Commentary: Variability matters—lessons for quality and health policy

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In this issue of the *Journal*, Greason and colleagues provide a detailed look at the variability within the Placement of Aortic Transcatheter Valves-2A (PARTNER-2A) trial. Variability is an often-overlooked but incredibly informative measure of quality. One reason for this is the complex statistics required that are neither common nor intuitive. In this study, the authors presented their results using more intuitive metrics such as hazard ratios. The other reason for limited variability analyses is that they require large sample sizes or high event rates.

Within the PARTNER-2A trial, there was an impressive amount of inter-site variability. There was a 4-fold range in relative risk of mortality across participating sites, for both transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR). Although this variability extended to stroke after SAVR, there was no identified variability for TAVR in this smaller population of only clinical trial patients. This point highlights the importance of big data, where the coordination of the Society of Thoracic Surgeons (STS) National Database and Transcatheter Valve Therapies database is going to be critical to the future success of TAVR. When the sample size is small or event rates are low, deviation from high-quality care is difficult to identify and therefore unable to be corrected. The inclusion of more than 99% of cardiac practices with high-volume mortality within the STS database also represents real-world results, rather than hand-picked sites that gave the trial the best chances of a success. Finally, much of the variability noted came after 30 days. The importance of post–30-day care and outcomes is becoming ever more evident, with meaningful patient outcomes now being measured at a year and alternative payment models bundling 90-day coverage.

Drivers of inter-site variability included case mix and volume, with 73% of the variability in mortality after TAVR. This is significantly more than for SAVR (37%), supporting procedural volume requirements for TAVR programs. In addition, low volume was associated with early death. These results from PARTNER-2A are corroborated by recently published data from the Transcatheter Valve Therapies database showing a 19.45% relative risk reduction between highest and lowest TAVR volume quartiles. In addition, there was considerable variability in low-volume centers, with mortality estimates ranging from 0% to >12.5%. The driver of this trend is likely that higher-volume programs have greater resources at their disposal, allowing for a more robust multidisciplinary advanced valve team. This also impacts case mix, where robust preoperative patient selection and optimization likely influences the variability seen. Because these teams work across both surgical and interventional procedures, it is not surprising that limited intra-site variability was noted. The relationship between TAVR and SAVR outcomes could also have policy implications from a regulatory standpoint. These findings are also consistent with the finding that hospitals tend to have similar valve and coronary outcomes. A strong team, whether that is the advanced valve team or the cardiac surgical team, is critical to achieving high-quality care.
References


