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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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TABLE 1 Baseline Characteristics

	All Patients (N = 9,616)	CoreValve (n = 5,806)	Evolut R (n = 3,810)	p Value
Age, yrs*	81.4 ± 8.1	81.6 ± 8.1	81.2 ± 8.0	0.02
Male	36.1	35.1	37.5	0.01
Body surface area, m^2	1.8 ± 0.2	1.8 ± 0.2	1.8 ± 0.3	0.01
STS-PROM, %	8.4 ± 5.4	8.7 ± 5.3	8.0 ± 5.4	<0.001
Diabetes mellitus	36.4	36.2	36.8	0.53
Coronary artery disease	65.3	66.0	64.3	0.08
Prior myocardial infarction	24.2	24.8	23.4	0.11
Prior PCI	35.6	36.1	34.7	0.14
Creatinine level >2 mg/dl	7.8	7.1	8.9	0.002
Chronic dialysis	3.9	3.5	4.5	0.02
Hypertension	90.4	90.3	90.7	0.50
Peripheral vascular disease	29.6	29.8	29.4	0.73
Prior stroke	12.4	12.5	12.1	0.52
Prior transient ischemic attack	9.9	10.1	9.6	0.45
Prior open cardiac surgery	24.7	25.7	23.2	0.01
STS severe chronic lung disease	15.1	16.0	13.7	0.003
Permanent pacemaker	16.9	16.8	17.1	0.66
ICD	3.8	3.9	3.6	0.43
Frailty				
BMI <21 kg/m^2	12.0	12.4	11.4	0.14
Albumin <3.3 g/dl	18.7	18.4	19.2	0.38
5-m gait speed, s	9.3 ± 8.0	9.3 ± 7.8	9.2 ± 8.3	0.56
Hostile mediastinum/chest	6.8	7.2	6.3	0.09
Porcelain aorta	5.1	5.7	4.2	0.001
Left ventricular ejection fraction, %	55.1 ± 14.1	54.8 ± 14.2	55.4 ± 14.0	0.05
Mean aortic valve gradient, mm Hg	44.1 ± 15.1	44.4 ± 14.9	43.7 ± 15.4	0.04
Aortic valve area, cm^2	0.67 ± 0.25	0.67 ± 0.25	0.68 ± 0.25	0.04
Peak AV velocity, m/s	4.1 ± 0.7	4.2 ± 0.7	4.1 ± 0.7	0.02
Moderate or severe AR	19.6	19.8	19.3	0.53
Moderate or severe MR	28.0	27.9	28.1	0.89
Moderate or severe TR	25.0	25.0	25.0	0.98
Aortic valve morphology				0.58
Unicuspid	0.1	0.1	0.1	
Bicuspid	2.6	2.8	2.4	
Tricuspid	89.2	89.0	89.4	
Uncertain	8.1	8.1	8.1	

Values are mean ± SD or %. *Subjects with age >90 years are reported as "90 plus" in the database and for calculations are set to 90.

AR = aortic regurgitation; AV = aortic valve; BMI = body mass index; ICD = implantable cardioverter-defibrillator; MR = mitral regurgitation; PCI = percutaneous coronary intervention; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; TR = tricuspid regurgitation.

Thoracic Surgeons-Predicted Risk of Mortality (STS-PROM) score, diabetes mellitus, creatinine >2 mg/dl, chronic dialysis, hypertension, peripheral vascular disease, prior stroke, prior myocardial infarction, prior cardiac surgery, coronary artery disease, severe chronic lung disease, albumin <3.3 g/dl, mean aortic valve gradient, aortic valve area, use of iliofemoral access, use of conscious or moderate sedation, valve size implanted (23, 26, or 29 mm), and use of the Evolut R platform. Continuous variables are reported as either mean ± SD or median (interquartile range), where appropriate. For all analyses, p values <0.05 were considered statistically significant.

RESULTS

PATIENTS. Between January 2014 and April 2016, there were 9,616 patients in the STS/ACC TVT Registry who underwent commercial TAVR in native aortic valves with a 23-, 26-, or 29-mm Medtronic self-expanding prosthesis (CoreValve or Evolut R) in the United States (Table 1, Figure 1). Patients were elderly (mean age 81.4 ± 8.1 years; 36.1% men), and significant morbidities were common (STS-PROM 8.4 ± 5.4%) in the analysis population. In comparison to those treated with the CoreValve platform, patients who underwent TAVR with the

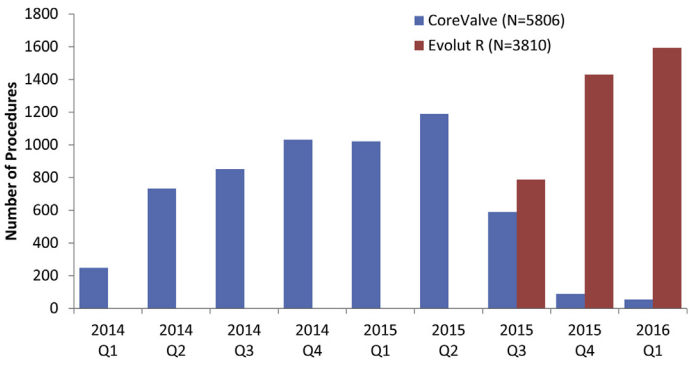
Evolut R platform more frequently were male, more commonly had severe renal insufficiency or dialysis, and had lower incidences of prior cardiac surgery, severe chronic lung disease, and porcelain aorta. Group comparisons for age, body surface area, and aortic valve hemodynamics were statistically significant because of the large size of the analysis population, although the absolute differences for these variables were relatively small. Overall, the STS-PROM was lower for Evolut R patients (8.0 ± 5.4% vs. 8.7 ± 5.3%; $p < 0.001$) in comparison to those treated with the CoreValve platform.

PROCEDURAL AND IN-HOSPITAL OUTCOMES. Overall, TAVR was performed electively in 91.3% of cases, with 29 mm as the most common prosthesis size (Table 2). Patients treated with the Evolut R platform more commonly underwent TAVR with iliofemoral access (91.6% vs. 89.2%; $p < 0.001$) and with conscious sedation for anesthesia (27.4% vs. 12.7%; $p < 0.001$). Following TAVR, patients who received Evolut R had slightly higher residual aortic valve gradients (8.6 ± 5.5 mm Hg vs. 7.9 ± 4.6 mm Hg; $p < 0.001$), but aortic valve areas were comparable (1.88 ± 0.59 cm^2 vs. 1.90 ± 0.64 cm^2; $p = 0.19$) (Figure 2). The hemodynamic comparisons differed across the different prosthetic sizes (23 mm, 13.7 ± 7.9 mm Hg vs. 12.1 ± 6.4 mm Hg; $p = 0.05$; 26 mm, 8.3 ± 5.7 mm Hg vs. 7.6 ± 4.3 mm Hg; $p = 0.001$; 29 mm, 8.5 ± 5.0 mm Hg vs. 7.7 ± 4.3 mm Hg; $p < 0.001$; all Evolut R vs. CoreValve, respectively).

For Evolut R patients, there was a lower rate of permanent pacemaker implantation (16.6% vs. 19.2%; $p = 0.002$), as well as lower need for a second prosthesis, less device migration, and lower rates of periprocedural atrial fibrillation and myocardial infarction. Severe paravalvular regurgitation in both groups was very low (0.2% Evolut R and 0.3% CoreValve), with moderate or severe paravalvular regurgitation being significantly lower for Evolut R patients (4.4% vs. 6.2%; $p < 0.001$). In-hospital mortality was lower (2.7% vs. 3.7%; $p = 0.01$), and there was a higher rate of acute device success for Evolut R patients (96.3% vs. 94.9%; $p = 0.001$). Patients treated with Evolut R also had shorter length of stay and a higher incidence of discharge directly to home (Figure 3).

30-DAY OUTCOMES. At 30-day follow-up, overall mortality in the study population, inclusive of procedural and in-hospital death, was 4.7% (Table 3). Patients who had TAVR with Evolut R had lower all-cause mortality (3.7% vs. 5.3%; $p < 0.001$). The rate of new permanent pacemaker or implantable cardioverter-defibrillator remained lower for Evolut R (18.3% vs. 20.1%; $p = 0.03$). In the entire cohort, the stroke rate was 3.1%, and the rates were comparable between the 2 groups. The rates of major vascular complications, device thrombosis, device fracture, and valve-related readmission, were low and also comparable. Quality of life, as measured by Kansas City Cardiomyopathy Questionnaire overall summary scores, improved significantly from baseline for both groups (Figure 4).

FIGURE 1 Commercial Adoption of TAVR



Commercial adoption of transcatheter aortic valve replacement (TAVR) with the CoreValve and Evolut R prostheses in the United States. Q = quarter.

By covariate adjustment analysis, the use of Evolut R remained significantly associated with lower 30-day mortality (unadjusted HR: 0.69 [95% confidence interval (CI): 0.56 to 0.85], $p < 0.001$; adjusted HR: 0.73 [95% CI: 0.58 to 0.92]; $p = 0.009$), shorter length of stay (both unadjusted and adjusted $p < 0.0001$), and greater device success (unadjusted odds ratio [OR]: 0.71 [95% CI: 0.58 to 0.88]; $p = 0.001$; adjusted OR, 0.79 [95% CI: 0.63 to 1.00]; $p = 0.05$).

DISCUSSION

For patients with aortic stenosis, TAVR is an established therapy that improves quality-of-life and survival, with outcomes that are either comparable or superior to that of surgery (1-7). Hence, TAVR is used routinely for patients at intermediate or high surgical risk, and randomized trials in comparison to surgery for those at low risk are well underway. Although there is known efficacy and benefit for patients with severe aortic stenosis who currently undergo TAVR, adverse clinical events may still occur without procedural success. These events may portend high morbidity and poor survival, particularly in those at high or extreme surgical risk, who are

TABLE 2 Procedural and In-Hospital Outcomes

	All Patients (N = 9,616)	CoreValve (n = 5,806)	Evolut R (n = 3,810)	p Value
Procedure status				0.84
Elective	91.3	91.3	91.4	
Urgent	8.4	8.5	8.3	
Emergency/salvage	0.2	0.2	0.3	
Type of anesthesia				<0.001
Conscious/moderate sedation	18.6	12.7	27.4	
General	80.7	86.4	72.1	
Access site				
Iliofemoral	90.2	89.2	91.6	<0.001
Surgical cut-down	22.2	24.0	19.6	<0.001
Subclavian	4.9	4.6	5.4	0.07
Axillary	0.9	1.0	0.7	0.09
Direct aortic	3.5	4.6	1.8	<0.001
Other	0.5	0.5	0.4	0.63
Valve size implanted				
23 mm	4.8	5.4	3.9	0.001
26 mm	34.6	34.3	35.2	0.36
29 mm	60.5	60.3	60.9	0.59
Need for a second prosthesis*	3.6	4.5	2.2	<0.001
Device migration	0.4	0.6	0.2	0.01
Device implanted	98.4	98.0	99.0	<0.001
Device success	95.5	94.9	96.3	0.001
Conversion to surgery	0.8	0.9	0.6	0.08
Life-threatening or major bleeding	7.0	7.3	6.6	0.21
Vascular complication	4.8	4.8	4.9	0.69
Major vascular complication	1.4	1.4	1.4	0.82
Unplanned vascular surgery	3.9	4.2	3.4	0.04
New PPM or ICD implantation†	18.1	19.2	16.6	0.002
Myocardial infarction	0.3	0.4	0.1	0.002
Atrial fibrillation	3.8	4.3	3.0	0.001
Stroke	2.7	2.7	2.6	0.74
Transient ischemic attack	0.3	0.3	0.3	0.68
All-cause mortality	3.3	3.7	2.7	0.01

Values are %. *More than 1 valve was implanted during the procedure. †Subjects with pacemaker or ICD at baseline are included.

ICD = implantable cardioverter-defibrillator; PPM = permanent pacemaker.

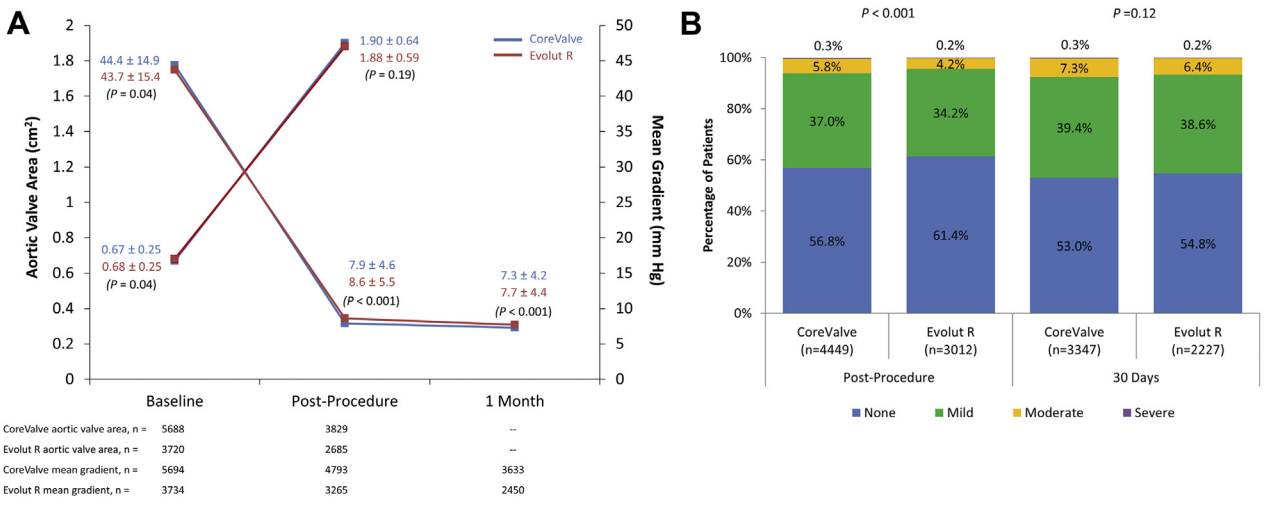
especially vulnerable to complications (12,13). Continual iteration of device technology and procedural techniques, therefore, remains essential for maximizing beneficial outcomes in patients with aortic stenosis who undergo TAVR.

The principal finding of this investigation is that the commercial adoption of the self-expanding Evolut R platform resulted in greater device success and lower procedural mortality. In comparison to those who received TAVR with a CoreValve prosthesis, patients who were treated with the Evolut R platform also had lower pacemaker dependence, less paravalvular regurgitation, and shorter hospital length-of-stay. Quality-of-life was significantly improved with both Evolut R and CoreValve therapies. These findings have important implications for the field of TAVR and its role in the treatment of patients with severe, native aortic stenosis.

On the basis of demonstrated efficacy and safety in randomized clinical trials, the self-expanding, Medtronic CoreValve prosthesis was introduced into commercial practice in the United States in 2014 (3–6). In 2015, the Evolut R, as a TAVR platform with several novel iterations, was approved for commercial use and rapidly adopted in the United States. In comparison to the CoreValve platform, principal features of Evolut R consist of a smaller delivery profile, improvements in frame design to provide increased oversizing, more consistent radial force across the annular range, and an extended skirt for enhanced sealing, as well as the ability to recapture and reposition the prosthesis. Although there are few data on the Evolut R platform in comparison to the CoreValve platform, studies of patients who had the Evolut R device as part of pre-approval clinical trials reported improved outcomes with lower rates of moderate or severe paravalvular regurgitation (5.3% to 8.5%), permanent pacemaker implantation (14.7% to 22.1%), and 30-day mortality (2.3% to 3.2%) (14–16). Thus far, whether or not these improved clinical outcomes have also occurred with widespread adoption of Evolut R in commercial practice in the United States remains unknown.

In this analysis, which represents the largest clinical experience for Evolut R in patients with aortic stenosis (N = 3,810), we observed improved device success and lower procedural mortality, in comparison to outcomes observed for patients commercially treated with the CoreValve platform in the U.S. Patients treated with Evolut R had greater use of iliofemoral access and lower rates of paravalvular regurgitation, device migration, and need for a second prosthesis. Post-procedural gradients were slightly higher with Evolut R (8.6 ± 5.5 mm Hg vs. 7.9 ± 4.6 mm Hg; $p < 0.001$), but still were low and well within acceptable hemodynamic bounds for device success, including comparable post-procedural aortic valve area. In addition, the incidence of moderate or severe paravalvular regurgitation was significantly improved with Evolut R (4.4% vs. 6.2%; $p < 0.001$), including a rate of severe paravalvular regurgitation of only 0.2% in these patients. It is important to note that these outcomes were observed in commercial practice in the United States, where the technology was rapidly adopted in a broad number of hospitals (i.e., 3,810 cases over 9 months in 298 hospitals) (**Figure 1**). These findings underscore the importance of continued device iteration for further optimizing patient outcomes, even when prior technology has been found to be effective, safe, and already used in routine use.

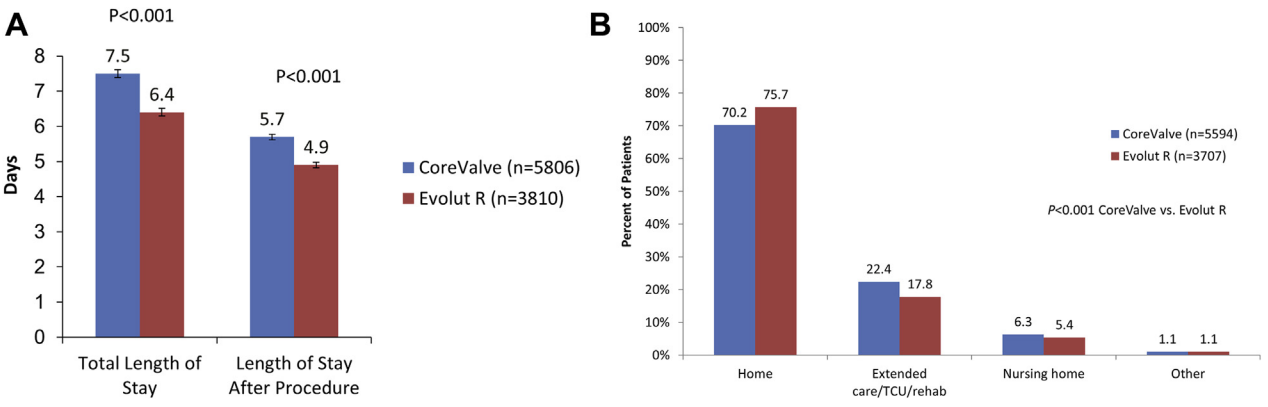
FIGURE 2 Hemodynamic Data Over Time



Hemodynamic data over time for mean gradient and aortic valve area **(A)** and residual paravalvular regurgitation **(B)** for patients commercially treated with CoreValve versus Evolut R TAVR in the United States. The source of post-procedural aortic valve area is pre-discharge, in-hospital data. In **A**, values are mean ± SD. In **B**, columns that do not sum to 100% are due to rounding.

The procedure for TAVR and the population of patients treated both have evolved significantly since its first introduction over 15 years ago, and this evolution was evident in this analysis of patients undergoing contemporary therapy. The present investigation is a report from a single-arm registry, with comparisons performed against historical patients and outcomes. Such analysis design is susceptible to the potential for selection bias, and there were differences in the comparator groups. With the notable exception of renal failure (creatinine >2 mg/dl, 8.9% vs. 7.1%, Evolut R vs. CoreValve, respectively; p = 0.002), patients who received TAVR with Evolut R had less morbidity and lower STS-PROM. Evolut R patients also more frequently underwent TAVR with conscious sedation, whose use has been associated with fewer procedural complications and reduced hospital length-of-stay (17).

FIGURE 3 Hospital Length of Stay and Discharge Location



Hospital length of stay **(A)** and discharge location **(B)** for patients commercially treated with CoreValve vs. Evolut R TAVR in the United States. Values in **A** reported as mean ± SE. Median hospital stay for Evolut R versus CoreValve TAVR was 4.0 days versus 5.0 days; p < 0.001.

TABLE 3 30-Day Clinical Outcomes

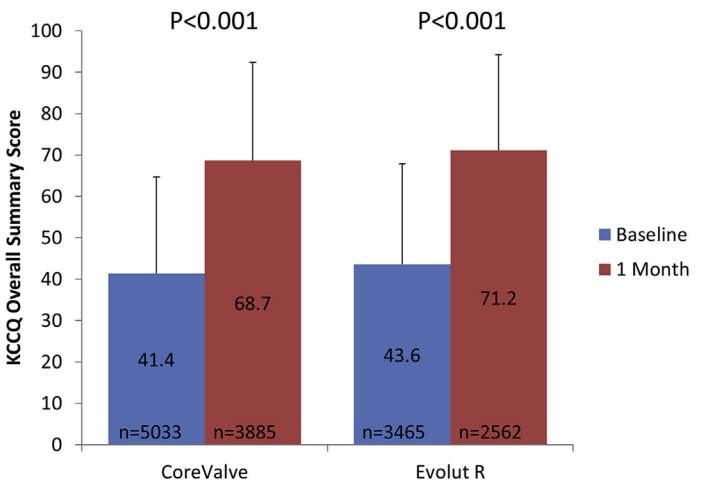
	All Patients (N = 9,616)	CoreValve (n = 5,806)	Evolut R (n = 3,810)	p Value
All-cause mortality	4.7	5.3	3.7	<0.001
Any stroke	3.1	3.1	3.1	0.94
Ischemic stroke	2.6	2.6	2.6	0.97
Hemorrhagic stroke	0.1	0.1	0.1	0.75
Undetermined stroke	0.4	0.4	0.5	0.51
Transient ischemic attack	0.6	0.5	0.7	0.33
Myocardial infarction	0.4	0.5	0.2	0.03
Life-threatening or major bleeding	7.7	8.0	7.3	0.24
Vascular complication	5.6	5.5	5.6	0.94
Major vascular complication	1.5	1.5	1.5	0.79
New permanent pacemaker or ICD*	19.4	20.1	18.3	0.03
Device thrombosis†	0.0	0.0	0.0	0.22
Device fracture	0.0	0.0	0.0	NA
Aortic valve reintervention	0.4	0.5	0.3	0.14
Valve-related readmission	1.1	1.0	1.2	0.49
New requirement for dialysis	1.1	1.2	1.0	0.31

Values are Kaplan-Meier event rates, reported as %, and include in-hospital reported events and events reported at 30-day follow-up. *Subjects with pacemaker or ICD at baseline are included. †n = 1 Evolut R patient experienced an event; due to large sample size, resulting event rate is 0.0%.

ICD = implantable cardioverter-defibrillator.

Moreover, the field of TAVR was relatively earlier in development for patients undergoing therapy with CoreValve in comparison to Evolut R. This analysis did not permit an examination of the relation of outcomes to differences in operator experience and how this experience could have influenced adoption of iterative techniques and technology.

FIGURE 4 Improvement in KCCQ Overall Summary Scores



Improvement in Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scores for patients commercially treated with CoreValve versus Evolut R TAVR in the United States. Values are mean ± SD.

Similar decreases in the risk profile of patients with commercial adoption of TAVR have been reported previously (18). Importantly, the present investigation includes only commercial patients when TAVR, by product indication, was limited largely to patients at high or extreme surgical risk. To account for baseline differences in the 2 populations, multivariate adjustments models were performed and demonstrated persistent association of the use of Evolut R with lower 30-day mortality (unadjusted HR: 0.69 [95% CI: 0.56 to 0.85]; $p < 0.001$; adjusted HR: 0.73 [95% CI: 0.58 to 0.92]; $p = 0.009$), shorter length of stay (both unadjusted and adjusted $p < 0.001$), and greater device success (unadjusted OR: 0.71 [95% CI: 0.58 to 0.88]; $p = 0.001$; adjusted OR: 0.79 [95% CI: 0.63 to 1.00]; $p = 0.05$). It is important to note that the large number of patients examined in this analysis greatly increases the power to detect small differences between groups, even though such differences, arguably, may not be clinically relevant. Taken together, our findings do support the notion that device iterations are significantly associated with improved clinical outcomes.

Vascular injury is a potentially devastating complication in patients who undergo TAVR. In the present investigation, the incidences of vascular complications (4.9% vs. 4.8%, Evolut R vs. CoreValve, respectively; $p = 0.69$) or any bleeding event (6.6% vs. 7.3%, Evolut R vs. CoreValve, respectively; $p = 0.21$) were comparable for Evolut R device-treated patients and those treated with the CoreValve platform. Although a lower delivery profile would intuitively be expected to be associated with a lower risk of vascular complications, the absence of such differences may arise for multiple reasons. Ratio of sheath size to minimal lumen diameter (MLD) is an important predictor of vascular complications (19). The use of Evolut R, with its lower profile delivery system, permits the selection of patients with lower MLD (5.0 mm for 23-, 26-, and 29-mm prostheses) in comparison to the recommendations for the CoreValve platform (6 mm). Operators using Evolut R, therefore, could have selected patients with relatively lower MLD for iliofemoral TAVR, when these patients would not have been candidates for devices with larger delivery profiles. Data on MLD in the peripheral arteries used for TAVR are not available in this registry. Nonetheless, it is notable that there was a greater use of iliofemoral access in the Evolut R patients (91.6% vs. 89.2%; $p < 0.001$), and less use of surgical cut-down (19.6% vs. 24.0%; $p < 0.001$). For patients who undergo TAVR with Evolut R, the relation between patient selection,

peripheral access, and vascular injury requires further study.

STUDY LIMITATIONS. The study design of this registry has inherent limitations. Although participation in the STS/ACC TVT Registry helps to fulfill national coverage determination criteria for Centers for Medicare & Medicaid Services reimbursement, data entry is voluntary. Data quality is maximized with assistance from the ACC National Cardiovascular Data Registry (NCDR) data warehouse and Duke Clinical Research Institute Data Analysis Center, who both implement data quality checks, including checks on data range and consistency. Site training also is conducted by the NCDR through frequent informational webinars. Of note, echocardiographic data are site-reported, and not adjudicated by a core laboratory. Although recapturing and repositioning is a key feature of the Evolut R platform, data on the occurrence of these events and their relation to clinical outcomes are not available in the STS/ACC TVT Registry. In prior studies, use of recapture has been reported to be approximately 22% (14,15). In the present investigation, the lower incidences of need for second prosthesis and device migration with Evolut R support the potential benefit of the technological iteration. Nonetheless, the reasons for device migration, need for second prosthesis, as well as rates of pre- or post-dilatation were not available in the TVT registry. Finally, comparable data on use of 31-mm CoreValve prosthesis and the 34-mm Evolut R device were not available, because the latter prosthesis was not commercially available during this analysis period, and the former was excluded because there was not a comparative valve for Evolut R.

CONCLUSIONS

For patients who undergo TAVR with self-expanding prostheses, the use of Evolut R is associated with significant improvements in procedural success and lower mortality. These findings demonstrate the importance of device iterations for the benefit of these patients, and these beneficial outcomes should be considered when evaluating patients for TAVR.

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PERSPECTIVES

WHAT IS KNOWN? Transcatheter aortic valve replacement with Medtronic self-expanding prostheses is a life-saving therapy, and the technology continues to evolve.

WHAT IS NEW? The commercial adoption of the Evolut R platform for TAVR is associated with greater device success and lower 30-day mortality.

WHAT IS NEXT? Further analysis on the long-term implications of these improvements in acute procedural success is needed.

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