Relationship Between Procedure Volume and Outcome for Transcatheter Aortic Valve Replacement in U.S. Clinical Practice:

Insights from the STS/ACC TVT Registry

Sunday, April 3, 2016, 11:45 am

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STS/ACC TVT Registry™

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Disclosures

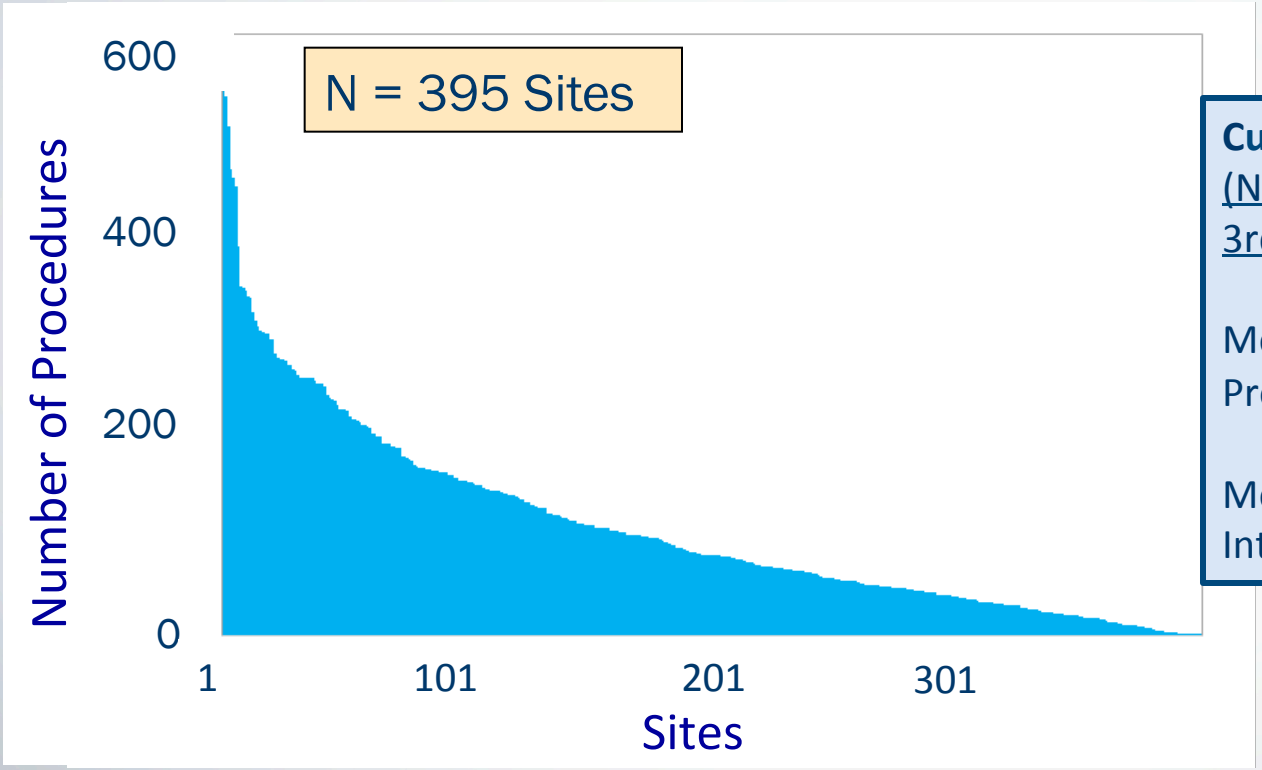
John D. Carroll, MD

- Direct Flow (Clinical Trial Agreement)
- Edwards LifeSciences (Clinical Trial Agreement)
- Medtronic (Clinical Trial Agreement)
- Tendyne (DSMB & CEC)

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.*

There is a Wide Range of TAVR Volumes in US Practice



Cumulative Volume
(November 2011 thru
3rd Quarter 2015)

Mean ± Std Dev = 108.8 ± 96.7 Procedures

Median = 80 Procedures
Interquartile Range = 39 – 154

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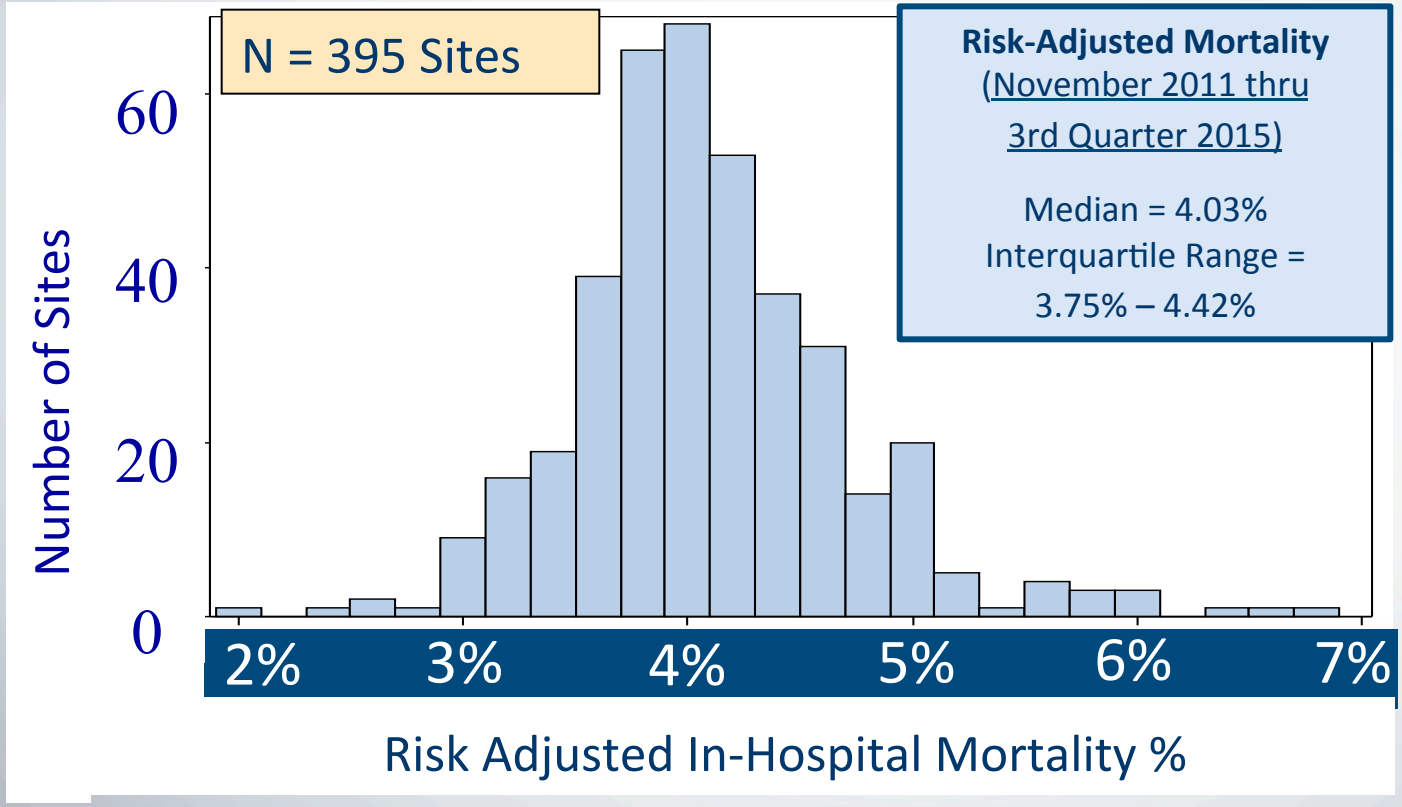
There is a Range of TAVR Mortality in US Practice



Risk Adjustment:

Using variables from the previously developed TVT in-hospital mortality model.

Edwards et al. JAMA Cardiology 2016.

Purpose of Study

To examine the possible relationship between cumulative TAVR volume and in-hospital outcomes in clinical practice in the United States.

Background

The National Coverage Determination (NCD) from the Centers for Medicaid & Medicare Services (CMS) specifies that reimbursement for TAVR is restricted to hospitals meeting specific qualifications.

- Minimum volumes are required for selected procedures and surgical operations – i.e. ***it was presumed that volume was a key determinant of outcomes for TAVR.***

Patient Cohort

Data Source:

STS-ACC TVT Registry: TAVR Module

Time Frame:

November 2011 thru 3rd Quarter 2015

All Commercial TAVR Cases:

Using FDA Approved Technologies

Start Population: n = 47,270 Patients

Final Population n = 42,988 Patients

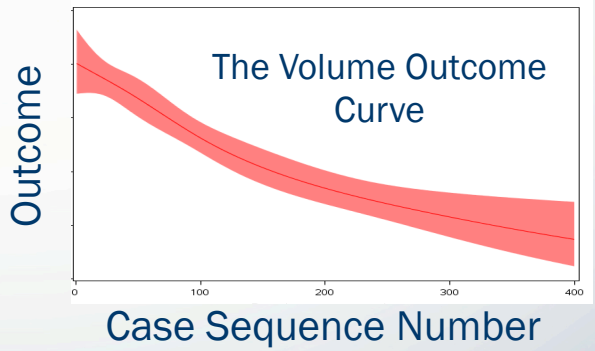
Exclusions:

Primary AI: 274, Bicuspid Valves: 862, Failed Bioprosthetic Valve, Prior SAVR/ TAVR, and Valve-in-Valve Procedures: 2,839, Emergent, Salvage Procedures: 66, Repeat TAVR Procedures 241

The Case Sequence Approach to Volume Stratification-tion

Hospital	Total procs	'11 q4	2012	2013	2014	2015
A	500					
B	120					
C	70					
D	65					
E	30					
F	20					

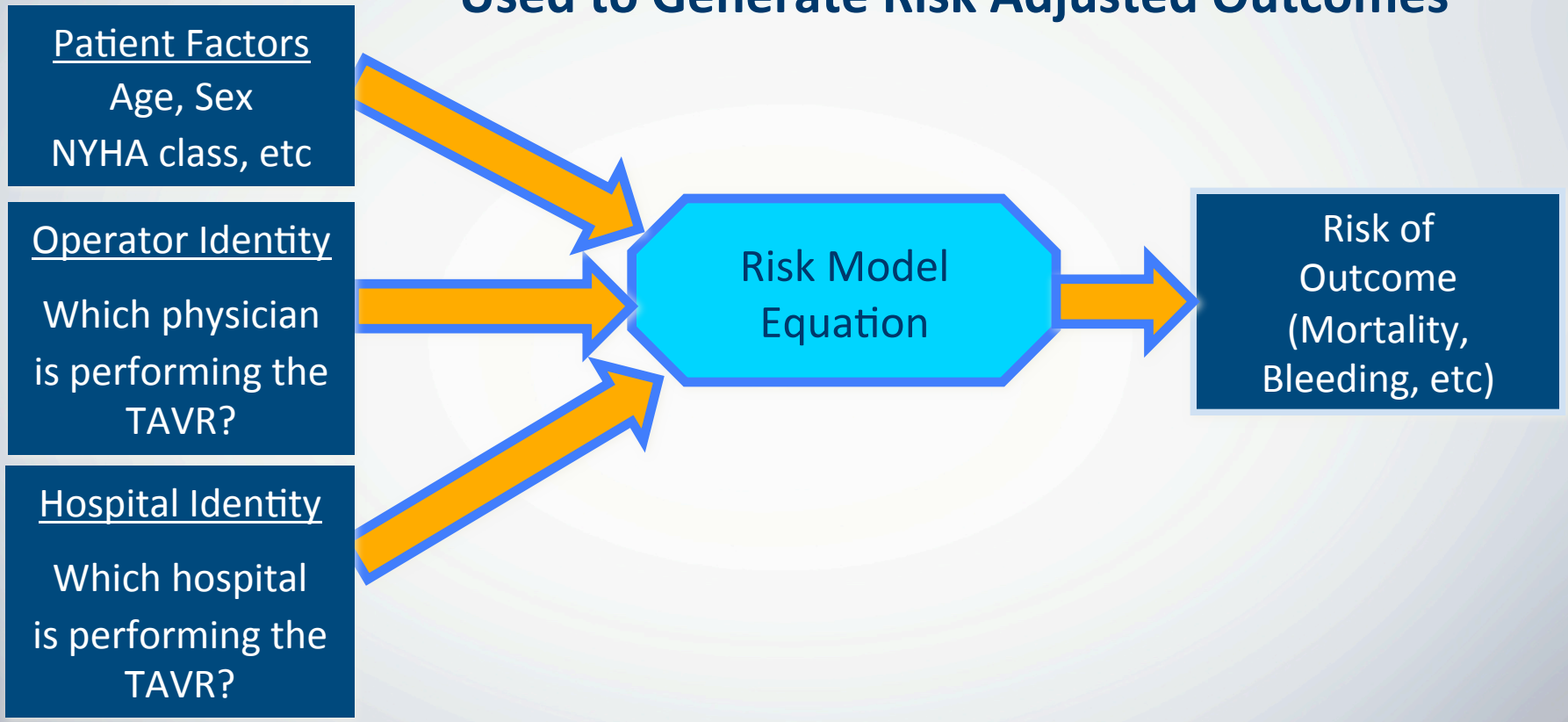
Case Sequence Quartiles	Hospitals A
1-30	√
31-71	√
72-137	√
138-602	√



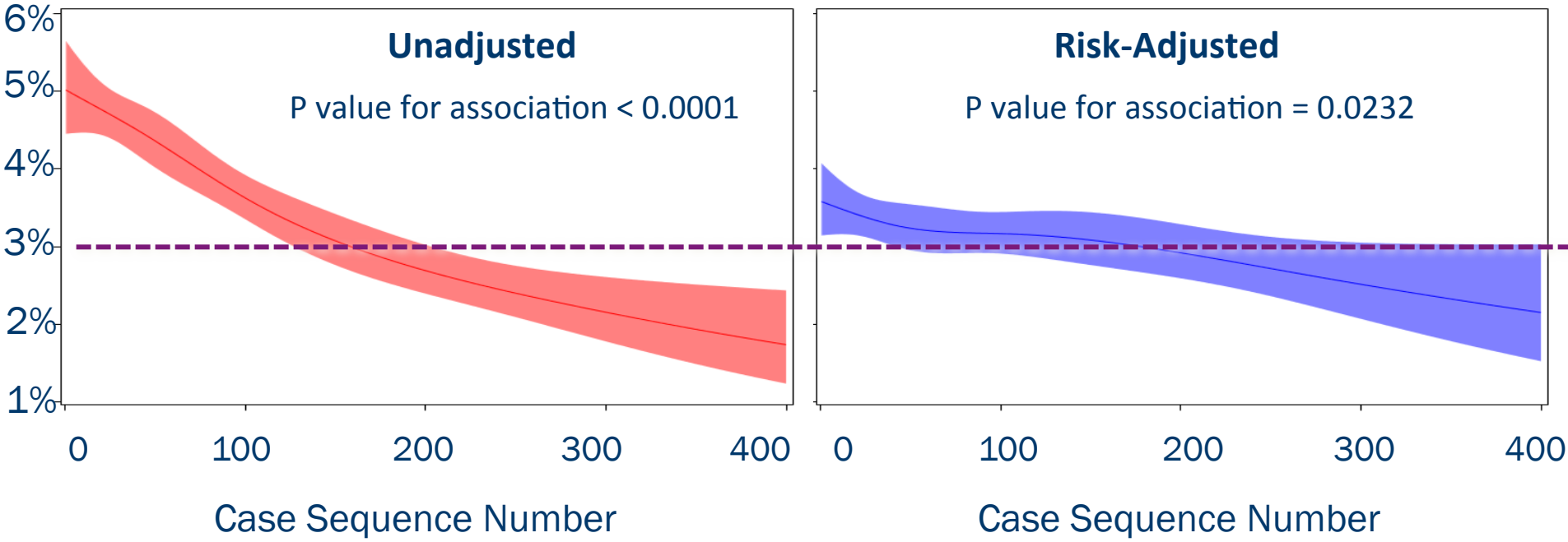
Overview of Case Sequence Categorization

Case Sequence	1-30	31-71	72-137	138-602
Sample size	10,653	10,880	10,676	10,770
Hospitals	395	319	215	119
Timeframe Range	Nov 9, 2011- Nov 12, 2015	Mar 13, 2012 - Nov 16, 2015	Jun 25, 2012 - Nov 12, 2015	Jan 11, 2013 - Nov 13, 2015
Median Timeframe	Jun 18, 2013	Apr 18, 2014	Oct 15, 2014	Mar 19, 2015
Patient Age Median (25th, 75th)	84 (78,88)	84 (78,88)	83 (77,88)	83 (77,88)

Three-Level Hierarchical Model Methodology Used to Generate Risk Adjusted Outcomes



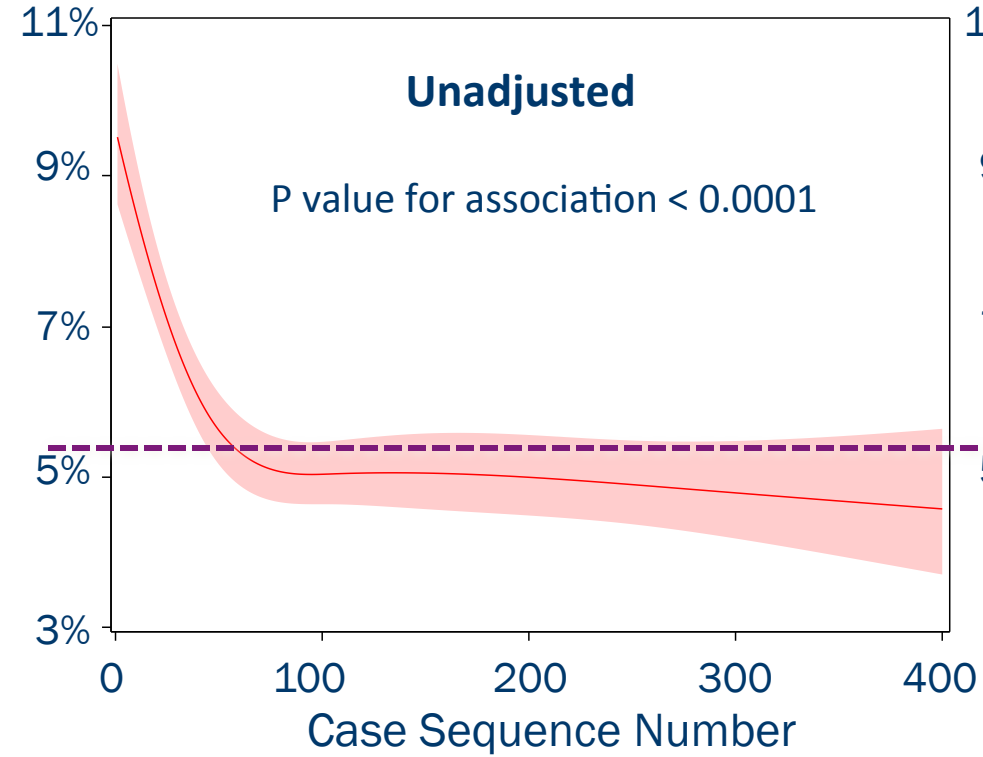
In-Hospital Mortality

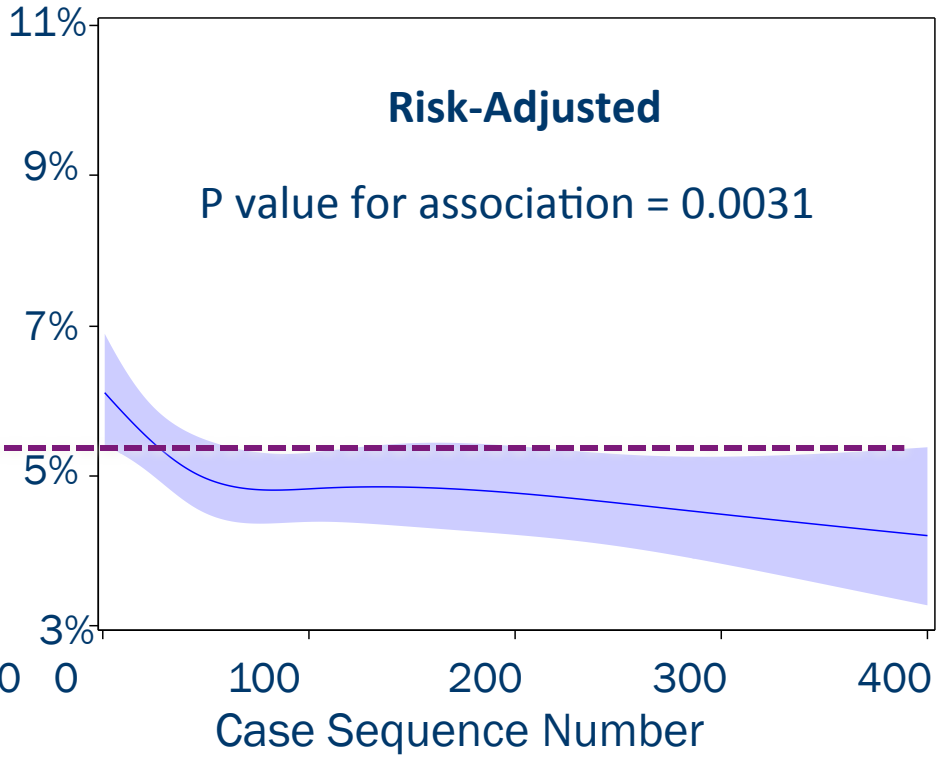


95% Confidence limits represented by colored bands

Vascular Complications

Unplanned vascular surgery for vascular complication, RP bleed, major or minor vascular access site complication

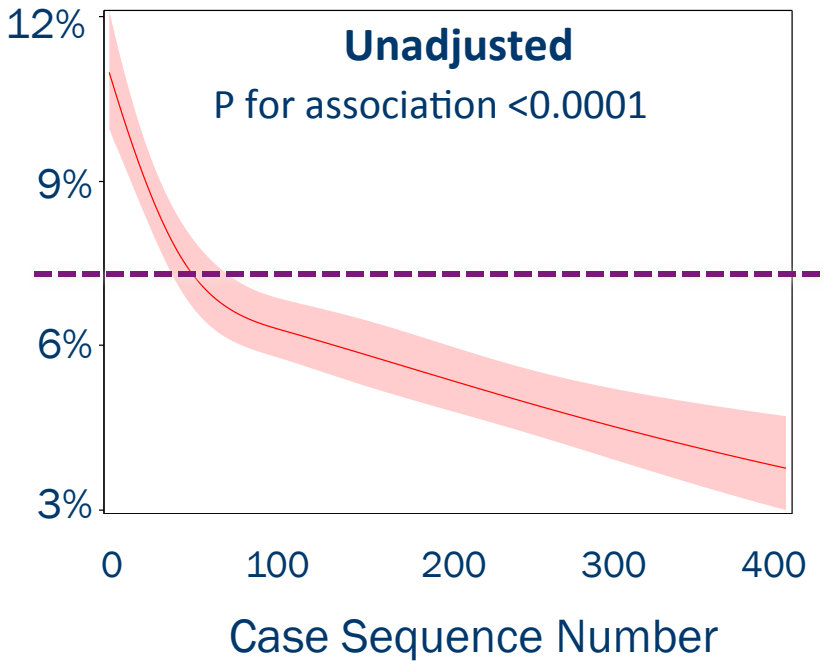


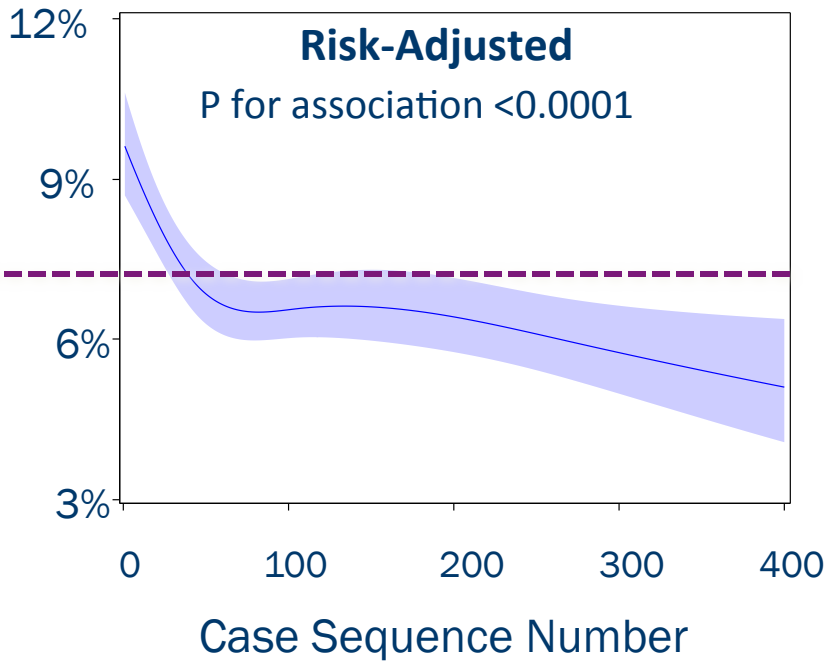


Risk-adjusted algorithm incorporates relevant TVT data elements such as sheath size, TF access versus alternative access, etc.

Bleeding Complications

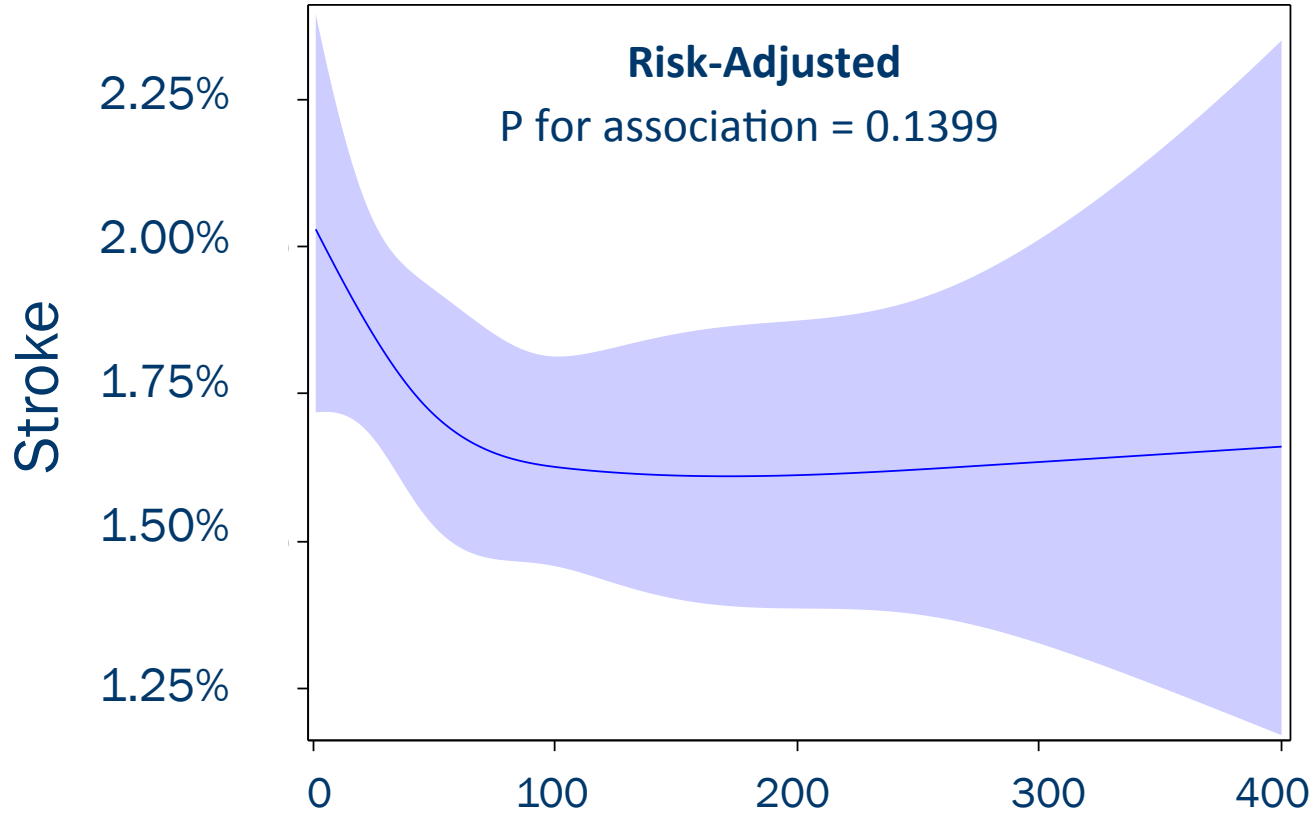
VARC Major Bleeding or VARC Life-Threatening Bleeding





Risk-adjusted algorithm incorporates relevant TVT data elements.

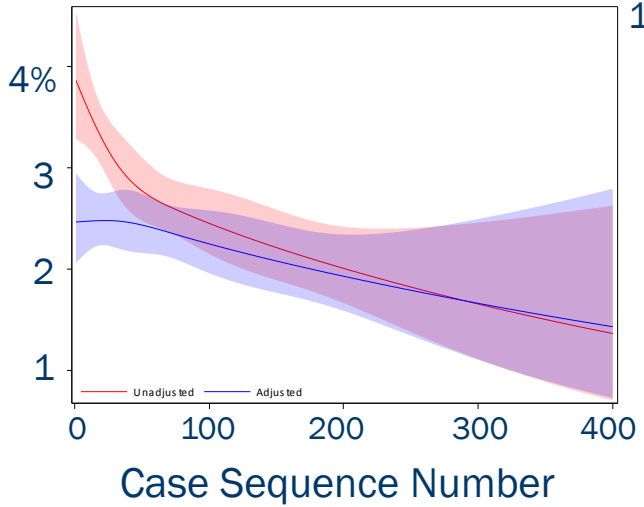
Stroke Complication



Transfemoral Population

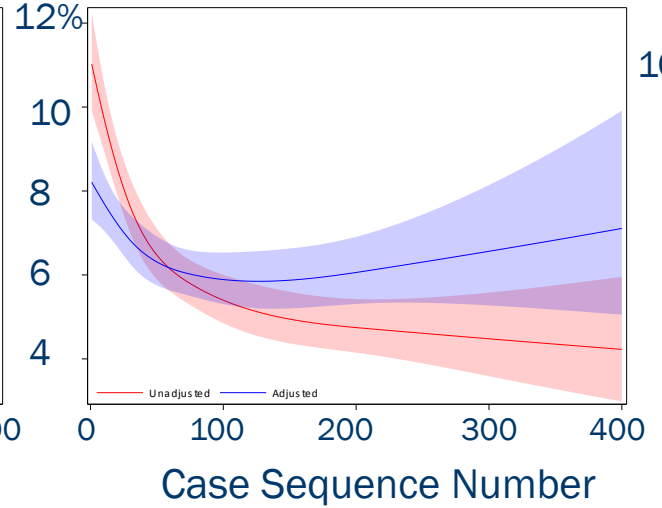
In-Hospital Outcomes - Volume

Mortality



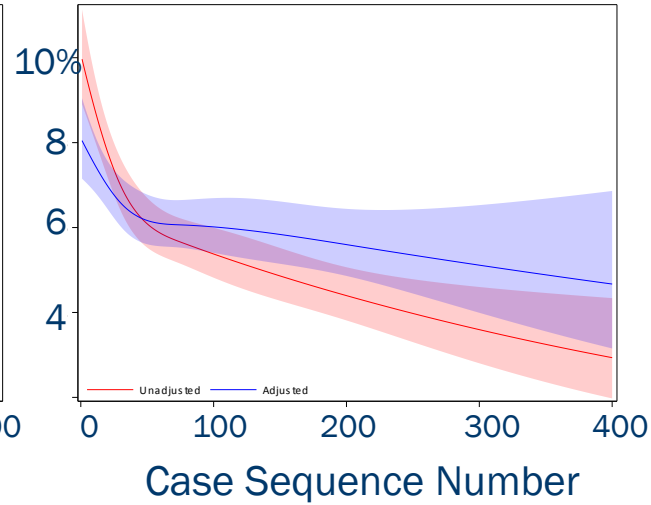
P Value for Association
Unadjusted < 0.0001
Adjusted = 0.1494

Vascular Complications



P Value for Association
Unadjusted < 0.0001
Adjusted < 0.0001

Bleeding Complications



P Value for Association
Unadjusted < 0.0001
Adjusted < 0.0001

Limitations

- This is an observational study.
- Analysis of the volume-outcome relationship is complex.
- A relationship between outcomes and volume does not prove causality and there is a potential for unmeasured confounding.
- Only the risk-adjustment model for the in-hospital mortality outcome has been validated and published.
- Changes in TAVR technology were adjusted in this analysis with a "time from November 2011" variable.
- The TVT Registry captures commercial not research cases. An attempt to adjust for research case volume for some sites was not feasible.
- TAVR in US is a recently introduced treatment and therefore does not represent a "steady state" of experience, technology, or technique.

Conclusions

The STS-ACC TVT Registry provides important insights into transcatheter therapy during its introduction into US clinical practice:

1. **TAVR outcomes have substantially improved with increasing TAVR volume in the United States.**
2. **The volume-outcome relationship for TAVR is both statistically significant and clinically important.**
    - **True for multiple clinically meaningful outcomes analyzed.**
    - ***cum hoc ergo propter hoc:* an association does not prove causality.**
    - **Yet the relationship did persist after adjustments for patient characteristics and time as a surrogate for evolving TAVR technology.**

Conclusions

3. The learning curve and the volume-outcome relationship are intertwined in TAVR.
   - The *early period* ("learning curve"), at low site volumes, has the steepest relationship for some outcomes.
   - The *later period,* after achieving modest volumes (>100 cases), shows further improvement in outcomes. The confidence limits are broad at high volumes.
4. These results can inform decisions regarding optimizing TAVR in the US health care system.

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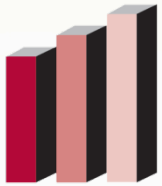

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