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EDITORIAL COMMENT

The Results of Transcatheter Aortic Valve Replacement Continue to Improve

The Specific Example of a Self-Expandable Transcatheter Heart Valve in a Real-Life Registry*

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The cardiology field has markedly evolved in the last years, changing the course of cardiovascular diseases. One of the best examples is interventional cardiology, which rapidly embraces new technologies while promoting continuous technological innovations.

Transcatheter aortic valve replacement (TAVR) is one of the last revolutions in this field. While technique and technological iterations were taking place, evidence supported the expansion of indications for TAVR from patients at high or prohibitive risk toward those at intermediate surgical risk (1).

SEE PAGE 2090

In this issue of *JACC: Cardiovascular Interventions*, Sorajja et al. (2) show the benefits associated with the technological iterations of TAVR, with the specific example of self-expandable valves. Compared with its predecessor, the CoreValve device (Medtronic, Minneapolis, Minnesota), the Evolut R (Medtronic) incorporated several advances, the main ones being its ability to be repositioned and recaptured. A subanalysis of the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapies) registry was performed on a total of 9,616 high-risk elderly patients undergoing TAVR between 2014 and 2016. This study, which is the largest one on self-expandable prostheses, included 5,806 patients who received a CoreValve and, since the third quarter of 2015, 3,810 patients who were treated using an Evolut R. The use of an Evolut R device was independently associated with a higher rate of device success (96.3% vs. 94.9%; $p = 0.05$) mostly driven by a reduction in the need for a second prosthesis, a shorter length of stay (6.4 days vs. 7.5 days; $p < 0.0001$), and a slightly reduced unadjusted 30-day rate of permanent pacemaker implantation (18.3% vs. 20.1%; $p = 0.03$). Notably, the recapture or repositioning ability of the Evolut R device did not increase the risk of stroke or reduce the rate of moderate or severe paravalvular leaks at 30 days, which was similarly low in both groups. Despite the lower profile of the EnVeo R delivery catheter (Medtronic), vascular complications were also identical. Finally, an independent reduction in 30-day mortality was observed with the Evolut R in comparison with the CoreValve group (3.7% vs. 4.0%; $p < 0.001$).

Several limitations of this study should be highlighted. First, it is voluntary; second it is observational in nature and potential bias might remain despite results being adjusted for potential confounders; third, the large number of patients included in this registry allowed for detecting statistically significant differences—which were small in magnitude—and the clinical relevance of some of these differences could be debatable; fourth, procedures using the CoreValve device were performed earlier in time than those using the Evolut R device. As a consequence, the improved results observed in patients receiving an Evolut R device might also be related to the shift toward lower risk patients, increased experience of operators, and procedural

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simplification (higher use of percutaneous vascular closure and local anesthesia). Nonetheless, the use of conscious sedation and percutaneous closure remains low in this series when compared with European studies, despite TAVR being performed through the transfemoral approach in a high proportion of patients (3,4). Fifth, it remains to be demonstrated that the 34-mm Evolut XL device (Medtronic) outperforms the 31-mm CoreValve devices because both devices were not used in the study. Sixth, finally, the Evolut PRO device (Medtronic), which is the last generation of the CoreValve family, has already obtained the Food and Drug Administration and Conformité Européenne mark of approval, and has started to be used in clinical practice. It will probably rapidly replace the Evolut R device.

Overall, these "real-life" data confirm the trend observed in the latest studies showing improved outcomes and a reduced mortality of TAVR when using newer-generation devices including the Evolut R (4,5) and other prostheses such as the SAPIEN 3 (Edwards Lifesciences, Irvine, California) (3,6) and the Lotus (Boston Scientific, Marlborough, Massachusetts) (7) devices. It is important to note that the results observed today with the new TAVR devices suggest that the complementarity of different devices will be useful to further improve results when individualizing their use according to the characteristics of patients.

Large-scale registries, which encompass patients frequently excluded from randomized clinical trials, are a unique opportunity to evaluate clinical practices as well as the effectiveness of new devices and therapies, and determine whether the results of randomized trials are applicable to real life (8,9). Thus, initiatives such as the TVT registry as well as other large National registries such as the AQUA (German Aortic Valve Replacement Quality Assurance) registry (10), French registry (11), and UK registry (12) should be encouraged. In parallel, long-term follow-up data will be crucial to assess valve durability. These data will be essential in basing future indications of TAVR on solid evidence.

The final message here is that the results of TAVR continue to improve and this translates to better patient outcomes, which is our ultimate goal.

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