

# Significant Mitral Regurgitation (EF, LVEdD, PH or AF): **Five Challenges**

**Two Etiologies (Primary, Secondary),  
Three Approaches (Medical, Clipping, Surgical)**

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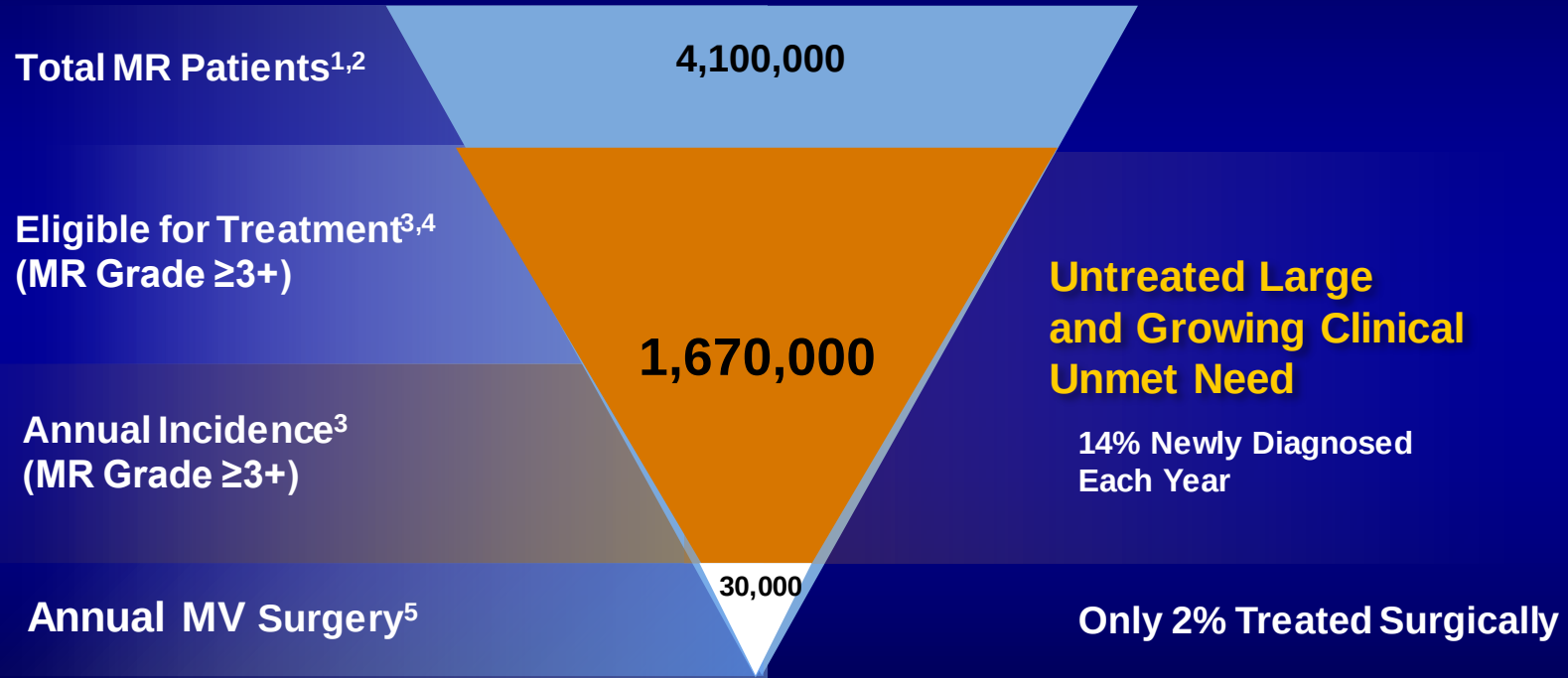
*COI: No relationship to disclose for this presentation*



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# A Largely Untreated Patient Population

## Mitral Regurgitation 2009 U.S. Prevalence



1. US Census Bureau. Statistical Abstract of the US: 2006, Table 12.

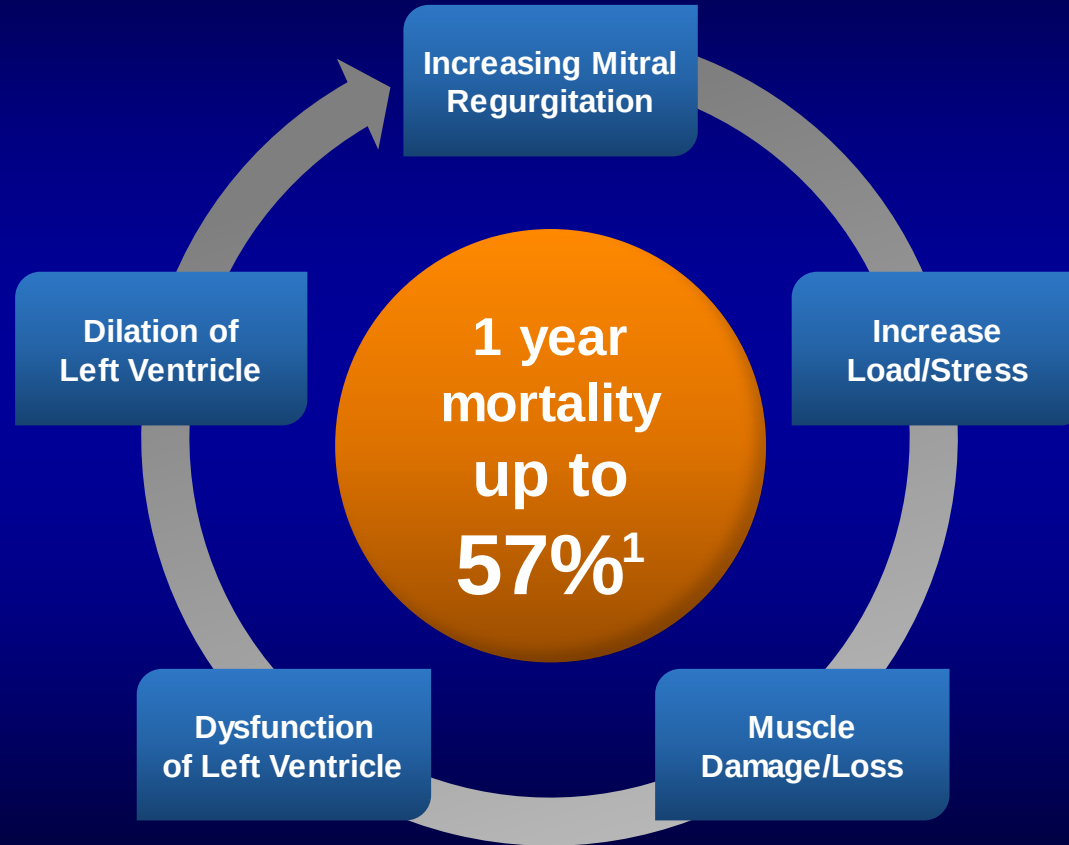
2. Nkomo et al., Burden of Valvular Heart Disease: A Population-based Study, Lancet, 2006; 368: 1005-11.

3. Patel et al. Mitral Regurgitation in Patients with Advanced Systolic Heart Failure, J of Cardiac Failure, 2004.

4. ACC/AHA 2008 Guidelines for the Management of Patients with Valvular Heart Disease, Circulation: 2008

5. Gammie, J et al, Trends in Mitral Valve Surgery in the United States: Results from the STS Adult Cardiac Database, Annals of Thoracic Surgery 2010.

# Untreated Severe MR is Associated with Increased Morbidity and Mortality

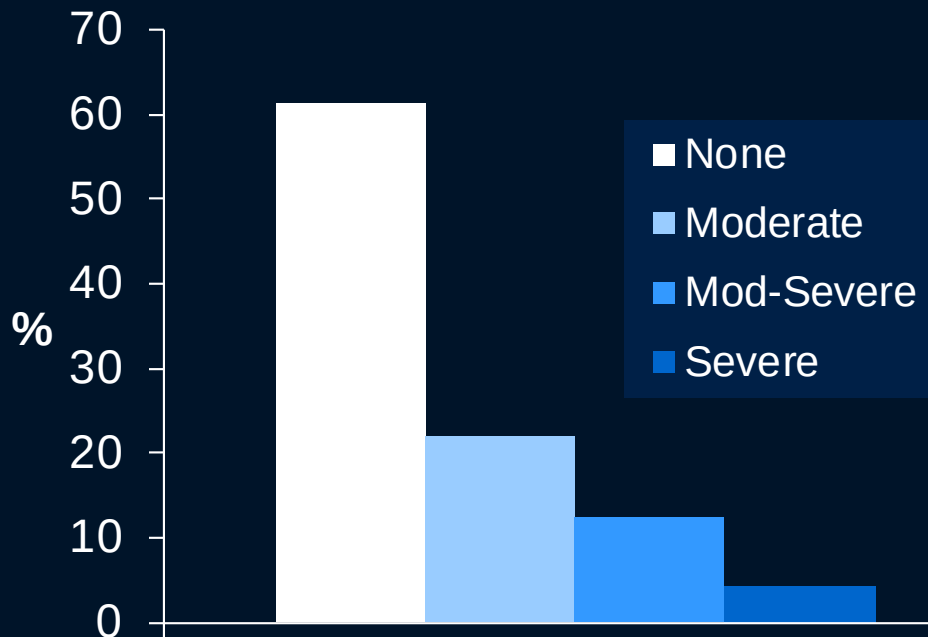


<sup>1</sup> Cioffi G, et al. Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. *European Journal of Heart Failure* 2005 Dec;7(7):1112-7

# MR and Heart Failure

## Prevalence in CHF

### Advanced Heart Failure



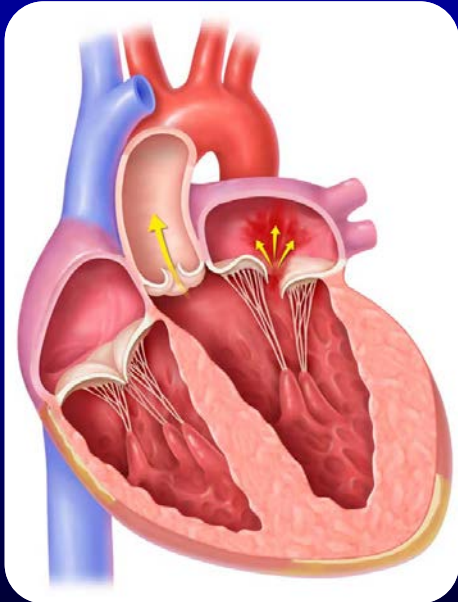
Moderate or  
severe MR  
present in  
**~40%**

**~5 million people with heart failure in U.S.**

# Classification of MR – 2 Types

**Incompetent mitral  
valve closure**

**Systolic retrograde blood flow  
from the LV into the LA**



**Primary:**  
Anatomic abnormality  
the mitral valve

- Leaflets
- Subvalvular apparatus
- Chordae and papillary muscles



**Secondary :**  
LV dilation; often  
secondary to ischemic  
heart disease

- Leads to mitral annular dilation
- Incomplete coaptation of the mitral valve

# Prognostic Determinants of Mitral Regurgitation (MR)

**Severity**

**Left Ventricular Function**

**Symptoms**

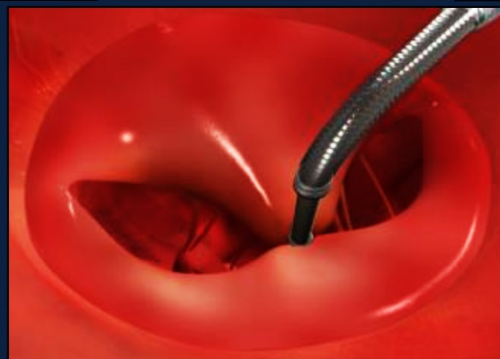
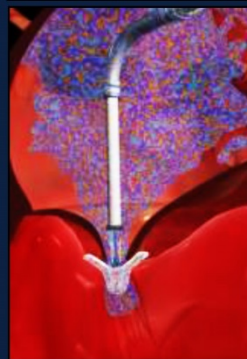
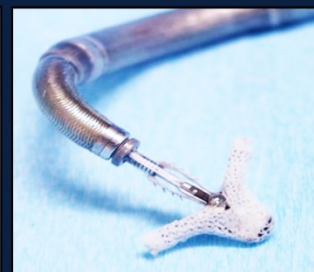
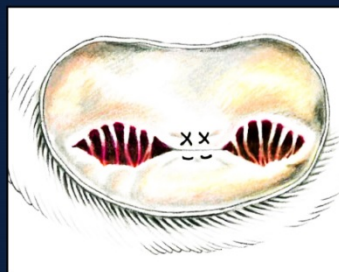
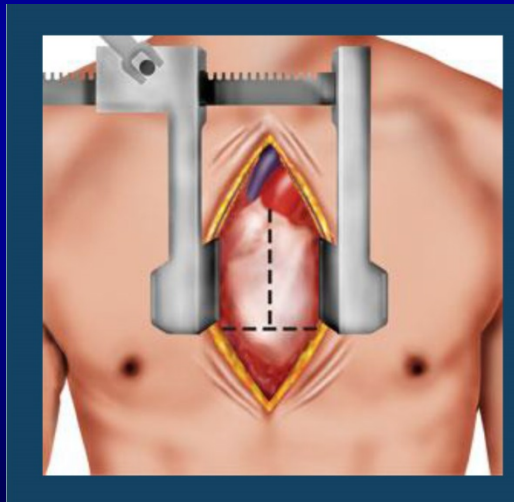
# EVEREST II Randomized Clinical Trial

## Surgical and Percutaneous Therapy for Mitral Regurgitation

Mitral Valve Surgery  
Repair/Replacement

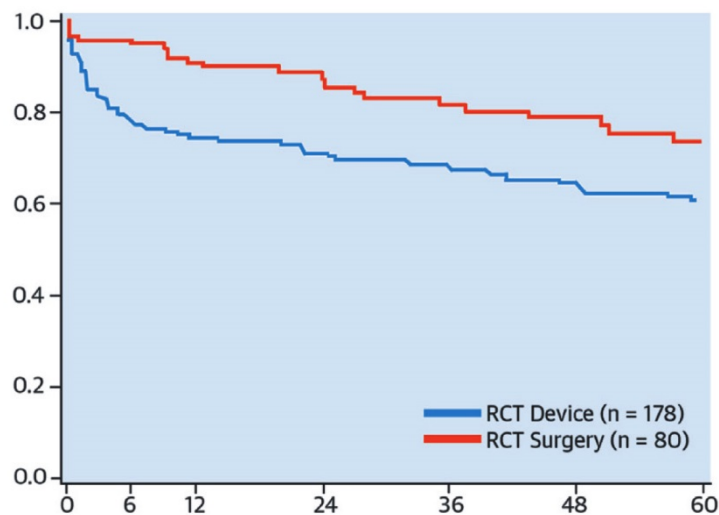
or

Catheter Based Mitral Valve Repair  
MitraClip System



# EVEREST II Trial: 5-Year Clinical Outcomes – Percutaneous Repair and Surgery for Mitral Regurgitation

## Freedom from Death, MV Surgery or Reoperation

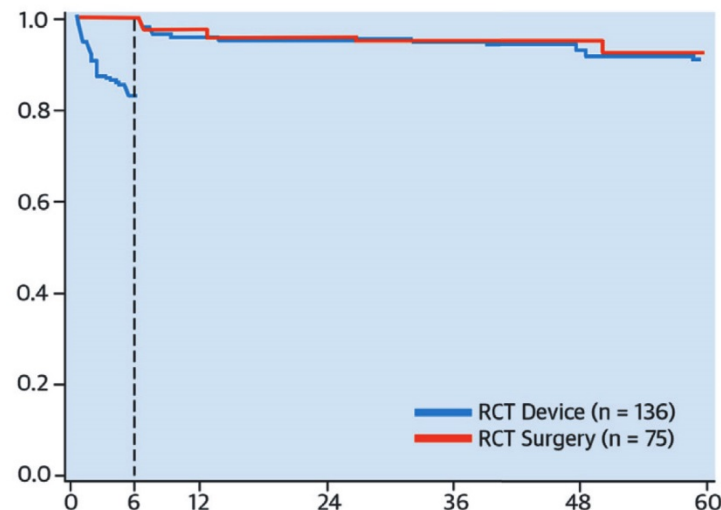


Patients At Risk

Months

|               |     |     |     |     |     |    |    |
|---------------|-----|-----|-----|-----|-----|----|----|
| Device Group  | 178 | 136 | 128 | 117 | 109 | 98 | 45 |
| Control Group | 80  | 75  | 69  | 63  | 54  | 49 | 21 |

## Landmark Analysis of Freedom from Death, MV Surgery or Reoperation Beyond 6 Months



Patients At Risk

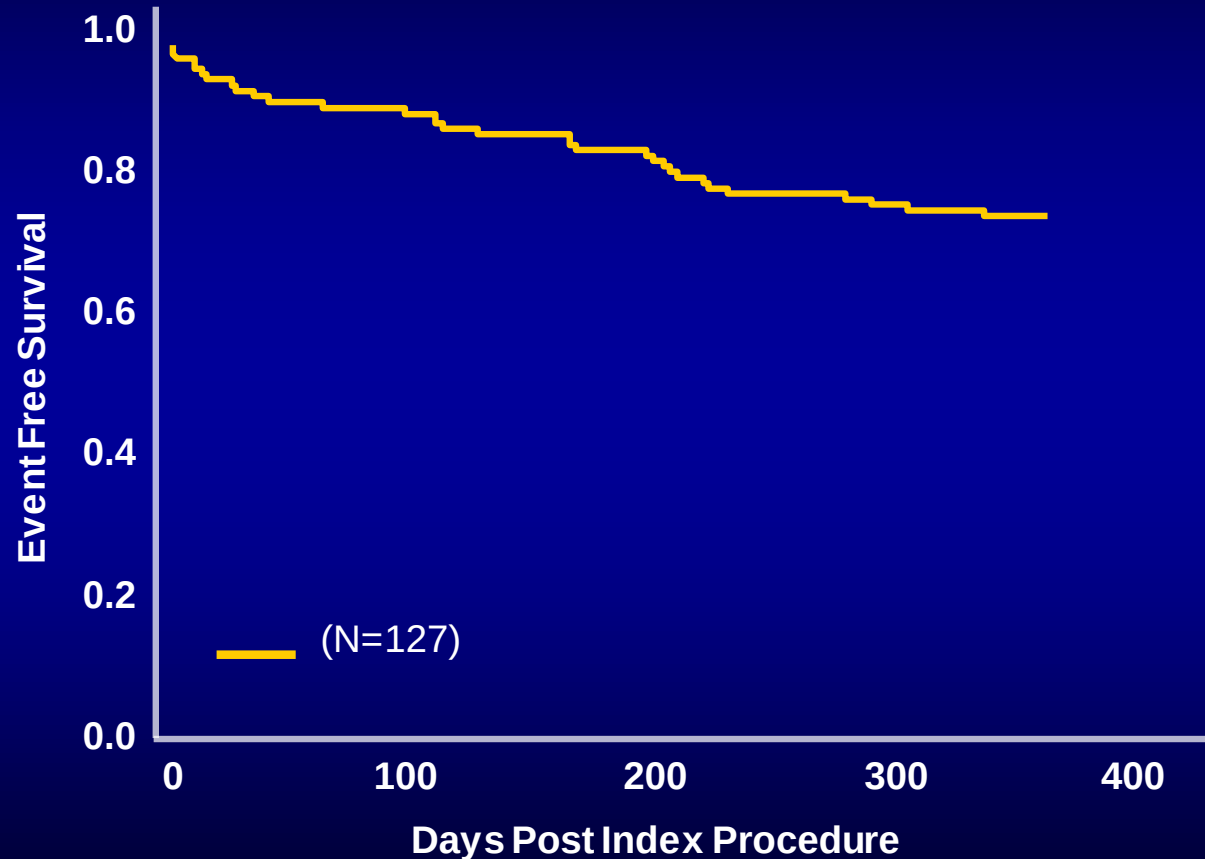
Months

|               |     |     |     |     |     |    |    |
|---------------|-----|-----|-----|-----|-----|----|----|
| Device Group  | 178 | 136 | 128 | 117 | 109 | 98 | 45 |
| Control Group | 80  | 75  | 69  | 63  | 54  | 49 | 21 |



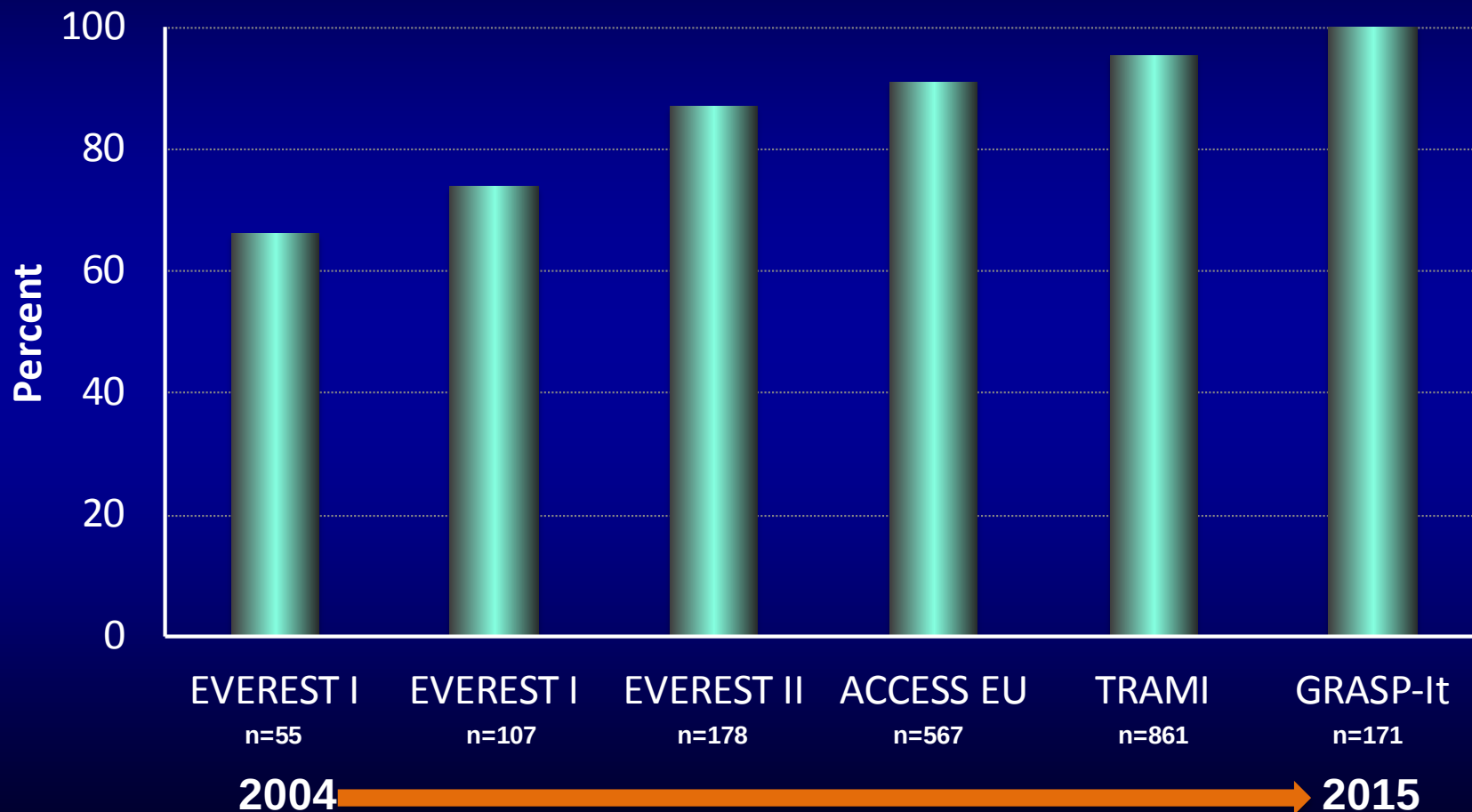
# Prohibitive Surgical Risk DMR Cohort (n=127)

- 95% implant success
- No procedural deaths
- LOS = 2.9 days



# Acute Procedure Success Rate

*MitraClip(s) implanted & MR  $\leq 2+$*



# Worldwide Experience Using the MitraClip

| Study                       | Population                                   | N                             |
|-----------------------------|----------------------------------------------|-------------------------------|
| EVEREST I (Feasibility)     | Feasibility patients                         | 55                            |
| EVEREST II (Pivotal)        | Pre-randomized patients                      | 60                            |
| EVEREST II (Pivotal)        | Non-randomized patients<br>(High Risk Study) | 78                            |
| EVEREST II (Pivotal)        | Randomized patients<br>(2:1 Clip Surgery)    | 279<br>184 Clip<br>95 Surgery |
| REALISM (Continued Access)  | Non-randomized patients                      | 899                           |
| Compassionate/Emergency Use | Non-randomized patients                      | 66                            |
| ACCESS Europe Phase I       | Non-randomized patients                      | 567                           |
| ACCESS Europe Phase II      | Non-randomized patients                      | 286                           |
| Commercial Use              | Commercial patients                          | >40,000                       |
| <b>TOTAL</b>                |                                              | <b>&gt;45,000</b>             |

# Clinical Outcomes at 1-year after Commercial Transcatheter Mitral Valve Repair in the United States

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Paul Sorajja, MD, Sreekanth Vemulapalli MD, Ted Feldman, MD, Michael Mack, MD,  
David R. Holmes, Jr. MD, Amanda Stebbins, MS, Saibal Kar, MD, Vinod Thourani, MD,  
and Gorav Ailawadi, MD

ACC – Washington, DC, USA – March 18, 2017\*

\* This slide deck has been modified from that presented to include the following required information: *Indications for Use, Safety Information*, and an internal Abbott document number for identification. In addition, the coding appendix (in German) has been deleted.

STS/ACC TVT Registry™

Important Safety Information  
referenced within



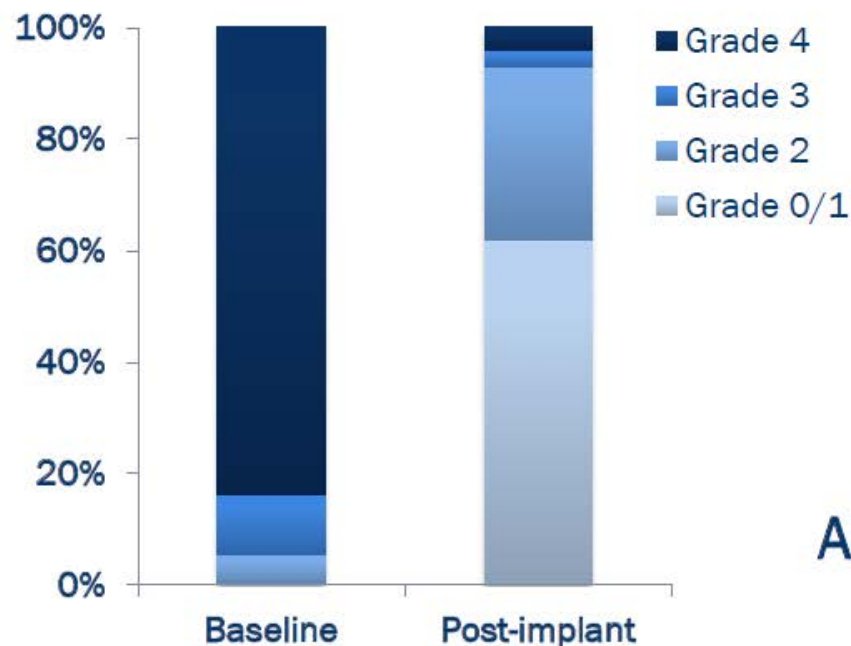
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# Acute Procedural Results



92.8% with post-procedural MR  $\leq 2$

SLDA, 1.5%

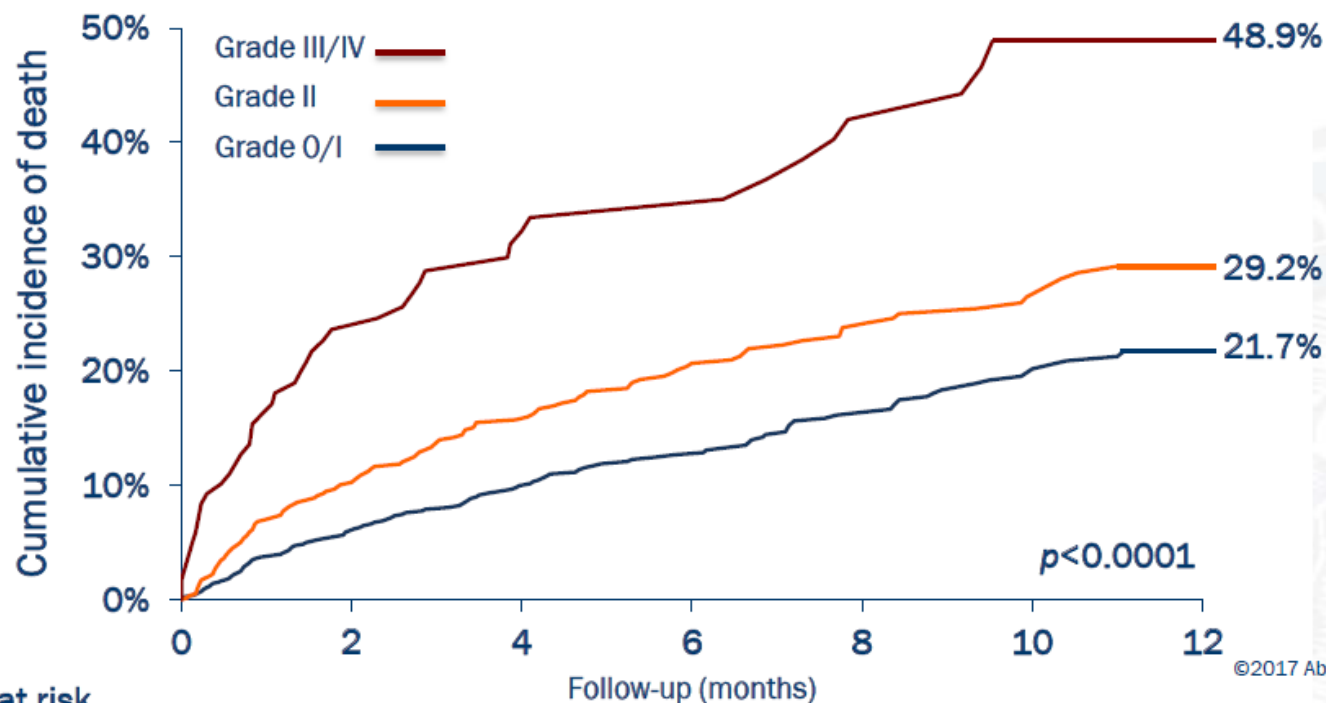
In-hospital mortality = 2.7%

85.9% discharged home

Median LOS, 2 days (1, 5 days)

**Acute procedure success = 91.8%**

# Post-Procedural MR and Survival



No. at risk

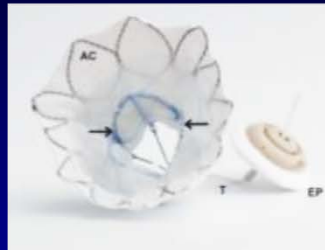
|        |      |     |     |     |     |
|--------|------|-----|-----|-----|-----|
| III/IV | 114  | 65  | 47  | 25  | 17  |
| II     | 591  | 408 | 278 | 168 | 104 |
| 0/I    | 1146 | 810 | 559 | 373 | 213 |

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**Tendyne**



**Intrepid Twelve**



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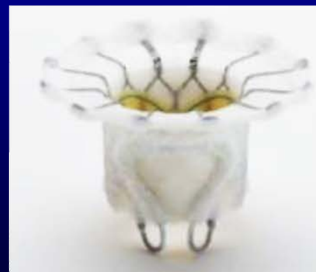


## Mitral Valve Replacement Devices Active Clinical Programs

**CardiAQ**



**FORTIS**



**Highlife**



# Conclusion

- **MitraClip results in clinically significant MR reduction** in a majority of patients. TEE is essential for procedural optimization
- **MitraClip is safer than surgery** with shorter time to recovery but is less effective than surgery for MR ↓
- **MitraClip results in similar patient centered outcomes** to surgery including improvement in HF class and QOL and reduction in readmission
- **Therefore MitraClip is ideally suited for poor surgical candidates with appropriate anatomy**



## Conclusion Contd.

- **MitraClip therapy is now FDA approved** for symptomatic patients with severe MR of degenerative etiology who are poor surgical candidates.
- For patients with **symptomatic functional MR** MitraClip will be available when COAPT trial results will be presented.
- TMVR devices for native MV disease have potential but are a long way off
- **TMVR using Sapien valve has recently been approved by FDA for use in Bio-prosthetic Mitral valve degeneration**



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