JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 3, 2017

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.11.025

Initial Experience of a Second-Generation Self-Expanding Transcatheter Aortic Valve

The UK & Ireland Evolut R Implanters' Registry

Sundeep S. Kalra, MA,[a] Sami Firoozi, MBBS,[a] James Yeh, PhD,[b] Daniel J. Blackman, MBBS, MD,[c] Shabnam Rashid, MBChB, BSc,[c] Simon Davies, MA,[c] Neil Moat, MBBS,[c] Miles Dalby, MD,[c] Tito Kabir, PhD,[c] Saib S. Khogali, MD,[d] Richard A. Anderson, MBBS, BSc, MD,[e] Peter H. Groves, MD,[e] Darren Mylotte, MBBS, MD,[f] David Hildick-Smith, MBBS, MD,[g] Rajiv Rampat, MBBS,[g] Jan Kovac, MD,[h] Ashan Gunarathne, MBBS,[h] Jean-Claude Laborde, MD,[a] Stephen J. Brecker, MD[a]

ABSTRACT

OBJECTIVES The authors present the UK and Irish real-world learning curve experience of the Evolut R transcatheter heart valve.

BACKGROUND The Evolut R is a self-expanding, repositionable, and fully recapturable second-generation transcatheter heart valve with several novel design features to improve outcomes and reduce complications.

METHODS Clinical, procedural, and 30-day outcome data were prospectively collected for the first 264 patients to receive the Evolut R valve in the United Kingdom and Ireland.

RESULTS A total of 264 consecutive Evolut R implantations were performed across 9 centers. The mean age was 81.1 ± 7.8 years, and the mean logistic European System for Cardiac Operative Risk Evaluation score was 19.9 ± 13.7%. Procedural indications included aortic stenosis (72.0%), mixed aortic valve disease (17.4%), and failing aortic valve bioprostheses (10.6%). Conscious sedation was used in 39.8% of patients and transfemoral access in 93.6%. The procedural success rate was 91.3%, and paravalvular leak immediately after implantation was mild or less in 92.3%. Major complications were rare: cardiac tamponade in 0.4%, conversion to sternotomy in 0.8%, annular rupture in 0.0%, coronary occlusion in 0.8%, major vascular in 5.3%, acute kidney injury in 6.1%, new permanent pacemaker implantation in 14.7%, and procedure-related death in 0.0%. At 30-day follow-up, survival was 97.7%, paravalvular leak was mild or less in 92.3%, and the stroke rate was 3.8%.

CONCLUSIONS This registry represents the largest published real-world experience of the Evolut R valve. The procedural success rate was high and safety was excellent, comparable with previous studies of the Evolut R valve and other second-generation devices. The low rate of complications represents an improvement on first-generation devices. (J Am Coll Cardiol Intv 2017;10:276–82) © 2017 by the American College of Cardiology Foundation.

From the [a]Cardiology Clinical Academic Group, St. George's University Hospitals NHS Foundation Trust & St. George's University of London, London, United Kingdom; [b]Cardiology Department, Royal Brompton and Harefield NHS Trust, London, United Kingdom; [c]Cardiology Department, Leeds Teaching Hospital, Leeds, United Kingdom; [d]Cardiology Department, The Royal Wolverhampton Hospitals, Wolverhampton, United Kingdom; [e]Cardiology Department, University Hospital of Wales, Cardiff, United Kingdom; [f]Cardiology Department, University Hospital Galway, Galway, Ireland; [g]Cardiology Department, Brighton and Sussex University Hospitals, Brighton, United Kingdom; and the [h]Cardiology Department, Glenfield Hospital, Leicester, United Kingdom. Dr. Blackman is a proctor and consultant for Medtronic and Boston Scientific. Dr. Khogali is a proctor for Medtronic and Boston Scientific. Dr. Hildick-Smith is a proctor for Boston Scientific and Medtronic. Dr. Kovac is a proctor for Medtronic, Boston Scientific, and Edward Lifesciences. Dr. Jean-Claude Laborde is a proctor and consultant for Medtronic. Dr. Brecker is a proctor and consultant for Medtronic; and a member of a steering committee for Boston Scientific. Dr. Mylotte is a proctor and consultant for Medtronic and Microport. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received July 19, 2016; revised manuscript received October 24, 2016, accepted November 17, 2016.

Transcatheter aortic valve replacement (TAVR) is an established therapy for severe aortic stenosis in patients considered at high or extreme risk for surgical aortic valve replacement, on the basis of trials and registries of first-generation devices. For self-expanding technology with the CoreValve (Medtronic, Minneapolis, Minnesota), this evidence includes the ADVANCE Registry (1) and the U.S. Pivotal Trial (2,3) among others.

The trials and registries of first-generation TAVR devices demonstrated important limitations and periprocedural complications (4). Second-generation TAVR devices are designed to improve on these limitations and complications.

SEE PAGE 283

The Evolut R is a self-expanding, repositionable, and fully recapturable second-generation TAVR prosthesis. It incorporates several design changes from the first-generation CoreValve (5). First, vascular access is achieved with a 14-F equivalent system (incorporating an In-Line sheath). The lower profile system is designed to improve deliverability and reduce vascular complications. Second, the Enveo R delivery system provides a more predictable 1:1 deployment response and allows repositioning and full recapture. This novel delivery system permits optimal valve deployment. Third, the valve has an extended inflow skirt, and the frame exhibits more consistent radial force. These adaptations aim to reduce paravalvular leak (PVL) and the need for permanent pacemaker (PPM) implantation.

Early studies of the Evolut R suggest reduced complication rates compared with the first-generation device (6,7). In this study we report the real-world learning curve experience of implanting the Evolut R in consecutive unselected patients in the United Kingdom and Ireland.

METHODS

Prospective clinical, procedural, and outcome data were collected for the first 264 consecutive patients receiving the Evolut R valve across 9 centers in the United Kingdom and Ireland, between December 2013 and May 2016.

Choice of TAVR as treatment and pre-procedural assessment for TAVR was undertaken by the heart team at each implantation center. Implantation was carried out as previously described (8,9). Procedural success was defined according to the Valve Academic Research Consortium 2 (VARC-2) criteria (4): 1) absence of procedural mortality; 2) correct positioning of a single prosthetic heart valve; 3) intended performance of the prosthetic heart valve (no prosthesis-patient mismatch and mean aortic valve gradient <20 mm Hg); and 4) no moderate or severe PVL. Periprocedural complications were also classified according to the VARC-2 criteria (4). Mortality, cerebrovascular accident, and PVL rates were collected at post-discharge 30-day follow-up.

ABBREVIATIONS AND ACRONYMS

PPM = permanent pacemaker

PVL = paravalvular leak

TAVR = transcatheter aortic valve replacement

VARC-2 = Valve Academic Research Consortium 2

STATISTICAL ANALYSIS. Statistical analysis was performed using SPSS (IBM, Armonk, New York). Continuous variables are reported as mean ± SD and categorical variables as percentages. Continuous variables were compared using a 2-tailed Student *t* test with a 95% confidence interval.

RESULTS

BASELINE CHARACTERISTICS. The baseline pre-procedural patient characteristics are summarized in Table 1. The mean age was 81.1 ± 7.8 years, and 58.3% of patients were female. Important comorbidities included diabetes mellitus (25.0%), coronary artery disease in >1 vessel (19.3%), previous cardiac surgery (31.1%), chronic pulmonary disease (26.9%), previous cerebrovascular disease (11.7%), extracardiac arteriopathy (23.9%), and poor left ventricular systolic function (9.1%). Pre-operative cardiac rhythm disturbances included atrial fibrillation (22.0%), other conduction disease (23.7%; conduction disturbances including atrioventricular node disease, bundle branch disease, or fascicle hemiblock), and prior PPM placement (7.2%). The mean logistic European System for Cardiac Operative Risk Evaluation score was 19.9 ± 13.7%, and the mean Society of Thoracic Surgeons Predicted Risk of Mortality score was 6.0 ± 5.6%.

New York Heart Association functional class III or IV was evident in 86.7% of patients, and 16.2% of procedures were performed urgently (during acute hospital admissions for decompensated heart failure).

Isolated aortic stenosis was the most common indication (72.0%), though mixed aortic valve disease (17.4%) and failing aortic valve bioprostheses (10.6%) were also treated. The mean aortic valve gradient was 47.0 ± 16.2 mm Hg, and the mean aortic valve area was 0.68 ± 0.23 cm^2 (Figure 1). Screening multislice computed tomography was performed in 90.9% of cases.

PROCEDURAL CHARACTERISTICS. The procedural characteristics are summarized in Table 2. Conscious

TABLE 1 Baseline Patient Characteristics (n = 264)

Demographics	
Age (yrs)	81.1 ± 7.8
Female	154 (58.3)
Body mass index (kg/m^2)	26.9 ± 5.5
Comorbidities	
Diabetes mellitus	66 (25.0)
Creatinine (mmol/l)	99.6 ± 53.8
Coronary artery disease in >1 vessel*	51 (19.3)
Previous cardiac surgery	82 (31.1)
Chronic pulmonary disease	71 (26.9)
Previous cerebrovascular disease	31 (11.7)
Extracardiac arteriopathy	63 (23.9)
Pre-operative cardiac rhythm disturbances	
Atrial fibrillation	58 (22.0)
Conduction disease†	58 (23.7)
Pre-existing permanent pacemaker	19 (7.2)
Left ventricular ejection fraction (%)	
≥50	177 (67.0)
30–50	63 (23.9)
<30	24 (9.1)
Logistic EuroSSCORE (%)	19.9 ± 13.7
STS score (%)	6.0 ± 5.6
Aortic valve	
Aortic valve pathology	
Aortic stenosis	190 (72.0)
Mixed aortic valve disease	46 (17.4)
Failing aortic valve bioprosthesis	28 (10.6)
Mean aortic valve gradient (mm Hg)	47.0 ± 16.2
Aortic valve area (cm^2)	0.68 ± 0.23
Aortic annular mean diameter (mm)	23.3 ± 1.82
MSCT assessment of aortic annular diameter	240 (90.9)
Other	
Elective cases	218 (83.8)
NYHA class III or IV	229 (86.7)

Values are mean ± SD or n (%). *Coronary artery disease defined by stenosis >50%. †Conduction disturbances including atrioventricular node disease, bundle branch disease, or fascicle hemiblock.

EuroSCORE = European System for Cardiac Operative Risk Evaluation; MSCT = multislice computed tomographic; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

sedation was used in 39.8% of cases. Vascular access was predominantly via the transfemoral route (93.6%), with subclavian (5.3%) and direct aortic (1.1%) access also used. Most transfemoral cases used percutaneous access (96.8%), and 69.5% of these cases were completed using the 14-F In-Line sheath only. Dedicated closure devices (Prostar or ProGlide, Abbott Vascular, Santa Clara, California) were used in 95.8% of the percutaneous transfemoral procedures, and in the remaining 4.2%, planned or unplanned surgical repair was undertaken.

More than one-half of the cases (58.7%) were guided by intraprocedural transesophageal echocardiography. Pre-implantation balloon aortic valvuloplasty was performed in 27.7% of the procedures. All 3 Evolut R valve sizes were used in this cohort: 23 mm (18.2%), 26 mm (28.8%), and 29 mm (53.0%). Valve deployment was successful in 91.3% of the cases, as defined by VARC-2 criteria (4). In the 3 unsuccessful cases, there was 1 case of a detached nose cone, 1 case of an end-cap separation, and 1 case of clinical instability necessitating that the procedure be abandoned. Valve repositioning was required in 20.5% of cases, as defined by partial recapture of the valve after initial deployment. Full valve recapture (valve retrieval) was necessary in 17.2%, and post-implantation balloon dilation was performed in 23.0%. Post-procedural PVL was mild or less 92.3% of patients (Figure 2). At the end of the procedure, the mean aortic valve gradient was 8.3 ± 6.0 mm Hg (47.0 ± 16.1 mm Hg pre-procedurally), and mean valve area was 1.7 ± 0.45 cm^2 (0.68 ± 0.23 cm^2 pre-procedurally) (Figure 1).

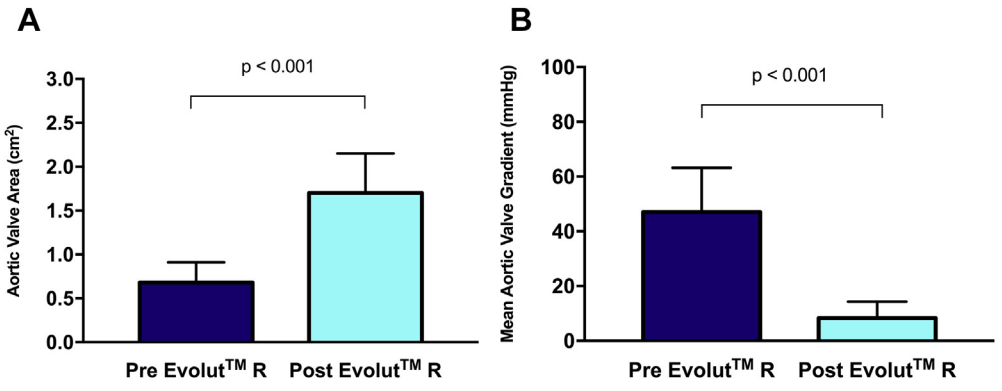
COMPLICATIONS AND OUTCOMES. Two patients required emergency sternotomy, 1 case for left ventricular wire perforation with cardiac tamponade and the other case for acute occlusion of the right coronary artery that could not be treated with bailout angioplasty (Table 3). There were no annular ruptures. There was 1 further case of acute coronary artery occlusion, which was treated with bailout angioplasty. VARC-2-defined major vascular complications occurred in 5.3% of patients. Acute kidney injury (stages 1 to 3 as defined by the Acute Kidney Injury Network [10]) occurred in 6.1% of the patients, and 2 (0.8%) required renal replacement therapy. New PPM implantation was required in 14.7% of patients, at a median time of 3 days post-procedure. The indications for new PPM implantation included third-degree heart block (38.9%), second-degree heart block (22.2%), and new left bundle branch block (38.9%). There were no procedure-related deaths.

At 30 days, the survival rate was 97.7% (4 of 6 deaths occurred during the hospital admission but were unrelated to the procedure), the stroke rate was 3.8% (all nondisabling, as per VARC-2 definition [4]), and PVL was mild or less in 92.3% (Figure 2).

DISCUSSION

This study describes the cohort of consecutive real-world patients treated with the Medtronic Evolut R transcatheter heart valve at 9 experienced TAVR centers in the United Kingdom and Ireland. The major findings of this study were a high procedural success rate (successful valve deployment in 91.3%), few

FIGURE 1 Changes in Aortic Valve Area and Mean Aortic Valve Gradient



Changes in **(A)** aortic valve area and **(B)** mean aortic valve gradient, pre- and post-Evolut R implantation.

procedure-related complications (major vascular in 5.3%, new PPM implantation in 14.7%, and no procedure-related deaths), and excellent 30-day outcomes (mild or less PVL in 92.3%, mortality in 2.3%, and stroke in 3.8%).

Although the baseline patient characteristics are broadly similar to those of previous TAVR registries, there were some important differences in this cohort. First, a large proportion of patients were treated for mixed aortic valve disease (17.4%) or failing surgical aortic valve bioprostheses (10.6%). Second, a large proportion of cases (16.2%) were undertaken urgently, in patients who presented with acute decompensated cardiac function. Third, despite a high incidence of cardiac conduction disease at baseline (23.7%), the pre-existing PPM prevalence was low (7.2%), and there was no routine practice of prophylactic implantation of PPMs in this at-risk subgroup. Fourth, there was high, but importantly not universal, use of pre-procedural multislice computed tomography (90.9%) to assess aortic annular geometry to guide valve size selection.

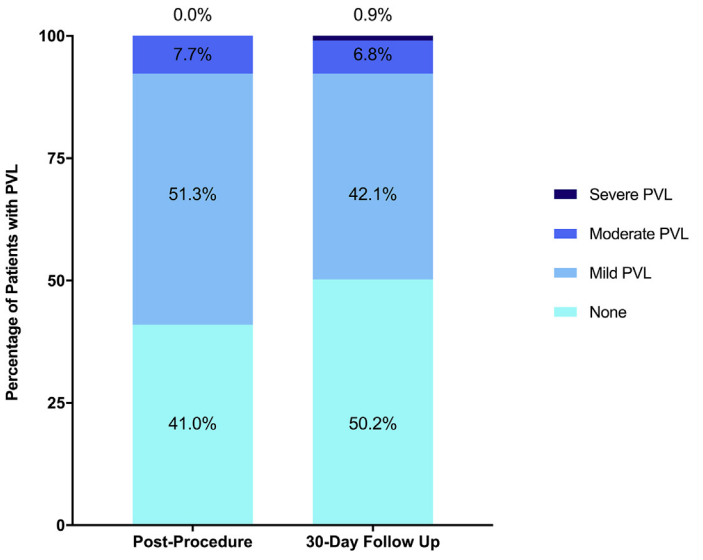
A large proportion of cases (39.8%) were undertaken using conscious sedation only, a trend that is becoming increasingly common in contemporary TAVR practice (6,7,11–15). This represents an increase in the use of sedation in U.K. practice (16). The rate of transfemoral vascular access was unusually high (93.6%) compared with previous TAVR registries, and the majority of cases were completed percutaneously using the lower profile 14-F equivalent InLine sheath. Successful hemostasis was achieved in 95.8% of the percutaneous transfemoral access cases using closure devices, again mirroring the paradigm shift in seen in current TAVR practice. Historically transfemoral access has been associated with high rates of major vascular complications (6.2% to 16.4%) (1–3,17–19) and associated morbidity and mortality. The low rate of major vascular complications (5.3%), compared with other second-generation devices (11,13–15), may reflect the lower profile 14-F equivalent sheath and the routine

TABLE 2 Procedural Characteristics (n = 264)

Conscious sedation	105 (39.8)
Vascular access route	
Transfemoral*	247 (93.6)
Subclavian	14 (5.3)
Direct aortic	3 (1.1)
Percutaneous transfemoral sheath	
14-F InLine only	166 (69.5)
14-F InLine and 18-F sheath	73 (30.5)
Transfemoral percutaneous closure device	229 (95.8)
Transesophageal echocardiographic guidance	155 (58.7)
Pre-implantation balloon aortic valvuloplasty	73 (27.7)
Valve size implanted (mm)	
23	48 (18.2)
26	76 (28.8)
29	140 (53.0)
Successful valve deployment†	241 (91.3)
Valve repositioning‡	46 (20.5)
Valve retrieval (full recapture)	37 (17.2)
Post-implantation balloon dilatation	60 (23.0)
End procedure mean aortic valve gradient (mm Hg)	8.3 ± 6.0
End procedure aortic valve area (cm^2)	1.7 ± 0.45
End procedure paravalvular leak mild or less	241 (92.3)

Values are n (%) or mean ± SD. *A total of 239 percutaneous transfemoral cases and 8 surgical access transfemoral cases. †Successful valve deployment defined as per Valve Academic Research Consortium 2 recommendations. ‡Valve repositioning defined as any counterclockwise rotation of the Enveo R delivery system after initial deployment commenced.

FIGURE 2 Changes in Paravalvular Leak



Paravalvular leak post-procedurally and at 30-day follow-up.

practice of percutaneous closure (95.8%). The low rate of alternative access suggests that many of the patients in this cohort treated using transfemoral access may have a burden of vascular disease that in the past would have dictated alternative access; the 14-F equivalent sheath makes it possible to perform transfemoral TAVR in arteries as small as 5 mm. Despite this, vascular complications were gratifyingly low.

TABLE 3 Complications and Outcomes (n = 264)

Cardiac tamponade	1 (0.4)
Conversion to sternotomy	2 (0.8)
Annular rupture	0 (0)
Coronary occlusion	2 (0.8)
Major vascular complications*	14 (5.3)
Acute kidney injury (stages 1-3)†	16 (6.1)
Requiring renal replacement therapy	2 (0.8)
New permanent pacemaker implantation	36 (14.7)
New third-degree heart block	14 (38.9)
New second-degree heart block	8 (22.2)
New left bundle branch block	14 (38.9)
30-day cerebrovascular accident	10 (3.8)
Procedure-related death	0 (0)
30-day survival	258 (97.7)
30-day paravalvular leak mild or less‡	217 (92.3)

Values are n (%). *Major vascular complications as defined by the Valve Academic Research Consortium 2 criteria. †Acute kidney injury as defined by the Acute Kidney Injury Network criteria. ‡Data available for only 235 of 258 surviving patients.

In this intermediate risk population (mean Society of Thoracic Surgeons score 6.0 ± 5.6%), mortality at 30 days was low in this cohort (2.3%) compared with studies of the first-generation device (8.0%) (1-3) and was similar to rates in recent other studies of the Evolut R (2.5% to 3.1%) (6,7). None of the deaths were directly related to the procedure. This must reflect generic experience with TAVR, improved patient selection, improved preprocedural analysis with computed tomography, effective complication management, and an improved device.

The rate of more than mild PVL at 30 days (7.7%) was lower than seen with the first-generation device (11.4% to 14.2%) (1-3) and similar to those in other studies of the Evolut R (3.9% to 5.4%) (6,7). The Evolut R has important design changes compared with the first-generation device. The novel nitinol cell design means that the frame exerts a more consistent radial force across the operating range of annular size for a given implant size. The inflow skirt is extended downward, and the frame design is straighter at the inflow. All of these factors contribute to the reduced PVL rate compared with the first-generation CoreValve. However, the rate of more than mild PVL in this cohort (7.7%) (**Figure 2**) is higher than that reported for the Lotus valve (Boston Scientific, Natick, Massachusetts) (0.6% to 1.0%) (11,13,20-22) and the SAPIEN 3 (Edwards Lifesciences, Irvine, California) (1.0% to 3.4%) (14,15). Unlike the Evolut R, the Lotus and SAPIEN 3 valves have sealing skirts outside to reduce PVL. Future iterations of the Evolut R will have this feature, but this will increase the profile of the delivery catheter and could be associated with higher pacing rates (14,15,20,22). There are some other considerations as well. First, this study reflected real-world practice, and a number of patients were implanted urgently rather than electively; second, more than 10% of patients did not undergo pre-procedural computed tomography. Both of these may have influenced the slightly higher PVL rate than the CE mark (6) and U.S. (7) studies.

The rate of new PPM implantation in this study at 30 days was 13.6%, which is considerably lower than seen with the first-generation device (26.4%) (1) and comparable with rates in other studies of the Evolut R (11.7% to 16.4%) (6,7). This pacemaker rate is similar to that of the SAPIEN 3 valve and is greatly lower than that of the Lotus valve (11,13-15,20-22). The novel design features of the Evolut R, including repositionability and cell design enabling a more consistent radial force, appear to translate to lower rates of pacing overall.

Cerebrovascular accidents remain an important concern post-TAVR and principally occur during balloon dilation and valve implantation. In this study, the stroke rate was low (3.8%) and comparable with those in other TAVR series of second-generation devices (6,7,11,13–15). Importantly, the requirement to recapture and reposition the device did not appear to increase the risk for stroke.

In this study, pre-implantation balloon valvuloplasty was carried out in only 27.7%, reflecting that in the vast majority of cases, this valve can be deployed without pre-implantation valvuloplasty. Post-deployment valvuloplasty was required in 23.0%.

STUDY LIMITATIONS. The study findings should be interpreted in light of the study design. Participation in this registry was voluntary, and all data were self-reported by each center, without core laboratory validation. However, this study has considerable strengths, including prospective granular data collection and the enrollment of real-world, unselected participants reflecting day-to-day clinical practice. Further study is required to demonstrate the longer term durability of this prosthesis.

CONCLUSIONS

We present the largest experience of unselected, real-world patients treated with the Medtronic Evolut R valve. Our data demonstrate high procedural success and excellent safety, with low rates of complications.

ADDRESS FOR CORRESPONDENCE: Dr. Stephen J. Brecker, Cardiology Clinical Academic Group, St. George's University Hospitals NHS Foundation Trust & St. George's University of London, Blackshaw Road, Tooting, London SW17 0QT, United Kingdom. E-mail: sbrecker@sgul.ac.uk.

PERSPECTIVES

WHAT IS KNOWN? Early studies of the Evolut R TAVR prosthesis suggested higher procedural success rates and reduced complication rates compared with first-generation devices.

WHAT IS NEW? This registry represents the largest real-world world experience of the Evolut R valve to date. The procedural success rate was high (91.3%), and the safety profile was excellent (a 30-day survival rate of 97.7%, PVL mild or less in 92.3%, and a stroke rate of 3.8%).

WHAT IS NEXT? Future studies of the Evolut R valve are needed to evaluate the longer term durability of this prosthesis beyond 30 days. Additionally, formal clinical trials of this device in low- and intermediate-risk groups of patients would corroborate its procedural success rate and safety for wider use.

REFERENCES

1. Linke A, Wenaweser P, Gerckens U, et al. Treatment of aortic stenosis with a self-expanding transcatheter valve: the international multi-centre ADVANCE study. Eur Heart J 2014;35:2672–84.

2. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014;370:1790–8.

3. Popma JJ, Adams DH, Reardon MJ, et al. 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;63:1972–81.

4. Kappetein AP, Head SJ, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. EuroIntervention 2012;8:782–95.

5. Sinning JM, Werner N, Nickenig G, Grube E. Medtronic CoreValve Evolut R with EnVeo R. EuroIntervention 2013;9 Suppl:S95–6.

6. Manoharan G, Walton AS, Brecker SJ, et al. Treatment of symptomatic severe aortic stenosis with a novel resheathable supra-annular self-expanding transcatheter aortic valve system. J Am Coll Cardiol Intv 2015;8:1359–67.

7. Williams MS, Slater J, Saric M, et al. Early outcomes with the Evolut R repositionable self-expanding transcatheter aortic valve in the United States. J Am Coll Cardiol 2016;67:2172.

8. Sinning JM, Werner N, Nickenig G, Grube E. Medtronic CoreValve Evolut valve. EuroIntervention 2012;8 Suppl Q:Q94–6.

9. Piazza N, Martucci G, Lachapelle K, et al. First-in-human experience with the Medtronic CoreValve Evolut R. EuroIntervention 2014;9:1260–3.

10. Mehta RL, Kellum JA, Shah SV, et al. Acute Kidney Injury Network: report of an initiative to improve outcomes in acute kidney injury. Crit Care 2007;11:R31.

11. Rampat R, Khawaja MZ, Byrne J, et al. Transcatheter aortic valve replacement using the repositionable Lotus valve: United Kingdom experience. J Am Coll Cardiol Intv 2016;9:367–72.

12. Brecker SJ, Bleiziffer S, Bosmans J, et al. Impact of anesthesia type on outcomes of transcatheter aortic valve implantation (from the multicenter ADVANCE study). Am J Cardiol 2016;117:1332–8.

13. De Backer O, Gotberg M, Ihlberg L, et al. Efficacy and safety of the Lotus Valve System for treatment of patients with severe aortic valve stenosis and intermediate surgical risk: results from the Nordic Lotus-TAVR registry. Int J Cardiol 2016;219:92–7.

14. Vahanian A, Urena M, Walther T, et al. Thirty-day outcomes in patients at intermediate risk for surgery from the SAPIEN 3 European approval trial. EuroIntervention 2016;12:e235–43.

15. Kodali S, Thourani VH, White J, et al. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. Eur Heart J 2016;37:2252–62.

16. Moat NE, Ludman P, de Belder MA, et al. Long-term outcomes after transcatheter aortic valve implantation in high-risk patients with

severe aortic stenosis: the U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) registry. J Am Coll Cardiol 2011;58:2130–8.

17. Lefevre T, Kappetein AP, Wolner E, et al. One year follow-up of the multi-centre European PARTNER transcatheter heart valve study. Eur Heart J 2011;32:148–57.

18. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607.

19. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011;364:2187–98.

20. Meredith IT, Walters DL, Dumonteil N, et al. 1-Year outcomes with the fully repositionable and retrievable lotus transcatheter aortic replacement valve in 120 high-risk surgical patients with severe aortic stenosis: results of the REPRISE II study. J Am Coll Cardiol Intv 2016;9:376–84.

21. Meredith IT, Walters DL, Dumonteil N, et al. Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRISE II study. J Am Coll Cardiol 2014;64:1339–48.

22. Meredith IT, Worthley SG, Whitbourn RJ, et al. Transfemoral aortic valve replacement with the repositionable Lotus Valve System in high surgical risk patients: the REPRISE I study. EuroIntervention 2014;9:1264–70.

KEY WORDS aortic stenosis, complication, Evolut R, outcome, transcatheter aortic valve replacement, transcatheter heart valve