

Safety and Efficacy of Transcatheter Edge-to-Edge Repair in Degenerative Mitral Regurgitation

An Analysis from the STS/ACC TVT Registry

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Disclosure statement

- Grant/research support and consulting fee from Edwards Lifesciences, Medtronic, Abbott and Boston Scientific
- The views expressed in this presentation represent those of the author(s) and do not necessarily represent the official views of the NCDR or its associated professional societies.

Background and Objective

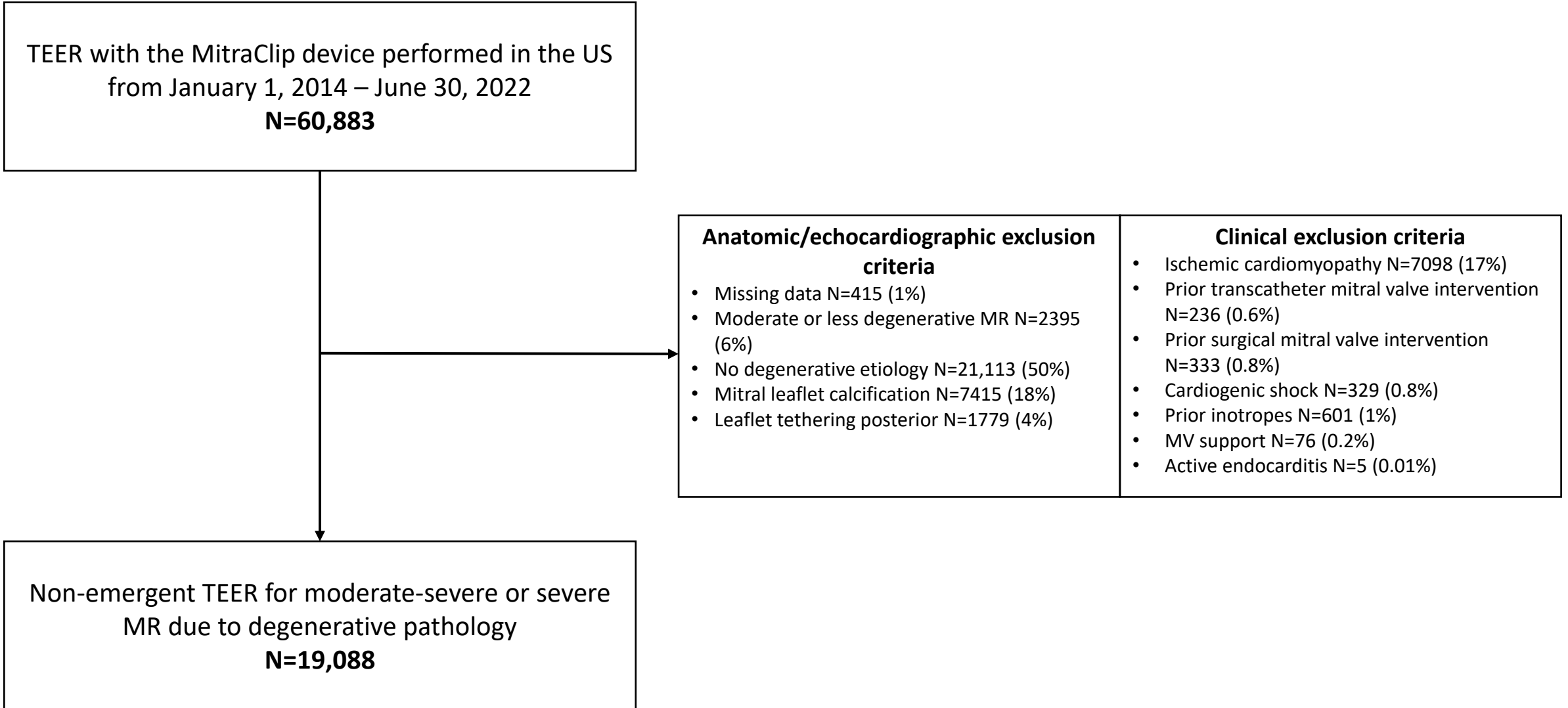
- Transcatheter mitral-valve edge-to-edge repair (TEER) is currently FDA approved for degenerative mitral regurgitation (MR) in high surgical-risk patients.
- The contemporary outcomes of TEER in degenerative MR in the real-world setting are unknown.
- We sought to evaluate the trends, procedural, and clinical outcomes of TEER for degenerative MR in the real-world STS/ACC TVT registry.

Study Population

The STS/ACC TVT registry is a national database of all consecutive patients undergoing commercial transcatheter mitral-valve repair in the United States.

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Study Design and Participants

- Clinical data on etiology and severity of MR were site-reported*.
- Degenerative MR was defined as *“MR secondary to abnormal leaflets and/or chordae. The leaflets may prolapse or flail into the left atrium”*.
- The severity of MR was graded as none/trace, mild (1+), moderate (2+), moderate-severe (3+) and severe (4+).
- All statistical analyses were conducted at the Duke Clinical Research Institute.

* Data were entered in the registry according to the standardized definitions included in the TVT Registry data dictionary and according to American Society of Echocardiography guidelines

Outcomes

- **Primary end-point:**

- MR success, defined as post-repair residual MR \leq moderate and absence of severe stenosis (mean mitral gradient <10 mmHg)

- **Secondary end-points:**

- In-hospital, 30-day and 1-year clinical outcomes including death, heart failure readmission, and mitral valve reintervention
- Death and heart failure readmission, based on residual MR and mitral valve gradients

Baseline Characteristics

	Overall
	N=19,088
Age, median (IQR)	82 (76 - 86)
Female	9295 (49.0%)
STS score, median (IQR)	4.57% (2.8% - 7.4%)
Prior PCI	4506 (23.6%)
Prior CABG	3155 (16.6%)
Prior aortic valve procedure	1693 (8.9%)
Stroke	1875 (9.8%)
TIA	1267 (6.6%)
PAD	2596 (13.6%)
Current/recent smoker	904 (4.8%)
Hypertension	16183 (84.8%)
Diabetes mellitus	3934 (20.6%)

	Overall
	N=19088
Hemodialysis	470 (2.5%)
Chronic lung disease	6042 (31.9%)
Home oxygen	1963 (10.3%)
Prior MI	2828 (14.8%)
Heart failure within 2 weeks	14238 (77.0%)
Carotid stenosis	1659 (12.5%)
Atrial fibrillation/flutter	11460 (60.1%)
CAD	8483 (47.0%)
Number of diseased vessels	
1 Vessel	2875 (17.5%)
2 Vessels	1892 (11.5%)
3 Vessels	2619 (15.9%)

Baseline Echo

	Overall
	N=19,088
LVEF	58 (53 - 63)
LVISD	3.30 (2.9 - 3.9)
LVIDD	5.00 (4.4 - 5.5)
MR severity	
Moderate to severe	3391 (17.8%)
Severe	15697 (82.2%)
Mitral stenosis	805 (4.3%)
MV area	4.00 (2.8 - 5.0)
MV mean gradient	2.00 (2.0 - 4.0)

	Overall
Mitral valve anatomy	N=19,088
Leaflet prolapse	11754 (80.2%)
Leaflet prolapse location	
Anterior	2421 (16.5%)
Posterior	6740 (46.0%)
Bi-leaflet	2593 (17.7%)
Flail leaflet	7703 (62.7%)
Leaflet flail location	
Anterior	1365 (11.1%)
Posterior	6062 (49.3%)
Bi-leaflet	276 (2.3%)

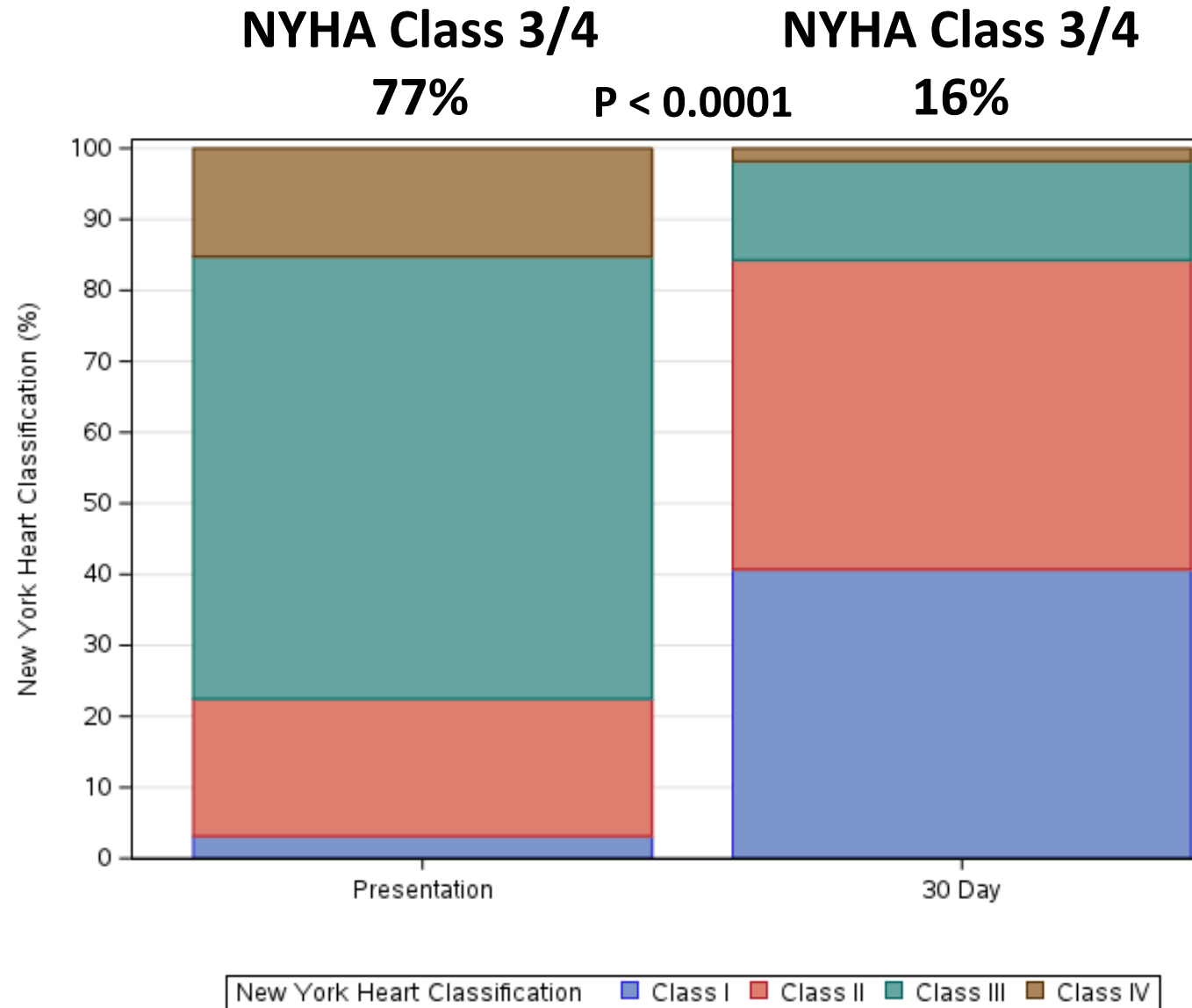
In-hospital outcomes

Variable	Overall
	N=19,088
Death	207 (1.1%)
Death during the procedure	11 (0.06%)
Unplanned cardiac surgery or intervention	207 (1.1%)
Stroke	118 (0.62%)
Ischemic stroke	108 (0.57%)
Hemorrhagic stroke	11 (0.06%)
Transient ischemic attack	20 (0.1%)
Stroke or TIA	138 (0.72%)
New requirement for dialysis	65 (0.34%)
Cardiac arrest	115 (0.6%)

30-day Outcomes

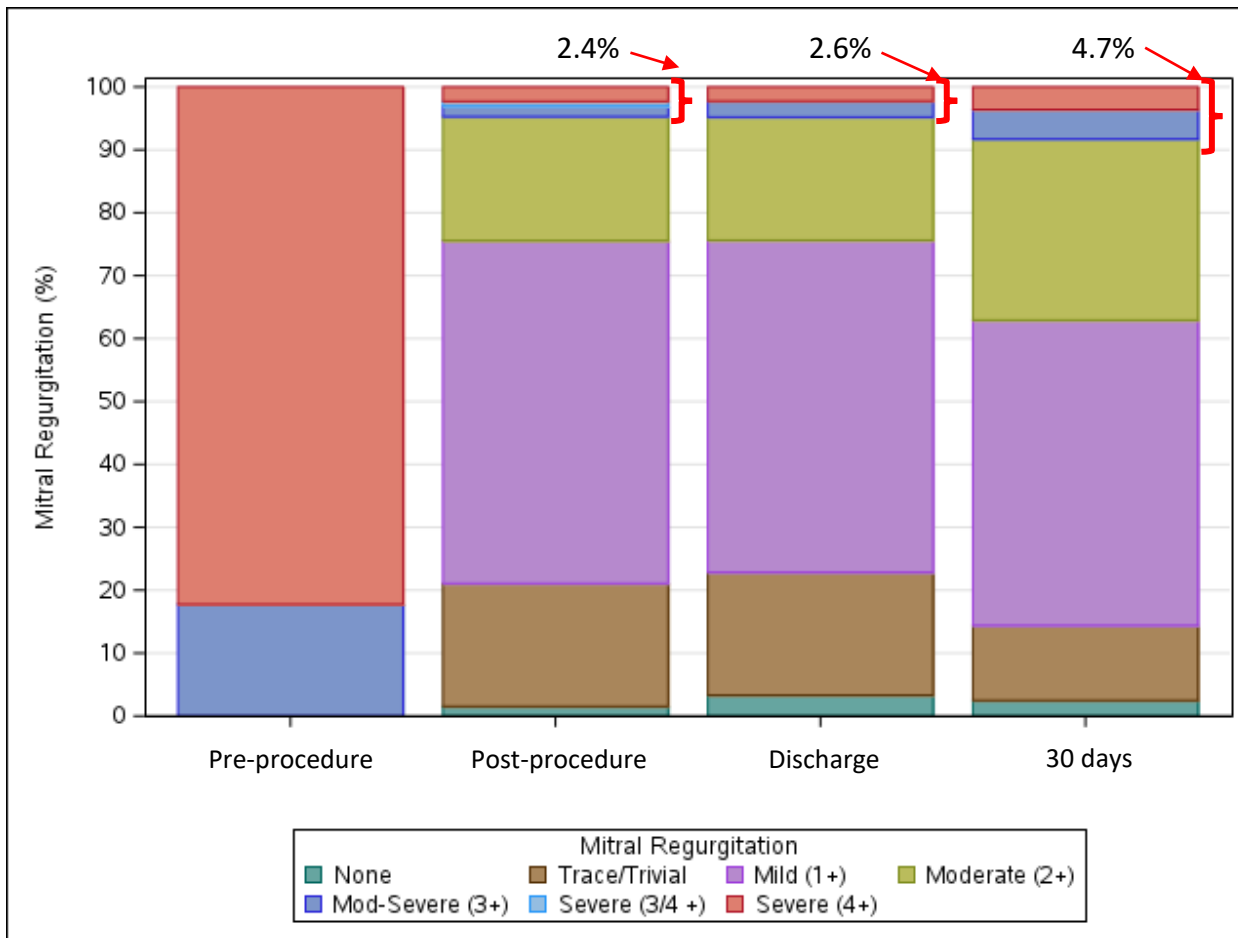
Variables	Overall
	N=19,088
Death	464 (2.66%)
MV Reintervention	164 (0.97%)
Heart failure readmission	437 (2.6%)
Unplanned cardiac surgery or intervention	283 (1.7%)
Unplanned vascular surgery or intervention	100 (0.59%)
Stroke	195 (1.2%)
Stroke or TIA	235 (1.4%)
New requirement for dialysis	86 (0.51%)

NYHA Class



Echocardiographic outcomes

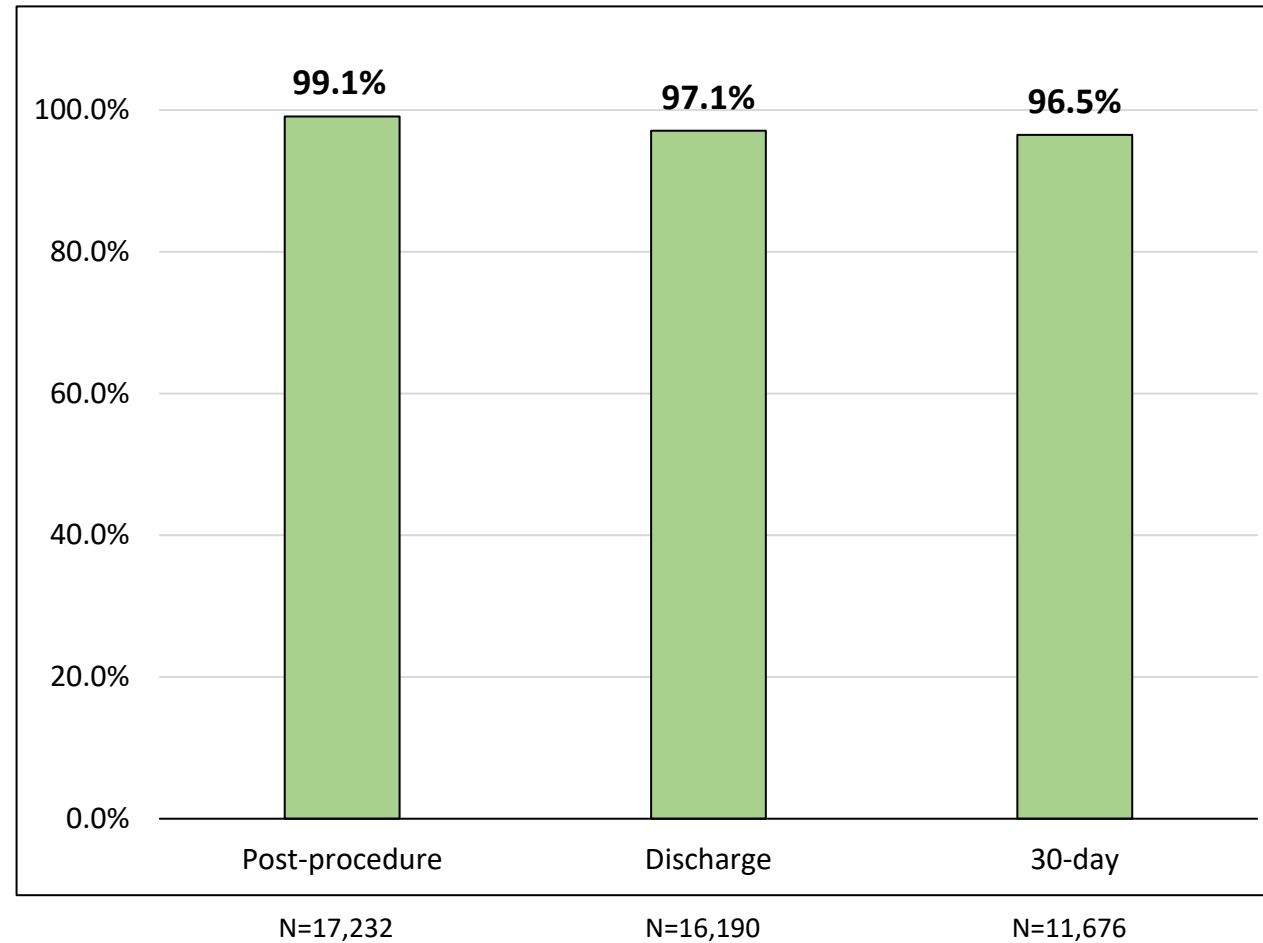
MR severity



MR severity ≤ 2+	
Post-procedure	17,292 (97.6%)
Discharge	16,325 (97.4%)
30 days	11,119 (95.3%)
MR severity ≤ 1+	
Post-procedure	13,725 (77.5%)
Discharge	12,969 (77.4%)
30 days	7,669 (65.7%)

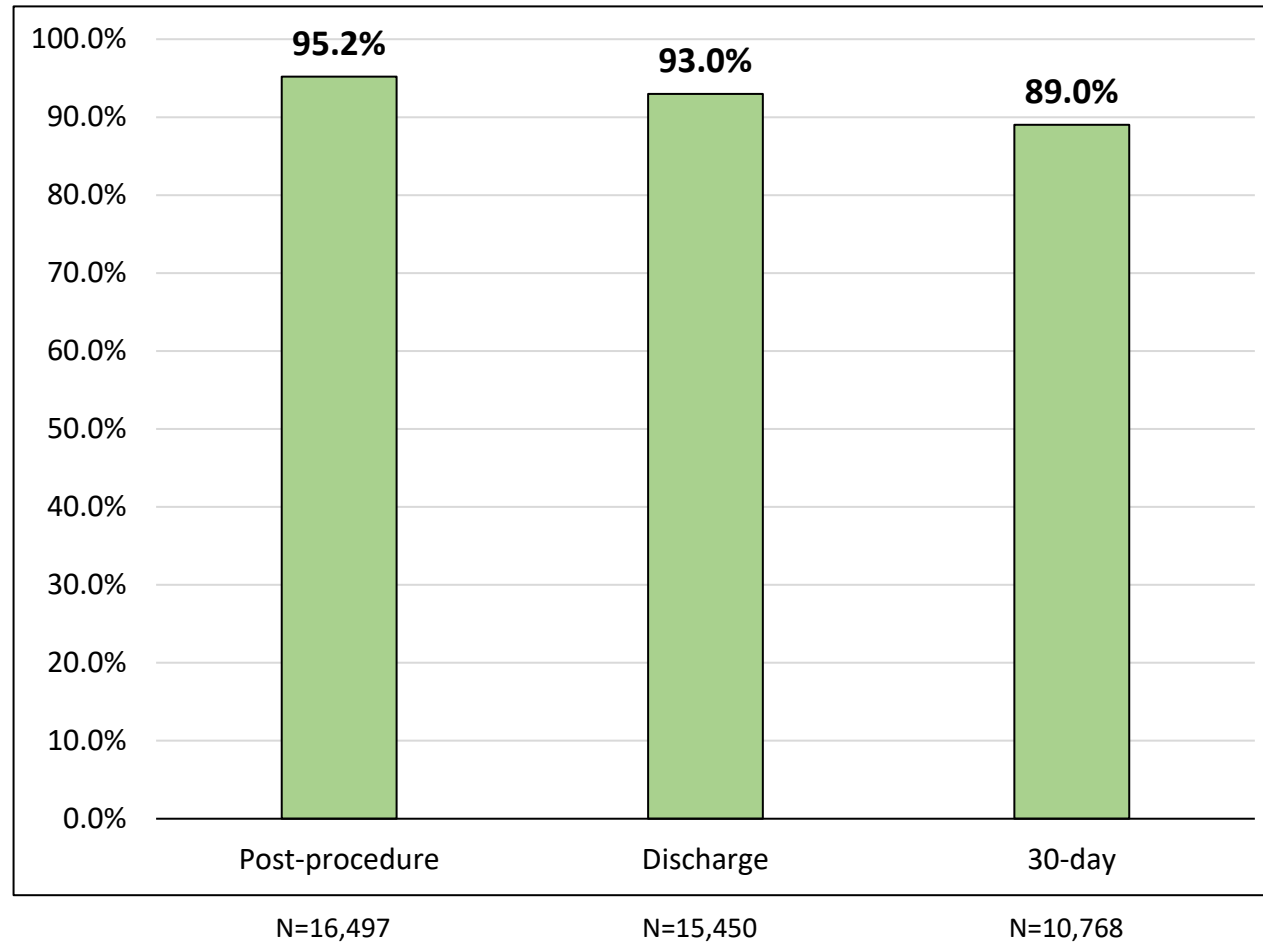
Echocardiographic outcomes

Mean mitral valve gradient < 10mmHg

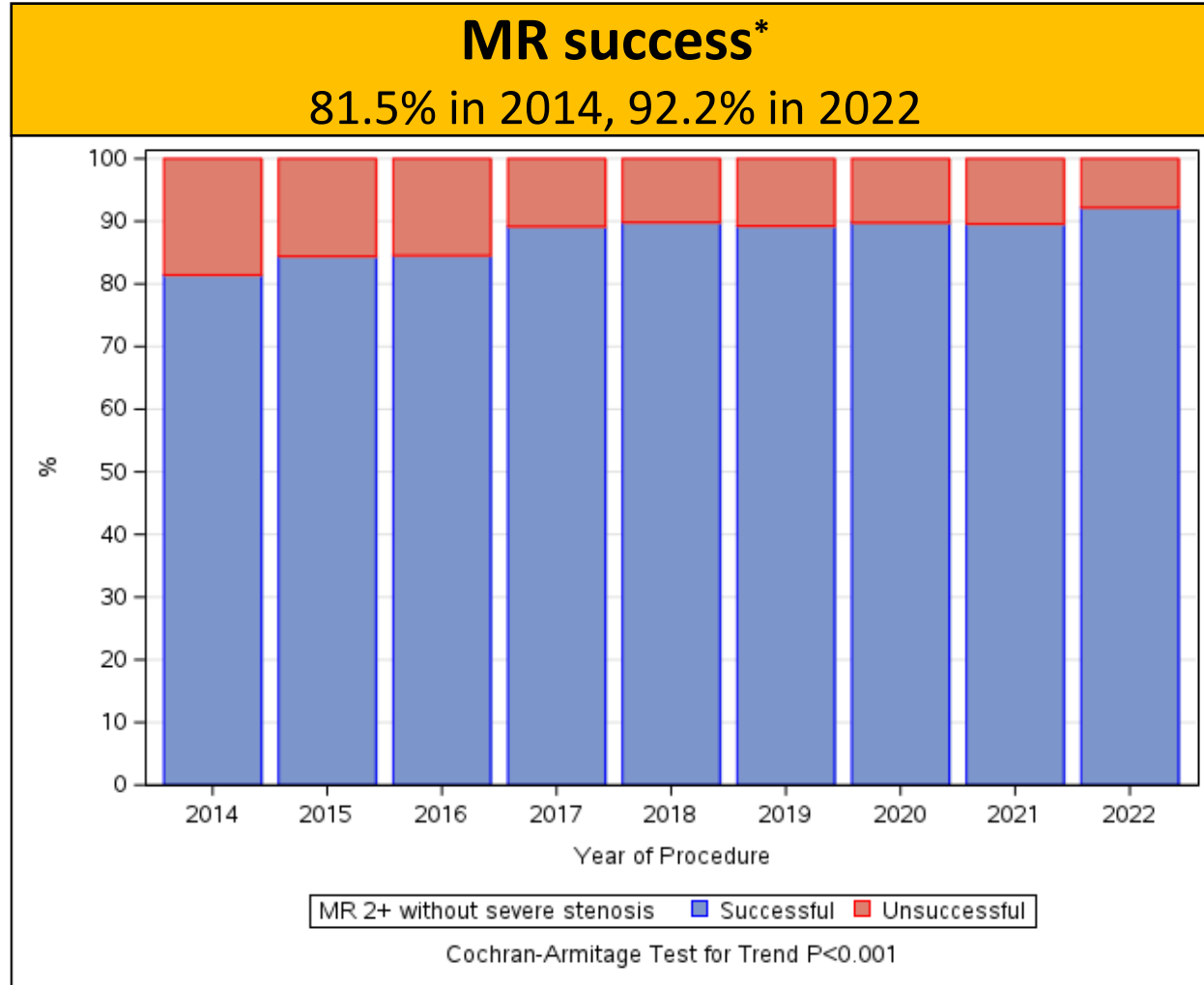


Primary end-point

MR success (MR \leq 2+ and mean mitral gradient $<$ 10mmHg)



Annualized MR success

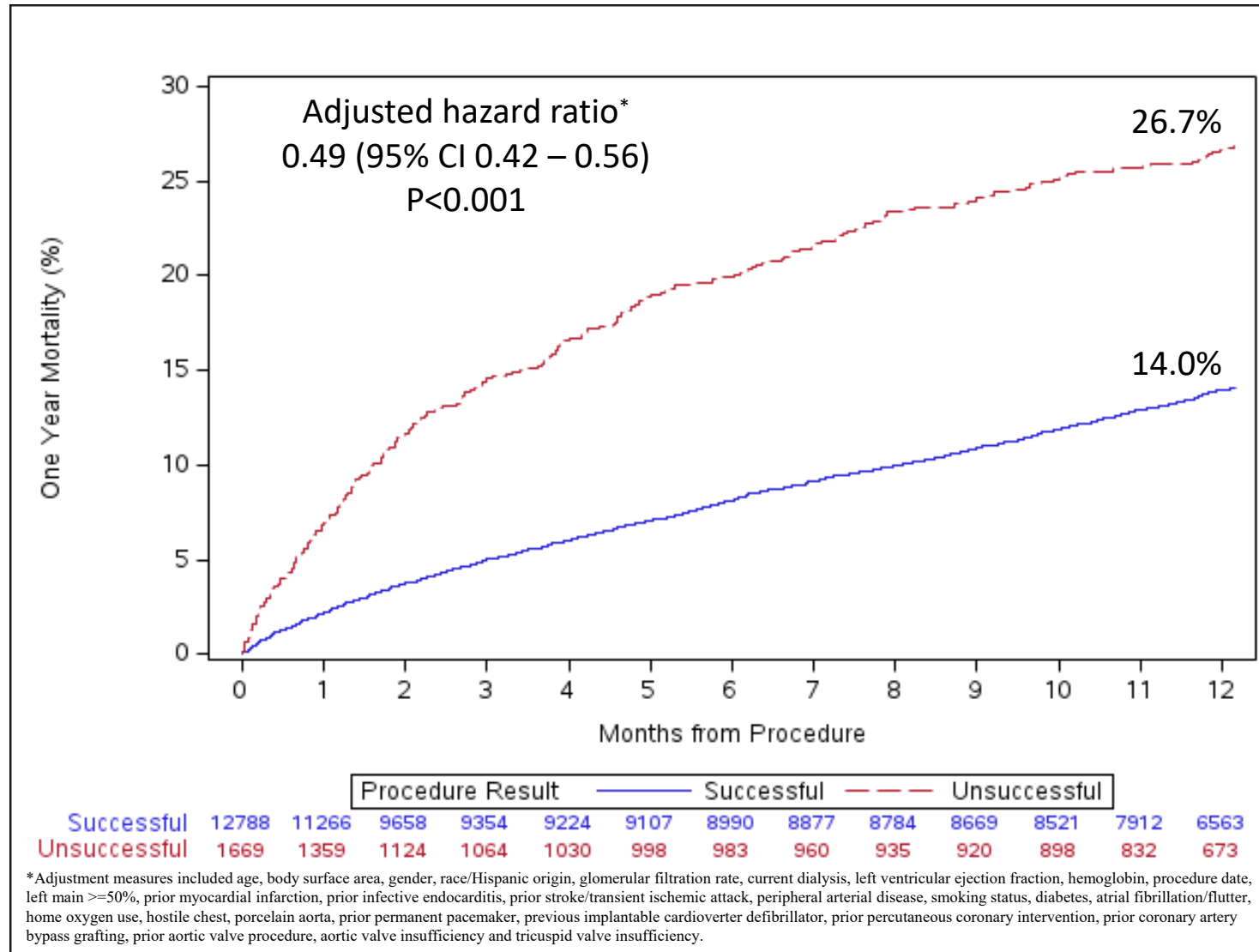


* Overall MR success was calculated using reported 30-day measures; if 30-day measures were not reported, then the reported discharge measures were used; if discharge measures were missing, then post-procedure measures were used.

	Overall (N=18,766)		2014 (N=415)		2015 (N=879)		2016 (N=1,443)		2017 (N=1,986)		2018 (N=2,321)		2019 (N=3,161)		2020 (N=3,062)		2021 (N=3,718)		2022 (N=1,781)	
MR success	16,699	89.0%	338	81.5%	742	84.4%	1,220	84.6%	1,771	89.2%	2,085	89.8%	2,821	89.2%	2,749	89.8%	3,331	89.6%	1,642	92.2%

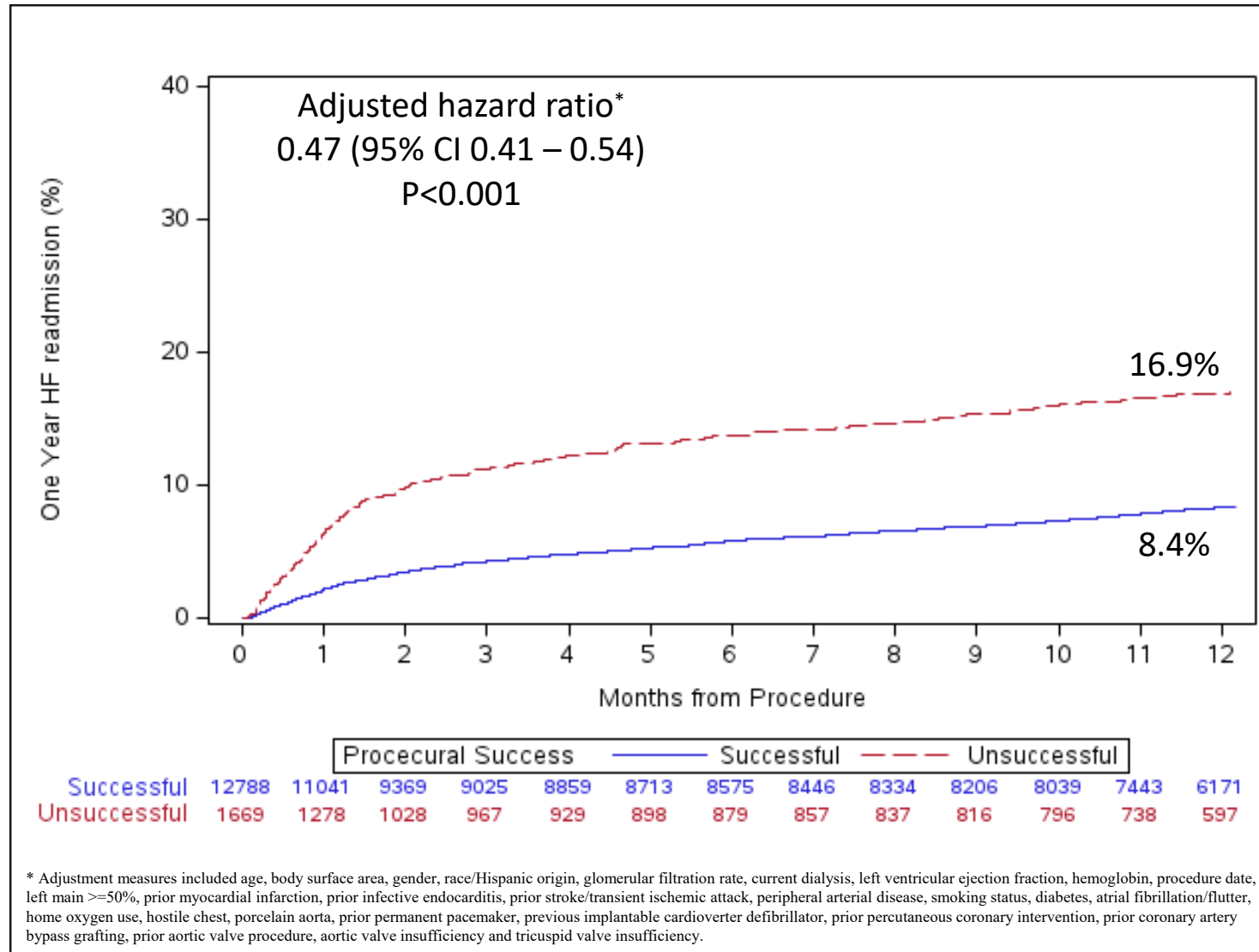
Mortality at 1 year

MR success vs unsuccessful procedure



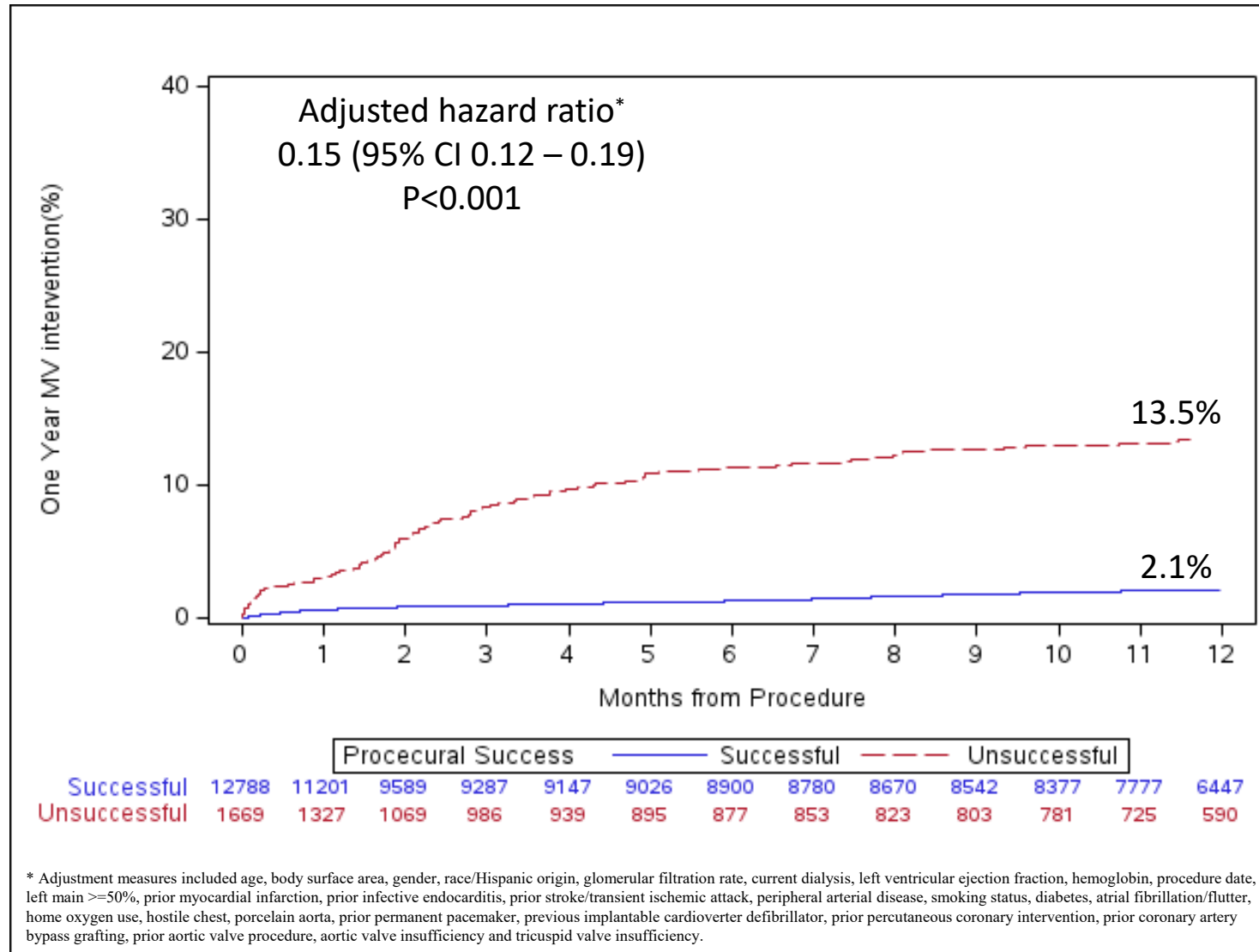
Heart failure readmission at 1 year

MR success vs unsuccessful procedure

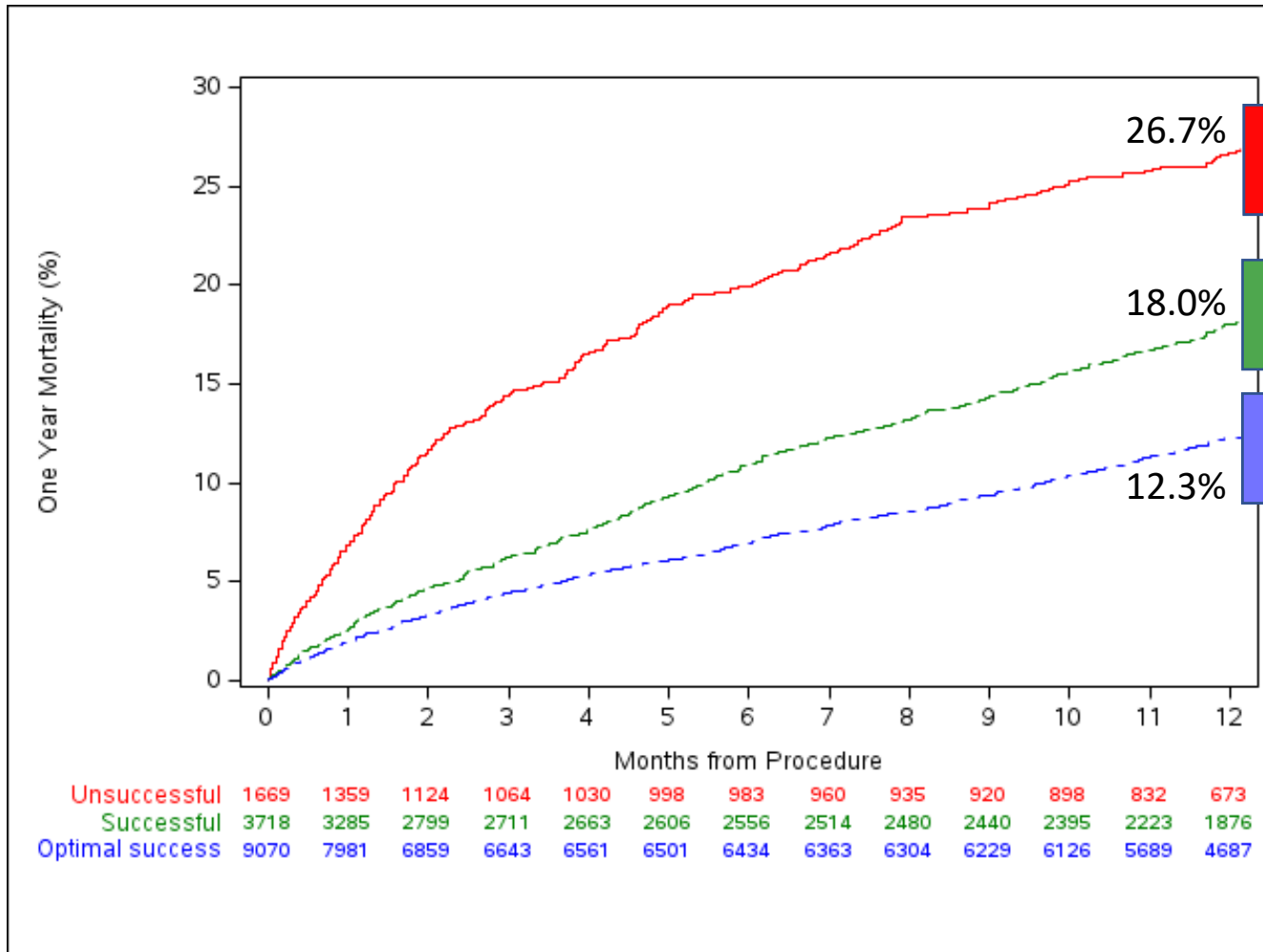


Mitral valve reintervention at 1 year

MR success vs unsuccessful procedure



Mild MR vs moderate MR vs Unsuccessful Procedure Death at 1 year



Unsuccessful procedure

Mod MR/
gradient < 10mmHg

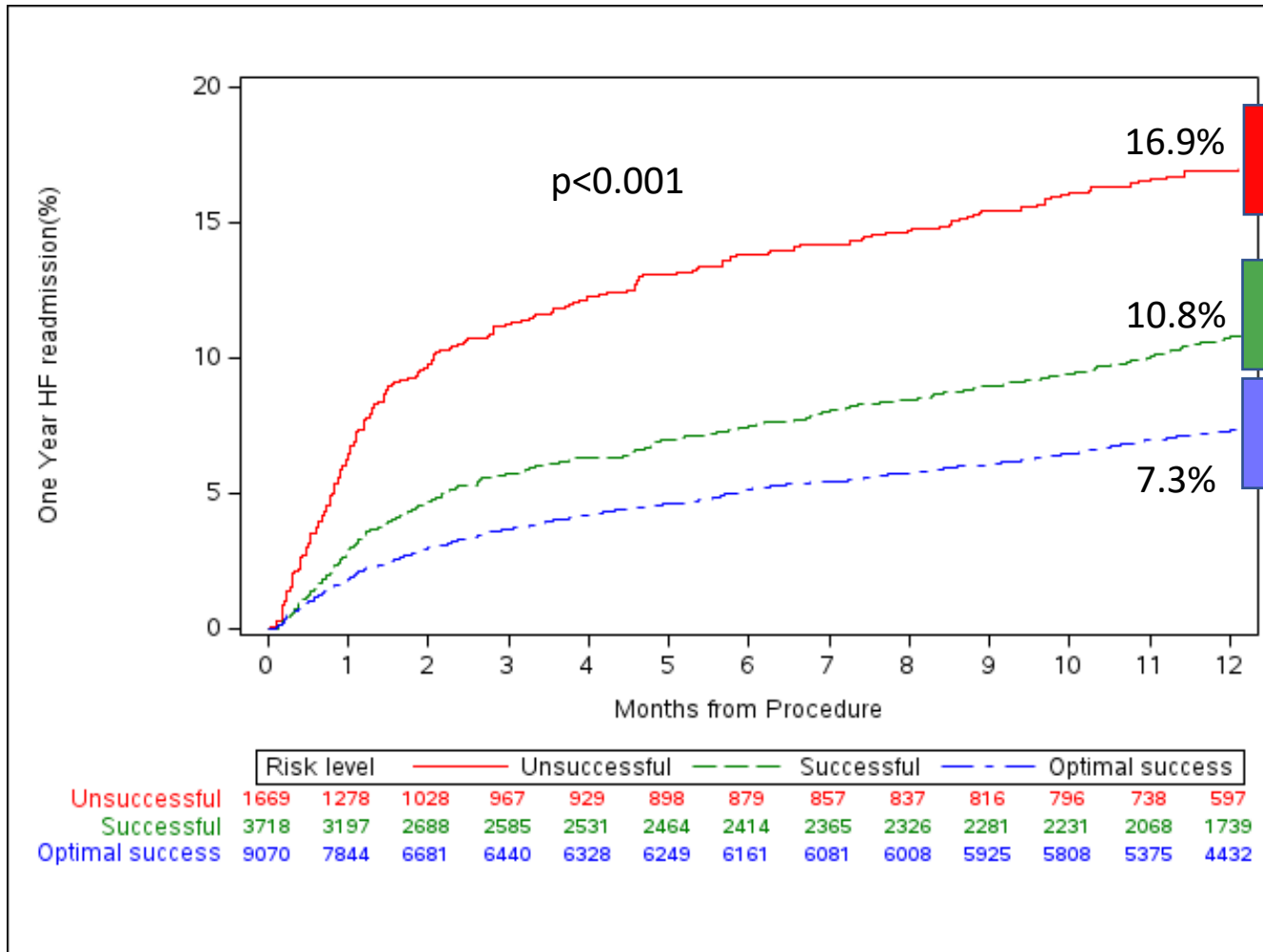
Mild MR/
gradient < 10mmHg

Adjusted HR* 0.73 (0.66 – 0.82)
p < 0.001

*Adjustment measures included age, body surface area, gender, race/Hispanic origin, glomerular filtration rate, current dialysis, left ventricular ejection fraction, hemoglobin, procedure date, left main >=50%, prior myocardial infarction, prior infective endocarditis, prior stroke/transient ischemic attack, peripheral arterial disease, smoking status, diabetes, atrial fibrillation/flutter, home oxygen use, hostile chest, porcelain aorta, prior permanent pacemaker, previous implantable cardioverter defibrillator, prior percutaneous coronary intervention, prior coronary artery bypass grafting, prior aortic valve procedure, aortic valve insufficiency and tricuspid valve insufficiency.

Mild MR vs moderate MR vs Unsuccessful Procedure

Heart failure readmission at 1 year



Unsuccessful procedure

Mod MR/
gradient < 10mmHg

Mild MR/
gradient < 10mmHg

Adjusted HR 0.68 (0.60 - 0.78)
P < 0.001

*Adjustment measures included age, body surface area, gender, race/Hispanic origin, glomerular filtration rate, current dialysis, left ventricular ejection fraction, hemoglobin, procedure date, left main $\geq 50\%$, prior myocardial infarction, prior infective endocarditis, prior stroke/transient ischemic attack, peripheral arterial disease, smoking status, diabetes, atrial fibrillation/flutter, home oxygen use, hostile chest, porcelain aorta, prior permanent pacemaker, previous implantable cardioverter defibrillator, prior percutaneous coronary intervention, prior coronary artery bypass grafting, prior aortic valve procedure, aortic valve insufficiency and tricuspid valve insufficiency.

Categories of MR success

Mean mitral valve gradient	≥ 10mmHg	Unsuccessful procedure 11.0%	
	< 10mmHg	MR success 89.0%	Unsuccessful procedure
		2+ or less MR	3+/4+ MR
		Residual MR	

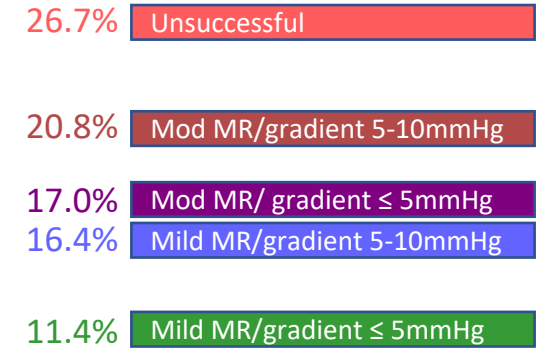
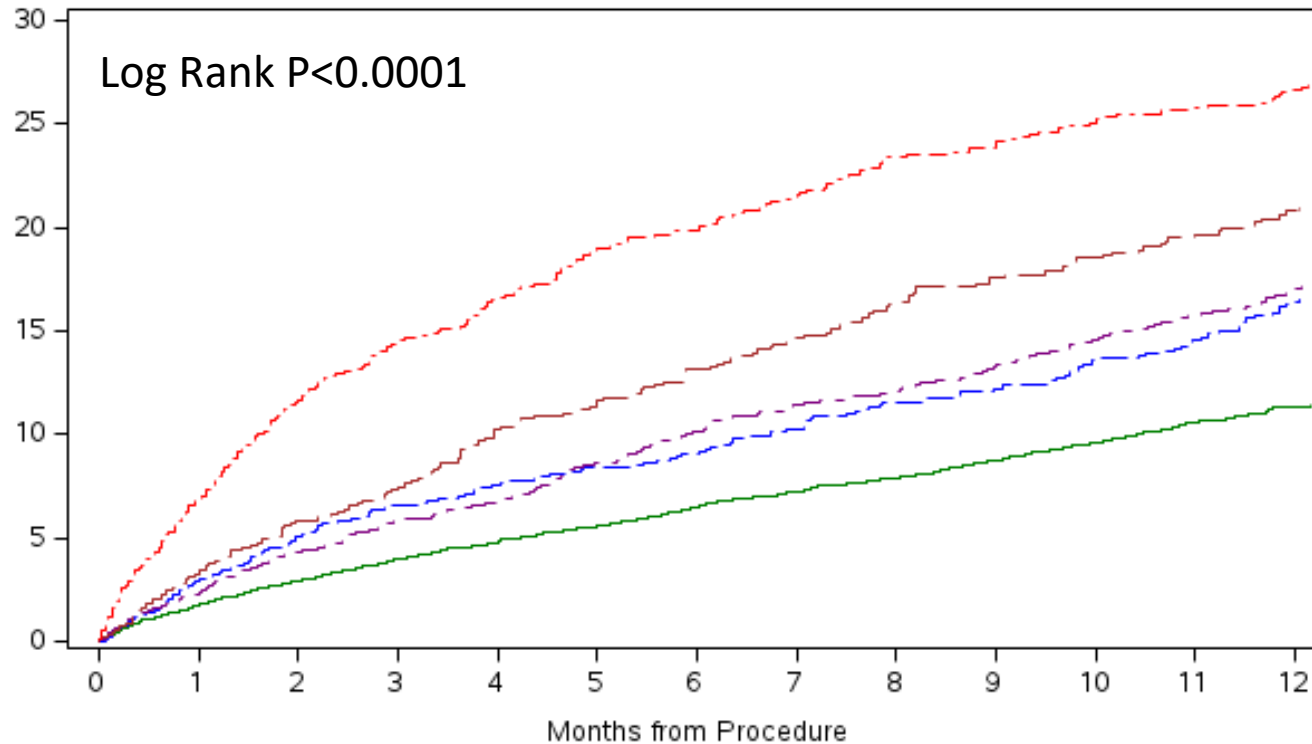
Categories of MR success

Mean mitral valve gradient	≥ 10mmHg	Unsuccessful procedure 11.0%		Unsuccessful procedure
	5-10mmHg	Mild MR Mitral gradient 5-10mmHg	Moderate MR Mitral gradient 5-10mmHg	
	≤ 5mmHg	Mild MR Mitral gradient ≤ 5mmHg	Moderate MR Mitral gradient ≤ 5mmHg	
		1+ MR or less	2+ MR	3+/4+ MR
		Residual MR		

Categories of MR success

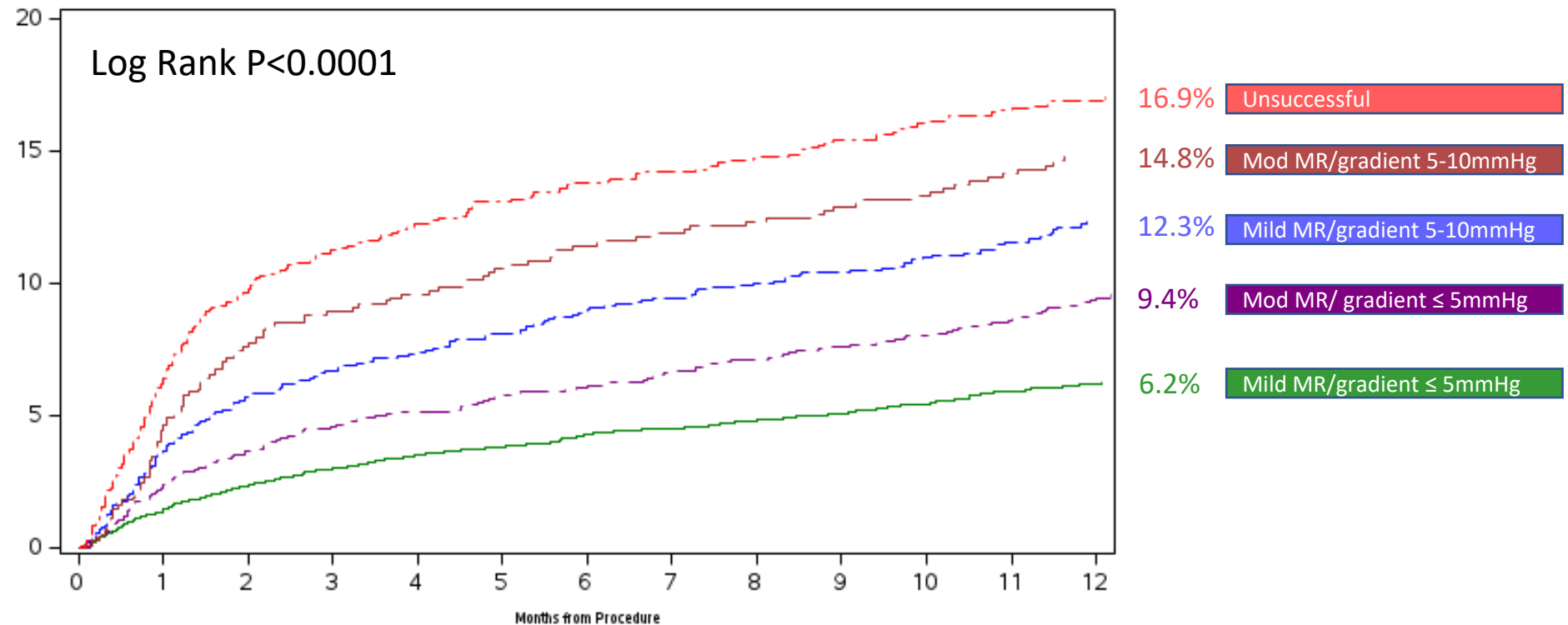
Mean mitral valve gradient	≥ 10mmHg	Unsuccessful procedure 11.0%		Unsuccessful procedure
	5-10mmHg	Mild MR Mitral gradient 5-10mmHg 11.8%	Moderate MR Mitral gradient 5-10mmHg 6.4%	
	≤ 5mmHg	Mild MR Mitral gradient ≤ 5mmHg 52.4%	Moderate MR Mitral gradient ≤ 5mmHg 18.4%	
		1+ MR or less	2+ MR	3+/4+ MR
Residual MR				

Mortality at 1 year, stratified according to categories of MR success



Mild MR/gradient ≤ 5mmHg	7399	6521	5632	5467	5402	5354	5296	5243	5199	5136	5058	4699	3889
Mild MR/gradient 5-10mmHg	1671	1460	1227	1176	1159	1147	1138	1120	1105	1093	1068	990	798
Mod MR/gradient ≤ 5mmHg	2750	2433	2099	2033	2008	1962	1926	1896	1875	1843	1807	1677	1429
Mild MR/gradient 5-10mmHg	968	852	700	678	655	644	630	618	605	597	588	546	447
Unsuccessful	1669	1359	1124	1064	1030	998	983	960	935	920	898	832	673

Heart failure readmission at 1 year, stratified according to categories of MR success



Mild MR/gradient ≤ 5 mmHg	7399	6434	5515	5331	5241	5183	5110	5050	4996	4927	4836	4480	3713
Mild MR/gradient 5-10mmHg	1671	1410	1166	1109	1087	1066	1051	1031	1012	998	972	895	719
Mod MR/gradient ≤ 5 mmHg	2750	2382	2034	1960	1927	1876	1839	1800	1772	1736	1697	1576	1335
Mild MR/gradient 5-10mmHg	968	815	654	625	604	588	575	565	554	545	534	492	404
Unsuccessful	1669	1278	1028	967	929	898	879	857	837	816	796	738	597

Study limitations

- Site-reported data with no echocardiographic core laboratory or independent adjudication of clinical events.
- Incomplete echocardiographic and clinical follow-up.
- Lack of a surgical or medically treated group as the comparator arm.
- Follow-up limited to 1-year.

Conclusions

In this national registry analysis of 19,088 patients undergoing TEER with the MitraClip device for degenerative MR

Conclusions

In this national registry analysis of 19,088 patients undergoing TEER with the MitraClip device for degenerative MR

- The safety profile was excellent despite advanced age (82 years) and significant comorbidities (median STS 4.6).

In-hospital mortality 1.08%, stroke 0.62%, unplanned cardiac surgery or intervention 1.08% and new requirement for dialysis 0.34%.

- Successful repair, defined as reduction in MR severity to moderate or less and no severe stenosis, was achieved in 89% of the patients.
- Patients with successful repair, compared to those with unsuccessful repair, had lower mortality (14.0% vs 26.7%), heart failure readmission (8.4% vs 16.9%) and mitral valve reintervention (2.1% vs 13.5%) rates at 1 year.

Conclusions, *cont'd.*

- Both residual MR and mitral gradients were associated with death and heart failure readmission at 1 year, with the best clinical outcomes in patients with mild or less residual MR *and* no mitral stenosis.
- Over an 8-year time period during the study, the procedural volumes and success rates increased significantly.

Study implications

- Transcatheter mitral valve repair with the MitraClip device is a safe and effective treatment for degenerative MR patients who are at elevated risk for surgery.
- The goal of transcatheter mitral valve repair for degenerative MR should be to achieve mild or less residual MR without creating significant mitral stenosis.