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

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The views expressed in this presentation represent those of the authors, and do not necessarily represent the official views of these organizations. Learn more about the STS/ACC TVT Registry at *www.tvtregistry.org.*

The number of MitraClip procedures in this study may not reflect all such procedures performed during the study period. These data were obtained from hospitals who participated in the TVT Registry during the study period. It is possible that cases were performed at non-participating hospitals or that certain patients cases were excluded due to missing or incomplete information.

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Disclosures

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Transcatheter Mitral Valve Repair
MitraClip™

24 Fr, transseptal system for leaflet apposition and reduction in MR

>40,000 patients worldwide

Approval in U.S. in October 2013 with 250 current sites

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Study Objective

To examine the acute, 30-day, and one-year clinical outcomes of commercial transcatheter mitral valve repair with MitraClip in the U.S.

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Methods

- Enrolled all commercial patients from the STS/ACC TVT registry through September 2015
- Linked patient records to CMS claims data for 30-day and one-year outcomes

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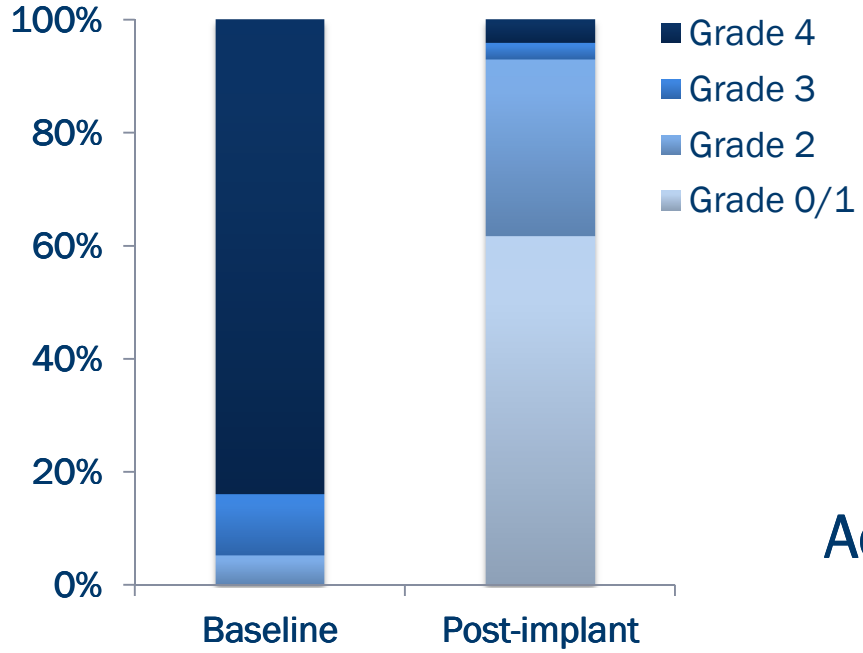
Data Analysis

- Patient characteristics, procedural, and in-hospital events sourced from TVT registry (n=2,952)
  - Acute procedural success defined as post-procedural MR ≤2, without surgery or death
- 30-day and 1-year events from linked CMS claims data (n=1,867 or 63%)
  - Examined death, MV surgery, and re-hospitalization for heart failure

Patients

- Median age..... 82 yrs (74, 86 yrs)
- Male gender..... 55.8%
- NYHA III or IV..... 85.0%
- Grade 3 or 4 MR..... 93.0%
- Degenerative MR only..... 85.9%
- Functional MR only..... 8.6%
- DMR and FMR..... 8.9%
- Frailty..... 50.3%
- STS-PROM (MV repair)..... 6.1% (3.7%, 9.9%)
- STS-PROM (MV replacement)..... 9.2% (6.0%, 14.1%)

Acute Procedural Results



92.8% with post-procedural MR ≤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%

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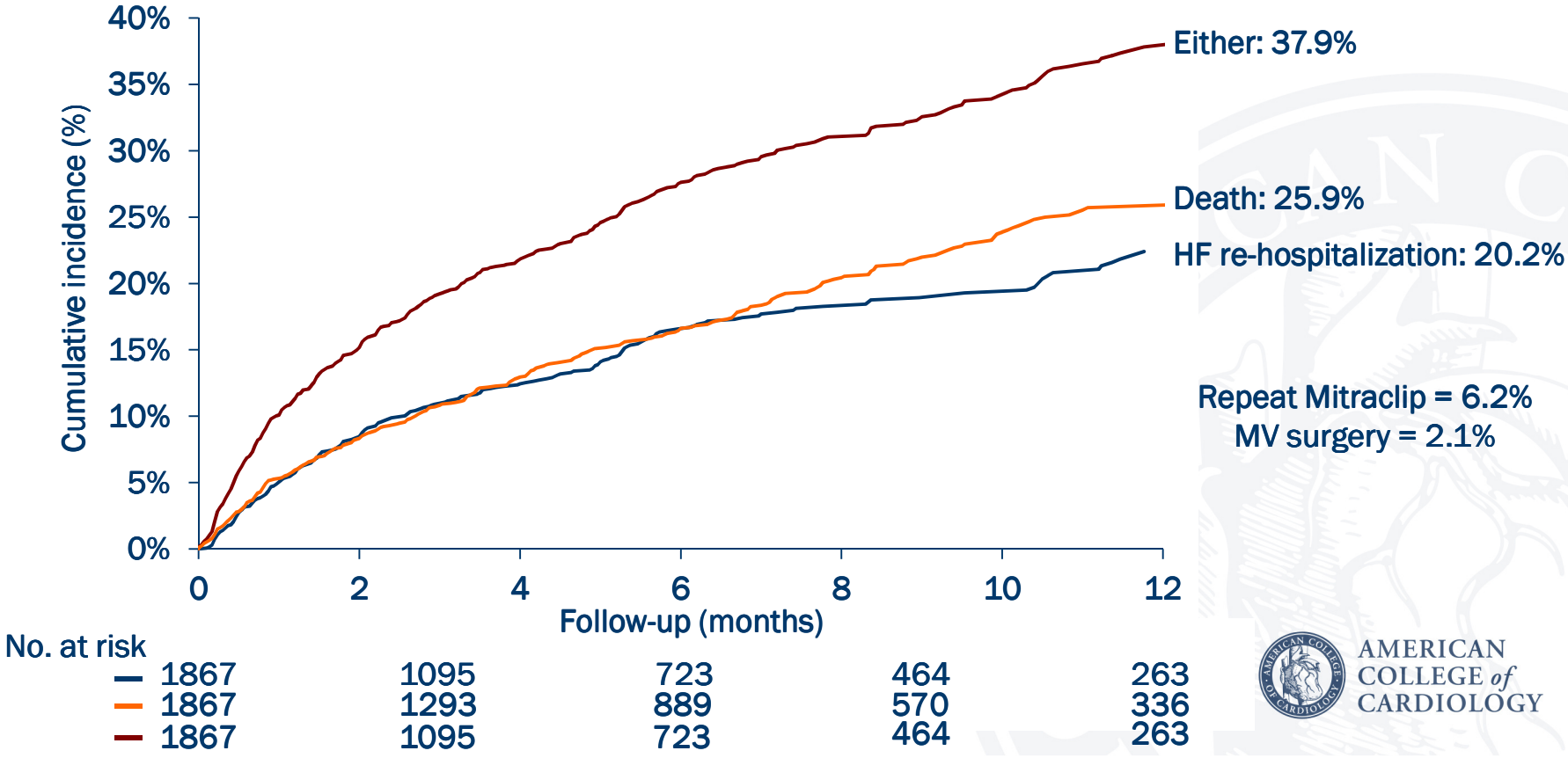
Clinical Outcomes at One-Year



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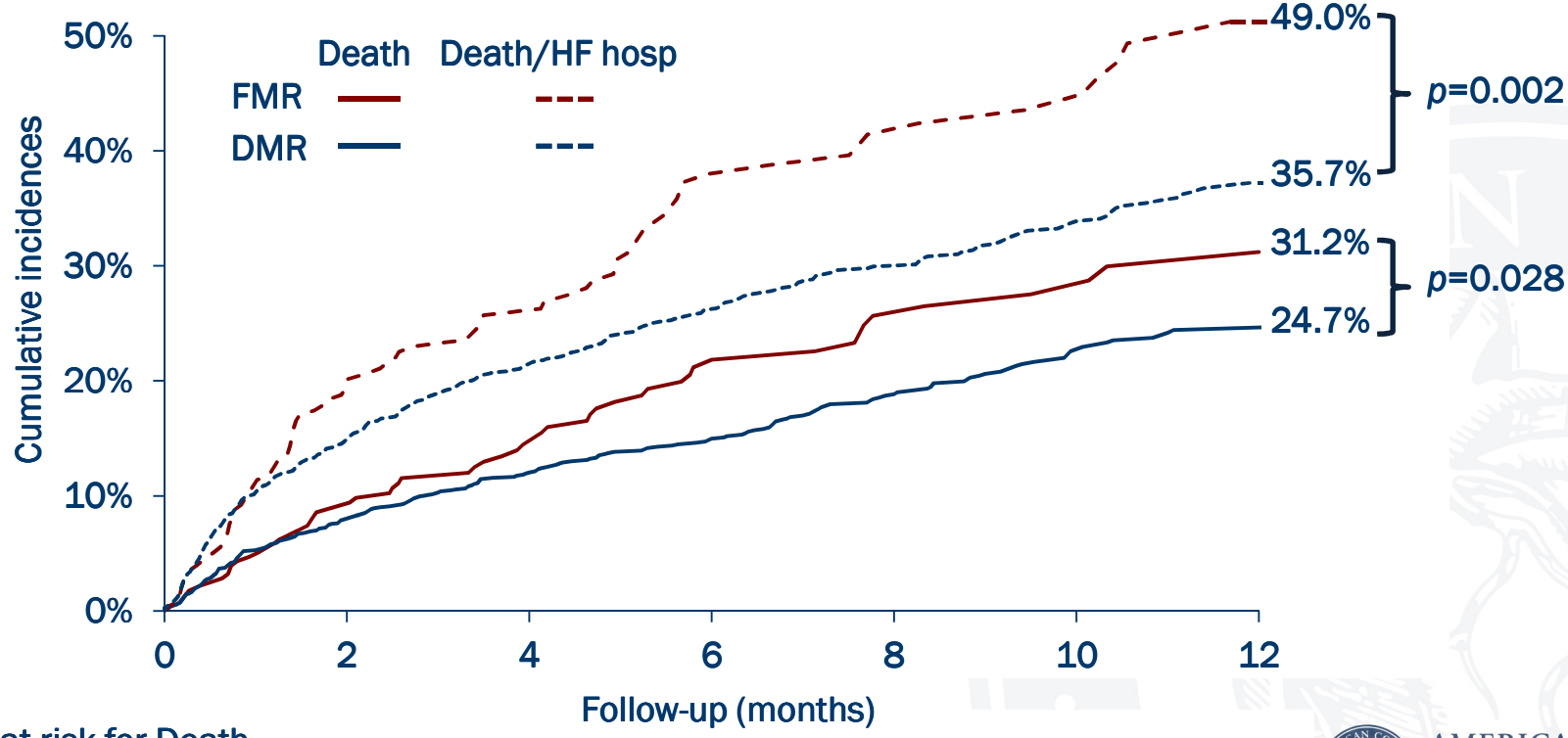
Etiology of MR and Outcome



No. at risk for Death

FMR	297	196	123	73	40
DMR	1485	1024	726	472	287

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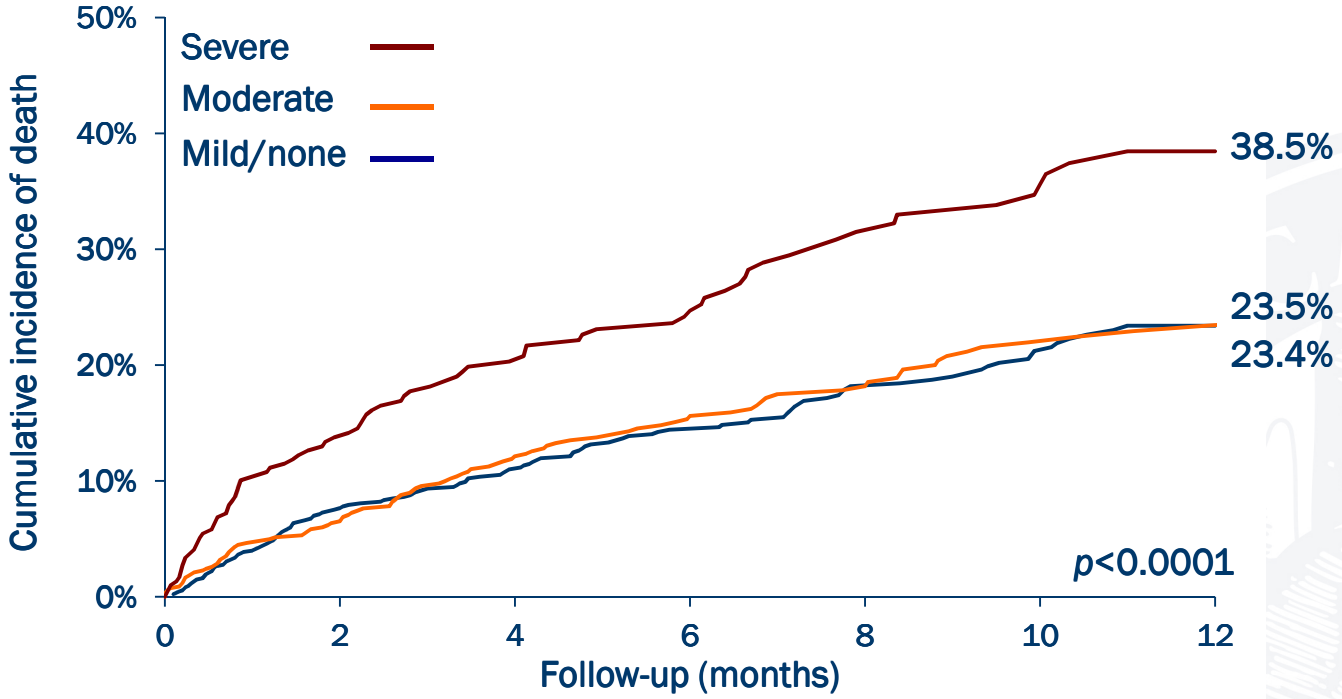
Impact of Tricuspid Regurgitation



No. at risk

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

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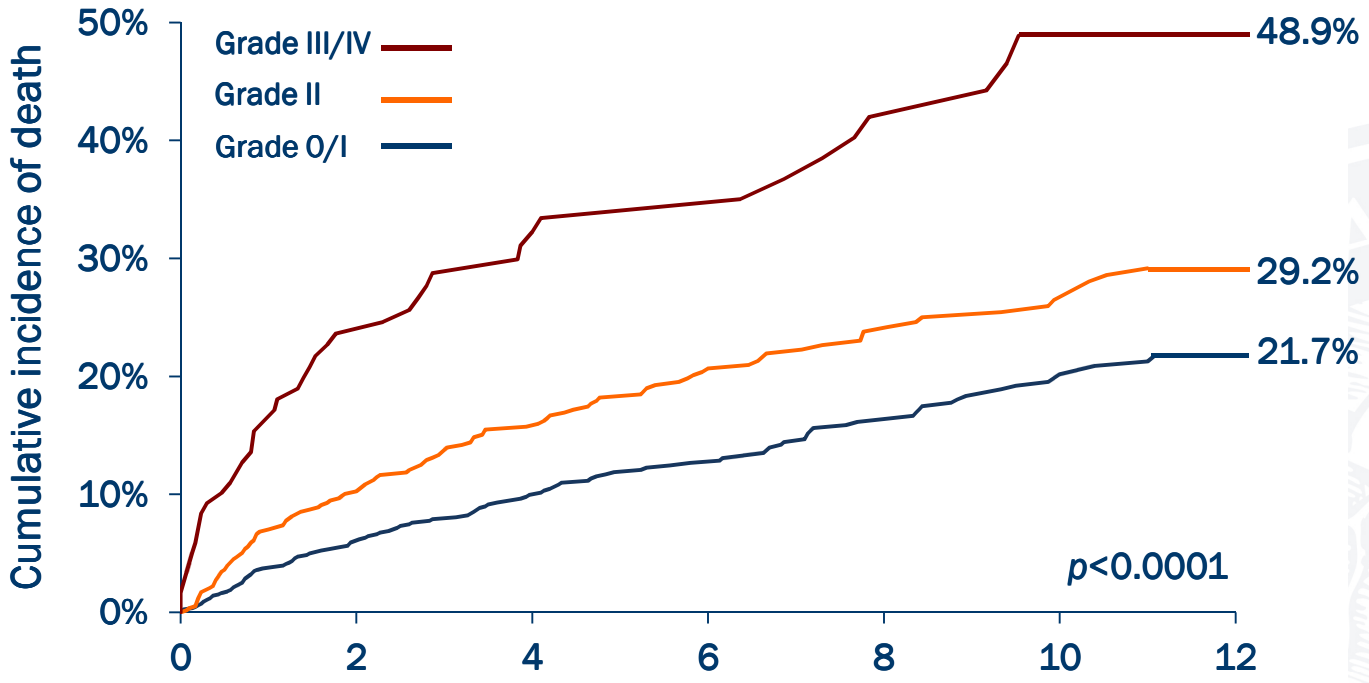
Post-Procedural MR and Survival



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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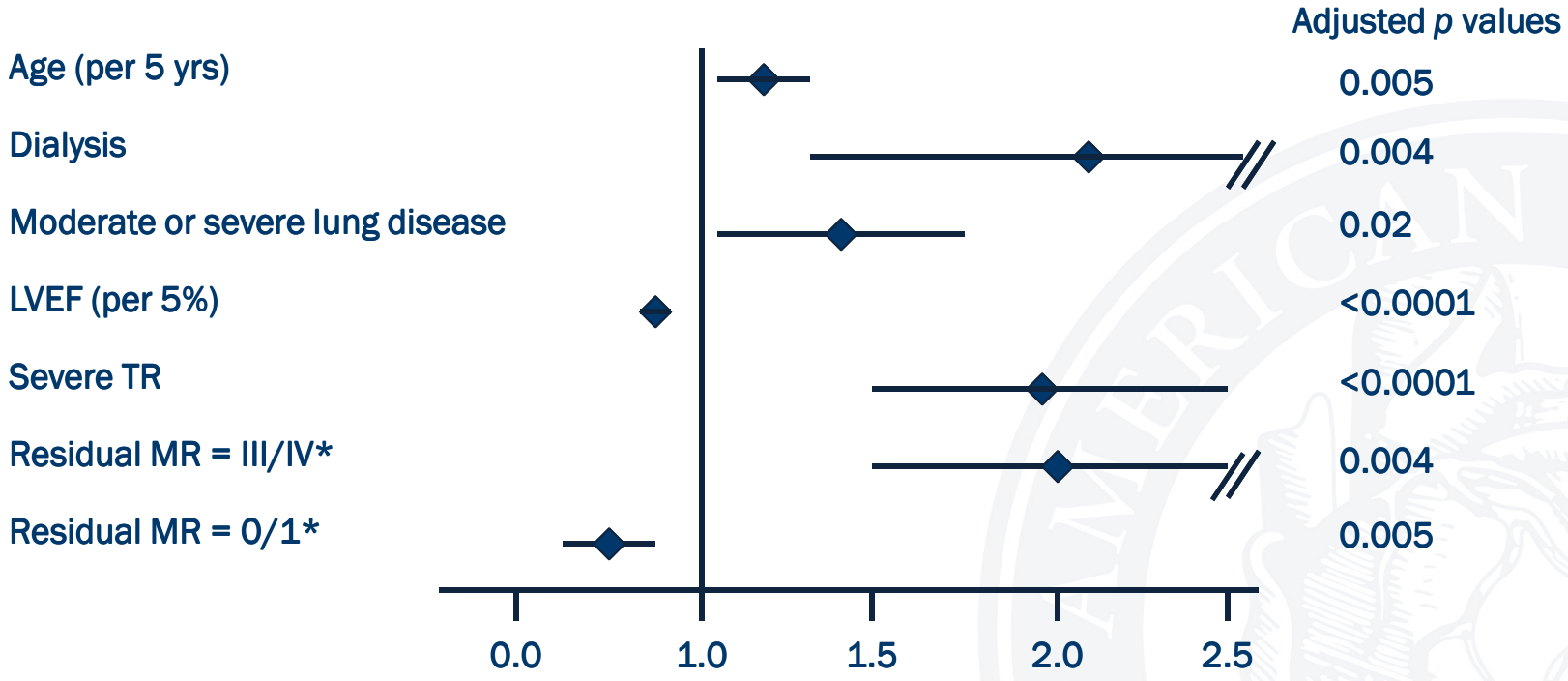
Multivariate Models for 1-yr Mortality



**vs. residual MR grade = 2*

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Data Summary

- Acute procedural success in 92.8%, including in-hospital mortality of 2.7%
- At 1-year, mortality = 25.9%, HF re-hospitalization = 20.2%; either = 37.9%
- The one-year outcomes varied according to baseline characteristics and procedural results
- Significant co-variates in models for one-year outcomes were age, dialysis, moderate-severe lung disease, LVEF, severe TR, and residual MR

Comparative Studies

	Age (yrs)	DMR	Acute success	1-yr Mortality	1-yr HF hosp.
• STS/ACC TVT	82	85.9%	92.8%	25.9%	20.2%
• SENTINEL	74	28.0%	95.4%	15.3%	22.8%
• ACCESS-EU	74	20.6%	91.7%	19.2%	19.8%
• EVEREST II HRS	76	29.9%	86.0%	22.8%	
• EVEREST PR	82	100%	95.3%	23.6%	18.0%

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Conclusions

- Our study demonstrates the acute effectiveness and safety of transcatheter MV repair in the U.S.
- A subset of these high-risk patients have mortality or heart-failure re-hospitalization by one year
- Certain clinical variables (age, LVEF, severe TR, lung disease, dialysis) and the degree of MR reduction are significant predictors of these long-term clinical outcomes.

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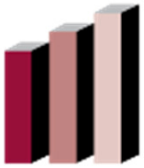

STS National Database™

Using data to drive quality

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