Use of a Percutaneous Left Ventricular Assist Device For High-Risk Cardiac Interventions and Cardiogenic Shock

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ABSTRACT: Objective. We sought to describe the use of the TandemHeart percutaneous left ventricular assist device (PVAD) in a group of high-risk patients undergoing complex cardiovascular procedures. **Background.** There is a substantial risk of acute decompensation and death in patients with cardiogenic shock or a reduced cardiac reserve undergoing high-risk cardiovascular interventions. The TandemHeart PVAD provides near-total hemodynamic support in this setting. **Methods.** Thirty-seven high-risk patients underwent placement of the TandemHeart PVAD during 38 separate procedures between April 2007 and April 2009. PVAD insertion was considered emergent if a patient was not expected to survive more than 6 hours without PVAD support. Technical success was defined as successful initiation of the PVAD and completion of the intended interventional procedure. **Results.** All 37 patients were in cardiogenic shock or undergoing complex coronary and valvular interventions with a high probability of hemodynamic collapse. The mean (± standard deviation) patient age was 73 ± 14 years; 97% were in either NYHA class III–IV heart failure or cardiogenic shock; and the mean EuroSCORE was 11 ± 3.4. Indications for ventricular assist device placement included critical aortic stenosis (n = 8), severe left main coronary stenosis (n = 18), severe multivessel coronary stenosis (n = 19) and severe cardiomyopathy (n = 23). Four patients were being managed for fulminant myocarditis, ventricular free-wall rupture, flail mitral valve or severe paravalvular leak. Despite their critical status and frequent (82%) need for post-procedure blood transfusion, this complex and high-risk patient population tolerated PVAD-supported intervention well and technical success was achieved in all patients. Seventy-one percent of patients survived to hospital discharge with improved functional status. Most deaths occurred in patients not expected to survive due to their moribund status and multiorgan failure. **Conclusion.** This experience demonstrates the utility and effectiveness of TandemHeart PVAD support in patients with advanced disease, critical clinical status and limited therapeutic options.

J INVASIVE CARDIOL 2010;22:360–364

Key words: left ventricular assist device, percutaneous coronary intervention, cardiogenic shock

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Disclosure: Dr. Steven Burstein is on the Speaker's Bureau for Cardiac Assist, Inc., manufacturer of the TandemHeart Device.

Manuscript submitted January 29, 2010, provisional acceptance given March 22, 2010, final version accepted May 18, 2010.

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The management of patients in cardiogenic shock and during high-risk cardiac interventions remains a challenge despite significant advances in percutaneous techniques and devices. Until recently, mechanical hemodynamic support was limited to the use of intra-aortic balloon pump (IABP) counterpulsation during percutaneous and surgical procedures or during recovery. Although the IABP is widely available and effective, the main limitation is that it can only augment cardiac output and is unable to provide full circulatory support.[1,2]

Patients with severe coronary atherosclerotic, valvular and myopathic conditions may present in profound cardiogenic shock (CS) and have little reserve with which to tolerate complex percutaneous procedures. Many of these patients are considered too "high risk" to undergo traditional cardiac surgery and/or have significant comorbid conditions that preclude surgery. Use of the TandemHeart (*CardiacAssist, Inc., Pittsburgh, Pennsylvania*) percutaneous ventricular assist device (PVAD) provides a level of periprocedural hemodynamic security and therefore allows treatment of complex and critically ill patients for whom there are no alternative therapies. The TandemHeart PVAD provides circulatory support using an extracorporeal continuous-flow centrifugal pump. Oxygenated blood is withdrawn through a transseptal left atrial cannula placed via the femoral vein and returned through an inflow cannula in the femoral artery.[3,4] The device may be discontinued following an intervention or used to provide continued support in a critical-care unit.

Experience with the TandemHeart continues to increase, though only a small portion of interventional centers have access to this technology.[5] In addition, another percutaneous assist device is now available in the United States, though it does not provide as significant an augmentation of cardiac output as the TandemHeart device.[6,7] The published data for the TandemHeart PVAD includes two randomized trials primarily focused on hemodynamic indices in CS following myocardial infarction[2,8] and multiple case series. This report describes our experience with the use of the TandemHeart PVAD in a series of patients with severe cardiovascular disease, and it represents the largest published experience with this device.

Methods

Between April 2007 and April 2009, a total of 37 patients underwent placement of the TandemHeart PVAD device during 38 separate procedures. Patient data was retrospectively

Table 1. Patient characteristics of the study group.

	n = 37 (%)
Age (years, median)	73 ± 14
Female gender	14 (37.8)
Hypertension	24 (64.8)
Diabetes mellitus	13 (35.1)
Chronic lung disease	8 (21.6)
Prior stroke	1 (2.7)
Prior coronary artery disease	20 (54.1)
Recent myocardial infarction	13 (35.1)
Functional Status	
NYHA Class I–II	1 (2.7)
NYHA Class III–IV	18 (48.6)
Cardiogenic shock	18 (48.6)
Pressor support	17 (45.9)
Intra-aortic balloon pump	9 (24.3)
Ventilator support	12 (32.4)
Prior PCI†	4 (10.8)
Prior CABG‡	5 (13.5)
Peripheral arterial disease	7 (18.9)
Chronic kidney disease	14 (37.8)

†Percutaneous coronary intervention; ‡Coronary artery bypass grafting; NYHA = New York Heart Association

analyzed by medical chart abstraction and review of the angiographic data. Most patients had more than one severe cardiac condition requiring circulatory support. Twenty-eight (74%) patients required PVAD only during an interventional procedure, and the remaining 9 required continued support following the procedure.

PVAD insertion was considered emergent if a patient was not expected to survive more than 6 hours without PVAD support. Patients with a left ventricular ejection fraction (LVEF) ≤ 30% were considered to have a severe cardiomyopathy. Myocardial infarction (MI) was considered recent if it occurred within 14 days. Cardiogenic shock (CS) was defined by either systolic blood pressure (SBP) < 90 mmHg or need for supportive measures to maintain SBP > 90 mmHg and a cardiac index < 2.2 L/min/m^2 in the setting of a pulmonary capillary wedge pressure > 18 mmHg. Transfusion, thrombolysis in myocardial infarction (TIMI) major and minor bleeding were assessed by reviewing the medical record and blood bank reports. A baseline hematocrit of < 0.30 was considered severe anemia. Chronic kidney disease was defined as an estimated glomerular filtration rate of ≤ 60 ml/min/1.73 m^2. Technical success was defined as successful initiation of the PVAD and completion of the intended interventional procedure. For percutaneous coronary intervention (PCI), technical success was defined as < 30% residual diameter stenosis and TIMI 3 flow in the treated vessel. Percutaneous aortic balloon valvuloplasty (PABV) was successful if a greater than one-third reduction in the mean transvalvular gradient was obtained. Cardiac surgical risk was assessed using the online EuroSCORE calculator.[9]

Set-up and use of the TandemHeart device has been described in detail previously.[4] In this series, arterial and venous access was obtained with 6 French (Fr) sheaths placed in the right and left femoral veins and arteries. Arterial punctures for the large cannula were routinely closed using the "preclose" method.[10,11] A similar suture deployment technique was performed on the femoral vein used for transeptal catheterization

Table 2. Cardiovascular conditions of the study group.

	n = 37 (%)
Coronary artery disease	32 (86.5)
Left main disease	18 (48.6)
3-vessel disease	19 (51.4)
Severe aortic stenosis	8 (21.6)
Myocarditis	1 (2.7)
Ventricular free-wall rupture	1 (2.7)
Flail mitral valve	1 (2.7)
Paravalvular leak	1 (2.7)
Ejection fraction %, median/mean	22.5/30.6

Table 3. Procedures performed.

	n = 38 (%)
Elective PVAD	28 (73.7)
Emergent PVAD	10 (26.3)
PCI	28 (73.7)
Left main	16 (42.1)
Unprotected left main	13 (34.2)
Multivessel	18 (47.3)
Rotational atherectomy	13 (34.2)
Aortic valvuloplasty	7 (18.4)
Arterial inflow cannula	
15 Fr size	31 (81.5)
17 Fr size	6 (15.8)
Iliac angioplasty/stent	3 (7.9)
Arterial preclosure	30 (78.9)
PVAD removed in lab	28 (73.7)

PVAD = percutaneous ventricular assist device; PCI = percutaneous coronary intervention

Table 4. Procedural and clinical outcomes.

	n = 38 (%)
PVAD technical success	38 (100)
In-lab death	1 (2.6)
Survival to discharge	27 (71)
Stroke	1 (2.6)
Bleeding	
TIMI minor	12 (32)
TIMI major	31 (82)
Emergent surgery	0
Transfusion	31 (82)
Discharge status, survivors	
NYHA Class I–II	20 (74)
NYHA Class III–IV	7 (26)

NYHA = New York Heart Association; PVAD = percutaneous ventricular assist device

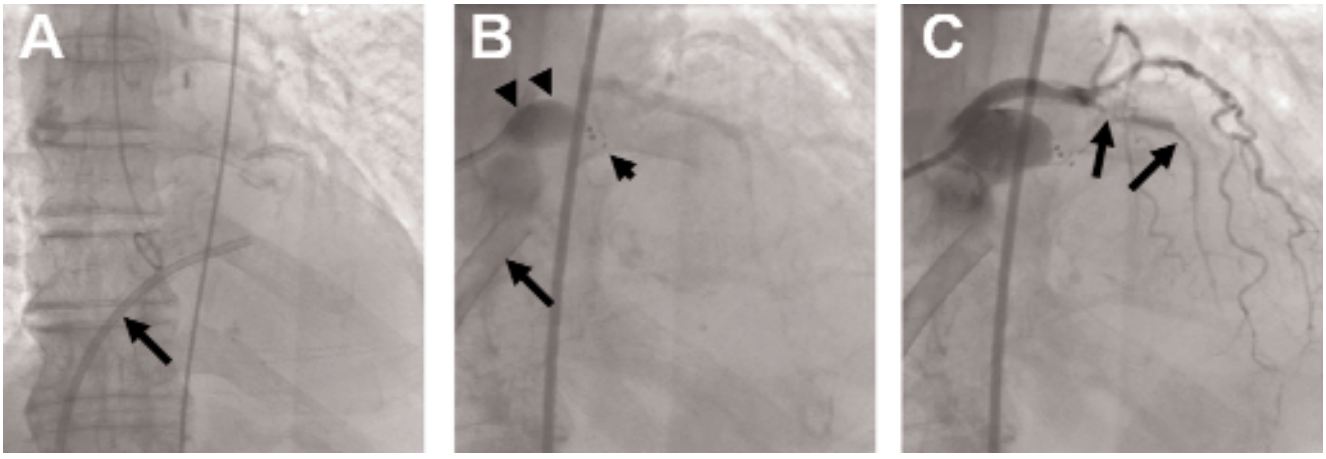

Figure 1. *Left anterior descending artery coronary intervention with TandemHeart support in a patient with severely reduced left ventricular function.* **(A)** *Transeptal sheath (arrow) within the left atrium. Pigtail catheter in the ascending aorta.* **(B)** *Left atrial cannulae within the left atrium (arrow). Arrowhead shows the distal radio-opaque marks on the left atrial cannulae. Stasis of contrast (double arrowheads) within the aortic cusps during full TandemHeart support.* **(C)** *Complex, severe lesions (arrows) with extensive calcium in the mid portion of the left anterior descending artery.*

in a large portion of cases. Dilation of the interatrial septum and placement of both venous (21 Fr) and arterial (15–17 Fr) cannulae were performed over a 0.035" Amplatzer guidewire (*AGA Medical, Golden Valley, Minnesota*). Two smaller arterial cannulae were used in 1 patient in lieu of a standard 15 or 17 Fr cannula. One patient had unilateral iliofemoral arterial occlusion, and the arterial inflow cannula was placed via the patent femoral vessel and PCI performed from a brachial artery approach. Transeptal puncture was performed under transesophageal echocardiogram guidance in a single case, and the remainder were done under fluoroscopic guidance using standard techniques. Once initiated, the TandemHeart device was set to maximum output throughout the procedure and all patients were fully anticoagulated with unfractionated heparin. Patients receiving continued PVAD support were transferred to the intensive care unit and received continued anticoagulation. For hemodynamically stable patients, the PVAD and both cannulae were removed in the catheterization laboratory. Hemostasis was achieved with the predeployed suture devices and Femostop *(Radi Medical Systems, Wilmington, Massachusetts)* compression.

Results

A total of 37 patients underwent PVAD support at our institution during the study period primarily for hemodynamic support during high-risk cardiac interventions. One patient underwent PVAD-supported PCI on two occasions 9 months apart for a total of 38 PVAD implantations. This cohort includes a predominantly elderly population with a median age of 73 ± 14 years and multiple comorbid conditions. Over half of the patients had a prior history of coronary artery disease and hypertension, and 35% had a recent MI. Five patients were undergoing active treatment for cancer. Most patients were critically ill at the time of initial assessment and placement of the PVAD (Table 1). Eighteen patients (49%) were in NYHA class III–IV heart failure and another 18 patients were in CS. An intra-aortic balloon pump was in place in 24% of patients prior to the procedure and 46% were receiving vasopressor medications. Twelve patients were on a mechanical ventilator due to respiratory insufficiency.

Multiple severe cardiac conditions were present in most patients. The majority (62%) had severe cardiomyopathy with a median left ventricular ejection fraction (LVEF) of 23%. Thirteen patients had a LVEF ≤ 15%. Thirty-two patients had severe coronary artery disease. Eight patients had severe aortic stenosis. One patient each had an acute flail mitral leaflet, fulminant myocarditis, a severe prosthetic mitral paravalvular leak and an MI complicated by ventricular free-wall rupture (Table 2).

The surgical risk was estimated for the 36 patients with conditions potentially managed by open surgery. The mean EuroSCORE was 11 ± 3.4, reflecting the high acuity and complexity of this cohort. In addition, 24 (67%) of these patients had been formally evaluated and declined by a cardiac surgeon either at the referring institution or at our center.

The PVAD was placed emergently in 10 patients not expected to survive without PVAD initiation (Table 3). The remainder were placed electively to support a high-risk intervention. PCI was performed in 28 cases, including 16 left main coronary interventions. Eighteen patients underwent multivessel PCI, and rotational atherectomy was used in 46% of all coronary interventions. PABV was performed on 7 of the 8 patients with severe aortic stenosis. One patient underwent PCI following valvuloplasty. Post-valvuloplasty gradients were assessed with PVAD support at < 1 liter/minute flow prior to the end of the procedure.

Prior to PVAD initiation, angioplasty and stenting of an iliac artery was required to accommodate the large arterial cannula in 3 cases. The "preclose" technique was used in nearly 80% of procedures, and the PVAD was removed in the catheterization laboratory in 28/38 procedures. For patients requiring continued support, the PVAD was in place for 1–4 days. No patients required surgical repair of the arterial access site.

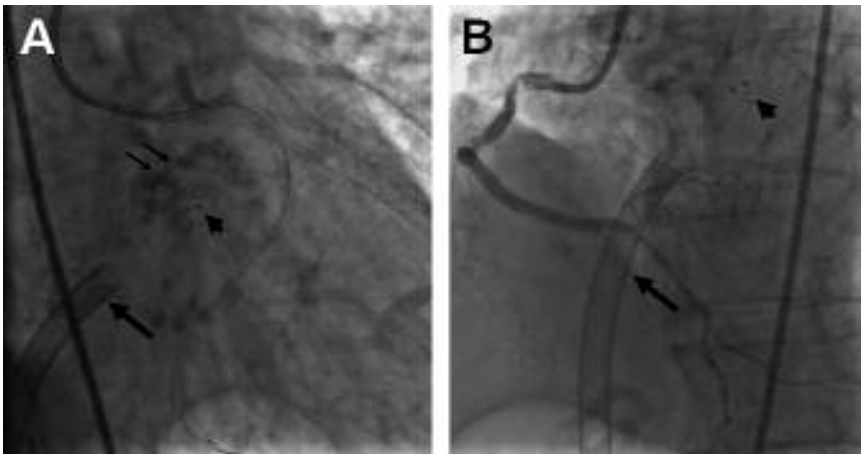

Figure 2. *Left circumflex and right coronary artery coronary interventions with the TandemHeart support in a patient with critical aortic stenosis.* **(A)** *Left circumflex coronary intervention. A guidewire is present in the left circumflex vessel. The body (arrow) and distal portion (arrowhead) of the left atrial cannulae are shown. Severe aortic valve calcium (double arrows) secondary to aortic stenosis.* **(B)** *Right coronary artery intervention. Preprocedural angiogram with severe disease in the proximal, mid and distal right coronary artery. The body (arrow) and distal portion of the left atrial cannulae are shown.*

PVAD initiation and the planned cardiac intervention were technically successful in all cases (Table 4). There was 1 death in the catheterization laboratory in a patient with a post-infarction ventricular free-wall rupture. There were 10 other deaths prior to discharge for a hospital survival rate of 71%. One patient undergoing PABV suffered an acute stroke immediately following discontinuation of the PVAD, with no evidence of cerebral arterial occlusion on angiography. This patient expired after extensive hemorrhagic conversion of the stroke. The other deaths occurred exclusively in patients with CS and multiorgan dysfunction or sepsis.

Periprocedural bleeding and transfusion were common. Forty-seven percent of cases had at least minor bleeding during PVAD initiation or discontinuation or at femoral access sites. TIMI major bleeding occurred in 31 patients (82%), and 31 patients (82%) required a blood transfusion either during or following the procedure (Table 4). There was no relationship between bleeding or transfusion and survival to discharge.

A total of 27 (71%) patients were discharged from the hospital in a stable condition following treatment with the PVAD. Twenty patients were in NYHA functional class I–II upon discharge, while the remaining 7 were in NYHA class III–IV. There were no further deaths out to 30-day follow up.

Discussion

This series demonstrates the utility of a PVAD to provide hemodynamic support for patients with refractory CS and during high risk cardiac interventions in patients not deemed to be appropriate surgical candidates. The TandemHeart system can be safely initiated and discontinued in both elective and emergent situations in a diverse and complex subset of patients. This technique allows complete control of a patient's hemodynamic status during procedures in which there is a high risk of circulatory collapse and death.

Two randomized trials have evaluated the TandemHeart PVAD in comparison to IABP in patients with CS primarily due to acute myocardial infarction.[2,8] In both studies, PVAD was significantly more effective at improving the cardiac index and reducing the pulmonary capillary wedge pressure. Though there were no differences in mortality between the two treatments, the trials were not designed or powered to assess survival differences.

Multiple case series have been published describing the use of the TandemHeart PVAD for CS and high risk coronary interventions.[4,11–18] These have included between 3 and 20 patients. A report by Vranckx et al detailed the use of the TandemHeart over 6 years in 23 patients undergoing high-risk PCI or with acute heart failure following acute coronary syndrome.[19] In this group, the mean EuroSCORE was 6.5 — significantly lower than the population reported here. Twenty-six percent of patients had minor access-site bleeding, and survival to hospital discharge was 74%.

The present series comprises an extreme example of procedural risk as reflected by the EuroSCORE assessment and patient characteristics. A EuroSCORE value of 6 or more is considered high risk, and a value greater than 8 is very high risk. The mean value in this series was 11 ± 3.4 with a range of 5 to 17. A standard EuroSCORE of 11 equates with a logistic EuroSCORE predicted mortality of over 25%.[20,21] In addition, of the 36 patients with potential surgical indications, 24 had been formally declined operation by a cardiac surgeon. These represent the "no surgical option" patients for whom PVAD may prove to be invaluable.

In the present study, most patients had severe multivessel coronary disease, severe cardiomyopathy or severe valvular disease. Forty-nine percent had two of these diagnoses and 4 patients had multivessel disease with severe aortic stenosis and severe cardiomyopathy. One-third of patients were at least 80 years old. Nearly half were in CS. Twenty-three patients had a LVEF < 30% and 13 had a LVEF < 15%. In-hospital mortality in this patient group was low in light of the frequency of CS, advanced age and left ventricular dysfunction. Half of the patients who did not survive had been transferred to our institution already in shock with multiorgan dysfunction — one of whom expired while on PVAD support, presumably due to sepsis and bowel infarction.

The technical requirements for an interventional PVAD program are significant. Physician experience with transeptal heart catheterization, large-bore access cannulae and arterial closure techniques is necessary. Nursing staff must be trained on the new device and controls, unfamiliar hemodynamic readings and intravascular volume management. With adequate training, a large catheterization laboratory staff can become highly effective at rapid initiation, management and discontinuation of the PVAD.

Despite the fact that arterial "preclosure" techniques were utilized and no patient required surgical repair at the vascular access sites, the majority of patients received transfusions following PVAD support. All patients had four arterial and venous sheaths including large TandemHeart cannulae and additional arterial cannulae up to 14 Fr size for PABV procedures. Only 6 patients had severe bleeding according to the TIMI major bleeding definition. One patient had hemorrhagic conversion of a large stroke that occurred following PABV. One patient with fulminant myocarditis had continued access-site bleeding during 4 days of PVAD support. The other 4 major bleeding events were qualified based on a drop in hemoglobin and transfusion requirements.

The need for transfusion during or after PVAD support has infrequently been reported in the literature. The preclose technique has been demonstrated to be an effective method of managing large- bore arterial cannulae.[10] A large series of 20 patients all managed with the preclose technique prior to PVAD insertion demonstrated a low vascular complication rate, but transfusion rates were not reported.[11] In one of the two randomized PVAD versus IABP trials, 19 of 21 patients receiving PVAD support required blood transfusion. This was twice as frequent as in the IABP group.[2] Such findings are similar to our experience. It does seem logical that using the PVAD during PCI may have higher associated bleeding risks than when the PVAD is used solely for a bridge to transplant. Contemporary PCI involves not only systemic anticoagulation, but various antiplatelet strategies as well.[22,23]

The high rate of post-procedure transfusion could not be explained by baseline anemia (present in 15 patients) or prolonged access-site bleeding or hematoma. There are likely multiple explanations for frequent transfusion. Blood loss may occur with de-airing of the cannulae prior to PVAD initiation, the interventional procedure itself, or during sequential dilation of arterial and venous puncture sites to accommodate large-bore catheters. Despite returning the blood remaining in the pump housing and tubing to the femoral vein after PVAD, there is a small volume of blood lost in the discarded cannulae, tubing and device. Precautionary transfusion post procedure may also occur and be unnecessary. As bleeding itself is a strong risk factor for poor patient outcomes,[24,25] adjustments to minimize blood loss and transfusion are a primary goal as this interventional PVAD program moves forward.

Certain high-risk patients are unable to undergo cardiac surgery due to their critical status and comorbidities. Other patients do not have the cardiovascular reserve to tolerate advanced percutaneous procedures to treat coronary and valvular diseases. The ability to safely initiate and maintain near-total circulatory support in the catheterization laboratory with the PVAD is a giant step forward for interventional cardiology. This series demonstrates that PVAD has a role for that identifiable cohort of patients with extreme procedural risk profiles. This tool can be safely used in a diverse and aged population for CS and during complex interventions, though transfusion and bleeding may be common. It can be expected that percutaneous devices like the TandemHeart will be used to support the next generation of catheter-based revascularization and valve therapies.

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