

A Novel Mechanical Circulatory Approach for Patients with Cardiogenic Shock in the Intensive Care Unit

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ABSTRACT

Background. The capacity of the heart to maintain cardiac output can be acutely impaired as a result of myocardial infarction, graft failure after transplantation, or other cardiac events. Medical therapy or the use of an intra-aortic balloon pump may be insufficient to help the patient overcome acute cardiogenic shock. The set-up of mechanical assist devices such as extracorporeal membrane oxygenation or patient relocation into the operating room requires valuable time that is often not available. The aim of our study was to test whether a novel left ventricular assist device can be percutaneously implanted without fluoroscopy under echocardiographic navigation in a preclinical model.

Methods. Pigs were subjected to percutaneous implantation of a novel left ventricular assist device under navigation of transesophageal echocardiography (TEE) without fluoroscopic support. Percutaneous puncture of the interatrial septum using a Brockenbrough needle and insertion of the afferent cannula into the femoral vein and its advance to the right atrium and through the interatrial septum into the left atrium was performed under echocardiographic control. The efferent cannula was inserted into the contralateral femoral artery using the Seldinger technique.

Results. In all animals, the percutaneous implantation of a left ventricular assist device was successful under only TEE navigation.

Conclusions. The ability to abstain from fluoroscopy and the feasibility of inserting the afferent cannula across the interatrial septum guided by TEE allows for application of this system in intensive care units, saving precious time as well as financial and human resources.

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BACKGROUND

Cardiogenic shock is a serious complication following myocardial infarction and cardiomyopathy with mortality rates of 60% and 75%, respectively, despite aggressive treatment approaches [Goldstein 2000; Barron 2001]. When medical treatment modalities are exhausted, intra-aortic balloon pump (IABP) counter-pulsation is the first-step mechanical assist device, assisting by diastolic augmentation of the coronary blood flow and systolic support of the left ventricle [DeWood 1980]. However, the main disadvantage of the IABP is the lack of active cardiac support [Hochman 2000]. Numerous ventricular assist devices (VAD) have been applied for temporary and permanent ventricular assist support, which in most cases requires thoracotomy and extensive operations [Miller 2006]. When patients in intensive care units (ICU) develop low cardiac output syndrome or cardiogenic shock refractory to medical therapy, relocation and transfer to the operating room (OR) for VAD implantation involving cardiopulmonary bypass may pose a considerable risk to the patient. The availability of a temporary VAD that allows for on-site implantation without a need for cardiopulmonary bypass would significantly facilitate patient management. For this purpose, extracorporeal membrane oxygenation (ECMO) or a centrifugal pump whose cannulae are inserted through the femoral or subclavian artery (efferent) and vein (afferent) are interesting alternatives. However, in such a biventricular support constellation, the flow generated by these devices often does not suffice to meet the circulatory demands because of the peripheral position of the cannulae. Moreover, selective left or right ventricular support is not possible. Additionally, the use of ECMO requires strong anticoagulation for the oxygenator, causing bleeding complications.

The Tandem Heart (Tandem Heart pVAD, Cardiac Assist Technologies, Pittsburgh, PA, USA) is a percutaneous left VAD (pVAD) designed for short-term extracorporeal support and operates without mechanical bearings or seals. The rotor is magnetically levitated so that rotation is achieved without friction or wear, which seems to minimize blood trauma and mechanical failure. This novel pVAD has been clinically approved and is already being used clinically by cardiologists in the United States and Europe for the

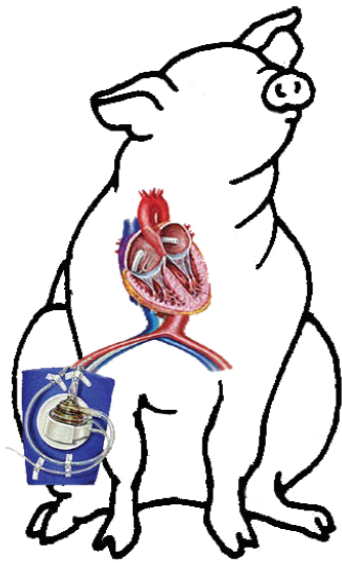


Figure 1. The final setup on the implanted percutaneous left ventricular assist device is depicted in this image. The left ventricle is unloaded by the afferent cannula in the left atrium. The blood is then propelled to the femoral artery. The small centrifugal pump is mounted on the thigh.

treatment of cardiogenic shock [Thiele 2001]. In 2 recent studies, Thiele et al as well as Burkhoff et al were able to show that in cardiogenic shock hemodynamic and metabolic parameters could be reversed more effectively by the Tandem Heart pVAD than by standard treatment with IABP [Thiele 2005; Burkhoff 2006]. In fact, the pVAD is usually implanted in the cardiac catheterization lab under fluoroscopic control, which again requires patient relocation from the ICU.

The aim of our study was to test whether the pVAD can be percutaneously implanted without fluoroscopy under echocardiographic guidance in a preclinical model, eventually enabling clinical application in the ICU.

MATERIALS AND METHODS

Transesophageal Echocardiography

In all animals, transesophageal echocardiography TEE (Sonos 7500; Philips, Bothell, WI, USA) was performed in general anesthesia before, during, and after pVAD implantation. Multiplane TEE (T 6210; Agilent Technologies, Santa Clara, CA, USA) was performed with a 5-MHz multiplane transducer, and all data were recorded on a magneto-optical disc for subsequent analysis. All examinations were performed standardized in long-axis 4- and 2-chamber view, as well as in short-axis views (mitral valve, papillary muscle, and apical level), and, if required, completed with some atypical oblique views for the best demonstration of the interatrial septum. The clear and incessant visibility of both atria with emphasis of the interatrial septum was imperative.

Surgical Technique

During all experiments, the Principles of Laboratory Animal Care (NIH publication No. 86-23, revised 1985) as well as the specific German Law on the Protection of Laboratory Animals were followed. Three female pigs (50 kg bodyweight) each received 200 IE heparin/kg bodyweight. The pVAD was implanted by insertion of a cannula through the femoral vein (Figure 1). Under TEE control, a Mullins sheath and subsequently a standard Brockenbrough needle were advanced to the right atrium. The interatrial septum was punctured, and the tip of the needle retracted. The left-atrial position of the Brockenbrough catheter was confirmed by a bubble test. The Brockenbrough catheter was then replaced by a stiff guide wire with a distal soft-wire loop. The trans-septal puncture site was then dilated with a 21F 2-stage dilator followed by the insertion of a venous inflow cannula. The efferent cannula consisted of a standard 19F catheter, which was inserted percutaneously into the femoral artery. After de-airing, a flow of 4l/min at a pump speed of 7500 rpm was possible, supplying left-atrial blood to a centrifugal pump and unloading the left ventricle. Oxygenated blood would then be propelled by the impeller from the outflow of the pump and returned to the animal via a femoral arterial cannula.

RESULTS

Figure 1 shows the final setup of our experiment. In our model, the pVAD implantation for left-ventricular support under exclusive TEE guidance was feasible and no fluoroscopy was needed. TEE images in Figure 2 show the

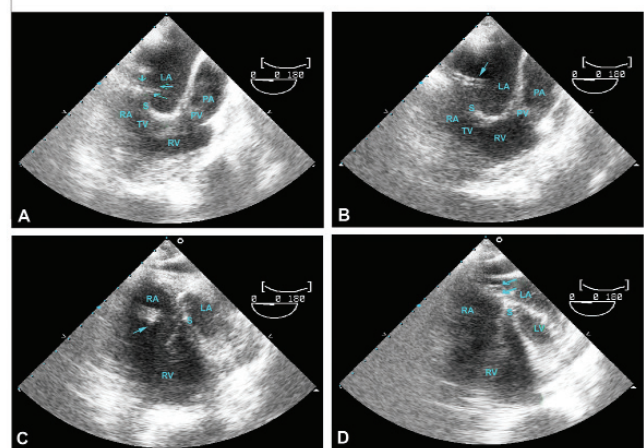


Figure 2. Transesophageal echocardiography during the intervention, showing the right atrium (RA), left atrium (LA), the septum (S), right ventricle (RV), tricuspid valve (TV), pulmonary valve (PV), and pulmonary artery (PA). A, Penetration of the Brockenbrough needle (arrow) through the interatrial septum. B, Insertion of the 2-stage dilator (arrow) through the septum. C, The venous inflow cannula (arrow) is in the right atrium prior to transfer into the left atrium through the septum. D, The inflow cannula has passed the septum (arrows point to the outlines of the cannula).

successful advance of the stiff guide wire across the interatrial septum, followed by the dilator.

DISCUSSION

Cardiogenic shock and low-output syndrome are serious complications following acute myocardial infarction and cardiomyopathy. Rapid medical and mechanical support is therefore imperative for the prognosis of patients. Whereas numerous mechanical assist systems are available in the OR or catheterization labs when the use of IABP has proven futile, mechanical circulatory support for patients with acute cardiogenic shock refractory to medical therapy and IABP in the ICU remains problematic. Assist devices usually used in the ICU such as ECMO have the drawbacks of mere peripheral cannulae and low output for biventricular support. The relatively new Tandem Heart pVAD seems safer than older generation devices, especially considering the lower rate of hemolysis and reported thromboembolic complications. Relocation to the OR or catheterization lab is required for the implantation of devices with high output. The Tandem Heart pVAD may fill this therapeutic gap as it can be implanted under TEE navigation, which is usually available in every ICU. Moreover, it allows exclusive left ventricular support because of the central position of the afferent catheter in the left atrium. Right ventricular support where a Swan-Ganz catheter navigates a stiff guidewire into the pulmonary artery with subsequent positioning of the efferent cannula has also been described (unpublished reports). Another advantage is the abandonment of the cardiopulmonary bypass system with its typical drawbacks. The use of the pVAD device enables mechanical circulatory support without emergency off- or on-pump surgical left ventricular or biventricular assist device insertion. The combined use of a nonpulsatile Tandem Heart device with the pulsatile support provided by the IABP is useful. The pVAD support can be used as a rescue pump or as a bridge to bridge device. Under the percutaneous mechanical support, the change to extracorporeal circulation can easily be performed by using the Tandem Heart cannula in the femoral vein and artery.

In cases of a large left atrium, distorted anatomy, or contraindications for TEE, the use of intracardiac echocardiography via the venous system would be an alternative for intracardiac navigation as it has been done for interventions on cardiac structures such as percutaneous transvenous mitral commissurotomy [Liang 2006].

CONCLUSIONS

This series of experiments demonstrates that a substantial number of patients who experience reversible

myocardial injury may eventually benefit from TEE-guided implantation of a centrifugal VAD in the ICU by short-term unloading of the left or right ventricle. The described technique does not require great echocardiographic experience and can easily be handled. Several questions are still unanswered concerning the complications: appropriate anticoagulation, consecutive groin hematoma on the puncture side, leg ischemia, compartment syndrome, and thromboembolic events are the known complications of Tandem Heart device application. The mid- and long-term prognosis of the patients with respect to survival merits further study.

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