

# Compare apples with apples to call a spade a spade: Improving transcatheter aortic valve replacement outcomes nationally



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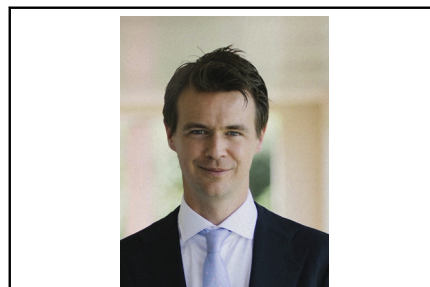
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## Central Message

STS/ACC TVT Registry results are inferior to those of major trials and large-volume expert centers. It would be nice to define risk better and aim higher with outcomes for patients undergoing TAVR.

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Since US Food and Drug Administration approval was granted, the number of centers performing transcatheter aortic valve replacement (TAVR) has grown significantly, from 198 centers performing 4627 procedures in 2012 to 414 centers performing 24,808 procedures in 2015.<sup>1</sup> By the end of 2017, there were more than 560 sites performing TAVR and 48,000 TAVR procedures performed in the United States. (unpublished data). The Transcatheter Valve Therapy (TVT) Registry was developed in 2011 by the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) to monitor the real-world outcomes of TAVR.<sup>2</sup> Currently, participation is mandated by the US Centers for Medicare & Medicaid Services as a condition of hospital reimbursement.

In this issue of the *Journal*, Henn and colleagues<sup>3</sup> compare observed to expected (O:E) mortality ratios in 546 patients from their institution who underwent TAVR between 2008 to 2015, with the expected mortality determined with the STS Predicted Risk of Mortality (STS-PROM) score. Henn and colleagues<sup>3</sup> are to be congratulated for their institution's excellent results, which are consistent across patient groups and over time. Henn and colleagues<sup>3</sup> highlight that the results of the major trials (and their own) are better (O:E 0.4-0.6) than those reported in the TVT Registry (O:E 0.88-1.09). They argue that a higher bar should be used than an O:E of 1.0 for those patients undergoing TAVR in the US TVT Registry.

Despite the TVT Registry results being similar to that of other European Registries,<sup>4</sup> an explanation is required to account for discrepancies in "controlled trial" and "real-world" outcomes in the commercial application of TAVR. One potential explanation is the performance of TAVR by low-volume centers. A relationship between procedure volume and outcome was established in the initial adoption of TAVR through examination of the TVT Registry<sup>5</sup> and is

currently a very controversial topic. There was an inverse relationship between periprocedural morbidity and mortality and TAVR volume that persisted up to 400 cases. Some centers may still be negotiating their learning curves, given the rapid uptake of the technique by an increasing number of centers. The relationship between annual center and proceduralist volume with clinical outcomes is established for mitral valve repair,<sup>6</sup> but it has yet to be fully explored in detail for TAVR. This is urgently required.

Further work is required to assess risk better, which by default will lead to improved outcomes in TAVR. The use of O:E ratios to measure risk-adjusted outcomes is simple and elegantly allows comparison with other data sets. The STS-PROM is used to assess risk in most studies; as is clearly apparent, however, this score was calculated from the outcomes of surgical patients, not those undergoing TAVR. The STS-PROM does not include other factors by which patients are selected for TAVR (frailty, porcelain aorta, liver failure or other organ dysfunction, and procedure-specific factors), and these factors are known to influence outcomes.<sup>7</sup> To date, 2 risk models for mortality are derived solely from patients undergoing TAVR: the STS/ACC TVT Registry<sup>8</sup> and the FRANCE 2 (FRench Aortic National CoreValve and Edwards) Registry.<sup>9</sup> The TVT Registry model includes the largest number of patients

and was found to predict mortality better when compared with the STS-PROM, euroSCORE and FRANCE 2 models; however, it is only gated on in-hospital metrics.<sup>8</sup> Although a 30-day TVT-specific predicted risk of mortality score is being developed by our committees, we do not currently have a comparable score to the 30 day STS-PROM score. Gait speed is now included in data collection for the TVT Registry as a measure of frailty but is yet to be included in risk assessment models. Continued accumulation of TVT Registry data will allow the formulation of more accurate and useful predictors of risk and outcomes.

As practicing heart teams for the management of aortic stenosis, it is incumbent upon us to provide the absolutely best outcomes for our patients in both the short and long terms, whether with surgical aortic valve replacement or with TAVR. As we concentrate on TAVR outcomes and the TVT Registry, we need to also be mindful of surgical aortic valve replacement outcomes and the STS database. Although volume and repetition are clearly important in outcomes, an even more important variable may be high-quality, objective measures.

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