

Debate: MitraClip Would be a Better Option

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Disclosure Statement of Financial Interest

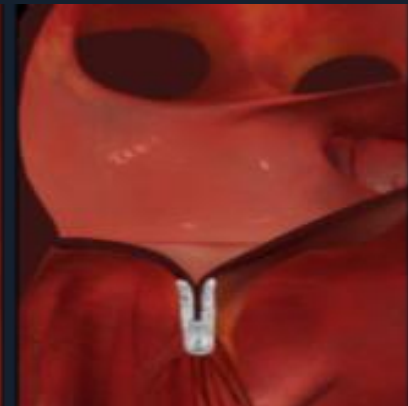
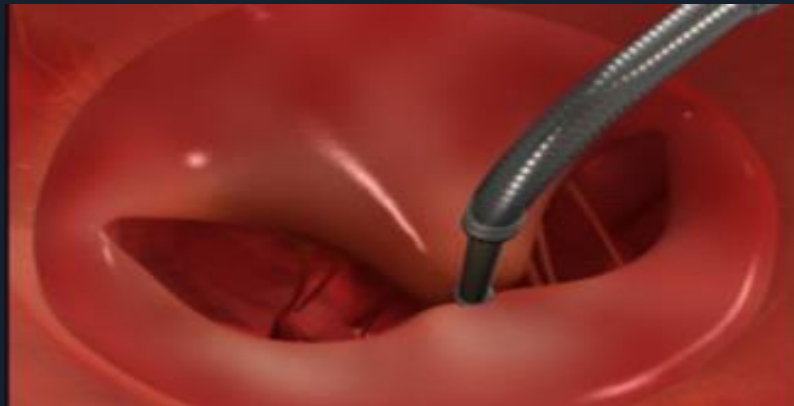
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship
Consulting Fees/Honoraria

Company
Abbott Vascular

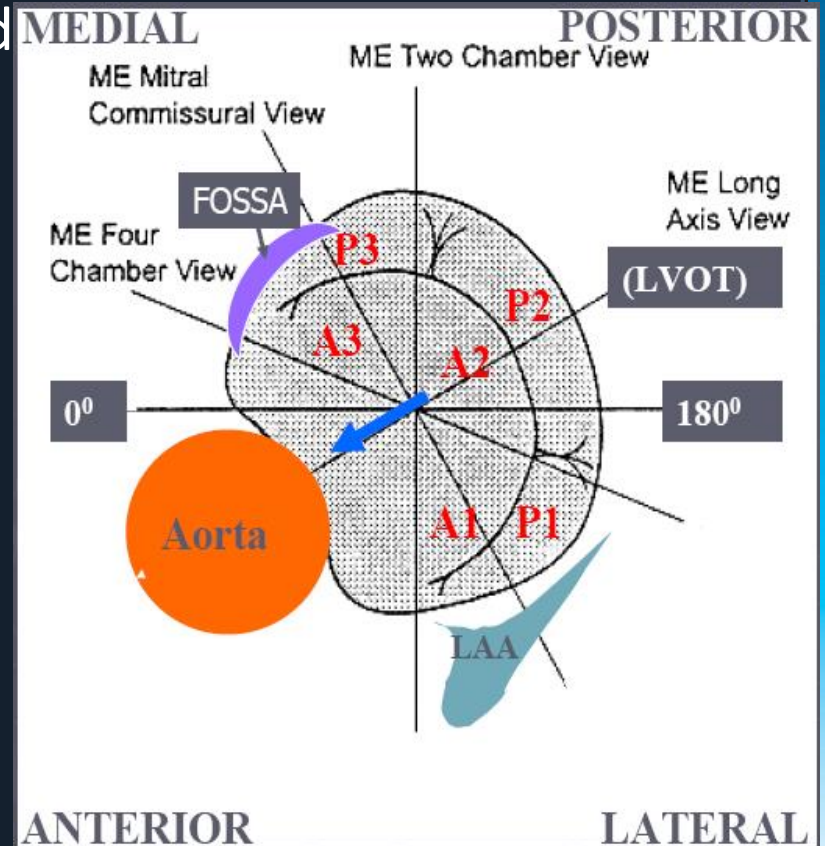
MitraClip MV Repair

- The only FDA approved percutaneous therapy for MR in the US

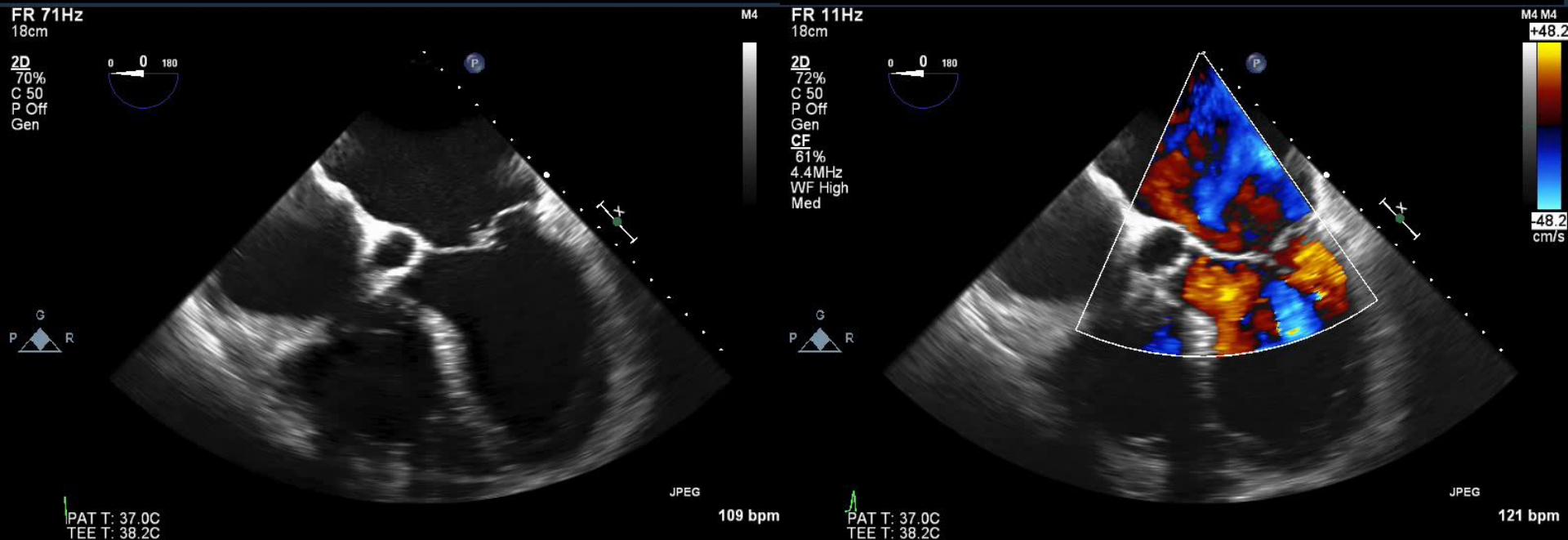


Anatomy and Etiology

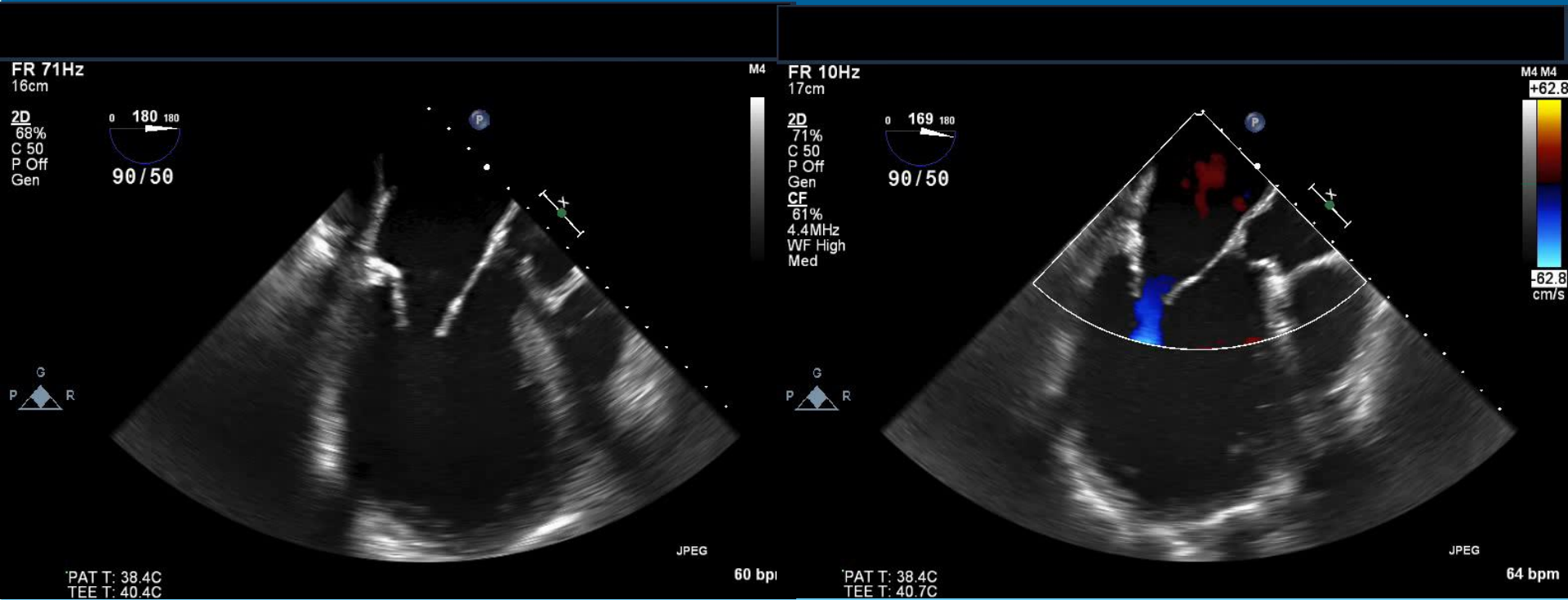
- **Degenerative MR**
 - Redundant leaflets, elongated or ruptured chords
- **Functional MR**
 - Annular dilation
 - Annular calcification
 - Papillary muscle dysfunction
 - Fixed (LV dysfunction related posterior tethering)
 - Transient (ischemia)
- **Rheumatic changes**
- **Endocarditis**



Degenerative MR



Functional MR



MitraClip System US Clinical Trial Experience

EVEREST I
Feasibility Study

N = 55

EVEREST II RCT
MitraClip vs. Surgery

**Continued Access: Surgical
Candidates**

N = 279
184 clip
95 surgery

N = 272

Surgical Candidates

High Surgical Risk

High Risk Cohort
N = 351

**High Risk
Single-
Arm**

**Continued Access:
High Risk**

N = 78

N = 273

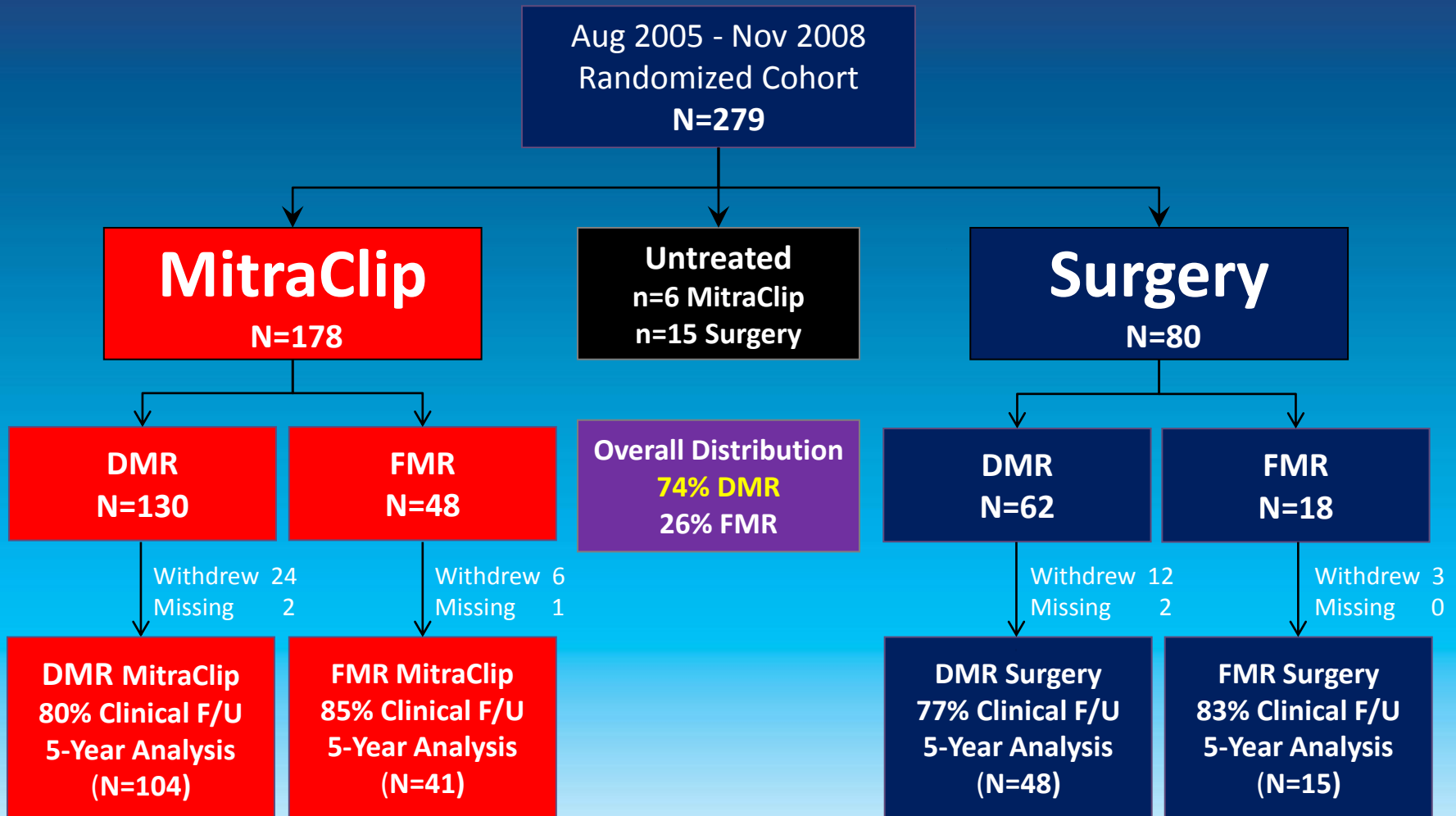
2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012

One



Carolina HealthCare System

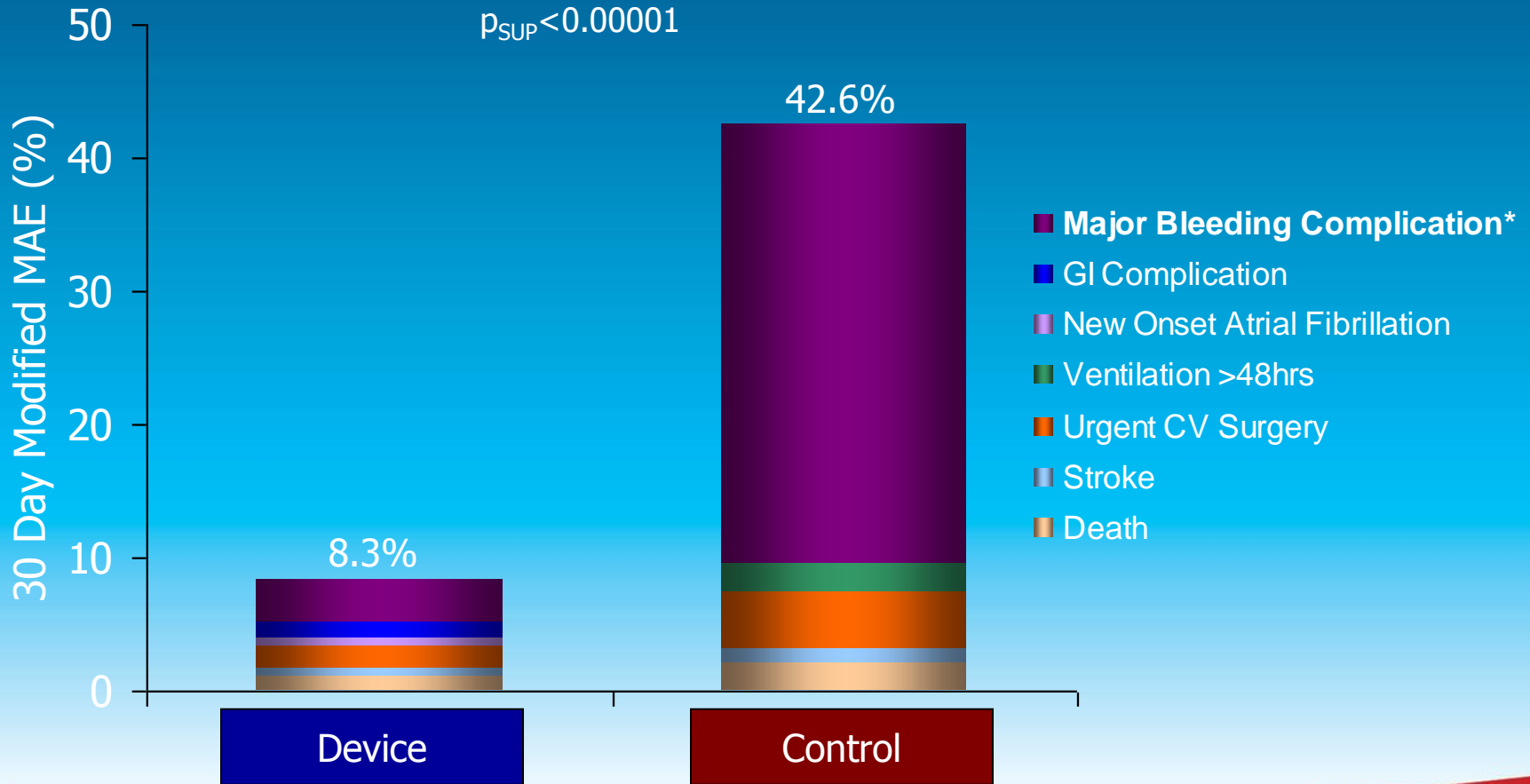
EVEREST II Randomized Clinical Trial



Median follow-up 4.93 years. 1,007 total patient-years of follow-up.

Safety

30 Day Modified * MAE Intent to Treat

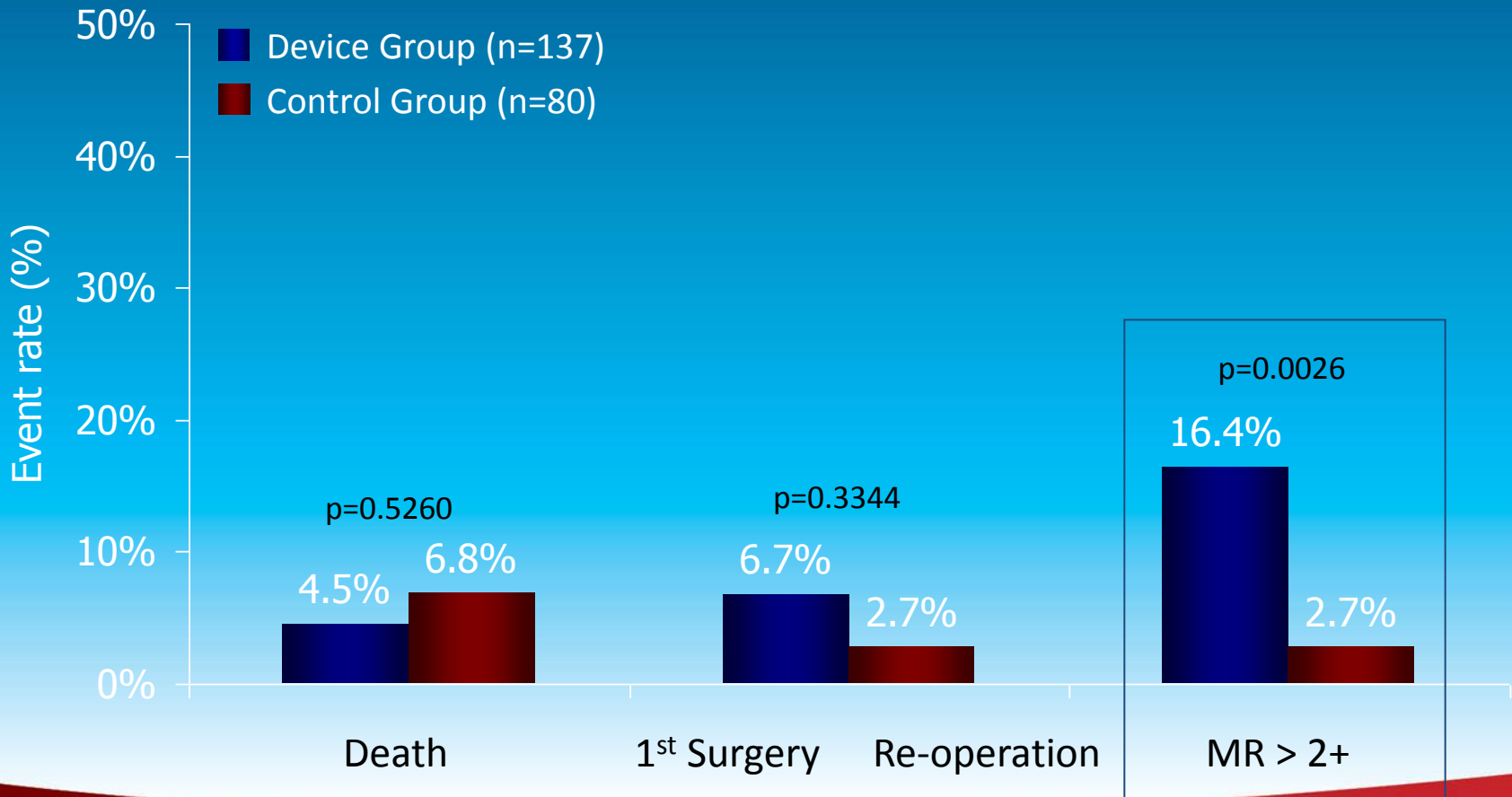


*Major bleeding requiring transfusion $\geq 2U$, or surgical intervention.



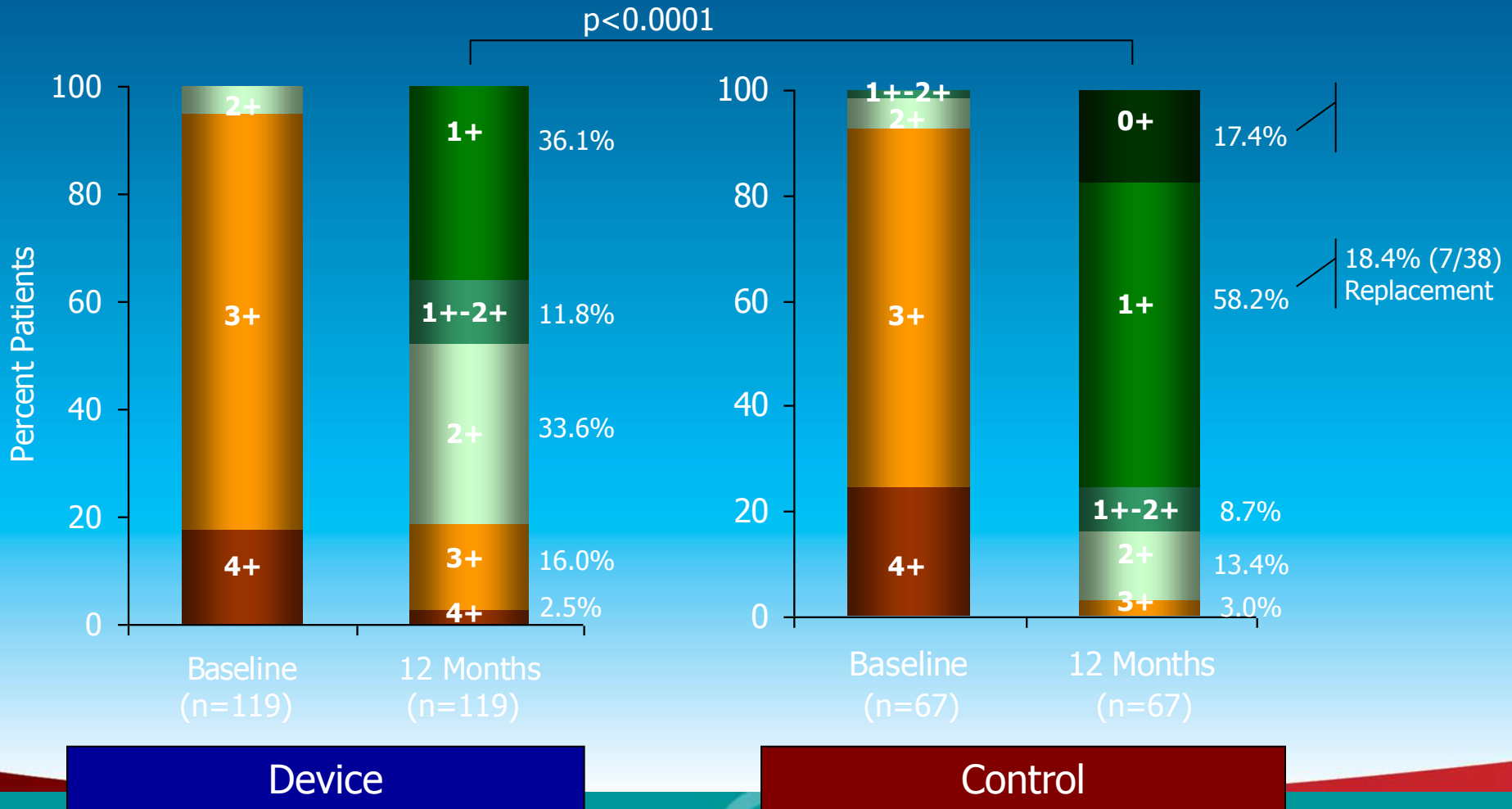
Primary Effectiveness

Per Protocol Cohort



MR Reduction

Baseline vs. 12 Months, Per Protocol

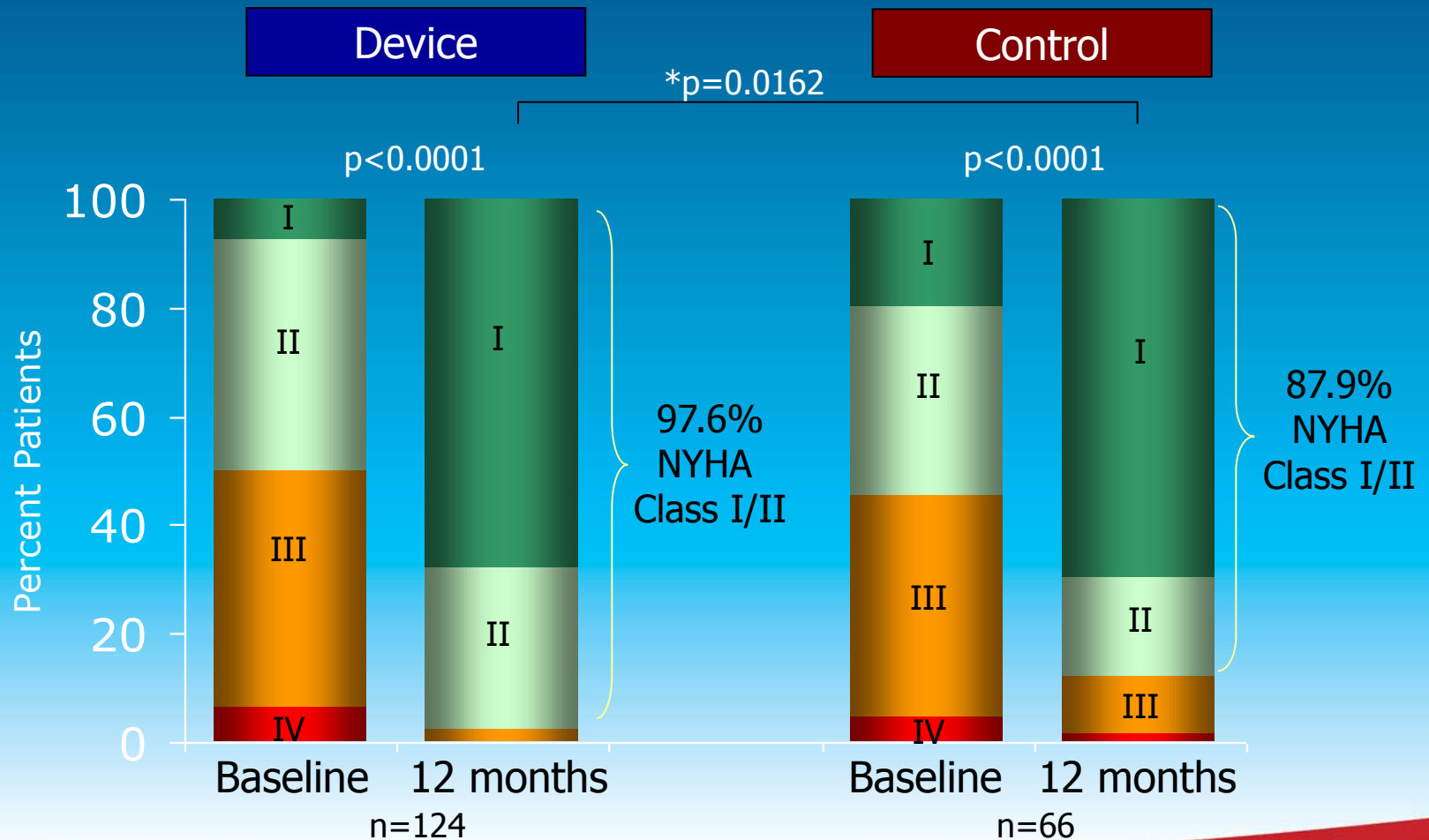


p-value compares the distribution of MR grade in device with the distribution of MR grade in control at 12 months (Fishers' Exact test)



NYHA Functional Class

Baseline vs 12 Months, Per Protocol, Matched Cases



p-value compares the distribution of NYHA class at baseline to the distribution at 12 months within device and control
*p-value compares the distribution of NYHA class in device to the distribution in control at 12 months (Fisher's Exact test)

Mitral Regurgitation Grade at 5 Years

DMR

FMR

MitraClip
(N=130)

Surgery
(N=62)

MitraClip
(N=48)

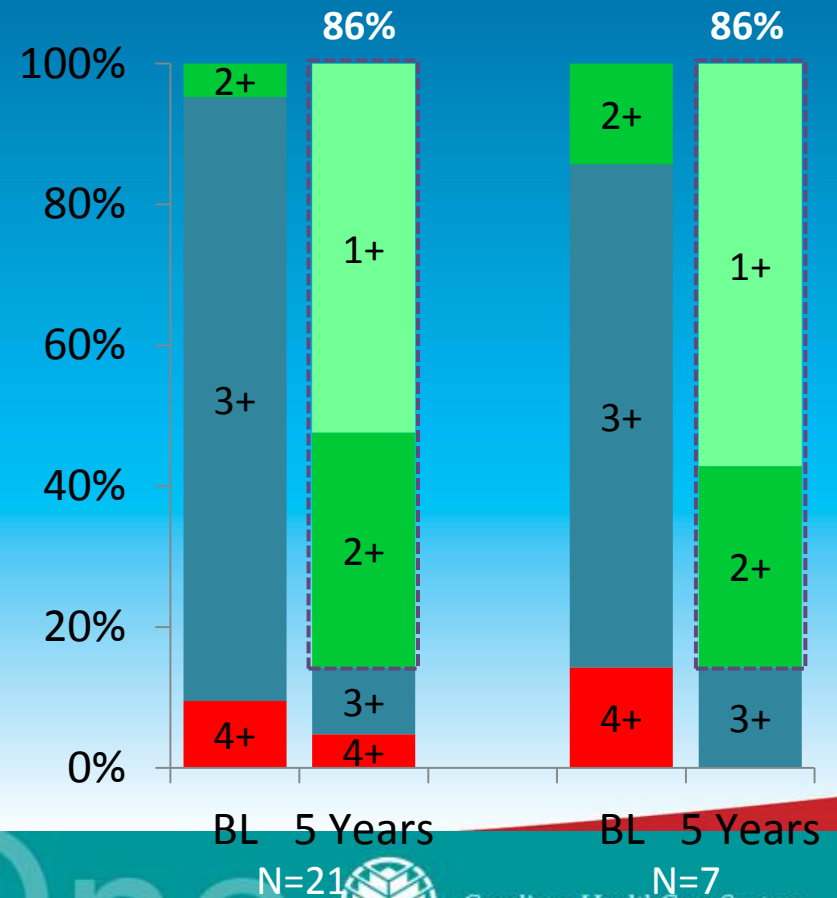
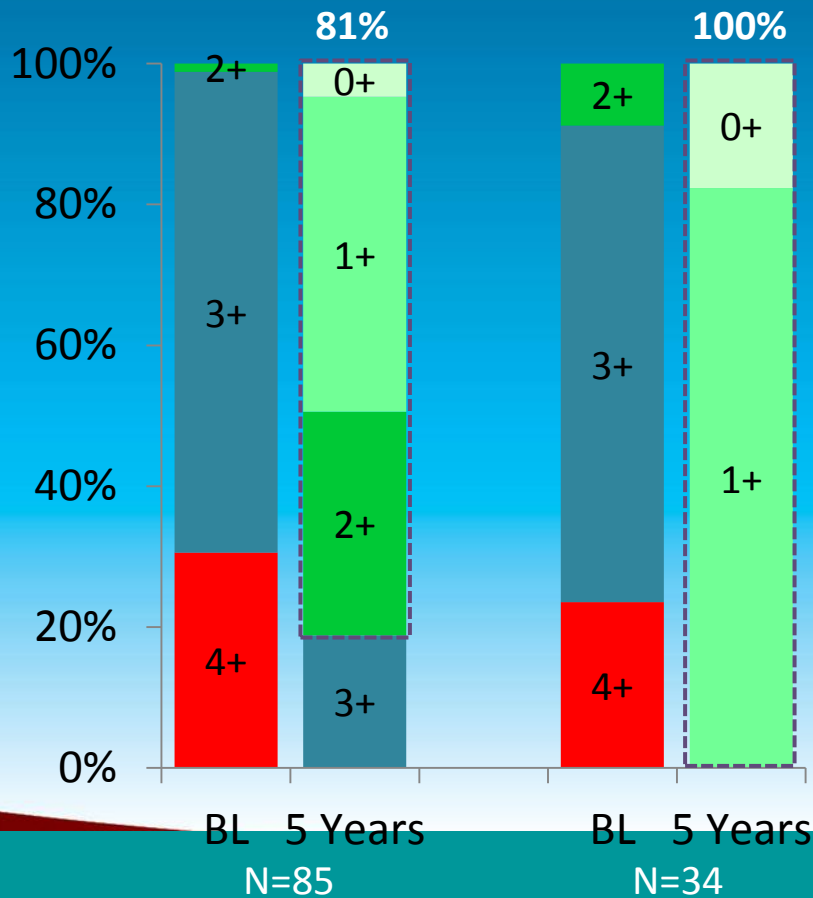
Surgery
(N=18)

p<0.005

p<0.005

p<0.05

p=0.82



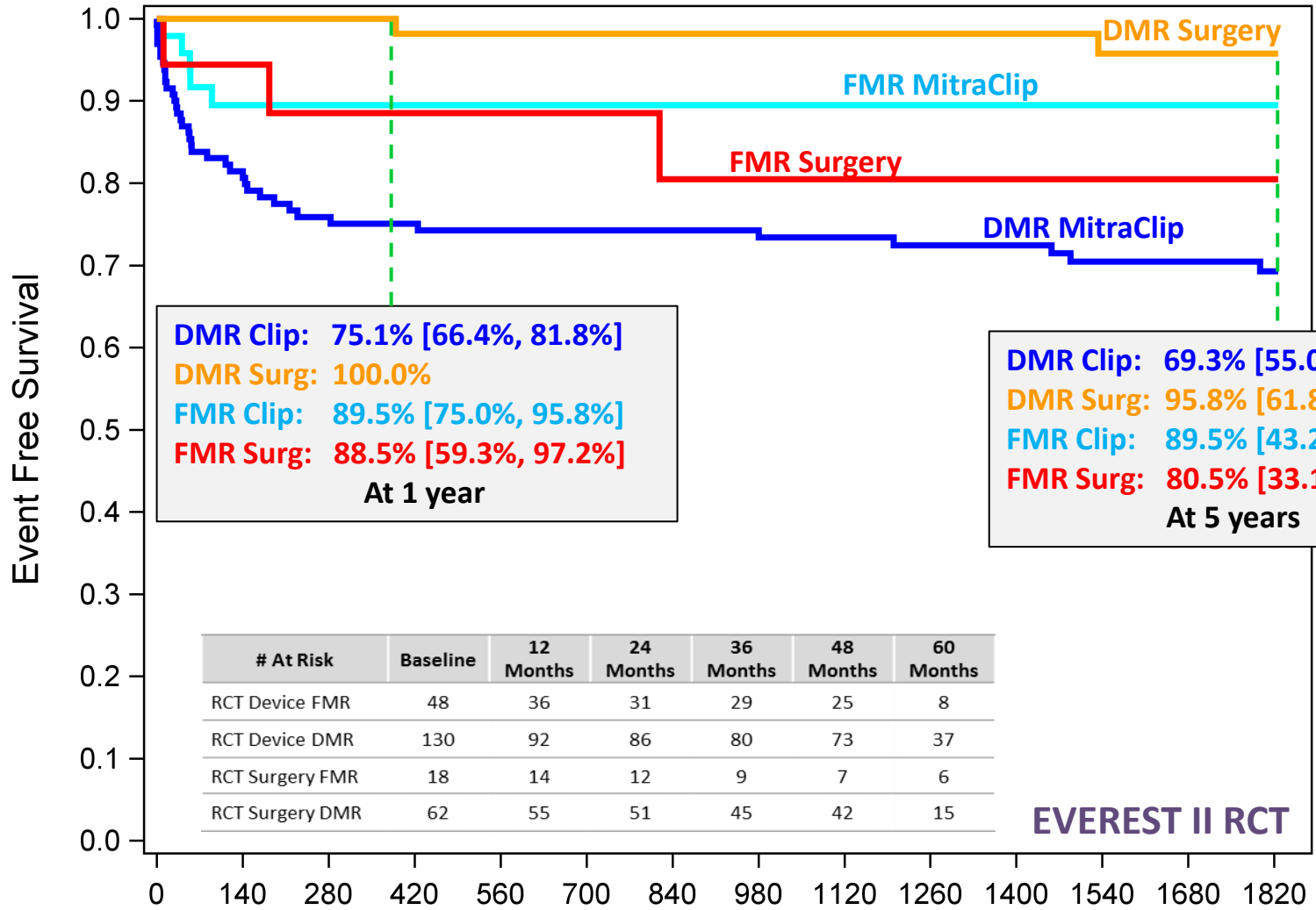
N = survivors with paired data; p-values for descriptive purposes only



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Freedom From MV Surgery or Re-Operation

EVEREST II RCT – DMR and FMR Subgroups



EVEREST II RCT

Kaplan-Meier estimate, with deaths censored

MitraClip System

US Clinical Trial Experience

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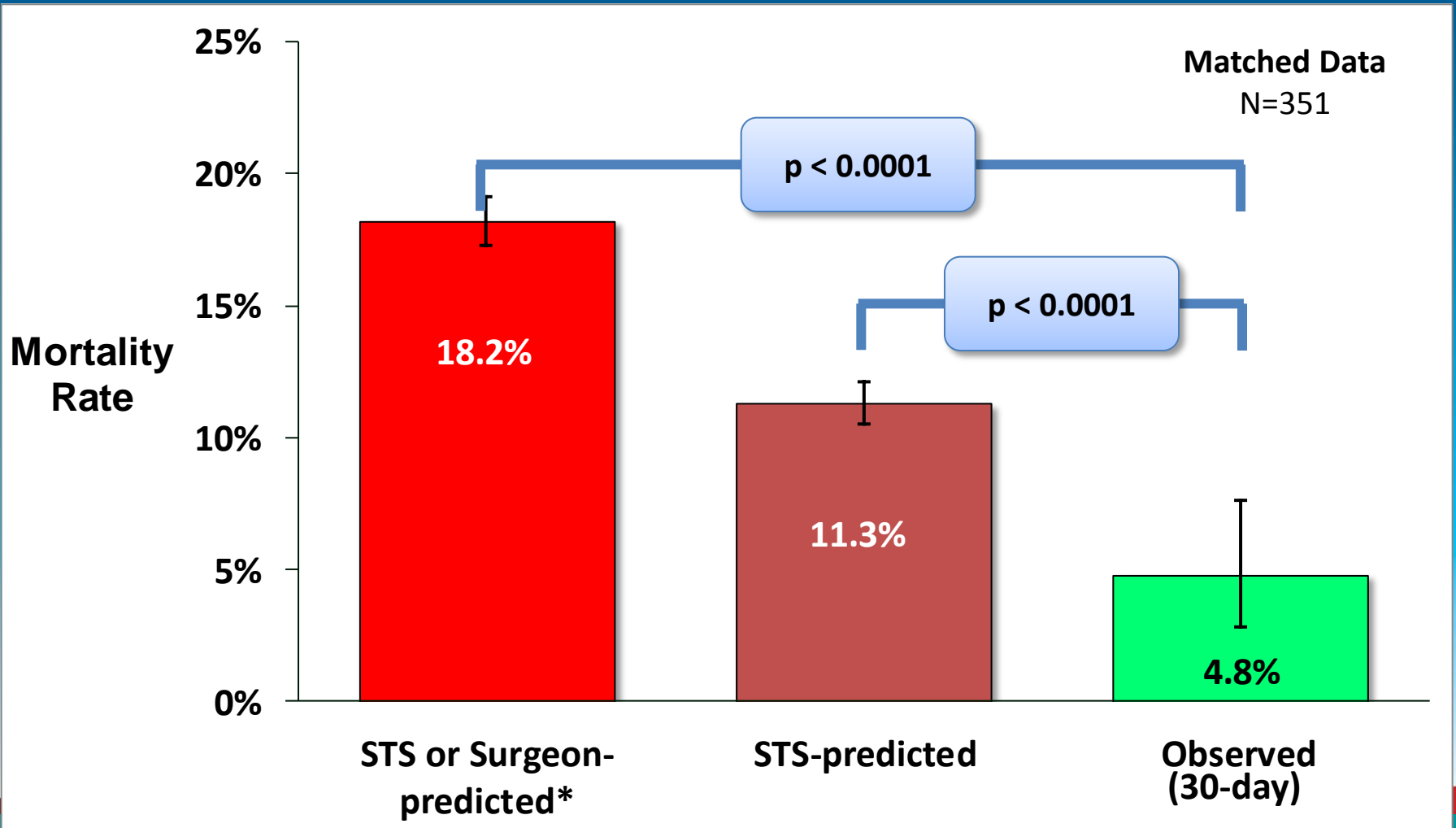
2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012

One



High Risk Cohort

30 Day Mortality



*Protocol-specified

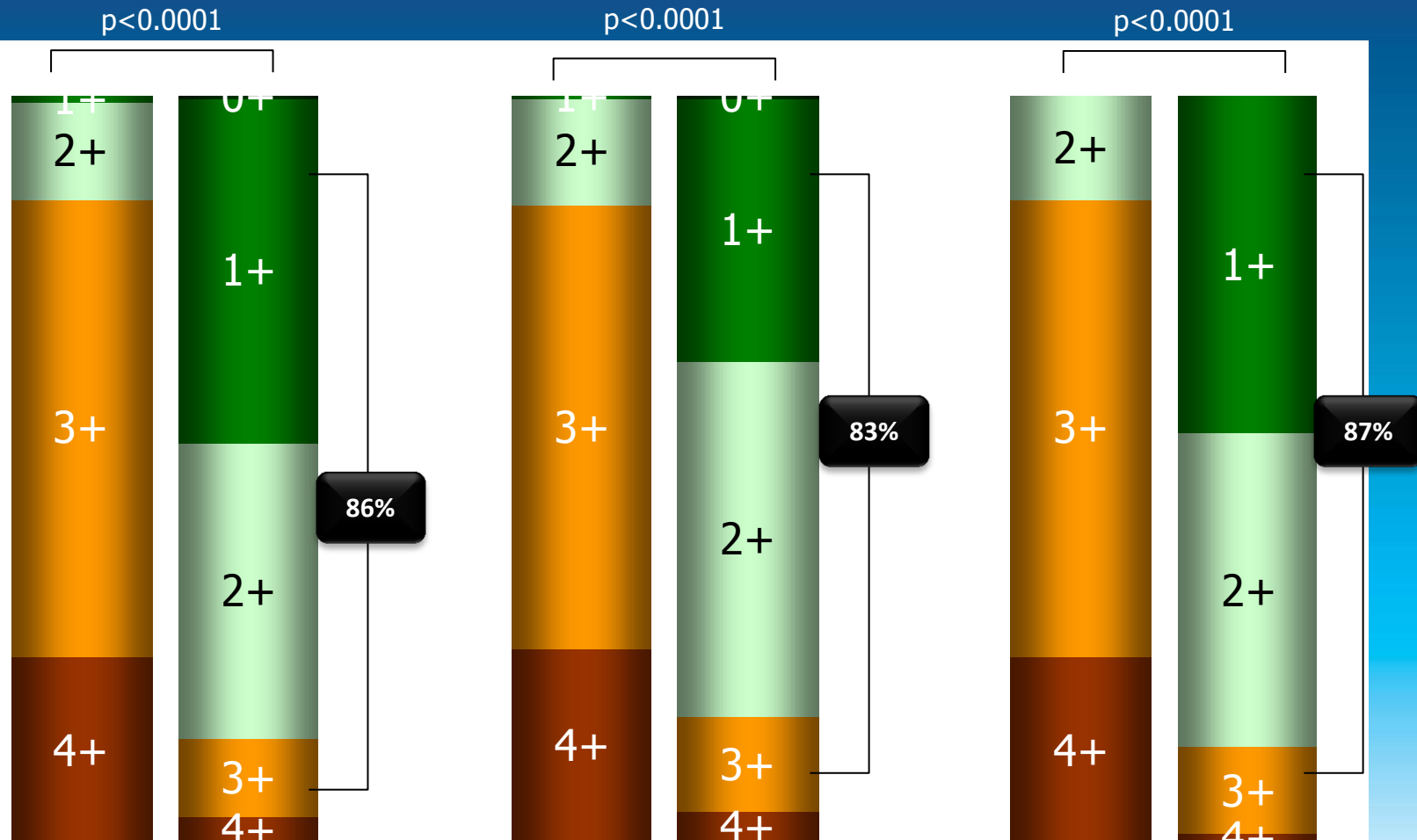
Source: EVEREST II High Risk Cohort



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High Risk Cohort

MR Grade



Paired data (N=325)

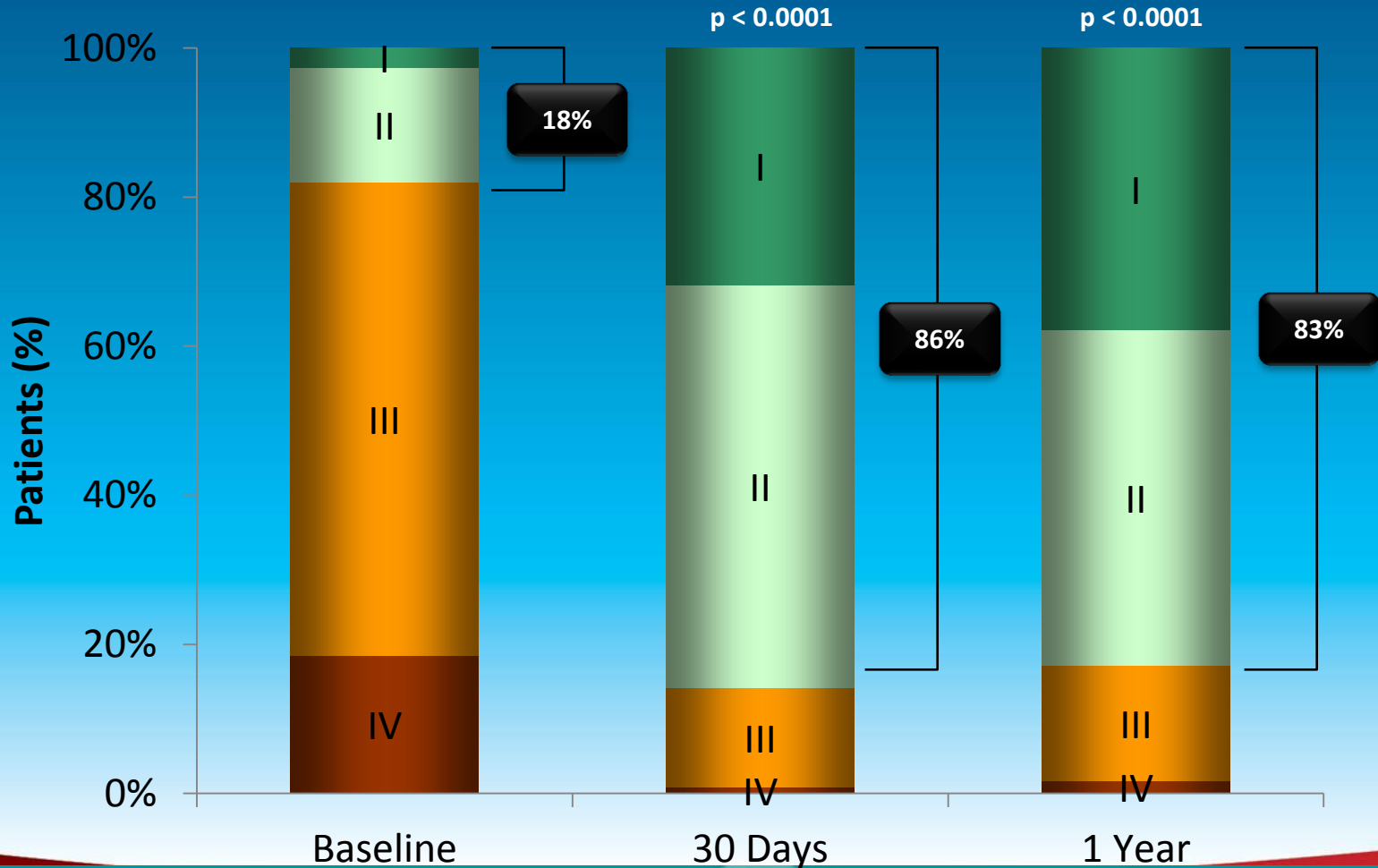
Paired data (N=221)



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Paired data (N=109)

High Risk Cohort

NYHA Functional Class



Paired data (N=233)



Carolina HealthCare System

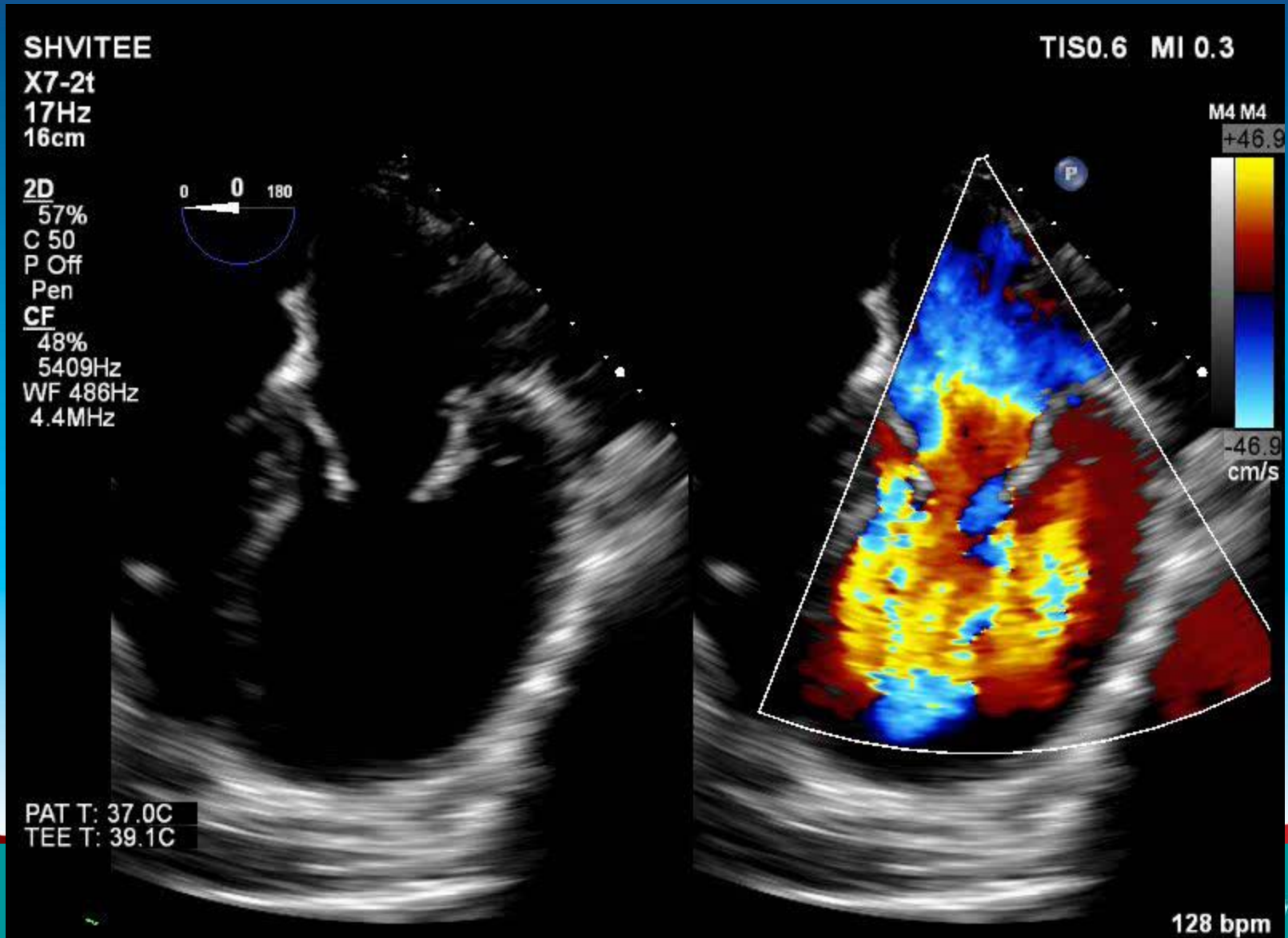
Case Example

- 45yo M with a month of progressive SOB and abdominal pain
- AF with RVR, elevated LFTs, INR 2, Cr 1.7
- TTE severe MR due to P2 flail with EF 35% and RV failure
- Cath CI 1.5, wedge 30 with V 45, PA systolic 64, coronaries patent
- IABP placed and transferred

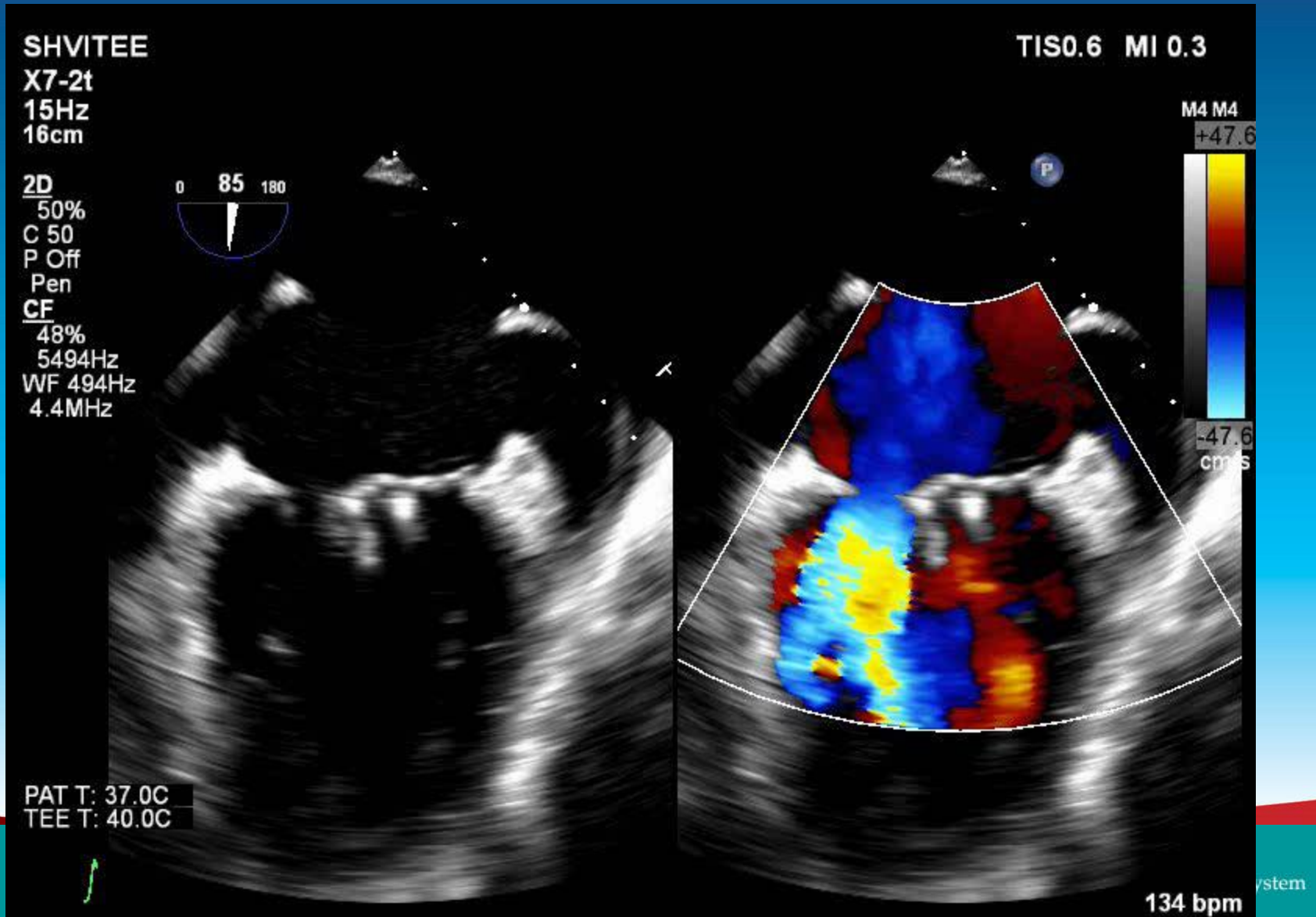
Sub-Acute MR with Shock

- Given severe RV failure and multi-organ failure his operative mortality was felt to be too high for conventional surgery
- **MitraClip for Sub-Acute MR with shock?**

Sub-Acute MR with Shock



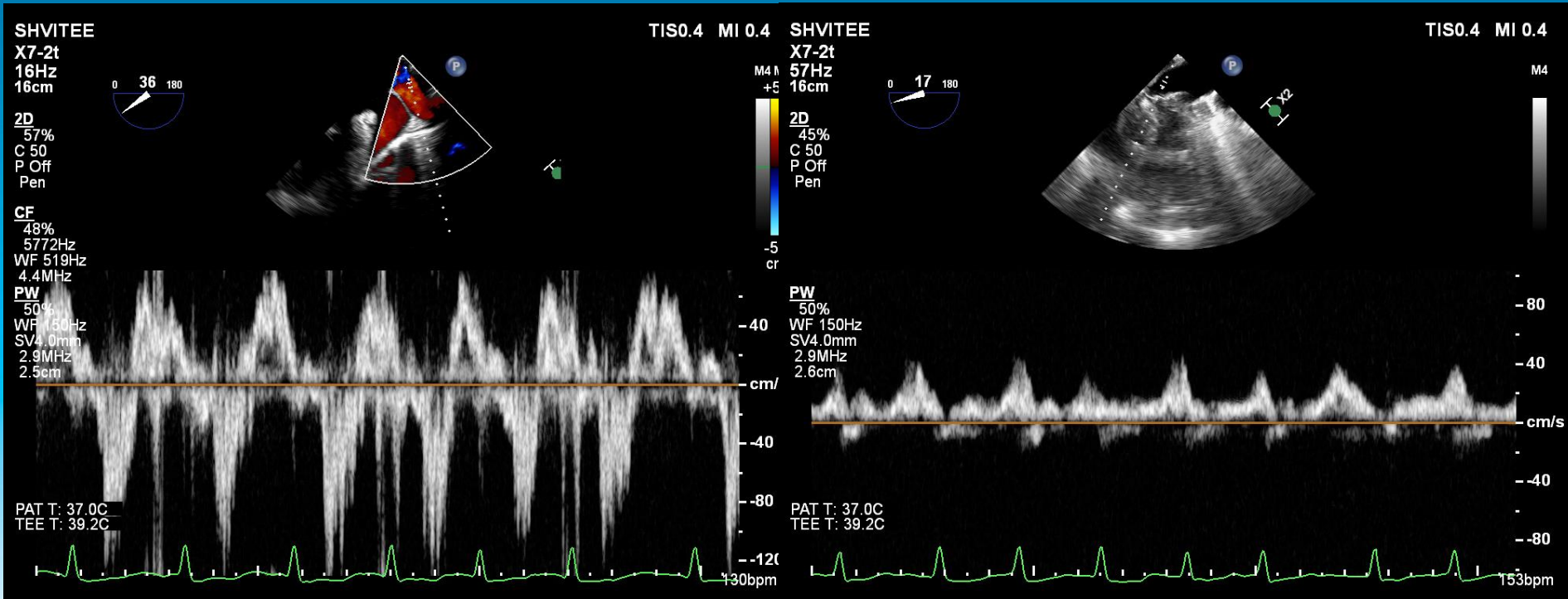
Mild MR after 2 Clips – IC view



PV flow reversal now eliminated

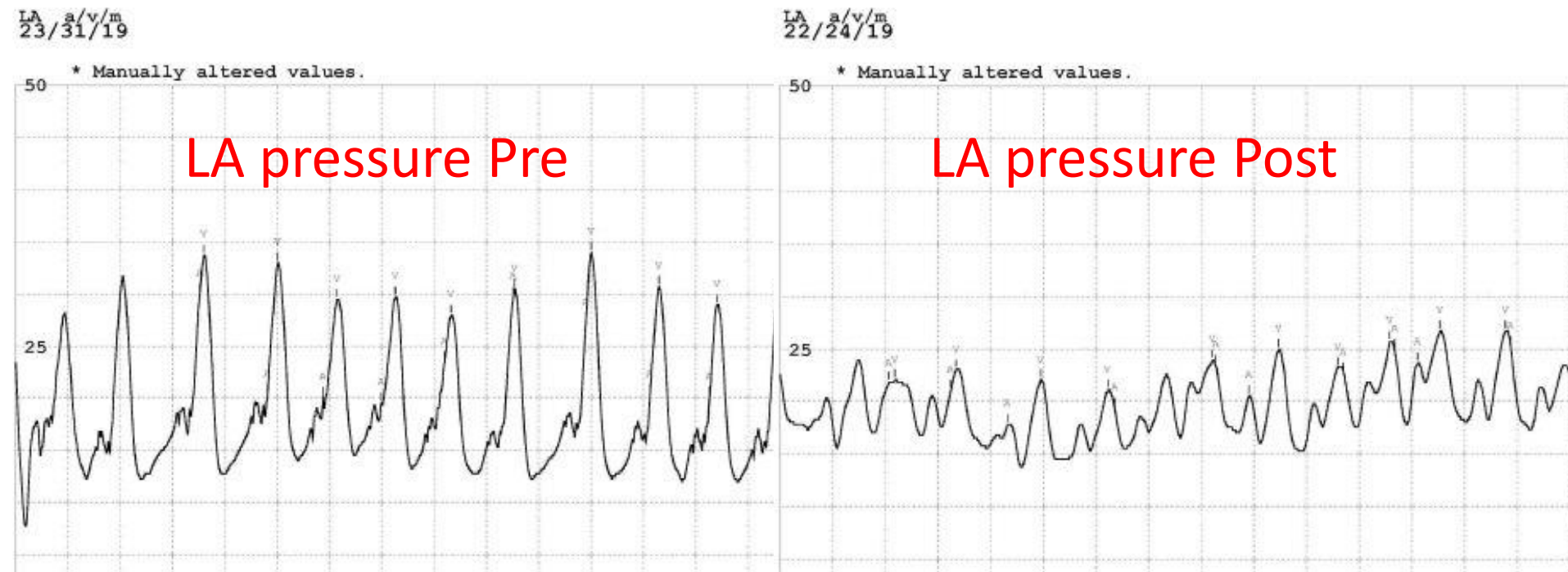
Pre-Clip

Post-Clip 2



Favorable Outcome

- CI increased from 1.7 to 2.9
- Eventually extubated and home



Conclusion

- MitraClip is the most effective and widely adopted therapy for high surgical risk patients
- Effective for degenerative and functional etiology
- For High Surgical Risk Patients MitraClip Therapy is the better option compared with Conventional Surgery or Medical Therapy alone
 - Majority of data is for Degenerative Etiology
 - For Functional Etiology it may be the treatment of choice for most patients

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Congress of Cardiology 2014



HỘI TIM MẠCH HỌC
VIỆT NAM