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TAVR for Bicuspid Aortic Valves: Past Is Prologue or Tempest in a Teapot?

Nagaraja and colleagues set out to compare the outcomes for TAVR in bicuspid aortic valves (BAV) and tricuspid aortic valves (TAV) by looking at all adult TAVR cases extracted by ICD code in the National Inpatient Sample (NIS) database [1]. The NIS is the biggest all-payer inpatient health care database. This includes clinical outcomes of all-cause in hospital mortality, length of stay, and the total charge for the hospitalization. These outcomes were extracted for each discharge. Procedural complications were identified using ICD-9 codes. The time period for the study was from January 2011 until December 2014. The search yielded a total of 40,601 cases with 407 (1%) BAV and 40,197 (99%) TAV cases. After propensity matching, there was no difference for mortality, any of the measured complications, length of stay, or costs. The authors concluded that TAVR for BAV "should not be considered prohibitive and can be successfully performed for BAV with similar peri-procedural outcomes compared to those with TAV." We fully agree with their conclusion.

We congratulate the authors on a detailed analysis of what represents a substantial amount of work. Their findings and conclusions add to our knowledge of TAVR and BAV disease. There are a number of issues, however, that one must keep in mind when reading this excellent paper. With the rapid advancements in TAVR, the time period that ended over 4 years ago is helpful but now almost ancient history. The rapid advancement and improvement seen in TAVR make it difficult for any paper to be truly current, but we believe this large data set helps us understand the basis for considering TAVR in BAV. Additionally, we see only 1% of these cases listed as BAV. One must ask if this number is real or represents more wishful thinking in the classification by sites to avoid doing an "off label" procedure. We have seen on numerous occasions a Sievers 1 BAV with left/right fusion described as a "functionally bicuspid tricuspid valve" – an entity that does not exist. These are of course all congenital BAV, and the number of these self-reported cases in the database likely markedly underrepresents the true number of BAV cases done. Additionally, experienced TAVR implanters early on learned to recognize BAV anatomy more likely to allow successful TAVR, and the cases seen in this database are likely carefully selected for favorable anatomy and likely selected to be at higher risk by the local heart team and therefore passed up for surgery. This type of selection bias is difficult, if not impossible, to fully match out. One of the major worries in TAVR for BAV is the risk of paravalvular leak, and this information is not available from the database used. Despite these considerations, this well-analyzed, large data set helps define the initial BAV experience and sets the stage for future development.

Contemporary results from the Bicuspid AS TAVR registry, an international, multicenter, observational study initiated in 2013, looked at outcomes of 561 patients with bicuspid aortic stenosis (AS) and 4546 patients with tricuspid AS [2]. These were compared after propensity-score matching assembling 546 pairs of patients with similar baseline characteristics. They found more frequent procedural events for BAV versus TAV in the early generation TAVR valves, that which no longer present in the current generation valves. For both early and current-generation valves, there is no difference in 2-year mortality. Core lab-adjudicated results will eventually be available for the bicuspid registry arm of the Partner IIIA low-risk trial as well as the Evolut low risk-bicuspid trial, which is currently enrolling. These trials are built upon past learning such as seen in the analysis by Nagaraja. The Bard was correct, past is prologue and, perhaps when considering TAVR in BAV, this tempest really is only in a teapot.

References

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