CHAPTER 24

THE TANDEMHEART SYSTEM: DEVICE DESCRIPTION AND CLINICAL RESULTS

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TANDEMHEART DESCRIPTION

The TandemHeart System (CardiacAssist, Inc. Pittsburgh, Pennsylvania) is an extracorporeal circulatory assist device that drains blood from the left atrium (LA) and pumps it back into the femoral artery to bypass the left ventricle. The TandemHeart System (Fig. 24–1) has four major components: (1) an extracorporeal centrifugal pump (2) a 21-Fr transseptal cannula, (3) an arterial cannula, and (4) a microprocessor-based controller. The System can provide up to 5 L/min of blood flow percutaneously and is CE marked for 30 days and approved by the Food and Drug Administration (FDA) for use up to 6 hours.[1-4] The device has been used in over 2000 patients[5] and has undergone several clinical trials.[1,6-8]

The TandemHeart pump is a centrifugal blood pump that has a priming volume of 7 mL, weighs 280 g, and contains a hydrodynamic bearing to support the spinning impeller.[9] The pump has a motor chamber and a blood chamber that are separated by a polymeric seal (Fig. 24–2). The motor is a brushless direct current motor consisting of a laminated stack of stainless steel plates wound with copper wire embedded in a heat-dissipative epoxy. The rotor is centered in the stator, is spun by the motor through an electromagnetic coupling, and is attached directly to the impeller. Saline flows at 10 mL/h through the motor chamber and completely surrounds the rotor.[10] Lift pads in the lower housing of the motor chamber provide thrust forces to stabilize the rotor in the axial direction. The saline flows between a journal and the rotor toward the impeller to provide radial stability. The impeller shaft passes through the center of the seal, and the saline (heparinized with 90,000 U/L) flows around the impeller shaft-seal interface to flush the area to prevent thrombus formation. The impeller contains six blades and rotates between 3000 and 7500 rpm (revolutions per minute) to provide flow rates from 1 to 8 L/min, depending on the size of the cannulae.[9]

The pump is small enough to be surgically implanted in the chest cavity (formerly named the AB-180). In the AB-180 embodiment, the inflow cannula to the pump was inserted into the LA and a 10-mm thin-walled polytetrafluoroethylene (PTFE) graft connected the outflow port of the pump anastomosed to the aorta. The device underwent implantation in 17 patients for the treatment of postcardiotomy cardiogenic shock (CS), decompensated cardiomyopathy, viral myocarditis, and acute myocardial infarction (AMI) with hemodynamic instability. The pump was used for an average of 8 days with 58% of the patients weaned and 29% of the patients survived.[9] The pump and controller were then adapted for extracorporeal and percutaneous use (TandemHeart System) by incorporating the transseptal cannula for the pump inflow and a femoral arterial cannula for the pump outflow.

The transseptal cannula (Fig. 24–3) is made of a smooth polyurethane material and is wire-reinforced to prevent kinking. The insertable length is available in two sizes: 62 cm and 72 cm. The cannula tip distal to the wire-wound portion is 1.2 cm in length, and drainage of the LA is achieved through 14 side holes in addition to being open at the distal end. The tip contains three radiopaque marker disks that can be seen under fluoroscopy to instruct the user of the location of the cannula tip. The insertable portion is 21 Fr and contains centimeter markings for reference as to where the tip is in relationship to the insertion site. A suture wing is included at the proximal end of the cannula to help prevent cannula migration. The arterial cannula is similar in construction to the transseptal cannula and ranges in size from 12 to 17 Fr.

The Escort (Fig. 24–4) is the controller that drives the pump and supplies saline to the pump. The controller includes self-diagnostics and alarm features to ensure patient support without the need for constant operator surveillance. Built-in batteries allow for uninterrupted operation for 60 minutes during patient transport or in the event of an AC power failure. The controller has dual redundant motor control units. In the event of a catastrophic failure of the controller hardware, the controller will automatically switch to an emergency backup mode. Although the system display screen and monitoring functions may not be functional, basic pump operation such as pump start and pump speed control will continue to function. A built-in pressure transducer measures the operating pressure of the infusion system. Alarms are linked to changes in the infusion system operating pressure to alert the user of a problem with the delivery of saline to the pump. The air bubble detector monitors for air in the infusion system. The Escort weighs 21 lb and can be mounted to an IV pole to facilitate transportation.

IMPLANTATION PROCEDURE

The TandemHeart system can be inserted percutaneously in the catheterization laboratory through standard insertion techniques. The femoral vein is accessed for transseptal puncture, which is performed under fluoroscopic guidance using the Brockenbrough needle and a Mullins sheath, as is done during atrial fibrillation ablations.[11] Once the puncture is made in the fossa ovalis, heparin is given to achieve a target activated clotting time (ACT) of more than 300 seconds before inserting the cannula. After confirming the position of the Mullins sheath in the LA, a stiff wire (Inoue Wire TRG-25175, Toray International,

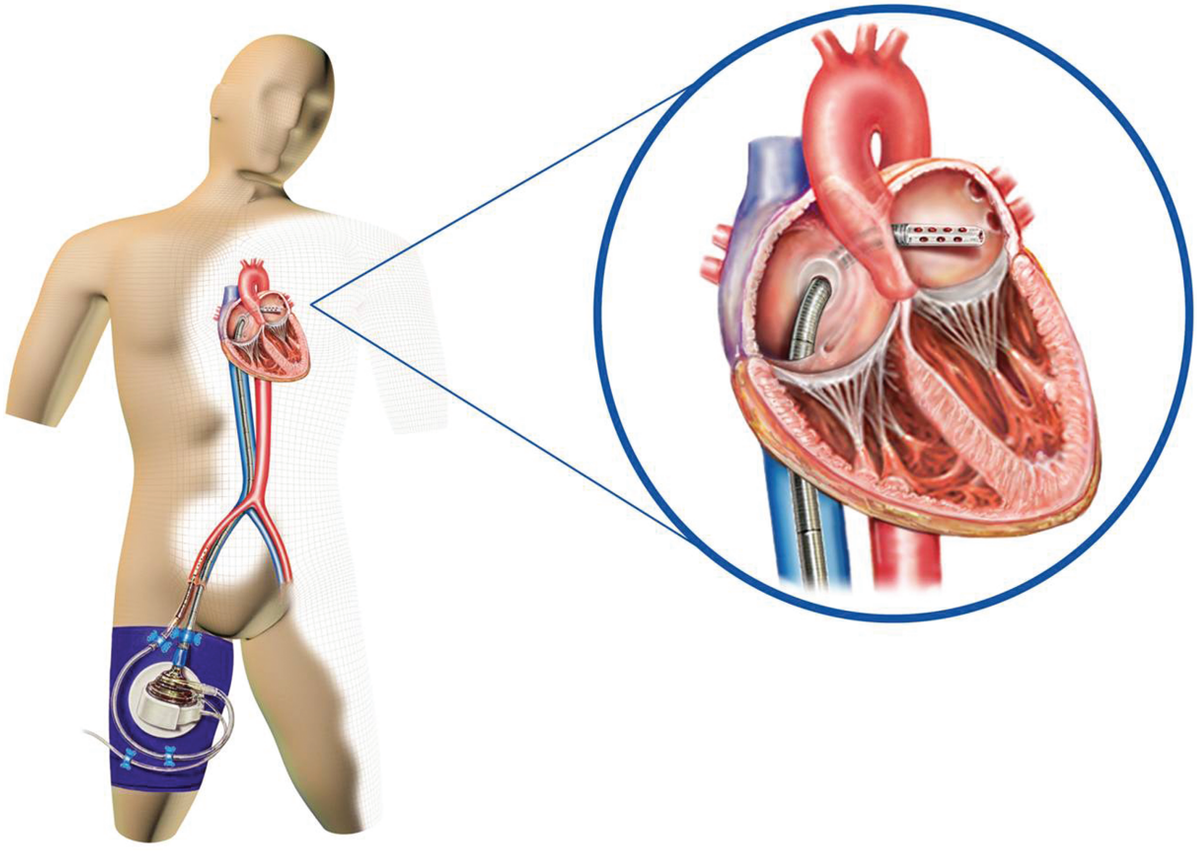

FIGURE 24–1. TandemHeart System including the 21-Fr transseptal venous cannula, the extracorporeal centrifugal pump, and the arterial cannula. Blood is withdrawn from the left atrium and pumped into the femoral artery to bypass the left ventricle. (Reproduced with permission from CardiacAssist, Inc.)

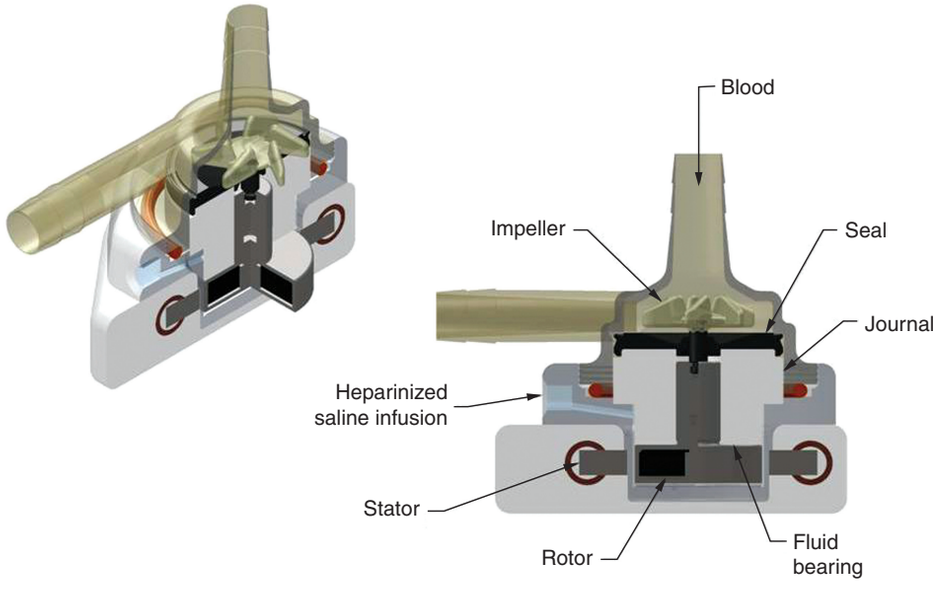

FIGURE 24–2. TandemHeart pump cutaway. Heparinized saline flows into the motor chamber and then up into the blood chamber. Fluid forces in the lower housing act stabilize the rotating impeller axially, and fluid forces in the journal stabilize the impeller radially. (Reproduced with permission from CardiacAssist, Inc.)

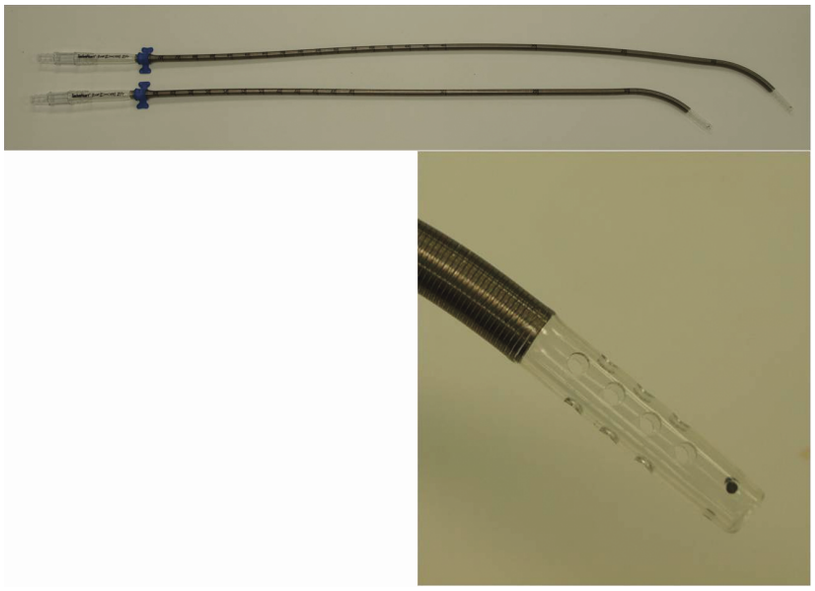

FIGURE 24–3. The TandemHeart transseptal cannula comes in two sizes with insertable lengths of 62 and 72 cm. The cannula features a wire-wound construction for kink resistance, and radiopaque marker discs at the tip to aid in visualization of the tip location in the left atrium under fluoroscopy. (Reproduced with permission from CardiacAssist, Inc.)

Houston, TX) is placed into the LA and the Mullins sheath is exchanged for the TandemHeart 14-Fr/21-Fr two-stage dilator. The dilator increases the septum puncture site diameter and enables the 21-Fr transseptal cannula to be inserted into the LA. The cannula tip contains three radiopaque marker disks that can be viewed under fluoroscopy to confirm that the position of the cannula tip is in the LA. Transesophageal echocardiography has also been used to help with the insertion and cannula tip placement.[12] The end of the cannula outside of the patient is sutured to the thigh to help prevent cannula dislodgement. Color Doppler has been used to visualize flow through the holes of the cannula tip to verify correct placement.[12]

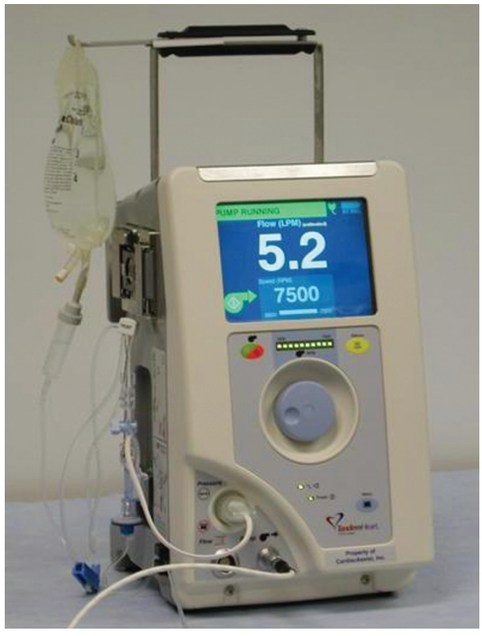

FIGURE 24–4. The TandemHeart Escort is a microprocessor-based controller that powers the pump and has built-in alarms and diagnostics such as flow measurement that help assess pump function. (Reproduced with permission from CardiacAssist, Inc.)

The arterial cannula is placed in the femoral artery with the distal end sitting above the aortic bifurcation and is also sutured to the thigh to prevent cannula migration or dislodgement. Prior to arterial cannula insertion, the patients should be subjected to a femoral artery angiogram using a 4-Fr arterial sheath dilator before upsizing to a larger French arterial sheath to ensure peripheral vascular disease will not prevent insertion. If the artery is greater than 5 mm, Perclose devices can be deployed to assist in achieving hemostasis following arterial cannula removal.[13] Other preclosure devices have also been used to reduce arterial complications during cannula removal.[14] Additional manual compression can be employed when needed. In some patients the femoral artery is too small or too calcified for insertion of the standard cannula. Therefore, a graft can be sewn onto the femoral artery and connected to the outflow of the pump with a connector. Busch et al describe the procedure where they use a partial occlusion clamp to sew an 8-mm reinforced GORE-TEX graft to the femoral artery in an end-to-side fashion using 5-0 polypropylene sutures.[15] Once the transseptal and arterial cannulae are in place, the pump and cannulae are de-aired and connected via a wet-to-wet connection to remove all air from the circuit. The pump is then connected to the TandemHeart controller, and its speed is adjusted to provide the desired level of support.

UNIQUE INSERTION PROCEDURES AND PATIENT MANAGEMENT OF THE TANDEMHEART SYSTEM

The transseptal cannula can also be inserted surgically allowing the chest to be closed for the device to be removed percutaneously following support.[16,17] The surgical cannulation uses an "open transseptal" technique when a sternotomy has already been performed. The patient is placed on cardiopulmonary bypass (CPB) through bicaval cannulation. The transseptal cannula is inserted into the femoral vein, and the tip is brought into the right atrium (RA) prior to insertion of the inferior vena cava (IVC) cannula. Placing a tourniquet around the IVC ensures adequate occlusion of blood around the CPB and TandemHeart cannulae, which are adjacent to each other. The RA is opened through the appendage, a stab wound is placed through the fossa ovalis with a scalpel, and the tip of the cannula is placed across the septum into the LA by direct visualization. The patient can then be weaned off of bypass, the atrium de-aired, and the

patient placed on TandemHeart support. Surgical cannulation of the LA has also been accomplished by placing the cannula through the right superior pulmonary vein into the LA.[17] For failure to wean patients, the IVC cannula is clamped, the snare around the IVC cannula is released, and the transseptal cannula is threaded into the RA. A small incision is made in the atrial septum and the transseptal cannula tip is pushed across. The RA is closed and CPB can be resumed or weaned as TandemHeart flows are increased.

The TandemHeart System has also been placed in the axillary artery and vein to allow for patient mobility.[18] The right axillary artery and vein were exposed in a right thoracotomy. An 8-mm Dacron graft (Hemashield; Boston Scientific, Natick, MA) was sutured in an end-to-side fashion to the axillary artery using 5-0 polypropylene. A wire-reinforced arterial cannula was then inserted through the graft to a point 1 cm close to the anastomosis and secured with silk ties, both within the wound and outside the skin. The pump inflow cannula was tunneled through the axillary vein and into the LA through direct visualization via a right atriotomy. The advantage of the axilloaxillary approach is that it avoids the risk of lower limb vascular complications, avoids infection complications of the groin, and enables the patient to sit in bed at a 45-degree angle.

Bleeding can be an issue with circulatory assist devices.[19-24] For patients with heparin-induced thrombocytopenia (HIT), type II Argatroban has been used successfully with the TandemHeart. Before transseptal cannula insertion, the patient was given a bolus of 3500 μg of Argatroban and during support the Argatroban infusion rate was titrated to maintain an activated partial thromboplastin time (aPTT) at or near 2.5 times normal. A dosage of 7000 μg of Argatroban was used in the 1 L of saline infusate[25] to prevent thrombus and bleeding complications. For non-HIT patients, systemic heparin is given to maintain ACTs of 180 to 220 seconds or partial thromboplastin time (PTT) of 65 to 80 seconds.

TANDEMHEART SYSTEM CLINICAL DATA

Left atrial to femoral artery bypass was first attempted in 1962 and has been investigated by several groups since that time.[26-34] The TandemHeart System was evaluated for the reversal of CS following AMI in 18 patients. The mean flow rate of blood was 3.2 ± 0.6 L/min. The cardiac index (CI) improved from 1.7 ± 0.3 L/min/m^2 at baseline to 2.4 ± 0.6 L/min/m^2 while on support ($P < 0.001$). Mean blood pressure increased from 63 ± 8 to 80 ± 9 mm Hg ($P < 0.001$) and pulmonary capillary wedge pressure (PCWP) decreased from 21 ± 4 to 14 ± 4 mm Hg ($P < 0.001$). The survival rate was 56%.[7] The conclusion of the study was that the TandemHeart could be rapidly deployed to potentially aid in reverting CS.

A randomized follow-up study was conducted by Thiele to compare the use of the intra-aortic balloon pump (IABP) to the TandemHeart for patients with an AMI complicated by CS.[8] The inclusion criteria included the presence of shock complicating AMI and the intention to revascularize the infarcted artery by percutaneous coronary intervention (PCI) as the first-line treatment option. CS was defined as (1) persistent systolic blood pressure less than 90 mm Hg or vasopressors required to maintain blood pressure greater than 90 mm Hg; (2) evidence of end organ failure (eg, urine output < 30 mL/h, cold skin and extremities, and serum lactate > 2 mmol/L); (3) evidence of elevated left ventricular filling pressures PCWP greater than 15 mm Hg; (4) CI less than 2.1 L/min/m^2. Exclusion criteria were age greater than 75 years, mechanical complications of AMI, duration of CS longer than >12 hours, right heart failure, sepsis, significant aortic regurgitation, severe cerebral damage, resuscitation longer than 30 minutes, severe peripheral vascular disease, and other diseases with reduced life expectancy. Twenty patients were enrolled in the IABP arm, and 21 patients were enrolled in the TandemHeart arm. The primary outcome measure of cardiac power index (CPI) was improved more effectively with the TandemHeart from 0.22 W/m^2 preimplant to 0.37 W/m^2 postimplant compared to the balloon pump which only increased the CPI from 0.22 to 0.28 W/m^2 ($P = .004$). The study was not powered to detect differences in mortality between the two groups, and 30-day mortality was similar (IABP 45% vs VAD 43% $P = .86$). Complications such as bleeding and leg ischemia were higher for the TandemHeart group.

In the United States, the TandemHeart was evaluated for safety in a feasibility study consisting of 13 patients with CS from five centers.[6] The enrollment criteria were broader than those of Thiele in that CS was secondary to AMI (n = 8), decompensated idiopathic cardiomyopathy (n = 1), decompensated ischemic cardiomyopathy (n = 1), postcardiotomy syndrome (n = 2), and high-risk intervention (n = 1). As seen in the previous studies, hemodynamic variables including CI, MAP, and PCWP were improved following initiation of TandemHeart support. Survival rate was 54% in this high-risk group of patients.

A randomized multicenter trial was then initiated to compare the TandemHeart to the IABP for patients presenting within 24 hours of developing CS.[1] The primary objective was to test whether the TandemHeart device provided superior hemodynamic benefits compared with the IABP in patients with medically refractory CS. The secondary objective was to compare survival 30 days after randomization. Patients who had a balloon pump and still met the criteria for CS were eligible for the trial. Forty-two patients were enrolled at 12 centers. Of the 42 patients, 26 were diagnosed with AMI, 3 had coronary artery bypass graft (CABG), and 1 underwent a left ventricular assist device (LVAD) implant. Most of the remaining patients had decompensated chronic heart failure. Compared to the IABP, patients with the TandemHeart had significantly greater increases in CI and greater decreases in PCWP. An independent data safety monitoring board (DSMB) reviewed the data and concluded that the hemodynamic effects of the TandemHeart group were superior to those of IABP group and that no definitive conclusion regarding mortality was achievable. Therefore, the study was halted.[1] In a summary of several technologies for treating AMI complicated by CS, Garatti et al cited the TandemHeart to have the highest wean and highest survival rate of 75% and 58%, respectively.[35] Bleeding remained the leading complication of the TandemHeart, and no significant left-to-right shunt

has been observed following removal of the transseptal cannula.[36] The small sample sizes in the trial prevented a statistically significant mortality benefit; however, different subgroups of CS patients have been shown to benefit from the TandemHeart more than others.[37-41]

Since the clinical trials, the TandemHeart has been used during cardiac procedures other than patients with CS. Tanaka et al described the use of the TandemHeart on patients turned down by surgery for aortic valvuloplasty.[42] Seven patients underwent insertion of the TandemHeart prior to valvuloplasty and were compared to four patients who had the valvuloplasty without TandemHeart support. The patients with the TandemHeart were able to have to balloon inflated for 37 ± 10 seconds compared to 11 ± 3 seconds for the patients not on TandemHeart. All seven TandemHeart patients survived to at least 30 days whereas only two of the four non-TandemHeart patients survived to 30 days. Rajdev et al used the device to treat a 58-year-old man during an aortic valvuloplasty.[43,44] The patient had a left ventricular ejection fraction of 10%, mitral regurgitation, aortic stenosis, pulmonary artery hypertension, and New York Heart Association (NYHA) class III-IV symptoms of heart failure. He also had triple vessel disease and had been considered too high risk for surgery. The TandemHeart was inserted and the speed adjusted to provide a flow rate of 2.5 L/min. The balloon aortic valvuloplasty was performed, the TandemHeart removed, and the patient was discharged the following day. The TandemHeart has been shown to be effective at several other institutions for assisting with valvuloplasty particularly in patients who have been turned down for surgery.[4,13,42]

CONCLUSION

The TandemHeart System has demonstrated the feasibility of a left atrial to femoral artery bypass circuit. Clinical trials in Europe and the United States provided evidence that the TandemHeart can increase CI, MAP, and decrease PCWP which may be beneficial for patients with depressed cardiac function. Future improvements to the cannula and pump may reduce complications such as bleeding and increase the utility of the device.[45,46]

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