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ORIGINAL ARTICLE

Aortic annulus angulation does not attenuate procedural success of transcatheter aortic valve replacement using a novel self-expanding bioprosthesis

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Abstract
The objectives of the study were to evaluate the impact of aortic angulation (AA) on success of transcatheter aortic valve replacement (TAVR) with a new generation self-expandable prosthesis (Medtronic Evolut R®). Specific anatomical conditions, such as for example the presence of a horizontal aorta with elevated AA, have seemed to pose a significant challenge for the correct positioning and consequent functioning of self-expandable TAVR prostheses. We assessed 146 patients treated with Evolut R. AA was measured at computed tomography and two groups were identified using as cutoff the mean AA value. Acute outcomes were collected and compared. AA mean value was 49.6 ± 9.4° (AA ≥ 50°: 76 and AA < 50°: 70 patients). Risk profile (Logistic euroSCORE: AA ≥ 50°: 15.7; 75% IQR: 11.1–22.1 vs. AA < 50°: 14.7; 75% IQR: 10.7–24.0; $p = 0.8$) was equivalent. Perioperative results were similar: valve resheathing (AA ≥ 50°: 21.0% vs. AA < 50°: 24.2%; $p = 0.6$), recapturing (AA ≥ 50°: 19.7% vs. AA < 50°: 25.7%; $p = 0.3$), fluoroscopy time (AA ≥ 50°: 11.1 IQR: 8.6–17.0 min. vs. AA < 50°: 11.0 IQR: 8.0–15.7 min.; $p = 0.9$), and contrast agent use (AA ≥ 50°: 99.0 ± 41.8 ml. vs. AA < 50°: 104.2 ± 38.5 ml.; $p = 0.4$). At discharge, moderate paravalvular leak was present in 8/76 (10.5%) of the AA ≥ 50° and 6/70 (8.6%) of the AA < 50° ($p = 0.7$) patients. Severe paravalvular leak, implantation of a second valve, and/or conversion to surgery did not occur. Early safety (AA ≥ 50°: 7.8% vs. AA < 50°: 5.7%; $p = 0.6$) was similar in the two groups. AA did not affect procedural outcomes and valve performance of the Evolut R prosthesis.

Keywords Transcatheter · Prosthesis · Aorta · Angle · Self-expandable

Introduction

Transcatheter aortic valve replacement (TAVR) has become a valid tool to treat patients with severe aortic valve stenosis (AVS) at risk for conventional aortic valve replacement (AVR). There are specific anatomical conditions, such as for example the presence of a horizontal aorta with elevated aortic angle (AA), that may pose a challenge for the correct positioning and consequent functioning of self-expandable TAVR prostheses [1, 2]. The designing of new generation self-expandable prostheses has been aimed at facilitating the procedure, reducing its risks and optimizing its results, even in challenging anatomical scenarios. In this context, the present manuscript investigates the impact of AA on procedural success of TAVR with a new generation self-expandable prosthesis, i.e., the CoreValve Evolut R® (Medtronic, Inc., Minneapolis, Minnesota).

Materials and methods

Detailed design characteristics of the Evolut R system have been already presented [3, 4]. The system includes the prosthesis (Evolut R) and the delivery system (EnVeo R) with

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the InLine sheath. The valve and sealing skirt are of porcine pericardium that has been sutured in a supra-annular position on a compressible and self-expandable nitinol frame. The prosthesis overall design and release system are basically unchanged from 23- to 34-mm size (except for profile and compatible sheath size). The device has the added features of valve resheathing and valve recapturing allowing for controllable and correctable valve positioning before final release.

All patients included in the present series had been diagnosed with symptomatic severe calcific AVS and underwent TAVR from March 2015 to March 2018.

During this period, a total of 470 TAVRs were performed by the same team using different prostheses. The present manuscript includes only those 146 patients undergoing TAVR with Evolut R prosthesis for whom complete preoperative and perioperative data were available, including detailed preoperative EKG-gated cardiac computerized tomography (CT) images, 3mensio ® (3mensio Medical Imaging BV, Bilthoven, NL) image reconstruction data (with AA calculation), and peri-procedural intra-hospital information. Starting from the CT images, an angiographic nadir view was derived with the 3mensio software and AA was defined as the angle between the AV annulus plane and the horizontal plane (Fig. 1).

Multi-slice program was used to derive dimensions of the aortic unit including aortic annulus, aortic root, aortic bulbus, and left ventricular outflow tract (LVOT). The aspect of the AV and the presence and distribution of AV calcification were assessed and classified (Mild, Moderate, and Severe AV calcification) as described in previous publications [5].

Patients with bicuspid AV and AV annular dimensions below or above the recommended limits proposed by the manufacturing company, as well as patients with previous AVR or TAVR were excluded from the present analysis.

A pre-shaped stiff-wire (Safari™®, Boston Scientific, Marlborough, Massachusetts, USA) was adopted in all patients. Valve resheathing was defined as intentional resheath of only a portion of the Evolut R bioprosthesis back into the capsule of the delivery catheter. Valve recapturing was defined as full resheath of the entire Evolut R bioprosthesis [3, 4].

Events were recorded according to the valve academic research consortium criteria (VARC) [6].

All patients had signed an informed consent to data collection and data handling. The study was purely observational in nature and for this reason submission to the local scientific/ethical committee was waved.

Statistical analysis

Data were prospectively collected, categorized, analyzed and are presented as absolute numbers, rates, mean ± standard deviation for normally distributed variables and median with 75% interquartile ranges (IQR) for non-normally distributed variables.

Two groups were identified using the overall cohort mean AA as cutoff value, as described in previous literature [2]. Group differences were investigated by means of Student's *t* test, Wilcoxon signed-rank test, χ-square, and Fisher's exact test, whenever appropriate. A p value < 0.05 was considered as significant. The statistical calculations were run using the SPSS 11.0 software.

Results

A total of 146 patients were included in the study. The mean AA was 49.6 ± 9.4°. This value was used as cutoff to identify the two study groups (AA ≥ 50°: 76 and AA < 50°: 70 patients). Pre-procedural demographic, clinical, echocardiographic, and CT data were similar in the 2 groups, apart from a significantly steeper AA in the AA ≥ 50° group (Table 1).

Acute perioperative results are summarized in Table 2. A pre-implantation balloon aortic valvuloplasty was used

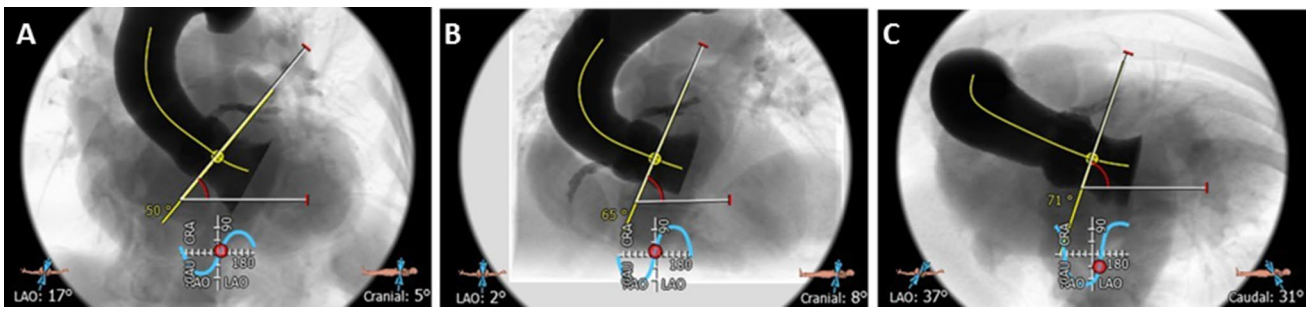

Fig. 1 Aortic Angulation (AA) was calculated starting from the CT images. An angiographic nadir view was derived with 3mensio and AA was calculated at the level of the aortic annulus and was defined as the angle between the AV annulus plane and the horizontal plane. **a** AA of 50°, **b** AA of 65°, **c** AA of 71°

Table 1 Preoperative clinical and CT data according to aortic angle (AA)

	AA ≥ 50° (76)	AA < 50° (70)	*p* value
Age (years)	82.3 ± 6.3	81.6 ± 6.2	0.5
Gender % (female/male)	54.3/45.7	67.1/32.9	0.1
LVEF%	52.0 ± 13.4	55.3 ± 13.0	0.2
AVA (cm^2)	0.6 ± 0.1	0.7 ± 0.2	0.4
Mean gradient (mmHg)	45.6 ± 5.5	42.7 ± 5.1	0.5
AR ≥ II	11 (14.4%)	7 (10.0%)	0.4
MR ≥ II	26 (34.2%)	17 (24.2%)	0.2
Logistic ES	15.7; 75% IQR: 11.1–22.1	14.7; 75% IQR: 10.7–24.0	0.8
ES II	3.8; 75% IQR: 2.5–6.1	4.3; 75% IQR: 2.9–6.1	0.5
STS score	4.0; 75% IQR: 2.6–6.0	4.3; 75% IQR: 2.6–6.7	0.1
AA°	56.7 ± 5.7	41.6 ± 5.6	< 0.000
Mean annulus diameter (mm)	24.1 ± 2.3	24.2 ± 2.0	0.8
LVOT diameter (mm)	23.7 ± 2.5	23.2 ± 2.6	0.3
Bulbus diameter (mm)	30.2 ± 4.6	29.7 ± 2.8	0.6
Degree of AV calcification (%)			
Mild	13.2	17.1	0.4
Moderate	36.8	42.9	
Severe	50.0	40.0	

LVEF left ventricular ejection fraction, *AVA* aortic valve area, *AR* aortic regurgitation, *MR* mitral regurgitation, *ES* euro-SCORE, *STS* Society of Thoracic Surgeons, *LVOT* left ventricular outflow tract, *AV* aortic valve

Table 2 Intraoperative findings according to aortic angle (AA)

	AA ≥ 50° (76)	AA < 50° (70)	*p* value
General anesthesia (%)	42 (55.2)	43 (61.4)	0.4
Implanted valve size			
23	6 (7.9)	0	0.02
26	13 (17.1)	22 (31.4)	
29	43 (56.6)	39 (55.7)	
34	14 (18.4)	9 (12.9)	
Prosthesis/annular sizing (%)	19.6 ± 7.3	19.2 ± 6.0	0.7
Pre-BAV (%)	28 (36.8)	39 (55.7)	0.02
Post-BAV (%)	11 (14.5)	8 (11.4)	0.5
Resheathing (%)	16 (21.0)	17 (24.2)	0.6
Recapturing (%)	15 (19.7)	18 (25.7)	0.3
Contrast agent amount (ml)	99.0 ± 41.8	104.2 ± 38.5	0.4
Fluoroscopy time (min)	11.1; 75% IQR 8.6–17.0	11.0; 75% IQR 8.0–15.7	0.9
Radiation dose (μGycm^2)	5986.0; 75% IQR 4135.0–9037.0	5370.4; 75% IQR 3768.2–7485.5	0.7
Evolut R nadir LCS[a] (mm)	6.3 ± 2.1	6.3 ± 2.3	0.9
Evolut R nadir NCS[a] (mm)	3.1 ± 1.8	3.8 ± 2.0	0.3

BAV balloon aortic valvuloplasty, *LCS* left coronary sinus, *RCS* right coronary sinus

[a]Measured after final valve release using the implantation projection as reference

more often in patients with AA < 50° (AA ≥ 50°: 28/76 36.8% vs. AA < 50°:39/70 55.7%; $p = 0.02$). Prosthesis implantation was mainly performed under a short period of rapid ventricular pacing (160–180 bpm). Although mean prosthesis size (AA ≥ 50°: 28.9 ± 3.0 mm vs. AA < 50°: 28.7 ± 2.4 mm; $p = 0.6$) and prosthesis size/native annulus size (AA ≥ 50°: 19.6 ± 7.3% vs. AA < 50°:19.2 ± 6.0%; $p = 0.7$) were similar in the two groups, there was a different distribution of implanted prosthesis size within the two groups (Table 2).

Prosthesis resheathing (AA ≥ 50°: 21.0% vs. AA < 50°: 24.2%; $p = 0.6$) and recapturing (AA ≥ 50°: 19.7% vs. AA < 50°: 25.7%; $p = 0.3$) occurred with similar rates in the two AA groups. Post-implantation balloon valvuloplasty to treat > grade I residual paravalvular leak was necessary in 14.5% of the AA ≥ 50° and in 11.4% of the AA < 50° patients ($p = 0.5$).

Eight patients had an AA ≥ 70° (Figs. 2, 3).

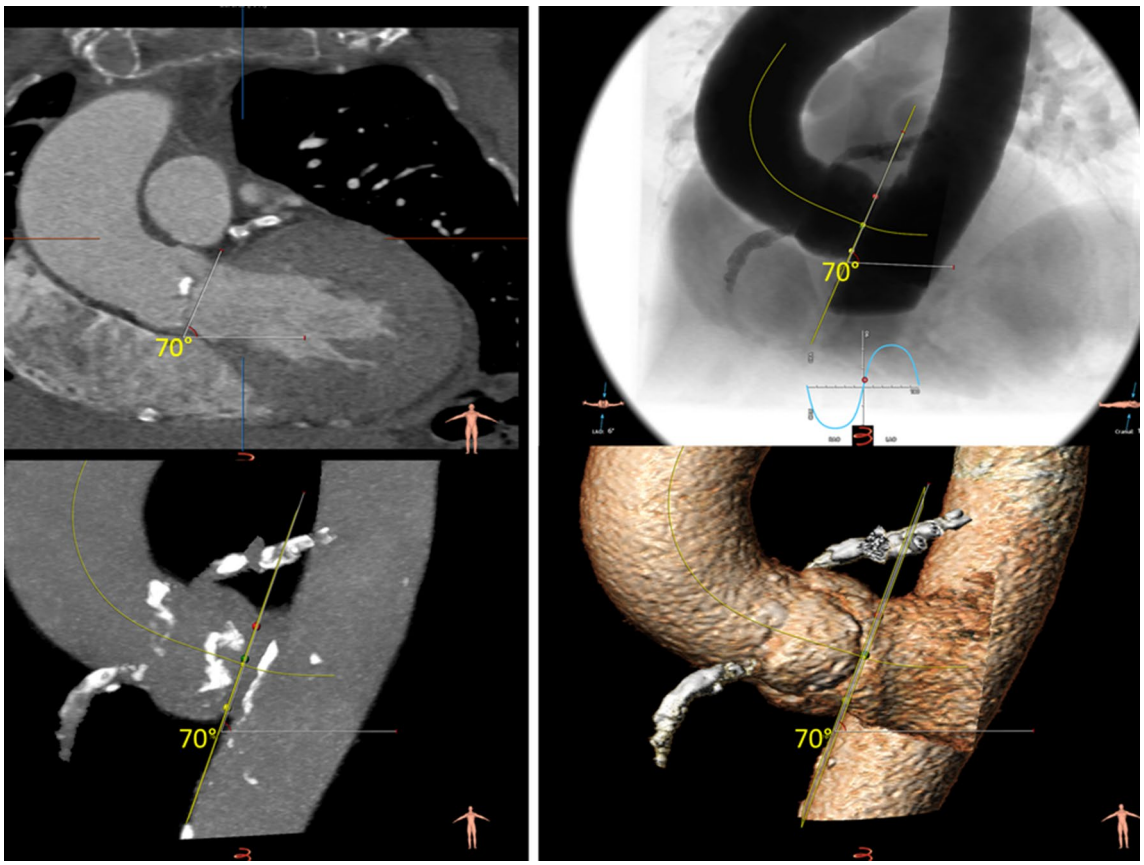

Fig. 2 Pre-procedural CT imaging of a transcatheter aortic valve replacement candidate with an aortic angle of 70° (CT coronal multiplanar reconstruction, angiographic nadir view, calcifications enhanced view, 3-D reconstruction)

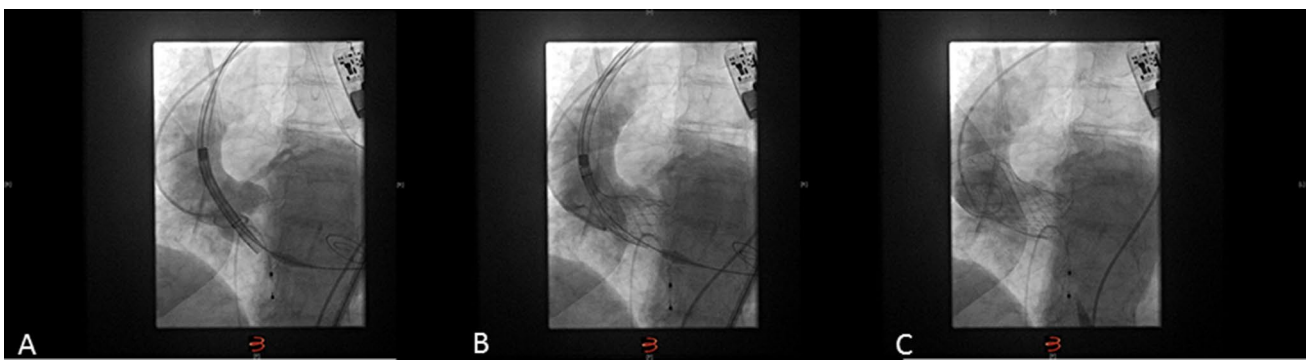

Fig. 3 Intraoperative transcatheter aortic valve replacement (Evolut 29 mm) fluoroscopic images of the same patient. **a** Prosthesis unsheathing is started with the distal part of the nitinol frame at the level of the aortic annulus (non-coronary sinus). As a result of the aortic angulation, the marker pigtail is displaced in the right coronary sinus. Note the use of a pre-shaped stiff wire that is pushed to the left ventricular apex. **b** Angiographic control before complete prosthesis release. At this stage, the system has centralized itself within the angulated aortic annulus. The distal part of the nitinol frame has achieved contact at the level of both the non-coronary (annular level) and left coronary (few millimeters below the annulus) sinuses. **c** Final angiographic control confirming good valve position and function with a mild paravalvular leak at the level of the left coronary sinus (confirmed at control echocardiography)

Table 3 Procedural outcomes at 30 days according to aortic angle (AA)

	AA ≥ 50° (76)	AA < 50° (70)	*p* value
Early safety (%)	6 (7.8)	4 (5.7)	0.6
All-cause mortality (%)	3 (3.9)	2 (2.8)	0.7
All stroke (%)	2 (2.6)	1 (1.4)	0.6
Major vascular complications (%)	6 (7.8)	4 (5.7%)	0.6
AKI ≥ 2 (%)	2 (2.6)	1 (1.4)	0.6
Valve dysfunction with repeat procedure (%)	0	0	
Life threatening bleed (%)	5 (6.6)	3 (4.2)	0.5
Coronary artery occlusion (%)	0	0	
New PPMI (%)	12/65 (18.4)	10/55 (18.1)	0.9
Hospitalization length (days)	10.8 ± 6.0	9.0 ± 4.5	0.2

AKI acute kidney injury, *PPMI* permanent pacemaker implantation

Table 4 Echocardiographic data according to aortic angle (AA)

	AA ≥ 50°	AA < 50°	*p* value
Paravalvular AR 0 (%)	46 (60.5)	44 (62.9)	0.7
Paravalvular AR I (%)	22 (28.9)	20 (28.6)	
Paravalvular AR II (%)	8 (10.5)	6 (8.6)	
Mean aortic gradient (mmHg)	7.3 ± 2.3	6.1 ± 3.0	0.2

AR aortic regurgitation (measured at last echocardiography available before discharge)

Table 5 Intraoperative and echocardiographic data according to aortic angle (AA ≥ 70° and AA < 70°)

	AA ≥ 70° (8)	AA < 70° (138)	*p* value
Resheathing (%)	1 (12.5)	32 (23.1)	0.4
Recapturing (%)	1 (12.5)	32 (23.1)	0.4
Paravalvular AR 0 (%)	5 (62.5%)	85 (61.6%)	0.9
Paravalvular AR I (%)	2 (25.0%)	40 (29.0%)	
Paravalvular AR II (%)	1 (12.5%)	13 (9.4%)	

AR aortic regurgitation (measured at last echocardiography available before discharge)

Maximal depth of the prosthetic frame within the native annulus (nadir) was routinely measured from the last contrasted angiography in the valve release fluoroscopic projection. Nadir depths were similar in the two groups (Table 2).

Median fluoroscopy time (AA ≥ 50°: 11.1; IQR: 8.6–17.0 min. vs. AA < 50°: 11.0; 75% IQR: 8.0–15.7 min.; $p = 0.9$), and contrast agent amount (AA ≥ 50°: 99.0 ± 41.8 ml. vs. AA < 50°: 104.2 ± 38.5 ml.; $p = 0.4$) were similar in the two groups. No patient required a second valve and no conversion to standard aortic valve replacement was necessary.

Complications rate (VARC) were similar in the two groups (Table 3). Early safety (AA ≥ 50°: 7.8% vs. AA < 50°: 5.7%; $p = 0.6$) was similar in the two groups. There were no intraoperative deaths.

The 30-day all-cause mortality was 3.9% (3/76) in the AA ≥ 50° vs. 2.8% (2/70) in the AA < 50° group ($p = 0.7$).

Table 4 summarizes echocardiographic findings at hospital discharge. No severe paravalvular leaks were reported. Moderate paravalvular leak was present in 8/76 (10.5%) of the AA ≥ 50° and 6/70 (8.6%) of the AA < 50° patients ($p = 0.7$). No prosthetic valve dysfunction was reported and mean trans-valvular gradient was similar in the 2 groups (AA ≥ 50°: 7.3 ± 2.3 mmHg vs. AA < 50°: 6.1 ± 3.0 mmHg; $p = 0.2$). Valve effective orifice area was not routinely measured and, for this reason, no VARC device success rate could be derived.

In a sub-analysis, we have focused on eight patients with AA ≥ 70°. Re-sheathing/re-capturing and final prostheses hemodynamics were comparable even in these patients with extreme AA (Table 5).

Discussion

Specific anatomical features of the aortic unit may represent a challenge for TAVR. Although in a limited number of published experiences, the presence of a horizontal aorta with increased AA has been described as adversely influencing TAVR outcomes with self-expandable prostheses [1, 2]. Sherif et al. were the first to propose a possible relationship between AA and residual paravalvular leak after TAVR with the first generation Medtronic Core valve [1]. In their series, the angle between the axis of the LVOT and the first tract of the ascending aorta (measured at angiography) was the strongest independent determinant of paravalvular regurgitation [1]. At receiver operating characteristic (ROC) statistics, a cutoff value of 25° predicted the occurrence of paravalvular leak. The authors suggested using alternative TAVR prostheses (balloon expandable) in patients with angles > 25° [1].

More recently, Abramowitz et al. have assessed the impact of AA (defined and measured as in our protocol)

upon outcomes of TAVR with balloon expandable and self-expandable prostheses [2].

Although AA did not influence acute procedural success and/or short-term clinical outcome of two groups of TAVR patients (AA < 48° and AA ≥ 48°) treated with a balloon-expandable prosthesis, an increased AA (AA ≥ 48°) was found to negatively impact upon procedural success of 102 TAVR patients treated with the self-expandable Medtronic CoreValve [2]. The authors suggested that the shorter frame of the balloon-expandable prosthesis together with the active flexion of its catheter provided greater flexibility and less resistance to device advancement through an angulated aortic annulus [2]. ROC statistics confirmed that the numerical cutoff for AA with the highest sum of sensitivity and specificity for device success was ≥ 48° (sensitivity 85%, specificity 61%) [2].

Some operative tools have been proposed to facilitate TAVR in the presence of an angulated aorta. The "buddy balloon technique" may for example enhance the advancement of the undeployed valve into the annulus [7]. Moreover, mounting a snare catheter onto the delivery system may help exerting traction during valve release to better center the valve within the native annulus [8].

Although these ingenious strategies have shown to be of help in skilled hands, none was used in the present patients´ series. In fact, the designing of new generation prostheses is aimed at facilitating and standardizing the TAVR procedure even in the most challenging anatomical scenarios.

In this context, the fourth-generation Evolut R includes a 14-F or 16-F equivalent EnVeo R Deliver Catheter System, a modified nitinol design at the annulus level, a longer porcine pericardial sealing skirt, and a nitinol delivery catheter capsule that allows resheathing and recapturing. Moreover, the overall height of the Evolut nitinol frame is approximately 10% shorter than the original Medtronic CoreValve frame. All these added features have been specifically addressed to optimize implantation and fit, even in difficult native anatomy.

The acute safety and clinical performance of the CoreValve Evolut R TAVR system have been confirmed in the Medtronic CoreValve Evolut R CE Mark Clinical Study [3] and the Evolut R U.S. Study [4]. Thanks to the technical ameliorations of the new device, the rate of moderate/severe paravalvular leak has been reduced to less than 5% and the necessity for a second prosthesis to 1% [3, 4]. The overall success needs now to be tested in more specific and challenging anatomical scenarios like, for example, in the presence of an angulated aorta.

In our present report, we have shown that the Evolut R has allowed for precise positioning and satisfactory hemodynamic performance even in steeper AAs. The 50° AA value that we have used as cutoff for our sub-group analysis is slightly higher than the 48° AA cutoff proposed by Abramowitz et al. [2].

There are some technical points to be discussed when dealing with an angulated aortic annulus during TAVR. In this specific anatomical condition if the delivery prosthesis system is not flexible enough, valve self-centering may be hampered. Moreover, anticipating the valve nitinol frame final depth at the level of the non-hinge point (left coronary sinus) may result difficult. The shorter stent frame of the Evolut R valve, the increased trackability of the catheter, and the possibility of performing a slow/controlled release may all lead to a greater system flexibility resulting in less resistance to device advancement and better prosthesis self-centering within the angulated annulus. In addition, prosthesis self-centering within the native annulus during release is also affected by the adopted supporting wire. More specifically, in the entire experience herein presented, we have used pre-shaped stiff wires (Boston Scientific Safari), adequately sized according to the patient ventricular dimension (large, small, extra-small). This may have contributed to enhance the procedure by making the angle between the catheter and the native annulus more perpendicular and centralizing the catheter and prosthesis before and during the release. When looking more specifically at our findings, we have been able to treat successfully even eight patients with AA ≥ 70° (Figs. 2, 3). Although they represent just a fraction of the overall cohort herein discussed, patients with such an extreme anatomy had been previously excluded from trials with earlier generation self-expandable prostheses [9].

The feature of resheathability may be of particular advantage in angled aortic anatomies. In truth, the resheath/recapture mechanism has been used with equal frequencies in both AA groups and we have adopted this possibility even multiple times (maximum of 3 recapturing), always while maintaining adequate hemodynamics. We have experienced that at least a fifth of patients will benefit from resheathing/recapturing and optimized repositioning. Although this rate is slightly higher than that proposed in the previous literature [3, 4], we have never experienced damaging of the resheathing mechanism and of the prosthetic structure.

Finally, the presence of a more angulated aorta has not resulted, in our experience with the Evolut R, in a significant increase in operative time, radiation exposure, and contrast agent use.

Most importantly, prosthesis performance at discharge did not appear to be influenced by AA and we were able to achieve a similar prosthesis implantation depth in both groups.

Although the 10.5% moderate paravalvular leak rate we have observed in patients with AA ≥ 50° is more than twice of that reported in prospective trials with the Evolut R [3, 4], we have noticed a similar rate of 8.6% in patients with AA < 50°.

Moreover, while we were not able to specifically calculate the cumulative VARC endpoint of device success (mainly for lack of consistent measurements of prosthesis area), we did not require any second valve implantation, no prosthesis dysfunction was reported, and the early safety of the procedure was similar to those reported in previous literature [3, 4] and was consistent in the two AA groups.

Limitations

The present study includes a limited number of patients and, although we were able to identify two similarly sized groups using the AA cutoff of 50°, the number of patients with extremely angulated aortas ($\geq 70°$) was limited. In reality, this ratio represents the anatomical pattern of patients nowadays referred for TAVR.

Conclusion

To the best of our knowledge, this is the first report focusing upon Evolut R performance according to AA. Data represent a real-world single institution experience with this newly introduced device. When adopted within the premises of teams that have already a wide experience with TAVR, the Evolut R system has shown satisfactory acute clinical and hemodynamic results for the treatment of patients with severe AV stenosis, independently of the AA degree.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

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