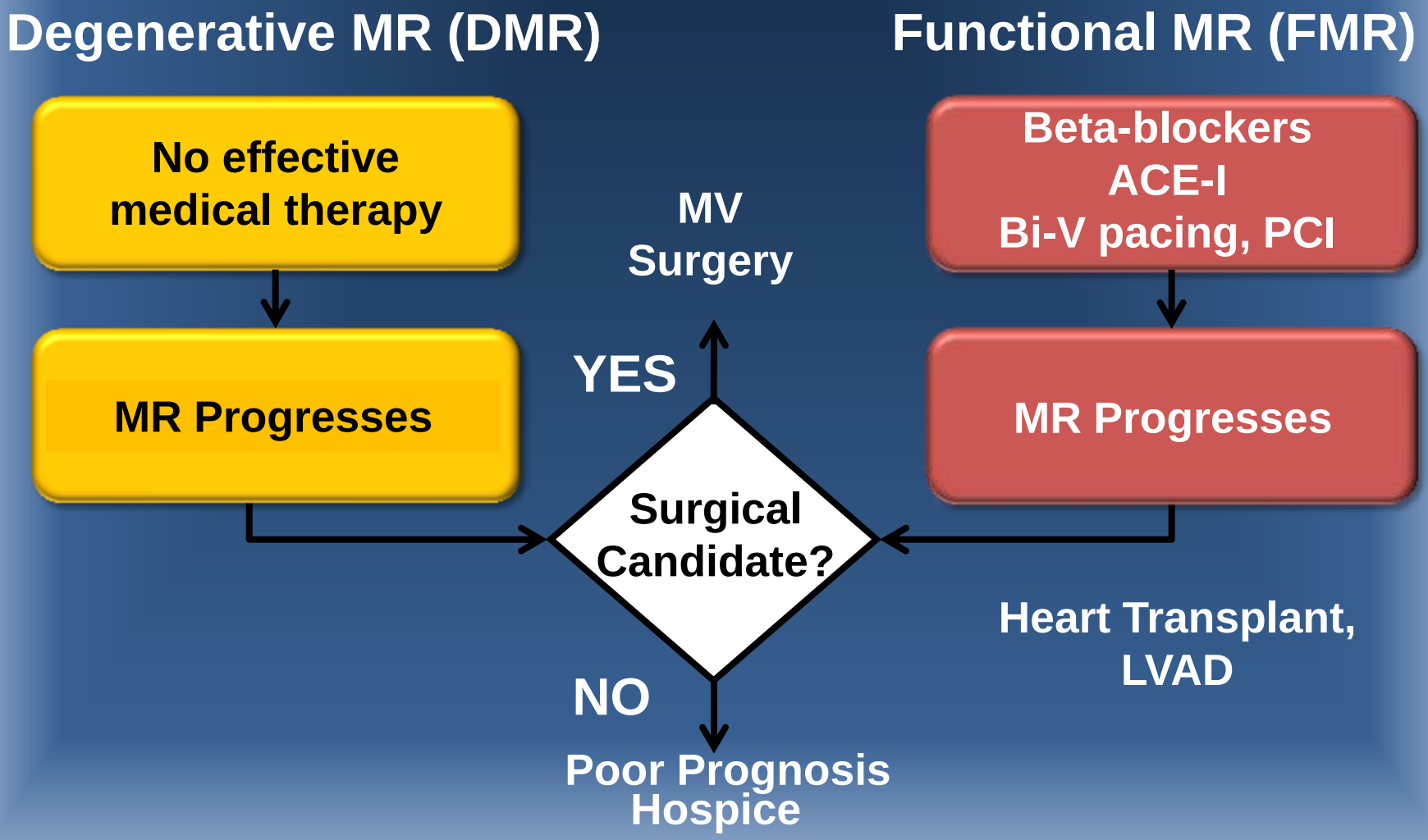
Current Clinical Evidence with the MitraClip System: What Have We Learned?

Chuck Simonton MD, FACC, FSCAI
CMO, DVP Medical Affairs
Abbott Vascular
Santa Clara, CA, USA

TCTAP 2014
Seoul, South Korea

Limited Treatment Options for Mitral Regurgitation



MitraClip® Clip Delivery System For Mitral Valve Repair in Patients Too High-Risk for Open Mitral Valve Surgery

Indications:
MitraClip Clip Delivery System: The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 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. **Steerable Guide Catheter:** The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.
See Important Safety Information Within.

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MitraClip® : US Clinical Program

Surgical Candidates

EVEREST II RCT
MitraClip® vs. Surgery

→

REALISM
Continued Access
Surgical Candidates

2005-06	2007	2008	2009-12

High Surgical Risk

EVEREST II
High Risk
Registry

→

REALISM
Continued Access
High Surgical Risk

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Surgical Candidates

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Continued Access
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Surgical Candidates

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High Surgical Risk

EVEREST II
High Risk
Registry

→

REALISM
Continued Access
High Surgical Risk

N = 78

N = 273

Integrated High Surgical Risk Cohort N=351

MitraClip® High Risk Cohort:

Pre-specified Safety and Effectiveness Endpoints

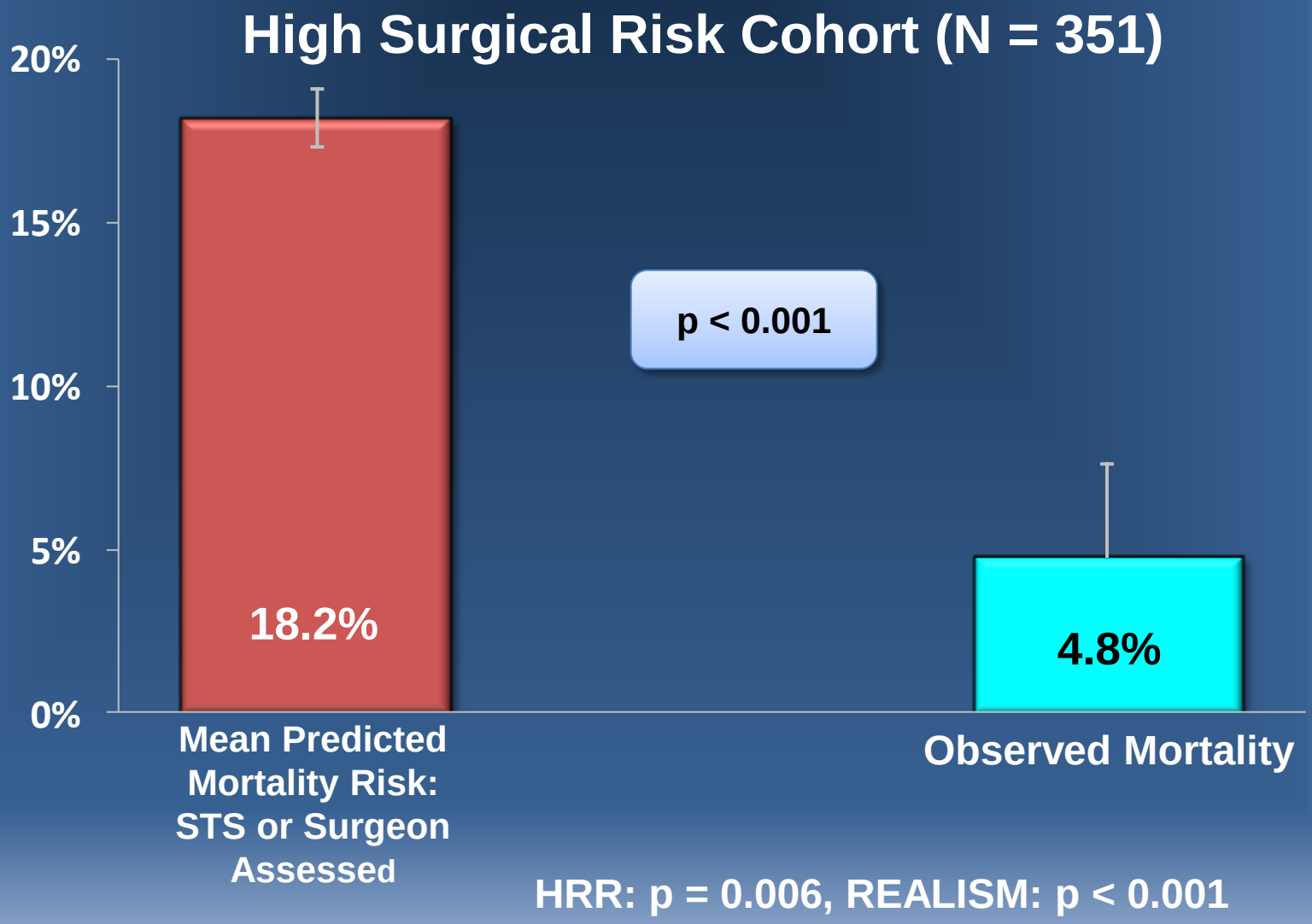
Safety Endpoint

30-day all-cause mortality

Effectiveness Endpoint

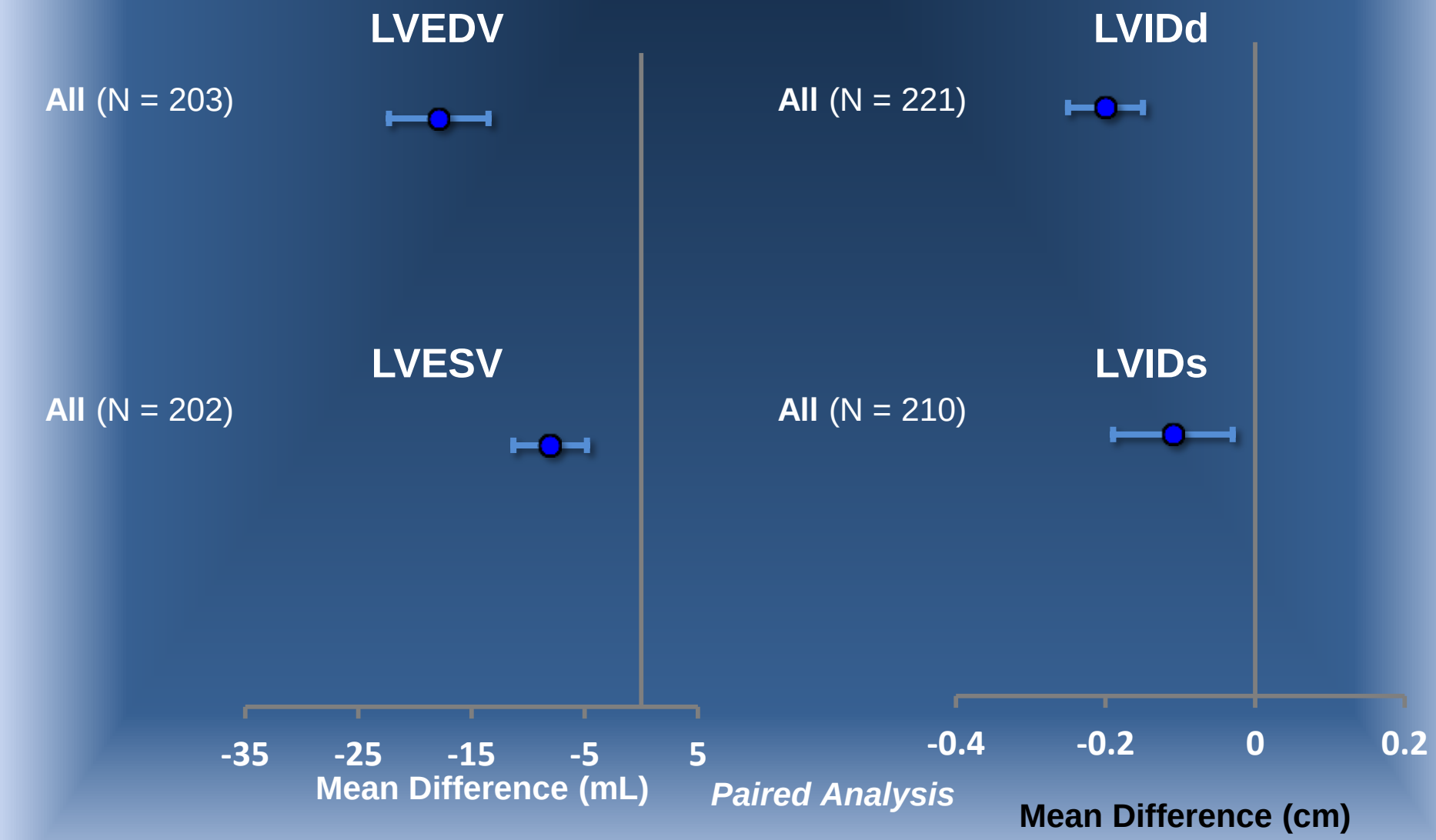
Change in LV size from baseline to 1 year

Primary Safety Endpoint: 30-Day Observed Mortality Lower than Predicted



HRR: p = 0.006, REALISM: p < 0.001

MitraClip® Effectiveness:
Reduction in LV Size at 1 Year



MR Severity at 1 Year by MR Severity at Discharge

Discharge	
MR	N=232
1+	115
2+	92
3+	23
4+	2

1 Year MR (%)			
≤ 1+	2+	3+	4+
54	48	13	0
26	53	10	3
6	7	5	5
0	1	0	1

- 34% - MR increased from discharge
- 66% - MR improved or same as discharge

Paired Analysis

84% of Patients Treated With MitraClip Experienced Durable Results

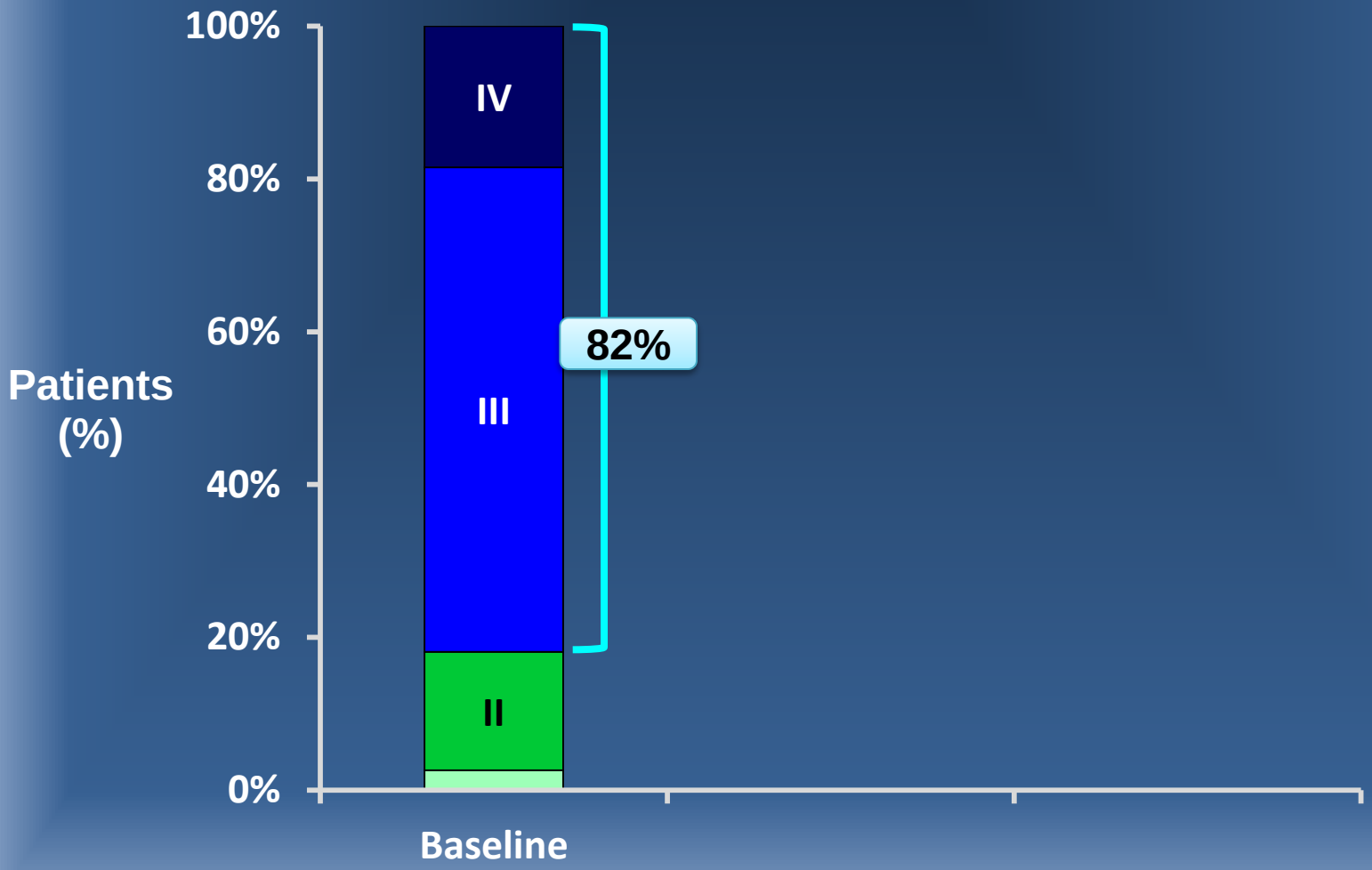
Discharge		1 Year MR (%)			
MR	N=232	≤ 1+	2+	3+	4+
1+	115	54	48	13	0
2+	92	26	53	10	3
3+	23	6	7	5	5
4+	2	0	1	0	1

- 34% - MR increased from discharge
- 66% - MR improved or same as discharge
- 84% - 1+/2+ at 1 year

Paired Analysis

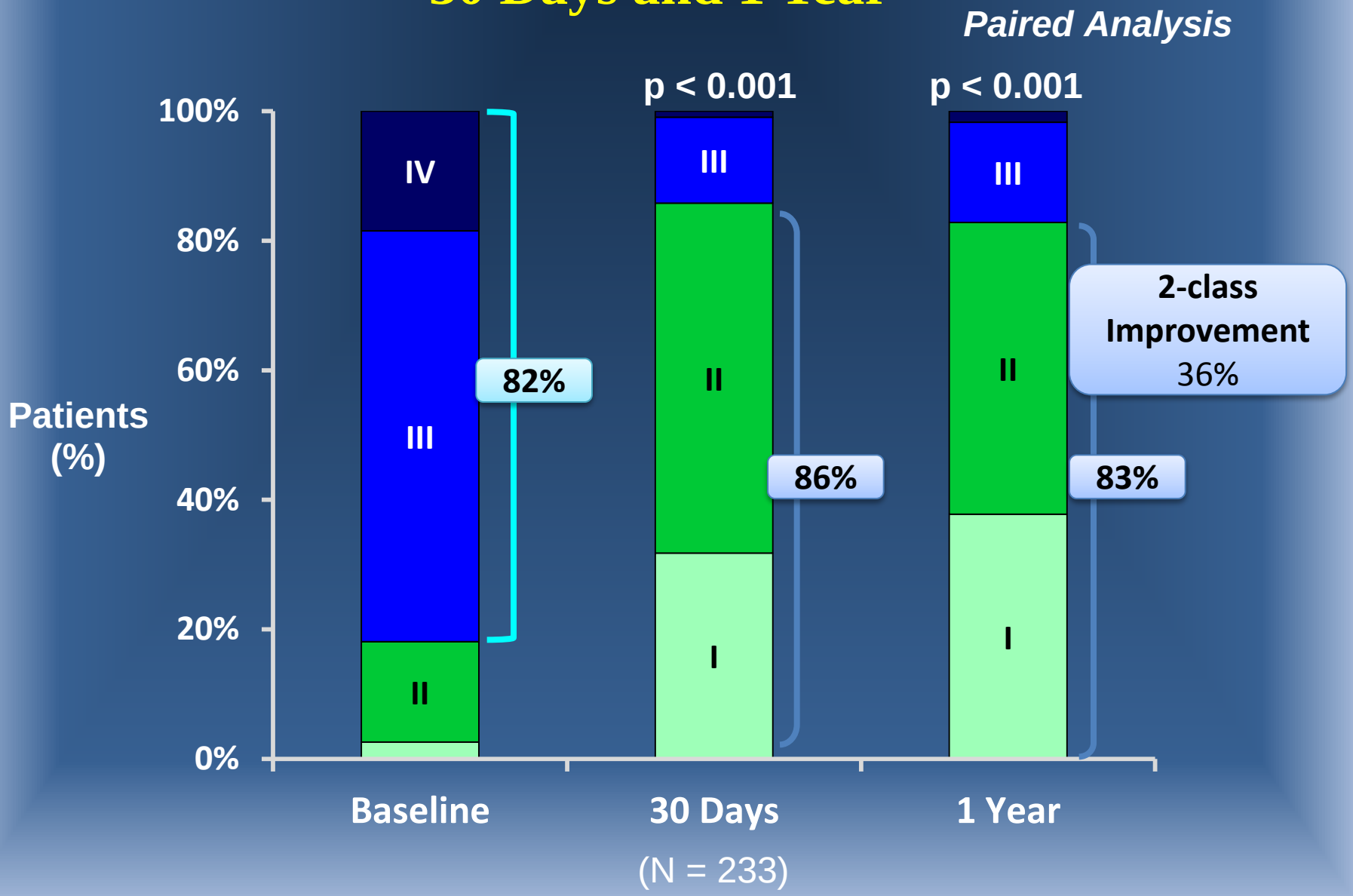
Improved NYHA Class Symptoms at 30 Days and 1 Year

Paired Analysis

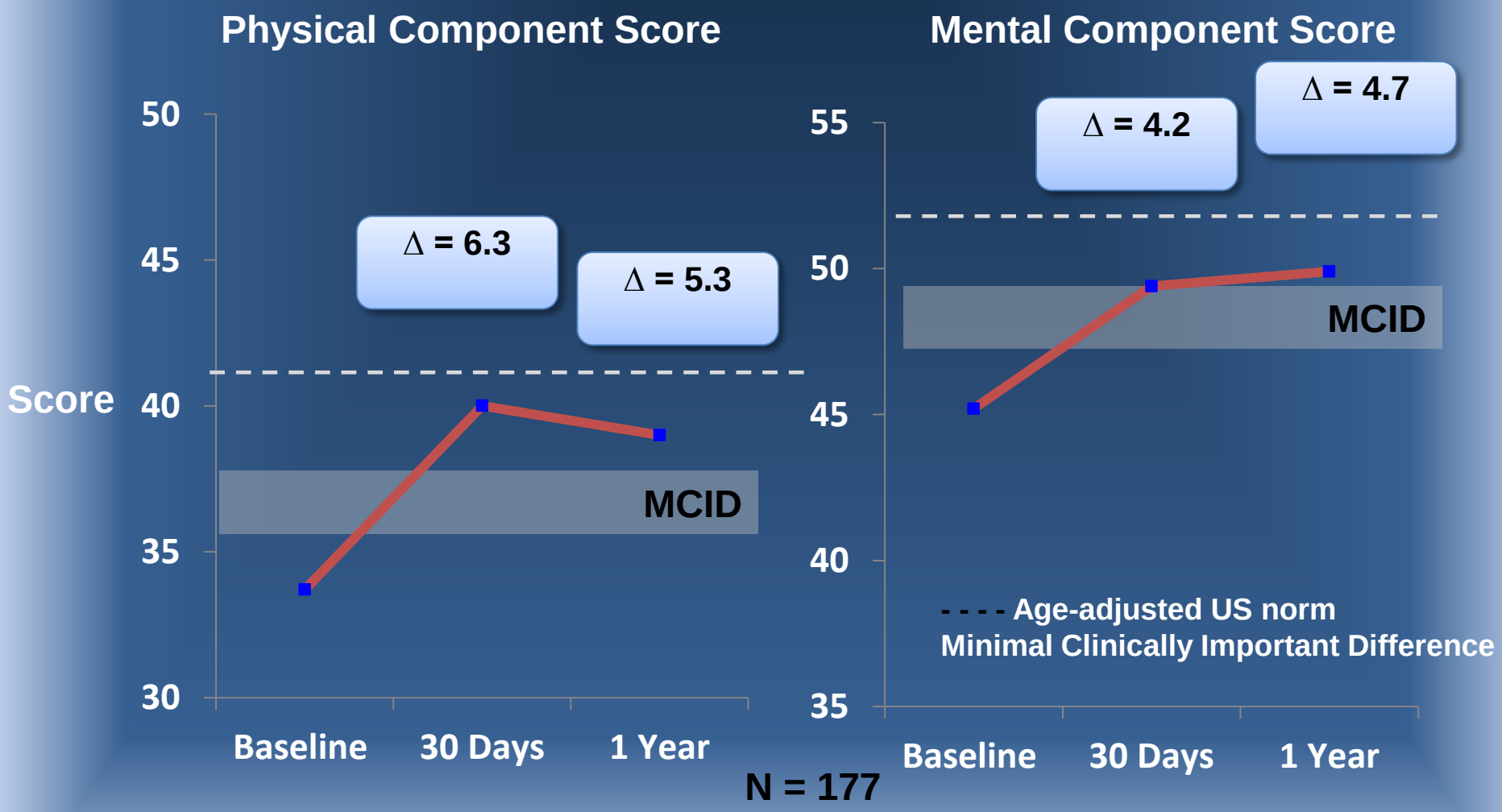


(N = 233)

Improved NYHA Class Symptoms at 30 Days and 1 Year

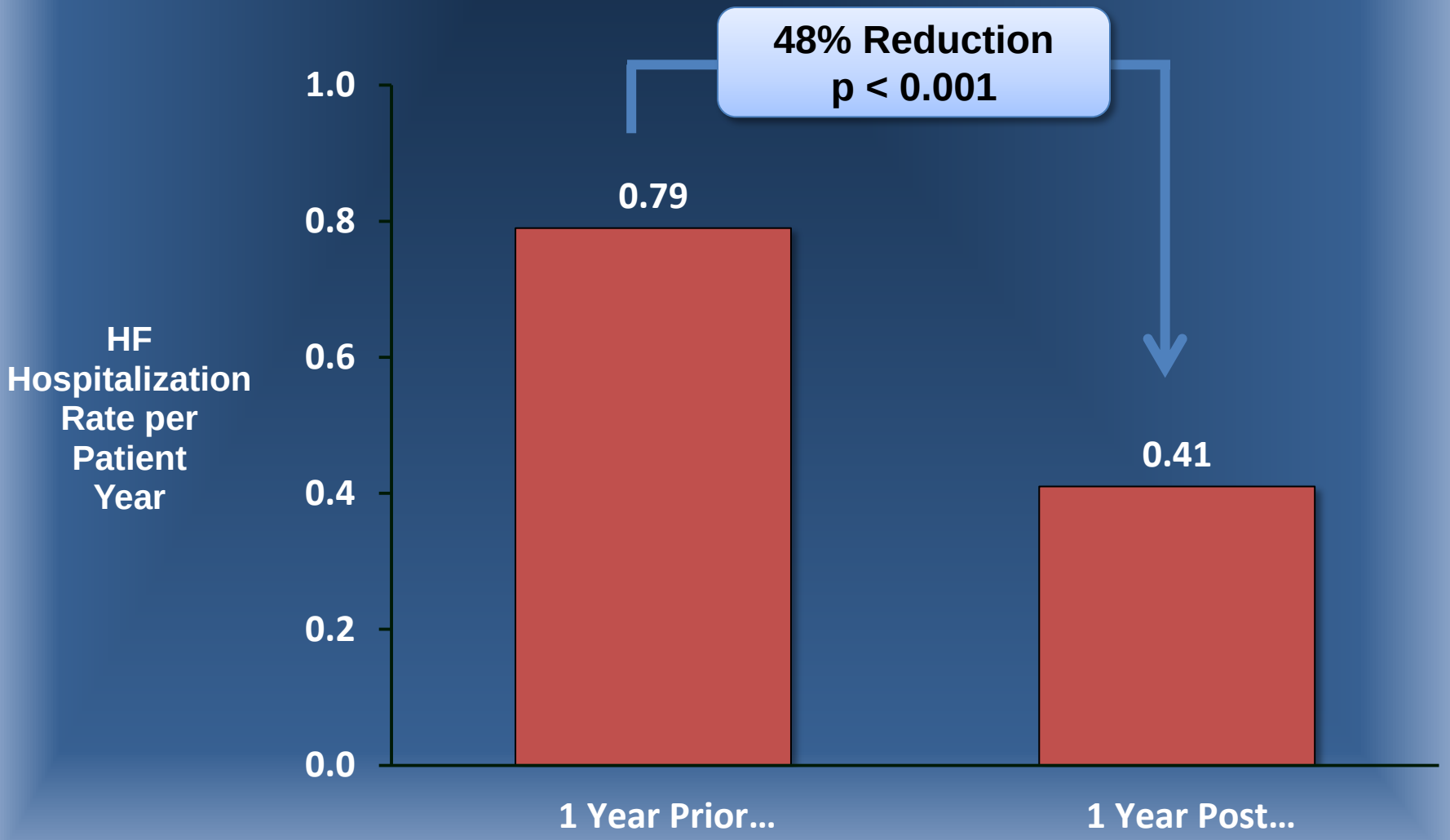


Improved Quality of Life (SF36) at 30 Days and 1 Year



Significant Reduction in HF Hospitalization Rate

All Treated

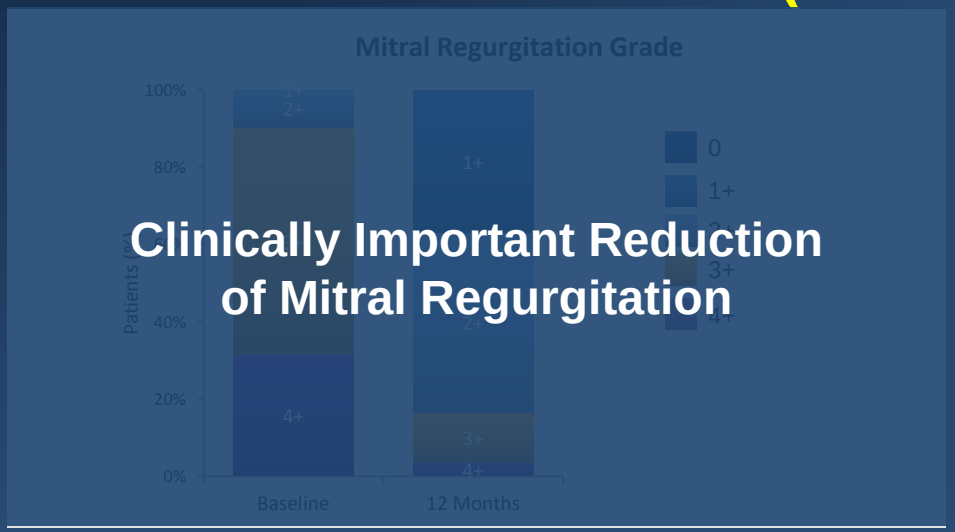


MitraClip® Outcomes in Prohibitive Risk DMR

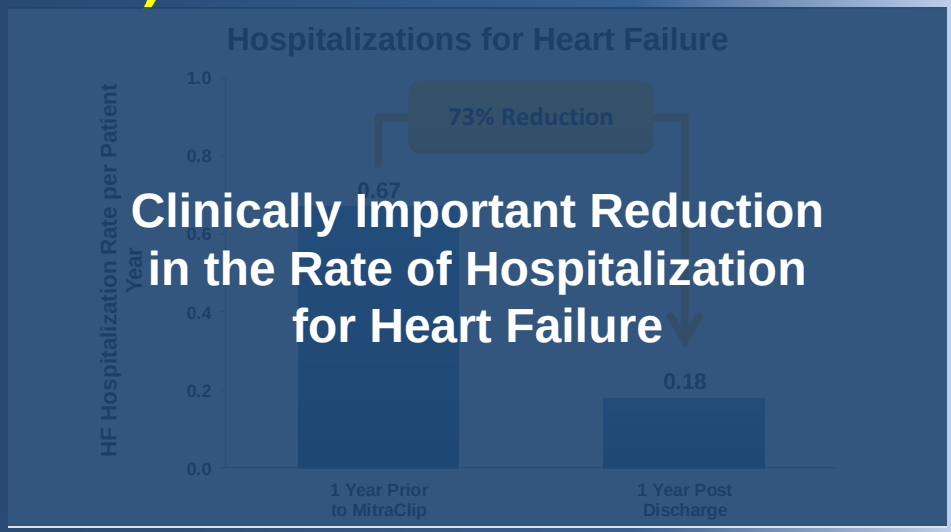
Ted Feldman, MD
on behalf of the EVEREST II Investigators

TCT 2013
San Francisco, CA

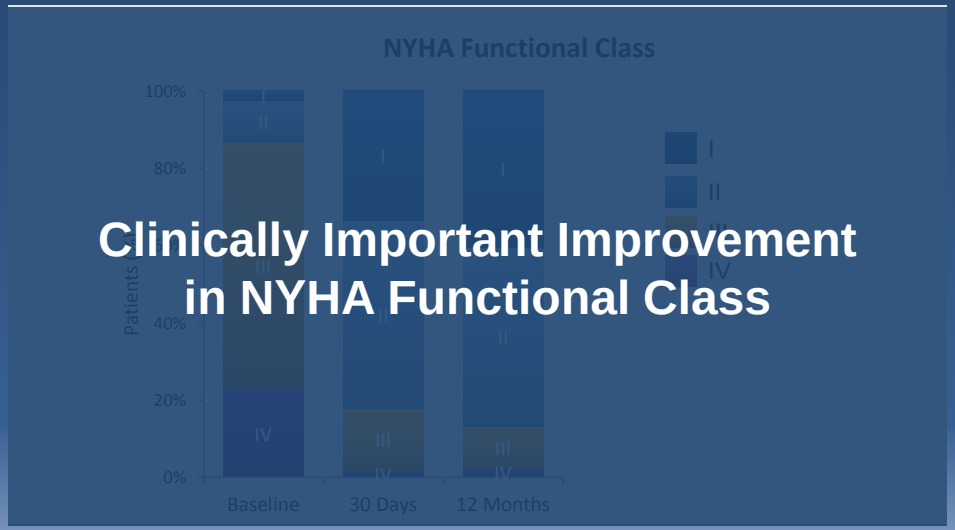
Prohibitive Surgical Risk DMR Cohort (n=127)



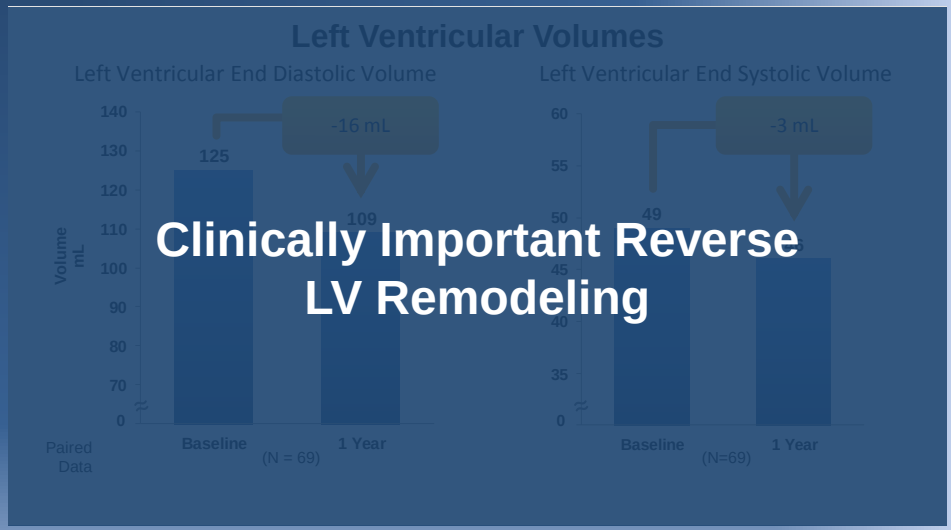
Clinically Important Reduction of Mitral Regurgitation



Clinically Important Reduction in the Rate of Hospitalization for Heart Failure



Clinically Important Improvement in NYHA Functional Class



Clinically Important Reverse LV Remodeling

Source: MitraClip® Clip Delivery System Instructions for Use.
See important safety information referenced within.

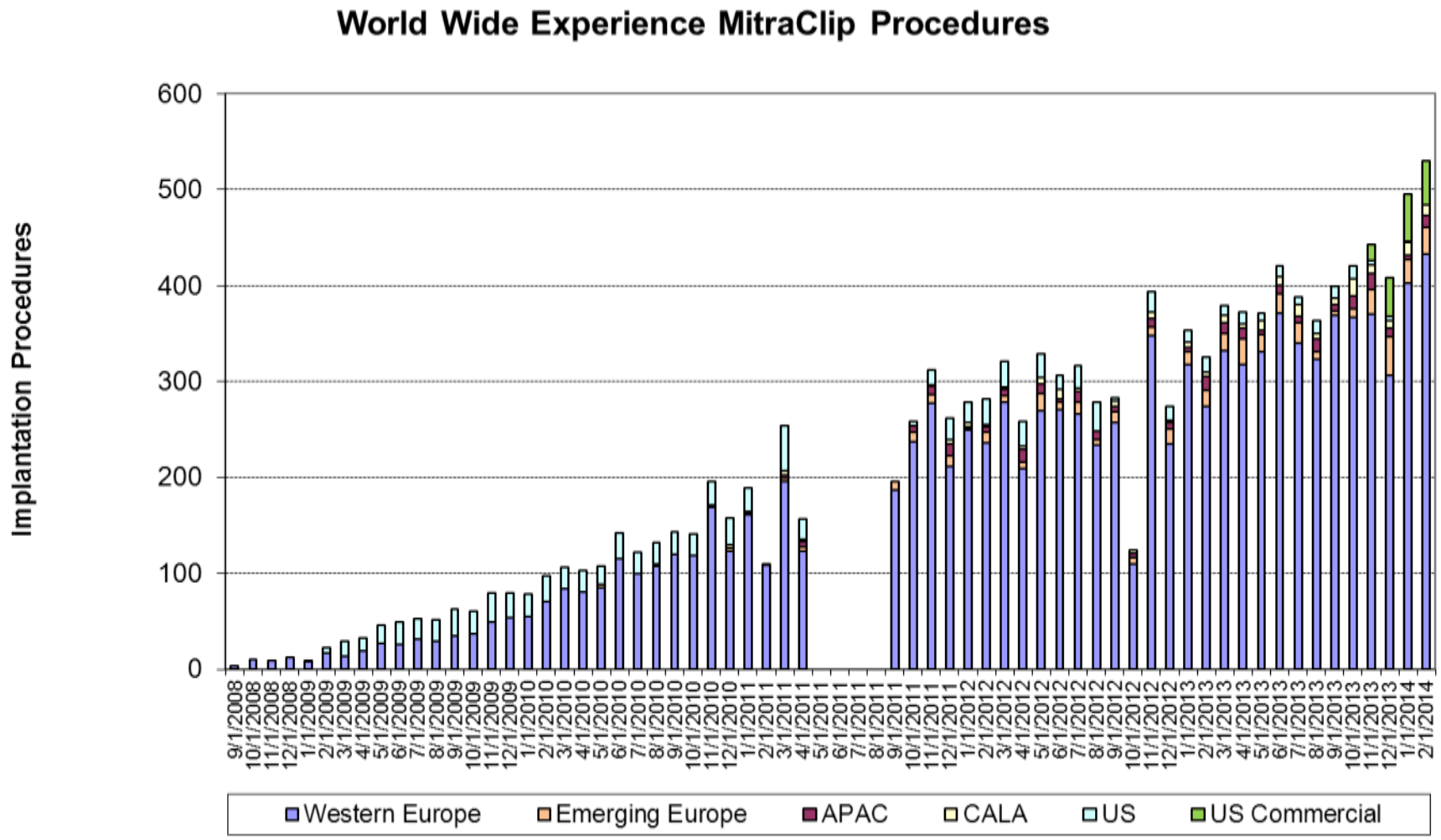
Worldwide Clinical Experience

Study	Population	n
EVEREST I (Feasibility)	Non-randomized	55
EVEREST II (Pivotal)	Pre-randomization	60
EVEREST II (Pivotal)	Non-randomized patients (High Risk Study)	78
EVEREST II (Pivotal)	Randomized patients	279 184 clip
REALISM (Continued Access)	Patients	965
US Commercial Patients	Patients	151
COAPT RCT	Randomized patients	46
COAPT RCT	Pre-Randomized patients	25
World Wide Commercial Use	Patients	11,456
Total		13,020 +95 surgery

*Data as of 2/28/2014

Source: Abbott Vascular Data on File.

Global MitraClip Procedures



*Data as of 2/28/2014. Sources: Apollo System; Case Observation Forms. This includes all submitted and reviewed procedures, including successful and unsuccessful procedures as reported in Apollo.

RESHAPE-HF European Trial

- 800 FMR patients with severe heart failure
- Commercial post market
- Randomized to medical management
- Primary endpoint - HF hospitalization and death composite
- Enrollment ongoing

Source: RESHAPE-HF Clinical Investigation Plan 12-513

COAPT North American Trial

- 430 heart failure patients with FMR deemed not appropriate for surgery
- Randomized to medical management
- Primary endpoint - HF hospitalization rates
- Primary Data Analysis – expected ~ 2017

Source: COAPT Clinical Investigation Plan 11-512

MitraClip® : Conclusions

1. Patients with severe MR (3+/4+) who are at prohibitive risk for surgery represent a significant *unmet clinical need*

2. MitraClip® clinical studies show that the procedure is safe and effective in these patients

3. The documented improvement in left ventricular dimensions, symptoms, QOL, and HF hospitalizations is consistent across DMR and FMR patients and durable in surviving patients

4. Worldwide MitraClip® procedural volume continues to grow, and is now included in both ESC and ACC/AHA Practice Guidelines