ACC.20/WCC:

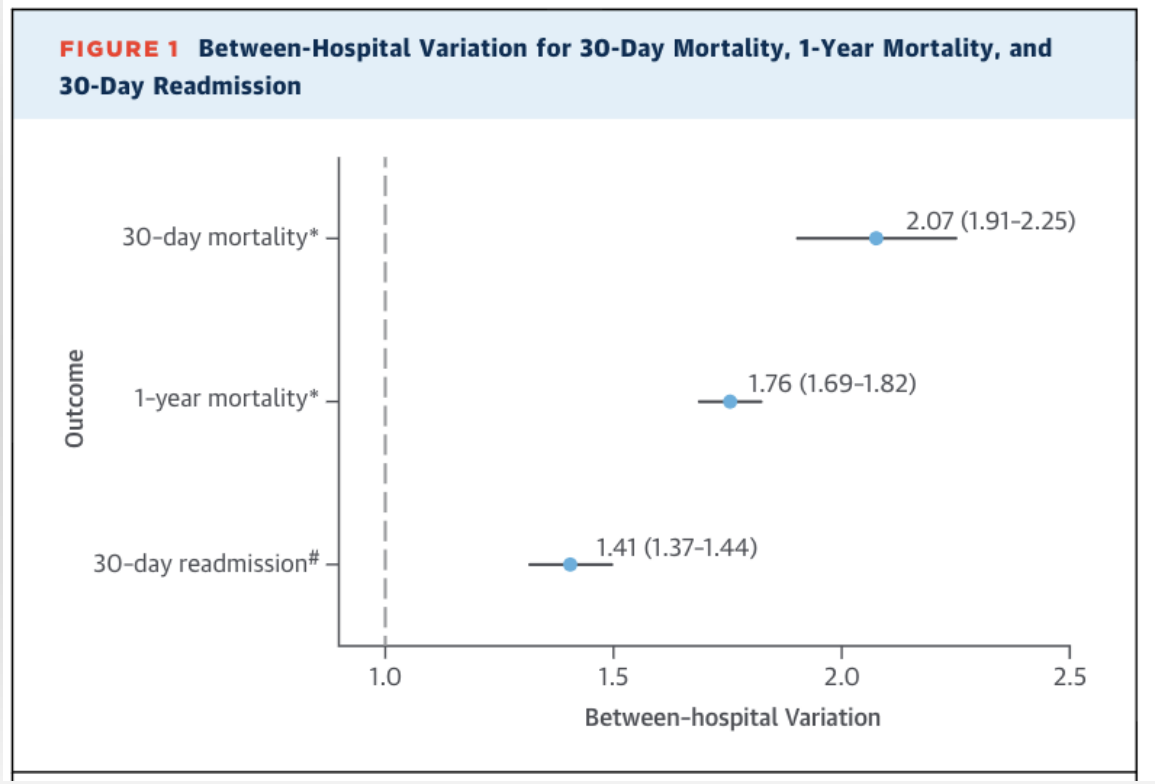
A Composite Metric For Benchmarking Site Performance In Transcatheter Aortic Valve Replacement: Results From The STS/ACC TVT Registry

Nimesh D. Desai MD PhD
On behalf of the STS/ACC TVT Registry Risk Modeling Subcommittee

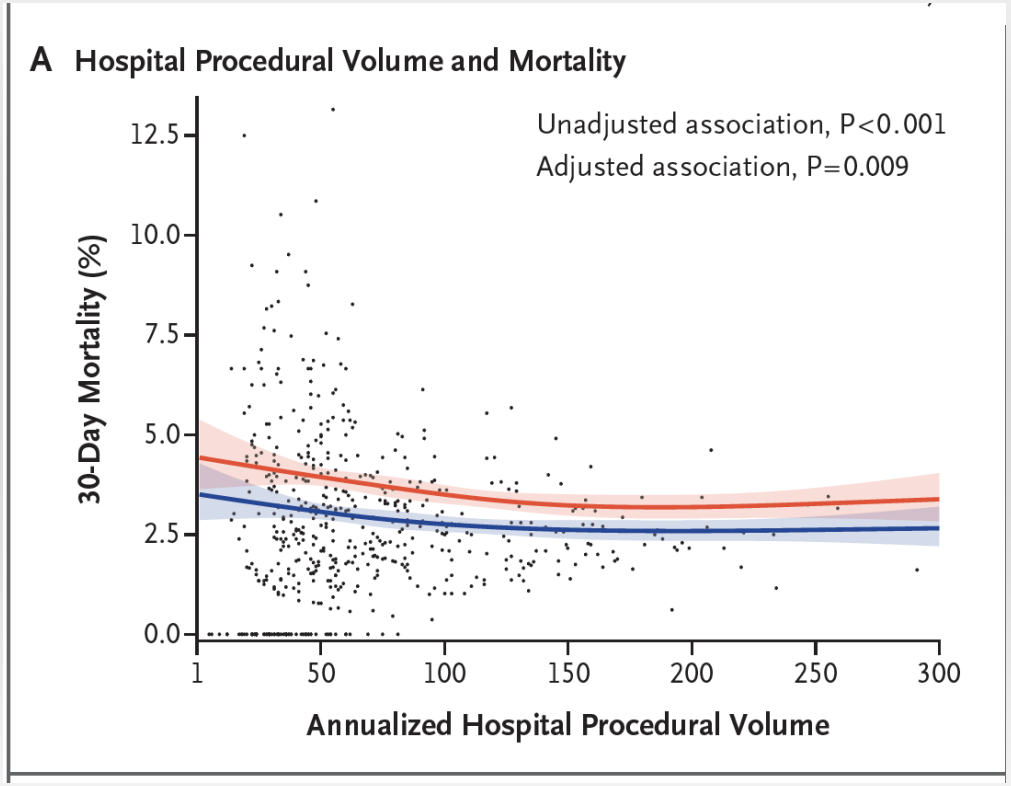
NCDR | STS National Database *Using data to drive quality* | STS/ACC TVT Registry™

TAVR Outcomes in the United States

Wide variation in TAVR mortality is occurring at the SITE level



Murugiah et al JACC 2015



Vemulapalli et al NEJM 2019

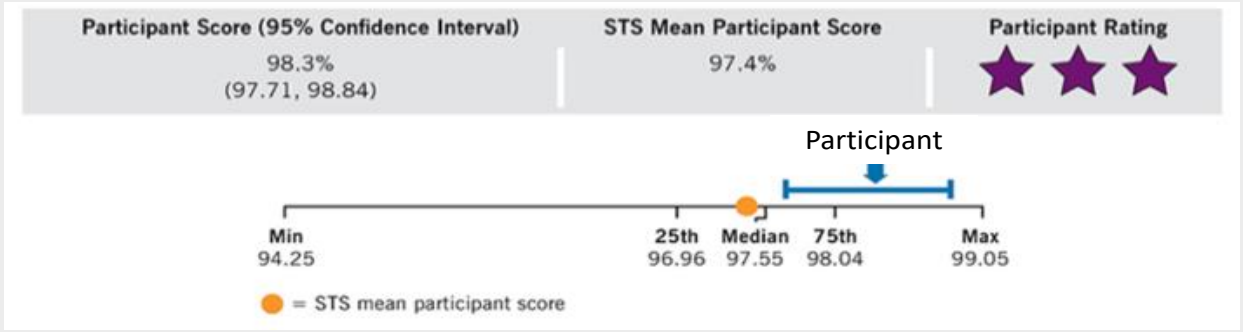
NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

Going Beyond Mortality Outcomes:

Why Develop a Composite Morbidity and Mortality Measure for TAVR?

- ***Patients care about outcomes beyond peri-procedural mortality***
  - ***Alive and Well with improved functional status and quality of life***
- Composite measures can summarize all available information about the quality of care delivered using high quality, validated clinical data
- Move away from surrogate measures of quality such as volume towards real clinical outcomes
- Concept is well established in CABG, Valve Surgery



NCDR | STS National Database — Using data to drive quality

STS/ACC TVT Registry™

Study Purpose

- *The purpose of this study was to determine if there is site-level variation in quality of care in TAVR in the United States using a novel patient-centric 30-day composite outcome measure.*

Key Features:

- Fatal and Non-Fatal Outcomes
- Robust, non-parsimonious
- Incorporating novel data elements such as gait speed and KCCQ
  - functional status, patient reported health status
- Highly patient-centric, meaningful endpoints
- Responsive to changes in patient populations and technologies

Methods: Patient Cohort

- All patients undergoing ***TRANSFEMORAL*** TAVR in the United States for symptomatic aortic stenosis between Jan 1, 2015 – Dec 31, 2017 were included from the STS/ACC TVT Registry
- Based on conventions established for the TVT 30-day mortality model, data from hospitals with >10% missing data for the outcome variable and other key study variables were excluded.

Derivation cohort of Composite Mortality and Morbidity Risk Model

Inclusion-Exclusion	Sites	Records
Inclusion: Index TAVRs procedures in patients discharged from 01JAN2015-31DEC2017	556	114121
Inclusion: Sites with >=90% completeness data for Ranked Endpoint, KCCQ-baseline and 5 m walk	301	54217
Inclusion: Ranked Endpoint status available	301	52561

NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

Methods: Development of Ranked Composite Outcome
Understanding what Matters to Patients

- The selection and rank order of the periprocedural complications for the composite was determined by their adjusted association with 1-year mortality and patient quality of life(KCCQ)
  - Not Expert Opinion, Delphi Process
- Any outcome with significant HR was maintained
- (New Pacemaker and Major Vascular complications were not significant)

	1-yr Mortality		***1-yr KCCQ-OS***	
30-day Non-fatal complications after TAVR	Adjusted Hazard Ratio	P-value	Adjusted Estimate	P-value
Any stroke	2.2(1.7,2.9)	<.001	-5.8 (-9.2,-2.4)	<.001
Major or Life-threatening/Disabling Bleed	1.9(1.4,2.6)	<.001	-.41 (-2.0,1.19)	0.619
Acute kidney injury (Stage III)	1.8(1.4,2.4)	<.001	-3.3 (-6.8,0.28)	0.071
Paravalvular Leak (Moderate/Severe)	1.5(1.2],1.8)	<.001	-2.0 (-3.8,-.30)	0.021

NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

TVT Risk Model Composite: Global Ranking of Endpoints

Death	• In-Hospital or 30-day mortality
Stroke	• In-Hospital or 30-day stroke
Bleed	• In-hospital or 30-day VARC major/life threatening/disabling bleed
AKI	• In-hospital of 30-day creatinine increase or 30 day new dialysis (AKI III)
PVL	• In-hospital or 30-day moderate/severe peri-valvular leak (PVL)
None	• None of the above

If a patient experienced multiple outcomes captured in the global rank composite measure, the outcome with the highest rank was assigned.

Results:
Morbidity and Mortality Composite Components

Frequency of Global Ranking Categories in Study Cohort

Endpoint Category	Number (N = 52,561)	Percent
1 = In-hospital/30-day death	1671	3.2%
2 = In-hospital/30-day stroke	1077	2.0%
3 = In-hospital/30-day VARC major/life threatening/disabling bleed	3024	5.8%
4 = AKI: In-hospital/30-day sig creatinine increase or new dialysis	336	0.6%
5 = In-hospital/30-day moderate/severe peri-valvular leak (PVL)	1304	2.5%
6 = None of the above	45149	85.9%

Primary End-point Assessment:

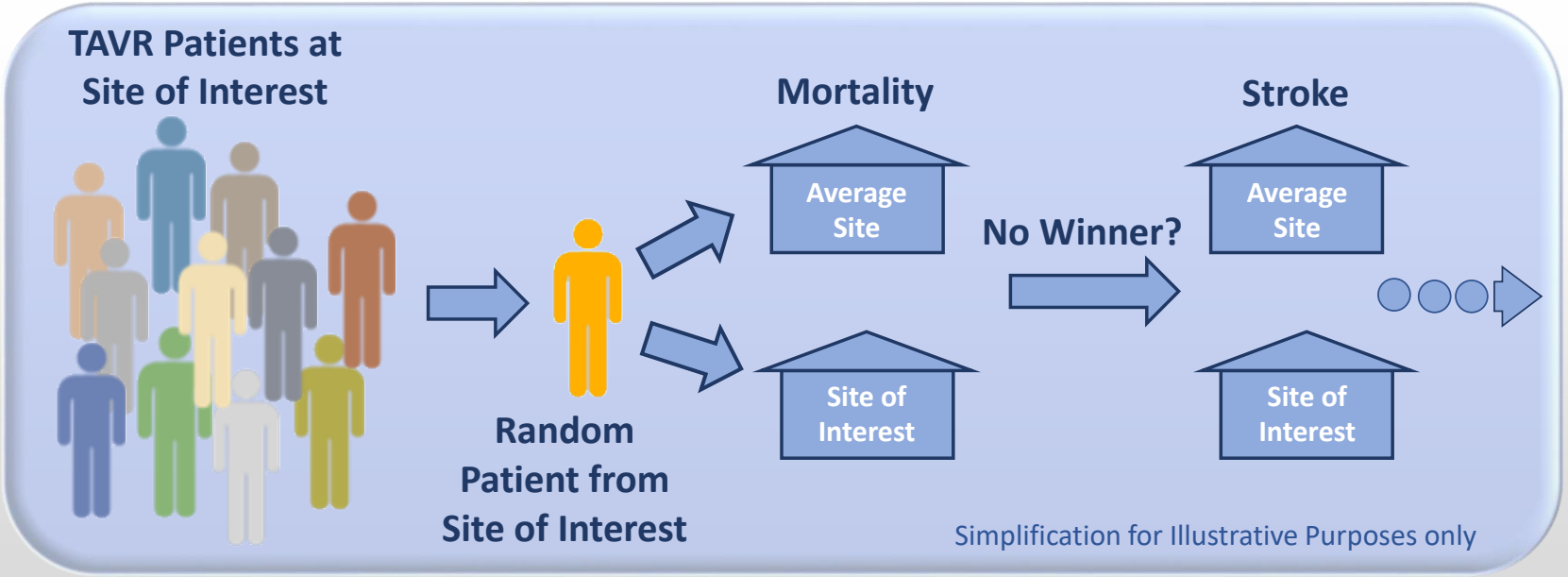
Overall Model:

Hierarchical multi-category logistic regression model which estimates a set of hospital-specific odds ratios

Site Difference

Novel metric incorporating elements similar to 'Win Ratio'

Risk Adjusted with 46 Covariates incl. Baseline KCCQ and Gait Speed



SITE DIFFERENCE =
pRandom Patient does Worse at Avg Hospital -
pRandom Patient does Better at Avg Hospital

Positive Site Difference is good, Negative Site Difference is bad.

Sites whose outcomes were outside 95% confidence intervals of the average sites were considered to be performing worse or better than expected. No prespecified outlier proportions.

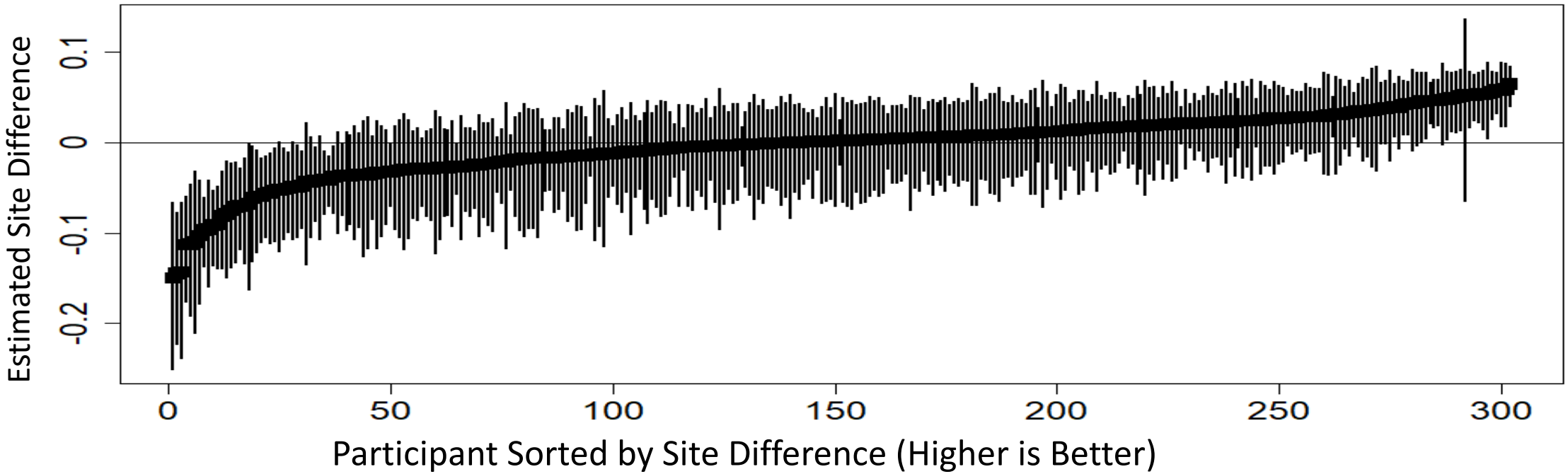
NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

Results: TVT Risk Model – Site Difference Morbidity and Mortality Composite (3 yr)

Number of Hospitals by Statistical Categorization Based on 95% Interval

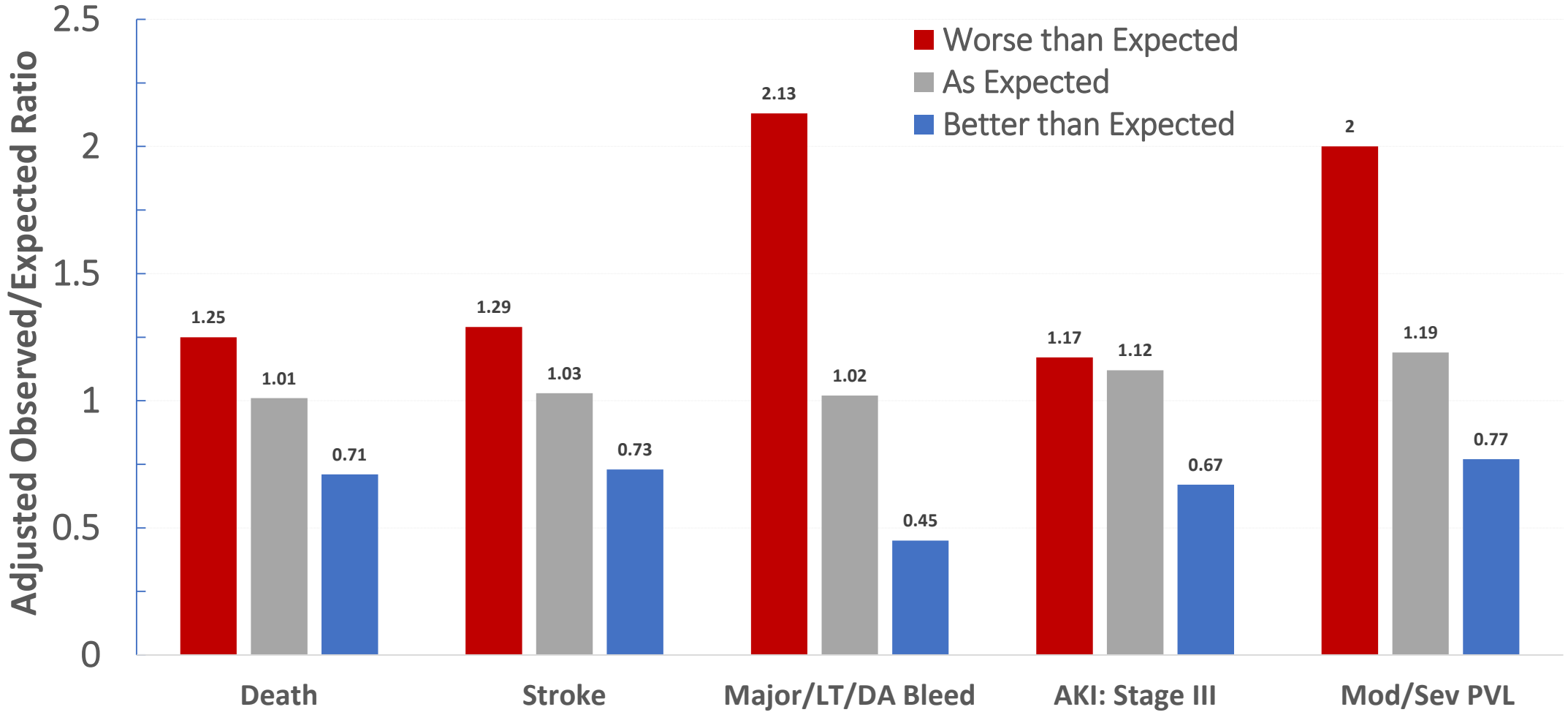
Worse Than Expected	As Expected	Better Than Expected
34 / 301 (11%)	242 / 301 (80%)	25 / 301 (8%)



NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

Validity: Risk Adjusted Outcomes by Site Status



NCDR

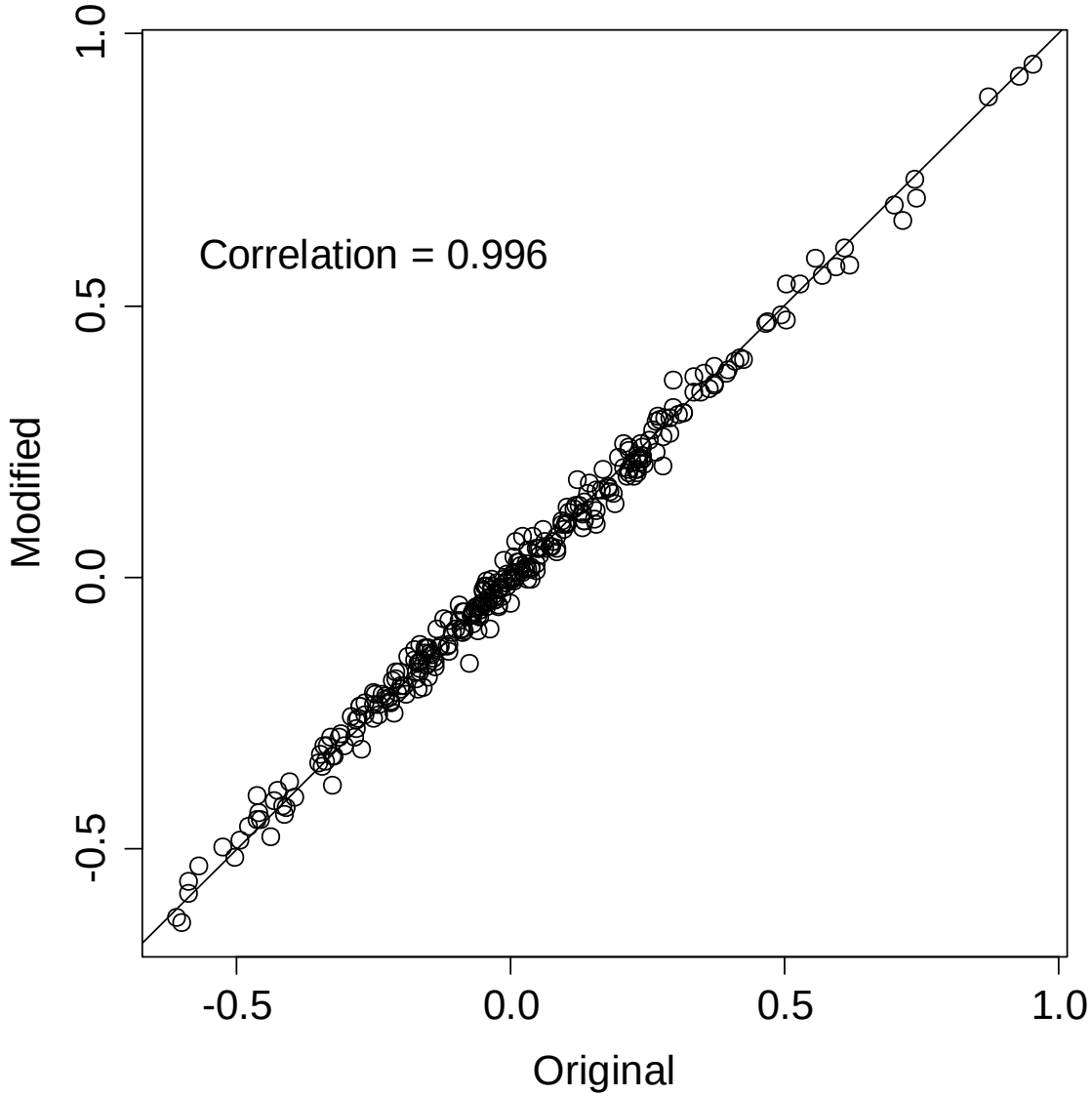
STS National Database
Using data to drive quality

STS/ACC TVT Registry™

Sensitivity Analyses: Remove KCCQ and Gait Speed

Eligible Centers in cohort: 301 to 447

1 of 301 Original Sites Change Star Category



Sensitivity Analyses: 3 State instead of 6 State model

Death

- **In-Hospital or 30-day mortality**

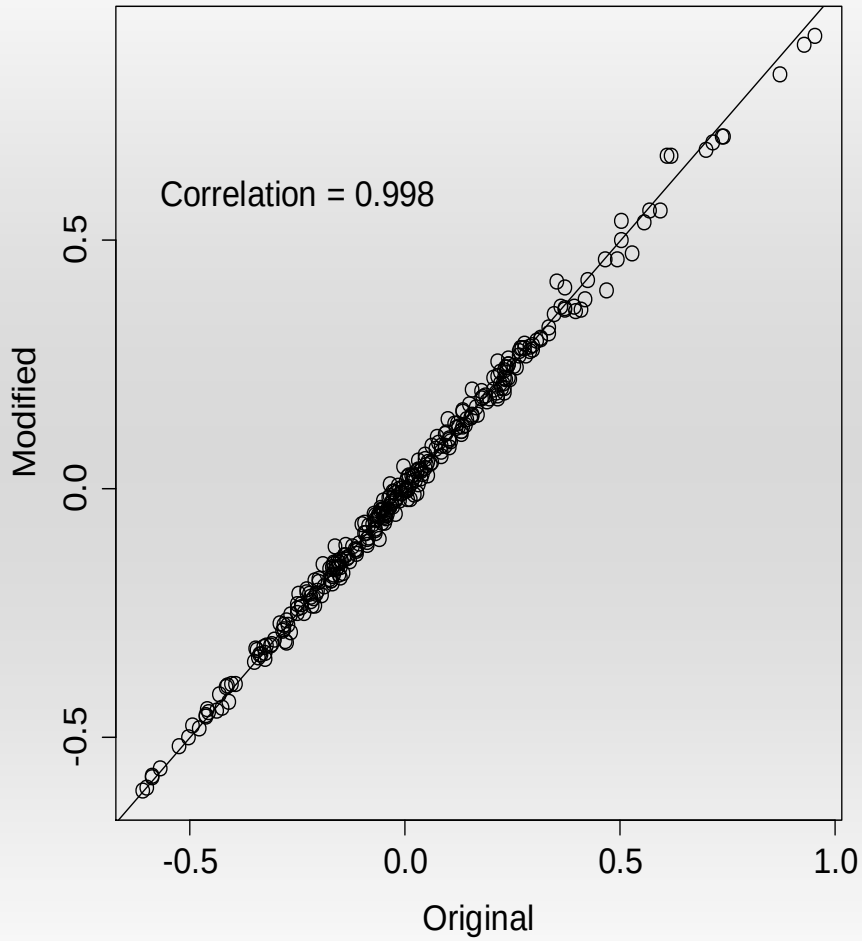
Major Comp

- **In-Hospital or 30-day major complication**

None

- **None of the above**

2 of 301 Sites Change Star Category



NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

Reliability Testing

- Reliability: A measure of how well one can confidently distinguish the performance of one site from another (Signal to Noise)
- There are three main drivers of reliability: sample size, differences between sites, and measurement error.

Value below 0.5 indicates poor reliability

Value above 0.5 indicates acceptable reliability

Values above 0.7-0.8 are desirable

Potential Causes of Poor Reliability:

- **Low Event Rates**
- **Short Periods of Observation(1-3 years of data)**
- **Programs with Small Sample Size**
- **Limited Variation in Outcomes b/w Programs**

Estimated reliability as a function of volume threshold for reporting

Hospital TAVR Volume	Outcome Measure	
	30-Day Mortality	30-Day Mortality and Morbidity Ranked Composite
Hospitals with at least 10 cases	0.14	0.58
Hospitals with at least 25 cases	0.17	0.62
Hospitals with at least 50 cases	0.19	0.67
Hospitals with at least 75 cases	0.22	0.71
Hospitals with at least 100 cases	0.26	0.74
Hospitals with at least 200 cases	0.34	0.82
Hospitals with at least 500 cases	0.50	0.89

Derived from Monte Carlo Simulation

How does the model perform with contemporary data?

Jan 1, 2015 to Dec 31, 2017

Endpoint Category	Number	Percent
Death	1671	3.2%
Stroke	1077	2.0%
VARC Major or LT/Disabling Bleed	3024	5.8%
AKI (Stage III)	336	0.6%
Moderate/Severe peri-valvular leak	1304	2.5%
None of the above	45149	85.9%

Worse Than Expected	As Expected	Better Than Expected
34 / 301 (11%)	**242 / 301 (80%)**	**25 / 301 (8%)**

Jan 1, 2018 to Jun 30, 2019

Endpoint Category	Number	Percent
Death	1307	2.6%
Stroke	1009	2.0%
VARC Major or LT/Disabling Bleed	2513	5.0%
AKI (Stage III)	250	0.5%
Moderate/Severe peri-valvular leak	625	1.2%
None of the above	45037	88.8%

Worse Than Expected	As Expected	Better Than Expected
34/373 (9%)	**328/373 (88%)**	**11/373 (3%)**

NCDR | STS National Database *Using data to drive quality*

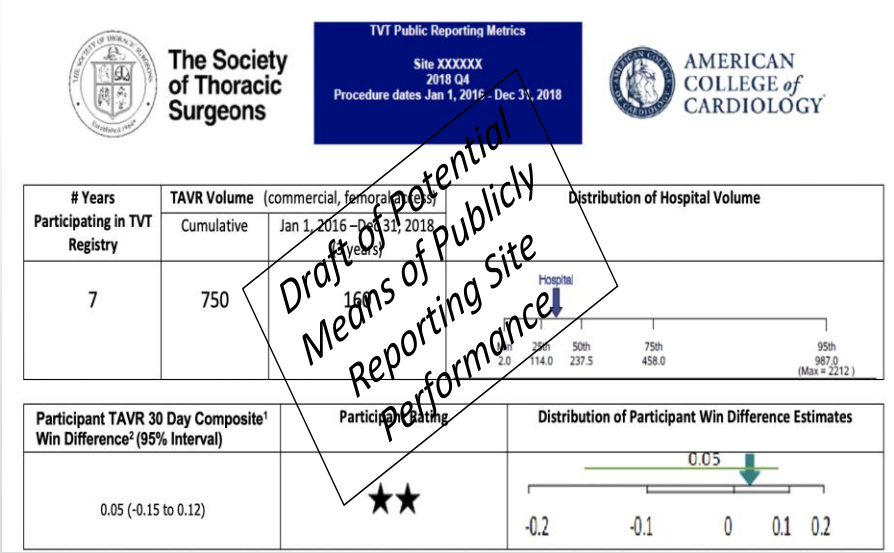
STS/ACC TVT Registry™

Limitations

- This analysis does not examine quality of care in patients who underwent TAVR using non-femoral access
- Missing baseline KCCQ-12 and gait speed data limited the number of sites included in this analysis.
  - Sensitivity analyses showed that exclusion of these variables did not meaningfully change the categorization of sites
  - significant educational efforts are being made to improve compliance and the inclusion of these variables within the TVT registry remains ***mandated*** by CMS.
  - **2019: 92% completeness for KCCQ**

Conclusions

- We developed a novel patient-centric composite outcome for TAVR based on 30-day outcomes and their ranked association with both 1-year mortality and quality of life.
- We have identified significant site-level variation in mortality and major complications after TAVR procedures in the United States.
- The model demonstrated excellent performance including internal validity and moderate to high reliability even when including lower-volume programs
- This 30-day composite metric is appropriate for high-stakes applications such as public reporting.



STS/ACC Registry Risk Modeling Subcommittee:
Chairs: Nimesh D. Desai MD PhD, David J Cohen MD MSc
Members: John Carroll MD, Sreekanth Vemulapalli MD, Sean O'Brien PhD, John Forrest MD, Vinod Thourani MD, Ajay Kirtane MD, Brian O'Neil MD, Pratik Manandhar MD, David Shahian MD, Vinay Badhwar MD, Suzanne V Arnold MD MHA, Joseph E Bavaria MD
ACC/STS Staff: Carole Crohn, Joan Michaels, Susan Fitzgerald, Donna Macdonald

NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™