

**Percutaneous Left Ventricular Assist Device,
TandemHeart™, for high-risk percutaneous coronary
revascularization. A single centre experience.**

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Abstract

Patients with severe depression of left ventricular ejection fraction and high-risk coronary lesions are at risk of developing complications during percutaneous coronary interventions (PCI). Intra-aortic balloon pump (IABP) is a support that helps the interventionalist in such hemodynamic complications during high-risk PCI, but it does not offer complete circulatory support. Instead, TandemHeart™ (Cardiac Assist, Pittsburg, PA, USA) is a percutaneous left ventricular assist device (pLVAD) that gives total left circulatory support and can be used for patients in cardiogenic shock or for elective PCI at high-risk. TandemHeart™ is a percutaneous transseptal ventricular assist device that allows a rapid percutaneous left ventricular support without the need for surgical implantation. Between November 2003 and April 2005, 6 patients admitted to our coronary care unit (CCU) underwent either emergency (n = 3) or elective (n = 3) placement of the TandemHeart™ device before a high-risk procedure. From our initial experience we conclude that the percutaneous transseptal ventricular assist device, TandemHeart™, can be easily and rapidly deployed either in emergency or in elective high-risk PCI to achieve complete cardiac assistance.

Key words: shock; heart-assist device; extracorporeal circulation; high-risk PCI; TandemHeart.

PCI: Percutaneous Coronary Intervention

IABP: Intra-Aortic Balloon Pump

pLVAD: percutaneous Left Ventricular Assist Device

CCU: Coronary Care Unit

NSTEMI: Non ST Elevation Myocardial Infarction

LAD: Left Anterior Descending

LCx: Left Circumflex artery

LMCA: Left Main Coronary Artery

HIT: Heparin-Induced Thrombocytopenia

ICE: IntraCardiac Echocardiography

Introduction. Patients with severe depression of left ventricular ejection fraction and high-risk coronary lesions are at risk of developing complications during percutaneous coronary interventions (PCI). Intra-aortic balloon pump (IABP) is a hemodynamic support that helps the interventionalist during high-risk PCI but does not offer complete circulatory support (1,2). Instead, TandemHeart™ (Cardiac Assist, Pittsburg, PA, USA) is a percutaneous left ventricular assist device (pLVAD) that gives complete left circulatory support and can be used for patients undergoing emergency or elective high-risk PCI (3,4). TandemHeart™ is a percutaneous transseptal ventricular assist device that allows rapid percutaneous left ventricular support without the need for surgical implantation. It consists of a continuous-flow centrifugal blood pump (Figure 1), operating at least at 7500 rpm that provides non-pulsatile blood flow up to 4 liters/min of cardiac output. It is positioned via a 21 Fr. transseptal cannula (Figure 2) which drains oxygenated blood from left atrium, and an arterial cannula (12, 15 or 17 Fr.) for femoral-artery-reperfusion. Since November 2003, 6 patients admitted to our coronary care unit (CCU) underwent emergency or elective placement of the TandemHeart™ device (Table I, II).

Case #1: A 77-year-old man was admitted to our CCU for acute Non-ST-Elevation Myocardial Infarction (NSTEMI) of the anterior wall. On admission, ECG showed T-wave inversion on leads V1-V6. Peak values of creatine kinase (CK-MB) and of troponin were 60 ng/ml and 14 ng/ml, respectively. Coronary angiography revealed chronic total occlusion of the right coronary artery at proximal tract and of left circumflex artery (LCx) at mid tract, and proximal and mid stenosis (90 and 80% respectively) of left anterior descending (LAD) coronary artery with severe depression of left ventricular function (EF 20%). He was considered surgically inoperable because of the high operative risk. During in-hospital stay he developed ventricular tachycardia promptly resolved by DC shock. After ten days, because of acute pulmonary edema refractory to medical therapy, he was intubated and mechanically

ventilated; he was brought to the cath lab for emergent placement of IABP (Datascope Corporation, Fairfield, NJ, USA). This mechanical support was not sufficient, as blood pressure was 80/60 mmHg (on IABP), heart rate 110 bpm (sinus rhythm) and he was anuric. So we opted for emergent implantation of the percutaneous ventricular assist device (TandemHeart™). Access to left atrium was achieved under transesophageal-echocardiography control, using a Brockenbrough needle and Mullins sheath and dilator combination. The interatrial septum was punctured at the fossa ovalis. Then the 21 Fr. cannula, with a 2-stage dilator, was positioned in the left atrium, sutured to the skin and clamped. Another 17 Fr. cannula was positioned in the right femoral artery after angioplasty and stenting of the iliac artery. Then the cannulas were connected to the pump and circulation started; ACT was 400 seconds. Systemic hemodynamics dramatically improved. Mean arterial pressure went from 80/60 (mean 67) mmHg (on IABP) to 84 mmHg with no arterial pulse waveform. Flow became nonpulsatile, indicating almost complete left ventricular support by pump. PCWP decreased from 28 mmHg to 11 mmHg on pump. No increase in right atrial pressure was detected. Cardiac index (by thermodilution) went from 1.3 to 2.6 liters/min/m² on pump. PTCA with stenting, via brachial artery, was then performed on the proximal and mid LAD with good angiographic result, final TIMI III grade. The patients started to urinate approximately 200 ml/hour. Then he was brought to the intensive care. The pump was removed after 15 hours of support. The arterial cannula was surgically removed and then the patient was extubated. As soon as the 21 Fr. transseptal cannula was removed, a modest interatrial shunt was detected by color Doppler. The shunt had disappeared by one month, when a follow-up transesophageal-echocardiography was performed. No hemolysis, detected by haptoglobin, or major bleeding occurred. After twenty-five months he is free of cardiac events and EF is 40%.

Case #2: A 74-year-old man was admitted to our CCU for acute pulmonary edema. On admission, ECG showed negative T waves on leads V4-V6, DI and aVL. He was stabilized with diuretics, iv nitrates, enoxaparin, and aspirin. Peak values of troponin were 0.38 ng/ml. Coronary angiography revealed chronic total occlusion of the right coronary artery at the ostium and severe stenosis (80%) of the circumflex artery at mid tract, and mid tract stenosis (90%) of left anterior descending (LAD) coronary artery, with severe depression of left ventricular function (EF 30%). He was considered surgically inoperable because of comorbidity disease. So he was scheduled for percutaneous revascularization with TandemHeart™ pVAD. The patient was not intubated, so TandemHeart™ was implanted after trans-septal puncture guided by intracardiac echocardiography (ICE) performed using a 9 Fr. - 9 MHz, 110 cm long transducer (Ultra ICE™, Ep Technologies, Boston Scientific Corporation, San Jose, CA, USA). On pump, blood pressure was 140/80 mmHg (mean 100 mmHg), and PCWP decreased from 22 mmHg to 10 mmHg. Cardiac index went from 2.1 to 3.4 liters/min/m² on pump. PTCA with stenting was performed to the mid LAD and LCx with good angiographic result, final TIMI III grade. The pLVAD was removed 8 hours after the PCI. The arterial cannula was removed and manual compression was done. He required transfusion of 6 packed red blood cells because of gastric bleeding. Follow-up transesophageal-echocardiography revealed no interatrial shunt at one month. After twenty-four months he remains free of cardiac events.

Case #3: A 73-year-old man was admitted to our CCU for NSTEMI. ECG on admission revealed diffuse ischemia. Coronary angiography revealed severe stenosis (85%) of the right coronary artery at the mid tract, stenosis (75%) of the circumflex artery at proximal tract, and a critical stenosis of the left main coronary artery (LMCA) (70%) and of the proximal LAD (80%) coronary artery, with severe depression of left ventricular function (EF 25%). He had also mild aortic stenosis. He was considered for surgical revascularization.

During in-hospital stay he developed pneumonia, complicated by acute pulmonary edema that required intubation and implantation of IABP. Despite this mechanical circulatory assistance and inotropic support he was hemodynamically unstable; blood pressure was 110/60 mmHg (mean 77 mmHg on IABP), heart rate 100 bpm, urine output <20 ml/h, so it was decided for an emergent placement of the TandemHeart™ assist device. The device was positioned after trans-septal puncture guided by transesophageal-echocardiography. Hemodynamics dramatically improved; blood pressure was 130/70 mmHg (mean 90 mmHg on pump), heart rate 84 bpm, PCWP decreased from 32 mmHg to 8 mmHg; cardiac index increased from 1.9 to 2.9 liters/min/m² on pump. PTCA with double stent was performed to LMCA and LAD with a good angiographic result, final TIMI III grade. Duration of support was 24 hours; the pLVAD was surgically removed because of acute limb ischemia that required an urgent percutaneous revascularization of the superficial femoral artery. The patient developed also a heparin-induced thrombocytopenia (HIT) six days after removal. At discharge ejection fraction was 50%. After two months the patient was rehospitalized for heart failure. No interatrial shunt was detected by transesophageal-echocardiography and he is alive at twenty months follow-up.

Case #4: A 75-year-old man underwent elective placement of the TandemHeart™ device. His medical history accounts a recent NSTEMI complicated by left ventricular failure. One year before he suffered a stroke and 85% narrowing of both internal carotid arteries was detected by angiography. He also had abdominal aortic aneurysm. Coronary angiography revealed three-vessel disease with severe depression of left ventricular function (EF 25%). He was considered surgically inoperable because of comorbidity. So he was scheduled for percutaneous revascularization with TandemHeart™ pLVAD. Since the patient was initially awake, intracardiac echocardiography performed using a 9 Fr. – 9 MHz, 110 cm long transducer (Ultra ICE™, Ep Technologies, Boston Scientific Corporation, San Jose, CA,

USA) was used to guide transseptal puncture. After declamping of the 21 Fr. cannula, before connection with the centrifugal pump, some air (between 10 to 20 cc) was aspirated by the cannula in the left atrium. The patient developed acute pulmonary edema so he was promptly intubated and mechanically ventilated. The pump was promptly started. On pump blood pressure was 110/77 mmHg (mean 84 mmHg), PCWP decreased from 23 mmHg to 11 mmHg with no changes during balloon inflation. Cardiac index went from 2.53 to 3.2 liters/min/m² on pump. PTCA with stenting was performed to the proximal LAD, proximal and mid LCx and proximal RCA with a good angiographic result, final TIMI III grade. The pLVAD was removed after 48 hours from the PCI. The arterial cannula was surgically removed. He required transfusion of 6 units of packed red blood cells because of haemolysis. At discharge, ejection fraction was 35%. After one month he was free of cardiac events. We explain the air aspiration through the 21 Fr. cannula, despite a positive pressure in left atrium, because of the presence of globus abdomen that compressed the cannula and probably made a sort of vacuum that facilitated aspiration of the air. There were no consequences for the patient because of the prompt start of the centrifugal pump, that initially left the air in the ascending aorta without embolization; during pLVAD assistance that air eventually dissolved into blood avoiding further consequence for the patients. After eighteen months he remains free of cardiac events.

Case #5: A 61-year-old man was admitted to our Institution for elective percutaneous coronary revascularization with TandemHeart™ pLVAD. His medical history was positive for acute myocardial infarction treated with lysis two months before. Coronary angiography revealed severe stenosis (90%) of the ostium of the LAD coronary artery with severe depression of left ventricular function (EF 18%). ECG on admission revealed right bundle branch block. Stress test was positive for myocardial viability. He refused surgical revascularization. The device was positioned, after trans-septal puncture guided by

intracardiac echocardiography performed using a 9 Fr. – 9 MHz, 110 cm long transducer (Ultra ICE™, Ep Technologies, Boston Scientific Corporation, San Jose, CA, USA). Hemodynamics dramatically improved: blood pressure was 110/70 mmHg (mean 85 mmHg on pump), heart rate 84 bpm, PCWP decreased from 22 mmHg to 8 mmHg; cardiac index went from 1.7 to 3.1 liters/min/m² on pump. PTCA with stenting was performed at the ostium of the LAD and LCx with a good angiographic result, final TIMI III grade. The duration of support was 6 hours; the pVAD was removed in the cath lab with manual compression on the femoral artery. The patient was discharged after ten days. After two months the patient was rehospitalized for heart failure, and he is alive at sixteen months follow-up.

Case #6: A 56-year-old woman was admitted to our CCU for acute myocardial infarction complicated by cardiogenic shock. She was sent to cath lab for primary PCI. She was intubated and mechanically ventilated. An IABP was implanted and inotropic agent infused iv. Coronary angiography demonstrated occlusion of the LCx at the ostium and a hemodynamically significant stenosis of the LMCA. Primary PCI was performed with a V stenting of the LMCA, LAD and LCx with a good angiographic result, final TIMI III flow. After two days on IABP hemodynamics remained poor (cardiac index was 1.4 liters/min/m²) and an acute thrombosis of the iliac artery occurred, so we decided to implant a total left circulatory support with TandemHeart™ pLVAD. The device was positioned, after trans-septal puncture guided by transesophageal-echocardiography. Hemodynamics dramatically improved, mean blood pressure rose from 63 mmHg to 90 mmHg on pump, PCWP decreased from 28 mmHg to 12 mmHg; no change in right atrial pressure was recorded. Cardiac index went from 1.4 to 2.8 liters/min/m² on pump. The patient subsequently underwent surgical removal of the thrombus in the iliac artery. After the vascular operation she developed a reperfusion syndrome with acute renal failure and died after 64 hours of support.

Discussion. TandemHeart™ pLVAD gives an active hemodynamic support, by ensuring an adequate coronary and systemic perfusion, valuable to perform high-risk percutaneous revascularization (5,6). Moreover, it may allow complete recovery from cardiogenic shock, in patients with severe acute left ventricular failure due to a mechanical cause, with a trend toward reduction in mortality in contrast to the standard therapy with IABP (3,7); however, there were more complications encountered by the highly invasive procedure and the extracorporeal support.

In this series, TandemHeart™ was placed in emergency in three patients with acute coronary syndromes complicated by acute pulmonary edema with severe left ventricular dysfunction, and prophylactically in three other patients with low ejection fraction, three vessel disease, scheduled to perform high-risk PCI. After the initial learning curve, the device can be implanted completely percutaneously in less than 30 minutes.

The good support offered by the heart-assist device, as demonstrated by the hemodynamic indices (Figure 3, Table III), provides the necessary stability to perform high-risk PCI; in three patients an IABP was implanted initially; however, it did not afford hemodynamic stabilization, likely because the intra-aortic counterpulsation does not actively support the left ventricle and it requires a residual level of left ventricular function. Instead, the left ventricular assist device induces a reduction of the filling pressure in the left ventricle, cardiac workload and oxygen demand.

A limitation to the implantation of the pLVAD is peripheral vascular disease that can reduce the duration of assistance because of limb ischemia. This could be minimized using either bilateral cannulas (12 Fr. or 15 Fr.) or a cannula (8 Fr.) inserted into the superficial femoral artery, to perfuse the limb antegradely, in addition to the retrograde cannula in common femoral artery. No major bleeding, at puncture site, significant hemolysis or thromboembolic phenomena were observed during pVAD assist. No adverse hemodynamic

effects were observed by the nonpulsatile pump flow also in critical setting of acute left ventricular dysfunction.

A limiting point is also trans-septal puncture that can be safely performed guided by transesophageal-echocardiography or ICE if the patients is awake. ICE allows a proper visualization of the fossa ovalis, also facilitating all stages of the deployment process monitoring. In this case, we employed Ultra ICE™ (Ep Technologies, Boston Scientific Corporation, San Jose, CA, USA); other steerable ICE are also available, such as the AcuNav™ (Acuson-Siemens Co., Mountain View, CA, USA), a system that provides ultrasound high-quality two-dimensional and color Doppler images as well as continuous and pulsed wave Doppler. However, in our case ICE was used only as a means to confirm the site in the fossa ovalis to puncture; thus, color-flow Doppler capability and more detailed image were not strictly necessary.

The in-hospital death of one patient was due to vascular complication related to the previous vascular access of the IABP and not to the implantation of the TandemHeart™ (Table IV).

Conclusion. This series of patients demonstrate the feasibility and the safety of percutaneous placement of left ventricular assist device, TandemHeart™, both for emergency and in elective percutaneous coronary interventions. It can be used either in emergency and prophylactically with no major bleeding or hemolysis. PLVAD is helpful in situations in which despite inotropes and IABP a stable hemodynamic to perform high-risk PCI is not achievable. Indications to this device could be patients in cardiogenic shock refractory to inotropes and IABP, high-risk PCI, including complex coronary lesions, multivessel coronary artery disease, left main disease, bypass graft disease and low ejection fraction. Further studies are warranted to define the indications and to demonstrate the clinical benefit.

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Figure legend.

Figure 1. Centrifugal blood pump.

Figure 2. Chest X-ray visualizing the 21 Fr. cannula in left atrium inserted through femoral vein (solid arrow) and Swan-Ganz catheter inserted through jugular vein (dotted arrow).

Figure 3. Hemodynamic parameters before and during VAD implantation. PCWP = pulmonary capillary wedge pressure (mmHg); CVP = central venous pressure. Measurements of patient 1, 3 and 6 before pVAD are done on IAB-Pump.