Propensity-Matched Comparison of Evolut-R Transcatheter Aortic Valve Implantation With Surgery in Intermediate-Risk Patients (from the SURTAVI Trial)

Steven J. Yakubov, MD[a,*], Nicolas M. Van Mieghem, MD, PhD[b], Michael J. Reardon, MD[c], Patrick W. Serruys, MD, PhD[d], Hemal Gada, MD[e], Mubashir Mumtaz, MD[e], G. Michael Deeb, MD[f], Susheel Kodali, MD[g], Isaac George, MD[g], Stephan Windecker, MD, PhD[h], Neal Kleiman, MD[c], Stanley J. Chetcuti, MD[f], Carlos Sanchez, MD[a], Harold L. Dauerman, MD[i], Shuzhen Li, PhD[j], and Jeffrey J. Popma, MD[k]

The SURTAVI trial demonstrated the noninferiority of transcatheter aortic valve implantation (TAVI) to surgical aortic valve replacement (SAVR) in patients with severe, symptomatic aortic stenosis at intermediate surgical risk. Most TAVI patients received an early generation device which is no longer commercially available. This analysis compares TAVI outcomes in patients that received the Evolut R valve to those of similar patients randomized to SAVR in the SURTAVI trial. The continued access study of SURTAVI (CAS) enrolled 290 patients. Of them, 252 were implanted with the 23, 26, or 29 mm Evolut R device. Propensity-score matching between this group and SURTAVI SAVR patients with annular diameter of 26 mm or less was based on 22 clinical characteristics, resulting in 197 matched pairs for analysis. The primary end point for comparison was the rate of all-cause mortality or disabling stroke at 1-year. The mean age for TAVI and SAVR patients in the propensity-score matched population was 79.1 years and STS-PROM was 4.0 ± 1.5% for TAVI and 3.9% ± 1.3% for SAVR. The rate of all-cause mortality or disabling stroke at 30-days significantly favored TAVI (0.5% vs 5.1%; p = 0.006). At 1-year TAVI was numerically favored (4.1% vs 8.2%; p = 0.082). In conclusion, compared with SAVR, TAVI using Evolut R had a favorable 30-day safety profile, significantly better hemodynamic performance, and a comparable 1-year rate of all-cause mortality or disabling stroke, suggesting this may be a preferred treatment for patients with severe, symptomatic aortic stenosis at intermediate surgical risk. **(Am J Cardiol 2020;131:82−90)**

The Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial demonstrated the noninferiority of transcatheter aortic valve implantation (TAVI) using a self-expanding bioprosthesis to surgical aortic valve replacement (SAVR) for the primary end point of all-cause mortality or disabling stroke at 2 years in patients with severe, symptomatic aortic stenosis at intermediate risk for surgery.[1] The majority of TAVI patients in the SURTAVI trial (84%) received the first generation CoreValve bioprosthesis (Medtronic, Minneapolis, Minnesota). Following completion of randomization, additional eligible patients were enrolled in the SURTAVI continued-access study (CAS). Most of the CAS patients (93%) underwent TAVI with the Evolut R bioprosthesis, a newer-generation supra annular self-expanding bioprosthetic valve that allows repositioning of the valve out to 90% of valve deployment.[2] Data comparing outcomes of TAVI with the Evolut R transcatheter aortic valve versus SAVR in this intermediate-risk population are limited. The purpose of this analysis was to compare outcomes of the CAS patients treated with the Evolut R bioprosthesis to outcomes of patients from a comparable SAVR cohort.

Methods

Patients included in this analysis underwent SAVR in the randomized SURTAVI Trial or TAVI with the Evolut R device in the single-arm, observational SURTAVI CAS. Both studies enrolled patients with severe, symptomatic

[a]Riverside Methodist − Ohio Health, Columbus, Ohio; [b]Erasmus University Medical Center, Rotterdam, The Netherlands; [c]Houston-Methodist-Debakey Heart and Vascular Center, Houston, Texas; [d]International Centre for Circulatory Health, NHLI, Imperial College London, London, United Kingdom; [e]University of Pittsburgh Medical Center Pinnacle Heath, Harrisburg, Pennsylvania; [f]University of Michigan Hospitals, Ann Arbor, Michigan; [g]Structural Heart and Valve Center, Columbia University Medical Center, New York, New York; [h]University Hospital Bern, Bern, Switzerland; [i]University of Vermont Medical Center, Burlington, Vermont; [j]Medtronic, Minneapolis, Minnesota; and [k]Beth Israel Deaconess Medical Center, Boston, Massachusetts. Manuscript received March 9, 2020; revised manuscript received and accepted June 16, 2020.

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*Corresponding author: Tel: (614) 262-6772

E-mail address: steven.yakubov@ohiohealth.com (S.J. Yakubov).

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aortic stenosis in New York Heart Association (NYHA) functional class II or higher and had similar inclusion and exclusion criteria with 2 important exceptions.[1] First, in the randomized SURTAVI trial, the criteria for intermediate surgical risk evolved over time. For patients enrolled between June 2012 and May 2014, those with a Society of Thoracic Surgeons' Predicted Risk of Mortality (STS-PROM) score of at least 4% but less than 10% were deemed intermediate risk for surgical mortality within 30 days. From May 2014 until June 2016, intermediate risk was determined by the local multidisciplinary heart team and based on an STS-PROM score of ≥3% and <15% and overall clinical status, including frailty, disability, and co-morbid conditions. These latter eligibility criteria were also applied in CAS, which enrolled patients between September 2016 and July 2017. Second, the acceptable native aortic annulus size differed between studies, ranging from 18 to 29 mm in SURTAVI and 18 to 30 mm in CAS. This allowed use of the Evolut R 34 mm valve for patients with annuli between 26 and 30 mm in diameter. To isolate clinically and anatomically similar patients from these 2 studies, SURTAVI SAVR patients enrolled from May 2014 onward and all patients in SURTAVI and CAS with an annular diameter ranging from 18 to 26 mm were considered eligible for this analysis.

The SURTAVI Trial and CAS complied with the Declaration of Helsinki, all local ethics committees approved the research protocols, and written informed consent was obtained from all patients.

The primary end point for this analysis was the composite of all-cause mortality or disabling stroke at 1 year. An independent clinical events committee adjudicated all clinical events for both SURTAVI and CAS. Stroke assessment was consistent across studies. A trained neurologist or stroke specialist examined all patients at baseline, and follow-up neurological assessments were done at discharge, 30 days, 6 months, and 1 year. Neurological events were adjudicated by a neurologist on the clinical events committee, using Valve Academic Research Consortium-2 (VARC-2) stroke definitions.[3] For both studies, the same echocardiographic core laboratory (Mayo Clinic, Rochester, Minnesota) analyzed echocardiograms for total aortic regurgitation (AR) (defined according to VARC-2), mean aortic valve gradient (AVG), and effective orifice area (EOA). The presence of no, moderate, and severe prosthesis-patient mismatch at post procedure/discharge, 6 months, and 1 year was determined using VARC-2 definitions.

A propensity score model was used to reduce the potential confounding in comparison of outcomes between the 2 groups by accounting for differences in patient baseline characteristics. The model was developed using a multivariable logistic regression with 22 baseline characteristics (**Table 1**) with STS score log-transformed. A 5-to-1 digits greedy 1:1 matching algorithm was used to form a propensity-matched cohort for analysis.[4] Absolute standardized differences were calculated to evaluate the balance before and after matching, with values <10% used to indicate no

Table 1
Baseline characteristics before and after propensity-score matching

Variable	Before matching				After matching			
	Evolut R (n = 252)	SAVR (n = 318)	p-Value	Absolute standardized difference	Evolut R (n = 197)	SAVR (n = 197)	p-Value	Absolute standardized difference
Age (years)	79.1 ± 6.2	78.8 ± 5.8	0.539	5.2%	79.1 ± 6.1	79.1 ± 5.8	0.966	0.4%
STS-PROM (%)	4.1 ± 1.5	3.8 ± 1.3	0.009	2.21%	4.0 ± 1.5	3.9 ± 1.3	0.465	7.4%
Body mass index (kg/m^2)	30.7 ± 7.1	29.3 ± 5.9	0.011	2.19%	30.4 ± 7.0	29.9 ± 6.2	0.515	6.6%
Men (%)	106 (42.1%)	130 (40.9%)	0.776	2.4%	80 (40.6%)	81 (41.1%)	0.918	1.0%
NYHA III/IV	115 (45.6%)	172 (54.1%)	0.045	17.0%	94 (47.7%)	92 (46.7%)	0.840	2.0%
Need for revascularization	29 (11.5)	59 (18.6%)	0.021	19.8%	23 (11.7%)	24 (12.2%)	0.877	1.6%
5-m gait speed >6 s or wheelchair bound	117/250 (46.8%)	159/309 (51.5%)	0.274	9.3%	94 (47.7%)	97 (49.2%)	0.762	3.1%
Falls in the past 6 mo	21 (8.3%)	34 (10.7%)	0.344	8.1%	17 (8.6%)	15 (7.6%)	0.712	3.7%
Katz score, ≥1 deficit	24 (9.5%)	21 (6.6%)	0.199	10.7%	18 (9.1%)	15 (7.6%)	0.585	5.5%
Diabetes controlled by insulin	26 (10.3%)	31 (9.7%)	0.822	1.9%	19 (9.6%)	18 (9.1%)	0.862	1.7%
Peripheral vascular disease	66 (26.2%)	65 (20.4%)	0.105	13.6%	52 (26.4%)	47 (23.9%)	0.561	5.9%
Prior stroke	13 (5.2%)	20 (6.3%)	0.566	4.9%	10 (5.1%)	7 (3.6%)	0.457	7.5%
Coronary artery disease	142 (56.3%)	175 (55.0%)	0.753	2.7%	106 (53.8%)	104 (52.8%)	0.840	2.0%
Pre-existing pacemaker/defibrillator	15 (6.0%)	21 (6.6%)	0.751	2.7%	9 (4.6%)	12 (6.1%)	0.501	6.8%
Heart failure	209 (82.9%)	299 (94.0%)	<0.001	3.53%	182 (92.4%)	179 (90.9%)	0.585	5.5%
Atrial fibrillation/flutter	57 (22.6%))	60 (18.9%)	0.271	9.3%	40 (20.3%)	46 (23.4%)	0.464	7.4%
Moderate/severe chronic lung disease	44 (17.5%)	35 (11.0%)	0.027	18.6%	25 (12.7%)	28 (14.2%)	0.657	4.5%
Home oxygen	2/251 (0.8%)	8/317 (2.5%)	0.198	13.6%	2 (1.0%)	2 (1.0%)	>0.99	0.0%
LVEF (%)	64.4 ± 8.4 (251)	62.8 ± 9.3 (317)	0.036	17.8%	64.0 ± 8.6	64.4 ± 8.4	0.672	4.3%
Mean gradient, mmHg	44.3 ± 12.1 (245)	48.7 ± 14.5 (317)	<0.001	33.2%	45.7 ± 11.9	45.5 ± 12.0	0.913	1.1%
Aortic regurgitation ≥ mild	99/247 (40.1%)	141/316 (44.6%)	0.279	9.2%	75 (38.1%)	76 (38.6%)	0.918	1.0%
Mitral regurgitation moderate/severe	12/251 (4.8%)	7/314 (2.2%)	0.095	13.9%	8 (4.1%)	7 (3.6%)	0.792	2.7%

Data are presented as mean ± standard deviation (no. of patients with available data) or no. of patients / no. of patients with available data (%). An absolute standardized difference >10% represents an imbalance between groups. LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; STS-PROM = Society of Thoracic Surgeons' Predicted Risk of Mortality.

meaningful imbalance.[5] Categorical variables were compared using the chi square test, or Fisher's exact test where appropriate. Continuous variables were presented as mean ± standard deviation and compared using the independent samples *t* test. Kaplan-Meier estimates were used to construct the graph of all-cause mortality or disabling stroke for the time-to-event analysis, with the time origin being the start of the procedure. The log-rank test was used to compare the time to event distributions between TAVI and SAVR groups. All testing used a 2-sided alpha level of 0.05. Statistical analyses were performed with the use of SAS software, version 9.4 (SAS Institute, Cary, North Carolina).

Results

A total of 318 SAVR patients from SURTAVI and 252 Evolut R patients from CAS were eligible for propensity-score matching, and the final modeling resulted in 197 matched pairs (**Figure 1**). Several baseline characteristics were significantly different between groups before matching, including the STS-PROM score NYHA class III/IV, need for revascularization and moderate/severe chronic lung disease (**Table 1**). After matching, the STS-PROM was approximately 4%, mean age was 79.1 years, and approximately 60% of patients were female in each group, and absolute standardized differences indicated that the groups were well matched.

Table 2 displays 30-day and 1-year clinical outcomes for the unmatched and matched cohorts. In the unmatched cohort, the primary end point of all-cause mortality or disabling stroke at 1 year was 8.3% in the SAVR group and 3.2% in the Evolut R group ($p = 0.011$). In the matched cohort at 1 year, the primary endpoint was 8.2% in the SAVR-treated patients and 4.1% in the Evolut R-treated patients ($p = 0.082$) (**Table 2** and **Figure 2**).

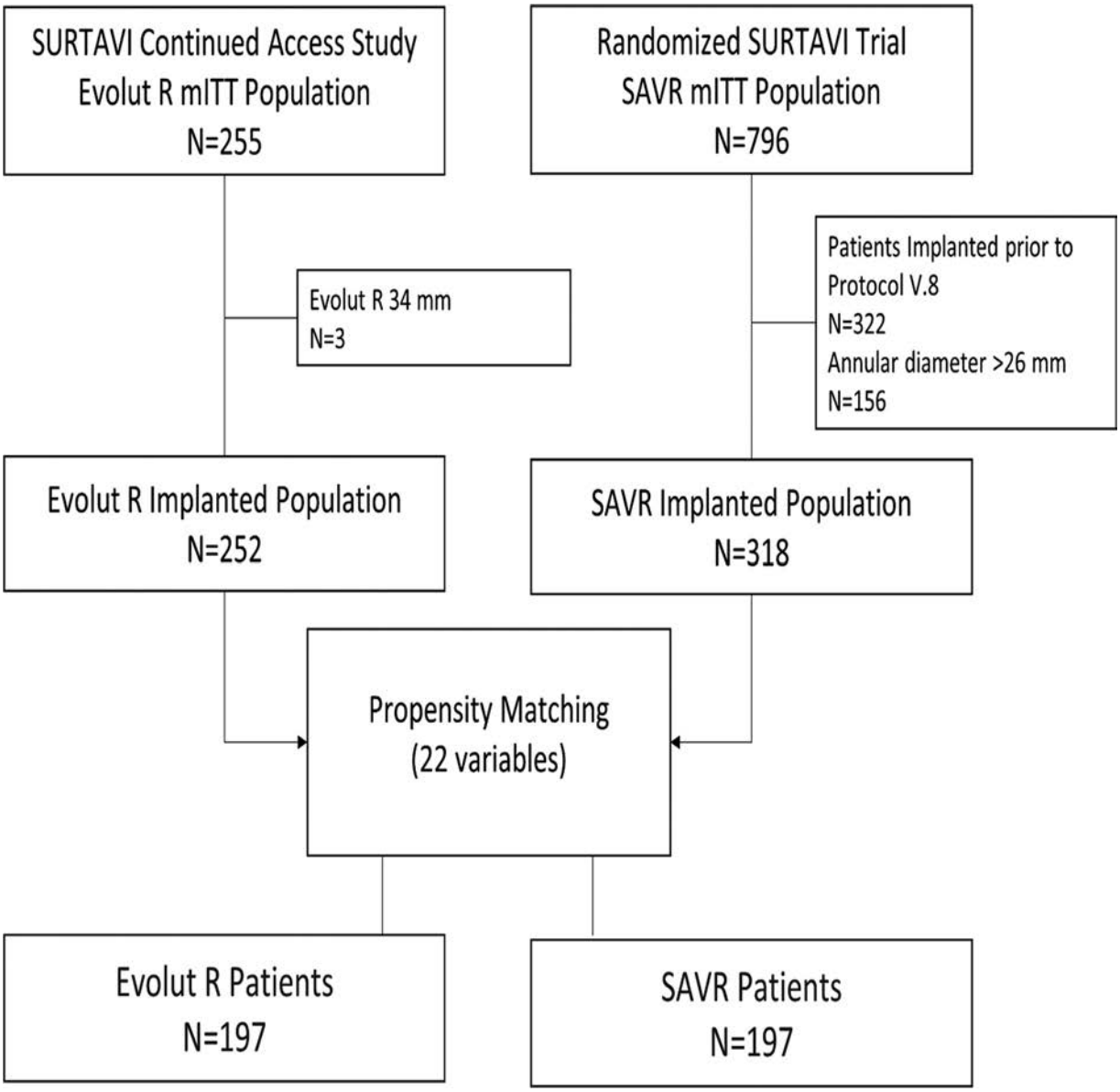


Figure 1. Patient flow of propensity-score matched cohorts. SAVR = surgical aortic valve replacement; mITT = modified intention to treat.

Table 2
Clinical outcomes in the before matching and the propensity-score matched cohorts

Outcome	Before matching				Propensity score matched					
	30 Days		1 Year		30 Days			1 Year		
	Evolut R (n = 252)	SAVR (n = 318)	Evolut R (n = 252)	SAVR (n = 318)	Evolut R (n = 197)	SAVR (n = 197)	p-value*	Evolut R (n = 197)	SAVR (n = 197)	p-value*
All-cause mortality or disabling stroke	1 (0.4%)	16 (5.1%)	8 (3.2%)	26 (8.3%)	1 (0.5%)	12 (5.1%)	0.006	9 (4.1%)	18 (8.2%)	0.082
All-cause mortality	0	10 (3.2%)	7 (2.8%)	20 (6.4%)	0	5 (2.6%)	0.024	7 (3.6%)	11 (5.7%)	0.311
Cardiovascular mortality	0	10 (3.2%)	4 (1.6%)	17 (5.4%)	0	5 (2.6%)	0.024	4 (2.0%)	8 (4.1%)	0.226
Stroke	5 (2.0%)	20 (6.3%)	11 (4.6%)	21 (6.7%)	6 (2.5%)	14 (6.6%)	0.053	13 (5.3%)	14 (6.6%)	0.504
Disabling	1 (0.4%)	8 (2.5%)	2 (0.8%)	8 (2.5%)	1 (0.5%)	7 (3.1%)	0.056	2 (1.0%)	7 (3.1%)	0.149
Nondisabling	4 (1.6%)	12 (3.8%)	10 (4.2%)	13 (4.1%)	5 (2.0%)	7 (3.6%)	0.353	11 (4.8%)	7 (3.6%)	0.621
Transient ischemic attack	0	4 (1.3%)	4 (1.6%)	8 (2.6%)	0	3 (1.5%)	0.081	5 (2.0%)	3 (1.5%)	0.735
Life-threatening or disabling bleeding	2 (0.8%)	16 (5.1%)	8 (3.2%)	19 (6.1%)	2 (1.0%)	8 (4.1%)	0.054	8 (4.1%)	9 (4.6%)	0.768
Major vascular complications	9 (3.6%)	3 (0.9%)	10 (4.0%)	3 (0.9%)	7 (3.0%)	2 (1.0%)	0.155	8 (3.6%)	2 (1.0%)	0.094
Acute kidney injury stage 2 and 3	4 (1.6%)	14 (4.4%)	4 (1.6%)	14 (4.4%)	4 (2.0%)	5 (2.6%)	0.736	4 (2.0%)	5 (2.6%)	0.736
Myocardial infarction	1 (0.4%)	2 (0.6%)	3 (1.2%)	2 (0.6%)	1 (0.5%)	1 (0.5%)	>0.99	3 (1.5%)	1 (0.5%)	0.329
Pacemaker implantation	38 (15.1%)	22 (7.0%)	45 (17.9%)	26 (8.4%)	26 (13.2%)	12 (6.2%)	0.014	30 (15.3%)	15 (7.8%)	0.015
Atrial fibrillation	30 (11.9%)	127 (40.2%)	42 (16.8%)	132 (41.9%)	29 (13.7%)	75 (35.8%)	<0.001	42 (18.3%)	79 (37.4%)	<0.001
Aortic valve reintervention	0	0	2 (0.8%)	1 (0.3%)	0	0	NA	2 (1.0%)	1 (0.5%)	0.58
Rehospitalization	5 (2.0%)	10 (3.2%)	13 (5.2%)	18 (5.9%)	3 (1.5%)	7 (3.6%)	0.189	10 (4.6%)	14 (6.8%)	0.329

All data are reported as the number of events (Kaplan-Meier estimates as percentages) at the specific time point and do not equal the number of patients with events divided by the total number of patients in each treatment group. SAVR = surgical aortic valve replacement.

* P value comparing event rates between TAVI with the Evolut R valve and SAVR at each time point.

At 30 days, the rate of all-cause mortality was significantly lower in the Evolut R group than the SAVR group in both the unmatched and matched cohorts (unmatched: 0.0% vs 3.2%, p = 0.005; matched: 0.0% vs 2.6%, p = 0.024). The observed-to-expected (O:E) 30-day mortality ratio was 0.0 for TAVI and 0.67 for SAVR for the matched cohort. The rates of disabling stroke at 30 days were also lower in the Evolut R group than the SAVR group in both cohorts, but the difference was not statistically significant in the matched cohort. At 1 year in the unmatched cohort, all-cause mortality remained lower in the Evolut R group (2.8% vs 6.4%, p = 0.045), but there was no statistically significant difference in all-cause mortality in the propensity-matched groups at this time point (Evolut R, 3.6%; SAVR, 5.7%; p = 0.312) (**Figure 3**). Although rates of disabling stroke at 1 year were lower in the Evolut R group than the SAVR groups in both the unmatched cohort and matched cohorts, the differences were not statistically significant (**Figure 3**). There were 14 strokes of any severity within the first year following SAVR, and all occurred before day 30. There were 6 strokes of any severity within the first 30 days after an Evolut R implant; an additional 7 events occurred between day 31 and 1 year.

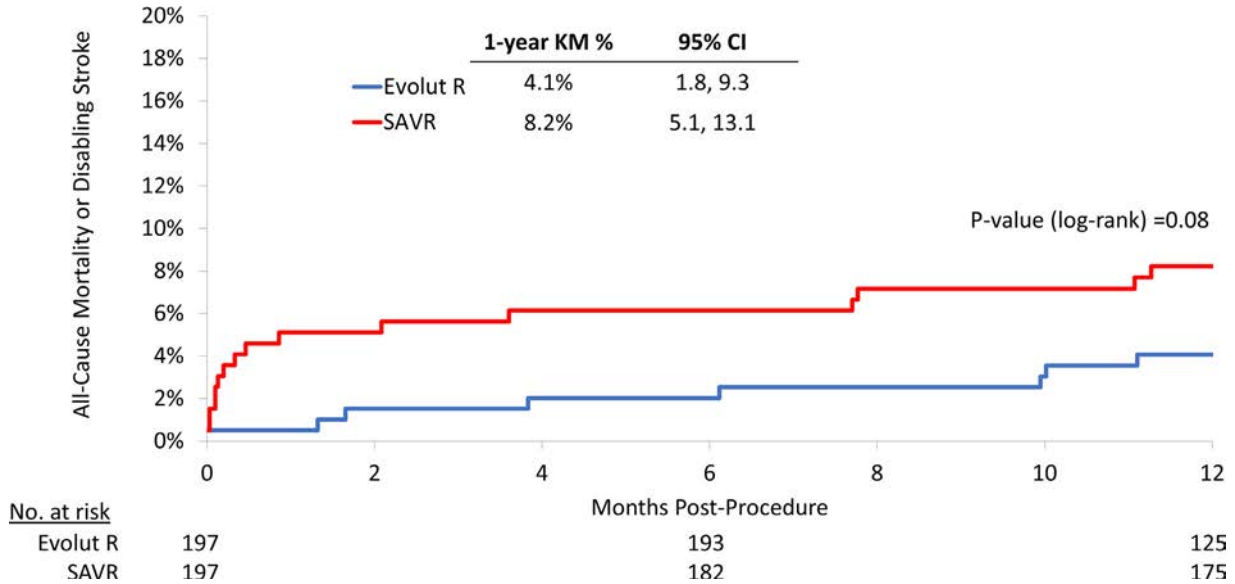


Figure 2. Kaplan-Meier estimates of the composite endpoint (All-Cause Mortality or Disabling Stroke) in the Evolut R and SAVR Groups at 1 Year. SAVR = surgical aortic valve replacement; CI = confidence interval.

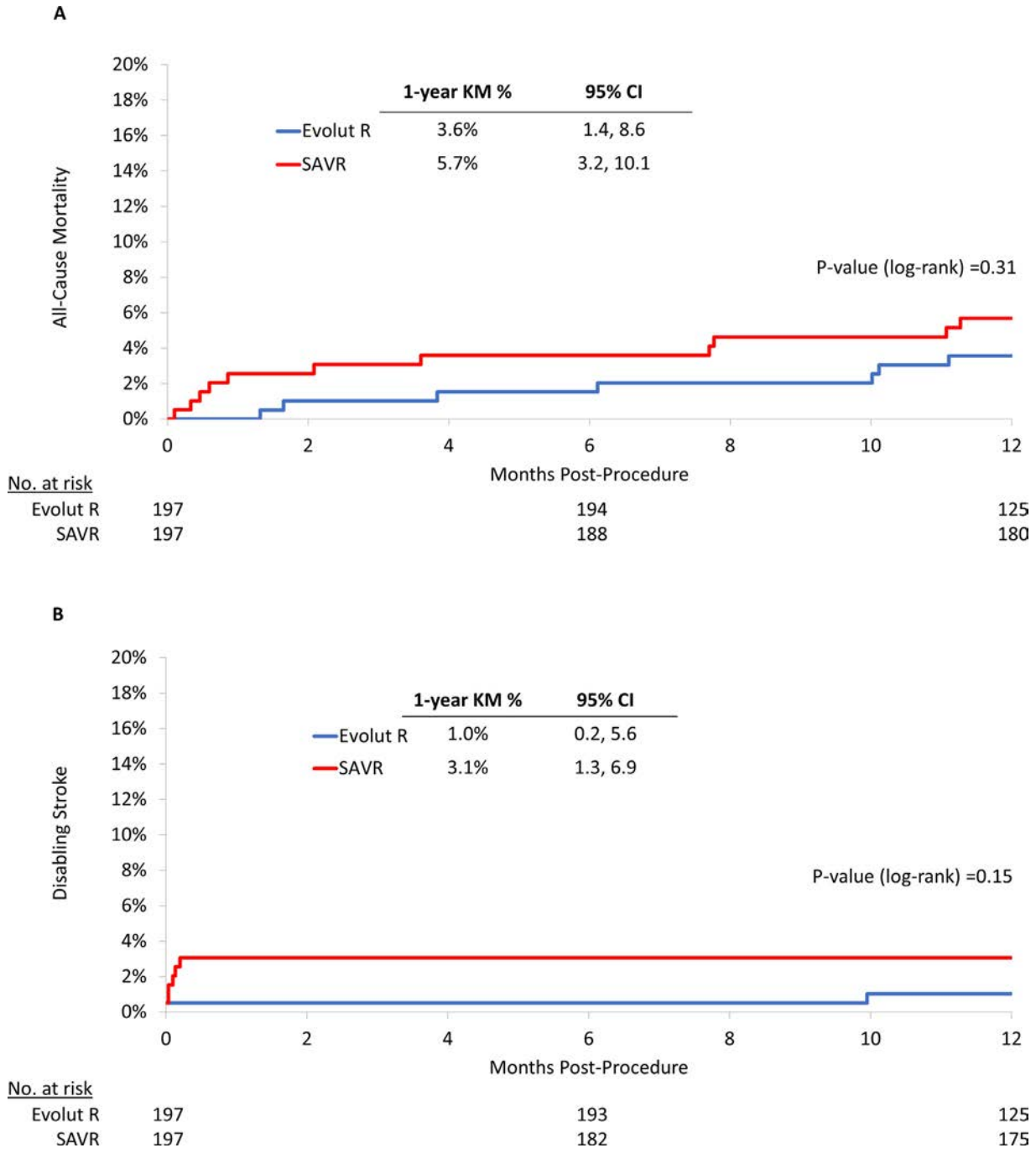


Figure 3. Kaplan-Meier estimates of (A) all-cause mortality and (B) disabling stroke in the Evolut R and SAVR Groups at 1 Year. SAVR = surgical aortic valve replacement; CI = confidence interval.

In the matched cohort, reintervention was needed in 2 Evolut R patients and one SAVR patient (p = 0.579) through 1 year. Ten (4.6%) Evolut R patients and 14 (6.8%) SAVR patients were rehospitalized by 1 year (p = 0.329; Table 2). Atrial fibrillation was more common after SAVR than after TAVI in both the unmatched and matched cohorts at 30 days and 1 year, whereas permanent pacemaker implantation was more common after TAVI than SAVR in both cohorts at 30 days and 1 year (Table 2).

The rates of moderate or severe total AR were similar in the matched Evolut R and SAVR groups at the time of hospital discharge (p = 0.501), but moderate or severe AR was more common in the Evolut R group at 1 year (p = 0.003; Figure 4). There were no cases of severe total AR in either group through 1 year. The Evolut R group had a significantly lower mean AVG and larger EOA at each follow-up time-point compared with SAVR (Figure 5). The proportions of patients with moderate and severe prosthesis-patient mismatch (PPM) were lower in the Evolut R group at 6 months and 12 months in both the unmatched and matched cohorts (Table 3).

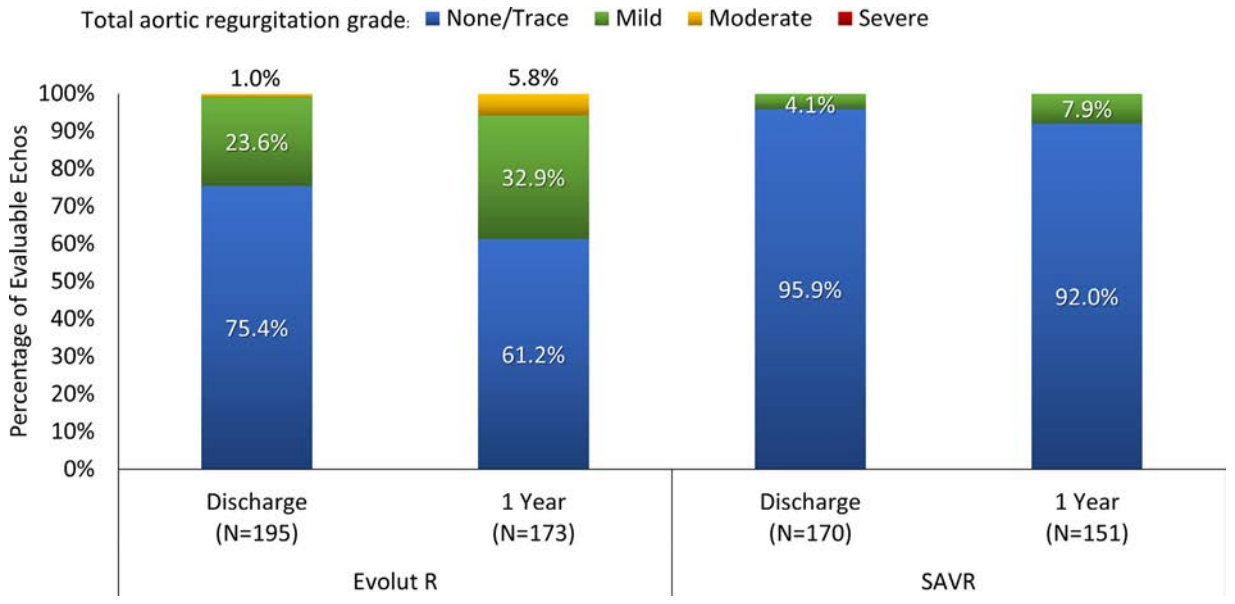
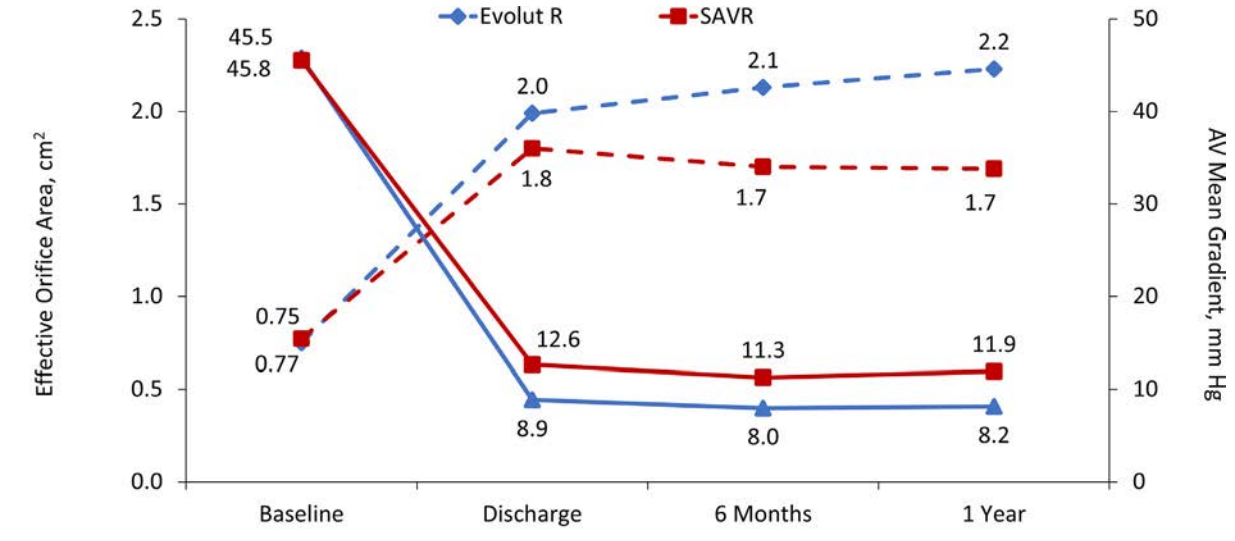


Figure 4. Aortic regurgitation through 1 year. Core-lab reported total aortic regurgitation for the Evolut R and SAVR groups. SAVR = surgical aortic valve replacement.



No. of patients with echo data				
Evolut R AVG	191	190	178	168
SAVR AVG	197	175	164	151
Evolut R EOA	171	154	158	149
SAVR EOA	181	133	150	130

Figure 5. Valve hemodynamics through 1 year. Core-lab reported effective orifice area (EOA, *dashed lines*) and aortic valve mean gradient (AVG, *solid lines*) over time in the Evolut R *(blue lines)* and SAVR *(red lines)* groups. Transcatheter valve replacement was associated with larger effective orifice area and smaller mean gradient at each time point compared with surgery (all $p < 0.01$). SAVR = surgical aortic valve replacement.

Discussion

This analysis is a propensity-score-matched comparison of patients who underwent TAVI in the SURTAVI CAS using the newer generation Evolut R bioprosthesis with patients who underwent SAVR in the later phase of the SURTAVI Trial. Propensity matching was performed using 22 baseline characteristics to reduce confounding of results and to avoid biased estimates of outcomes associated with each treatment.[6] Our analysis demonstrated that the primary composite endpoint of all-cause mortality or disabling stroke was significantly lower with TAVI at 30 days and remained numerically lower at 1 year. The overall 30-day safety profile favored TAVI over SAVR with no deaths and low rates of periprocedural complications other than new pacemaker implantation which favored SAVR

Table 3
Prosthesis-patient mismatch in unmatched and propensity-score matched cohorts

Interval	Before matching			Propensity-score matched		
	CAS Evolut R	SAVR	p-Value	CAS Evolut R	SAVR	p-Value
Postprocedure/discharge	n = 197	n = 211		n = 154	n = 133	
Severe PPM	10 (5.1%)	28 (13.3%)	<0.001	9 (5.8%)	18 (13.5%)	0.045
Moderate PPM	31 (15.7%)	49 (23.2%)		24 (15.6%)	23 (17.3%)	
No PPM	156 (79.2%)	134 (63.5%)		121 (78.6%)	92 (69.2%)	
6 Months	n = 202	n = 234		n = 158	n = 150	
Severe PPM	4 (2.0%)	27 (11.5%)	<0.001	4 (2.5%)	16 (10.7%)	<0.001
Moderate PPM	14 (6.9%)	53 (22.6%)		12 (7.6%)	33 (22.0%)	
No PPM	184 (91.1%)	154 (65.8%)		142 (89.9%)	101 (67.3%)	
12 Months	n = 192	n = 210		n = 149	n = 130	
Severe PPM	1 (0.5%)	30 (14.3%)	<0.001	1 (0.7%)	19 (14.6%)	<0.001
Moderate PPM	12 (6.3%)	51 (24.3%)		9 (6.0%)	32 (24.6%)	
No PPM	179 (93.2%)	129 (61.4%)		139 (93.3%)	79 (60.8%)	

VARC-2 definitions of PPM were used: severe PPM = (BMI <30 and EOAI <0.65 cm^2/m^2) or (BMI ≥30 and EOAI <0.60 cm^2/m^2); moderate PPM = (BMI <30 and 0.65≤ EOAI ≤0.85 cm^2/m^2) or (BMI ≥30 and 0.60≤ EOAI ≤0.70 cm^2/m^2); and no PPM = (BMI <30 and EOAI >0.85 cm^2/m^2) or (BMI ≥30 and EOAI >0.70 cm^2/m^2).

The significantly lower rate of all-cause mortality or disabling stroke at 30 days with Evolut R TAVI versus SAVR suggests TAVI may be a lower risk procedure. This was observed in the setting of excellent surgical results as evidenced by an O:E ratio of 0.67 for the 30-day surgical mortality of 2.6%. At 1 year the primary composite outcome was twice as high in the SAVR group as in the Evolut R group but the difference did not reach statistical significance. Overall clinical results are consistent with other studies of the CoreValve self-expanding THV in intermediate- and high-risk patients but with encouraging lower rates of all-cause mortality and disabling stroke after Evolut R compared with the earlier generation CoreValve device.[1, 7, 8]

Thourani et al[9] reported unadjusted 30-day and 1-year all-cause mortality rates of 1.1% and 7.4% in patients who underwent TAVI with a Sapien 3 (S3) valve, compared with 30-day rates of 0.0% and 1-year rates of 2.8% and 3.6% in the patients who underwent TAVI with the Evolut R device (unmatched and matched cohorts, respectively). Disabling stroke at 1-year occurred in 2.3% of the S3 patients,[9] and in 0.4% and 1.0% of the Evolut R patients (unmatched and matched cohorts, respectively) in this analysis.

Pagnesi et al[10] performed a propensity-score-matched analysis of the Acurate neo and Evolut PRO self-expanding TAVI devices (N = 251 pairs) and reported no statistically significant differences in any 30-day clinical outcomes, including all-cause mortality (3.2% vs 1.2%, p = 0.221) and any stroke (2.4% vs 2.8%, p = 1.000). In our propensity-matched analysis of 30-day outcomes in the Evolut R group, the rate of all-cause mortality was 0.0% and any stroke was 2.5%. The 30-day rates for the Evolut R reported here are lower than or similar to the rates published in the first report of early results with this device.[2]

In a matched comparison of the Evolut R and Evolut PRO devices in high-risk patients, Hellhammer et al[11] reported comparable clinical outcomes for the two devices. The 30-day mortality rate in both devices was 1.4%.

At 1 year, rehospitalization related to heart failure or need for aortic valve reintervention were lower for TAVI compared with SAVR, although the differences were not statistically significant. These similarities are consistent with data from SURTAVI and the low-risk clinical trials.[1, 12]

New conduction disturbances following TAVI implantation are a persistent concern, although rates of new pacemaker implantation vary in clinical trials. The rate of new pacemaker implantation was lower in the current Evolut R analysis (13.2%) than in the SURTAVI trial that employed the older generation CoreValve bioprosthesis in most TAVI procedures. The rate in the present study is lower than in the CoreValve Evolut R US Study (16.4%) and the CoreValve Evolut R FORWARD Study (19.7%), which included a broader all-comer population.[2, 13] The Evolut Pro US Clinical Study has the lowest reported permanent pacemaker implantation rate of 11.8%.[14] These improvements in new pacemaker implantation may be attributable to improvements in transcatheter heart valve (THV) systems, as well as technique improvements in THV deployment, such as degree of annular oversizing, depth of implantation, balloon dilation strategies, and THV recapturing. These data are consistent with a trend toward lower pacemaker rates following TAVI. Moreover, wide adoption of the recently reported novel implant technique for the Evolut bioprosthesis may furthermore drastically reduce rates of pacemaker use.[15]

There were lower AVGs and larger EOAs in the TAVI group, most likely related to the supra-annular design of the self-expanding Evolut R THV. The superior hemodynamics seen with Evolut R compared with SAVR are also reflected in the significantly lower rates of severe PPM at discharge, 6- and 12-months post procedure. An analysis of SURTAVI data using indexed annular sizing to predict PPM found the rate of PPM to be significantly lower after TAVI than SAVR across all indexed annular size groups, but clinical outcomes at 1 year were comparable.[16–20]

Limitations of this post-hoc analysis include surgical patients selected from the randomized trial and TAVI patients from the nonrandomized continued access study of SURTAVI, thus patients were not treated during the same time period. In the randomized SURTAVI trial, the criteria for intermediate surgical risk evolved over time, which may

have contributed to patient selection bias. However, only later enrolled SAVR patients were included so that patient selection criteria were consistent. Although patients were propensity-score-matched based on 22 baseline characteristics, it is possible that other confounding factors such as need for revascularization and concomitant procedures may have influenced the results. Recent observations of a downward trend in the estimation of 30-day risk based on STS score could have led to a bias in favor of SAVR.[21]

In conclusion, in this propensity-matched analysis of patients at intermediate risk of surgery, TAVI with the Evolut R transcatheter valve had improved outcomes compared with a similar group of patients who underwent SAVR, particularly driven by superior clinical outcomes at 30 days. TAVI patients had less all-cause mortality, disabling stroke, atrial fibrillation, and valve-related rehospitalization compared with SAVR. There were more new pacemaker implantations and a greater incidence of mild or more total AR in the TAVI group. Hemodynamic performance favored TAVI at all time-points in the analysis. Longer follow-up continues to further assess the comparative safety and effectiveness of TAVI and SAVR in this intermediate-risk population.

Author Contributions

Steven J. Yakubov: Conceptualization, investigation, writing - Original draft preparation, review & editing, supervision; **Nicolas M. Van Mieghem**: Investigation, writing - review & editing; **Michael J. Reardon**: Supervision, investigation, writing – review and editing; **Patrick W. Serruys**: Investigation, Writing - review & editing; **Hemal Gada**: Investigation, Writing - review & editing; **Mubashir Mumtaz**: Investigation, writing - review & editing; **G. Michael Deeb**: Investigation, writing - review & editing; **Susheel Kodali:** Investigation, writing - review & editing; **Isaac George:** Investigation, writing - review & editing; **Stephan Windecker:** Investigation, writing - review & editing; **Neal Kleiman**: Investigation, writing - review & editing; **Stanley J. Chetcuti**: Investigation, writing - review & editing; **Carlos Sanchez**: Investigation, writing - review & editing; **Harold L. Dauerman:** Investigation, writing - review & editing; **Shuzhen Li:** Formal analysis, data curation, writing - review & editing **Jeffrey J. Popma**: Supervision, investigation, writing- review & editing

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