JACC: CARDIOVASCULAR INTERVENTIONS
PUBLISHED BY ELSEVIER ON BEHALF OF THE AMERICAN
COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 10, NO. 20, 2017
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2017.07.030

EDITORIAL COMMENT

A Comparison of the ACURATE Neo and Sapien 3 Valves

Making Progress*

Kreton Mavromatis, MD

Transcatheter heart valve (THV) technology has revolutionized aortic valve stenosis treatment. Currently, 2 THVs dominate the market worldwide, the balloon-expandable Sapien 3 (Edwards Lifesciences, Irvine, California) and the self-expanding Evolut (Medtronic, Minneapolis, Minnesota). However, several additional THVs have a small, but growing, presence outside the United States. One, the ACURATE Neo TF (Symetis, Lausanne, Switzerland), has gained prominence recently (1). The ACURATE Neo TF was first approved for commercial use in Europe in September 2014. Preceded by the ACURATE TA, a transapical device, the ACURATE Neo is a transfemorally delivered, self-expanding nitinol valve with porcine pericardial leaflets that operate in a supra-annular position, and a lower skirt for annular sealing. The 18-F delivery system is compatible with standard 18-F sheaths or a 15-F Solopath (Terumo Medical, Somerset, New Jersey). Available valve sizes (S, M, and L) are suitable for 21- to 27-mm diameter aortic valve annuli. Its unique design consists of aortic stabilization arches, which assist in centering the valve; an "upper crown" that anchors the valve supra-annularly; a waist that captures the native aortic valve leaflets; and a "lower crown," which rests in the upper left ventricular outflow tract. The valve is deployed from "top to bottom" and generally does not require rapid ventricular pacing.

A potential advantage of the ACURATE Neo over the more widely used Sapien 3 and Evolut valves is a more predictable and accurate deployment within the aortic root complex, minimizing the chance of aortic or ventricular migration, which can result in embolization, paravalvular leak (PVL), and/or conduction system disturbances. An additional advantage over the self-expanding Evolut valve is the absence of stent cells in the sinotubular junction and aorta, potentially allowing better coronary ostia access. Additional advantages over the balloon-expandable Sapien 3 include the absence of need for rapid ventricular pacing during deployment, with its resultant hemodynamic disturbance; the lower risk of annular rupture; and the supra-annular THV leaflet position, resulting in lower valve gradients and less leaflet thrombosis (2).

SEE PAGE 2078

The transcatheter aortic valve replacement (TAVR) study of the ACURATE Neo by Husser et al. (3) in this issue of *JACC: Cardiovascular Interventions* is the largest published experience to date and the first involving multiple centers, as well as a propensity-matched Sapien 3 control group. With 311 patients receiving ACURATE Neo and 622 matched patients receiving Sapien 3, the study revealed few significant procedural differences with the exception of more pre- and post-dilation when using ACURATE Neo than when using Sapien 3. Device success was similar (89.1% vs. 90.4%), with ACURATE Neo's higher frequency of PVL (4.8% vs. 1.8%; $p = 0.008$) counterbalanced by its lower occurrence of elevated (>20 mm Hg) gradients (3.2% vs. 6.9%; $p = 0.021$). There was no specific evidence of improved device accuracy, with 99% of both valve types placed in "correct position" and no difference in the need for multiple valves or conversion to surgical aortic valve replacement.

Interestingly, ACURATE Neo's new permanent pacemaker implantation (PPI) requirement was lower

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

From the Cardiology Division, Department of Medicine, Atlanta VA Medical Center, Emory University School of Medicine, Decatur, Georgia. Dr. Mavromatis has reported that he has no relationships relevant to the contents of this paper to disclose.

than with Sapien 3 (9.9% vs. 15.5%; p = 0.024). However, the Sapien 3 PPI requirement, although consistent with early Sapien 3 studies, is higher than what is now expected with the recent evolution towards a shallower implantation depth (4,5). Whether procedural changes (such as less aggressive predilation) may also result in lower PPI requirements with ACURATE Neo remains to be seen (6). No differences were seen in a subgroup analysis based on aortic cusp calcification or aortic annulus eccentricity as detected by multidetector computed tomography angiography.

Clinical outcomes at 30 days were also similar between ACURATE Neo and Sapien 3, with no difference in VARC-2 early safety (84.2% and 84.4%, respectively) or individual endpoint components. The lower PPI requirement favoring ACURATE Neo remained at 30 days. Also in ACURATE Neo's favor were lower mean THV gradients (8 ± 4 vs. 12 ± 5; p < 0.001), a finding consistent across all 3 valve sizes, and consistent with the supra-annular design.

The performance of ACURATE Neo in this study is generally consistent with the 1,000-patient single-arm SAVI TF (Symetis ACURATE Neo Valve Implantation Transfemoral) registry presented at EuroPCR in 2016, which showed a relatively low PPI rate of 8.2% and a PVL ≥2+ frequency of 4.1% (7). However, the present study has several important limitations in its ability to detect important differences between these THVs. Selection bias (311 ACURATE Neo TAVRs were performed compared with 810 Sapien 3 TAVRs during the same time period) undoubtedly occurred, and was likely based on multidetector computed tomography angiography features of transfemoral access and the aortic valve complex. These were unlikely to have been totally "corrected for" using the propensity matching used in this study. The lack of a core lab assessment of PVL and the lack of adjudication of clinical events are also important limitations. Finally, the study lacks the power to detect differences in infrequent, but catastrophic, events, such as annular rupture, valve embolization, etc. Identifying any differences between ACURATE Neo and other THVs is critically important for it to survive in the increasingly crowded market. To this end, the SCOPE I (Safety and Efficacy of the Symetis ACURATE Neo/TF Compared to the Edwards SAPIEN 3 Bioprosthesis; NCT03011346) and SCOPE II (Safety and Efficacy Comparison of Two TAVI Systems in a Prospective Randomized Evaluation II; NCT03192813) randomized controlled trials, comparing ACURATE Neo to Sapien 3 and Evolut are underway.

Also important to ACURATE Neo's future is its comparability to surgical aortic valve replacement (SAVR), particularly as TAVR moves to low-risk patients. Although the ACURATE Neo PPI requirement approximates that of SAVR, the PVL rate is substantially higher than with SAVR. The next-generation ACURATE, the Neo AS, is the same as the Neo with exception of an "Advanced Sealing" feature designed to reduce PVL. The first 30 patients of a 120-patient European registry show no evidence of ≥2+ PVL (8).

Perhaps most important to the ACURATE Neo is Boston Scientific's commitment to the ACURATE program. Edward's Sapien and Medtronic's Evolut THVs are under continuous evolution and improvement. With the completion of the REPRISE III (Safety and Efficacy Study of Lotus Valve for Transcatheter Aortic Valve Replacement) study, Boston Scientific's other THV, the repositionable LOTUS valve appears to be ahead of ACURATE in the Food and Drug Administration approval process. How long and how intensely Boston Scientific will develop both valves remains to be seen.

ADDRESS FOR CORRESPONDENCE: Dr. Kreton Mavromatis, Department of Medicine, Atlanta VA Medical Center, 1670 Clairmont Road, 111B, Decatur, Georgia 30033. E-mail: kmavro@emory.edu.

REFERENCES

1. Boston Scientific Closes Symetis Acquisition. Acquisition Expands Company's Structural Heart Portfolio; Increases Offerings for the Treatment of Patients with Valvular Heart Disease. Boston Scientific Corporation, 2017. Available at: http://news.bostonscientific.com/2017-05-16-Boston-Scientific-Closes-Symetis-Acquisition. Accessed June 28, 2016.

2. Chakravarty T, Sondergaard L, Friedman J, et al. Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study. Lancet 2017;389:2383–92.

3. Husser O, Kim W-K, Pelligrini C, et al. Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves. J Am Coll Cardiol Intv 2017;10:2078–87.

4. Husser O, Pellegrini C, Kessler T, et al. Predictors of permanent pacemaker implantations and new-onset conduction abnormalities with the SAPIEN 3 balloon-expandable transcatheter heart valve. J Am Coll Cardiol Intv 2016;9:244–54.

5. Schwerg M, Fulde F, Dreger H, Poller WC, Stangl K, Laule M. Optimized implantation height of the Edwards SAPIEN 3 valve to minimize pacemaker implantation after TAVI. J Interv Cardiol 2016;29:370–4.

6. Toggweiler S, Nissen H, Mogensen B, et al. Low new permanent pacemaker rate with ACURATE Neo. Paper presented at: EuroPCR 2017; May 17, 2017; Paris, France.

7. Moellman H. SAVI TF Registry. EuroPCR; May 17, 2016; Paris, France.

8. Moellman H. ACURATE Neo AS: Advanced Sealing Technology-First Data Presentation. EuroPCR 2017; May 17, 2017; Paris, France.

KEY WORDS pacemaker, paravalvular aortic regurgitation, transcatheter aortic valve replacement