

First Human Case Description of TandemHeart™-Assisted High-Risk Percutaneous Balloon Aortic Valvuloplasty Using Bivalirudin Anticoagulation

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ABSTRACT: TandemHeart™ is a recently-introduced percutaneous left ventricular assist device that can be used for hemodynamic support during high-risk interventional procedures in severely compromised patients. Angioplasty and stent placement in patients with coronary artery disease and high-risk coronary anatomy including the left main coronary artery have been described using this device. We report the first human case description of a high-risk percutaneous balloon aortic valvuloplasty for critical bicuspid aortic stenosis using the TandemHeart for periprocedural hemodynamic support. Also not previously reported is the use of bivalirudin as the periprocedural antithrombin agent during and after high-risk aortic valvuloplasty.

J INVASIVE CARDIOL 2007;19:E5-E8

Success of high-risk interventional procedures depends upon periprocedural hemodynamic stability. The TandemHeart™ (Cardiac Assist, Inc., Pittsburgh, Pennsylvania) is a percutaneous nonpulsatile centrifugal left ventricular (LV) assist device used to support the ailing heart in a variety of high-risk interventional procedures. Most of these procedures have been directed towards arterial revascularization.¹⁻⁴ In addition, it has been used to support the heart during recovery from cardiogenic shock secondary to myocardial infarction^{5,6} and as a temporary assist device for post-cardiotomy cardiac failure.⁷ Although, the application of this device during percutaneous aortic valve replacement in an animal model has been described,⁸ thus far, the use of the TandemHeart device to support a poorly-functioning LV during aortic valvuloplasty in humans has not been reported. We report our experience utilizing the TandemHeart device for periprocedural hemodynamic support in a patient with severe bicuspid aortic stenosis with severely depressed biventricular function undergoing percutaneous balloon aortic valvuloplasty. The patient was not a surgical aortic valve replacement candidate due to prohibitive perioperative mortality risk.

Case Report. *The patient was a 56-year-old male who was referred to cardiovascular surgery at our institution for consideration of an aortic valve replacement to treat critical bicuspid aortic valve stenosis. The patient had New York Heart Association Class III-IV symptoms of heart failure. His past medical history was sig-*

nificant for episodes of congestive heart failure requiring hospitalization, dyslipidemia, use of alcohol and tobacco. His medications included aspirin 81 mg daily, ramipril 2.5 mg twice daily, digoxin 0.125 mg once daily, pravastatin 10 mg once daily, furosemide 20 mg daily and potassium chloride 10 mEq once a day. A two-dimensional transthoracic echocardiogram (TTE) revealed LV and right ventricular (RV) ejection fractions of 10% and 15%, respectively. The aortic valve was bicuspid, thickened and with severely restricted mobility. It showed prominent systolic doming with poststenotic dilatation of the aorta. The peak instantaneous and mean gradients using continuous-wave Doppler across the aortic valve were 65 and 39 mmHg, respectively. The aortic valve area using continuity equation was calculated to be 0.5 cm². The aortic root measured 27 mm. There was mild-to-moderate aortic regurgitation. Pulmonary artery systolic pressure by tricuspid regurgitation jet was estimated at 51 mmHg. A preprocedure right heart catheterization showed pulmonary artery pressures of 92/49, with a mean of 65 mmHg. The patient's mean pulmonary capillary wedge pressure was 29 mmHg. His pulmonary vascular resistance was 774 dyne-second-cm⁻⁵ and his pulmonary artery saturation was 24%. Cardiac output and indices by thermodilution and assumed Fick methods were 3.7 L/minute and 2.09 L/minute/m², and 1.72 L/minute and 0.97 L/minute/m², respectively. Coronary angiography performed using ioxilan showed no significant obstructive atherosclerotic coronary artery disease. The risk of surgical aortic valve replacement was considered prohibitively high due to reduced biventricular ejection fraction and high pulmonary artery pressures. After discussing possible treatment alternatives, the patient opted for balloon aortic valvuloplasty.

Procedure for TandemHeart Placement. *The patient was given mild sedation. Right and left sided common femoral arterial and venous accesses were obtained. The fossa ovalis was identified with the help of intracardiac echocardiography (ICE) guidance using an Acunav 10 Fr 10-MHz ultrasonic catheter (Acunav, Acuson, Mountain View, California) inserted through the left femoral vein. From the right femoral venous approach, a transeptal puncture was performed using the Brockenbrough needle and Mullins sheath as during balloon mitral valvuloplasty. The Mullins sheath was exchanged for the 14/21 Fr two-stage dilator over a 0.038-inch J-tip 260 cm Amplatz Super Stiff™ guidewire (Medi-Tech, Boston Scientific Corporation, Natick, Massachusetts). Next, the 21 Fr TandemHeart transeptal cannula was advanced along with the 13 Fr obturator over the Amplatz Super Stiff™ guidewire and was placed in the left atrium (Figure 1). The position of the cannula in the left atrium was confirmed by ICE (Figure 2). The obturator and the wire were then removed. At this*

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Disclosure: Dr. Hillegass is a member of the speakers' bureau of The Medicines Company.

Manuacript submitted on July 5, 2006, provisional acceptance given August 14, 2006, manuscript accepted September 1, 2006.

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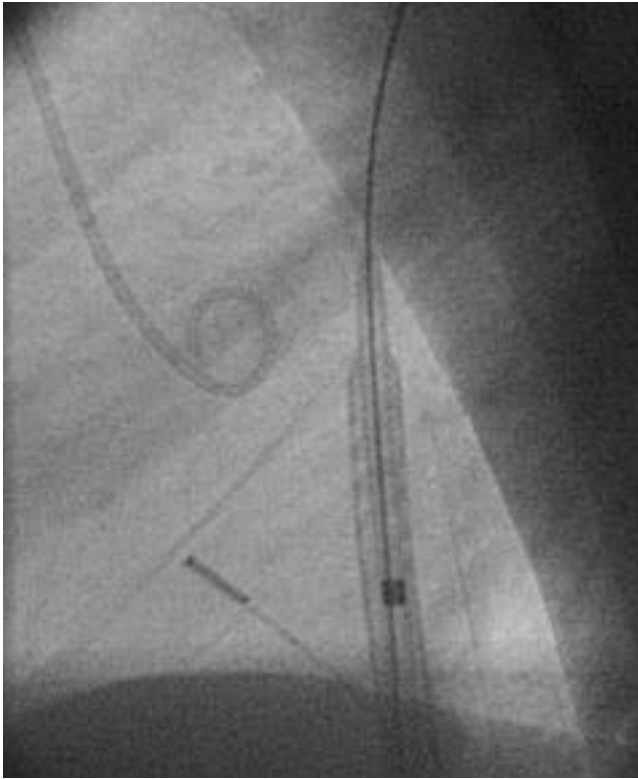


Figure 1. Lateral angiographic cine projection showing the advancement of TH cannula and the obturator into the left atrium over Amplatz Super Stiff™ guidewire. A pigtail catheter and ICE probe can be seen anteriorly.



Figure 2. Intracardiac echocardiography (ICE) picture showing the TandemHeart transseptal cannula (arrowheads) traversing the interatrial septum and into the left atrium.



Figure 3. ICE picture showing a 0.038-inch J-tip 260 cm Amplatz Super Stiff™ guidewire (arrowheads) across the stenotic aortic valve (AV) before balloon inflation.

point, a 0.75 mg/kg bolus dose of bivalirudin was given intravenously and an infusion at 1.75 mg/kg/hour was started. Care was taken to place all the sideholes of the TandemHeart cannula into the

left atrium to avoid possible right-to-left shunt during the device operation. The proximal end of the cannula was sutured to the skin of the patient's thigh and clamped. A 15 Fr femoral arterial perfusion cannula was placed through the right femoral artery with the distal end of the cannula lying above the aortic bifurcation. The proximal end of the cannula was similarly sutured to the patient's thigh and clamped. The femoral venous cannula was connected to the inflow conduit and the femoral arterial canula to the outflow conduit of the TandemHeart pump after performing de-airing as per the specified protocol. A saline infusate was started which provided hydrodynamic bearing and local cooling for the motor of the pump. The pump was then connected to the TandemHeart controller and its speed adjusted to provide a support of 2.5 L/minute, which provided the best systemic arterial blood pressure.

Through the left femoral artery sheath, an AL1 diagnostic catheter and a 0.035-inch straight-tip wire was used to cross the aortic valve. The AL1 catheter was advanced over the straight wire into the LV and the straight-tip wire exchanged for a J-tip 260 cm Amplatz Super Stiff™ guidewire (Figure 3). The AL1 catheter was then exchanged for a 25 mm x 6.0 cm balloon dilatation catheter (Z-Med II™, Numed Inc., Hopkinton, New York) over the Amplatz wire. Multiple inflations across the aortic valve were performed until the waist on the balloon disappeared (Figures 4 and 5). The TandemHeart pump was left in situ running overnight along with the bivalirudin infusion drip.

Hospital Course. Postprocedure, two-dimensional TTE performed the next day revealed significant improvement in LV ejection fraction which rose to 20–25%. The RV ejection fraction, however, remained the same. The aortic valve gradient was reduced to a peak instantaneous/mean gradient of 48/28 mmHg, and the aortic valve area increased to 1.3 cm² without any

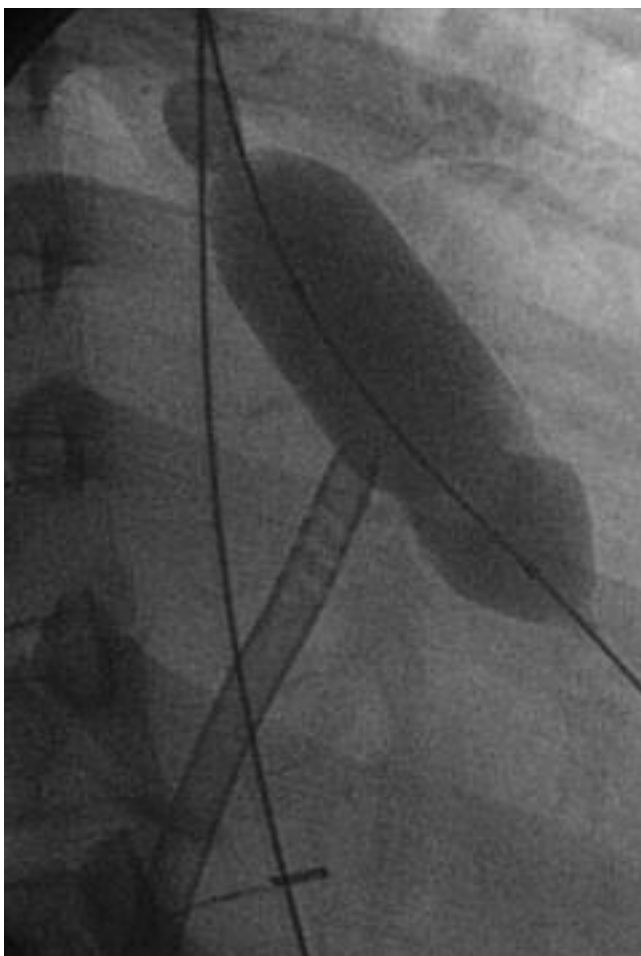


Figure 4. A 30-degree right anterior oblique angiographic cine picture showing Z-Med II balloon across the aortic valve in an inflated position; the waist on the balloon on either side is visible. TandemHeart transseptal cannula is seen crossing the spine into the left atrium. The ICE probe can be seen in the right atrium at the bottom lefthand side of the picture.

increase in the degree of aortic regurgitation. The estimated pulmonary artery systolic pressure remained the same. Twenty-four hours postprocedure, the TandemHeart pump was removed and the bivalirudin infusion was discontinued. The patient's activated clotting time during bivalirudin infusion was checked every 6 hours and maintained above 250 seconds. The in-hospital course of the patient was uneventful with no bleeding complications, and he was discharged after 2 days with a plan for consideration of elective aortic valve replacement at a later date.

Discussion. Intra-aortic balloon pump (IABP) therapy has been used since the late 1960s to support the failing left ventricles in patients with acute myocardial infarction and cardiogenic shock. The TandemHeart is a novel device used to mechanically assist the heart in the setting of severe LV dysfunction. This device offers a number of advantages over the IABP. These include better metabolic and hemodynamic physiology reflected in a more effective improvement in car-

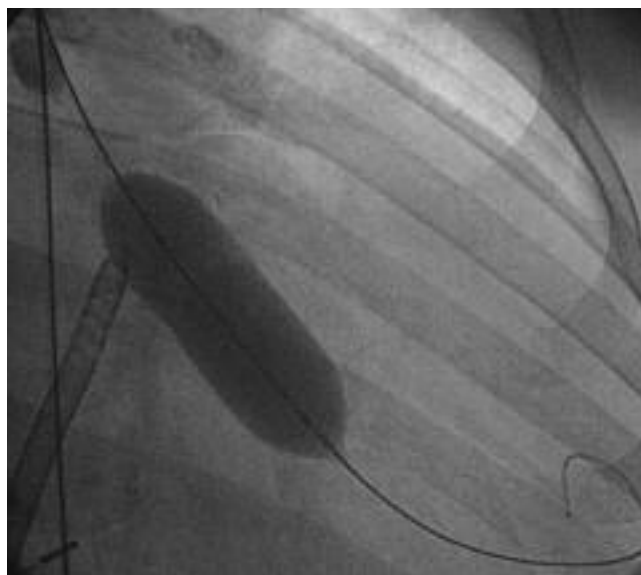


Figure 5. Right anterior oblique cine angiographic view showing the Z-Med II balloon across the aortic valve in a fully open position with minimal waist suggesting good result from inflation. The TandemHeart transseptal cannula and ICE probe can also be appreciated, as in Figure 4.

diac output, pulmonary artery pressure, pulmonary capillary wedge pressure, serum lactate and renal perfusion.⁶ Moreover, unlike the IABP, which often requires specific algorithms and adjustments in patients with arrhythmia, the TandemHeart device operates well in patients with arrhythmia.³ These advantages have made TandemHeart deployment an attractive option for periprocedural hemodynamic support in patients with severely compromised LV function and who have risk factors for and/or manifest arrhythmia. There has not been any reported experience of utilizing the TandemHeart device in patients with severe aortic valvular stenosis with very poor LV function. The patient described here had been denied surgery on the grounds of high perioperative mortality risk, which led to the contemplation of a high-risk interventional procedure. Periprocedural hemodynamic support was felt to be required in this procedure, given the significant risk of bradycardiac collapse and death in a patient with severe LV and RV systolic dysfunction during balloon inflations across the calcific aortic valve. Since IABP therapy is triggered by either pressure waveform or electrocardiogram, it is not as effective or reliable for hemodynamic support during aortic valvuloplasty, a procedure that may involve periods of bradycardia and asystole. Given these factors in estimating periprocedural risk in our patient, aggressive and effective periprocedural hemodynamic support with the TandemHeart device was considered prudent.

The depressed ejection fraction in many patients with severe aortic stenosis represents excessive afterload.⁹ Relief of afterload after aortic valvuloplasty and the resultant improvement in LV function offers potential for future therapeutic options to such patients. The use of the TandemHeart in our

patient may have contributed to an uncomplicated and technically successful procedure and uneventful postprocedural course in an otherwise prohibitively high-risk patient. Our hope is that unloading the LV with the successful aortic valvuloplasty will allow sufficient functional recovery to bridge our patient to an alternative, more durable procedure such as conventional aortic valve replacement and/or heart transplantation at a later date.

A distinction must be made between the patient described here and those who would undergo a percutaneous aortic valve implantation for symptomatic severe aortic stenosis with multiple comorbid conditions. Percutaneous heart valve placement using a retrograde approach remains a viable last resort option for inoperable patients with severe calcific aortic stenosis with very poor LV function and associated comorbidities¹⁰ with encouraging short¹¹ and mid-term follow-up results.¹² However, the patient subset selected for percutaneous valve replacement represents extremely sick individuals in advanced stages of heart failure and/or with comorbidities that would not permit valve replacement surgery or cardiac transplantation due to excessively high surgical risk. Thus percutaneous heart valve placement has been used in these inoperable patients as the “definitive option” or “destination therapy”. With LV recovery, our patient may become an operative candidate.

This case is also unique because bivalirudin was used to anticoagulate the patient during the procedure. This also is the first report of the use of bivalirudin in this type of procedure. Bivalirudin confers several potential advantages over unfractionated or low-molecular weight heparins including predictable anticoagulant effect and perhaps a reduced risk of access site bleeding, as has been observed in other percutaneous procedures.¹³⁻¹⁴ Since larger-diameter sheaths are associated with an increased risk of blood loss and bleeding with heparin anticoagulation, we hypothesize that the use of bivalirudin will result in a lower risk of bleeding in TandemHeart procedures where multiple large-diameter arterial and venous sheaths are required.¹⁵ To date, we have not needed to rapidly reverse anticoagulation in a procedure requiring TandemHeart support. If such a need were to arise, this could be a potential disadvantage of bivalirudin compared to unfractionated heparin as the periprocedural antithrombin therapy. In our experience, however, the removal of cardiopulmonary percutaneous support and other large-diameter

sheaths after heparin therapy has been fraught with a high rate of vascular access site bleeding and complications. We found the use of bivalirudin feasible, safe and effective in initiating and maintaining anticoagulation during the procedure using the TandemHeart without any local or systemic bleeding complications.

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