MAYO CLINIC

CRF® TCT

Transcatheter Edge-to-Edge Repair in Patients with Severe Mitral Regurgitation and Cardiogenic Shock: Insights from the TVT Registry

Mohamad Alkhouli MD
Professor of Medicine, Mayo Clinic

STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

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	Company
Grant/Research Support	Boston Scientific, Philips
Consultation fees	Abbott, Biosense Webster, Philips, Boston Scientific

Funding Support and Disclaimer

This research was supported by the American College of Cardiology Foundation's National Cardiovascular Data Registry (NCDR) and The Society of Thoracic Surgeons National Database. The views expressed in this presentation represent those of the author(s), and do not necessarily represent the official views of either organization. Learn more about the STS/ACC TVT Registry at *www.tvtregistry.org.*

Cardiogenic Shock
Basic Facts

- Continues to have a persistently high mortality[1]
- Few interventions have improved its prognosis[1]
- There is an increasing complexity & multi-morbidity of patients with CS (e.g., more non-AMI related CS)[1-3]
- Moderate-severe MR is present in up to 1 in 5 patients admitted with CS & it increases mortality risk by 60%[1-3]

STS/ACC TVT Registry™

1 Mihatov et al. J Am Coll Cardiol 2022;79:1223-1235
2 Parlow et al. Can J Cardiol 2022 Epub ahead of print
3 Thompson et al. J Am Coll Cardiol 2000;36:1104-9

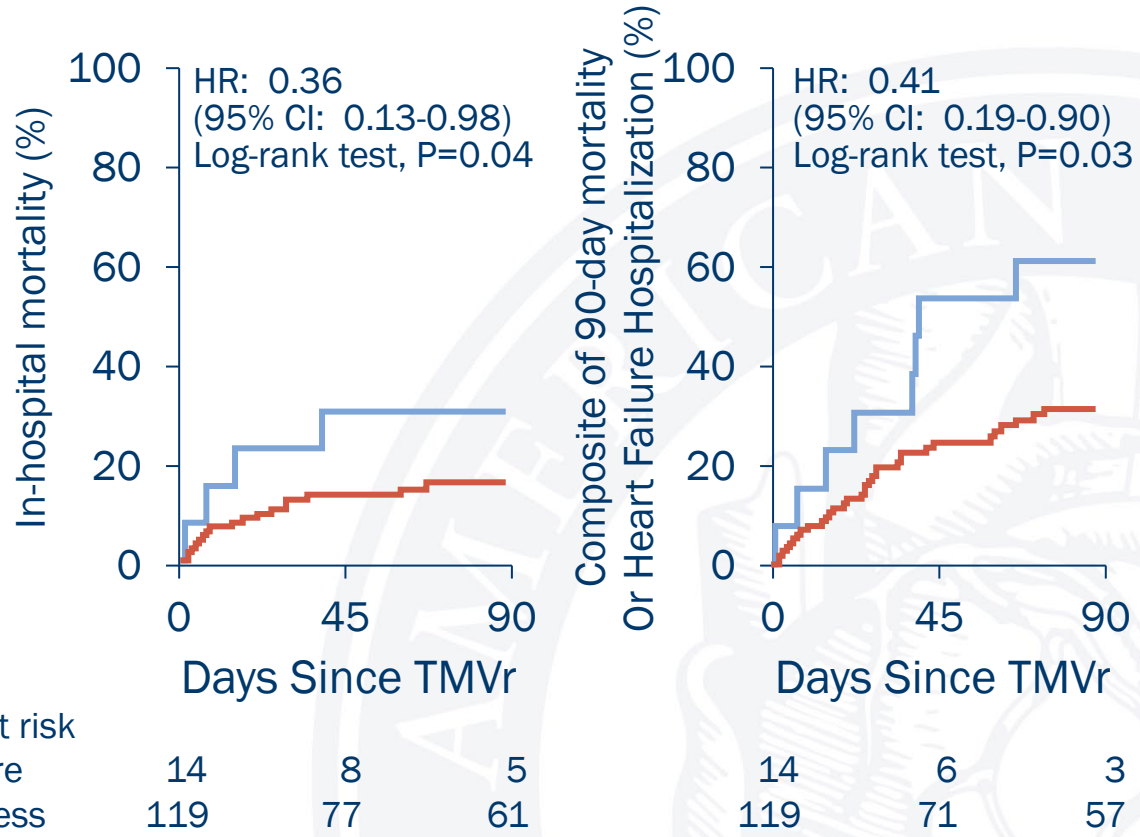
The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

Cardiogenic Shock & Mitral Regurgitation

Data on the Role of TEER are Limited

- Multicenter registry (n=141 patients with CS)
- Procedural success (≤2+ MR) was 88.7%
- TEER success was associated with lower short-term mortality & HF admissions



STS/ACC TVT Registry™

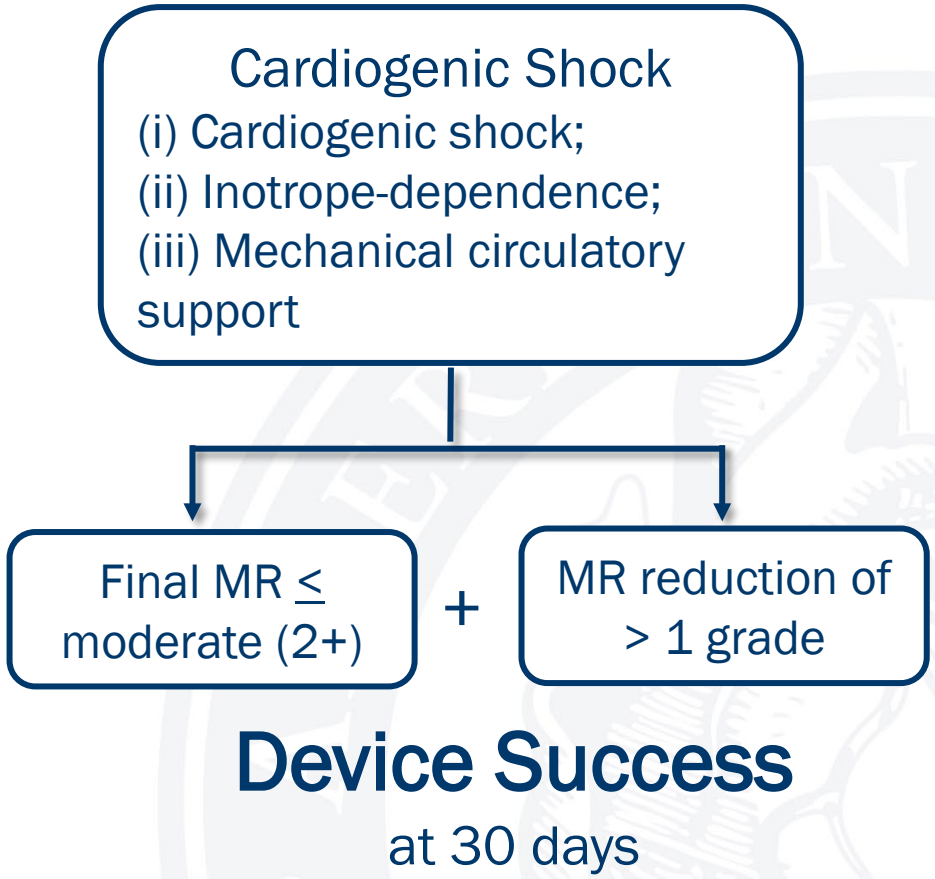
Jung et al. JACC Cardiovasc Interv. 2021:11;14(1):1-11

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER for MR and Cardiogenic Shock
Insight From the ACC/TVT/STS Registry

- Patients with CS undergoing TEER between Nov 2013 to Dec 2021
- Objectives:
  - Describe risk profile & device success rates
  - Assess association of device success with 1-year outcomes



STS/ACC TVT Registry™

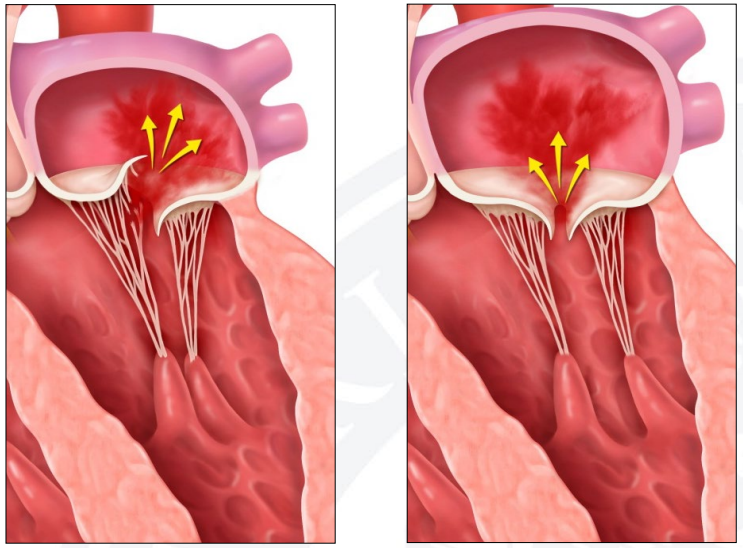
*Excluded combined procedures and patients with missing CS, inotrope dependence, MCS prior to procedure status

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER for MR and Cardiogenic Shock
Baseline Characteristics

- 3,797 patients were included
- Mean age was 73.0±11.9 years
- 59.9% of patients were males
- 82.7% were of White race
- STS risk of mortality for MVr was:
  - 14.9±15.3 (Mean±SD)
  - 9.5/4.8-19.1 (Median/25th-75th)
- 90.5% in NYHA III/IV prior 2 weeks



DMR 53.4%

FMR 27.5%

LVEF= 41.1±17.5%
LVEDD= 5.6±1.1 cm

STS/ACC TVT Registry™

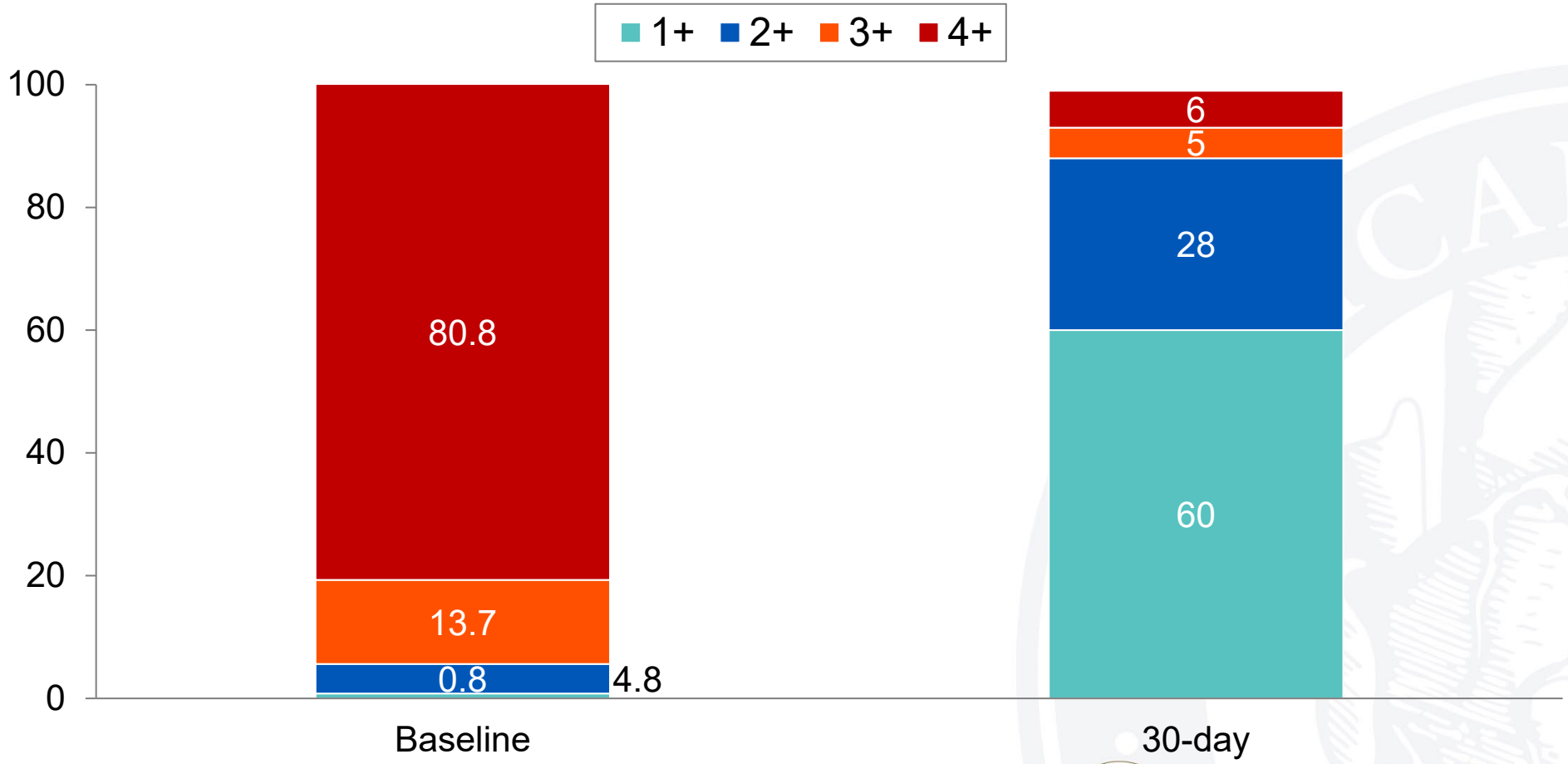
The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER for MR and Cardiogenic Shock
Procedural Characteristics

- Time from admission to TEER (Mean 5.6±8.1, Median 2.7 [0.2, 7.9] days)
- 47.8% >1 clip implanted (93.9% A2-P2)
- Complications:
  - VARC major bleed 3.6%, life threatening/disabling bleed 4.0%
  - Stroke 1.6%
  - SLDA 1.3%
  - Conversion to surgery 0.6%
- Non-home discharge 25.8%
- Length of stay (Mean 12.5±15.0, Median 9.0 [2.0, 17.0] days)

TEER for MR and Cardiogenic Shock
Echocardiographic Outcomes



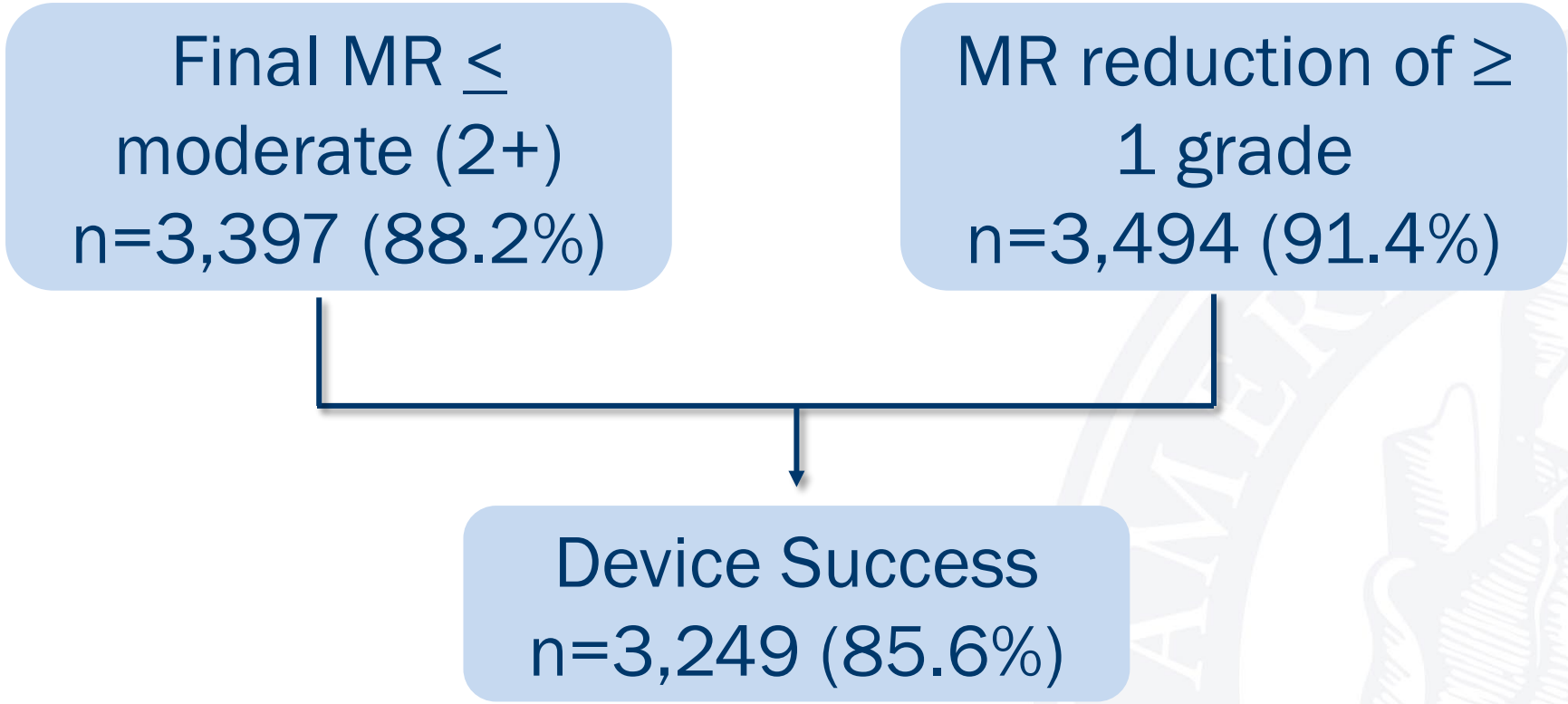
STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER for MR and Cardiogenic Shock

Device Success



TEER for MR and Cardiogenic Shock
Device Success vs Device Failure Groups

Patient Characteristics	Device Success n=3249	Device Failure n=548	P value
Age (mean ± SD)	73.2±11.8	71.9±12.7	0.03
Male (%)	60.3%	54.7%	0.01
STS PROM (mean ± SD)	14.8±15.3	15.0±15.4	0.97
LVEF (mean ± SD)	40.7±17.5	42.9±17.4	0.009
MR ≥3+ (%)	96.1%	84.9%	<.001
Degenerative MR (%)	52.3%	60.4%	0.004

STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER for MR and Cardiogenic Shock
30-Day Mortality

Device Failure 30-day Mortality			Device Success 30-day Mortality		
STS-Expected	Observed	Observed/Expected	STS-Expected	Observed	Observed/Expected
15.0%	23.0%	1.53	14.9%	13.1%	0.88

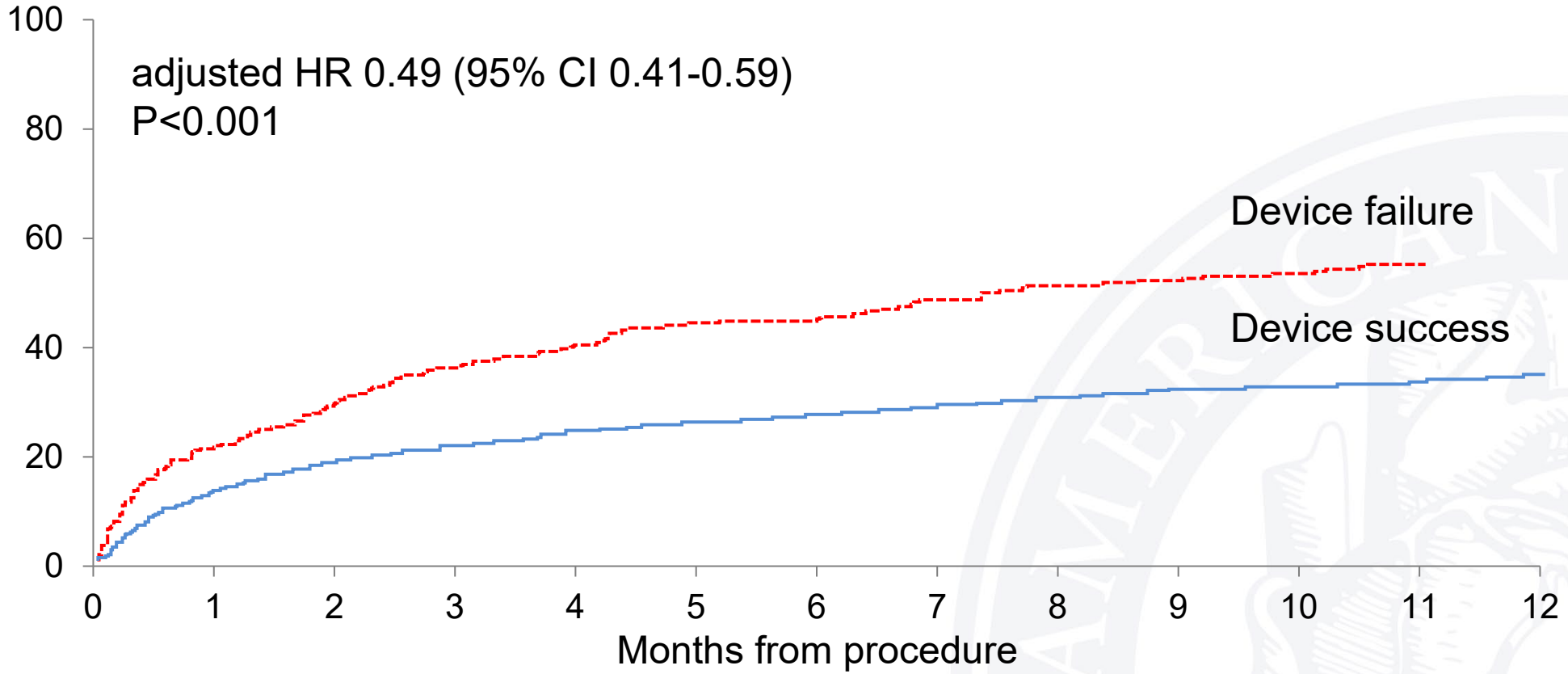
STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER Device Success and 1-Year Outcomes

All-cause Mortality



Device failure	397	272	202	178	166	154	149	141	133	130	126	103	79
Device success	2,334	1,786	1,418	1,318	1,271	1,238	1,214	1,186	1,161	1,129	1,110	1,023	821

* IPW used to account for missing mortality (26%) and HF admission data (25%) at 1 year

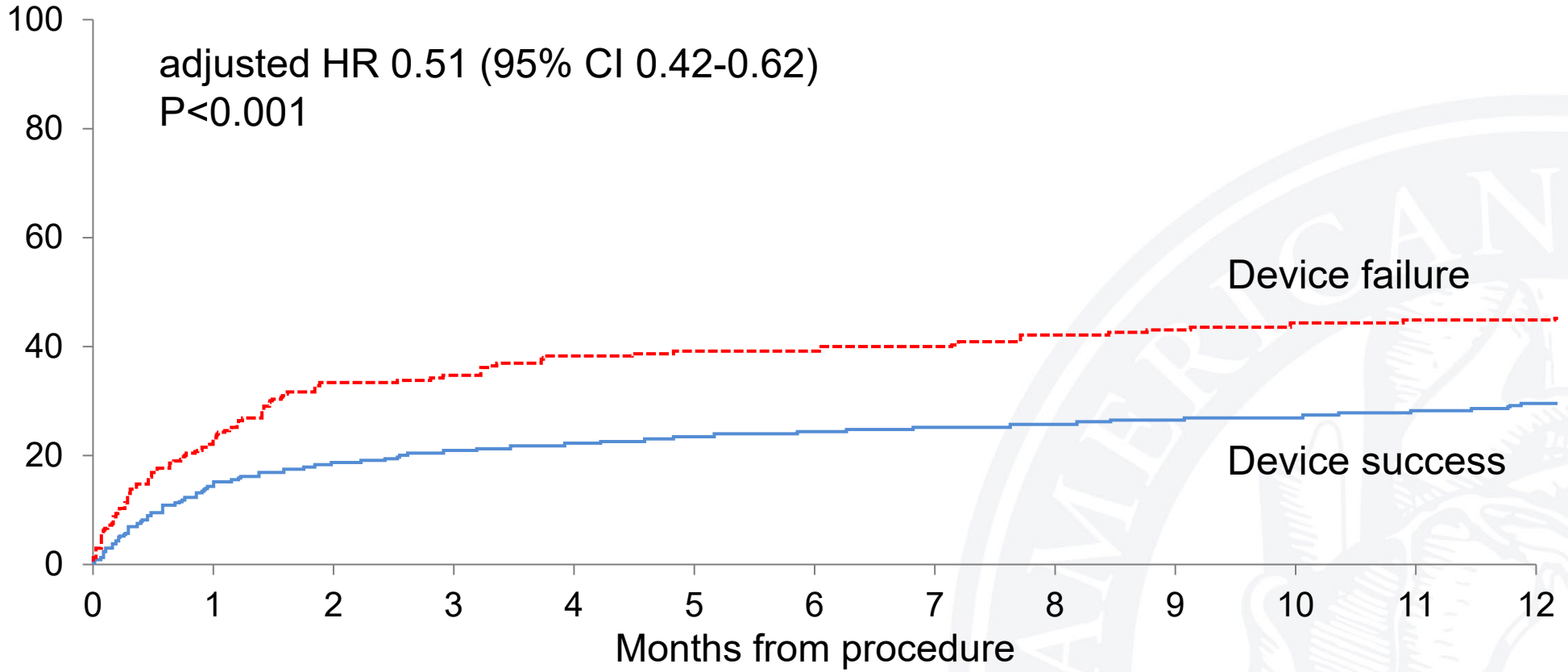
STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

TEER Device Success and 1-Year Outcomes

Mortality or HF Admission



Device failure	397	243	152	137	124	117	115	112	105	102	97	80	59
Device success	2,334	1,670	1,255	1,141	1,089	1,052	1,027	1,003	985	960	944	864	684

* IPW used to account for missing mortality (26%) and HF admission data (25%) at 1 year

STS/ACC TVT Registry™

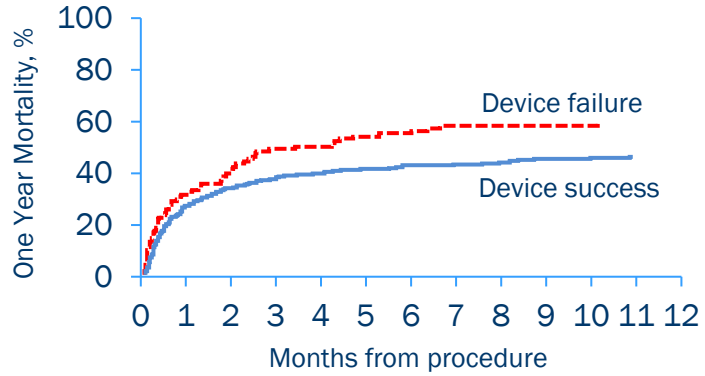
The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

Device Success and Outcomes by CS Definition

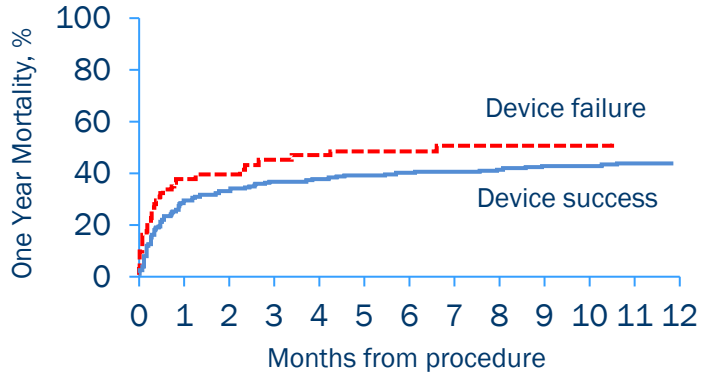
Mortality

Cardiogenic shock



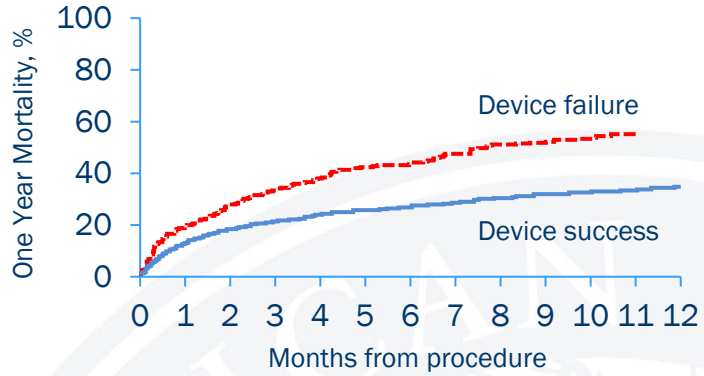
Device failure	138	82	60	51	50	46	43	41	41	41	41	32	28
Device success	666	431	331	298	288	280	274	272	267	260	257	236	192

Mechanical Circulatory Support



Device failure	75	41	33	29	28	27	26	25	25	25	25	17	15
Device success	348	224	117	158	156	152	150	149	146	142	141	132	110

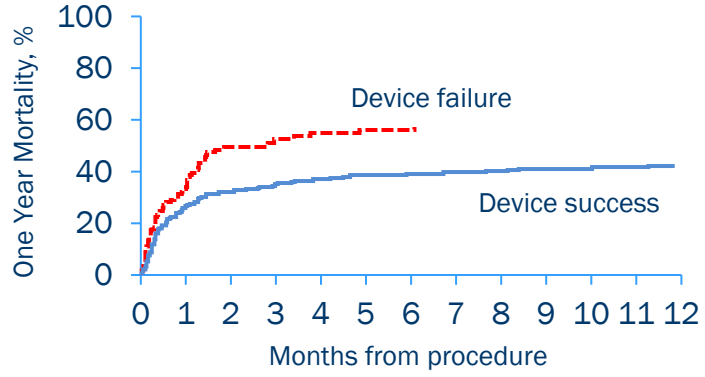
Inotrope Use



Device failure	336	236	179	156	147	135	130	122	114	111	107	89	69
Device success	2081	1598	1260	1178	1134	1104	1082	1056	1033	1003	986	908	721

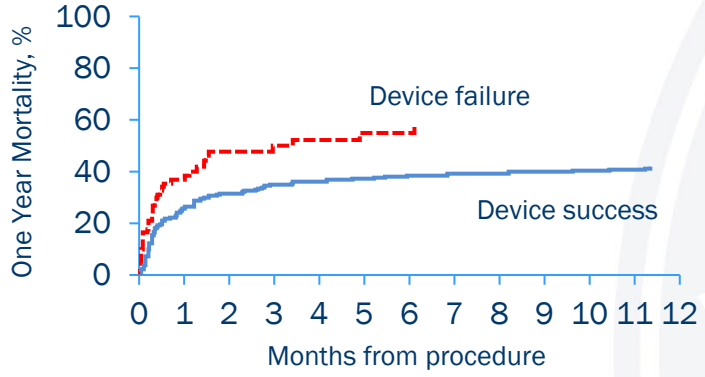
Mortality or HF admission

Cardiogenic shock



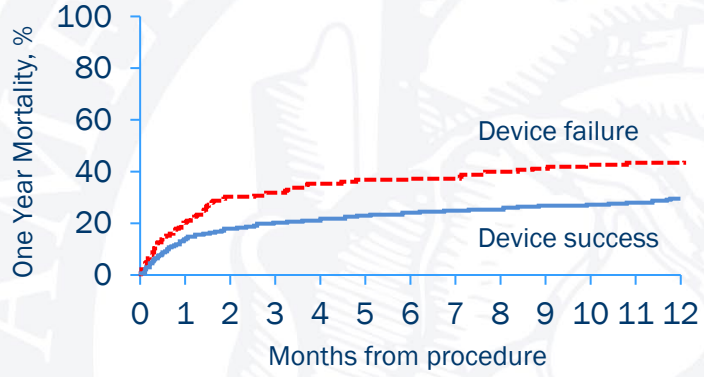
Device failure	138	74	43	37	35	33	32	30	30	30	29	23	19
Device success	666	402	289	259	244	234	229	226	221	215	212	194	156

Mechanical Circulatory Support



Device failure	75	38	26	21	20	18	18	17	17	17	17	10	8
Device success	348	215	161	140	133	130	126	124	121	120	118	110	89

Inotrope Use



Device failure	336	209	136	122	109	102	100	97	90	87	82	69	52
Device success	2081	1490	1118	1017	969	934	910	888	872	847	834	762	596

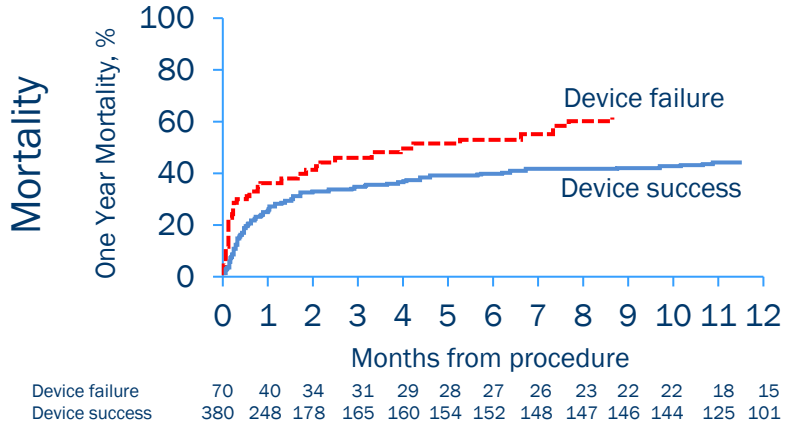
STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

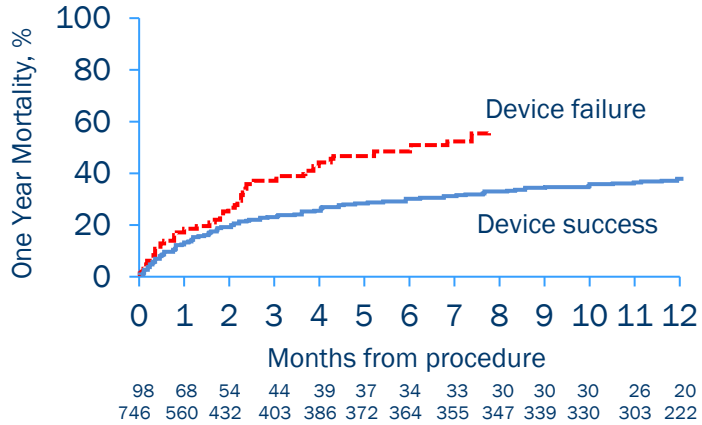
Device Success and Outcomes by Presentation

Acute Coronary Syndrome (ACS)*



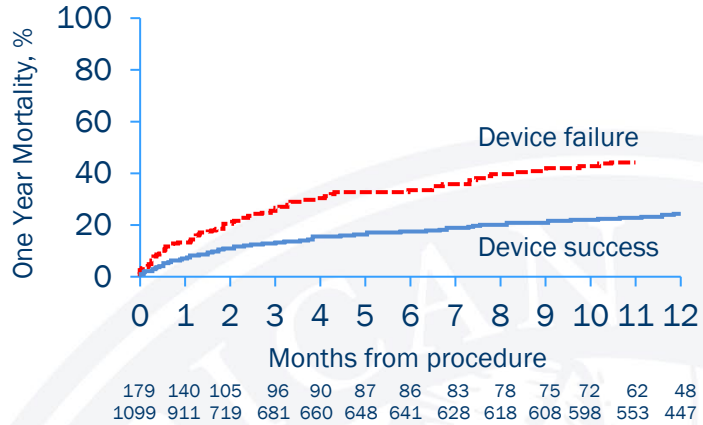
Device failure	70	40	34	31	29	28	27	26	23	22	22	18	15
Device success	380	248	178	165	160	154	152	148	147	146	144	125	101

LVEF <30%*



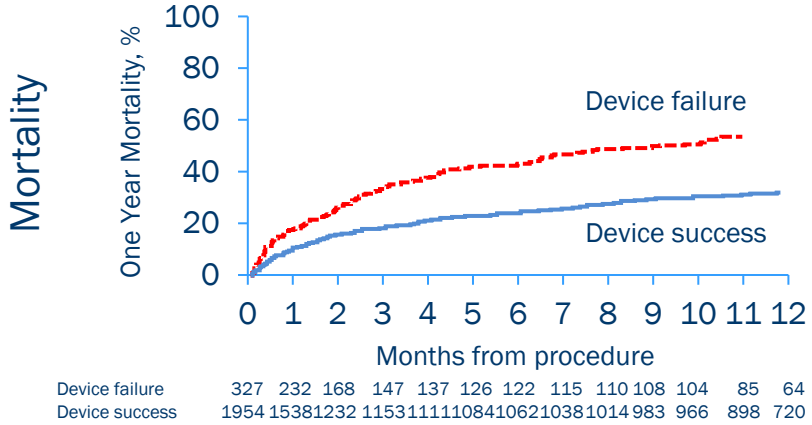
Device failure	98	68	54	44	39	37	34	33	30	30	30	26	20
Device success	746	560	432	403	386	372	364	355	347	339	330	303	222

NYHA Class IV



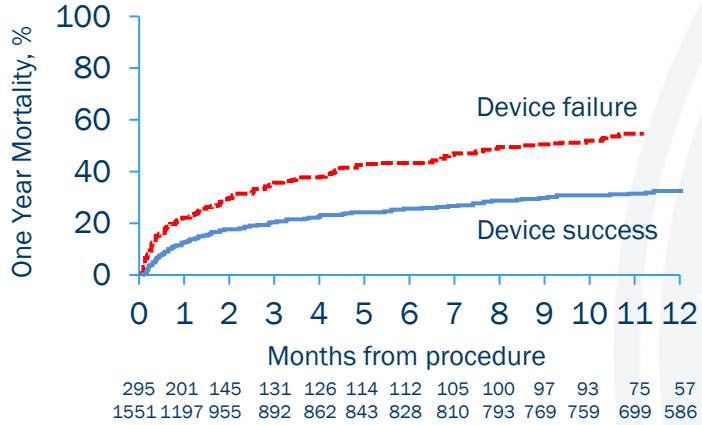
Device failure	179	140	105	96	90	87	86	83	78	75	72	62	48
Device success	1099	911	719	681	660	648	641	628	618	608	598	553	447

Non-Acute Coronary Syndrome (ACS)



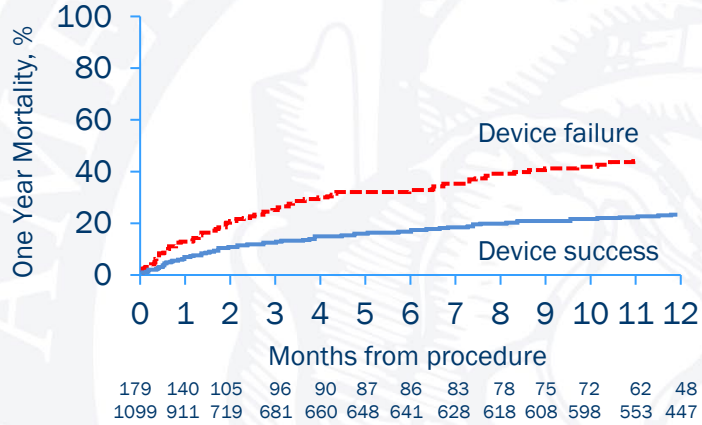
Device failure	327	232	168	147	137	126	122	115	110	108	104	85	64
Device success	1954	1538	1232	1153	1111	1084	1062	1038	1014	983	966	898	720

LVEF ≥30%



Device failure	295	201	145	131	126	114	112	105	100	97	93	75	57
Device success	1551	1197	955	892	862	843	828	810	793	769	759	699	586

NYHA Class <IV



Device failure	179	140	105	96	90	87	86	83	78	75	72	62	48
Device success	1099	911	719	681	660	648	641	628	618	608	598	553	447

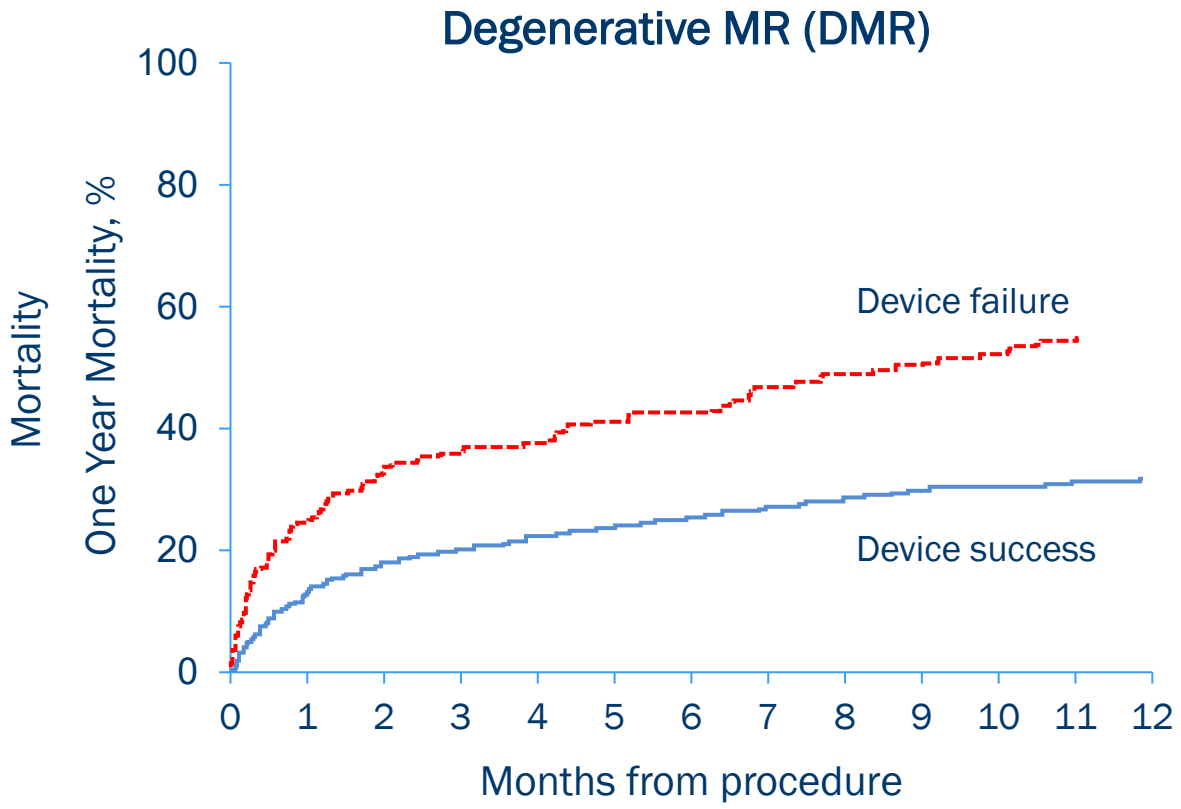
STS/ACC TVT Registry™

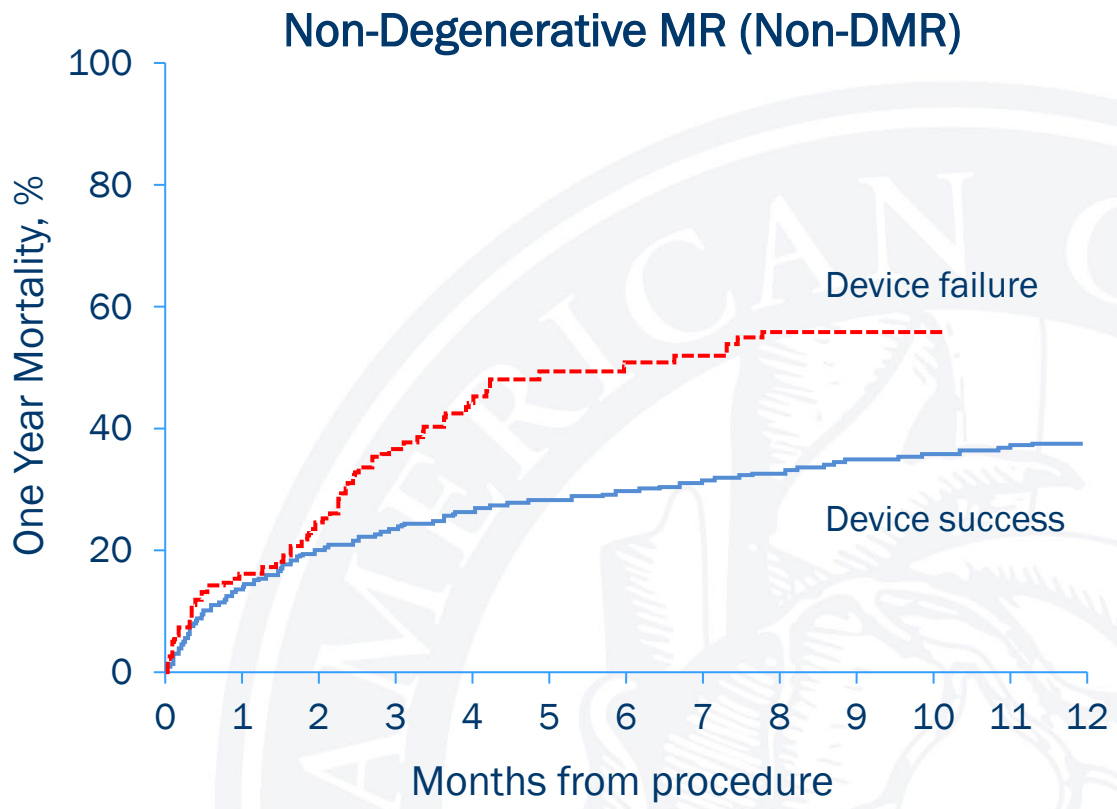
*Interaction analysis p value NS

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

Device Success and Outcomes by MR Etiology





Device failure	248	163	119	110	106	99	96	89	85	82	80	65	53
Device success	1290	979	778	733	709	694	680	665	651	635	626	579	465

Device failure	149	109	83	68	60	55	53	52	48	48	46	38	26
Device success	1044	807	632	685	562	544	534	521	510	494	484	444	356

STS/ACC TVT Registry™

*Interaction analysis p value NS

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY

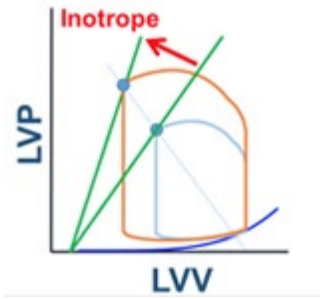
WF1299367-17

TEER for MR and Cardiogenic Shock
Limitations

- Reporting/coding cardiogenic shock
- Selection and immortal time bias
- No control arm (device failure used as control)
- Outcomes are site reported and not adjudicated
- Association with lower mortality ≠ causal effect of TEER

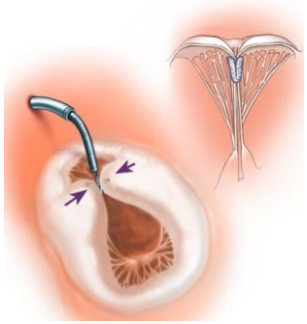
Conclusions

3,797 Patients in TVT Registry



Severe MR + Cardiogenic Shock

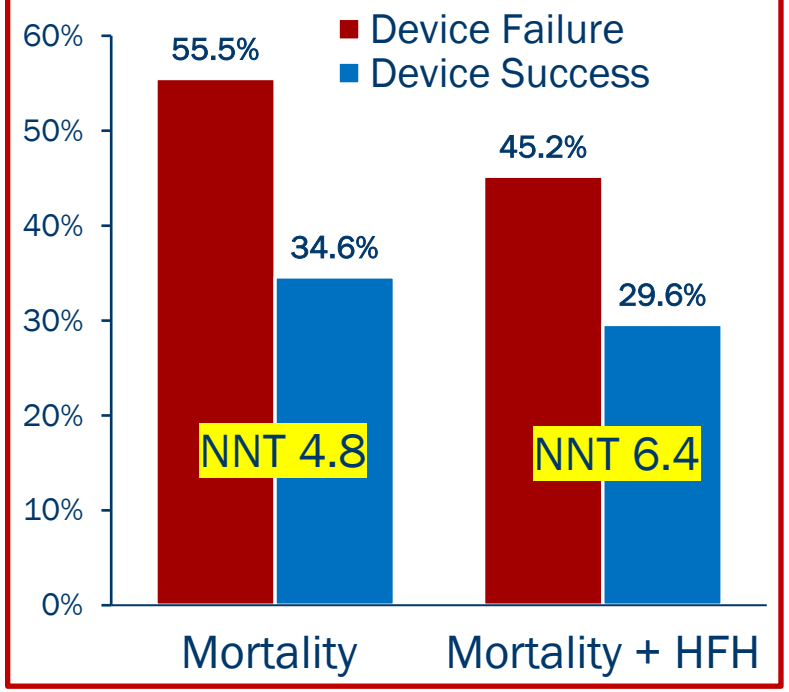
Transcatheter edge-to-edge repair



Device Success **85.6%**

Device Failure **14.4%**

1-Year Outcomes



- Successful MR reduction is achievable in most patients with CS and is associated with significantly lower mortality and HF hospitalization at 1-year.
- Randomized trials to clarify the role of TEER in CS are needed.

QUESTIONS & ANSWERS

STS/ACC TVT Registry™

The Society of Thoracic Surgeons

AMERICAN COLLEGE of CARDIOLOGY