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*Valvular Disease*

# Outcomes and Hemodynamic Performances of Transcatheter Aortic Valve Replacement with Two Generations of Self-Expanding Transcatheter Aortic Valves

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***Background:*** The superiority of the new-generation self-expanding Evolut R compared with the first-generation CoreValve with regards to outcomes after transcatheter aortic valve replacement (TAVR) is unclear. The aim of this study was to investigate the hemodynamic and clinical performance of Evolut R compared with its direct predecessor, CoreValve, in a Taiwanese population.

***Methods:*** This study included all consecutive patients who underwent TAVR with either CoreValve or Evolut R between March 2013 and December 2020. Thirty-day Valve Academic Research Consortium-2 (VARC-2)-defined outcomes and hemodynamic performances were investigated.

***Results:*** There were no significant differences in baseline demographic characteristics between the 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 in CoreValve recipients. Evolut R significantly reduced 30-day composite safety endpoint (4.3% vs. 15.4%, p = 0.004).

***Conclusions:*** Advancements in transcatheter valve technologies have resulted in improved outcomes for patients undergoing TAVR with self-expanding valves. With the new-generation Evolut R, device success was high and the 30-day composite safety endpoint was significantly reduced after TAVR compared with CoreValve.

**Key Words:** Aortic stenosis • Self-expanding valve • Transcatheter aortic valve replacement

**Abbreviations**

| | |
|---|---|
| AKI | Acute kidney injury |
| AS | Aortic stenosis |
| EOA | Effective orifice area |
| EuroSCORE | European System for Cardiac Operative Risk Evaluation |
| PPM | Prosthesis-patient mismatch |
| PVL | Paravalvular leakage |
| SAVR | Surgical aortic valve replacement |
| SD | Standard deviation |
| TAVR | Transcatheter aortic valve replacement |
| VARC-2 | Valve Academic Research Consortium-2 |

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## 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 death.[1] 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 increasingly being used in this lower risk population.[4-6] In Taiwan, the CoreValve transcatheter aortic bioprosthesis (Medtronic, Minneapolis, MN, USA) was the first commercially available valve approved in December 2012. The second-generation self-expanding Evolut R valve (Medtronic) became available in Taiwan in March 2017.[7] To date, more than 1000 TAVR procedures using self-expanding Medtronic devices have been performed in Taiwan. 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.

In this single-center study, we compared Evolut R with its direct precursor, CoreValve, with regards 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. The remaining 234 patients with severe aortic stenosis were included in the analysis, of whom 117 received CoreValve and 117 Evolut R (Figure 1). Patients were selected for TAVR when considered unsuitable or at high risk for SAVR after discussion with the heart team. Operative risk was assessed using the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) score. Patient selection for TAVR was based on the approved indications for TAVR.[8]

### Ethical approval statement

This retrospective chart review study involving human participants was conducted 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 previously 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 has 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 ac-

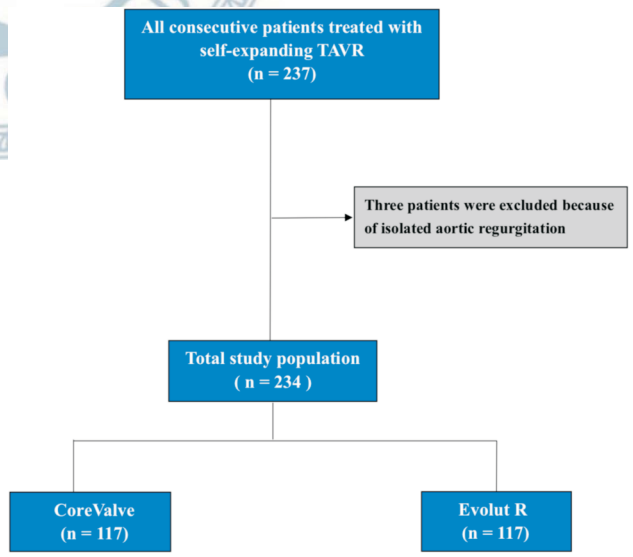


***Figure 1.*** *Study population. Total 234 patients underwent transcatheter aortic valve replacement (TAVR) for severe aortic stenosis, of 117 patients with CoreValve and 117 with Evolut R.*

cess, alternative access routes such as trans-subclavian, direct aortic trans-abdominal aortic, or trans-carotid access were used.[9] Adjunct pharmacologic therapy included heparin during the procedure, 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 computed tomography as recommended by the manufacturer.

### Echocardiographic assessment

Standardized transthoracic echocardiography was performed before and after TAVR by board-certified cardiologists. Calculation of the effective orifice area (EOA) required calculation of left ventricular stroke volume using the outer-to-outer diameter of the stented valve paired with pulsed wave Doppler placed just apical to the stented valve as recommended by Hahn et al.[10]

### Study endpoints

All clinical endpoints of this study were defined according to the VARC-2 criteria.[11] "Device success" was defined as the absence of procedural mortality (≤ 72 h post-procedure) 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 paravalvular leakage (PVL)]. Following valve deployment, assessment of valve function was performed using transthoracic echocardiography. The VARC-2 criteria suggest using the AKIN system for the reporting of acute kidney injury (AKI). AKI was defined as an absolute (< 48 h) reduction in kidney function, 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 was 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 ± standard deviation (SD), and analyzed with the Student's t test or Wilcoxon rank sum test, depending on variable distribution. Categorical variables were compared using the chi-square test with Yates' correction for continuity or Fisher's exact test. For all comparisons, a p value < 0.05 was considered statistically significant. All data were analyzed using SPSS version 24.0 (IBM, Armonk, NY, USA).

## RESULTS

### Baseline characteristics

The demographic and echocardiographic characteristics are shown in Table 1. The mean age of the patients 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 significantly differ between groups except that valve-in-valve procedures for failed surgical bioprosthesis (0.9% vs. 6.8%, p = 0.018) were performed significantly more often with Evolut R. At baseline, echocardiographic assessment of valve function showed an aortic valve area of 0.71 ± 0.21 $cm^2$. 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 ± 11.0% vs. 56.6 ± 9.9%, p = 0.027) in the Evolut R group.

### Procedural characteristics

The 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), and non-transfemoral access was performed numerically less frequently 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 the two groups (4.3% vs. 3.4%, p = 0.725). The mean perimeter-derived diameter of the aortic annulus was smaller in the Evolut R

**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 |
| Mean PG, mmHg | 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, mmHg | 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; SD, standard deviation.

**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 |
| Balloonpost-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 (%). SD, standard deviation.

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 the 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 prostheses were more frequently used in the CoreValve group (16.2% vs. 4.3%, p < 0.001). The mean contrast media volume was significantly lower (123.6 ± 55.1 vs. 72.2 ± 32.5 ml, p < 0.001) in the Evolut R recipients.

### VARC-2 outcome at 30 days

Thirty-day outcomes according to the VARC-2 criteria are presented in Table 3. At 30 days of follow-up, the overall all-cause mortality rate was low (8/234, 3.4%), and it was numerically lower among the 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 the Evolut R group than in the CoreValve group. There were numerically lower frequencies of major vascular complications (5.1% vs. 0.9%, p = 0.055) and stage 2 or 3 AKI (8.6% vs. 3.7%, p = 0.159) in the 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 of the patients developed valve-related dysfunction requiring repeat procedure, such as balloon aortic valvuloplasty, TAVR, or SAVR. Device success was achieved in 93.2% of the CoreValve recipients and 97.4% of the Evolut R recipients (p = 0.123). The composite safety endpoint occurred in 15.4% of the CoreValve patients and 4.3% of the Evolut R patients (p = 0.004) (Figure 2).

### Hemodynamic performance

Figure 3 shows the baseline and 30-day EOA and mean pressure gradient for CoreValve and Evolut R. There was no significant difference in EOA between the two groups (1.70 ± 0.38 vs. 1.74 ± 0.37 $cm^2$, p = 0.467).

**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* | 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# | 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, mmHg | 7.7 ± 3.9 | 8.2 ± 3.9 | 7.1 ± 3.8 | 0.032 |
| Peak PG, mmHg | 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; SAVR, surgical aortic valve replacement; SD, standard deviation; TAVR, transcatheter aortic valve replacement.

* Excluding patients on dialysis. # Excluding patients with prior permanent pacemakers.

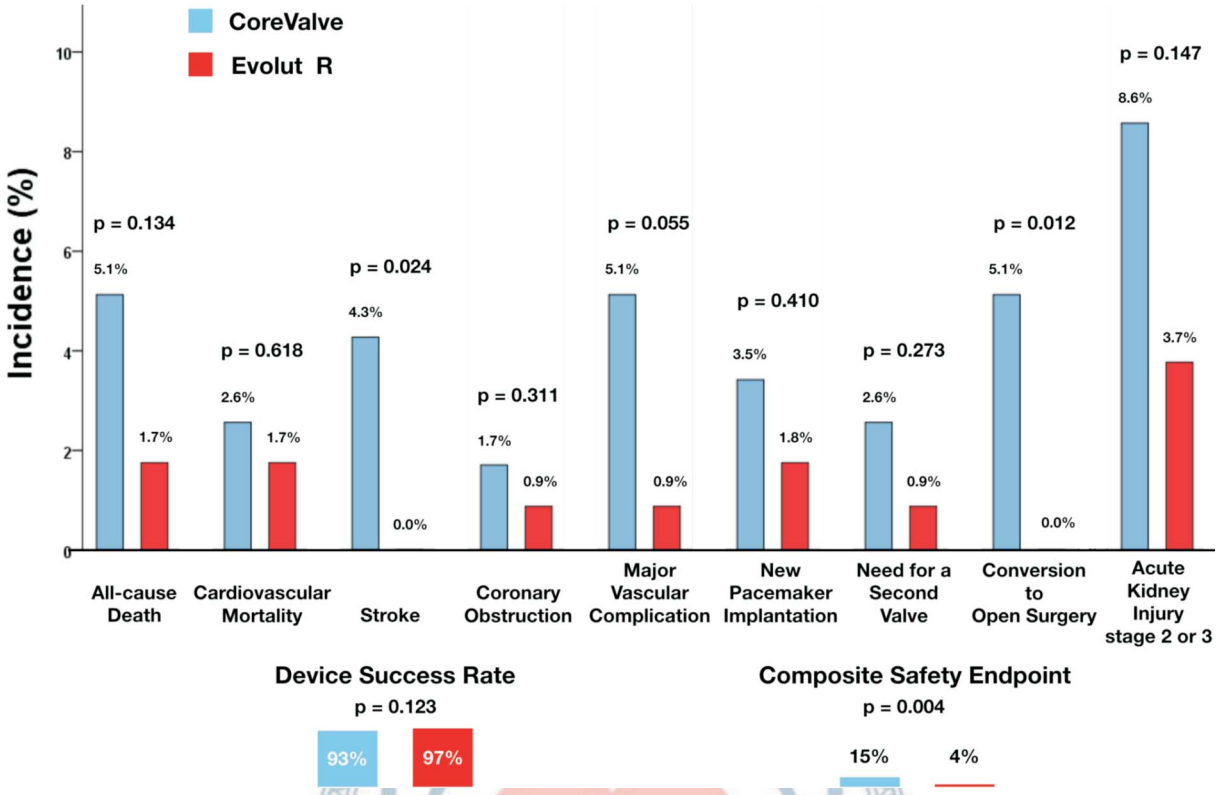


***Figure 2.*** *VARC-2 outcome at 30 days. Thirty-day outcome according to Valve Academic Research Consortium-2 criteria between CoreValve and Evolut R system.*

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 the Evolut R group than in the CoreValve group (Table 3). Moderate PVL was observed in 4.3% of the CoreValve recipients and 1.7% of the Evolut R recipients, however none of the patients in either group developed severe PVL.

## DISCUSSION

The Evolut R valve was built on the well-established foundation of the CoreValve platform. Advances in technology have allowed for a lower delivery profile (14-16 French) to reduce vascular complications and the need for alternative TAVR access, enhanced nitinol frame geometry to enable better housing inside the aortic root, and a completely recapturable platform that allows for an optimized implantation depth upon deployment. Our results support the better short-term efficacy and safety performance of Evolut R compared with CoreValve. Evolut R significantly reduced the 30-day composite safety endpoint, driven by numerically lower mortality, major stroke, life-threatening or disabling bleeding, and stage 2 or 3 AKI including renal replacement therapy.

The InLine sheath used in the Evolut R system has a lower profile (14-16 French) than that used in the CoreValve system (18 French), which reduced the need for alternative TAVR access, which has historically been associated with inferior outcomes in patients undergoing TAVR, from 7.7% to 2.6%. Pre-dilatation was observed significantly more often in the CoreValve group, which may be responsible for the longer procedure duration and increased contrast agent administration. The higher volume of contrast use is one of the underlying mechanisms leading to AKI, 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 have been associated with a

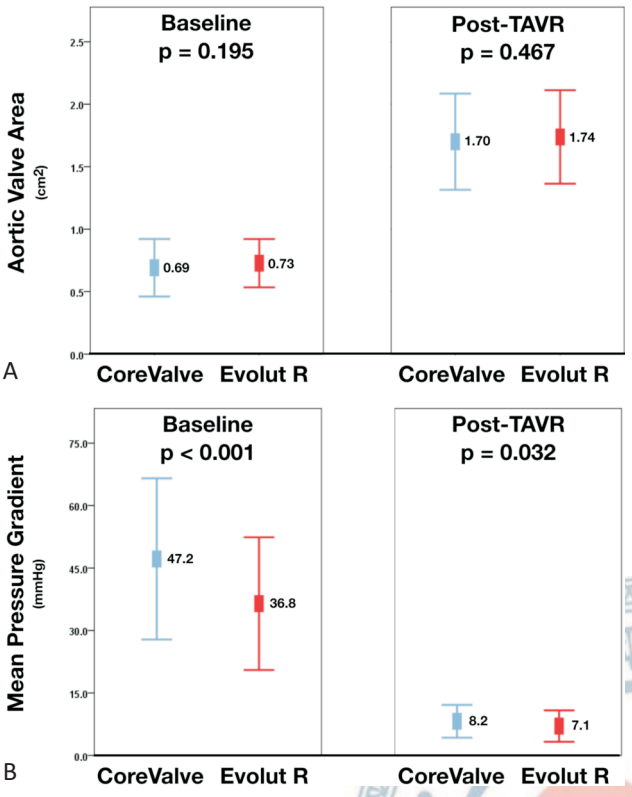


***Figure 3.*** *Hemodynamic performance. Baseline and post-transcatheter aortic valve replacement hemodynamic performance between CoreValve and Evolut R. (A) Aortic valve area. (B) Mean pressure gradient. TAVR, transcatheter aortic valve replacement.*

four-fold higher mortality rate and three-fold higher stroke rate at 30 days.[12] Compared to CoreValve, a key feature of Evolut R is the option to fully recapture and to reposition the valve during deployment. Three (2.6%) of the CoreValve-treated patients required the implantation of a second valve, compared to one (0.9%) in the Evolut R group. In addition, the option to recapture allowed for 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, and it usually occurs due to direct trauma by the Amplatz Super Stiff guidewire, which is used exclusively in the deployment of CoreValve. Amplatz Super Stiff guidewire is 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 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 1 month were due to pericardial tamponade, while 39% of "in-lab" deaths were due to cardiac perforation causing pericardial tamponade.[13] Notably, the use of a dedicated pre-shaped Confida Brecker guidewire, which features a continuous, tapered core and pre-shaped curve, in the Evolut R recipients reduced the risk of left ventricular perforation necessitating emergent cardiac surgery, from 5.1% in the CoreValve group to 0% in the Evolut R recipients.

The primary goal of TAVR is to achieve a maximum orifice area with a minimum flow velocity. Given that severe prosthesis-patient mismatch (PPM) was associated with an 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 Registry,[14] there have been concerns regarding PPM in Asian patients with small aortic annuli. Studies on East Asian populations have demonstrated that the Sapien 3 valve had a smaller EOA ($2.07 \pm 0.61$ vs. $1.70 \pm 0.49$ cm$^2$, $p < 0.001$)[15] and caused PPM about 1.92 times[16] more frequently than the Sapien XT valve. Thus, TAVR with supra-annular self-expanding valves was associated with superior hemodynamic outcomes compared with balloon-expandable valves in patients with small aortic annuli. These findings pave the way for further trials regarding appropriate prosthesis selection for TAVR in patients with in East Asian patients with small aortic annuli.

### Limitations

This study was conducted at only a single center 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 benefits of Evolut R may have been overstated to some extent.

## CONCLUSIONS

Advancements in valve technologies with the option to recapture and reposition with Evolut R, the introduction of the InLine sheath with a lower profile, and dedicated pre-shaped guidewires have resulted in improved outcomes for patients undergoing TAVR with supra-an-

nular self-expanding valves. Compared to CoreValve, Evolut R significantly reduced 30-day the composite safety endpoint, driven by significantly lower stroke and life-threatening or disabling bleeding, as well as numerically lower deaths and stage 2 or 3 AKI including renal replacement therapy.

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## DECLARATION OF CONFLICTS OF INTEREST

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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