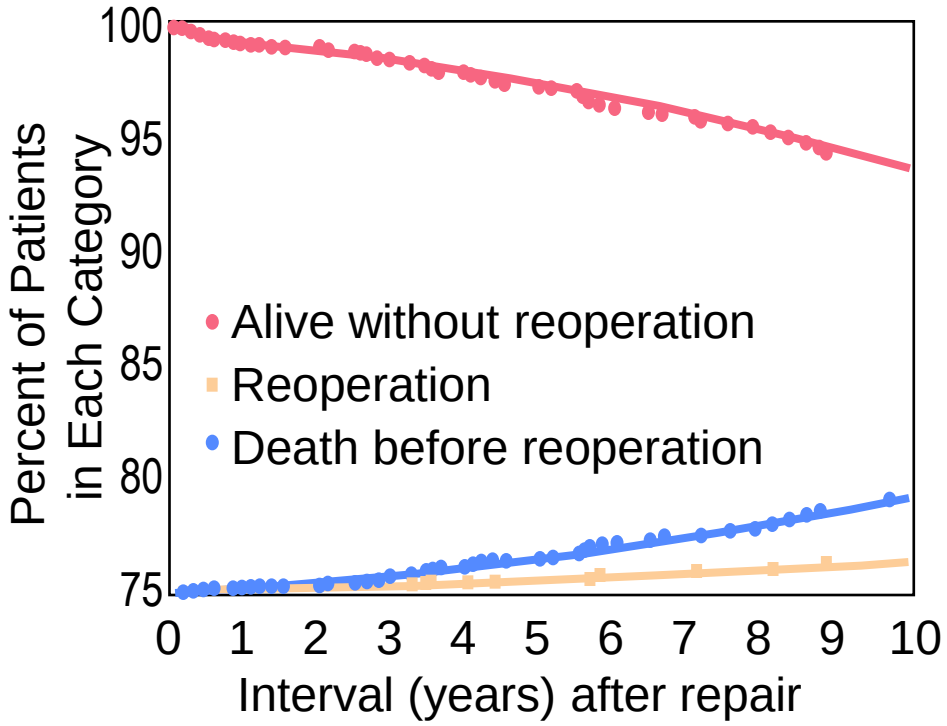
P3

Does this apply?
Degenerative Mitral Valve Disease: 10 year Outcome





18% above age 70, none above 90 and redo

Gillinov et al, The Journal of Thoracic and Cardiovascular Surgery, 1998

MV Surgery:
Impact of Age and Comorbidities

- **Older age is associated to**
  - **Higher mortality (x3)**
  - **More stroke (x3)**
  - **Higher morbidity (x3)**
  - **Longer LOS (x1.5)**

Characteristics	< 50 yrs	50-59 yrs	60-69 yrs	70-79 yrs	≥ 80 yrs
Sample Size	4315	5037	8472	11144	2720
Complications (%)	13.51	17.79	23.11	29.47	35.48
Permanent stroke (%)	1.23	1.79	2.70	4.16	4.52
Reoperation for bleeding (%)	3.75	4.61	5.21	6.74	8.53
Renal failure (%)	3.87	5.74	8.23	11.28	15.22
Deep sternal wound infection (%)	0.44	0.75	0.74	0.68	0.51
Length of stay (d)					
Mean (SD)	11.43 (12.23)	12.36 (13.52)	13.32 (13.20)	15.18 (14.66)	16.31 (14.13)
Postoperative length of stay (d)					
Mean (SD)	8.71 (9.74)	9.69 (11.04)	10.58 (11.37)	12.21 (13.11)	13.22 (13.17)
Operative mortality (%)	4.08	5.46	7.91	12.19	16.99

Mehta et al., Ann Thorac Surg 2002;74:1459-67

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

Ted Feldman, MD,* Saibal Kar, MD,† Sammy Elmariah, MD, MPH,‡§ Steven C. Smart, MD,* Alfredo Trento, MD,‖ Robert J. Siegel, MD,† Patricia Apruzzese, MS,§ Peter Fail, MD,¶ Michael J. Rinaldi, MD,# Richard W. Smalling, MD, PhD,** James B. Hermiller, MD,†† David Heimansohn, MD,‡‡ William A. Gray, MD,§§ Paul A. Grayburn, MD,‖‖ Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,*** Howard C. Herrmann, MD,††† Michael A. Acker, MD,‡‡‡ Frank E. Silvestry, MD,††† Elyse Foster, MD,§§§ Andrew Wang, MD,‖‖‖ Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,§### for the EVEREST II Investigators

ABSTRACT

BACKGROUND In the second Endovascular Valve Edge-to-Edge Repair Study trial, treatment of mitral regurgitation (MR) with a novel percutaneous device showed superior safety compared with surgery, but less effective reduction in MR at 1 year.

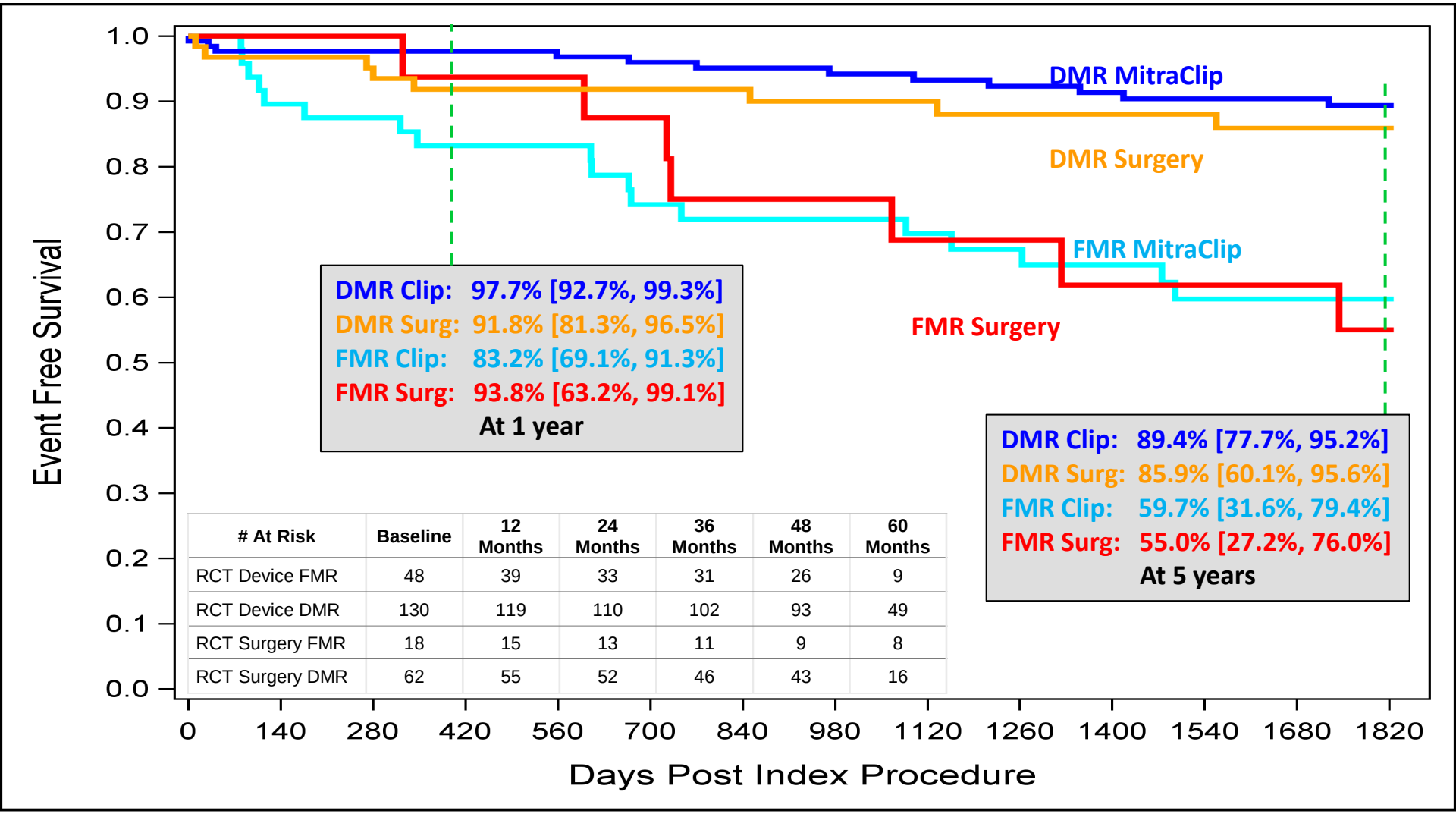
OBJECTIVES This study sought to evaluate the final 5-year clinical outcomes and durability of percutaneous mitral valve (MV) repair with the MitraClip device compared with conventional MV surgery.

METHODS Patients with grade 3+ or 4+ MR were randomly assigned to percutaneous repair with the device or conventional MV surgery in a 2:1 ratio (178:80). Patients prospectively consented to 5 years of follow-up.

RESULTS At 5 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the as-treated population was 44.2% versus 64.3% in the percutaneous repair and surgical groups, respectively ($p = 0.01$). The difference was driven by increased rates of 3+ to 4+ MR (12.3% vs. 1.8%; $p = 0.02$) and surgery (27.9% vs. 8.9%; $p = 0.003$) with percutaneous repair. After percutaneous repair, 78% of surgeries occurred within the first 6 months. Beyond 6 months, rates of surgery and moderate-to-severe MR were comparable between groups. Five-year mortality rates were 20.8% and 26.8% ($p = 0.4$) for percutaneous repair and surgery, respectively. In multivariable analysis, treatment strategy was not associated with survival.

CONCLUSIONS Patients treated with percutaneous repair more commonly required surgery for residual MR during the first year after treatment, but between 1- and 5-year follow-up, comparably low rates of surgery for MV dysfunction with either percutaneous or surgical therapy endorse the durability of MR reduction with both repair techniques. (EVEREST II Pivotal Study High Risk Registry; NCT00209274). (J Am Coll Cardiol 2015;66:2844–54) © 2015 by the American College of Cardiology Foundation.

Freedom From Mortality & Re-intervention



# At Risk	Baseline	12 Months	24 Months	36 Months	48 Months	60 Months
RCT Device FMR	48	39	33	31	26	9
RCT Device DMR	130	119	110	102	93	49
RCT Surgery FMR	18	15	13	11	9	8
RCT Surgery DMR	62	55	52	46	43	16

J Am Coll Cardiol 2014;64:182–92

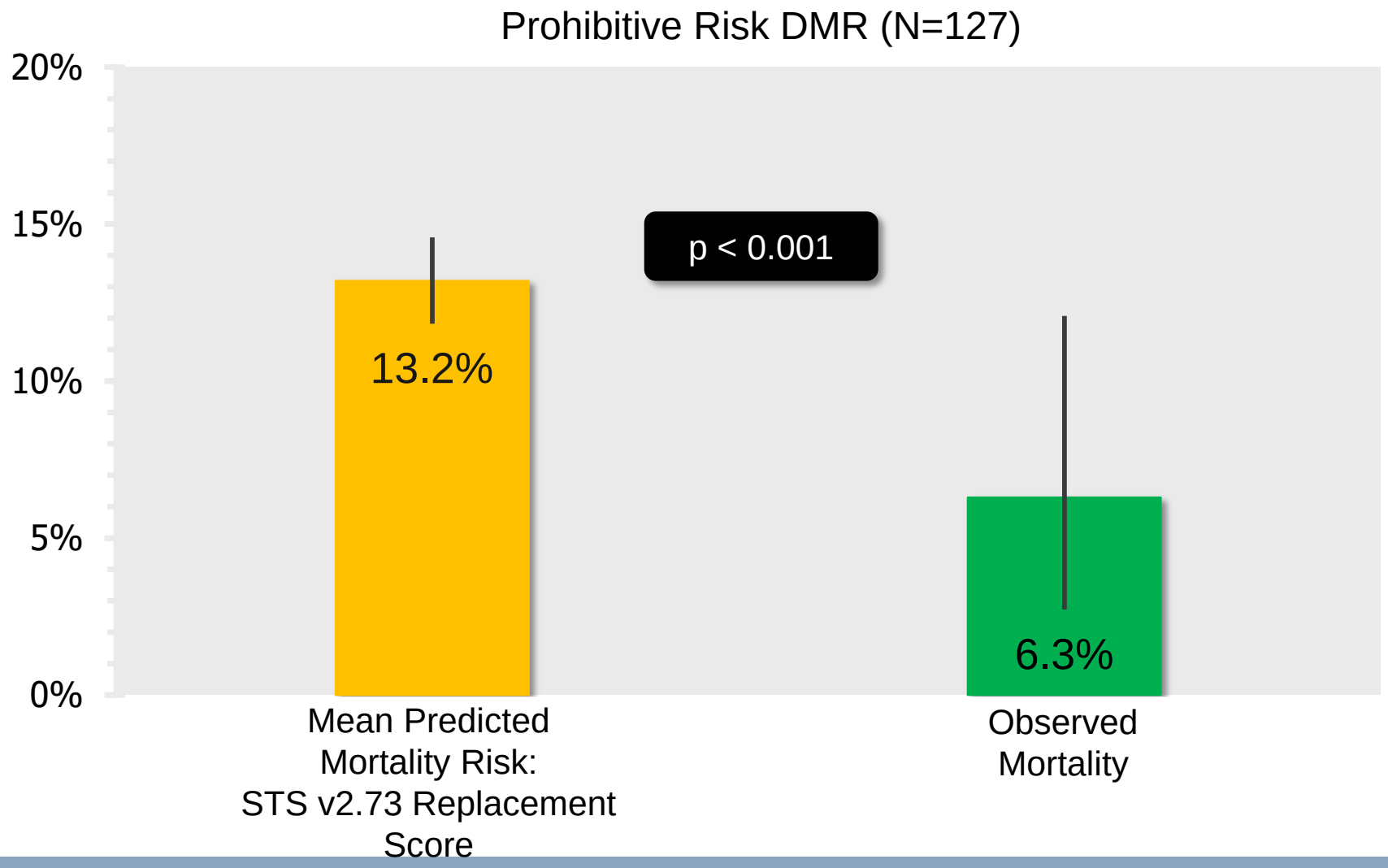
Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation Following Transcatheter Mitral Valve Repair with the MitraClip® System

Lim DS, MD, Reynolds MR, MD, Feldman T, MD, Kar S, MD, Herrmann HC, MD, Wang A, MD, Whitlow PL, MD, Gray WA, MD, Grayburn P, MD, Mack MJ, MD, Glower D, MD:

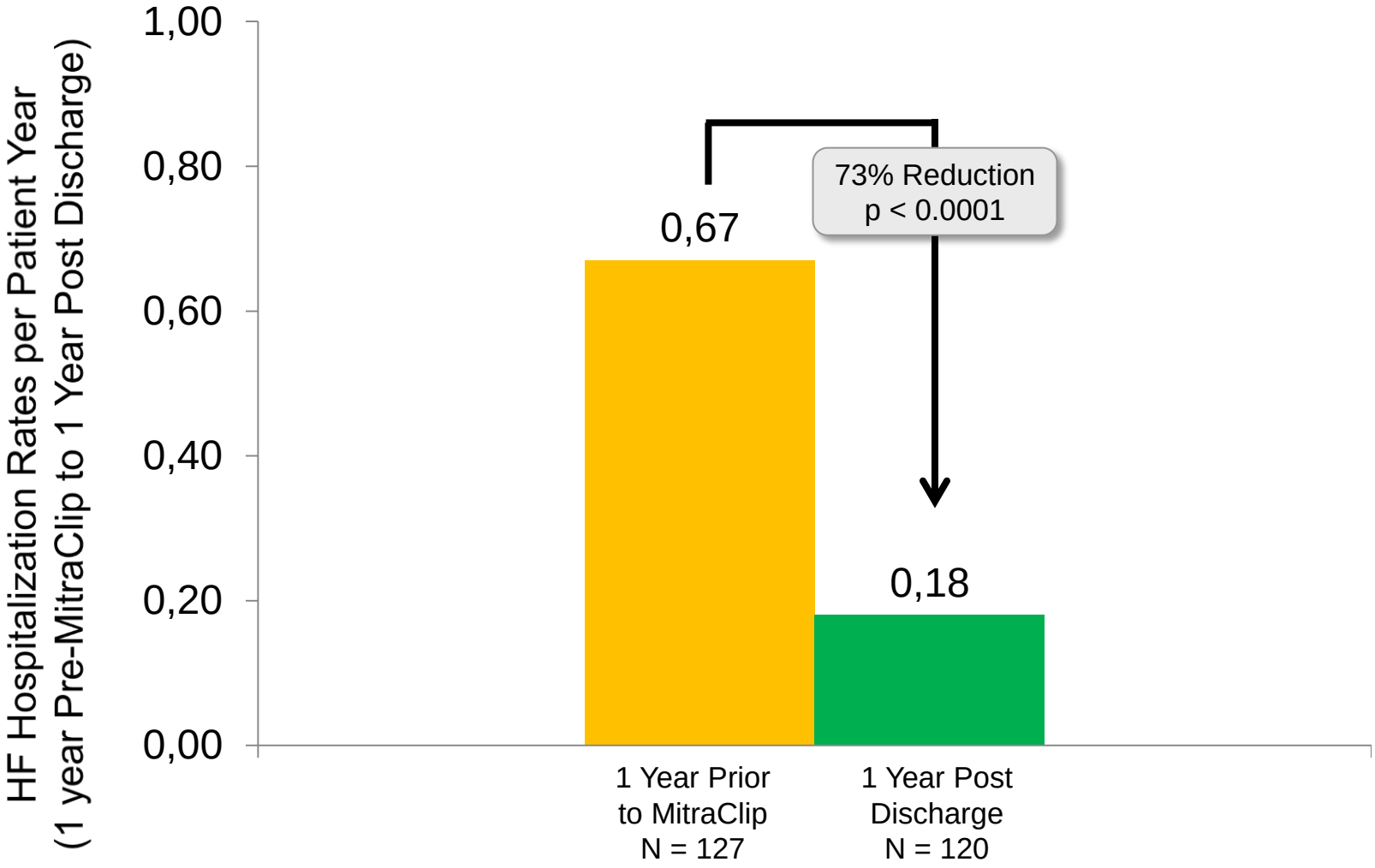
High Risk DMR Patients

- **141 high surgical risk DMR patients treated in the EVEREST Registries with 1-year follow-up available**
- **Prohibitive risk definition retrospectively applied by heart team**
  - **Two cardiac surgeons experienced in MV surgery**
  - **Cardiologist experienced in MV disease**
- **127 patients were documented to meet prohibitive risk**

30 Day Mortality: Predicted vs Observed

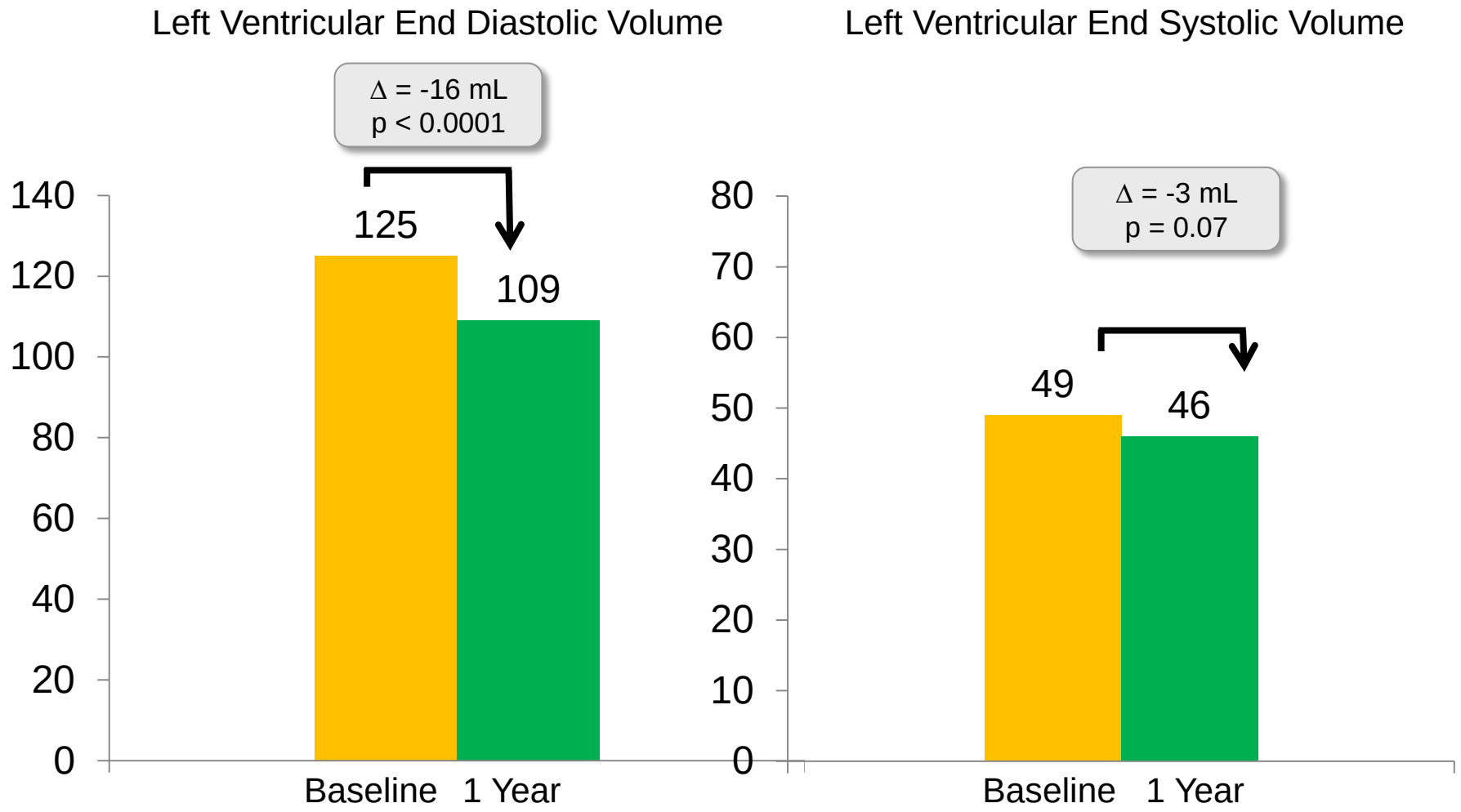


Hospitalizations For Heart Failure



J Am Coll Cardiol 2014;64:182–92

Left Ventricular Volumes At 1 Year



J Am Coll Cardiol 2014;64:182–92

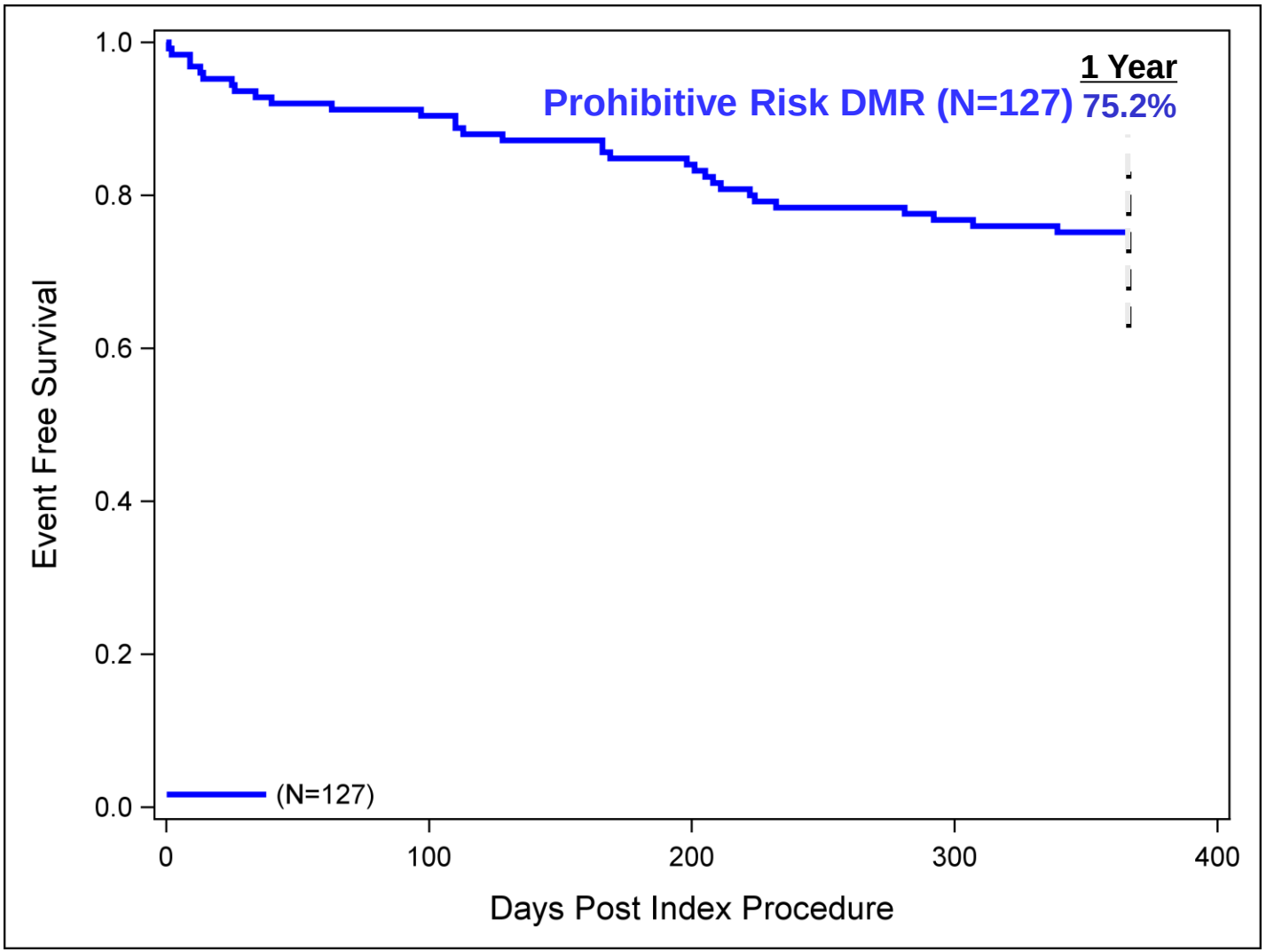
CEC-Adjudicated Safety Events

Event (Non-Hierarchical)	Prohibitive Risk DMR (N=127)			
	30 Days		1 Year	
	n	%	n	%
Death*	8	**6.3%**	30	23.6%
Myocardial Infarction	1	0.8%	1	0.8%
Non-elective CV Surgery for AEs	1	0.8%	1	0.8%
Stroke	3	2.4%	3	2.4%
New onset of permanent AF	0	0	0	0
Renal Failure	2	1.6%	5	3.9%
Ventilation > 48 hours	4	3.1%	6	4.7%
GI complication requiring surgery	1	0.8%	3	2.4%

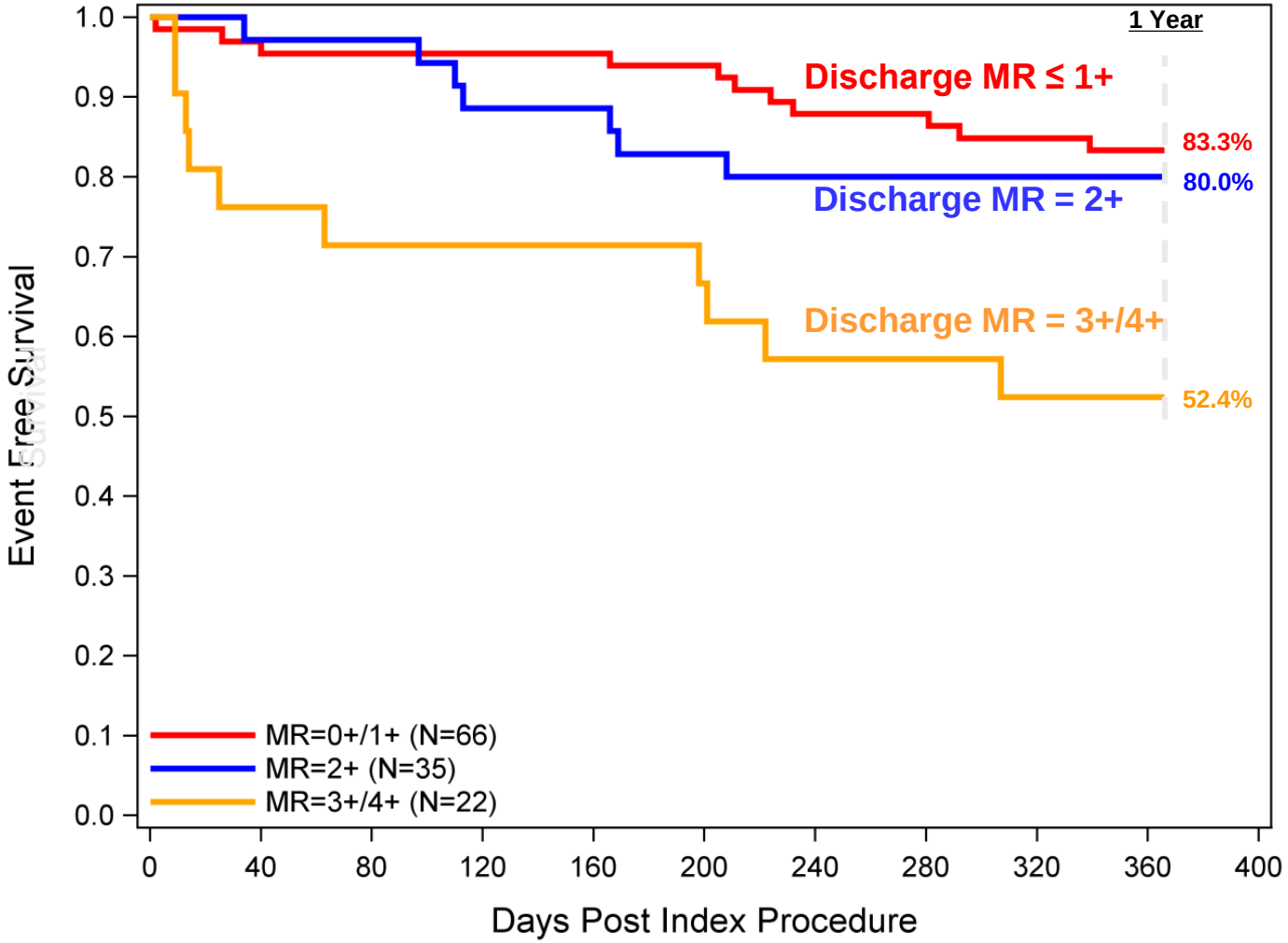
* No intra-procedural or cath lab deaths

Kaplan-Meier Freedom From Mortality

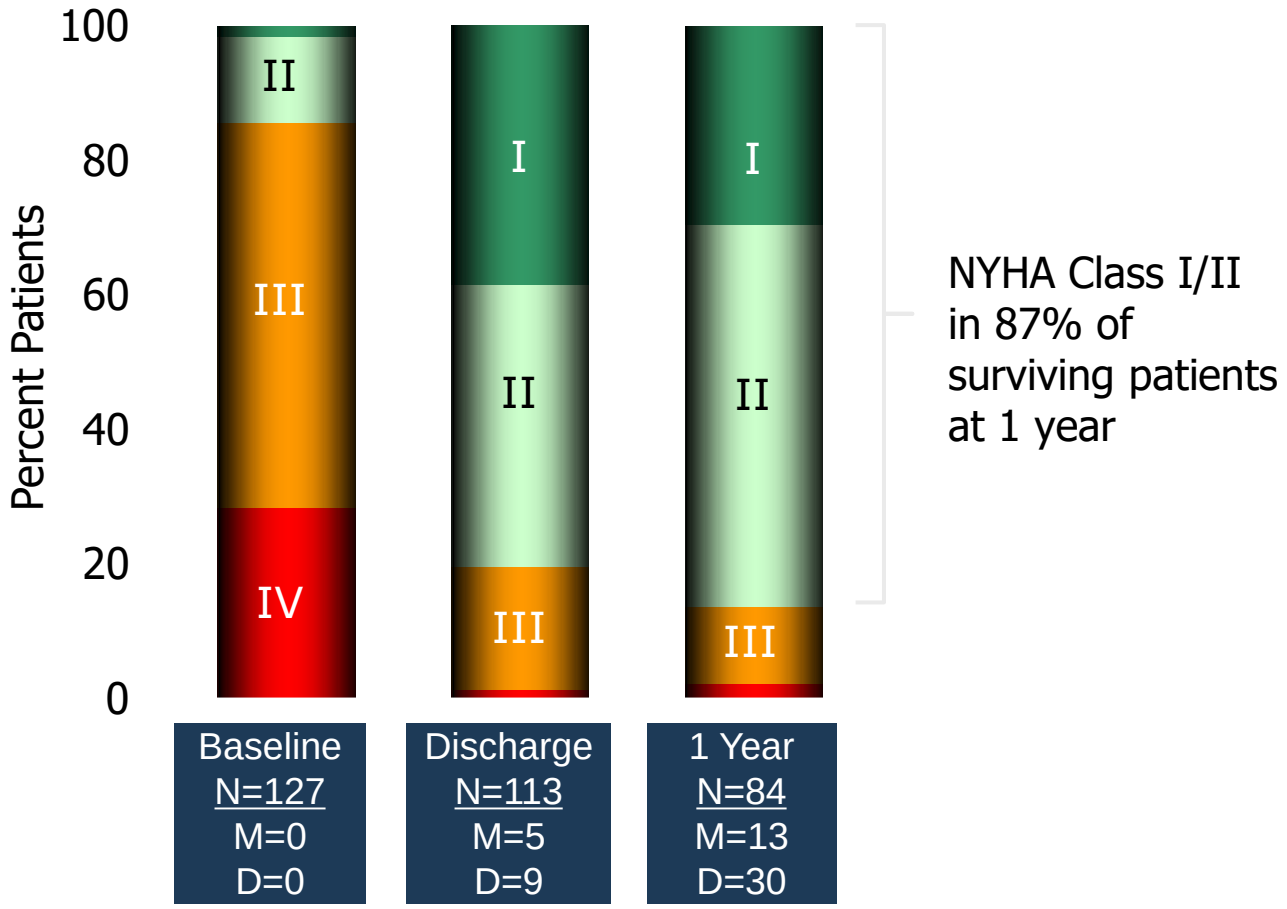
Through 1 Year



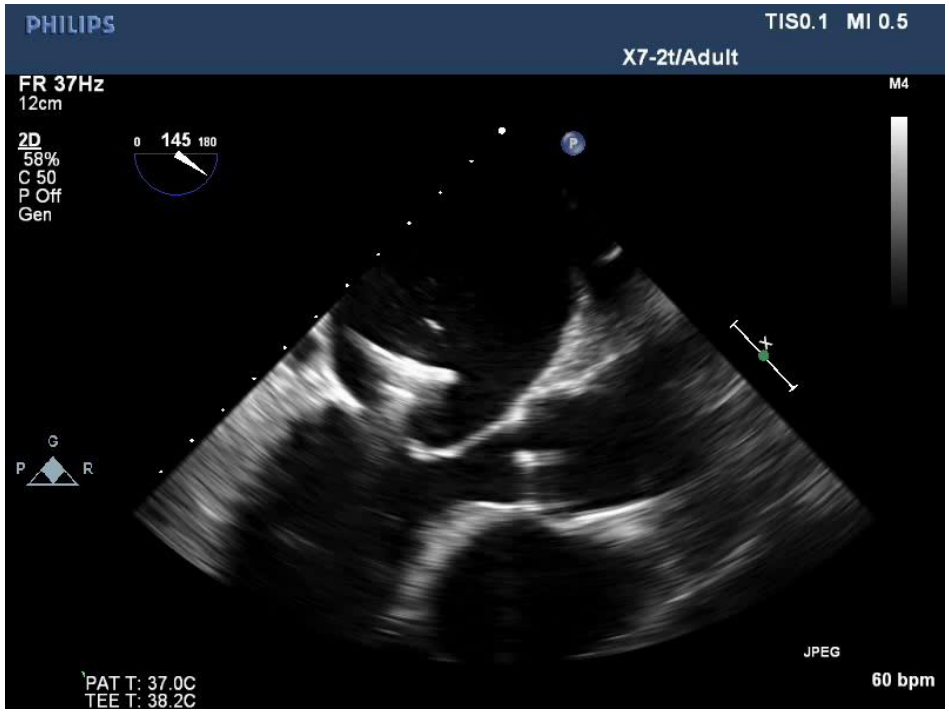
Kaplan-Meier Freedom From Mortality
Through 1 Year By Discharge MR Severity

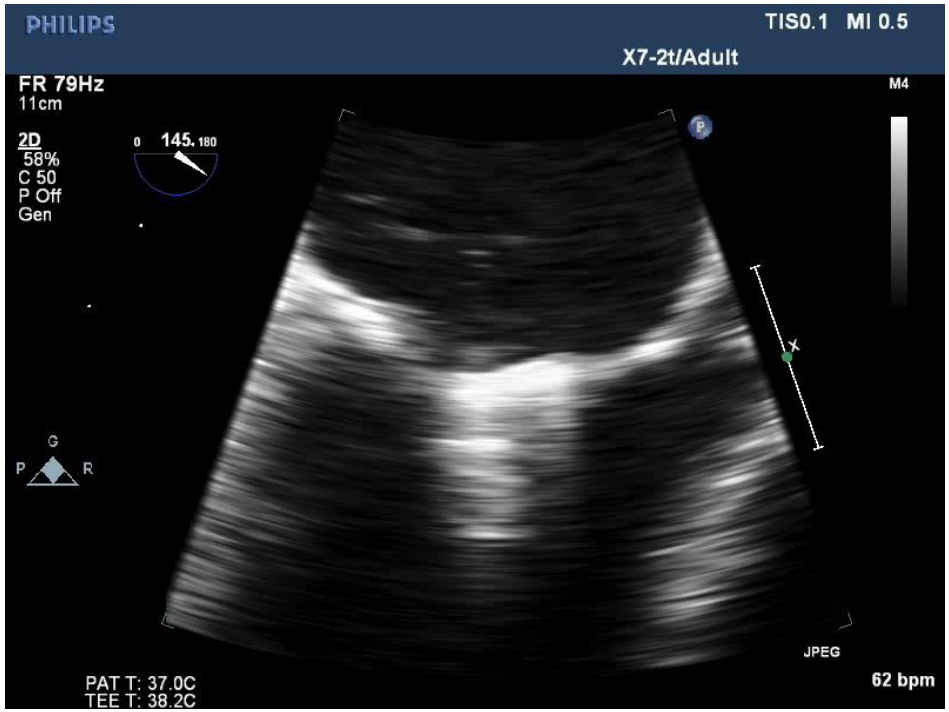


NYHA Functional Class Through 1 Year

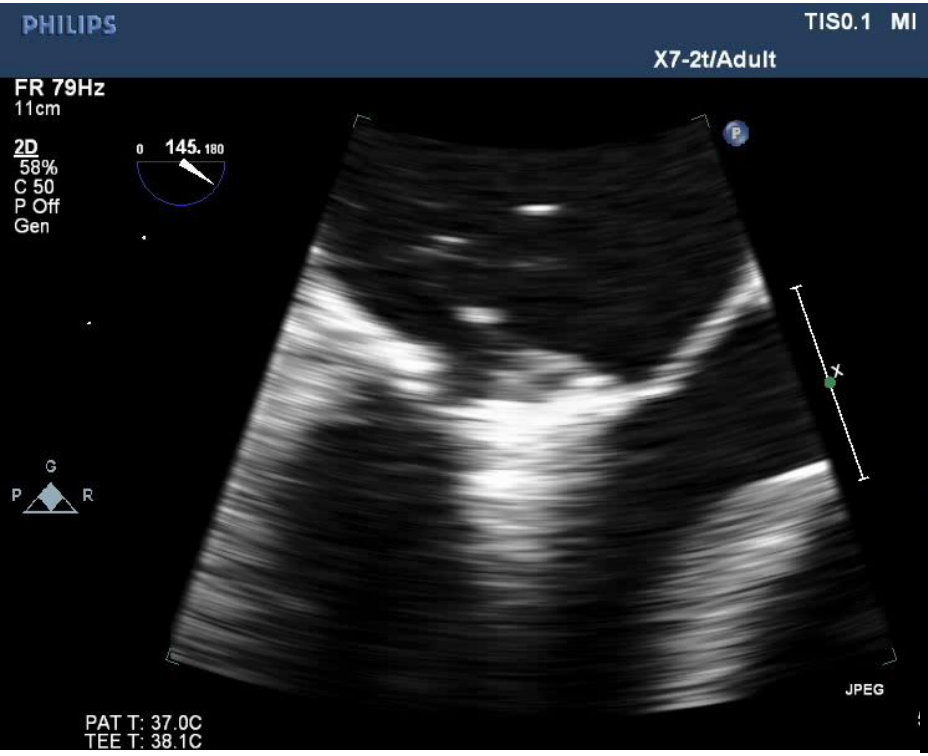


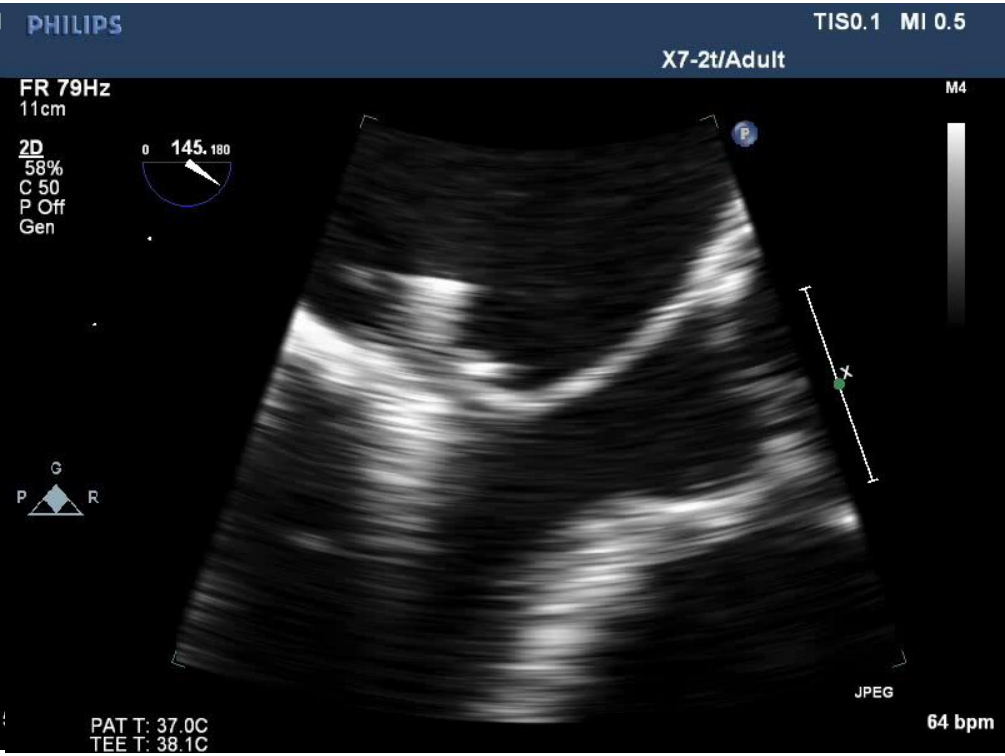
Procedure


PHILIPS
TIS0.1 MI 0.5
X7-2t/Adult
FR 37Hz
12cm
M4
2D
58%
C 50
P Off
Gen
0 145 180
G
P R
JPEG
PAT T: 37.0C
TEE T: 38.2C
60 bpm

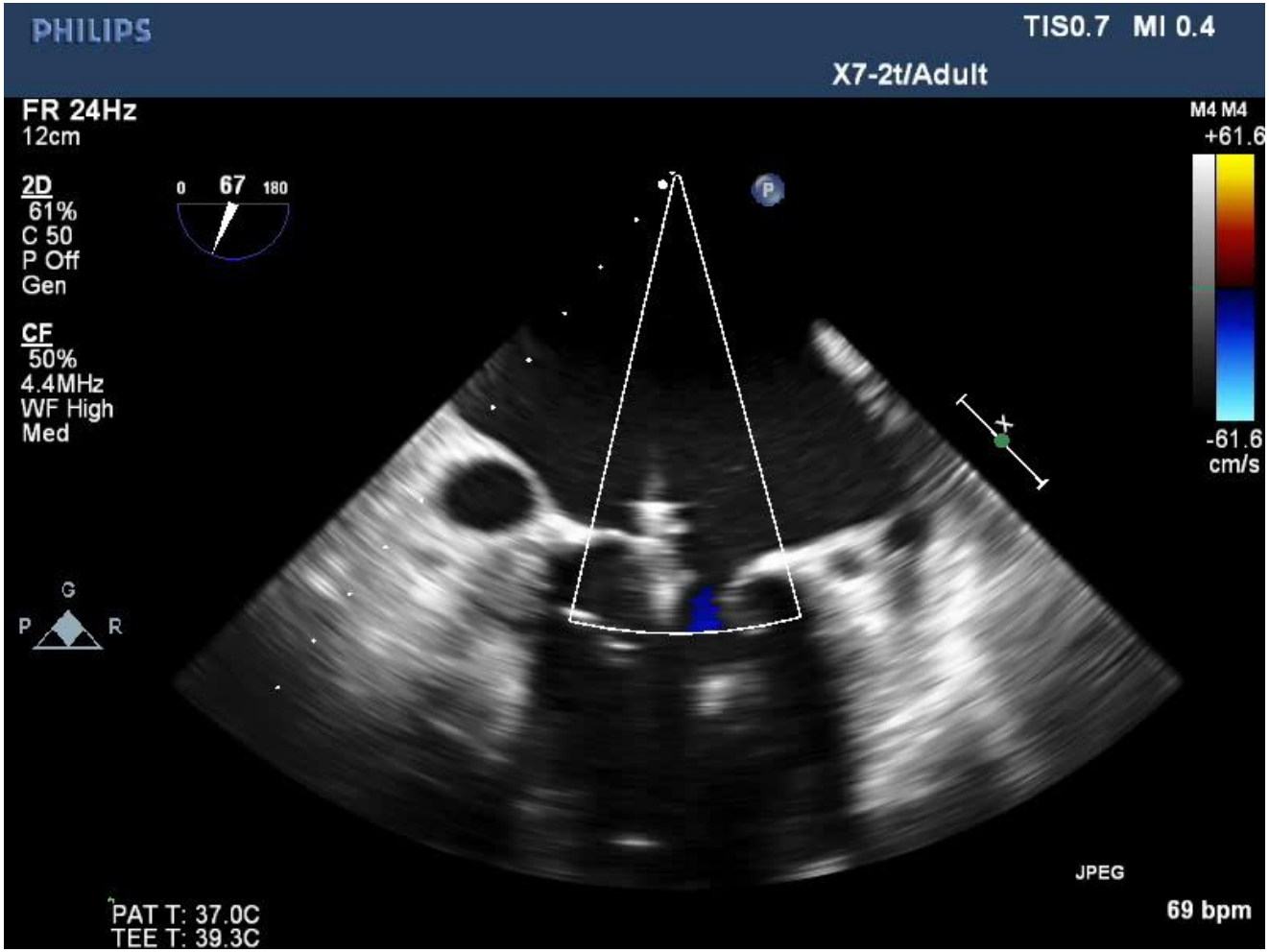

PHILIPS
TIS0.1 MI 0.5
X7-2t/Adult
FR 79Hz
11cm
M4
2D
58%
C 50
P Off
Gen
0 145. 180
G
P R
JPEG
PAT T: 37.0C
TEE T: 38.2C
62 bpm

Clip Insertion

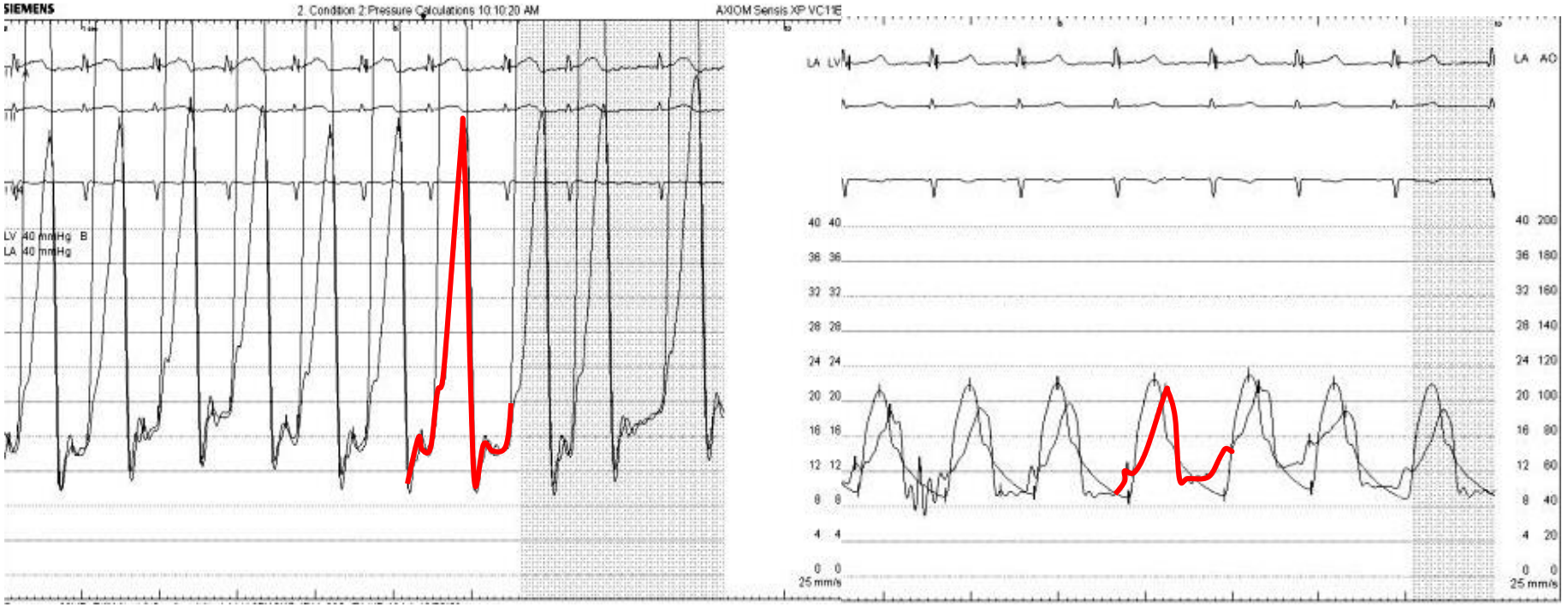




Result – 2+ MR (from 4 ++ MR)



Hemodynamics



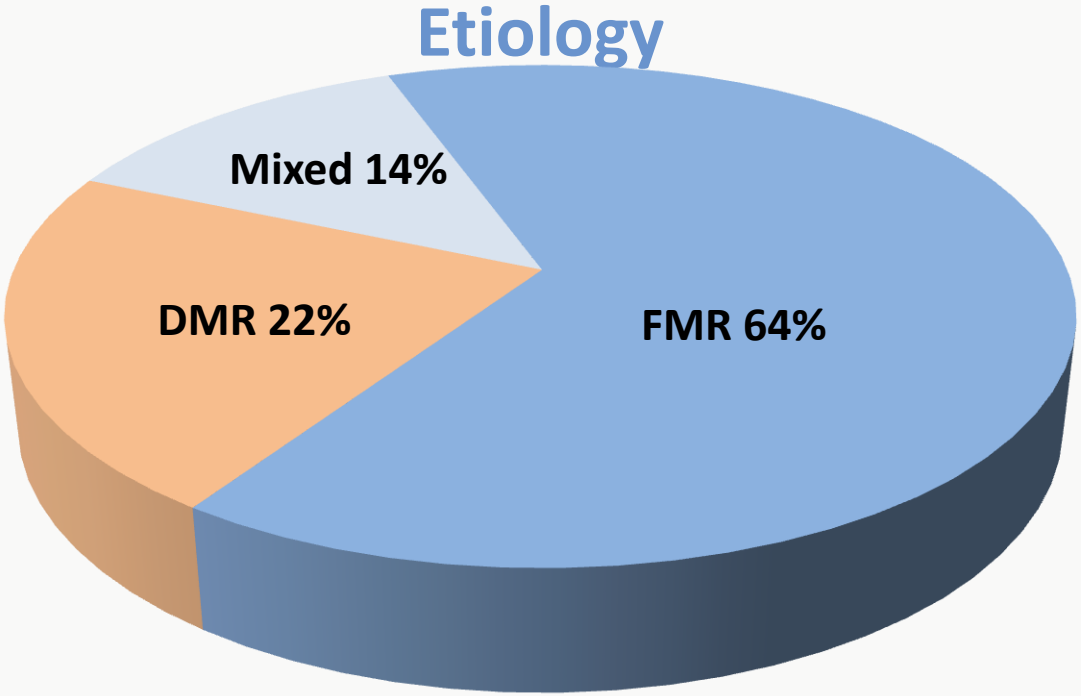
Do we need data for these patients?

- **Clearly no randomized data**
- **However, FDA approved the clip for these patients**
- **We will not have randomized data for prohibitive risk degenerative patients against “standard” therapy**

MitraClip Worldwide Experience

>45,000 Patients

Implant Rate: 97%



Data as of April 2017. Source: Abbott Vascular

International Registry / Trial Data

Study	N	Age (yrs)	DMR (%)	MR ≤ 2	Hosp Mortality (%)
EVEREST I	51	71	79	74	0.9
EVEREST II RCT	279	67	73	77	1.1
REALISM FMR	619	73	0	86	3.6
Sentinel	628	74	28	95	2.9
ACCESS EU	567	74	23	91	-
TRAMI	1064	75	29	95	2.9
MitraSwiss	100	77	38	85	4.0
FRANCE	62	73	23	88	3.3
GRASP-IT	117	72	24	100	-
MARS (Asia)	163	73	46	94	4.2
STS/TVT Registry*	1867	82	86	93	2.7

* Presented at ACC 2017

Percutaneous Mitral Valve Interventions in the Real World

Early and 1-Year Results From the ACCESS-EU, A Prospective, Multicenter, Nonrandomized Post-Approval Study of the MitraClip Therapy in Europe

Francesco Maisano, MD,* Olaf Franzen, MD,† Stephan Baldus, MD,‡ Ulrich Schäfer, MD,§

	ACCESS-EU Phase I		
	All (N=567)	FMR (N=393)	DMR (N=117)
Age, yrs	73.7 ± 9.6	73.0 ± 8.9	75.6 ± 12.1
Male	63.8% (362/567)	67.9% (267/393)	50.4% (59/117)
Logistic EuroSCORE	23.0 ± 18.3	24.8 ± 18.9	15.5 ± 13.3
NYHA III/IV	84.9% (466/549)	87.3% (331/379)	74.0% (85/115)
LVEF <30%	34.3% (193/562)	44.3% (172/388)	4.3% (5/117)
MR grade ≥3+	97.7% (554/567)	98.5% (387/393)	96.6% (113/117)
MR etiology			
Functional	77.1% (393/510)	100% (393)	----
Degenerative	22.9% (117/510)	----	100% (117)

JACC 2013;62:1052-61

ACCESS EU Study

Safety outcomes at 30 Days & 12 Months

Table 3 Site-Reported Safety Outcomes at 30 Days and 12 Months

	ACCESS-EU Phase I					
	30 Days			12 Months		
Safety Outcomes	All Patients (N = 567)	FMR Patients (n = 393)	DMR Patients (n = 117)	All Patients (N = 567)	FMR Patients (n = 393)	DMR Patients (n = 117)
Death	3.4% (19/567)	2.8% (11/393)	6.0% (7/117)	17.3% (98/567)	17.0% (67/393)	17.1% (20/117)
Stroke	0.7% (4/567)	0.5% (2/393)	0.9% (1/117)	1.1% (6/567)	1.0% (4/393)	0.9% (1/117)
Myocardial infarction	0.7% (4/567)	0.8% (3/393)	0.9% (1/117)	1.4% (8/567)	1.8% (7/393)	0.9% (1/117)
Renal failure	4.8% (27/567)	5.1% (20/393)	2.6% (3/117)	8.6% (49/567)	9.4% (37/393)	6.0% (7/117)
Respiratory failure	0.7% (4/567)	1.0% (4/393)	0% (0/117)	0.9% (5/567)	1.0% (4/393)	0.0% (0/117)
Need for resuscitation	1.8% (10/567)	2.3% (9/393)	0.9% (1/117)	2.1% (12/567)	2.8% (11/393)	0.9% (1/117)
Cardiac tamponade	1.1% (6/567)	1.0% (4/393)	0.9% (1/117)	1.2% (7/567)	1.0% (4/393)	0.9% (1/117)
Bleeding complications	3.9% (22/567)	3.8% (15/393)	3.4% (4/117)	4.8% (27/567)	4.6% (18/393)	3.4% (4/117)

Maisano et al. JACC 2013;62:1052-61

ACCESS EU Study

MR severity

Table 4 MR Severity at Baseline, Discharge, 6 and 12 Months

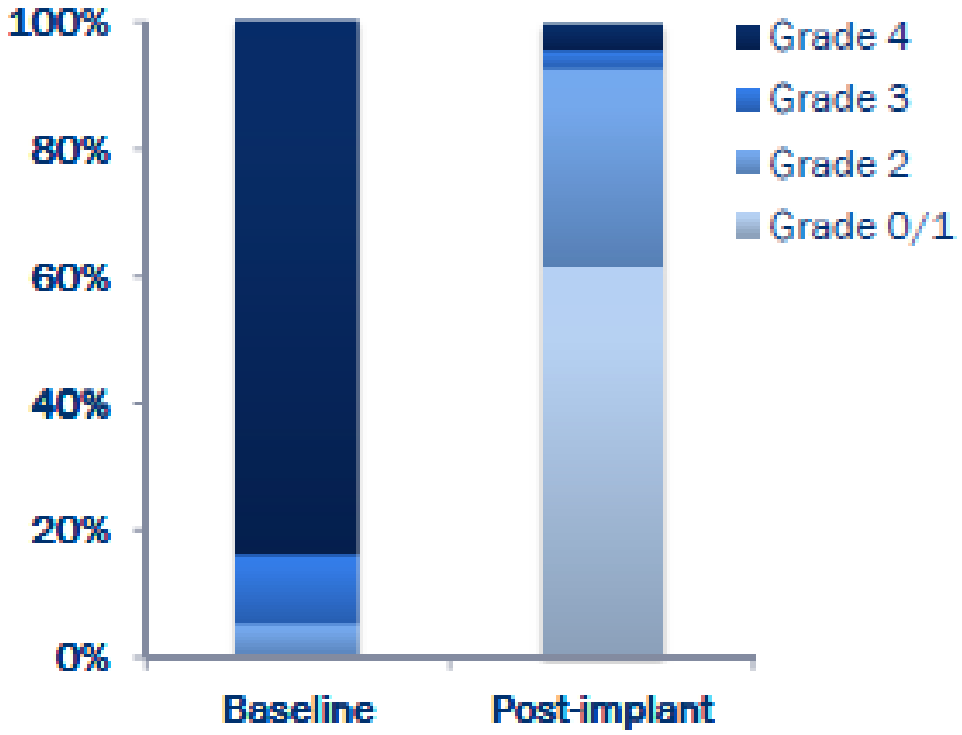
	ACCESS-EU Phase I											
	All Patients (N = 567)				FMR Patients (n = 393)				DMR Patients (n = 117)			
MR Severity	Baseline	Discharge	6 Months	12 Months	Baseline	Discharge	6 Months	12 Months	Baseline	Discharge	6 Months	12 Months
0	—	4.4% (23/521)	2.4% (10/411)	2.8% (9/327)	—	5.0% (18/361)	2.6% (7/271)	1.4% (3/219)	—	3.8% (4/106)	3.2% (3/94)	8.5% (6/71)
1+	—	46.4% (242/521)	27.7% (114/411)	27.8% (91/327)	—	47.9% (173/361)	27.3% (74/271)	30.6% (67/219)	—	52.8% (56/106)	35.1% (33/94)	23.9% (17/71)
2+	2.3% (13/567)	40.3% (210/521)	48.9% (201/411)	48.3% (158/327)	1.5% (6/393)	38.8% (140/361)	48.7% (132/271)	46.6% (102/219)	3.4% (4/117)	32.1% (34/106)	39.4% (37/94)	42.3% (30/71)
3+	40.6% (230/567)	7.5% (39/521)	17.8% (73/411)	16.5% (54/327)	39.4% (155/393)	7.8% (28/361)	19.6% (53/271)	18.3% (40/219)	37.6% (44/117)	7.5% (8/106)	13.8% (13/94)	16.9% (12/71)
4+	57.1% (324/567)	1.3% (7/521)	3.2% (13/411)	4.6% (15/327)	59.0% (232/393)	0.6% (2/361)	1.8% (5/271)	3.2% (7/219)	59.0% (69/117)	3.8% (4/106)	8.5% (8/94)	8.5% (6/71)

Maisano et al. JACC 2013;62:1052-61

Demographics

Age	82 years (74, 86)
Male	55.8 %
NYHA III/IV	85.0 %
MR grade 3/4	93.0 %
DMR only	85.9 %
FMR only	8.6 %
Mixed etiology	8.9 %
Frail	50.3 %
STS PROM (repair)	6.1 % (3.7%, 9.9%)
STS PROM (replacement)	9.2 % (6.0%, 14.1%)

Acute Procedural Results



Acute procedural success 92.8%

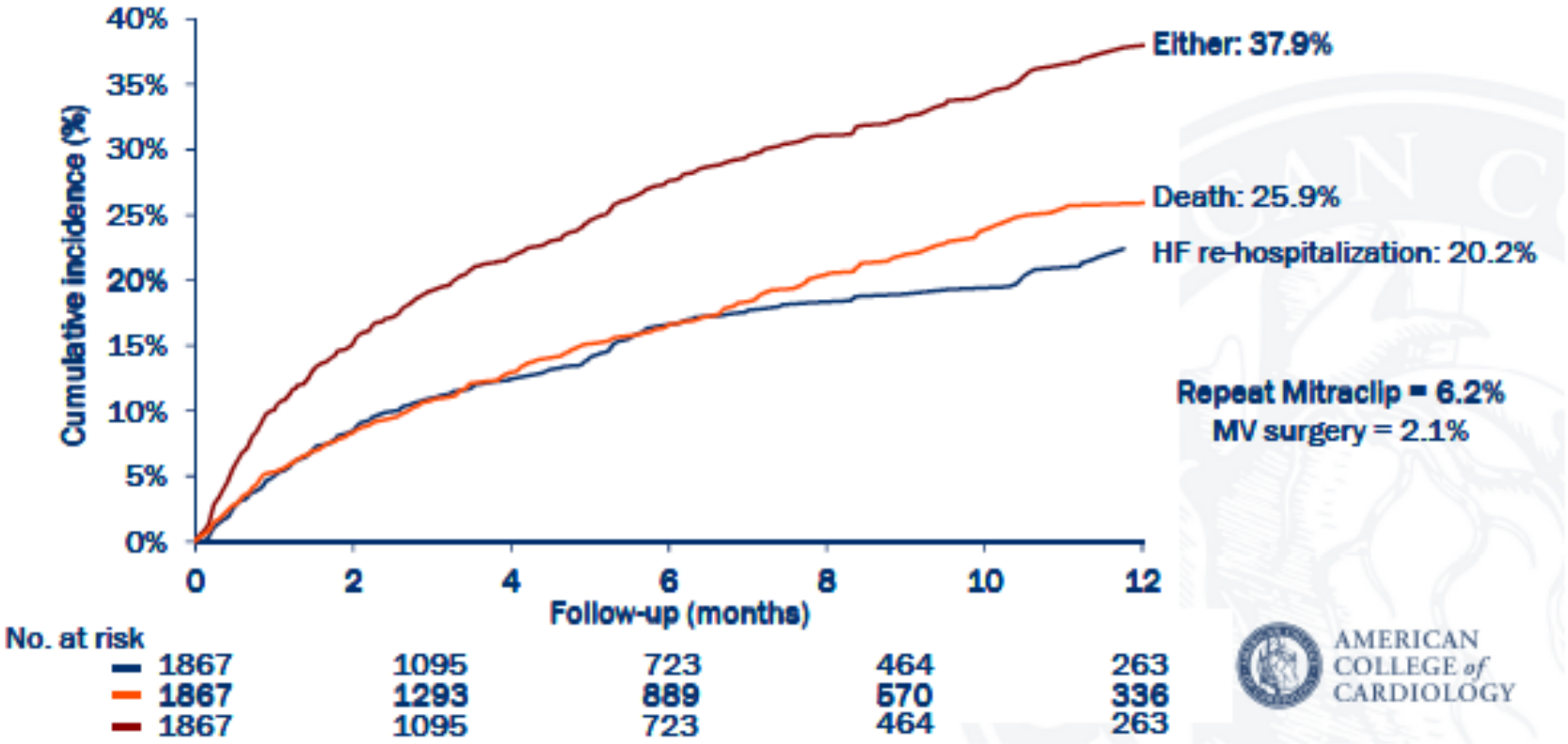
SLDA 1.5%

Hospital mortality 2.7%

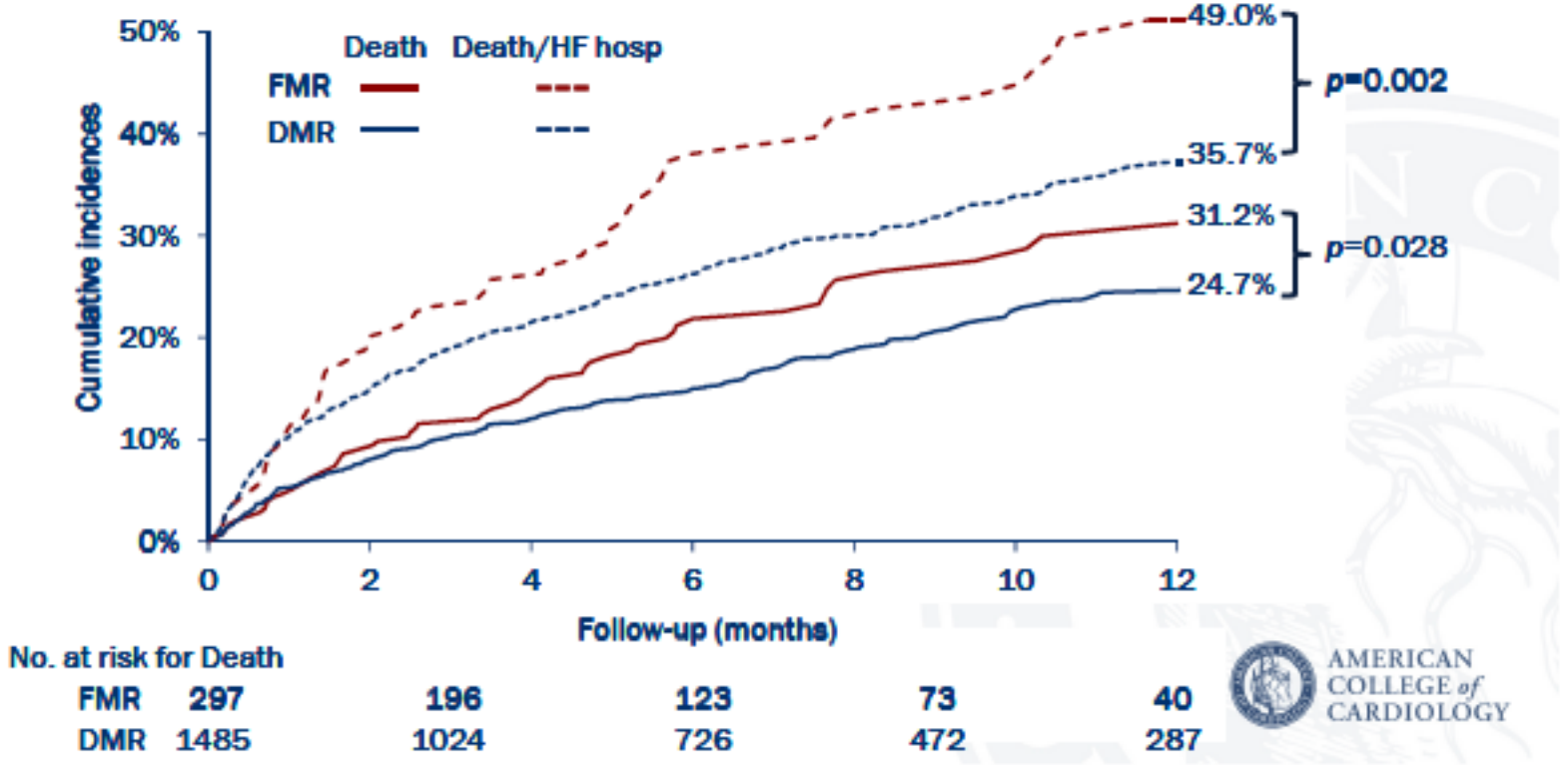
D/C home 85.9%

HOS (median) 2 days (1, 5)

One-Year Outcomes



Outcomes: FMR vs DMR



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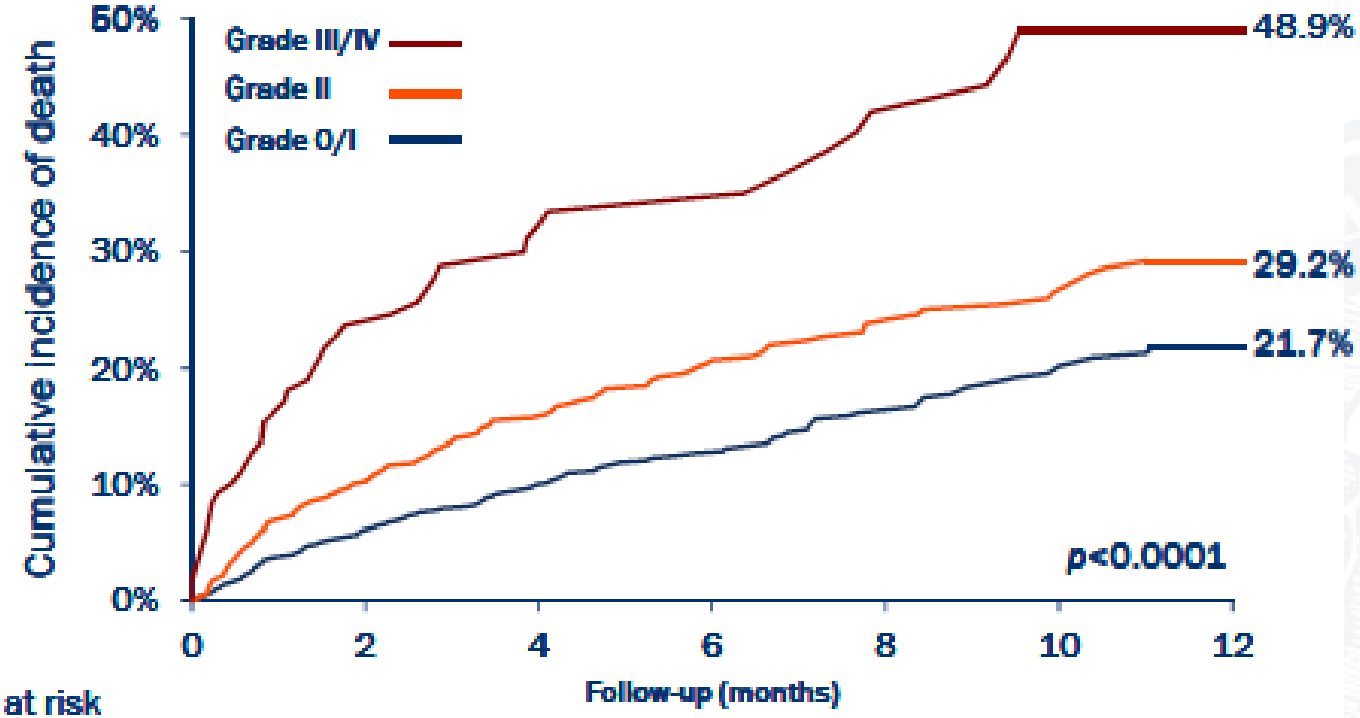
Effect of Residual MR on Outcomes



No. at risk					
III/IV	591	65	47	25	17
II	114	408	278	168	104
0/I	1146	810	559	373	213

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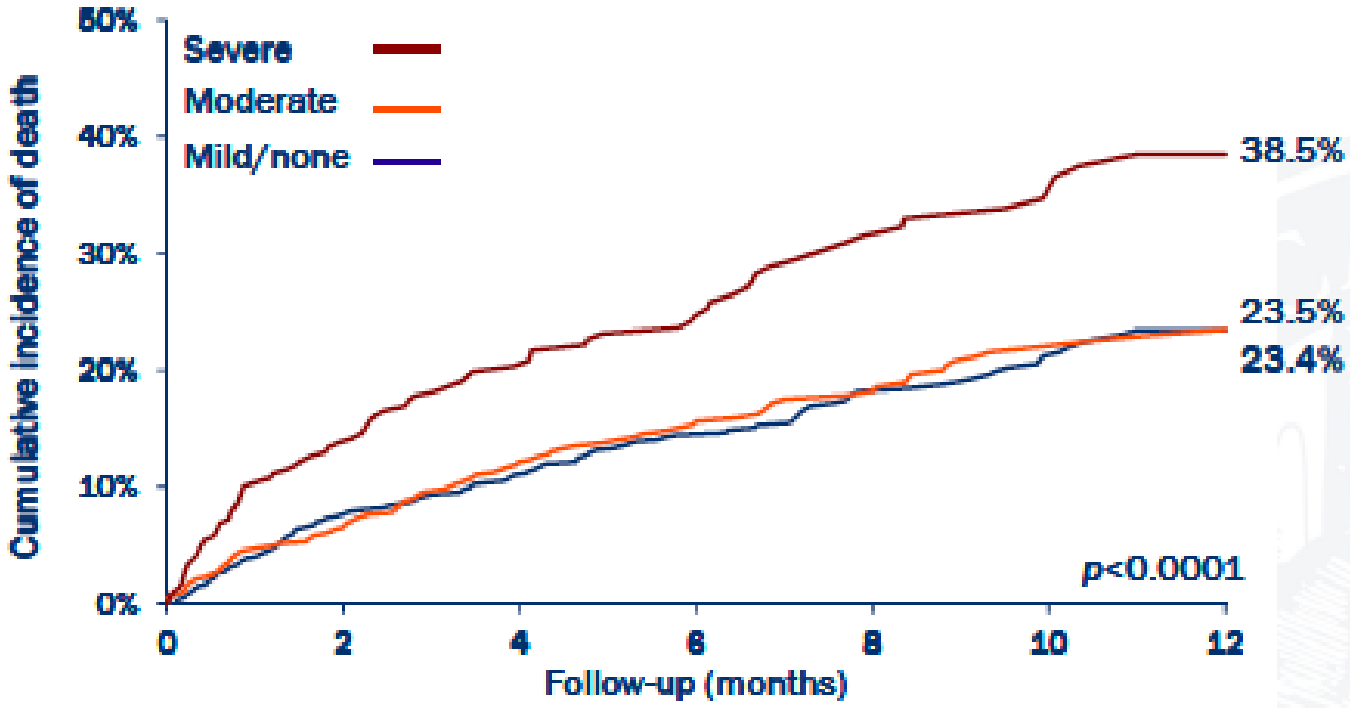
Impact of TR on Outcomes

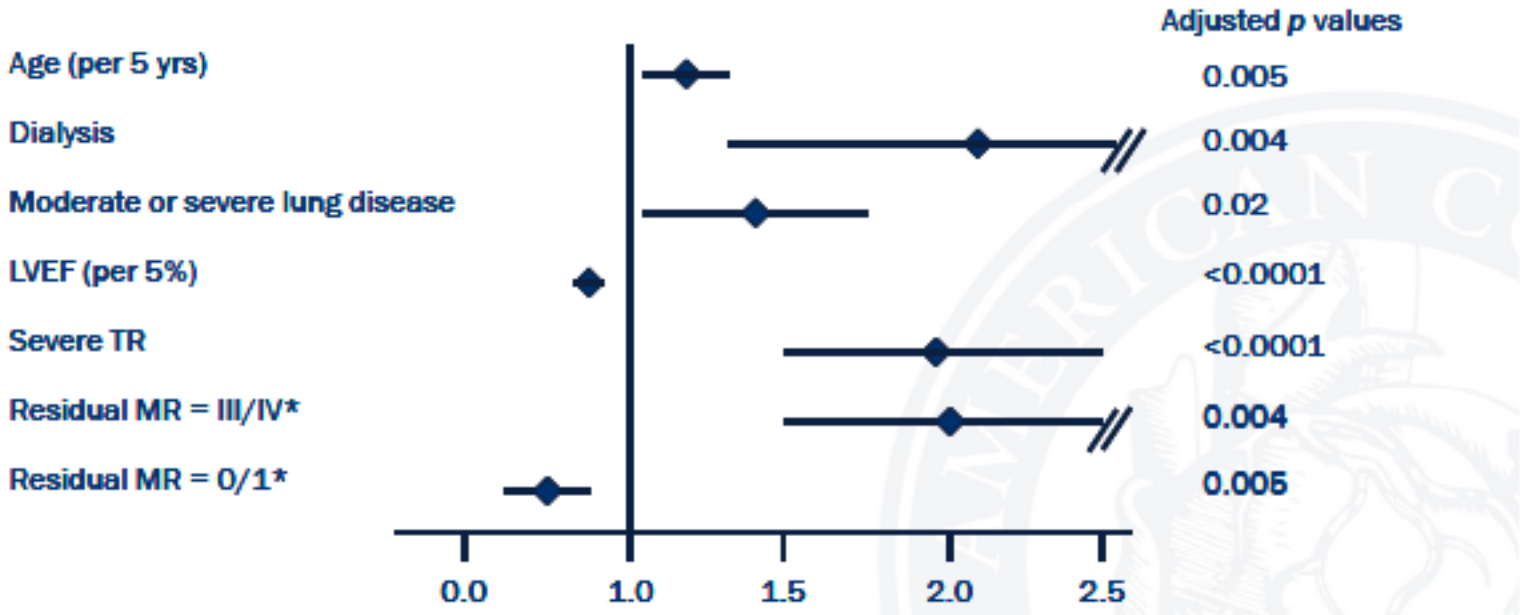


No. at risk

Severe	298	198	141	83	47
Moderate	666	451	307	203	131
Mild/none	883	631	431	277	153

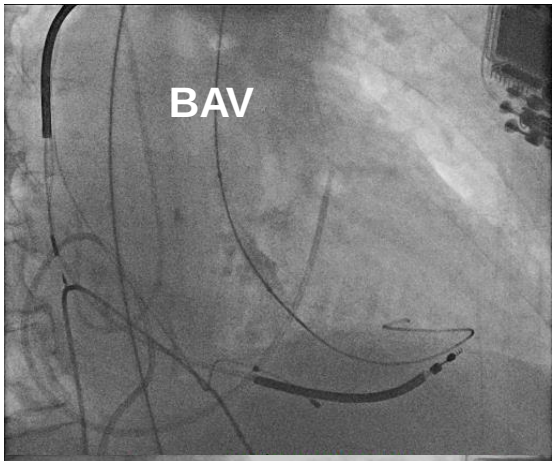
AMERICAN COLLEGE of CARDIOLOGY

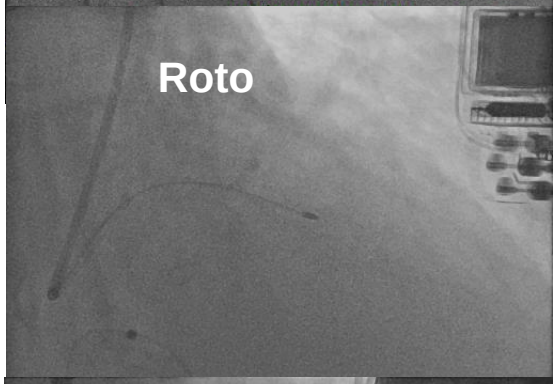
Multivariate Predictors of Outcome

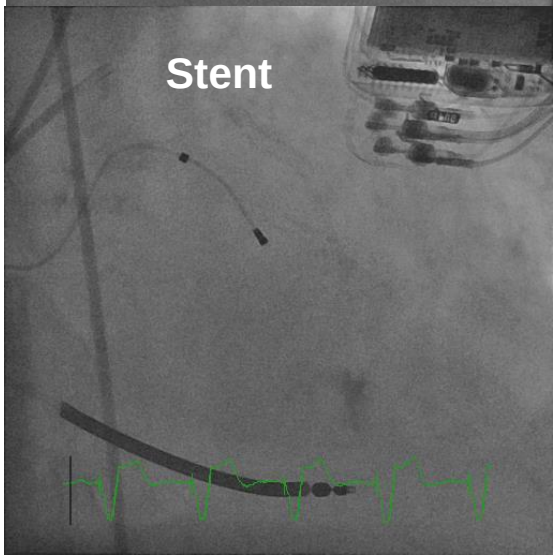


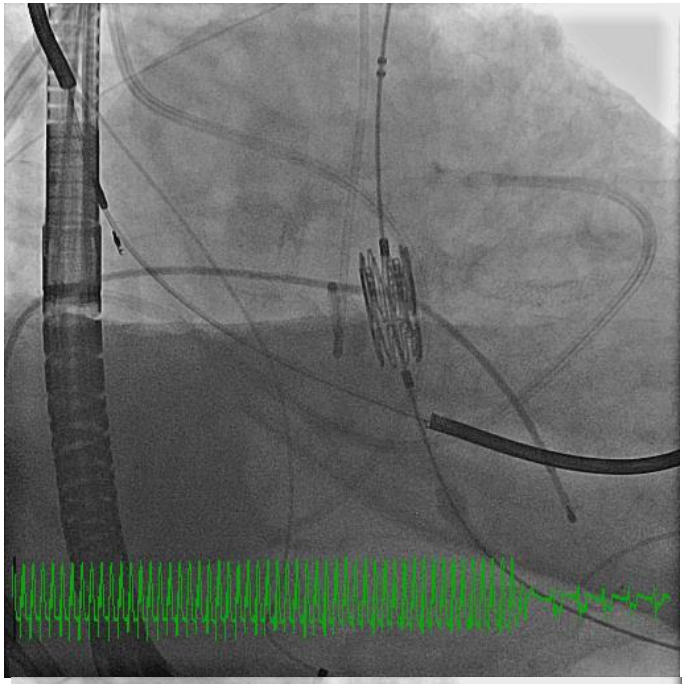
Primary MR

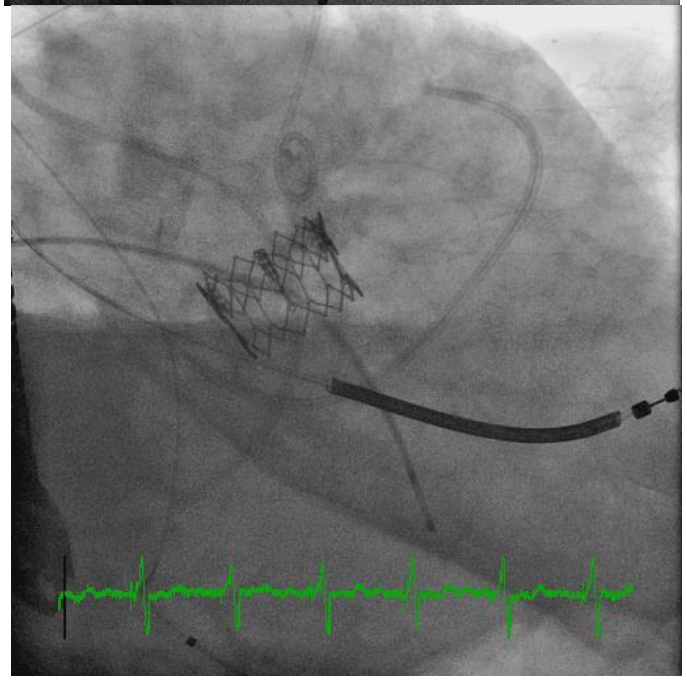
- 78 year old patient sent to Hospice for
  - Severe MR
  - Severe AS
  - Severe CAD
- Normal EF
- BAV and Roto stent to LAD
- TAVR
- Last step of MitraClip

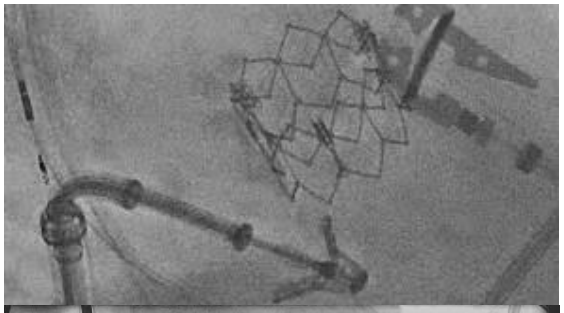

BAV

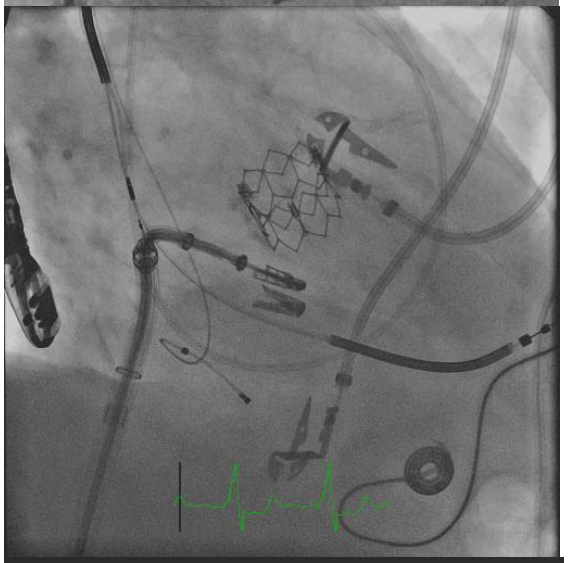

Roto

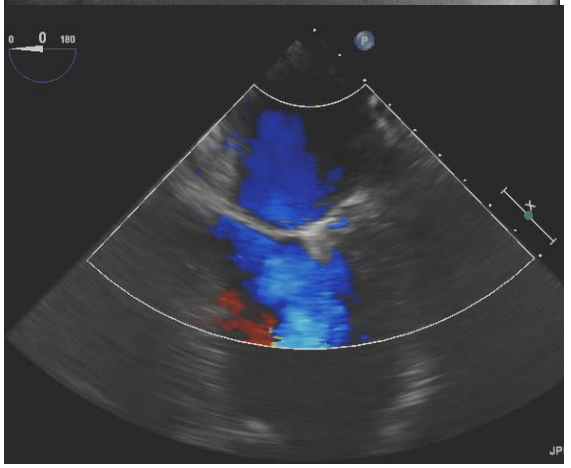

Stent



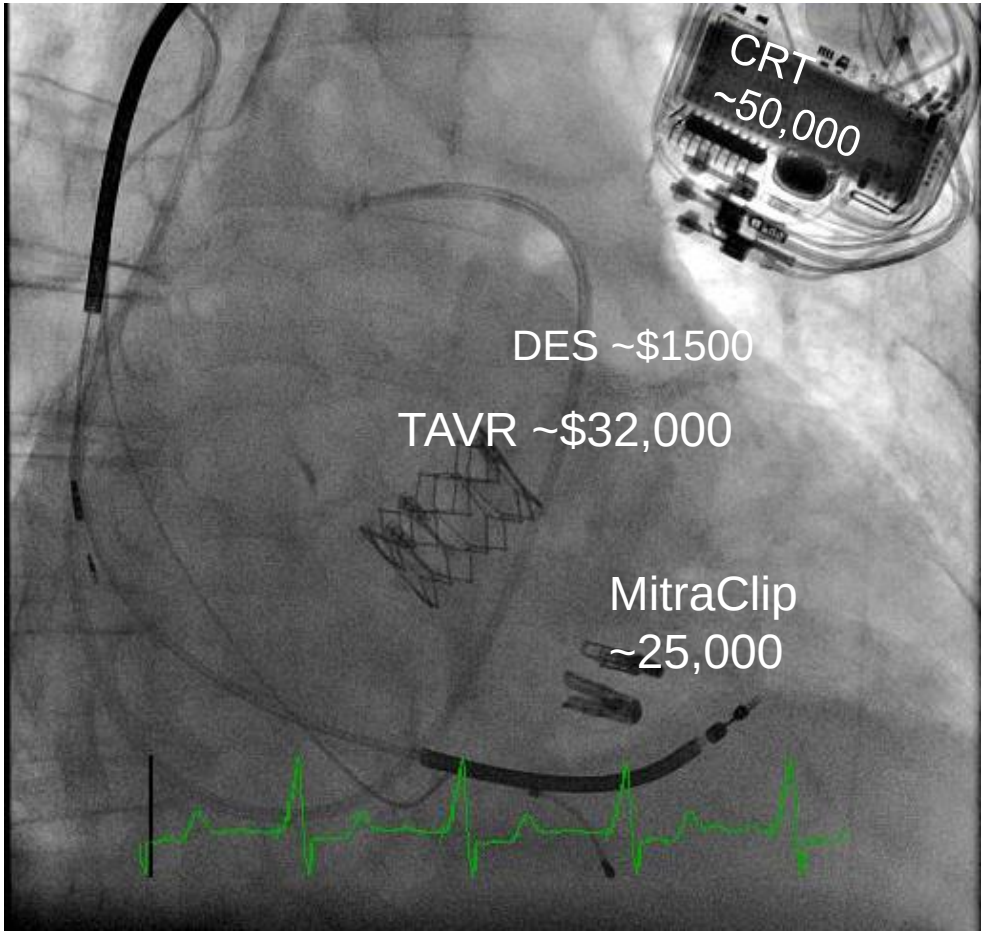







0
0
180

What Is the Cost?



Thank you for attention

Questions