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Percutaneous Ventricular Assist during Aortic Valvuloplasty

Potential Application to the Deployment of Aortic Stent-Valves

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We evaluated the short-term safety and efficacy of using the TandemHeart® percutaneous ventricular assist device in high-risk patients undergoing aortic valvuloplasty procedures.

Aortic valvuloplasty was performed in 4 patients who had no ventricular assist device support and in 7 patients who used the TandemHeart for hemodynamic support. The age range was 65 to 94 years (mean, 83 ± 11 yr). The mean ejection fraction was 0.30 ± 0.14. A transseptal antegrade approach to the aortic valve was used in 8 patients and a retrograde approach in the remaining 3.

With the TandemHeart, all procedures were technically successful: each patient survived at least 1 month after the procedure. The mean total balloon inflation time was 37 ± 10 sec. The aortic valve area was 0.6 ± 0.1 cm² before the procedure and 0.9 ± 0.2 cm² afterwards (P=0.006). Without TandemHeart support, 1 patient died of cardiac arrest during the procedure. The mean total balloon inflation time was 11 ± 3 sec. Aortic valve area was 0.6 ± 0 cm² before the procedure and 1.1 ± 0.3 cm² afterwards (P=0.3). No patient developed aortic regurgitation.

We conclude that use of the TandemHeart for hemodynamic support during high-risk aortic valvuloplasty is associated with favorable intraprocedural and short-term outcomes. With the TandemHeart in place, balloon placement was precise, and inflation was maintained for up to 45 sec without balloon displacement. These attributes are essential during stent-valve placement, are achieved without rapid ventricular pacing, and may reduce the risk of global ischemia and death. **(Tex Heart Inst J 2007;34:36-40)**

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Aortic valve replacement is the treatment of choice for severe aortic stenosis.[1] However, the surgical procedure has an operative mortality rate that ranges from 10% to 50% when performed in high-risk patients with comorbid conditions such as left ventricular failure, concomitant coronary artery disease with prior bypass surgery, chronic obstructive pulmonary disease, small body surface area, and advanced age.[2] In such cases, percutaneous aortic balloon valvuloplasty (PABV) has been used as an alternative or as a bridge to surgical valve replacement.[3] To decrease risks in this procedure, a number of circulatory support techniques have been used, including intra-aortic balloon counterpulsation[4,5] and percutaneous cardiopulmonary support.[6] The TandemHeart®[7,8] (CardiacAssist, Inc.; Pittsburgh, Pa) is a left ventricular assist device (LVAD) that can be placed percutaneously to provide short-term cardiac support for high-risk patients who are undergoing cardiac procedures. We performed this study in order to evaluate the short-term safety and efficacy of using the TandemHeart in high-risk patients who undergo aortic valvuloplasty procedures.

Patients and Methods

Patient Population

From May 2003 through August 2005, 11 patients (age, 83 ± 11 yr; range, 62–94 yr; 6 men [55%]) with symptomatic valvular aortic stenosis underwent PABV procedures at our institution (Table I). All patients had previously been evaluated by both a cardiologist and a cardiothoracic surgeon and had been found to be unsuitable candidates for valve replacement surgery. The valvuloplasty was performed in

TABLE I. Patient Characteristics (n=11)

	Variable
Age at valvuloplasty (yr)	83 ± 11
Male	6 (55%)
Coronary artery disease	4 (36%)
With TandemHeart	7 (63%)
Baseline ejection fraction	0.31 ± 0.14
Baseline aortic valve area (cm²)	0.62 ± 0.12
Baseline transaortic valve gradient (mmHg)	58.3 ± 17.8

Data are expressed as number, percent, or mean ± SD.

4 patients without any LVAD support, and 7 patients were treated using the TandemHeart for increased hemodynamic stability. The decision to use the TandemHeart device depended on its availability and not on any patient characteristics. Transthoracic and transesophageal echocardiography in each patient showed a severely calcified aortic valve, with a mean valve area of 0.62 ± 0.12 cm².

Valvuloplasty Procedure

Percutaneous aortic balloon valvuloplasty was performed after informed consent was obtained. Conscious sedation was used in 5 patients, and general anesthesia was used in the other 6. Venous access from the right femoral vein was attained with a 6F sheath, and subsequently the access site was dilated in a stepwise fashion until a 14F sheath was placed. The left atrium was reached by means of an 8F Mullins sheath (Cook Medical Inc.; Bloomington, Ind) from the right femoral vein, using standard transseptal puncture techniques. Intracardiac echocardiography was used to guide the transseptal puncture in 5 cases. Heparin was administered to maintain the activated whole blood clotting time (ACT) between 250 and 300 sec.

Subsequently, a 7F Berman end-holed catheter (Arrow International; Reading, Pa) was advanced—using balloon flotation together with a 0.038-inch hydrophilic or Wholey guidewire (Mallinckrodt, Inc.; Hazelwood, Mo)—through the Mullins sheath into the left atrium, then into the left ventricle and past the left ventricular outflow tract, and then across the aortic valve into the aortic arch. At this point, the guidewire was removed and replaced with a 0.032-inch stiff exchange-length 260-cm wire. This was passed through the Berman catheter into the abdominal aorta. The 0.032-inch wire was snared in the distal abdominal aorta and secured by means of a 15-mm microsnare catheter. The snare was secured to the wire and left inside a 60-cm left femoral artery sheath, providing support to advance an Inoue balloon catheter (Toray Marketing & Sales, Inc.; Hous-

ton, Tex) from the right femoral vein through the atria and left ventricle, and then across the aortic valve. The balloon was inflated across the aortic valve to a diameter of 22 to 26 mm. The Inoue balloon could not be advanced antegrade in 3 of the 11 patients; the procedure was tried by the retrograde approach in those cases. In 2 patients, the Inoue balloon could not be advanced even retrograde, so a Medi-tech balloon (Boston Scientific; Natick, Mass) was passed in a retrograde fashion. In all, we used the Inoue balloon in 9 procedures (1 retrograde approach and 8 antegrade approaches) and the Medi-tech balloon in 2 procedures (both via retrograde approaches).

Implantation of TandemHeart

The technique for insertion of the TandemHeart has been described previously.[7,8] Briefly, a 21F catheter is placed in the left atrium to withdraw oxygenated blood and to decompress the left ventricle. The blood is circulated via a centrifugal pump, and it re-enters the arterial system at a rate of up to 4 L/min, through a 15F or 17F cannula placed in the femoral artery.

Statistical Analysis

Normally distributed data are presented as mean ± standard deviation. Serial comparisons between baseline and follow-up were determined by the paired Student's t test. Comparisons between the 2 groups were determined by the unpaired Student's t test. A χ^2 or a Fisher's exact test was used to find significant differences between categorical variables. The level of significance was set at $P < 0.05$. For statistical evaluation, SPSS software, version 11.5 (SPSS Inc.; Chicago, Ill) was used.

Results

Of the 11 patients with symptomatic valvular aortic stenosis who underwent a PABV procedure, all were deemed high-risk surgical candidates due to advanced age and comorbidities; their mean ejection fraction was 0.30 ± 0.14). Of the 4 patients who underwent valvuloplasty without LVAD support, 1 died during the procedure, and another died the next day. All 7 patients who had TandemHeart assistance survived for at least 1 month after the procedure.

With TandemHeart Assistance

Aortic valvuloplasty with TandemHeart assistance was performed in 7 patients (4 of them men) who had a mean age of 79 ± 12 yr) (Table II). The average output of the TandemHeart device was 3.0 ± 0.7 L/min. The antegrade approach to the aortic valve was used in 4 patients, and the retrograde approach was used in the remaining 3 patients. The Inoue balloon was used in 5 of the procedures, and a Medi-tech balloon was used

TABLE II. Comparison of Clinical and Hemodynamic Characteristics with or without TandemHeart

Variable	TandemHeart Yes (n=7)	No (n=4)	P Value
Age at valvuloplasty (yr)	79 ± 12	89 ± 6	0.2
Male	4 (57)	2 (50)	1
Antegrade approach (%)	4 (57)	4 (100)	0.2
Coronary disease (%)	2 (29)	2 (50)	0.6
Balloon diameter (mm)	23.6 ± 4.0	24.3 ± 1.3	0.8
Number of balloon inflations	2.3 ± 0.8	2.8 ± 1.5	0.5
Total inflation time (sec)	37.1 ± 9.5	11.3 ± 2.5	0.001
Baseline ejection fraction	0.24 ± 0.09	0.47 ± 0.10	0.005
Baseline aortic valve area (cm²)	0.59 ± 0.11	0.68 ± 0.14	0.3
Baseline transaortic valve gradient (mmHg)	61.5 ± 20.9	52.8 ± 11.1	0.5
Procedure time (min)	336 ± 111	183 ± 41	0.011
Fluoroscopy time (min)	52 ± 20	32 ± 10	0.1

Results before and after the procedure

		TandemHeart Yes (n=7)	No (n=4)	
Ejection fraction	before	0.24 ± 0.09	—	
	after	0.27 ± 0.08 (P=0.28)	—	
Aortic valve area (cm²)	before	0.59 ± 0.11	0.60 ± 0.00	
	after	0.88 ± 0.22 (P=0.006)	1.06 ± 0.34 (P=0.3)	
Aortic valve gradient (mmHg)	before	61.5 ± 20.9	53.3 ± 13.6	
	after	44.6 ± 15.1 (P=0.02)	27.7 ± 14.2 (P<0.0001)	

Data are expressed as number, percent, or mean ± SD.

in 2. Two of the patients had coexistent coronary artery disease and required coronary stenting in addition to the valvuloplasty: 1 patient underwent concurrent carotid artery stenting, and the other underwent concurrent iliac artery stenting. All of the procedures were technically successful, because each patient survived at least 1 month after the procedure. The long-term benefit was variable and depended on the baseline ejection fraction and on the patient's comorbid conditions. On echocardiography, aortic valve function improved: the aortic valve area increased from 0.59 ± 0.11 cm² to 0.88 ± 0.22 cm² (P=0.006), and the transvalvular gradient decreased from 61.5 ± 20.9 mmHg to 44.6 ± 15.1 mmHg (P=0.02). No patient developed aortic regurgitation or had significant hemolysis. One patient had major bleeding and required blood transfusion (5 units). The mean duration of the procedures, including concomitant coronary artery stenting, was 336 ± 111 min, and the mean fluoroscopy time was 52 ± 20 min. Patients were connected to the TandemHeart for a mean duration of 40 ± 86 hr (range, 1.5–216 hr). Most (6 of 7) had the TandemHeart only temporarily; it was removed in the catheterization laboratory or shortly after the procedure. Surgical repair of the TandemHeart insertion site was required in 4 of 7 patients.

Without TandemHeart Assistance

Four patients (mean age, 89 ± 6 yr) underwent valvuloplasties without LVAD support (Table II). The Inoue balloon, advanced antegrade in all cases, was inflated an average of 2.8 ± 1.5 times, to an average diameter of 24.3 ± 1.3 mm. The average maximum inflation time was 4.5 ± 1.0 sec/inflation, and the average total inflation time was 11.3 ± 2.5 sec. The average ejection fraction was 0.47 ± 0.10. Two of the patients had coexistent coronary artery disease that required coronary artery stenting, and 1 patient presented with an acute myocardial infarction. One patient died of cardiac arrest during the procedure. It is believed that the wire compressed the anterior leaflet of the mitral valve, causing mitral regurgitation, which in turn produced systemic hypotension and pulmonary edema. Another patient had a technically successful procedure but died the following day. Before the procedure, this patient had presented with cardiogenic shock that had required hemodynamic support with multiple vasopressors. The cause of death was brady/asystolic cardiac arrest.

Aortic valve function improved, as evaluated by post-procedure echocardiography: the transvalvular gradient decreased from 53.3 ± 13.6 mmHg to 27.7 ± 14.2 mmHg, and the aortic valve area increased from 0.60 ± 0 cm^2 to 1.06 ± 0.34 cm^2. No patient sustained aortic regurgitation or significant hemolysis. The mean duration of the procedures was 183 ± 41 min, and the mean fluoroscopy time was 32 ± 10 min.

Discussion

This was a small series of PABV performed in very ill patients—nonsurgical candidates with critical aortic stenosis. It has been shown that PABV usually reduces transaortic valve gradients, increases calculated aortic valve areas, and improves left ventricular ejection fractions.[9-11] However, short- and intermediate-term follow-up data indicate that these cardiac hemodynamic variables can revert to their pre-valvuloplasty baseline levels as early as 2 hours after the procedure.[12] These observations demonstrate that balloon valvuloplasty in calcific aortic valve stenosis is a palliative procedure. The results of these aortic balloon dilations, by either the antegrade or the retrograde approach, do not provide dramatic improvements. Nevertheless, the procedure did provide some temporary relief in most of our patients, reduced instances of congestive heart failure, and improved their functional status for a few months. In 2 of the patients who received the TandemHeart device, PABV served as a successful bridge to surgical valve replacement.

The elective use of the TandemHeart for circulatory support during these high-risk balloon valvuloplasty procedures preserved hemodynamic stability in our patients, regardless of the intrinsic cardiac function, and enabled precise placement of the valvuloplasty balloon. In addition, balloon expansion was maintained continuously for up to 45 sec without forward flow across the aortic valve and without balloon displacement. These attributes of precise positioning and adequate time for inflation without ejection of the balloon are essential during stent-valve placement. The development by Cribier and associates[13] of percutaneous implantable prosthetic aortic valves could, in the near future, offer an alternative to patients in similar clinical conditions and perhaps improve the long-term prognoses. Ideally, patients with critical, inoperable aortic stenosis might be treated with nonsurgical implantation of a prosthetic aortic valve, and PABV might be used as a bridge to this procedure in selected patients. To prevent stent-valve displacement during balloon inflation, it has been recommended that operators decrease aortic blood flow during device delivery by means of rapid cardiac pacing (200–220 beats/min) of the right ventricle. In place of this rapid pacing, use of the TandemHeart can support the circulation and unload the left ventricle during deployment of a stent-valve, thereby reducing the risk of global ischemia and death in this high-risk patient group. Moreover, some of the other techniques for percutaneous placement of prosthetic aortic valves, now under development,[14] may be facilitated by percutaneous LVAD hemodynamic support, because they too will require precise placement.

These observations are presented in the hope of providing a methodological concept to improve the safety and accuracy of percutaneous aortic valve placement. In the initial group of 20 high-risk patients with critical aortic stenosis who received the Cribier-Edwards percutaneous valve (Edwards Lifesciences; Irvine, Calif),[15,16] the mortality rate was approximately 20%. There are several explanations of why this initial mortality rate was so high, but possible reasons include the premorbid condition of the patients, the need to rapidly pace the right ventricle to temporarily decrease cardiac output so that the balloon will stay in place during the crucial seconds of stent-valve deployment, and the development of significant paravalvular aortic regurgitation. For at least 1 of these patients, rapid right ventricular pacing induced ventricular fibrillation. In addition, use of the antegrade approach can place pressure on the anterior mitral valve leaflet, drawing it anteriorly toward the left ventricular outflow tract, thereby producing mitral regurgitation. This hemodynamic stress—poorly tolerated by the hypertrophied, poorly compliant left ventricle—can result in global left ventricular ischemia with release of intracellular calcium, producing a "stone heart" similar to that which sometimes occurs during surgical repair of aortic stenosis. Subsequent reports of this procedure have demonstrated a decrease in mortality associated with a greater use of the retrograde approach and better selection of cases with referral of patients who have severely calcified aortas to a percutaneous apical left ventricular approach.

Our series of percutaneous aortic balloon valvuloplasties in critically ill patients suggests that percutaneous heart valve deployment could be performed more safely and precisely in selected patients with use of the TandemHeart percutaneous LVAD.

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