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STRUCTURAL

The SAVI-TF Registry

1-Year Outcomes of the European Post-Market Registry Using the ACURATE neo Transcatheter Heart Valve Under Real-World Conditions in 1,000 Patients

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ABSTRACT

OBJECTIVES The SAVI-TF (Symetis ACURATE neo Valve Implantation Using Transfemoral Access) registry was initiated to study the ACURATE neo transcatheter heart valve in a large patient population treated under real-world conditions.

BACKGROUND The self-expanding, supra-annular ACURATE neo prosthesis is a transcatheter heart valve that gained the Conformité Européene mark in 2014, but only limited clinical data are available so far.

METHODS This prospective, multicenter registry enrolled 1,000 patients at 25 European centers who were followed for 1 year post-procedure.

RESULTS Mean patient age was 81.1 ± 5.2 years; mean logistic European System for Cardiac Operative Risk Evaluation I score, European System for Cardiac Operative Risk Evaluation II score, and Society of Thoracic Surgeons score were 18.1 ± 12.5%, 6.6 ± 7.5%, and 6.0 ± 5.6%, respectively. At 1 year, 8.0% (95% confidence interval [CI]: 6.3% to 9.7%) of patients had died, 2.3% (95% CI: 1.3% to 3.2%) had disabling strokes, and 9.9% (95% CI: 8.1% to 11.8%) had permanent pacemaker implantations. Through 1 year, 5 reinterventions (0.5%; 95% CI: 0.1% to 1.0%) were performed: 3 valve-in-valve and 2 surgical aortic valve replacements. Mean effective orifice area was 1.84 ± 0.43 cm^2, mean gradient was 7.3 ± 3.7 mm Hg, and greater than mild paravalvular leakage was observed in 3.6% of patients.

CONCLUSIONS Transfemoral implantation of the ACURATE neo prosthesis resulted in favorable 1-year clinical and echocardiographic outcomes with very low mortality and new pacemaker rates. (J Am Coll Cardiol Intv 2018;11:1368–74)

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In 2007, the first transcatheter heart valves (THVs) gained the Conformité Européene (CE) mark. Since then, procedural techniques have been refined and newer THVs have been developed, leading to an improved safety profile, higher rates of clinical success, and more widespread adoption of the technology (1,2). Longer-term results with THVs demonstrating continued valve durability and clinical outcomes, comparable with or better than surgical valve replacement, have been reported (3–5).

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The self-expanding ACURATE neo prosthesis (Symetis, a Boston Scientific company, Ecublens, Switzerland) is a next-generation device that is implanted using a 2-step top-down deployment. The upper crowns are responsible for supra-annular anchoring of the prosthesis and capping of the native leaflets, stabilization arches contribute to axial self-alignment, and the pericardial skirt acts as a seal to prevent paravalvular leaks (PVLs) (6). The prosthesis received the CE mark in September 2014 on the basis of the TF89 CE-approval cohort (7). Thereafter, the SAVI-TF (Symetis ACURATE neo Valve Implantation Using Transfemoral Access) registry was initiated to assess outcomes with ACURATE neo in routine clinical practice in a large patient population. Thirty-day results showed promising outcomes, with very low mortality and pacemaker rates (8). We now report 1-year outcomes from SAVI-TF, which to our knowledge is the largest body of 1-year data available on ACURATE neo to date.

METHODS

The study design has been previously described (8). In brief, SAVI-TF is a prospective, single-arm, multicenter, all-comers registry of patients in whom transfemoral implantation of an ACURATE neo prosthesis was attempted.

Patients could be enrolled if they qualified for transcatheter aortic valve replacement with the ACURATE neo prosthesis via transfemoral access as per instructions for use, provided written informed consent, and were willing to attend follow-up visits. The only exclusion criterion was for patients who were not eligible for treatment with ACURATE neo. Treatment was conducted per each center's standard of care. Follow-up occurred at discharge or 7 days, at 30 days, and at 1 year post-procedure (the latter preferably as an on-site visit including echocardiography and New York Heart Association classification).

The study was registered at ClinicalTrials.gov (NCT02306226), conducted according to the Declaration of Helsinki, and approved by the local ethics committees. All patients provided written informed consent. Monitoring was not performed, but outliers were queried.

The ACURATE neo aortic bioprosthesis and the ACURATE TF transfemoral delivery system have been described previously (6–8). The supra-annular prosthesis consists of a self-expanding nitinol frame with porcine pericardial leaflets with anticalcification treatment. During the SAVI-TF registry, the ACURATE TF delivery system had to be used with an 18-F or larger introducer sheath.

Clinical endpoints were defined according to Valve Academic Research Consortium-2 criteria and included mortality, stroke (disabling and nondisabling), myocardial infarction, bleeding, acute kidney injury, vascular complications, conduction disturbances and other transcatheter aortic valve replacement-related complications (9).

Data were entered in an electronic database; database management was performed by the study sponsor. Clinical outcomes were analyzed on an

ABBREVIATIONS AND ACRONYMS

CE = Conformité Européene

EuroSCORE = European System for Cardiac Operative Risk Evaluation

PVL = paravalvular leak

THV = transcatheter heart valve

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