Comparison of Clinical and Echocardiographic Outcomes After Transcatheter Aortic Valve Implantation With 31-mm CoreValve Versus 34-mm Evolut R Bioprostheses from the STS/ACC TVT Registry

Gilbert H.L. Tang, MD, MSc, MBA[a,*], Michael J. Reardon, MD[b], Susheel K. Kodali, MD[c], James B. Hermiller Jr, MD[d], Paul Sorajja, MD[e], Wilson Y. Szeto, MD[f], Angie Zhang, MS[g], and Jeffrey J. Popma, MD[h]

Transcatheter aortic valve implantation with a bioprosthetic valve of insufficient size is associated with a higher risk of aortic regurgitation (AR). The 31-mm CoreValve and the next generation 34-mm Evolut R bioprostheses were designed to address the need for larger diameter aortic annuli. This analysis examined the clinical and hemodynamic outcomes following commercial transcatheter aortic valve implantation with the 31-mm CoreValve and 34-mm Evolut R in the Society of Thoracic Surgeons/the American College of Cardiology Transcatheter Valve Therapy Registry. Patients receiving a 31-mm CoreValve or 34-mm Evolut R valve for symptomatic severe native aortic stenosis from January 2014 to September 2017 in the Transcatheter Valve Therapy Registry underwent propensity score matching using baseline demographics, clinical and frailty measures, and procedural variables. Procedural characteristics, in-hospital and 30-day clinical and echocardiographic outcomes were compared. Of 4545 patients implanted with a 31-mm CoreValve and 3036 patients with a 34-mm Evolut R valve, matching resulted in 1813 patient sets. Most patients were male (>92%), elderly (~80 years) with the Society of Thoracic Surgeons score of 6.6%. Use of the 34-mm versus 31-mm valve resulted in shorter median procedural time (113.0 [85.0, 150.0] vs 93.0 [71.0, 126.0] min, p <0.001), higher device success (98.1% vs 93.9%, p <0.001), fewer pacemakers (16.7% vs 24.6%, p <0.001), less ≥moderate AR with the 34-mm (5.5% vs 13.7%), p <0.001) and shorter hospital stay (3.0 [2.0, 4.0] vs 4.0 [3.0, 6.0] days, p <0.001). In conclusion, this largest experience with the 34-mm Evolut R valve showed higher device success, reduced hospital stay, lower pacemaker rates and less ≥moderate AR compared with the 31-mm CoreValve bioprosthesis. **(Am J Cardiol 2019;124:1091−1098)**

Transcatheter aortic valve implantation (TAVI) with a valve of insufficient size, shape or position is associated with a higher risk of postprocedural aortic regurgitation (AR; primarily as paravalvular leak),[1,2] due to inadequate sealing against the annulus and left ventricular outflow tract. The 31-mm CoreValve bioprosthesis (Medtronic, Minneapolis, Minnesota) was previously the largest transcatheter valve approved in the United States, but it was limited by its inability to be repositioned to optimize implantation. The 34-mm Evolut R (Medtronic) valve approved in the US in October 2016, is currently the largest transcatheter valve commercially available to address large annular dimensions, and offers the ability to be repositioned. Experience of the 34-mm Evolut R remains limited to small single- or multicenter series.[3−8] We therefore compared the clinical and echocardiographic outcomes in patients undergoing TAVI with the 34-mm Evolut R versus 31-mm CoreValve bioprostheses, using a propensity score-matched analysis of patients included in the Society of Thoracic Surgeons/the American College of Cardiology Transcatheter Valve Therapy Registry (TVT Registry).

Methods

The TVT Registry serves as the national database in the United States for medical device tracking of transcatheter aortic valves implanted following commercialization. Entry of patient data into the TVT Registry is a condition of coverage by the Centers for Medicare and Medicaid Services. Data entered into the TVT Registry are audited by onsite or

[a]Mount Sinai Medical Center, New York, New York; [b]Houston Methodist DeBakey Heart and Vascular Institute, Houston, Texas; [c]Columbia University Medical Center − New York Presbyterian Hospital, New York, New York; [d]St. Vincent's Heart Center of Indiana, Indianapolis, Indiana; [e]Valve Science Center, Minneapolis Heart Institute Foundation, Abbott-Northwestern Hospital, Minneapolis, Minnesota; [f]University of Pennsylvania Medical Center, Philadelphia, Pennsylvania; [g]Medtronic, Department of Statistical Services, Minneapolis, Minnesota; and [h]Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts. Manuscript received May 3, 2019; revised manuscript received and accepted July 2, 2019.

See page 1097 for disclosure information.

*Corresponding author: Tel: (212) 659-6800; fax: (212) 659-6818.
E-mail address: gilbert.tang@mountsinai.org (G.H.L. Tang).

0002-9149/
https://doi.org/10.1016/j.amjcard.2019.07.010

remote review or both. The TVT Registry publication committee has reviewed the final manuscript. Patient consent is waived for this registry.

Site-reported data were extracted from the TVT Registry database on patients with native aortic stenosis (excluding TAV in TAV and TAV in failed surgical bioprosthetic valves), implanted with a 31-mm or 34-mm Medtronic self-expanding TAV from January 2014 to September 2017, with follow-up through December 2017. Data from patients implanted with the 31-mm valves were added to the TVT-Registry starting in January 2014 and data from patients with the 34-mm valve were added starting in October 2016 (Figure 1).

The annular sizing recommendations for the 31-mm CoreValve bioprosthesis is recommended for patients with an aortic annular diameter of 26 to 29 mm and the 34-mm Evolut R valve is for patients with an aortic annular diameter of 26 to 30 mm. Details of each valve type have been previously reported.[9,10] These valves comprise a supra-annular porcine pericardial valve sewn within a self-expanding Nitinol frame. The Evolut R valve is an iteration of the CoreValve device, except that it is shorter in height and can be partially or fully resheathed and repositioned during implantation for optimal positioning and deployment (Figure 2).

Data included in this report are based on version 2.0 of the TVT Registry data collection form. Risk status, baseline characteristics, demographics, medical history, procedural characteristics, and in-hospital and 30-day outcomes are reported. Quality of life was measured using the Kansas City Cardiomyopathy Questionnaire (KCCQ). Device success was defined based on the original Valve Academic Research Consortium definitions.[11] All echocardiographic assessments are performed based on standard practices and are site-reported. Baseline, postprocedural and 30-day echocardiographic measures are reported.

For the patients implanted with a 31-mm and a 34-mm valve, continuous variables are reported as mean and standard deviation or median and first and third quartiles as appropriate, and were compared between groups using the independent samples *t* test or Wilcoxon rank-sum test as appropriate. Categorical variables are reported as counts and percentages and were compared using the chi-square test. A propensity score model was developed using a multivariable logistic regression with 28 baseline characteristics and 2 procedural characteristics (Table S1 in the Online Appendix). A 5-to-1 digits greedy 1:1 matching algorithm was used to form a propensity-matched cohort for analysis. Absolute standardized differences were calculated to evaluate the balance before and after matching, with values <10% used to indicate no meaningful imbalance. Categorical in-hospital outcomes are reported as frequencies and comparisons performed using the chi-square test. Continuous in-hospital outcomes are reported as median and first and third quartiles, and compared using the Wilcoxon rank-sum test. Adverse event rates at 30 days are reported as Kaplan-Meier estimates and comparisons between groups were made using the log-rank test. Comparisons in KCCQ scores between groups were performed using the

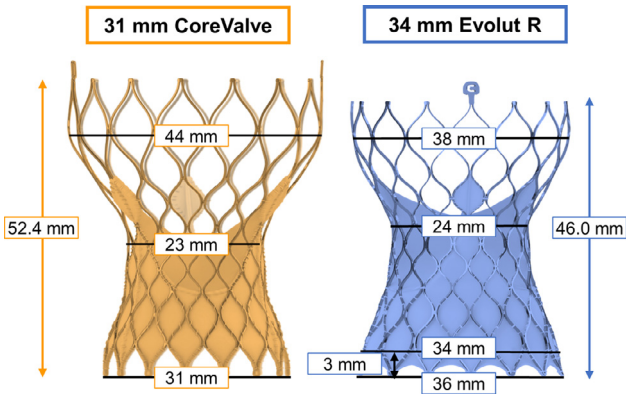


Figure 2. Large self-expanding valves.
Comparison of the dimensions of the 31-mm CoreValve and 34-mm Evolut R valves.

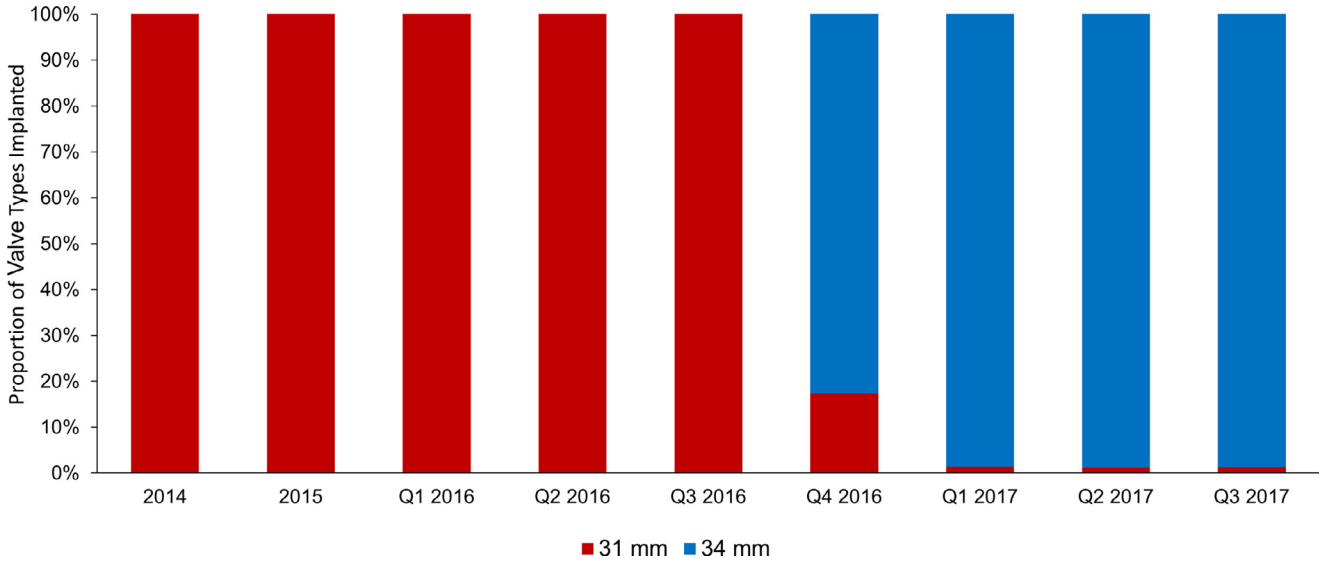


Figure 1. Valve usage over time for the 2 large self-expanding valves.
The distribution of 31-mm CoreValve versus 34-mm Evolut R valves used by calendar quarter (Q) and year in the US.
The 34-mm valve was added to the TVT Registry after October, 2016.

independent samples *t* test, differences in the change from baseline was based on an ANCOVA regression model. All statistical analyses were performed using Statistical Analysis Systems software, version 9.4 (SAS Institute, Cary, North Carolina).

Results

Baseline characteristics for all patients (4545 31-mm CoreValve and 3036 34-mm Evolut R) and the propensity score-matched groups (N = 1813) are shown in Table 1. Before matching, patients in the 34-mm valve versus the 31-mm valve group were younger (79.4 ± 8.6 vs 80.3 ± 8.2 years, p <0.001), had a lower Society of Thoracic Surgeons score (6.3% ± 4.4% vs 7.7% ± 5.1%, p <0.001), and had fewer comorbid conditions. After matching the groups were well balanced, except for the proportion of patients identified as extreme risk (30.1% in the 31-mm group vs. 11.2% in the 34-mm group, p <0.001). Interestingly, mean Society of Thoracic Surgeons scores were similar between the 2 valve

Table 1
Baseline characteristics and medical history for all patients and for matched patients

	Unmatched				Matched			
Characteristic	CoreValve 31 mm (N = 4545)	Evolut R 34 mm (N = 3036)	p Value	Absolute standardized differences	CoreValve 31 mm (N = 1813)	Evolut R 34 mm (N = 1813)	p Value	Absolute standardized differences
Age (years)	80.3 ± 8.2	79.4 ± 8.6	<0.001	10.1%	79.6 ± 8.5	79.8 ± 8.2	0.69	1.3%
Body surface area (m^2)	2.0 ± 0.2	2.0 ± 0.2	<0.001	14.9%	2.0 ± 0.2	2.0 ± 0.2	0.02	7.6%
Men	4164 (91.7%)	2821 (92.9%)	0.05	4.7%	1677 (92.5%)	1683 (92.8%)	0.70	1.3%
Society of Thoracic Surgeons Predicted Risk of Mortality (%)	7.7 ± 5.1	6.3 ± 4.4	<0.001	29.6%	6.6 ± 3.9	6.6 ± 4.5	0.82	0.7%
Risk Status							<0.001	
Extreme risk or high risk	4289 (94.7%)	2386 (78.6%)	<0.001	48.5%	1709 (94.4%)	1462 (80.6%)	<0.001	42.4%
Intermediate risk or low risk*	241 (5.3%)	648 (21.4%)			102 (5.6%)	351 (19.4%)		
New York Heart Association III/IV symptoms	3767 (83.7%)	2338 (77.8%)	<0.001	15.0%	1448 (79.9%)	1444 (79.6%)	0.87	0.6%
Diabetes mellitus	1802 (39.7%)	1249 (41.3%)	0.17	3.2%	747 (41.2%)	750 (41.4%)	0.92	0.3%
Serum creatinine > 2 mg/dL	523 (11.5%)	297 (9.8%)	0.02	5.5%	192 (10.6%)	188 (10.4%)	0.83	0.7%
Hemoglobin (mg/dL)	12.0 ± 1.9	12.2 ± 2.0	<0.001	13.4%	12.2 ± 1.9	12.2 ± 1.9	0.98	0.1%
Hypertension	4046 (89.1%)	2750 (90.8%)	0.02	5.6%	1639 (90.4%)	1631 (90.0%)	0.66	1.5%
Peripheral vascular disease	1471 (32.4%)	955 (31.5%)	0.44	1.8%	557 (30.7%)	612 (33.8%)	0.05	6.5%
Prior stroke	596 (13.1%)	347 (11.5%)	0.03	5.0%	228 (12.6%)	212 (11.7%)	0.42	2.7%
Chronic lung disease	2303 (51.1%)	1326 (44.1%)	<0.001	14.1%	866 (47.8%)	872 (48.1%)	0.84	0.7%
Home oxygen	528 (11.6%)	277 (9.2%)	<0.001	8.1%	178 (9.8%)	189 (10.4%)	0.54	2.0%
Immunosuppressive therapy	530 (11.7%)	240 (7.9%)	<0.001	12.6%	151 (8.3%)	164 (9.0%)	0.44	2.6%
Previous open heart cardiac surgery	1635 (36.5%)	965 (32.0%)	<0.001	9.4%	616 (34.0%)	599 (33.0%)	0.55	2.0%
Previous myocardial infarction	1319 (29.1%)	809 (26.8%)	0.03	5.2%	495 (27.3%)	497 (27.4%)	0.94	0.3%
Previous percutaneous coronary intervention	1833 (40.4%)	1171 (38.7%)	0.13	3.5%	716 (39.5%)	721 (39.8%)	0.87	0.6%
Prior coronary artery bypass surgery	1629 (35.9%)	900 (29.7%)	<0.001	13.1%	594 (32.8%)	572 (31.5%)	0.43	2.6%
Atrial fibrillation/atrial flutter	2255 (49.7%)	1483 (49.0%)	0.55	1.4%	874 (48.2%)	893 (49.3%)	0.53	2.1%
Pre-existing pacemaker or defibrillator	1179 (26.0%)	732 (24.3%)	0.10	3.9%	423 (23.3%)	454 (25.1%)	0.21	4.2%
Congestive heart failure (recent 2 weeks)	3763 (82.9%)	2393 (79.1%)	<0.001	9.9%	1442 (79.5%)	1443 (79.6%)	0.97	0.1%
Aortic valve area (cm^2)	0.7 ± 0.3	0.8 ± 0.3	<0.001	8.2%	0.7 ± 0.2	0.8 ± 0.3	0.33	3.2%
Aortic valve area index (cm^2/m^2)	0.4 ± 0.1	0.4 ± 0.2	0.10	4.0%	0.4 ± 0.1	0.4 ± 0.2	0.78	1.0%
Maximum aortic valve velocity (m/sec)	4.0 ± 0.7	3.9 ± 0.7	0.002	7.8%	4.0 ± 0.7	4.0 ± 0.7	0.60	1.8%
Mean aortic valve gradient (mm Hg)	41.3 ±13.6	40.1 ± 13.8	<0.001	8.1%	41.0 ± 13.3	41.0 ± 13.9	0.95	0.2%
Left ventricular ejection fraction (%)	48.0 ± 15.4	49.5 ± 14.9	<0.001	9.4%	49.5 ± 15.2	49.2 ± 14.8	0.59	1.8%
Moderate to severe aortic regurgitation	844 (18.7%)	471 (15.7%)	<0.001	8.0%	293 (16.2%)	289 (15.9%)	0.86	0.6%
Moderate to severe mitral regurgitation	1231 (27.3%)	646 (21.4%)	<0.001	13.6%	415 (22.9%)	415 (22.9%)	>0.99	0.0%
Body mass index < 21 kg/m^2	304 (6.7%)	149 (4.9%)	0.002	7.6%	86 (4.7%)	88 (4.9%)	0.88	0.5%
Albumin <3.3 g/dL	772 (19.2%)	478 (17.7%)	0.12	3.9%	313 (17.3%)	328 (18.1%)	0.51	2.2%
5 Meter gait speed > 6 seconds	2083 (69.0%)	1424 (62.8%)	<0.001	12.9%	996 (64.5%)	999 (65.2%)	0.68	1.5%
Aortic valve annular calcification	3661 (82.0%)	24.3 (80.4%)	0.09	4.0%	1470 (81.8%)	1461 (81.3%)	0.73	1.2%
Porcelain aorta	171 (3.8%)	73 (2.4%)	0.001	7.9%	46 (2.5%)	39 (2.2%)	0.44	2.6%
Hostile mediastinum/chest	327 (7.2%)	217 (7.2%)	0.95	0.2%	119 (6.6%)	130 (7.2%)	0.47	2.4%

Data presented as means ± standard deviation or no. (percentage) that reflect missing values.
* Not a United States Food and Drug Administration approved transcatheter aortic valve replacement indication at the time of this writing.

Table 2
Procedural characteristics for all patients and matched patients

Characteristic	Unmatched			Matched		
	CoreValve (N = 4545)	Evolut R (N = 3036)	p Value	CoreValve (N = 1813)	Evolut R (N = 1813)	p Value
Procedure location			<0.001			0.005
Hybrid operating room	2903 (63.9%)	1710 (56.4%)		1126 (62.2%)	1081 (59.7%)	
Catheterization laboratory*	1633 (36.0%)	1305 (43.0%)		680 (37.6%)	715 (39.5%)	
Other	4 (0.1%)	17 (0.6%)		3 (0.2%)	16 (0.9%)	
General anesthesia†	3726 (82.1%)	1798 (59.4%)	<0.001	1301 (71.8%)	1307 (72.1%)	0.82
Vascular access						
Iliofemoral†	4145 (91.3%)	2844 (93.7%)	<0.001	1692 (93.3%)	1690 (93.2%)	0.89
Subclavian	236 (5.2%)	116 (3.8%)	0.005	72 (4.0%)	75 (4.1%)	0.80
Direct aortic	119 (2.6%)	26 (0.9%)	<0.001	39 (2.2%)	20 (1.1%)	0.01
Valve-in-valve procedure	160 (3.5%)	41 (1.4%)	<0.001	63 (3.5%)	22 (1.2%)	<0.001
Conversion to open heart surgery	8 (0.2%)	4 (0.1%)	0.77	4 (0.2%)	2 (0.1%)	0.45
Device success†	4236 (94.2%)	2942 (97.6%)	<0.001	1687 (93.9%)	1766 (98.1%)	<0.001
Procedure time (min)	126.1 ± 57.5	106.0 ± 54.0	<0.001	124.5 ± 57.5	105.8 ± 51.9	<0.001

Data presented as means ± standard deviation or no. (percentage) that reflect missing values.
* Includes hybrid catheterization laboratory.
† Procedural variables used in propensity score matching; the absolute standardized difference was 0.7% for the use of general anesthesia and 0.4% for iliofemoral access between groups after matching. ‡Per Valve Academic Research Consortium version 1.[11]

groups (6.6% ± 3.9% in the 31-mm group vs 6.6% ± 4.5% in the 34-mm group, p = 0.82, absolute standardized difference of 0.7%).

Procedural characteristics for the unmatched and matched datasets are shown in Table 2. There were significant differences between the 2 valve groups before and after matching. After matching, significant differences remained with more patients in the 31-mm compared with 34-mm group requiring a TAV-in-TAV procedure (3.5% vs 1.2%, p <0.001). For the 34-mm valve group, the device success rate was significantly higher than the 31-mm group (98.1% vs 93.9%, p <0.001) and the mean procedure time was shorter (105.8 ± 51.9 vs 124.5 ±57.5 min, p <0.001). The use of general anesthesia and iliofemoral access route were used in the propensity score matching and were well balanced in the matched patient groups (both absolute standardized differences <1%).

In-hospital outcomes for the matched cohorts are shown in Table 3. After matching, the patients in the 34-mm group

Table 3
In-hospital outcomes for matched patient datasets

Variable	CoreValve (N = 1813)	Evolut R (N = 1813)	p Value
All-cause mortality	39 (2.2%)	35 (1.9%)	0.64
Stroke	36 (2.0%)	39 (2.2%)	0.73
Ischemic	30 (1.7%)	35 (1.9%)	0.53
Hemorrhagic	3 (0.2%)	0	0.25
Myocardial infarction	6 (0.3%)	1 (0.1%)	0.12
Infective endocarditis	0	0	NA
Life-threatening or major bleeding	119 (6.6%)	83 (4.6%)	0.009
Vascular complication	54 (3.0%)	39 (2.2%)	0.12
Major vascular complication	9 (0.5%)	5 (0.3%)	0.28
Coronary artery obstruction	1 (0.1%)	1 (0.1%)	> 0.99
Percutaneous coronary intervention	3 (0.2%)	2 (0.1%)	> 0.99
Atrial fibrillation	54 (3.0%)	29 (1.6%)	0.006
Permanent pacemaker or implantable cardioverter defibrillator*	422 (23.3%)	276 (15.2%)	<0.001
Bioprosthesis migration	10 (0.6%)	6 (0.3%)	0.32
Bioprosthesis thrombosis	0	0	NA
Aortic valve reintervention	13 (0.7%)	4 (0.2%)	0.05
Unplanned other cardiac surgery or intervention	19 (1.0%)	14 (0.8%)	0.38
Time in intensive care unit (hours)	30.2 (23.2, 54.2)	24.0 (9.0, 38.0)	<0.001
Postprocedure length of stay (days)	4.0 (3.0, 6.0)	3.0 (2.0, 4.0)	<0.001
Discharged home	1379 (77.7%)	1515 (85.3%)	<0.001

In-hospital event data presented as patients with an event (relative frequencies as percentage). Hospitalization duration reported as median (first and third quartiles).
* Includes patients with a pacemaker or implantable cardioverter defibrillator at baseline. NA = Not analyzable.

Table 4
Thirty-day outcomes for matched patient datasets

Variable	CoreValve (N = 1813)	Evolut R (N = 1813)	p Value
All-cause mortality	76 (4.3%)	56 (3.2%)	0.11
Stroke	42 (2.4%)	49 (2.8%)	0.43
Ischemic	32 (1.8%)	40 (2.2%)	0.32
Hemorrhagic	7 (0.4%)	1 (0.1%)	0.04
Myocardial infarction	7 (0.4%)	4 (0.2%)	0.37
Infective endocarditis	0	0	NA
Life-threatening or major bleeding*	138 (7.7%)	94 (5.3%)	0.004
Bioprosthesis thrombosis	0	1 (0.1%)	0.30
Permanent pacemaker or implantable cardioverter defibrillator†	440 (24.6%)	298 (16.7%)	<0.001
Aortic valve reintervention	16 (0.9%)	6 (0.3%)	0.04
Percutaneous coronary intervention	5 (0.3%)	5 (0.3%)	0.97
Valve-related readmission	35 (2.1%)	14 (0.8%)	0.004

Data presented as no. of patients with an event (Kaplan-Meier rates as percentage).
* After the index procedure.
† Includes patients with a pacemaker or implantable cardioverter defibrillator at baseline. NA = not analyzable.

had less life-threatening or major bleeding (4.6% vs 6.6%, p = 0.009), a lower pacemaker rate (15.2% vs 23.3%, p <0.001), shorter postprocedural hospitalization (3.0 [2.0, 4.0] vs 4.0 [3.0, 6.0] days, p <0.001), and were more frequently discharged home (85.3% vs 77.7%, p <0.001). Details of the patients who had a valve migration, aortic valve reintervention or other cardiac or vascular surgery or intervention are described in Table S2 in the Online Appendix.

Clinical outcomes for the matched cohorts at 30 days are shown in Table 4. There were no differences in serious clinical outcomes between the 2 groups, although the 34-mm group had a significantly lower pacemaker rate (16.7% vs 24.6%, p <0.001) and fewer valve-related readmissions (0.8% vs 2.1%, p = 0.004).

Valve hemodynamics are shown in Table 5. Postprocedure, patients in the the 34-mm valve group had significantly higher effective orifice areas (2.1 ± 0.7 vs 2.0 ± 0.7 cm^2, p <0.001) and lower mean gradients (7.5 ± 3.8 vs 8.9 ± 4.8 mm Hg, p <0.001) compared with the 31-mm valve group. The severity of total AR was significantly improved with the 34-mm valve at postprocedure and 30 days.

The mean KCCQ overall summary scores for the matched cohorts are shown in Figure 3. The mean baseline scores were similar (44.0 ± 24.0 vs 43.6 ± 23.6, p = 0.66), and were higher at 30 days in the patients treated with the 34-mm valve (71.4 ± 23.6 vs 69.1 ± 24.2, p = 0.01). The change in KCCQ score from baseline to 30 days was greater in the 34-mm group (26.6 ± 26.9 vs 24.3 ± 28.7, p = 0.01).

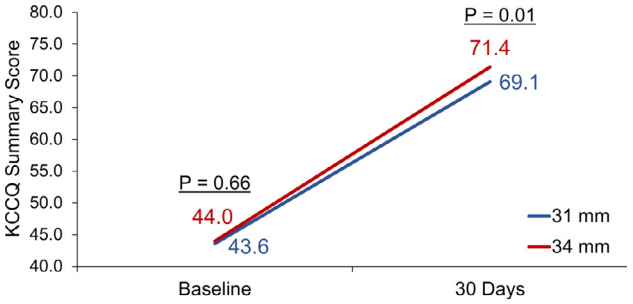
Discussion

TAVI technologies have rapidly advanced over the last decade. Stroke rates and AR rates have improved with device iterations and indications have expanded to lower risk patients.[12–14] TAVI has now become the preferred

Table 5
Valve hemodynamics postprocedure and at 30 days

Variable	CoreValve (N = 1813)	Evolut R (N = 1813)	p Value
Postprocedure			
Effective orifice area (cm^2)	2.0 ± 0.7	2.1 ± 0.7	<0.001
Mean aortic valve gradient (mm Hg)	8.9 ± 4.8	7.5 ± 3.8	<0.001
Aortic valve regurgitation	1633	1687	<0.001
None or trace	873 (53.5%)	1101 (65.3%)	
Mild	588 (36.0%)	514 (30.5%)	
Moderate	154 (9.4%)	66 (3.9%)	
Severe	18 (1.1%)	6 (0.4%)	
30 days*			
Mean aortic valve gradient, (mm Hg)	8.4 ± 3.8	7.2 ± 3.5	<0.001
Aortic valve regurgitation	1287	1376	<0.001
None or trace	617 (47.9%)	804 (58.4%)	
Mild	494 (38.4%)	497 (36.1%)	
Moderate	160 (12.4%)	71 (5.2%)	
Severe	16 (1.2%)	4 (0.3%)	
Left ventricular ejection fraction (%)†	51.6 ± 13.1	51.8 ± 12.8	0.79

Data presented as mean ± standard deviation or no. of patients (percentage) that reflect missing values.
* Aortic valve area not collected at 30 days.
† Not collected postprocedure.



Change from Baseline to 30 Days	
31 mm	24.3± 28.7
34 mm	26.6 ± 26.9
P Value	0.01

Figure 3. KCCQ overall summary scores.
Quality of life at baseline and 30 days as measured by the Kansas City Cardiomyopathy Questionnaire overall summary scores for the patients in the matched cohorts. Comparisons between scores by *t* test; ANCOVA for changes from baseline.

therapy to treat symptomatic severe aortic stenosis in intermediate- or greater-risk patients.[15] Recent randomized controlled trials in low-risk patients showed balloon-expandable TAVI was superior to SAVR at 1 year and self-expanding TAVI was noninferior to SAVR at 2 years.[16,17] However, mild AR (mostly PVL) still occurs in >20% of patients after TAVI and has been associated with higher mortality at 5 years.[9,10,18] Optimal annular-to-prosthesis sizing, routinely determined by multidetector computed tomographic analysis in contemporary practice, is necessary to minimize AR. The 31-mm CoreValve bioprostheses was previously the largest available transcatheter valve to be implanted in TAVI, but performance has been limited by higher pacemaker implant rates and need for a second prosthesis.[19] With the newer generation 34-mm Evolut R valve, the larger inflow diameter and a more consistent radial force at the inflow of the Evolut R frame, helps seal against larger annular and left ventricular outflow tract anatomies to reduce AR, and the ability to recapture and reposition for optimal implantation may help reduce the risk of permanent pacemaker implantation. However, reports of the 34-mm Evolut R valve have been limited to small single- or multicenter experience.[3–8]

The key findings of our study are as follows: (1) The 34-mm Evolut R had a higher device success rate than its predicate 31-mm CoreValve. (2) Total AR and permanent pacemaker implantation rates were less with the 34-mm Evolut R, and (3) Patients receiving the 34-mm valve had a shorter hospital length of stay.

Our current experience with the 34-mm Evolut R, the largest reported thus far, is similar to that previously reported in the US and Europe (Table 6): 30-day mortality and stroke rates were low, and PVL and permanent pacemaker rates were similar to other recent large Evolut R experience.[17,20] Despite a larger inflow and more oversizing to the aortic annulus, the pacemaker rate was actually lower with the 34-mm Evolut R. This may be due to the ability to partially or fully reposition the valve or to operator experience. Even though the 20-Fr delivery system required to implant the 34-mm Evolut R is larger than the 18-Fr required for the 31-mm CoreValve, major vascular complication remained similar, and life-threatening or major bleeding was less with the 34-mm Evolut R. This improvement in outcomes was likely attributed to evolution in TAVI techniques and increased operator experience. The reduced complications likely also accounted for a shorter ICU and length of stay post-TAVI with the 34-mm Evolut R.

Table 6
Comparisons of 34-mm Evolut R valve performance across studies

Study	Bajwa et al[3]	Eitan et al[5]	Kuhn et al[8]	Harnarth et al[6]	Kalogeras et al[7]	Dowling et al[4]	Tang et al*
Study period	6/2016-10/2016	1/2017-8/2017	1/2017-NR	1/2017-9/2017	1/2017-9/2017	1/2017-4/2018	10/2016-9/2017
No. of patients	60	37	101	124	35	217	3036
Age (years)	81.8±8.2	82.4±5.8	80.7±6.6	81.3±5.9	80.4±10.5	79.5±8.8	79.4±8.6
STS PROM (%)	5.5±2.8	4.6±2.4	4.9±5.9	5.2±3.9	NR	5.2±3.4	6.3±4.4
Procedural Characteristics and In-Hospital Outcomes							
Conscious sedation	43%	6%	NR	48%	91%	59%	40%
Pre-balloon aortic valvuloplasty	63%	81%	55%	85%	6%	52%	NR
Post dilatation	37%	32%	47%	23%	12%	22%	NR
Device success	NR	97%	92%	NR	85%	80%	98%
All-cause mortality	NR	0	NR	NR	NR	NR	2%
Stroke	NR	5%	NR	NR	0	NR	3%
Major vascular complication	2%	0	1%	NR	0	2%	1%
Pacemaker	NR	29%	NR	NR	6%	NR	16%
Moderate/severe paravalvular leak	NR	NR	5%	2%	3%	7%	NR
30-Day Outcomes							
All-cause mortality	2%	NR	2%	2%	NR	3%	3%
Stroke	NR	NR	3%	NA	NR	4%	3%
Disabling stroke	0	NR	1%	2%	NR	NR	NR
Pacemaker	18%	NR	19%	22%	NR	16%	18%
Moderate paravalvular leak	2%	NR	NR	NR	NR	7%	5%

* Unmatched patient data from this report. In-hospital rates reported as frequencies and 30-day outcomes reported as Kaplan-Meier rates. ± denotes means and standard deviation.
NR = not reported; STS PROM = Society of Thoracic Surgeons Predicted Risk of Mortality.

Our study has several limitations, first of which the TVT Registry is based on site-reported events and the data were not centrally adjudicated and thus contained inherent limitations and biases typical of registries. Second, due to missing data, we did not include the self-reported risk categories, a subjective variable documented in the TVT Registry by the implanting site, in our original propensity score matching. However, since there were significant differences in risk categories after matching, we performed a sensitivity analysis using the risk category in our matching analysis, which resulted in broadly consistent findings. Third, this study focused on only the 31-mm and 34-mm the US Food and Drug Administration (FDA)-approved self-expanding valves and the outcomes should not be generalized to other transcatheter valve devices. Fourth, considering there were over 2 years of time difference between the implantation of some of the 31-mm CoreValve and the availability of 34-mm Evolut R, changes and improvements in implant techniques, likely contributed to the differences in procedural characteristics and in-hospital outcomes, which could not be overcome by matching baseline and select procedural characteristics. Finally, our study reported only early outcomes since 1-year follow-up data compliance was 67.2%, making longer-term data interpretation challenging.

The 34-mm Evolut R valve was associated with improved device success, reduced hospital stay, lower pacemaker rates, and less more than mild AR than the earlier generation 31-mm CoreValve in this largest study of both valves.

Disclosures

Dr. Tang is a physician proctor for Edwards Lifesciences and Medtronic; Dr. Reardon reports consulting fees paid to his institution from Medtronic; Dr. Kodali has received grants and research support from Medtronic, Boston Scientific, Claret Medical, and Edwards Lifesciences; has served on steering committees for Claret Medical, Edwards Lifesciences, and Meril; has held equity in Thubrikar Aortic Valve; and has received honoraria from Claret Medical and St. Jude Medical; Dr. Hermiller serves on the Steering Committee for the reported trial and the speakers bureau for Medtronic and serves as a consultant to Edwards Lifescience; Dr. Sorajja serves as a consultant to Edwards Lifesciences, Abbott Structural, Boston Scientific, Medtronic, Admedus, Gore, and Cardionomics, and has received grants from Edwards Lifesciences, Abbott Structural, Boston Scientific, Medtronic; Dr. Szeto serves as a speaker, investigator and Steering Committee member of the PARTNER Trial (Edwards Lifesciences) and as a clinical investigator for Medtronic; Ms. Zhang is an employee and shareholder of Medtronic, plc; Dr. Popma reports grants from Medtronic, grants and personal fees from Edwards Lifesciences, grants and personal fees from Boston Scientific, grants from Abbott Vascular.

This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR). The views expressed in this manuscript represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR.

Acknowledgments

Medtronic obtained the data from the TVT Registry and funded the analyses for this report. Under the direction of Dr. Tang, Jane Moore, MS, ELS, an employee of Medtronic, drafted the methods section, some tables and figures, and provided copyediting assistance.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.07.010.

1. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, Gleason TG, Buchbinder M, Hermiller J Jr., Kleiman NS, Chetcuti S, Heiser J, Merhi W, Zorn G, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte J, Maini B, Mumtaz M, Chenoweth S, Oh JK, Investigators USCC. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014;370:1790–1798.
2. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, Mumtaz M, Adams DH, Deeb GM, Maini B, Gada H, Chetcuti S, Gleason T, Heiser J, Lange R, Merhi W, Oh JK, Olsen PS, Piazza N, Williams M, Windecker S, Yakubov SJ, Grube E, Makkar R, Lee JS, Conte J, Vang E, Nguyen H, Chang Y, Mugglin AS, Serruys PW, Kappetein AP, Investigators S. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2017;376:1321–1331.
3. Bajwa T, O'Hair DP, Williams M, Mumtaz M, Gada H, Chetcuti S, Deeb GM, Popma JJ. Transcatheter aortic valve replacement with a 34-mm repositionable self-expanding bioprosthesis. *J Am Coll Cardiol* 2017;70(Suppl):B147.
4. Dowling C, Firoozi S, Doyle N, Blackman DJ, Malkin CJ, Cunnington MS, Saraf S, Buch MH, Levy R, Chowdhary S, Spence MS, Manoharan G, Owens CG, Brennan PF, Roberts D, More R, Wiper A, Abdelaziz HK, Mylotte D, Neylon A, Martin N, Mercanti F, Dorman S, Panoulas V, Dalby M, Kashyap MN, Kabir T, Kovac J, Kontoprias K, Malik IS, Ghada MW, Sen S, Ruparelia N, Demir OM, Frame A, Uren NG, Anderson R, Rajathurai T, Tapp L, Deegan L, Grech E, Hall I, Neville M, Rampat R, Hildick-Smith D, Mullen M, Kennon S, Chandrala P, Doshi S, Brecker SJ. Initial experience of a large, self-expanding, and fully recapturable transcatheter aortic valve: the UK & Ireland Implanters' registry. *Catheter Cardiovasc Interv* 2019;93:751–757.
5. Eitan A, Witt J, Stripling J, Haselbach T, Riess FC, Schofer J. Performance of the Evolut-R 34 mm versus Sapien-3 29 mm in transcatheter aortic valve replacement patients with larger annuli: early outcome results of Evolut-R 34 mm as compared with Sapien-3 29 mm in patients with Annuli ≥26 mm. *Catheter Cardiovasc Interv* 2018;92:1374–1379.
6. Harnath A, Gomes B, Herwig V, Gatto F, Watremez S, Katus HA, Bekeredjian R. First experience with the 34 mm self-expanding Evolut R in a multicentre registry. *EuroIntervention* 2018;14:e298–e300.
7. Kalogeras K, Kabir T, Mittal T, Mirsadraee S, Skondras E, Rahman Haley S, Zuhair M, Vavuranakis M, Tousoulis D, Dalby M, Panoulas V. Real-world comparison of the new 34 mm self-expandable transcatheter aortic prosthesis Evolut R to its 31 mm CoreValve predecessor. *Catheter Cardiovasc Interv* 2019;93:685–691.
8. Kuhn C, Frerker C, Meyer AK, Kurz T, Schafer U, Deuschl F, Abdel-Wahab M, Schewel D, Elghalban A, Kuck KH, Frey N, Frank D. Transcatheter aortic valve implantation with the 34 mm self-expanding CoreValve Evolut R: initial experience in 101 patients from a multicentre registry. *EuroIntervention* 2018;14:e301–e305.
9. Manoharan G, Walton AS, Brecker SJ, Pasupati S, Blackman DJ, Qiao H, Meredith IT. Treatment of symptomatic severe aortic stenosis with a novel resheathable supra-annular self-expanding transcatheter aortic valve system. *J Am Coll Cardiol Intv* 2015;8:1359–1367.
10. Popma JJ, Adams DH, Reardon MJ, Yakubov SJ, Kleiman NS, Heimansohn D, Hermiller J Jr., Hughes GC, Harrison JK, Coselli J, Diez J, Kafi A, Schreiber T, Gleason TG, Conte J, Buchbinder M, Deeb GM, Carabello B, Serruys PW, Chenoweth S, Oh JK, CoreValve

United States Clinical Investigators. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol* 2014;63:1972–1981.
11. Leon MB, Piazza N, Nikolsky E, Blackstone EH, Cutlip DE, Kappetein AP, Krucoff MW, Mack M, Mehran R, Miller C, Morel MA, Petersen J, Popma JJ, Takkenberg JJ, Vahanian A, van Es GA, Vranckx P, Webb JG, Windecker S, Serruys PW. Standardized endpoint definitions for Transcatheter Aortic Valve Implantation clinical trials: a consensus report from the Valve Academic Research Consortium. *J Am Coll Cardiol* 2011;57:253–269.
12. Shreenivas S, Kaneko T, Tang GHL. Predicting the future of TAVR: an obituary to open aortic valve replacement? *Curr Opin Cardiol* 2019;34:112–123.
13. Tang GH, Lansman SL, Panza JA. Beyond PARTNER: appraising the evolving trends and outcomes in transcatheter aortic valve replacement. *Cardiol Rev* 2015;23:1–10.
14. Tsai MT, Tang GH, Cohen GN. Year in review: transcatheter aortic valve replacement. *Curr Opin Cardiol* 2016;31:139–147.
15. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP 3rd, Fleisher LA, Jneid H, Mack MJ, McLeod CJ, O'Gara PT, Rigolin VH, Sundt TM 3rd, Thompson A. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. *Circulation* 2017;135:e1159–e1195.
16. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR, Investigators P. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019. https://doi.org/10.1056/NEJMoa1814052. [Epub ahead of print].
17. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, Bajwa T, Heiser JC, Merhi W, Kleiman NS, Askew J, Sorajja P, Rovin J, Chetcuti SJ, Adams DH, Teirstein PS, Zorn GL 3rd, Forrest JK, Tchetche D, Resar J, Walton A, Piazza N, Ramlawi B, Robinson N, Petrossian G, Gleason TG, Oh JK, Boulware MJ, Qiao H, Mugglin AS, Reardon MJ, Evolut Low Risk Trial I. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019. https://doi.org/10.1056/NEJMoa1816885. [Epub ahead of print].
18. Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, Lee JS, Kleiman NS, Chetcuti S, Hermiller JB Jr., Heiser J, Merhi W, Zorn GL 3rd, Tadros P, Robinson N, Petrossian G, Hughes GC, Harrison JK, Conte JV, Mumtaz M, Oh JK, Huang J, Adams DH, CoreValve US Pivotal High Risk Trial Clinical Investigators. Five-year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *J Am Coll Cardiol* 2018;72:2687–2696.
19. Attizzani GF, Ohno Y, Latib A, Petronio AS, Giannini C, Ettori F, Curello S, Bedogni F, Todaro D, Brambilla N, Bruschi G, Colombo P, Presbitero P, Fiorilli R, Poli A, Martina P, Colombo A, Barbanti M, Tamburino C. Acute and long-term (2-years) clinical outcomes of the CoreValve 31mm in large aortic annuli: a multicenter study. *Int J Cardiol* 2017;227:543–549.
20. Sorajja P, Kodali S, Reardon MJ, Szeto WY, Chetcuti SJ, Hermiller J Jr., Chenoweth S, Adams DH, Popma JJ. Outcomes for the commercial use of self-expanding prostheses in transcatheter aortic valve replacement: a report from the STS/ACC TVT Registry. *JACC Cardiovasc Interv* 2017;10:2090–2098.