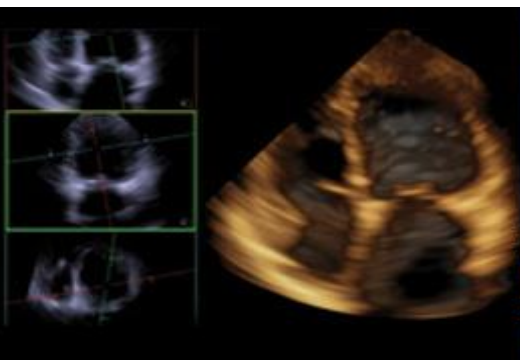




EuroValve

January 26-27, 2017
Barcelona, SPAIN



“The present and the future of TMVR”

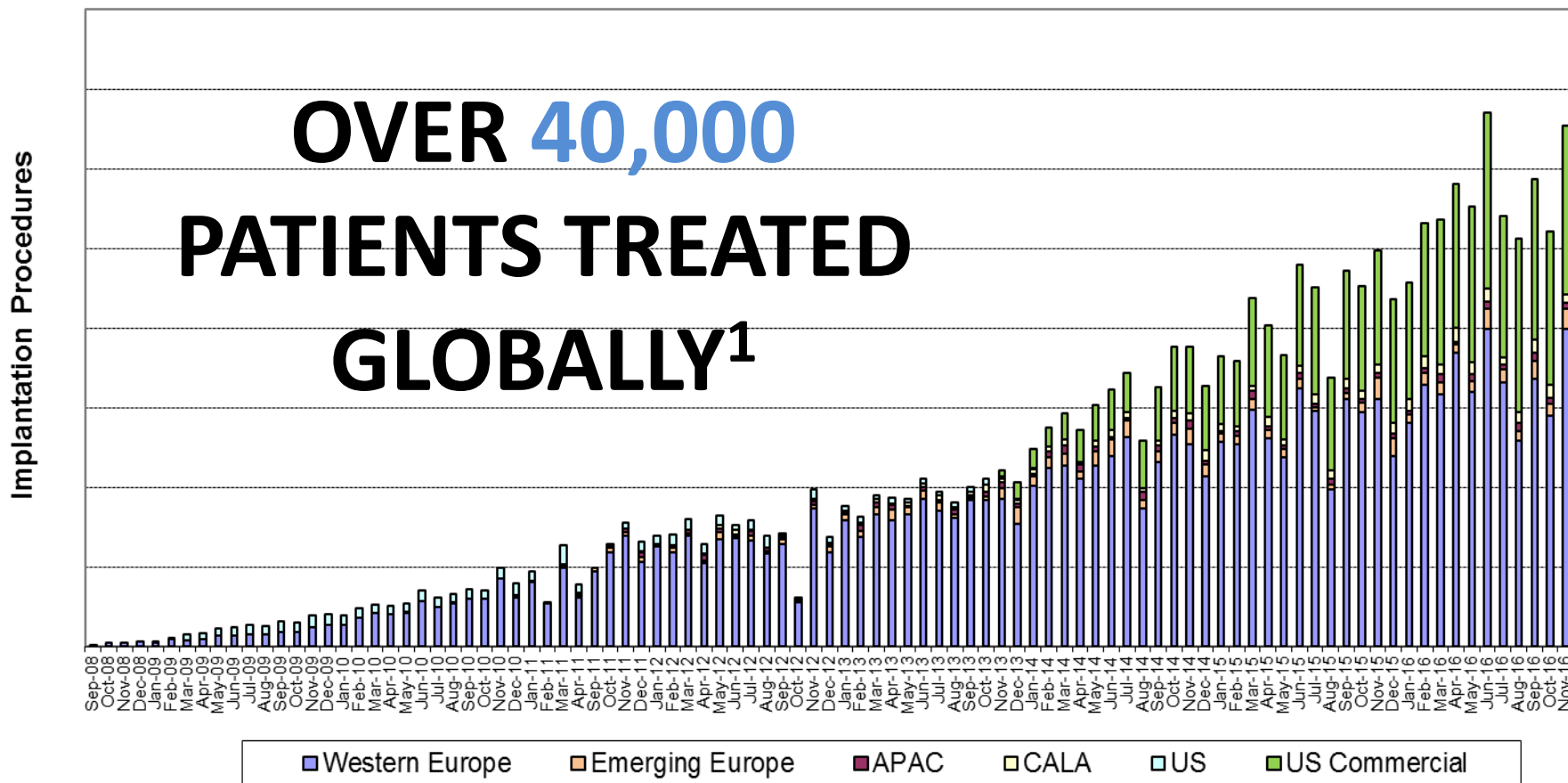
Why to refer now to TMVR Therapy?

Fausto Castriota MD, FESC
Chairman Cardiovascular Units
GVM Care and Research – (Italy)

Maria Cecilia Hospital
Cotignola

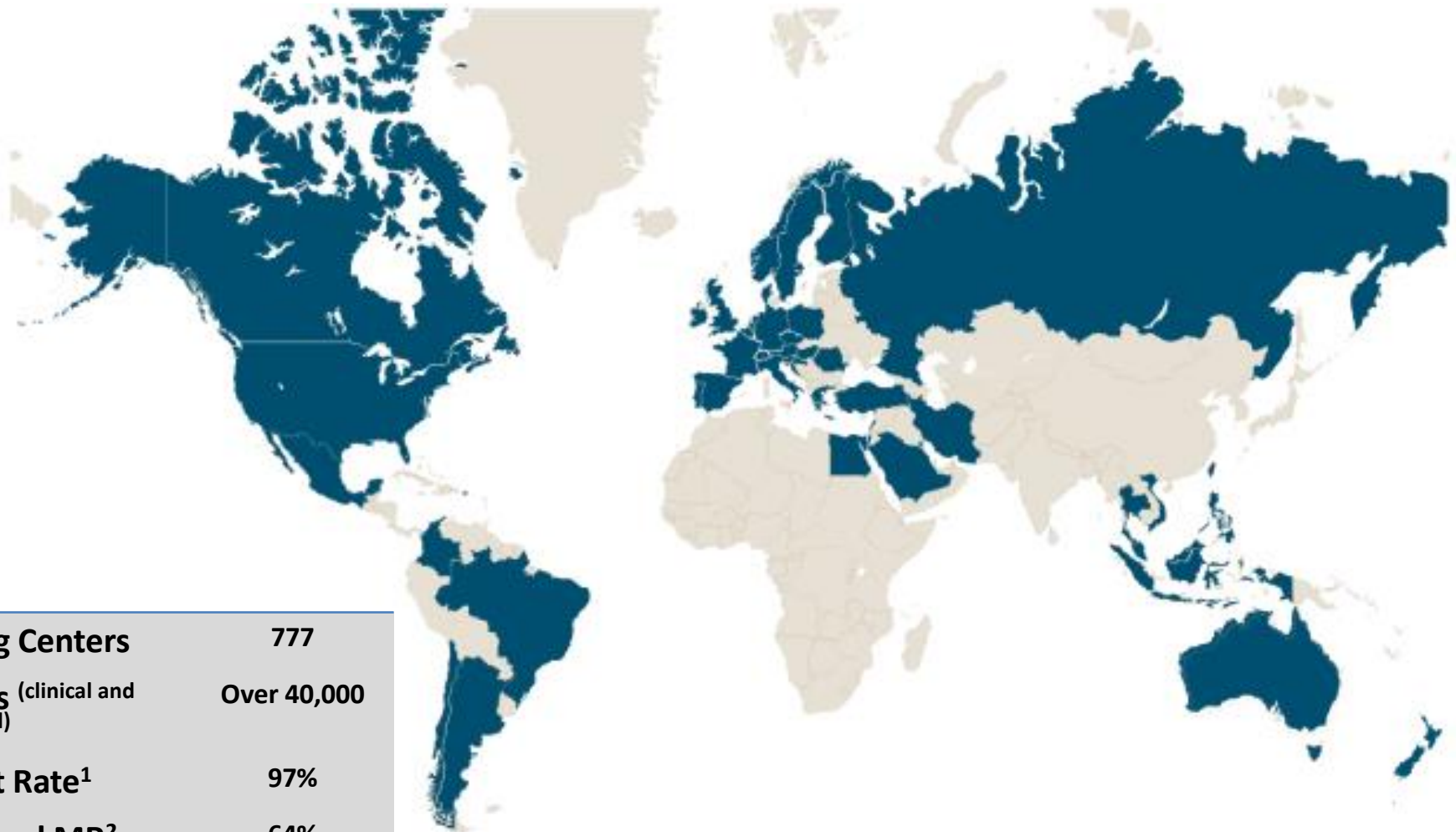


Global MitraClip Experience



1. Includes clinical and commercial procedures as of 30/11/2016. Source: Data on file at Abbott Vascular

MitraClip Therapy Current Global Adoption



Treating Centers	777
Patients (clinical and commercial)	Over 40,000
Implant Rate¹	97%
Functional MR²	64%
Degenerative MR^{2,3}	22%
Mixed	14%

1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. OUS Commercial Experience
3. Etiology not inclusive of U.S. cases as of 14/04/2014

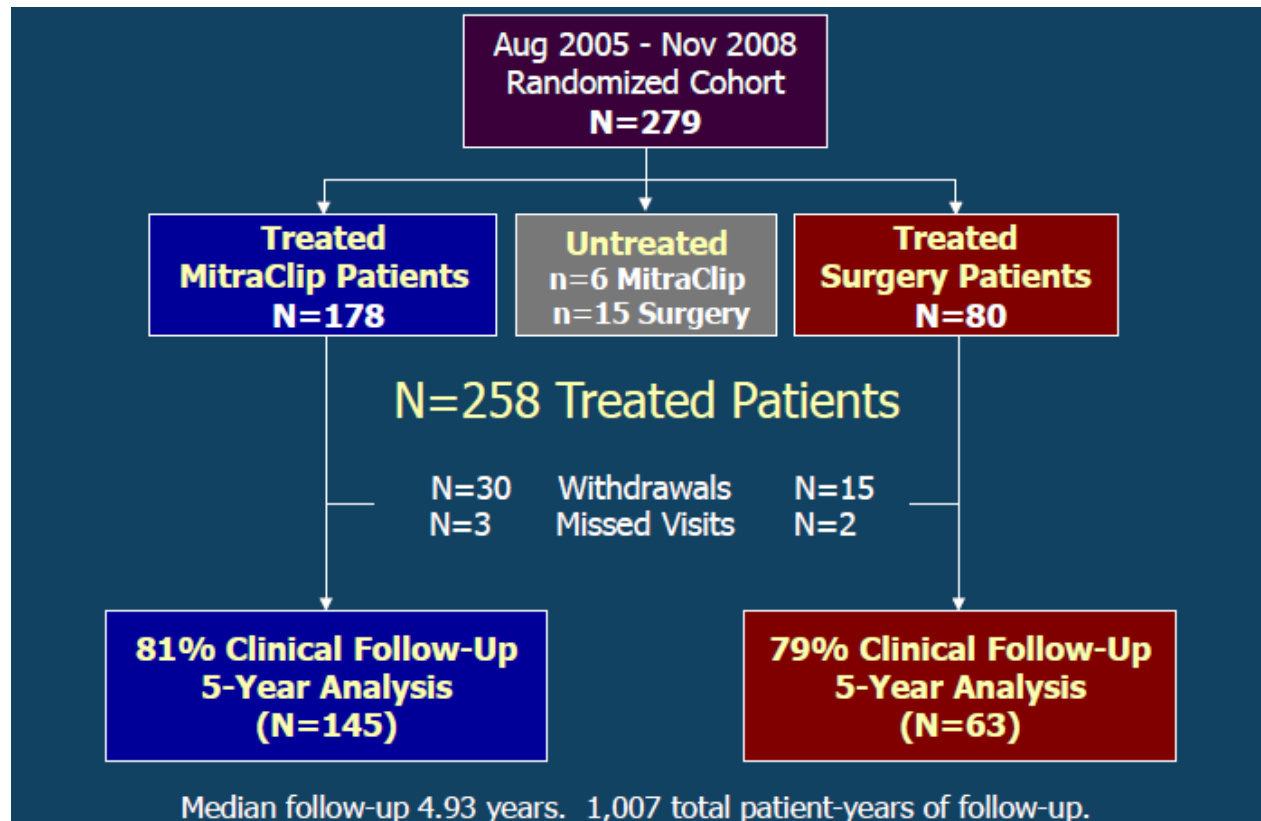
Data As of November 30, 2016. Source: Data on file at Abbott Vascular

EVEREST - Endovascular Valve Edge-to- Edge Repair Study

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engerson, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

The EVEREST II RCT was a prospective, multi-center trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of patients with significant ($\geq 3+$) mitral regurgitation



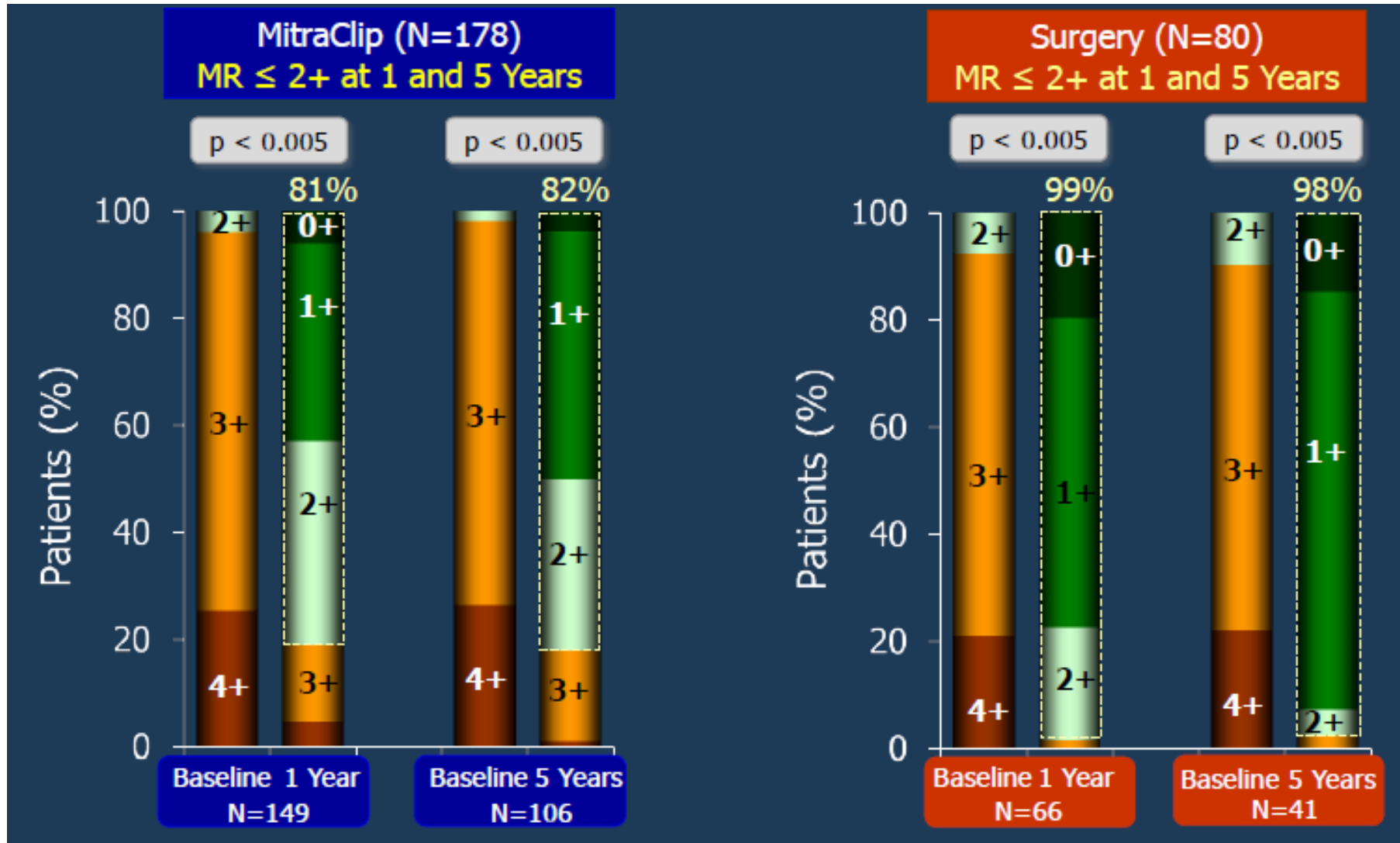
Long- Term MitraClip Device Safety

	Through 1 Year # (%) of patients	1 Year to 5 Years # (%) of patients
Single Leaflet Device Attachment (SLDA)	10 (6.3%)	0 (0.0%)
MV stenosis	1 (0.6%)	0 (0.0%)
Device Embolization	0 (0.0%)	0 (0.0%)

Based on N=158 who were implanted with 1 or 2 MitraClip devices

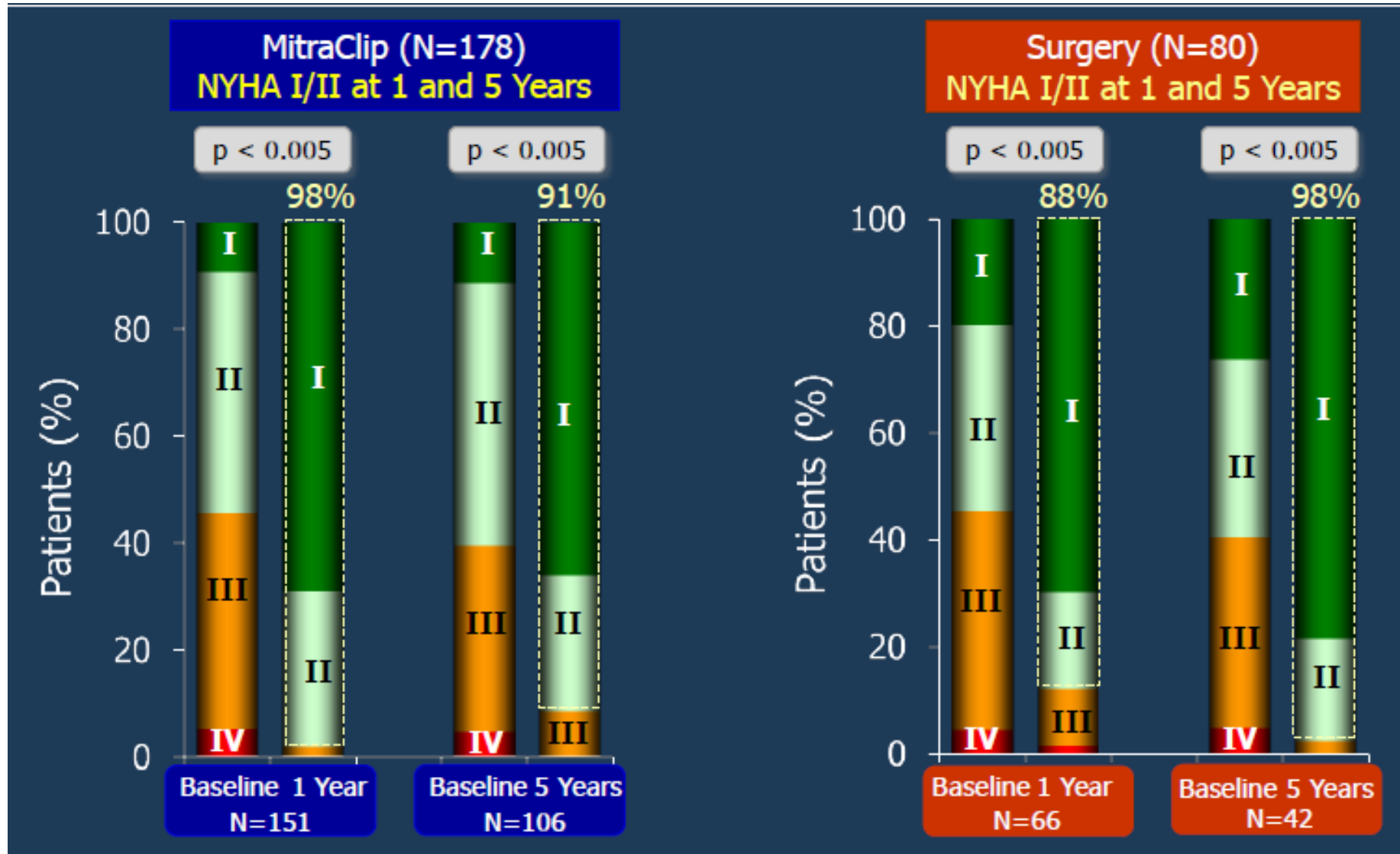
Mitral Regurgitation Grade

Everest II RCT all treated patients 258

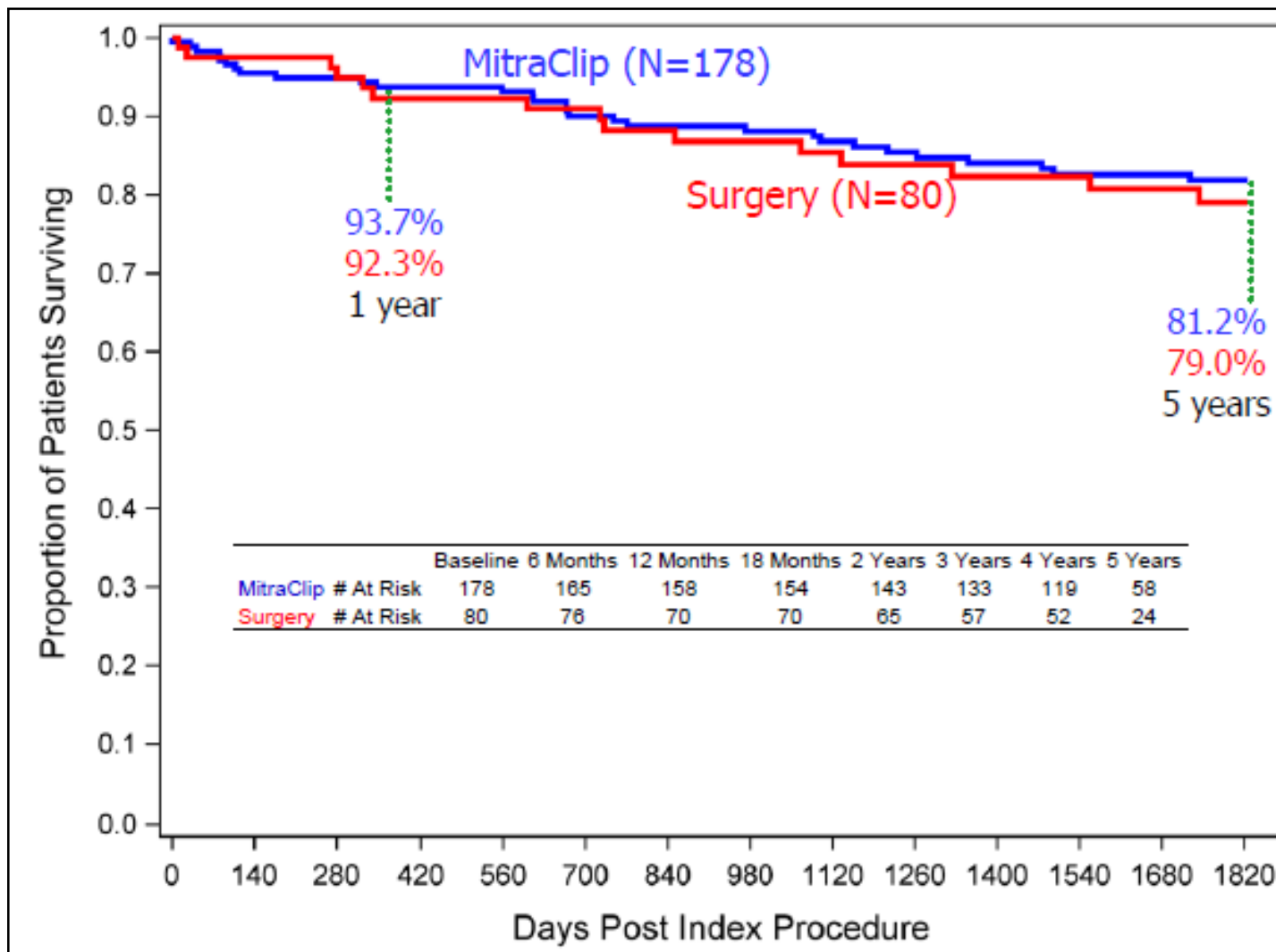


Stable improvement NYHA Functional Class

Everest II RCT all treated patients 258

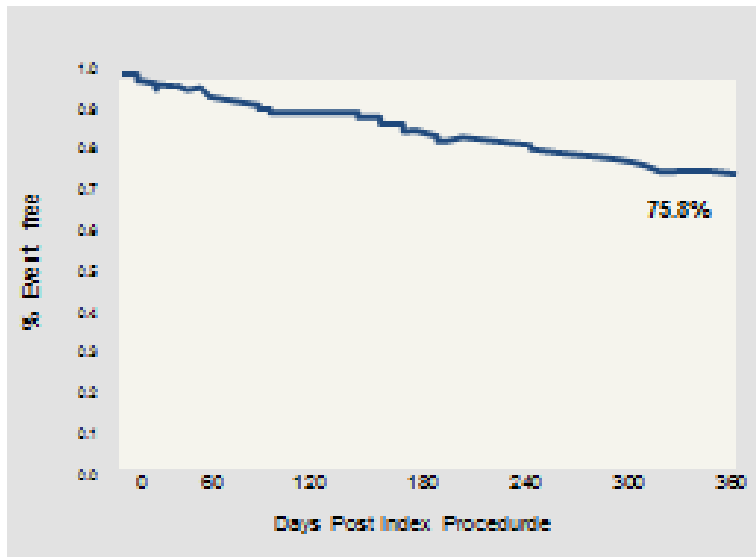
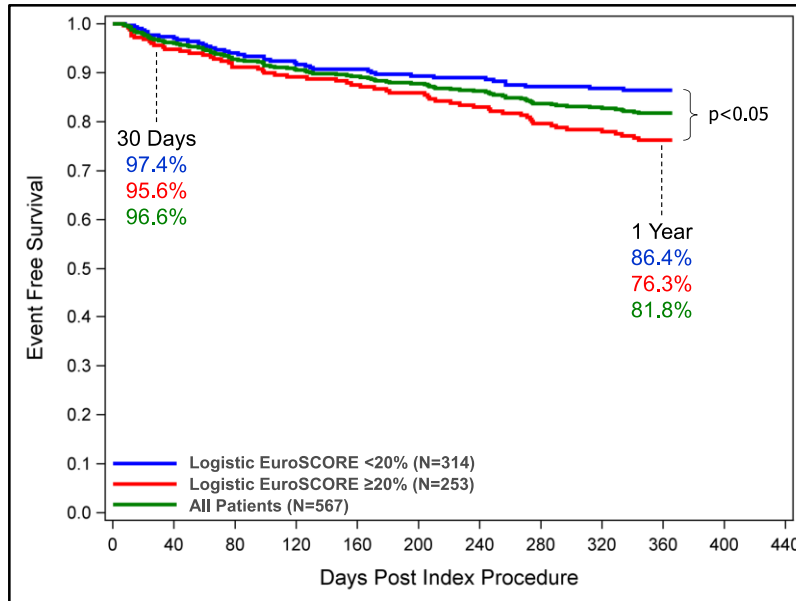


5-Years FU mortality in EVEREST II



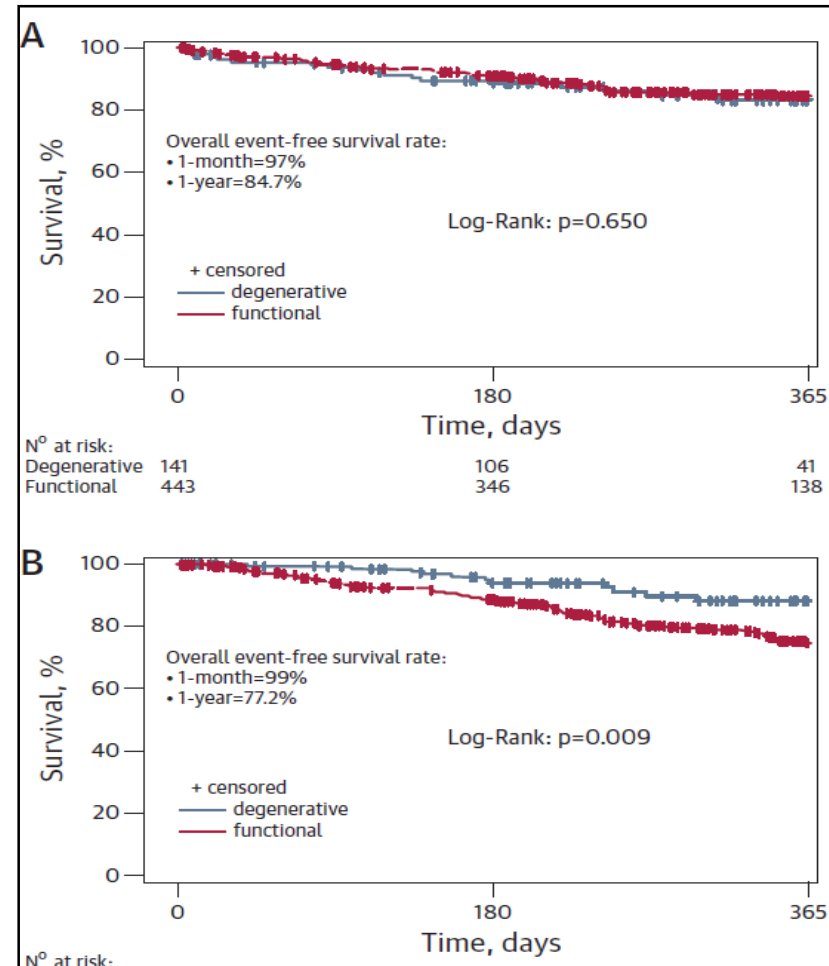
EU Registries in the Real World

**Access EU
N = 487**



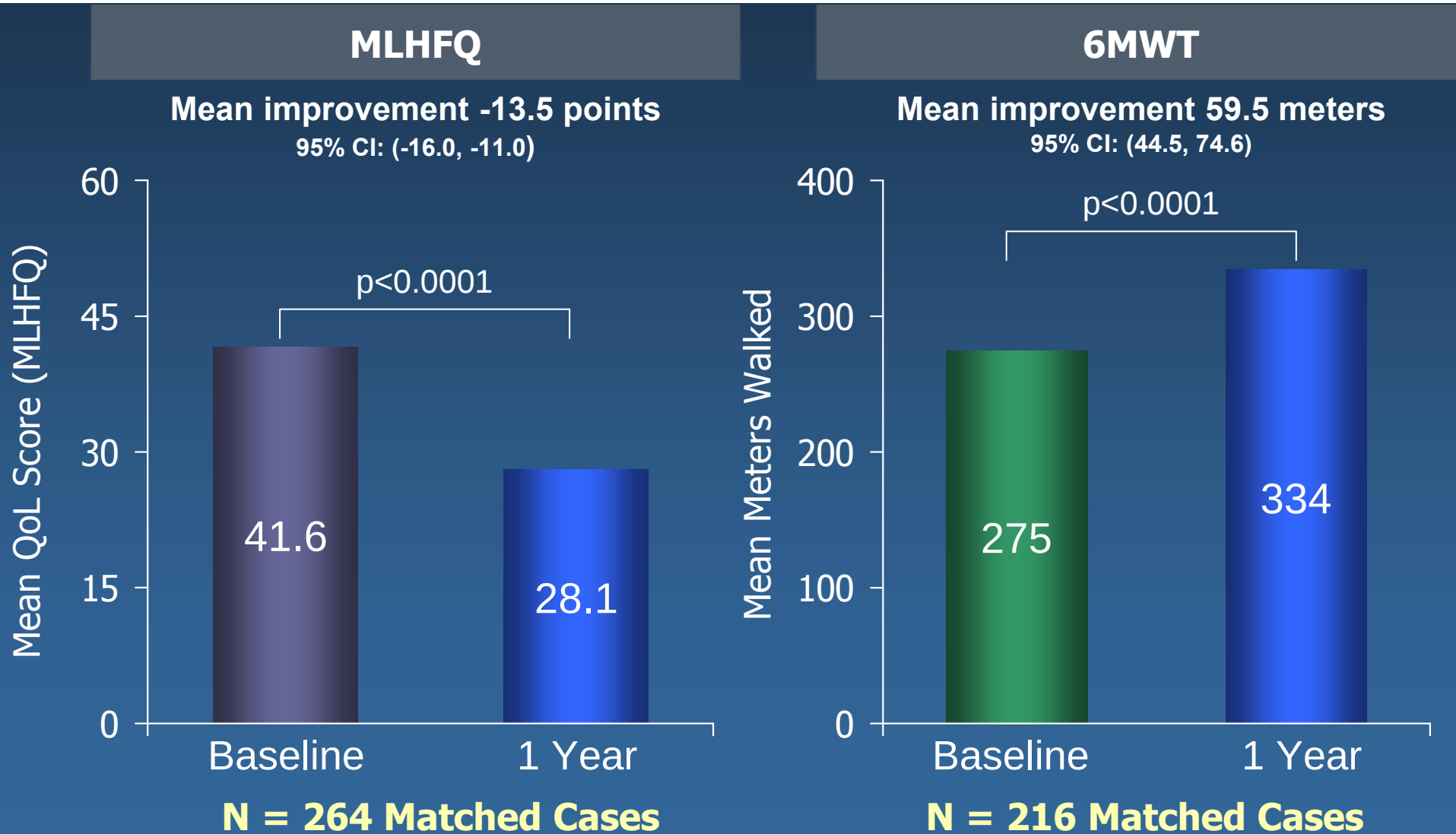
**Grasp-IT
N = 304**

**Sentinel
N = 552**

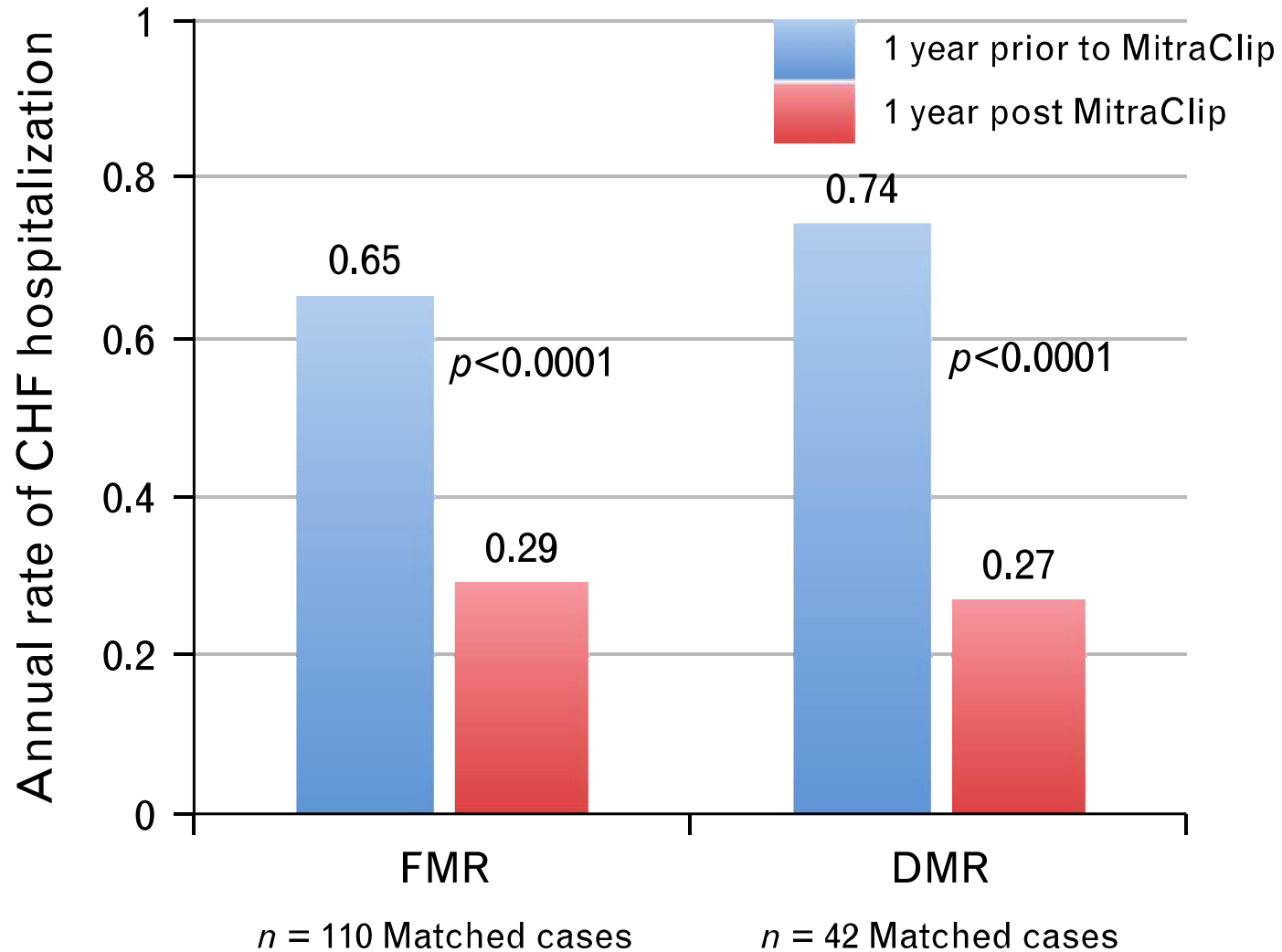


(A) Death, (B) rehospitalization due to heart failure,

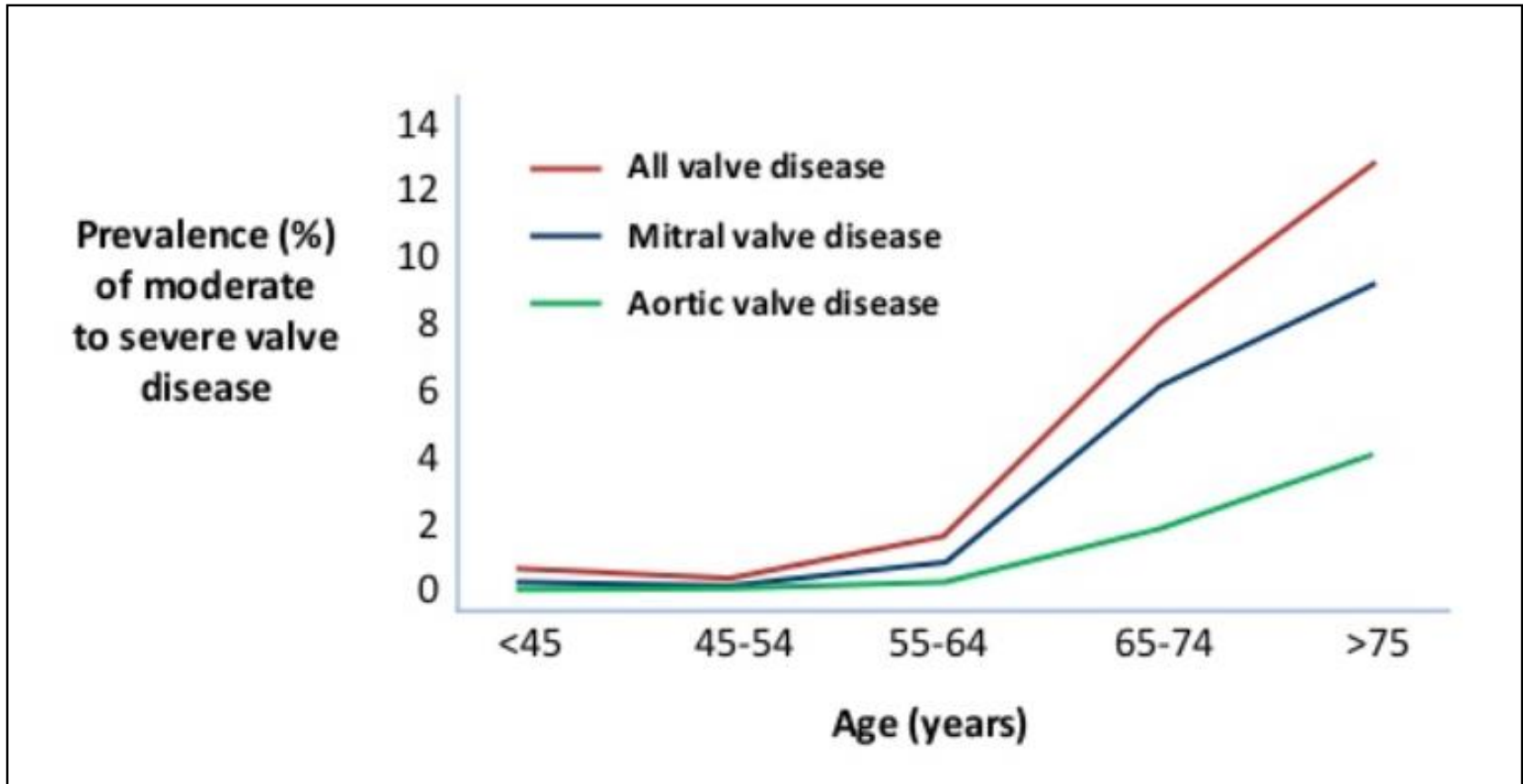
Quality of Life Score (MLHFQ) and 6-minute Walk Distance



Hospitalization



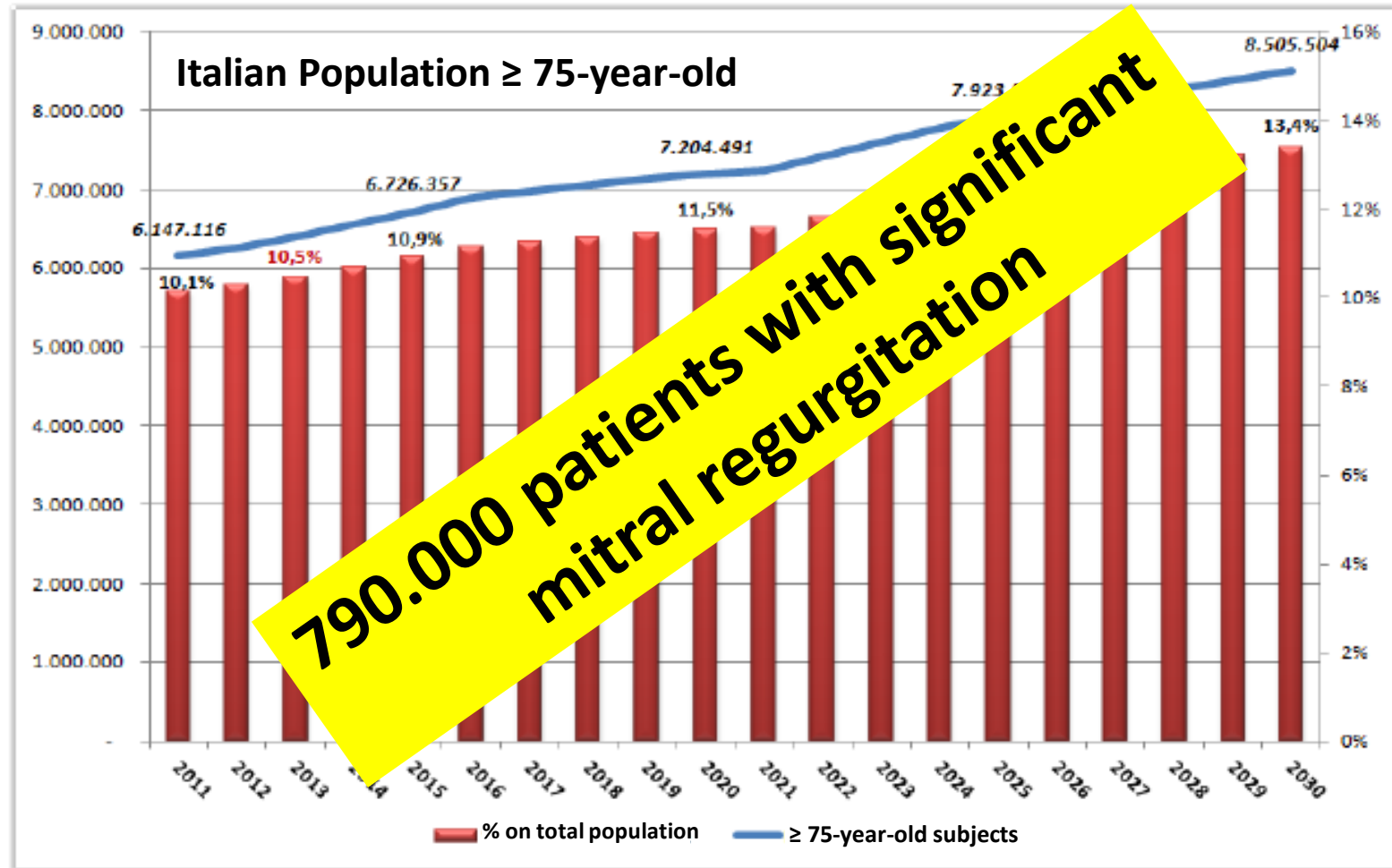
Prevalence of Mitral Regurgitation



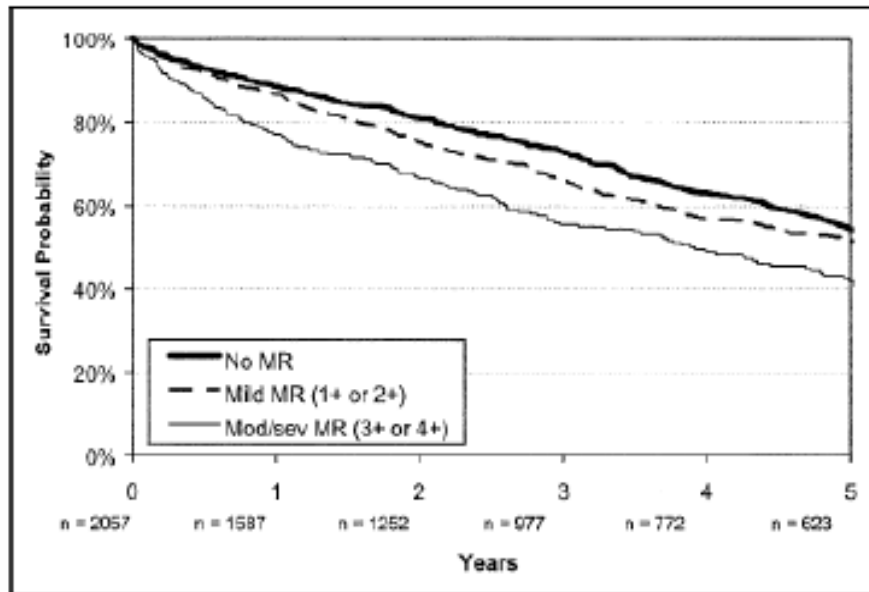
Moderate or severe MR is estimated to be present in 1.7% of the adult population
The prevalence rises strikingly with advancing age (**> 9% for ≥ 75 -year-old subjects, $p<.0001$**)¹

1. Nkomo et al. Burden of valvular heart diseases: a population-based study. Lancet 2006 Sep 16;368(9540):1005-11.

Trend of Aging Population

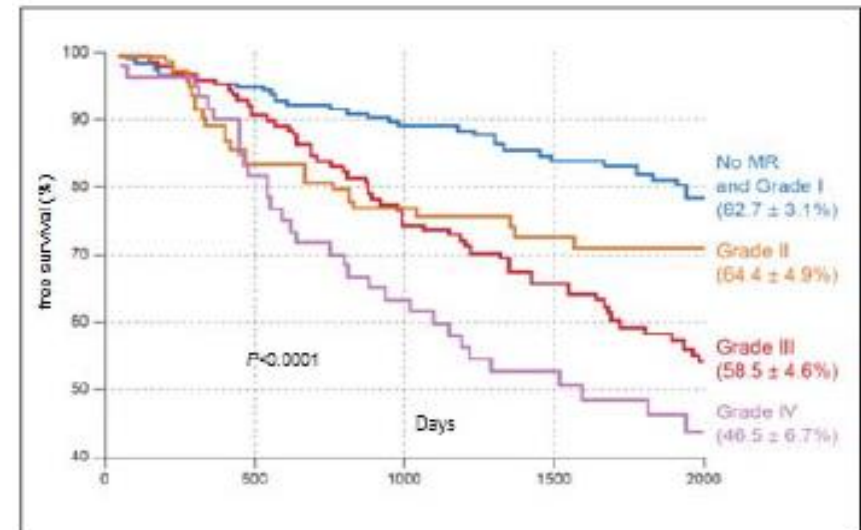


Prognostic implications of Mitral Regurgitation



Relation of frequency and severity of mitral regurgitation to survival among patients with left ventricular systolic dysfunction and heart failure

Benjamin H Trichon, Felker, Shaw, Cabell, O'Connor, MD
 American Journal of cardiology
 2003; Volume 91, 538-543



Prognostic implications of functional mitral regurgitation according to the severity of the underlying chronic heart failure: a long-term outcome study

Bursi F, Barbieri A, Grigioni F, et al. Eur J Heart Fail.
 2010;12(4):382-388.

...TMVR: what have we learned?

2014

Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients

Martin J. Swaans, MD,* Annelies L. M. Bakker, MD,* Arash Alipour, MD, PhD,* Martijn C. Post, MD, PhD,*

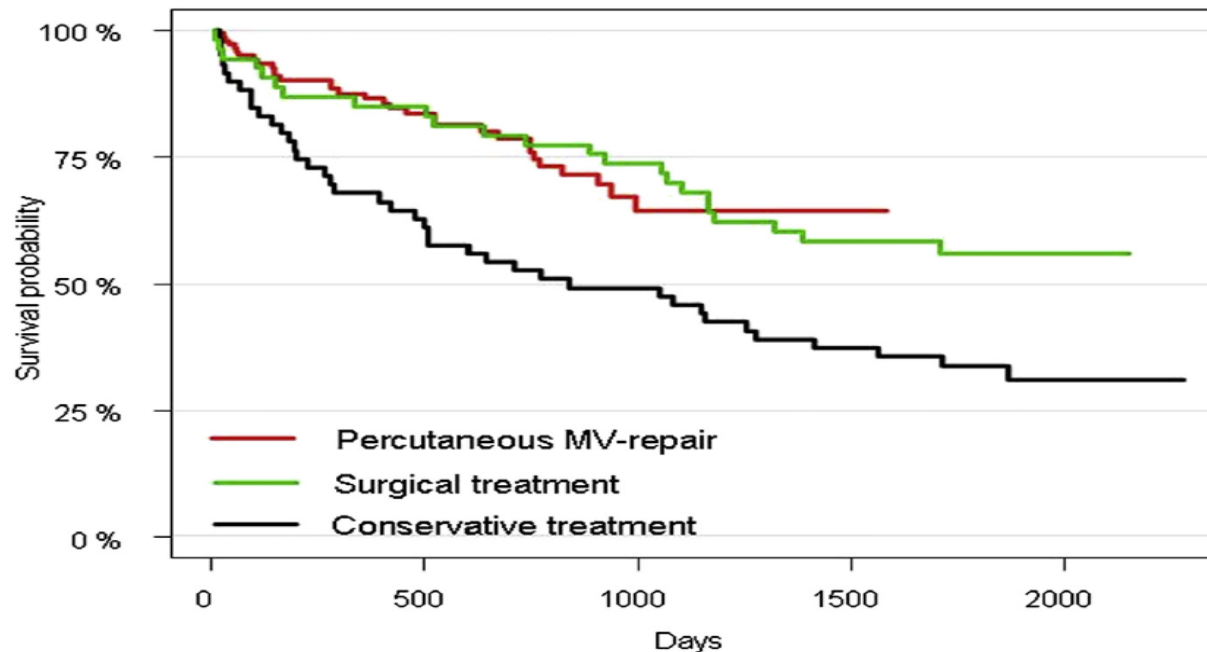
OBJECTIVES The goal of this study was to compare survival between transcatheter mitral valve (MV) repair using MitraClip system (Abbott Vascular, Santa Clara, California), MV-surgery, and conservative treatment in high-surgical-risk patients symptomatic with severe mitral valve regurgitation (MR).

BACKGROUND Up to 50% of high-surgical-risk patients with symptomatic severe MR may benefit from transcatheter MV repair.

METHODS Consecutive patients with symptomatic severe MR were treated with transcatheter MV repair (n = 53) and conservatively (n = 59) according to the logistic European System for Cardiac Assessment and Surgery as judged by the heart team.

RESULTS The log EuroSCORE II was higher in surgical patients (43.9 ± 14.4) and conservatively treated patients (34.5 ± 16.5) compared with transcatheter MV repair patients (14.2 ± 8.9). The same trend was observed when controlling for risk factors, both for surgical treatment compared with conservative treatment (OR 0.78, $p = 0.006$) and surgical treatment compared with transcatheter MV repair (OR 2.16, $p = 0.430$).

CONCLUSIONS Despite a higher log EuroSCORE II, high-surgical-risk patients with symptomatic severe MR treated with transcatheter MV repair show similar survival rates compared with surgically treated patients, with both displaying survival benefit compared with conservative treatment. (J Am Coll Cardiol Intv 2014;7:875-81) © 2014 by the American College of Cardiology Foundation.



Characteristic	MitraClip	High-Risk Surgery	Conservative Treatment
No.	139	53	59
Age, yrs	74.6 ± 9.4	70.2 ± 9.5	71.7 ± 9.6
Male, %	94 (67.6)	27 (50.9)	32 (54.2)
		26.7 ± 5.3	26.5 ± 4.5
		43.9 ± 14.4	34.5 ± 16.5
		14.2 ± 8.9	18.7 ± 13.2
		28 (52.8)	25 (42.4)
		10 (18.9)	17 (28.8)
		27 (50.9)	24 (40.7)
		15 (28.3)	19 (32.2)
		28 (52.8)	45 (76.3)
		13 (24.5)	25 (42.4)
		5 (9.4)	9 (15.3)
		9 (17.0)	11 (18.6)
		1 (1.9)	2 (3.4)
		9 (17.0)	18 (30.5)
		11 (20.8)	14 (23.7)
		28 (52.8)	26 (44.1)
		14 (26.4)	19 (32.2)
		6 (11.3)	8 (13.6)
III	91 (65.5)	38 (71.7)	35 (59.3)
IV	32 (23.0)	9 (17.0)	16 (27.1)
Etiology			
FMR	107 (77.0)	31 (58.5)	48 (81.3)
DMR	25 (18.0)	17 (32.1)	4 (6.8)
Mixed	7 (5.0)	5 (9.4)	7 (11.9)

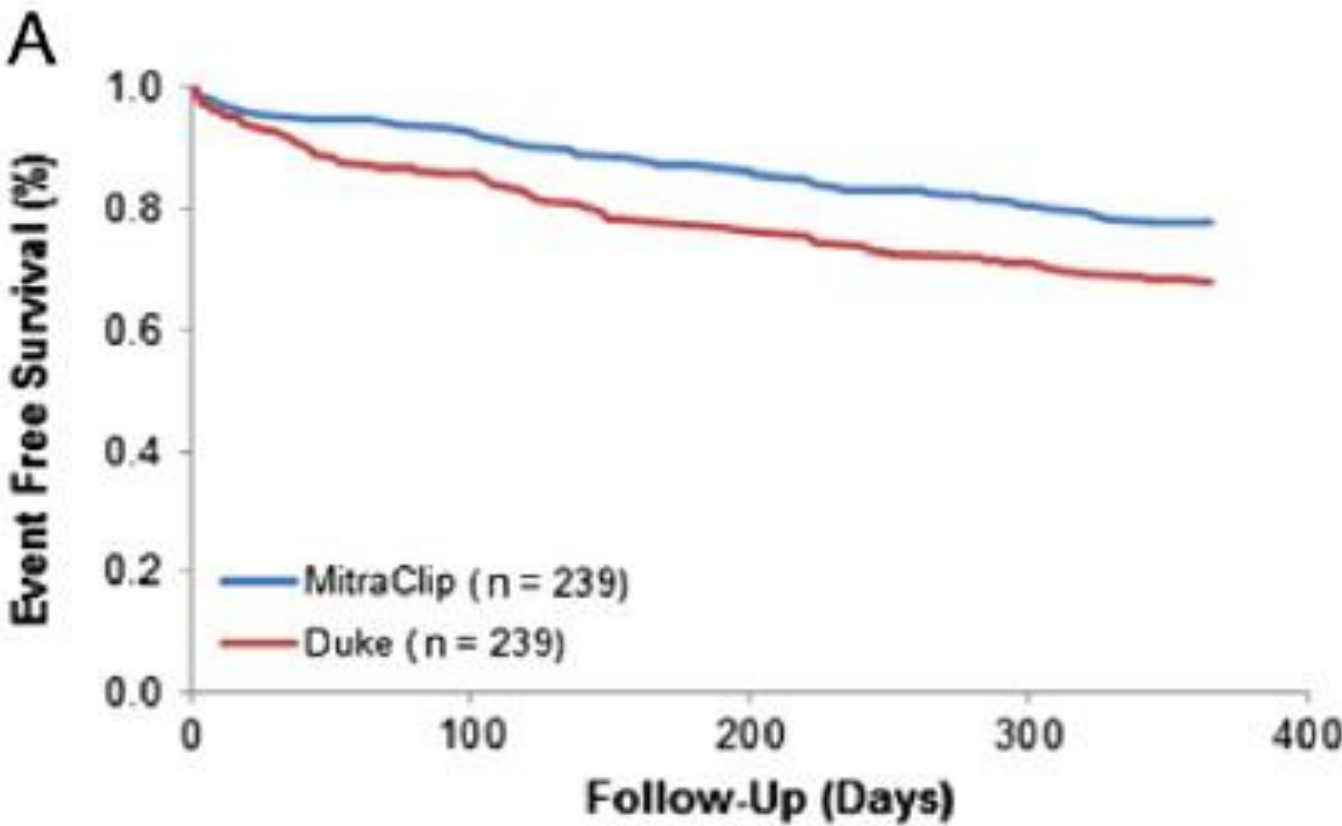
The MitraClip and survival in patients with mitral regurgitation at high risk for surgery: A propensity-matched comparison



Eric J. Velazquez, MD,^{a,b} Zainab Samad, MD, MHS,^b Hussein R. Al-Khalidi, PhD,^a Chithra Sangli, MA,^c Paul A. Grayburn, MD,^d Joseph M. Massaro, PhD,^c Susanna R. Stevens, MS,^a Ted E. Feldman, MD,^f and Mitchell W. Krucoff, MD^{a,b} *Durham, NC; Abbott Park, Evanston, IL; Dallas, TX; and Boston, MA*

American Heart Journal, Nov 2015. 170 (5) p.1050-1059

Background
the MitraClip
Laboratory D
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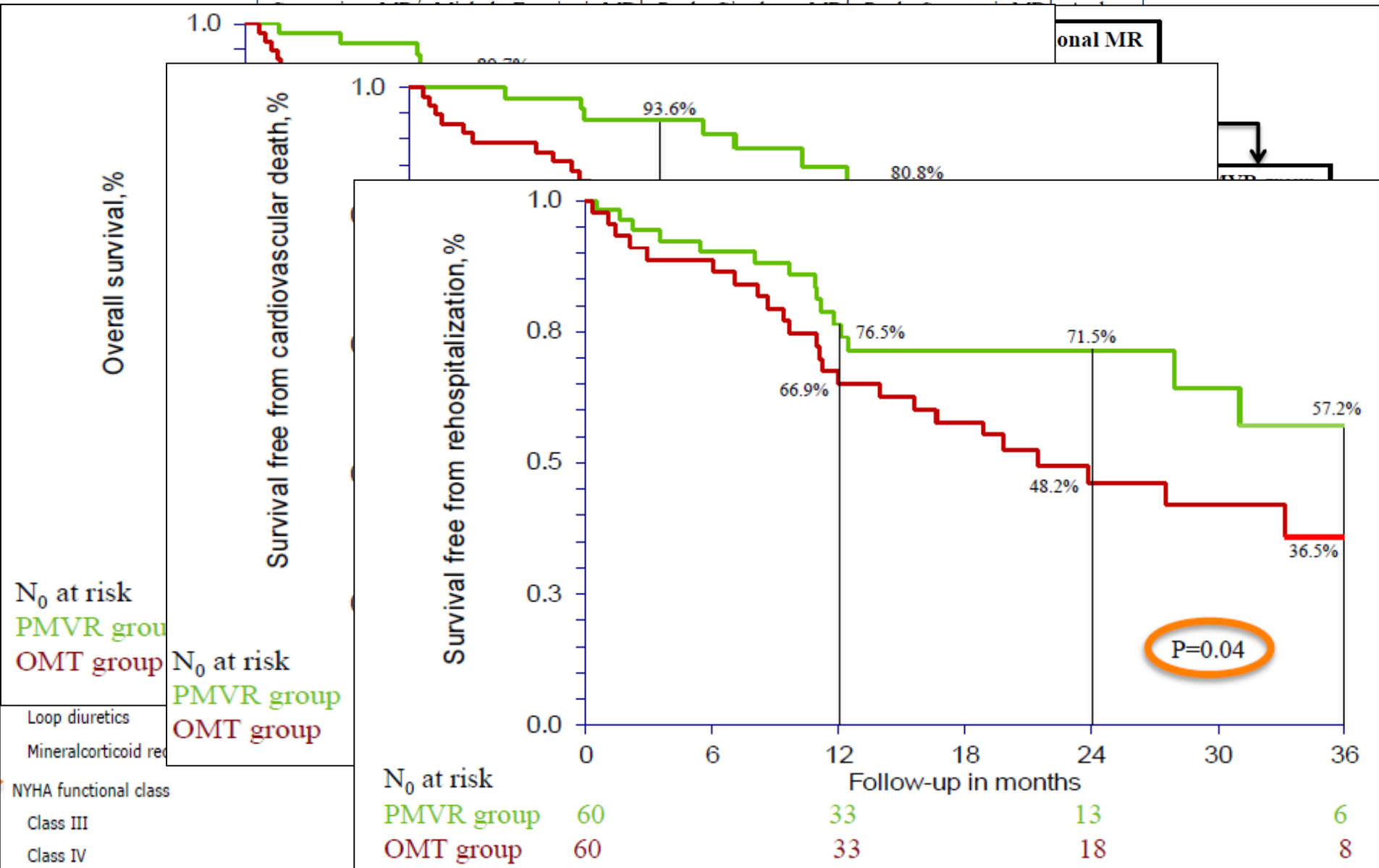
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MR		
Functional	82.8 (198)	90.8 (217)
Degenerative	17.2 (41)	9.2 (22)
LVEF, mean±SD, %	41.5±12.0	42.0±10.7
LVID, mean±SD, systole (cm)	4.71±1.00	3.91±0.97
STS valve replacement score, mean±SD	9.93±7.00	13.8±10.9

2016

Comparison of Percutaneous Mitral Valve Repair Versus Conservative Treatment in Severe Functional Mitral Regurgitation

Cristina Giannini, MD, PhD¹, Francesca Fiorelli, MD¹, Marco De Carlo¹, MD, PhD, Fabio



...TMVR works very well but.....

Predictors of Poor Prognostic Implication



UNIVERSITÄTSmedizin.

2. Medizinische Klinik

MAINZ



European Journal of Heart Failure (2015) 17, 108–115
doi:10.1093/eurjhf/hfu214

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

Michael Neuss¹, Thomas Schauf², Marek Schoepf, Martin Seifert, Frank Hölcherhmann, Jürgen Meyhöfer, and Christian Butter

TABLE VII. Preprocedural Predictors of Long-Term Cardiac Mortality in Multivar

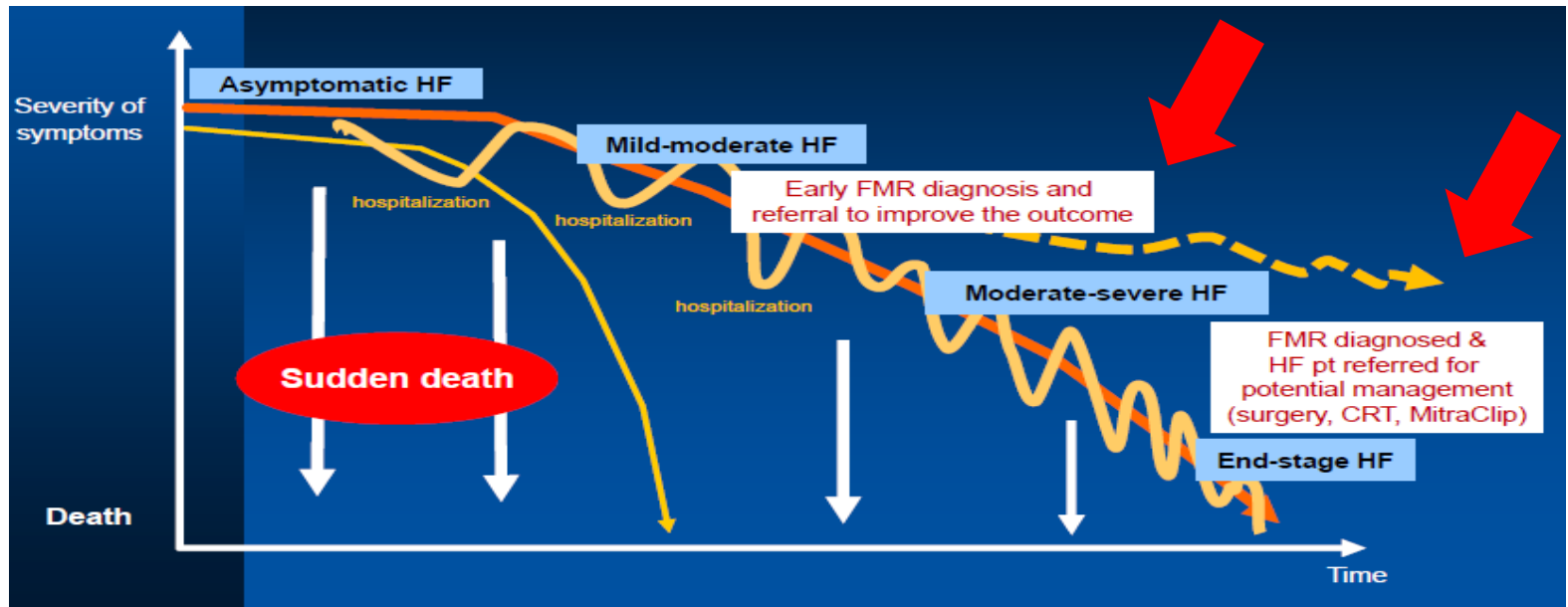
Table 4 Predictors of the combined event (primary endpoint: combination of all-cause mortality, left ventricular assist device implantation, mitral valve surgery, unsuccessful implantation) in univariate and multivariate analysis (Cox model)

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.

WHEN refer to TMVR: Timing is crucial

The importance of a timely intervention at an early stage



Piotr Ponikowski, MD, PhD, FESC

Medical University, Centre for Heart Disease Clinical Military Hospita HFA Athens 2014

Conclusion

Why to refer now to TMVR Therapy?

Why it works

Thank You
for your
attention