TVT Registry

for Raj Makkar, MD

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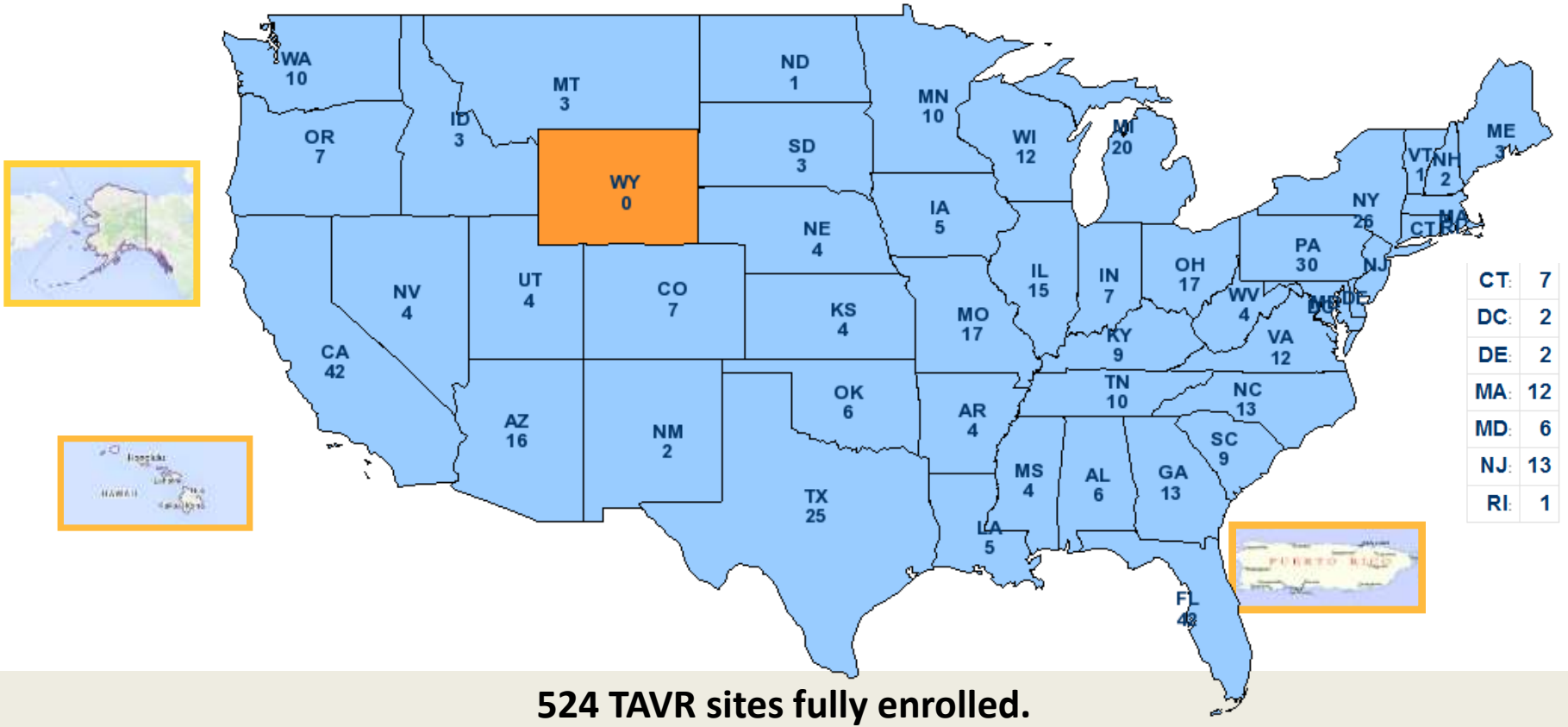
NATIONAL CARDIOVASCULAR DATA REGISTRY

Sites Participating in the STS/ACC TVT Registry



524 TAVR sites fully enrolled.

212 sites performing MitraClip Procedures

98 Mitral Replacement Sites

TAVR Centers in North America

Alaska: 1
Hawaii: 1

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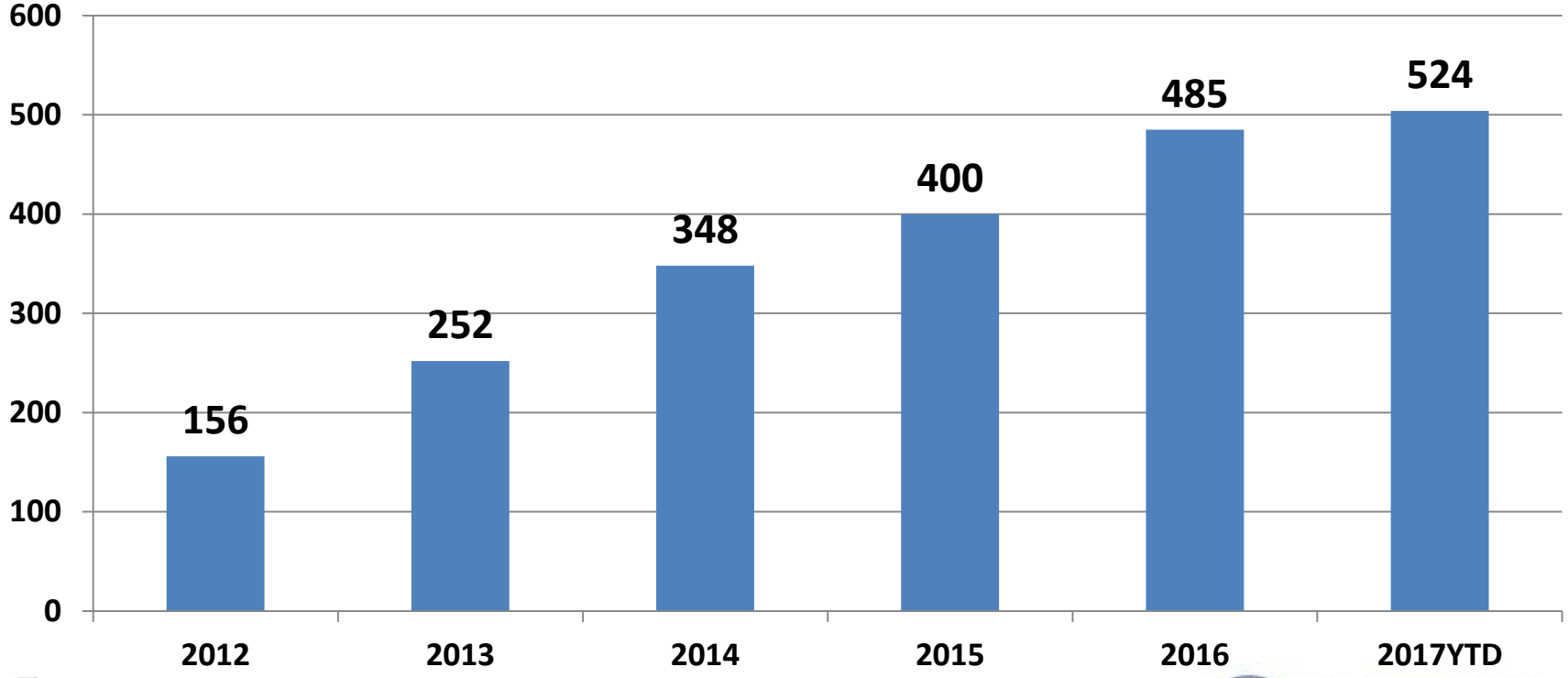
Sites Enrolled in TVT Registry as of June 13, 2017



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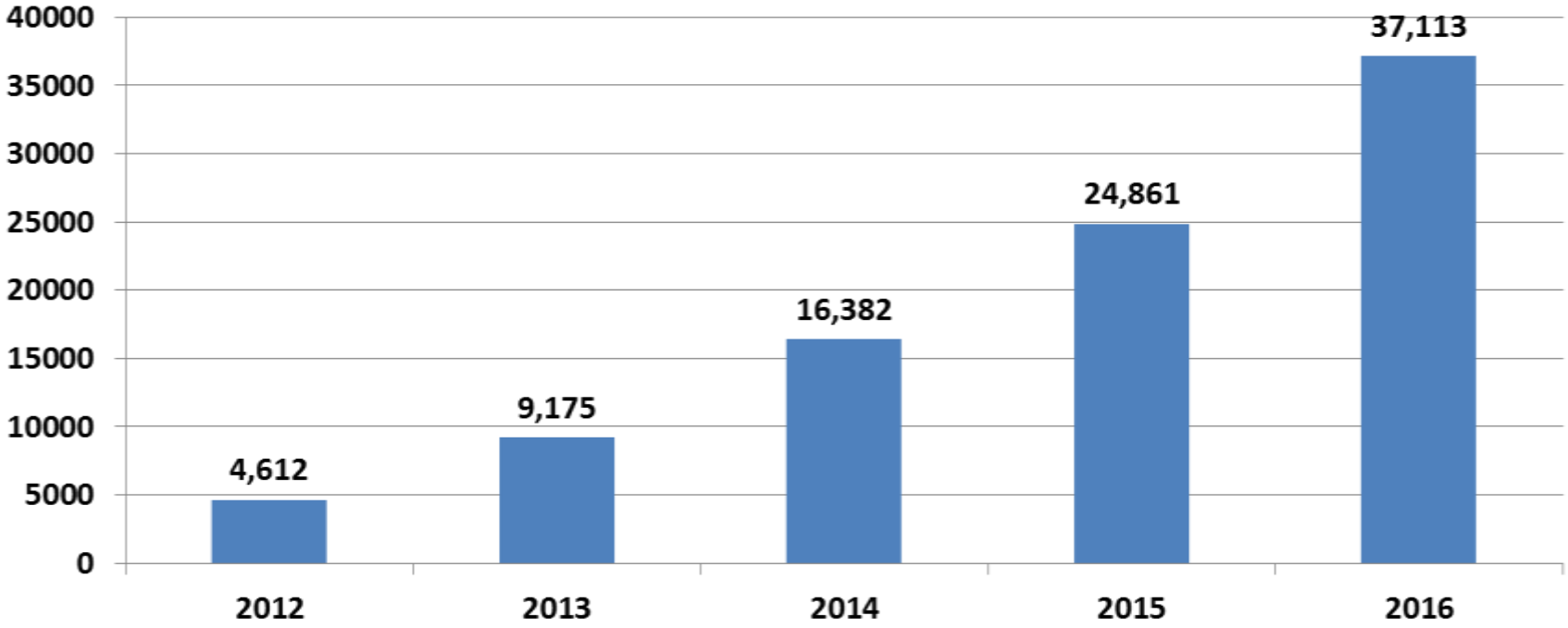
TAVR Volume



Source: STS/ACC TVT Registry Database.
as of April 10, 2017

As of April 2017

Over 101,264, Patients in US Have Received FDA Approved TAVR Therapy

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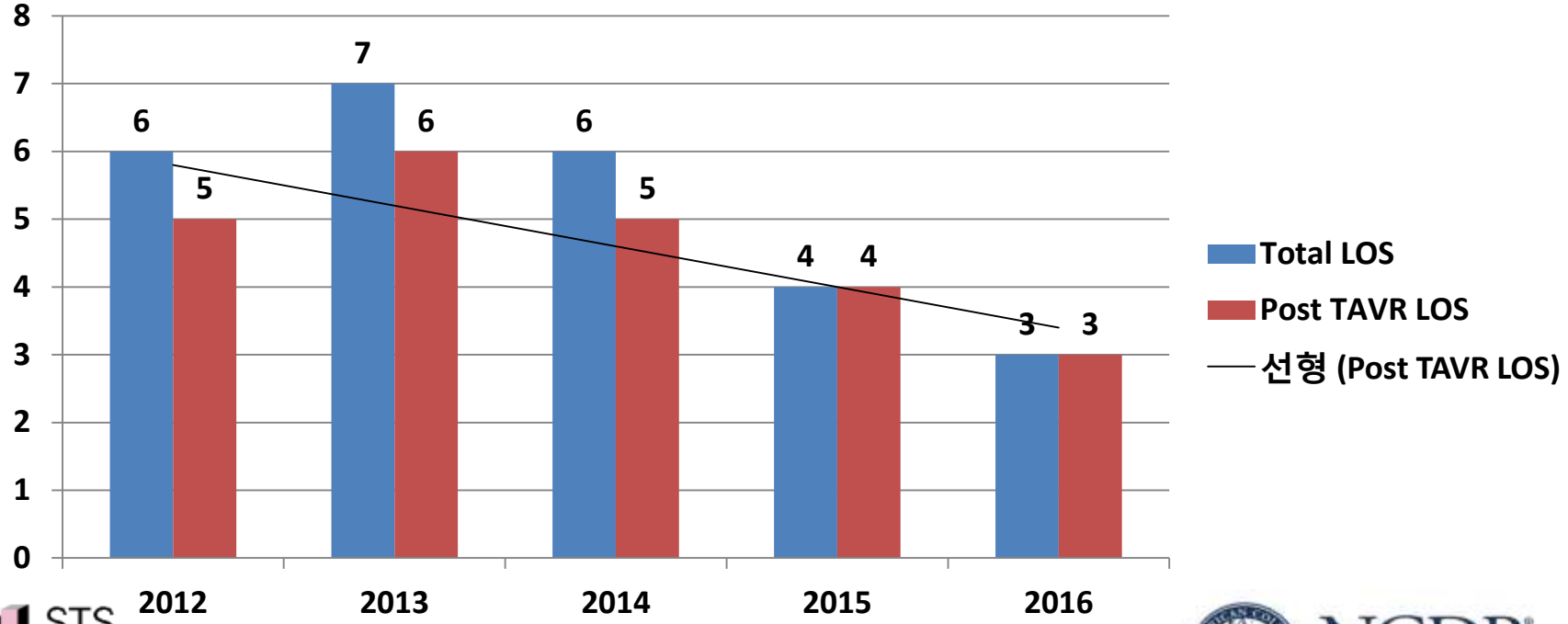
TAVR Median LOS (Days)



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Source: STS/ACC TVT Registry Database
as of April 10, 2017

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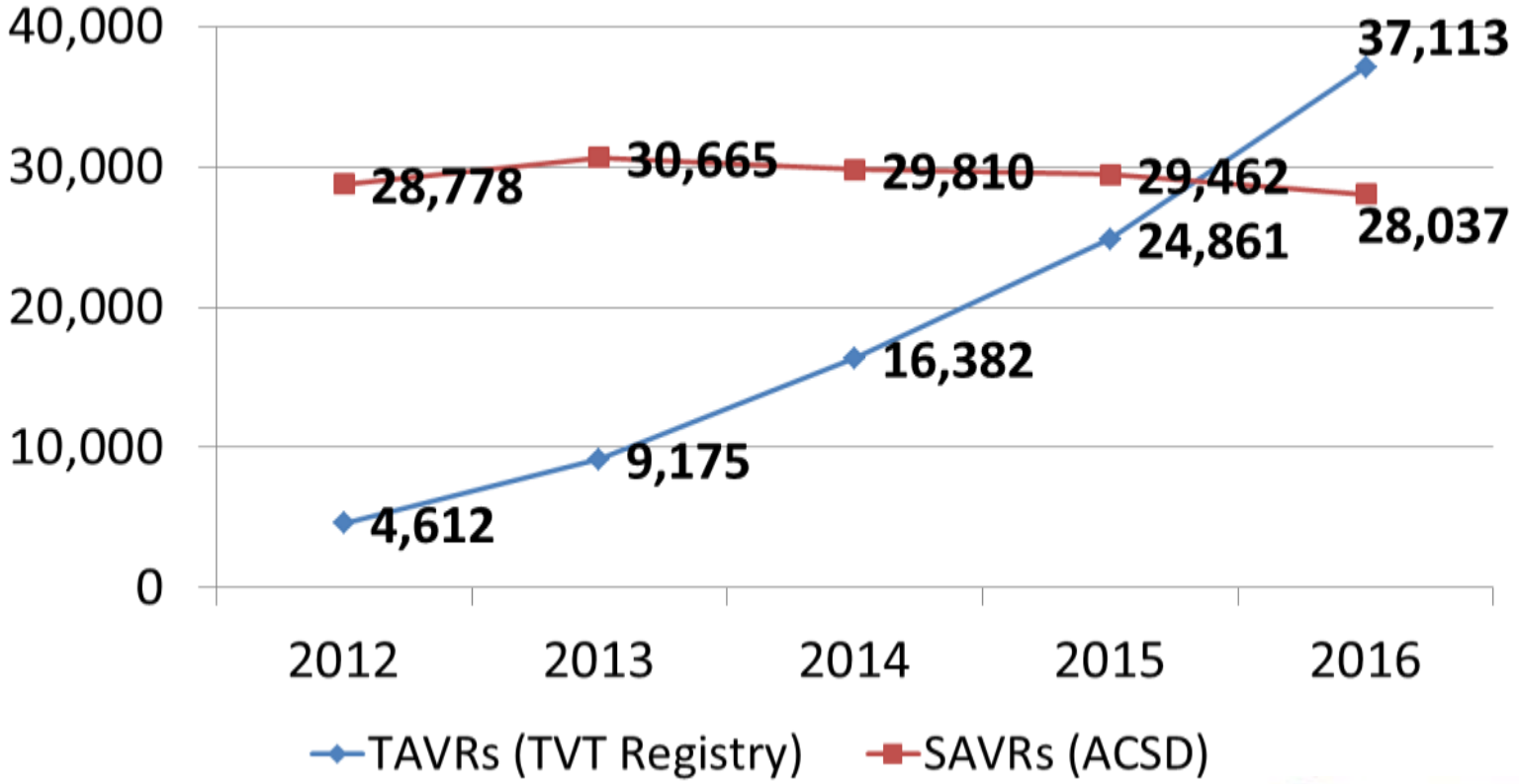
TAVR and SAVR* Procedures In the TVT Registry and STS ACSD*



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Source: STS/ACC TVT Registry Database and STS Database
2017

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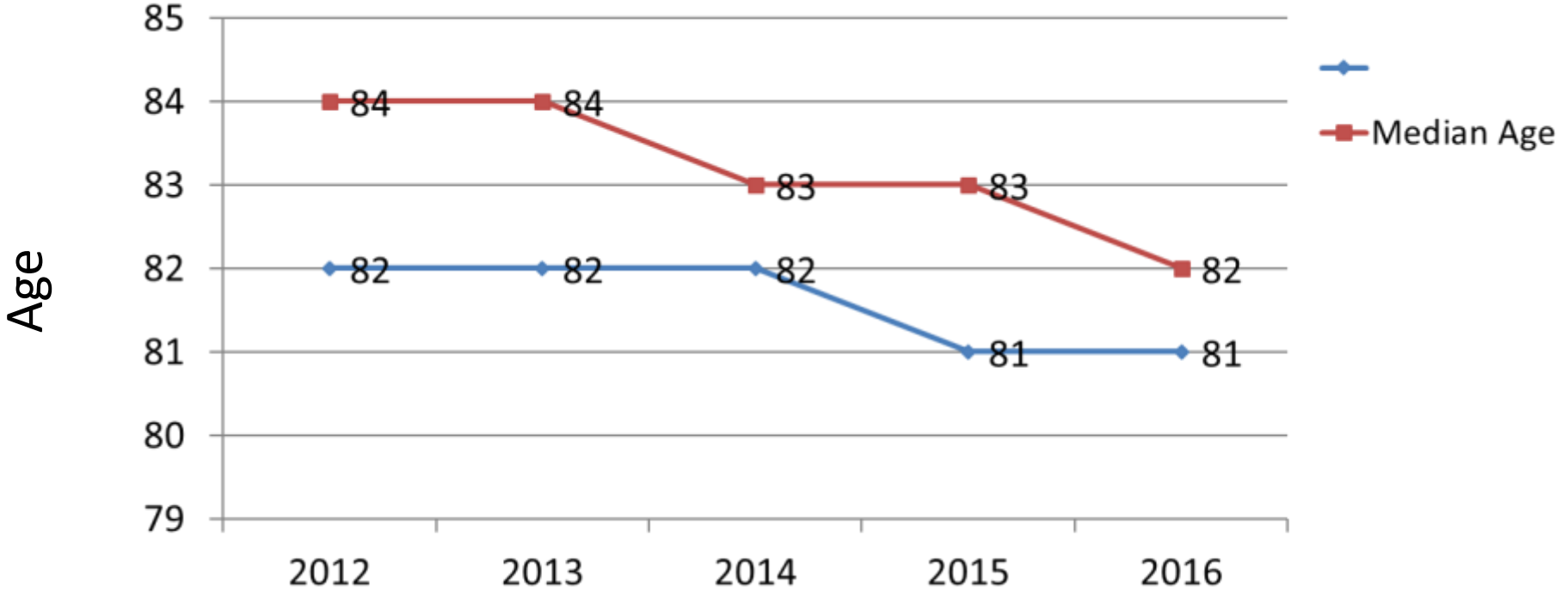
TAVR: Mean and Median Age



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Source: STS/ACC TVT Registry Database.
as of April 10, 2017

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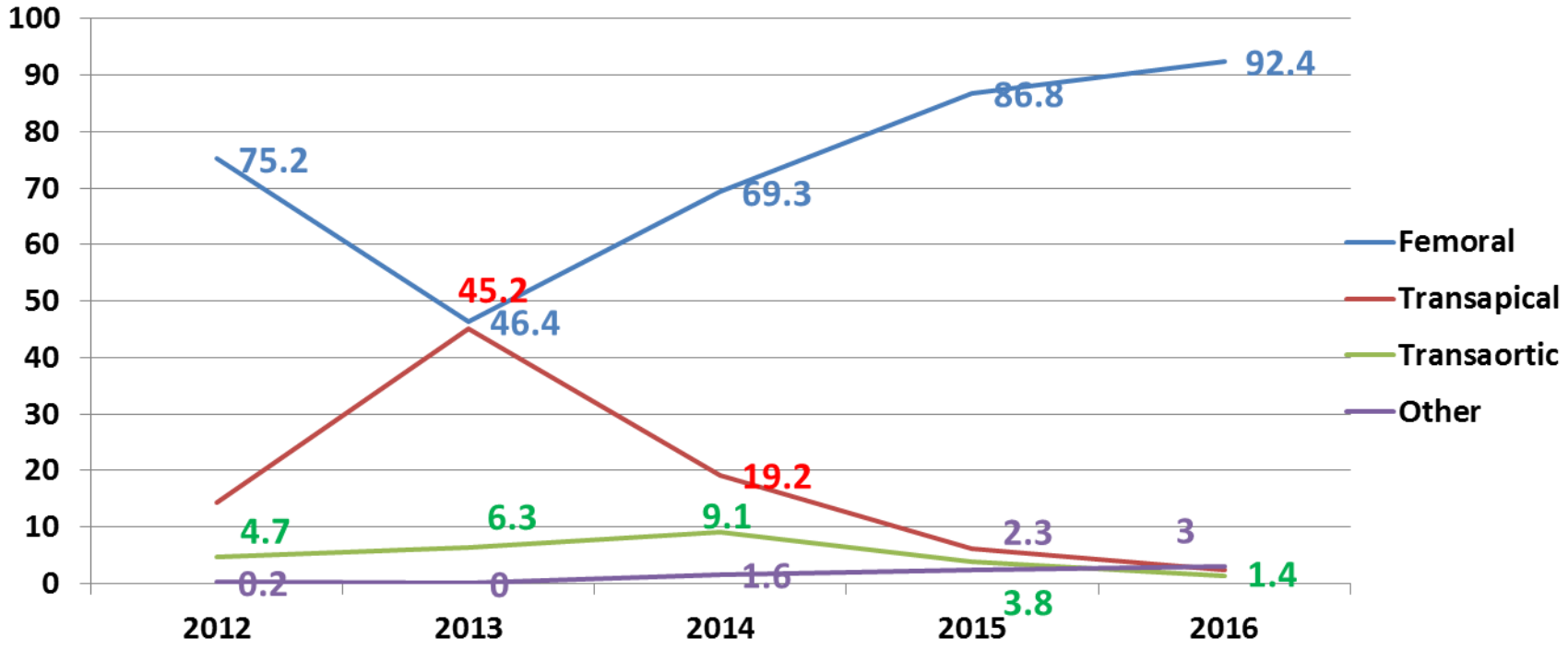
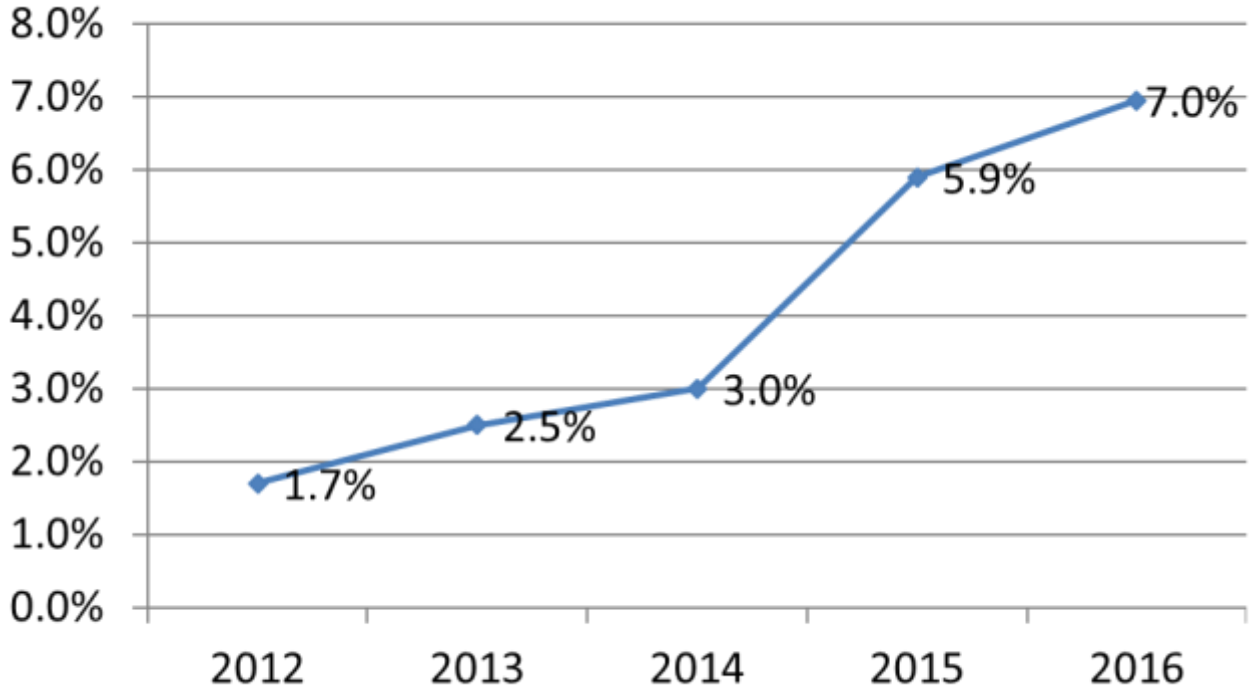
TAVR Access Site %



Source: STS/ACC TVT Registry Database.
as of April 10, 2017

% of TAVRs that are Elective Valve-in-Valve Procedures



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Source: STS/ACC TVT Registry Database.
as of April 10, 2017

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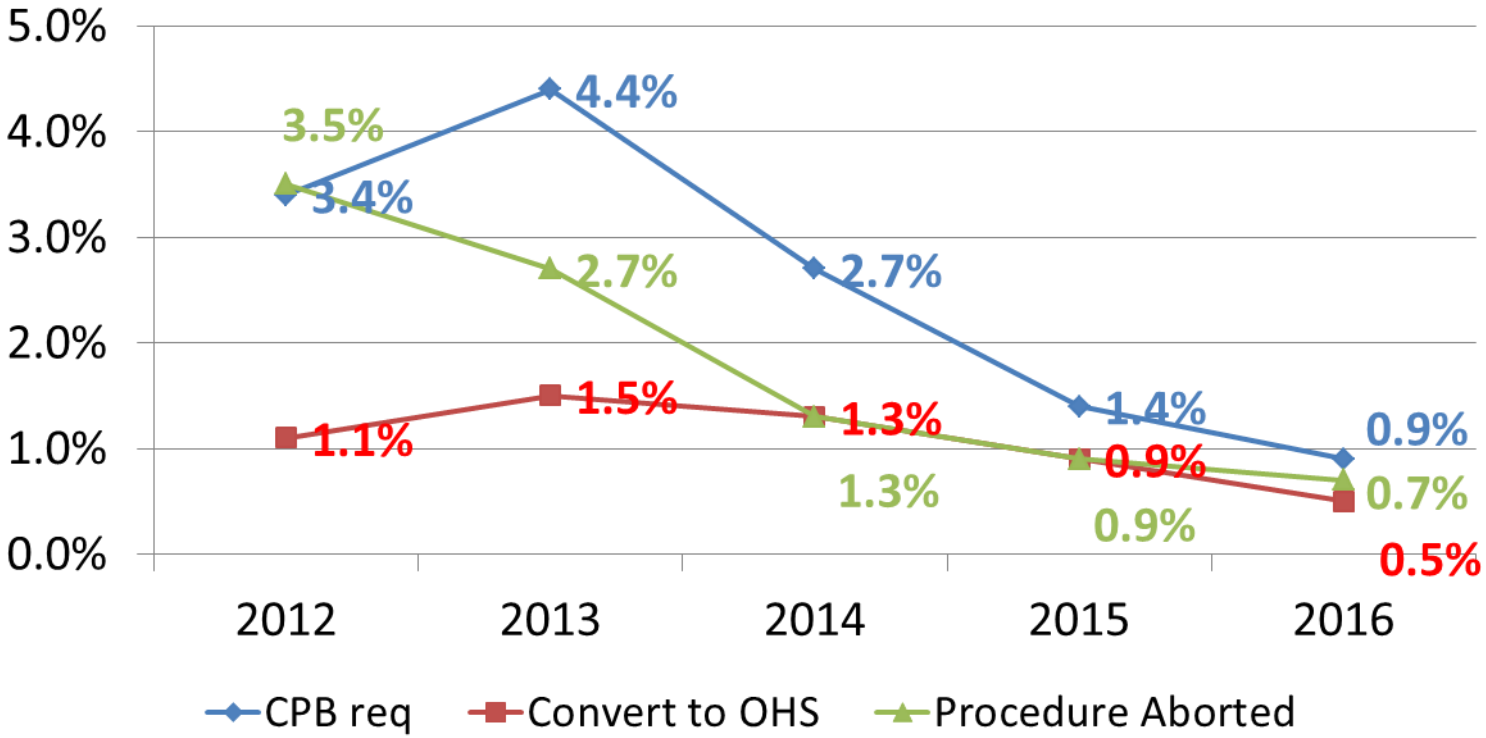
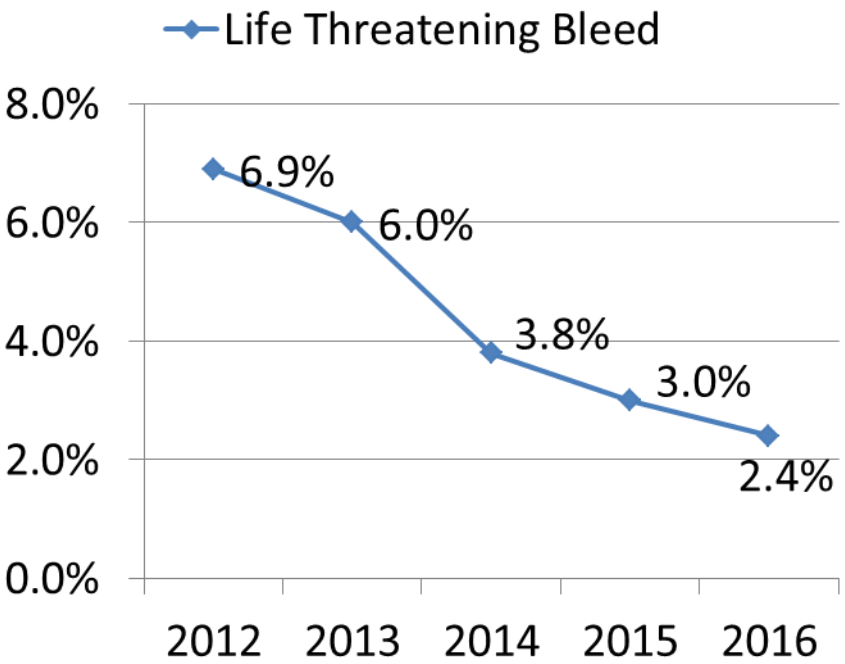
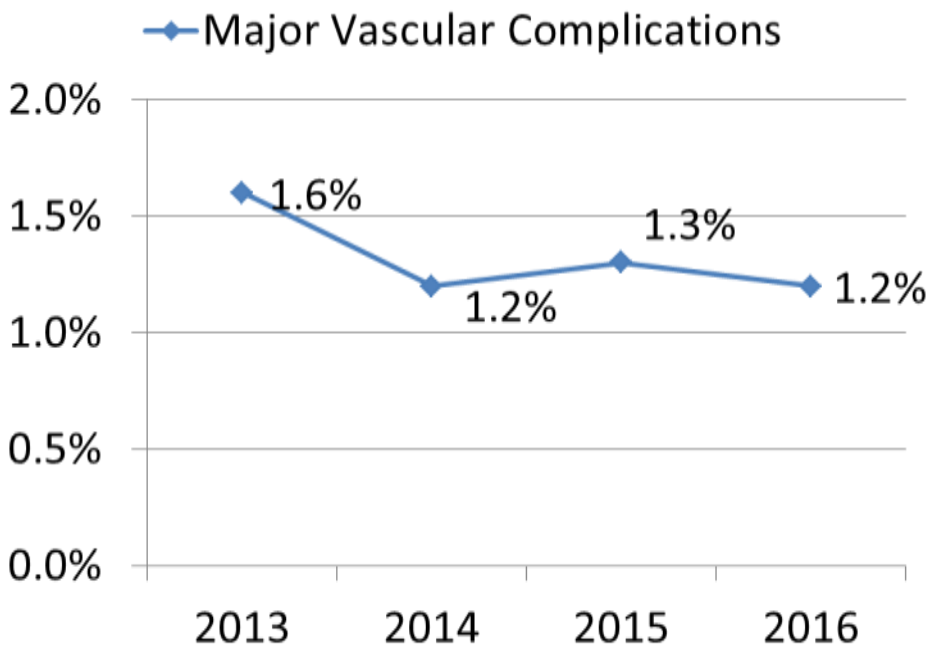
TAVR: Procedure Details



Source: STS/ACC TVT Registry Database.
as of April 10, 2017

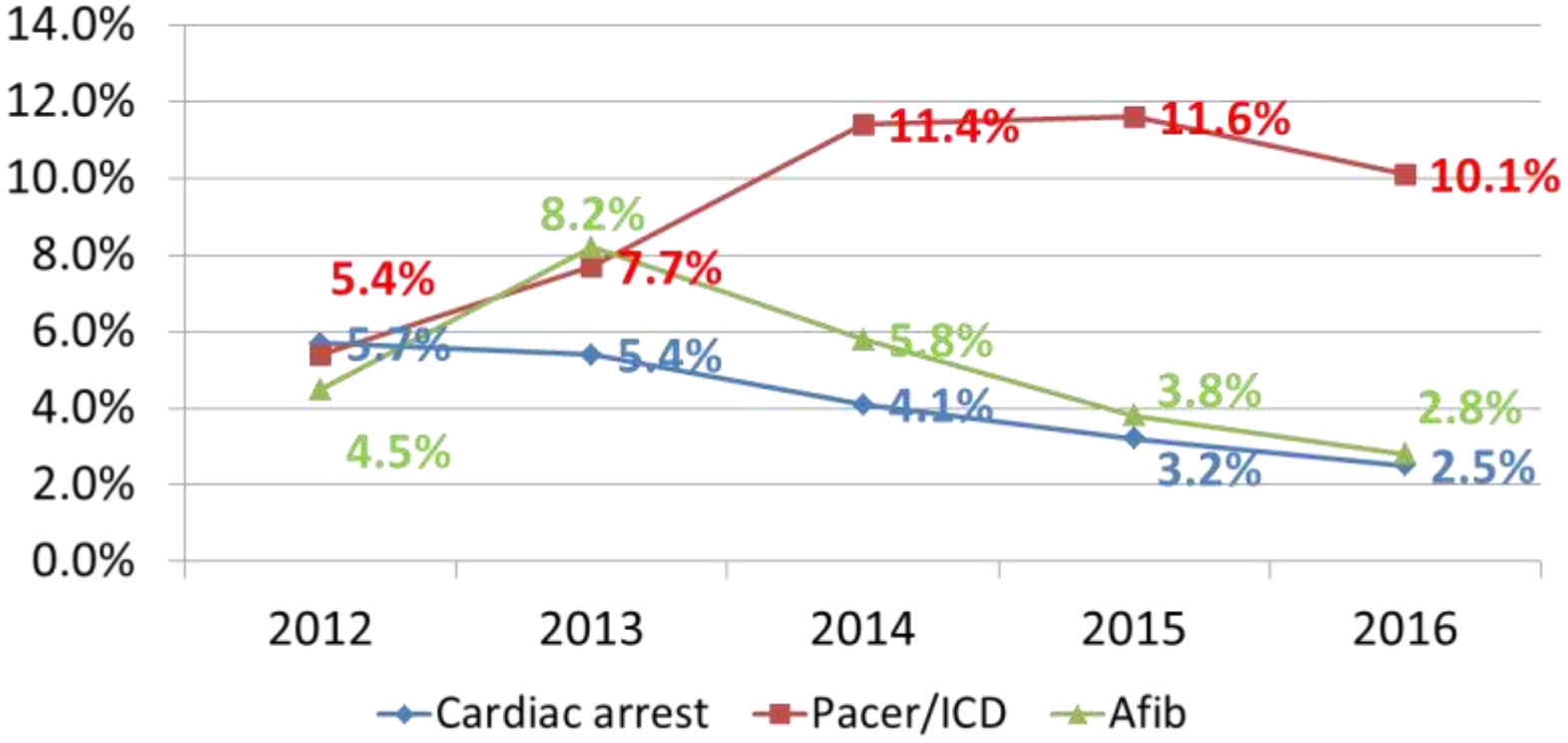
TAVR: Bleeding and Major Vascular Complications





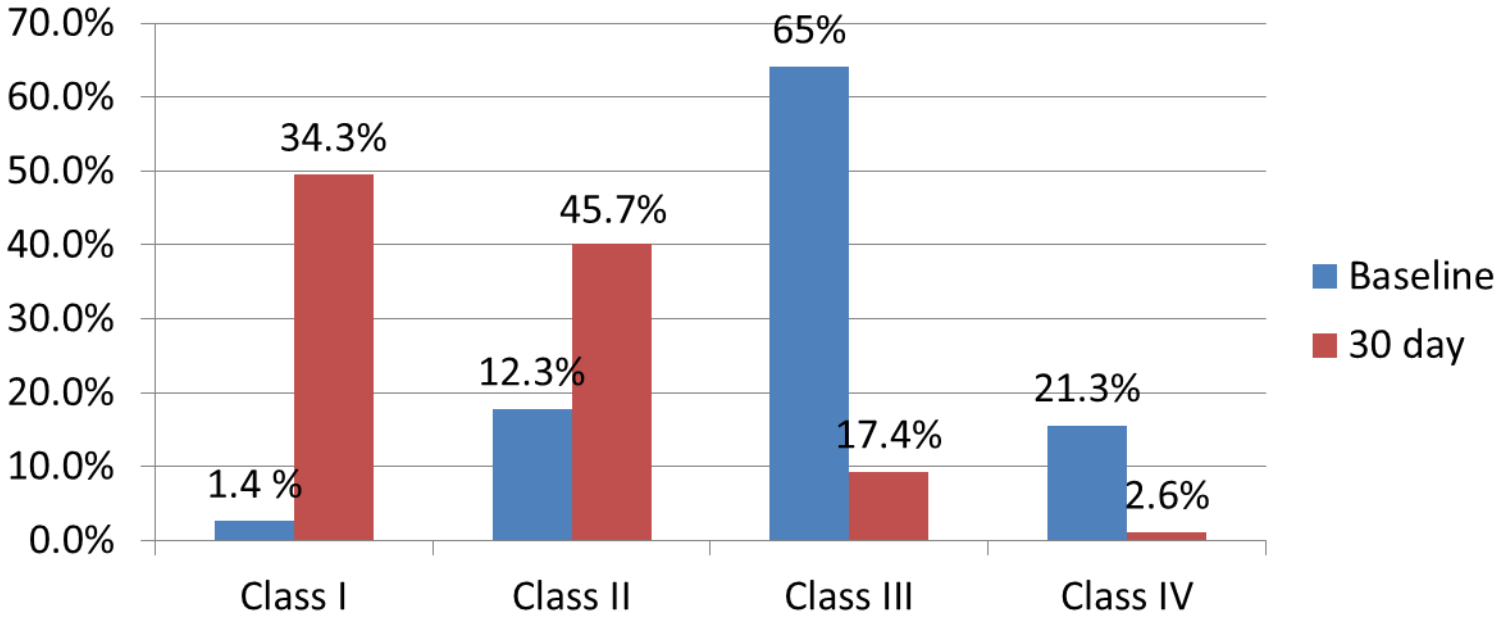
Source: STS/ACC TVT Registry Database
as of April 10, 2017

TAVR: In-Hospital Adverse Events



Source: STS/ACC TVT Registry Database.
as of April 10, 2017

TAVR Procedures – NYHA
2016 Q4 Data



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Source: STS/ACC TVT Registry Database
as of April 10, 2017

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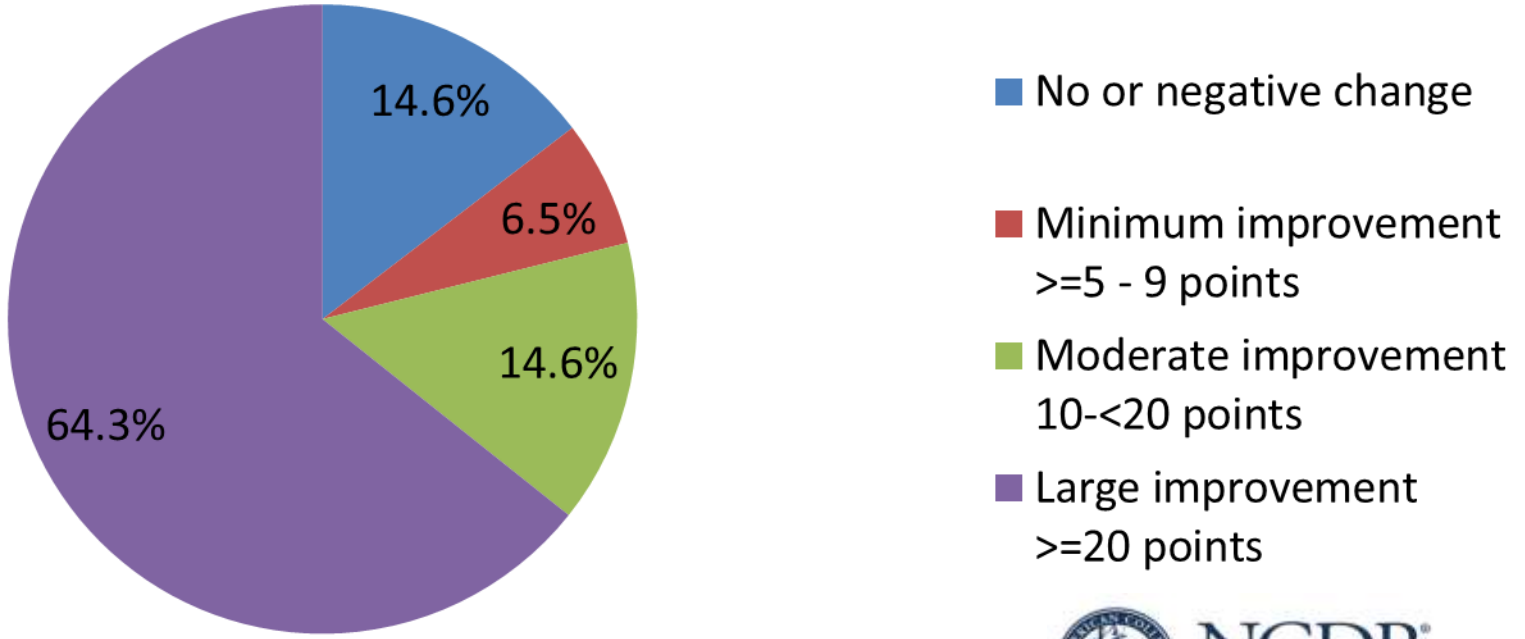
TAVR and KCCQ

Change in KCCQ score from baseline to 30 days



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Source: STS/ACC TVT Registry Database.
as of April 10, 2017

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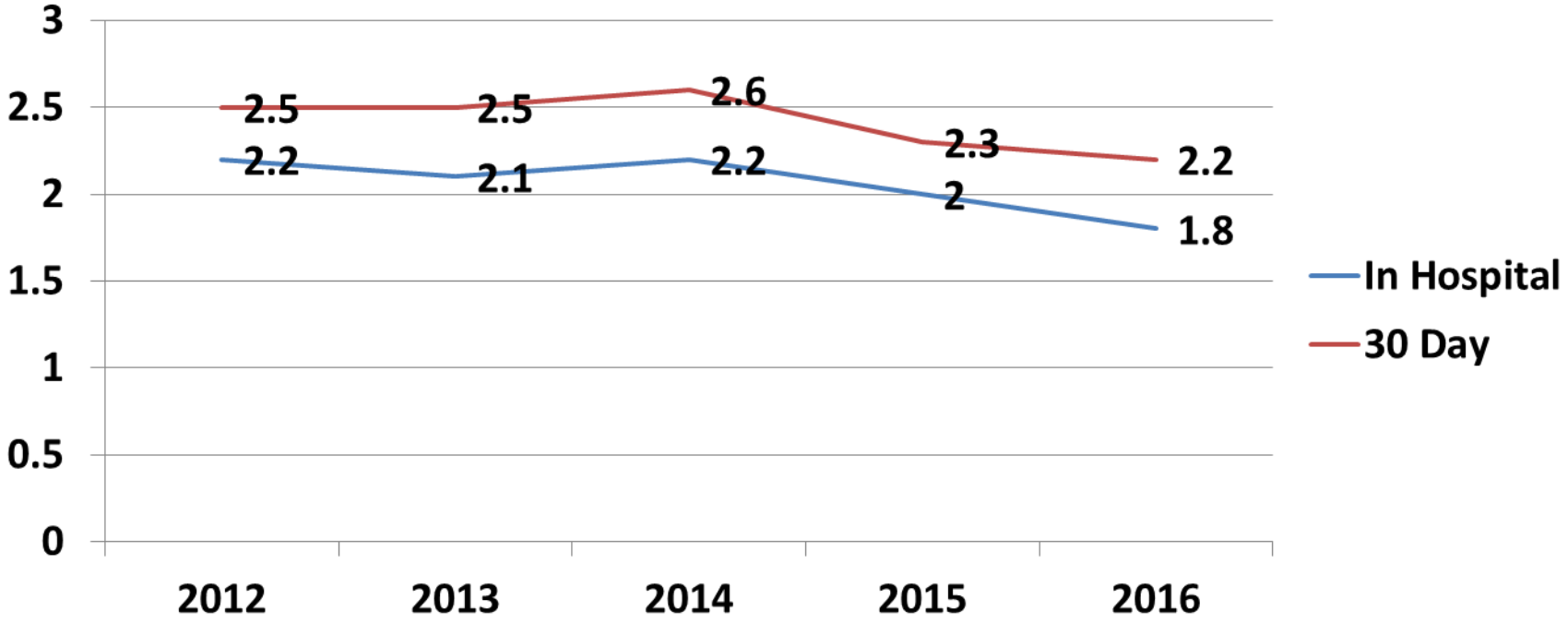
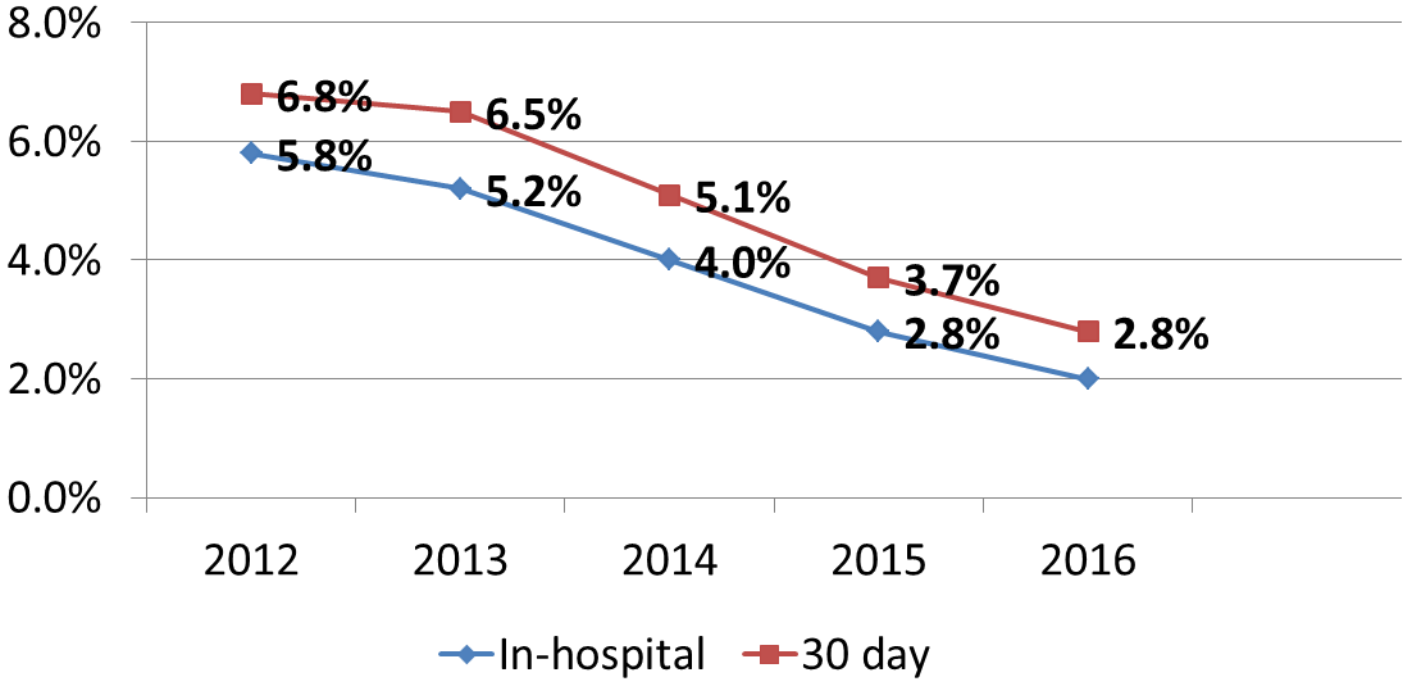
TAVR Stroke %



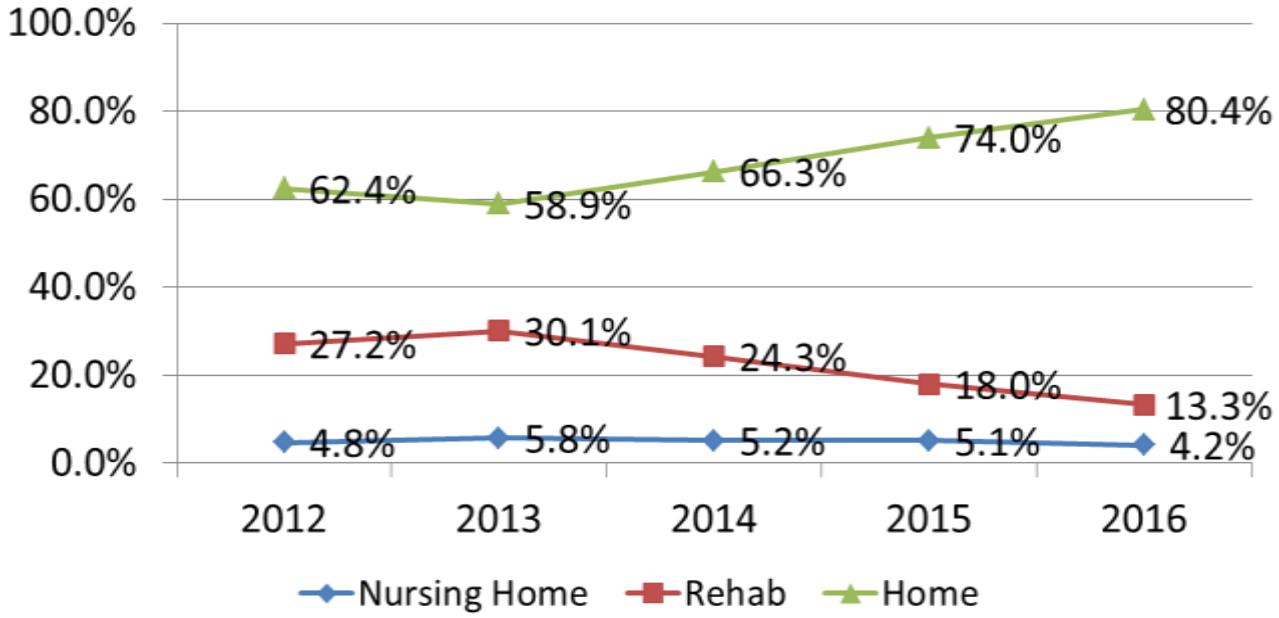
Source: STS/ACC TVT Registry Database.
as of April 10, 2017

TAVR Mortality



Source: STS/ACC TVT Registry Database
as of April 10, 2017

TAVR: Discharge Disposition



Source: STS/ACC TVT Registry Database.
as of April 10, 2017

In-Hospital Risk Adjusted Mortality Rate
Distribution of Hospital Performance

Percentile	10th	25th	50th (Median)	75th	90th
Reporting timeframe (based on 3 yrs of data)	← Worse			Better →	
2012-2014	5.54%	5.12%	4.79%	4.50%	4.15%
2013 Q 4-2016 Q3	3.43%	3.22%	2.98%	2.82%	2.54%

Source: STS/ACC TVT Registry Database
as of April 10, 2017

Background and Objectives

- TAVR has been introduced into U.S. clinical practice with efforts to optimize outcomes and minimize the learning curve.
- The goal of this study was to assess the degree to which increasing experience during the introduction of this procedure, separated from other outcome determinants including patient and procedural characteristics, is associated with outcomes.

J Am Coll Cardiol 2017;70:29–41.

Patient Cohort

Data Source:

STS-ACC TVT Registry: TAVR Module

Time Frame:

November 2011 thru 3rd Quarter 2015

All Commercial TAVR Cases:

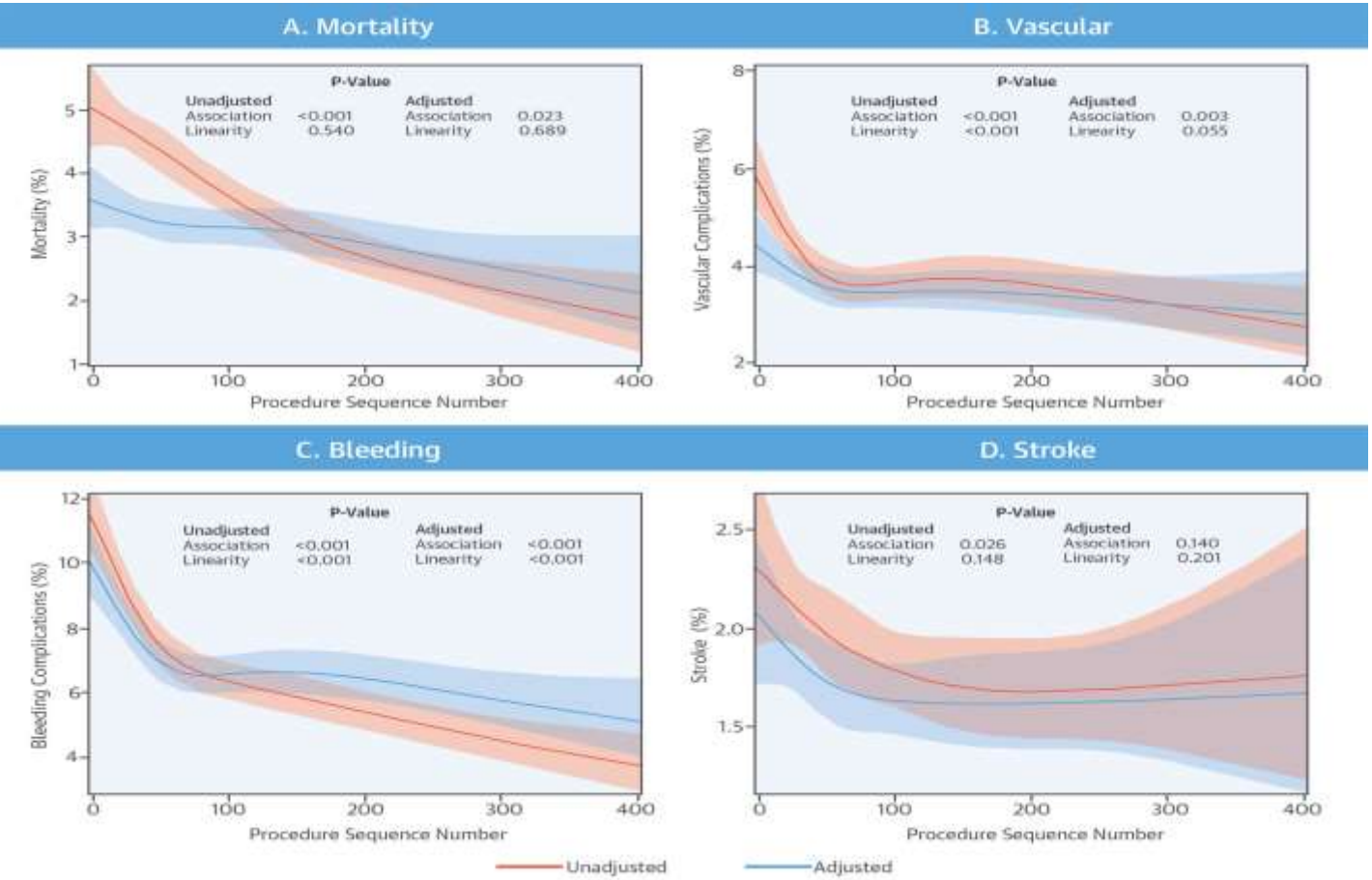
Using FDA Approved Technologies

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



- Unadjusted **(orange)** and risk-adjusted **(blue)** frequency of outcomes.
- The p value < 0.05 for linearity suggests a nonlinear relationship.
- The **orange**- and **blue-colored** bands represent 95% confidence limits, which are broader for stroke due to the low rate of site-reported stroke and the fewer hospital sites contributing cases.

J Am Coll Cardiol 2017;70:29–41.

CONCLUSIONS

- The initial adoption of TAVR into practice in the United States showed that increasing experience was associated with better outcomes.
- This association, whether deemed a prolonged learning curve or a manifestation of a volume–outcome relationship, suggested that concentrating experience in higher volume heart valve centers might be a means of improving outcomes.

Real World Data from STS/ACC TVT Registry

Since that approval, FDA has sharpened its focus on access to innovative medical devices. On June 5th, 2017, FDA became the first regulatory body in the world to approve the most recent iteration of the Sapien valve, the Sapien 3, to treat high-risk patients whose surgically-placed aortic or mitral bioprosthetic valves were old and worn out. The Sapien 3 is intended to slip into these valves using a so-called "valve-in-valve" option, a procedure that can be done without open heart surgery through a patient's blood vessel or a small cut in the chest.

— SAPIEN 3 Heart Valve Device

To narrow the gap from 42nd to first required creativity and commitment. The FDA Heart Valve Review Team first streamlined FDA's expectations for nonclinical testing – something that had been a huge rate-limiting factor for translating innovative TAVR devices from bench to bedside. We became more consistent, predictable, and transparent about our expectations, which helped significantly reduce the total time to initiating clinical studies. And we worked closely with the industry on creative clinical trial designs and the use of other sources of clinical evidence that could demonstrate that the device is safe and effective when used in the intended patient population.

This latest approval is the most recent example of our increasing use of real-world evidence, made possible in this case by the Transcatheter Valve Therapy (TVT) Registry, a partnership of the American College of Cardiology and the Society of Thoracic Surgeons. The TVT registry collects clinical data on the performance of transcatheter valve replacement procedures performed in the U.S. once a product goes to market –

Big News based on TVT Registry Data…

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