

Self-expandable transcatheter aortic valve implantation for aortic stenosis after mitral valve surgery

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Abstract

OBJECTIVES: Transcatheter aortic valve implantation has emerged as a valuable option to treat patients with symptomatic severe aortic stenosis, who are not being considered for surgery because of significant comorbidities. Concerns exist over treating patients who have previously undergone mitral valve surgery for possible interference between the percutaneous aortic valve and the mitral prosthesis or ring.

METHODS: At our centre, from May 2008 to December 2012, 172 patients (76 male) with severe symptomatic aortic stenosis were eligible for transcatheter aortic valve implant. Nine patients, affected by severe aortic stenosis, had previously undergone mitral valve surgery (4 mono-leaflet, 3 bileaflet, 1 bioprosthesis, 1 mitral ring); they were considered high-risk surgical candidates following joint evaluation by cardiac surgeons and cardiologist and had undergone TAVI.

RESULTS: Seven patients underwent standard femoral retrograde CoreValve® (Medtronic Inc., Minneapolis, USA) implantation, two patients underwent a direct aortic implantation through a mini-thoracotomy. All patients experienced immediate improvement of their haemodynamic status. No deformation of the nitinol tubing of the CoreValve, nor distortion or malfunction of the mechanical valve or mitral ring, occurred as assessed by echographical and fluoroscopic evaluation. No major postoperative complications occurred. In all patients, echocardiography indicated normal valve function during follow-up.

CONCLUSIONS: Our experience confirms the feasibility of CoreValve implantation in patients with mechanical mitral valves or mitral annuloplasty ring.

Keywords: Aortic valve • Replacement • Heart valve • Transapical • Percutaneous • Heart valve • Mechanical

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has emerged as an important therapeutic strategy to treat patients with severe aortic stenosis (AS) who are at high risk for surgery [1, 2]. Recently, this technique has proven to be as effective as surgery in reducing mortality up to 3 years in this population [3, 4].

Nevertheless, patients with prior mitral valve surgery have often been excluded from this cohort of patients because concerns exist over possible interference between the percutaneous aortic valve and the mitral prosthesis or annuloplasty ring. Indeed previous mitral valve replacement is classified as a contraindication for implantation of the Edwards SAPIEN valve by its manufacturer (Edwards Lifesciences, Irvine, CA, USA) [5].

As a consequence, evidence concerning TAVI outcomes in this group of patients remains sparse and limited to a few case reports.

We report our single centre experience with the implantation of the self-expandable CoreValve® (Medtronic Inc., Minneapolis,

MN, USA) bioprosthetic aortic valve in nine patients who had previously had mitral valve surgery.

PATIENTS AND METHODS

At our centre, from May 2008 to December 2012, 172 patients (76 male) with severe symptomatic aortic stenosis, mean age 80 ± 9 years, underwent transcatheter aortic valve implantation. Patient evaluation was in all cases made by the 'heart team', composed of a cardiac surgeon, an interventional cardiologist, the referring cardiologist, a cardiac anaesthesiologist and a radiologist. According to the statement of the European Association for Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC) the team's role is to confirm the severity of aortic stenosis, evaluate patients' symptoms, analyse surgical risk, evaluate patients' life expectancy and quality of life and assess the possibility and exclusion of contraindications for TAVI [6]. After the 'heart team' evaluation, transcatheter aortic valve

implantation with a CoreValve prosthesis was preferred in 157 patients. In nine of them (seven female) the procedure was performed as re-operation after previous mitral valve surgery. Written informed consent was obtained from all patients and the local ethics committee approved the procedures. All patients had a logistic EuroSCORE >23% (range 23–77%) and a mean Society of Thoracic Surgeons risk of mortality of 12.7%. In addition to standard transthoracic echocardiogram and coronary angiogram, multislice computed tomography (MSCT) was performed before TAVI in all patients, in order to carefully assess (i) aortic root diameters, (ii) peripheral arterial axes and (iii) relationship between aortic annulus and mitral prosthetic valve or ring (Fig. 1A and B). The current third-generation CoreValve® ReValving system with the standard retrograde delivery system was used in all patients. The CoreValve system consists of three unique components: a self-expanding support frame with a tri-leaflet porcine pericardial tissue valve; an 18 Fr catheter delivery system and a disposable loading system: details have been described previously [2]. The procedures were performed by the cardiovascular team, composed of interventional cardiologists, cardiac surgeons with expertise in hybrid procedures and cardiac anaesthesiologists. Pre-procedural antiplatelet treatment consisted of acetylsalicylic acid (100 mg q.d.) and clopidogrel 75 mg q.d. All outcomes were defined according to the Valve Academic Research Consortium (VARC) [7].

RESULTS

The median patient age was 73.6 years (range 31–83 years). Seven patients were female. Table 1 summarizes the baseline characteristics of all patients. Four patients had undergone two previous operations on the mitral valve. The mean interval between TAVI and the last operation was 12.5 years (range: 6–21 years). The mean transmitral prosthetic gradient was 5.1 ± 3 mmHg (range: 2–12 mmHg). The mean pre-procedural pulmonary artery systolic pressure was 51.7 ± 9.9 mmHg (range: 33–70 mmHg), with three patients having pulmonary hypertension (≥ 60 mmHg). Table 2 summarizes the baseline echocardiographic parameters of all patients. All patients were on chronic controlled atrial fibrillation and oral anticoagulant therapy. Three patients had previous stroke without any permanent sequelae.

A self-expandable CoreValve bioprosthesis was implanted retrogradely in all patients under angiographic, fluoroscopic and echocardiographic guidance. A transfemoral approach was used in seven patients and a direct aortic access—through a right anterior mini-thoracotomy in the second intercostal space—in two cases. Technical details of the procedures have been described previously [8, 9]. Table 3 summarizes the procedures and outcomes.

The CoreValve prosthesis was implanted in all patients (Fig. 1), with immediate improvement of their haemodynamic status. In all patients, mean aortic gradient immediately dropped below

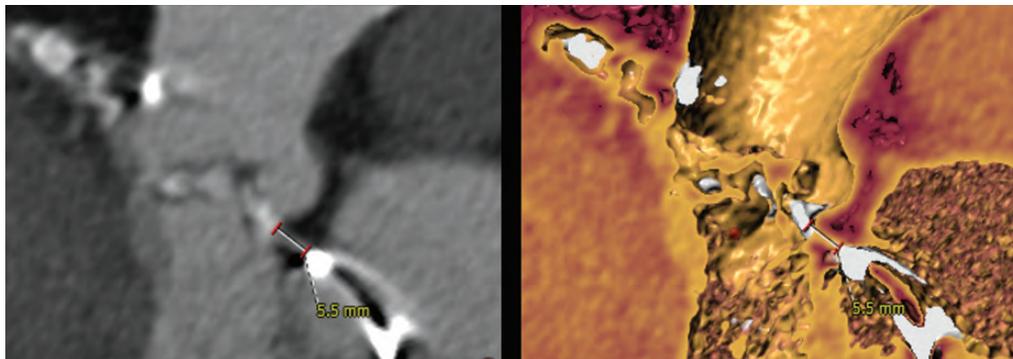


Figure 1: Multislice cardiac computed tomography (Fig. 1A) and 3D multislice cardiac computed tomography reconstruction (Fig. 1B), showing the distance between the aortic annulus and the mitral valve housing.

Table 1: Baseline preoperative patient characteristics

Pt	Gender	Age (yy)	Surgery	Years from surgery	Redo number	STS mortality	Prior PPM	Preop AF	NYHA class
1	F	72	MVR + TVA	21	1	7.7	0	1	III
2	F	77	MVR + TVA	12	1	7.8	1	1	III
3	F	60	MVR	18	2	7	1	1	IV
4	F	77	MVR + TVA	11	2	6.8	1	1	IV
5	F	74	MVR	17	2	7.9	1	1	III
6	M	31	AVR + MVR + TVA	8	1	36.8	0	1	III
7	F	76	MR + CABG	6	1	6.1	1	1	III
8	M	72	MVR + CABG	7	1	17.1	0	1	III
9	F	83	MVR	13	2	17.5	0	1	IV

AF: atrial fibrillation; AVR: aortic valve replacement; CABG: coronary artery bypass graft; F: female; M: male; MVR: mitral valve replacement; MR: mitral repair; NYHA: New York Heart Association; PPM: permanent pacemaker; Pt: patient; yy: years; STS: Society of Thoracic Surgeons; TVA: tricuspid valve annuloplasty.

3 mmHg after CoreValve deployment: no CoreValve balloon post-dilatation was needed.

Clinical and echocardiographic outcomes

Procedural success was achieved in all patients; no cases of procedural death, stroke, myocardial infarction or urgent cardiac surgery occurred. Post-TAVI, one patient required implantation of a new pacemaker for complete heart block. Mean post-operative echocardiographic aortic gradient was 10 ± 4 mmHg.

Table 2: Baseline preoperative echocardiographic patient characteristics

Pt	LVEF (%)	AoVarea cm ²	Peak Ao Δ	MAo Δ mmHg	MΔ mitral mmHg	M PAPs mmHg	Aortic annulus
1	21	0.6	98	60	4	67	23
2	40	0.7	88	53	5	52	22
3	25	0.8	74	47	4	61	20
4	50	0.9	80	48	4	50	22
5	56	0.6	102	50	5	50	22
6	20	0.8	72	45	12	63	23
7	30	0.7	37	21	4	45	27
8	50	0.6	87	52	4	33	20
9	30	0.6	35	25	4	51	25

Ao Δ: peak transaortic gradient; AoVarea: aortic valve area; LVEF: left ventricular ejection fraction; MAo Δ: mean transaortic gradient; MΔ mitral: mean transmitral gradient; M PAPs: mean pulmonary artery pressure peak; Pt: patient.

Paravalvular aortic regurgitation was absent or mild in all nine cases. The mitral prosthetic function remained unaffected in all patients. All the procedures were uneventful and the patients were discharged after a mean hospitalization of 12 days (range: 6–20 days) except the patient who underwent aortic and mitral valve replacement, who was discharged four months after TAVI. There was no 30-day mortality and all patients improved, with 90% in functional class I to II. At a mean follow-up of 23 ± 16 months (range: 4–45 months), there was one non-valve-related death for multiorgan failure, which occurred 2 years after TAVI. At a mean follow-up of 18 ± 14 months (range: 3–36 months), echocardiographic evaluation revealed no structural valve deterioration or displacement.

Sorin Allcarbon monodisc

Four patients had a Sorin Allcarbon monodisc mitral valve prosthesis (Sorin Biomedical Cardio S.p.A., Saluggia VC, Italy). The prosthesis is a single-piece cage, coated with Carbofilm™. The graphite substrate is coated with bulk pyrolytic carbon. A tantalum wire allows radiographic visualization. The opening angle is 60°.

All patients were treated by a percutaneous femoral approach. In all cases a NuMED NuCLEUS™ PTV balloon (NuMED Inc., Hopkinton, NY, USA) of 40 mm in length was used for implantation balloon aortic valvuloplasty (BAV). In Patient 3—a 60-year-old female with a severe valvular cardiomyopathy affected by combined aortic stenosis and 3+/4+ aortic insufficiency (0: no AR; 1+/4+: trivial AR; 2+/4+ : mild AR; 3+/4+: moderate; 4+/4+: severe), with a depressed left ventricular (LV) function, 21% ejection fraction (EF) and pulmonary hypertension, treated as bridge to heart transplantation—a balloon displacement was noted during valvuloplasty but no rapid pacing was

Table 3: Procedure considerations and outcomes

Pt	Prosthesis type	Housing visualization	Leaflet visualization	CoreValve No.	Access site	Angio AR	Echo AR	Echo MAo Δ	PM implant	Vasc. comp	Stroke	Follow-up (months)	Death
1	Sorin Allcarbon monodisc No. 31	Yes	Yes	26	TF	0	0	11	0	0	0	24.3	1
2	Sorin Allcarbon monodisc No. 29	Yes	Yes	26	TF	0	1	11	0	0	0	45.3	0
3	Sorin Allcarbon monodisc No. 25	Yes	Yes	26	TF	0	0	7	0	0	0	38.3 ^a	0
4	Sorin Bicarbon bileaflet No. 29	Yes	Yes	26	TF	1	1	5	0	0	0	39.7	0
5	Sorin Allcarbon monodisc No. 27	Yes	Yes	26	TF	1	1	8	0	0	0	24.3	0
6	Carpentier-Edwards No. 23	Yes	No	26	TF	1	1	19	0	0	0	2b	0
7	Edwards Physio ring No. 26	Yes	-	29	TF	1	1	12	0	0	0	17.9	0
8	On-X bileaflet No. 25	Yes	Yes	26	DA	0	1	9	1	0	0	12.5	0
9	Sorin Bicarbon bileaflet No. 25	Yes	Yes	26	DA	0	0	9	0	0	0	4	0

Angio: angiographic; AR: aortic regurgitation; DA: direct aortic; Echo: echocardiographic; MAo Δ: mean transaortic gradient; TF: transfemoral; DA: direct aortic. Vasc comp: vascular complication

^aPatient 3 underwent successful bridge to heart transplantation.

^bPatient 6 underwent successful bridge to aortic and mitral valve replacement.

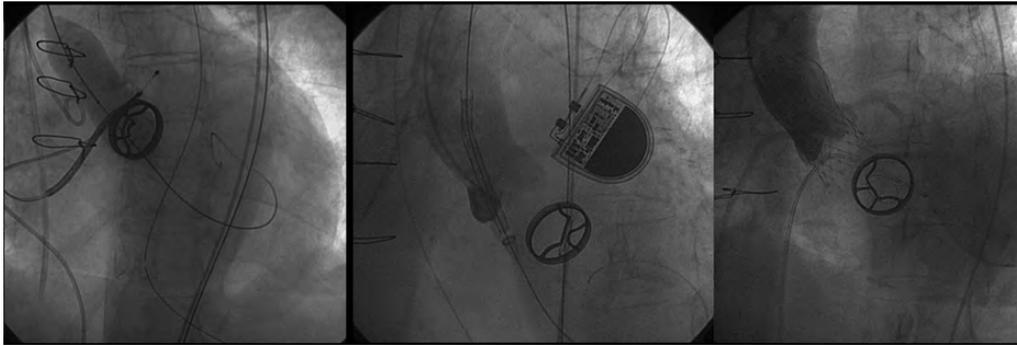


Figure 2: Sorin Allcarbon monodisc. (A) Full expansion of NuCLEUS™ PTV balloon during balloon aortic valvuloplasty. (B) Starting position of CoreValve® deployment with no interference between the capsule and nose cone of the delivery system and mechanical mitral valve. (C) Fully expanded valve prosthesis across the native aortic valve: aortogram demonstrates good opacification of the left main and anterior descending artery and of the right coronary artery; no evidence of aortic regurgitation and no interference or distortion of the CoreValve nitinol tube, nor malfunction of the mono-disc mechanical valve (notice complete disc opening).



Figure 3: Sorin Bicarbon heart valve. (A) Echocardiographic evaluation of the distance between the aortic annulus and mitral valve housing and extent of the leaflet protrusion into the left ventricle outflow tract. (B) Full expansion of NuCLEUS™ PTV balloon during balloon aortic valvuloplasty via a direct aortic approach through a right anterior mini-thoracotomy (notice complete leaflet opening at fluoroscopy). (C) Full CoreValve® expansion: aortogram demonstrates no evidence of aortic regurgitation and no interference or distortion of the CoreValve nitinol tube, nor malfunction of the bileaflet mechanical valve (notice complete leaflet opening at fluoroscopy).

used because of severely impaired LV function (Fig. 2A). In all four cases there was sufficient distance between the landing zone of the 26-mm CoreValve and the mitral prosthesis (Fig. 2B). No interference within the nitinol tube or the disc movement was noted after full deployment of the CoreValve (Fig. 2C). No additional balloon post-dilatation was needed in any patient; only trace paravalvular leakage was evident.

Sorin Bicarbon heart valve

Two patients had a Sorin Bicarbon bileaflet mitral valve prosthesis. The prosthesis has the unique characteristic feature of curved pyrolytic carbon leaflets; it has a rigid titanium Carbofilm coated housing; the valve has a hinge mechanism, a passive washing and Carbofilm coated composite sewing ring.

One patient, affected by severe peripheral vasculopathy, was treated by a direct aortic approach. In both cases there was sufficient distance between the aortic annulus and the mitral prosthesis (Fig. 3A). A NuCLEUS PTV balloon of 40 mm in length was used for implantation BAV during rapid ventricular pacing; no evidence of balloon shift was noticed (Fig. 3B). No interference within the CoreValve nitinol tube or the bileaflet valve was noted after full valve deployment (Fig. 3C). No additional balloon post-dilatation was needed in any patient; trace paravalvular leakage was evident in only one patient.

On-X® bileaflet valve

Seven years prior to TAVI, one patient had undergone coronary artery bypass grafting and mitral valve replacement with a 25-mm On-X® bileaflet valve (On-X Life Technologies Inc., Austin, Texas, USA). The On-X is a pure carbon bileaflet heart valve prosthesis. The valve leaflets are free to follow the flow and valve closure is assured even when leaflets are open to the full 90°. The On-X prosthesis has distinctive 'leaflet guards' that extend the orifice of the prosthesis to form an effective barrier, which protects the leaflet motion from impingement by tissue. The patient underwent a direct aortic CoreValve 26-mm implantation because of severe peripheral vasculopathy (Fig. 4A). No interference was noted between the On-X 'leaflet guards' nor with the 22-mm NuCLEUS PTV balloon used for BAV, nor with the CoreValve nitinol tube (Fig. 4B and C).

Mitral bioprosthesis

Eight years prior to TAVI, a 31-year-old male underwent aortic and mitral valve replacement and tricuspid valve repair with a Carpentier-Edwards Magna PERIMOUNT bioprosthesis (Edwards Lifesciences Corp., Irvine, CA, USA). The Carpentier-Edwards Magna is a bovine pericardial tissue-based bioprosthetic device with a cobalt chromium alloy stent. The valve has an

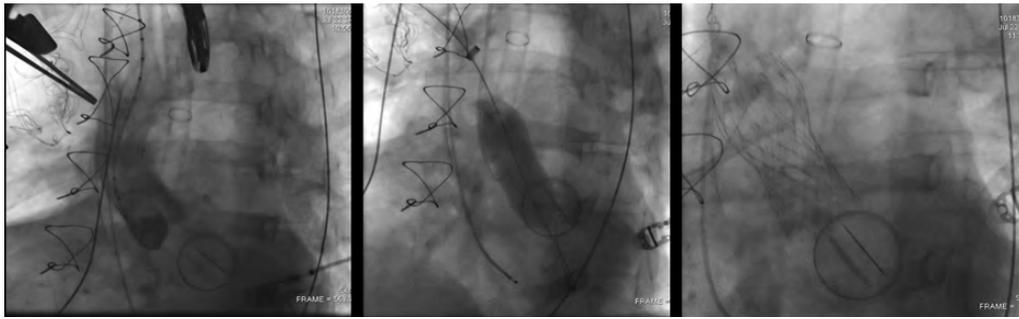


Figure 4: On-X® bileaflet valve. (A) Direct aortic approach, angiographic evaluation of the distance between the aortic annulus and the entry site in the ascending aorta (forceps tips) and between aortic annulus and mitral On-X valve. (B) Full expansion of NuCLEUS™ PTV balloon during balloon aortic valvuloplasty via a direct aortic approach: the complete leaflet opening is evident under fluoroscopy. (C) Full CoreValve expansion: there is no evidence of interference or distortion of the CoreValve nitinol tube, nor malfunction of the bileaflet mechanical valve with both leaflets completely open.

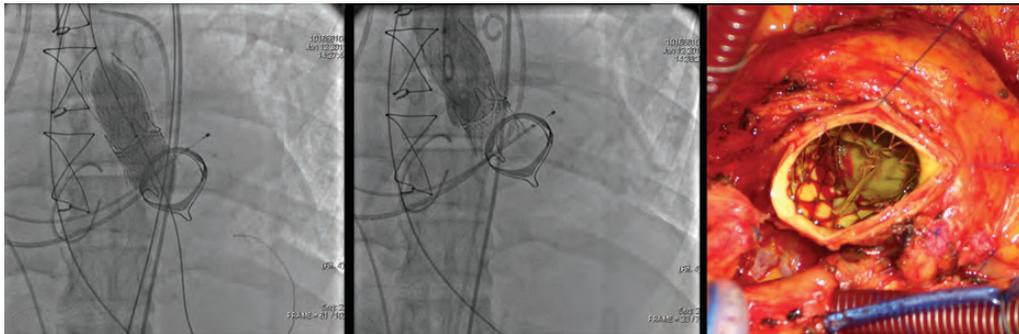


Figure 5: Mitral bioprosthesis. (A) Carpentier-Edwards 23 mm post-dilatation with a 22-mm NuCLEUS™ PTV balloon. (B) Full CoreValve® expansion: aortogram demonstrates normal coronary flow, 1+ aortic regurgitation and no distortion of the nitinol tube from mitral bioprosthesis, even when the position of the CoreValve was deeper than usual. (C) Normal evidence of CoreValve at surgical procedure at 2 months following TAVI.

asymmetrical shape that mimics the native mitral anatomy and provides a low effective profile and low ventricular projection. This, combined with a supra-annular position, reduces the risk of LV outflow tract protrusion. The patient was admitted to our department in cardiogenic shock and severe end-organ dysfunction. Echocardiogram revealed aortic bioprosthesis degeneration with severe stenosis (peak gradient 80 mmHg; LVEF 30%) and mitral valve leakage. A CoreValve implantation was preferred as bridge to clinical stabilization. No BAV was performed during CoreValve 26 mm implantation in the 23-mm Carpentier-Edwards valve; post-dilatation was performed with a 22-mm NuCLEUS PTV balloon (Fig. 5A) to achieve a peak gradient of 15 mmHg; trace aortic paravalvular regurgitation was evident. No interference between the CoreValve and the Carpentier-Edwards stent was noticed (Fig. 5B). The patient underwent successful mitral and aortic valve replacement with mechanical valves 60 days after TAVI (Fig. 5C).

Mitral annuloplasty ring

In 2004, a 76-year-old female underwent ‘undersized’ mitral annuloplasty repair with a 26-mm Carpentier-Edwards Physio ring (Edwards Lifesciences, Irvine, CA, USA) and concomitant coronary artery revascularization. The Carpentier-Edwards Physio ring is made of layers of Elgiloy® cobalt alloy and plastic strips and has a sewing ring margin that consists of a layer of silicone rubber covered by a polyester knit fabric. Variable flexibility of the ring is created by the movement of Elgiloy bands

separated by plastic bands. A successful retrograde transfemoral CoreValve 26 mm implantation was performed. No distortion of the Carpentier-Edwards Physio ring was noticed during BAV with a 22-mm NuCLEUS PTV balloon. No deformation of the nitinol tubing of the CoreValve, nor distortion or changes in mitral regurgitation, occurred as assessed by echographic and fluoroscopic evaluation after full valve deployment.

DISCUSSION

Transcatheter aortic valve implantation has emerged as an alternative therapy to treat patients with symptomatic severe aortic stenosis, who are considered to be high-risk surgical candidates because of multiple comorbidities [1–3]. Subjects who have undergone previous sternotomy may be included in this group. In fact, aortic valve replacement after previous mitral valve repair or replacement is a high-risk procedure, particularly in older patients with several comorbidities and reduced ejection fraction: redo cardiac surgery in these patients is burdened by a higher mortality rate of 5–26% and the possibility of adopting a percutaneous approach is a very attractive concept [10, 11]. Nevertheless a pre-existing prosthetic valve or ring is considered an exclusion criterion in both the currently ongoing trials, namely the Placement of AoRTic TraNscathetER (PARTNER) Trial II with the Edwards Sapien valve and the Medtronic CoreValve U.S Pivotal Trial [12, 13]. This is because concerns exist about possible interference between the mitral prosthetic housing or bioprosthetic struts and transcatheter valve, that might interfere

with optimal valve deployment, increasing the risk of prosthesis shift and misplacement.

Few single-centre experiences have been published in the literature on TAVI in patients with biological or mechanical mitral valve prostheses, which involve both the Sapien and CoreValve prostheses [14–17]. As reported by other authors, the presence of a mechanical valve in the mitral position might complicate TAVI because of the reduction of the mitro-aortic space to accommodate the transcatheter valve and because the presence of a mechanical valve can limit the expansion of the percutaneous prosthesis.

Mechanical valves have a rigid housing cage, with or without protruding pivot guards. The Sorin valve has a narrow housing cage: in contrast, the On-X mechanical valve has a high, rigid housing cage with distinctive 'leaflet guards' that extend the orifice of the prosthesis protruding in the left ventricle outflow tract (LVOT). Bioprostheses have more prominent commissural struts that are invariably impinging on the left ventricle, in close proximity to the aortic annulus within the LVOT. This may cause balloon displacement towards the aorta during inflation, with resultant valve malposition or embolization [17]. In our experience, we did not observe any displacement or deformation of the nitinol frame of the CoreValve, nor distortion of the housing or interference with the leaflet excursion of the mitral prosthesis, as assessed by fluoroscopy and serial echocardiographic evaluation; at the same time, the presence of a mitral prosthesis did not affect the rate of paravalvular leak.

This observation may tend to suggest that, in this population, self-expanding valve implantation may guarantee more stability during deployment and probably a direct aortic access with a short distance between the entry site and aortic annulus and that better valve deployment control should be advantageous in these patients. Also the particular characteristics of the non-cylindrical frame design of the CoreValve, combined with three totally different degrees of radial and hoop strength of the nitinol frame and anchoring on the aortic position, should represent an advantage over balloon-expandable valves.

Echocardiographical assessment and MSCT scan reconstruction are crucial to determine both the distance between the aortic annulus and the housing of the mitral prosthesis and the extent of prosthetic strut protrusion into the LVOT.

Our experience—characterized by a multidisciplinary approach, necessary to offer the safest conditions and care for patients—shows that CoreValve implantation can be performed successfully in patients with mechanical or biological mitral valves or annuloplasty mitral rings. However, the small sample size of our experience prevents reaching any definitive and concrete conclusions on this important issue. Therefore, prospective studies involving larger numbers of patients and long-term follow-up are required to confirm these beneficial findings.

Conflict of interest: G. Bruschi is a consultant for Medtronic.

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