Original paper

Comparison of outcomes in patients with severe aortic stenosis treated with small and large Medtronic Evolut R and Evolut PRO self-expandable prosthetic valves

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Abstract

Introduction: Indications for transcatheter aortic valve implantation (TAVI) continue to expand. Very often TAVI must be done in large annuli. Implantation of the bigger prostheses is often associated with more procedural problems, which may affect the outcomes.

Aim: To compare the outcomes of TAVI procedures using the self-expandable Medtronic Evolut R 34 with the smaller Evolut R or Evolut Pro 23, 26 or 29.

Material and methods: We analysed 87 patients who received self-expandable Medtronic Evolut R and Pro valves. Group I consisted of 59 (67.81%) patients with Evolut 23, 26 or 29, and group II consisted of 28 (32.18%) patients who received an Evolut 34 valve.

Results: EuroSCORE II was 5.59 in group I vs 7.87 in group II (p = 0.02). The oversizing rate was higher in group II: 24.1% vs. 18.5% (p < 0.001). The procedure and fluoroscopy times were longer in group II: 209 vs. 187 min (p = 0.03), 44 vs. 27 min (p = 0.01). Moderate paravalvular leak was found more frequently in group II: 5 v 1 (p = 0.04). There was less device success in group II: 22 (78.57%) vs. 57 (96.6%) (p = 0.05). Early safety criteria were similar in both groups: 52 (88.1%) and 24 (92.3%) (p = 0.56). 30-day mortality was similar: 4 (6.7%) vs. 0 in group I and II respectively (p = 0.16).

Conclusions: TAVI procedures in patients requiring an Evolut R 34 prosthesis are more challenging than in those who need smaller valves. Paravalvular leaks are more frequently observed after TAVI with Evolut R 34, which results in lower device success.

Key words: aortic stenosis, transcatheter aortic valve implantation, paravalvular leak, self-expandable prosthesis.

Summary

Transcatheter aortic valve implantation (TAVI) procedures in patients requiring an Evolut R 34 prosthesis are more challenging than in those who need smaller valves. Paravalvular leaks are more frequently observed after TAVI with Evolut R 34, which results in lower device success.

Introduction

Aortic stenosis (AS) is currently the most common valvular heart disease in Europe and America. Its occurrence is rising along with age, and among patients over 75 years, its prevalence is increasing exponentially [1–3]. For 20 years, an alternative to classic surgical aortic valve replacement (SAVR) – transcatheter aortic valve implantation (TAVI) – has been developing. This is mainly due

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to gaining experience and improved TAVI devices [4, 5]. Studies on the feasibility and utility of this method systematically expand its indications – a procedure introduced as a rescue for patients disqualified from SAVR is now being performed in younger patients with intermediate surgical risk. Moreover, it can be assumed that in the years to come, patients with low surgical risk will also be candidates for TAVI [6–8]. Since 2021, according to recent European guidelines, patients with low risk and age over 75 who are eligible for transfemoral implantation are good candidates for TAVI [9].

To perform TAVI, a variety of devices are being used, such as self-expandable Medtronic Evolut R and Evolut PRO (Medtronic, 49 Minneapolis, MN, USA), available in a few different sizes: 23, 26, 29 and 34 mm [10, 11]. Among TAVI patients, there is a group that requires special attention – those who need the largest available Evolut R – 34. An anatomically large aortic annulus that exceeds an area of > 585 mm^2 or perimeter of > 85 mm on a multi-slice computed tomography (MSCT) scan is still a challenge for the operators, as it is associated with technical issues, such as implantation depth and need for post-dilatation. These, in turn, increase the risk of pacemaker implantation or valve embolization – particularly important complications among younger patients with lower surgical risk [12, 13]. Although studies on TAVI in patients with large aortic annuli are constantly being published, their conclusions are still ambiguous [3, 12, 14, 15].

Aim

The aim of this study was to compare the outcomes in patients with severe aortic stenosis treated with TAVI using the largest available Medtronic Evolut R 34 valve with the smaller ones: Medtronic Evolut R and Pro 23, 26 and 29 valves.

Material and methods

The study was based on data acquired from the TAVI Zabrze Registry – a database comprising patients with severe AS treated with TAVI. Its purpose is to assess and monitor the outcomes of the treatment applied.

The adopted time interval was between 10 August 2015 (the very first patient with an Evolut R/PRO valve implanted) and 31 December 2019. At that time, 282 patients with severe AS were treated in our centre, including 120 patients treated by our heart team. This analysis includes 87 who received self-expandable Medtronic Evolut R and Evolut PRO valves (sizes: 23, 26, 29 and 34; no patients needed the smallest 23 mm valve). This study excluded patients with a previously implanted aortic valve prosthesis (no valve-in-valve). Selection criteria for the adequate valve size were made using a multi-slice computed tomography (MSCT) scan. They were based on an annulus diameter calculated by the following formula: annulus perimeter/3.14 and according to the Medtronic recommendations. Patients with extra-large annuli (annulus > 30 mm, area > 683 mm^2 or perimeter > 94.2 mm – not recommended by Medtronic) were not analysed.

All patients were divided into two groups: Group I: 59 (67.81%) patients treated with Evolut 26 and 29 valves, and Group II: 28 (32.18%) patients treated with Evolut 34 valves.

MSCT scans

The MSCT scans were acquired with a Siemens Medical, Erlangen, Germany, scanner according to the protocol described earlier [15, 16]. Measurements of the annulus, such as the minimal and maximal diameter, perimeter and area, were made. The diameter was calculated using the following formula: perimeter/3.14 – assuming the circular shape of the annulus. Moreover, the diameter was also measured from the arithmetic average of maximal and minimal annulus size. The exact evaluation was carried out with the OsiriX Pro (Pixmeo SARL, Switzerland) software. The oversizing factor was calculated as a ratio of the implanted valve perimeter to the aortic annulus perimeter and presented in the percentage form (the formula: valve perimeter/annulus perimeter × 100% – 100).

TAVI procedure

The TAVI procedures were carried out in a hybrid room or catheterization laboratory. A total of 87 Evolut R and 4 Evolut PRO valves were implanted. Twenty-three patients received a 26 mm Evolut valve, 36 patients received 29 mm valves, and 28 patients received 34 mm valves. The access route was femoral or direct aortic. In the minority of cases, general anaesthesia was applied. A large portion of transfemoral TAVI was performed percutaneously under sedation and local anaesthesia, and the vessels were either closed with dedicated closure devices (Prostar XL (Abbott Vascular, Abbott Park, Illinois, USA), ProGlide (Abbott Vascular, Abbott Park, Illinois, USA)) or surgically. All the TAVI procedures were elective.

Angiographic assessment

A paravalvular leak (PVL) was assessed angiographically after valve implantation in accordance with the Sellers *et al*. criteria [17]. A volume of 15–20 ml of contrast was administered at a flow rate of 10 ml/s (450 PSI). The assessment was done independently by three experienced invasive cardiologists. In the event of discrepancies, a consensus was reached after a joint assessment. Eighty-one aortographies were suitable for analysis after TAVI.

Composite end points were adopted according to the Valve Academic Research Consortium (VARC 2) criteria [18]:

– Device success – a composite end point consisting of the absence of procedural mortality, correct positioning of a single prosthetic aortic valve into the proper anatomical location and intended performance of the

prosthetic aortic valve. As data regarding prosthesis mismatch and peak velocity were scarce, the authors decided to adopt the VARC-2 device success criteria without these parameters;
– Early safety at 30 days – a composite 30-day end point consisting of all-cause mortality, stroke, life-threatening haemorrhage, acute kidney injury stage 2 or 3, coronary artery obstruction requiring intervention and valve-related dysfunction requiring another procedure.

The study was conducted following the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Due to the retrospective design of the study, no additional patient consent was required.

Statistical analysis

A database created in Microsoft Excel 2016 and 2014 Statistica 13.3, StatSoft, Inc., were used for the statistical analysis. Data are presented in the form of the mean and standard deviation, whereas qualitative parameters are presented as numbers of cases followed by percentages for the group. The median and inter-quartile range (IQR) values were given if the data did not show normal distribution. The distribution type was tested with the Kolmogorov-Smirnov and Shapiro-Wilk tests. Student's *t*-test was used to analyse variables with normal distribution, while a non-parametric Mann-Whitney *U* test was employed for data not fitting the assumptions of normal distribution. The χ^2 test (with Yates' correction) was used to compare qualitative data. The statistical significance level of $p < 0.05$ was adopted.

Results

The data regarding patients' demographics are presented in Table I.

Patients' clinical characteristics were significantly different in terms of sex: males 37.39% vs. 89.29%, in Group I and II, respectively ($p < 0.001$), height: 1.62 vs. 1.71 m ($p < 0.001$), weight: 73.51 vs. 80.98 kg ($p = 0.01$), BSA: 1.77 vs. 1.92 ($p < 0.001$), active tobacco smoking: 89.83% vs. 67.83% ($p = 0.01$), EuroSCORE II: 5.59 vs. 7.87 ($p = 0.02$) and NT-pro-BNP: 3170 pg/ml vs. 9675 pg/ml ($p < 0.001$). Other parameters did not differ statistically significantly.

The echocardiographic and MSCT data are presented in Table II.

Group I patients had better left ventricle ejection fraction (LVEF): 49.06% vs. 41.21% ($p = 0.01$), and their valves were less oversized: 18.52% vs. 24.11% ($p < 0.001$). The

Table I. Patients' demographics

Variable	All patients ($n = 87$)	Group I ($n = 59$)	Group II ($n = 28$)	*P*-value
Age [years]	80 (6)	81 (6)	79 (6)	0.17
Male	47 (54.02%)	22 (37.29%)	25 (89.29%)	< 0.001
BMI	30.76 (2.86)	32.22 (3.98)	27.76 (3.16)	0.81
Height [m]	1.65 (0.09)	1.62 (0.08)	1.71 (0.06)	< 0.001
Weight [kg]	75.88 (13.44)	73.51 (13.49)	80.98 (12.14)	< 0.001
BSA [m^2]	1.82 (0.18)	1.77 (0.16)	1.92 (0.17)	< 0.001
NYHA class:				
I	4 (4.60%)	4 (6.78%)	0 (0%)	0.39
II	34 (39.00%)	22 (37.29%)	12 (42.86%)	0.22
III	44 (49.43%)	30 (50.85%)	13 (46.43%)	0.86
IV	6 (6.90%)	3 (5.08%)	3 (10.71%)	0.19
Arterial hypertension	9 (10.34%)	7 (11.86%)	2 (7.14%)	0.49
Diabetes	46 (52.87%)	29 (49.15%)	17 (60.71%)	0.17
Active tobacco smoking	72 (86.76%)	53 (89.83%)	19 (67.83%)	0.01
COPD	14 (16.09%)	10 (16.95%)	4 (14.29%)	0.75
Previous stroke/TIA	14 (16.09%)	9 (15.25%)	5 (17.86%)	0.76
Previous MI	30 (34.48%)	17 (28.81%)	13 (46.43%)	0.11
Previous CABG	26 (29.89%)	15 (25.42%)	11 (39.29%)	0.18
Renal dysfunction	46 (52.87%)	33 (55.93%)	13 (46.43%)	0.40
Implanted pacemaker	18 (20.69%)	10 (16.95%)	8 (28.58%)	0.21
Log EuroSCORE (%)	26.22 (21.49)	24.70 (22.56)	29.66 (18.52)	0.11
Standard EuroSCORE	10.98 (4.94)	10.22 (2.91)	12.64 (7.54)	0.19
EuroSCORE II	6.32 (4.91)	5.59 (4.74)	7.87 (4.96)	0.02
NT-pro-BNP [pg/ml]	5419 (2807–4548)	3170 (1852–3862)	9675 (452–-11087)	< 0.001
BAV	35 (40.23%)	22 (37.29%)	13 (46.43%)	0.41

BMI – body mass index, BSA – body surface area, NYHA – New York Heart Association, COPD – chronic obstructive pulmonary disease, TIA – transient ischaemic attack, MI – myocardial infarction, CABG – coronary artery bypass grafting, NT-proBNP – N-terminal pro-B-type natriuretic peptide, BAV – bicuspid aortic valve.

Table II. Echocardiography and MSCT results

Variable	All patients (*n* = 87)	Group I (*n* = 59)	Group II (*n* = 28)	*P*-value
Echocardiography				
AVA [cm^2]	0.68 (0.20)	0.65 (0.18)	0.75 (0.22)	0.14
AVPG mean [mm Hg]	43.32 (15.55)	44.01 (16.61)	41.80 (13.11)	0.99
LVEF (%)	46.21 (11.64)	49.06 (9.81)	40.21 (13.03)	0.01
MSCT:				
Mean diameter (obtained from max./min.) [mm]	24.71 (2.48)	23.55 (1.95)	27.06 (1.64)	< 0.001
Mean diameter (perimeter derived) [mm]	24.84 (2.53)	23.52 (1.76)	27.61 (1.43)	< 0.001
Annulus perimeter [mm]	77.80 (7.70)	73.89 (5.58)	86.05 (4.23)	< 0.001
Annulus area [mm^2]	468.44 (102.39)	419.33 (66.65)	571.93 (86.44)	< 0.001
Annulus diameter (area derived) [mm]	24.15 (2.85)	22.86 (2.07)	26.90 (2.19)	< 0.001
Oversizing ratio (%)	20.32 (6.59)	18.52 (5.93)	24.11 (6.40)	< 0.001

AVA – aortic valve area, AVPG – aortic valve pressure gradient, LVEF – left ventricular ejection fraction.

Table III. TAVI procedure and post-procedural assessment

Variable	All patients (*n* = 87)	Group I (*n* = 59)	Group II (*n* = 28)	*P*-value
TAVI procedure:				
Access route:				
TAo	3 (3.45%)	3 (5.08%)	0 (0%)	0.39
TF	84 (96.55%)	56 (94.92%)	28 (100%)	0.54
Number of attempts (repositioning/retrieval):				
One	71 (81.61%)	48 (81.35%)	23 (82.14%)	0.89
Two	8 (9.19%)	6 (10.17%)	2 (7.14%)	0.65
Three	5 (5.71%)	3 (5.08%)	2 (7.14%)	0.72
Four	3 (3.44%)	2 (3.39%)	1 (3.57%)	0.95
Post-dilatation	20 (23.25%)	10 (16.95%)	10 (37.04%)	0.04
Procedure duration time [min]	194 (87)	187 (92)	209 (71)	0.03
Fluoroscopy time [min]	32 (29)	27 (12)	44 (49)	0.01
Radiation dose, median, IQR [mGy]	1401.20 (752–786)	1372.74 (744–814)	1466.41 (911–748)	0.59
Contrast volume [ml]	143.19 (53.14)	144.28 (53.13)	140.76 (54.18)	0.78
Sedation and local anaesthesia	60 (68.96%)	37 (62.72%)	23 (82.14%)	0.04
Post-procedural variables:				
LVEF (echo) (%)	46.93 (9.65)	49.27 (8.39)	42.25 (10.44)	0.003
EOA (echo) [cm^2]	2.15 (0.74)	2.20 (0.81)	1.94 (0.35)	0.41
AVPG mean [mm Hg] (echo)	7.42 (2.97)	7.58 (3.07)	7.11 (2.72)	0.3
In-hospital PPM implantation	4 (5.20%)	4 (8.16%)	0 (0.00%)	0.18
PVL – echocardiography:				
None	48 (55.17%)	34 (66.10%)	14 (50.00%)	0.71
Mild	33 (37.93%)	24 (42.86%)	9 (30.77%)	0.44
Moderate	6 (7.89%)	1 (1.69%)	5 (17.86%)	< 0.001
Severe	0 (0%)	0 (0%)	0 (0%)	1.00
Aortography:	79 (90.79%)	56 (94.91%)	23 (82.14%)	
PVL grade 0	31 (39.24%)	26 (46.42%)	5 (21.73%)	0.035
PVL grade 1	30 (37.97%)	19 (33.92%)	11 (47.82%)	0.89
PVL grade 2	15 (18.98%)	10 (17.85%)	5 (21.73%)	0.62
PVL grade 3	3 (3.79%)	1 (1.78%)	2 (8.69%)	0.13
PVL grade 4	0 (0%)	0 (0%)	0 (0%)	1.00
PLV grade:				
0 + 1 + 2	76 (87.35%)	55 (98.22%)	21 (91.67%)	0.12
3 + 4	3 (3.44%)	1 (1.78%)	2 (8.33%)	0.13

TAVI – transcatheter aortic valve implantation, Tao – transaortic, TF – transfemoral, LVEF – left ventricular ejection fraction, EOA – effective orifice area, AVPG – aortic valve pressure gradient, PPM – permanent pacemaker, PVL – paravalvular leak.

aortic valve area (AVA) and mean aortic valve pressure gradient (AVPG) did not differ significantly between the groups.

However, the MSCT results revealed significant differences between the groups – this was due to patients' characteristics: Group II patients with larger valves had a larger annulus area, diameter, perimeter and oversizing ratio when compared to Group I.

The procedural variables and post-procedural haemodynamic results are presented in Table III.

The parameters that differed significantly between the groups were fluoroscopy time (27 min vs. 44 min, $p < 0.001$), procedure duration time (187 min vs. 209 min, $p = 0.03$), local anaesthesia (62.72 vs. 82.14, $p = 0.04$) and need for post-dilatation (16.95% vs. 37.04%, $p = 0.04$) in Group I and Group II, respectively. Overall, transfemoral access was chosen in 84 patients. Echocardiography after the procedure showed a significant difference in LVEF (49.30% vs. 42.92%, $p < 0.003$).

After the procedure, the groups differed with regard to device success composite end points. One patient did not receive a dedicated Evolut R 34 valve because of the inability to cross the bicuspid valve with the wire (the patient was further treated with a transapical Sapien 3 valve). Notably, patients from Group II more frequently showed moderate PVL assessed on echo – this was also noted in aortography; however, it was not significant.

During the in-hospital period, 4 patients from Group I had a permanent pacemaker implanted due to a third-degree atrioventricular block. In terms of early safety measured within 30 days after TAVI, both groups showed similar outcomes. The results are presented in Table IV.

Discussion

We present TAVI treatment results using different valve sizes (26 and 29 vs. 34) manufactured by Medtronic. The Evolut R/PRO 34 devices were introduced in Europe at the beginning of 2017 to improve haemodynamic outcomes and the safety of patients with large annuli. This is a single-centre study with the same valve size choice criteria based on the MSCT measurements for devices used. At this point, the exact proportion of patients with large annuli is uncertain; however, approximately 7% of TAVI patients in our database had large annuli.

According to the American Heart Association guidelines, a small or large aortic annulus is a factor in favour of SAVR; however, the decision must be suitable to the patient's condition. Therefore, it is common practice that patients with large aortic annuli are also treated with TAVI. In our database, 6 patients (not included in the analysis) had an annulus area over 683 mm^2 (> 30 mm in diameter) on MSCT, which is considered extra-large, yet the TAVI procedure may be a better choice for those patients [19]. The Evolut R and recently released Evolut 34+ are the largest valves available for patients with large and extra-large annuli; however, their use in the extra-large annulus cases is considered off-label.

TAVI could be a challenging procedure for several reasons in patients with large and very large aortic annuli. Firstly, there is an issue regarding implantation depth because of the haemodynamic result, as higher deployment is associated with a greater chance of valve embolization. In contrast, deeper implantation is often associated with conduction system impairment. The available data suggest that lower implantation depth and higher radial forces could be associated with an increased risk of a conduct-

Table IV. Device success according to the VARC-2 criteria and early safety parameters within 30 days after TAVI

Parameter	Group I ($n = 59$)	Group II ($n = 28$)	*P*-value
Device success (VARC-2):			
Survival	59 (100%)	28 (100%)	1.00
Correct positioning of a single prosthetic heart valve into the proper anatomical location	59 (100%)	27 (96.43%)	0.14
Mean AVPG < 20 mm Hg	58 (98.31%)	27 (100%)*	0.82
No moderate or severe prosthetic valve regurgitation on echocardiography	58 (98.31%)	22 (81.48%)*	0.04
Composite end point expressed in the number of patients	2 (3.39%)	6 (21.42%)	0.05
Early safety (30 days):			
All-cause mortality	4 (6.68%)	0 (0.00%)	0.16
Stroke	0 (0.00%)	0 (0.00%)	1.00
Life-threatening haemorrhage	3 (5.08%)	0 (0.00%)	0.25
AKI stage 2/3	4 (6.68%)	1 (3.70%)	0.57
Coronary artery occlusion	0 (0.00%)	0 (0.00%)	1.00
Valve dysfunction resulting in additional procedure	0 (0.00%)	0 (0.00%)	1.00
Major vascular complications	1 (1.69%)	0 (0.00%)	0.49
Composite end point expressed in the number of patients who did not have a particular single parameter	52 (88.14%)	24 (92.31%)	0.56

**These parameters were calculated for 27 patients, as one valve was not implanted during the TAVI procedure. VARC – Valve Academic Research Consortium, AKI – acute kidney failure, AVPG – aortic valve pressure gradient.*

ibility defect, which was not observed in smaller valves [20–22]. However, there is no consensus about what time after TAVI a PPM implantation should be associated with TAVI. Most centres accepted that PPM implantation within 3 days after the procedure is related to TAVI. Our study did not find an increased incidence of pacemaker implantation after TAVI during the in-hospital period.

The difference regarding the higher oversizing ratio in Group II after TAVI could result from the valve size itself. The Evolut R 34 has a 5 mm larger diameter than Evolut 29, whereas the differences among 23, 26 and 29 are 3 mm. With current sizing recommendations and larger differences in the diameter of valves for the 26–30 mm annulus, the oversizing could be higher and result in higher valve gradients.

Furthermore, the analysed valves do not align well with the aorta axis, and so when the device is below the non-coronary cusp, it is not perpendicular to the aortic annulus. This could change implantation depth regarding the aortic annulus during deployment – the valve is implanted in a high position by the non-coronary cusp and in a low position by the right or left coronary cusps. The difference between implantation depth across the valve rises with the annulus size. These factors imply that the use of a larger valve could increase the risk of both too-low implantation, resulting in conductibility complications, and too-high implantation, which could result in valve embolization. However, by taking advantage of the valve's ability to reposition in our study group, this complication did not occur, and due to the high implantation technique, the PPM implantation rate was relatively low.

The next issue that needs to be discussed is treating patients with bicuspid aortic valves, which generally are larger in diameter. In this study, the patients from Group II had BAV more frequently. In our analysis, the percentage of patients with BAV was significantly higher than the figures reported in the literature – 40% vs. 0.5% to 2.5% [19, 23, 24]. Additionally, when the aortic valve is bicuspid, the next question is whether the same sizing method should be applied as in the case of tricuspid valves [25]. From the authors' perspective, it is more common for patients with BAV to have larger annuli when compared to tricuspid aortic valves. All these aspects make the TAVI procedure even more challenging. Very often, bicuspid valves have more oval orifices, and the self-expandable valve assumes a more oval shape after implantation. This, in turn, may result in PVL and/or make the retrieval of the delivery system difficult after implantation [26–28].

Our analysis focused on the treatment outcomes achieved with Evolut R 34 when compared to smaller 26 and 29 valves. We found that procedure time and fluoroscopy time were longer in patients with larger valves. This could indicate that TAVI in those patients is more challenging. In terms of device success, we found that Evolut R 34 was associated with higher occurrence of moderate PVL assessed on echocardiography, and the composite end point was reached by 3.39% and 21.42% of patients in Group I and Group II, respectively. However, a PVL analysis based on aortography revealed no significant differences. On the other hand, the early safety composite end point did not differ significantly. An additional limitation of the early safety criteria was mortality, as patients who died up to 30 days after TAVI were much older and suffered from numerous co-morbidities (a similar situation did not occur with the Evolut R 34). Hence, a particular early safety criterion regarding valve function did not reveal a difference between the groups.

New solutions are emerging for the treatment of patients with large annuli. For instance, Meril Life Sciences has developed the Myval transcatheter heart valve (THV), available in a large variety of sizes with ranges of approximately 1.5–2 mm, 20–32 mm, and even for extra-large valves with an annulus area up to 840 mm^2 [29]. The first clinical in-human research regarding the use of Myval devices was MyVal-1, performed on a group of 100 patients and published recently. The authors reported that in the follow-up of 12 months, they found four all-cause deaths, but PVL, aortic regurgitation or need for new PPM was not observed. The authors concluded that Myval THVs are safe and feasible in patients with severe AS. However, their study has major limitations – a relatively small cohort and a short follow-up period (12 months after TAVI). What is more, it was not made clear what exact sizes of Myval THV were used [30]. There is also an ongoing multicentre, randomized clinical trial, LANDMARK, with 768 patients with severe aortic stenosis, whose objective is to compare the safety and effectiveness of the Myval THV series to the contemporary valves (Sapien and Evolut THV valves) [31]. The latest publication regarding multicentre experience with Myval THVs involves 68 patients with a range of available valve sizes. After the implantation, only 3% had moderate or severe PVL, and 6.5% had new PPM implanted. This could indicate that with the wider range of valve sizes, a heart team could match the appropriate size for the particular annulus and thus minimize adverse effects, especially in patients with large aortic annuli [32].

Armijo et al. compared the feasibility and effectiveness of third-generation balloon and self-expandable valves (Edward Sapien 3, 29 mm and Evolut R, 34 mm) in patients with large and extra-large aortic annuli. They chiefly aimed to assess whether the use of study devices is feasible in patients with extra-large annuli, as their use is currently considered off-label. They found that both types of valves are appropriate for extra-large annuli, but the Evolut R 34 demonstrated a higher occurrence of PVL, valve embolization and need for a second valve, which resulted in lower device success. Thus, the authors concluded that balloon-expandable valves have a slight advantage over the self-expandable ones [12].

However, not only a novel device could improve TAVI for large annuli. Recent research from Gada *et al.*

assessed how a cusp overlap technique (COT) would change outcomes of TAVI with Evolut R 34 regarding the need for PPM implantation. According to the authors, the pacemaker implantation rate in those patients reached 16.7%. In our database, we had a much lower rate: 8.16% and 0% in Group I and Group II, respectively. Thus, a different approach to valve implantation itself could alter this outcome. As the authors describe, the cusp overlap view is achieved by overlapping the left and right coronary cusps in the RAO plane, which then provides an adequate anatomical reference for deployment depth at the point of contact, with good reference to the conduction system. As a result, only 5.2% of patients needed a PPM implantation after TAVI, and 3.9% had moderate PVL (according to our data, a moderate PVL was found in 7.89% of patients assessed on echo). As the authors conclude, this approach, when standardized, could be useful in lowering the risk of AV blocks due to the impairment of the conduction system during TAVI [14]. Our centre started using this technique on 3 July 2020.

Several limitations of this study must be taken into consideration.

1. It used a retrospective study design.
2. It is a single-centre study.
3. We were able to analyse a relatively small population of patients in the group with the Evolut 34 valve.
4. Nowadays, an equivalent of Evolut-Pro for the size 34 Evolut prosthesis has become available (Evolut 34+), which may potentially diminish the PVL rate observed in patients receiving this valve. This model, however, was not available when the studied patients were treated.

Conclusions

TAVI procedures in patients assigned an Evolut R 34 prosthesis are more complex and technically more demanding. The procedures are generally longer, have longer fluoroscopy time and require more post-dilatations. The outcomes are affected by more paravalvular leaks, although usually moderate. Overall outcomes, however, in the whole study group are acceptable, and the clinical outcomes are similar in patients requiring both big and smaller valves. Nevertheless, device success is lower in bigger valves, chiefly due to paravalvular leaks. Further investigations and studies focused on this issue are warranted.

Conflict of interest

The authors declare no conflict of interest.

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