



STS/ACC TVT Registry

An initiative of the STS National Database and the ACC's NCDR

Companion Guide for Public Reporting

The mission of the TVT Registry[™] is to track patient safety and real-world outcomes related to transcatheter valve replacement or repair procedures. The registry is an initiative of the Society of Thoracic Surgeons (STS) and the American College of Cardiology Foundation (ACCF).

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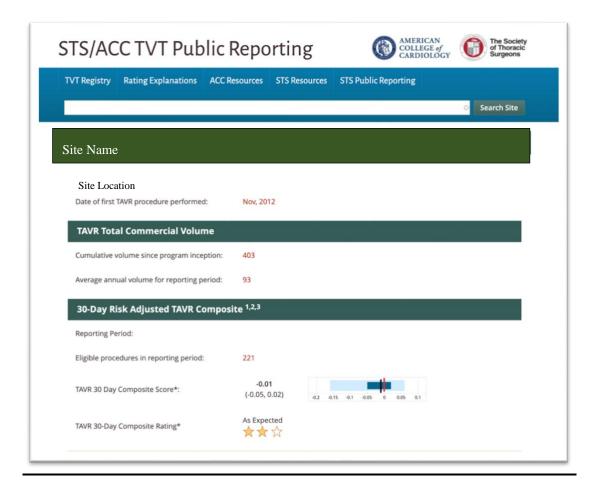
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TAVR Volume Metric

Report example:



- 1. Month and year the first procedure was submitted to Registry
- 2. Cumulative volume since enrollment
- 3. Annual volume (most recent last four quarters)
- 4. Site volume as compared to volume across all registry hospitals (distribution diagram)

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TAVR 30-Day Morbidity/Mortality Composite:

The TAVR 30-day morbidity/mortality composite was developed by a TVT Registry Workgroup (physician leaders of the registry and statisticians at Duke Clinical Research Institute) for the purpose of providing feedback in the institutional outcome reports. The model is a hierarchical, multi-category risk model that estimates risk standardized results (reported as a "site difference" and including the calculation of 1-3 stars for public reporting) for 5 endpoints (outcomes) at 30 days (mortality, stroke, major or life-threatening bleeding, acute kidney injury, or moderate-severe paravalvular (leakage around the new heart valve) aortic regurgitation). If a patient experiences multiple outcomes, the outcome with the highest rank is assigned. The model includes 46 variables including the Kansas City Cardiomyopathy Questionnaire (KCCQ) and gait speed (5-meter walk) and is reported on **rolling 3 years** of data. The KCCQ is a patient reported outcome used to assess patient's perception of their health status, and the 5-meter walk test is used to assess patient's frailty.

Model Specifications

A. Model Outcomes* **

- 1. Mortality (in-hospital or 30 day)
- 2. Stroke (in-hospital or 30-day ischemic, hemorrhagic, or undetermined stroke)
- 3. Bleed (in-hospital or 30-day VARC major/life threatening bleed)
- 4. Acute Kidney Injury (in-hospital AKI stage III, or in-hospital/30-day new dialysis)
- 5. Paravalvular Aortic Regurgitation (leakage around the new heart valve) (in-hospital or 30-day moderate to severe paravalvular regurgitation)

B. **Timeframe:** Rolling 3-years with a lag of the published reporting timeframe by one quarter (to assure data completeness in the 30-day endpoints). For example, 2020 quarter 4 report includes patients discharged from 2017 quarter 4 to 2020 quarter 3.

C. Model Eligibility

- i. Site must have >=90% completeness of Kansas City Cardiomyopathy Questionnaire at baseline, Five-meter walk at baseline and assessment of outcomes at 30 days across the rolling 3-year reporting period:
- ii. At least 60 TAVR procedures.
- iii. Enrolled and submitted data prior to the rolling 3-year timeframe.

^{*}If one patient experiences multiple outcomes, the outcome with the highest rank is assigned.

^{**}Table 1 defines model outcome definitions

D. Variables (see manuscript)

E. Report details

a. What is a site difference?

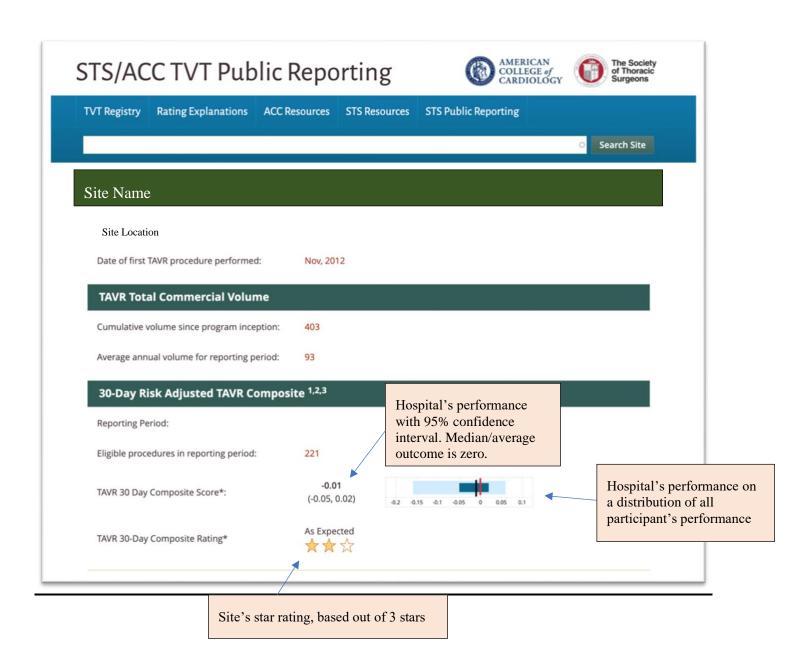
A site difference (also called a "win-difference") is a new method to report risk standardized composite outcomes (fatal and non-fatal). The model provides different weights for each event, based on the clinical importance and timing of the outcomes. It is used in clinical trials that have a composite of primary endpoints and is a newer method that creates the foundation of site rankings.

<u>In statistics, a site difference is defined as:</u> The probability that a random patient at your hospital would have a **worse outcome** at an average hospital (vs your hospital) MINUS the probability that a random patient at your hospital would have a **better outcome** at an average hospital (vs your hospital).

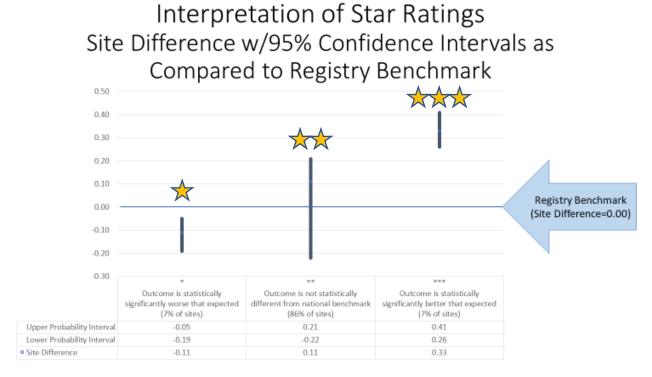
A simpler definition is: The probability an average patient is better off going to YOUR hospital (vs an average hospital) MINUS the probability an average patient is better off going to an AVERAGE hospital (vs your hospital)

F. Site Difference interpretation:

- a. Site Difference >0 (positive number) implies that a random patient is better off at hospital A (vs an average hospital). This implies hospital A has better than expected performance.
- b. Site Difference <0 (negative number) implies that a random patient is better off at an average hospital (not hospital A). This implies hospital A has worse than expected performance.



G. Interpretation of Star Ratings



Star ratings:

- 1. The hospital's site difference and confidence intervals (CI) are all <0 (negative numbers) and do not cross the registry benchmark of 0.00. This implies that a hospital has worse than expected performance.
- 2. The hospital's site confidence intervals are within the range of the registry benchmark (in this case, 0.00). This implies the hospital's performance is not different from the registry benchmark (approximately 86% of all hospitals have two stars).
- 3. The hospital's site difference and confidence intervals are all >0 (positive numbers) that do not cross the registry benchmark of 0.00. This implies a hospital has better than expected performance.