The Heart Surgery Forum #2010-1148
14 (3), 2011 [Epub June 2011]
doi: 10.1532/HSF98.20101148

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Transcatheter Aortic Valve Implantation after Previous Mechanical Mitral Valve Replacement: Expanding Indications?

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ABSTRACT

Background: Cardiac operation for severe aortic stenosis after previous mitral valve replacement is a surgical challenge in older patients with multiple morbidities. Transcatheter aortic valve implantation (TAVI) after previous mechanical mitral valve replacement has been considered a high-risk procedure, owing to possible interference with the mitral valve prosthesis.

Methods: Since August 2008, 5 female high-risk patients with severe aortic stenosis and previous mitral valve replacement (mean ± SD age, 80 ± 5.1 years; logistic EuroSCORE, 39.3% ± 20.5%) underwent TAVI with a pericardial xenograft valve that was fixed with a stainless steel, balloon-expandable stent (Edwards Lifesciences SAPIEN). We used a transapical approach in 4 patients and a transfemoral approach in 1 patient. Transesophageal echocardiography and multidetector computed tomography were used for preoperative planning and assessment of operation feasibility. The mean distance between the aortic annulus and the mitral valve prosthesis was 10 ± 1 mm (range, 9-11 mm).

Results: TAVI was performed successfully in all 5 patients. There was no direct or functional interference with the mechanical mitral valve prostheses. Echocardiography revealed good valve function with no more than mild paravalvular incompetence early in the postoperative period and during routine follow-up. There were no neurologic events. After an initially uneventful course with good aortic valve function at the most recent echocardiography evaluation, however, 2 of the patients died from fulminant pneumonia on postoperative days 4 and 48.

Conclusion: TAVI is technically feasible in high-risk patients after previous mechanical mitral valve replacement; however, careful patient selection is mandatory with respect to preoperative clinical status and anatomic dimensions regarding the distance between aortic annulus and mitral valve prosthesis.

Received October 22, 2010; accepted November 29, 2010.

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INTRODUCTION

An older age in conjunction with several comorbidities increases the perioperative risk for all types of valvular surgery [Rao 1996]. A history of previous cardiac surgical procedures with sternotomy further increases the risk because of adhesions and the subsequent risk for cardiac and vascular injury [Odell 1996; Elahi 2005]. Transcatheter aortic valve implantation (TAVI) is a minimally invasive strategy that minimizes the periprocedural risk by avoiding conventional sternotomy and by performing the aortic valve implantation off pump on the beating heart [Lichtenstein 2006; Beyersdorf 2007; Walther 2007a; Walther 2007b; Ye 2007]. Transfemoral and transapical approaches have recently been introduced into clinical practice. These techniques may be beneficial for elderly high-risk patients who require a redo procedure for symptomatic aortic stenosis. Avoidance of extracorporeal circulation is particularly appealing for these patients. TAVI after previous mechanical mitral valve replacement, however, is still considered a high-risk procedure because of the potential to interfere with the mitral valve prosthesis. The aim of the present study was therefore to assess the feasibility of TAVI as a redo procedure after mitral valve replacement and to analyze the early follow-up results.

MATERIALS AND METHODS

Inclusion Criteria and Patient Characteristics

From August 2008 until February 2010, 5 female high-risk patients with severe aortic stenosis and previous mechanical mitral valve replacement underwent TAVI with a pericardial xenograft valve that was fixed with a stainless steel, balloon-expandable stent (Edwards SAPIEN THV transcatheter heart valve; Edwards Lifesciences, Irvine, CA, USA). A transapical approach was used in 4 patients, and a transfemoral approach was used in 1 patient. Transesophageal echocardiography (TEE) and multidetector computed tomography (Brilliance iCT; Philips Medical Systems, Best, the Netherlands) was used for preoperative planning and assessment of feasibility. The distance between the aortic annulus and the mitral valve prosthesis had to be >8 mm to avoid direct or functional interference with the mechanical mitral valve prosthesis (Figure 1). The mean (±SD) measured distance was

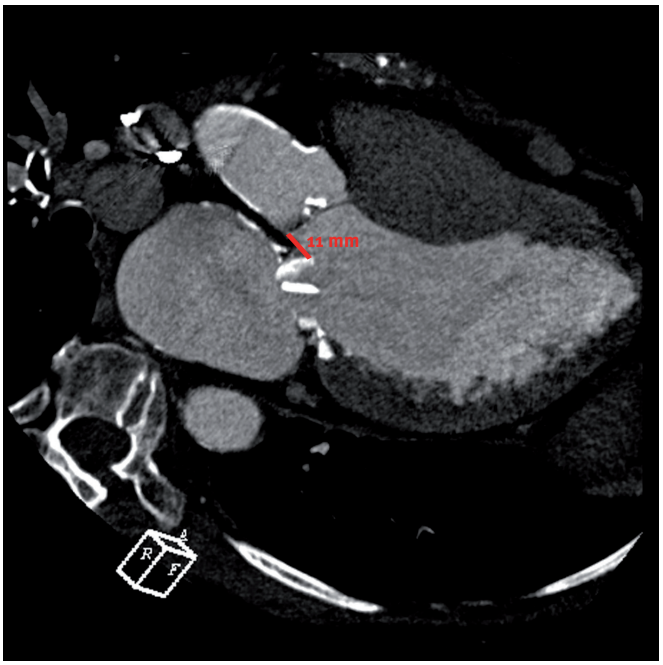

Figure 1. Preoperative multidetector cardiac computed tomography scan for measuring the distance between the mitral valve prosthesis and the aortic annulus as the main criterion for technical feasibility of the procedure. In this patient, the maximum distance was 11 mm.

Table 1. Patient Demographics and Comorbidities*

Age, y	80 ± 5.1
Body weight, kg	66.4 ± 16.1
Body surface area, m^2	1.7 ± 0.2
NYHA class	3 ± 0
Ejection fraction, %	50.2 ± 8.7
Aortic incompetence, grade	1 ± 0
Logistic EuroSCORE, %	39.3 ± 20.5
Chronic pulmonary disease, n (%)	1 (20)
Pulmonary hypertension, n (%)	5 (100)
Neurologic dysfunction, n (%)	2 (40)
Peripheral vascular disease, n (%)	4 (80)
Renal dysfunction, n (%)	3 (60)
Atrial fibrillation, n (%)	4 (80)
Previous PTCA/stent, n (%)	3 (60)
Previous pacemaker/AICD, n (%)	3/1 (60)

*Continuous data are presented as the mean ± SD; numerical data are presented as the number of patients (percentage). NYHA indicates New York Heart Association; PTCA, percutaneous transluminal coronary angioplasty; AICD, automatic implantable cardioverter-defibrillator.

10 ± 1 mm (range, 9-11 mm). For selection of the appropriate size of valve prosthesis, the diameter of the aortic annulus was measured. In all cases, the aortic annulus diameter was between 21 and 24 mm. This procedure allowed systematic oversizing of the catheter-based valves with 26-mm prostheses, except for one of the transapical patients, who received a 23-mm prosthesis. All available therapeutic options, including high-risk open heart surgery, were presented to each patient and extensively discussed. Informed consent for TAVI was given by all of the patients.

All 5 female patients had a high perioperative risk profile, with a mean logistic EuroSCORE of 39.3% ± 20.5%. The mean (SD) age was 80 ± 5.1 years. One patient was in a critical preoperative state with moderate left ventricular dysfunction. Table 1 lists additional details of patient demographic characteristics and comorbidities.

Technical Aspects of Transapical Implantation

Prior to implantation, the valves were rinsed and crimped upon the balloon catheter under sterile conditions. The procedures were carried out by a multidisciplinary team consisting of cardiac surgeons, cardiologists, and anesthesiologists, with extracorporeal circulation maintained on standby as backup.

All patients were intubated and ventilated during the procedure. Patients were fully equipped for the anesthesiologic monitoring usual for open heart surgery. Whenever possible, short-acting intravenous medications were used to ensure early extubation. The left side of the chest was slightly elevated. Parallel to the placement of a femoral venous guidewire and a 6F femoral arterial sheath as access for emergency cardiopulmonary bypass, an anterolateral minithoracotomy was performed in the fifth or sixth intercostal space to expose the left ventricular apex. After placement of pericardial stay sutures and insertion of an epicardial ventricular pacing wire, 2 circular apical purse-string sutures were placed with Teflon pledgets as reinforcement. The left ventricular apex was punctured, and a soft guidewire was inserted with fluoroscopic guidance through the stenosed aortic valve into the descending aorta. After insertion of a 14F introducer sheath, the soft guidewire was exchanged for an Amplatz superstiff wire (Boston Scientific, Natick, MA, USA), which was placed in the descending aorta. For the injection of contrast into the aortic root, a pigtail catheter was placed via the femoral arterial sheath into the aorta and positioned just above the aortic valve.

Under rapid ventricular pacing, the balloon aortic valvuloplasty was performed with aid of a 20-mL balloon. The sheath was then exchanged for a 33F sheath, and the loader with the prosthetic valve was connected and deaired. With fluoroscopic and TEE guidance, the valve was then positioned in the aortic annulus. Considering the distance of approximately 10 mm between the aortic annulus and the mitral valve, the 16-mm-high valved stent was aimed in a 50:50 ratio to the aortic annulus. During rapid ventricular pacing, the balloon-mounted prosthesis was inflated, causing an approximately 8-mm portion of the stent to extend below the aortic annulus into the left ventricular outflow tract. After optimal positioning was confirmed with angiography and TEE, the sheath and wire were removed from the apex, and the previously placed purse-string sutures were tied under rapid pacing to achieve

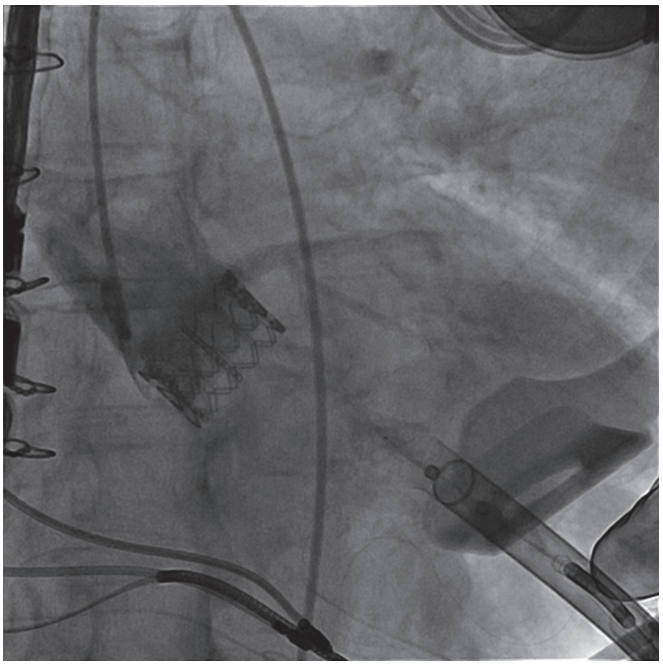

Figure 2. Postoperative aortic root angiogram after transapical deployment of the stent-based aortic valve showing competent valve function with only mild paravalvular incompetence and patent coronary ostia.

optimal hemostasis. Possible apical bleeding was controlled with additional deep sutures supported with large-sized Teflon pledgets. After insertion of a chest tube, the minithoracotomy was closed in a routine fashion. All sheaths were removed, and the femoral arteries were sealed with the Angio-SEAL device (St. Jude Medical, St. Paul, MN, USA).

Technical Aspects of Transfemoral Implantation

The operative setup and the preparation of the valve prior to implantation were similar to the transapical approach. Thus, only technical aspects specific to the transfemoral technique are described in brief.

The procedure was performed with the patient under analgosedation with local anesthesia. Thus, TEE was not performed during device implantation. First, a transjugular pacemaker was placed into the right ventricular apex. The right femoral artery was used as the main access site for the valve. A 28F RetroFlex sheath (Edwards Lifesciences) was inserted after placement of the sutures for the ProStar™ XL 10F system (Abbott Vascular, Abbott Park, IL, USA) and predilatation of the femoro-iliac arteries. A straight guidewire was advanced retrogradely across the aortic valve into the left ventricle for placement of a pigtail catheter. Then, an extrastiff guidewire was introduced into the left ventricle. A 23-mm RetroFlex balloon catheter (Edwards Lifesciences) was used under rapid pacing for balloon valvuloplasty. The crimped 26-mm bioprosthesis/balloon assembly was advanced through the 28F RetroFlex sheath until the bioprosthesis exited from the sheath tip. Then, the RetroFlex catheter was pushed up the descending aorta and the tip was deflected to track over the guidewire and around the aortic arch. The native valve was crossed under fluoroscopic and aortographic guidance, and the bioprosthesis was positioned within the annulus. The balloon-mounted valve was then inflated under rapid pacing. After the balloon and the RetroFlex catheter were removed, the femoral access site was closed with the prepositioned ProStar XL sutures.

Statistics

Results for continuous variables are expressed as the mean ± SD, and categorical variables are expressed as proportions.

RESULTS

TAVI was performed successfully in all 5 patients (transapical approach in 4 patients and transfemoral implantation in 1 patient). In 4 cases, 26-mm stented valves were used with slight oversizing of the prosthesis compared with the native valve. In only 1 transapical case was a 23-mm prosthesis used. No direct or functional interference of the catheter-based aortic valve with the mechanical mitral valve prosthesis was observed. After the transfemoral procedure, a temporary grade III atrioventricular block was observed, but this patient had undergone previous pacemaker implantation for absolute bradyarrhythmia. Therefore, no further intervention was required. No neurologic events were observed perioperatively or postoperatively. Echocardiography evaluations revealed good aortic valve function in all patients, with no or at most mild paravalvular incompetence (3 cases) in the early postoperative period and during routine follow-up examinations at

Table 2. Postoperative Data*

	Patient No.					
	1	2	3	4	5	Median
Ventilation time, h†	24	360	36	1	—	30
ICU stay, d	5	48	4	2	2	4
Hospital stay, d	20	48	4	15	9	15
Follow-up, d	575	48	4	40	142	48

*ICU indicates intensive care unit.

†For only transapical cases, cumulative ventilation hours are shown for patients 2 and 3 because of reintubation.

1 month, at 3 months, and after 1 year. Postoperative angiography examinations detected no transvalvular gradients (Figure 2), and echocardiography examinations during follow-up also measured no significant transvalvular gradients (Table 2).

Early extubation was attempted in all cases and was initially successful; however, 2 patients had to be reintubated on the second postoperative day because of respiratory failure. One of these patients died on postoperative day 4 from septic shock in the context of fulminant pneumonia. The other patient was recompensated and again extubated initially. Owing to her critical preoperative status with moderate left ventricular dysfunction and recurrent preoperative cardiac decompensation, this patient developed left heart failure with pulmonary edema and massive pleural effusions and consequently required repeated intubation. Furthermore, the patient developed acute-on-chronic renal failure with a need for hemofiltration. Despite maximal intensive care treatment, the patient finally died on postoperative day 48 from fulminant pneumonia. In both cases, the most recent echocardiographic evaluation had shown good aortic valve function with only mild paravalvular incompetence in one of the cases.

DISCUSSION

In the last 2 years, TAVI has been introduced into clinical practice for both the transapical and transfemoral approaches [Lichtenstein 2006; Walther 2007a; Svesson 2008]. Transapical implantation may be advantageous in cases of a thrombogenic aortic arch and may lead to a lower risk of stroke [Walther 2009a]. This approach should be favored in cases of peripheral artery disease, a small femoral artery diameter, or vessel tortuosity—conditions that prohibit a transfemoral implantation. The experience with TAVI use after previous mechanical mitral valve replacement is very limited, however. There are case reports of a transfemoral approach with the CoreValve prosthesis (Medtronic, Minneapolis, MN, USA) [Bruschi 2009] and of a transapical approach with the Edwards Lifesciences SAPIEN prosthesis [Scherner 2009; Walther 2009b]. We successfully used the SAPIEN prosthesis for both approaches in our series; however, the short distances between the aortic valve and the nearby mitral valve prosthesis and the mechanism for positioning in the transapical approach may allow more control for deployment of the stent graft, compared with the long approach from the groin required for the transfemoral approach.

In our series, the use of TAVI in high-risk patients with aortic stenosis after previous mechanical mitral valve replacement was technically feasible without direct or functional interference with the mechanical mitral valve prostheses. Our experience indicates that the target for deployment at the aortic annulus should be a 50:50 ratio of the valve stent height. This strategy causes an 8-mm portion of the 16-mm stent to reach below the aortic annulus into the left ventricular outflow tract. Given that the distance between the aortic annulus and the mitral valve prosthesis in our patients was 10 mm on average, but never less than 9 mm, interference between the 2 valve prostheses is unlikely; however, careful patient selection with respect to the anatomic distance between the aortic annulus and mitral valve prosthesis is mandatory. The use of multidetector cardiac computed tomography scanning for preoperative assessment and planning of the procedure is very helpful in this regard. In cases of previous mitral valve replacement with a bioprosthetic valve, this consideration will be even more important because of a higher risk of interference of the stented aortic valve with the mitral valve struts possibly protruding into the left ventricular outflow tract. TAVI after previous mechanical mitral valve replacement remains a high-risk procedure; however, a multidisciplinary approach with a team of experienced cardiac surgeons, interventional cardiologists, and cardioanesthetists makes the procedure for optimal positioning of the stented aortic valve technically feasible. In our series, we observed no obstruction of coronary ostia, which is a rare but potentially lethal complication [Kempfert 2008]. Furthermore, all procedures could be performed off pump; no cardiopulmonary bypass was necessary. Dissection of the apex was uneventful in all of the transapical cases, and there were no complications of bleeding from the purse-string sutures at the apex. In addition, no vascular-access complications were observed after transfemoral implantation.

Two patients died from causes unrelated to the valve procedure, from fulminant pneumonia early and 48 days postoperatively. Therefore, careful patient selection is necessary for patients with a critical preoperative clinical status combined with an impaired left ventricular function. Very aggressive fluid management may be required to ensure long-term success of TAVI as a redo procedure after previous mechanical mitral valve replacement.

DATA SUPPLEMENT

The Video is a cineangiographic sequence of transapical stent-based valve inflation under rapid pacing after previous native balloon valvuloplasty. The valve is positioned slightly higher than the optimal 50:50 ratio of stent height in relation to the aortic annulus.

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