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Outcomes for the Commercial Use of Self-Expanding Prostheses in Transcatheter Aortic Valve Replacement

A Report From the STS/ACC TVT Registry

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ABSTRACT

OBJECTIVES The authors sought to compare the outcomes of commercial transcatheter aortic valve replacement (TAVR) with the repositionable Evolut R platform to those observed with the CoreValve device in the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry.

BACKGROUND TAVR continues to evolve, with rapid adoption of iterative changes for commercial practice. Insight into the outcomes of this adoption is needed.

METHODS Patients in the TVT Registry who had TAVR using a 23-, 26-, or 29-mm self-expanding prosthesis were enrolled. Site-reported events for procedural, in-hospital, and 30-day outcomes were examined.

RESULTS Between January 2014 and April 2016, 9,616 patients underwent TAVR with a self-expanding prosthesis with data entered in the TVT Registry. Compared with patients treated with CoreValve TAVR, those who received Evolut R TAVR had a lower STS-PROM score (8.0 ± 5.4% vs. 8.7 ± 5.3%; $p < 0.001$), more iliofemoral access (91.6% vs. 89.2%; $p < 0.001$), and more frequently had conscious sedation (27.4% vs. 12.7%; $p < 0.001$). With Evolut R TAVR, there was less need for a second prosthesis (2.2% vs. 4.5%; $p < 0.001$), less device migration (0.2% vs. 0.6%; $p = 0.01$), a lower incidence of moderate/severe paravalvular regurgitation (post-procedure, 4.4% vs. 6.2%; $p < 0.001$), and shorter median hospital stay (4.0 vs. 5.0 days; $p < 0.001$). Patients treated with Evolut R TAVR had greater device success (96.3% vs. 94.9%; $p = 0.001$). At 30 days, Evolut R patients had both lower mortality (3.7% vs. 5.3%; $p < 0.001$) and less need for a pacemaker (18.3% vs. 20.1%; $p = 0.03$).

CONCLUSIONS Commercial adoption of the Evolut R platform is associated with significant improvements in acute outcomes for patients undergoing TAVR for aortic stenosis. (J Am Coll Cardiol Intv 2017;10:2090–8)

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Transcatheter aortic valve replacement (TAVR) is a life-saving therapy for patients with symptomatic, severe aortic stenosis (1,2). As a revolutionary therapy, the procedure continues to evolve with the ultimate goal being optimization of clinical outcomes and safety. Self-expanding prostheses for TAVR were first used for commercial practice in the United States with the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) in 2014, followed by introduction of the repositionable Evolut R platform in 2015 (3–7). Insight into the clinical impact of these iterative changes is needed to further understand their role in the treatment of patients with aortic stenosis.

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Accordingly, we undertook the present investigation to examine the clinical outcomes for the repositionable Evolut R platform in comparison to those observed with the CoreValve prosthesis in the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry. The STS/ACC TVT Registry is a national repository for data on clinical outcomes that enables procedural surveillance of commercially approved devices in the United States, in addition to fulfilling national coverage determination requirements (8). In this investigation, we examined the U.S. commercial experience for TAVR with Evolut R, and compared the procedural, in-hospital, and 30-day outcomes to the CoreValve platform to determine clinical improvements that may occur with device iterations.

METHODS

THE STS/ACC TVT REGISTRY. The patient population for this study was derived from the STS/ACC TVT Registry, which is a national registry designed to serve as a platform for device and procedural surveillance, quality assurance and improvement initiatives, and the conduct of studies that facilitate innovation and expansion of device labeling through evidence development (8–10). Participation in the STS/ACC TVT Registry satisfies Centers for Medicare & Medicaid Services national coverage determinations, in which national registry participation is a requirement for reimbursement for commercial therapies and those devices that are under clinical investigation. Centers that participate in the TVT registry collect data on demographics, morbidities, functional status, quality of life, hemodynamic status, procedural details, as well as procedural, 30-day, and 1-year clinical outcomes. The activities of the STS/ACC TVT Registry have been approved by a central institutional review board, and the Duke University School of Medicine institutional review board granted a waiver of informed consent and authorization for this study.

STUDY POPULATION. All patients who underwent TAVR in the STS/ACC TVT Registry who met the following criteria were included in the present analysis: 1) native aortic valve disease; 2) use of a Medtronic self-expanding prosthesis (CoreValve or Evolut R), in the sizes of 23, 26, or 29 mm; and 3) a commercial indication for TAVR. Patients who had been treated with a 31-mm CoreValve device were excluded, because no comparator for that prosthesis size was commercially available for the Evolut R platform during the analysis enrollment period. Patients who had TAVR as part of research studies also were excluded.

DATA ANALYSES. Site-reported procedural, in-hospital, and 30-day outcomes were analyzed. Device success, as site-reported in the STS/ACC TVT Registry, is defined as successful deployment of a single TAVR prosthesis in the proper anatomic location and retrieval of the delivery system, with intended performance of the prosthetic heart valve (aortic valve area >1.2 cm^2 and mean aortic valve gradient <20 mm Hg or peak velocity <3 m/s, without moderate or severe prosthetic regurgitation) (11). Group comparisons were performed for patients treated with the CoreValve platform and those who received TAVR with the Evolut R platform. Unadjusted comparisons were performed using the chi-square test for categorical data, the Student *t* test for continuous data, paired *t* test for change from baseline, and log-rank test for Kaplan-Meier analysis. For the endpoints of device success, using logistic regression, mortality, using Cox proportional hazards model, and length of stay, using analysis of variance multivariate adjustments (modeling) were performed with the following variables: age, male sex, body mass index, Society of

ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

MLD = minimal lumen diameter

NCDR = National Cardiovascular Data Registry

OR = odds ratio

STS = Society of Thoracic Surgeons

STS-PROM = Society of Thoracic Surgeons-Predicted Risk of Mortality

TAVR = transcatheter aortic valve replacement

TVT = transcatheter valve therapy

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