The PERIGON Investigators avail us of the Avalu

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Disclosures: Author has nothing to disclose with regard to commercial support.

Received for publication April 12, 2018; accepted for publication April 12, 2018; available ahead of print June 5, 2018.

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J Thorac Cardiovasc Surg 2018;156:1378-9

0022-5223/\$36.00

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<https://doi.org/10.1016/j.jtcvs.2018.04.060>

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Central Message

Regulatory agency criteria for approval of a new valve are reported.

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In this issue of the *Journal*, Sabik and colleagues¹ report early and 1-year outcomes of the Medtronic Pericardial Surgical Aortic Valve Replacement Pivotal Trial (PERIGON trial) of the Avalu aortic valve (Medtronic, Minneapolis, Minn) conducted by 36 centers across 8 countries. In a cohort of 864 patients, 30-day and 1-year outcomes for this new pericardial stented valve were compared with regulatory agency objective performance criteria for heart valves.¹ The valve performs similar to other valves currently in use, and Sabik and colleagues¹ provide early and 1-year survival comparisons with 4 other bioprosthetic valves. At 1 year, adverse events were not dissimilar to those found with comparable bioprosthetic valves; however, late hemorrhagic events, at a rate above that expected from objective performance criteria, and patient-prosthetic mismatch (PPM) are some of the findings that stand out.

Sabik and colleagues¹ reasoned that the increased bleeding rate was unlikely to be due to valve-related factors. Rather, the high proportion of patients (68%) receiving antiplatelet agents or anticoagulation for preexisting conditions skewed the results of the whole. Except when induced atrial dysrhythmia or thromboembolic events are the reason for treatment, it is intuitively obvious that the valve itself should not be a cause for hemorrhagic events. The incidence of thromboembolic events was low (1.4% for early events and 1.7% for late events). A greater proportion of patients, however, required antiplatelet agents or anticoagulants early in their treatment. At discharge, many (42.8%) of these patients were receiving anticoagulants, with or without antiplatelet agents; by 1 year, however, the proportion receiving anticoagulants (16.1%) was substantially less. Because only 576 patients made it out to the 1-year mark, they would have contributed less to the linearized rate. Sabik and colleagues¹ reason that because a greater proportion of the whole approach the 1-year mark, the linearized rate of hemorrhage should decrease, assuming that bleeding is due to anticoagulant use and assuming the trend to decreased usage of anticoagulant

continued in the patients getting further out from surgery. Neither of these assumptions is unreasonable.

PPM is a concern to most surgeons, but the significance of PPM varies according to the population studied. PPM may impact younger patients (age <70 years), those with lower body mass index, and those with concomitant coronary artery bypass grafting more than others.² In the PERIGON study,¹ according to indexed effective orifice area, one-third of patients had no PPM, 44% had moderate PPM and 22% had severe PPM. These ratios are similar to those in a recent meta-analysis.² As expected, the distribution of PPM severity correlated to size of the prosthesis, with the larger (29 mm) valves having proportionally the fewest cases of severe PPM and the most cases of absent PPM; conversely, the smaller valve (19 mm) had proportionally more severe PPM and less absent PPM. Each valve size had except for the largest (29 mm) and the smallest (17 mm) valve sizes, more than 50% of patents had at least moderate PPM; however, the numbers of patients were low, with only 9 patients having a 29-mm valve implanted and 1 patient having a 17-mm valve implanted. Although the PERIGON Investigators³ found no significant effect of PPM on 1-year outcomes, differences may emerge with time. The Avalu will be another aortic valve available to patients, and it will be of interest where it finds its niche.

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