

Outcomes and Hemodynamic Performances of Transcatheter Aortic Valve Replacement With Two Generations of Self-expanding Transcatheter Aortic Valves

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Abstract

The aim of this study was to investigate the hemodynamic and clinical performance of the Evolut R compared with its direct predecessor, CoreValve, in Taiwanese population. This study included all consecutive patients who underwent TAVR with either the CoreValve or Evolut R between March 2013 to December 2020. Thirty-day Valve Academic Research Consortium-2 (VARC-2)-defined outcomes and hemodynamic performances were investigated. There were no significant differences in baseline demographic characteristics between patients receiving CoreValve (n= 117) or Evolut R (n=117). Aortic valve-in-valve procedures for failed surgical bioprosthesis and procedures under conscious sedation were performed significantly more often with Evolut R. Pre-dilatation was performed significantly more often and contrast media volume was significantly higher with CoreValve. Stroke (0% vs 4.3%, $p = 0.024$) and the need for emergent conversion to open surgery (0% vs 5.1%, $P = 0.012$) were significantly lower in Evolut R than CoreValve recipients. Evolut R significantly reduce 30-day composite safety endpoint (4.3% vs 15.4%, $p = 0.004$). In conclusion, advancements in transcatheter valve technologies have resulted in improved outcomes for patients undergoing TAVR with self-expanding valves. With new-generation Evolut R, device success was high and significantly reduced 30-day composite safety endpoint after TAVR compared with CoreValve.

Introduction

Degenerative aortic stenosis (AS) is the most common valvular heart disease in adults, with a prevalence of approximately 4% in patients over 80 years of age. After the onset of symptoms (angina, syncope, or heart failure), the average survival time is 2 to 3 years, with a high risk of sudden death¹. In clinical practice, more than 30% of patients with severe symptomatic AS do not undergo surgical aortic valve replacement (SAVR) due to advanced age, left ventricular dysfunction, or the presence of multiple coexisting conditions^{2,3}. Based on recent randomized trials showing the non-inferiority of transcatheter aortic valve replacement (TAVR) compared to SAVR in high- and intermediate-risk patients, TAVR is now being increasingly used also in this lower risk population⁴⁻⁶. In Taiwan, the CoreValve transcatheter aortic bioprosthesis (Medtronic, Minneapolis, MN, USA) was the first commercially available valve approved in December 2012, and the second-generation self-expanding Evolut R valve (Medtronic) was available in March 2017⁷. To date, more than 1000 TAVR procedures using self-expanding Medtronic devices have been performed in Taiwan. The continuous device iterations, along with growing operator experience and refinement of procedural techniques, have played a major role in improving the safety and efficacy of TAVR procedures.

We performed a single-center study, comparing the Evolut R with its direct precursor, the CoreValve, with regard to 30-day Valve Academic Research Consortium-2 (VARC-2)-defined safety and efficacy outcomes.

Methods

Patient population. Between March 2013 and December 2020, 237 consecutive patients treated with self-expanding TAVR were enrolled. Three patients were excluded because TAVR was performed for isolated aortic regurgitation. Remaining 234 patients with severe aortic stenosis were included in the analysis, of 117 patients with the CoreValve and 117 with the Evolut R (Figure 1). Patients were selected for TAVR when considered unsuitable or at high risk for SAVR by heart team discussion. Operative risk was calculated using the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) score. Patient selection for TAVR was based on the approved indications for TAVR⁸.

Ethical approval statement. This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Institutional Review Board of Taipei Veterans General Hospital (approval number: 2020-11-002BC). Informed consent was obtained from all individual participants included in the study.

Procedural details. All patients underwent TAVR with CoreValve or Evolut R prostheses as described^{8,9}. All procedures were performed in a specially equipped hybrid operating suite. At the beginning of our experience, TAVR procedures were performed under general anesthesia. Since December 2013, local anesthesia with conscious sedation had been exclusively used for transfemoral TAVR. The standard approach for both valves was through the transfemoral route, if feasible. In patients who did not have adequate anatomy to allow safe transfemoral access, alternative access routes such as trans-subclavian, direct aortic trans-abdominal aortic, or transcarotid access were used⁹. Adjunct pharmacologic therapy included heparin during the procedure and aspirin (100 mg/day) indefinitely and clopidogrel (75 mg/day) for 3-6 months following the procedure. Valve size was selected according to ranges of perimeter-derived annulus diameters based on CT recommended by the manufacturer.

Echocardiographic assessment. Standardized transthoracic echocardiography was performed before and after TAVR by board-certified cardiologists. The calculation of effective orifice area (EOA) required calculation of LV stroke volume using the outer-to-outer diameter of the stented valve paired with the pulsed wave Doppler placed just apical to the stented valve recommended by Hahn et al¹⁰.

Study endpoints. All clinical endpoints of this study were defined according to the VARC-2 criteria¹¹. "Device success" was defined as the absence of procedural mortality (≤ 72 h postprocedure) and correct positioning of a single prosthetic heart valve into the proper anatomical location and intended performance of the prosthetic heart valve [no prosthesis-patient mismatch and mean aortic valve gradient < 20 mmHg or peak velocity < 3 m/s, and no moderate or severe prosthetic valve regurgitation (PVL)]. Following valve deployment, assessment of valve function was performed using transthoracic echocardiography. VARC-2 proposed using the AKIN system for the reporting of acute kidney injury (AKI). AKI was defined as an absolute (< 48 hours) reduction in kidney function and defined as: stage 2 – increase in serum creatinine to 200- 299% (2.0-2.9 x increase compared with baseline) or urine output < 0.5 ml/kg/h for > 12 h but < 24 h and stage 3 – increase in serum creatinine to $> 300\%$ (> 3 x increase compared with baseline) or serum creatinine of > 4.0 mg/dL with an acute increase of at least 0.5 mg/dL

or the new need for renal replacement therapy post TAVR. The 30-day-combined safety endpoint is a combined endpoint defined by VARC-2 as a composite of all-cause mortality, major stroke, life-threatening or disabling bleeding, acute stage 2 or 3 kidney injury including renal replacement therapy, major vascular complications, coronary artery obstruction requiring intervention, and repeat procedure for valve-related dysfunction.

Statistical analysis. Continuous variables were expressed as mean \pm standard deviation (SD), and analyzed with the Student's t test or the Wilcoxon rank sum test, depending on the variable distribution. Categorical variables were compared using the chi-square test with Yates' correction for continuity or the Fisher's exact test. For all comparisons, p value < 0.05 was considered statistically significant. The data were analyzed using SPSS software, version 24.0 (IBM, Armonk, NY, USA).

Results

Baseline characteristics. The demographic and echocardiographic characteristics are displayed in Table 1. The mean age of the population was 80.8 ± 8.8 years and the mean logistic EuroSCORE was 18.3%. Fifty-five percent of the study population were female. Twenty-seven (11.5%) had a bicuspid aortic valve and 9 (3.8%) underwent aortic valve-in-valve procedures for failed surgical bioprosthesis. Baseline demographic characteristics did not differ between groups except that valve-in-valve procedures for failed surgical bioprosthesis (0.9% vs. 6.8%, $p = 0.018$) was performed significantly more often with Evolut R. At baseline, echocardiographic assessment of valve function showed an aortic valve area was 0.71 ± 0.21 cm². The mean transvalvular pressure gradient was decreased (47.2 ± 19.4 vs. 36.8 ± 15.5 mmHg, $p < 0.001$) and left ventricular ejection fraction was increased ($53.7 \pm 11.0\%$ vs. $56.6 \pm 9.9\%$, $p = 0.027$) in Evolut R group.

Table 1
Baseline characteristics and echocardiographic assessment.

	All patients (n = 234)	CoreValve (n = 117)	Evolut R (n = 117)	P value
Age, years	80.8 ± 8.8	80.6 ± 8.6	80.9 ± 9.2	0.791
Female	129 (55.1)	62 (53.0)	67 (57.3)	0.513
BMI, kg/m ²	24.5 ± 4.1	24.5 ± 4.3	24.5 ± 4.0	0.929
BSA, m ²	1.62 ± 0.20	1.63 ± 0.20	1.61 ± 0.19	0.417
LogEuroSCORE (%)	18.3 ± 15.1	18.5 ± 15.0	18.2 ± 15.2	0.884
Hypertension	178 (76.1)	85 (72.6)	93 (79.5)	0.222
Diabetes	80 (34.2)	45 (38.5)	35 (29.9)	0.101
Coronary artery disease	104 (44.4)	49 (41.9)	55 (47.0)	0.432
Prior PCI	83 (35.5)	37 (31.6)	46 (39.3)	0.221
Prior CABG	11 (4.7)	6 (5.1)	5 (4.3)	0.759
Prior MI	13 (5.6)	7 (6.0)	6 (5.1)	0.776
Cerebrovascular disease	47 (20.1)	20 (17.1)	27 (23.1)	0.269
Peripheral artery disease	59 (25.2)	25 (21.4)	34 (29.1)	0.233
COPD	33 (14.1)	17 (14.5)	16 (13.7)	0.852
Prior pacemaker	8 (3.4)	3 (2.6)	5 (4.3)	0.474
Atrial fibrillation	55 (23.5)	31 (26.5)	24 (20.5)	0.508
eGFR, ml/min	42.1 ± 21.9	41.5 ± 22.3	43.0 ± 21.4	0.612
Dialysis	21 (9.0)	12 (10.3)	9 (7.6)	0.495
Bicuspid aortic valve	27 (11.5)	13 (11.1)	14 (12.0)	0.857
Valve-in-valve procedure	9 (3.8)	1 (0.9)	8 (6.8)	0.018
Echocardiographic assessment				
AVA, cm ²	0.71 ± 0.21	0.69 ± 0.23	0.73 ± 0.19	0.137

Values are mean ± SD or n (%). AR, aortic regurgitation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass surgery; COPD, chronic obstruction pulmonary disease; eGFR, estimated glomerular filtration rate; EuroSCORE, European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; PG, pressure gradient.

	All patients (n = 234)	CoreValve (n = 117)	Evolut R (n = 117)	P value
Mean PG, mm Hg	42.1 ± 18.2	47.2 ± 19.4	36.8 ± 15.5	<0.001
LVEF, %	55.3 ± 10.5	53.7 ± 11.0	56.6 ± 9.9	0.041
Moderate to severe AR	39 (16.7)	22 (18.8)	17 (14.5)	0.165
Moderate to severe MR	39 (16.7)	21 (17.9)	18 (15.4)	0.343
PAP, mm Hg	42.4 ± 16.4	44.5 ± 16.5	39.9 ± 15.8	0.028
Computed tomography data				
Perimeter-derived annulus diameter, mm	23.2 ± 2.6	24.0 ± 2.7	22.3 ± 2.3	<0.001
Values are mean ± SD or n (%). AR, aortic regurgitation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass surgery; COPD, chronic obstruction pulmonary disease; eGFR, estimated glomerular filtration rate; EuroSCORE, European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention; PG, pressure gradient.				

Procedural characteristics. Procedural characteristics are presented in Table 2. Conscious sedation was used more often in the Evolut R group (69.2% vs. 89.7%, $p < 0.001$), whereas non-transfemoral access was performed numerically less frequent in the Evolut R group (7.8% vs. 2.6%, $p = 0.076$). Pre-dilatation was performed more often in the CoreValve group (78.6% vs. 51.3%, $p < 0.001$), whereas post-dilatation was comparable between 2 groups (4.3% vs. 3.4%, $p = 0.725$). The mean perimeter-derived diameter of aortic annulus was smaller in Evolut R group (24.0 ± 2.7 vs. 22.3 ± 2.2 mm, $p < 0.001$), thus resulting in the use of a smaller prosthesis size in Evolut R group. Twenty-three-millimeter valves were more frequently used in the Evolut R group (1.7% vs. 14.5%, $p < 0.001$), whereas 31- or 34-mm prosthesis was more frequent in the CoreValve group (16.2% vs. 4.3%, $p < 0.001$). The mean contrast media volumes were significantly lower (123.6 ± 55.1 vs. 72.2 ± 32.5 ml, $p < 0.001$) in the Evolut R recipients.

Table 2
Procedural characteristics.

	All patients (n = 234)	CoreValve (n = 117)	Evolut R (n = 117)	P value
Valve size				<0.001
23 mm	19 (8.1)	2 (1.7)	17 (14.5)	
26 mm	98 (41.9)	41 (35.0)	57 (48.7)	
29 mm	93 (39.7)	55 (47.0)	38 (32.5)	
31 or 34 mm	24 (10.3)	19 (16.2)	5 (4.3)	
Conscious sedation	186 (79.5)	81 (69.2)	105 (89.7)	<0.001
Access				0.240
Transfemoral	222 (94.9)	108 (92.2)	114 (97.4)	
Trans-subclavian	3 (1.3)	3 (2.6)	0 (0.0)	
Trans-aortic	3 (1.3)	2 (1.7)	1 (0.9)	
Trans-carotid	5 (2.1)	3 (2.6)	2 (1.8)	
Trans-abdominal aortic	1 (0.4)	1 (0.9)	0 (0.0)	
Oversizing by perimeter, %	18.9 ± 7.9	17.8 ± 8.4	19.9 ± 7.2	0.044
Balloon pre-dilation	153 (65.4)	92 (78.6)	60 (51.3)	<0.001
Balloon post-dilation	9 (3.9)	5 (4.3)	4 (3.4)	0.725
Contrast volume, ml	97.8 ± 51.8	123.6 ± 55.1	72.2 ± 32.5	<0.001
Values are mean ± SD or n (%).				

VARC-2 outcome at 30 days. Thirty-day outcome according to VARC-2 criteria are presented in Table 3. At 30-day follow-up, all-cause mortality was overall low (8/234, 3.4%) and was numerically lower amongst patients treated with Evolut R (5.1% vs. 1.7%, p = 0.134). Stroke (4.3% vs. 0%, p = 0.024) and the need for emergent conversion to open surgery (5.1% vs. 0%, p = 0.012) were significantly lower in Evolut R than CoreValve recipients. There was a numerically lower frequency of major vascular complications (5.1% vs. 0.9%, p = 0.055), and acute kidney injury, stage 2 or 3 (8.6% vs. 3.7%, p = 0.159) amongst Evolut R recipients. The need for a second valve was numerically reduced with the recapturable Evolut R system (2.6% vs. 0.9%, p = 0.147). The rate of new pacemaker implantation was low (3.5% vs. 1.8%, p = 0.410) and comparable between groups. None developed valve-related dysfunction requiring repeat procedure, such as balloon aortic valvuloplasty, TAVR, or SAVR. Device success was achieved in 93.2% of CoreValve

recipients and 97.4% amongst patients treated with Evolut R ($p = 0.123$). Composite safety endpoint occurred in 15.4% of CoreValve patients and 4.3% of Evolut R patients ($p = 0.004$) (Figure 2).

Table 3

Thirty-day outcomes according to Valve Academic Research Consortium-2 (VARC-2) criteria and hemodynamic performance.

Variables	All patients (n = 234)	CoreValve (n = 117)	Evolut R (n = 117)	P value
VARC-2 defined outcomes at 30 days				
All-cause death	8 (3.4)	6 (5.1)	2 (1.7)	0.134
Cardiovascular mortality	5 (2.1)	3 (2.6)	2 (1.7)	0.618
Stroke	5 (2.1)	5 (4.3)	0 (0.0)	0.024
Major vascular complication	7 (3.0)	6 (5.1)	1 (0.9)	0.055
Conversion to open surgery	6 (2.6)	6 (5.1)	0	0.012
Need for a second valve	4 (1.7)	3 (2.6)	1 (0.9)	0.273
Acute kidney injury, stage 2 or 3 ^a	13 (6.1)	9 (8.6)	4 (3.7)	0.147
Coronary obstruction	3 (1.3)	2 (1.7)	1 (0.9)	0.311
New pacemaker implantation ^b	6 (2.7)	4 (3.5)	2 (1.8)	0.410
Valve-related dysfunction requiring repeat procedure (BAV, TAVR, or SAVR)	0	0	0	NA
Device success	223 (95.3)	109 (93.2)	114 (97.4)	0.123
Composite safety endpoint	23 (9.8)	18 (15.4)	5 (4.3)	0.004
Echocardiographic assessment				
Effective orifice area	1.72 ± 0.38	1.70 ± 0.38	1.74 ± 0.37	0.467
Mean PG, mm Hg	7.7 ± 3.9	8.2 ± 3.9	7.1 ± 3.8	0.032

Values are mean ± SD or n (%). BAV, Balloon aortic valvuloplasty; PG, pressure gradient; PVL, paravalvular leak; TAVR, transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

^a excluding patients on dialysis.

^b excluding patients with prior permanent pacemakers.

Variables	All patients (n = 234)	CoreValve (n = 117)	Evolut R (n = 117)	P value
Peak PG, mm Hg	14.5 ± 7.4	15.6 ± 7.4	12.9 ± 7.0	0.016
Post-procedural PVL				
Moderate	7 (3.0)	5 (4.3)	2 (1.7)	0.201
Severe	0	0	0	
Values are mean ± SD or n (%). BAV, Balloon aortic valvuloplasty; PG, pressure gradient, PVL, paravalvular leak; TAVR, transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.				
^a excluding patients on dialysis.				
^b excluding patients with prior permanent pacemakers.				

Hemodynamic performance. Figure 3 shows the baseline and 30-day EOA and mean pressure gradient for CoreValve and Evolut R. There were no significant differences in EOA between both groups (1.70 ± 0.38 vs. 1.74 ± 0.37 cm², $p = 0.467$). Post-procedural mean pressure gradient (8.2 ± 3.9 vs. 7.1 ± 3.8 mmHg, $p = 0.032$) and peak pressure gradient (15.6 ± 7.4 vs. 12.9 ± 7.0 mmHg, $p = 0.016$) at 30 days were significantly lower in Evolut R than CoreValve (Table 3). Moderate PVL was observed in 4.3% in the CoreValve group and 1.7% in the Evolut R recipients and none of both groups developed severe PVL.

Discussion

During the past several years, technological advancement of Evolut R was built on the well-established foundation of the CoreValve platform, fortified with lower delivery profile (14-16 French) to reduce vascular complications and alternative TAVR access necessity, enhanced Nitinol frame geometry to enable better housing inside the aortic root, and a complete recapturable platform that allows optimized implantation depth upon deployment. Our results support short-term efficacy and safety performance of the Evolut-R compare with the CoreValve. Evolut R significantly reduce 30-day composite safety endpoint, driven by numerically lower deaths, major stroke, life-threatening or disabling bleeding, and acute stage 2 or 3 kidney injury including renal replacement therapy.

The InLine sheath used in the Evolut R system has a lower profile (14-16 French) than CoreValve (18 French), which lowered the need for alternative TAVR access, which has historically been associated with inferior outcomes in patients undergoing TAVR, from 7.7–2.6%. Pre-dilatation was observed significantly more often in the CoreValve group, which may be responsible for longer procedure duration and increased

contrast agent administration. The higher volume of contrast use is one of the underlying mechanisms leading to acute kidney injury which remains one of the strongest predictors of short- and long-term mortality after TAVR.

Valve malposition may still occur even after all necessary precautions have been taken, while prosthesis migration and embolization were associated with a four-fold higher mortality and three-fold higher stroke rate at 30 days¹². Compared to CoreValve, a key feature of the Evolut-R is the option to fully recapture and to reposition the valve during deployment. There were 3 cases (2.6%) in the CoreValve treated patient requiring the implantation of a second valve, and one (0.9%) in the Evolut R group. In addition, the option to recapture allowed a less ventricular implantation depth, resulting in a numerically lower incidence of new pacemaker implantation and moderate PVL in the Evolut R recipients.

Left ventricular perforation is the most serious complications of TAVR, usually occurs as a direct trauma by the Amplatz Super Stiff guidewire, which was used exclusively for the deployment of CoreValve. Amplatz Super Stiff guidewire are not designed for TAVR procedures and the operators must bend the wire to achieve the optimal shape to sit safely in the ventricle for TAVR, during which procedure the central core can be damaged or the desired shape may not be achieved, A pooled analysis of causes of perioperative mortality after TAVR (12 studies examining 1223 patients) showed that 10.1% of deaths at one month were due to pericardial tamponade while 39% of “in-lab” mortality was due to cardiac perforation causing pericardial tamponade¹³. Notably, the adoption of a dedicated pre-shaped Confida Brecker guidewire, features a continuous, tapered core and pre-shaped curve, in the Evolut R recipients reduce the risk of left ventricular perforation, which necessitated emergent cardiac surgery, from 5.1% in the CoreValve group to none in the Evolut R recipients.

The primary goal of TAVR is to achieve the maximum orifice area with a minimum flow velocity. Given severe prosthesis-patient mismatch (PPM) was associated with increased risk of 1-year mortality (hazard ratio: 1.19) and heart failure re-hospitalization (hazard ratio: 1.12) following TAVR in 62,125 patients enrolled in the STS/ACC TVT Registry¹⁴, there has been a concern regarding PPM in Asian patients with small aortic annulus. Studies in east Asian populations demonstrated Sapien 3 valve had smaller EOA (2.07 ± 0.61 vs. 1.70 ± 0.49 cm², $p < 0.001$)¹⁵ and caused PPM about 1.92 times¹⁶ more than Sapien XT valve. Thus, TAVR with supra-annular self-expanding was associated with superior hemodynamic outcomes compared with balloon-expandable valves in patients with small aortic annulus. These findings pave the way for further trials regarding appropriate prosthesis selection for TAVR in patients with in East Asian population with small aortic annulus.

Limitations

Our study was only a single-center investigation and was limited by its retrospective and observational design. In addition, the results of CoreValve could have been affected by the learning curve of TAVR in the early stages, thus the benefit of Evolut R might have been overstated to some extent.

Conclusions

Advancements in valve technologies with the option to recapture and reposition of Evolut R, the introduction of InLine sheath with a lower profile, and dedicated pre-shaped guidewires have resulted in improved outcomes for patients undergoing TAVR with supra-annular self-expanding valves. Compared to CoreValve, Evolut R significantly reduce 30-day composite safety endpoint, driven by significantly lower stroke and life-threatening or disabling bleeding, as well as numerically lower deaths and acute stage 2 or 3 kidney injury including renal replacement therapy.

Declarations

Data availability

Patient data is unavailable due to protection reasons

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Author contributions

CC Kuo, and YH Chen designed the study and wrote the manuscript. IM Chen and SM Lin involved in the data curation. CC Kuo, HB Leu and PL Chen performed statistical analysis and interpretation of data. HH Chang and YH Chen conducted the literature review and supervised the study. All authors discussed the results, reviewed the manuscript and approved the final version.

Competing Interests Statement

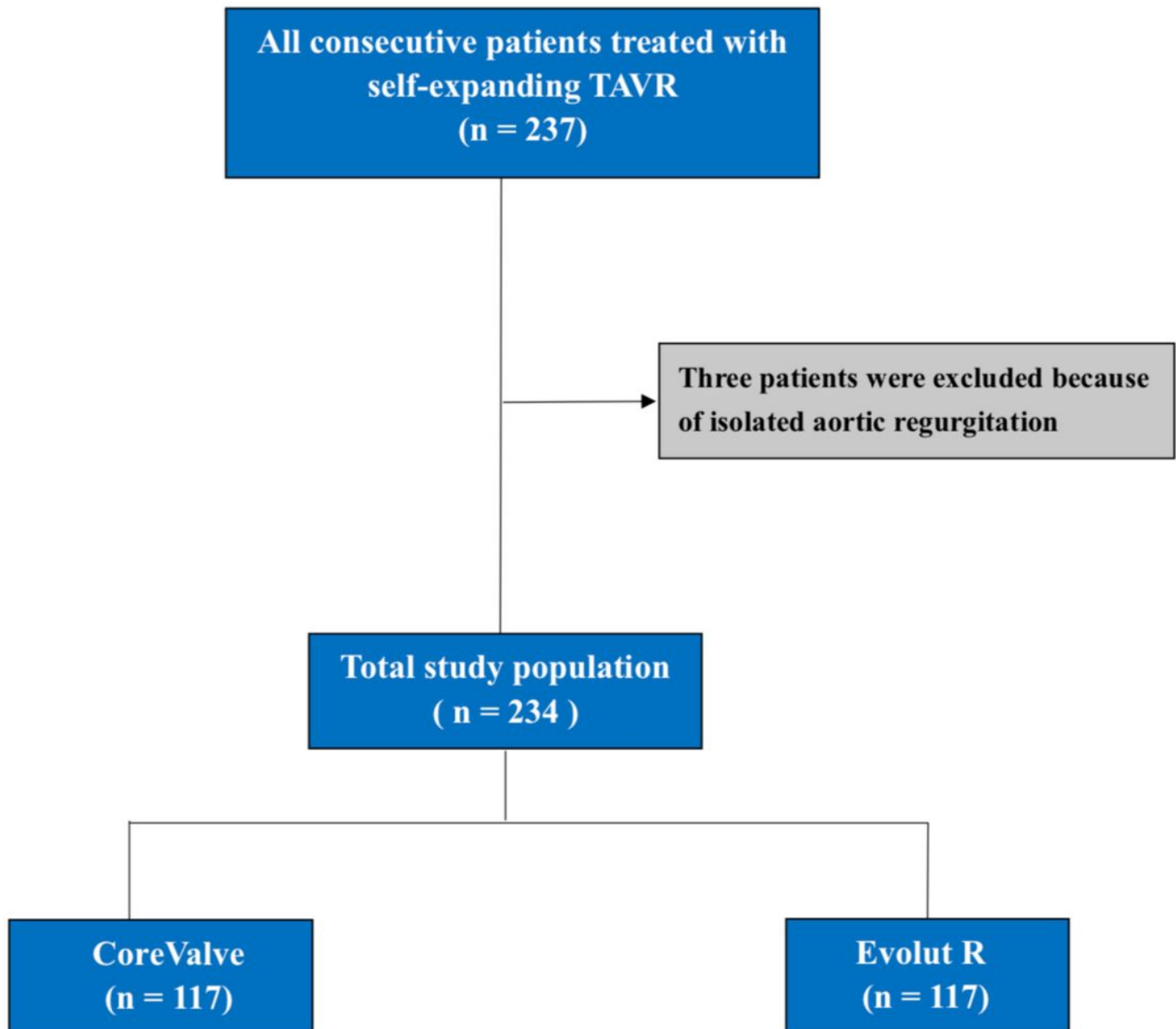
Dr. Ying-Hwa Chen and Dr. Hsiao-Huang Chang are proctors for the Medtronic CoreValve and Evolut R. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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Figures



TAVR = transcatheter aortic valve replacement.

Figure 1

Study population. Total 234 patients underwent transcatheter aortic valve replacement for severe aortic stenosis, of 117 patients with CoreValve and 117 with Evolut R.

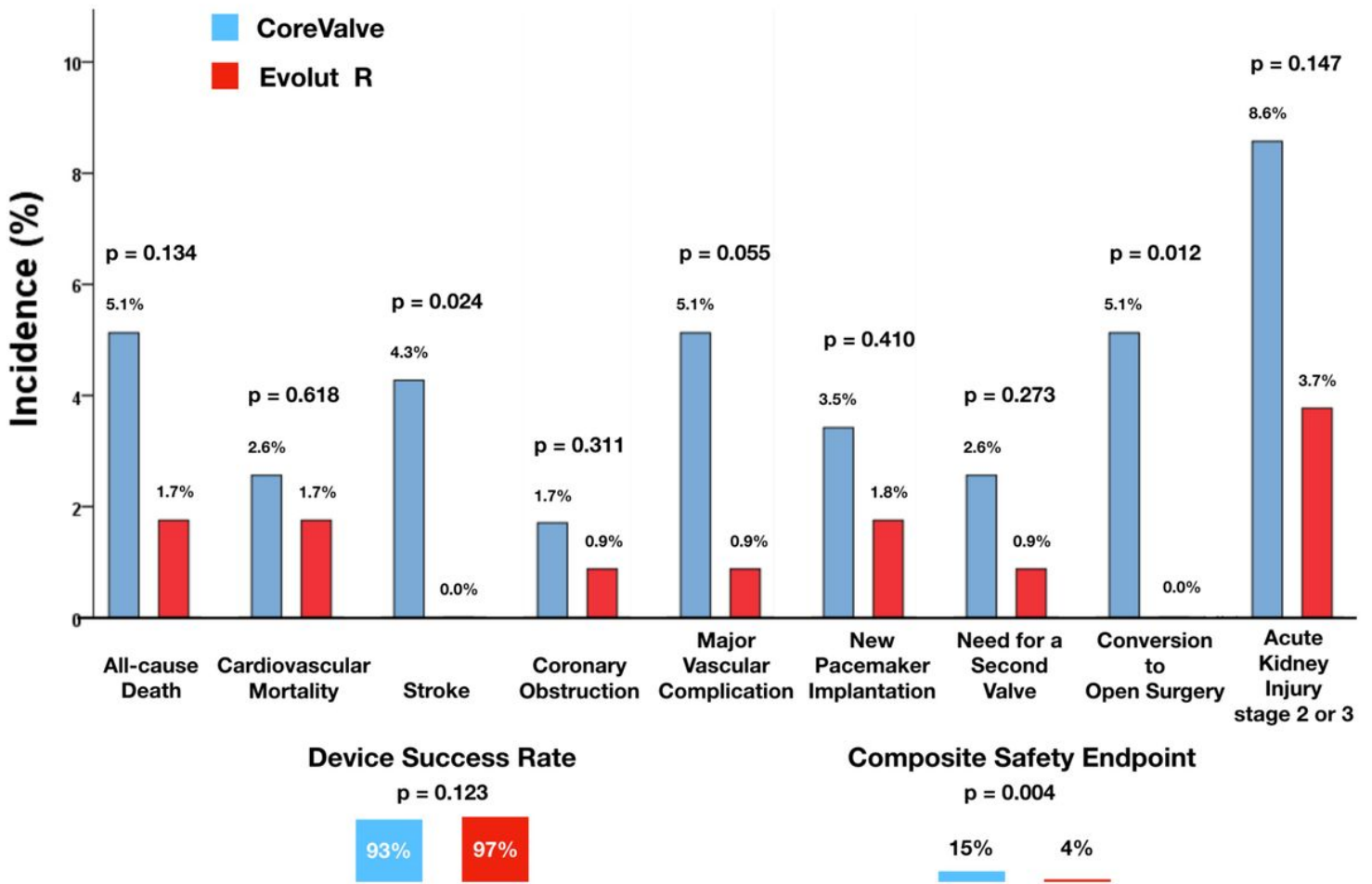


Figure 2

VARC-2 outcome at 30 days. Thirty-day outcome according to Valve Academic Research Consortium-2 Criteria between CoreValve and Evolut R system.

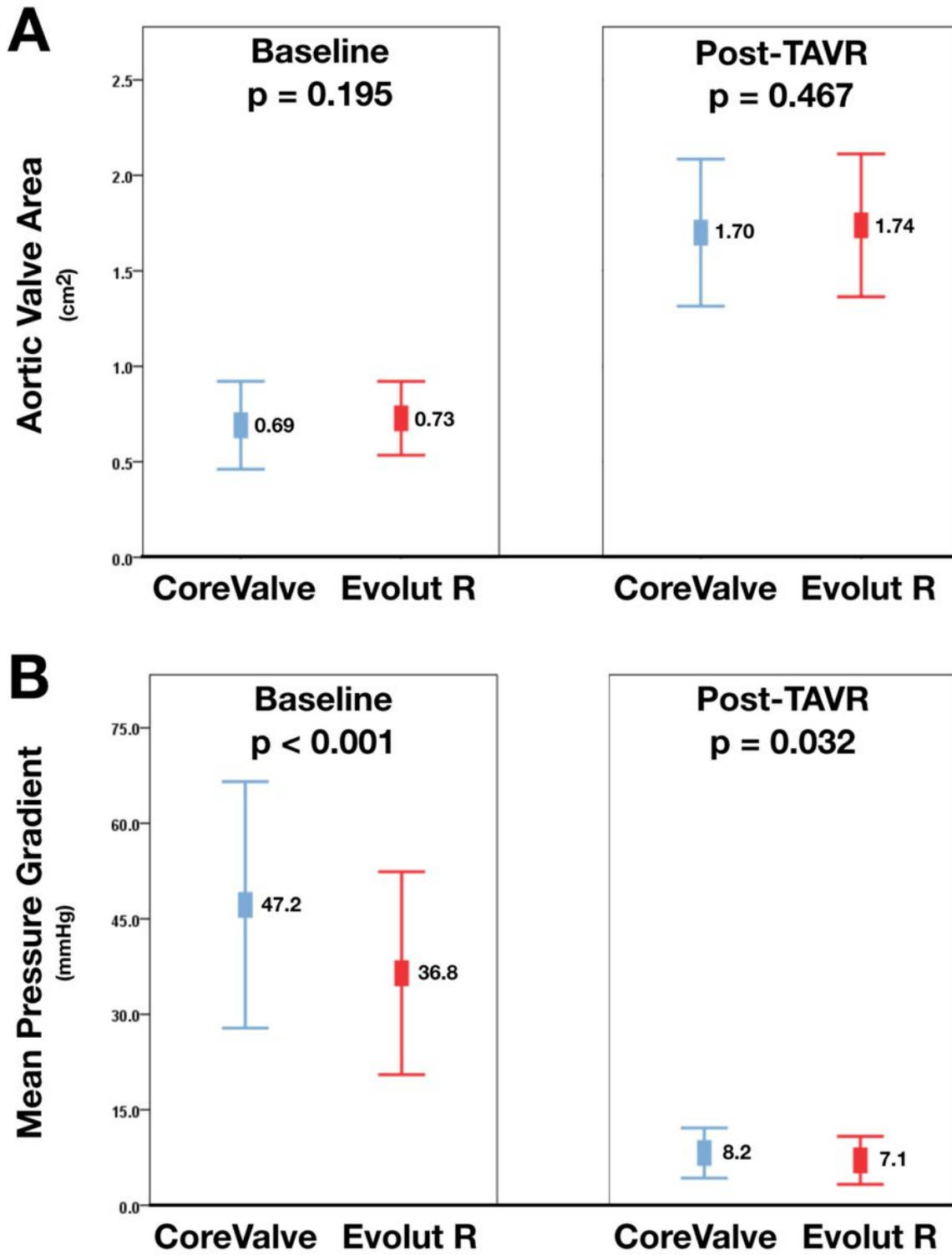


Figure 3

Hemodynamic performance. Baseline and Post-transcatheter aortic valve replacement hemodynamic performance between CoreValve and Evolut R. (A) aortic valve area. (B) mean pressure gradient