risk of PPI implantation after RD-AVR is reduced over time in expert centers, suggesting that implant technique influences the incidence of heart block for these new devices akin to how surgical technique (eg, annular debridement and suture placement) likely influence the incidence of heart block with conventional SAVR.

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Commentary: Pacemaker requirement with rapid-deployment aortic valves

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"You and I travel to the beat of a different drum"
—Linda Ronstadt

The treatment options for severe aortic stenosis in symptomatic patients have changed dramatically in the last decade. When we started our practices and the decision to treat aortic stenosis was made, the only option was surgery and the only choice was between mechanical and tissue valves. True, there were multiple types of mechanical and tissue valves, but selecting a specific valve was usually a decision of minor consequence. Once this choice was

CENTRAL MESSAGE

With multiple options now available for aortic valve replacement, the outcomes of different approaches play an important role in the decision process.

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Disclosures: Dr Reardon was the surgical national principal investigator for the Evolut Low-risk trial and serves as a consultant to Medtronic. Dr Kleiman reports the following: Medtronic educational grants, Medtronic clinical trial, Edwards LS clinical trial, BSC clinical trial, and Abbott clinical trial.

Received for publication Feb 3, 2020; accepted for publication Feb 4, 2020; available ahead of print Feb 14, 2020.

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J Thorac Cardiovasc Surg 2021;162:813-5

0022-5223/\$36.00

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<https://doi.org/10.1016/j.jtcvs.2020.02.012>

made, competing claims for superiority of one valve over the other were usually difficult to substantiate. Fast-forward to current day, and we now have new options to consider, including transcatheter aortic valve replacement (TAVR), minimally invasive surgical techniques, and rapid-deployment (RD) surgical valves. Each option has potential advantages and disadvantages that become increasingly important as we treat younger and lower-risk patients whose potential postoperative survival is longer. Two RD valves are currently available: the balloon-expandable Intuity valve (Edwards Lifesciences, Irvine, Calif) and the self-expanding Perceval valve (LivaNova, London, England).

In this issue of the *Journal*, Coti and colleagues¹ report the risk of pacemaker implantation after aortic valve replacement with the Intuity RD balloon-expandable valve. The current study encompasses 700 consecutive patients over a 19-year period who received an Intuity valve. Permanent pacemakers were present preoperatively in 37 patients (5.3%); these were excluded, leaving 663 patients in whom the risk of new pacemaker requirement could be evaluated. The median follow-up was 20 months, with the length of time between the median and the final longest follow-up extending to 9 years. The primary end point was the need for an early (within the first 14 days) pacemaker. Secondary end points of the need for a pacemaker at any time and new-onset conduction defects were also examined. Patients' mean age was 73.4 ± 7.8 years, median Society of Thoracic Surgeons score was 2.2%, and 30-day operative mortality was 0.6%. The need for a new pacemaker was 9.4% at 14 days, 10.3% at 30 days, 11.7% at 1 year, and 15.3% at 5 years. These findings are slightly lower than in the report of patients treated with the Intuity valve in the US Transform trial, in which the pacemaker rate was 12.3%,² but are slightly higher than in the current reported European experience of 6% and 6.8% for the Perceval and Intuity valves, respectively.³ In a landmark analysis in the current study, the need for a new pacemaker did not influence survival at 1 year. Of the patients receiving a new pacemaker, pacemaker interrogation was performed in 51 of 80 patients (64%) who had 1-year follow-up at the authors' institution. Of this group, 31 patients (60.1%) were found to be pacemaker-dependent (using a rather rigorous definition). Factors associated with the need for a new pacemaker were preexisting conduction defects, especially right bundle branch block, advanced age, and associated procedures, such as mitral valve surgery or a Maze procedure for atrial fibrillation.

It is critical to view these findings in light of the most recent trials comparing TAVR with surgical aortic valve replacement (SAVR). These trials have been scrutinized rigorously and monitored extensively, and thus are likely to represent the most robust estimates available of pacemaker implantation rates after aortic valve replacement. In the 2 recently published pivotal studies of TAVR in patients at low risk for SAVR, the demographics were strikingly similar to those reported in the current study, particularly in terms of the nearly identical median age (73–74 years), Society of Thoracic Surgeons risk scores (<2.5%), and low operative mortality (<1.5%).^{4,5} The 9.4% pacemaker implant rate in the current study is considerably higher than those reported after SAVR in the surgical arms of the low-risk trials (4.0% and 6.1%, respectively) and is intermediate between those reported for TAVR (6.1% and 17.4%, respectively) in the PARTNER 3 and Evolut Low-risk trials. Notably,

concomitant procedures such as mitral valve surgery and Maze procedures were performed in a small number of patients in the current series. Although patients known to require concomitant procedures, other than coronary artery bypass, were technically excluded from the low-risk TAVR trials, surgeons in both low-risk trials performed these procedures in a small number of patients. Approximately one-third of the surgical valves in the Evolut low-risk TAVR trial were RD valves (data presented at the European Association for Cardio-Thoracic Surgery 2019), which likely represents an attempt by surgeons to achieve more TAVR-like hemodynamics.

How the medical community chooses to use this information to select treatments remains to be seen. RD valves offer several potential advantages over traditional surgical valves, including lower gradients and shorter pump times. However, RD valves have also been beset by reports of higher valve thrombosis rates and higher pacemaker rates. Although it is encouraging to see an exceedingly low operative mortality and a reasonably low pacemaker rate in this low risk-appearing group of patients, it is important not to underestimate the morbidity associated with pacemaker implantation in the low-risk group studied here. The authors report no effect of pacemaker on survival; however, it should be recognized that median follow-up was only 20 months with an interquartile range extending to 41 months, so the study is not adequately powered to assess longer-term mortality among pacemaker recipients. Pacemaker implantation can be achieved rapidly and with little procedural morbidity by experienced operators. However, mortality may be too blunt an instrument to assess the total impact of pacemaker requirement. Such long-term effects as lead entrapment of tricuspid leaflets leading to significant tricuspid regurgitation and dyssynchronous ventricular contraction may cause persistence of the symptoms that were meant to be alleviated by aortic valve replacement. It is hoped that advances in pacemaker technology such as leadless pacemakers and His bundle pacing will help alleviate these drawbacks.

As indicated by Coti and colleagues,¹ selecting conventional aortic prostheses for patients with preexisting conduction defects will almost certainly reduce the need for pacemakers after implanting RD valves, as would avoiding older patients and those requiring concomitant procedures. However, avoiding RD valves in these groups would deprive the patients who stand to benefit the most from the low gradients and shorter pump times of the advantages of an RD valve.

The report by Coti and colleagues¹ is important in that it confirms the higher pacemaker implantation rate previously reported for RD valves. Although increased experience with these valves will undoubtedly lead to some moderation of the pacemaker rate, this risk is clearly one more factor that will have to be taken into account when considering

the expanded options now available to treat aortic stenosis and in framing physician–patient discussion of these options. How individual physicians and patients weigh each factor will influence how they choose. In these cases, perhaps we will march to the beat of a different drum.

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