

Lessons from the TVT Registry 2015

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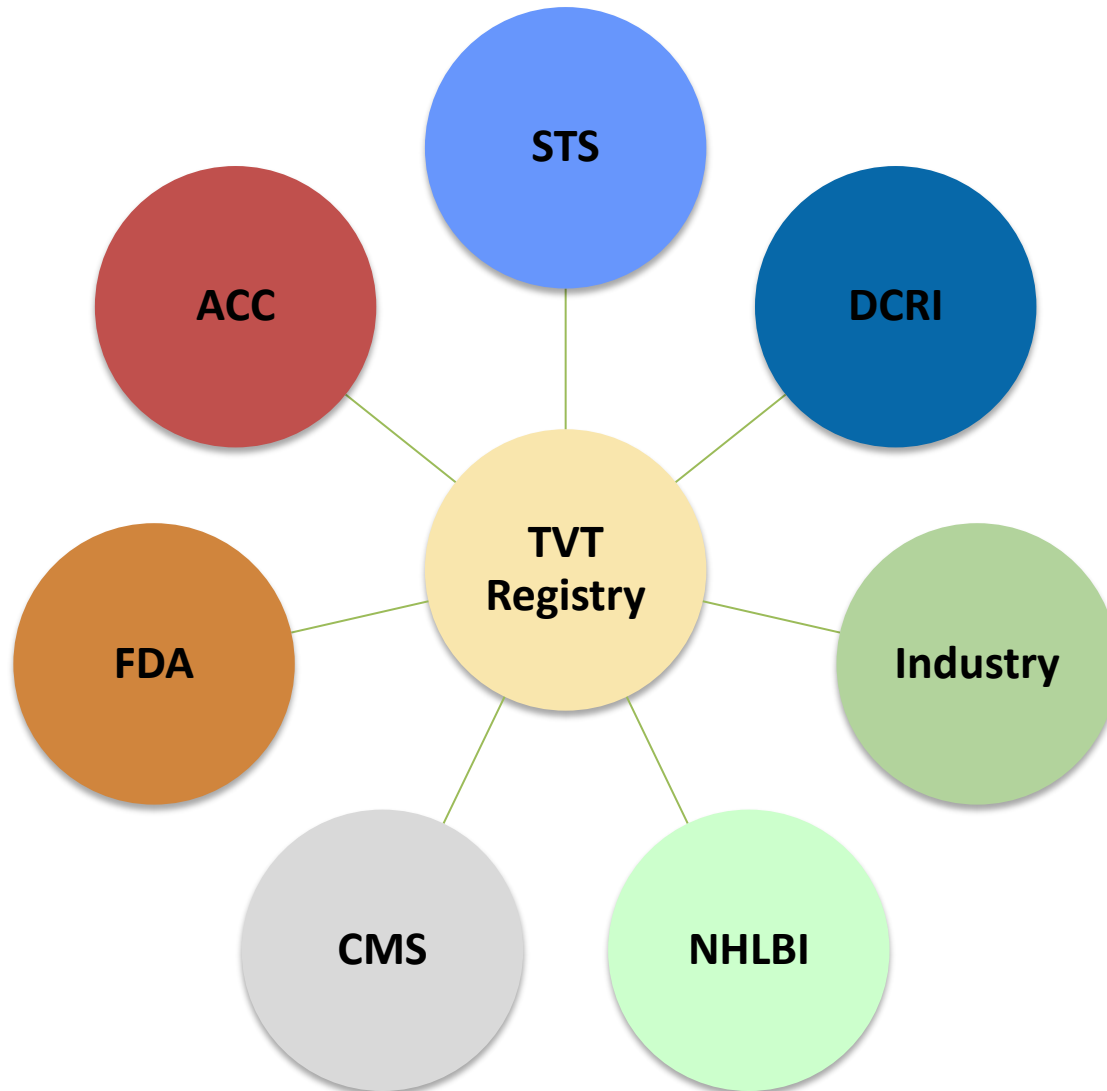
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Financial disclosure: None

The Partners



STS-ACC TVT Registry

Three Modules

Transcatheter Aortic Valve Replacement (TAVR)

•Types

- Native
- Valve-in-
Valve

•Technologies

- Sapien™
- CoreValve™
- Sapien XT™

Transcatheter Mitral Valve Repair

•Types

- Direct Leaflet

•Technologies

- MitraClip™
M

•Future Additions

- Annular
Reduction

Transcatheter Mitral Valve Replacement

•Types

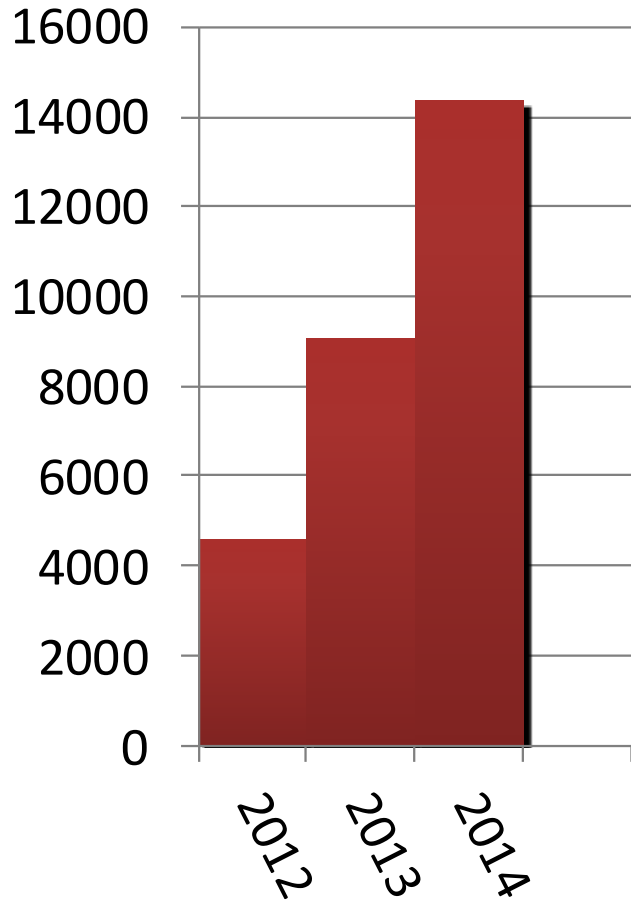
- Native
- Valve-in-
Valve
- Valve-in-
Ring

•Technologies

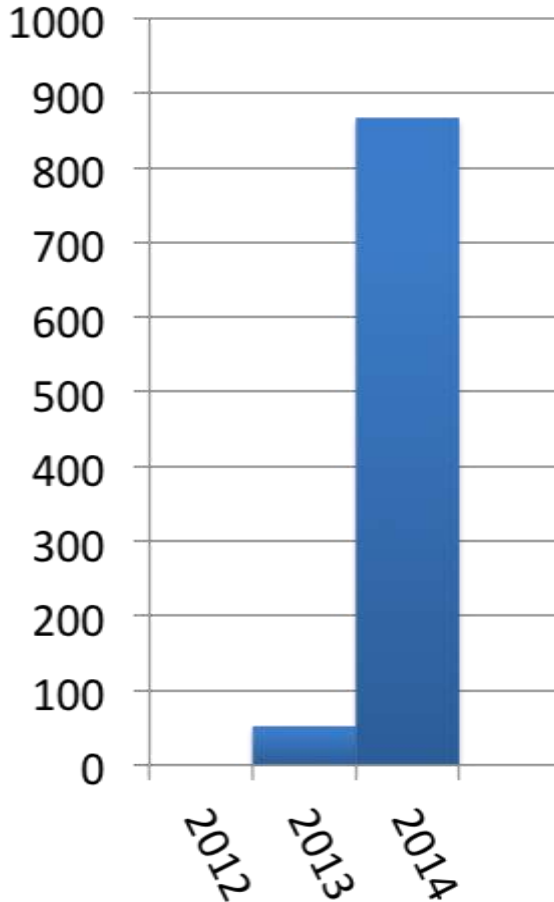
- SapienXT™
- New
technologies

Yearly Registry Volume By Procedure Type

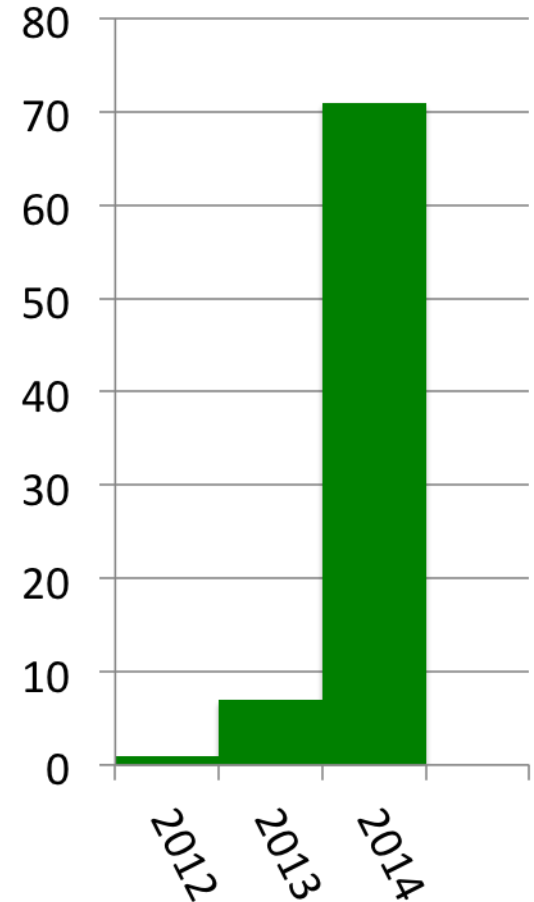
Transcatheter Aortic Valve Replacement



Transcatheter Mitral Valve Repair

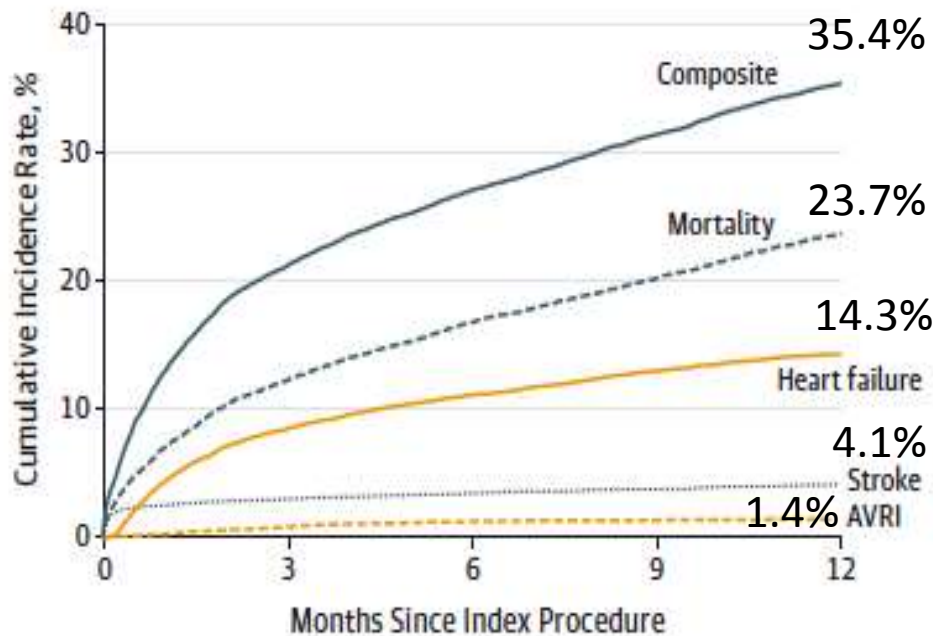


Transcatheter Mitral Valve-in-Valve Replacement



Clinical Outcomes at 1 Year Following Transcatheter Aortic Valve Replacement

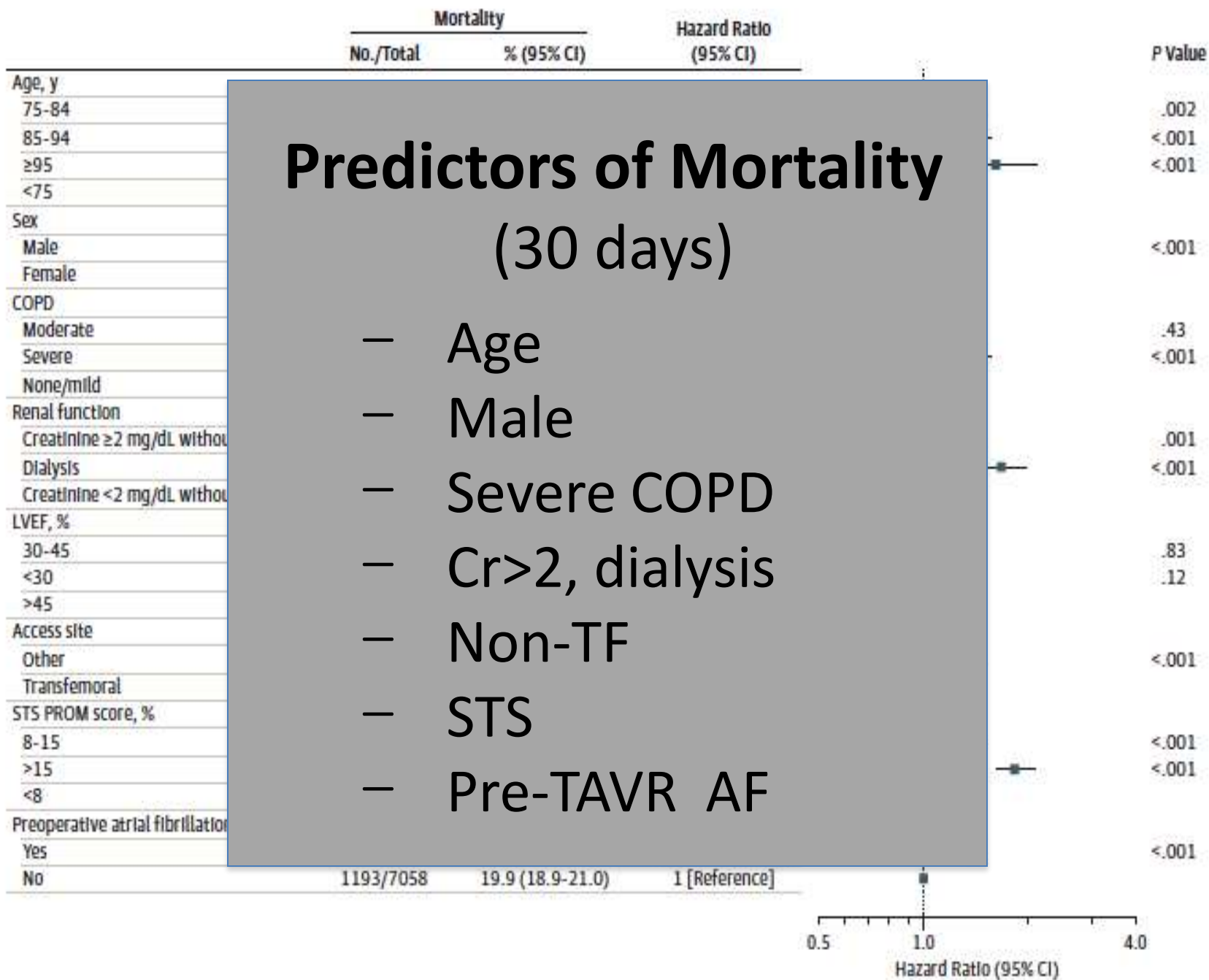
David R. Holmes Jr, MD; J. Matthew Brennan, MD, MPH; John S. Rumsfeld, MD, PhD; David Dai, PhD; Sean M. O'Brien, PhD; Sreekanth Vemulapalli, MD; Fred H. Edwards, MD; John Carroll, MD; David Shahian, MD; Fred Grover, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; Ralph G. Brindis, MD, MPH; Michael J. Mack, MD; for the STS/ACC TVT Registry JAMA 2015;313:1019-28



- 12 182 patients
- 299 US hospitals
- 11/11 – 6/13
- 84 yrs., 48% men (2.1% > 95 yrs.)
- STS 7.1%
- Linked w/ CMS data
- 60% DC home

No. at risk	0	3	6	9	12
Mortality	12 182	9669	7724	6190	4790
Stroke	12 182	9508	7585	6063	4681
Heart failure	12 182	8951	7007	5519	4239
AVRI	12 182	9653	7669	5814	4516
Composite	12 182	8686	6782	5343	4096

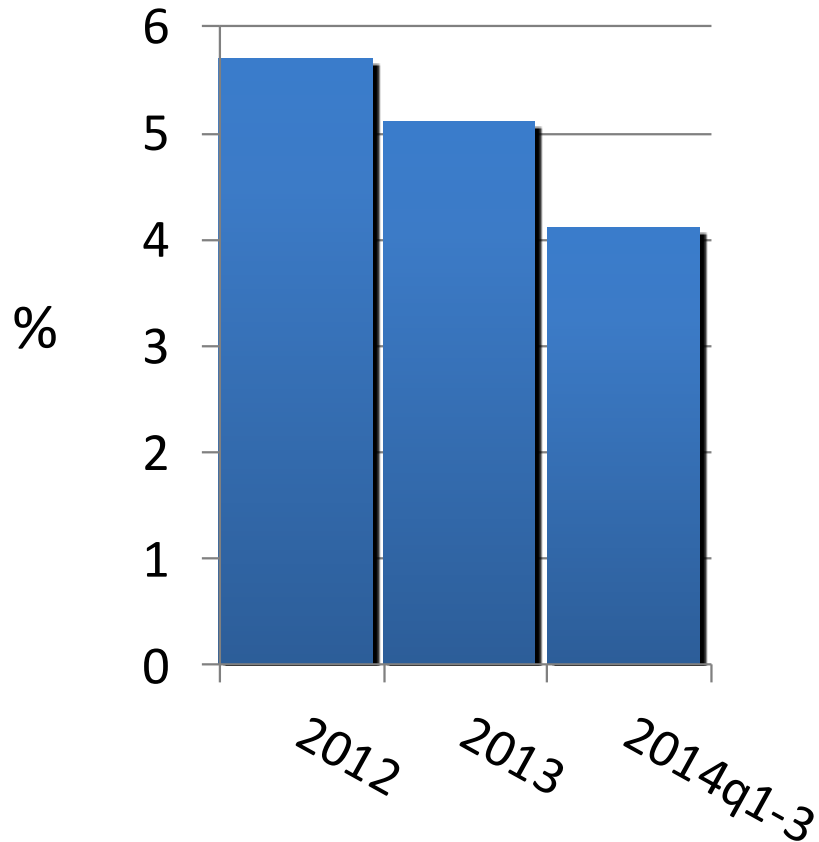
Figure 2. Multivariate Risk-Adjusted Outcome of Mortality



TAVR: 1 Year Outcomes

	Centers N	Patients N	Death %	Stroke %	Author
TVT/CMS	299	12,182	23.7	4.1	TVT
PARTNER B	21	179	30.7	11.2	Leon
PARTNER A	25	348	24.3	8.7	Smith
UK TAVI	25	870	21.4	NR	Moat
Canadian TAVI	6	339	24.0	NR	Rodes-Cabau
France 2	33	3,195	24.0	4.1	Gilard
Belgium	15	328	26.0	NR	Bosmans
Pragmatic	4	793	14.3	NR	Chieffo
SOURCE Reg	93	2,706	21.1	7.1	Treede

TAVR: In-Hospital Mortality Decreasing (*Not Risk Adjusted*)

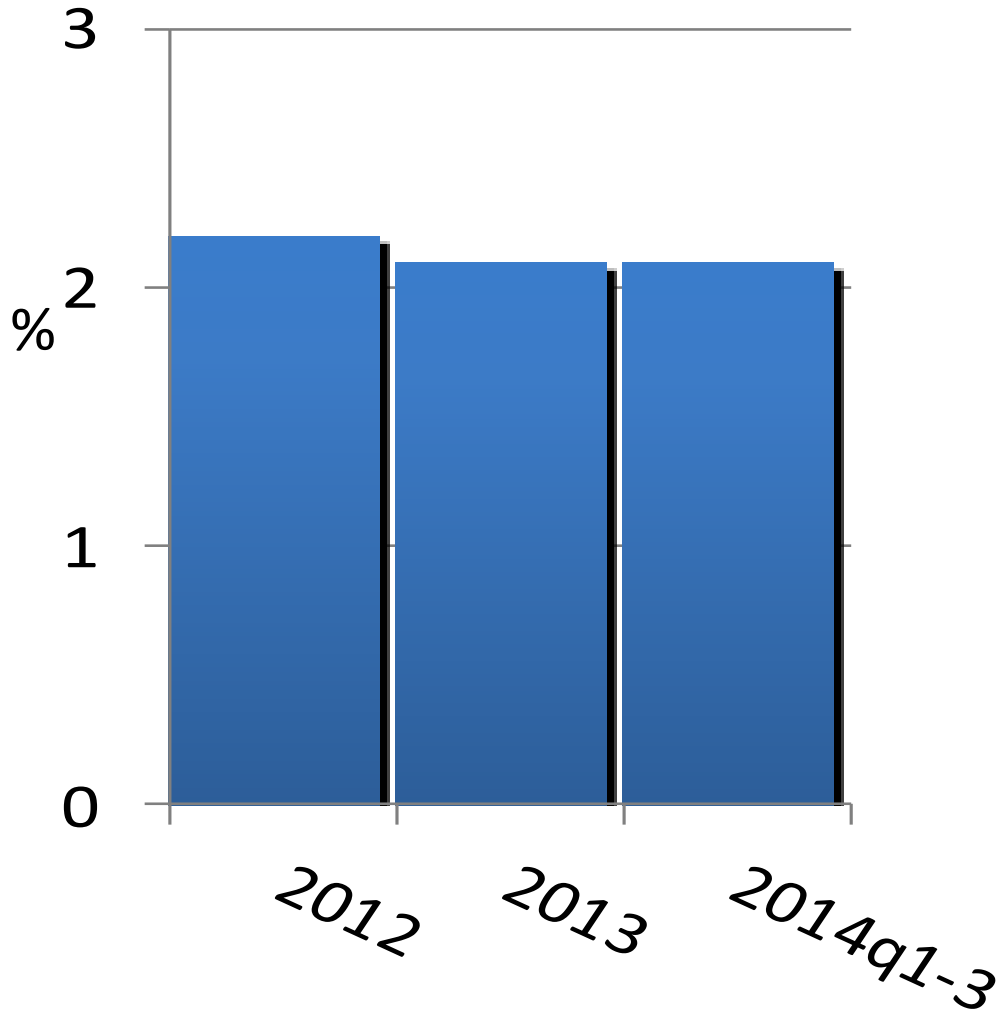


Explanation?

- A. Related to treating lower risk patients.
- B. Related to improved site performance.
- C. Related to next generation TAVR technology.
- D. All of the above.

Source: STS/ACC TVT Registry Database
23,557 records from 2012q1-2014q3 as of 2-13-15

TAVR: Any Stroke During TAVR Hospitalization

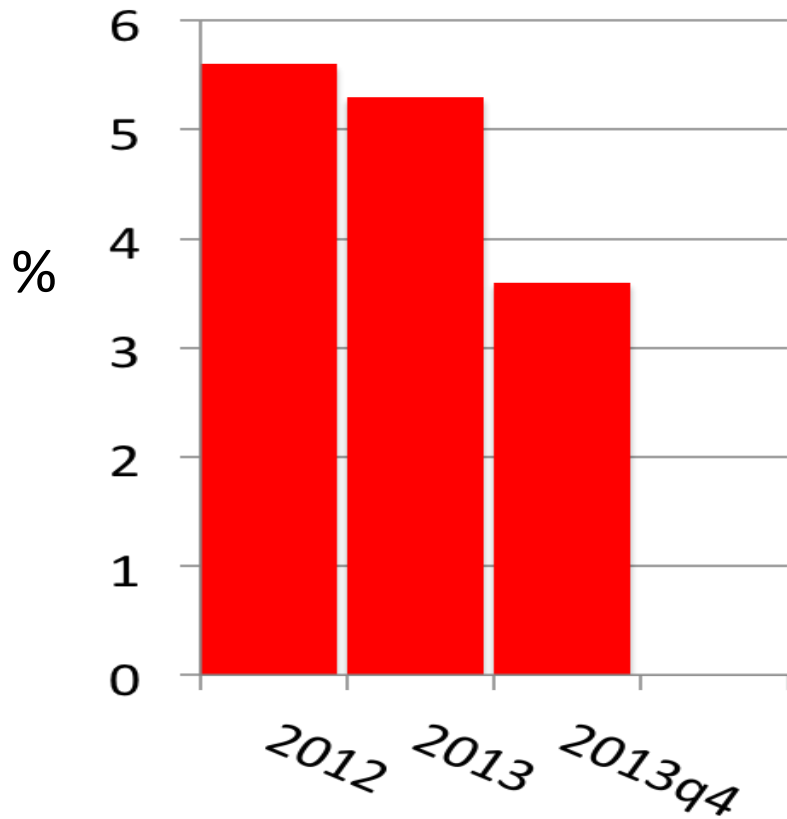


- Site reported
- Most likely reflects clinically apparent-important strokes?

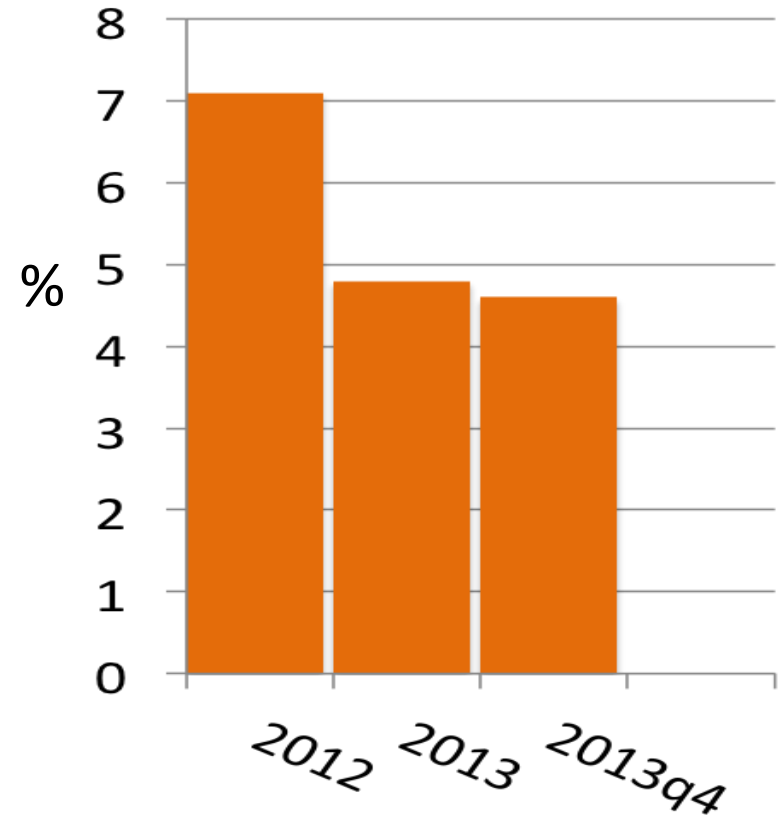
Source: STS/ACC TVT Registry Database
23,557 records from 2012q1-2014q3 as of 2-13-15

TAVR: Bleeding and Vascular Complications

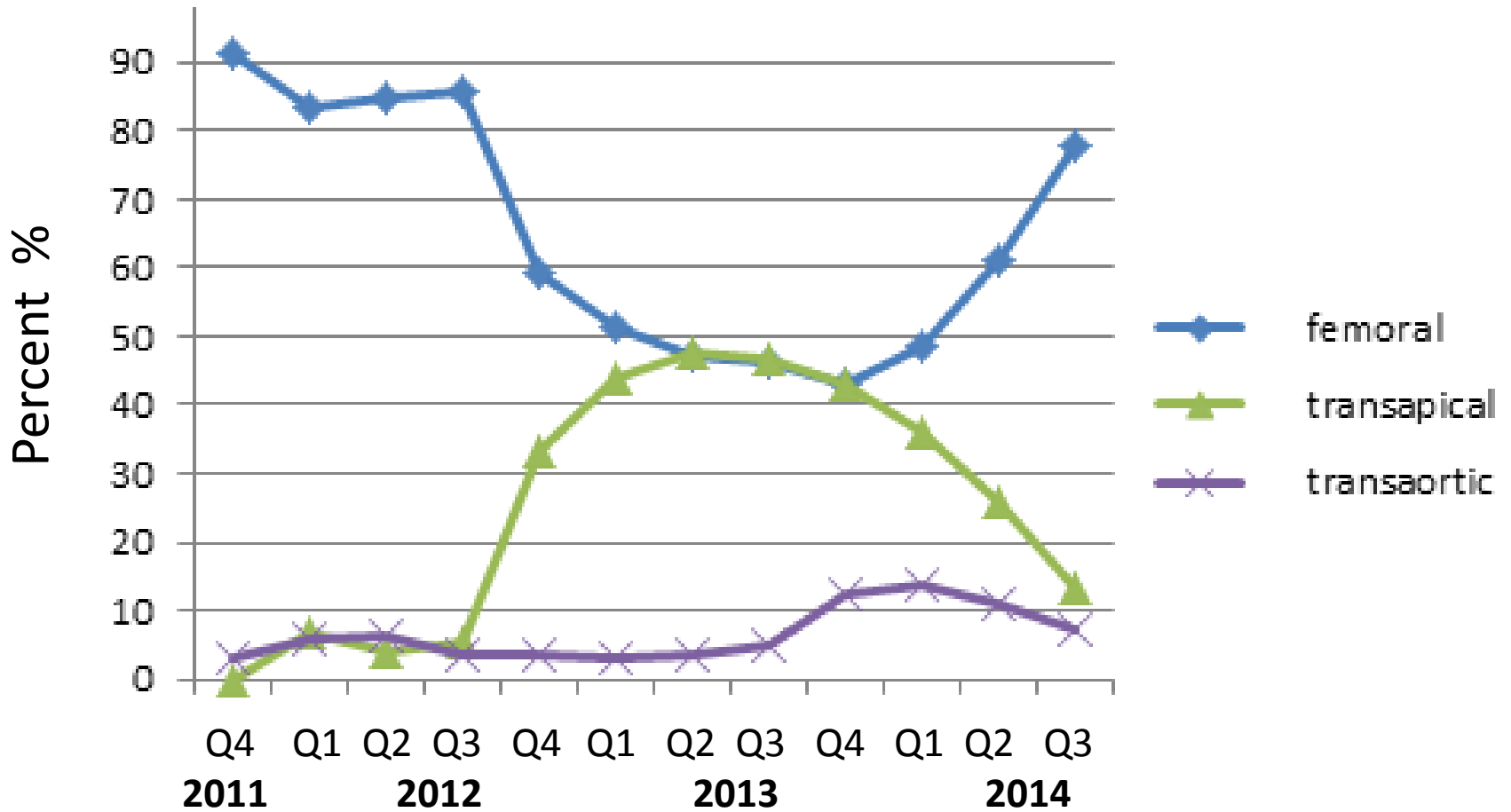
Life Threatening or
Disabling Bleeding



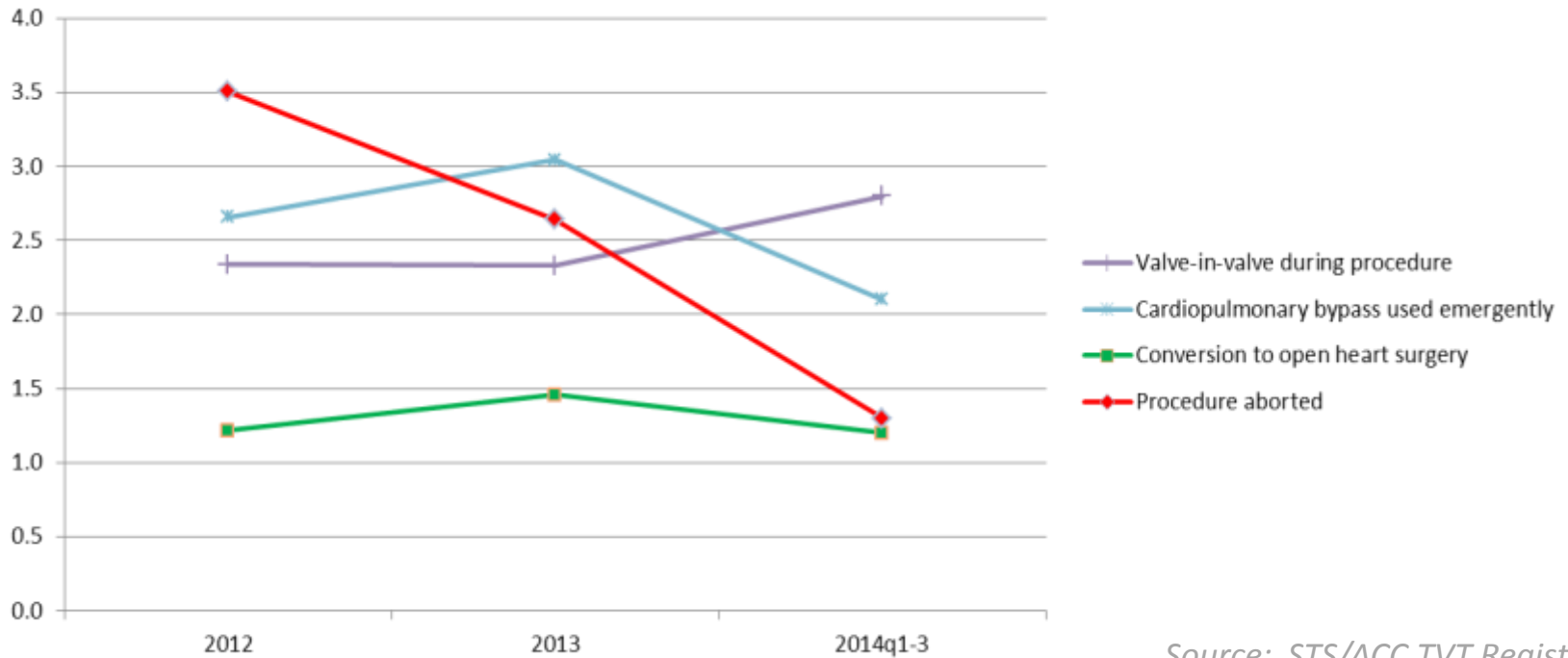
Vascular
Complications (any)



Changing TAVR Access in US



Procedure Outcomes



Source: STS/ACC TVT Registry Database

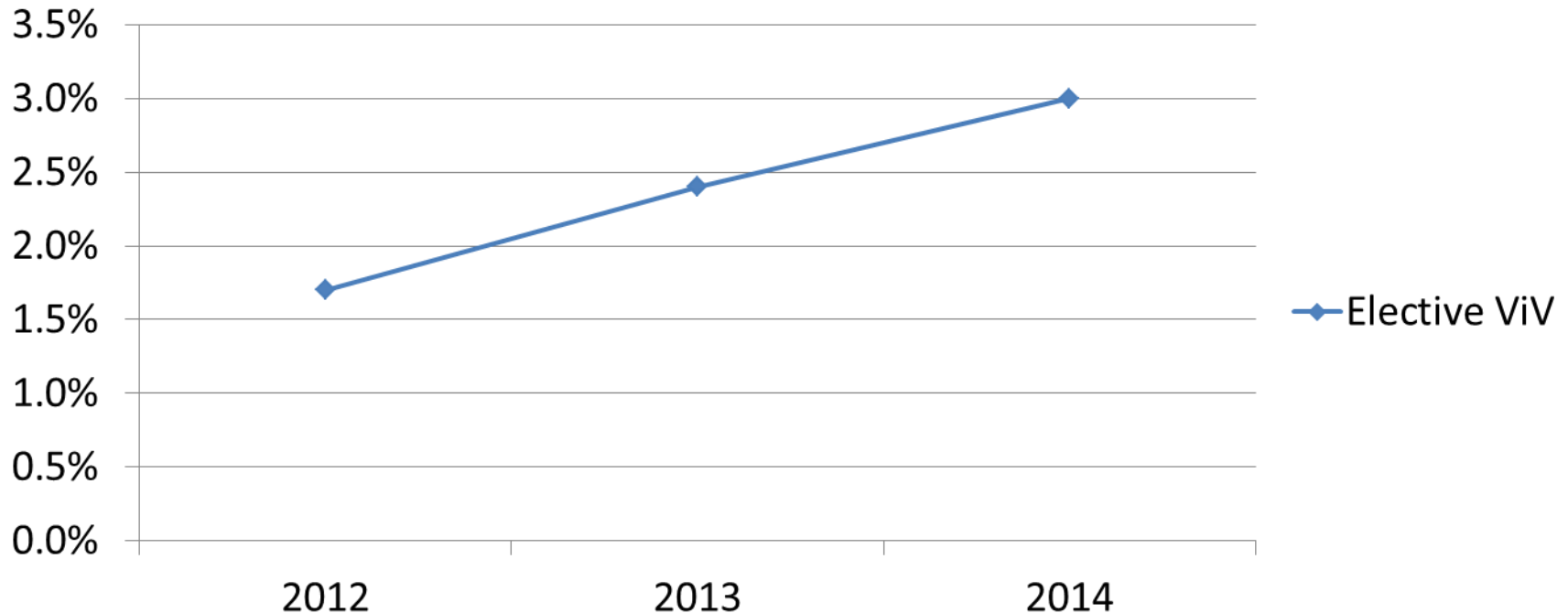
23,557 records from 2012q1-2014q3
as of 2-13-15

Major Trend: Reduced frequency of aborted procedures.

The most frequent reason for an aborted procedure has been failure of access site, i.e. the femoral access was tried and did not work.

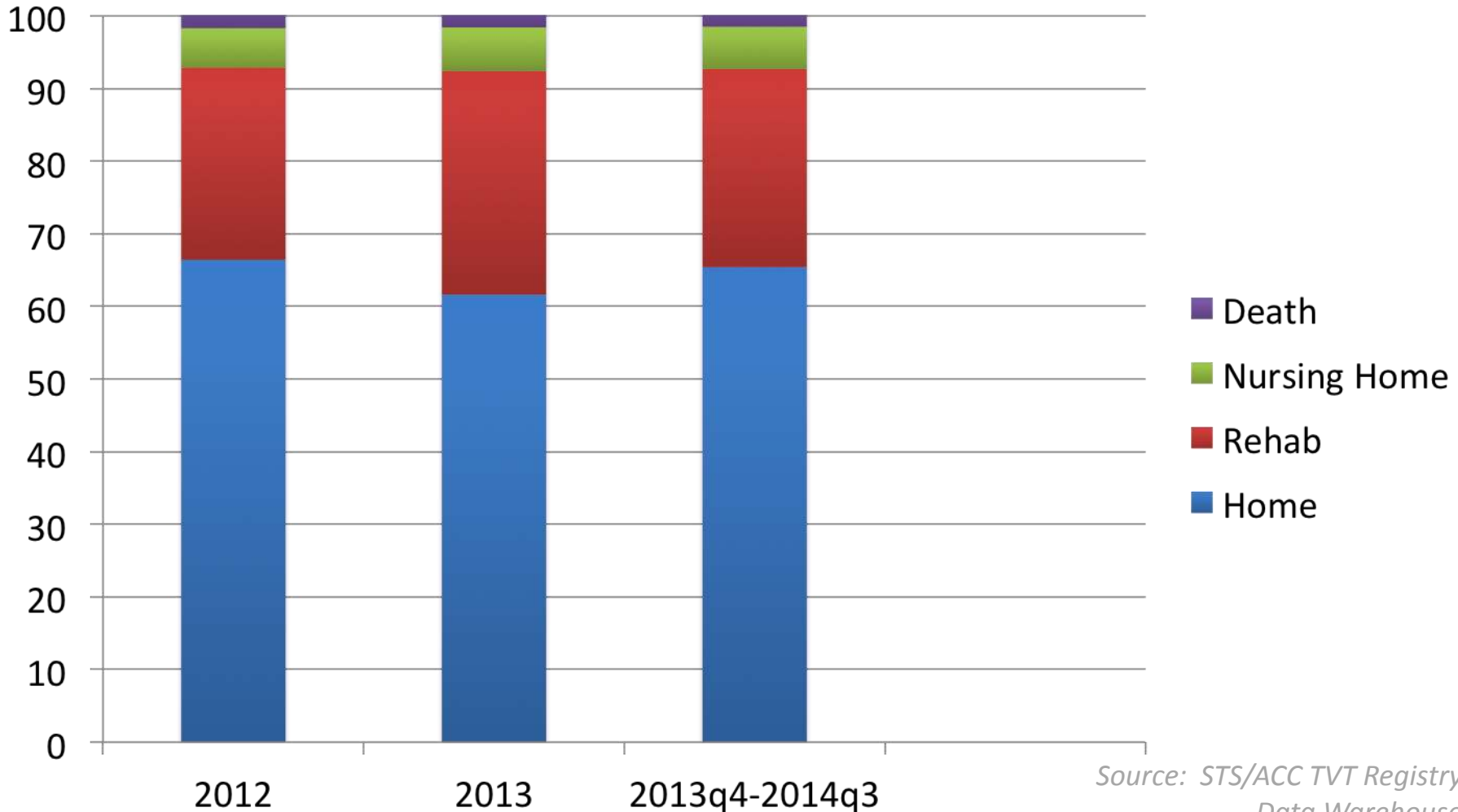
Elective Valve-in-Valve

The use of TAVR to treat prosthetic (tissue) valve failure, especially in the high to prohibitive surgical risk patient, is an outstanding issue for the community. Decision-time for regulatory and clinical communities...



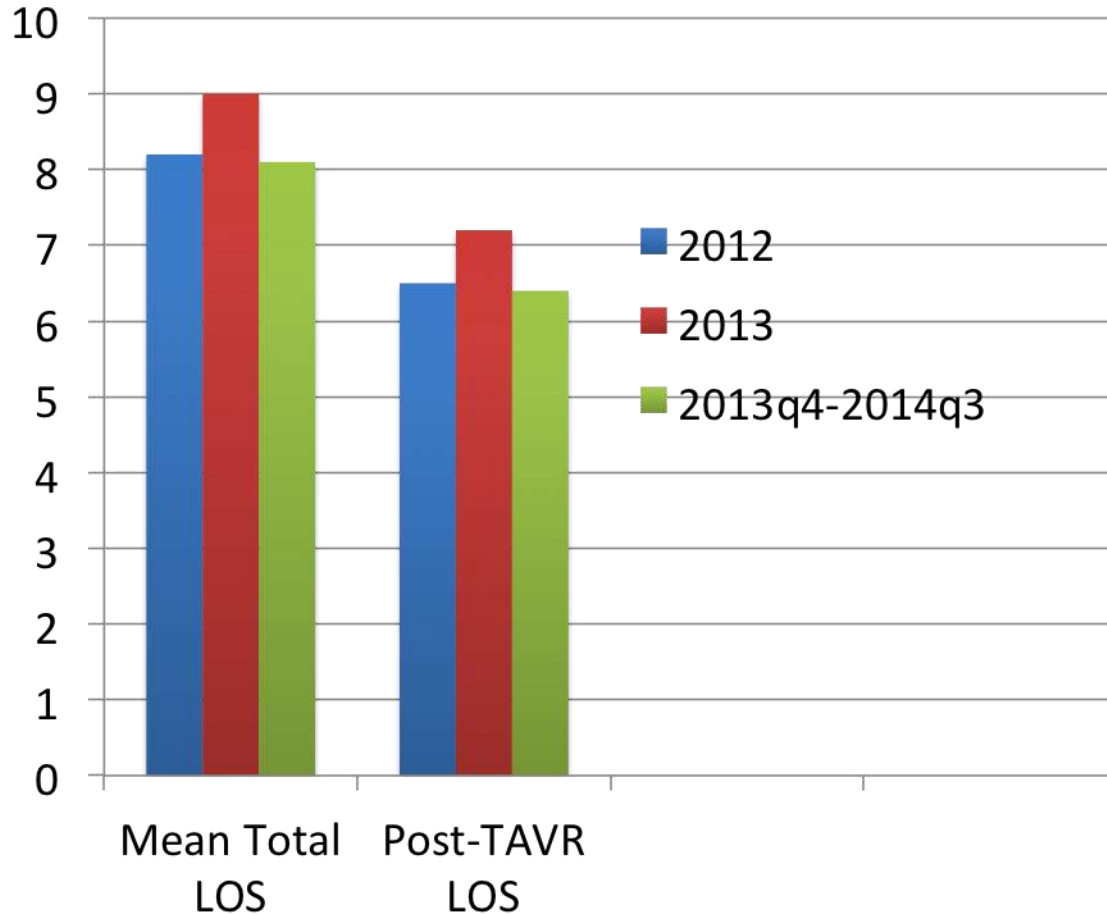
*Source: STS/ACC TVT Registry Database
23,557 records from 2012q1-2014q3 as of 2-13-15*

After TAVR – The “Disposition”



Source: STS/ACC TVT Registry
Data Warehouse
as of Nov-Dec 2014

TAVR: How Long Do I Need to Stay in the Hospital, Doc?



- Surprisingly not much change over time despite more experience.
- Appears to parallel changes in access site with an ongoing elderly population of patients.

Source: STS/ACC TVT Registry Data Warehouse
as of Nov-Dec 2014

Risk Adjusted Mortality in the Institutional Outcomes

TAVR Outcome Metrics (In-Hospital)			Distribution of Hospital Performance	
			10th percentile	Better → 90th percentile
1	Mortality – In-Hospital Risk Adjusted Mortality Rate			
	My Hospital R4Y	All Hospital 50th Pctl		
	5.0%	5.76%	3.03%	
Your hospital's risk adjusted mortality rate for all patients, adjusted using the STS/ACC TVT Registry risk adjustment model. [Detail Line: xxxx]				
2	Mortality – In-Hospital Risk Standardized Mortality Ratio			
	My Hospital R4Y	All Hospital 50th Pctl		
	0.77	0.85	0.37	
Your hospital's risk standardized mortality ratio for all patients, adjusted using the STS/ACC TVT Registry risk adjustment model. [Detail Line: xxxx]				

Risk Adjusted Mortality (all patients)	
Eligible patients	100
Observed mortality (among eligible)	5
Observed mortality rate	5.00%
Risk adjusted mortality rate	5.05%
Standardized mortality ratio	1.1
SMR lower 95% confidence limit	0.50
SMR upper 95% confidence limit	1.95

STS/ACC TVT Registry

- ≈30,000 patients entered
- ≈360 sites in 48 states and Puerto Rico participate
- Ability to evaluate treatment of AS (SAVR / TAVR)
- Mortality and strokes rates after TAVR in US are comparable to contemporary registries
- Data to detect infrequent events
- Data for regulatory purposes
- Quality metrics for centers and physicians
- TAVR risk score
- A step toward global TVT registry
- Potential to improve patient care