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Valve in valve implantation of the CoreValve Evolut R in degenerated surgical aortic valves

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Abstract

Background: *The new CoreValve Evolut R has an improved design to minimize paravalvular leakage and allows repositioning of the valve. For patients with degenerated bioprosthetic aortic valves, transcatheter aortic valve implantation (TAVI) represents a less invasive option. Herein reported are valve-in-valve (ViV) implantations of this new valve.*

Methods: *A total of 26 patients (mean age 79.4 ± 6.1 years, 17 males and 9 females) were treated for severe prosthesis stenosis (n = 9), severe regurgitation (n = 8) or severe combination of stenosis and regurgitation (n = 9). All patients underwent transthoracic echocardiography before and after ViV implantation.*

Results: *Valve-in-valve implantation of a CoreValve Evolut R was performed successfully in all patients. The mean transaortic gradient for stenotic valves determined by transthoracic echocardiography was reduced significantly from 37.5 ± 15.3 mmHg in patients with prosthesis stenosis to 16.3 ± 8.2 mmHg ($p < 0.001$). In all cases with severe prosthesis regurgitation, regurgitation was reduced to none or mild. All-cause mortality after 30 days was 0%.*

Conclusions: *It was concluded that CoreValve Evolut R is well suited for ViV implantation.* (Cardiol J 2018; 25, 3: 301–307)

Key words: aortic valve, transcatheter aortic valve implantation, valve-in-valve

Introduction

For patients with a degenerated bioprosthetic heart valve, transcatheter aortic valve implantation (TAVI) is a less invasive treatment option. A reoperation of these mostly elderly patients with frequent comorbidities is associated with a higher perioperative mortality [1]. Some experience with valve-in-valve (ViV) implantation of the balloon-expandable Edwards Sapien XT valve and the self-expandable Medtronic CoreValve system has already been published [2, 3]. However, data on the new Medtronic CoreValve Evolut R valve is scarce [4, 5].

The new Medtronic CoreValve Evolut R has an improved design to minimize paravalvular leakage. In addition, its new delivery system allows for repositioning of the valve [6]. Herein are reported 26 cases of degenerated aortic bioprostheses managed with CoreValve Evolut R.

Methods

Since 2009, more than 1700 patients underwent TAVI in the documented center. From April 2013 to October 2017, 26 patients were treated for a failing surgical aortic valve with a CoreVave Evolut R. All patients presented with severe comorbidities preferring an interventional approach as determined by an interdisciplinary heart team (Table 1). In all patients, transesophageal echocardiography was performed to determine valve pathology prior to the procedure. The aortic annulus diameter was measured in the mid-esophageal long-axis view and/or by computed tomography. In all cases a transfemoral access was used.

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Table 1. Baseline parameters.

Patient	Age [years]	Sex	BMI [kg/m^2]	EuroScore [%]	STS [%]	Systolic PAP [mmHg]	MR [grade]	TR [grade]	EF [%]	Comorbidities
1	93	Male	25.4	37.4	15.6	69	II	II	60	Pacemaker, chronic kidney failure, pulmonary hypertension, previous GI-bleeding, permanent atrial fibrillation, previous penumonia
2	73	Female	29.4	40.4	6.3	88	III	III	40	Chronic obstructive pulmonary disease, TR III, MR III
3	82	Male	23.5	20.3	4.9	55	I	III	45	Chronic kidney failure, MR III, pacemaker, coronary bypass surgery
4	78	Female	27.0	43.0	5.3	60	II	II	20	Gastrointestinal bleeding
5	73	Female	26.5	21.5	5.1	36	I	I	50	Pacemaker, coronary bypass surgery, replacement of ascending aorta, closure of ventricular septal defect
6	82	Male	24.6	8.4	4.5	41	I	I	50	CKD, reconstruction of mitral valve
7	76	Female	23.7	12.8	10.9	85	I	0	35	CAD, chronic kidney failure
8	81	Female	28.3	28.0	9.3	76	II	II	60	Pacemaker, atrial fibrillation, GI-bleeding, COPD
9	85	Male	26.3	15.4	4.9	NA	0	0	60	Coronary artery bypass surgery
10	82	Male	25.2	26.2	4.0	80	I	II	45	Coronary artery bypass surgery, COPD with pulmonary hypertension
11	77	Female	26.1	5.3	5.8	32	0	0	60	After two thoracotomies, postoperative wound healing disorder, CAD
12	67	Male	38.0	12.9	4.5	30	II	II	45	CRT-D, CAD, chronic kindney failure
13	71	Male	25.6	3.2	4.5	30	II	III	36	Pacemaker, coronary bypass surgery, CKD, after two times surgical aortic valve replacement
14	84	Male	21.5	7.9	4.1	30	II	II	60	Coronary bypass surgery, ulcerative colitis, previous GI-bleeding
15	80	Male	30.9	17.7	5.6	66	II	II	45	CRT-D, coronary bypass surgery, pulmonary hypertension
16	81	Male	30.1	13.2	3.5	NA	I	0	60	CKD
17	71	Male	24.8	1.9	3.2	32	I	0	48	Bechterews disease, restrictive lung disease
18	86	Male	23.9	13.4	9.6	24	I	I	40	COPD, CKD, coronary bypass surgery
19	80	Male	31.2	14.5	7.5	NA	III	II	40	Coronary bypass surgery, GI bleeding
20	78	Female	27.8	14.3	4.9	62	I	I	42	Pulmonary hypertension, pacemaker
21	74	Male	33.6	16.9	4.6	31	I	I	55	Pacemaker, coronary bypass surgery, severe paravalvular leakage

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Table 1. (cont). Baseline parameters.

Patient	Age [years]	Sex	BMI [kg/m^2]	EuroScore [%]	STS [%]	Systolic PAP [mmHg]	MR [grade]	TR [grade]	EF [%]	Comorbidities
22	88	Male	21.5	19.5	11.5	NA	II	I	40	Chronic kidney failure, CAD, insulin--dependent diabetes, peripheral arterial disease
23	76	Male	36.0	10.5	3.4	36	I	I	20	Coronary bypass surgery, insulin-dependent diabetes
24	90	Female	24.7	12.6	6.7	29	I	I	60	Chronic kidney failure
25	81	Male	28.4	20.6	8.0	70	II	I	60	Atrial fibrillation, Insulin-dependent diabetes, peripheral arterial disease, status post lung cancer
26	75	Female	24.0	11.0	2.7	38	II	I	40	CAD, atrial fibrillation

BMI — body mass index; CAD — coronary artery disease; CRT-D — cardiac resynchronization therapy with defibrillator; COPD — chronic obstructive pulmonary disease; CKD — chronic kidney disease; EF — ejection fraction; GI — gastrointestinal; MR — mitral regurgitation; NA — not applicable; PAP — pulmonary artery pressure: STS — Society of Thoracic Surgeons; TR — tricuspid regurgitation

A clinical examination, an electrocardiography and a transthoracic echocardiography were performed before TAVI and before discharge.

TAVI was performed in a specially equipped hybrid suite under general anesthesia by an interdisciplinary heart team consisting of a cardiac surgeon, a cardiologist and an anesthesiologist. All relevant baseline, procedural, and follow-up data were collected retrospectively.

A total of 26 patients (mean age 79.4 ± 6.1 years, 17 male and 9 female) were treated for degenerated aortic prosthesis following surgical aortic valve replacement. The exact type of surgical bioprosthesis are listed in Table 2. Severe aortic stenosis was defined as an effective aortic orifice area (EOA) < 1 cm^2. 7 prostheses showed a high-grade stenosis, 7 prostheses had severe aortic regurgitation and 7 showed high grade stenosis combined with serve aortic regurgitation. The elevated surgical risk is underscored by the STS score for risk of mortality (6.2 ± 3.0%) and EuroScore II (17.3 ± 10.5%). All patients were analyzed for 30 day survival.

Statistical analysis

Wilcoxon matched pairs signed rank test for statistical significance (GraphPad Prism 6, La Jolla, CA, USA) was performed. A p-value < 0.05 was considered to be statistically significant. When appropriate, data are presented as box plots with the boundaries of the box as the 75th and 25th percentiles, and with a line in the box indicating the median. Whiskers above and below the box mark maximum and minimum values, respectively.

Compliance with ethical standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Results

The ViV implantation of the CoreValve Evolut R was performed successfully in all patients. In 18 patients, an Evolut 23 mm was used, 5 patients received an Evolut 26 mm, 2 patients received an Evolut 29 mm and 1 patient received an Evolut 34 mm. The mean transaortic gradient determined by transthoracic echocardiography was reduced significantly from 37.5 ± 15.3 mmHg in patients with prosthetic stenosis to 16.3 ± 8.2 mmHg ($p < 0.001$)

Table 2. Baseline and post transcatheter aortic valve implantation (TAVI) characteristics

	Aortic valve characteristics										
	Type of surgical bioprosthesis	Time since valve replacement [years]	CoreValve Evolut [mm]	Baseline				Post TAVI			
				EOA [cm^2]	Max. gradient [mmHg]	Mean gradient [mmHg]	AR [grade]	EOA [cm^2]	Max. gradient [mmHg]	Mean gradient [mmHg]	AR [grade]
1	Hancock II 23	21	23	0.7	58	31	I	1.2	24	13	I
2	MitroFlow 21	28	23	1.0	47	26	II	1.1	29	17	0
3	Hancock 23	4	23	1.3	32	19	II	1.5	29	14	I
4	Carpentier 23	12	23	0.5	102	67	III	1.2	36	21	I
5	Carpentier 19	12	23	0.7	51	30	0	0.7	51	34	I
6	Carpentier 23	10	23	0.4	92	74	0	2.4	17	10	I
7	MitroFlow 21	10	23	1.2	28	14	III	1.2	28	15	0
8	Labcor 21	3	23	0.8	110	52	0	1.3	67	35	0
9	Baxter Prima 25	17	26	NA	NA	NA	III	1.9	13	6	0
10	Hancock 23	9	23	0.9	88	46	III	1.7	37	20	I
11	MitroFlow 21	7	23	1.5	41	25	III	1.2	51	25	I
12	Hancock II 23	11	23	0.9	43	25	III	1.2	28	15	0
13	MitroFlow 23	8	23	0.8	48	31	0	1.6	22	12	I
14	Carpentier 23	12	23	0.9	57	33	I	1.4	23	15	0
15	Hancock II 25	10	23	0.8	75	35	I	1.6	25	12	0
16	Carpentier 23	16	23	1.5	38	NA	III	1.3	44	23	I
17	Perimount 25	12	26	0.9	64	46	II	1.9	10	5	I
18	Elan 25	15	26	1.8	12	6	III	1.9	7	4	0
19	BaxterPrimo 27	16	29	NA	NA	NA	III	1.4	14	9	I
20	Freedom 25	6	29	0.5	71	45	II	1.3	19	10	0
21	Elan 27	8	34	2.6	21	9	III	3.0	18	9	I
22	Sapien 3 26	7	26	1.3	38	20	II	4.5	10	5	I
23	Carpentier 23	12	23	0.6	43	25	I	1.4	32	20	I
24	MitroFlow 23	13	23	0.7	79	42	0	1.4	37	15	0
25	Hancock II 23	6	23	NA	36	23	III	NA	9	5	0
26	MitroFlow 23	6	23	1.0	52	28	II	1.2	39	21	I

AR — aortic regurgitation; EOA — effective oriffice area; NA — not applicable

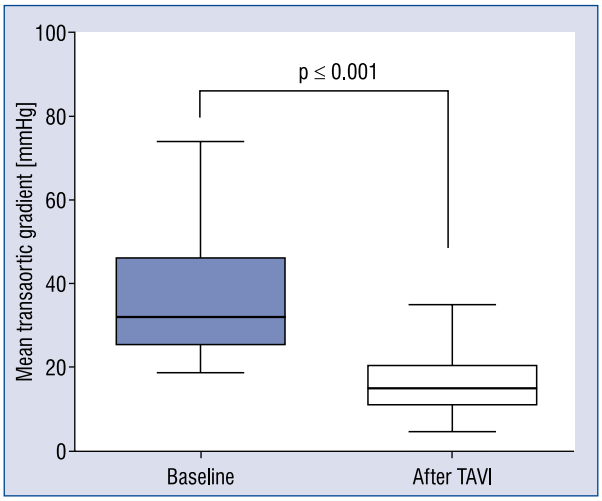

Figure 1. Mean pressure gradients at baseline and after valve-in-valve transcatheter aortic valve implantation (TAVI) ($p < 0.001$).

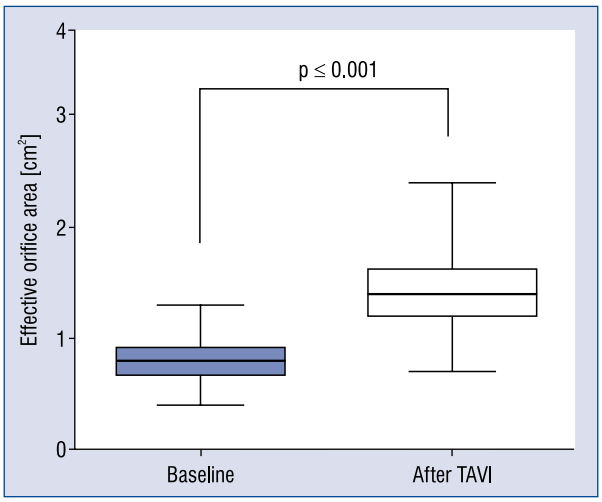

Figure 2. Effective orifice area at baseline and after valve-in-valve transcatheter aortic valve implantation (TAVI) ($p < 0.001$).

(Fig. 1). The EOA increased from 0.8 ± 0.2 cm^2 in patients with prosthesis stenosis to 1.5 ± 0.4 cm^2 ($p < 0.001$) (Fig. 2). In all cases with severe aortic regurgitation, the regurgitation was reduced to none or mild regurgitation. There was no case of moderate or severe regurgitation after ViV. In 3 patients, a postdilatation was performed due to excessive calcification. The mean EOA was 1.4 ± ± 0.4 cm^2 for the 23 mm Evolut valve that was used the most.

In 3 patients, implantation of a permanent pacemaker was necessary. In 2 patients (No. 9 and No. 21) pacemaker implantation was necessary due to a complete atrioventricular block after TAVI. In these cases, the CoreValve Evolut R had to be implanted deep into the left ventricular outflow tract to avoid obstruction of the right coronary artery for patient 9 and to cover a paravalvular regurgitation in patient No. 21. In 1 patient, the pacemaker was implanted due to symptomatic sick sinus syndrome 6 days after ViV. In all other cases, no new conduction disturbances were observed.

In patient No. 5, the CoreValve Evolut R dislocated into the ascending aorta after deployment. A second CoreValve Evolut R was implanted into the surgical valve fixating the first valve in the ascending aorta without obstruction of the brachiocephalic artery. In this patient, a reduction of the mean transaortic gradient was not accomplished.

In 4 patients (No. 7, 11, 16 and 26), the transaortic gradient was not reduced or even increased slightly. In these patients a combination of stenosis and regurgitation was an indication for ViV. The regurgitation was reduced effectively in all patients. In these patients, a short acceleration time of the transaortic outflow (< 100 ms) was measured before TAVI suggesting a prosthesis-patient mismatch in addition to valve degeneration as the reason for elevated gradients. Since all patients were considered unfit for surgery, the interdisciplinary heart team recommended TAVI to reduce regurgitation.

Further complications included 2 strokes in patients No. 21 and No. 18. In both patients neurological symptoms regressed spontaneously.

In patient No. 18, periprocedural obstruction of the left coronary artery had to be treated with by stent implantation in the left main stem.

All patients were discharged after an average postoperative stay of 10 ± 8 days. All-cause mortality after 30 days was 0%.

Discussion

Trancatheter ViV implantation for failing surgical aortic valves represents an advantageous option for high risk patients. The CoreValve Evolut R is a new generation valve with approval for ViV implantation.

Insufficient reduction of the transaortic gradients after TAVI is a major problem for ViV implantations in small surgical valves — especially in patients with prosthesis-patient mismatch [7]. Accordingly, 4 patients in this study with prosthesis-patient mismatch, transaortic gradient could not be improved significantly. In these patients, however, the indication for ViV was a mix of aortic

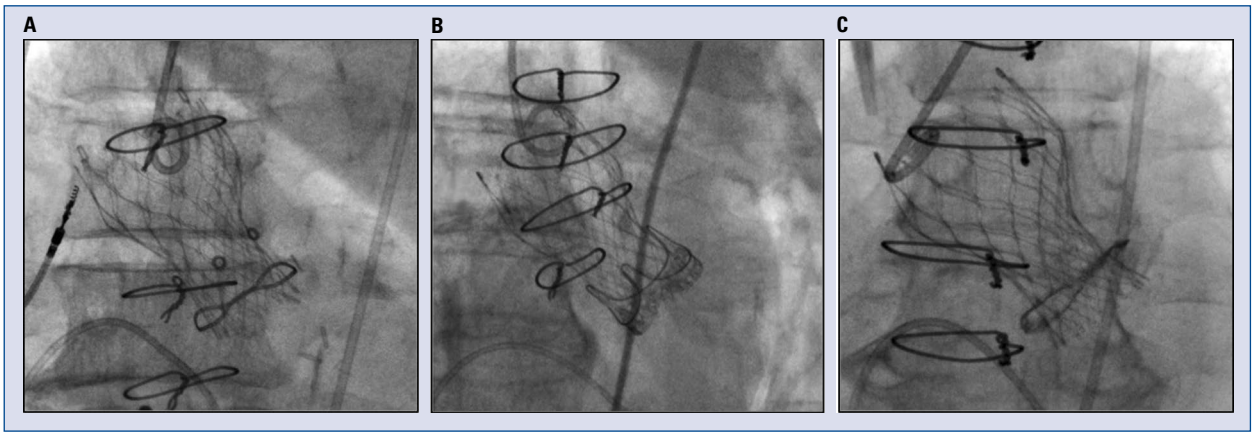

Figure 3. Examples of valve-in-valve implantations in patients with different surgical bioprostheses; **A.** Hancock; **B.** Carpentier; **C.** MitroFlow.

valve disease with predominant aortic regurgitation which was sufficiently reduced. Nevertheless, ViV implantations in patients with suspected prosthesis-patient mismatch should be reserved for patients with very high operative risk. The rate of insufficient reduction of the transaortic gradient was 19% and therefore comparable with the rate for postprocedural elevated gradients in small valves of 23.4% for a previous generation of self-expanding valves [8].

Moderate or severe paravalvular regurgitations were not observed in any cases. While clearly limited by the low number of patients included, the present data suggests that the new CoreValve Evolut R is suited for successful interventional treatment of degenerated surgical prosthetic valves. This is an improvement over data for the older generation of self-expanding valves with a rate for at least moderate regurgitation of 8.9% [8].

Despite the high EuroScore II and STS score no patient died within 30 day follow-up.

According to the available literature, ViV implantations are associated with a lower incidence of relevant conduction disturbances — most likely due to the ability of rigid rings of stented surgical valves which prevent pressure load on the atrioventricular conduction system during TAVI [7]. In 2 patients, complete atrioventicular block occurred after ViV and permanent pacemaker implantation was performed. Notably, a stentless Baxter Prima 25 mm was the degenerated surgical valve in 1 patient and a very deep implantation of Evolut was necessary to avoid obstruction of the right coronary artery. In the other patient, again a stentless Elan 27 mm valve was the degenerated surgical valve and a very deep implantation of the Evolut R was necessary to cover paravalvular regurgitation. Both factors likely contributed to heart block in our patients as we have previously shown that deeper implantation is associated with higher risk for permanent pacemaker implantation in patients receiving an Edwards Sapien 3 [9]. The third pacemaker was implanted due to, most likely preexisting, sick sinus syndrome. This rate is comparable to the rate of permanent pacemaker implantation after ViV procedure with previous generations of self-expanding valves [8].

In one other patient, the ViV implantation did not reduce the transaortic gradient. In this patient, a first CoreValve Evolut R dislocated into the ascending aorta after supraannular implantation. A second valve was placed intraannularly and thereby both replaced the degenerated aortic prosthesis and fixated the first valve. In addition, in this patient the surgical valve was a 19 mm Carpentier aortic valve. In preoperative computed tomography-scan, an internal diameter of 18 mm was measured. The combination of a small surgical valve and the necessity of two transfemoral valves probably resulted in an unchanged gradient over the aortic valve. This result is comparable with the literature for the previous generation of self-expanding ViV procedures with a rate which required a second valve of 7.5% [8].

In general, current literature suggests that an intraanular placement of the valve may result in residual stenosis due to incomplete expansion and leaflet distortion. Accordingly, a supraannular placement of the valve in ViV implantations should be performed to optimize EOA as shown in Figure 3 [10].

Conclusions

It is concluded that the CoreValve Evolut R is well suited for ViV implantation. In patients with high surgical risk, transcatheter ViV implantation represents a beneficial option with low periprocedural complications. Promising early results should be confirmed by a larger series with long-term follow up.

Conflict of interest: None declared

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