

EDITORIAL COMMENT

Expert Article Analysis for:

[One-year clinical outcome with a novel self-expanding transcatheter heart valve](#)

A novel self-expanding transcatheter heart valve: Shaping the story beyond accuracy

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Key Points

- As transcatheter aortic valve implantation expands to low risk patients, the key to prolonged survival would be large effective orifice area with extremely low rates of paravalvular leak and permanent pacemaker implantation.
- New transcatheter valve technologies look promising to enable this, ACURATE neo is one such device.
- The results of ongoing trials with ACURATE neo and ACURATE neo2 are keenly awaited.

"Fast is fine but being accurate could be everything—WYATT EARP"

Over the last 15-years, fair to say due to collaborative efforts between interventional cardiologists and cardiac surgeons in conducting pivotal robust trials, transfemoral Transcatheter Aortic Valve Implantation (TAVI) has established itself as the "standard of care" for most of the elderly patients with severe aortic stenosis. The initial drawbacks of the therapy compared to surgical aortic valve

replacement namely uncertain sizing, unpredictable deployment, large bore arterial access and resultant vascular complications, higher incidence of para valvular leaks (PVL) adversely affecting long term survival and the high rate of conduction disturbances requiring permanent pacemaker implantation (PPI) are gradually being overcome to an extent by device iterations and technique modifications to improve the simplicity, safety, and effectiveness of the procedure. As we move down the risk profile of aortic stenosis patients who are therefore younger and with longer life ahead, what matters most in addition to durability of the valve and accessibility of the coronary arteries is also large effective orifice areas and extremely low rates of PVL and PPI. Hence, research and development into newer transcatheter heart valve (THV) and techniques needs to continue.

In this issue of the journal, Pellergrini and colleagues¹ publish their single center VARC-2 defined 1 year outcomes with a novel self-expanding THV, the ACURATE neo (Symetis/Boston Scientific, Ecublens, Switzerland) in a population of intermediate risk patients (median logistic Euroscore I = 13.8). The ACURATE neo is a second generation Nitinol self-expanding, supra annular porcine pericardial tissue THV. It has a unique top to down two-step deployment, which enables valve stabilization as the first step and instantaneous and accurate deployment of the valve as the second step with minimal protrusion into the LV cavity and is not recapturable.² The valve is delivered through 18F–20F sheath and more recently through a 14F expandable sheath. At the outset, it is important to point out that the study is observational data on a small number of patients (151) who underwent TAVR with this valve very early after its CE mark in September 2014 and unlike current practice 94% procedures were performed under general anesthesia. They demonstrated device success in 88.1% (133/151), procedure related mortality was 0.7% (1/151). At 1-year, all-cause mortality was 3.3% (5/151), and PPI was needed in 12.7% (19/151) patients. The "clinical efficacy after 30 days" was observed in 24.8% (37/151), where the main contributor was symptom worsening in 14.8% (22/151) of cases. "Time-related valve safety" occurred in 22.0% (33/151) with structural valve deterioration as main contributor in 10.7% (16/151) of cases.

These favorable results for survival, stroke and PPI with this novel THV were also demonstrated in the subsequent 1,000 patients SAVI-TF multicenter registry of ACURATE neo in intermediate and high risk patients which at 1 year showed low all-cause mortality at 8%, one of the lowest reported PPI rates at 9.9% (possibly related to low radial force and minimal protrusion of the lower crowns into left ventricular outflow tract of this THV thereby decreasing compression of the conduction system) and very low rates of moderate to severe PVL at 3.5%.³

However, the proof of potential advantages of different TAVI devices lies in robust comparative randomized trials and it is a credit of the investigators and the company to have done one of the first such studies to compare the promising “kid” - the ACURATE neo to the well-established “champ” - the balloon expandable Sapien 3 (Edwards Lifesciences, Irvine, CA) looking at a composite endpoint of safety and efficacy at 30-days in a noninferiority trial, the SCOPE-1 which was presented at the TCT in San Francisco in September 2019 with simultaneous publication.⁴ Seven hundred and thirty nine patients (mean age 82.8 years) at increased surgical risk were randomized. ACURATE neo unfortunately did not meet the noninferiority endpoint. The superiority of Sapien 3 was mainly driven by higher acute kidney injury (AKI) and moderate to severe PVL (9% vs. 3%) in the ACURATE neo group. On the plus side, ACURATE neo resulted in larger effective orifice area and lower gradients as well as low stroke and PPI rates. The ACURATE neo group had significantly longer procedure time, more pre and post dilation and more contrast use all of which could have increased the incidence of AKI. The significantly higher incidence of PVL with accurate neo could be related to low radial strength of the device especially in heavily calcified valves as well as to the absence of a sealing skirt. Both these issues are probably solvable by device iterations. The next generation of this valve - ACURATE neo2 which has a sealing skirt is already available and initial European single arm prospective multicenter registry of 120 patients demonstrated low AKI rates of 0.8% and more than mild PVL rates of only 2.5% at 1 year. The results of SCOPE-II randomized trial comparing ACURATE neo to self-expanding Evolut R/PRO and also powered for superiority for PPI are awaited.

The quest for newer THV which would improve on the current outcomes and decrease the complications further must continue.

It would not just be a vital component of expansion of TAVI to lower risk patients but more choices could be an important enabler to bring down the cost of therapy in the environment of constrained healthcare spends worldwide.

CONFLICT OF INTEREST

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How to cite this article: Seth A, Kumar V. A novel self-expanding transcatheter heart valve: Shaping the story beyond accuracy. *Catheter Cardiovasc Interv.* 2019;94:793-794. <https://doi.org/10.1002/ccd.28568>