

# Introduction

Despite conventional medical therapy, the published mortality of cardiogenic shock hovers at 50-70%. The ongoing prevalence of acute heart failure and the treatment of this fragile population is the foundation for the research and development of the products from CardiacAssist, Inc. CardiacAssist has emerged as the leader in mechanical circulatory assist through percutaneous transseptal ventricular assist, or PTVA, for support of acute heart failure patients. In the United States, the TandemHeart System is available by prescription for short-term use, and a randomized multi-center clinical trial is studying the use of the TandemHeart System for the treatment of cardiogenic shock. Concurrently in Europe and elsewhere, utilization also includes support of compromised patients during high-risk percutaneous coronary interventions and revascularization.

With more than two centuries of combined staff knowledge, CardiacAssist's commitment focuses on the development and manufacture of products to address this broad population with novel solutions for heart failure therapy through ventricular support.

CardiacAssist, Inc. is pleased to bring you this complimentary first Edition of our Compendium of Selected Readings as an educational tool to describe an array of experiences with the device. CardiacAssist, Inc. is a privately held company with offices in Pittsburgh, Pennsylvania.

We would like to thank our investigators for their invaluable contributions to this first Edition as well as to the ongoing educational support of our technology.





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# Reversal of Cardiogenic Shock by Percutaneous Left Atrial-to-Femoral Arterial Bypass Assistance

Holger Thiele, MD; Bernward Lauer, MD; Rainer Hambrecht, MD; Enno Boudriot, MD;  
Howard A. Cohen, MD; Gerhard Schuler, MD

**Background**—Recovery of myocardial function after revascularization of acutely occluded coronary arteries may require several days. During this critical time, patients in cardiogenic shock may have low output. A newly developed percutaneous left ventricular assist device (VAD) may offer effective treatment for these patients by providing active circulatory support.

**Methods and Results**—Between May 2000 and May 2001, VADs were implanted in 18 consecutive patients who had cardiogenic shock after myocardial infarction. The device was connected to the patient's circulation by insertion of a 21F venous cannula into the left atrium by transseptal puncture; blood was returned to the iliac artery through an arterial cannula. Mean duration of cardiac assistance was  $4\pm 3$  days. Mean flow of the VAD was  $3.2\pm 0.6$  L/min. Before support, cardiac index was  $1.7\pm 0.3$  L/min per  $m^2$  and improved to  $2.4\pm 0.6$  L/min per  $m^2$  ( $P<0.001$ ). Mean blood pressure increased from  $63\pm 8$  mm Hg to  $80\pm 9$  mm Hg ( $P<0.001$ ). Pulmonary capillary wedge pressure, central venous pressure, and pulmonary artery pressure were reduced from  $21\pm 4$ ,  $13\pm 4$ , and  $31\pm 8$  mm Hg to  $14\pm 4$ ,  $9\pm 3$ , and  $23\pm 6$  mm Hg (all  $P<0.001$ ), respectively. Overall 30-day mortality rate was 44%.

**Conclusions**—A newly developed VAD can be rapidly deployed in the catheterization laboratory setting. This device provides up to 4.0 L/min of assisted cardiac output, which may aid to revert cardiogenic shock. The left ventricle is unloaded by diverting blood from the left atrium to the systemic circulation, making recovery more likely after an ischemic event. The influence of this device on long-term prognosis warrants further investigation. (*Circulation*. 2001; 104:2917-2922.)

**Key Words:** shock ■ heart-assist device ■ extracorporeal circulation ■ myocardial infarction

Cardiogenic shock develops in 7% to 10% of cases after acute myocardial infarction and remains the most common cause of death in these patients.<sup>1,2</sup> Despite aggressive treatment modalities such as fibrinolysis and PTCA, mortality rates of cardiogenic shock remain at an unacceptably high level.<sup>1,3,4</sup> Recovery of myocardial performance after successful revascularization of the infarcted vessel may require several days. During this period, many patients have low cardiac output. In the past, intra-aortic balloon pumping (IABP) has been the method of choice for mechanical assistance in these patients. It has been shown that IABP can result in initial hemodynamic stabilization; however, in the majority of studies death was merely delayed.<sup>5,6</sup> The main limitation of the IABP is the lack of active cardiac support and the requirement of a certain level of left ventricular function. In many patients with severe depression of left ventricular function or persistent tachyarrhythmias, hemodynamic support and left ventricular unloading derived from IABP is insufficient to reverse cardiogenic shock.<sup>7</sup>

Total circulatory support can be achieved by extracorporeal membrane oxygenation, a method fraught with all the

drawbacks of extracorporeal circulation such as activation of cellular elements, the need of an oxygenator, and surgery for implantation. Therefore, in recent years, efforts were made to develop ventricular assist devices (VAD) capable of rendering complete hemodynamic support, which are readily connected to the patient's circulation by interventional methods without the need for extracorporeal oxygenation and surgical procedures. This study was designed to evaluate the utility of a newly developed percutaneous left VAD (Tandem Heart pVAD, Cardiac Assist Technologies, Inc) for short-term stabilization of patients with cardiogenic shock until recovery of the jeopardized myocardium or as a bridge to definite surgical treatment.

## Methods

A clinical trial with a newly developed percutaneous left atrial-to-femoral arterial VAD was conducted from May 2000 to May 2001 in 18 patients with cardiogenic shock as a result of an acute myocardial infarction. Cardiogenic shock was defined as (1) persistent systolic blood pressure  $<90$  mm Hg or vasopressors required to maintain blood pressure  $>90$  mm Hg in the setting of a normal intravascular

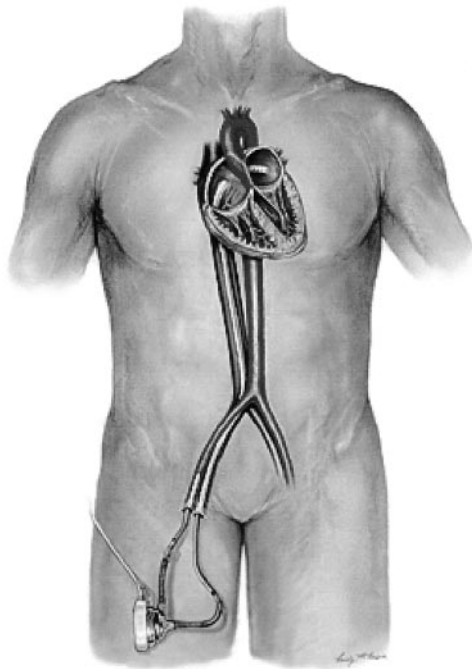
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**Figure 1.** Tandem Heart pVAD and associated blood circuit components.

volume; (2) evidence of end-organ failure (eg, urine output <30 mL/h, cold and/or diaphoretic skin and extremities, altered mental status, serum lactate >2 mmol/L); (3) evidence of elevated left ventricular filling pressures, such as pulmonary congestion or pulmonary capillary wedge pressure (PCWP) >15 mm Hg; (4) cardiac index (CI) of <2.0 L/min per m<sup>2</sup>.

Patients were informed of the experimental nature of the procedure if their mental status permitted, otherwise the procedure was

discussed with their relatives. The protocol for this study was approved by the local ethics committee.

**Description of the VAD System**

The Tandem Heart pVAD is a low-speed centrifugal continuous-flow pump with a low blood surface contact area, resulting in reduced potential for hemolysis and thromboemboli. It is dual chambered with an upper housing and a lower housing assembly. The upper housing provides a conduit for inflow and outflow of blood. The lower housing assembly provides communication with the controller, the means for rotating the impeller of the VAD, and an anticoagulation infusion line integral to the pump to provide a hydrodynamic bearing, cooling of the bearing, and local anticoagulation.

The controller is a microprocessor-based electromechanical drive and infusion system. It is designed to operate on AC current or on internal batteries. The controller generates the signals to drive the VAD, which turns the impeller and serves to infuse the anticoagulant solution. For high reliability and enhanced safety, it is provided with a backup control unit.

**Implantation of the Device**

After percutaneous puncture of the right femoral vein, a standard Brockenbrough catheter was inserted into the superior vena cava; with the use of a modified Ross needle, the interatrial septum was punctured in the fossa ovalis.<sup>8</sup> The position of the Brockenbrough catheter within the left atrium was documented by manual dye injection. If the position was deemed satisfactory, the Brockenbrough catheter was exchanged for a stiff guide wire with a distal soft wire loop identical to the device used for mitral valvuloplasty by the Inoue method (Toray Europe Ltd). The transseptal puncture site was then dilated to 21F with a 2-stage dilator followed by insertion of a venous inflow cannula, which was sutured to the skin of the thigh and cross-clamped. This cannula is made of polyurethane, with a large end hole and 14 side holes to facilitate aspiration of oxygenated blood from the left atrium. An arterial perfusion catheter of 14F to 19F was inserted percutaneously into the right femoral artery or two arterial perfusion catheters of 12F into both femoral arteries and then

**TABLE 1. Patient Characteristics and Outcomes**

Patient No.	Age, y/Sex	Cause of Shock	Extent of CAD	IRA	Adjunctive PTCA/Stent	EF, %	Arterial Cannula (French)	Mean Flow, L/min	Days Supported	Complications	Additional Procedure
1	48/F	AMI	3	LM	Yes	24	2×12	2.7	2	Groin bleeding	CABG
2	53/M	AMI	3	RCA	Yes	22	17	2.5	2	...	...
3	89/F	AMI	1	RCA	Yes	46	14	1.7	1	...	...
4	72/M	AMI	3	RCA	Yes	30	2×12	2.5	3	Dislocation arterial cannula	...
5	54/M	AMI	2	RCA	No	30	17	3.1	4	Limb ischemia	CABG planned
6	69/F	VSD	1	LAD	Yes	45	17	3.6	9	...	VSD closure
7	78/F	VSD	1	LAD	Yes	45	17	3.4	7	Stroke?	VSD closure planned
8	49/M	AMI	3	LAD	Yes	26	17	3.2	3	...	...
9	61/M	AMI	2	LAD	Yes	30	17	3.5	2	Groin bleeding	...
10	74/F	VSD	2	LAD	No	45	17	3.4	1	...	VSD closure planned
11	60/M	AMI	1	LAD	Yes	35	17	3.5	5	Groin bleeding	...
12	64/M	AMI	3	RCA	Yes	12	15	3.0	3	...	...
13	44/M	VSD	1	LAD	Yes	17	17	3.6	14	Groin bleeding	VSD closure
14	51/M	AMI	3	LAD	Yes	13	17	3.6	4	...	...
15	70/M	VSD	1	LAD	Yes	30	19	4.0	7	Groin bleeding	VSD closure
16	70/M	AMI	2	LAD	Unsuccessful	10	17	3.6	1	...	CABG
17	64/M	AMI	1	LAD	Yes	23	17	3.8	6	...	...
18	59/F	AMI	1	LAD	Yes	45	17	3.6	4	Limb ischemia	...

CAD indicates coronary artery disease; IRA, infarct-related artery; EF, ejection fraction; AMI, acute myocardial infarction; VSD, ventricular septal defect; LM, left main; RCA, right coronary artery; LAD, left anterior descending coronary artery; and MODS, multiorgan dysfunction syndrome.

advanced into the lower abdominal aorta. Heparin-coated Tygon tubing with a total length of 30 cm was used for connection to the device after carefully deairing according to standard techniques (Figure 1). The pump was activated at low speed, and all air bubbles were removed through a 3-way stopcock inserted into the arterial line next to the pump. When all lines were completely air free, the arterial clamp was removed and the pump speed increased to maximum (7500 rpm). Flow through the arterial line was measured by an electromagnetic flowmeter (HT 311, Transonic). Heparin was administered continuously through the lubrication system of the device, and the activated clotting time was maintained at  $\approx 200$  seconds by adjusting the amount of added heparin.

### Hemodynamic Monitoring

Hemodynamic data were acquired before and after implantation of the VAD. On the following days, measurements were obtained daily with "pump off" and "pump on." For "pump on," the VAD was operated at full speed (7500 rpm); for "pump off," the speed of the pump was reduced to 3000 rpm and the arterial cannula was clamped. Because of the danger of clotting, the pump must not be switched off completely. The following parameters were measured: cardiac output, CI, blood pressure, pulmonary artery pressure, PCWP, central venous pressure, and heart rate. For quantification of ventricular left-to-right shunts in patients with infarct-related ventricular septal defect (VSD), shunt volume, shunt-flow ratio, and effective cardiac output were determined by the Fick method. Additionally, standard base excess, serum lactate, and pH were determined with the use of a commercially available Astrup System.

### Weaning and Explantation of the Device

Those patients who did not undergo emergency CABG or VSD closure were weaned from the VAD if no more inotropic drugs were required and the hemodynamic parameters remained stable. A stepwise reduction of the pump output in steps of 500 mL/min was performed according to the hemodynamic stability of the patient. Further reduction was performed after approximately 1 to 2 hours, resulting in a weaning procedure of 6 to 12 hours in most patients.

TABLE 1. Continued

Outcome
Alive
Alive
Died of right heart failure
Died of refractory cardiogenic shock
Died of left heart failure 4 d after explantation of VAD
Died of MODS 19 d after surgical closure of VSD
Died of peritonitis
Alive
Alive
Died of worsening VSD
Alive
Alive
Alive
Alive
Died intraoperatively
Alive
Died of left heart failure 17 d after explantation of VAD
Alive

After weaning, the venous and arterial cannula were removed by surgical approach.

### Statistical Analysis

Each categorical factor is described as the number and the percentage of patients. For continuous parameters, mean  $\pm$  SD values are given. After testing of the assumption that the differences are sampled from a gaussian distribution, results were compared by a paired *t* test for preimplantation and postimplantation and "pump on" and "pump off" status. Continuous parameters not sampled from a gaussian distribution were compared by the nonparametric Wilcoxon rank-sum test with the use of statistical software (SigmaStat 2.03, Version 2.0 SPSS Inc). A value of  $P < 0.05$  was considered statistically significant.

## Results

### Patient Characteristics

A total of 18 patients (12 men and 6 women) were enrolled in this study. Mean age was  $63 \pm 12$  (range, 44 to 89) years. At the time of enrollment, all patients were in cardiogenic shock according to the criteria previously defined. The underlying cause was acute myocardial infarction in all patients; in 5 patients, a ventricular septal defect had been diagnosed within 1 to 3 days after the acute myocardial infarction. Mean duration of cardiac support was  $4 \pm 3$  days. Further patient characteristics, clinical course, and outcome are described in Table 1.

### Hemodynamic Characteristics

Hemodynamic indexes before and after implantation of Tandem Heart pVAD are shown in Table 2. Hemodynamic data after implantation were collected during the first 2 hours after transfer from the catheterization laboratory to the intensive care unit. Hemodynamic parameters were improved in all patients after implantation of the VAD (Figure 2). Metabolic acidosis and serum lactate could be reversed (Figure 3). CI, mean blood pressure, PCWP (Figure 4), and all other hemodynamic parameters were improved with the active Tandem Heart pVAD system compared with the "pump off" status during the duration of support. In patients with infarct-related VSD, the left-to-right-shunt volume was reduced from  $4.5 \pm 0.8$  L/min to  $2.0 \pm 1.0$  L/min; the shunt flow ratio was reduced from  $2.6 \pm 0.4$  to  $1.6 \pm 0.2$ ; and the effective CI was increased from  $1.4 \pm 0.3$  to  $2.0 \pm 0.4$  L/min per  $m^2$  by the VAD.

The mean flow of the VAD was  $3.3 \pm 0.6$  L/min. The device can be operated at various speeds, which can be continuously adjusted from 3000 rpm to 7500 rpm. Under optimal conditions, with the use of a large arterial cannula, up to 4 L/min can be provided at 7500 rpm and nearly 0 L/min at 3000 rpm. During operation at maximum output, pulsatile blood flow is reduced substantially and is partially replaced by nonpulsatile flow. Transesophageal echocardiographic examinations performed during operation of the device showed that blood flow in the aorta was reversed up to the level of the aortic arch.

### Clinical Course and Outcome

The implantation procedure was uneventful in all patients. Hemolysis remained negligible, as monitored by plasma-free hemoglobin and haptoglobin. During the follow-up period, 5 patients required transfusions of packed red blood cells as the

**TABLE 2. Hemodynamic Parameters Before and After VAD Implantation**

	Before Implantation	After Implantation	<i>P</i>
Cardiac output, L/min	3.5±0.8	4.8±1.1	<0.001
Cardiac index, L/min per m <sup>2</sup>	1.7±0.3	2.4±0.6	<0.001
Blood pressure mean, mm Hg	63.1±7.8	80.2±8.9	<0.001
Heart rate, beats/min	109.4±20.4	103.2±20.1	0.005
PCWP, mm Hg	20.8±3.6	14.2±3.5	<0.001
Central venous pressure, mm Hg	12.7±3.7	9.3±3.0	<0.001
Pulmonary artery pressure mean, mm Hg	31.2±8.1	23.2±6.3	<0.001
Serum lactate, mmol/L	4.7±2.6	3.0±1.7	<0.001
Standard base excess, mmol/L	-6.3±3.5	-4.3±3.5	<0.001
pH	7.33±0.1	7.37±0.1	0.01

PCWP indicates pulmonary capillary wedge pressure.

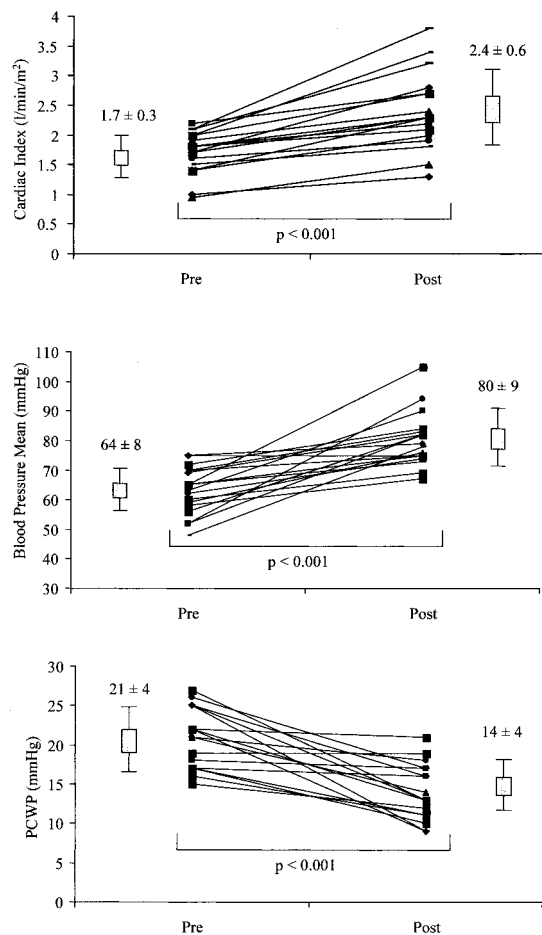
result of bleeding at the arterial access site. After compression with a femoral compression system (FemoStop II Plus, RADI Medical Systems) and a mild reduction of the heparin dose, bleeding was stopped. In two patients with peripheral arterial occlusive disease, ischemia of the right lower limb developed some hours after implantation of a 17F arterial cannula. Limb ischemia was resolved in both by surgical implantation of an accessory antegrade cannula into the right common femoral artery.

During support, there were 4 patient deaths. One of these patients was extremely overweight (130 kg). This patient was hemodynamically stable until a standard length arterial cannula of 6.5 cm (Fem-Flex II, Baxter Deutschland GmbH) dislodged during daily routine nursing care. He immediately had profound arterial hypotension and died in cardiogenic shock before the problem could be resolved. To minimize the danger of dislodgment, an 18-cm-long arterial cannula (Bio-Medicus, Medtronic, Inc) was used in subsequent patients. The second patient had an ischemic stroke 24 hours after initiation of the extracorporeal support. This patient had an infarct-related VSD before the use of the VAD. Computer tomography of the brain showed multiple small infarctions. The patient died 6 days later of bacterial peritonitis, which was caused by a colon perforation after manipulation with a rectal cannula, which was used to treat severe diarrhea. At autopsy, disseminated cerebral infarctions were detected, most likely as the result of multiple cerebral emboli. The edge of the large VSD, measuring 4×2 cm, was surrounded by a large thrombus. In addition, smaller thrombi had formed at the left atrial puncture site despite the continuous use of anticoagulation drugs. The third patient had a proximal occlusion of the right coronary artery (RCA). This patient had right ventricular failure. Her right atrial pressures approached pulmonary artery pressures, thus resulting in insufficient support by the VAD. The fourth patient had an infarct-related VSD. This patient died as a result of a sudden deterioration of the VSD. The autopsy revealed a VSD of 6×2 cm, which probably led to right ventricular overload.

Four more patients died after weaning from the Tandem Heart pVAD: Two died of recurrent cardiogenic shock, one died during surgery, and one on a long-term VAD died after successful surgical closure of a VSD. The remaining 10 patients were discharged and remained alive 30 days after support. Overall 30-day mortality rate was 44% (Table 1).

## Discussion

In patients with acute myocardial infarction, hemodynamic failure is the most frequent cause of in-hospital death. In the present study, an initial experience with a newly developed percutaneous VAD has shown that complete hemodynamic support can be instituted within 30 minutes in these patients.



**Figure 2.** Hemodynamic parameters before and after VAD implantation.

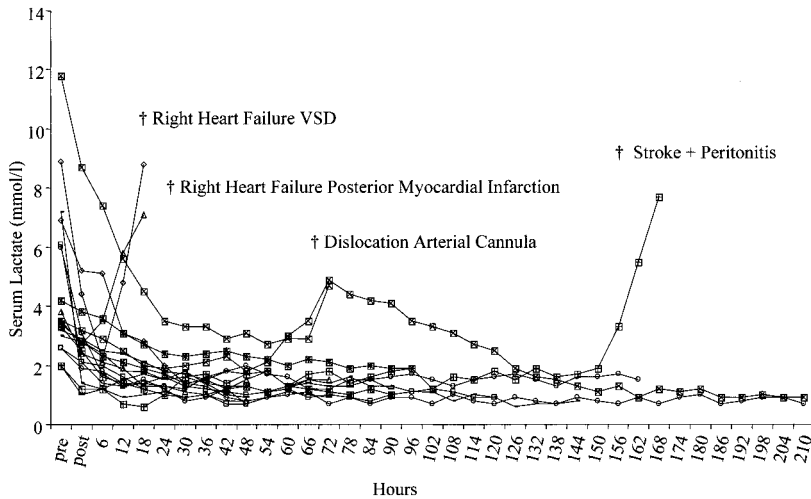


Figure 3. Time course of serum lactate.

Pulmonary edema and metabolic derangements associated with cardiogenic shock disappear within hours even in patients with profound depression of left ventricular performance. The use of the left VAD provides a crucial time window for revascularization of the infarcted vessel and recovery of myocardial contractility.

The implantation procedure is straightforward, relying on standard heart catheter techniques such as transseptal puncture without the need for surgical exposure of vascular access. The

key part is a centrifugal pump, which is capable of supplying sufficient support independent of residual left ventricular performance. This feature is not provided by the IABP. Hemodynamic assessments before and after implantation were significantly improved during the use of the device. In addition, cardiogenic shock was reversed in all but one patient with right ventricular failure, which is deemed a contraindication when the right ventricular failure is predominant. In this patient, insufficient blood was supplied to the device as the result of low left atrial pressures rendering the pump ineffective.

Several problems have been encountered during the initial clinical operation of this device, including the dislodgment of a standard-length arterial cannula of 6.5 cm in an overweight patient and the sudden loss of hemodynamic support during the daily nursing care of the patient. These problems were resolved by using an extra-long arterial cannula (18 cm in length) in subsequent patients.

In this study, one patient had thrombi at the edge of a large VSD and to a lesser extent at the atrial puncture site despite adequate anticoagulation with heparin. This event resulted in cerebral emboli, which may have been caused by a state of hypercoagulability secondary to cardiogenic shock.

Two patients with peripheral occlusive artery disease had distal limb ischemia, probably caused by the use of the 17F arterial cannula. To minimize ischemic problems in patients with small pelvic arteries and in patients with arterial occlusive disease, visualization of the vessels by dye injection before insertion of the cannula may be prudent.

A VSD is deemed to be a relative contraindication for left atrial-to-femoral arterial bypass support because of the risk of right-to-left shunting with subsequent hypoxemia. However, our experiences could show that by careful hemodynamic monitoring, unloading of the left ventricle is never complete and therefore no right-to-left shunt could be detected. The VAD reversed cardiogenic shock in patients with a VSD, which allowed bridging to surgical repair.

Currently, little is known about the fate of the transseptal puncture site after removal of the 21F venous cannula. In patients undergoing mitral valvuloplasty by Inoue balloon, a left-to-right shunt can be detected in the majority of patients. However, it decreases or disappears completely after 6

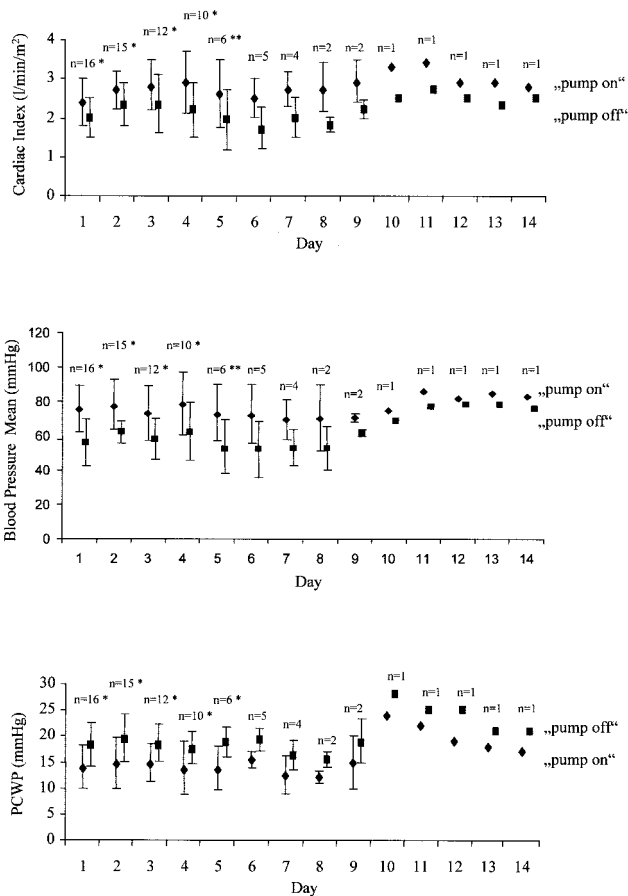


Figure 4. Hemodynamic parameters with pump on and pump off at follow-up. \*P<0.01, \*\*P<0.05.

months, with no significant effect on hemodynamic parameters.<sup>9</sup> In previous animal studies, the atrial septal defects induced by left atrial cannulation during the use of a VAD have been shown to heal completely at the end of 4 to 6 weeks or result in a clinically insignificant left-to-right shunt.<sup>10</sup> This hypothesis was confirmed by the absence of a relevant left-to-right shunt after weaning the patients from the VAD.

### Previous Left Atrial-to-Femoral Arterial Bypass Support

In 1962, Dennis et al<sup>11</sup> were the first to describe the left atrial-to-femoral bypass system by the jugular approach. Consecutively, left atrial-to-femoral arterial VAD were mostly used in patients who could not be weaned from cardiopulmonary bypass after cardiothoracic surgery.<sup>12,13</sup> Currently, there are only few reports of totally percutaneous approaches in which the VAD was implanted in the catheterization laboratory setting for patients undergoing high-risk interventions with a mean operating time of 43 minutes or in two patients for cardiogenic shock.<sup>14,15</sup> However, until now, this technique has not achieved widespread popularity as a circulatory support because of the lack of a transeptal cannula that can accommodate the flow rates necessary to provide adequate circulatory support for long-term clinical use. Furthermore, the pumps used so far were operated at a higher speed and were not provided with an additional housing assembly, which allows the high local concentration of anticoagulant within the pump and avoids warming up. Both are of paramount importance to avoid thrombus formation at the impeller and to substantially reduce the inherent hemolysis of centrifugal pumps.

### Effects of Left Atrial-to-Femoral Arterial Bypass

Recovery of the myocardium after revascularization occurs by diverting blood from the left atrium to the systemic circulation, which will result in reducing filling pressure in the left ventricle, cardiac workload, and oxygen demand. Previous animal studies have demonstrated a substantial decrease in the size of acute myocardial infarction by use of these left VADs with or without recanalization of the infarct related artery.<sup>10,16</sup>

Furthermore, left atrial-to-femoral arterial support results in an increased systemic blood pressure, which may favorably affect the imbalance between oxygen demand and supply of the jeopardized myocardium<sup>17</sup> and may lead to optimal tissue perfusion. However, little is known about the effects of a continuous flow in contrast to a pulsatile flow in coronary arteries.

### Study Limitations

This major limitation of this prospective cohort study is the lack of a control group. The small number of patients does not allow matching with other patient groups, although considering the low mortality rate of 31% in patients without a VSD, which also includes our initial learning curve, the results are promising in comparison to the mean 60% mortality rate in the Shock Trial Registry.<sup>4</sup>

### Conclusions

The systemic circulation of patients with cardiogenic shock can be substantially improved by using a newly developed percutaneous left atrial-to-femoral arterial VAD. This device may aid to reverse cardiogenic shock by unloading the left ventricle and allowing the recovery of the myocardium after an ischemic event. The influence of this device on long-term prognosis warrants further investigation.

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### References

- Goldberg RJ, Samad NA, Yarzebski J, et al. Temporal trends in cardiogenic shock complicating acute myocardial infarction. *N Engl J Med*. 1999;340:1162-1168.
- Holmes DR Jr, Bates ER, Kleiman NS, et al. Contemporary reperfusion therapy for cardiogenic shock: the GUSTO-I trial experience. The GUSTO-I Investigators. Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries. *J Am Coll Cardiol*. 1995;26:668-674.
- Hochman JS, Sleeper LA, Webb JG, et al. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. SHOCK Investigators. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock. *N Engl J Med*. 1999;341:625-634.
- Hochman JS, Buller CE, Sleeper LA, et al. Cardiogenic shock complicating acute myocardial infarction: etiologies, management and outcome: a report from the SHOCK trial registry. *J Am Coll Cardiol*. 2000;36:1063-1070.
- Scheidt S, Wilner G, Mueller H, et al. Intra-aortic balloon counterpulsation in cardiogenic shock: report of a co-operative clinical trial. *N Engl J Med*. 1973;288:979-984.
- DeWood MA, Notske RN, Hensley GR, et al. Intraaortic balloon counterpulsation with and without reperfusion for myocardial infarction shock. *Circulation*. 1980;61:1105-1112.
- Pae W, Pierce W. Temporary left ventricular assistance in acute myocardial infarction and cardiogenic shock. *Chest*. 1981;79:692-695.
- Ross JJ, Braunwald E, Morrow A. Left heart catheterization by the transeptal route: a description of the technique and complications. *Circulation*. 1960;22:927-934.
- Cequier A, Bonan R, Serra A, et al. Left-to-right atrial shunting after percutaneous mitral valvuloplasty: incidence and long-term hemodynamic follow-up. *Circulation*. 1990;81:1190-1197.
- Fonger JD, Zhou Y, Matsuura H, et al. Enhanced preservation of acutely ischemic myocardium with transeptal left ventricular assist. *Ann Thorac Surg*. 1994;57:570-575.
- Dennis C, Carlens C, Senning A, et al. Clinical use of a cannula for left heart bypass without thoracotomy. *Ann Surg*. 1962;156:623-637.
- Killen DA, Piehler JM, Borkon AM, et al. Bio-medicus ventricular assist device for salvage of cardiac surgical patients. *Ann Thorac Surg*. 1991;52:230-235.
- Pavie A, Leger P, Nzomvuama A, et al. Left centrifugal pump cardiac assist with transeptal percutaneous left atrial cannula. *Artif Organs*. 1998;22:502-507.
- Glassman E, Chinitz LA, Levite HA, et al. Percutaneous left atrial to femoral arterial bypass pumping for circulatory support in high-risk coronary angioplasty. *Cathet Cardiovasc Diagn*. 1993;29:210-216.
- Satoh H, Kobayashi T, Nakano S, et al. Clinical application of percutaneous left ventricular support with a centrifugal pump. *ASAIO J*. 1993;39:153-155.
- Laschinger J, Grossi E, Cunningham J, et al. Adjunctive left ventricular unloading during myocardial reperfusion plays a major role in minimizing myocardial infarct size. *J Thorac Cardiovasc Surg*. 1985;90:80-85.
- Maroko P, Braunwald E. Modification of myocardial infarct size. *Ann Intern Med*. 1973;79:720-733.

# **High-Risk Revascularization Supported With Percutaneous Transseptal Ventricular Assistance (PTVA<sup>®</sup>)**

Based on a Case Report by Philip Urban, MD, Hôpital de La Tour, Geneva, Switzerland

# High-Risk Revascularization Supported With Percutaneous Transseptal Ventricular Assistance (PTVA®)

Based on a Case Report by Philip Urban, MD, Hôpital de La Tour, Geneva, Switzerland

## Abstract:

*High risk revascularization of a 44 year old male patient with severe multi-vessel disease (80% left main stenosis) and critically depressed left ventricular function (LVEF 11%) was supported by use of a novel percutaneous left ventricular assist system.*

## Introduction

Severely impaired left ventricular ejection fraction (LVEF <30%)<sup>1</sup> and multi-vessel disease (> 3 vessels) are commonly categorized as high risk factors for percutaneous coronary intervention. Cath lab interventions in this patient group bear an increased risk for complications such as myocardial infarction. Additionally, many of these patients are considered poor candidates for surgical revascularization. A new ventricular assist system (TandemHeart PTVA™ System, CardiacAssist, Inc., Pittsburgh, PA, USA), makes it possible to rapidly institute percutaneous mechanical circulatory support in the cath lab setting. The TandemHeart is designed to provide stabilization and maintenance of hemodynamic and metabolic parameters and to effectively facilitate high-risk percutaneous coronary procedures. The main component of the TandemHeart System, a miniaturized centrifugal pump, uniquely combines a hydrodynamic bearing with magnetic suspension of the impeller. Circulatory support is established by a left atrial to femoral artery bypass circuit (Figure 1.).

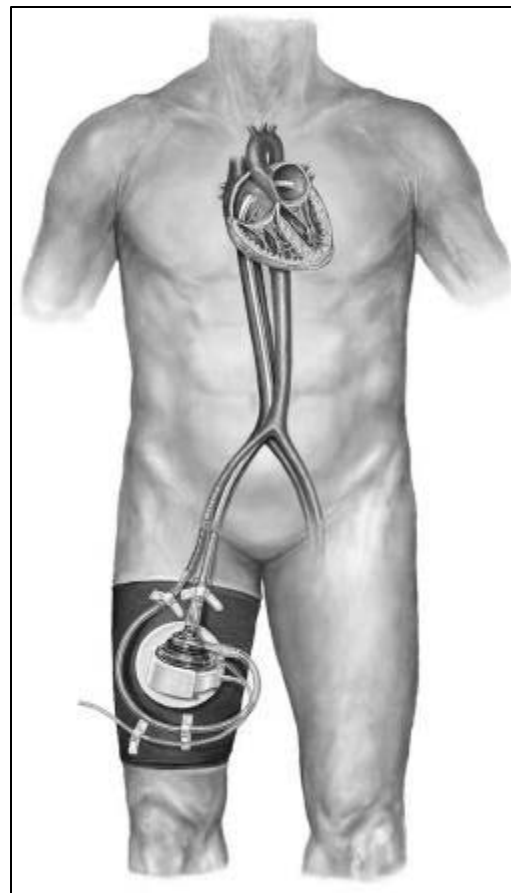
## Case Report

A 44 year old male patient presented to the hospital with multi-vessel disease including 80% left main stem distal stenosis, 80% stenosis in a small first diagonal branch, subtotal proximal left coronary circumflex stenosis and a chronically occluded dominant right coronary artery. Left ventricular ejection fraction was measured at 11%. Due to the poor left ventricular function, the patient was not considered for surgery, and IABP therapy was deemed to provide insufficient support to sustain the patient through a percutaneous revascularization procedure.

The patient had suffered prior acute myocardial infarction, was on treatment for grade II congestive heart failure and had silent ischemia in the antero-lateral region of the left ventricle. Further risk factors included smoking, high cholesterol, and hypertension.

Since the degree of CHF did not yet justify cardiac transplantation, there were no conventional options left for this

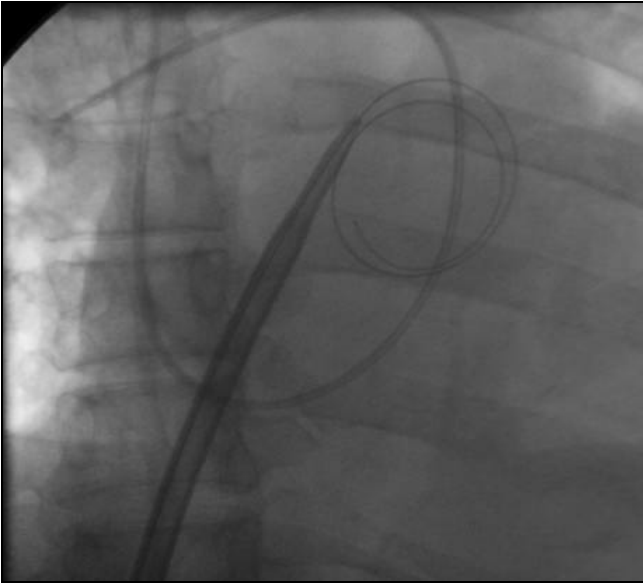
patient and the prognosis on medical therapy alone appeared very poor. The best possible alternative was to provide left ventricular support to sustain hemodynamic parameters during the high-risk angioplasty procedure.



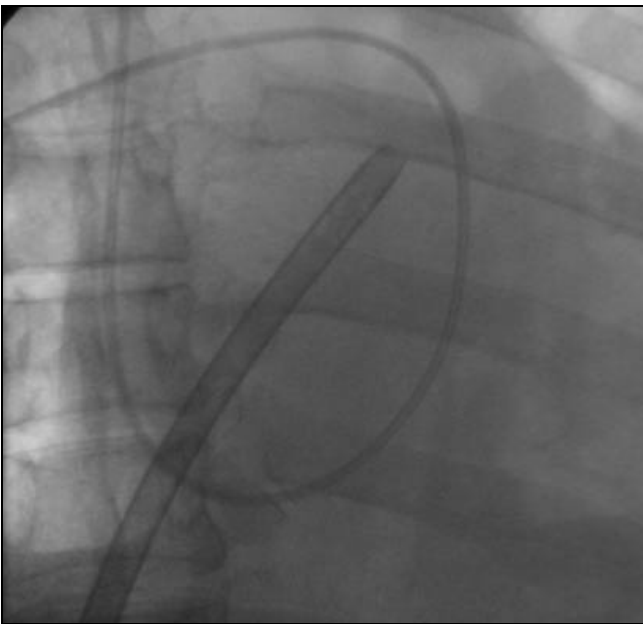
(Figure 1.) TandemHeart Setup

The TandemHeart was implanted in the cath lab under light general anesthesia. A standard transseptal puncture was performed using a Brockenbrough needle and Mullin sheath. A valvuloplasty guidewire was placed in the left

atrium to facilitate catheter exchanges. The septal puncture was dilated with a 14/21FR dilator (Figure 2). A 21FR transseptal cannula and obturator assembly was advanced over the guidewire and placed in the left atrium. Positioning of the cannula was confirmed with echo (Figure 3.), the guidewire and obturator were removed, and the cannula clamped.



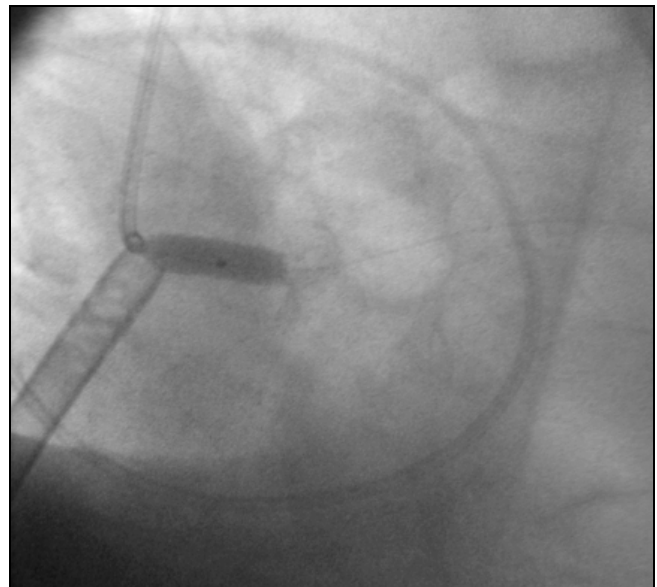
**(Figure 2.)** Dilation of the transseptal puncture



**(Figure 3.)** Transseptal cannula in the left atrium

Using the Seldinger technique a single 14FR arterial cannula was placed in the right femoral artery and clamped off. Both cannulae were secured with suture tie-downs. The outflow port of the pump was connected to the arterial

cannula using standard 3/8" heparin coated bypass tubing. Additional 3/8" tubing was connected to the inflow port of the pump and clamped off. The clamps on the tubing were released carefully and the pump and tubing back-filled with blood. To close the circuit, a wet-to-wet connection was established between the transseptal cannula and the tubing connected to the inflow port of the pump. Circulatory support was initiated with a measured flow of 2.65 L/min at 6000 RPM. Mean arterial pressure (MAP) increased from 80mmHg to 88-104mmHg with pump support. The high risk PTCA procedure was performed immediately after initiation of support. Three stents were placed in the LMS, LAD and LCX, facilitated by use of Intravascular Ultrasound (IVUS). During balloon inflations (Figure 4.), despite rapid disappearance of phasic arterial blood pressure, mean pressure was safely maintained at 80mmHg with a measured pump output of 2.7 L/min. The TandemHeart was explanted immediately following the PTCA. The particular anatomy (femoral vein passing under the iliac bifurcation) complicated the extraction of the transseptal cannula and necessitated surgical closure in the catheterization lab.



**(Figure 4.)** Balloon inflation in the left main stem.

After explantation of the pump, the patient remained hemodynamically stable with an MAP of 93 mmHg, a cardiac index of 2.3 and a PCWP of 7 mmHg. On the day following explant, the patient was transferred from the ICU to the general ward. On the second day, the patient was discharged from the hospital. Long term therapy includes Aspirin and Clopidogrel. In three to six months following discharge a re-catheterization is planned to assess the left main coronary artery patency.

## Discussion

New techniques like direct stenting and new products like embolic protection devices have tremendously improved the procedural success rate of high-risk percutaneous coronary interventions. However, for certain patient populations, these techniques may not offer sufficient safety margin for a PCI. In these cases, temporary mechanical circulatory support can provide the necessary hemodynamic safeguard throughout even long and complicated revascularization procedures. Essential requirements for a suitable assist device are:

- significant circulatory support
- rapid setup
- implantation and explantation without the need for surgery

Only recently has such a ventricular assist device become available. The TandemHeart pVAD offers circulatory support of up to 4.0 L/min and can be implanted percutaneously using standard cath lab techniques in less than 30 minutes. This device seems to fill a gap in the treatment of high risk revascularization and acute heart failure therapy.

## Acknowledgement

We wish to acknowledge Dr. Urban for his assistance in developing this important case report and for his excellence in clinical practice.

## References

- 1 Kaul U, Sahay S, Bahl VK, Sharma S, Wasir HS, Venugopal P. Coronary angioplasty in high risk patients: comparison of elective intraaortic balloon pump and percutaneous cardiopulmonary bypass support--a randomized study. *J Interventional Cardiology* 1995 Apr;8(2):199-205
- 2 DeGeare VS, Stone GW, Grines L, Brodie BR, Cox DA, Garcia E, Wharton TP, Boura JA, O'Neill WW, Grines CL. Angiographic and clinical characteristics associated with increased in-hospital mortality in elderly patients with acute myocardial infarction undergoing percutaneous intervention (a pooled analysis of the primary angioplasty in myocardial infarction trials). *Am J Cardiol* 2000 Jul 1;86(1):30-4

# **Surgical High-Risk Coronary Revascularization Supported by Use of Percutaneous Transseptal Ventricular Assistance (PTVA®)**

Based on a case report by Paul R. Vogt<sup>1</sup>, MD, FETCS, Martin Heidt<sup>1</sup>, MD, Erwin P. Bauer<sup>2</sup>, MD, FETCS

<sup>1</sup>Department of Cardiovascular Surgery, University Hospital, Giessen, Germany

<sup>2</sup>Kerckhoff-Clinic Foundation, Bad Nauheim, Germany

Supported by the European Center for Cardiovascular Research (ECCR)

# Surgical High-Risk Coronary Revascularization Supported by Use of Percutaneous Transseptal Ventricular Assistance (PTVA®)

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## Abstract

*This report describes the elective, perioperative use of the TandemHeart percutaneous ventricular assist system in a 65 year old female patient undergoing conventional coronary artery bypass grafting, presenting with grade IV angina and grade IV dyspnoe, low output syndrome evidenced by a cardiac index of 1.2 L/min/m<sup>2</sup>, a left ventricular ejection fraction between 10% to 15%, and grade I aortic valve regurgitation. The patient was successfully stabilized by the TandemHeart prior to and after the high risk CABG procedure.*

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## Introduction

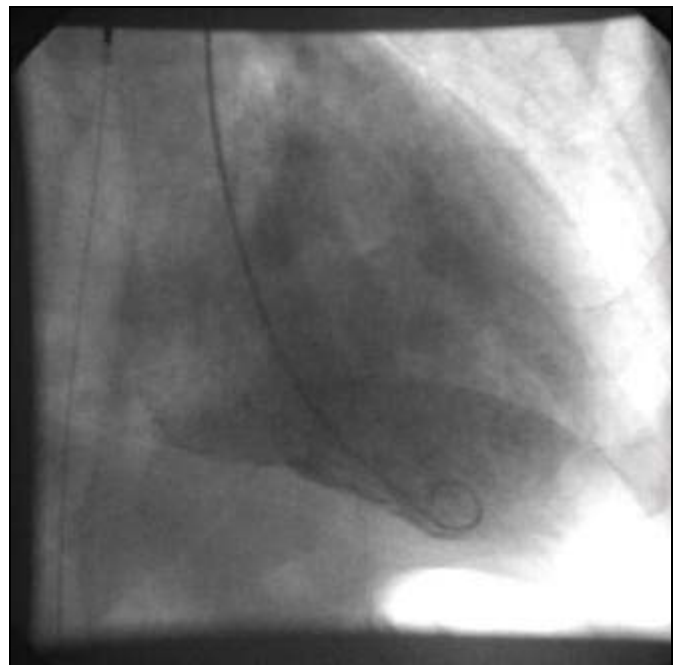
The prophylactic use of the intra aortic balloon pump (IABP) has been recommended, e.g. for surgical revascularization in high-risk patients, and is said to decrease the perioperative mortality in this particular subset of patients<sup>1</sup>. However, the IABP has its limitations and is contraindicated in patients with aortic valve regurgitation. The prophylactic use of a percutaneous left ventricular assist device, such as the TandemHeart™ pVAD, may support patients with decompensated heart failure and severely depressed cardiac function who could potentially benefit from cardiac surgery.

## Case Report

A 65-year old female patient with long-standing insulin-dependent diabetes mellitus was referred to our institution with grade IV angina and dyspnoe. Despite maximal medical therapy the patient was bedridden. Cardiac catheterization revealed severe triple-vessel disease and a left ventricular ejection fraction (LVEF) between 10% and 15% (Figure 1. and 2). Right ventricular function was normal. Szintigraphy suggested viable myocardium infero-posteriorly, however, a dobutamin stress-echocardiography was inconclusive, even at high doses of dobutamin. Preoperative hemodynamic measurements were as follows: cardiac index (CI) 1.2 L/min/m<sup>2</sup>; left ventricular end diastolic pressure (LVEDP) 26 mmHg; central venous pressure (CVP) 6mmHg; mean arterial pressure (MAP) 70 mmHg.

The patient was rejected for surgery at three different centers before she was transferred to our institution for surgery using prophylactic insertion of the intra aortic balloon pump. However, the presence of very severe LV dysfunction and moderate aortic regurgitation (grade I to II) indicated that an IABP might not provide enough support. The

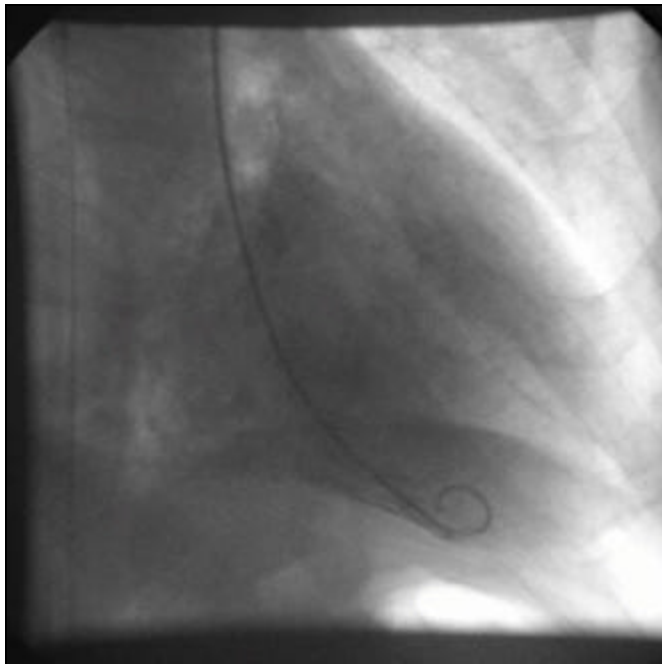
decision was then made to place the TandemHeart ventricular assist device.



**(Figure 1.)** End-Diastolic Volume in a 65 year old female patient with severely depressed left ventricular function

The patient was prepared on the cardiac catheterization table and heparin was administered. After a transseptal puncture, a 21 French cannula was inserted percutaneously into the right common femoral vein, advanced towards the right atrium, and placed into the left atrium. Correct positioning

was assessed by conventional radiography. Thereafter, the right common femoral artery was punctured and a 17 French arterial cannula was advanced until its tip was located at the aortic bifurcation. The patient was transferred back to the cardiac surgical intensive care unit and connected to the TandemHeart pVAD Controller.



**(Figure 2.) End-Systolic Volume**

Echocardiography confirmed complete unloading of the left ventricle, achieved by draining blood from the left atrium. A stable flow of 3 L/min was easily achieved, resulting in a low-normal CI of 2.8 L/min/m<sup>2</sup> with a normal mixed-oxygen venous saturation monitored by continuous cardiac output measurement.

Coronary artery bypass grafting was performed after 22 hours of support. The left internal mammary artery was used to bypass the left anterior descending coronary artery. The circumflex and right coronary artery both received saphenous vein grafts.

Surgery was performed using standard cardiopulmonary bypass techniques and moderate hypothermia of 32°C. All anastomosis were performed on the beating heart to avoid aortic cross-clamping. During the surgical procedure the patient was supported by a heart-lung-machine while the TandemHeart was stopped and clamped off. Weaning from cardiopulmonary bypass was uneventful with the TandemHeart delivering a steady flow of 3.5 L/min achieving a stable CI of 2.8 L/min/m<sup>2</sup> postoperatively. Catecholamines were not used pre- or postoperatively.

Transfer to the cardiac surgical ICU was uneventful. The patient was weaned from mechanical ventilation and extubated the first postoperative day demonstrating normal re-

covery from surgery. Full TandemHeart support was continued for 24 hours. The patient demonstrated hemodynamic stability and could therefore be gradually weaned from the device over the course of the next 12 hours. Prior to removal of the TandemHeart, transthoracic echocardiography revealed a left ventricular ejection of 25% and minimal residual pericardial fluid. The TandemHeart was removed surgically using local anesthesia performing direct reconstruction of the common femoral artery and vein. After removal, hemodynamic parameters were as follows: CI 2.8 L/min/m<sup>2</sup>, PCWP 14 mmHg, MAP 70 mmHg, and, CVP 3 mmHg.

Both the transeptal and the arterial cannula were examined macroscopically. The cannulae appeared normal and no thrombi could be found on the surface or intraluminally.

The patient was discharged from the intensive care unit after 5 days. At hospital discharge, the patient was free from angina and dyspnoea was estimated at grade II. Six months later, the patient had near-normal life quality being in New York Heart Association Class I. Transthoracic echocardiography revealed a left ventricular ejection fraction of 35%.

## Discussion

The number of high-risk patients needing cardiac surgery is rising. Patients are older and have multiple co-morbid diseases, as well as advanced cardiac pathology. These patients do not well with medical therapy, but can be difficult to care for before and after surgery. Nonetheless, the natural history of heart failure can be dramatically improved if surgery is possible and successful. Our patient who was bedridden and required constant care prior to surgery may serve as a good example of this point.

The prophylactic use of IABP therapy has been reported to substantially decrease the 30-day mortality rate and costs in patients undergoing conventional high-risk coronary surgery. In our patient however, the use of IABP was not possible due to aortic valve regurgitation and severe LV failure. The patient was previously rejected for surgery due to her advanced deterioration, which certainly put her at the most critical end of the risk scale for coronary bypass surgery.

The TandemHeart was inserted percutaneously to unload the left ventricle preoperatively. It is possible to do this with sedation in a non-intubated patient, however, anticipating subsequent surgery, our patient asked for intubation and mechanical ventilation prior to insertion of the device.

This device was introduced into our clinical program without any major problems. Insertion of the transeptal and femoral arterial cannulae was not difficult and operation of the pump was straight forward. Percutaneous removal of the device is easily accomplished and well documented. Nevertheless, open surgical removal with local anesthesia, as performed in our patient, may help to mobilize the patient immediately following device explant.

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The clinical indications for the TandemHeart are still evolving. In this case, it allowed us to salvage a patient with decompensated heart failure. In addition, the device could support patients with post-pump cardiac failure until recovery or required placement of a long-term LVAD.

### **Conclusion**

In conclusion, the TandemHeart is a short-term left ventricular assist device, which can be implanted percutaneously. In our patient, it proved to be reliable and easy to handle. It successfully stabilized the patient prior and after the high risk procedure. This new device may be helpful in managing very high risk patients with preoperative heart failure, and also for post cardiectomy shock.

### **Acknowledgement**

We wish to acknowledge Professor Vogt and his team for their assistance in developing this case report and for their contribution to the body of knowledge in cardiac surgery.

### **References**

- 1 *Christenson JT, Simonet F, Schmuziger M. Economic impact of preoperative intraaortic balloon pump therapy in high-risk coronary patients. Ann Thorac Surg. 2000;70:510-5*

# **High-Risk Beating Heart Coronary Revascularization Facilitated by Percutaneous Transseptal Ventricular Assistance (PTVA®)**

Based on a case report by Jeffrey Moses, MD, Gary Roubin, MD, Valvanur Subramanian, MD,  
Jim Fonger, MD, Lenox Hill Hospital, New York, NY

# High-Risk Beating Heart Coronary Revascularization Facilitated by Percutaneous Transseptal Ventricular Assistance (PTVA®)

Based on a case report by Jeffrey Moses, MD, Gary Roubin, MD, Valvanur Subramanian, MD, Jim Fonger, MD, Lenox Hill Hospital, New York, NY

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## Abstract

*A 56 year old male patient in cardiogenic shock failed to recover on full pressor support and IABP therapy. Selective cineangiography revealed multi-vessel coronary artery disease including high grade left main stenosis and a totally occluded left anterior descending coronary artery. Percutaneous ventricular assistance with the TandemHeart™ pVAD was employed to reverse shock before surgery. A quintuple bypass procedure on the beating heart was performed with continued TandemHeart support.*

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## Introduction

Over the past two decades advances in reperfusion therapy have significantly reduced the mortality rate and the number of complications associated with acute myocardial infarction (MI). Nevertheless, even today, cardiogenic shock (CS) remains a leading cause of death in patients hospitalized with acute MI<sup>1</sup>.

The pathophysiology of CS involves a vicious circle that perpetuates the thinning and dilation of the infarcted zone and the extension of the infarcted area. As left ventricular (LV) function worsens, hypoperfusion of both the infarcted as well as the non-infarcted myocardium propagates<sup>2</sup>. Treatments to break this vicious circle most commonly include pharmacological support with vasopressors and inotropic agents. An IABP may serve as a bridge to coronary revascularization. When aggressive medical management of CS fails, long term use of a ventricular assist device may be indicated<sup>3</sup>. However, all currently available short and long term ventricular assist devices require extensive surgery for implantation and explantation. The critical condition of patients in CS may prevent such a course of treatment. A new ventricular assist device (TandemHeart pVAD System, CardiacAssist, Inc. Pittsburgh, PA) has been designed for rapid percutaneous institution of support without the need for surgery. The TandemHeart was designed to deliver substantial left ventricular assistance with flow rates of up to 4 L/min.

## Case Report

A 56-year-old male patient experienced chest pain and shortness of breath. When paramedics arrived at his home he was in acute respiratory distress, and was intubated shortly thereafter. The patient was treated in the field with nitrates, and transported to the closest hospital with continued chest pain, and EKG changes in lead III and V. Intra aortic balloon therapy was initiated in the ER. The patient

was transferred to Lenox Hill on the balloon pump. In spite of pharmacological and IABP treatment the patient went into cardiogenic shock. The TandemHeart pVAD System was determined to be the only viable option to reverse cardiogenic shock and to allow time to plan the next course of therapy.

Prior to the procedure the patient's sedation was reduced and he was appropriately responsive. His cardiac output (CO) was 4.0 L/min and the cardiac index (CI) 1.8 L/min/m<sup>2</sup>. He had a mean arterial pressure (MAP) of 72 mmHg at a heart rate (HR) of 84 BPM.

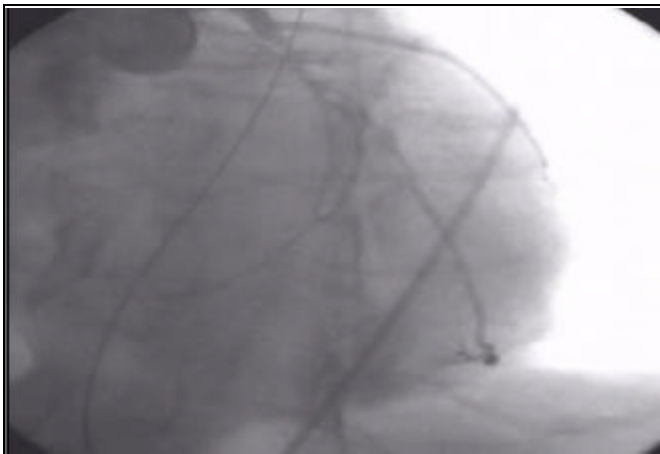
The intra-aortic balloon was removed and exchanged for an arterial sheath. A Swan-Ganz catheter was also in place in the left groin. The Swan was temporarily removed for the implantation procedure. Pressor support was transiently interrupted and systolic blood pressure decreased to 40 mmHg. Access was gained to the right femoral artery and vein using standard percutaneous technique. The inter atrial puncture was performed with a standard transseptal puncture kit (Brockenbrough needle, Mullen sheath). A 0.025" pigtail guidewire was inserted into the left atrium. A two-stage dilator (14/21 French) was advanced over the guidewire to dilate the puncture site. The dilator was then exchanged with a 21 French transseptal cannula to allow drainage of the left atrium. A single 15 French femoral arterial cannula was selected for blood return and introduced percutaneously. The blood circuit assembly was then completed and de-aired, and support was initiated (see Figure 1.) The patient's vital signs immediately improved to the following values: blood pressure (BP) 102/76 mmHg, MAP 83 mmHg, HR 80 BPM, CO 5.9 L/min, and CI 2.8 L/min/m<sup>2</sup>.

With the patient stabilized on TandemHeart support, selective coronary cineangiography was performed. The examination revealed a left dominant coronary vasculature. The



**(Figure 1.)** TandemHeart pVAD in operation with single arterial cannulation

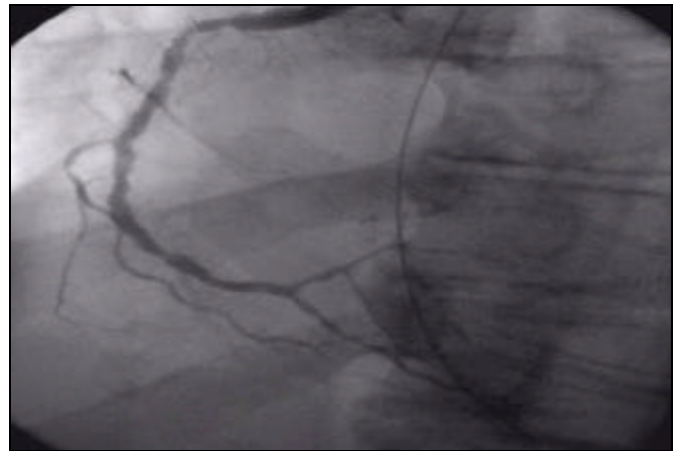
left main coronary artery showed 80% stenosis with a totally occluded LAD, and a high-grade circumflex lesion. The right coronary artery (RC) showed diffuse disease with a graftable distal target. The lateral wall showed a single obtuse marginal branch with a high grade proximal stenosis. The left ventricular function was severely depressed with an ejection fraction (EF) of 10-15%. See Figures 2. to 4. As a result of these findings, the cardiologists determined that CABG surgery would be the best option.



**(Figure 2.)** High grade left main disease

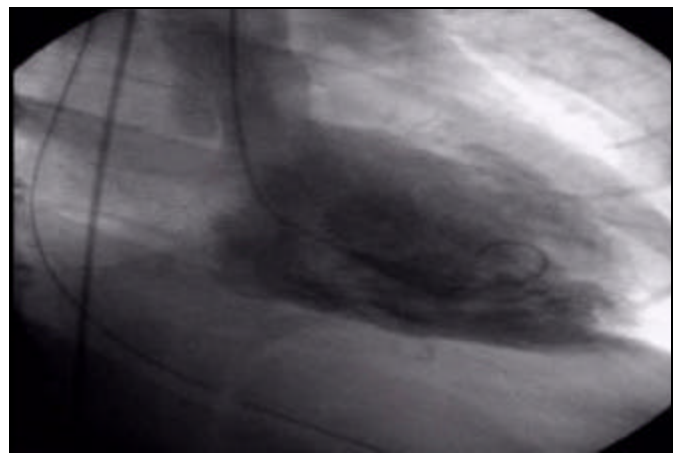
The patient was transferred without incident to the CCU where he remained stable throughout the night. He was resistant to heparin, and required doses over 1500 U/hr with additional bolus's to maintain an ACT of over 200 seconds. Presence of "coffee ground" NG tube drainage also complicated but did not compromise his therapeutic course. Throughout the first 48 hours of support the patient required pharmacological support with moderate doses of Dopamine and minimal doses of Levophed. These doses were steadily

reduced throughout his CCU stay, and may have been required as a result of the medication given to maintain the current level of sedation (Propofol). It was decided to keep the patient sedated to prevent him from moving his extremities.



**(Figure 3.)** Right coronary artery with diffuse disease throughout its course.

On the second day after initiation of support the patient's CO had improved to 6.0 L/min with a CI of 2.8 L/min/m<sup>2</sup>. He had a low-grade fever throughout his CCU stay and was maintained on wide spectrum IV antibiotics. At the beginning of day three of support, the patient was reliant only on small doses of dopamine for optimal pressures. Tandem-Heart support was temporarily discontinued for cardiac assessment. The patient's systolic pressure remained between 95 to 99 mmHg with a CO of 4.7 L/min, a CI of 2.2 L/min/m<sup>2</sup>, and a HR of 77 BPM. At this time substandard quality bedside echocardiography indicated an EF of 10%, with mild mitral valve regurgitation (MR) and no effusion. CK levels had reached a level of 1.2 mg/dL. Surgery was

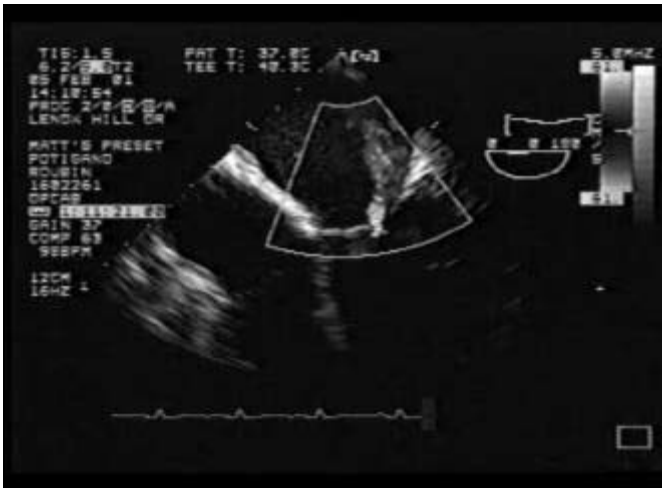


**(Figure 4.)** Severely depressed ventricular function

planned for the following day.

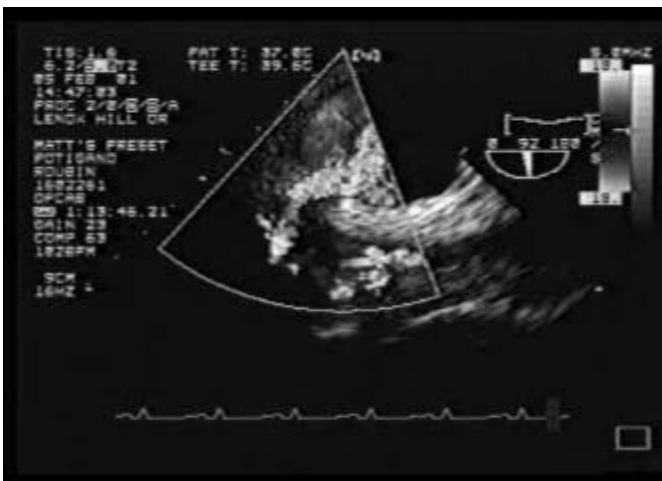
On the fourth day, the patient was transferred to the operat-

ing room. The decision was made to keep him on TandemHeart support while quintuple bypass grafting was performed on the beating heart. Color flow doppler performed immediately prior surgery showed markedly depressed left ventricular function and a grade II<sup>+</sup> MR (Figure 5).



(Figure 5.) Grade II<sup>+</sup> Mitral valve regurgitation

During surgery the pump delivered a steady flow of more than 3 L/min allowing the heart to be manipulated to expose lateral and posterior vessels. Figure 6. shows blood entering the tip of the transseptal cannula. The TandemHeart was removed in the OR immediately following surgery. The cannulation sites were closed by applying manual pressure. The patient remained in the hospital for two weeks to mobilize him and to begin rehabilitation. Several weeks later he had recovered to a point where he was able to walk several blocks.



(Figure 6.) Blood entering the Transseptal Cannula

## Discussion

Patients in cardiogenic shock after acute MI and with severe multi-vessel disease are in critical need for hemodynamic stabilization and revascularization. In this case, the IABP

did not provide the required amount of ventricular support to reverse shock or to prevent end organ hypoperfusion. At the same time, the extent of the patient's coronary disease did not allow percutaneous revascularization. The severely depressed ventricular function and the cardiogenic shock condition prevented immediate surgical intervention to revascularize or to implant a long-term VAD. The TandemHeart proved to be the ideal tool to stabilize the patient hemodynamically and to reverse cardiogenic shock and its effects on end-organ perfusion without subjecting the patient to an extensive surgical implantation procedure. During beating heart surgery the TandemHeart provided hemodynamic stability even during vigorous manipulation of the heart to reach lateral and posterior vessel targets. The TandemHeart System makes percutaneous ventricular assistance a viable option for patients in cardiogenic shock.

## Acknowledgement

We wish to acknowledge Drs. Moses, Subramanian, and Fonger for their assistance in developing this case report and for their participation in the US clinical trial series for the clearance of the TandemHeart pVAD System.

## References

- 1 Becker RC, Gore JM, Lambrew C, Weaver WD, Rubison RM, French WJ, Tiefenbrunn AJ, Bowlby LJ, Rogers WJ. A composite view of cardiac rupture in the United States National Registry of Myocardial Infarction. *J Am Coll Cardiol* 1996; 27: 1321-6
- 2 Califf RM, ed., "Atlas of Heart Diseases. Acute Myocardial Infarction and Other Acute Ischemic Syndromes", Vol VIII, Mosby, St. Louis, 1996, 12.1
- 3 Marso SP, Griffin BP, Topol EJ, ed., "Manual of Cardiovascular Medicine", Lippincott Williams & Wilkins, 2000, 109-110



