Transapical aortic valve implantation after previous aortic valve replacement: Clinical proof of the "valve-in-valve" concept

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Objective: The "valve-in-valve" concept may be applied in patients with previously implanted biological aortic valve prostheses. There are few reports of individual cases and as yet no clinical proof of safety and feasibility in a larger group of patients. We report the single-center outcome of transapical implantation of aortic valves into degenerated biological aortic valve prostheses (''valve-in-valve'') in very high-risk patients.

Methods: Since October 2008, 14 patients were treated by transapical valve implantation into degenerated biological aortic valve prostheses. Edwards SAPIEN (Edwards Lifesciences, Irvine, Calif) transcatheter heart valves were used in all patients. Mean (± standard deviation) patient age was 73.3 ± 13.1 years. Mean (± standard deviation) Society of Thoracic Surgeons score was 21.9% ± 10.9% (range, 4.2%–42.2%), and logistic euroSCORE was 45.3% ± 22.2%. Preoperatively, all patients were in New York Heart Association functional class III or IV.

Results: The procedural success was 100%. Preoperative transthoracic echocardiography mean transvalvular gradient was reduced from 37.1 ± 25.7 mm Hg to 13.1 ± 6.4 mm Hg, and mean aortic valve area increased from 0.68 ± 0.23 cm^2 to 1.35 ± 0.48 cm^2. There was no postoperative valve insufficiency. The postoperative course was short and uneventful in all but 1 patient. One patient underwent reoperation 3 months later because of endocarditis. Up to 20 months postoperatively, the patients were in New York Heart Association functional class I or II.

Conclusions: Transapical aortic valve implantation after previous aortic valve replacement was feasible and safe in our patients. The results are excellent with improvements in hemodynamics, but longer follow-up with more patients is needed. (J Thorac Cardiovasc Surg 2011;142:270-7)

ACD

Transcatheter aortic valve implantation is a successful new procedure for high-risk patients with severe stenosis of the native aortic valve. The procedure reduces surgical risk and enables easier and faster postoperative recovery.[1-10] Theoretically, the method may be useful in patients with previously implanted biological aortic valve prostheses (so-called valve-in-valve concept). This concept has been experimentally proved by Walther and colleagues,[11] and recently introduced into clinical practice, but there is only limited experience worldwide.[12-24] There are few anecdotal reports and still no clinical proof of safety and feasibility in a larger group of patients. The largest reports, published recently, included only 4 cases from 2 institutions treated by CoreValve (Medtronic Inc, Minneapolis, Minn) implantation using transfemoral access in 3 patients and transaxillary access in 1 patient,[22] and a multicenter experience with transfemoral access in 2 patients and transapical access in 8 patients.[24] There are limited reports on Edwards SAPIEN (Edwards Lifesciences, Irvine, Calif) valve implantation and the transapical approach. We present our experience in 14 consecutive patients who were treated by transapical implantation of Edwards SAPIEN valves into failed aortic bioprostheses and were followed up 5 to 20 months postoperatively.

MATERIALS AND METHODS

Since October 2008, a minimally invasive transcatheter redo aortic valve procedure was performed in 14 patients with degenerated biological aortic valve prostheses (Table 1). The transapical means of implantation using the Edwards SAPIEN transcatheter heart valves was used in all cases. All patients had a very high risk for conventional redo surgery because of comorbidities (as represented by the risk scores) or technical surgical considerations (porcelain aorta in 4 patients) (Tables 1 and 2). All patients underwent operation on an elective basis and were preconditioned for the procedure to optimize the organ functions (eg, renal function). The primary valve surgery was performed at a mean of 8.9 ± 4.7 years before the transapical procedure (Table 3). We accepted patients with degenerated biological valves with an external diameter of 23 mm or more. Patients with a smaller prosthesis (eg, external diameter 21 mm) had an internal diameter of approximately 17 mm and were accepted for the procedure only as an *ultima ratio* procedure. Paravalvular leakage and acute/subacute endocarditis were absolute contraindications for the procedure. Eleven patients had degeneration of a biological xenograft prosthesis (1 patient with a previously implanted Edwards SAPIEN valve), and 3 patients

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Abbreviations and Acronyms
LVEF = left ventricular ejection fraction
SD = standard deviation
TEE = transesophageal echocardiography

had degeneration of an aortic homograft (Tables 3 and 4). The external diameter of the degenerated prosthesis (as given by the manufacturer) was 21 mm in 4 patients, 23 mm in 7 patients, and 25 to 28 mm in 3 patients (Tables 3 and 4). We did not turn down any patients (eg, with larger valves or because of a particular type of valve). The size of the used valve prosthesis depends on the internal diameter of the old prosthetic valve. This criterion is similar as for the choice of the valve size for a stenotic native valve (see below).[10] We implanted four 26-mm valves (in homografts and previously implanted Edwards SAPIEN valve) and ten 23-mm valves (in other degenerated valves) in patients. The study was approved by the institutional review committee of the Deutsches Herzzentrum Berlin. All patients gave written informed consent.

Implantation Technique

Aortic valve implantation was performed through a mini left anterior thoracotomy via the transapical route with a balloon-expandable transcatheter stent-prosthetic xenograft (Edwards SAPIEN transcatheter heart valves) 23 or 26 mm in diameter. Implantations were performed in our hybrid operation room with a monoplane angiography system by our team of cardiac surgeons, a cardiologist, and anesthesiologists. A perfusionist and a heart–lung machine were present in the operating room. The principal surgical technique was described in detail by Walther and colleagues,[3] and we made some modifications.[10,25] First, balloon dilatation of the degenerated bioprosthesis was not principally performed. The most important modification of the technique was slow and gradual valve deployment (and not at once by forced and rapid inflation of the balloon, as in the original technique) supported by simultaneous angiographic visualization[10,25] (Figures 1 and 2). The old stented prosthesis was an excellent guide for the positioning of the new valve during valve deployment (Figure 1). If the position of the new prosthesis was not ideal, slow and gradual balloon inflation enabled easy correction of the valve position by pushing or pulling the catheter with the stented prosthetic valve. The valve-in-valve concept applied to a degenerated homograft in the aortic position or stentless xenograft aortic valve prosthesis is technically almost identical to the transapical aortic valve implantation into a stenotic native aortic valve. Especially in these situations, simultaneous angiographic visualization of the aortic root during slow valve deployment enables optimal positioning of the valve with perfect presentation of the relationships among the prosthetic valve, aortic valve annulus, aortic cusps, and coronary arteries.[10,25] The definitive optimal positioning of the new valve depends on the type of the old valves: For stentless valves, the rule of valve positioning is as for native valves,[3] and the position of a new valve in a degenerated stented valve is to be a bit higher to achieve good anchorage of the new valve into the old valve and to move and displace the degenerated leaflets of the previously implanted valve toward the scaffold of the old valve (Figures 1 and 2). The valve was always implanted during a short phase of ventricular rapid pacing of the heart.[3,25] Balloon-expandable transcatheter stent-prosthetic xenograft valves of 23 or 26 mm diameter with the corresponding delivering system (both Edwards Lifesciences) were used in all patients. The size of the new valve used was determined according to the internal diameter of the old prosthetic valve. Both internal and external diameters were measured by preoperative chest computed tomography, transthoracic echocardiography, and intraoperative transesophageal echocardiography (TEE), and data were analyzed and compared with the data of the manufacturers. A valve size of 23 mm was used for an internal diameter of the first prosthesis less than 21 mm, and a 26-mm prosthesis was used for an internal diameter more than 21 mm. The procedure was monitored by fluoroscopy, angiography, and intraoperative TEE. The hemodynamic parameters (gradient, aortic valve area) were intraoperatively taken only by TEE. The antegrade systolic velocity across the narrowed aortic valve, or aortic jet velocity, is measured using continuous-wave Doppler ultrasound. Transaortic pressure gradient (P) is calculated from velocity (v) using the Bernoulli equation as: $dP = 4v^2$. The maximum gradient is calculated from maximum velocity: $dPmax = 4vmax^2$, and the mean gradient is calculated by averaging the instantaneous gradients over the ejection period. Aortic valve area is calculated on the basis of the continuity-equation concept that the stroke volume (SV) ejected through the LV outflow tract (LVOT) all passes through the stenotic orifice (AVA), and thus SV is equal at both sites: $SV_{AV} = SV_{LVOT}$. Because volume flow rate through any CSA is equal to the CSA times flow velocity over the ejection period (the VTI of the systolic velocity curve), this equation can be rewritten as $AVA \times VTI_{AV} = CSA_{LVOT} \times VTI_{LVOT}$.

Invasive measurements were not performed to keep the procedure as simple as possible. If any problems had been anticipated, invasive monitoring would have been used. The temporary epicardial pacemaker wires were left in place for 1 week.

TABLE 1. Patients' preoperative characteristics

Parameter	Value (± SD)	Range
No. of patients, n	14	–
Female, n	5	–
Age, y	73.3 ± 13.1	38–87
BMI, kg/m^2	26.8 ± 4.0	20.3–35.7
Logistic euroSCORE, %	45.3 ± 22.2	21.1–89.0
STS score, %	21.9 ± 10.9	4.2–42.2
Aortic valve area, cm^2	0.68 ± 0.23	0.48–1.19
dP max, mm Hg (TTE)	57.7 ± 36.0	15–140
dP mean, mm Hg (TTE)	37.1 ± 25.7	8–100
LVEF, %	45 ± 13	10–65
LVEDD, mm	55 ± 11	42–80
Malignancy, n	2	–
Pulmonary hypertension, n	8	–
COPD, n	6	–
Peripheral art. disease, n	8	–
CAD, n	12	–
Previous stroke, n	6	–
Previous CABG, n	8	–
Previous PM/ICD, n	2	–
Previous MVR, n	1	–
Porcelain aorta, n	4	–
Severe AI, n	4	–
Severe MI, n	4	–
Creatinine, mg/dL	1.3 ± 0.4	0.7–2.0
NT-proBNP, pg/mL	5517 ± 9806	68–32,879

SD, Standard deviation; *BMI,* body mass index; *STS,* Society of Thoracic Surgeons; *dP,* transvalvular gradient; *TTE,* transthoracic echocardiography; *LVEF,* left ventricular ejection fraction; *LVEDD,* left ventricular end-diastolic diameter; *NYHA,* New York Heart Association; *COPD,* chronic obstructive pulmonary disease; *CAD,* coronary artery disease; *CABG,* coronary artery bypass grafting; *PM,* pacemaker; *ICD,* implantable cardioverter-defibrillator; *MVR,* mitral valve replacement; *AI,* aortic insufficiency; *MI,* mitral insufficiency; *NT-proBNP,* B-type natriuretic peptide.

Postoperative Medication

Postoperative medication consisted of aspirin and clopidogrel in addition to patients' individual therapy for other causes.

TABLE 2. Patients' baseline characteristics

Patients	Age (y)	Gender (female)	euroSCORE (%)	STS score (%)	NYHA class	Most relevant risk factor
Patient 1	38	–	23.0	13.1	IV	Porcelain aorta
Patient 2	74	–	27.8	18.9	III	Diffuse CAD
Patient 3	75	–	89.0	42.2	III	Poor LVEF
Patient 4	70	–	22.4	17.3	III	Poor LVEF
Patient 5	79	+	59.8	28.7	IV	Poor LVEF
Patient 6	86	+	61.5	21.6	IV	Age (polymorbidity)
Patient 7	81	–	55.9	27.7	IV	Age (polymorbidity)
Patient 8	84	–	66.5	37.0	III	Porcelain aorta
Patient 9	85	+	77.2	33.0	IV	Lung function
Patient 10	51	+	21.8	13.1	III	Porcelain aorta
Patient 11	84	+	48.5	29.4	III	Lung function
Patient 12	75	–	27.8	9.4	III	Diffuse CAD
Patient 13	73	–	21.1	11.3	III	Polymorbidity
Patient 14	71	–	31.8	4.2	IV	Porcelain aorta

STS, Society of Thoracic Surgeons; *NYHA,* New York Heart Association; *CAD,* coronary artery disease; *LVEF,* left ventricular ejection fraction.

RESULTS

Procedural Course

Technical procedural success was achieved in all patients. There was no conversion to open surgery. Cardiopulmonary bypass was used electively in 1 patient with a left ventricular ejection fraction (LVEF) of 10%. The cardiopulmonary bypass time was 12 minutes. One patient also received planned and elective coronary artery stenting for coronary artery disease. A renal artery stent was implanted electively in 1 patient. All procedures were straightforward with no complications. The diameters of the new implanted valves were 23 mm in 10 patients and 26 mm in 4 patients. The mean duration of the whole surgical procedure was 69 minutes (range, 45–120 minutes). The mean amount of contrast medium used per procedure was 76 mL (range, 36–137 mL). Mean fluoroscopy time was 9.8 minutes (range, 3.7–25.6 minutes).

Procedural Echocardiographic Data

After implantation of a new valve, the mean (± standard deviation [SD]) intraprocedurally measured TEE transvalvular gradient decreased from 27.2 ± 16.9 mm Hg to 10.3 ± 5.0 mm Hg (range, 3.0–25 mm Hg) (Table 5). The mean (± SD) aortic valve area increased from 0.81 ± 0.36 cm^2 to 1.35 ± 0.48 cm^2 (range, 0.85–2.50 cm^2) (Table 5). There was no valve insufficiency. For the 10 stented valves, the mean (± SD) transvalvular gradient decreased from 22.9 ± 12.9 mm Hg to 10.9 ± 4.7 mm Hg. The mean (± SD) aortic valve area increased from 0.70 ± 0.25 cm^2 to 1.29 ± 0.46 cm^2. For the 4 stentless valves, the mean (± SD) transvalvular gradient decreased from 38.5 ± 20.8 mm Hg to 9.5 ± 4.9 mm Hg. The mean (± SD) aortic valve area increased from 0.82 ± 0.28 cm^2 to 1.49 ± 0.51 cm^2. The preoperative mean (± SD) LVEF was 45% ± 13% with a range from 10% to 65%. At the end of the procedure,

TABLE 3. Data of previous aortic valve replacement and new implanted Edwards SAPIEN transcatheter heart valves

Patients	Time (y)	Prosthesis (type)	Size of old valve (mm)	Stentless	Size of new TAVI valve (Edwards SAPIEN) (mm)	Follow up (mo)
Patient 1	12.0	Homograft	23	+	26	20
Patient 2	8.6	Hancock (Medtronic Inc, Minneapolis, Minn)	23	–	23	19
Patient 3	12.7	Homograft	28	+	26	19
Patient 4	3.6	Hancock (Medtronic Inc)	23	–	23	18
Patient 5	0.9	SAPIEN (Edwards SAPIEN, Edwards Lifesciences, Irvine, Calif)	26	–	26	17
Patient 6	13.9	Freestyle (Medtronic Inc)	23	+	23	17
Patient 7*	6.9	Carpentier-Edwards	21	–	23	3*
Patient 8*	9.3	Mosaic (Medtronic Inc)	23	–	23	5*
Patient 9	14.0	Hancock (Medtronic Inc)	21	–	23	13
Patient 10	13.4	Carpentier-Edwards (after previous homograft)	21	–	23	13
Patient 11	2.7	Hancock ultra (Medtronic Inc)	21	–	23	11
Patient 12	2.1	Hancock ultra	23	–	23	10
Patient 13	9.8	Carpentier-Edwards	23	–	23	3
Patient 14	14.3	Homograft	25	+	26	2

TAVI , Transapical aortic valve implantation. *Patient died during follow-up.

TABLE 4. Preoperative transthoracic echocardiographic data of degenerated valves

Patients	Prosthesis (type)	Size of the old valve (mm)	dP max (mm Hg)	dP mean (mm Hg)	Valve regurgitation (°)
Patient 1	Homograft	23	96	65	2
Patient 2	Hancock (Medtronic Inc)	23	140	100	2
Patient 3	Homograft	28	20	10	2
Patient 4	Hancock (Medtronic Inc)	23	30	20	3
Patient 5	SAPIEN (Edwards SAPIEN)	26	17	8	3
Patient 6	Freestyle (Medtronic Inc)	23	80	50	1
Patient 7	Carpentier-Edwards	21	15	8	3
Patient 8	Mosaic (Medtronic Inc)	23	40	25	1
Patient 9	Hancock (Medtronic Inc)	21	43	25	2–3
Patient 10	Carpentier-Edwards	21	48	32	1
Patient 11	Hancock ultra (Medtronic Inc)	21	88	51	0
Patient 12	Hancock ultra	23	54	36	0–1
Patient 13	Carpentier-Edwards	23	89	70	1
Patient 14	Homograft	25	48	20	3

dP, Transvalvular gradient.

the mean LVEF was 49% ± 16% (range, 26%–75%). This difference was not statistically significant ($P = .59$).

Postoperative Clinical Outcome

The early postoperative course was uneventful in all but 1 patient who had respiratory problems. There were no postoperative bleeding complications, no wound healing problems, no postoperative myocardial infarction, no need for temporary postoperative dialysis, no need for postoperative pacemaker implantation, and no new clinical neurologic deficits. Two patients died of pulmonary problems and complications of urologic surgery 3 and 4.5 months after valve implantation, respectively. At the end of the follow-up, all other patients were in New York Heart Association class I or II. One patient underwent reoperation 3 months after the procedure because of endocarditis. He received a new biological valve by the conventional procedure, and his further postoperative course was uneventful. The explanted valves showed excellent fit of the transapically implanted valve in the original biological valve.

Follow-up Echocardiographic Data

At the end of the follow-up, transthoracic echocardiographic examinations showed a mean (± SD) transvalvular gradient of 13.1 ± 6.4 mm Hg (range, 5.0–29 mm Hg). There was no valve insufficiency. The mean (± SD) LVEF was 52% ± 11% (range, 30%–70%), and the mean left ventricular end-diastolic diameter was 53 ± 10 mm (range,

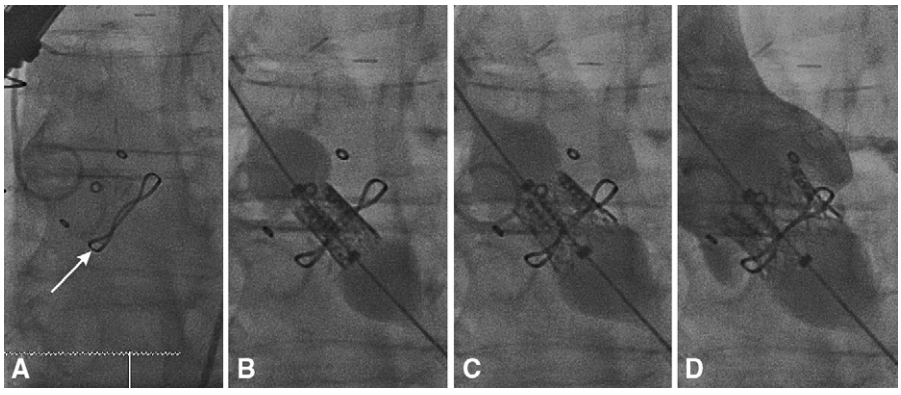

FIGURE 1. A, The metallic ring of the degenerated aortic valve prosthesis (*arrow*) enables an optimal working position to be easily found. B, The ideal position of the new valve is obtained by precise correction of the position relating to the metallic ring of the old prosthesis. C, The balloon is only slightly inflated, and the valve deployment begins. D, Forced complete inflation of the balloon is performed, and the valve is deployed in the desired position. Concomitant angiography is performed. The optimal positioning of the new valve in the old stented degenerated valve in regard to its annulus seems to be between $^2/_3 : {}^1/_3$ and $^3/_4 : {}^1/_4$. This higher position when the implantation is performed in a stented valve may enable better anchoring in the ring of the previously implanted valve and should compress the old prosthetic leaflets toward the scaffold of the old valve, not allowing overhanging of the old leaflets over the new prosthesis.

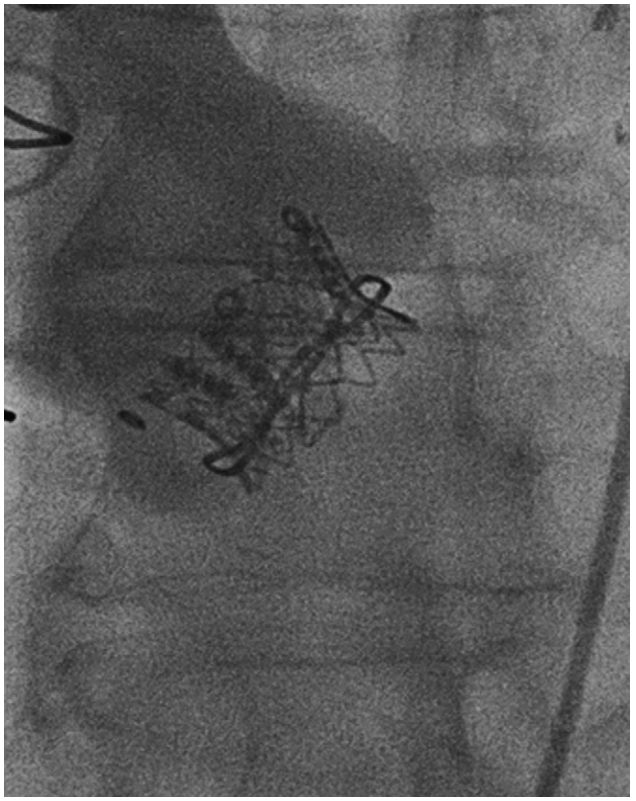

FIGURE 2. Angiography shows correct positioning of the new valve inside the old prosthesis with no paravalvular leak or valvular insufficiency. Note hour-glass shape of the new prosthesis enabling firm anchorage of the new prosthesis inside the old one. However, if the new valve is positioned too high, the wider dilation of the distal (aortic) end of the new valve in comparison with its proximal (ventricular) end may cause transvalvular insufficiency.

37–70 mm). Preoperative functional mitral insufficiency regressed in all patients and was not higher than grade 2 at the follow-up.

DISCUSSION

Favorable Outcome and Fast Postoperative Recovery

Our experience with 14 patients shows that transapical redo aortic valve implantation (''valve-in-valve'' concept) is a technically feasible, simple, and safe procedure after previous aortic valve replacement. The early results were excellent with an immediate improvement in hemodynamics. The patients' postprocedural recovery was impressively fast with a prompt and significant alleviation of symptoms that remained stable throughout the follow-up. We have not observed any valvular insufficiency. We used the transapical approach for implantation of Edwards SAPIEN transcatheter heart valves in all cases. It might be expected that the results of all types of transcatheter aortic valve implantation (transfemoral, transaxillary) with other types of valve would yield comparable results. Although our team uses all approaches of transcatheter aortic valve implantation (transfemoral, transapical, or transaxillary) with an experience of more than 300 transcatheter aortic valve implantations in a 2-year period, we decided to perform all valve-in-valve procedures by transapical implantation, which is a simple and direct procedure. The method possesses several advantages over the transfemoral (or transaxillary) route. The transapical approach is independent of the degree of the patient's peripheral arterial disease. Furthermore, advancing the wire antegradely through the valve is easy, rapid, and simple, in comparison with the retrograde

TABLE 5. Intraoperative transesophageal echocardiographic parameters of old degenerated prostheses and new Edwards SAPIEN transcatheter heart valves after valve-in-valve procedure

			Before implantation (old prosthesis)				After implantation (new prosthesis)			
Patients	Prosthesis (type)	Size (mm)	Annulus (mm)	dP max (mm Hg)	dP mean (mm Hg)	AVA (cm^2)	Annulus (mm)	dP max (mm Hg)	dP mean (mm Hg)	AVA (cm^2)
Patient 1	Homograft	23	19.5	94	64	0.50	17.3	29	16	0.85
Patient 2	Hancock (Medtronic Inc)	23	18.3	33	21	1.02	15.8	20	11	1.20
Patient 3	Homograft	28	20.8	11	6	1.19	18.5	7	3	2.03
Patient 4	Hancock (Medtronic Inc)	23	13.1	24	16	0.48	12.1	13	8	2.50
Patient 5	SAPIEN (Edwards SAPIEN)	26	19.0	17	8	1.66	18.9	17	10	1.20
Patient 6	Freestyle (Medtronic Inc)	23	16.9	76	42	0.60	15.6	14	7	1.14
Patient 7	Carpentier-Edwards	21	18.8	38	24	0.70	18.3	7	4	1.50
Patient 8	Mosaic (Medtronic Inc)	23	17.6	52	29	0.57	15.9	39	23	0.89
Patient 9	Hancock (Medtronic Inc)	21	14.6	43	25	0.70	13.3	21	13	0.90
Patient 10	Carpentier-Edwards	21	14.5	12	7	1.30	13.9	18	12	1.10
Patient 11	Hancock ultra (Medtronic Inc)	21	14.9	89	45	0.55	14.2	18	10	1.30
Patient 12	Hancock ultra	23	18.9	22	11	0.65	15.5	17	9	0.85
Patient 13	Carpentier-Edwards	23	17.5	73	43	0.40	15.0	20	9	1.50
Patient 14	Homograft	25	20.7	68	42	1.00	19.9	23	12	1.95
Mean ± SD			17.5 ± 2.3	46.5 ± 27.8	27.2 ± 16.9	0.81 ± 0.36	16.0 ± 2.2	18.6 ± 8.0	10.3 ± 5.0	1.35 ± 0.48
Range			13.1–20.8	11–94	6–64	0.40–1.66	12.1–19.9	7–39	3–23	0.85–2.50

dP, Transvalvular gradient; *AVA,* aortic valve area; *SD,* standard deviation.

approach used with transfemoral implantation, and may reduce or eliminate cerebral embolization during this phase of the procedure. We also expect a lower rate of neurologic complications because the danger of embolization during manipulation in the aortic arch is reduced or eliminated by the transapical route. However, our main reason for the exclusive use of the transapical approach is the excellent and safe possibility of precise deployment of the new valve in the desired position by applying our modified valve implantation technique (''Berlin addition'').[10,25] The inflation of the balloon during valve deployment is performed slowly, and not instantly as described in the principal technique,[3] allowing the valve position to be corrected if necessary. We would choose the transfemoral approach only when it is necessary to avoid general anesthesia and would perform the procedure with local anesthesia.

Decision-Making Process

It is not well established which patients are suitable for such an intervention, which steps during the screening phase are important, which examinations are mandatory, and which previous bioprostheses are technically suitable for the procedure. According to our limited preliminary experience, we consider all types of biological prostheses to be principally suitable for valve-in-valve implantation, but not all sizes of prosthesis (see below). A stented valve is optimal for implantation because there is no risk of postoperative atrioventricular block, coronary obstruction, or paravalvular leak. In contrast, stentless valves and allografts (homografts) are suitable for implantation, but in this situation the rules are the same as for transapical aortic valve implantation in the native aortic valve (risk of coronary obstruction, paravalvular leak, or atrioventricular block postoperatively). Our patients were younger than our usual high-risk population for transcatheter aortic valve implantation,[10] but they were also more morbid. The average age was only 73.3 years, with an average Society of Thoracic Surgeons score of 21.9% and logistic euroSCORE of 45.3%. Four patients had severe functional mitral valve regurgitation. This polymorbidity and high predicted risk for conventional heart surgery were the main reasons for applying this new approach.

Important Preoperative Steps During the Screening Phase

Preoperatively it is mandatory to exclude acute or subacute endocarditis. Patients' history should be meticulously evaluated in regard to fever and infections during the last several months, especially in the case of prosthetic failure shortly after primary valve replacement (eg, 2–3 years). Early valve degeneration, which is rare, should be distinguished from endocarditis and valve thrombosis, because these can cause embolic or infectious complications. Preoperative transthoracic echocardiography and TEE determine the degree of stenosis, valve gradients and aortic valve area, aortic regurgitation, and internal diameter of the old valve. These examinations should identify the cause of valve degeneration, amount of calcification, and possible floating structures on the leaflets to prevent possible postoperative embolic events. Most important, the examinations should exclude paravalvular leak as a cause of aortic regurgitation, in which case the ''valve-in-valve'' concept is contraindicated. Coronary angiography is necessary to exclude or identify concomitant coronary artery disease. In patients with stentless prostheses, the distances from the annulus to the coronary ostia should be determined by cardio computed tomography.

''Valve-in-Valve'' Concept as a Palliative Approach

The diameter of the previously implanted biological aortic valve prosthesis is the main limiting factor for the ''valve-in-valve'' concept. A stented bioprosthesis with an external diameter of 21 mm usually has an internal diameter of approximately 17 mm. The new prosthesis in the old prosthesis would have a reduced valve orifice area compared with after primary transapical aortic valve implantation. Our data of primary transapical aortic valve implantation have been published.[10] The mean postoperative transvalvular gradient was 6.28 ± 2.94 mm Hg (range, 1.19–15.56 mm Hg), and the mean aortic valve area was 1.88 ± 0.51 cm^2 (range, 0.85–3.37 cm^2). Our echocardiographic data after valve-in-valve implantation still represent aortic valve stenosis but less than before transapical aortic valve implantation. This ''palliative approach'' may be enough for elderly or very high-risk patients requiring conventional redo valvular surgery. Most of these patients have reduced mobility and less demand for physical activities. Most of them should have an improvement in their quality of life, with relief of symptoms (dyspnea or angina) after reduction of the valve stenosis by transcatheter redo aortic valve implantation. This issue of prosthesis mismatch is a key problem in applying this strategy in all high-risk patients with failed aortic bioprosthesis. We believe that the implantation is still possible and acceptable (as in our 3 patients with previously implanted 21-mm stented valves) if the internal diameter of the first valve is approximately 17 to 18 mm (corresponding to a 21-mm stented valve), but it should be considered only as a palliative procedure. Therefore, this can be performed only in very high-risk patients and elderly patients in New York Heart Association class III or IV.

Advantages of the Procedure Over Conventional Aortic Valve Replacement

The procedure excludes the need for extensive surgical preparation because of the significant adhesions and, therefore, eliminates possible bleeding complications. Also,

there is no risk of bypass damage in patients with previous coronary artery bypass surgery. The procedure can be performed on the beating heart without aortic cross-clamping or cardiopulmonary bypass, reducing postoperative neurologic complications. The method is of extraordinary importance for patients with poor left ventricular function. There is no ischemic cardioplegic arrest, and myocardial recovery can already be seen in the operating room after elimination of the aortic valve stenosis. Cardiopulmonary bypass also can be used in patients with cardiogenic shock or poor left ventricular function to improve the safety of the procedure.[10] If used, the cardiopulmonary bypass time is then very short. In patients with significant coronary artery disease, a coronary stent can be simultaneously placed on an elective basis, if necessary.[10]

We consider the valve-in valve concept only as an alternative to standard surgery. With the exception of patients with porcelain aorta, all patients could have undergone operation via the conventional technique at Deutsches Herzzentrum Berlin. We perform more than 800 conventional aortic valve procedures at Deutsches Herzzentrum Berlin every year, and as a ''high-volume institution,'' the experience with conventional surgery in octogenarians and even nonagenarians has been expanded with favorable results. In most cases it is possible to perform conventional aortic valve surgery with an acceptable success rate, but the advantage of transcatheter aortic valve implantation over conventional surgery is faster and shorter postoperative recovery and fewer postoperative complications. Complications in these older patients are typically followed by a sequence of several others.

Advantages of the Procedure Over ''Conventional'' Transapical Aortic Valve Implantation

Principally, the intraoperative procedural course is simpler than the standard transapical valve implantation into a stenotic native aortic valve. (1) There is no need for balloon dilatation of the degenerated biological valve. Performing balloon valvuloplasty in a patient with failed aortic valve prosthesis is debatable, because it carries a risk of embolization and possible immediate massive aortic valve regurgitation that has to be treated by prompt implantation of a new valve. (2) Valve deployment is simple with the degenerated stented prosthesis as an excellent guide for the positioning of the new valve. Furthermore, our modification[25] with slow and gradual inflation of the balloon with a mounted new valve enables precise positioning of the valve. Some further minimal corrections in valve positioning are possible before it achieves its final open state. In this manner the procedure is completely under control and under visualization. Despite this modification, the valve deployment remains a short procedure, lasting only 5 to 10 seconds. Valve-in-valve treatment of a stentless bioprosthesis is a somewhat challenging procedure because of the lack of landing support (stent) for the anchoring of the transcatheter valve. The valve should be positioned at the level of the bioprosthetic valve. The absence of radiopaque markers (no valve calcification and no radiopaque markers in stentless valves) makes the positioning of the transcatheter valve comparable to the implantation of a transcatheter valve into a native stenotic aortic valve or somewhat more difficult. However, simultaneous angiography during slow and gradual valve deployment enables excellent visualization of the aortic root and the relationships among the prosthetic valve, aortic valve annulus, aortic cusps, and coronary arteries, and fine positioning of the new valve.[25] (3) The risk of coronary artery obstruction is decreased or even eliminated in patients with previously implanted stented bioprostheses (but not in stentless ones). (4) The need for procedurally caused pacemaker implantation is completely eliminated in patients with previously implanted stented valves because there is no risk of heart block as the new valve does not put pressure on the septum. None of our patients required postoperative pacemaker implantation. However, for safety reasons and per our standard institutional policy, we left epicardial wires in place for 1 week. (5) The amount of contrast medium used during the procedure is less than for ''conventional'' transapical valve implantation.

Theoretically, transcatheter valve implantation in the native calcified aortic valve may have the advantage that living tissue will have the potential for ingrowth into the new prosthesis, which would secure it over time. However, in a valve-in-valve procedure this ingrowth might not occur and there could be a theoretic risk when the expansion force of the prosthetic material decreases after longer follow-up, which might cause loosening of the prosthesis.

Durability of a New Valve

The long-term results are unknown. However, if the valve should degenerate earlier than expected, the risk of a new redo operation with conventional aortic valve replacement is not increased or is even reduced. Transcatheter valve implantation might be a good temporary solution. If a patient is not in stable condition, the ''valve-in-valve'' concept may be applied to improve clinical status before redo conventional heart surgery. If the good short-term results should be proven during a longer follow-up in a larger patient collective, transcatheter redo valve procedure would be a real alternative for standard redo valve replacement in all patients with degenerated biological valves. Theoretically, in regard to the type of the degenerated biological valve, primary pericardial bioprosthesis may have different results from the porcine bioprosthesis because of a risk of coronary ostia occlusion in a pericardial bioprosthesis.

The indications for the size choice for the new valve are similar as for primary valve implantation.[3,10,25] We need at least 2-mm oversizing for the new valve. In a borderline

situation with an internal diameter of 21 mm for an old prosthesis, we would use a 23-mm prosthesis. In this particular situation, the size is chosen on an individual basis because the anchorage of the prosthesis should be good. We do not yet know the long-term durability of the valve-in-valve procedure; therefore, the question is: When a 26-mm prosthesis is put into a degenerated bioprosthesis with an internal diameter of 21 mm, would this new valve open and close fully without any folds that may have an impact on long-term durability? It is an additional reason for more experience with more patients and longer follow-up.

Study Limitations

There are 3 main study limitations. (1) We had no control group of patients undergoing conventional aortic valve replacement, (2) the number of patients was small, and (3) the follow-up was limited. We claim that transapical aortic valve implantation after previous aortic valve replacement significantly reduces the risk of conventional re-do aortic valve surgery, but there is no comparison between the available 2 techniques. However, the calculated operative risk for the conventional operation as assessed by the Society of Thoracic Surgeons and euroSCORE is a valuable method of evaluating the procedural success. Our conclusions are based on our experience in only 14 patients. However, this is the largest single-center experience worldwide to date. We consider that our data show only a trend, and a study with larger patient numbers is required.

CONCLUSIONS

The valve-in-valve concept offers a new strategy for the treatment of patients with failed bioprostheses. The concept may have important advantages over conventional redo aortic valve replacement because of very low operative risk in comparison with the conventional redo procedure. This method is new and experience with it is, as yet, little. The early results were excellent, but a longer follow-up is needed. This new procedure needs to be validated by randomized trials and long-term follow-up results. Therefore, the indication for this type of surgery should be restrictively applied for high-risk patients until additional proof is available. For the time being, transcatheter valve implantation may be a good temporary solution.

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References

1. Grube E, Laborde JC, Gerckens U, et al. Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high-risk patients with aortic valve disease: the Siegburg first-in-man study. *Circulation*. 2006;114:1616-24.
2. Cribier A, Eltchaninoff H, Tron C, et al. Treatment of calcific aortic stenosis with the percutaneous heart valve. Mid-term follow-up from the initial feasibility studies: the French experience. *J Am Coll Cardiol*. 2006;47:1214-23.
3. Walther T, Dewey T, Borger MA, et al. Transapical aortic valve implantation: step by step. *Ann Thorac Surg*. 2009;87:276-83.
4. Webb JG, Pasupati S, Humphries K, et al. Percutaneous transaterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation*. 2007;116:755-63.
5. Grube E, Schuler G, Buellesfeld L, et al. Percutaneous aortic valve replacement for severe aortic stenosis in high-risk patients using the second- and current third-generation self-expanding CoreValve prosthesis: device success and 30-day clinical outcome. *J Am Coll Cardiol*. 2007;50:69-76.
6. Himbert D, Descoutures F, Al-Attar N, et al. Results of transfemoral or transapical aortic valve implantation following a uniform assessment in high-risk patients with aortic stenosis. *J Am Coll Cardiol*. 2009;54:303-11.
7. Webb JG, Altwegg L, Boone RH, et al. Transcatheter aortic valve implantation. Impact on clinical and valve-related outcomes. *Circulation*. 2009;119:3009-16.
8. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. *J Am Coll Cardiol*. 2010;55:1080-90.
9. Pasic M, Buz S, Dreysse, et al. Transapical aortic valve implantation in 194 patients: problems, complications and solutions. *Ann Thorac Surg*. 2010;90:1463-70.
10. Pasic M, Unbehaun A, Dreysse S, et al. Transapical aortic valve implantation in 175 consecutive patients: excellent outcome in very high-risk patients. *J Am Coll Cardiol*. 2010;56:813-20.
11. Walther T, Falk V, Dewey T, et al. Valve-in-valve concept for transcatheter minimally invasive repeat xenograft implantation. *J Am Coll Cardiol*. 2007;50:56-60.
12. Wenaweser P, Buellesfeld L, Gerckens U, Grube E. Percutaneous aortic valve replacement for severe aortic regurgitation in degenerated bioprosthesis: the first valve in valve procedure using the CoreValve Revalving System. *Catheter Cardiovasc Interv*. 2007;70:760-4.
13. Walther T, Kempfert J, Borger MA, et al. Human minimally invasive off-pump valve-in-valve implantation. *Ann Thorac Surg*. 2008;85:1072-3.
14. Zegdi R, Achouh P, Berrebi A, et al. Valve-in-valve implantation: a word of caution. *Ann Thorac Surg*. 2009;87:348.
15. Kelpis TG, Mezilis NE, Ninios VN, Pitsis AA. Minimally invasive transapical aortic valve-in-valve implantation for severe aortic regurgitation in a degenerated stentless bioprosthesis. *J Thorac Cardiovasc Surg*. 2009;138:1018-20.
16. Ussia GP, Barbanti M, Tamburino C. Treatment of severe regurgitation of stentless aortic valve prosthesis with a self-expandable biological valve. *J Invasive Cardiol*. 2009;21:E51-4.
17. Ye J, Webb JG, Cheung A, et al. Transcatheter valve-in-valve aortic valve implantation: 16-month follow-up. *Ann Thorac Surg*. 2009;88:1322-4.
18. Attias D, Himbert D, Hvass U, Vahanian A. "Valve-in-valve" implantation in a patient with stentless bioprosthesis and severe intraprosthetic aortic regurgitation. *J Thorac Cardiovasc Surg*. 2009;138:1020-2.
19. Hofmann S, Franz N, Billion M, et al. Successful catheter-based valve-in-valve implantation for a regurgitant stentless bioprosthesis. *J Heart Valve Dis*. 2009;18:713-6.
20. Olsen LK, Engstrom T, Sondergaard L. Transcatheter valve-in-valve implantation due to severe regurgitation in a degenerated aortic homograft. *J Invasive Cardiol*. 2009;21:E197-200.
21. Napodano M, Cutolo A, Fraccaro C, et al. Totally percutaneous valve replacement for severe aortic regurgitation in a degenerative bioprosthesis. *J Thorac Cardiovasc Surg*. 2009;138:1027-8.
22. Khawaja MZ, Haworth P, Ghuran A, et al. Transcatheter aortic valve implantation for stenosed and regurgitant aortic valve bioprosthesis. CoreValve for failed aortic valve replacements. *J Am Coll Cardiol*. 2010;55:97-101.
23. Maroto LC, Rodríguez JE, Cobiella J, Marcos P. Transapical off-pump aortic valve-in-valve implantation in two elderly patients with a degenerated porcine bioprosthesis. *Eur J Cardiothorac Surg*. 2010;37:738-40.
24. Webb JG, Wood DA, Ye J, et al. Transcatheter valve-in-valve implantation for failed bioprosthetic heart valves. *Circulation*. 2010;121:1848-57.
25. Pasic M, Dreysse S, Drews TH, et al. Improved technique of transapical aortic valve implantation: "The Berlin addition" *Ann Thorac Surg*. 2010;89:2058-60.