Pacemaker After Transcatheter Aortic Valve Replacement
Unexpected, But Not Infrequent Outcome*

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Transcatheter aortic valve replacement (TAVR) is a management choice for patients with severe symptomatic aortic stenosis (AS) who are deemed poor operative candidates. The decision to proceed with TAVR is by no means simple; it requires the evaluation of considerations such as the team performing the procedures, device suitability, and short-term and long-term outcomes. In the 2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement (1), the authors described the complexity of the device and the need for a team approach and monitoring of outcomes. Given the potential for complications in this delicate population, careful patient selection is required; ultimately, the procedure is offered with the understanding that surgery is prohibitively risky. The inherent risks of TAVR in the population deemed inoperable is balanced against the observation that inoperable patients with severe AS who do not receive a valve replacement face a 50% incidence rate of 1-year mortality (2).

When offering any new technology, it is critical to evaluate any unforeseen or device-specific complications that can arise. TAVR is associated with a number of clear risks, including vascular complications, bleeding, stroke, perivalvular leaks, and death. It is estimated that nearly one-third of patients with severe AS who could benefit from the hemodynamic correction of aortic valve placement are not operative candidates, and thus a large patient population could potentially be considered for TAVR (3).

In this issue of the Journal, Siontis et al. (4) focus on one particular outcome: the need for placement of a permanent pacemaker after TAVR. For comparative purposes, following surgical aortic valve replacement (AVR) in high-risk patients (with a mean Society of Thoracic Surgeons [STS] predicted risk of mortality of 16.3%), complications include the need for a new permanent pacemaker in 5% of patients (5). In the surgical population, a number of predictors indicating the need for a permanent pacemaker after AVR have been noted, including aortic insufficiency, pulmonary hypertension, and prior myocardial infarction. Proposed mechanisms for the increased risk include the effects of stretch associated with aortic insufficiency or pulmonary hypertension and prior ischemic injury to the conduction system (6). An alternate explanation for the increased risk of a pacemaker in those with preoperative aortic insufficiency may be related to the size of the aortic annulus and the larger size of the implanted prosthetic valve (7). Little is known about the long-term impact of pacemaker implantation in the surgical population.

Two commercially available valves are considered in the report by Siontis et al. (4): the Edwards Sapien valve (ESV) (Edwards Lifesciences, Inc., Irvine, California) and the Medtronic CoreValve Revalving System (MCRS) (Medtronic, Inc., Minneapolis, Minnesota). These 2 valves are significantly different in construction. The ESV is composed of a trileaflet bovine pericardial valve that is mounted on a balloon-expandable cobalt chromium alloy stent. In the United States, it is available in 23- and 26-mm sizes; in
Europe, sizes include 23 mm, 26 mm, and 29 mm. The MCRS is comprised of porcine pericardial tissue leaflets mounted on a self-expanding nitinol frame. The sizes available are 26 mm, 29 mm, and 31 mm. The overall profile of the MCRS is larger, and the nitinol frame extends further down into the left ventricular outflow tract. At the time of data extraction for the report by Siontis et al. (4), only the ESV was approved by the Food and Drug Administration in the United States but both valves were available in Europe. The MCRS now has gained Food and Drug Administration approval in the United States, and implantation has begun in selected centers.

The overall rate of requirement of a permanent pacemaker after TAVR (regardless of which valve was used) was 17% (4), as compared with the 5% rate reported with AVR (5). The rate of requirement of a permanent pacemaker was higher in patients treated with the MCRS (median of 28%) than with the ESV (6%). Similar to the surgical experience, Siontis et al. (4) identified several parameters that indicate a high risk of requirement of a permanent pacemaker. On the basis of their wide literature search, they were able to identify an increased risk irrespective of valve type in male patients; those with baseline first-degree atrioventricular (AV) block, left anterior hemiblock, or right bundle branch block; and those who developed periprocedural AV block. Use of the MCRS was associated with a 2.5-fold risk of requirement of a pacemaker.

Some light was shed on these observations by a recent study of the conduction system, which was prompted by observations of the risk of heart block in patients undergoing TAVR. In an anatomic study, Kawashima and Sato (8) reported that the AV node and left bundle branch are located more anteriorly, distally, and cranially and closer to the aortic root than previously believed. Thus, it is not surprising that patients with pre-existing right bundle branch block or first-degree AV block would be at greater risk for heart block with device manipulation in the left ventricular outflow. It also would be reasonable to anticipate a fairly high prevalence of pre-existing conduction abnormalities in the type of patient who would be a candidate for TAVR (i.e., an older population with calcific AS).

An interesting dynamic exists between the type of valve and theoretical concerns regarding heart block after TAVR. Similar to surgery, there can be improvement in conduction after initial disturbances following TAVR, presumably related to reversible procedural-related trauma to the conduction system (2,9). As such, when the patient is hemodynamically stable or has a functional temporary pacemaker, some delay before committing to a permanent pacemaker may be appropriate. However, the duration of “watchful waiting” is not defined either in the report by Siontis et al. (4) or in the surgical literature. On the other hand, the self-expanding MCRS may not fully expand for 7 to 10 days (10). Therefore, it is conceivable that the full extent of potential risk may not be immediately apparent at the time of TAVR. At this juncture, there are no concrete recommendations for indications for pacemaker implantation or timing of implantation after TAVR. Future data from TAVR centers and from pacemaker surveillance clinics may be elucidating.

The higher risk of pacemaker implantation in men is also an interesting observation, and it is not immediately apparent whether this is due to implantation of larger valves, with larger profiles leading to greater risk of mechanical trauma versus variations in anatomic factors (i.e., more advanced disease, greater degree of calcification).

When considering future applications and the development of prosthetic valves for percutaneous applications, the observations from the current study may point to important characteristics such as lower profile and shorter height. Alternatively, modifying implantation techniques could potentially reduce the risk of pacemaker implantation (11). In addition, the long-term consequences of pacemaker implantation and type of pacemaker devices used in these patients need to be evaluated. There are data showing that QRS duration following TAVR may be a predictor of outcomes. In a single-center prospective study of patients post-TAVR, those with a QRS duration of >150 ms had significantly higher all-cause mortality than did those with a QRS duration of ≤120 ms (12). One meta-analysis of the impact of pacemaker implantation after TAVR showed no impact on mortality in patients receiving new pacemaker implants after TAVR, but there was worsening of heart failure and prolongation of hospital stay (13).

These data underscore the importance of knowing the patient characteristics that confer risks for pacemaker implantation post-TAVR, as well described by Siontis et al. (4), and thereby taking steps to monitor patients appropriately. Furthermore, procedure modifications to potentially reduce risk and refinement of percutaneous valve types to minimize trauma to the conduction system are anticipated.

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